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| REGISTRATION REPORT  Part B  Section 7  Metabolism and Residues  Detailed summary of the risk assessment |
| Product code: CA3642  Product name(s): Joust Pro  Chemical active substance:  prothioconazole, 150 g/L  azoxystrobin, 150 g/L |
| Central Zone  Zonal Rapporteur Member State: Poland |
| CORE ASSESSMENT  New Authorisation (Art.33) |
| Sponsor: Nufarm Crop Products UK Limited  Applicant: Nufarm Polska Sp. z o. o.  Submission date: 1/02/2023, updated: 23/06/2023; 23/10/2023; 28/03/2024  MS Finalisation date: May 2024 (initial Core Assessment)  October 2024, December 2024 (final Core Assessment) |

Version history

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| --- | --- |
| When | What |
| February 2023 | Applicant version. First submission. |
| June 2023 | Update of Table 7.1-1 according to the request of the zRMS PL |
| October 2023 | Update from the applicant following zRMS PL comments. Additional data are highlighted in grey. |
| December 2023 | Initial zRMS assessment  The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.  Following the evaluation and before sending the document for commenting, all colored highlighting was removed, from the parts updated by the Applicant, for better legibility. |
| March 2024 | Update from the applicant with finalised report S23-100807 |
| May 2024 | Update to Initial zRMS assessment following the submitted residue study (S23-100807)  The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.  Following the evaluation and before sending the document for commenting, all colored highlighting was removed, from the parts updated by the Applicant, for better legibility. |
| October 2024 | Final report (Core Assessment updated following the commenting period)  Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency. |
| December 2024 | Final report (Core Assessment updated following the second commenting period)  No additional information or assessments after the commenting period. |

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# Metabolism and residue data (KCA section 6)

## Summary and zRMS Conclusion

### Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation CA3642 are presented in Table 7.1‑1. They have been selected from the individual GAPs in the zone. A list of all intended uses within the zone is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs for prothioconazole and azoxystrobin as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of prothioconazole residues, including the triazole derivative metabolites, and of azoxystrobin are unlikely to present a public health concern.

There are sufficient independent residue trials to support the proposed major uses of PPP on cereals and winter oilseed rape and these uses are accepted.

According to Article 51 of Regulation 1107/2009 the proposed minor uses of PPP on spring oilseed rape, sunflower, linseed, poppy, mustard, gold of pleasure seeds can be accepted.

As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended uses.

According to available data, no specific mitigation measures should apply.

Data gaps

Noticed data gaps are: none

Table 7.1‑1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

| **1** | **2** | **3** | **4** | **5** | **6** | **7** | | **8** | | | | **9** | | | **10** | **11** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **GAP number (see Part B.0)** | **Crop and/ or situation** | **Zone** | **Product Code** | **F, Fn, Fpn G, Gn, Gpn or I** | **Pests or Group of pests controlled**  **(Additionally: developmental stages of the pest or pest group)** | **Formulation** | | **Application** | | | | **Application rate per treatment** | | | **PHI (days)** | **Conclusion** |
| **Type** | **Conc. of as** | **Method / Kind** | **Timing / Growth stage of crop & season** | **Number**  **Min - Max** | **Min. interval between applications**  **(days) min** | **L product / ha**  **a) max. rate per appl.**  **b) max. total rate per crop/season** | **g as/ha**  **a) max. rate per appl.**  **b) max. total rate per crop/season** | **Water L/ha**  **min / max** |
| 1-14 | Wheat (winter & spring)  Spelt  Einkorn wheat  Emmer Wheat  Tritordeum | Central Zone | CA3642 | F | Septoria leaf spot  *Zymoseptoria tritici*  *Mycosphaerella graminicola*  (SEPTTR)  Glume blotch  *Stagonospora nodorum*  (LEPTNO)  Brown Rust  *Puccinia recondita*  *Puccinia triticina*  (PUCCRT)  Yellow Rust  *Puccinia striiformis*  (PUCCST)  Powdery mildew  *Blumeria graminis*  (ERYSGR)  Eyespot  *Oculimacula acuformis / Pseudocercosporella herpotrichoides*  (PSDCHE)  Tan Spot  *Pyrenophora tritici-repentis*  (PYRNTR)  Head blight of cereals  *Fusarium spp.*  (FUSASP)  *Microdochium spp.*  (MICDSP) | EC | 250 g/L | foliar spray | BBCH 30 – 69  (spring) | 1-2 | 14-21 | a) 1.2-1.4  b) 2.4-2.8 | a) 360-420  (180+180 – 210+210)  b) 720-840  (360+360 – 420+420) | 100-400 | 35 | A |
| 15-25 | Durum Wheat | Central Zone | CA3642 | F | Septoria leaf spot  *Zymoseptoria tritici*  *Mycosphaerella graminicola*  (SEPTTR)  Brown Rust  *Puccinia recondita*  *Puccinia triticina*  (PUCCRT)  Yellow/stripe Rust  *Puccinia striiformis*  (PUCCST)  Powdery mildew  *Blumeria graminis*  (ERYSGR)  Head blight of cereals  *Fusarium spp.*  (FUSASP)  *Microdochium spp.*  (MICDSP) | EC | 250 g/L | foliar spray | BBCH 30 – 69  (spring) | 1-2 | 14-21 | a) 1.2-1.4  b) 2.4-2.8 | a) 360-420  (180+180 – 210+210)  b) 720-840  (360+360 – 420+420) | 100-400 | 35 | A |
| 26-38 | Triticale  (winter & spring) | Central Zone | CA3642 | F | Septoria leaf spot  *Zymoseptoria tritici*  *Mycosphaerella graminicola*  (SEPTTR)  Brown Rust  *Puccinia recondita*  *Puccinia triticina*  (PUCCRT)  Leaf blotch  *Rhynchosporium secalis*  (RHYNSE)  Yellow Rust  *Puccinia striiformis*  (PUCCST)  Glume blotch  *Stagonospora nodorum*  (LEPTNO)  Powdery mildew  *Blumeria graminis*  (ERYSGR)  Head blight of cereals  *Fusarium spp.*  (FUSASP)  *Microdochium spp.*  (MICDSP) | EC | 250 g/L | foliar spray | BBCH 30 – 69  (spring) | 1-2 | 14-21 | a) 1.2-1.4  b) 2.4-2.8 | a) 360-420  (180+180 – 210+210)  b) 720-840  (360+360 – 420+420) | 100-400 | 35 | A |
| 39-52 | Rye  (winter & spring) | Central Zone | CA3642 | F | Septoria leaf spot  *Zymoseptoria tritici*  *Mycosphaerella graminicola*  (SEPTTR)  Leaf blotch  *Rhynchosporium secalis*  (RHYNSE)  Brown rust  *Puccinia recondita/* *Puccinia recondita f. sp. Recondite*  (PUCCRE/PUCCRR)  Eyespot  *Pseudocercosporella herpotrichoides* (PSDCHE)  Powdery mildew  *Blumeria graminis*  (ERYSGR)  Head blight of cereals  *Fusarium spp.*  (FUSASP)  *Microdochium spp.*  (MICDSP) | EC | 250 g/L | foliar spray | BBCH 30 – 69  (spring) | 1-2 | 14-21 | a) 1.2-1.4  b) 2.4-2.8 | a) 360-420  (180+180 – 210+210)  b) 720-840  (360+360 – 420+420) | 100-400 | 35 | A |
| 53-65 | Oat (winter & spring) | Central Zone | CA3642 | F | Crown Rust  *Puccinia coronate*  (PUCCCO)  Powdery mildew  *Blumeria graminis*  (ERYSGR)  Leaf spot of oat  *Pyrenophora chaetomioides* (PYRNAV)  Eyespot  *Oculimacula acuformis / Pseudocercosporella herpotrichoide*  (PSDCHE) | EC | 250 g/L | foliar spray | BBCH 30 – 61  (spring) | 1-2 | 14-21 | a) 1.0  b) 2.0 | a) 300  (150+150)  b) 600  (300+300) | 100-400 | 35 | A |
| 66-78 | Barley (winter & spring) | Central Zone | CA3642 | F | Leaf spot of Barley  *Ramularia collo-cygni*  (RAMUCC)  Eyespot  *Oculimacula acuformis / Pseudocercosporella herpotrichoides*  (PSDCHE)  Brown Rust  *Puccinia hordei*  (PUCCHD)  Powdery mildew  *Blumeria graminis*  (ERYSGR)  Leaf Blotch  *Rhynchosporium secalis*  (RHYNSE)  Net Blotch  *Pyrenophora teres*  (PYRNTE) | EC | 250 g/L | foliar spray | BBCH 30 – 61  (spring) | 1-2 | 14-21 | a) 1.0  b) 2.0 | a) 300  (150+150)  b) 600  (300+300) | 100-400 | 35 | A |
| 79-90 | Winter Oilseed Rape | Central Zone | CA3642 | F | Phoma leaf spot/stem canker  *Leptosphaeria maculans*  (LEPTMA)  Sclerotinia stem rot  *Sclerotinia sclerotiorum*  (SCLESC)  Powdery mildew  *Erysiphe cruciferarum*  (ERYSCR)  Alternaria leaf spot  *Alternaria brassicae*  (ALTEBA)  Light leaf spot  *Pyrenopeziza brassicae*  (PYRPBR)  Grey mould  *Botryotinia cinerea*  (BOTRCI) | EC | 250 g/L | foliar spray | BBCH 14 – 18  (Autumn)  or  BBCH 20 – 69  (Spring) | 1 | N/A | a) 1.0-1.2  b) 1.0-1.2 | a) 300 - 360  (150+150-180+180)  b) 300 - 360  (150+150-180+180) | 100-400 | 56 | A |
| 91-10~~3~~2 | Spring Oilseed Rape | Central Zone | CA3642 | F | Phoma leaf spot/stem canker  *Leptosphaeria maculans*  (LEPTMA)  Sclerotinia stem rot  *Sclerotinia sclerotiorum*  (SCLESC)  Powdery mildew  *Erysiphe cruciferarum*  (ERYSCR)  Alternaria leaf spot  *Alternaria brassicae*  (ALTEBA)  Light leaf spot  *Pyrenopeziza brassicae*  (PYRPBR)  Grey mould  *Botryotinia cinera*  (BOTRCI) | EC | 250 g/L | foliar spray | BBCH 20 – 69  (Spring) | 1 | N/A | a) 1.0-1.2  b) 1.0-1.2 | a) 300 - 360  (150+150-180+180)  b) 300 - 360  (150+150-180+180) | 100-400 | 56 | A  only for minor use according to Article 51 |
| 103 | Sunflower | Central Zone | CA3642 | F | Sclerotinia Stem rot  *Sclerotinia sclerotiorum (*SCLESC)  Grey mould  *Botryotinia cinera* (BOTRCI)Stalk rot of sunflower  *Diaporthe helianthi* (DIAPHE)  Black stem of Sunflower  *Plenodomus lindquistii* (LEPTLI) | EC | 250 g/L | foliar spray | BBCH 16– 64  (spring) | 1 | N/A | a) 1.0-1.2  b) 1.0-1.2 | a) 240-360  (120+120 – 180+180)  b) 240-360  (120+120 – 180+180) | 100-400 | 56 | A  only for minor use according to Article 51 |
| 104 | Flax (for fiber production only) | Central Zone | CA3642 | F | Powdery mildew flax  *Erysiphe spp* (ERYSPP) | EC | 250 g/L | Foliar spray | BBCH 33 – 51 | 1 | N/A | a) 1.0-1.2  b) 1.0-1.2 | a) 300 - 360  (150+150-180+180)  b) 300 - 360  (150+150-180+180) | 100-400 | N/A | A |
| 105-116 | Linseeds, Poppy, Mustard and Gold of pleasure | Central Zone | CA3642 | F | Phoma leaf spot/stem canker  *Leptosphaeria maculans*  (LEPTMA)  Sclerotinia stem rot  *Sclerotinia sclerotiorum*  (SCLESC)  Powdery mildew  *Erysiphe cruciferarum*  (ERYSCR)  Alternaria leaf spot  *Alternaria brassicae*  (ALTEBA)  Light leaf spot  *Pyrenopeziza brassicae*  (PYRPBR) | EC | 250 g/L | foliar spray | BBCH 14 – 18  (Autumn)  or  BBCH 20 – 69  (Spring) | 1 | N/A | a) 1.0-1.2  b) 1.0-1.2 | a) 300 - 360  (150+150-180+180)  b) 300 - 360  (150+150-180+180) | 100-400 | 56 | A  minor use according to Article 51 |

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

\*\* Use also code numbers according to Annex I of Regulation (EU) No 396/2005

\*\*\* F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for Column 11 “Conclusion”

|  |  |
| --- | --- |
| A | Exposure acceptable without risk mitigation measures, safe use |
| R | Further refinement and/or risk mitigation measures required |
| N | Exposure not acceptable, no safe use |

### Summary of the evaluation

The preparation CA3642 is composed of prothioconazole, an active substance belonging to the triazole chemical group and azoxystrobin.

The toxicological reference values of azoxystrobin, prothioconazole and the main metabolites of prothioconazole - prothioconazole-desthio and the triazole derivative metabolites (TDMs), are presented in the table hereafter.

Table 7.1‑2: Toxicological reference values for the dietary risk assessment of azoxystrobin, prothioconazole, prothioconazole-desthio and TDMs

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference value** | **Source** | **Year** | **Value** | **Study relied upon** | **Safety factor** |
| **Prothioconazole-desthio** | | | | | |
| ADI | EFSA | 2007 | 0.01 mg/kg bw/day | 18-Month Mouse Carcinogenicity | 100 |
| ARfD | EFSA | 2007 | 0.01 mg/kg bw | Developmental study in ~~rabbits~~ rat | 100 |
| **1,2,4-triazole (1,2,4-T)** | | | | | |
| ADI | EFSA Journal 2018; 16(7):5376 | 2018 | 0.023 mg/kg bw/day | Rat 12-month study | 300 |
| ARfD | 2018 | 0.1 mg/kg bw | Rabbit developmental study | 300 |
| **Triazole alanine (TA)** | | | | | |
| ADI | EFSA Journal 2018; 16(7):5376 | 2018 | 0.3 mg/kg bw/day | Rabbit developmental study | 100 |
| ARfD | 2018 | 0.3 mg/kg bw | Rabbit developmental study | 100 |
| **Triazole acetic acid (TAA)** | | | | | |
| ADI | EFSA Journal 2018; 16(7):5376 | 2018 | 1 mg/kg bw/day | Rat 2 generation and Rabbit developmental studies | 100 |
| ARfD | 2018 | 1 mg/kg bw | Rat 2 generation and Rabbit developmental studies | 100 |
| **Triazole lactic acid (TLA)** | | | | | |
| ADI | EFSA Journal 2018; 16(7):5376 | 2018 | 0.3 mg/kg bw/day | Bridging from TA |  |
| ARfD | 2018 | 0.3 mg/kg bw | Bridging from TA |  |
| **Azoxystrobin** | | | | | |
| ADI | EFSA Journal 2010; 8(4):1542 | 2010 | 0.2 mg/kg bw/day | 2-year rat | 100 |
| ARfD | 2010 | Not necessary | - | - |

#### Summary for prothioconazole

Table 7.1‑3: Summary for prothioconazole

| Use-No.\* | Crop | Plant metabolism covered? | Sufficient residue trials? | PHI sufficiently supported? | Sample sto­rage covered by stability data? | MRL compliance | Chronic risk for consumers identified? | Acute risk for consumers identified? |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1-14 | Wheat (winter & spring)  Spelt  Einkorn wheat  Emmer Wheat  Tritordeum | Yes | Yes | Yes | Yes | Yes | No | No |
| 15-25 | Durum Wheat | Yes | Yes | Yes | Yes | Yes | No |
| 26-38 | Triticale  (winter & spring) | Yes | Yes | Yes | Yes | Yes | No |
| 39-52 | Rye  (winter & spring) | Yes | Yes | Yes | Yes | Yes | No |
| 53-65 | Oat (winter & spring) | Yes | Yes | Yes | Yes | Yes | No |
| 66-78 | Barley (winter & spring) | Yes | Yes | Yes | Yes | Yes | No |
| 79-90 | Winter Oilseed Rape | Yes | Yes | Yes | Yes | Yes | No |
| 91-102 | Spring Oilseed Rape | Yes | Yes  only for minor use according to Article 51 | Yes | Yes | Yes | No |
| 103 | Sunflower | Yes | Yes  only for minor use according to Article 51 | Yes | Yes | Yes | No |
| 104 | Flax (for fiber production only) | Not applicable - Non food/feed use | | | | | No |
| 105-116 | Linseeds, Poppy, Mustard and Gold of pleasure | Yes | Yes  only for minor use according to Article 51 | Yes | Yes | Yes | No |

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

The effects of processing on the nature of active substance residues have been investigated. Data on effects of processing on the amount of residue have been submitted.

Regarding TDMs, studies show that they remained stable under the standard hydrolysis conditions. Studies on magnitude of residues in processed commodities in wheat, barley and oilseed rape after treatment with prothioconazole were presented in the Triazole Derivate Metabolites Addendum - Confirmatory data (B.7.5.2, UK, 2018). These data were not considered for the risk assessment (the most critical processing factors, considering data provided for all active substances belonging to the triazole group, were taken into account in the TDM EU risk assessment).

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that prothioconazole residues will be present in succeeding crops.

Regarding TDMs, in the framework of the confirmatory data, several field rotational crop trials have been conducted to investigate the magnitude of TDM residues in rotational crops after the use of triazole active substances. Residues of TA, TLA and TAA were found above 0.01 mg/kg in succeeding crops. These results were considered in the consumer risk assessment performed in the framework of the review of TDMs confirmatory data.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock for both prothioconazole and TDMs. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Regarding TDM arising from prothioconazole uses, as concluded by the UK, “further consideration is not required due to the fact that none of the TDMs were identified” in the available livestock metabolism studies conducted with prothioconazole.

#### Summary for azoxystrobin

Table 7.1‑4: Summary for azoxystrobin

| Use-No.\* | Crop | Plant metabolism covered? | Sufficient residue trials? | PHI sufficiently supported? | Sample sto­rage covered by stability data? | MRL compliance | Chronic risk for consumers identified? | Acute risk for consumers identified? |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1-14 | Wheat (winter & spring)  Spelt  Einkorn wheat  Emmer Wheat  Tritordeum | Yes | Yes | Yes | Yes | Yes | No | No |
| 15-25 | Durum Wheat | Yes | Yes | Yes | Yes | Yes | No |
| 26-38 | Triticale  (winter & spring) | Yes | Yes | Yes | Yes | Yes | No |
| 39-52 | Rye  (winter & spring) | Yes | Yes | Yes | Yes | Yes | No |
| 53-65 | Oat (winter & spring) | Yes | Yes | Yes | Yes | Yes | No |
| 66-78 | Barley (winter & spring) | Yes | Yes | Yes | Yes | Yes | No |
| 79-90 | Winter Oilseed Rape | Yes | Yes | Yes | Yes | Yes | No |
| 91-102 | Spring Oilseed Rape | Yes | Yes  only for minor use according to Article 51 | Yes | Yes | Yes | No |
| 103 | Sunflower | Yes | Yes  only for minor use according to Article 51 | Yes | Yes | Yes | No |
| 104 | Flax (for fiber production only) | Not applicable - Non food/feed use | | | | | No |
| 105-116 | Linseeds, Poppy, Mustard and Gold of pleasure | Yes | Yes  minor uses according to Article 51 | Yes | Yes | Yes | No |

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

There are sufficient independent residue trials to support the proposed major uses of PPP on cereals and winter oilseed rape.

Based on the SANTE/2019/12752, four residue trials on oilseed rape can be used for extrapolation to following minor uses ~~crops~~: sunflower (in PL), spring oilseed rape, linseed, poppy, mustard and gold of pleasure seeds before and after forming of the edible part. So the proposed minor uses ~~on minor crops~~ (art. 51): spring oilseed rape and sunflower, linseed, poppy, mustard, gold of pleasure seeds are considered acceptable.

The effects of processing on the nature of azoxystrobin residues have been investigated. Data on effects of processing on the amount of residue have been submitted. These data were not considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

#### Summary for CA3642

Table 7.1‑5: Information on CA3642 (KCA 6.8)

| Crop | PHI for CA3642  proposed by applicant | PHI sufficiently supported for | | PHI for CA3642  proposed by zRMS | zRMS Comments  (if different PHI proposed) |
| --- | --- | --- | --- | --- | --- |
| Prothioconazole | Azoxystrobin |
| Barley (winter & spring) | 35 | Yes | Yes | 35 | - |
| Oat (winter & spring) | 35 | Yes | Yes | 35 | - |
| Wheat (winter & spring), Spelt, Einkorn wheat  Emmer Wheat  Tritordeum,  Durum Wheat, Triticale (winter & spring) | 35 | Yes | Yes | 35 | - |
| Rye (winter & spring) | 35 | Yes | Yes | 35 | - |
| Oilseed rape (winter & spring) | 56 | Yes | Yes | 56 | - |
| Sunflower | 56 | Yes | Yes | 56 | - |
| Flax (for fibre production only) | Not applicable - Non-food/feed use | | | | |
| Linseeds, Poppy, Mustard and Gold of pleasure | 56 | Yes | Yes | 56 | - |

Table 7.1‑6: Waiting periods before planting succeeding crops

|  |  |  |  |
| --- | --- | --- | --- |
| Waiting period before planting succeeding crops | | | Overall waiting period proposed by zRMS for CA3642 |
| Crop group | Led by prothioconazole | Led by azoxystrobin |
| All crops | Not needed | Not needed | Not needed |

Assessment

## Prothioconazole

## 

The applicant Nufarm has a letter of access from Bayer CropScience AG which authorizes the respective authorities to access the summaries of some studies on prothioconazole owned by Bayer Group in support of Nufarm application to obtain a registration under Art.33 of EU Regulation 1107/2009. These summaries are presented in the document provided by Bayer CropScience AG (Bayer doc. No. M-777951-01-1). It should be noted that the applicant Nufarm does not have access to the study reports owned by Bayer Group and therefore kindly asks the zRMS to refer to them.

The active substance prothioconazole belongs to the triazole chemical group. Triazole derivative metabolites (TDMs) are common metabolites of all triazole fungicides and have to be considered in the consumer risk assessment. The data on TDMs provided in the present application are from the “Triazole Derivate Metabolites addendum – confirmatory data prepared by the rapporteur Member State, the United Kingdom” (UK, 2018). As confirmatory data, they are out of data protection. Following this, EFSA issued the “Peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted” (EFSA, 2018). These conclusions were taken into account in the present assessment.

**According to SANTE/11509/2013– rev. 5.2 and since the active substance prothioconazole is not yet renewed, the “old data requirements” (Reg. (EU) No 544/2011) and the endpoints from the inclusion of prothioconazole (DAR) apply to the current assessment. Studies from the DAR are not protected anymore.**

General data on prothioconazole are summarized in the table below (last updated 2022/11/22).

**Table 0‑1: General information on prothioconazole**

|  |  |
| --- | --- |
| Active substance (ISO Common Name) | Prothioconazole |
| IUPAC | (RS)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-  2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3-  thione |
| Chemical structure |  |
| Molecular formula | C14 H15 Cl2 N3 O S |
| Molar mass | 344.26 g/mol |
| Chemical group | Triazole |
| Mode of action (if available) | Steroid demethylation in the ergosterol biosynthesis pathway |
| Systemic | Yes |
| Company | Bayer CropScience\* |
| Rapporteur Member State (RMS) | First approval: the United Kingdom  Renewal (ongoing): Poland |
| Approval status | Approved |
| Restriction | No |
| Review Report | SANCO/3923 /07 - final  10 December 2007 – Updated 26 January 2021 |
| Current MRL regulation | Regulation (EU) ~~2019/552~~ 2024/1318 |
| Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed | Yes |
| EFSA Journal: Conclusion on the peer review | Yes (EFSA, 2007) |
| EFSA Journal: conclusion on article 12 | Yes (EFSA, 2014 and EFSA, 2020) |
| Current MRL applications on intended uses | No |

\* Notifier in the EU process to whom the a.s. belongs

### Stability of Residues (KCA 6.1)

#### Stability of residues during storage of samples

Available data

~~Two~~ Three new stability study summaries have been submitted by the applicant in the framework of this application. Two of the relevant ~~two~~ studies have already been mentioned by EFSA during the Article 12 MRL review process (EFSA, 2014 and EFSA, 2020) and are currently under review in the EU approval renewal process for prothioconazole. The other one was finalised in 2023 on oilseed rape (grain and straw).

In addition, a new study investigating the storage stability of prothioconazole-desthio, its hydroxies and the triazole derivative metabolites in bee products has been performed (Kalathoor, R., report S20-09716).

All available results are summarized in the Tables below. The detailed assessments of these studies are presented in Appendix 2.

Table 0‑2: Summary of stability data achieved at ≤ ‑ 18°C (unless stated otherwise) – Prothioconazole, prothioconazole-desthio and prothioconazole-hydroxy-desthio

| Matrix | Characteristics of the matrix | Acceptable Maximum Storage duration | Reference |
| --- | --- | --- | --- |
| **Data relied on in EU** | | | |
| Plant products | | | |
| Wheat grain | Dry commodities/ High starch content | PTZ: 6 months  PTZ-desthio: 18 months | EFSA, 2007  Heinemann, O., 2001, Report MR-282/00  (*Not protected)* |
| Wheat straw | No group | PTZ: 6 months  PTZ-desthio: 18 months |
| Wheat forage/green matter | High water content | PTZ: 6 months  PTZ-desthio: 18 months |
| Animal Products: No EU data | | | |
| **New data** | | | |
| Plant products | | | |
| Canola, seeds | High oil content | PTZ-desthio: 24 months  PTZ-OH-desthio: 25 months | PTZ-desthio: Freitag, T., 2007, report MR-07/282 (EFSA, 2014)  *(Access from Bayer)*  PTZ-OH-desthio: Freitag, T., 2011, report MR-08/024 (EFSA, 2020)  *(Access from Bayer)* |
| Canola, whole plant | High water content | PTZ-desthio: 24 months |
| Canola, pod | No group | PTZ-desthio: 24 months |
| Orange fruit | High acid content | PTZ-OH-desthio: 25 months |
| Potato tuber | High starch content | PTZ-OH-desthio: 25 months |
| Tomato fruit | High water content | PTZ-OH-desthio: 25 months |
| Soybean | High oil content | PTZ-OH-desthio: 25 months |
| Animal Products: | | | |
| Ruminant muscle, fat, liver, kidney and milk | No group | PTZ-desthio: 1 month  Prothioconazole-3-OH-desthio (M14): 1 month  Prothioconazole-4-OH-desthio (M15): 1 month | Animal feeding study, Report No.: MR-535/00  (*Not protected)* |
| Honey | No group | PTZ-desthio: 182 days  PTZ-OH-desthio: 157 days, except for PTZ-α-OH-desthio (134 days) | Kalathoor, R., Report No: S20-09716  *(Nufarm, protected)* |

PTZ-OH-desthio (α-OH, 3-OH, 4-OH, 5-OH and 6-OH): prothioconazole-hydroxy-desthio, which includes prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, and prothioconazole-6-hydroxy-desthio, respectively.

**Table 0‑3: Summary of stability data achieved at ≤ ‑ 18°C (unless stated otherwise) – TDMs**

| **Matrix** | **Characteristics of the matrix** | **Acceptable Maximum Storage duration (months)** | | | | **Reference** |
| --- | --- | --- | --- | --- | --- | --- |
| **1,2,4-Triazole** | **Triazole Alanine** | **Triazole Acetic Acid** | **Triazole Lactic Acid** |
| **Data relied on in EU** | | | | | | |
| **Plant products** | | | | | | |
| Apples, tomatoes, mustard leaves, wheat forage, radishes tops/roots, turnips roots, sugar beet roots, cabbages, lettuces | High water content | 6 | 53 | 53 | 48  (Only lettuce tested) | EFSA, 2018 |
| Barley, wheat | High starch content | 12 | 26 | 26 | 48 |
| Rapeseeds, soyabeans | High oil content | 12 (soya bean only; not stable in rape seed) | 26 (soya bean only; not stable in rape seed) | 53 | 48 |
| Peas, dry; Navy beans | High protein content | No data | 15 | 25 | 48 |
| Oranges | High acid content | No data | No data | No data | 48 |
| Barley, wheat | Cereal straw | 12 | 53 | 40 | No data |
| **Animal products** | | | | | | |
| Ruminant | Milk | 18 | No data | No data | No data | EFSA, 2018 |
| Poultry | Eggs | 12 | No data | No data | No data |
| Ruminant/poultry | Liver | 12 | No data | No data | No data |
| Muscle | 12 | No data | No data | No data |
| Fat | 12 | No data | No data | No data |
| **New data** | | | | | | |
| **Plant products** | | | | | | |
| Oilseed rape, grain | High oil content | 55 days | 55 days | - | - | Winter, O., Report No: S22-08287  *(Nufarm, protected)* |
| Oilseed rape, straw | No group | 55 days | 55 days | 55 days | 55 days |
| **Animal products** | | | | | | |
| Honey | No group | 182 days | 182 days | 182 days | 182 days | Kalathoor, R., Report No: S20-09716  *(Nufarm, protected)* |

Summary of studies reported in the EU - Prothioconazole

*EFSA Journal 2014;12(5):3689*

“In the framework of the peer review, storage stability of prothioconazole-desthio residues was demonstrated at -18 °C for 18 months in high water content matrices (wheat green matter), dry commodities (cereal grain) and straw (EFSA, 2007b; United Kingdom, 2004, 2007). Furthermore, storage stability of prothioconazole-desthio residues was subsequently demonstrated for a period of 24 months at – 18 °C in commodities with high water content (spinach, sugar beet, tomatoes), high oil content (canola seeds), dry commodities (dried peas) and canola straw (EFSA, 2009, 2010a, 2010b, 2012; Netherlands, 2007)”.

*EFSA Journal 2020;18(2):5999*

“Freezer storage stability of prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio was investigated in high water content (tomatoes), high starch content (potatoes), high oil content (soya beans, oilseed rape) and high acid content (oranges) commodities for a period of 24 months *[nominal period; actual period is 25 months according to RAR, UK, 2018]*. Samples were fortified with a mixture containing all five analytes at a level of 0.1 mg/kg each.

Since all these compounds are included in the residue definition for risk assessment, spiking with a mixture was considered acceptable. Results demonstrate stability of all compounds in all matrices for a maximum of 24 months (duration of study) *[nominal period; actual period is 25 months according to RAR, UK, 2018]* when stored at ≤ 18°C.

It is noted that according to EU guidelines (European Commission, 1997f), applicable for the current assessment, cereals are considered as dry matrix, for which the storage stability of hydroxylated metabolites of prothioconazole-desthio has not been investigated. However, it is noted that the applicant has generated data according to the OECD guidelines (OECD, 2007) in the framework of the renewal of the approval of prothioconazole. According to OECD guideline, cereals are considered as high starch matrix. EFSA accepted the storage stability data on potatoes (high starch matrix) to address the storage stability in cereals.”

Summary of studies reported in the EU - TDMs

*EFSA Journal 2018;16(7):5376*

“From the submitted storage stability data, it can be concluded that the residue trials analysing TA, TAA and TLA residues in high water-, high oil-, high protein- and high starch content commodities were supported by acceptable storage stability data on these compounds, except for TA (raspberries, peas, rapeseeds) and TAA (raspberries). The residue trials analysed 1,2,4-T residues in most of the crops within a time interval for which acceptable storage stability of this compound could not be demonstrated, except for stone fruit, stem vegetables, soya beans and oats grain. Storage stability data were not provided and are required for 1,2,4-T, TA and TAA in high acid-content commodities, for 1,2,4-triazole in high protein-content commodities and for TLA in cereal straw to cover the maximum storage time interval of all residue trials in primary and rotational crops (data gap). For products of animal origin, the available storage stability data demonstrated acceptable freezer storage stability of 1,2,4-T in milk for 18 months and in eggs, liver, muscle and fat for 12 months. Additional storage stability data analysing for the residues of TA and TAA in milk and eggs were also provided but were not considered as acceptable since the homogenised samples of milk and eggs were fortified with a mixture of TA and TAA and not with the individual compound, respectively”.

Conclusion on stability of residues during storage

For prothioconazole and its metabolite, the provided studies on magnitude of residues are sufficiently supported by available storage stability data. For hydroxylated metabolites of prothioconazole-desthio, it is noted that EFSA accepted the storage stability data on potatoes (high starch matrix) to address the storage stability in cereals.

Regarding TDMs, 1,2,4-T and TA were shown ~~not~~ to be stable in oilseed rape seeds up to 55 days (Study S22-08287). ~~However, the first storage interval tested was 113 days, thus not allowing to determine when a significant degradation of 1,2,4-T and TA occurs. In the new residue trials performed and presented in this dossier, some seeds samples were stored for less than or around 30 days before analyses (trials -02, -06, -09 of study S20-01046 and trial -01 of study S21-00259). Residue levels of TA in seeds in those trials are comparable to those obtained in the other available trials on oilseed rape (see 7.2.3). Thus, it is considered that all TA results in seeds are reliable and can be used for risk assessment.~~

~~1,2,4-T is not present in plants in general, as confirmed in the available residue trials on cereals and oilseed rape.~~

Regarding TLA, since storage stability was demonstrated for up to 12 months in all crop categories no additional storage stability data for this compound is required.

Therefore, all residue trials submitted to support the intended uses are sufficiently supported by storage stability data available on TDMs.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **zRMS comments:**  Information given by the Applicant is acceptable and sufficient.  Studies on the storage stability of prothioconazole and its metabolite in crop and animal tissues under frozen conditions were assessed in the framework at the EU level.  Residues of prothioconazole-desthio are stable for 18 months under deep-freeze storage in high water content matrices (wheat green matter), dry commodities (cereal grain) and straw and for 24 months at – 18 °C in commodities with high water content (spinach, sugar beet, tomatoes), high oil content (canola seeds), dry commodities (dried peas) and canola straw.    Additionally, the results of the study of Freitag (2011, report MR-08/024) demonstrate the stability of residues of prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, and prothioconazole-6-hydroxy-desthio upon deep frozen storage at – 18 °C for up to 24 months in all tested matrices of plant origin (rape oil seed, orange fruit, potato tuber, tomato fruit and soybean).  Additionally, new study on the storage stability of prothioconazole-desthio, its hydroxies and the triazole derivative metabolites in bee products (Kalathoor, R, Report No: S20-09716) were submitted in the framework of this application. It should be noted that this study was reviewed and accepted by zRMS-PL in RR, Part B7 for PPP of Joust (CA3301) in January 2023.  The study was conducted over a maximum storage period up to 6 months in accordance to OECD Guideline 506 covering the storage of treated samples analysed in EAS Study S21-00428.  The study is deemed sufficient for assessing the stability of   * prothioconazole-desthio in homogenates of matrices honey, nectar and pollen upon storage at -18 °C for over 6 months (182 days for honey,183 days for pollen, 198 days for nectar); * prothioconazole upon storage at -18 °C in homogenates of matrices nectar for more than 6 months (198 days); * prothioconazole-alpha-hydroxy-desthio in homogenates of matrices honey, nectar and pollen upon storage at -18 °C for 4.5 months (134 days for honey and nectar, 136 days for pollen); * prothioconazole-3, -4, -5 and -6-hydroxy-desthio in homogenates of matrices honey, nectar and pollen upon storage at -18 °C for 5 months (157 days); * 1,2,4-triazole, triazole alanine, triazole lactic acid and triazole acetic acid in homogenates of matrices honey, nectar and pollen upon storage at -18 °C for 6 months (182 days for honey and pollen, 185 days for nectar).   More details of this study are provided in Appendix 2.  Regarding the lack of the storage stability of 1,2,4-T and TA in oilseed rape, new stability study was submitted by Applicant (Winter, O., Report No: S22-08287). 1,2,4-T and TA were shown to be stable in oilseed rape seeds up to 55 days.  More details of this study are provided in Appendix 2.  Remark:  It should be noted that in the study S20-01046 the maximum period between sampling and last extraction was 73 days for seed samples (oilseed rape). There are insufficient stability data for 1,2,4-T and TA in oilseed rape to support the residue data presented in this study.  It should be noted that the storage period in the residue trials as a minor uncertainty which is not expected to impact the risk assessment.  The Applicant was asked by zRMS for additional clarification.  Nufarm points out that in the study report now submitted, the stability of 1,2,4-T and TA in oilseed rape grain is proven for 55 days.  With this in mind valid storage stability data for 1,2,4-T and TA can be considered the results from S20-01046-03.  Further to the above, Nufarm has performed 3 additional residue trials on oilseed rape (study S22-00257).  The magnitude of 1,2,4-T and TA residues in above residue trials, and the respective storage periods before the analysis are presented in the table below:   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Source | GAP | Storage (days) seed | Residues 1,2,4-T | Residues TA | | S22-00257 | 2 x 175 g as/ha, BBCH 69 | 2 trials with max 27 | 2x<0.003 | 1.2, 1.5 | | 1 trial with max 43 | <0.003 | 0.95 |   Nufarm notes that 1,2,4-T is not detected above the LoQ in any of the trials presented; this is further confirmed in the quote from 2018 RAR from the RMS UK: "no 1,2,4-triazole was detected in any matrix it is assumed that 1,2,4 triazole (M13) was rapidly transformed to the metabolites TA, THP and TA*A*". Therefore, storage stability data for 1,2,4-T are not deemed necessary.  Considering TA: taking into account the residue data available for TA from all trials: S20-01046, S21-00259 and the newly presented trial S22-00257, when comparing values of TA residues when storage exceeds 55 days, with the ones from trials stored up to 55 days, the values are comparable:    Consequently all TA residue data presented in the dossier are valid.  After commenting period cMS CZ does not agree with conclusion regarding the study S20-01046 (TA metabolite): “Mann-Whitney test results are not reliable in this case due to very limited data set.:  To make the statistical test more robust, TA levels measured in control samples are also included in the dataset. This approach is considered valid as the selection of the values used for the assessment considered both control and treated samples (the highest value was retained - the residue findings for TDMs were at a similar level in the untreated and treated samples due to the persistence of TDMs in soil following the widespread use of triazole pesticides by farmers as fungicides on various field crops).  As a result, a total of 8 samples is compared with 14 samples and the populations are found to be similar. Therefore, our conclusion is unchanged and all TA residue data presented in the dossier are valid.    **Conclusion:**  Sufficient stability data are available to support the residue data presented in the present dossier. No further data are required. |

#### Stability of residues in sample extracts (KCA 6.1)

In available studies on magnitude of residues, batch recoveries were carried out in parallel and stored in the same conditions as the analytical batches. Acceptable recoveries were achieved, indicating acceptable stability of residue in extracts.

|  |
| --- |
| **zRMS comments:**  Information given by the Applicant is acceptable and sufficient.  No further data are required. |

### Nature of residues in plants, livestock, and processed commodities

#### Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 0‑4: Summary of plant metabolism studies – Prothioconazole

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Crop Group | Crop | Label position | Application and sampling details | | | | | Reference |
| Method,  F or G (a) | Rate  (g a.s./ha) | No | PHI | Remarks |
| **EU data** | | | | | | | | |
| Cereals/grass | Wheat | [U-14C-phenyl]-PTZ | G  (Spring wheat) | 220 | 2  BBCH  32–65 | Forage: 6days  Hay: 26 days  Grain & Straw:48 days |  | EFSA, 2007; FAO, 2008a, 2008b  Haas, M.; Bornatsch, W., 2000  Report No.:  MR-198/99  *(Not protected)* |
| [3,5-14C-triazole]-PTZ-desthio | G  (Summer wheat) | 250 | 2  BBCH 31–59) | Forage: 0, 14 days  Grain& Straw:48 days |  | EFSA, 2007; FAO, 2008a, 2008b  Vogeler, K.; Sakamoto, H.; Brauner, A., 1993, Report No.:  PF3906  *(Not protected)* |
| [3,5-14C-triazole]-PTZ | F  (Spring wheat) | 180-290 | 2 BBCH 32–65 | Forage, hay, grain,  straw |  | FAO, 2008a, 2008b  Duah, F., 2004  Report No.:  200733  *(Not protected)* |
| [U-14C-phenyl]-PTZ | G  (Spring wheat, seed treatment) | 20 g a.s./100 kg seed (N) or 100 g a.s./100 kg seed (5N) | 1 | Forage:57days  Hay: 110 days  Grain &Straw: 153 days |  | EFSA, 2007; FAO, 2008a, 2008b  Haas, M., 2001, Report No.:  MR-467/99  *(Not protected)* |
| Pulses/Oilseeds | Peanut | [U-14C-phenyl]-PTZ | G | 300 | 3  (21d interval)  BBCH 66-75 | Hay & nuts without shells, 14 days |  | EFSA, 2007; FAO, 2008a, 2008b  Haas, M., 2001, Report No.:  MR-193/01  *(Not protected)* |
| [3,5-14C-triazole]-PTZ | G | 300 | 3  (21d interval)  BBCH 66-75 | Hay & nuts without shells, 14 days |  | EFSA, 2014; FAO, 2008a, 2008b  Haas, M.; 2003, Report No.:  MR-194/02 *(Not protected)* |

Summary of plant metabolism studies reported in the EU - Prothioconazole

*EFSA Journal 2014;12(5):3689*

*Wheat (cereals/grass)*

“In the foliar treated wheat samples, the TRR levels accounted for 0.08 and 5 mg eq/kg in grain, 10 and 8 mg eq/kg in forage, 8.9 and 11.2 mg eq/kg in hay and 27 and 7.9 mg eq/kg in straw, respectively for the phenyl and the triazole labelling forms of prothioconazole. The level of metabolites identification accounted for 73 % and 66 % of the TRR in forage, 65 % and 75 % of the TRR in hay, 66 % and 61 % of the TRR in straw and 34 % and 94 % TRR in grain, respectively for the phenyl and triazole labellings. In all the wheat matrices, prothioconazole was extensively metabolized.

Prothioconazole-desthio was the major compound of the total residues in all wheat plant parts for the phenyl labelling form: 35.4 % of the TRR (3.70 mg eq/kg) in forage, 18.5 % of the TRR (1.64 mg eq/kg) in hay, 22.3 % of the TRR (5.95 mg eq/kg) in straw and 16 % of the TRR (0.014 mg eq/kg) in grain. The hydroxylated derivative metabolites of prothioconazole-desthio (M14, M15, M17) and their glucoside conjugates were also identified in forage (13.4 % of the TRR, 1.42 mg eq/kg), hay (19.5 % of the TRR, 1.74 mg eq/kg), grain (9.5 % of the TRR, 0.007 mg eq/kg ) and straw (14.8 % of the TRR, 3.93 mg eq/kg). The parent compound and other minor metabolites were identified in all matrices and accounted each for less than 10 % TRR.

For the triazole labelling form, a similar metabolic pattern as for the phenyl labelling was observed in all wheat plant parts with the parent prothioconazole being also extensively metabolised (< 10 % TRR). Besides, cleavage of the triazole moiety of the prothioconazole-desthio occurred in all wheat matrices resulting in the formation of the following ‘triazole derivative metabolites’ (TDMs): triazole alanine and triazole acetic acid mainly recovered in grain at proportions of 71 % and 19 % of the TRR, respectively. It is noted that these compounds are common, unspecific metabolites of triazole fungicides.

In wheat after foliar application using [3,5-14C-triazole]-prothioconazole-desthio, the highest total residues levels were identified in straw (28.67 mg eq/kg), in forage (10.87 mg eq/kg) and to a minor extent in grain (2.85 mg eq/kg). Prothioconazole-desthio constituted the major compound of the total radioactive residues in forage (up to 86.8 % TRR, 8.94 mg eq/kg in green material) and in straw (71.9 % TRR, 20.61 mg eq/kg) whilst the triazole alanine and triazole acetic acid metabolites were significantly translocated to wheat grains, where they both represented 92.1 % of the TRR (2.63 mg eq/kg).

Following seed treatment on wheat with the phenyl labelled prothioconazole, very low levels of radioactive residues were recovered in wheat grain (TRR <0.01 mg/kg) and no metabolites’ identification could be attempted. In straw, forage and hay, TRR accounted for 0.03 - 0.28, 0.02 - 0.07 and 0.02 - 0.09 mg eq/kg, after the 1X and 5X experiments, respectively. Identification procedures in these matrices were performed in the 5X experiment and showed that the metabolic pattern of prothioconazole in the wheat plant parts after seed treatment was similar to the one depicted following foliar application. Indeed, parent compound was extensively metabolised: prothioconazole-desthio and its hydroxylated forms (including their glucosides) (M14, M15, M17) constituted the major compounds in all crop parts. Prothioconazole-desthio represented 10.9 % of the TRR (0.008 mg eq/kg) in forage, 6.6 % of the TRR (0.019 mg eq/kg) in straw and 6.4 % of the TRR (0.005 mg eq/kg) in hay. Its hydroxylated metabolites and their corresponding glucosides amounted together to 19.7 % of the TRR (0.055 mg eq/kg) in straw, 13.5 % of the TRR (0.011 mg eq/kg) in fodder and 5.6 % of the TRR (0.005 mg eq/kg) in hay. Parent and all other metabolites were below 10 % of the TRR.”

*Peanuts (pulses/oilseeds)*

“In peanuts, following both labelling applications, the highest total radioactive residues were identified in peanut hay (47.4 - 107.5 mg eq/kg). In nutmeat, the total residues accounted for only 0.29 to 1.40 mg eq/kg. The level of identification of the total residues in hay and nutmeat for both labels ranged from 65.1 % to 82.7 % of the TRR. In peanut hay, following both labels, prothioconazole-desthio constituted the major component of the total radioactive residues (up to 28.2 % TRR, 30.4 mg eq/kg), whilst metabolite M2724 was also recovered as a significant metabolite in hay after phenyl label application only (14.1 % TRR, 15.09 mg eq/kg). The hydroxylated derivative metabolites of prothioconazole-desthio (M14, M15) accounted together for 9.6 % of the TRR (up to 10.31 mg eq/kg). Parent compound and all other identified metabolites were recovered at levels below 10 % of the TRR. In nutmeat, after phenyl label application, M27 was the predominant compound of the total residues, accounting for up to 12.2% of the TRR (0.04 mg/eq/kg). M2425 was also identified and accounted for up to 9 % of the TRR (0.03 mg eq/kg). Neither parent compound nor prothioconazole-desthio were detected and the major part of the radioactivity was incorporated into the fatty acids matrix (up to 47.8 % TRR, 0.14 mg eq/kg). For the triazole labelling form, the major compounds identified in nutmeat were triazole lactic acid and triazole alanine (24.5 % and 47.8 % TRR, respectively) whilst other compounds amongst which the parent compound and prothioconazole-desthio were identified at a level below 10% of the TRR”.

*EFSA Journal 2020;18(2):5999*

“Based on metabolism study results, the MRL review derived the following tentative conversion factors to account for hydroxy metabolites of prothioconazole-desthio: 2 in cereal grains, pulses and oilseeds, leafy vegetables and tuber vegetables and 3 in cereal straw (EFSA, 2014).”

“The above studies do not investigate the possible impact of plant metabolism on the isomer ratio of prothioconazole. EFSA (2020) proposed that this matter is further considered in the framework of the renewal of the approval process of prothioconazole.”

Summary of plant metabolism studies reported in the EU - TDMs

*EFSA Journal 2018;16(7):5376*

“Based on the metabolism data in primary and rotational crops that were compiled from the assessment of the 18 triazole active substances the triazole active substances were shown to degrade into the common metabolites 1,2,4-T, TA, TLA and TAA, known as TDMs.

Besides the parent compound that was identified at significant residue levels in all crop groups, TA was predominantly found in the organs of storage (79% total radioactive residue (TRR) in potato tuber, 31–88% TRR in oil seeds, 8–69% TRR in cereal grains) but also in cereal straw (1–16% TRR) and in fruit crops (up to 80% TRR). TAA was only detected at significant proportions in cereal grain and straw (5–35% and 7–41% TRR, respectively) and TLA in fruit crops (up to 67% TRR) and in cereal straw (up to 43% TRR). 1,2,4-T was detected at lower levels in all crop parts (up to 12% TRR).

Similar metabolic patterns were depicted both in primary and in rotational crops. Pesticide residues monitoring data (DE survey, 2014–2015) on unprocessed food commodities (mainly fruits and vegetables) showed residue levels above the limit of quantification (LOQ) for each of the TDMs, i.e. 0.035–0.064 mg/kg for 1,2,4-T, 1.2–1.4 mg/kg for TA, 0.39–0.45 mg/kg for TAA and 0.78–2.4 mg/kg for TLA. These results confirmed the occurrence of each of the TDMs in primary and rotational crops from the compiled metabolism data in plants”.

Conclusion on metabolism in primary crops

For the intended uses on cereals and oilseed rape, the metabolism of prothioconazole is considered sufficiently addressed.

Prothioconazole is extensively metabolised, and the metabolic pathway was similar in all crops investigated. Prothioconazole-desthio was the predominant compound of the total residues with further hydroxylation (with the formation of several closely related metabolites) and glucosidation steps, whilst cleavage of the triazole bound of prothioconazole-desthio molecule resulted in the formation of TDMs.

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| **zRMS comments:**  Information given by the Applicant is acceptable and sufficient.  In the framework of the peer review under Directive 91/414/EEC and the Art.12 MRL review (EFSA, 2007, 2014), the metabolism of prothioconazole was investigated by foliar applications on root (sugar beet), pulses/oilseeds (peanut) and cereal/grass (wheat) crop groups and by seed treatment on cereal (wheat) (EFSA, 2007). In addition, the metabolism of prothioconazole-desthio labelled in the triazole moiety was investigated after foliar applications on cereals (EFSA, 2007).  Prothioconazole is extensively metabolised and the metabolic pathway was similar in all crops investigated. Prothioconazole-desthio was the predominant compound of the total residues with further hydroxylation (with the formation of several closely related metabolites) and glucosidation steps, whilst cleavage of the triazole bound of prothioconazole-desthio molecule resulted in the formation of TDMs.  In EFSA Journal 2018;16(7):5376 it is stated that *Primary crops metabolism data are reported for a total of 16 approved triazole compounds, and 2 triazole active substances that are not approved at EU level (bitertanol, flusilazole), on fruit crops, cereals (straw and grain), pulses and oilseeds and root crops.(…)* *Based on the metabolism data in primary and rotational crops that were compiled from the assessment of the 18 triazole active substances the triazole active substances were shown to degrade into the common metabolites 1,2,4-T, TA, TLA and TAA, known as TDMs.*  The residue definitions  Taking into account conclusions EFSA regarding residue definitions presented in EFSA Journal 2020;18(2):5999, EFSA Journal 2014;12(5):3689 and EFSA Journal 2018;16(7):5376, based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites and degradation products, the residue definitions for plant products were proposed as ‘**prothioconazole-desthio (sum of isomers)**’ for enforcement and, as follows, for the risk assessment:  1) sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)  2) Triazole alanine (TA) and triazole lactic acid (TLA)  3) Triazole acetic acid (TAA)  4) 1,2,4-triazole (1,2,4-T).  These residue definitions are applicable to primary crops, rotational crops and processed products and for both foliar and seed treatments.  Since all compounds included in the residue definitions are a mixture of enantiomers and since there are no enantiospecific analytical methods, the residue definitions are expressed as “sum of isomers”.  Although the residue definition for risk assessment includes consideration of all metabolites containing a common moiety, it is not possible to develop a common moiety method to meet the residue definition for risk assessment. For this reason, all the analytes have to be determined separately. 6 analytes, representing the major portion of the TRR (Total Radioactive Residue) for prothioconazole in the plant metabolism studies, should be determined in residue trials. These are: prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and alpha-hydroxy-prothioconazole-desthio (including all their acid-hydrolysable conjugates).  No further data are required. |

#### Nature of residue in rotational crops (KCA 6.6.1)

All crops under consideration can be grown in a crop rotation.

According to soil degradation studies, investigated in the framework of the EU pesticides peer review, prothioconazole itself is of very low persistence in soil (DT90 field of 5.5 days (median)), whereas prothioconazole-desthio is of low persistence with DT90 field of 140 days (median) (EFSA, 2007).

Available data

No new data submitted in the framework of this application.

Table 0‑5: Summary of metabolism studies in rotational crops - Prothioconazole

| Crop group | Crop | Label position | Application and sampling details | | | | Reference |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Method,  F or G \* | Rate  (g a.s./ha) | Sowing intervals  (DAT) | Harvest Timing |
| **EU data** | | | | | | | |
| Leafy vegetables | Swiss chard | [U-14C-phenyl]-PTZ | G | 1 x 580 | 28, 146, and 269 | 80, 188 and 348 days after treatment | EFSA, 2007  Phenyl-label: Haas, M., 2001, Report MR-159/00  *(Not protected)*  EFSA, 2014  Triazole label: Duah, F. K.; Kraai, M. J.; 2004, Report No. 200623  *(Not protected)* |
| [3,5-14C-triazole]-PTZ | G | 4 x 204 | 30, 125 and 366 |  |
| Root and tuber vegetables | Turnip | [U-14C-phenyl]-PTZ | G | 1 x 580 | 28, 146, and 269 | Turnip top and root, 94, 201 and 349 days after treatment |
| [3,5-14C-triazole]-PTZ | G | 4 x 204 | 30, 125 and 366 |  |
| Cereals | Wheat | [U-14C-phenyl]-PTZ | G | 1 x 580 | 28, 146, and 269 | Green material, 73, 178, and 327 days after treatment  Hay, 111, 231, and 377 days after treatment  Straw and grain, 145, 269, and 412 days after treatment |
| [3,5-14C-triazole]-PTZ | G | 4 x 204 | 30, 125 and 366 |  |

\* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Summary of rotational crop metabolism studies reported in the EU - Prothioconazole

*EFSA Journal 2014;12(5):3689*

“In wheat grain, the total radioactive residues were recovered at a trace level at all DATs (≤ 0.007 mg eq/kg) and no further metabolites’ identification was attempted. In wheat green material, hay and straw, TRR ranged from 0.021 mg eq/kg (green material, DAT 28) to 0.450 mg eq/kg (straw, DAT 28). In turnip roots, tops and Swiss chard, the highest residue levels ranged from 0.043 mg eq/kg (turnip root, DAT 28) to 0.053 mg eq/kg (Swiss chard, DAT 146). No significant decline of the residue levels was observed for any crop part throughout the first, second and third rotation.

In the edible parts of the crops at harvest 61 to 87 % of the total residues were extracted and the level of identification ranged between 34.4 % TRR (Swiss chard, DAT 269) to 77.2 % TRR (turnip leaves, DAT 28). The major compounds of the total residues were identified as prothioconazole-desthio, its hydroxylated derivative metabolites, either free or conjugated (M14, M15, M16, M17), M27, free and conjugated and M0230. Residue levels of the main metabolites recovered in wheat were in general higher in straw than in hay. In straw, they reached the following levels: prothioconazole-desthio (0.066 mg eq/kg) (DAT 28), M02 (0.063 mg eq/kg) (DAT 269), glucoside of M27 (0.056 mg eq/kg) (DAT 269) and glucosides of the hydroxylated metabolites of prothioconazole-desthio (0.097 mg eq/kg) (DAT 28). In Swiss chard, levels of prothioconazole-desthio reached 0.014 mg eq/kg at 28 DAT, while levels of M27 glucosides were below 0.01 mg eq/kg at all sowing intervals. In turnip roots and leaves, the residue levels of the identified major metabolites were always below 0.01 mg eq/kg.

Consequently, the metabolism of prothioconazole in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.

No rotational crop studies with prothioconazole radiolabelled on the triazole ring were assessed in the framework of the peer review but such studies were reported and assessed by the JMPR (FAO, 2008a, 2008b). These indicated a cleavage of the triazole linkage with the formation of the major metabolites found in all rotational crop matrices as triazole alanine, triazole lactic acid and triazole acetic acid. Both the parent prothioconazole and prothioconazole-desthio were identified as minor metabolites.

Considering the application rates of prothioconazole reported in the authorized European GAPs, it can be concluded that prothioconazole residue levels in food and feed rotational commodities are expected to be covered by the residue levels in primary crops and no risk mitigation measures need to be proposed.”

For prothioconazole radiolabelled on the triazole ring, it is proposed to refer to the unprotected study Duah, F. K.; Kraai, M. J.; 2004 (Report No. 200623), also presented in the draft RAR (UK, 2018).

*Draft Renewal Assessment Report of Prothioconazole (UK, 2018)*

“The nature and accumulation of [triazole-3,5-14C] prothioconazole residues was studied in confined rotational crops (cereals, leafy vegetables, and root crops) in the US.

The major residues found in all rotational crop matrices were triazolyl alanine (TA), triazolyl hydroxy propionic acid (THP) [also called Triazole lactic acid (TLA)], and triazolyl acetic acid (TAA).

TA (M31) represented 44 - 51 % of the TRR (0.120 - 0.252 mg/kg) in wheat forage, 33 - 36 % (0.719 - 0.846 mg/kg) in wheat hay, 15 - 28 % (0.197 - 0.407 mg/kg) in wheat straw, 58 - 68 % (2.264 - 3.940 mg/kg) in wheat grain, 49 - 56 % (0.023 - 0.096 mg/kg) in Swiss chard, 74 - 92 % (0.077 - 0.377 mg/kg) in turnip tops, and 81 - 93 % (0.048 - 0.411 mg/kg) in turnip roots.

THP (M30) represented 32 - 35 % (0.087 - 0.184 mg/kg) of the TRR in wheat forage, 24 - 39 % (0.562 - 0.871 mg/kg) in wheat hay, 28 - 33 % (0.382 - 0.498 mg/kg) in wheat straw, <1 - 1 % (0.023 - 0.047 mg/kg) in wheat grain, 30 - 32 % (0.038 - 0.060 mg/kg) in Swiss chard, 7 % (0.035 mg/kg) in turnip tops at 125 DAT, and 1 - 5 % (0.003 - 0.005 mg/kg) in turnip roots at 30 DAT and 125 DAT.

TAA represented 1 - 6 % (0.006 - 0.034 mg/kg) of the TRR in wheat forage, 10 - 22 % (0.222 - 0.578 mg/kg) in wheat hay, 17 - 26 % (0.233 - 0.437 mg/kg) in wheat straw, 23 - 29 % (0.958 - 1.485 mg/kg) in wheat grain, 1 - <18 % (0.001 - <0.008 mg/kg) in Swiss chard, <7 % (0.009 mg/kg or less) in turnip tops, and <5 % (<0.005 mg/kg) in turnip roots.

The minor residues found in the rotational crops were prothioconazole-desthio (M04), <1 - 4 % of the TRR (0.001 - 0.020 mg/kg) in all matrices except wheat grain; prothioconazole-triazolyl-ethanol-glucoside (M46), <1 - 5 % of the TRR (0.001 - 0.063 mg/kg) in all matrices except wheat grain and Swiss chard; prothioconazole-triazolyl-ethanol (M45), <1 - 7 % of the TRR (0.002 - 0.030 mg/kg) in all matrices except wheat grain; and prothioconazole-α-hydroxy-desthio (M18), <1 - 2 % of the TRR (0.002 - 0.026 mg/kg) in all matrices except wheat grain and Swiss chard. No prothioconazole was detected in any matrix at any DAT interval.

The major metabolites found in all crops were prothioconazole-desthio (M04), TA (M31), THP (M30) and TAA (M29). As no 1,2,4-triazole was detected in any matrix it is assumed that 1,2,4 triazole (M13) was rapidly transformed to the metabolites TA, THP and TAA.”

Summary of rotational crop metabolism studies reported in the EU - TDMs

*Triazole Derivate Metabolites, addendum – confirmatory data (UK, 2018)*

“For the rotational crops, metabolism data are available on leafy crops, root crops and cereal grain and straw for a total of 12[[1]](#footnote-1) approved triazole active substances and one non approved triazole active substance (flusilazole).

The rotational crop metabolism studies for the triazole active substances demonstrate that triazole alanine (TA), triazole acetic acid (TAA) and/or triazole lactic acid (TLA) were often found to represent a significant portion of the total radioactive residue in the rotational crops; in addition, 1,2,4-triazole (T) was detected but usually at much lower levels. Therefore, a number of field rotational crop trials have been conducted to investigate the magnitude of triazole derivative metabolite (TDM) residues in rotational crops after the use of triazole active substances”.

*EFSA Journal 2020;18(2):5999*

“During the peer review of TDMs in light of confirmatory data, the metabolism of various triazole compounds in rotational and primary crops was investigated. It was concluded that for TDMs similar metabolic patterns were depicted both in primary and rotational crops (EFSA, 2018)”. See also 7.2.2.1.

Conclusion on metabolism in rotational crops

The metabolism of prothioconazole and TDMs in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not necessary.

Since the intended cGAPs are covered by the authorized European GAPs (EFSA RO, 2014), it can be concluded that prothioconazole residue levels in food and feed rotational commodities are expected to be covered by the residue levels in primary crops and no risk mitigation measures need to be proposed.

Regarding TDMs, in the framework of the confirmatory data, a number of field rotational crop trials have been conducted to investigate the magnitude of TDM residues in rotational crops after the use of triazole active substances.

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| **zRMS comments:**  Information given by the Applicant is acceptable and sufficient.  In EFSA Journal 2020;18(2):5999 it is stated that *The metabolism of prothioconazole in rotational crops was investigated in the framework of the EU pesticides peer review in Swiss chards, turnips and spring wheat following the treatment of bare soil with prothioconazole at an application rate of 580 g/ha using the compound labelled in the phenyl ring. The main compounds identified were prothioconazole-desthio and its hydroxylated derivative metabolites, either free or conjugated.*  *The MRL review concluded that metabolism of prothioconazole in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not necessary (EFSA, 2014).*  *The metabolism of prothioconazole labelled in triazole ring was assessed by the JMPR (FAO, 2009a) as reported in the MRL review. The studies indicate the cleavage of triazole linkage to form major metabolites TA, TLA and TAA (EFSA, 2014). During the peer review of TDMs in light of confirmatory data, the metabolism of various triazole compounds in rotational and primary crops was investigated.*  *It was concluded that for TDMs similar metabolic patterns were depicted both in primary and rotational crops (EFSA, 2018b).*  No further data are required. |

#### Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Summary of studies reported in the EU – Prothioconazole and TDMs

*EFSA Scientific Report (2007) 106, 1-98, Conclusion on the peer review of prothioconazole*

“As prothioconazole residues in treated commodities at harvest are at or near the LOQ and given the low degree of ADI exhaustion in consumer risk assessment, the effect of processing on the nature and level of residues were not investigated.”

*EFSA Journal 2020;18(2):5999*

“The TDMs remained stable under the standard hydrolysis conditions simulating processing of pasteurisation, baking, brewing and boiling and sterilisation.”

Conclusion on nature of residues in processed commodities

No prothioconazole residue above the trigger value of 0.1 mg/kg is expected in raw agricultural commodities from the intended uses. Therefore, studies investigating the nature and magnitude of prothioconazole residues in processed commodities are not required (Reg. (EU) No 544/2011).

Regarding TDMs, studies show that they remained stable under the standard hydrolysis conditions.

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| **zRMS comments:**  The effect on the nature of prothioconazole and prothioconazole-desthio has not been investigated in the framework of the EU pesticides peer review.  The TDMs are stable under hydrolysis studies simulating baking/brewing/boiling, pasteurisation and sterilisation (EFSA, 2018).  As residues of prothioconazole exceeding 0.1 mg/kg are not expected in the treated crops, there is no need to investigate the effect of industrial and/or household processing.  No further data are required. |

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#### Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 0‑6: Summary of the nature of residues in commodities of plant origin

|  |  |
| --- | --- |
| **Endpoints** | |
| Plant groups covered | Cereals (Wheat)  Pulses and oilseeds (Peanut) |
| Rotational crops covered | Cereals (Wheat)  Leafy crops (Swiss chards)  Root and tuber vegetables (Turnips) |
| Metabolism in rotational crops similar to metabolism in primary crops? | Yes |
| Processed commodities | Not required for prothioconazole.  TDMs are stable under standard hydrolysis conditions. |
| Residue pattern in processed commodities similar to pattern in raw commodities? | Not applicable. |
| Plant residue definition for monitoring | RD-Monit.: Prothioconazole: Prothioconazole-desthio (sum of isomers) (Reg. (EU) ~~2019/552~~ 2024/1318 and EFSA, 2020) |
| Plant residue definition for risk assessment | RD-RA1) Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA, 2014)  RD-RA2) TDMs (EFSA, 2018), with separate assessment of:  - Triazole alanine (TA) and triazole lactic acid (TLA)  - Triazole acetic acid (TAA)  - 1,2,4-triazole (1,2,4-T) |
| Conversion factor from enforcement to RA | Tentative conversion factors\* (based on metabolism study results) to account for hydroxy metabolites of prothioconazole-desthio:   * 2 in cereal grains, pulses and oilseeds, leafy vegetables and tuber vegetables (EFSA, 2014) * 2.3 in wheat straw (EFSA, 2020) * 3 in other cereal straw (EFSA, 2014) |

\*only applicable from RD-Monit. to RD-RA1 ; it is not possible to derive a CF from RD-Monit to RD-RA2.

#### Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

Table 0‑7: Summary of animal metabolism studies - Prothioconazole

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Group | Species | Label position | No of animal | Application details | | Sample details | | Reference |
| Rate  (mg/kg bw/d) | Duration  (days) | Commodity | Time of samp­ling |
| **EU data and New data** | | | | | | | | |
| Lactating ruminants | Goat | [U-14C-phenyl] prothioconazole | 1 | 10 (250 mg a.s./kg feed) | 3 | Milk | twice daily | EFSA, 2007  Report No.: MR-092/01  *(Not protected)* |
| Urine and faeces | Daily and at sacrifice |
| Tissues | at sacrifice |
| [U-14C-phenyl] prothioconazole-desthio | 1 | 10 (195 mg a.s./kg feed) | 3 | Milk | twice daily | EFSA, 2007  Report No.: MR-091/01 and MEF-06/469  *(Not protected)* |
| Urine and faeces | Daily and at sacrifice |
| Tissues | at sacrifice |
| [3,5-14C-triazole] prothioconazole | 1 | 10 | 3 | Milk | twice daily | EFSA, 2014  Report MR-448/02  *(Not protected)* |
| Urine and faeces | Daily and at sacrifice |
| Tissues | at sacrifice |
| Laying poultry | Hens | [U-14C-phenyl] prothioconazole | 6 | 10 | 3 | Eggs | Once daily | EFSA, 2007  Report No.: MR-309/01  *(Not protected)* |
| Excreta | At regular intervals |
| Tissues | at sacrifice (5 h after last administration) |
| [3,5-14C-triazole] prothioconazole | 6 | 10 | 3 | Eggs | Once daily | EFSA, 2014  Report No.: MEF-005/03  *(Not protected)* |
| Excreta | At regular intervals |
| Tissues | at sacrifice (5 h after last administration) |

Summary of livestock metabolism studies - Prothioconazole

*EFSA Journal 2014;12(5):3689*

“The nature of prothioconazole residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (United Kingdom, 2004, 2007). Reported metabolism studies include two studies in lactating goats using respectively [U-14C-phenyl]-labelled prothioconazole and prothioconazole-desthio and one study in laying hens using [U-14C-phenyl]-labelled prothioconazole. Besides, two additional studies were assessed by the JMPR (FAO, 2008a, 2008b) on lactating goats and laying hens, using both [3,5-14C-triazole]-labelled prothioconazole.

*Lactating goats*

In each study, lactating goats were dosed with 10 mg/kg bw per d of prothioconazole or prothioconazole-desthio. The metabolism study conducted with prothioconazole was reported for information purposes only since the animals are mainly exposed to the prothioconazole-desthio residues. For prothioconazole-desthio, the application rate was overdosed, corresponding to approximately 48 times the exposure of meat ruminants.

In the studies performed with both phenyl and triazole ring labelling of prothioconazole, the highest residue levels were found in kidney (6.8 - 4.5 mg eq/kg) and liver (6.1 - 6.2 mg eq/kg), respectively.

The total radioactive residues accounted respectively for 0.037 - 0.15 mg eq/kg in milk, 0.088 - 0.117 mg eq/kg in muscle and 0.169 - 0.174 mg eq/kg in fat. The extractabilities of the radioactive residues in all matrices ranged from 77 % (fat) to 98 % of the TRR (kidney). Identified radioactivity accounted for 57 % to 78 % of the TRR. Prothioconazole was rapidly adsorbed and extensively metabolised in all matrices but remained a significant compound of the residues in liver (13 – 17 % TRR), muscle, kidney, and fat (7 - 20 % TRR) and to a minor extent in milk (0.9 % - 3 % TRR). Prothioconazole-desthio was detected at low levels in all matrices (< 5 % TRR), except in fat (19 % TRR, 0.032 mg eq/kg). The only identified triazole related metabolite was the thiocyanate metabolite: 41 % TRR (0.061 mg eq/kg) in milk, 30 % TRR (0.035 mg eq/kg) in muscle, 12 % TRR (0.022 mg eq/kg) in fat, 9 % TRR (0.41 mg eq/kg) in kidney and 2 % TRR (0.13 mg eq/kg) in liver. At the maximum dietary burden of meat ruminants, this metabolite is expected to occur at a trace level in all matrices (up to 0.004 mg eq/kg in kidney). There is therefore no need to further address its toxicological properties.

In the study performed with [U-14C-phenyl]-labelled prothioconazole-desthio, the highest residue levels were found in kidney and liver (up to 19 mg eq/kg). Total radioactive residues in milk, muscle and fat accounted for 0.286 mg eq/kg, 0.266 mg eq/kg and 0.231 mg eq/kg, respectively. The extractabilities of the residues in all matrices ranged from 82 % (liver) to 97 % of TRR (kidney). The rate of identification amounted to 70 % to 89 % of the TRR. Prothioconazole-desthio was the predominant compound of the total residues in liver (31.2 % TRR - 5.7 mg eq/kg) and in kidney both under its free and glucuronide conjugated forms (32 % TRR – 6 mg eq/kg) whilst it was extensively metabolised as glucuronide conjugates of the hydroxylated related metabolites in milk, muscle and fat. Metabolite M32[[2]](#footnote-2) both under its free and glucuronide conjugated form was the predominant compound of the total residues in muscle (32 % TRR – 0.085 mg eq/kg), fat (27 % TRR – 0.063 mg eq/kg) and kidney (23 % TRR - 4.299 mg eq/kg). In milk, only prothioconazole-desthio under its glucuronide conjugated form was detected at a rather low level (6 % TRR – 0.017 mg eq/kg) whilst the sulphate conjugates of hydroxylated derivative prothioconazole-desthio metabolites (M14/M15/M16/M17/M28[[3]](#footnote-3)/M34[[4]](#footnote-4)/M35[[5]](#footnote-5)) constituted the major part of the total residue in milk (44 % TRR, 0.126 mg eq/kg). All other compounds accounted for less than 10 % TRR.

Following prothioconazole administration to rats, metabolite 1,2,4-triazole was recovered in urine at minor amounts (2.3 % AR), whilst it was not recovered in goats. Therefore, meanwhile a harmonized approach on how to consider TDMs in the risk assessment, the general metabolic pathways in rodents and ruminants can be considered as comparable, mainly involving various types of hydroxylation affecting the chlorophenyl ring and leading to the formation of metabolites both under their free and glucuronide or sulphate conjugated forms. The metabolic pathway of prothioconazole-desthio depicted in ruminants can therefore be extrapolated to pigs.

*Laying hens*

Laying hens were dosed with 10 mg/kg bw per d of phenyl and triazole labelled prothioconazole, respectively. The major part of the total administered dose (AR) was recovered in excreta (66 % and 78 % AR for the triazole and phenyl ring labelling, respectively) and only trace amounts of radioactivity were detected both in eggs (0.01 % AR) and tissues (about 0.9 % AR).

The total radioactive residues accounted for 4.0 – 3.5 mg eq/kg in liver, 0.036 – 0.05 mg eq/kg in eggs, 0.45 – 0.29 mg eq/kg in subcutaneous fat and 0.089 – 0.12 mg eq/kg in muscle, respectively for the phenyl and triazole ring labelling. The extractability of the total radioactive residues ranged from 77 % TRR in eggs to 98 % TRR in fat.

Prothioconazole was the major compound of the total residues in liver (25 % - 31 % TRR, 1.0 - 1.1 mg/kg) and in fat (30 % - 16 % TRR, 0.14 - 0.046 mg/kg) for the phenyl and triazole labels, respectively. Prothioconazole-desthio (29 % - 27 % TRR, 0.13 - 0.08 mg eq/kg) and M01[[6]](#footnote-6) (20 % - 29 % TRR, 0.083 - 0.088 mg eq/kg) in fat as well as M06[[7]](#footnote-7) in liver (12 % - 15 % TRR, 0.48 - 0.53 mg eq/kg) were the only metabolites exceeding 10 % of the TRR in these commodities. In muscle, the major compounds were M45[[8]](#footnote-8) (28 % TRR, 0.035 mg eq/kg) and 1,2,4-triazole (19 % TRR, 0.023 mg eq/kg) specific to the triazole labelling, and M06 (16 % - 10 % TRR, 0.014 - 0.012 mg eq/kg) and parent prothioconazole (11 % - 2.5 % TRR, 0.01 - 0.003 mg eq/kg) for phenyl and triazole labelling, respectively. Prothioconazole-desthio accounted for only 7 % - 2.1 % TRR (0.006 - 0.003 mg eq/kg). In eggs, the major compounds of the total residues were M06 (24 % - 16 % TRR, 0.012 - 0.014 mg eq/kg) and prothioconazole-desthio (20 % - 6.2 % TRR, 0.007 - 0.003 mg eq/kg) for phenyl and triazole label, respectively. For the triazole labelling moiety, the metabolites M45 (15.6% TRR, 0.008 mg eq/kg) and 1,2,4-triazole (11 % TRR, 0.006 mg eq/kg) were also identified. Prothioconazole accounted for only 3.6 % - 3.4 % TRR (0.001 - 0.002 mg eq/kg), for phenyl and triazole label, respectively. All other metabolites identified were either glucuronic acid or sulphate conjugates of the hydroxylated prothioconazole and accounted for less than 10 % TRR.

*Overall assessment*

It is noted that in poultry no study was performed with prothioconazole-desthio and that the fate of the triazole moiety in livestock was only investigated for prothioconazole. However, the available studies indicate similar metabolic patterns for the different compounds and moieties investigated. Additional studies addressing these requirements are therefore not expected to provide different results. It is also noted that no livestock metabolism study was performed with administration of all the metabolites included in the residue definition set for risk assessment in plants. Nevertheless, EFSA assumes that the administration of prothioconazole-desthio only in the livestock metabolism studies is acceptable since no different metabolic route of degradation would be expected if all the metabolites containing the moiety of the residue definition for risk assessment in plants were considered. Therefore, no additional metabolism data are deemed necessary.

Based on the overall metabolic picture of prothioconazole and prothioconazole-desthio in animals, the residue definition for enforcement in animal products is proposed as prothioconazole-desthio (sum of isomers) for all livestock matrices. It is noted that although only the glucuronide conjugates of prothioconazole-desthio were detected in milk, the actual residue levels are expected at a trace level at the calculated dietary burden (< 0.01 mg/kg) and EFSA considers that analysing the conjugates of prothioconazole-desthio would have a negligible impact on the residue levels enforced in milk. In case the livestock dietary burden is further increased in the future due to additional uses on feed items, the residue definition for enforcement might have to be revised by including the glucuronide conjugates of prothioconazole-desthio for all livestock matrices.

For risk assessment, since all the metabolites are structurally related to prothioconazole-desthio and consist mainly in hydroxylated derivatives, EFSA assumes as a worst case that the toxicological end points allocated to prothioconazole-desthio should also be applied to these metabolites. The residue is therefore defined in all commodities of animal origin as the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2- chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers).”

Summary of livestock metabolism studies - TDMs

*EFSA Journal 2018;16(7):5376*

“Compiled metabolism data respectively for ruminants (11[[9]](#footnote-9)) and for poultry (6[[10]](#footnote-10)) from approved triazole active substances were available.

The compilation of the poultry and ruminant metabolism studies conducted with the triazole pesticide active substances with the 14C labelling on the triazole moiety showed that besides the parent compound that was detected in significant proportions in all animal matrices ranging between 27% and 81% TRR in milk, eggs and tissues, 1,2,4-T was also found to be a predominant compound of the total residues with levels ranging from 31% to 86% TRR in those matrices. TA was identified at very low levels in poultry muscle only (< 10% TRR) and at levels between 22% and 39% TRR in ruminant matrices.

Since TA is a major component in feed items, the potential transfer of this compound in poultry andruminant matrices was further investigated in a metabolism study conducted with 14C-TA. TA remainsthe major compound of the total residues in all poultry matrices (84–97.2% TRR) and in ruminanttissues (56–76% TRR) while TA and 1,2,4-T accounted for 8% and 86% TRR, respectively, in milk. TLAand TAA were detected in very low levels in all matrices (< 1% TRR). The potential transfer of TAA,TLA and 1,2,4-T present in feed items to the animal matrices was not further investigated. Althoughthere are indications from the ruminant metabolism study conducted with the 14C-TA, that there is noaccumulation of TAA and TLA (4.2% and < 1% of the total administered dose in urine, respectively),these metabolites were however detected in the ruminant matrices from the feeding study conductedwith TA.”

Conclusion on metabolism in livestock

The available studies indicate similar metabolic patterns for the different compounds and moieties investigated. Although no livestock metabolism study was performed with administration of all the metabolites included in the residue definition set for risk assessment in plants, EFSA assumed that the administration of prothioconazole-desthio only in the livestock metabolism studies is acceptable since no different metabolic route of degradation would be expected if all the metabolites containing the moiety of the residue definition for risk assessment in plants were considered. Therefore, no additional metabolism data are deemed necessary.

According to SANTE/11509/2013 – rev. 5.2 and since the active substance prothioconazole is not yet renewed, the “old data requirements” (Reg. (EU) No 544/2011) and the endpoints from the inclusion of prothioconazole (DAR) apply to the current assessment. Therefore, no residue data on fish are required.

|  |
| --- |
| **zRMS comments:**  Information given by the Applicant is acceptable and sufficient.  In EFSA Journal 2014;12(5):3689 it is stated that *Based on the overall metabolic picture of prothioconazole and prothioconazole-desthio in animals, the residue definition for enforcement in animal products was set as* ***prothioconazole-desthio (sum of isomers)*** *for all the livestock matrices. This compound is fat soluble.*  *(…) For risk assessment, the residue was defined in all commodities of animal origin as the* ***sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2- chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers).***  According to the EFSA Journal 2018;16(7):5376: *Ruminant and poultry metabolism studies labelled on the triazole ring are available.*  *(…) Based on the metabolism studies conducted, respectively, with triazole pesticide active substances and TA and considering the results of the livestock feeding studies carried out with TA and TAA, respectively, the experts agreed on the following residue definitions:*   * *Residue definition for enforcement: triazole parent compound only* * *Residue definition for risk assessment:*  1. *Triazole parent compound and any other relevant metabolite exclusively linked to the parent compound;* 2. *TA and TLA, since these compounds share the same toxicity;* 3. *TAA;* 4. *1,2,4-triazole.*   No further data are required. |

#### Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 0‑8: Summary on the nature of residues in commodities of animal origin

|  |  |
| --- | --- |
|  | Endpoints |
| Animals covered | Lactating goats |
| Laying hens |
| Time needed to reach a plateau concentration | 1-2 days in milk |
| Not observed in eggs |
| Animal residue definition for monitoring | Prothioconazole-desthio (sum of isomers) (EFSA, 2014 and Reg. (EU) ~~2019/552~~ 2024/1318) |
| Animal residue definition for risk assessment | RD-RA1) Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA, 2014)  RD-RA2) TDMs (EFSA, 2018), with separate assessment of:  - Triazole alanine (TA) and triazole lactic acid (TLA)  - Triazole acetic acid (TAA)  - 1,2,4-triazole (1,2,4-T) |
| Conversion factor | EFSA, 2014\*:   * Ruminant liver: 2 * Ruminant kidney: 9 * not necessary for milk, ruminant muscle and ruminant fat |
| Metabolism in rat and ruminant similar | Yes |
| Fat soluble residue | Yes, Log Pow for prothioconazole-desthio = 3.04 |

\*Only applicable from RD-Monit. to RD-RA1; it is not possible to derive a CF from RD-Monit to RD-RA2.

### Magnitude of residues in plants (KCA 6.3)

#### Summary of European data and new data supporting the intended uses

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarized in the Tables below. The detailed assessment of these studies is presented in Appendix 2.

It should be noted that:

* Only trials performed in the northern residue zone are presented.
* The selection of supporting data was made based on the BBCH growth stage at last application as according to SANTE/2019/12752 “In some cases (e.g., cereals, oilseeds), the crop growth stage at application is more important to consider for the selection of GAP-compliant trials while PHI (if specified in the GAP) may be of secondary relevance”.

#### Prothioconazole

The residue levels according to the residue definition for monitoring (E = prothioconazole-desthio: sum of isomers) and for risk assessment n°1 (RA1 = sum of prothioconazole-desthio and its hydroxy metabolites) are presented in the Table 0‑10.

In the framework of the active substance first inclusion, trials measuring levels of prothioconazole-desthio only in barley, wheat and oilseed rape were assessed in the DAR (UK, 2007). A summary is presented in the table below. These EU data were not considered as new trials measuring all compounds relevant to the RD-RA1 were performed and provided by the applicant in the present dossier.

Table 0‑9: Summary of EU data - Prothioconazole

| Commodity | Source | Residue zone (N-EU, S-EU, EU, outside EU) | Evaluation GAP Residue levels (mg/kg) E = prothioconazole-desthio (sum of isomers) RA1 = sum of prothioconazole-desthio and its hydroxy metabolites |
| --- | --- | --- | --- |
| Barley  Grain | DAR (UK, 2007)  EFSA, 2007 | N-EU  (9) | GAP on which EU a.s. assessment is based: 2 x 200 g a.s./ha, BBCH 30-61  E: 9 x <0.01  RA1: no data on prothioconazole-hydroxy-desthio |
| Barley  Straw | DAR (UK, 2007)  EFSA, 2007 | N-EU  (9) | GAP on which EU a.s. assessment is based: 2 x 200 g a.s./ha, BBCH 30-61  E: 0.05, 0.08, 2x 0.10, 2x 0.13, 2x 0.14, 0.30  RA1: no data on prothioconazole-hydroxy-desthio |
| Wheat  Grain | DAR (UK, 2007)  EFSA, 2007 | N-EU  (11) | GAP on which EU a.s. assessment is based: 3 x 200 g a.s./ha, BBCH 26-69  E: 11 x <0.01  RA1: no data on prothioconazole-hydroxy-desthio |
| Wheat  Straw | DAR (UK, 2007)  EFSA, 2007 | N-EU  (11) | GAP on which EU a.s. assessment is based: 3 x 200 g a.s./ha, BBCH 26-69  E: 11 x <0.01  RA1: no data on prothioconazole-hydroxy-desthio |
| Oilseed rape  Seeds | DAR (UK, 2007)  EFSA, 2007 | N-EU  (8) | GAP on which EU a.s. assessment is based: 2 x 175 g a.s./ha, start BBCH 53, 14-28d int.  E: 5 x < 0.01, 1 x 0.01, 2 x 0.02  RA1: no data on prothioconazole-hydroxy-desthio |

Table 0‑10: Summary of new data supporting the intended uses of CA3642 and conformity to existing MRL – Prothioconazole

| Commodity | Source | Residue zone (N-EU, S-EU, EU, outside EU) | Evaluation GAP Residue levels (mg/kg) E = prothioconazole-desthio (sum of isomers) RA1 = sum of prothioconazole-desthio and its hydroxy metabolites | STMR (mg/kg) | HR (mg/kg) | Unrounded OECD calculator MRL (mg/kg)  (Rounded) | Current EU MRL  (mg/kg)  \* | MRL compliance |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Barley 🡪 Oat  Grain | New trials  *Study 10-2204* | N-EU  (2) | Trials GAP: 2 x 150 g a.s./ha, BBCH 61, PHI 34-35d  E: 2x <0.01  RA1: 2x <0.06 | N/A | | | | |
| New trials  *Studies 13-2137 & 13-2158* | N-EU  (4) | Trials GAP: 2 x 125-135 g a.s./ha, BBCH 61, PHI 35-68d  E: 3x <0.01, 0.011  RA1: 3x <0.06, 0.061 |
| New trials  *Study 17-2076* | N-EU  (2) | Trials GAP: 2 x 140 g a.s./ha, BBCH 61, PHI 43-56d  E: 2x <0.01  RA1: 2x <0.06 |
| **Overall supporting data for cGAP**  ***Barley grain*** | N-EU  (8)  *New trials* | **Intended cGAP: 2 x 150 g a.s./ha, BBCH 30-61**  E: 7x <0.01, 0.011  RA1: 7x <0.06, 0.061 | E: 0.01\*  RA: 0.06\* | E: 0.011  RA: 0.061 | 0.013 (0.015) | Barley 0.2;  Oat 0.05 | Yes  Yes |
| Barley 🡪 Oat  Straw | New trials  *Study 10-2204* | N-EU  (2) | Trials GAP: 2 x 150 g a.s./ha, BBCH 61, PHI 34-35d  E: 0.11, 0.54  RA1: 0.41, 1.2 | N/A | | | | |
| New trials  *Studies 13-2137 & 13-2158* | N-EU  (4) | Trials GAP: 2 x 125 g a.s./ha, BBCH 61, PHI 35-68d  E: 0.039, 0.044, 0.087, 0.81  RA1: 0.10, 0.18, 0.43, 2.2 |
| New trials  *Study 17-2076* | N-EU  (2) | Trials GAP: 2 x 140 g a.s./ha, BBCH 61, PHI 43-56d  E: <0.01, 0.14  RA1: <0.06, 0.34 |
| **Overall supporting data for cGAP**  ***Barley straw*** | N-EU  (8)  *New trials* | **Intended cGAP: 2 x 150 g a.s./ha, BBCH 30-61**  E: <0.01, 0.039, 0.044, 0.087, 0.11, 0.14, 0.54, 0.81  RA1: <0.06, 0.10, 0.18, 0.34, 0.41, 0.43, 1.2, 2.2 | E: 0.099  RA: 0.375 | E: 0.81  RA: 2.2 | - | - | N/A |
| Wheat 🡪 Triticale, Rye  Grain | New trials  *Study 17-2015* | N-EU  (4) | Trials GAP: 2 x 200 g a.s./ha, BBCH 69, PHI 26-61d  E: 4x <0.01  RA1: 4x <0.06 | N/A | | | | |
| New trials  *Study 16-2046* | N-EU  (4) | Trials GAP: 2 x 200 g a.s./ha, BBCH 65-69, PHI 50-62d  E: 4x <0.01  RA1: 4x <0.06 |
| New trials  *Study S19-01268* | N-EU  (4) | Trials GAP: 2 x 200 g a.s./ha, BBCH 71-73, PHI 35d  E: 2x <0.003, <0.01, 0.01  RA1: 4x <0.06 |
| **Overall supporting data for cGAP**  ***Wheat grain*** | N-EU  (12)  *New trials* | **Intended cGAP: 2 x 210 g a.s./ha, BBCH 30-69**  E: 2x <0.003, 9x <0.01, 0.01  RA1: 12x <0.06 | E: 0.01\*  RA: 0.06\* | E: 0.01  RA: 0.06\* | 0.02 | Wheat, Triticale, Spelt 0.1;  Rye 0.05 | Yes  Yes |
| Wheat 🡪 Triticale, Rye  Straw | New trials  *Study 17-2015* | N-EU  (4) | Trials GAP: 2 x 200 g a.s./ha, BBCH 69, PHI 26-61d  E: 0.041, 0.089, 0.15, 0.18  RA1: 0.28, 0.30, 0.64, 1.01 | N/A | | | | |
| New trials  *Study 16-2046* | N-EU  (4) | Trials GAP: 2 x 200 g a.s./ha, BBCH 65-69, PHI 50-62d  E: 0.040, 0.046, 0.083, 0.094  RA1: 0.11, 0.12, 0.38, 0.60 |
| New trials  *Study S19-01268* | N-EU  (4) | Trials GAP: 2 x 200 g a.s./ha, BBCH 71-73, PHI 35d  E: 0.15, 0.28, 0.42, 0.98  RA1: 0.39, 1.4, 1.19, 2.93 |
| **Overall supporting data for cGAP**  ***Wheat straw*** | N-EU  (12)  *New trials* | **Intended cGAP: 2 x 210 g a.s./ha, BBCH 30-69**  E: 0.040, 0.041, 0.046, 0.083, 0.089, 0.094, 0.15, 0.15, 0.18, 0.28, 0.42, 0.98  RA1: 0.11, 0.12, 0.28, 0.30, 0.38, 0.39, 0.60, 0.64, 1.01, 1.4, 1.19, 2.93 | E: 0.12  RA: 0.495 | E: 0.98  RA: 2.93 | - | - | N/A |
| Oilseed rape 🡪 Sunflower, Linseed, Poppy, Mustard, Gold of pleasure  Seeds | New trials  *Study S19-01269* | N-EU  (4) | Trials GAP: 2 x 175 g a.s./ha, BBCH 69, PHI 56-39d  E: 2x <0.01, 0.01, 0.03a  RA1: 2x <0.06, 0.06, 0.08a | N/A | | | | |
| New trials  *Study S20-01046* | N-EU  (3) | Trials GAP: 2 x 175 g a.s./ha, BBCH 69-76, PHI 56-59d  E: <0.003, 0.01, 0.02  RA1: <0.06, 0.06, 0.07 |
| New trials  *Study S21-00259* | N-EU  (1) | Trials GAP: 2 x 175 g a.s./ha, BBCH 69, PHI 56d  E: <0.003  RA1: <0.03 |  | | | | |
| New trials  *Study S22-00257* | N-EU  (3) | Trials GAP: 2 x 175 g a.s./ha, BBCH 69, PHI 56d  E: 3x <0.01  RA1: 0.03, <0.04, 0.06 |  | | | | |
| **Overall supporting data for cGAP**  ***OSR seeds*** | N-EU  ~~(8~~) 11  *New trials* | **Intended cGAP: 1 x 180 g a.s./ha, BBCH 69**  E: 2x <0.003, ~~2x~~ 5x<0.01, 2x 0.01, 0.02, 0.03a  RA1: <0.03, 0.03, 0.04, 3x <0.06, ~~2x~~ 3x0.06, 0.07, 0.08a | E: 0.01  RA: 0.06 | E: 0.03  RA: 0.08 | ~~0.048 (0.05)~~  ~~Rber 0.04/Rmax 0.04~~  0.050 (0.05)  Rber 0.02/Rmax 0.03 | Rapeseed 0.15.  Linseed, Poppy, Mustard 0.09.  Gold of pleasure 0.04 | Yes  Yes  Yes, according to HR, Rber/Rmax |
| **Overall supporting data for gold of pleasure** | Merged N-EU + S-EU  ~~(16)~~  (19) | **Intended cGAP: 1 x 180 g a.s./ha, BBCH 69**  NEU:  ~~E: 2x <0.003, 2x <0.01, 2x 0.01, 0.02, 0.03~~~~a~~  ~~RA1: <0.03, 3x <0.06, 2x 0.06, 0.07, 0.08~~~~a~~  E: 2x <0.003, ~~2x~~ 5x<0.01, 2x 0.01, 0.02, 0.03a  RA1: <0.03, 0.03, 0.04, 3x <0.06, ~~2x~~ 3x0.06, 0.07, 0.08a  SEU:  E: 3x <0.003, 2x <0.01, 2x 0.01, 0.02  RA1: 0.03, 5x <0.06, 0.06, 0.08 | E: 0.01  RA: 0.06 | E: 0.03  RA: 0.08 | 0.04 (0.04) | Gold of pleasure 0.04 | Yes |

\* Source of EU MRL: Reg. (EU) ~~2019/552~~ 2024/1318

a Oilseed rape: positive control for PTZ-desthio in seeds which leads to a higher residue level (highest value found in control seeds). As a worst case approach the value from the control sample was used for MRL compliance and risk assessment: results of the calculation show that no MRL exceedance and no unacceptable risk for consumers (see 7.2.8) is expected. The applicant will launch new trials in 2022 to address this.

#### Triazole derivative metabolites (TDMs)

Triazole derivative metabolites (TDMs) are common metabolites of all triazole fungicides and have to be considered in the consumer risk assessment. The data on TDMs provided in the present application are from the “Triazole Derivate Metabolites addendum – confirmatory data prepared by the rapporteur Member State, the United Kingdom” (UK, 2018). As confirmatory data, they are out of data protection. Only trials performed with prothioconazole were considered and presented hereafter. Detailed results tables are reported in Appendix 2.

In most trials, TDMs were at a similar level in the control and treated samples. As triazoles are a common ingredient of numerous pesticides which were widely used as fungicides in various field crops and that TDMs show a great persistence in the soils, the contamination of control samples is most likely origin in former usage of pesticides containing triazoles on the sampling sites or nearby. The highest level between control and treated samples were therefore selected for the assessment.

The residue levels according to the residue definition for risk assessment n°2 (TDMs) are presented in Table 0‑11.

Table 0‑11: Summary of EU reported and new data supporting the intended uses of CA3642 and conformity to existing MRL – TDMs

| Commodity | Source | Residue zone (N-EU, S-EU, EU, outside EU) | Evaluation GAP Residue levels (mg/kg) RA2  TDMs | STMR (mg/kg) | HR (mg/kg) | Unrounded OECD calculator MRL (mg/kg) | Current EU MRL  (mg/kg)  \* | MRL compliance |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Barley 🡪 Oat  Grain | Confirmatory data TDMs – Prothioconazole (UK, 2018) | N-EU  (8)  Except TLA (4) | Trials GAP: 2 x 150-200 g a.s./ha, BBCH 61, PHI 34-63d  1,2,4-T: 7x <0.01, 0.011  TAA: 0.033, 0.057, 0.057, 0.067, 0.157, 0.172, 0.217, 0.32  TA: 0.043, 0.184, 0.190, 0.226, 0.230, 0.250, 0.405, 0.440  TLA: 3x <0.01, 0.012 | N/A | | | | |
| N-EU  (2) | Trials GAP: seed treatment 27 g a.s./ha + foliar 2 x 200 g a.s./ha, BBCH 61, PHI 49-55  1,2,4-T: 2x <0.01  TAA: 0.022, 0.050  TA: 0.169, 0.382  TLA: 2x <0.01 |
| New trials  *Study* *17-2076* | N-EU  (2) | Trials GAP: 2 x 140 g a.s./ha, BBCH 61, PHI 43-56d  1,2,4-T: 2x <0.01  TAA: 0.024, 0.078  TA: 0.052, 0.13  TLA: 2x <0.01 |
| **Overall supporting data for cGAP**  ***Barley grain*** | N-EU  *All data*  1,2,4-T (10+2)  TAA (10+2)  TA (10+2)  TLA (6+2) | **Intended cGAP: 2 x 150 g a.s./ha, BBCH 30-61**  1,2,4-T:: 9x <0.01, 0.011; 2x <0.01  TAA: 0.022, 0.024, 0.033, 0.050, 0.057, 0.057, 0.067, 0.078, 0.157, 0.172, 0.217, 0.32  TA: 0.043, 0.052, 0.13, 0.184, 0.190, 0.226, 0.230, 0.250, 0.405, 0.440; 0.169, 0.382  TLA: 3x <0.01, 2x <0.01a, 0.012; 2x <0.01 | 1,2,4-T: 0.01\*  TAA: 0.062  TA: 0.21  TLA: 0.01\* | 1,2,4-T: 0.011  TAA: 0.32  TA: 0.44  TLA: 0.012 | - | - | N/A |
| Barley 🡪 Oat  Straw | Confirmatory data TDMs – Prothioconazole (UK, 2018) | N-EU  (4)  Except TLA (0) | Trials GAP: 2 x 150-200 g a.s./ha, BBCH 61, PHI 34-62d  1,2,4-T: 4x <0.05  TAA: 2x <0.05, 0.134, 0.136  TA: 4x <0.05  TLA: straw not analysed | N/A | | | | |
| N-EU  (2) | Trials GAP: seed treatment 27 + foliar 2 x 200 g a.s./ha, BBCH 61, PHI 49-55  1,2,4-T: 2x <0.01  TAA: <0.01, 0.013  TA: 0.015, 0.017  TLA: 0.085, 0.157 |
| New trials  *Study 17-2076* | N-EU  (2) | Trials GAP: 2 x 140 g a.s./ha, BBCH 61, PHI 43-56d  1,2,4-T: 2x <0.01  TAA: 0.010, 0.026  TA: <0.01, 0.030  TLA: 0.013, 0.028 |
| **Overall supporting data for cGAP**  ***Barley straw*** | N-EU  *All data*  1,2,4-T(6+2)  TAA (6+2)  TA (6+2)  TLA (2+2) | **Intended cGAP: 2 x 150 g a.s./ha, BBCH 30-61**  1,2,4-T: 2x <0.01, 4x <0.05; 2x <0.01  TAA: 2x <0.05, 0.010, 0.026, 0.134, 0.136; <0.01, 0.013  TA: <0.01, 0.030, 4x <0.05; 0.015, 0.017  TLA: 0.013, 0.028; 0.085, 0.157 | 1,2,4-T: 0.01\*  TAA: 0.038  TA: 0.04  TLA: 0.057 | 1,2,4-T: 0.05\*  TAA: 0.136  TA: 0.05  TLA: 0.157 | - | - | N/A |
| Wheat 🡪 Triticale, Rye  Grain | Confirmatory data TDMs – Prothioconazole (UK, 2018) | N-EU  (4)  Except TLA (0) | GAP on which EU a.s. assessment is based: 3 x 187.5 g a.s./ha, BBCH 69, PHI 34-47d  1,2,4-T: 4x <0.01  TAA: 0.138, 0.230, 0.243, 0.517  TA: 0.332, 0.586, 0.684, 1.069  TLA: not analysed | N/A | | | | |
| N-EU  (2) | Trials GAP: seed treatment 30 + foliar 3 x 200 g a.s./ha, BBCH 69, PHI 43-49d  1,2,4-T: 2x <0.01  TAA: 0.193, 0.377  TA: 0.486, 0.952  TLA: 2x <0.01 |
| New trials  *Study 17-2015* | N-EU  (4) | Trials GAP: 2 x 200 g a.s./ha, BBCH 69, PHI 26-61d  1,2,4-T: 4x <0.01  TAA: 0.085, 0.087, 0.092, 0.23  TA: 0.21, 0.37, 0.53, 0.65  TLA: 4x <0.01 |
| New trials  *Study 16-2046* | N-EU  (4) | Trials GAP: 2 x 200 g a.s./ha, BBCH 65-69, PHI 50-62d  1,2,4-T: 4x <0.01  TAA: 0.11, 0.13, 0.22, 0.26  TA: 0.23, 0.36, 0.77, 0.88  TLA: 4x <0.01 |
| New trials  *Study S19-01268* | N-EU  (4) | Trials GAP: 2 x 200 g a.s./ha, BBCH 71-73, PHI 35d  1,2,4-T: 2x <0.003, 2x <0.01  TAA: 0.16, 0.23, 0.35, 0.48  TA: 0.49, 0.71, 0.74, 1.10  TLA: 3x <0.01, 0.01 |
| **Overall supporting data for cGAP**  ***Wheat grain*** | N-EU  *All data*  1,2,4-T(16+2)  TAA (16+2)  TA (16+2)  TLA (12+2) | **Intended cGAP: 2 x 210 g a.s./ha, BBCH 30-69**  1,2,4-T: 2x <0.003, 14x <0.01; 2x <0.01  TAA: 0.085, 0.087, 0.092, 0.11, 0.13, 0.138, 0.16,  0.23, 0.22, 2x 0.230, 0.243, 0.26, 0.35, 0.48, 0.517; 0.193, 0.377  TA: 0.21, 0.23, 0.332, 0.36, 0.37, 0.49, 0.53, 0.586, 0.65, 0.684, 0.71, 0.74, 0.77, 0.88, 1.069, 1.10; 0.486, 0.952  TLA: 11x <0.01, 0.01; 2x <0.01 | 1,2,4-T: 0.01\*  TAA: 0.225  TA: 0.62  TLA: 0.01\* | 1,2,4-T: 0.01\*  TAA: 0.517  TA: 1.10  TLA: 0.01 | - | - | N/A |
| Wheat 🡪 Triticale, Rye  Straw | Confirmatory data TDMs – Prothioconazole (UK, 2018) | N-EU  (4)  Except TLA (0) | GAP on which EU a.s. assessment is based: 3 x 187.5 g a.s./ha, BBCH 69, PHI 34-47d  1,2,4-T: 4x <0.05  TAA: 0.05, 0.067, 0.078, 0.307  TA: 3x <0.05, 0.079  TLA: not analysed | N/A | | | | |
| N-EU  (2) | Trials GAP: seed treatment 30 + foliar 3 x 200 g a.s./ha, BBCH 69, PHI 43-49d  1,2,4-T: 2x <0.01  TAA: 0.020, 0.047  TA: 0.019, 0.028  TLA: 0.048, 0.160 |
| New trials  *Study 17-2015* | N-EU  (4) | Trials GAP: 2 x 200 g a.s./ha, BBCH 69, PHI 26-61d  1,2,4-T: 4x <0.01  TAA: 0.010, 0.014, 0.048, 0.26  TA: <0.01, 0.010, 0.016, 0.10  TLA: <0.01, 0.033, 0.065, 0.11 |
| New trials  *Study 16-2046* | N-EU  (4) | Trials GAP: 2 x 200 g a.s./ha, BBCH 65-69, PHI 50-62d  1,2,4-T: 4x <0.01  TAA: 0.018, 0.031, 0.036, 0.097  TA: 2x 0.011, 0.019, 0.063  TLA: 0.015, 0.019, 0.021, 0.14 |
| New trials  *Study S19-01268* | N-EU  (4) | Trials GAP: 2 x 200 g a.s./ha, BBCH 71-73, PHI 35d  1,2,4-T: 4x <0.003  TAA: 0.04, 0.05, 0.06, 0.12  TA: <0.01, 2x 0.01, 0.02  TLA: <0.01, 0.11, 0.18, 0.21 |
| **Overall supporting data for cGAP**  ***Wheat straw*** | N-EU  *All data*  1,2,4-T(16+2)  TAA (16+2)  TA (16+2)  TLA (12+2) | **Intended cGAP: 2 x 210 g a.s./ha, BBCH 30-69**  1,2,4-T: 4x <0.003, 4x <0.01, 4x <0.01, 4x <0.05; 2x <0.01  TAA: 0.010, 0.014, 0.018, 0.031, 0.036, 0.04, 0.048, 2x 0.05, 0.06, 0.067, 0.078, 0.097, 0.12, 0.26, 0.307; 0.020, 0.047  TA: 2x <0.01, 3x 0.01, 2x 0.011, 0.016, 0.019, 0.02, 3x <0.05, 0.063, 0.079, 0.10; 0.019, 0.028  TLA: 2x <0.01, 0.015, 0.019, 0.021, 0.033, 0.065, 2x 0.11, 0.14, 0.18, 0.21; 0.048, 0.160 | 1,2,4-T: 0.01\*  TAA: 0.049  TA: 0.019  TLA: 0.057 | 1,2,4-T: 0.05\*  TAA: 0.307  TA: 0.1  TLA: 0.21 | - | - | N/A |
| Oilseed rape 🡪 Sunflower, Linseed, Poppy, Mustard, Gold of pleasure  Seeds | Confirmatory data TDMs – Prothioconazole (UK, 2018) | N-EU  (4) | Trials GAP: 2 x 150 g a.s./ha, BBCH 69-79, PHI 49-56d  1,2,4-T: 4x <0.01  TAA: 4x <0.01  TA: 0.12, 0.16, 0.34, 0.70  TLA: 2x <0.01, 0.01, 0.03 | N/A | | | | |
| New trials  *Study S19-01269* | N-EU  (4) | Trials GAP: 2 x 175 g a.s./ha, BBCH 69, PHI 56-39d  1,2,4-T: 4x <0.003  TAA: 3x 0.01, 0.03,  TA: 2x 1.2, 1.4, 2.1  TLA: 0.04, 0.05, 0.09, 0.16 |
| New trials  *Study S20-01046* | N-EU  (3) | Trials GAP: 2 x 175 g a.s./ha, BBCH 69-76, PHI 56-59d  1,2,4-T: 3x <0.003  TAA: <0.01, 2x 0.01  TA: 0.43, 1.1, 1.4  TLA: 0.03, 0.04, 0.05 |
| New trials  *Study S21-00259* | N-EU  (1) | Trials GAP: 2 x 175 g a.s./ha, BBCH 69, PHI 56d  1,2,4-T: <0.003  TAA: 0.01  TA: 2.3  TLA: 0.10 |
| New trials  *Study S22-00257* | N-EU  (3) | Trials GAP: 2 x 175 g a.s./ha, BBCH 69, PHI 56d  1,2,4-T: 3x <0.003  TAA: 3x 0.01  TA: 0.95, 1.2, 1.5  TLA: 0.04, 0.06, 0.07 |  | | | | |
| **Overall supporting data for cGAP**  ***OSR seeds*** | N-EU  *New trials*  1,2,4-T (11)  TAA (11)  TA (11)  TLA (11) | **Intended cGAP: 1 x 180 g a.s./ha, BBCH 69**  1,2,4-T: ~~8~~ 11x <0.003  TAA: 2x <0.01, ~~5~~ 8x 0.01, 0.03  TA: 0.43, 0.95, 1.1, ~~2~~ 3x1.2, 2x 1.4, 1.5, 2.1, 2.3  TLA: 0.03, ~~2~~ 3x 0.04, 2x 0.05, 0.06, 0.07, 0.09, 0.10, 0.16 | 1,2,4-T: 0.003\*  TAA: 0.01  TA: ~~1.3~~ 1.2  TLA: 0.05 | 1,2,4-T: 0.003\*  TAA: 0.03  TA: 2.3  TLA: 0.16 | - | - | N/A |

#### Conclusion on the magnitude of residues in plants

***Barley, Oat***

Barley and Oat are major crops in northern regions.

According to SANTE/2019/12752, extrapolation to oat is possible with a minimum of 8 trials on barley, which is the case here.

According to the available data, the intended uses on barley and oat are considered sufficiently supported in the Northern residue zone.

The data submitted show that no exceedance of the MRL will occur for all intended crops when CA3642 is applied according to the proposed GAP.

***Wheat, Rye, Triticale and Spelt, Einkorn wheat, Emmer Wheat, Tritordeum***

Wheat and rye are major crops in northern regions. Triticale, spelt, *Einkorn wheat, Emmer Wheat and Tritordeum* are ~~minor~~ major crops.

According to SANTE/2019/12752, extrapolation to rye, triticale, spelt, *Einkorn wheat, Emmer Wheat, and Tritordeum* is possible with a minimum of 8 trials on wheat, which is the case here.

According to the available data, the intended uses on wheat, ~~oat~~, rye, triticale and spelt, *Einkorn wheat, Emmer Wheat, and Tritordeum* are considered sufficiently supported in the Northern residue zone. The intended application rate of 210 g a.s./ha is slightly higher than most of the trials’ application rate (200 g a.s./ha) but is included within the acceptable tolerance margin of 25%.

The data submitted show that no exceedance of the MRL will occur for all intended crops when CA3642 is applied according to the proposed GAP.

***Oilseed rape, Sunflower, Linseed, Poppy, Mustard and Gold of pleasure***

Oilseed rape and sunflower are major crops in northern regions. Linseed, poppy, mustard and gold of pleasure are minor crops.

According to SANTE/2019/12752, extrapolation to sunflower, linseed, poppy, mustard and gold of pleasure is possible.

According to the available data, the intended uses on oilseed rape, sunflower, linseed, poppy, mustard and gold of pleasure are considered sufficiently supported in the Northern climatic zone.

All trials were performed with 2 applications, which can be considered as a worst-case situation and therefore cover the intended GAP as the BBCH remains the same. The intended application rate of 180 g a.s./ha is slightly higher than most of the trials’ application rate (175 g a.s./ha) but is included within the acceptable tolerance margin of 25%.

Although the calculated OECD MRL (~~0.048 mg/kg, rounded at~~ 0.05 mg/kg) is slightly above the in-force MRL of gold of pleasure (0.04 mg/kg), the highest residue level, Rber and Rmax were below this MRL. In addition, GAP compliant trials from the DAR confirm an MRL exceedance is not expected for gold of pleasure. And MRL was set considering a pooled NEU and SEU dataset.

Therefore, the data submitted show that no exceedance of the MRL will occur for all intended crops when CA3642 is applied according to the proposed GAP.

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| **zRMS comments:**  Residue Definitions (EFSA 2020; Reg EU ~~2019/552~~  2024/1318):  Monitoring (Mo): Prothioconazole-desthio (sum of isomers)  Risk Assessment (RA):  1) Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA, 2014)  2) TDMs (EFSA, 2018), with separate assessment of:  - Triazole alanine (TA) and triazole lactic acid (TLA)  - Triazole acetic acid (TAA)  - 1,2,4-triazole (1,2,4-T)  **Wheat, rye, triticale and spelt, einkorn wheat, emmer wheat, tritordeum**  Wheat and rye are the major crops in northern Europe (SANTE/2019/12752). A minimum of eight trials are required. Based on the SANTE/2019/12752, 8 residue trials on wheat can be used for extrapolation to rye, triticale and spelt before and after forming of the edible part. So the uses are also considered acceptable on rye, triticale and spelt, einkorn wheat, emmer wheat, tritordeum.  Sufficient trials on wheat conducted according to the residue definition for monitoring only (trials measuring levels of prothioconazole-desthio only) were previously presented and evaluated (DAR, 2007). There are no data on prothioconazole-hydroxy-desthio in the DAR (2007).  Three magnitude of residue studies were submitted in the framework of this application: studies 17-2015, S19-01268, 16-2046. It should be noted that the above-mentioned studies are currently being reviewed as part of the EU approval process for prothioconazole.  Summary is presented below.  Table 1: Comparison of intended and critical EU GAPs for wheat, rye   | Type of GAP | Number of applications | Application rate per treatment  (precise unit) | Interval between application | Growth stage at last application | PHI (days) | | --- | --- | --- | --- | --- | --- | | cGAP NEU + SEU (DAR, UK, 2007) | 3 | 200 | 14-21 | BBCH 26-69 | 35 | | Intended cGAP NEU | 2 | 210 | 14-21 | BBCH 30-69 | 35 |   Summary  **1. Study 17-2015**  Four N-EU trials were conducted in accordance with the following GAP: 2 x 200 g a.s. /ha, application interval - 21 days, 2nd application at BBCH 69, outdoor.  Residues of prothioconazole-desthio and hydroxy- derivatives of prothioconazole-desthio, in wheat grain at harvest were <0.01 mg/kg.  Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest were <0.06 mg/kg.  Residues of 1,2,4-triazole and triazole lactic acid, in wheat grain at harvest were <0.01 mg/kg.  Residues of triazole alanine, in wheat grain at harvest ranged between 0.21 and 0.65 mg/kg.  Residues of triazole acetic acid, in wheat grain at harvest ranged between 0.085 and 0.14 mg/kg.  **2. Study S19-01268**  Four N-EU trials were conducted in accordance with the following GAP: 2 x 200 g a.s. /ha, application interval - 14 days, 2nd application at BBCH 71-73, outdoor.  Residues of prothioconazole-desthio, in wheat grain at harvest were between <0.003 and 0.01 mg/kg.  Residues of hydroxy- derivatives of prothioconazole-desthio, in wheat grain at harvest were <0.01 mg/kg.  Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest were <0.06 mg/kg.  Residues of 1,2,4-triazole and triazole lactic acid, in wheat grain at harvest were between <0.003 and 0.01 mg/kg.  Residues of triazole alanine, in wheat grain at harvest ranged between 0. 49 and 1.1 mg/kg.  Residues of triazole acetic acid, in wheat grain at harvest ranged between 0.16 and 0.48 mg/kg.  **3. Study 16-2046**  Four N-EU trials were conducted in accordance with the following GAP: 2 x 200 g a.s. /ha, application interval – 20-24 days, 2nd application at BBCH 65-69, outdoor.  Residues of prothioconazole-desthio and hydroxy- derivatives of prothioconazole-desthio, in wheat grain at harvest were <0.01 mg/kg.  Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest was <0.06 mg/kg.  Residues of 1,2,4-triazole and triazole lactic acid, in wheat grain at harvest were < 0.01 mg/kg.  Residues of triazole alanine, in wheat grain at harvest ranged between 0.11 and 0.26 mg/kg.  Residues of triazole acetic acid, in wheat grain at harvest ranged between 0.23 and 0.88 mg/kg.  Storage periods of residue samples covered by available storage stability studies.  Available results show that the in force MRL of prothioconazole on wheat of 0.1 mg/kg and on rye of 0.05 (Reg. (EU) ~~2019/552~~  2024/1318) will not be exceeded. The current EU MRL for prothioconazole is sufficient to support the proposed uses.  The trials are supported by valid storage stability data and validated analytical methods.  **The proposed uses on wheat, rye, triticale, spelt, einkorn wheat, emmer wheat and Tritordeum are considered acceptable**.  **Barley, oat**  Barley and oat are the major crops in northern Europe (SANTE/2019/12752). A minimum of eight trials are required. Based on the SANTE/2019/12752, 8 residue trials on barley can be used for extrapolation to oat before and after forming of the edible part. So the uses are also considered acceptable on barley and oat.  Sufficient trials on barley conducted according to the residue definition for monitoring only (trials measuring levels of prothioconazole-desthio only) were previously presented and evaluated (DAR, 2007). There are no data on prothioconazole-hydroxy-desthio in the DAR (2007).  Four magnitude of residue studies were submitted in the framework of this application: study 13-2158, 13-2137, 10-2204 and 17-2076. It should be noted that the above-mentioned studies are currently being reviewed as part of the EU approval process for prothioconazole.  Summary is presented below.  Table 2: Comparison of intended and critical EU GAPs for barley and oat   | Type of GAP | Number of applications | Application rate per treatment  (precise unit) | Interval between application | Growth stage at last application | PHI (days) | | --- | --- | --- | --- | --- | --- | | cGAP NEU + SEU (DAR, UK, 2007) | 2 | 200 | 14-21 | BBCH 30-61 | 35 | | Intended cGAP | 2 | 150 | 14-21 | BBCH 30-61 | 35 |   Summary  **1. Study 10-2204**  Two N-EU trials were conducted in accordance with the following GAP: 2 x 150 g a.s. /ha; application interval - 14 days, 2nd application at BBCH 61, outdoor.  The residues of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio in barley grain at harvest were <0.01 mg/kg.  In grain at harvest, the total residue was always <0.06 mg/kg.  **2. Studies 13-2137 and 13-2158**  Four N-EU trials were conducted in accordance with the following GAP: 2 x 125 g a.s. /ha; application interval – 6-20 days, 2nd application at BBCH 61, outdoor.  The residues of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio in barley grain at harvest were <0.01 mg/kg.  In grain at harvest, the total residue was always <0.06 mg/kg except for trial 13-2137-02, where the total residue reached 0.061 mg/kg.  **3. Studies 17-2076**  Two N-EU trials were conducted in accordance with the following GAP: 2 x 140 g a.s. /ha; application interval – 6-20 days, 2nd application at BBCH 61, outdoor.  Residues of prothioconazole-desthio and hydroxy- derivatives of prothioconazole-desthio, in barley grain at harvest were <0.01 mg/kg. In grain at harvest, the total residue was always <0.06 mg/kg.  Residues of 1,2,4-triazole and of triazole lactic acid in barley grain at harvest were < 0.01 mg/kg.  Residues of triazole alanine in barley grain at harvest ranged between 0.052 and 0.13 mg/kg.  Residues of triazole acetic acid in barley grain at harvest ranged between 0.024 and 0.078 mg/kg.  Storage periods of residue samples covered by available storage stability studies.  Available results show that the in force MRL of prothioconazole on barley of 0.2 mg/kg and on oat of 0.05 (Reg. (EU) ~~2019/552~~  2024/1318) will not be exceeded. The current EU MRL for prothioconazole is sufficient to support the proposed uses.  The trials are supported by valid storage stability data and validated analytical methods.  **The proposed uses on barley and oat are considered acceptable**.  **Oilseed rape, sunflower, linseed, poppy, mustard, gold of pleasure seeds**  Oilseed rape and sunflower are the major crop in northern Europe (SANTE/2019/12752). A minimum of eight trials are required. Linseed, poppy, mustard, gold of pleasure seeds are the minor crops in N-EU.  Based on the SANTE/2019/12752, 4 residue trials on oilseed rape can be used for extrapolation to following minor crops: linseed, poppy, mustard and gold of pleasure seeds before and after forming of the edible part.  Sufficient trials on oilseed rape conducted according to the residue definition for monitoring only (trials measuring levels of prothioconazole-desthio only) were previously presented and evaluated (DAR, 2007). There are no data on prothioconazole-hydroxy-desthio in the DAR (2007).  Three new magnitude of residue studies were submitted in the framework of this application: studies S19-01269, S20-01046, S21-00259. Summary is presented below.  Table 3: Comparison of intended and critical EU GAPs for oilseed rape   | Type of GAP | Number of applications | Application rate per treatment  (precise unit) | Interval between application | Growth stage at last application | PHI (days) | | --- | --- | --- | --- | --- | --- | | cGAP NEU + SEU (DAR, UK, 2007) | 2 | 175 | 14-28 | Start BBCH 53 | 56 | | Intended cGAP NEU | 2 | 180 | 14 | BBCH 69 | 56 |   Summary  **1. Study S19-01269**  Six N-EU trials were conducted in accordance with the following GAP: 2 x 175 g a.s. /ha, application interval - 14 days, 2nd application at BBCH 69, outdoor.  Residues of prothioconazole-desthio and hydroxy- derivatives of prothioconazole-desthio, in oilseed rape grain at harvest were between <0.003 and 0.03 mg/kg.  Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest ranged between <0.06 and 0.08 mg/kg.  Residues of 1,2,4-triazole in oilseed rape grain at harvest were < 0.003 mg/kg.  Residues of triazole alanine in oilseed rape grain at harvest ranged 1.2 – 2.1 mg/kg.  Residues of triazole acetic acid in oilseed rape grain at harvest ranged between <0.01 and 0.1 mg/kg.  Residues of triazole lactic acid in oilseed rape grain at harvest were between 0.02 and 0.12 mg/kg.  **2. Study S20-01046**  Four N-EU trials were conducted in accordance with the following GAP: 2 x 175 g a.s. /ha, application interval - 14 days, 2nd application at BBCH 69, outdoor.  Residues of prothioconazole-desthio and hydroxy- derivatives of prothioconazole-desthio in oilseed rape grain at harvest were between <0.003 and 0.02 mg/kg.  Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest ranged between <0.06 and 0.07 mg/kg.  Residues of 1,2,4-triazole in oilseed rape grain at harvest were < 0.003 mg/kg.  Residues of triazole alanine in oilseed rape grain at harvest ranged between 0.43 and 1.4 mg/kg.  Residues of triazole acetic acid in oilseed rape grain at harvest ranged between <0.01 and 0.01 mg/kg.  Residues of triazole lactic acid in oilseed rape grain at harvest were between 0.03 and 0.04 mg/kg.  **3. Study S21-00259**  One N-EU trial was conducted in accordance with the following GAP: 2 x 175 g a.s. /ha, application interval – 14 days, 2nd application at BBCH 69, outdoor.  Residues of prothioconazole-desthio and hydroxy- derivatives of prothioconazole-desthio, in oilseed rape grain at harvest were between <0.003 and <0.01 mg/kg.  Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest was <0.03 mg/kg.  Residues of 1,2,4-triazole in oilseed rape grain at harvest were < 0.003 mg/kg.  Residues of triazole lactic acid in oilseed rape grain at harvest were 0.1 mg/kg.  Residues of triazole alanine in oilseed rape grain at harvest were 2.3 mg/kg.  Residues of triazole acetic acid in oilseed rape grain at harvest were 0.01 mg/kg.  **4.** **Study S22-00257**  Three N-EU trials were conducted in accordance with the following GAP: 2 x 175 g a.s. /ha, application interval - 14 days, 2nd application at BBCH 69, outdoor.  Residues of prothioconazole-desthio, PTZ-alpha-hydroxy-desthio and PTZ-4-hydroxy-desthio were below LOQ (0.01 mg/kg) in treated oilseed rape grain samples of all trials.  Residues of PTZ-3-hydroxy-desthio were between < 0.01 mg/kg and 0.02 mg/kg.  No residues of PTZ-5-hydroxy-desthio and PTZ-6-hydroxy-desthio were found in treated oilseed rape grain samples of all trials.  1,2,4-T: 3x <0.003 mg/kg  TAA: 3x 0.01 mg/kg  TA: 0.95, 1.2, 1.5 mg/kg  TLA: 0.04, 0.06, 0.07 mg/kg.   |  |  |  | | --- | --- | --- | | 0400000 | **OILSEEDS AND OIL FRUITS** | **MRLs of prothioconazole-desthio (sum of isomers) (F)**  **Reg. (EU) 2019/552** | | 0401000 | Oilseeds |  | | 0401010 | Linseeds | 0.09 | | 0401030 | Poppy seeds | 0.09 | | 0401050 | Sunflower seeds | 0.2 | | 0401060 | Rapeseeds/canola seeds | 0.15 | | 0401080 | Mustard seeds | 0.09 | | 0401130 | Gold of pleasure seeds | 0.04 |   Available results show that the in force MRL of prothioconazole on oilseed rape of 0.15 mg/kg, on sunflower of 0.2 mg/kg, on linseeds, poppy seeds and mustard seeds of 0.09 mg/kg and on gold of pleasure seeds of 0.04 mg/kg (Reg. (EU) ~~2019/552~~  2024/1318) will not be exceeded. The current EU MRL for prothioconazole is sufficient to support the proposed uses.  The trials are supported by valid storage stability data and validated analytical methods.  **The proposed uses on oilseed rape and uses on minor ~~crops~~ uses (art. 51): sunflower, linseed, poppy, mustard, gold of pleasure seeds are considered acceptable**. |

### Magnitude of residues in livestock

The proposed uses include crops relevant as feed items.

#### Dietary burden calculation

**Prothioconazole**

In the framework of the review of the existing MRLs for prothioconazole (EFSA, 2014) and its confirmatory data (EFSA, 2020), the median and maximum dietary burdens were calculated for different groups of livestock.

The input values used in the EU calculation were compared to the residue levels found in the trials supporting the intended uses of CA3642 (see Table 0‑12). The EU inputs sufficiently cover the intended uses of CA3642. It is therefore proposed to refer to EFSA Reasoned Opinion (EFSA, 2020).

Table 0‑12: Comparison of EU input values for risk assessment with results from trials supporting the intended uses of CA3642 – Prothioconazole

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Feed Commodity | EU inputs  (EFSA, 2020) | | Data from trials supporting the intended uses of CA3642 | | EU data cover ? (Y/N) |
| Barley grain | 0.07 | STMRMonit x CF (2) | 0.02 | STMRMonit (0.01) x CF (2) | Y |
| Oat grain | 0.02 | STMRMonit x CF (2) | 0.02 | STMRMonit (0.01) x CF (2) | Y |
| Wheat grain | 0.04 | STMRMonit x CF (2) | 0.02 | STMRMonit (0.01) x CF (2) | Y |
| Rye grain | 0.02 | STMRMonit x CF (2) | 0.02 | STMRMonit (0.01) x CF (2) | Y |
| Barley straw | 1.96  7.50 | STMRMonit x CF (3)  HRMonit x CF (3) | 0.30  2.43 | STMRMonit (0.099) x CF (3)  HRMonit (0.81) x CF (3) | Y |
| Oat straw | 1.26  7.50 | STMRMonit x CF (3)  HRMonit x CF (3) | 0.30  2.43 | STMRMonit (0.099) x CF (3)  HRMonit (0.81) x CF (3) | Y  Y |
| Wheat straw | 2.69  5.52 | STMRRA  HRMonit x CF (2.3) | 0.495  2.25 | STMRRA  HRMonit (0.98) x CF (2.3) | Y  Y |
| Rye straw | 2.25  5.52 | STMRMonit x CF (3)  HRMonit x CF (2.3) | 0.65  3.68 | STMRRA  HRMonit (1.6) x CF (2.3) | Y  Y |
| Rapeseed, seeds | 0.08 | STMRRA | 0.06 | STMRRA | Y |
| Linseed, seeds | 0.06 | STMRMonit x CF (2) | 0.02 | STMRMonit Rapeseed (0.01) x CF (2) | Y |

Table 0‑13: Input values for the dietary burden calculation – Prothioconazole (considering the uses evaluated in Art. 12 procedure and the uses under consideration) (EFSA, 2020)

| Feed Commodity | Median dietary burden | | Maximum dietary burden | |
| --- | --- | --- | --- | --- |
| Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Risk assessment residue definition in plant commodities: sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) | | | | |
| **Rape seed meal** | 0.16 | STMR x PF (2)(a)  (EFSA, 2020) | 0.16 | STMR x PF(2)(a)  (EFSA, 2020) |
| Sunflower seed meal | 0.04 | STMR x CF (2) x PF (2)(a)  (EFSA, 2015a,b)(a) | 0.04 | STMR x CF (2) x PF (2)(a) (EFSA, 2015a,b)(a) |
| Head cabbage | 0.02 | STMR x CF (EFSA, 2014) | 0.12 | HR x CF (EFSA, 2014) |
| Maize silage | 0.01 | STMR (EFSA, 2014) | 0.01 | HR (EFSA, 2014) |
| Maize grain | 0.02 | STMR (FAO, 2014) x CF (2) (EFSA, 2014) | 0.02 | STMR (FAO, 2014) x CF (2) (EFSA, 2014) |
| Maize, milled  by-products(b)  Maize, hominy  meal(b)  Maize gluten feed/  gluten meal(b)  Distiller`s grain(b) | 0.02 | STMR (FAO, 2014) x CF (2) (EFSA, 2014) | 0.02 | STMR (FAO, 2014) x CF (2)  (EFSA, 2014) |
| **Barley grain** | 0.07 | STMR (FAO, 2009b) x CF (2) (EFSA, 2014) | 0.07 | STMR (FAO, 2009b) x CF (2)  (EFSA, 2014) |
| **Brewer`s grain** | 0.23 | STMR barley grain (FAO, 2009b) x CF (2) (EFSA,  2014) x PF (3.3)(a) | 0.23 | STMR barley grain (FAO, 2009b) x CF (2) (EFSA, 2014) x PF (3.3)(a) |
| **Oat grain** | 0.02 | STMR (FAO, 2009a) x CF (2) (EFSA, 2014) | 0.02 | STMR (FAO, 2009a) x CF (2)  (EFSA, 2014) |
| **Wheat grain** | 0.04 | STMR (FAO, 2009b) x CF (2) (EFSA, 2014) | 0.04 | STMR (FAO, 2009b) x CF (2) (EFSA, 2014) |
| **Wheat gluten**  **meal**(b) | 0.04 | STMR wheat grain (FAO, 2009b) x CF (2) x PF (1.8)(a) | 0.04 | STMR wheat grain (FAO, 2010) x CF (2) x PF (1.8)(a) |
| **Wheat milled**  **by-products**(b) | 0.28 | STMR wheat grain (FAO, 2009b) x CF (2) x PF (7)(a) | 0.28 | STMR wheat grain (FAO, 2010) x CF (2) x PF (7) (a) |
| **Rye grain** | 0.02 | STMR (FAO, 2009a) x CF (2) | 0.02 | STMR (FAO, 2009a) x CF (2) |
| **Barley straw** | 1.96 | STMR (FAO, 2009b) x CF (3) (EFSA, 2014) | 7.50 | HR(d) x CF (3) (EFSA, 2014) |
| **Oats straw** | 1.26 | STMR(d) x CF (3) (EFSA, 2014) | 7.50 | HR(d) x CF (3) (EFSA, 2014) |
| **Wheat straw** | 2.69 | STMR x CF (3) (EFSA, 2020) | 5.52 | HR(d) (EFSA, 2014) x CF (3 2.3) |
| **Rye straw** | 2.25 | STMR(d) x CF (3) (EFSA, 2014) | 5.52 | HR(d) (EFSA, 2014) x CF (3 2.3) |
| Cotton seed | 0.10 | STMR (FAO, 2018) x CF (2) | 0.10 | STMR (FAO, 2018) x CF (2) |
| Cotton seed meal | 0.14 | STMR (FAO, 2018) x CF (2) x PF (1.3)(a) | 0.14 | STMR (FAO, 2018) x CF (2) x PF(1.3)(a) |
| Beans (dry) | 0.02 | STMR x CF (2) (EFSA, 2014) | 0.02 | STMR x CF (2) (EFSA, 2014) |
| Peas, lupins (dry) | 0.10 | STMR (FAO, 2009b) x CF (2) | 0.10 | STMR (FAO, 2009b) x CF (2) |
| Lupin seed meal | 0.11 | STMR (FAO, 2009b) x CF (2) x PF (1.1)(a) | 0.11 | STMR (FAO, 2009b) x CF (2) x PF(1.1)(a) |
| Potatoes | 0.01 | STMR (EFSA, 2014) | 0.01 | HR (EFSA, 2014) |
| Potato process  waste(b)  Potato dried pulp(b) | 0.01 | STMR potato (EFSA, 2014) x PF (1)(c) | 0.01 | HR potato (EFSA, 2014) x PF (1)(c) |
| Turnips, swedes,  carrot culls | 0.08 | STMR (EFSA, 2020) | 0.10 | HR (EFSA, 2020) |
| Peanut meal | 0.04 | STMR (FAO, 2009b) x CF (2) x PF (2) | 0.04 | STMR (FAO, 2009b) x CF (2) x PF(2) |
| **Linseed meal** | 0.12 | STMR x CF (2) x PF (2)(a) (EFSA, 2015a,b) | 0.12 | STMR x CF (2) x PF (2)(a) (EFSA, 2015a,b) |
| Soybean seed | 0.10 | STMR (FAO, 2014) x CF (2) | 0.10 | STMR (FAO, 2014) x CF (2) |
| Soybean seed meal | 0.13 | STMR (FAO, 2014) x CF (2) x PF (1.3)(a) | 0.13 | STMR (FAO, 2014) x CF (2) x PF(1.3)(a) |
| Soybean hulls(b) | 1.30 | STMR soybean (FAO, 2014) x CF (2) x PF (13)(a) | 1.30 | STMR soybean (FAO, 2014) x CF (2) x PF (13)(a) |

STMR: supervised trials median residue; HR: highest residue; PF: processing factor; CF: conversion factor for enforcement to risk assessment residue definition.

(a): For rape seed meal/sunflower seed meal, brewer’s grain, wheat gluten meal, wheat milled by-products, cotton seed meal, lupin seed meal, soybean meal, lupin seed meal, and soybean hulls in the absence of processing factors supported by data, default processing factors of 2, 3.3, 1.8, 7, 1.3, 1.1, 1.3 and 13 were, respectively, included in the calculation to consider the potential concentration of residues in these commodities.

(b): New commodities (OECD methodology), not considered in MRL review.

(c): Default processing factors were not applied because prothioconazole and its metabolites were below LOQ both in maize and potatoes, indicating no-residue situation. Thus, concentration of residues in these commodities is therefore not expected.

(d): The STMR and HR values derived by the JMPR (FAO, 2009a,b) are lower than the values derived for cereals straws for the authorised EU uses reported in the MRL review.

Table 0‑14: Results of the dietary burden calculation – Prothioconazole (EFSA, 2020)

| Relevant groups | Dietary burden expressed in | | | | Most critical  diet | Most critical commodity | | Trigger exceeded (Y/N)  0.1 mg/kg DM |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| mg/kg bw per day | | mg/kg DM | |
| Median | Maximum | Median | Maximum |
|  | | Risk assessment residue definition in plant commodities: sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) | | | | | | |
| Cattle (all diets) | 0.036 | 0.109 | 1.15 | 3.10 | Dairy cattle | Barley | Straw | Y |
| Cattle (dairy only) | 0.036 | 0.109 | 0.84 | 2.85 | Dairy cattle | Barley | Straw | Y |
| Sheep (all diets) | 0.075 | 0.236 | 1.77 | 5.5 | Lamb | Barley | Straw | Y |
| Sheep (ewe only) | 0.059 | 0.185 | 1.77 | 5.55 | Ram/ewe | Barley | Straw | Y |
| Swine (all diets) | 0.015 | 0.018 | 0.49 | 0.64 | Swine (finishing) | Swede | Roots | Y |
| Poultry (all diets) | 0.035 | 0.059 | 0.52 | 0.86 | Poultry layer | Wheat | Straw | Y |
| Poultry (layer only) | 0.035 | 0.059 | 0.52 | 0.86 | Poultry layer | Wheat | Straw | Y |

For prothioconazole residues, the results of the dietary burden calculation demonstrate that the exposure of all livestock species exceeds the trigger value of 0.1 mg/kg DM.

**TDMs**

In the framework of the Peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data (EFSA, 2018), the median and maximum dietary burdens were calculated by the UK (2018) for different groups of livestock considering available data on TDMs.

The input values used in the EU dietary burden calculation (B.7.4, UK, 2018) were compared to the residue levels found in the trials supporting the intended uses of CA3642. Except TA in oilseed rape seed for which the STMR from trials is 1.3 mg/kg instead of 1.039 mg/kg presented in EU confirmatory data, all EU inputs cover the residue levels found in the provided trials. A comparison table is presented below.

**Table 0‑15:** **Comparison of EU input values for risk assessment with results from trials supporting the intended uses of CA3642 – TDMs**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **EU inputs (B.7.4, UK, 2018)** | | | | | | | |
|  | **1,2,4-T** | | **TA** | | **TAA** | | **TLA** | |
|  | STMR | HR | STMR | HR | STMR | HR | STMR | HR |
| Cereals grains | 0.05 | \* | 0.621 | \* | 0.79 | \* | 0.022 | \* |
| Cereal straws/stover | 0.05 | 0.05 | 0.12 | 0.65 | 0.24 | 0.78 | 0.37 | 1.1 |
| Oilseeds grains | 0.05 | \* | 1.039 | \* | 0.12 | \* | 0.065 | \* |
|  | **Trials supporting the intended uses of CA3301 (see 7.2.3)** | | | | | | | |
|  | **1,2,4-T** | | **TA** | | **TAA** | | **TLA** | |
|  | STMR | HR | STMR | HR | STMR | HR | STMR | HR |
| Barley grains | 0.01 | \* | 0.21 | \* | 0.062 | \* | 0.01 | \* |
| Barley straw | 0.01 | 0.05 | 0.04 | 0.05 | 0.038 | 0.136 | 0.057 | 0.157 |
| Wheat grains | 0.01 | \* | 0.62 | \* | 0.225 | \* | 0.01 | \* |
| Wheat straw | 0.01 | 0.05 | 0.019 | 0.1 | 0.049 | 0.307 | 0.057 | 0.21 |
| OSR seeds | 0.003 | \* | 1.3 | \* | 0.01 | \* | 0.05 | \* |
|  | **Comparison** | | | | | | | |
|  | **1,2,4-T** | | **TA** | | **TAA** | | **TLA** | |
|  | STMR | HR | STMR | HR | STMR | HR | STMR | HR |
| Barley grains | ok | \* | ok | \* | ok | \* | ok | \* |
| Barley straw | ok | ok | ok | ok | ok | ok | ok | ok |
| Wheat grains | ok | \* | ok | \* | ok | \* | ok | \* |
| Wheat straw | ok | ok | ok | ok | ok | ok | ok | ok |
| OSR seeds | ok | \* | not covered | \* | ok | \* | ok | \* |

\* Only STMR values are used for seeds/grains in the consumer risk assessment. HR value was therefore not taken into account for these commodities.

1,2,4-T : 1,2,4-triazole ; TA: Triazole alanine ; TAA: Triazole acetic acid ; TLA: Triazole lactic acid

The EU input value for TA in oilseed rape seeds does not cover the level found in the new provided trials. A new calculation was therefore performed for TA only, using the input values used in the EU assessment from TDM confirmatory data (B.7.4, UK,2018) and the highest value found for TA in oilseed rape seed. The detailed values are presented in Appendix A 4.1.

For 1,2,4-T, TAA and TLA, it is proposed to refer to EU calculation (UK, 2018).

The results of the dietary burden are presented in the table below. The exposure of all livestock species exceeds the trigger value of 0.1 mg/kg DM and 0.004 mg/kg bw for all four triazole compounds (1,2,4-T, TA, TAA and TLA).

Table 0‑16: Results of the maximum dietary burden calculation – TDMs (B.7.4, UK, 2018 and new value for oilseed rape seeds)

| Relevant groups | Maximum Dietary burden expressed in | | | | | | | | | | Trigger exceeded (Y/N) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| mg/kg bw per day | | | | | mg/kg DM | | | | |
| 1,2,4-T (1) | TA(1) | TA(2) | TAA(1) | TLA(1) | 1,2,4-T (1) | TA(1) | TA(2) | TAA(1) | TLA(1) |
| Cattle (all diets) | 0.109 | 0.405 | 0.413 | 0.140 | 0.177 | 3.75 | 13.63 | 13.89 | 4.29 | 4.61 | Y |
| Cattle (dairy only) | 0.109 | 0.405 | 0.413 | 0.140 | 0.177 | 2.83 | 10.52 | 10.73 | 3.63 | 4.61 | Y |
| Sheep (all diets) | 0.121 | 0.454 | 0.463 | 0.170 | 0.187 | 3.63 | 13.63 | 13.90 | 4.37 | 5.61 | Y |
| Sheep (ewe only) | 0.121 | 0.454 | 0.463 | 0.146 | 0.187 | 3.63 | 13.63 | 13.90 | 4.37 | 5.61 | Y |
| Swine (all diets) | 0.047 | 0.178 | 0.181 | 0.109 | 0.055 | 2.04 | 7.71 | 7.84 | 3.76 | 2.37 | Y |
| Poultry (all diets) | 0.038 | 0.165 | 0.167 | 0.140 | 0.052 | 0.54 | 2.34 | 2.36 | 2.05 | 0.77 | Y |
| Poultry (layer only) | 0.032 | 0.149 | 0.150 | 0.140 | 0.052 | 0.46 | 2.18 | 2.19 | 2.05 | 0.77 | Y |

1. Results from TDM confirmatory data (UK, 2018)
2. For TA, results calculated in the present dossier by using the same input values than UK 2018, except for oilseed rape seeds where an STMR of 1.3 mg/kg was used (instead of 1.039 initially). This value was also extrapolated to cotton, soybean, canola, safflower and sunflower seeds, as made by the UK.

In a second part, it is proposed to calculate the dietary burden considering the intended uses of CA3642 only and compare it to the EU calculation.

A processing factor of 1 was applied when residues in raw agricultural commodities were below the LOQ. Otherwise, default processing factors were used.

Table 0‑17: Input values for the dietary burden calculation – TDMs (considering the uses under consideration)

| Feed Commodity | Median dietary burden - Input value (mg/kg) | | | | | Maximum dietary burden - Input value (mg/kg) | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1,2,4-T | TA | TAA | TLA | Comment | 1,2,4-T | TA | TAA | TLA | Comment |
| Barley straw | 0.01\* | 0.04 | 0.038 | 0.057 | STMR (§ 7.2.3) | 0.05\* | 0.05 | 0.136 | 0.157 | HR (§ 7.2.3) |
| Oat straw | 0.01\* | 0.04 | 0.038 | 0.057 | STMR barley | 0.05\* | 0.05 | 0.136 | 0.157 | HR barley |
| Rye straw | 0.01\* | 0.019 | 0.049 | 0.06 | STMR wheat | 0.05\* | 0.1 | 0.307 | 0.21 | HR wheat |
| Triticale straw | 0.01\* | 0.019 | 0.049 | 0.06 | STMR wheat | 0.05\* | 0.1 | 0.307 | 0.21 | HR wheat |
| Wheat straw | 0.01\* | 0.019 | 0.049 | 0.06 | STMR (§ 7.2.3) | 0.05\* | 0.1 | 0.307 | 0.21 | HR wheat |
| Barley grain | 0.01\* | 0.21 | 0.062 | 0.01\* | STMR (§ 7.2.3) |  |  |  |  | Same as median |
| Oat grain | 0.01\* | 0.21 | 0.062 | 0.01\* | STMR barley |  |  |  |  | Same as median |
| Rye grain | 0.01\* | 0.62 | 0.225 | 0.01\* | STMR wheat |  |  |  |  | Same as median |
| Triticale grain | 0.01\* | 0.62 | 0.225 | 0.01\* | STMR wheat |  |  |  |  | Same as median |
| Wheat grain | 0.01\* | 0.62 | 0.225 | 0.01\* | STMR (§ 7.2.3) |  |  |  |  | Same as median |
| Brewer's grain dried | 0.01\* | 0.69 | 0.20 | 0.010 | STMR barley x PF |  |  |  |  | Same as median |
| Canola (Rape seed) meal | 0.003\* | 2.60 | 0.02 | 0.10 | STMR (§ 7.2.3) x PF |  |  |  |  | Same as median |
| Distiller's grain dried | 0.01\* | 2.05 | 0.74 | 0.010 | STMR wheat x PF |  |  |  |  | Same as median |
| Flaxseed/Linseed meal | 0.003\* | 2.60 | 0.02 | 0.10 | STMR rapeseed x PF |  |  |  |  | Same as median |
| Rape meal | 0.003\* | 2.60 | 0.02 | 0.10 | STMR (§ 7.2.3) x PF |  |  |  |  | Same as median |
| Wheat gluten meal | 0.01\* | 1.12 | 0.41 | 0.01 | STMR wheat x PF |  |  |  |  | Same as median |
| Wheat milled by-pdts | 0.01\* | 4.34 | 1.58 | 0.01 | STMR wheat x PF |  |  |  |  | Same as median |

Table 0‑18: Results of the maximum dietary burden calculation – 1,2,4-triazole

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Relevant groups** | **Dietary burden expressed in** | | | | **Most critical diet (a)** | **Most critical commodity (b)** | | **Trigger exceeded (Yes/No)**  **0.004**  **mg/kg bw** |
| **mg/kg bw per day** | | **mg/kg DM** | |
| **Median** | **Maximum** | **Median** | **Maximum** |
| Cattle (all diets) | 0.000 | 0.001 | 0.01 | 0.03 | Dairy cattle | Barley | straw | No |
| Cattle (dairy only) | 0.000 | 0.001 | 0.01 | 0.03 | Dairy cattle | Barley | straw | No |
| Sheep (all diets) | 0.001 | 0.002 | 0.02 | 0.04 | Lamb | Barley | straw | No |
| Sheep (ewe only) | 0.001 | 0.001 | 0.02 | 0.04 | Ram/Ewe | Barley | straw | No |
| Swine (all diets) | 0.000 | 0.000 | 0.01 | 0.01 | Swine (finishing) | Barley | grain | No |
| Poultry (all diets) | 0.001 | 0.001 | 0.01 | 0.02 | Poultry layer | Wheat | straw | No |
| Poultry (layer only) | 0.001 | 0.001 | 0.01 | 0.02 | Poultry layer | Wheat | straw | No |

Table 0‑19: Results of the maximum dietary burden calculation – Triazole alanine

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Relevant groups** | **Dietary burden expressed in** | | | | **Most critical diet (a)** | **Most critical commodity (b)** | | **Trigger exceeded (Yes/No)**  **0.004**  **mg/kg bw** |
| **mg/kg bw per day** | | **mg/kg DM** | |
| **Median** | **Maximum** | **Median** | **Maximum** |
| Cattle (all diets) | 0.068 | 0.069 | 1.77 | 1.78 | Dairy cattle | Wheat | milled bypdts | Yes |
| Cattle (dairy only) | 0.068 | 0.069 | 1.77 | 1.78 | Dairy cattle | Wheat | milled bypdts | Yes |
| Sheep (all diets) | 0.120 | 0.120 | 2.81 | 2.81 | Lamb | Wheat | milled bypdts | Yes |
| Sheep (ewe only) | 0.075 | 0.076 | 2.26 | 2.28 | Ram/Ewe | Wheat | milled bypdts | Yes |
| Swine (all diets) | 0.085 | 0.085 | 2.82 | 2.82 | Swine (finishing) | Wheat | milled bypdts | Yes |
| Poultry (all diets) | 0.104 | 0.104 | 1.48 | 1.49 | Poultry broiler | Wheat | milled bypdts | Yes |
| Poultry (layer only) | 0.101 | 0.102 | 1.48 | 1.49 | Poultry layer | Wheat | milled bypdts | Yes |

Table 0‑20: Results of the maximum dietary burden calculation – Triazole acetic acid

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Relevant groups** | **Dietary burden expressed in** | | | | **Most critical diet (a)** | **Most critical commodity (b)** | | **Trigger exceeded (Yes/No)**  **0.004**  **mg/kg bw** |
| **mg/kg bw per day** | | **mg/kg DM** | |
| **Median** | **Maximum** | **Median** | **Maximum** |
| Cattle (all diets) | 0.025 | 0.027 | 0.65 | 0.71 | Dairy cattle | Wheat | milled bypdts | Yes |
| Cattle (dairy only) | 0.025 | 0.027 | 0.65 | 0.71 | Dairy cattle | Wheat | milled bypdts | Yes |
| Sheep (all diets) | 0.043 | 0.045 | 1.02 | 1.06 | Lamb | Wheat | milled bypdts | Yes |
| Sheep (ewe only) | 0.028 | 0.030 | 0.83 | 0.91 | Ram/Ewe | Wheat | milled bypdts | Yes |
| Swine (all diets) | 0.031 | 0.031 | 1.02 | 1.02 | Swine (finishing) | Wheat | milled bypdts | Yes |
| Poultry (all diets) | 0.038 | 0.039 | 0.54 | 0.57 | Poultry layer | Wheat | milled bypdts | Yes |
| Poultry (layer only) | 0.037 | 0.039 | 0.54 | 0.57 | Poultry layer | Wheat | milled bypdts | Yes |

Table 0‑21: Results of the maximum dietary burden calculation – Triazole lactic acid

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Relevant groups** | **Dietary burden expressed in** | | | | **Most critical diet (a)** | **Most critical commodity (b)** | | **Trigger exceeded (Yes/No)**  **0.004**  **mg/kg bw** |
| **mg/kg bw per day** | | **mg/kg DM** | |
| **Median** | **Maximum** | **Median** | **Maximum** |
| Cattle (all diets) | 0.002 | 0.003 | 0.05 | 0.08 | Dairy cattle | Barley | straw | No |
| Cattle (dairy only) | 0.002 | 0.003 | 0.04 | 0.07 | Dairy cattle | Barley | straw | No |
| Sheep (all diets) | 0.002 | 0.005 | 0.06 | 0.13 | Lamb | Barley | straw | Yes |
| Sheep (ewe only) | 0.002 | 0.004 | 0.06 | 0.13 | Ram/Ewe | Barley | straw | Yes |
| Swine (all diets) | 0.001 | 0.001 | 0.03 | 0.03 | Swine (finishing) | Canola | meal | No |
| Poultry (all diets) | 0.002 | 0.003 | 0.03 | 0.04 | Poultry layer | Wheat | straw | No |
| Poultry (layer only) | 0.002 | 0.003 | 0.03 | 0.04 | Poultry layer | Wheat | straw | No |

For 1,2,4-triazole (1,2,4-T), in contrast to EU calculation, the results of the dietary burden calculation when considering CA3642 uses only demonstrate that the exposure of all livestock species does not exceed the trigger value of 0.1 mg/kg DM or 0.004 mg/kg bw.

For triazole alanine (TA) and triazole acetic acid (TAA), the results of the dietary burden calculation demonstrate that the exposure of all livestock species exceeds the trigger value of 0.1 mg/kg DM or 0.004 mg/kg bw.

For triazole lactic acid (TLA), the results of the dietary burden calculation demonstrate that the exposure slightly exceeds the trigger value of 0.1 mg/kg DM or 0.004 mg/kg bw for sheep only.

The results of the dietary burden for all TDMs, considering the intended uses of CA3642, are however covered by the dietary burdens calculated by the UK (2018) for the different groups of livestock.

|  |
| --- |
| **zRMS comments:**  Information given by the Applicant is acceptable and sufficient.  Prothioconazole  The median and maximum dietary burdens for livestock were estimated for prothioconazole and were calculated using the animal model calculator developed by EFSA (Animal model 2017). The summary submitted by the Applicant reflects the conclusions of the EFSA Reasoned Opinion (EFSA, 2020).  The calculated dietary burdens for prothioconazole were found to exceed the trigger value of 0.1 mg/kg DM (or 0.004 mg/kg bw/d, respectively) for all livestock groups. Further investigation of residues is therefore required.  TDMs  Livestock dietary burden calculation has been performed respectively for each TDM compound in the addendum – confirmatory data on TDMs performed by UK in 2018 (UK, 2018) using results from residue trials and from rotational crops. Additionally Applicant presented Livestock dietary burden calculation with using the input values used in the EU assessment from TDM confirmatory data (UK, 2018) and the highest value found for TA in oilseed rape seed.  The calculated dietary burdens for 1,2,4-triazole (1,2,4-T) were not found to exceed the trigger value of 0.1 mg/kg DM for all livestock groups.  The calculated dietary burdens for triazole alanine (TA) and triazole acetic acid (TAA) were found to exceed the trigger value of 0.1 mg/kg DM for all livestock groups.  The calculated dietary burdens for triazole lactic acid (TLA) were found to exceed the trigger value of 0.1 mg/kg DM for sheep only.  The feeding studies are required for TA, TAA and TLA.  It should be noted that the results of dietary burdens for TDMs taking into account the intended uses of CA3642 are covered by the dietary burdens calculated by the UK (2018) for the different groups of livestock.  Remark on residue behaviour in fish (B.7.2.2.5 and B.7.2.4)  According to the new Working Documents on the nature and magnitude of pesticide residues in fish (SANTE/10254/2021, SANTE/10252/2021) as well as on the dietary burden calculator for pesticide residues in fish (SANTE/10250/2021), data on residue behaviour in fish are required when the pesticide use may lead to residues >0.1 mg/kg in the total diet (dry weight basis) and when the active substances and/or metabolites are fat soluble, i.e. have a log Po/w ≥3.  For prothioconazole-desthio the log Po/w is 3.04 and EFSA concluded that prothioconazole-desthio is fat soluble due to higher residue levels found in fat than in fat free muscle. Rape seed meal and cereal grains are used as a fish feeding stuff. However, residues of prothioconazole-desthio ranged from below the LOQ to 0.03 mg/kg in cereals grain and rape seeds. Residues above the trigger value of 0.1 mg/kg are therefore not expected. Further data are not required. |

#### Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

No new data were submitted in the framework of this application.

Summary of livestock feeding studies – Prothioconazole

*EFSA Journal 2014;12(5):3689 (Study Report No.: MR-535/00, not protected)*

“During the peer review under Directive 91/414/EEC, the magnitude of prothioconazole residues in ruminants was investigated in a feeding study with lactating cows (EFSA, 2007b; FAO, 2008a, 2008b; United Kingdom, 2004, 2007). Three groups of lactating cows, each consisting of three animals, were dosed for 28 consecutive days with prothioconazole-desthio at levels of 4, 25, and 100 mg/kg in the diet (equivalent to 0.145, 0.909 and 3.636 mg/kg bw per d, respectively). The samples were analysed for prothioconazole-desthio, M14 and M15. In milk, a plateau level was reached after 1 or 2 days of exposure, according to the dose level group. Since neither the metabolites (free and conjugated) containing the common moiety and included in the residue definition for risk assessment nor the glucuronide conjugates of prothioconazole-desthio were analysed, EFSA reported the residue levels for enforcement only (prothioconazole-desthio) and considered the conversion factors for enforcement to risk assessment of 2 and 9 respectively for liver and kidney based on the goat metabolism study with administration of prothioconazole-desthio. No tentative CF was derived for milk, muscle and fat since the residue levels in these matrices are expected to be negligible (<0.01 mg/kg) at the calculated dietary burden. However, conversion factors reported above should in principle be covered by a new feeding study to estimate prothioconazole metabolites containing the common moiety in accordance with the residue definition for risk assessment.

Furthermore, in the framework of the reported feeding study, the storage stability of prothioconazole-desthio, M14 [prothioconazole-3-hydroxy-desthio] and M15 [prothioconazole-4-hydroxy-desthio] was demonstrated in all matrices for up to 1 month when stored deep frozen and was shown to cover the storage time interval of the residue samples of the feeding study. Degradation of prothioconazole-desthio residues during storage of the feeding study residue samples is therefore not expected.

[…]

Finally, although the maximum dietary burden for poultry exceeds the threshold of 0.1 mg/kg DM, no appropriate feeding study is available and is required, since based on the metabolism study, no residues above the LOQ are expected in poultry matrices at the calculated dietary burden.”

Results of the ruminant livestock feeding study for prothioconazole residues are summarised in Table 0‑22.

Table 0‑22: Overview of the values derived from livestock feeding studies - Prothioconazole

| Commodity | Dietary burden | | Results of the livestock feeding study | | | | | | Median residue  (mg/kg)(c) | Highest residue  (mg/kg)(d) | Calculated MRL  (mg/kg) | In-force MRL  (mg/kg)  Reg. (EU) ~~2019/552~~  2024/1318 | CF for RA(e) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Med. (mg/kg bw/d) | Max. (mg/kg bw/d) | Dose Level (mg/kg bw/d)(a) | No | Result for enforcement | | Result for RA(b) | |
| Mean (mg/kg) | Max. (mg/kg) | Mean (mg/kg) | Max. (mg/kg) |
| **EU data (EFSA, 2014)** | | | | | | | | | | | | | |
| **Enforcement residue definition:** prothioconazole-desthio (sum of isomers).  **Risk assessment residue definition:** sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers). | | | | | | | | | | | | | |
| Pig muscle | 0.015 | 0.017 | 0.15 | 3 | <0.01 | <0.01 | n.a. | n.a. | <0.01 | <0.01 | 0.01\* | 0.01 | 1.0 |
| 0.91 | 3 | <0.01 | <0.01 | n.a. | n.a. |
| 3.64 | 3 | <0.01 | <0.01 | n.a. | n.a. |
| Pig fat | 0.15 | 3 | <0.01 | <0.01 | n.a. | n.a. | <0.01 | <0.01 | 0.01\* | 0.02 | 1.0 |
| 0.91 | 3 | <0.01 | 0.01 | n.a. | n.a. |
| 3.64 | 3 | 0.02 | 0.04 | n.a. | n.a. |
| Pig liver | 0.15 | 3 | 0.02 | 0.03 | n.a. | n.a. | <0.01 | <0.01 | 0.01\* | 0.5 | 2.0 |
| 0.91 | 3 | 0.14 | 0.18 | n.a. | n.a. |
| 3.64 | 3 | 0.68 | 1.20 | n.a. | n.a. |
| Pig kidney | 0.15 | 3 | <0.01 | <0.01 | n.a. | n.a. | <0.01 | <0.01 | 0.01\* | 0.5 | 9.0 |
| 0.91 | 3 | 0.03 | 0.03 | n.a. | n.a. |
| 3.64 | 3 | 0.13 | 0.24 | n.a. | n.a. |
| Milk | 0.036 | 0.109 | 0.15 | 42 | <0.005(f) | N/A | n.a. | n.a. | <0.005 | <0.005 | 0.005\* | 0.01\* | 1.0 |
| 0.91 | 42 | <0.005(f) | N/A | n.a. | n.a. |
| 3.64 | 39 | <0.005(f) | N/A | n.a. | n.a. |
| Ruminant muscle | 0.036 | 0.109 | 0.15 | 3 | <0.01 | <0.01 | n.a. | n.a. | <0.01 | <0.01 | 0.01\* | 0.01 | 1.0 |
| 0.91 | 3 | <0.01 | <0.01 | n.a. | n.a. |
| 3.64 | 3 | <0.01 | <0.01 | n.a. | n.a. |
| Ruminant fat | 0.15 | 3 | <0.01 | <0.01 | n.a. | n.a. | <0.01 | <0.01 | 0.01\* | 0.02 | 1.0 |
| 0.91 | 3 | <0.01 | 0.01 | n.a. | n.a. |
| 3.64 | 3 | 0.02 | 0.04 | n.a. | n.a. |
| Ruminant liver | 0.15 | 3 | 0.02 | 0.03 | n.a. | n.a. | 0.01 | 0.042 | 0.05 | 0.5 | 2.0 |
| 0.91 | 3 | 0.14 | 0.18 | n.a. | n.a. |
| 3.64 | 3 | 0.68 | 1.20 | n.a. | n.a. |
| Ruminant kidney | 0.15 | 3 | <0.01 | <0.01 | n.a. | n.a. | <0.01 | 0.012 | 0.02 | 0.5 | 9.0 |
| 0.91 | 3 | 0.03 | 0.03 | n.a. | n.a. |
| 3.64 | 3 | 0.13 | 0.24 | n.a. | n.a. |

N/A: Not applicable – only the mean values are considered for calculating MRLs in milk.

n.a.: Not analysed.

(a): Based on a 560 kg animal consuming 20 kg feed DM/day.

(b): In the feeding study, residues were not determined according to the residue definition for risk assessment. Indeed, only prothioconazole-desthio, M14 and M15 were analysed.

(c): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009b).

(d): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009b).

(e): The tentative conversion factors for enforcement to risk assessment in liver and kidney were derived on the basis of the available metabolism study on ruminants. For muscle, fat and milk, no CF was derived as residue levels are expected at the maximum meat ruminant dietary burden in these matrices are negligible (<0.01 mg/kg).

(f): Mean residue level from day 1 or 4 until day 29 (3 cows, 13 or 14 sampling days).

(\*): Indicates that the MRL is set at the limit of analytical quantification.

Summary of livestock feeding studies – TDMs

*EFSA Journal 2018;16(7):5376*

“Poultry and ruminants feeding studies were conducted respectively with TA and TAA and analysed for the magnitude of TA, TAA, 1,2,4-T and TLA residues.

The poultry feeding study conducted with TA showed that TA remained predominant in all matrices and a slight metabolisation to 1,2,4-T in whole eggs, liver and muscle at the highest dosing level was noted. When the animals were fed with TAA, this compound was detected in eggs, fat and liver with residues of TA in liver only at all dosing levels.

From the ruminant feeding study conducted with TA, TA remained predominant in all tissues but with a significant metabolisation of TA into 1,2,4-T in milk and to a minor extent into 1,2,4-T and TAA in tissues. TLA was identified in fat only but its detection was rather attributed to a contamination as the respective levels were independent from the dosing levels.

When ruminants were fed with TAA, this metabolite was only detected at the highest dose level in whole milk and in all tissues whilst TA was identified in liver, muscle and kidney at all the dosing levels. 1,2,4-T and TLA compounds were never detected (< 0.01 mg/kg).

Animal tissues, milk and eggs samples were analysed within 30 days of sampling.

Since livestock feeding studies were not conducted to address the potential transfer of 1,2,4-T and TLA in products of animal origin, the experts agreed that transfer factors for TA derived from the feeding studies conducted with TA should be applied to 1,2,4-T, assuming that the absorption and excretion behaviour of TA and 1,2,4-T are similar. Similarly transfer factors for TAA derived from the feeding studies conducted with TAA should be applied to TLA assuming that the absorption and excretion behaviour of TAA and TLA are comparable and because of the similarity of the functional groups. From the available toxicological studies, the absorption and excretion of TA, 1,2,4-T and TAA were shown to be similar and the experts agreed to estimate the 1,2,4-T residue levels in animal matrices by applying transfer factors for TA derived from the feeding study conducted with TA. A feeding study conducted with 1,2,4-T is therefore not required as no further metabolism of this compound in animal matrices is expected.

In contrast and since a similar absorption and excretion behaviour of TLA compared to the other TDMs could not be demonstrated, livestock feeding studies conducted with TLA or metabolism studies performed in accordance with the current recommendations as a surrogate to these feeding studies should be provided (data gap).

Meanwhile and provisionally, transfer factors for TAA derived from the feeding study conducted with TAA were applied to estimate the residue levels of TLA in animal commodities. The magnitude of residues of each TDM in animal matrices were therefore estimated by using the approach of a separate dietary burden calculation for each TDM and the application of transfer factors respectively to 1,2,4-T and to TLA for which feeding studies are not available.

Furthermore, the residues of the TDMs (mainly 1,2,4-T and to a minor extent, TA) arising from the metabolism of triazole pesticide active substances in livestock should also be considered to derive the total residue levels of the individual TDMs in animal matrices. In the framework of these confirmatory data assessments and since feeding studies conducted with the triazole compounds were not available, the residue levels of 1,2,4-T and TA were estimated from the metabolism studies conducted with the triazole compounds when these were available. For any future assessment of triazole pesticide active substances, livestock feeding studies or, alternatively metabolism studies should be conducted with the triazole compounds to carry out a complete livestock exposure assessment.”

Conclusion on feeding studies

For prothioconazole residues, the requested uses do not modify the theoretical maximum daily intake for animals. Regarding available feeding data, there is no risk for animal MRL to be exceeded.

Finally, as concluded by EFSA, although the maximum dietary burden for poultry exceeds the threshold of 0.1 mg/kg DM, no appropriate feeding study is available and none is required, since based on the metabolism study, no residues above the LOQ are expected in poultry matrices at the calculated dietary burden.

Regarding TDMs, the requested uses do not modify the theoretical maximum daily intake for animals and are covered by UK calculation made in the framework of the confirmatory data on TDM (UK, 2018 and EFSA, 2018). The intended uses are considered sufficiently supported considering current available data and the European assessment on T, TA, TLA and TAA.

|  |
| --- |
| **zRMS comments:**  Information given by the Applicant is acceptable and sufficient.  The livestock feeding studies was investigated during the peer review of prothioconazole. The intended uses do not modify the theoretical maximum daily intake for animals for prothioconazole and TDMs. The residues in animal commodities will not exceed MRLs (Reg. (EU) ~~2019/552~~  2024/1318).  No further data are required to support the intended uses of CA3642/Joust Pro.  Remark:  It should be noted that EFSA recommended providing a ruminant feeding study to estimate the potential exposure to all the prothioconazole metabolites containing the common moiety in accordance with the residue definition for risk assessment.  Additionally, regarding TDMs EFSA identified livestock exposure assessment as a data gap. |

### Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

#### Available data for all crops under consideration

No prothioconazole residue above the trigger value of 0.1 mg/kg is expected in raw agricultural commodities from the intended uses. Therefore, studies investigating the nature and magnitude of prothioconazole residues in processed commodities are not required (Reg. (EU) No 544/2011).

Regarding TDMs, the trigger value of 0.1 mg/kg is exceeded for TAA and TA in barley and wheat grains, and for TAA, TA and TLA in oilseed rape seeds.

In the framework of the peer review for TDM confirmatory data, a number of studies have been undertaken to assess the magnitude of residues in processed commodities. Processing factors were calculated, except when the residues were below the limit of quantification (LOQ) in the raw agricultural commodity.

Studies investigating the processing of wheat (1 trial) and barley (2 trials) treated with product containing prothioconazole only were presented in the confirmatory data (UK, 2018).

Studies investigating the processing of oilseed rape treated with product containing prothioconazole only (2 trials), and treated with prothioconazole and tebuconazole (1 trial) are presented in the confirmatory data (UK, 2018). For detailed summaries, please refer to Triazole Derivate Metabolites, addendum – confirmatory data (B.7.5.2, UK, 2018).

Table 0‑23: Overview of the available processing studies - TDMs

| Processed commodity | Individual Processing factors  (Median) | | | | Comments | Reference |
| --- | --- | --- | --- | --- | --- | --- |
| 1,2,4-T | TA | TAA | TLA |
| **EU confirmatory data (B.7.5.2, UK, 2018)** | | | | | | |
| Wheat, aspirated grain fractions | NC | 0.20 | 0.39 | NA |  | UK, 2018 |
| Wheat, Bran | NC | 3.7 | 2.1 | NA |  |
| Wheat, Flour | NC | 0.30 | 0.89 | NA |  |
| Wheat, Germ | NC | 4.9 | 1.3 | NC |  |
| Wheat, Middlings | NC | 0.66 | 0.80 | NC |  |
| Wheat, Shorts | NC | 1.7 | 1.2 | NC |  |
| Barley, Brewer’s malt | NC, NC | 0.78, 0.77  (0.775) | 1.0, 1.1  (1.05) | >1.1, >1.5  (>1.3) |  |
| Barley, Brewer’s grain | NC, NC | <0.04, <0.03  (<0.035) | <0.05, <0.04  (<0.045) | NC, NC |  |
| Barley, Brewer’s yeast | NC, NC | 0.24, 0.14  (0.19) | 0.23, 0.23  (0.23) | NC, NC |  |
| Barley, Beer | NC, NC | 0.15, 0.13  (0.14) | 0.29, 0.13  (0.21) | NC, NC |  |
| Rapeseed, meal | NC, NC, NC, NC | 2.9, 0.52, 0.81, 1.9  (1.35) | >1.2, >2, >2, NC  (>2) | NA, >1, >3, >2  (>2) |  |
| Rapeseed, press cake | NC, NC, NC | 0.61, 0.78, 1.3  (0.78) | NC, NC, >1 | >2, >2, NC  (>2) |  |
| Rapeseed, refined oil | NC, NC, NC, NC | <0.02, <0.03, <0.04, <0.03  (<0.03) | NC, NC, NC, NC | NA, NC, NC, NC |  |

NA not analysed

NC Not calculated since the residues were below the limit of quantification both in the raw agricultural commodity and in the processed fraction, no processing factor could be derived.

#### Conclusion on processing studies

No prothioconazole residue above the trigger value of 0.1 mg/kg is expected in raw agricultural commodities from the intended uses. Therefore, studies investigating the nature and magnitude of prothioconazole residues in processed commodities are not required.

Regarding TDMs, available studies show that TDM do not concentrate in processed wheat grains, barley grains and oilseed rape seeds, in general, except TA and TAA in wheat bran; TA in wheat germ and shorts; TA, TAA and TLA in rapeseed meal; and TLA in rapeseed press cake.

|  |
| --- |
| **zRMS comments:**  Information given by the Applicant is acceptable and sufficient.  As residues of prothioconazole exceeding 0.1 mg/kg are not expected in the treated crops, there is no need to investigate the magnitude of prothioconazole residues in processed commodities.  Regarding TDMs, processing studies on wheat and oilseed rape grain have been evaluated in confirmatory data for Triazole Derivate Metabolites (UK, 2018).  Calculated processing factors show concentration of:   * TA and TAA in wheat bran, * TA in wheat germ and shorts, * TA, TAA and TLA in rapeseed meal, * and TLA in rapeseed press cake.   No further data are required. |

### 

### Magnitude of residues in representative succeeding crops

#### Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.

Summary of field rotational crop studies reported in the EU - Prothioconazole

*EFSA Journal 2014;12(5):3689*

“Based on the confined rotational crop study, considering that the application rate of prothioconazole within the EU ranges between 0.009 – 0.600 kg a.s./ha and due to the fact that prothioconazole was applied to a bare soil in the metabolism study (interception of prothioconazole by the plants is expected in practice), it can be concluded that prothioconazole residue levels in food and feed rotational commodities are expected to be covered by the residue levels in primary crops (see also 7.2.2.2). Therefore, no risk mitigation measures (plant back restrictions) need to be proposed”.

Summary of field rotational crop studies reported in the EU - TDMs

During the peer review of TDMs in light of confirmatory data (UK, 2018 and EFSA, 2018), a number of field rotational crop trials have been conducted to investigate the magnitude TDM residues in rotational crops after the use of triazole active substances.

Field rotational crop studies with prothioconazole conducted at different sites within Europe were evaluated in the framework of the peer review for TDM confirmatory data. For detailed summaries, please refer to Triazole Derivate Metabolites, addendum – confirmatory data (Appendix D, UK, 2018).

*Confirmatory data on Triazole Derivative Metabolites (B.7.6.2.6; UK, 2018)*

“Supervised field trials to investigate the residues in rotational crops after the use of FS and EC formulations containing 100 g/L and 250 g/L of prothioconazole were conducted at four test sites in Germany, the Netherlands, southern France and Spain. At each test site three ranges of plant-back intervals (20-35 days, 60-200 days and 270-365 days) and three crop groups (root crops represented by turnip and carrot, leafy crops represented by lettuce, cereals represented by barley) were investigated.

In the trials simulating a crop failure (emergency rotation) the EC formulation was applied once to bare soil at the rate of 630 g a.s./ha of prothioconazole. The rotational crops were sown or planted 21-34 days after the application. In the trials simulating a normal rotation the FS formulation was used to treat wheat seed at the rate of 15 g as/dt. The seed was sown at a nominal rate of 200 kg seed/ha and the wheat plants received 3 spray treatments at the rate of 200 g a.s./ha with the EC formulation. The treatments were conducted at the growth stages BBCH 32, BBCH 39 and BBCH 65-69, respectively, with intervals of 7-30 days between subsequent treatments. At harvest the wheat straw was ploughed in and the plot was left bare until rotational crops were sown or planted. The plant-back intervals were variable depending on the crop and ranged between 56 and 200 days for the short crop rotation and between 277 and 345 days for the annual crop rotation.

A summary of the median (STMR) and highest residues (HR) of 1,2,4-T, TA, TAA and TLA measured in the rotational crops for emergency rotation and normal rotation is given below”.

**Table 0‑24: STMRs and HRs for the triazole derived metabolites in carrot / turnip, lettuce and barley grown as succeeding crops following the use of FS and EC formulations containing 100 g/L and 250 g/L of prothioconazole (UK, 2018)**



Note: For the calculation of the STMRs and HRs the residue values measured in the control samples were taken into account whenever they exceeded the values measured in the corresponding treated samples. The STMRs were calculated based on the highest residue levels from each trial. Separate STMRs and HRs were calculated based on the trials involving soil application and based on the trials with application to a preceding crop, respectively. The worst case STMR and the worst-case HR were then determined by selecting the greater STMR and the greater HR from the two datasets.

Conclusion on rotational crops studies

For prothioconazole, residues in rotated crops at harvest were <0.01 mg/kg in food and less than primary crop residues in feed, therefore further investigation into the magnitude of residues in rotational crops is not required.

Regarding TDMs, no residue of T above 0.01 mg/kg was found in succeeding crops. TA and TLA residues above 0.01 mg/kg were found in all tested succeeding crops. TAA was found in lettuce, barley straw and grain. These results were considered in the consumer risk assessment performed in the framework of the review of TDMs confirmatory data (UK, 2018).

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| **zRMS comments:**  Information given by the Applicant is acceptable and sufficient.  No residues are expected in rotational crops for the intended uses of CA3642 (Joust Pro), so additional field rotational crop studies are not considered required.  Regarding TDMs, rotational crop studies were considered by the UK in the assessment of confirmatory data on TDMs (the UK, 2018). |

### Other / special studies (KCA 6.10, 6.10.1)

#### Effect on the residue level in pollen and bee products

Prothioconazole is currently authorized based on the old data requirements, for which no residue study on honey was required in the DAR 2004. Consequently, the assessment of the present application is based on the same data requirements as for the active substance 2004 re-approval since prothioconazole is not renewed yet. This will avoid any distortion of competition in favour of the previous Art.33 dossiers for which no data on honey was required. Therefore, in the present application, information on honey is considered as informative only.

According to SANTE/11956/2016 rev. 9, rapeseed and some other oilseeds are considered as melliferous crops. As prothioconazole is proposed to be applied during the flowering stage (BBCH 60-69) and since the active substance is systemic, effects on the residue level in pollen and bee products have been investigated.

Summary of new residue studies on bee products

Five residue trials located in Northern and Southern Europe were conducted with winter oilseed rape as a melliferous source. Prothioconazole 250 g/L EC (CA3301) was applied twice, at a nominal application rate of 175 g a.s./ha for each application. This can be considered as a worst-case situation in term of application rate as only one application of 180 g a.s./ha is intended on rapeseed and other oilseeds for CA3642.

The first application was conducted before flowering and 14 days before the second application which was conducted at BBCH 61-63. As all trials were performed with 2 applications, they can be considered as a worst-case situation and therefore cover the intended GAP as the application rate and BBCH remains the same.

Forager bees (for nectar sampling) and pollen from pollen traps were collected. Honey was sampled from combs.

No residues (not detected, i.e., <0.003 mg/kg) of prothioconazole-desthio, alpha-OH, 3-OH, 4-OH 5-OH, 6-OH and 1,2,4-triazole were found in honey samples of all trials. The data submitted show that no exceedance of the MRL (0.05\* mg/kg) will occur in honey when CA3642 is applied according to the GAP on oilseed rape.

Residues of the metabolite triazole alanine (TA) were found in the untreated and treated honey samples of trial -02 and trial -04. The values found ranged from 0.0131 mg/kg to 0.0298 mg/kg. Residues of triazole acetic acid (TAA) were also detected in untreated and treated honey samples of trial -04 with values from 0.0330 mg/kg to 0.0646 mg/kg. Residues of the metabolite triazole lactic acid (TLA) were not quantified in treated honey samples of all trials, but was quantified (0.0179 - 0.0194 mg/kg) in untreated honey samples of trial -04.

The detailed assessment of these studies is presented in Appendix 2.

Conclusion

No exceedance of the MRL (0.05\* mg/kg) will occur in honey when CA3642 is applied according to the GAP on oilseed rape.

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| **zRMS comments:**  Information given by the Applicant is acceptable and sufficient.  The Applicant submitted an additional study to determine residues of prothioconazole in nectar, pollen and honey collected from honey bees from winter oilseed rape plants after two applications of CA3301 (175 g prothioconazole/ha) under semi-field conditions.  Residues in honey  No residues of prothioconazole-desthio, alpha-OH, 3-OH, 4-OH 5-OH, 6-OH and 1,2,4-triazole were found in treated honey samples of all trials.  Residues of triazole alanine (TA) ranged from 0.0131 mg/kg to 0.0298 mg/kg. The highest residues of triazole acetic acid (TAA) was 0.0330 mg/kg in one sample. Residues of triazole lactic acid (TLA) were not detectable in treated honey samples of all trials except trial -04 with values below LOQ.  This study complies with the requirements of SANTE /11956/2016 rev. 9, so the study is acceptable.  More details of the residue study in nectar, pollen and plants of oilseed rape is provided in Appendix 2. |

### Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

#### Input values for the consumer risk assessment

**Prothioconazole**

TMDI calculation was performed using the in-force MRLs. The following conversion factors for enforcement to risk assessment were used:

* Oilseeds: 2 (derived from residue trials) (EFSA, 2014)
* Wheat: 2 (derived from residue trials) (EFSA, 2014)
* Root and tuber vegetables (except sugar beet): 2.7 (EFSA, 2020)
* Potatoes: 1 (derived from metabolism study) (EFSA, 2014)
* Maize: 1 (derived from metabolism study) (EFSA, 2014)
* Cranberries and Sweet corn: no conversion factor was available as the MRLs for these crops originate from CXLs which are derived according to a different residue definition
* A conversion factor of 2 for crops where no data according to the risk assessment residue definition are available and for which a risk management decision is pending: pulses, flowering brassica, Brussels sprouts, head cabbages, shallots, onions, leeks, rye, barley, oats (EFSA, 2020)
* All other crops: tentative conversion factor of 2 derived for all plant commodities (EFSA, 2014)
* Ruminant and pig liver: 2 (EFSA, 2014)
* Ruminant and pig kidney: 9 (EFSA, 2014)

Table 0‑25: Input values for the consumer risk assessment - Prothioconazole

| Commodity | Chronic risk assessment | | Acute risk assessment | |
| --- | --- | --- | --- | --- |
| Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| **Risk assessment residue definition 1:** Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) | | | | |
| Barley | 0.4 | EU MRL 0.2 x CF (2) | 0.06\* | STMRRA (see 7.2.3) |
| Wheat | 0.2 | EU MRL 0.1 x CF (2) | 0.06\* | STMRRA (see 7.2.3) |
| Oat, Rye | 0.1 | EU MRL 0.05 x CF (2) | 0.06\* | Extrapolation from barley and wheat |
| Rapeseed | 0.30 | EU MRL 0.15 x CF (2) | 0.06 | STMRRA (see 7.2.3) |
| Linseed, Poppy, Mustard | 0.18 | EU MRL 0.09 x CF (2) | 0.06 | Extrapolation from rapeseed |
| Gold of pleasure | 0.08 | EU MRL 0.04 x CF (2) | 0.06 | Extrapolation from rapeseed |
| Swine: Muscle/meat | 0.01 | EU MRL | 0.01\* | HREnf (see 7.2.4.2) |
| Swine: Fat tissue | 0.02 | EU MRL | 0.01\* | HREnf (see 7.2.4.2) |
| Swine: Liver | 1.0 | EU MRL 0.5 x PF (2) | 0.02\* | HREnf x PF (2) (see 7.2.4.2) |
| Swine: Kidney | 4.5 | EU MRL 0.5 x PF (9) | 0.09\* | HREnf x PF (9) (see 7.2.4.2) |
| Bovine, Sheep, Goat, Equine muscle/meat | 0.01 | EU MRL | 0.01\* | HREnf (see 7.2.4.2) |
| Bovine, Sheep, Goat, Equine fat | 0.02 | EU MRL | 0.01\* | HREnf (see 7.2.4.2) |
| Bovine, Sheep, Goat, Equine liver | 1 | EU MRL 0.5 x PF (2) | 0.084 | HREnf x PF (2) (see 7.2.4.2) |
| Bovine, Sheep, Goat, Equine kidney | 4.5 | EU MRL 0.5 x PF (9) | 0.108 | HREnf x PF (9) (see 7.2.4.2) |
| Poultry, muscle, fat | 0.01\* | EU MRL | 0.01\*(1) | See 7.2.4.2 |
| Poultry, liver, kidney | 0.1 | EU MRL | 0.01\*(1) | See 7.2.4.2 |
| Milk | 0.01\* | EU MRL | 0.005\* | HREnf (see 7.2.4.2) |
| Eggs | 0.01\* | EU MRL | 0.01\* | EU MRL |
| Honey | 0.05\* | EU MRL | 0.003\* | HREnf (see 7.2.7.1) |
| All other commodities | EU MRLs | EU MRLs (Reg. (EU) 2019/552) x CF (EFSA, 2014) | Acute risk assessment performed only for intended uses | |

(\*): Indicates that the input value is proposed at the limit of analytical quantification.

(1) Based on the metabolism study, no residues above the LOQ are expected in poultry matrices at the calculated dietary burden (EFSA, 2014)

**TDMs**

In the framework of the Peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data (EFSA, 2018), the chronic risk assessment was calculated by the UK (2018) considering available data on TDMs.

The input values used in the EU calculation were compared to the residue levels found in the trials supporting the intended uses of CA3642 (see Table 0‑15). Except TA in oilseed rape seed for which the STMR from trials is ~~1.3~~ 1.2 mg/kg instead of 1.039 mg/kg presented in EU confirmatory data, all EU inputs cover the residue levels found in the provided trials.

A new calculation was therefore performed for the chronic risk assessment for TA only, using STMR values presented in the table below.

For T, TAA and TLA, it is proposed to refer to the results from the EU chronic risk calculation (UK, 2018).

A summary of the STMR input values used in the consumer intake assessments performed by the UK and in the present dossier is presented in the table below.

Table 0‑26: Input values for the chronic risk assessment – TDMs (UK, 2018 and uses under consideration)

| **Crop group** | **Residue (mg/kg)** | | | |
| --- | --- | --- | --- | --- |
| **1,2,4-T** (1) | **TA** | **TAA**(1) | **TLA**(1) |
| **Plants** | | | | |
|  | **STMR** | **STMR** | **STMR** | **STMR** |
| Citrus fruit | 0.05 | 0.32 | 0.05 | 0.04 |
| Pome fruit | 0.01 | 0.039 | 0.03 | 0.03 |
| Stone fruit | 0.01 | 0.32 | 0.02 | 0.038 |
| Berries | 0.01 | 0.06 | 0.05 | 0.04 |
| Banana | 0.05 | 0.05 | 0.05 | n.a |
| Root & tuber vegetables | 0.01 | 0.184 | 0.01 | 0.021 |
| Bulb vegetables | 0.01 | 0.06 | 0.01 | 0.01 |
| Fruiting vegetables | 0.01 | 0.21 | 0.01 | 0.03 |
| Brassica vegetables | 0.039 | 0.17 | 0.01 | 0.01 |
| Leafy vegetables | 0.015 | 0.047 | 0.023 | 0.08 |
| Legume vegetables | 0.01 | 0.09 | 0.01 | 0.01 |
| Stem vegetables | 0.01 | 0.09 | 0.02 | 0.01 |
| Pulses | 0.05 | 0.17 | 0.05 | 0.01 |
| **Oilseeds** | 0.05 | 1.039(1) / ~~1.3~~ 1.2(2) | 0.12 | 0.065 |
| Oilfruits | 0.05 | 1.039(1) / ~~1.3~~ 1.2 (2) | 0.12 | 0.065 |
| **Cereals** | 0.05 | 0.621 | 0.79 | 0.022 |
| Sugar plants | 0.05 | 0.05 | 0.05 | 0.01 |
| **Animals** | | | | |
| Ruminant meat | 0.27 | 0.46 | 0.04 | 0.04 |
| Ruminant fat | 0.18 | 0.22 | 0.05 | 0.07 |
| Ruminant liver | 0.31 | 1.01 | 0.05 | 0.04 |
| Ruminant kidney | 0.32 | 0.49 | 0.15 | 0.09 |
| Ruminant milk | 0.3 | 0.04 | 0.04 | 0.04 |
| Sheep meat | 0.29 | 0.51 | 0.04 | 0.04 |
| Sheep fat | 0.19 | 0.23 | 0.06 | 0.07 |
| Sheep liver | 0.34 | 1.13 | 0.05 | 0.04 |
| Sheep kidney | 0.34 | 0.55 | 0.18 | 0.09 |
| Sheep milk | 0.32 | 0.04 | 0.04 | 0.04 |
| Swine meat | 0.13 | 0.21 | 0.04 | 0.04 |
| Swine fat | 0.1 | 0.09 | 0.04 | 0.07 |
| Swine liver | 0.13 | 0.5 | 0.04 | 0.04 |
| Swine kidney | 0.14 | 0.22 | 0.11 | 0.05 |
| Poultry meat | 0.04 | 0.11 | 0.04 | 0.04 |
| Poultry fat | 0.04 | 0.1 | 0.04 | 0.04 |
| Poultry liver/kidney | 0.04 | 0.27 | 0.05 | 0.04 |
| Poultry Eggs | 0.04 | 0.06 | 0.04 | 0.04 |
| Honey | - | 0.033(3 | - | - |

n.a not analysed

1. Input values from TDM confirmatory data (UK, 2018)
2. For TA, results calculated in the present dossier by using the same input values than UK 2018, except for oilseed rape seeds where an STMR of 1.2 mg/kg was used (instead of 1.039 initially). This value was extrapolated to the whole group of oilseeds and oilfruits, as made by the UK.
3. Results from honey trials was considered in the new chronic risk assessment for TA. The HR value was used as input since no STMR can be calculated based on 2 trials per zone.

As none of the TDMs were found to concentrate in fat then the residue levels for meat can be taken as the residue levels found in muscle.

For pulses, oilseeds, cereals and milk for the acute risk assessment the STMR has been used given these commodities are bulked and the uses of the triazole pesticides are pre-harvest uses.

The acute consumer risk assessment was performed considering the trials supporting CA3642 uses only.

Table 0‑27: Input values for the acute risk assessment – TDMs (uses under consideration)

| Commodity | Source | Acute risk assessment - Input value (mg/kg) | | | |
| --- | --- | --- | --- | --- | --- |
| 1,2,4-T | TA | TAA | TLA |
| Barley | STMR (see 7.2.3) | 0.01\* | 0.21 | 0.062 | 0.01\* |
| Oat | Extrapolation from barley | 0.01\* | 0.21 | 0.062 | 0.01\* |
| Wheat | STMR (see 7.2.3) | 0.01\* | 0.62 | 0.225 | 0.01\* |
| Rye | Extrapolation from wheat | 0.01\* | 0.62 | 0.225 | 0.01\* |
| Rapeseed | STMR (see 7.2.3) | 0.003\* | ~~1.3~~ 1.2 | 0.01 | 0.05 |
| Linseed, Poppy, Mustard | Extrapolation from rapeseed | 0.003\* | ~~1.3~~ 1.2 | 0.01 | 0.05 |
| Gold of pleasure | Extrapolation from rapeseed | 0.003\* | ~~1.3~~ 1.2 | 0.01 | 0.05 |
| Ruminant/Equine meat | HR (UK, 2018) | 0.31 | 0.62 | 0.04 | 0.04 |
| Ruminant/Equine fat | HR (UK, 2018) | 0.24 | 0.34 | 0.08 | 0.1 |
| Ruminant/Equine liver | HR (UK, 2018) | 0.36 | 1.36 | 0.05 | 0.04 |
| Ruminant/Equine kidney | HR (UK, 2018) | 0.34 | 0.58 | 0.22 | 0.13 |
| Ruminant/Equine milk | HR (UK, 2018) | 0.35 | 0.04 | 0.04 | 0.04 |
| Sheep/Goat meat | HR (UK, 2018) | 0.33 | 0.68 | 0.04 | 0.04 |
| Sheep/Goat fat | HR (UK, 2018) | 0.26 | 0.38 | 0.08 | 0.11 |
| Sheep/Goat liver | HR (UK, 2018) | 0.39 | 1.80 | 0.05 | 0.04 |
| Sheep/Goat kidney | HR (UK, 2018) | 0.37 | 0.65 | 0.25 | 0.13 |
| Sheep/Goat milk | HR (UK, 2018) | 0.37 | 0.04 | 0.04 | 0.04 |
| Swine meat | HR (UK, 2018) | 0.17 | 0.27 | 0.04 | 0.04 |
| Swine fat | HR (UK, 2018) | 0.13 | 0.14 | 0.05 | 0.08 |
| Swine liver | HR (UK, 2018) | 0.17 | 0.61 | 0.05 | 0.04 |
| Swine kidney | HR (UK, 2018) | 0.20 | 0.27 | 0.14 | 0.08 |
| Poultry meat | HR (UK, 2018) | 0.04 | 0.12 | 0.04 | 0.04 |
| Poultry fat | HR (UK, 2018) | 0.04 | 0.11 | 0.04 | 0.04 |
| Poultry liver/kidney | HR (UK, 2018) | 0.04 | 0.31 | 0.05 | 0.04 |
| Poultry Eggs | HR (UK, 2018) | 0.04 | 0.06 | 0.04 | 0.04 |
| Honey | HR (see 7.2.7.1) | 0.003\* | 0.033 | 0.065 | 0.019 |

#### Conclusion on consumer risk assessment

Extensive calculation sheets are presented in A 2.2.

Table 0‑28: Consumer risk assessment

|  |  |
| --- | --- |
| **Prothioconazole-desthio** | |
| TMDI (% ADI) according to EFSA PRIMo | 41% (based on NL toddler) |
| IEDI (% ADI) according to EFSA PRIMo | Not triggered |
| IESTI (% ARfD) according to EFSA PRIMo\* | ~~9% Wheat~~  ~~7% Bovine: Liver~~  ~~6% Milk: Cattle~~  Highest IESTI:  Unprocessed commodities:  for children: 9% ARfD (wheat)  for adults: 5% ARfD (wheat)  Processed commodities:  for children: 7% ARfD (wheat/milling (flour)  for adults: 4% ARfD (barley/beer) |
| **1,2,4-triazole (1,2,4-T)** | |
| TMDI/IEDI (% ADI) according to EFSA PRIMo | 93% (based on NL toddler) (UK, 2018) |
| IESTI (% ARfD) according to EFSA PRIMo\* | ~~43% Milk: Cattle~~  ~~9% Milk: Goat~~  ~~3% Bovine: Liver~~  Highest IESTI:  Unprocessed commodities:  for children: 43% ARfD (Milk: Cattle)  for adults: 13% ARfD (Milk: Cattle)  Processed commodities:  for children: 0.1% ARfD (wheat/milling (flour))  for adults: 0.1% ARfD (barley/beer) |
| **Triazole alanine (TA)** | |
| TMDI/IEDI (% ADI) according to EFSA PRIMo | 6% (based on NL toddler) (UK, 2018)  6% (based on NL toddler) (present assessment) |
| IESTI (% ARfD) according to EFSA PRIMo\* | ~~4% Bovine: liver~~  ~~3% Wheat~~  ~~2% Milk: Cattle~~  Highest IESTI:  Unprocessed commodities:  for children: 4% ARfD (Bovine: Liver)  for adults: 2% ARfD (Bovine: Liver)  Processed commodities:  for children: 2% ARfD (wheat/milling (flour))  for adults: 0.9% ARfD (wheat/bead/pizza) |
| **Triazole acetic acid (TAA)** | |
| TMDI/IEDI (% ADI) according to EFSA PRIMo | 1% (based on NL toddler) (UK, 2018) |
| IESTI (% ARfD) according to EFSA PRIMo\* | ~~0.5% Milk: Cattle~~  ~~0.3% Wheat~~  ~~0.1% Rye~~  Highest IESTI:  Unprocessed commodities:  for children: 0.5% ARfD (Milk: Cattle)  for adults: 0.2% ARfD (Wheat)  Processed commodities:  for children: 0.3% ARfD (wheat/milling (flour))  for adults: 0.1% ARfD (wheat/bead/pizza) |
| **Triazole lactic acid (TLA)** | |
| TMDI/IEDI (% ADI) according to EFSA PRIMo | 1% (based on NL toddler) (UK, 2018) |
| IESTI (% ARfD) according to EFSA PRIMo\* | ~~2% Milk: Cattle~~  ~~0.3% Milk: Goat~~  ~~0.2% Poultry: Muscle/meat~~  Highest IESTI:  Unprocessed commodities:  for children: 2% ARfD (Milk: Cattle)  for adults: 0.5% ARfD (Milk: Cattle)  Processed commodities:  for children: 0.0% ARfD (wheat/milling (flour))  for adults: 0.0% ARfD (Barley/beer) |

\* include raw and processed commodities if both values are required for PRIMo

The proposed uses of prothioconazole in the formulation CA3642 do not represent unacceptable acute and chronic risks for the consumer.

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| --- |
| **Evaluator comment:**  Calculations presented by the Applicant are acceptable and sufficient.  Prothioconazole  The calculation of the TMDI using EFSA model (version 3.1) and MRLs values according to the Regulation (EU) ~~2019/552~~  2024/1318 and appropriate conversion factors for enforcement to risk assessment led to a utilisation of the ADI of 41% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is wheat with 8% of the ADI. The intended uses will not result in a consumer chronic exposure exceeding the ADI for prothioconazole-desthio.  An acute consumer risk assessment was performed based on the highest residue values (HR) of barley, oat, wheat, rye, triticale, oilseed rape, mustard, linseed, poppy, gold of pleasure and animals commodities. The highest International Estimated Short-Term Intake (IESTI) is at 9% and 5% of the ARfD for the consumption of wheat by children and by adults respectively.  TDMs  The dietary risk assessment was calculated using PRIMo rev 3.1 for each TDM. Toxicological reference values and input values from EFSA conclusion on confirmatory data on TDMs (EFSA, 2018) and for TA only, STMR value for oilseed rape were taken into account.  The data available are considered sufficient for risk assessment. The chronic and the short-term intakes of prothioconazole residues and TDMs are unlikely to present a public health concern.  The intended uses of CA3642 / Joust Pro are accepted. |

## Azoxystrobin

**According to SANTE/11509/2013– rev. 5.2 and since the active substance azoxystrobin is not yet renewed (AIR4), the “old data requirements” (Reg. (EU) No 544/2011) and the endpoints from the previous monograph of azoxystrobin (DAR, 2009) apply to the current assessment. Studies from the DAR are not protected anymore.**

For your information, the applicant Nufarm has a letter of co-ownership by the Azoxystrobin Task Force which authorizes Nufarm to access to the studies submitted during the AIR4 renewal of azoxystrobin (process currently ongoing).

General data on azoxystrobin are summarized in the table below (last updated 2022/11/22).

**Table 7.3‑1: General information on azoxystrobin**

|  |  |
| --- | --- |
| Active substance (ISO Common Name) | Azoxystrobin |
| IUPAC | Methyl (*E*)-2-{2[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate |
| Chemical structure |  |
| Molecular formula | C22H17N3O5 |
| Molar mass | 403.4 |
| Chemical group | Strobilurin |
| Mode of action (if available) | Inhibition of electron transport, consequently inhibiting  fungal respiration. |
| Systemic | Yes |
| Companies | Adama (formerly Mahkteshim Agan)\*  Syngenta\* |
| Rapporteur Member State (RMS) | Austria  (Initially United Kingdom) |
| Approval status | Approved  Regulation (EU) 2011/703  Regulation (EU) 2019/291 (extension of approval) |
| Restriction | Use as fungicide only |
| Review Report | SANCO/11027/2011 Rev 3 (17 June 2011) |
| Current MRL regulation | ~~Reg. (EU) 2022/476~~  ~~Reg. (EU) 2022/1363 (not yet applicable)~~  ~~COMMISSION REGULATION (EU) 2023/129 of 18 January 2023 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, prosulfocarb, sedaxane and valifenalate in or on certain products (not yet applicable)~~  COMMISSION REGULATION (EU) 2024/1078 of 15 April 2024 amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, flonicamid, isofetamid, mefentrifluconazole, metazachlor, pyrimethanil and quartz sand in or on certain products |
| Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed | Yes |
| EFSA Journal: Conclusion on the peer review | Yes (EFSA, 2010) |
| EFSA Journal: conclusion on article 12 | Yes (EFSA, 2013) |
| Current MRL applications on intended uses | EFSA-Q-2021-00039 (Greece)  Rapeseeds and linseeds  Status: Reasoned opinion available (EFSA Journal 2022;20(1):7051) – New MRL of 0.7 mg/kg for rapeseed (not yet voted or adopted) |

\* Notifier in the EU process to whom the a.s. belongs

### Stability of Residues (KCA 6.1)

#### Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.3‑2: Summary of stability data achieved at ≤ ‑ 18°C (unless stated otherwise)

| Matrix | Characteristics of the matrix | Acceptable Maximum Storage duration | Reference |
| --- | --- | --- | --- |
| Data relied on in EU | | | |
| Plant products – Azoxystrobin and R230310 (z-isomer), separately | | | |
| Cereal grain | Dry/High starch content | 2 years | EFSA, 2010, 2013  UK, 2009a |
| Cereal straw | No group | 2 years |
| Oilseed rape | High lipid content | 2 years |
| Soybean meal | 2 years |
| Pecans, nutmeat | 2 years |
| Peanut, nutmeat | 2 years |
| Peanut, oil | 2 years |
| Grapes | High acid content | 2 years |
| Orange | 2 years |
| Apples | High water content | 2 years |
| Banana | 2 years |
| Peach | 2 years |
| Tomatoes | 2 years |
| Cucumber | 2 years |
| Lettuce | 2 years |
| Carrot root | 2 years |
| Animal Products – Azoxystrobin and R230310 (z-isomer), separately | | | |
| Ruminant, Poultry | Muscle, fat, liver, kidney | 10 months | EFSA, 2010, 2013  UK, 2009a |
| Ruminant | Milk | 10 months |
| Poultry | Eggs | 10 months |
| Honey | No group | 81 days | AIR4 M-CA S6, Dec. 2021 *(access from Task Force)*  Appeltauer, A., 2022 (Report No S21-01128) |

Conclusion on stability of residues during storage

The storage stability of azoxystrobin and its Z-isomer R230310 was evaluated under the peer review of Directive 91/414/EEC (United Kingdom, 2009). Both compounds were shown to be stable up to 2 years in cereals and oilseeds commodities, and up to 10 months in livestock commodities.

For azoxystrobin, the provided studies on magnitude of residues are sufficiently supported by available storage stability data.

To support the magnitude of residues in honey studies, which are considered as additional data[[11]](#footnote-11), the storage stability of azoxystrobin and its isomer in honey is currently being assessed in the framework of azoxystrobin AIR4 renewal. The report is now available, and results show that azoxystrobin and its isomer are stable up to 81 days in honey.

#### Stability of residues in sample extracts (KCA 6.1)

In available studies on magnitude of residues, batch recoveries were carried out in parallel and stored in the same conditions as the analytical batches. Acceptable recoveries were achieved, indicating acceptable stability of residue in extracts.

|  |
| --- |
| **zRMS comments:**  In EFSA Journal 2013;11(12):3497 it is stated that *The potential degradation of residues during storage of the residue trials samples was also assessed. In the framework of the peer review, storage stability of azoxystrobin was demonstrated for a period of 24 months at -18°C in commodities with high water content (banana, peach, tomato, cucumber, lettuce, carrot), high acid content (grape, apple, orange), high oil content (soybean meal, oilseed rape, pecans, peanut), dry commodities (cereal grain) as well as cereal straw (United Kingdom, 2009a).*  *(…)* *The storage stability of azoxystrobin residues in animal products was evaluated under the peer review of Directive 91/414/EEC (United Kingdom, 2009a). Studies demonstrated storage stability of azoxystrobin in milk, muscle, fat, liver and kidney, eggs for up to 10 months when stored deep frozen.*  Additionally the Applicant submitted the study on storage stability of azoxystrobin in honey (Appeltauer, 2022; Report S21-01128, access from Task Force). It should be noted that this study was reviewed and accepted by zRMS-PL in RR, Part B7 for PPP of Orondis Evo in June 2023.  Azoxystrobin and R230310 have been shown to be stable in honey for at least 81 days when stored frozen at -18oC.  The residue data are valid with regard to storage stability.  No additional data are required. |

### Nature of residues in plants, livestock, and processed commodities

#### Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.3‑3: Summary of plant metabolism studies

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Crop Group | Crop | Label position | Application and sampling details | | | | | Reference |
| Method,  F or G (a) | Rate  (kg a.s./ha) | No | Sampling (DAT) | Remarks |
| **EU data** | | | | | | | | |
| Fruits and fruiting vegetable | Grapes | 14C-pyrimidinyl  14C-cyanophenyl  14C-phenylacrylate  (b) | Foliar, F | 0.25+  1+  1+  0.25 | 4 | 21 | - | EFSA, 2010, 2013  UK, 2009a |
| Pulses and oilseeds | Peanuts | Foliar, F | 0.85+  0.85+  0.3 | 3 | 10 | - |
| Cereals | Winter wheat | Foliar, F | 0.5 | 2 | Forage: 13  Grain & straw:  61-62 | Forage: 13  Grain & straw:  61-62 |
| 14C-pyrimidinyl | Foliar, F | n.r. | 1 | 28 | Application at BBCH 71 |

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)

(b): A study with each label was performed for each crop, separately

n.r.: not reported

Summary of plant metabolism studies reported in the EU

*EFSA Journal 2013;11(12):3497*

“The metabolism pattern was similar in all plant groups, parent azoxystrobin being the major compound, accounting for 17-43 % TRR in cereal grain and straw, 35-65 % TRR in grapes, and 14-48 % TRR in peanut hulls and hay. Azoxystrobin was not detected in peanut nuts, where radioactivity was found to be mainly incorporated in fatty acids (up to 49 % TRR), but no individual metabolite was present in peanut kernels at a level greater than 1 %. In the other crops, the major metabolites identified were M28, resulting from the cleavage of the ester link between the phenylacrylate and pyrimidyl ring, and metabolite M09 (Z-isomer of azoxystrobin), both mostly below 10 % TRR. Other metabolites were identified but they were all present in very small amounts (EFSA, 2010).

Consequently, the residue for enforcement and risk assessment in all plant commodities following foliar application is defined as azoxystrobin only.”

Conclusion on metabolism in primary crops

The metabolism of azoxystrobin in plants is considered sufficiently addressed. The metabolism pattern was similar in all plant groups, with parent azoxystrobin being the major compound.

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| **zRMS comments:**  According to the OECD 501 a metabolism in crops study should be submitted for each type of crop group for which use is proposed. In order to extrapolate metabolism of a pesticide to all crop groupings, metabolism studies on a minimum of three representative crops (from the five different crop categories) should be conducted. If the results of these three studies indicate a comparable metabolic route, then additional studies will not be needed.  In EFSA Journal 2022;20(1):7051 it is stated that *The metabolism of azoxystrobin following foliar applications was investigated in crops belonging to the groups of fruit crops (grapes), cereals/grass (wheat) and pulses/oilseeds (peanuts). The metabolism pattern was similar in all plant groups with the parent azoxystrobin being the major compound, accounting for 17–43% total radioactive residue (TRR) in cereal grain and straw, 35–65% TRR in grapes and 14–48% TRR in peanut hulls and hay.*  *Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies and the capabilities of enforcement analytical methods,* ***the residue definition for enforcement and risk assessment in all plant commodities following foliar application was proposed as ‘azoxystrobin’*** *(EFSA, 2010, 2013). The same residue definition is applicable to rotational crops and processed products. The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above mentioned residue definition.*  For the intended uses, the metabolic behaviour in primary crops is sufficiently addressed.  No additional data are required. |

#### Nature of residue in rotational crops (KCA 6.6.1)

All crops under consideration can be grown in a crop rotation.

According to the soil degradation studies evaluated in the framework of the EU peer review, DT50 values of azoxystrobin range around 262 days. Thus, DT90 value is expected to be higher than the trigger value of 100 days (EFSA, 2010).

Available data

No new data submitted in the framework of this application.

Table 7.3‑4: Summary of metabolism studies in rotational crops

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Crop group | Crop | Label position | Application and sampling details | | | | | Reference |
| Method,  F or G (a) | Rate  (kg a.s./ha) | Sowing intervals  (DAT) | Harvest  Intervals (DAT) | Remarks |
| **EU data** | | | | | | | | |
| Leafy vegetables | Lettuce | 14C-pyrimidinyl  14C-cyanophenyl  14C-phenylacrylate  (b) | Application on bare soil, G | 2.2 | 30  200  365 | At maturity | - | EFSA, 2010, 2013  UK, 2009a |
| Root and tuber vegetables | Radish |
| Cereals | Wheat |

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)

(b): A study with each label was performed for each crop, separately

Summary of plant metabolism studies reported in the EU

*EFSA Journal 2013;11(12):3497*

“The metabolism of azoxystrobin in rotational crops – radish, lettuce, and wheat – has been evaluated (United Kingdom, 2009a). The TRR in soil declined on average from 0.74–1.0 mg/kg at treatment to 0.79, 0.67 and 0.24 mg/kg at 30, 200, and 365 days after treatment, respectively. The metabolism of azoxystrobin in rotational crops was complex with a large number of conjugated metabolites formed. The residues declined significantly at longer plant back intervals. Radioactive residues in the 365-day crops were generally in concentrations below 0.01 mg/kg. As in the primary crops, parent azoxystrobin represented the major residue detected in all rotational crops (up to 17–44% TRR); with very low residue levels in the tested crops (< 0.01–0.08 mg/kg at 30 days and < 0.01–0.01 mg/kg at 200 days). In wheat forage and wheat straw at 30 days, TRRs were 0.15–0.34 and 1.4–1.9 mg/kg, respectively, which declined significantly at the longer plant back intervals of 200 days (0.02–0.05 and 0.06– 0.12 mg/kg, respectively) and 365 days (< 0.01 mg/kg). Azoxystrobin residues in wheat grain were < 0.01 mg/kg even in wheat planted 30 days after the treatment. Compounds G219, M4220, N121, N222, O223 and O324, which are the principal metabolites in rotated crops, are glucose conjugates and were also found in the primary crops in both free and conjugated forms. These metabolites are not more toxicologically significant than parent (United Kingdom, 2009a).

The peer-review concluded that the metabolism of azoxystrobin in succeeding crops is almost similar for all the analysed crops and also similar to that observed in the primary crops. The relevant residue in rotational crops should therefore be defined as parent azoxystrobin”.

Conclusion on metabolism in rotational crops

The metabolism of azoxystrobin in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not necessary.

Since the intended cGAPs are covered by the authorized European GAPs (EFSA RO, 2013), it can be concluded that azoxystrobin residue levels in food and feed rotational commodities are expected to be covered by the residue levels in primary crops.

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| **zRMS comments:**  In accordance with the soil degradation studies evaluated in the framework of the peer review, the DT50 value of azoxystrobin is 262 days (EFSA, 2010). DT90 value is expected to be higher than the trigger value of 100 days (EFSA, 2010), and therefore, studies investigating the nature of residues in rotational crops are required.  In EFSA Journal 2016;14(5):4459 it is stated that *The nature and magnitude of azoxystrobin residues in rotational crops were investigated during the peer review. On the basis of studies conducted in lettuce, radish and wheat at a maximum dose rate of 2,200 g/ha, it was concluded that the metabolism of azoxystrobin is similar to that of the primary crops and that residues above 0.05 mg/kg are not expected in the rotational crops (EFSA, 2013).*  The peer-review concluded that the metabolism of azoxystrobin in succeeding crops is almost similar for all the analysed crops and also similar to that observed in the primary crops. The relevant residue in rotational crops should therefore be defined as parent azoxystrobin. |

#### Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

**Table 7.3‑5: Nature of the residues in processed commodities**

| Conditions (Duration, Temperature, pH) | Identified compound(s) (%) | Reference |
| --- | --- | --- |
| **EU data** | | |
| **Pasteurisation**  (20 minutes, 90°C, pH 4) | Azoxystrobin (99.7-102.1%) | United Kingdom, 2009a  EFSA, 2013 |
| **Baking, boiling, brewing**  (60 minutes, 100°C, pH 5) | Azoxystrobin (95.5-96.8%) | United Kingdom, 2009a  EFSA, 2013 |
| **Sterilisation**  (20 minutes, 120°C, pH 6) | Azoxystrobin (95.9-98.6%) | United Kingdom, 2009a  EFSA, 2013 |

Summary of studies reported in the EU

*EFSA Journal 2013;11(12):3497*

“The effect of processing on the nature of azoxystrobin was investigated in the framework of the EU peer review. Studies were conducted simulating representative hydrolytic conditions for pasteurisation (20 minutes at 90°C, pH 4), boiling/brewing/baking (60 minutes at 100°C, pH 5) and sterilisation (20 minutes at 120°C, pH 6). From these studies, it was concluded that processing by pasteurization, baking/brewing/boiling and sterilization is not expected to have a significant impact on the composition of residues in matrices of plant origin (United Kingdom, 2009a). The relevant residue for enforcement and risk assessment in processed commodities is therefore expected to be the same as for primary crops”.

Conclusion on nature of residues in processed commodities

No significant degradation of azoxystrobin was observed following standard incubations at different pH and temperatures. The relevant residue for enforcement and risk assessment in processed commodities is therefore expected to be the same as for primary crops.

|  |
| --- |
| **zRMS comments:**  Standard hydrolysis studies simulating the effect on the nature of azoxystrobin residues under processing conditions representative of pasteurisation, boiling and sterilisation were assessed in the peer review and it was concluded that the compound is hydrolytically stable (EFSA, 2010). Thus, for processed commodities, the same residue definition as for raw agricultural commodities is applicable.  Studies to assess the magnitude of azoxystrobin residues during processing have been assessed in the framework of the peer review and the Article 12 MRL review and processing factors were derived for several crops (EFSA, 2010, 2013).  No further data are required to support the proposed uses. |

#### Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.3‑6: Summary of the nature of residues in commodities of plant origin

|  |  |
| --- | --- |
| **Endpoints** | |
| Plant groups covered | Cereals (Wheat)  Fruit crops (Grapes)  Pulses and oilseeds (Peanut) |
| Rotational crops covered | Cereals (Wheat)  Root and tuber vegetables (Radish)  Leafy crops (Lettuce) |
| Metabolism in rotational crops similar to metabolism in primary crops? | Yes |
| Processed commodities | Azoxystrobin (no significant degradation observed under standard hydrolysis conditions) |
| Residue pattern in processed commodities similar to pattern in raw commodities? | Yes |
| Plant residue definition for monitoring | Azoxystrobin (EFSA, 2010, EFSA, 2013 and Reg. (EU) ~~2019/552 Reg. (EU) 2023/129~~ Reg. (EU) 2024/1078) |
| Plant residue definition for risk assessment | Azoxystrobin (EFSA, 2010, EFSA, 2013) |
| Conversion factor from enforcement to RA | None (EFSA, 2010, EFSA, 2013) |

#### Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

Table 7.3‑7: Summary of animal metabolism studies

| Group | Species | Label position | No of animal | Application details | | Sample details | | Reference |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Rate  (mg/kg bw/d) | Duration  (days) | Commodity | Time of samp­ling |
| **EU data** | | | | | | | | |
| Lactating ruminants | Goat | 14C-pyrimidinyl-  or  14C-cyanophenyl-  or  14C-phenylacrylate | n.r. | 23.2-32.7 | 7 | Milk | Twice daily | EFSA, 2010, 2013  UK, 2009a |
| Urine and faeces | Daily |
| Tissues | After sacrifice |
| 14C-cyanophenyl | 1 | 25 | 7 | Milk | Twice daily |
| Urine and faeces | Daily |
| Tissues | After sacrifice |
| Laying poultry | Hens | 14C-pyrimidinyl-  or  14C-cyanophenyl-  or  14C-phenylacrylate | n.r. | 11 | 10 | Eggs | Daily |
| Excreta | Daily |
| Tissues | After sacrifice |
| 10 | 12.5 | 10 | Eggs | n.r. |
| Excreta | Daily |
| Tissues | After sacrifice |

Summary of livestock metabolism studies reported in the EU

*EFSA Journal 2013;11(12):3497*

The nature of azoxystrobin residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (United Kingdom, 2009a).

Lactating goats were dosed with approximately 25 mg/kg in the diet of azoxystrobin, corresponding to approximately 1.2 times the exposure of meat ruminant. Laying hens were dosed with 11 - 12.5 mg/kg in the diet of azoxystrobin, corresponding to approximately 7 - 8 times the exposure of poultry. All studies showed that azoxystrobin was rapidly excreted in both lactating goats and laying hens. The transfer in tissues was limited, the TRRs in muscle, fat, milk and egg white being <0.02 mg/kg. Thus, characterisation of residues was only performed in goat liver and kidney, and in poultry liver and egg yolk, where the TRRs were in the range of 0.05 to 1.19 mg/kg. In these matrices, the metabolism was shown to be very extensive, more than 20 compounds being identified/characterised, each accounting mostly for less than 5 % of the TRR. Some metabolites (M28, M2025, L426…) were however observed in higher proportions in some matrices, depending on the 14C-label. The parent compound was less than 2 % of the TRR, except in egg yolk (12 % TRR for the cyanophenyl label). The general metabolic pathways in rodents and ruminants were found to be comparable; the findings in ruminants can therefore be extrapolated to pigs.

As none of these compounds were considered as a sufficient marker for the residue in animal matrices, the residue for enforcement was then defined by default as azoxystrobin only. Validated analytical methods for enforcement of the proposed residue definition are available (see also section 1.2). However, no conclusion could be drawn on the toxicological profile of metabolites L127, L4 and L928 (EFSA, 2010). Additional data on the toxicological relevance of metabolites L1, L4 and L9 are therefore required. Meanwhile, it is proposed, on a tentative basis, to also define the residue for risk assessment as azoxystrobin only.

The conclusions reached by EFSA reflect the views of the RMS and are also in line with those of the JMPR (FAO, 2008). In the framework of the peer review, the proposed residue was not considered to be fat soluble based on the fact that the log Po/w of azoxystrobin is lower than 3”.

*EFSA Journal 2020;18(8):6231 - Evaluation of confirmatory data following the Article 12*

“The previously derived residue definition for monitoring is still applicable (see Appendix B.2.1). The RMS proposed to confirm the residue definition for risk assessment in animal commodities which was tentatively set as azoxystrobin, pending information on the toxicological profile of metabolites L1, L4 and L9. This is discussed in Section 5”.

“Regarding the toxicological assessment of livestock metabolites L1, L4 and L9, the submitted data allowed to conclude that the genotoxic potential of these three compounds can be ruled out. However, data addressing the general toxicity of these compounds were not provided. Based on calculations to demonstrate that the expected dietary exposure of consumers to these metabolites was lower than the TTC, the RMS concluded that further data addressing the general toxicity of these compounds were not needed and thus proposed to confirm the residue definition for risk assessment in animal commodities as azoxystrobin alone. EFSA highlighted that the TTC approach cannot be applied in this context. EFSA concludes that the data gap identified in the framework of the MRL review was only partially addressed. Further risk management considerations should be given to decide whether the argument of the low exposure calculated for metabolites L1, L4, L9 and K1 (conjugate of L1) is acceptable to waive the need to submit data on the general toxicity of L1, L4 and L9. Meanwhile, the residue definition for risk assessment in animal commodities is still deemed tentative”.

Conclusion on metabolism in livestock

The metabolism of azoxystrobin in animals is considered sufficiently addressed. All studies showed that azoxystrobin was rapidly excreted in both lactating goats and laying hens. The metabolism pattern was similar in ruminants and rodents and can therefore be extrapolated to pigs. The residue definition for livestock was set as azoxystrobin only for the monitoring (default) and also for the risk assessment (tentative).

According to SANTE/11509/2013– rev. 5.2 and since the active substance azoxystrobin is not yet renewed (AIR4), the “old data requirements” (Reg. (EU) No 544/2011) and the endpoints from the previous monograph of azoxystrobin (DAR, 2009) apply to the current assessment.Therefore, no residue data on fish are required.

|  |
| --- |
| **zRMS comments:**  Information given by the Applicant is sufficient.  In EFSA Journal 2010; 8(4):1542 it is stated that *Azoxystrobin was rapidly excreted in the metabolism studies performed on goats (2N dose) and poultry (8N dose). The transfer in tissues was limited, the TRRs in muscle, fat, milk and egg white being <0.02 mg/kg. Thus, characterisation of residues was only performed in goat liver and kidney, and in poultry liver and egg yolk, where the TRRs were in the range of 0.05 to 1.19 mg/kg. In these matrices, the metabolism was shown to be very extensive, more than 20 compounds being identified/characterised, each accounting mostly for less than 5% of the TRR. Some metabolites (M28, M20, L4…) were however observed in higher proportions in some matrices, depending on the 14C-label. The parent compound was less than 2% of the TRR, except in egg yolk (12% TRR for the cyanophenyl label). None of these compounds were considered as a sufficient marker for the residue in animal matrices, and* ***the residue for monitoring and risk assessment was then defined by default as azoxystrobin only****. However, the definition for risk assessment has to be considered provisional, pending additional information on the toxicological relevance of metabolites L1, L4 and L9.*  The data on *the toxicological relevance of metabolites L1, L4 and L9* provided in the present application are from the EFSA Journal 2020;18(8):6231 – “Evaluation of confirmatory data following the Article 12 and modification of the existing MRLs for azoxystrobin”. As confirmatory data, they are out of data protection.  According to the EFSA Journal 2020;18(8):6231 – “Evaluation of confirmatory data following the Article 12 and modification of the existing MRLs for azoxystrobin” *In the framework of the MRL review, EFSA identified data gaps related to the toxicological relevance of metabolites L1, L4 and L9, which were identified in ruminant liver and kidney (data gap number 35). In order to address this data gap, the applicant provided, in the framework of the current assessment, information that allowed to conclude that the genotoxic potential of these three compounds can be ruled out (see Section 1). However, the applicant did not provide data on the general toxicity of these metabolites. Instead, calculations were provided to demonstrate that the expected dietary exposure of consumers to these metabolites (from the intake of liver and kidney) is low and would therefore not be of toxicological concern.*  *(…) Regarding the toxicological assessment of livestock metabolites L1, L4 and L9, the submitted data allowed to conclude that the genotoxic potential of these three compounds can be ruled out.*  *(…) general toxicity of these metabolites was not addressed.*  As confirmatory data, they are out of data protection.  **Metabolism studies, methods of analysis and residue definitions in livestock (EFSA, 2020):**    The log Po/w value for azoxystrobin is 2.5 (at 20°C) which is consistent with no accumulation potential in fish tissues. As the log Po/w of all components of the plant Residue Definition for Risk Assessment does not exceed 3, metabolism studies in fish are not required.  No further data are required to support the proposed uses. |

#### Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.3‑8: Summary on the nature of residues in commodities of animal origin

|  |  |
| --- | --- |
|  | Endpoints |
| Animals covered | Lactating goats |
| Laying hens |
| Time needed to reach a plateau concentration | In milk and eggs, a plateau level was never reached and no residues at or above 0.01 mg/kg was found in any of the samples (EFSA, 2013) |
| Animal residue definition for monitoring | Azoxystrobin (EFSA, 2010, EFSA, 2013, 2020 and Reg. (EU~~) 2019/552 Reg. (EU) 2023/129~~ Reg. (EU) 2024/1078) |
| Animal residue definition for risk assessment | Azoxystrobin – *tentative* (EFSA, 2010, EFSA, 2013)  [genotoxicity of metabolites L1, L4 and L9 can be ruled out  but general toxicity of these metabolites was not addressed] (EFSA, 2020) |
| Conversion factor | None (EFSA, 2010, EFSA, 2013, 2020) |
| Metabolism in rat and ruminant similar | Yes |
| Fat soluble residue | No (log PO/W = 2.5 at 20°C without pH dependence) |

### Magnitude of residues in plants (KCA 6.3)

#### Summary of European data and new data supporting the intended uses

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2. Additional new study was finalised in March 2024: “Determination of residues of Azoxystrobin after a single application of CA2702 in Oilseed rape (outdoor) at 4 sites in Northern Europe 2023” (KCA 6.3.3/07 – Study S23-100807). Data are added in the following table.

It should be noted that:

* Only trials performed in the northern residue zone are presented.
* The selection of supporting data was made based on the BBCH growth stage at last application as according to SANTE/2019/12752 “In some cases (e.g. cereals, oilseeds), the crop growth stage at application is more important to consider for the selection of GAP-compliant trials while PHI (if specified in the GAP) may be of secondary relevance”.

Table 7.3‑9: Summary of EU reported and new data supporting the intended uses of CA3642 and conformity to existing MRL

| Commodity | Source | Residue zone (N-EU, S-EU, EU, outside EU) | Evaluation GAP Residue levels (mg/kg)  E = RA = Azoxystrobin | STMR (mg/kg) | HR (mg/kg) | Unrounded OECD calculator MRL  (Rounded) (mg/kg) | Current EU MRL  (mg/kg)  \* | MRL compliance |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Barley 🡪 Oat  Grain | EFSA, 2010 | N-EU (8) | GAP on which EU a.s. assessment is based: 2 x 250 g a.s./ha, BBCH 59, PHI 35d  E=RA: <0.01, 0.01, 0.02, 2x 0.04, 0.08, 0.20, 0.43 | N/A | | | | |
| New trials  *ChR-10-8230*  *\*\*see remark below* | NEU (4) | Trials GAP: 2 x 260 g a.s./ha, BBCH 57-59, PHI 34-40d  E=RA: 0.042, 0.058, 0.10, 0.13 |
| New trials  *JCB-11-10126* | NEU (4) | Trials GAP: 2 x 250 g a.s./ha, BBCH 59, PHI 45-71d  E=RA: <0.01, 0.011, 0.015, 0.016 |
| Overall supporting data for cGAP | NEU (16) | **Intended cGAP: 2 x 150 g a.s./ha, BBCH 30-61, PHI 35d**  E=RA: <0.01, <0.01, 0.01, 0.011, 0.015, 0.016, 0.02, 0.04, 0.04, 0.042, 0.058, 0.08, 0.10, 0.13, 0.20, 0.43outlier | 0.04 | 0.43 | 0.509 (0.5) | 1.5 | Yes |
| Barley 🡪 Oat  Straw | EFSA, 2010 | N-EU (8) | GAP on which EU a.s. assessment is based: 2 x 250 g a.s./ha, BBCH 59, PHI 35d  E=RA: 0.11, 0.39, 0.48, 0.91, 1.3, 1.5, 2.7, 5.1 | N/A | | | | |
| New trials  *ChR-10-8230*  *\*\*see remark below* | NEU (4) | Trials GAP: 2 x 260 g a.s./ha, BBCH 57-59, PHI 34-40d  E=RA: 1.72, 2.54, 3.18(a), 3.64 |
| New trials  *JCB-11-10126* | NEU (4) | Trials GAP: 2 x 250 g a.s./ha, BBCH 59, PHI 45-71d  E=RA: 0.23, 0.29, 0.93, 1.5 |
| Overall supporting data for cGAP | NEU (16) | **Intended cGAP: 2 x 150 g a.s./ha, BBCH 30-61, PHI 35d**  E=RA: 0.11, 0.23, 0.29, 0.39, 0.48, 0.91, 0.93, 1.3, 1.5, 1.5, 1.72, 2.54, 2.7, 3.18(a), 3.64, 5.1 | 1.4 | 5.1 | - | - | - |
| Wheat 🡪 Triticale, Rye  Grain | EFSA, 2010 | N-EU (9) | GAP on which EU a.s. assessment is based: 2 x 250 g a.s./ha, BBCH 69, PHI 35d  E=RA: 3x <0.01, 0.01, 2x 0.04, 0.07, 0.09, 0.23 | N/A | | | | |
| New trials  *ChR-10-8231*  *\*\*see remark below* | N-EU (4) | Trials GAP: Trials GAP: 2 x 260 g a.s./ha, BBCH 69, PHI 40-46d  E=RA: <0.01, <0.01, 0.01, 0.013 |
| New trials  *JCB-11-10125* | N-EU (4) | Trials GAP: Trials GAP: 2 x 250 g a.s./ha, BBCH 69, PHI 36-66d  E=RA: <0.01, <0.01, 0.022, 0.028 |
| Overall supporting data for cGAP | N-EU (17) | **Intended cGAP: 2 x 210 g a.s./ha, BBCH 37-59, PHI 35d**  E=RA: 7x <0.01, 2x 0.01, 0.013, 0.022, 0.028, 2x 0.04, 0.07, 0.09, 0.23 | 0.01 | 0.23 | 0.257 (0.3) | 0.5 | Yes |
| Wheat 🡪 Triticale, Rye  Straw | EFSA, 2010 | N-EU (9) | GAP on which EU a.s. assessment is based: 2 x 250 g a.s./ha, BBCH 69, PHI 35d  E=RA: 0.34, 0.58, 0.65, 0.75, 0.82, 1.5, 2x 1.6, 2.0 | N/A | | | | |
| New trials  *ChR-10-8231*  *\*\*see remark below* | N-EU (4) | Trials GAP: Trials GAP: 2 x 260 g a.s./ha, BBCH 69, PHI 40-46d  E=RA: 1.50, 2.02, 2.02, 2.29 |
| New trials  *JCB-11-10125* | N-EU (4) | Trials GAP: Trials GAP: 2 x 250 g a.s./ha, BBCH 69, PHI 36-66d  E=RA: 0.41, 1.2, 1.7, 10.1 |
| Overall supporting data for cGAP | N-EU (17) | **Intended cGAP: 2 x 210 g a.s./ha, BBCH 37-59, PHI 35d**  E=RA: 0.34, 0.41, 0.58, 0.65, 0.75, 0.82, 1.2, 2x 1.5, 2x 1.6, 1.7, 2.0, 2x 2.02, 2.29, 10.1 | 1.5 | 10.1 | - | - | - |
| Oilseed rape seeds 🡪 Sunflower, Linseed, mustard, poppy, gold of pleasure seeds | New trials  *GBU-11-10127* | N-EU (4) | Trials GAP: 1 x 250 g a.s./ha, BBCH 69, PHI 60-66d  E=RA: 4x <0.01 | N/A | | | | |
| New trials  *ChR-10-8214*  *\*\*see remark below* | N-EU (4) | Trials GAP: 1 x 250 g a.s./ha, BBCH 69, PHI 48-52d  E=RA: <0.001, <0.01, 0.032, 0.13 |
| New trials  (S23-100807) | N-EU (4) | Trials GAP: 1 x 250 g a.s./ha, BBCH 69, PHI 49-60d  E=RA: 4x <0.01 | - | | | | |
| Overall supporting data for cGAP | N-EU (8) | **Intended cGAP: 1 x 180 g a.s./ha, BBCH 69, PHI 56d**  E=RA: <0.001, ~~5~~ 9x <0.01, 0.032, 0.13 | 0.010 | 0.13 | ~~0.197~~ 0.161 (0.2) | Rapeseed: ~~0.5 /~~ 0.7~~b~~, Mustard, Poppy, Gold of pleasure: 0.5  Linseed: 0.4 | Yes |

\* Source of EU MRL: ~~Reg. (EU) 2022/476. MRLs from Reg. (EU) 2022/1363 and PLAN/2022/1665 are not yet applicable. Please note there is no MRL change for the intended crops, except for rapeseed in PLAN/2022/1665 for which the MRL is proposed to be raised at 0.7 mg/kg. Reg. (EU) 2023/129~~ Reg. (EU) 2024/1078

\*\* According to the SANTE/2019/12752 trials from study ChR-10-8214, ChR-10-8230 and ChR-10-8231 are not considered independent. More details - see zRMS comments below and Appendix 2.

(a) Trial ChR-10-8233 PL02 at PBI 2 months (rotational crops) and trial ChR-10-8230 PL04 (primary crops) were performed in similar conditions (location, variety, date, and similar application rate on the primary crop barley). The residue level measured in barley straw is higher in rotational crops (3.18 mg/kg) compared to primary crop (1.93 mg/kg) and was therefore considered.

~~(b) Commission Regulation (EU) 2023/129 of 18 January 2023 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, prosulfocarb, sedaxane and valifenalate in or on certain products: MRL for oilseed rape seeds is raised to 0.7 mg/kg. Not yet applicable.~~

#### Conclusion on the magnitude of residues in plants

***Barley, Oat***

Barley and Oat are major crops in northern regions.

According to SANTE/2019/12752, extrapolation to oat is possible with a minimum of 8 trials on barley, which is the case here.

The last application in the provided trials was performed slightly earlier (BBCH 59) compared to the intended GAP (BBCH 61). However, sufficient trials at the intended PHI of 35 days are available. In addition, all trials are overdosed (2 x 250-260 g a.s./ha instead of 2 x 150 g a.s./ha) and can be considered as a worst-case situation. They show that no MRL exceedance will occur. Therefore, no MRL exceedance will occur when CA3642 is applied according to the proposed GAP.

According to the available data, the intended uses on barley and oat are considered sufficiently supported in the Northern residue zone.

***Wheat, Rye, Triticale and Spelt, Einkorn wheat, Emmer Wheat, Tritordeum***

Wheat and rye are major crops in northern regions. Triticale, spelt, *Einkorn wheat, Emmer Wheat and Tritordeum* are ~~minor~~ major crops.

According to SANTE/2019/12752, extrapolation to rye, triticale, spelt, *Einkorn wheat, Emmer Wheat, and Tritordeum* is possible with a minimum of 8 trials on wheat, which is the case here.

All trials are slightly overdosed (2 x 250-260 g a.s./ha instead of 2 x 210 g a.s./ha) ~~and the last application was performed later (BBCH 69) compared to the intended GAP (BBCH 59)~~. Consequently, these trials can be considered as a worst-case situation. They show that no MRL exceedance will occur. Therefore, no MRL exceedance will occur when CA3642 is applied according to the proposed GAP.

According to the available data, the intended uses on wheat, ~~oat,~~ rye, triticale and spelt, *Einkorn wheat, Emmer Wheat, and Tritordeum* are considered sufficiently supported in the Northern residue zone.

***Oilseed rape, Sunflower, Linseed, Poppy, Mustard and Gold of pleasure***

Oilseed rape and Sunflower are a major crop in northern regions. Linseed, poppy, mustard, and gold of pleasure are minor crops.

According to SANTE/2019/12752, extrapolation to sunflower, linseed, poppy, mustard, and gold of pleasure is possible.

All trials are overdosed (1 x 250 g a.s./ha instead of 1 x 180 g a.s./ha) and consequently they can be considered as a worst-case situation. They show that no MRL exceedance will occur. Therefore, no MRL exceedance will occur when CA3642 is applied according to the proposed GAP.

According to the available data, the intended uses on oilseed rape, sunflower, linseed, poppy, mustard, and gold of pleasure are considered sufficiently supported in the Northern residue zone.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **zRMS comments:**  Residue Definitions (EFSA 2010, 2013; Reg. (EU) 2024/1078):  Monitoring (Mo): Azoxystrobin  Risk Assessment (RA): Azoxystrobin  **Wheat, rye, triticale and spelt, einkorn wheat, emmer wheat, tritordeum**  Wheat and rye are the major crops in northern Europe (SANTE/2019/12752). A minimum of eight trials are required. Based on the SANTE/2019/12752, 8 residue trials on wheat can be used for extrapolation to rye, triticale and spelt before and after forming of the edible part. So the uses are also considered acceptable on rye, triticale and spelt, einkorn wheat, emmer wheat, tritordeum.  Sufficient trials on wheat (9 trials) conducted according to the residue definition for monitoring and for risk assessment were previously presented and evaluated (EFSA, 2010). All trials are slightly overdosed (2 x 250 g a.s./ha instead of 2 x 210 g a.s./ha). Consequently, these trials can be considered as a worst-case situation.  Residues of azoxystrobin were: 3x <0.01, 0.01, 2x 0.04, 0.07, 0.09, 0.23 mg/kg.  Two additional magnitude of residue studies were submitted in the framework of this application: studies ChR-10-8231 and JCB-11-10125.  Summary is presented below.  **1. Study ChR-10-8231**  Four N-EU trials were conducted in accordance with the following GAP: 2 x 260 g a.s. /ha, application interval - 21 days, 2nd application at BBCH 69, PHI 40 - 46d, outdoor.  Residues of azoxystrobin in wheat grain at harvest were 2x<0.01, 0.01, 0.013 mg/kg.  Remark:  According to the SANTE/2019/12752 four trials from study ChR-10-8231 are not considered independent. More details - see Appendix 2, point A 2.2.3.2.1.  **2. Study JCB-11-10125**  Four N-EU trials were conducted in accordance with the following GAP: 2 x 250 g a.s. /ha, application interval - 14 days, BBCH 69, PHI 36 - 66d, outdoor.  Residues of azoxystrobin in wheat grain at harvest were 2x<0.01, 0.022, 0.028 mg/kg.  Storage periods of residue samples covered by available storage stability studies.  So overall, the data residue trials presented for wheat is complete even if the ChR-10-8231 trials are considered as not independent.  Available results show that the in force MRL of azoxystrobin on wheat and rye of 0.5 mg/kg (Reg. (EU) 2024/1078) will not be exceeded. The current EU MRL for azoxystrobin is sufficient to support the proposed uses.  The trials are supported by valid storage stability data and validated analytical methods.  **The proposed uses on wheat, rye, triticale, spelt, einkorn wheat, emmer wheat and Tritordeum are considered acceptable**.  **Barley, oat**  Barley and oat are the major crops in northern Europe (SANTE/2019/12752). A minimum of eight trials are required. Based on the SANTE/2019/12752, 8 residue trials on barley can be used for extrapolation to oat before and after forming of the edible part. So the uses are also considered acceptable on barley and oat.  Sufficient trials on barley (8 trials) conducted according to the residue definition for monitoring and for risk assessment were previously presented and evaluated (EFSA, 2010). All trials are slightly overdosed (2 x 250 g a.s./ha instead of 2 x 150 g a.s./ha). Consequently, these trials can be considered as a worst-case situation.  Residues of azoxystrobin were: <0.01, 0.01, 0.02, 2x 0.04, 0.08, 0.20, 0.43 mg/kg.  Two additional magnitude of residue studies were submitted in the framework of this application: studies ChR-10-8230 and JCB-11-10126.  Summary is presented below.  **1. Study ChR-10-8230**  Four N-EU trials were conducted in accordance with the following GAP: 2 x 260 g a.s. /ha, application interval - 14 days, 2nd application at BBCH 59, outdoor.  Residues of azoxystrobin in barley grain at harvest were 0.042, 0.058, 0.10, 0.13 mg/kg.  Remark:  According to the SANTE/2019/12752 four trials from study ChR-10-8230 are not considered independent. More details- see Appendix 2, point A 2.2.3.1.1.  **2. Study JCB-11-10126**  Four N-EU trials were conducted in accordance with the following GAP: 2 x 250 g a.s. /ha, application interval - 14 days, BBCH 59, outdoor.  Residues of azoxystrobin in barley grain at harvest were <0.01, 0.011, 0.015, 0.016 mg/kg.  Storage periods of residue samples covered by available storage stability studies.  So overall, the data residue trials presented for barley is complete even if the ChR-10-8230 trials are considered as not independent.  Available results show that the in force MRL of azoxystrobin on barley and oat of 1.5 mg/kg (Reg. (EU) 2024/1078) will not be exceeded. The current EU MRL for azoxystrobin is sufficient to support the proposed uses.  The trials are supported by valid storage stability data and validated analytical methods.  **The proposed uses on barley and oat are considered acceptable**.  **Oilseeds**  **Major crop: winter oilseed rape**  **Minor ~~crops~~uses (article 51): sunflower (PL), spring oilseed rape, linseed, poppy, mustard, gold of pleasure seeds**  Oilseed rape and sunflower are the major crops in northern Europe (SANTE/2019/12752). A minimum of eight trials are required.  Linseed, poppy, mustard, gold of pleasure seeds are the minor crops in N-EU and a minimum of four trials are required.  Eight new residue trials (GBU-11-10127 and ChR-10-8214) were conducted on oilseed rape in N-EU according to the residue definition for monitoring and for risk assessment. All trials are overdosed (1 x 250 g a.s./ha instead of 1 x 180 g a.s./ha) and consequently they can be considered as a worst-case situation.  Summary  **1. Study GBU-11-10127**  Four N-EU trials were conducted in accordance with the following GAP: 1 x 250 g a.s. /ha, application at BBCH 69, outdoor.  Residues of azoxystrobin in oilseed rape grain were below 0.01 mg/kg.  **2. Study ChR-10-8214**  Four N-EU trials were conducted in accordance with the following GAP: 1 x 250 g a.s. /ha, application at BBCH 69, outdoor.  Residues of azoxystrobin in oilseed rape grain ranged from <0.001 mg/kg to 0.13 mg/kg (2x<0.001, 0.032, 0.13 mg/kg).  Remark:  According to the SANTE/2019/12752, four trials from study ChR-10-8214 are not considered independent. More details - see Appendix 2, point A 2.2.3.3.2.  For oilseed rape, the dossier includes 4 trials from GBU-11-10127 and the 4 trials from ChR-10-8214, which are not considered independent. According to the SANTE/2019/12752, a minimum of eight independent trials are required to support the proposed use on major crop - winter oilseed rape.  Taking into account, Nufarm provided (March 2024) four additional independent residue trials on OSR (study S23-100807) to support registration of CA3642 / Joust Pro.  **3. Study S23-100807**  Four N-EU trials were conducted in accordance with the following GAP: 1 x 250 g a.s. /ha or 1 x 750 g a.s./ha, application at BBCH 69, outdoor.  Residues of azoxystrobin in oilseed rape grain were <0.01 mg/kg.  Available results show that the in force MRL of azoxystrobin on oilseed rape of 0.7 mg/kg (Reg. (EU) 2024/1078) will not be exceeded. The current EU MRLs for azoxystrobin are sufficient to support the proposed minor uses.  Storage periods of residue samples covered by available storage stability studies.  **The proposed use on winter oilseed rape (major crop) is considered acceptable**.  **Minor uses ~~crops~~ (article 51):** **sunflower (in PL),** **spring oilseed rape,** **linseed, poppy, mustard and gold of pleasure seeds**  No new residue studies on minor crops have been submitted by the applicant in the framework of this application.  Based on the SANTE/2019/12752, four residue trials on oilseed rape can be used for extrapolation to following minor **uses** ~~crops~~:sunflower (in PL), spring oilseed rape, linseed, poppy, mustard and gold of pleasure seeds before and after forming of the edible part.  Nine independent trials conducted on oilseed rape are available. Residues of azoxystrobin in oilseed rape grain ranged from <0.001 mg/kg to 0.13 mg/kg.   |  |  |  | | --- | --- | --- | | 0400000 | **OILSEEDS AND OIL FRUITS** | **MRLs of Azoxystrobin**  **Reg. (EU) 2024/1078** | | 0401000 | Oilseeds |  | | 0401010 | Linseeds | 0.4 | | 0401030 | Poppy seeds | 0.5 | | 0401050 | Sunflower seeds | 0.5 | | 0401060 | Rapeseeds/canola seeds | 0.7 | | 0401080 | Mustard seeds | 0.5 | | 0401130 | Gold of pleasure seeds | 0.5 |   Available results show that the in force MRL of azoxystrobin on oilseed rape of 0.7 mg/kg, on sunflower, poppy seeds, gold of pleasure seeds and mustard seeds of 0.5 mg/kg, on linseeds of 0.4 mg/kg (Reg. (EU) 2024/1078) will not be exceeded. The current EU MRLs for azoxystrobin are sufficient to support the proposed minor uses.  The trials are supported by valid storage stability data and validated analytical methods.  **The proposed minor uses ~~on minor crops~~ (art. 51): spring oilseed rape and sunflower, linseed, poppy, mustard, gold of pleasure seeds are considered acceptable**. |

### Magnitude of residues in livestock

#### Dietary burden calculation

In the framework of the review of the existing MRLs for azoxystrobin (EFSA, 2013) and its confirmatory data (EFSA, 2020), the median and maximum dietary burdens were calculated for different groups of livestock.

The input values used in the EU calculation were compared to the residue levels found in the trials supporting the intended uses of CA3642 (Table 7.3‑10). The EU inputs sufficiently cover the intended uses of CA3642. It is therefore proposed to refer to EFSA Reasoned Opinion (EFSA, 2020).

Table 7.3‑10: Comparison of EU input values for risk assessment with results from trials supporting the intended uses of CA3642 – Azoxystrobin

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Feed Commodity | EU inputs  (EFSA, 2020) | | Data from trials supporting the intended uses of CA3642 | | EU data cover? (Y/N) |
| Barley, Oat grain | 0.1 | STMR (EFSA, 2013) | 0.04 | STMR (§ 7.3.3) | Y |
| Wheat, Rye grain | 0.08 | STMR (EFSA, 2013) | 0.01 | STMR (§ 7.3.3) | Y |
| Barley, Oat straw | 2.3  5.5 | STMR (EFSA, 2013)  HR (EFSA, 2013) | 1.4  5.1 | STMR (§ 7.3.3)  HR (§ 7.3.3) | Y |
| Wheat, Rye, Triticale straw | 3.85  10.1 | STMR (EFSA, 2013)  HR (EFSA, 2013) | 1.5  10.1 | STMR (§ 7.3.3)  HR (§ 7.3.3) | Y |
| Rapeseed, seeds | 0.055 | STMR (EFSA, 2013) | 0.01 | STMR (§ 7.3.3) | Y |
| Linseed, seeds | 0.02 | STMR (EFSA, 2016b) | 0.01 | STMR (§ 7.3.3) | Y |

Table 7.3‑11: Results of the dietary burden calculation (EFSA, 2020)

| Relevant groups | Dietary burden expressed in | | | | Most critical commodity(b) | | Trigger exceeded (Y/N)  0.1 mg/kg DM |
| --- | --- | --- | --- | --- | --- | --- | --- |
| mg/kg bw per day | | mg/kg DM | |
| Median | Maximum | Median | Maximum |
| Risk assessment residue definition: Azoxystrobin | | | | | | | |
| Cattle (all diets) | 0.46 | 0.59 | 12.0 | 15.4 | Dairy cattle | Citrus, dried pulp | Y |
| Cattle (dairy only) | 0.46 | 0.59 | 12.0 | 15.4 | Dairy cattle | Citrus, dried pulp | Y |
| Sheep (all diets) | 0.10 | 0.23 | 2.5 | 5.79 | Lamb | Rye, straw | Y |
| Sheep (ewe only) | 0.10 | 0.19 | 2.85 | 5.49 | Ram/Ewe | Rye, straw | Y |
| Swine (all diets) | 0.20 | 0.25 | 8.76 | 10.6 | Swine (breeding) | Citrus, dried pulp | Y |
| Poultry (all diets) | 0.05 | 0.10 | 0.66 | 1.42 | Poultry layer | Wheat, straw | Y |
| Poultry (layer only) | 0.05 | 0.10 | 0.66 | 1.42 | Poultry layer | Wheat, straw | Y |

\* These categories correspond to those (formerly) assessed at EU level.

For azoxystrobin, the results of the dietary burden calculation demonstrate that the exposure of all livestock species exceeds the trigger value of 0.1 mg/kg DM.

|  |
| --- |
| **zRMS comments:**  Azoxystrobin is authorised for use on several crops that might be fed to livestock. The median and maximum dietary burdens has been calculated for different groups of livestock using the EFSA Animal model 2017.  The calculated dietary burden for azoxystrobin was found to exceed the trigger value of 0.1 mg/kg DM (or 0.004 mg/kg bw/d, respectively) for all groups of livestock. Therefore, further investigation of residues is required.  Remark on residue behaviour in fish (B.7.3.2.5 and B.7.3.4)  In accordance with SANCO/10254/2021, an assessment of metabolism in fish is required when pesticide use may lead to significant residues of an active substance or a major metabolite in total diet (i.e. ≥ 0.1 mg/kg feed on a dry matter basis) which also have the potential to accumulate (i.e. log Po/w > 3). Azoxystrobin is the only analyte considered relevant to the consumer from exposure to plants and the log Po/w value for azoxystrobin is 2.5 (at 20°C) which is consistent with no accumulation potential in fish tissues. As the log Po/w of all components of the plant Residue Definition for Risk Assessment does not exceed 3, metabolism studies in fish are not required. |

#### Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

No new data were submitted in the framework of this application.

Summary of livestock feeding studies

*EFSA Journal 2013;11(12):3497*

“During the peer review under Directive 91/414/EEC, the magnitude of azoxystrobin residues in livestock was investigated in feeding studies with lactating cows and laying hens (United Kingdom, 2009a).

Four groups of lactating cows, each consisting of three animals, were dosed for 30 consecutive days with azoxystrobin at levels of 5, 25, 75 and 250 mg/kg in the diet (equivalent to 0.18, 0.91, 2.73 and 9.09 mg/kg bw). Three groups of laying hens, each consisting of twelve animals were dosed for 28 consecutive days with azoxystrobin at levels of 6, 18, and 60 mg/kg in the diet (equivalent to 0.39, 1.2 and 3.9 mg/kg bw). The samples were analyzed for parent azoxystrobin. Results of both livestock feeding studies are summarized in Table 3-8. In milk and eggs, a plateau level was never reached and no residues at or above 0.01 mg/kg was found in any of the samples.

The storage stability of azoxystrobin residues in animal products was evaluated under the peer review of Directive 91/414/EEC (United Kingdom, 2009a). Studies demonstrated storage stability of azoxystrobin in milk, muscle, fat, liver and kidney, eggs for up to 10 months when stored deep frozen. According to the RMS, all samples reported in the PROFile were stored in compliance with the above reported storage conditions.

Consequently, the available data are considered sufficient for deriving MRLs in ruminants, pigs and poultry. These MRLs were derived in compliance with the latest recommendations on this matter (FAO, 2009) and are summarized in Table 3-7. Significant residues in tissues of ruminants, pigs and poultry, eggs and milk, are not expected and MRLs for these commodities can be established at the LOQ. Considering that the residue definition for risk assessment is tentative, these MRLs are also considered tentative”.

*EFSA Journal 2020;18(8):6231*

In the framework of the MRL review, EFSA identified data gaps related to the toxicological relevance of metabolites L1, L4 and L9, which were identified in ruminant liver and kidney.

“Regarding the toxicological assessment of livestock metabolites L1, L4 and L9, the submitted data allowed to conclude that the genotoxic potential of these three compounds can be ruled out. However, data addressing the general toxicity of these compounds were not provided. Based on calculations to demonstrate that the expected dietary exposure of consumers to these metabolites was lower than the TTC, the RMS concluded that further data addressing the general toxicity of these compounds were not needed and thus proposed to confirm the residue definition for risk assessment in animal commodities as azoxystrobin alone. EFSA highlighted that the TTC approach cannot be applied in this context. EFSA concludes that the data gap identified in the framework of the MRL review was only partially addressed. Further risk management considerations should be given to decide whether the argument of the low exposure calculated for metabolites L1, L4, L9 and K1 (conjugate of L1) is acceptable to waive the need to submit data on the general toxicity of L1, L4 and L9. Meanwhile, the residue definition for risk assessment in animal commodities is still deemed tentative”.

The MRLs for animal commodities calculated during the Evaluation of confirmatory data following the Article 12 MRL review are presented in the table hereafter.

Table 7.3‑12: Overview of the values derived from livestock feeding studies (EFSA, 2020)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Animal commodity** | **Residues at the closet feeding level** (mg/kg) | | **Estimated value at 1N level** | | **MRL proposal** (mg/kg) |
|
| STMRMo(mg/kg) | HRMo (mg/kg) |
| Mean | Highest |
| **Cattle (all diets)** |  |  |  |  |  |
| Closest feeding level: | 0.91 | mg/kg bw |  | 1.5 N rate (c) | |
| Muscle | <0.01 | <0.01 | <0.01 | <0.01 | **0.01\*** |
| Fat | <0.01 | <0.01 | <0.01 | <0.01 | **0.01\*** |
| Liver | 0.01 | 0.01 | <0.01 | <0.01 | **0.01\* (f)** |
| Kidney | <0.01 | <0.01 | <0.01 | <0.01 | **0.01\* (f)** |
| **Cattle (dairy only)** |  |  |  |  |  |
| Closest feeding level: | 0.91 | mg/kg bw |  | 1.5 N rate (c) |  |
| Milk (d) | <0.01 | n.a. | <0.01 | <0.01 | **0.01\*** |
| **Sheep (all diets) (e)** |  |  |  |  |  |
| Closest feeding level: | 0.18 | mg/kg bw |  | 0.8 N rate (c) | |
| Muscle | <0.01 | <0.01 | <0.01 | <0.01 | **0.01\*** |
| Fat | <0.01 | <0.01 | <0.01 | <0.01 | **0.01\*** |
| Liver | <0.01 | <0.01 | <0.01 | <0.01 | **0.01\* (f)** |
| Kidney | <0.01 | <0.01 | <0.01 | <0.01 | **0.01\* (f)** |
| **Sheep (dairy only)** |  |  |  |  |  |
| Closest feeding level(a): | 0.18 | mg/kg bw |  | 0.9 N rate (c) |  |
| Milk(d) | <0.01 | n.a. | <0.01 | <0.01 | **0.01\*** |
| **Swine** |  |  |  |  |  |
| Closest feeding level: | 0.18 | mg/kg bw |  | 0.7 N rate (c) | |
| Muscle | <0.01 | <0.01 | <0.01 | <0.01 | **0.01\*** |
| Fat | <0.01 | <0.01 | <0.01 | <0.01 | **0.01\*** |
| Liver | <0.01 | <0.01 | <0.01 | <0.01 | **0.01\* (f)** |
| Kidney | <0.01 | <0.01 | <0.01 | <0.01 | **0.01\* (f)** |
| **Poultry (all diets)** |  |  |  |  |  |
| Closest feeding level(a): | 0.39 | mg/kg bw |  | 4 N rate (c) | |
| Muscle | <0.01 | <0.01 | <0.01 | <0.01 | **0.01\*** |
| Fat | <0.01 | <0.01 | <0.01 | <0.01 | **0.01\*** |
| Liver | <0.01 | <0.01 | <0.01 | <0.01 | **0.01\*** |
| **Poultry (layer only)** |  |  |  |  |  |
| Closest feeding level: | 0.39 | mg/kg bw |  | 4 N rate (c) |  |
| Eggs | <0.01 | <0.01 | <0.01 | <0.01 | **0.01\*** |

n.a.: not applicable.

\*: Indicates that the MRL is proposed at the limit of quantification.

(a): Median residues recalculated at the 1N rate for the median dietary burden.

(b): Highest residues recalculated at the 1N rate for the maximum dietary burden.

(c): Closest feeding level and N dose rate related to the maximum dietary burden.

(d): For milk, mean was derived from samplings performed from day 1 to day 30 (daily mean of four cows).

(e): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.

(f): Noting that the general toxicity of metabolites L1, L4 and L9 (found in liver and kidney) was not addressed.

Conclusion on feeding studies

The requested uses do not modify the theoretical maximum daily intake for animals. Regarding available feeding data, there is no risk for animal MRL to be exceeded.

|  |
| --- |
| **zRMS comments:**  Data presented by Applicant in point 7.3.4.2 have been accepted and are sufficient to support the proposed uses.  The requested uses and the new mode of calculation do not modify the theoretical maximum daily intake for animals and regarding available feeding data, there is no risk for animal MRL to be exceeded (Reg. (EU) 2024/1078).  No additional data are required. |

### Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

#### Available data for all crops under consideration

Azoxystrobin residue above the trigger value of 0.1 mg/kg is expected in raw agricultural commodities from the intended uses. Therefore, investigation on the magnitude of residues in processed commodities is required.

New processing studies have been submitted by the applicant in the framework of this application. These studies are summarized in the table below. Only processing factors relevant for risk assessment were presented.

The detailed results are presented in Appendix 2.

Table 7.3‑13: Overview of the available processing studies

| Processed commodity | Number of studies | Median PF \*  (Individual values) | Median CF \*\* | Comments | Reference |
| --- | --- | --- | --- | --- | --- |
| Enforcement residue definition: Azoxystrobin | | | | | |
| **EU data - Processing factors recommended (sufficiently supported by data)** | | | | | |
| Barley, brewing malt | 4 | 0.19 | 1 | Processing factor for malt, beer and pot are actually lower than the value reported as residues were below the LOQ in the processed commodities (worst case assumption) | United Kingdom, 2009a |
| Barley, beer | 4 | 0.23 | 1 |
| Barley, pot/pearl | 4 | 0.25 | 1 |
| Barley, bran | 4 | 3.25 | 1 |
| Wheat/rye, whole-meal flour | 4 | 0.68 | 1 | Processing factor for cooked beans is lower than 0.29 as residues were below the LOQ in the processed commodities (worst case assumption) | United Kingdom, 2009a |
| Wheat/rye, whole-meal bread | 4 | 0.51 | 1 |
| Wheat/rye, white flour | 4 | 0.45 | 1 |
| Wheat/rye, bran | 4 | 1.67 | 1 |
| **New data** | | | | | |

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| Barley, beer | 4 | 0.03 | 1 | Residues were below the LOQ in the processed commodities (worst case assumption) | Roussel, C-H., 2011  Report No.: ChR-10-8230 |
| Barley, pot | 4 | 0.14 | 1 | - |
| Wheat, whole-meal flour | 4 | 0.82 | 1 | - | Roussel, C-H., 2011  Report No.: ChR-10-8231 |
| Wheat, whole-meal bread | 4 | 0.56 | 1 | - |
| Wheat, white flour | 4 | 0.26 | 1 | Residues were below the LOQ in the processed commodities (worst case assumption) |
| Wheat, bran | 4 | 2.80 | 1 | - |
| Rapeseed, cake | 1 | 0.86 | 1 | - | Roussel, C-H., 2011  Report No.: ChR-10-8214 |
| Rapeseed, raw oil | 4 | 0.37 | 1 |  |
| Rapeseed, refined oil | 4 | 0.36 | 1 |  |
| Rapeseed, cake | 1 | 0.03 | 1 |  | North, L., 2024  Report No.: S23-100807 |
| Rapeseed, crude oil | 1 | 0.04 | 1 |  |
| Rapeseed, refined oil | 1 | 0.04 | 1 |  |
| Rapeseed, meal | 2 | 0.265  (0.03; 0.5) | 1 |  |
| Rapeseed, extracted oil | 1 | 0.02 | 1 |  |

\* The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

\*\* The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

#### Conclusion on processing studies

According to the available processing studies, azoxystrobin residues tends to be diluted in all relevant processed commodities from barley, wheat and oilseed rape, except for cereals bran in which a concentration of azoxystrobin residues is observed.

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| **zRMS comments:**  Data presented by Applicant in point 7.3.5 have been accepted and are sufficient to support the proposed uses.  Processing studies are normally required if the supervised residue trials reveal that the total residues in commodities exceed the trigger value of 0.1 mg/kg, or if the total Theoretical Maximum Daily Intake (TMDI) is more than 10% of the ADI.  Based on these data requirements, processing studies are required for wheat, barley and oilseed rape.  Summary of processing studies reported in the EU:  United Kingdom, 2009  *“Adequate mass balance and follow-up processing studies are available for determining transfer factors for azoxystrobin residues in processed wheat commodities. These transfer factors can be used in consumer assessments to estimate dietary exposures to azoxystrobin in the following processed wheat commodities: wheat grain into flour, wheat germ, and bread. As a result of the low incurred residues seen in the processing studies the calculated processing factors are unreliable and careful judgement should be exercised if they are used quantitatively.”*  EFSA, 2013  *“Robust processing factors for enforcement and risk assessment were derived for peeled bananas, white wine, must, grape juice, grape pomace (wet and dry), brewing malt, beer, barley pot, barley bran, whole-meal and white flour, bread, wheat bran, fresh beans with pods cooked and canned. The processing factors reported for the other processed commodities should be considered as indicative as a minimum of 3 processing studies is normally required.”*  Four new processing studies for cereals and oilseed rape have been submitted by the Applicant in the framework of this application.  The studies demonstrate that azoxystrobin residues concentrate in cereals bran whereas a reduction is observed in other processed commodities of wheat, barley and oilseed rape.  More details of these studies are provided in Appendix 2.  No additional data are required. |

### Magnitude of residues in representative succeeding crops

#### Field rotational crop studies (KCA 6.6.2)

Summary of field rotational crop studies reported in the EU

Several rotational crop field trials were evaluated in the framework of the peer review (United Kingdom, 2009a, 2009b).

*EFSA Journal 2013;11(12):3497 48*

“Azoxystrobin was applied on wheat, cucumber or lettuce at 2 x 0.896 kg a.s./ha, 7-8 x 0.224 kg a.s./ha and 6 x 0.373 kg a.s./ha respectively. After harvest of these crops, rotational crops (mustard, lettuce, radish, turnip, beetroot and wheat) were sown at one, two or three different plant-back intervals (29 to 60 days following application of the active substance) and magnitude of residues was investigated in the different commodities thereof. Considering that all trials were overdosed, a correction factor was applied to the highest residue found in each commodity. At harvest, azoxystrobin residues were expected to be below the LOQ (0.01 mg/kg) in all mature plant parts except in wheat forage and wheat straw. The highest residues were expected to be 0.05 mg/kg and 0.04 mg/kg, respectively.”

Summary of new study on field rotational crop studies

In addition, new studies for residues in succeeding crops have been submitted by the applicant in the framework of this application. The detailed results are presented in Appendix 2.

Two foliar applications of 260 g azoxystrobin/ha were applied on barley (initial crop) at BBCH 39 and 59. Twenty days after application barley crop was destroyed and the succeeding crops radish, lettuce and barley were planted at three different plant back intervals (PBI) of 30 days, 2 months and 10 months. The succeeding crops were then sampled at normal harvest stage. At all tested PBI, azoxystrobin residues were found to be below the LOQ (0.01 mg/kg) in radish root and leaves, lettuce and barley grain, straw and green material.

Conclusion on rotational crops studies

According to available field rotational crop studies, no azoxystrobin residues above 0.01 mg/kg is expected in succeeding crops when CA3642 is applied according to the proposed GAP. Therefore, further investigation into the magnitude of residues in rotational crops is not required. No mitigation measure is necessary.

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| **zRMS comments:**  Data presented by Applicant in point 7.3.6 have been accepted and are sufficient to support the proposed uses.  EFSA concluded in EFSA Journal 2022;20(1):7051 that *The possible transfer of azoxystrobin residues to crops that are grown in crop rotation has been assessed in the EU pesticides peer review and the MRL review (EFSA, 2010, 2013). In the context of the MRL review, it was concluded that no residues above the LOQ (0.01 mg/kg) are expected in crop parts intended for human consumption and that residues are very low in commodities intended for feed purposes (0.05 mg/kg in wheat forage and 0.04 mg/kg in wheat straw) (EFSA, 2013).*  *Since the maximum annual application rate for the crops under consideration (i.e. 0.5 kg a.s./ha) is lower than the maximum seasonal application rate assessed during the MRL review (i.e. 1 kg a.s./ha), the previous conclusion remains valid, provided that the active substance is applied according to the proposed GAP.*  Additionally new rotational crop studies for radish, lettuce and barley planted at three different plant back intervals (PBI) of 30 days, 2 months and 10 months have been submitted by the Applicant in the framework of this application.  The studies demonstrate that no azoxystrobin residues above 0.01 mg/kg is expected in succeeding crops when CA3642 is applied according to the proposed GAP.  More details of this study are provided in Appendix 2.  No additional data are required. |

### Other / special studies (KCA6.10, 6.10.1)

#### Effect on the residue level in pollen and bee products

Azoxystrobin is currently authorized based on the old data requirements, for which no residue study on honey was required in the DAR 2009. Consequently, the assessment of the present application is based on the same data requirements as for the active substance 2009 re-approval since azoxystrobin is not AIR4 renewed yet. This will avoid any distortion of competition in favour of the previous Art.33 dossiers for which no data on honey was required. Therefore, in the present application, information on honey is considered as informative only.

According to SANTE/11956/2016 rev. 9, rapeseed and some other oilseeds are considered as melliferous crops. As azoxystrobin is proposed to be applied during the flowering stage (BBCH 60-69) and since the active substance is systemic, effects on the residue level in pollen and bee products should be investigated.

The applicant Nufarm has a letter of co-ownership by the Azoxystrobin Task Force which authorizes Nufarm to access to the studies submitted during the AIR4 renewal of azoxystrobin (process currently ongoing).

For the residue studies on bee products, the applicant kindly asks the zRMS to refer to the studies submitted for the AIR4 renewal of azoxystrobin. It should be noted that during the AIR4 renewal process, one study was still ongoing. As the report is now available, the study was summarized in the present dossier.

Summary of residue studies on bee products reported in the EU (AIR4)

*Summary from Azoxystrobin AIR 4 MCA Section 6 CA 6.10.1:*

Bocksch 2008, T011298-06-REG

“Three semi-field trials are available that determine the magnitude of azoxystrobin residues in honey following application of azoxystrobin to oilseed rape (1 x 250 g a.s./ha, BBCH 63; honey sampled at maturity). Residues of azoxystrobin in samples of treated honey ranged from < 0.01 mg/kg to 0.01 mg/kg”.

Lebrun 2019, 349-2018

“A fourth semi-field trial is also available, in which residues of azoxystrobin were determined in nectar following the application of azoxystrobin to oilseed rape at BBCH 60 and BBCH 65 (2 x 250 g a.s./ha). Residues of azoxystrobin in samples of treated nectar ranged from < 0.005 mg/kg to 0.046 mg/kg. In accordance with SANTE/11956/2016 rev. 9, residues in nectar can be used as a surrogate for residues in honey.

Based on the available data, residues of azoxystrobin in honey are not expected to exceed the established MRL.

The available semi-field trials are considered a ‘worst-case’ situation because oilseed rape is a crop with a high melliferous capacity (SANTE/11956/2016 rev. 9).”

“A new study with four semi-field trials is currently being conducted, with 2 applications during flowering made to oilseed rape. This guideline compliant study will be available by December 2022 and will permit a robust assessment of residues of azoxystrobin in honey”.

As the report is now available, the study was included in the present dossier. A summary is presented hereafter and details in Appendix 2.

Summary of new residue study (results not reported in AIR4 MCA S6)

Four residue trials, located in Germany, Austria and Spain were conducted in 2021 with winter oilseed rape as a melliferous source. Azoxystrobin was applied twice, at a nominal application rate of 250 g a.s./ha for each application. The applications were conducted during flowering between BBCH 62-65 and separated by a 5–7-day interval. Honey was sampled and azoxystrobin residues were measured.

Azoxystrobin was found to be below the LOQ (0.01 mg/kg) in honey samples, except for trial S21-01128-01 in which residue was quantified at 0.02 mg/kg at 2 DALA. It should be noted the sampling in this trial occurs earlier (2 DALA) compared to the other trials (12-18 DALA). In all trials, honey was sampled mature at honeycomb-closure (honeybees started to cover the honey storage cells) or water content in honey was ~20 %.

Conclusion

Based on available data, no exceedance of the MRL (0.05\* mg/kg) will occur in honey when CA3642 is applied according to the GAP on oilseed rape.

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| **zRMS comments:**  Data presented by Applicant in point 7.3.7 have been accepted and are sufficient to support the proposed uses.  Additionally new residue study on oilseed rape have been submitted by the Applicant in the framework of this application (Appeltauer, 2022; Report S21-01128, access from Task Force). It should be noted that this study was reviewed and accepted by zRMS-PL in RR, Part B7 for PPP of Orondis Evo in June 2023.  **Appeltauer, 2022; S21-01128**  The study contained five field trials (four were performed successfully) on winter oilseed rape was conducted in northern/southern Europe. Azoxystrobin was applied to winter oilseed rape as A12705B, an SC formulation containing nominally 250 g azoxystrobin per litre. Two applications, (applied at growth stage 62-65 BBCH), separated by a 5-7 day interval were made at a nominal rate of 250 g ai/ha. Mature honey was then collected 2-18 days after last application (DALA).  The ranges of residues of azoxystrobin were <0.01 – 0.02 mg/kg and R230310 were <0.01 mg/kg.  No residues of azoxystrobin and its metabolite R230310 at or above the limit of quantification of 0.01 mg/kg were found in any of the untreated honey samples.  Samples were stored frozen for a maximum period of 76 days from sampling to extraction. The residue data are valid with regard to storage stability.  The residues arising from the proposed uses will not exceed the MRLs established for azoxystrobin for honey of 0.05 mg/kg in Reg. (EU) 2024/1078.  No additional data are required. |

### Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

As an ARfD was not deemed necessary, acute risk assessment is not relevant.

#### Input values for the consumer risk assessment

TMDI calculation was performed using the in-force MRLs (Reg. (EU) 2024/1078) and EFSA PRIMo rev.3.1.

Table 7.3‑14: Input values for the consumer risk assessment

| Commodity | Chronic risk assessment | | Acute risk assessment | |
| --- | --- | --- | --- | --- |
| Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| **Risk assessment residue definition:** Azoxystrobin | | | | |
| Barley, Oat | 1.5 | EU MRL | Not relevant as setting of an ARfD was not necessary. | |
| Wheat, Rye | 0.5 | EU MRL |
| Rapeseed | 0.7 | EU MRL |
| ~~Rapeseed,~~ Poppy, Mustard, Gold of pleasure | 0.5 ~~a~~ | EU MRL |
| Linseed | 0.4 | EU MRL |
| Swine: Muscle/meat | 0.01\* | EU MRL |
| Swine: Fat tissue | 0.05 | EU MRL |
| Swine: Liver | 0.07 | EU MRL |
| Swine: Kidney | 0.07 | EU MRL |
| Bovine, Sheep, Goat, Equine muscle/meat | 0.01\* | EU MRL |
| Bovine, Sheep, Goat, Equine fat | 0.05 | EU MRL |
| Bovine, Sheep, Goat, Equine liver | 0.07 | EU MRL |
| Bovine, Sheep, Goat, Equine kidney | 0.07 | EU MRL |
| Poultry, muscle, fat, liver, kidney | 0.01\* | EU MRL |
| Milk | 0.01\* | EU MRL |
| Eggs | 0.01\* | EU MRL |
| Honey | 0.05\* | EU MRL |
| All other commodities | EU MRLs | EU MRLs (~~Reg. (EU)~~ ~~2022/476~~ ~~Reg. (EU) 2023/129~~ Reg. (EU) 2024/1078) ~~a~~ |

~~aMRLs which are currently in-force are from Reg. (EU) 2022/476. MRLs from Reg. (EU) 2022/1363 are not yet applicable. Please note there is no MRL change for the intended crops.~~ ~~In addition, in “Commission Regulation (EU) 2023/129 of 18 January 2023 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council” the MRLs of azoxystrobin in oilseed rape seeds and guavas were raised to 0.7 mg/kg and 0.2 mg/kg, respectively. No impact on the assessment conclusions is expected.~~

#### Conclusion on consumer risk assessment

Extensive calculation sheets are presented in A 2.2.

Table 7.3‑15: Consumer risk assessment

|  |  |
| --- | --- |
| TMDI (% ADI) according to EFSA PRIMo | ~~83~~82% (based on NL toddler) |
| IEDI (% ADI) according to EFSA PRIMo | Not triggered |
| IESTI (% ARfD) according to EFSA PRIMo\* | Not relevant as setting of an ARfD was not necessary. |

\* include raw and processed commodities if both values are required for PRIMo

\*\* if national model is available

The proposed uses of azoxystrobin in the formulation CA3642 do not represent unacceptable acute and chronic risks for the consumer.

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| **zRMS comment:**  The calculation of the TMDI using EFSA model (PRIMo ver. 3.1) and MRLs according to Reg. (EU) 2024/1078 has been conducted by evaluator and led to a utilisation of the ADI of 82% for the NL toddler diet being the population group with the highest value. For this diet, the highest contributor is oranges with 17% of the ADI. The intended uses will not result in a consumer chronic exposure exceeding the ADI.    The refinement using STMRs is not required as the unrefined risk assessment does not represent unacceptable chronic risk to the consumer.  An acute consumer risk assessment was not deemed necessary.  The proposed uses of azoxystrobin in the product CA3642 (Joust Pro) do not represent unacceptable chronic risk for the consumer.  No further data are required to support the proposed uses. |

## Combined exposure and risk assessment

The product is a mixture of prothioconazole and azoxystrobin. Although no acute reference dose has been allocated to azoxystrobin, acute reference doses were set for the TDMs. Therefore, the risk assessment of combined exposure is relevant.

As first approach, dose-addition of residues of the individual active substances is assumed by making use of the Hazard Index (HI) concept. The Hazard Quotient (HQ) is calculated for all compounds in the PPP that are acutely toxic.

An ARfD has been established for prothioconazole, T, TA, TAA and TLA. An acute consumer risk assessment from combined exposure can be performed using Hazard Index (HI), calculated with the following formula:

HI = Σ HQ

with HQ (Hazard Quotient) = IESTI/ARfD

Results for each use are reported in the table hereafter.

The Hazard Index for the commodities under consideration is <1. Thus, combined exposure to all residues in CA3642 is not expected to present a consumer risk. No further refinement of the assessment is required.

Table 7.4‑1: Hazard Index (HI) for relevant commodities based on IESTI according to EFSA PRIMo Rev.3.1

|  | **CHILDREN - Hazard Quotient (HQ)** | | | | |  | **ADULT - Hazard Quotient (HQ)** | | | | |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Commodity or group of commodities to which the MRLs apply** | **Prothioconazole** | **1,2,4-T** | **TA** | **TAA** | **TLA** | **Hazard Index (HI)** | **Prothioconazole** | **1,2,4-T** | **TA** | **TAA** | **TLA** | **Cumulative risk (HI)** |
| Linseeds | 0.0064 | 0.0000 | 0.0046 | 0.0000 | 0.0000 | **0.0113** | 0.0029 | 0.0000 | 0.0021 | 0.0000 | 0.0000 | **0.0051** |
| Poppy seeds | no acute RA | no acute RA | no acute RA | no acute RA | no acute RA | **0.0000** | 0.0042 | 0.0000 | 0.0030 | 0.0000 | 0.0000 | **0.0074** |
| Rapeseeds/canola seeds | 0.0083 | 0.0000 | 0.0060 | 0.0000 | 0.0000 | **0.0145** | 0.0032 | 0.0000 | 0.0023 | 0.0000 | 0.0000 | **0.0056** |
| Mustard seeds | 0.0061 | 0.0000 | 0.0044 | 0.0000 | 0.0000 | **0.0108** | 0.0042 | 0.0000 | 0.0030 | 0.0000 | 0.0000 | **0.0074** |
| Barley | 0.0337 | 0.0006 | 0.0039 | 0.0005 | 0.0003 | **0.0387** | 0.0290 | 0.0005 | 0.0034 | 0.0004 | 0.0003 | **0.0333** |
| Oat | 0.0067 | 0.0001 | 0.0008 | 0.0001 | 0.0001 | **0.0077** | 0.0038 | 0.0001 | 0.0004 | 0.0001 | 0.0000 | **0.0044** |
| Rye | 0.0379 | 0.0006 | 0.0131 | 0.0014 | 0.0014 | **0.0533** | 0.0291 | 0.0005 | 0.0100 | 0.0011 | 0.0011 | **0.0409** |
| Wheat | 0.0867 | 0.0014 | 0.0299 | 0.0033 | 0.0033 | **0.1217** | 0.0504 | 0.0008 | 0.0174 | 0.0019 | 0.0019 | **0.0708** |
| Swine: Muscle/meat | 0.0121 | 0.0206 | 0.0109 | 0.0005 | 0.0005 | **0.0457** | 0.0048 | 0.0082 | 0.0044 | 0.0002 | 0.0002 | **0.0182** |
| Swine: Fat tissue | 0.0017 | 0.0022 | 0.0008 | 0.0001 | 0.0001 | **0.0052** | 0.0020 | 0.0026 | 0.0009 | 0.0001 | 0.0001 | **0.0063** |
| Swine: Liver | 0.0012 | 0.0021 | 0.0025 | 0.0001 | 0.0001 | **0.0060** | 0.0014 | 0.0024 | 0.0029 | 0.0001 | 0.0001 | **0.0069** |
| Swine: Kidney | 0.0013 | 0.0025 | 0.0011 | 0.0002 | 0.0002 | **0.0055** | 0.0022 | 0.0044 | 0.0020 | 0.0003 | 0.0003 | **0.0095** |
| Bovine: Muscle/meat | 0.0072 | 0.0224 | 0.0149 | 0.0003 | 0.0003 | **0.0457** | 0.0057 | 0.0177 | 0.0118 | 0.0002 | 0.0002 | **0.0361** |
| Bovine: Fat tissue | 0.0021 | 0.0050 | 0.0024 | 0.0002 | 0.0002 | **0.0103** | 0.0010 | 0.0023 | 0.0011 | 0.0001 | 0.0001 | **0.0048** |
| Bovine: Liver | 0.0678 | 0.0290 | 0.0366 | 0.0004 | 0.0004 | **0.1349** | 0.0336 | 0.0144 | 0.0181 | 0.0002 | 0.0002 | **0.0669** |
| Bovine: Kidney | 0.0407 | 0.0128 | 0.0073 | 0.0008 | 0.0008 | **0.0632** | 0.0228 | 0.0072 | 0.0041 | 0.0005 | 0.0005 | **0.0354** |
| Sheep: Muscle/meat | 0.0054 | 0.0179 | 0.0123 | 0.0002 | 0.0002 | **0.0366** | 0.0047 | 0.0156 | 0.0107 | 0.0002 | 0.0002 | **0.0319** |
| Sheep: Liver | no acute RA | no acute RA | no acute RA | no acute RA | no acute RA | **0.0000** | 0.0235 | 0.0109 | 0.0168 | 0.0001 | 0.0001 | **0.0518** |
| Sheep: Kidney | no acute RA | no acute RA | no acute RA | no acute RA | no acute RA | **0.0000** | 0.0011 | 0.0004 | 0.0002 | 0.0000 | 0.0000 | **0.0017** |
| Goat: Muscle/meat | no acute RA | no acute RA | no acute RA | no acute RA | no acute RA | **0.0000** | 0.0016 | 0.0052 | 0.0035 | 0.0001 | 0.0001 | **0.0105** |
| Equine: Muscle/meat | 0.0060 | 0.0186 | 0.0124 | 0.0002 | 0.0002 | **0.0381** | 0.0048 | 0.0149 | 0.0099 | 0.0002 | 0.0002 | **0.0304** |
| Poultry: Muscle/meat | 0.0170 | 0.0068 | 0.0068 | 0.0007 | 0.0007 | **0.0335** | 0.0117 | 0.0047 | 0.0047 | 0.0005 | 0.0005 | **0.0232** |
| Poultry: Fat tissue | 0.0001 | 0.0000 | 0.0000 | 0.0000 | 0.0000 | **0.0002** | 0.0003 | 0.0001 | 0.0001 | 0.0000 | 0.0000 | **0.0006** |
| Poultry: Liver | 0.0011 | 0.0004 | 0.0011 | 0.0001 | 0.0001 | **0.0029** | 0.0047 | 0.0019 | 0.0049 | 0.0002 | 0.0002 | **0.0123** |
| Poultry: Kidney | no acute RA | no acute RA | no acute RA | no acute RA | no acute RA | **0.0000** | 0.0013 | 0.0005 | 0.0003 | 0.0001 | 0.0001 | **0.0023** |
| Milk: Cattle | 0.0621 | 0.4348 | 0.0166 | 0.0050 | 0.0050 | **0.5350** | 0.0193 | 0.1350 | 0.0051 | 0.0015 | 0.0015 | **0.1661** |
| Milk: Sheep | 0.0018 | 0.0132 | 0.0005 | 0.0001 | 0.0001 | **0.0161** | 0.0076 | 0.0559 | 0.0020 | 0.0006 | 0.0006 | **0.0681** |
| Milk: Goat | 0.0121 | 0.0894 | 0.0032 | 0.0010 | 0.0010 | **0.1089** | 0.0092 | 0.0681 | 0.0025 | 0.0007 | 0.0007 | **0.0829** |
| Eggs: Chicken | 0.0124 | 0.0050 | 0.0025 | 0.0005 | 0.0005 | **0.0220** | 0.0043 | 0.0017 | 0.0009 | 0.0002 | 0.0002 | **0.0075** |
| Eggs: Goose | no acute RA | no acute RA | no acute RA | no acute RA | no acute RA | **0.0000** | 0.0005 | 0.0002 | 0.0001 | 0.0000 | 0.0000 | **0.0009** |
| Eggs: Quail | no acute RA | no acute RA | no acute RA | no acute RA | no acute RA | **0.0000** | 0.0014 | 0.0006 | 0.0003 | 0.0001 | 0.0001 | **0.0025** |
| Honey and other apiculture products | 0.0011 | 0.0001 | 0.0004 | 0.0002 | 0.0002 | **0.0020** | 0.0004 | 0.0000 | 0.0002 | 0.0001 | 0.0001 | **0.0008** |

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| **zRMS comment:**  Information presented by Applicant in point 7.4 has been accepted.  The Hazard Index for the commodities under consideration is <1. Thus, combined exposure to all residues in CA3642 (Joust Pro) is not expected to present a consumer risk. No further refinement of the assessment is required. |

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**Triazole Derivate Metabolites**

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EFSA (European Food Safety Authority), 2018. Brancato A, Brocca D, Carrasco Cabrera L, Chiusolo A, Civitella C, Court Marques D, Crivellente F, De Lentdecker C, Erdos Z, Ferreira L, Goumenou M, Greco L, Istace F, Jarrah S, Kardassi D, Leuschner R, Medina P, Mineo D, Miron I, Molnar T, Nave S, Parra Morte JM, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Terron A, Theobald A, Vagenende B and Villamar-Bouza L. Conclusion on the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted. EFSA Journal 2018;16(7):5376, 20 pp. <https://doi.org/10.2903/j.efsa.2018.5376>

**Azoxystrobin**

United Kingdom, 2009a. Draft assessment report on the active substance azoxystrobin prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, May 2009

United Kingdom, 2009b. Final addendum to the draft assessment report on the active substance azoxystrobin prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, compiled by EFSA, December 2009

EFSA (European Food Safety Authority), 2010. Conclusion on the peer review of the pesticide risk assessment of the active substance azoxystrobin. EFSA Journal 2010;8(4):1542, 110 pp. doi:10.2903/j.efsa.2010.1542

EFSA (European Food Safety Authority), 2013. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for azoxystrobin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(12):3497, 97 pp. doi:10.2903/j.efsa.2013.3497

EFSA (European Food Safety Authority), Anastassiadou M, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Stanek A, Theobald A, Vagenende B and Verani A, 2020. Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review and modification of the existing maximum residue levels for azoxystrobin. EFSA Journal 2020;18(8):6231, 42 pp. <https://doi.org/10.2903/j.efsa.2020.6231>

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1. Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner | Previously evaluated |
| --- | --- | --- | --- | --- | --- | --- |
| Prothioconazole and TDMs | | | | | | |
| ~~KCA 6.1~~  ~~Bayer doc. No. M-777951-01-1~~ | ~~Stroech, K.~~ | ~~2021~~ | ~~Study Summaries of prothioconazole studies included in Data Access Agreement with Nufarm of September 27, 2021~~  ~~Bayer AG Crop Science Division~~  ~~Edition Number:~~ [~~M-777951-01-1~~](dart://dart/edition?ed_no=M-258955-02-1)  ~~Date: 2021-10-15~~  ~~GLP/GEP: yes, unpublished~~ | ~~N~~ | ~~Bayer CropScience~~ |  |
| KCA 6.1/01 | Freitag, T. | 2005 | Storage stability of prothioconazole-desthio in/on canola, spinach, sugar beet, tomato, and pea during freezer storage for 24 months  Bayer CropScience,  Report No.: MR-07/282,  Edition Number: [M-258955-02-1](dart://dart/edition?ed_no=M-258955-02-1)  Date: 2005-10-14  …Amended: 2007-06-04  GLP/GEP: yes, unpublished | N | Bayer CropScience | Yes,  in RR, Part B7 for CA3301/ Joust  (01.2023) |
| KCA 6.1/02 | Freitag, Th. | 2011 | Storage stability of prothioconazole-á-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, and prothioconazole-6-hydroxy-desthio in/on tomato fruit, potato tuber, soybean, orange fruit and oil seed rape for 24 months  Bayer CropScience,  Report No.: MR-08/024,  Edition Number: [M-405410-01-1](dart://dart/edition?ed_no=M-405410-01-1)  Date: 2011-04-13  GLP/GEP: yes, unpublished | N | Bayer CropScience | Yes,  in RR, Part B7 for CA3301/ Joust  (01.2023) |
| KCA 6.1/03 | Kalathoor, R. | 2021 | Storage Stability of Prothioconazole and metabolites in different matrices under Deep Frozen Conditions  Eurofins Agroscience Services  Report No: S20-09716  GLP/GEP: yes, unpublished | N | Nufarm Europe | Yes,  in RR, Part B7 for CA3301/ Joust  (01.2023) |
| KCA 6.1/04 | Winter, O. | 2023 | Storage Stability of the Triazole Derivative Metabolites in Oilseed Rape under Deep Frozen Conditions  Eurofins Agroscience Services  Report No: S22-08287 (NUK-2201L)  GLP/GEP: yes, unpublished | N | Nufarm Crop Products UK | No |
| KCA 6.3.1/01 | Schoening, R.; Bauer, J.; Koester, P. | 2011 | Determination of the residues of BYF 00587, HEC 5725 and prothioconazole in/on barley after spray application of bixafen & fluoxastrobin & prothioconazole EC 190 in the field in the Netherlands and Germany  Bayer CropScience,  Report No.: 10-2204,  Edition Number: M-414691-01-1  Date: 2011-09-28  GLP/GEP: yes, unpublished | N | Bayer CropScience  (Nufarm has a letter of access) | Yes,  in RR, Part B7 for CA3301/ Joust  (01.2023) |
| KCA 6.3.1/02 | Bellof, S.; van Berkum, S. | 2014 | Determination of the residues of fluoxastrobin and prothioconazole in/on barley and spring barley after spray application of Fluoxastrobin & Prothioconazole EC 200 in France (North)  Bayer CropScience,  Report No.: 13-2158,  Edition Number: M-501503-01-1  Date: 2014-11-05  GLP/GEP: yes, unpublished | N | Bayer CropScience  (Nufarm has a letter of access) | Yes,  in RR, Part B7 for CA3301/ Joust  (01.2023) |
| KCA 6.3.1/03 | Glaubitz, J. | 2014 | Determination of the residues of fluoxastrobin and prothioconazole in/on spring barley after spray application of fluoxastrobin & prothioconazole EC 200 in Germany  Bayer CropScience,  Report No.: 13-2137,  Edition Number: M-501711-03-1  Date: 2014-11-10  …Amended: 2015-01-30  GLP/GEP: yes, unpublished | N | Bayer CropScience  (Nufarm has a letter of access) | Yes,  in RR, Part B7 for CA3301/ Joust  (01.2023) |
| KCA 6.3.1/04 | Meklat, N.; Kerkering, S.; Effertz, C. | 2018 | Determination of the residues of prothioconazole, spiroxamine and trifloxystrobin in/on barley after spray application of PTZ & SPX & TFS EC 280.3 in the Netherlands, Belgium, southern France and Italy  Bayer  Report No.: 17-2076  Edition Number: M-641462-01-1  Date: 2018-11-28  GLP/GEP: Yes, unpublished | N | Bayer CropScience  (not protected) | Yes,  in RR, Part B7 for CA3301/ Joust  (01.2023) |
| KCA 6.3.2/01 | Meklat, N.; Kerkering, S. | 2019 | Determination of the residues of prothioconazole and spiroxamine in/on wheat after spray application of JAU 6476 & KWG 4168 EC 460 in Germany, northern France and the Netherlands  Bayer CropScience,  Report No.: 17-2015  Edition Number: M-659920-01-1  Date: 24-05-2019  GLP/GEP: yes, unpublished | N | Bayer CropScience  (Nufarm has a letter of access) | Yes,  in RR, Part B7 for CA3301/ Joust  (01.2023) |
| KCA 6.3.2/02 | North, L. | 2020 | Determination of residues of Prothioconazole-desthio (sum of isomers) after two applications of Prothioconazole in Wheat (outdoor) at 4 sites in Northern Europe and 4 sites in Southern Europe 2019  Eurofins Agroscience Services  Report No.: S19-01268  GLP/GEP: Yes, unpublished | N | Nufarm Europe | Yes,  in RR, Part B7 for CA3301/ Joust  (01.2023) |
| KCA 6.3.2/03 | Meklat, N.; Kerkering, S. | 2018 | Determination of the residues of prothioconazole and spiroxamine in/on spring wheat and winter wheat after spray application of JAU 6476 & KWG 4168 EC 460 in the United Kingdom, Germany and the Netherlands  Bayer  Report No.: 16-2046  Edition Number: [M-626175-01-1](dart://dart/edition?ed_no=M-626175-01-1)  Date: 2018-06-06  GLP/GEP: Yes, unpublished | N | Bayer CropScience  (not protected) | Yes,  in RR, Part B7 for CA3301/ Joust  (01.2023) |
| KCA 6.3.3/01 | North, L. | 2021 | Determination of residues of Prothioconazole-desthio (sum of isomers) after two applications of Prothioconazole 250EC in Oilseed rape (outdoor) at 4 sites in Northern Europe and 4 sites in Southern Europe 2019  Eurofins Agroscience Services  Report No.: S19-01269  GLP/GEP: Yes, unpublished | N | Nufarm Europe | Yes,  in RR, Part B7 for CA3301/ Joust  (01.2023) |
| KCA 6.3.3/02 | North, L. | 2021 | Determination of residues of Prothioconazole-desthio (sum of isomers) after two applications of Prothioconazole 250EC in Oilseed rape (outdoor) at 4 sites in Northern Europe and 4 sites in Southern Europe 2020  Eurofins Agroscience Services  Report No.: S20-01046  GLP/GEP: Yes, unpublished | N | Nufarm Europe | Yes,  in RR, Part B7 for CA3301/ Joust  (01.2023) |
| KCA 6.3.3/03 | North, L. | 2021 | Determination of residues of Prothioconazole-desthio (sum of isomers) after two applications of Prothioconazole in Oilseed rape (outdoor) at 1 site in Northern Europe in 2021  Eurofins Agroscience Services  Report No.: S21-00259  GLP/GEP: Yes, unpublished | N | Nufarm Europe | Yes,  in RR, Part B7 for CA3301/ Joust  (01.2023) |
| KCA 6.3.3/06 | North, L. | 2023 | Determination of residues of Prothioconazole-desthio (sum of isomers) after two applications of Prothioconazole in Oilseed rape (outdoor) and its processed fractions at 3 sites in Northern Europe in 2022  Eurofins Agroscience Services  Report No.: S22-00257  GLP: Yes, unpublished | N | Nufarm Crop Products UK | No |
| KCA 6.10/01 | Knoll, M. | 2021 | Determination of Residues of Prothioconazole in Nectar, Pollen and Honey of Winter Oilseed Rape after Two Applications of CA3301 in a Semi-Field Residue Study in Central and Southern Europe in 2021  Eurofins Agroscience Services  Report No.: S21-00428  GLP/GEP: Yes, unpublished | N | Nufarm Europe | Yes,  in RR, Part B7 for CA3301/ Joust  (01.2023) |

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner | Previously evaluated |
| --- | --- | --- | --- | --- | --- | --- |
| Azoxystrobin | | | | | |  |
| KCA 6.3.1/08 | Roussel, C-H. | 2011 | Magnitude Of The Residues Of Azoxystrobin In Summer Barley (RAC Grain And Straw) And Processed Fractions Following Two Applications Of NUL 2206, Poland, 2010  Staphyt  Report No.: ChR-10-8230  GLP/GEP: Yes, unpublished | N | Nufarm SAS | No |
| KCA 6.3.1/09 | Boissinot, J-C. | 2011 | Residues Of Azoxystrobin In Barley (RAC Whole Plant, Grain And Straw) Following Two Applications  Of CA 2702 (NUL 2206), Northern & Southern Europe – 2011  Staphyt  Report No.: JCB-11-10126  GLP/GEP: Yes, unpublished | N | Nufarm SAS | No |
| KCA 6.3.2/04 | Roussel, C-H. | 2011 | Magnitude Of The Residues Of Azoxystrobin In Winter Wheat (RAC Grain And Straw) And Processed Fractions Following Two Applications Of NUL 2206, Poland, 2010  Staphyt  Report No.: ChR-10-8231  GLP/GEP: Yes, unpublished | N | Nufarm SAS | No |
| KCA 6.3.2/05 | Boissinot, J-C. | 2011  (2012 amendment) | Residues Of Azoxystrobin In Wheat (RAC Whole Plant, Grain And Straw) Following Two Applications  Of CA 2702 (NUL 2206), Northern & Southern Europe – 2011  Final report and Amendment 1  Staphyt  Report No.: JCB-11-10125  GLP/GEP: Yes, unpublished | N | Nufarm SAS | No |
| KCA 6.3.3/04 | Boileau, G. | 2011 | Residues Of Azoxystrobin In Oilseed Rape, Following One Application Of CA 2702 (NUL 2206), Northern & Southern Europe – 2011  Final report and Amendment 1  Staphyt  Report No.: GBU-11-10127  GLP/GEP: Yes, unpublished | N | Nufarm SASe | No |
| KCA 6.3.3/05 | Roussel, C-H. | 2011 | Magnitude Of The Residues Of Azoxystrobin In Oilseed Rape (RAC Grain) And Processed Fractions Following One Application Of NUL 2206, Poland, 2010  Staphyt  Report No.: ChR-10-8214  GLP/GEP: Yes, unpublished | N | Nufarm SAS | No |
| KCA 6.3.3/07 | North, L. | 2024 | Determination of residues of Azoxystrobin after a single application of CA2702 in Oilseed rape (outdoor) at 4 sites in Northern Europe 2023  Eurofins Agroscience Services  Report No.: S23-100807  GLP/GEP: Yes, unpublished | N | Nufarm Crop Products UK | No |
| KCA 6.6.2/01 | Roussel, C-H. | 2011 | Magnitude Of The Residues Of Azoxystrobin In Rotational Crops Following Two Applications Of NUL 2206 On Summer Barley, Poland, 2010-2011  Staphyt  Report No.: ChR-10-8233  GLP/GEP: Yes, unpublished | N | Nufarm SAS | No |
| KCA 6.10/02 | Appeltauer, A. | 2022 | Azoxystrobin – Determination of Residues of Azoxystrobin and R230310 (z-isomer) in Honey after Two Applications of A12705B to Winter Oilseed rape at 5 Sites in Northern and Southern Europe in 2021  Eurofins Agroscience services  Report No.: S21-01128  GLP/GEP: Yes, unpublished  *Study included in the AIR4 renewal of azoxystrobin (process currently ongoing)* | N | Syngenta Ltd.  (Nufarm Crop Products UK has a letter of co-ownership) | Yes,  in RR, Part B7 for A22773A/ Orondis Evo  (06.2023) |

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
| Prothioconazole and TDMs | | | | | |
| KCA 6.1 | Heinemann, O. | 2001 | 18 months storage stability of residues of JAU 6476 and JAU 6476-Desthio during frozen storage in/on wheat matrices  Bayer AG, Leverkusen, Germany  Bayer CropScience,  Report No.: MR-282/00,  Edition Number: M-072461-01-1  Date: 2001-09-13  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 6.2.1 | Haas, M.; Bornatsch, W. | 2000 | Metabolism of JAU6476 in spring wheat (after foliar application)  Bayer AG, Leverkusen, Germany  Bayer CropScience,  Report No.: MR-198/99,  Edition Number: [M-041657-01-1](dart://dart/edition?ed_no=M-041657-01-1)  EPA MRID No.: 46246141  Date: 2000-07-10  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 6.2.1 | Vogeler, K.; Sakamoto, H.; Brauner, A. | 1993 | Metabolism of SXX 0665 in summer wheat  Bayer AG, Leverkusen, Germany  Bayer CropScience,  Report No.: PF3906,  Edition Number: [M-008633-01-1](dart://dart/edition?ed_no=M-008633-01-1)  Date: 1993-08-13  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 6.2.1 | Duah, F. K.; Lopez, R. T. | 2004 | The metabolism of [triazole-3,5-14 C] JAU 6476 in wheat  Bayer CropScience LP, Stilwell, KS, USA  Bayer CropScience,  Report No.: 200733,  Edition Number: [M-001524-01-1](dart://dart/edition?ed_no=M-001524-01-1)  EPA MRID No.: 46246143  Date: 2004-03-12  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 6.2.1 | Haas, M. | 2001 | Metabolism of JAU 6476 in spring wheat after seed dressing  Bayer AG, Leverkusen, Germany  Bayer CropScience,  Report No.: 110881,  Edition Number: [M-030412-01-3](dart://dart/edition?ed_no=M-030412-01-3)  EPA MRID No.: 46246142  Date: 2001-05-10  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 6.2.1 /05 | Haas, M. | 2001 | Metabolism of [phenyl-UL-14C]JAU6476 in peanuts  Bayer AG, Leverkusen, Germany  Bayer CropScience,  Report No.: MR-193/01,  Edition Number: [M-033059-01-2](dart://dart/edition?ed_no=M-033059-01-2)  EPA MRID No.: 46246145  Date: 2001-11-27  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 6.2.1 /06 | Haas, M. | 2003 | Metabolism of [triazole-UL-14C]JAU6476 in peanuts  Bayer CropScience,  Report No.: MR-194/02,  Edition Number: [M-103268-01-2](dart://dart/edition?ed_no=M-103268-01-2)  EPA MRID No.: 46246146  Date: 2003-12-01  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 6.6.1 | Haas, M. | 2001 | Confined rotational crop study with JAU6476  Bayer AG, Leverkusen, Germany  Bayer CropScience,  Report No.: MR-159/00,  Edition Number: [M-049955-01-1](dart://dart/edition?ed_no=M-049955-01-1)  EPA MRID No.: 46246225  Date: 2001-05-14  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 6.6.1 | Duah, F. K.; Kraai, M. J. | 2004 | The accumulation of [triazole-3,5-14C] JAU6476 in confined rotational crops  Bayer CropScience LP, Stilwell, KS, USA  Bayer CropScience,  Report No.: 200623,  Edition Number: [M-000784-01-1](dart://dart/edition?ed_no=M-000784-01-1)  EPA MRID No.: 46246226  Date: 2004-03-05  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 6.2.2 | XXXXXXXXXXX | 2001 | [Phenyl-UL-14C]JAU6476 – Absorption, distribution, excretion and metabolism in laying hens  xxxxx  Report No.: MR-309/01,  Date: 2001-10-29  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 6.2.2 | XXXXXXXXXXX | 2003 | [Triazole-UL-14C]JAU6476: Absorption, distribution, excretion, and metabolism in laying hens  xxxxx  Report No.: MEF-005/03,  Date: 2003-06-23  …Amended: 2003-07-14  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 6.2.3 | XXXXXXXXXXX | 2001 | [Phenyl-UL-14C]JAU6476 – Absorption, distribution, excretion and metabolism in the lactating goat  xxxxx  Report No.: MR-092/01,  … amended: 2018-08-15  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 6.2.3 | XXXXXXXXXXX | 2002 | [Phenyl-UL-14C]JAU6476-desthio – Absorption, distribution, excretion, and metabolism in the lactating goat  xxxxx  Report No.: MR-091/01,  Date: 2002-02-28  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 6.2.3 | XXXXXXXXXXX | 2003 | [Triazole-UL-14C]JAU 6476: Absorption, distribution, excretion, and metabolism in the lactating goat  xxxxx  Report No.: MR-448/02,  Date: 2003-10-20  …Amended: 2005-06-06  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 6.2.3 | XXXXXXXXXXX | 2006 | [Phenyl-UL-14C]JAU 6476-desthio: Absorption, distribution, excretion and metabolism in the lactating goat – Subsequent identification of metabolite hydrolysis products  xxxxx  Report No.: MEF-06/469,  Date: 2006-10-10  GLP/GEP: no, unpublished | Y | Bayer CropScience |
| KCA 6.3.1 /01 | Heinemann, O. | 2001 | Determination of residues of JAU 6476-Desthio on spring wheat following seed treatment of JAU 6476 200 FS in Great Britain, Germany and France  Bayer AG, Leverkusen, Germany  Bayer CropScience,  Report No.: RA-2010/99,  Edition Number: [M-073513-01-1](dart://dart/edition?ed_no=M-073513-01-1)  Date: 2001-09-18  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 6.3.1 /02 | Heinemann, O. | 2001 | Determination of residues of JAU 6476-desthio on spring wheat following seed treatment of JAU 6476 200 FS in Germany and France  Bayer AG, Leverkusen, Germany  Bayer CropScience,  Report No.: RA-2091/00,  Edition Number: [M-075017-01-1](dart://dart/edition?ed_no=M-075017-01-1)  Date: 2001-09-28  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 6.3.1 /04 | Heinemann, O. | 2001 | Determination of residues of JAU 6476-desthio on spring wheat and winter wheat following seed treatment of JAU 6476 200 FS and spray application of JAU 6476 250 EC in Germany, Northern France, and Great Britain  Bayer AG, Leverkusen, Germany  Bayer CropScience,  Report No.: RA-2003/99,  Edition Number: [M-075134-01-1](dart://dart/edition?ed_no=M-075134-01-1)  Date: 2001-10-04  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 6.3.1 /05 | Heinemann, O. | 2001 | Determination of residues of JAU 6476-desthio on spring wheat after spray application of JAU 6476 250 EC in Sweden, Germany, Northern France and Great Britain  Bayer AG, Leverkusen, Germany  Bayer CropScience,  Report No.: RA-2104/00,  Edition Number: [M-088723-01-1](dart://dart/edition?ed_no=M-088723-01-1)  Date: 2001-11-29  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 6.3.2 /01 | Heinemann, O. | 2001 | Determination of residues of JAU 6476-desthio on spring barley following seed treatment of JAU 6476 200 FS and spray application of JAU 6476 250 EC in Germany  Bayer AG, Leverkusen, Germany  Bayer CropScience,  Report No.: RA-2150/98,  Edition Number: [M-073128-02-1](dart://dart/edition?ed_no=M-073128-02-1)  Date: 2001-09-18  …Amended: 2001-09-24  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 6.3.2 /02 | Heinemann, O.; Elke, K. | 2001 | Determination of residues of JAU 6476-desthio on spring barley following seed treatment of JAU 6476 200 FS and spray application of JAU 6476 250 EC in Germany, France and Great Britain  Bayer AG, Leverkusen, Germany  Bayer CropScience,  Report No.: RA-2140/98,  Edition Number: [M-072786-02-1](dart://dart/edition?ed_no=M-072786-02-1)  Date: 2001-09-17  …Amended: 2001-09-24  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 6.3.2 /03 | Heinemann, O. | 2001 | Determination of residues of JAU 6476-desthio on spring barley after spray application of JAU 6476 250 EC in Sweden, Germany, Northern France and Great Britain  Bayer AG, Leverkusen, Germany  Bayer CropScience,  Report No.: RA-2101/00,  Edition Number: [M-086237-01-1](dart://dart/edition?ed_no=M-086237-01-1)  Date: 2001-11-21  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 6.3.3 /01 | Heinemann, O. | 2002 | Determination of residues of JAU 6476-desthio on rape after spray application of JAU 6476 250 EC in Germany, Sweden, Northern France and Great Britain  Bayer AG, Leverkusen, Germany  Bayer CropScience,  Report No.: RA-2088/00,  Edition Number: [M-091148-01-1](dart://dart/edition?ed_no=M-091148-01-1)  Date: 2002-01-14  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 6.3.3 /03 | Heinemann, O. | 2002 | Determination of residues of JAU 6476-desthio on rape spray application of JAU 6476 250 EC in Germany, Northern France and Great Britain  Bayer AG, Leverkusen, Germany  Bayer CropScience,  Report No.: RA-2178/01,  Edition Number: [M-035525-01-1](dart://dart/edition?ed_no=M-035525-01-1)  Date: 2002-02-08  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 6.4.2 | XXXXXXXX | 2001 | JAU 6476-desthio – Dairy cattle feeding study  xxxxx  Report No.: MR-535/00,  Date: 2001-10-15  GLP/GEP: yes, unpublished | Y | Bayer CropScience |

| Data point | Author(s) | | Year | | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Azoxystrobin | | | | | | | |
| IIA 6.1 (in DAR) | Allin, R. et al. | 1995 | | ICIA5504: Metabolism in Winter Wheat  RJ1888B RIP96-00104 | | N | Syngenta |
| IIA 6.1 (in DAR) | Earl, V.L. and Hadfield, S.T. | 1994 | | ICI5504: Metabolism in Vines  RJ1676B RIP96-00105 | | N | Syngenta |
| IIA 6.1 (in DAR) | Webb, J. et al. | 1995 | | ICIA5504: Metabolism in Peanuts RJ1807B RIP96-00106 | | N | Syngenta |
| IIA 6.1 (in DAR) | Wilkinson, M.J. et al. | 1994 | | ICIA5504: Metabolism in Winter Wheat  RJ1682B RIP96-00103 | | N | Syngenta |
| IIA 6.1 | Gill J. P. and Burke S. R. | 2002 (minor report amendment issued 2005) | | Azoxystrobin – Stability in Crops and Processed Commodities During Frozen Storage (Final Report) Report No. RJ3170B Document No. VV-340151 | | N | Syngenta |
| IIA 6.1 | Burke S. R. | 1996 | | Azoxystrobin and R230310: Storage Stability in Various Processed Crops Stored Deep Frozen for up to One Year. Final Report. Report No. RJ2221B Document No. VV-377264 | | N | Syngenta |
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| IIA 6.1.2 | Burke, S.R. | 1997 | | Azoxystrobin and R230310: storage stability in various crops stored deep frozen for up to two years. Final report. ZENECA Agrochemicals Report RJ2404B | | N | Syngenta |
| IIA 6.1.2 | Sapiets, A. | 1997 | | Azoxystrobin: Storage stability of residues in eggs and tissues Study 95JH229 ZENECA Agrochemicals Report Series RJ2352B | | N | Syngenta |
| IIA 6.1.2 | Hurt, A. and Campbell, A.J. | 1999 | | Residue analytical method for the analysis of azoxystrobin, R230310, R234886, R401553 and R402173 in water RAM 292/02 | | N | Syngenta |
| IIA 6.1.2 | Burke, S.R. | 1995 | | ICIA5504 and R230310: Validation of a Method for the Determination of Residues in Peanuts and Pecans Jealott’s Hill Research Station, UK RAM 260/01 Syngenta Unpublished Report RJ1787B Syngenta File No. ICI5504/0261 | | N | Syngenta |
| IIA 6.1.2 (in DAR) | xxxxx | 1994 | | The metabolism of 14C-Pyrimidinyl labelled ICIA5504 in the laying hen. ISN331/942668 RIP96-00110 | | Y | Syngenta |
| IIA 6.1.2 (in DAR) | xxxxx | 1995a | | The metabolism of 14C-Phenyl acrylate labelled ICIA5504 in the laying hen ISN333/950182 RIP96-00111 | | Y | Syngenta |
| IIA 6.1.2 (in DAR) | xxxxx | 1995 | | The metabolism of 14C-Cyanophenyl labelled ICIA5504 in the laying hen. ISN332/950918 RIP96-00109 | | Y | Syngenta |
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| IIA 6.2 (in DAR) | xxxxx | 1995 | | Further Investigation of Residues in Liver Following Oral Administration of Multiple Doses to the Lactating Goat RJ1957B RIP96-00108 | | Y | Syngenta |
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| IIA 6.2.2/02 | xxxxx | 1996 | | ICIA5504: Metabolism of Orally Administered Multiple Doses in the Lactating Goat. Report Number: RJ2083B Study dates: April 1993- January 1996 Syngenta File No. ICI5504/0739. | | Y | Syngenta |
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| IIA 6.5 | Sapiets, A. and Charnier, 0. | 1997 | | ICIA5504: Residue Levels in Malting Barley and Process Fractions from Studies Conducted in Germany during 1996 GLP Unpublished RJ2382B | | N | Syngenta |
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| IIA 6.5 | Jones, R.N. and Lake, A. | 2000 | | Azoxystrobin: Dissipation in an Outdoor Experimental Pond Zeneca Agrochemicals, UK Syngenta Unpublished Report RJ3062B  Syngenta File No. ICI5504/0831 | | N | Syngenta |
| IIA 6.5 | Sapiets, A., Chamier, 0. And Dittrich, R. | 1996 | | Processing study: milling/baking of wheat RJ2065B ICI5504/0718 | | N | Syngenta |
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| IIA 6.5 | Evans, P. | 2009 | | Response to PSD e-mail’s of 9 and 20 January 2009 requesting Syngenta’s clarification & comment on a number of points arising during the Dietary Safety assessment of the dossier | | N | Syngenta |
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| IIA 6.5.1/01 | Grout S. J. | 2002 | | 14C-Phenyl acryl ate Azoxystrobin: Aqueous hydrolysis at 90, 100 & 120°C. Report Number: RJ3296B Syngenta, UK. Syngenta File No. 1C15504/1393 | | N | Syngenta |
| IIA 6.5.3/01 | Gill, J.P. et al. | 2000 | | Azoxystrobin: Residue Levels in Beans (with Pods) and Processed Beans from Trials carried out in Italy during 1999 Report No. RJ2964B Zeneca, Jealott’s Hill International Research Centre Syngenta File No. ICI5504/0417 | | N | Syngenta |
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| IIA 6.6 | Grant, C. L. Et al. | 1996 | | ICI5504: Residue Levels on Rotated Crops from Trials Carried Out in The United States during 1995 RR 96-034B Syngenta File No. ICI5504/0732 | | N | Syngenta |
| IIA 6.6 | Roper, E. M | 1996 | | ICI5504: Residue Levels on Rotated Crops from Trials Carried Out in The United States during 1995-1996 RR 96-092B Syngenta File No. ICI5504/0733 | | N | Syngenta |
| IIA 6.6 | Ediger, K | 2002 | | Azoxystrobin – Magnitude of the Residues in Rotational Crops 492-01 Syngenta File No. ICI5504/1966 | | N | Syngenta |
| IIA 6.7 | xxxxx | 1995 | | R230310 – Acute Oral Toxicity to the Mouse Syngenta Unpublished Report  Syngenta File No, ICI5504/0234) | | Y | Syngenta |
| IIA 6.7 | xxxxx | 1995 | | R230310 – An Evaluation of Mutagenic Potential using *S.typhimuri* um and *E.coli*. xxxxx Syngenta Unpublished Report CTL/P/4711 Syngenta File No. ICI5504/0235 | | Y | Syngenta |
| IIA 6.7 | Saunders, J. | 1997 | | ICIA5504 (Azoxystrobin) Metabolites: Bioefficacy Data. Zeneca Agrochemicals UK.  Syngenta Unpublished Report TMJ3931B  Syngenta File No. ICI5504\_11353 | | N | Syngenta |
| IIA 6.7 | Wollerton, C. | 1997 | | Physical and Chemical Properties of Azoxystrobin (Storage Stability)  Zeneca Agrochemicals UK.  Syngenta Unpublished Report MAS 34  Syngenta File No. ICI5504/0038 | | N | Syngenta |

List of data submitted by the applicant and not relied on

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
| - | - | - | - | - | - |

List of data relied on and not submitted by the applicant but necessary for evaluation

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
| - | - | - | - | - | - |

1. Detailed evaluation of the additional studies relied upon
   1. Prothioconazole
      1. Stability of residues
         1. Stability of residues during storage of samples
            1. Storage stability of residues in plant products

Study 1 MR-07/282)

|  |  |
| --- | --- |
| Comments of zRMS: | It should be noted that the study of Freitag (MR-07/282) is currently under review in the EU approval renewal process for prothioconazole.  The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for CA3301/ Joust (January 2023). This study has not been reassessed in the framework of this application.  The conclusions of the assessment are presented below:  *The analysis results indicate that prothioconazole-desthio is stable under frozen storage at -18 °C or below for at least 734 days (approx 24 months) in canola (seed, pod, straw), spinach (leaves), sugar beet (root, leaf with root collar), tomato (fruit), and field pea (field pea dried). Mean procedural recoveries were in the range of 85 - 106% for all matrices.*  *It is noted that samples were fortified at 50x rather than 10x the LOQ as outlined in OECD 506. Nevertheless, this is considered to fulfil the aim of avoiding highly variable recoveries that would prevent the determination of the stability of the residues.*  *The study is acceptable.* |

|  |  |
| --- | --- |
| Reference: | KCA 6.1/01 |
| Report | Storage stability of prothioconazole-desthio in/on canola, spinach, sugar beet, tomato, and pea during freezer storage for 24 months  Freitag, T., 04.06.2007  Report No: M-258955-02-1  Reference No: MR-07/282 |
| Guideline(s): | Not specified |
| Deviations: | None |
| GLP: | Yes |
| Owner: | Bayer CropScience AG (Nufarm has a letter of access) |
| Acceptability: | Yes |

The following study is currently under review in the EU approval renewal process for prothioconazole.

Materials and methods

A deep-freezer storage stability study was conducted with prothioconazole-desthio in/on canola (seed, pod, straw), spinach (leaves), sugar beet (body, leaf with root collar), tomato (fruit), and field pea (field pea dried). Individual aliquots of the homogenised sample materials were fortified with 0.50 mg/kg of prothioconazole-desthio which corresponds to the 50-fold limit of quantitation of the residue analytical method. The fortified samples were stored in a freezer at about minus 18°C or below for up to ca. 24 months. Control samples that had not been fortified with prothioconazole-desthio were stored under the same conditions to allow procedural recovery determination from freshly fortified samples.

Samples were analysed after nominal storage periods of 0, 2, 4, 6, 12, and 24 months.

Three stored fortified samples (except for the day 0 samples where five samples have been spiked with prothioconazole-desthio), one stored control sample, and two stored control sample freshly fortified with prothioconazole-desthio at the same level as the stored fortified samples, were analysed for each matrix at each of the investigated storage periods. In addition, the analytical method was validated prior to analysis by running a set of two recoveries at the limit of quantitation (0.01 mg/kg).

Residues of prothioconazole-desthio were determined according to method 00647/E001 by HPLC-MS/MS in the multiple-reaction-monitoring mode (MRM) using an electrospray interface (ESI) after extraction, filtration, and dilution.

Results and discussions

The analytical method was validated prior to analysis by running a set of recoveries at the limit of quantitation (0.01 mg/kg). In addition, during analysis of the stored samples concurrent recoveries were determined at 0.50 mg/kg. Both validation and concurrent recovery experiments shown in **Błąd! Nie można odnaleźć źródła odwołania.** were performed by spiking two control samples with prothioconazole-desthio at each storage period.

In the case of recovery experiments for method validation, recoveries at the respective LOQ were performed at 0.01 mg/kg. The recovery rates for prothioconazole-desthio were in the range of 84 to 111%. For concurrent recoveries, control samples were fortified at 0.50 mg/kg. The recovery rates for prothioconazole-desthio were in the range of 84 to 107%. This demonstrates the accuracy of the analytical determination.

**Błąd! Nie można odnaleźć źródła odwołania.** summarises the amount of prothioconazole-desthio recovered in the stored samples after the various storage intervals. The values presented in these tables were neither corrected for the concurrent recoveries at the respective intervals nor for the recoveries at day 0, since the mean concurrent recoveries are in general within a range of 70% and 110%.

This storage stability study revealed that residues of prothioconazole-desthio were stable for a deep-freezer period of 24 months, in/on canola (seed, pod, straw), spinach (leaves), sugar beet (body, leaf with root collar), tomato (fruit), and field pea (field pea dried). Mean recovery rates for prothioconazole-desthio were between 94 and 107% (normalised to day 0).

Conclusion

The results of the study demonstrate the stability of prothioconazole-desthio residues upon deep frozen storage for up to 24 months in/on canola (seed, pod, straw), spinach (leaves), sugar beet (body, leaf with root collar), tomato (fruit), and field pea (field pea dried).

Table A 1: Method Validation Data (Fortification levels: 0.01 mg/kg for method validation and 0.50 mg/kg for concurrent recoveries)

| **Sample material** | **Storage interval (days)** | **Mean of recovery rates from two freshly fortified samples (%)** | |
| --- | --- | --- | --- |
| **Method Validation** | **Concurrent Recoveries** |
| Canola (Seed) | 0  64  128  174  336  735 | 98  --  --  88  92  90 | 90  88  88  86  89  85 |
| Canola (Pod) | 0  64  128  174  336  735 | 107  --  --  109  98  102 | 100  102  100  99  102  99 |
| Canola (Straw) | 0  64  128  174  336  735 | 96  --  --  99  102  101 | 98  100  100  98  98  97 |
| Spinach (Leaves) | 0  64  128  174  336  735 | 100  --  --  101  104  100 | 105  102  98  98  104  98 |
| Sugar Beet (body) | 0  63  127  173  336  734 | 101  --  --  98  96  102 | 95  96  98  97  98  96 |
| Sugar Beet (leaf with root collar) | 0  63  127  173  336  734 | 95  --  --  98  104  102 | 93  97  95  101  101  96 |
| Tomato (fruit) | 0  63  127  173  336  734 | 99  --  --  103  101  105 | 101  102  99  106  100  99 |
| Field pea (dried) | 0  63  127  173  336  734 | 106  --  --  94  102  97 | 95  90  92  94  100  90 |

Table A 2: Storage stability of prothioconazole-desthio in/on various crops for up to 24 months (Fortification levels: 0.50 mg/kg)

| **Commodity** | **Storage period (days/**  **months)\*** | **Residue Level in**  **Freezer Storage**  **Stability Sample**  **(mg/kg)** | **Mean\* (mg/kg)** | **Residue Level in**  **Freezer Storage**  **Stability Sample (%**  **of nominal spiking**  **level) (range plus**  **mean)** | **Residue Level in**  **Freezer Storage**  **Stability Sample (% of day 0)** | **Procedural**  **Recovery for**  **Freshly Spiked**  **Control Sample**  **(%)**  **Mean values in brackets** |
| --- | --- | --- | --- | --- | --- | --- |
| Canola Seed | 0 | 0.464, 0.402, 0.434, 0.445, 0.421 | 0.433 | 80-93 (87) | 100 | 88, 91 (90) |
| 64/2 | 0.436, 0.460, 0.446 | 0.447 | 87-92 (89) | 103 | 86, 89 (88) |
| 128/4 | 0.449, 0.463, 0.450 | 0.454 | 90-93 (91) | 105 | 89, 87 (88) |
| 174/6 | 0.419, 0.433, 0.423 | 0.425 | 84- 87 (85) | 98 | 87, 85 (86) |
| 336/11 | 0.456, 0.442, 0.468 | 0.455 | 88-94 (91) | 105 | 86, 91 (89) |
| 735/24 | 0.422, 0.428, 0.421 | 0.424 | 84-86 (85) | 98 | 84, 86 (85) |
| Canola (Pod) | 0 | 0.502, 0.478, 0.496, 0.495, 0.476 | 0.489 | 95-100 (98) | 100 | 99, 100 (100) |
| 64/2 | 0.506, 0.504, 0.503 | 0.504 | 101-101 (101) | 103 | 101, 103 (102) |
| 128/4 | 0.545, 0.516, 0.504 | 0.522 | 101-109 (104) | 107 | 100, 100 (100) |
| 174/6 | 0.490, 0.489, 0.499 | 0.493 | 98-100 (99) | 101 | 96, 101 (99) |
| 336/11 | 0.498, 0.497, 0.500 | 0.498 | 99-100 (100) | 102 | 104, 100 (102) |
| 735/24 | 0.484, 0.489, 0.484 | 0.486 | 97-98 (97) | 99 | 99, 99 (99) |
| Canola (Straw) | 0 | 0.520, 0.507, 0.511, 0.489, 0.507 | 0.507 | 98-104 (101) | 100 | 96, 100 (98) |
| 64/2 | 0.490, 0.488, 0.468 | 0.482 | 94-98 (96) | 95 | 103, 96 (100) |
| 128/4 | 0.501, 0.511, 0.525 | 0.512 | 100-105 (102) | 101 | 98, 101 (100) |
| 174/6 | 0.485, 0.480, 0.474 | 0.480 | 95-97(96) | 95 | 104, 92 (98) |
| 336/11 | 0.496, 0.495, 0.489 | 0.493 | 98-99 (99) | 97 | 100, 95 (98) |
| 735/24 | 0.493, 0.481, 0.491 | 0.488 | 96-99 (98) | 96 | 97, 96 (97) |
| Spinach (Leaves) | 0 | 0.520, 0.506, 0.539, 0.505, 0.504 | 0.515 | 101-108 (103) | 100 | 104, 105 (105) |
| 64/2 | 0.500, 0.489, 0.506 | 0.498 | 98-101 (100) | 97 | 102, 102 (102) |
| 128/4 | 0.495, 0.490, 0.506 | 0.497 | 98-101 (99) | 97 | 98, 98 (98) |
| 174/6 | 0.507, 0.501, 0.490 | 0.499 | 98-101 (100) | 97 | 97, 99 (98) |
| 336/11 | 0.501, 0.522, 0.515 | 0.513 | 100-104 (103) | 100 | 103, 104 (104) |
| 735/24 | 0.486, 0.486, 0.482 | 0.485 | 96-97(97) | 94 | 98, 97 (98) |
| Sugar beet (Body) | 0 | 0.470, 0.463, 0.473, 0.486, 0.491 | 0.477 | 93-98 (95) | 100 | 93, 97 (95) |
| 64/2 | 0.484, 0.489, 0.487 | 0.487 | 97-98(97) | 102 | 95, 97 (96) |
| 128/4 | 0.491, 0.487, 0.485 | 0.488 | 97-98 (98) | 102 | 97, 98 (97) |
| 174/6 | 0.484, 0.484, 0.498 | 0.489 | 97-100 (98) | 103 | 96, 98 (97) |
| 336/11 | 0.496, 0.505, 0.500 | 0.500 | 99-101 (100) | 105 | 98, 98 (98) |
| 735/24 | 0.481, 0.476, 0.473 | 0.477 | 95-96 (95) | 100 | 96, 96 (96) |
| Sugar Beet (Leaf with Root Collar) | 0 | 0.480, 0.493, 0.456, 0.473, 0.466 | 0.474 | 91-99 (95) | 100 | 94, 91 (93) |
| 64/2 | 0.497, 0.471, 0.479 | 0.482 | 94-96 (96) | 102 | 98, 96 (97) |
| 128/4 | 0.460, 0.468, 0.506 | 0.478 | 92-101 (96) | 101 | 94, 95 (95) |
| 174/6 | 0.482, 0.469, 0.457 | 0.469 | 91-96 (94) | 99 | 100, 101 (101) |
| 336/11 | 0.480, 0.488, 0.496 | 0.488 | 96-99 (98) | 103 | 101, 101 (101) |
| 735/24 | 0.473, 0.461, 0.456 | 0.463 | 91-95 (93) | 98 | 96, 96 (96) |
| Tomato (Fruit) | 0 | 0.510, 0.500, 0.507, 0.511, 0.501 | 0.506 | 100-102 (101) | 100 | 100, 101 (101) |
| 64/2 | 0.503, 0.489, 0.497 | 0.496 | 98-101 (99) | 98 | 101, 102 (102) |
| 128/4 | 0.514, 0.526, 0.522 | 0.521 | 103-105 (104) | 103 | 97, 100 (99) |
| 174/6 | 0.498, 0.496, 0.521 | 0.505 | 99- 104 (101) | 100 | 107, 105 (106) |
| 336/11 | 0.505, 0.513, 0.521 | 0.513 | 101-104 (103) | 101 | 99, 100 (100) |
| 735/24 | 0.494, 0.476, 0.490 | 0.487 | 95-99 (97) | 96 | 99, 98 (99) |
| Pea (Pea Dried) | 0 | 0.484, 0.469, 0.461, 0.474, 0.473 | 0.472 | 92-97 (94) | 100 | 96, 93 (95) |
| 64/2 | 0.463, 0.434, 0.444 | 0.447 | 87-93 (89) | 95 | 90, 90 (90) |
| 128/4 | 0.455, 0.474, 0.442 | 0.457 | 88-95 (91) | 97 | 93, 91 (92) |
| 174/6 | 0.458, 0.440, 0.455 | 0.451 | 88-92 (90) | 96 | 95, 92 (94) |
| 336/11 | 0.512, 0.507, 0.496 | 0.505 | 99-102 (101) | 107 | 100, 99 (100) |
| 735/24 | 0.464, 0.457, 0.474 | 0.465 | 91-95 (93) | 98 | 86, 94 (90) |

\* Mean from three analysed samples (except at day 0 where five samples have been spiked)

Study 2 MR-08/024)

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| Comments of zRMS: | It should be noted that the study of Freitag (MR-08/284) is currently under review in the EU approval renewal process for prothioconazole.  The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for CA3301/ Joust (January 2023). This study has not been reassessed in the framework of this application.  The conclusions of the assessment are presented below:  *The data suggests that prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, and prothioconazole-6-hydroxy-desthio are stable under frozen storage at -18 °C or below for at least 759 days (approx 25 months) in tomato fruit, potato tuber, soybean, orange fruit and oil seed rape.*  *Mean recovery rates at nominal 24 month storage intervals for all analytes were between 71 - 103%.*  *The study is acceptable.* |

|  |  |
| --- | --- |
| Reference: | KCA 6.1/02 |
| Report | Storage stability of prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, and prothioconazole-6-hydroxy-desthio in/on tomato fruit, potato tuber, soybean, orange fruit and oil seed rape for 24 months  Freitag, T., 13.04.2011  Report No: M-405410-01-1  Reference No: MR-08/024 |
| Guideline(s): | Not specified |
| Deviations: | None |
| GLP: | Yes |
| Owner: | Bayer CropScience AG (Nufarm has a letter of access) |
| Acceptability: | Yes |

The following study is currently under review in the EU approval renewal process for prothioconazole.

Materials and methods

Report MR-08/024 describes the stability of residues of the metabolites prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, and prothioconazole-6-hydroxy-desthio in fortified control samples of plant origin (tomato fruit, potato tuber, soybean, orange fruit and oil seed rape) during freezer storage for 24 months. The samples were fortified with a mixture containing all the analytes at a level of 0.10 mg/kg each (each expressed as parent equivalent).

The samples were stored in amber glass bottles at – 18 °C or below and were analysed at nominal intervals of 0, 30, 60, 90, 180, 360, 540 and 720 days.

5 g aliquots of the homogenised control materials were weighed into the bottles. These samples were fortified, resulting in levels of 0.10 mg/kg in all matrices. After fortification, the solvent was allowed to evaporate for about 15 - 30 min. In addition, untreated samples of each sample material were prepared for control and recovery experiments. Subsequently, the bottles were closed and deep-frozen until analysis. Samples were analysed in the 24 hours following their extraction.

Residues of the hydroxy metabolites of prothioconazole-desthio were determined by LC/MS/MS according to method 00979/M001.

Results and discussions

The analytical method was validated prior to analysis by running a set of recoveries for method validation. In addition, during analysis of the stored samples concurrent recoveries were determined.

At each storage interval, the samples for the determination of the method performance (concurrent recoveries and method validation) were extracted and analysed concurrently with the control sample and the spiked stored samples.

In the control samples (at each sampling event at least one control sample per matrix was analysed), the residues of each analyte were always below 30% of the LOQ.

Overall recoveries for method validation as well as overall concurrent recoveries were within the acceptable range of 70-110%. Overall RSDs were below 20%.

Recoveries for Method Validation:

To demonstrate the accuracy of prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, and prothioconazole-6-hydroxy-desthio determination during this study, a set of two recovery experiments were performed for each plant matrix at the nominal storage intervals of 0, 30 (except tomato and soybean), 180, 360, 540 and 720 days. For this purpose, control samples were freshly fortified with a mixture containing all analytes at 0.01 mg/kg each (expressed as prothioconazole-desthio equivalents) and then analysed.

Procedural (or “Concurrent”) Recoveries:

During analysis of the samples concurrent recovery experiments were performed by spiking control samples with a mixture containing all analytes. Concurrent recoveries were conducted in each plant matrix at the nominal storage intervals of 30, 60, 90 (except orange and potato), 180, 360, 540 and 720 days. On day 0 (zero time analyses) samples were analysed during the analysis of storage samples. Since these samples are recovery samples, it was not necessary to include concurrent recoveries. For this purpose, stored control samples were freshly fortified with a mixture containing all analytes at 0.10 mg/kg each (expressed as prothioconazole-desthio equivalents). The freshly fortified samples were then extracted and analysed concurrently with the control and spiked samples of these actual storage intervals. The obtained concurrent recovery data are presented in **Błąd! Nie można odnaleźć źródła odwołania.** to **Błąd! Nie można odnaleźć źródła odwołania.**.

**Błąd! Nie można odnaleźć źródła odwołania.** to **Błąd! Nie można odnaleźć źródła odwołania.** summarises the amount of each prothioconazole-hydroxy-desthio metabolite recovered in the stored samples after the various storage intervals. The values presented in these tables were not corrected for the concurrent recoveries at the respective intervals.

After a deep-freezer storage period of 24 months, mean recovery rates for all compounds analysed and in all plant matrices ranged between 71 and 103%. No degradation during the deep-freezer storage could be observed.

It is concluded that residues of prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, and prothioconazole-6-hydroxy-desthio are stable for at least 24 months under deep-freezer storage conditions in samples of plant origin (rape oil seed, orange fruit, potato tuber, tomato fruit and soybean).

Conclusion

The results of the study demonstrate the stability of residues of prothioconazole-α-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, and prothioconazole-6-hydroxy-desthio upon deep frozen storage at – 18 °C for up to 25 months in all tested matrices of plant origin (rape oil seed, orange fruit, potato tuber, tomato fruit and soybean).

Table A 3: Method performance for prothioconazole-α-hydroxy-desthio

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Date of Extraction** | **Sample Material** | **Storage Interval [days]** | | **Method Validation [%]**  **FL 0.01 mg/kg\*** | | | **Concurrent Recoveries [%]**  **FL 0.10 mg/kg\*** | | |
| **nominal** | **actual** | **Single Values** | | **Mean** | **Single Values** | | **Mean** |
| 2009-01-16 | Rape Oil  seed | 0 | 0 | 96 | 97 | 97 | --- | --- | --- |
| 2009-01-06 | 30 | 35 | 91 | 96 | 94 | 89 | --- | --- |
| 2009-02-02 | 60 | 62 | --- | --- | --- | 86 | 86 | 86 |
| 2009-03-09 | 90 | 97 | --- | --- | --- | 100 | 99 | 100 |
| 2009-06-09 | 180 | 189 | 106 | 111 | 109 | 94 | 97 | 96 |
| 2009-11-30 | 360 | 363 | 89 | 95 | 92 | 87 | 81 | 84 |
| 2010-09-06 | 540 | 643 | 105 | 102 | 104 | 104 | 103 | 104 |
| 2011-01-05 | 720 | 764 | 91 | --- | 91 | 91 | 90 | 91 |
| **Overall and RSD [%]** | | | | **98** | **7.2** |  | **93** | **7.8** |  |
| 2008-12-03 | Orange Fruit | 0 | 0 | 92 | 83 | 88 | --- | --- | --- |
| 2009-01-07 | 30 | 35 | --- | --- | --- | 89 | --- | 89 |
| 2009-02-03 | 60 | 61 | --- | --- | --- | 89 | 93 | 91 |
| 2009-03-11 | 90 | 98 | 98 | 89 | 94 | --- | --- | --- |
| 2009-06-10 | 180 | 189 | 101 | 92 | 97 | 104 | 95 | 100 |
| 2009-12-01 | 360 | 363 | 97 | 101 | 99 | 99 | 100 | 100 |
| 2010-09-08 | 540 | 644 | 98 | 100 | 99 | 106 | 108 | 107 |
| 2011-01-06 | 720 | 764 | 83 | --- | 83 | 96 | 96 | 96 |
| **Overall and RSD [%]** | | | | **94** | **7.1** |  | **98** | **6.5** |  |
| 2008-12-08 | Potato  Tuber | 0 | 0 | 95 | 97 | 96 | --- | --- | --- |
| 2009-01-08 | 30 | 31 | --- | --- | --- | 96 | 95 | 96 |
| 2009-02-06 | 60 | 60 | --- | --- | --- | 93 | 96 | 95 |
| 2009-03-11 | 90 | 95 | 98 | 89 | 94 | --- | --- | --- |
| 2009-06-23 | 180 | 197 | 90 | 96 | 93 | 97 | 93 | 95 |
| 2009-12-02 | 360 | 359 | 99 | 101 | 100 | 97 | 93 | 95 |
| 2010-10-07 | 540 | 668 | 105 | 97 | 101 | 97 | 101 | 99 |
| 2011-01-06 | 720 | 759 | 108 | 110 | 109 | 105 | 103 | 104 |
| **Overall and RSD [%]** | | | | **99** | **6.5** |  | **97** | **4.0** |  |
| 2008-12-09 | Tomato Fruit | 0 | 0 | 117 | 114 | 116 | --- | --- | --- |
| 2009-01-13 | 30 | 35 | --- | --- | --- | 91 | 94 | 93 |
| 2009-02-09 | 60 | 62 | --- | --- | --- | 110 | 95 | 103 |
| 2009-03-13 | 90 | 94 | --- | --- | --- | 106 | 104 | 105 |
| 2009-06-24 | 180 | 197 | 94 | 99 | 97 | 99 | 98 | 99 |
| 2009-12-03 | 360 | 359 | 83 | 98 | 91 | 92 | 100 | 96 |
| 2010-10-07 | 540 | 667 | 96 | 98 | 97 | 92 | 103 | 98 |
| 2010-01-10 | 720 | 762 | 108 | 106 | 107 | 104 | 104 | 104 |
| **Overall and RSD [%]** | | | | **101** | **10.0** |  | **99** | **6.0** |  |
| 2008-12-10 | Soybean | 0 | 0 | 105 | 98 | 102 | --- | --- | --- |
| 2009-01-12 | 30 | 33 | --- | --- | --- | 99 | 98 | 99 |
| 2009-02-09 | 60 | 61 | --- | --- | --- | 94 | 96 | 95 |
| 2009-03-13 | 90 | 93 | --- | --- | --- | 97 | 98 | 98 |
| 2009-06-25 | 180 | 197 | 101 | 96 | 99 | 101 | 101 | 101 |
| 2009-12-09 | 360 | 364 | 105 | 119 | 112 | 120 | 117 | 119 |
| 2010-10-07 | 540 | 666 | 87 | 99 | 93 | 95 | 100 | 98 |
| 2011-01-10 | 720 | 761 | 92 | 101 | 97 | 92 | 91 | 92 |
| **Overall and RSD [%]** | | | | **100** | **8.6** |  | **100** | **8.5** |  |

Table A 4: Method performance for prothioconazole-3-hydroxy-desthio

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Date of Extraction** | **Sample Material** | **Storage Interval [days]** | | | **Method Validation [%]**  **FL 0.01 mg/kg\*** | | | | **Concurrent Recoveries [%]**  **FL 0.10 mg/kg\*** | | |
| **nominal** | **actual** | | **Single Values** | | | **Mean** | **Single Values** | | **Mean** |
| 2009-01-16 | Rape Oil  seed | 0 | 0 | 99 | | 102 | | 101 | --- | --- | --- |
| 2009-01-06 | 30 | 35 | 93 | | 96 | | 94 | 87 | --- | 87 |
| 2009-02-02 | 60 | 62 | --- | | --- | | --- | 88 | 88 | 88 |
| 2009-03-09 | 90 | 97 | --- | | --- | | --- | 102 | 100 | 101 |
| 2009-06-09 | 180 | 189 | 91 | | 98 | | 95 | 92 | 98 | 95 |
| 2009-11-30 | 360 | 363 | 95 | | 92 | | 94 | 85 | 80 | 83 |
| 2010-09-06 | 540 | 643 | 101 | | 97 | | 99 | 105 | 105 | 105 |
| 2011-01-05 | 720 | 764 | 75 | |  | | 75 | 85 | 82 | 84 |
| **Overall and RSD [%]** | | | | **94** | | **7.8** | |  | **92** | **9.6** |  |
| 2008-12-03 | Orange Fruit | 0 | 0 | 78 | | | 79 | 79 | --- | --- | --- |
| 2009-01-07 | 30 | 35 | --- | | | --- | --- | 90 | --- | 90 |
| 2009-02-03 | 60 | 61 | --- | | | --- | --- | 90 | 95 | 93 |
| 2009-03-11 | 90 | 98 | 95 | | | 87 | 91 | --- | --- | --- |
| 2009-06-10 | 180 | 189 | 99 | | | 92 | 96 | 100 | 98 | 99 |
| 2009-12-01 | 360 | 363 | 89 | | | 99 | 94 | 95 | 93 | 94 |
| 2010-09-08 | 540 | 644 | 101 | | | 100 | 101 | 109 | 111 | 110 |
| 2011-01-06 | 720 | 764 | 72 | | | --- | 72 | 90 | 91 | 91 |
| **Overall and RSD [%]** | | | | **90** | | | **11.2** |  | **97** | **7.7** |  |
| 2008-12-08 | Potato  Tuber | 0 | 0 | 101 | | 97 | | 99 | --- | --- | --- |
| 2009-01-08 | 30 | 31 | --- | | --- | | --- | 99 | 100 | 100 |
| 2009-02-06 | 60 | 60 | --- | | --- | | --- | 97 | 99 | 98 |
| 2009-03-11 | 90 | 95 | 98 | | 90 | | 94 | --- | --- | --- |
| 2009-06-23 | 180 | 197 | 96 | | 96 | | 96 | 97 | 93 | 95 |
| 2009-12-02 | 360 | 359 | 98 | | 99 | | 99 | 96 | 95 | 96 |
| 2010-10-07 | 540 | 668 | 115 | | 104 | | 110 | 112 | 116 | 114 |
| 2011-01-06 | 720 | 759 | 94 | | 95 | | 95 | 103 | 99 | 101 |
| **Overall and RSD [%]** | | | | **99** | | **6.3** | |  | **101** | **6.8** |  |
| 2008-12-09 | Tomato Fruit | 0 | 0 | 96 | | 96 | | 96 | --- | --- | --- |
| 2009-01-13 | 30 | 35 | --- | | --- | | --- | 92 | 98 | 95 |
| 2009-02-09 | 60 | 62 | --- | | --- | | --- | 111 | 98 | 105 |
| 2009-03-13 | 90 | 94 | --- | | --- | | --- | 108 | 105 | 107 |
| 2009-06-24 | 180 | 197 | 95 | | 99 | | 97 | 99 | 98 | 99 |
| 2009-12-03 | 360 | 359 | 84 | | 92 | | 88 | 103 | 102 | 103 |
| 2010-10-07 | 540 | 667 | 100 | | 105 | | 103 | 106 | 115 | 111 |
| 2010-01-10 | 720 | 762 | 95 | | 93 | | 94 | 101 | 100 | 101 |
| **Overall and RSD [%]** | | | | **96** | | **5.8** | |  | **103** | **5.9** |  |
| 2008-12-10 | Soybean | 0 | 0 | 86 | | 75 | | 81 | --- | --- | --- |
| 2009-01-12 | 30 | 33 | --- | | --- | | --- | 102 | 103 | 103 |
| 2009-02-09 | 60 | 61 | --- | | --- | | --- | 98 | 97 | 98 |
| 2009-03-13 | 90 | 93 | --- | | --- | | --- | 96 | 97 | 97 |
| 2009-06-25 | 180 | 197 | 102 | | 100 | | 101 | 98 | 101 | 100 |
| 2009-12-09 | 360 | 364 | 106 | | 115 | | 111 | 110 | 110 | 110 |
| 2010-10-07 | 540 | 666 | 96 | | 108 | | 102 | 108 | 113 | 111 |
| 2011-01-10 | 720 | 761 | 81 | | 84 | | 83 | 90 | 90 | 90 |
| **Overall and RSD [%]** | | | | **95** | | **13.8** | |  | **101** | **7.1** |  |

\* FL: Fortification level expressed as prothioconazole-desthio equivalents

Table A 5: Method performance for prothioconazole-4-hydroxy-desthio

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Date of Extraction** | | **Sample Material** | **Storage Interval [days]** | | **Method Validation [%]**  **FL 0.01 mg/kg\*** | | | | **Concurrent Recoveries [%]**  **FL 0.10 mg/kg\*** | | |
| **nominal** | **actual** | **Single Values** | | | **Mean** | **Single Values** | | **Mean** |
| 2009-01-16 | | Rape Oil seed | 0 | 0 | 94 | | 95 | 95 | --- | --- | --- |
| 2009-01-06 | | 30 | 35 | 89 | | 93 | 91 | 83 | --- | 83 |
| 2009-02-02 | | 60 | 62 | --- | | --- | --- | 80 | 82 | 81 |
| 2009-03-09 | | 90 | 97 | --- | | --- | --- | 100 | 100 | 100 |
| 2009-06-09 | | 180 | 189 | 94 | | 100 | 97 | 92 | 98 | 95 |
| 2009-11-30 | | 360 | 363 | 88 | | 84 | 86 | 80 | 76 | 78 |
| 2010-09-06 | | 540 | 643 | 90 | | 102 | 96 | 102 | 98 | 100 |
| 2011-01-05 | | 720 | 764 | 82 | | --- | 82 | 85 | 82 | 84 |
| **Overall and RSD [%]** | | | | | **92** | | **6.7** |  | **89** | **10.6** |  |
| 2008-12-03 | | Orange Fruit | 0 | 0 | 73 | 74 | | 74 | --- | --- | --- |
| 2009-01-07 | | 30 | 35 | --- | --- | | --- | 87 | --- | --- |
| 2009-02-03 | | 60 | 61 | --- | --- | | --- | 85 | 89 | 87 |
| 2009-03-11 | | 90 | 98 | 93 | 84 | | 89 | --- | --- | --- |
| 2009-06-10 | | 180 | 189 | 99 | 92 | | 96 | 99 | 96 | 98 |
| 2009-12-01 | | 360 | 363 | 96 | 98 | | 97 | 90 | 93 | 92 |
| 2010-09-08 | | 540 | 644 | 101 | 98 | | 100 | 103 | 106 | 105 |
| 2011-01-06 | | 720 | 764 | 73 | --- | | 73 | 89 | 93 | 91 |
| **Overall and RSD [%]** | | | | | **89** | **12.5** | |  | **94** | **7.2** |  |
| 2008-12-08 | | Potato Tuber | 0 | 0 | 94 | | 91 | 93 | --- | --- | --- |
| 2009-01-08 | | 30 | 31 | --- | | --- | --- | 95 | 97 | 96 |
| 2009-02-06 | | 60 | 60 | --- | | --- | --- | 94 | 93 | 94 |
| 2009-03-11 | | 90 | 95 | 97 | | 91 | 94 | --- | --- | --- |
| 2009-06-23 | | 180 | 197 | 93 | | 98 | 96 | 97 | 93 | 95 |
| 2009-12-02 | | 360 | 359 | 93 | | 99 | 96 | 91 | 93 | 92 |
| 2010-10-07 | | 540 | 668 | 99 | | 98 | 99 | 96 | 100 | 98 |
| 2011-01-06 | | 720 | 759 | 106 | | 105 | 106 | 102 | 101 | 102 |
| **Overall and RSD [%]** | | | | | **97** | | **5.1** |  | **96** | **3.7** |  |
| 2008-12-09 | Tomato Fruit | | 0 | 0 | 95 | | 97 | 96 | --- | --- | --- |
| 2009-01-13 | 30 | 35 | --- | | --- | --- | 90 | 93 | 92 |
| 2009-02-09 | 60 | 62 | --- | | --- | --- | 104 | 93 | 99 |
| 2009-03-13 | 90 | 94 | --- | | --- | --- | 106 | 102 | 104 |
| 2009-06-24 | 180 | 197 | 92 | | 97 | 95 | 99 | 98 | 99 |
| 2009-12-03 | 360 | 359 | 82 | | 92 | 87 | 90 | 96 | 93 |
| 2010-10-07 | 540 | 667 | 88 | | 100 | 94 | 89 | 98 | 94 |
| 2010-01-10 | 720 | 762 | 106 | | 102 | 104 | 99 | 97 | 98 |
| **Overall and RSD [%]** | | | | | **95** | | **7.3** |  | **97** | **5.4** |  |
| 2008-12-10 | Soybean | | 0 | 0 | 89 | | 78 | 84 | --- | --- | --- |
| 2009-01-12 | 30 | 33 | --- | | --- | --- | 98 | 97 | 98 |
| 2009-02-09 | 60 | 61 | --- | | --- | --- | 91 | 94 | 93 |
| 2009-03-13 | 90 | 93 | --- | | --- | --- | 94 | 94 | 94 |
| 2009-06-25 | 180 | 197 | 102 | | 95 | 99 | 95 | 97 | 96 |
| 2009-12-09 | 360 | 364 | 106 | | 107 | 107 | 113 | 115 | 114 |
| 2010-10-07 | 540 | 666 | 91 | | 96 | 94 | 96 | 99 | 98 |
| 2011-01-10 | 720 | 761 | 89 | | 94 | 92 | 89 | 88 | 89 |
| **Overall and RSD [%]** | | | | | **95** | | **9.3** |  | **97** | **8.1** |  |

\* FL: Fortification level expressed as prothioconazole-desthio equivalents

Table A 6: Method performance for prothioconazole-5-hydroxy-desthio

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Date of Extraction** | **Sample Material** | | **Storage Interval [days]** | | | | | **Method Validation [%]**  **FL 0.01 mg/kg\*** | | | | | | | | | | **Concurrent Recoveries [%]**  **FL 0.10 mg/kg\*** | | | | | | |
| **nominal** | | | **actual** | | **Single Values** | | | | | | | | **Mean** | | **Single Values** | | | | | | **Mean** |
| 2009-01-16 | Rape Oil seed | | 0 | | | 0 | | 99 | | | | 98 | | | | 99 | | --- | | | | --- | | --- |
| 2009-01-06 | 30 | | | 35 | | 87 | | | | 92 | | | | 90 | | 80 | | | | --- | | 80 |
| 2009-02-02 | 60 | | | 62 | | --- | | | | --- | | | | --- | | 82 | | | | 84 | | 83 |
| 2009-03-09 | 90 | | | 97 | | --- | | | | --- | | | | --- | | 100 | | | | 100 | | 100 |
| 2009-06-09 | 180 | | | 189 | | 89 | | | | 102 | | | | 96 | | 92 | | | | 98 | | 95 |
| 2009-11-30 | 360 | | | 363 | | 89 | | | | 90 | | | | 90 | | 76 | | | | 75 | | 76 |
| 2010-09-06 | 540 | | | 643 | | 91 | | | | 99 | | | | 95 | | 102 | | | | 102 | | 102 |
| 2011-01-05 | 720 | | | 764 | | 83 | | | | --- | | | | 83 | | 84 | | | | 83 | | 84 |
| **Overall and RSD [%]** | | | | | | | **93** | | | | | | **6.5** | | |  | | **89** | | | **11.5** | | |  |
| 2008-12-03 | Orange Fruit | | 0 | | | 0 | | 76 | | 71 | | | | | | | 74 | --- | | --- | | | | --- |
| 2009-01-07 | 30 | | | 35 | | --- | | --- | | | | | | | --- | 87 | | --- | | | | --- |
| 2009-02-03 | 60 | | | 61 | | --- | | --- | | | | | | | --- | 86 | | 92 | | | | 89 |
| 2009-03-11 | 90 | | | 98 | | 96 | | 86 | | | | | | | 91 | --- | | --- | | | | --- |
| 2009-06-10 | 180 | | | 189 | | 89 | | 87 | | | | | | | 88 | 99 | | 97 | | | | 98 |
| 2009-12-01 | 360 | | | 363 | | 92 | | 98 | | | | | | | 95 | 97 | | 90 | | | | 94 |
| 2010-09-08 | 540 | | | 644 | | 100 | | 98 | | | | | | | 99 | 104 | | 107 | | | | 106 |
| 2011-01-06 | 720 | | | 764 | | 73 | | --- | | | | | | | 73 | 88 | | 89 | | | | 89 |
| **Overall and RSD [%]** | | | | | | | **88** | | **11.9** | | | | | | |  | | **94** | **7.6** | | | | |  |
| 2008-12-08 | Potato Tuber | | | | 0 | 0 | | 95 | | | | | | 91 | | | 93 | --- | | | | --- | | --- |
| 2009-01-08 | 30 | 31 | | --- | | | | | | --- | | | --- | 97 | | | | 97 | | 97 |
| 2009-02-06 | 60 | 60 | | --- | | | | | | --- | | | --- | 93 | | | | 95 | | 94 |
| 2009-03-11 | 90 | 95 | | 97 | | | | | | 90 | | | 94 | --- | | | | --- | | --- |
| 2009-06-23 | 180 | 197 | | 95 | | | | | | 104 | | | 100 | 97 | | | | 93 | | 95 |
| 2009-12-02 | 360 | 359 | | 92 | | | | | | 98 | | | 95 | 94 | | | | 93 | | 94 |
| 2010-10-07 | 540 | 668 | | 106 | | | | | | 98 | | | 102 | 96 | | | | 101 | | 99 |
| 2011-01-06 | 720 | 759 | | 98 | | | | | | 99 | | | 99 | 99 | | | | 97 | | 98 |
| **Overall and RSD [%]** | | | | | | | **97** | | | | | | **5.0** | | |  | | **96** | | | **2.6** | | |  |
| 2008-12-09 | | Tomato Fruit | | | 0 | 0 | | 94 | | | | | | 99 | | 97 | | --- | | | | | --- | --- |
| 2009-01-13 | | 30 | 35 | | --- | | | | | | --- | | --- | | 89 | | | | | 92 | 91 |
| 2009-02-09 | | 60 | 62 | | --- | | | | | | --- | | --- | | 106 | | | | | 95 | 101 |
| 2009-03-13 | | 90 | 94 | | --- | | | | | | --- | | --- | | 104 | | | | | 103 | 104 |
| 2009-06-24 | | 180 | 197 | | 94 | | | | | | 97 | | 96 | | 99 | | | | | 98 | 99 |
| 2009-12-03 | | 360 | 359 | | 84 | | | | | | 97 | | 91 | | 100 | | | | | 99 | 100 |
| 2010-10-07 | | 540 | 667 | | 91 | | | | | | 98 | | 95 | | 90 | | | | | 100 | 95 |
| 2010-01-10 | | 720 | 762 | | 100 | | | | | | 100 | | 100 | | 97 | | | | | 93 | 95 |
| **Overall and RSD [%]** | | | | | | | | **95** | | | | | | **5.2** | |  | | **98** | | | | | **5.3** |  |
| 2008-12-10 | | Soybean | | 0 | | 0 | | 92 | | | 82 | | | | 87 | | | --- | | | --- | | | --- |
| 2009-01-12 | | 30 | | 33 | | --- | | | --- | | | | --- | | | 97 | | | 98 | | | 98 |
| 2009-02-09 | | 60 | | 61 | | --- | | | --- | | | | --- | | | 93 | | | 96 | | | 95 |
| 2009-03-13 | | 90 | | 93 | | --- | | | --- | | | | --- | | | 94 | | | 94 | | | 94 |
| 2009-06-25 | | 180 | | 197 | | 101 | | | 94 | | | | 98 | | | 100 | | | 100 | | | 100 |
| 2009-12-09 | | 360 | | 364 | | 108 | | | 107 | | | | 108 | | | 106 | | | 110 | | | 108 |
| 2010-10-07 | | 540 | | 666 | | 86 | | | 93 | | | | 90 | | | 96 | | | 99 | | | 98 |
| 2011-01-10 | | 720 | | 761 | | 89 | | | 90 | | | | 90 | | | 85 | | | 87 | | | 86 |
| **Overall and RSD [%]** | | | | | | | | **94** | | | | | **9.1** | | |  | | **97** | | | | | **6.7** |  |

\* FL: Fortification level expressed as prothioconazole-desthio equivalents

Table A 7: Method performance for prothioconazole-6-hydroxy-desthio

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Date of Extraction** | **Sample Material** | | **Storage Interval [days]** | | **Method Validation [%]**  **FL 0.01 mg/kg\*** | | | | | **Concurrent Recoveries [%]**  **FL 0.10 mg/kg\*** | | |
| **nominal** | **actual** | **Single Values** | | | **Mean** | | **Single Values** | | **Mean** |
| 2009-01-16 | Rape Oil seed | | 0 | 0 | 84 | 88 | | 86 | | --- | --- | --- |
| 2009-01-06 | 30 | 35 | 77 | 84 | | 81 | | 71 | --- | 71 |
| 2009-02-02 | 60 | 62 | --- | --- | | --- | | 73 | 80 | 77 |
| 2009-03-09 | 90 | 97 | --- | --- | | --- | | 102 | 101 | 102 |
| 2009-06-09 | 180 | 189 | 86 | 87 | | 87 | | 92 | 98 | 95 |
| 2009-11-30 | 360 | 363 | 83 | 80 | | 82 | | 81 | 68 | 75 |
| 2010-09-06 | 540 | 643 | 87 | 85 | | 86 | | 92 | 88 | 90 |
| 2011-01-05 | 720 | 764 | 70 | --- | | 70 | | 74 | 75 | 75 |
| **Overall and RSD [%]** | | | | | **83** | | **6.5** |  | | **84** | **14.1** |  |
| 2008-12-03 | Orange Fruit | | 0 | 0 | 88 | 85 | | | 87 | --- | --- | --- |
| 2009-01-07 | 30 | 35 | --- | --- | | | --- | 77 | --- | 77 |
| 2009-02-03 | 60 | 61 | --- | --- | | | --- | 84 | 87 | 86 |
| 2009-03-11 | 90 | 98 | 89 | 82 | | | 86 | --- | --- | --- |
| 2009-06-10 | 180 | 189 | 93 | 97 | | | 95 | 90 | 92 | 91 |
| 2009-12-01 | 360 | 363 | 82 | 93 | | | 88 | 86 | 85 | 86 |
| 2010-09-08 | 540 | 644 | 93 | 92 | | | 93 | 98 | 101 | 100 |
| 2011-01-06 | 720 | 764 | 62 | --- | | | 62 | 75 | 76 | 76 |
| **Overall and RSD [%]** | | | | | **87** | **11.0** | |  | | **86** | **9.9** |  |
| 2008-12-08 | Potato Tuber | | 0 | 0 | 108 | | 108 | | 108 | --- | --- | --- |
| 2009-01-08 | 30 | 31 | --- | | --- | | --- | 98 | 98 | 98 |
| 2009-02-06 | 60 | 60 | --- | | --- | | --- | 97 | 96 | 97 |
| 2009-03-11 | 90 | 95 | 92 | | 86 | | 89 | --- | --- | --- |
| 2009-06-23 | 180 | 197 | 92 | | 98 | | 95 | 97 | 93 | 95 |
| 2009-12-02 | 360 | 359 | 100 | | 100 | | 100 | 95 | 99 | 97 |
| 2010-10-07 | 540 | 668 | 99 | | 89 | | 94 | 87 | 99 | 93 |
| 2011-01-06 | 720 | 759 | 93 | | 94 | | 94 | 92 | 91 | 92 |
| **Overall and RSD [%]** | | | | | **97** | | **7.1** | |  | **95** | **3.9** |  |
| 2008-12-09 | | Tomato Fruit | 0 | 0 | 96 | | 102 | 99 | | --- | --- | --- |
| 2009-01-13 | | 30 | 35 | --- | | --- | --- | | 84 | 92 | 88 |
| 2009-02-09 | | 60 | 62 | --- | | --- | --- | | 105 | 93 | 99 |
| 2009-03-13 | | 90 | 94 | --- | | --- | --- | | 103 | 102 | 103 |
| 2009-06-24 | | 180 | 197 | 93 | | 98 | 96 | | 99 | 98 | 99 |
| 2009-12-03 | | 360 | 359 | 76 | | 88 | 82 | | 96 | 101 | 99 |
| 2010-10-07 | | 540 | 667 | 94 | | 89 | 92 | | 86 | 93 | 90 |
| 2010-01-10 | | 720 | 762 | 89 | | 87 | 88 | | 87 | 85 | 86 |
| **Overall and RSD [%]** | | | | | **91** | | **7.9** |  | | **95** | **7.5** |  |
| 2008-12-10 | | Soybean | 0 | 0 | 91 | 81 | | 86 | | --- | --- | --- |
| 2009-01-12 | | 30 | 33 | --- | --- | | --- | | 98 | 97 | 98 |
| 2009-02-09 | | 60 | 61 | --- | --- | | --- | | 89 | 92 | 91 |
| 2009-03-13 | | 90 | 93 | --- | --- | | --- | | 95 | 95 | 95 |
| 2009-06-25 | | 180 | 197 | 100 | 94 | | 97 | | 103 | 103 | 103 |
| 2009-12-09 | | 360 | 364 | 100 | 107 | | 104 | | 105 | 106 | 106 |
| 2010-10-07 | | 540 | 666 | 80 | 87 | | 84 | | 89 | 91 | 90 |
| 2011-01-10 | | 720 | 761 | 80 | 74 | | 77 | | 82 | 84 | 83 |
| **Overall and RSD [%]** | | | | | **89** | | **12.1** |  | | **95** | **8.0** |  |

\* FL: Fortification level expressed as prothioconazole-desthio equivalents

Table A 8: Storage stability of Prothioconazole-α-hydroxy-desthio

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Commodity** | **Analyte** | **Storage period (days/months)\*** | **Residue Level in Freezer Storage Stability Sample**  **(mg/kg)** | **Residue Level in Freezer Storage**  **Stability Sample (% of nominal spiking level) (range plus mean)** | **Procedural Recovery for Freshly Spiked Control Sample (%)** |
| Rape oil seed | Prothioconazole-α-hydroxy-desthio | 0 | 0.091, 0.096, 0.098, 0.097, 0.098 | 91-98 (96) | --, --, (--) |
| 33/1 | 0.088, 0.091, 0.095 | 88-95 (91) | 89, -- (--) |
| 61/2 | 0.087, 0.088, 0.099 | 87-99 (91) | 86, 86 (86) |
| 93/3 | 0.102, 0.100, 0.104 | 100-104 (102) | 100, 99 (100) |
| 197/6.5 | 0.097, 0.097, 0.097 | 91-97 (97) | 94, 97 (96) |
| 364/12 | 0.089, 0.082, 0.078 | 78-89 (83) | 87, 81 (84) |
| 666/22 | 0.102, 0.098, 0.098 | 98-102 (99) | 104, 103 (104) |
| 761/25 | 0.092, 0.095, 0.090 | 90-95 (92) | 91, 90 (91) |
| Orange fruit | Prothioconazole-α-hydroxy-desthio | 0 | 0.080, 0.084, 0.078, 0.083, 0.083 | 78-84 (82) | ---, --- (---) |
| 33/1 | 0.093, 0.098, 0.092 | 92-98 (94) | 89, --- (89) |
| 61/2 | 0.091, 0.092, 0.097 | 91-97 (93) | 89, 93 (91) |
| 93/3 | 0.102, 0.102, 0.101 | 101-102 (102) | ---, --- (---) |
| 197/6.5 | 0.104, 0.101, 0.099 | 99-104 (101) | 104, 95 (100) |
| 364/12 | 0.094, 0.093, 0.098 | 93-98 (95) | 99, 100 (100) |
| 666/22 | 0.099, 0.098, 0.101 | 98-101 (99) | 106, 108 (107) |
| 761/25 | 0.108, 0.108, 0.093, 0.098 | 93-108 (100) | 96, 96 (96) |
| Potato tuber | Prothioconazole-α-hydroxy-desthio | 0 | 0.092, 0.090, 0.088, 0.091, 0.089 | 88-92 (90) | ---, --- (---) |
| 33/1 | 0.094, 0.097 | 94-97 (96) | 96, 95 (96) |
| 61/2 | 0.095, 0.093, 0.093 | 93-95 (94) | 93, 96 (95) |
| 93/3 | 0.099, 0.102, 0.099 | 99-102 (100) | ---, --- (---) |
| 197/6.5 | 0.099, 0.089, 0.093 | 89-99 (94) | 97, 93 (95) |
| 364/12 | 0.079, 0.078, 0.080 | 78-80 (79) | 97, 93 (95) |
| 666/22 | 0.092, 0.094, 0.098 | 92-98 (95) | 97, 101 (99) |
| 761/25 | 0.099, 0.098, 0.095 | 95-99 (97) | 105, 103 (104) |
| Tomato fruit | Prothioconazole-α-hydroxy-desthio | 0 | 0.097, 0.096, 0.092, 0.086, 0.089 | 86-97 (92) | --- --- --- |
| 33/1 | 0.092, 0.091, 0.100 | 91-100 (94) | 91, 94 (93) |
| 61/2 | 0.096, 0.097, 0.096 | 96-97 (96) | 110, 95 (103) |
| 93/3 | 0.103, 0.103, 0.101 | 101-103 (102) | 106, 104 (105) |
| 197/6.5 | 0.101, 0.101, 0.098 | 98-101 (100) | 99, 98 (99) |
| 364/12 | 0.094, 0.092, 0.089 | 89-94 (92) | 92, 100 (96) |
| 666/22 | 0.102, 0.101, 0.099 | 99-102 (101) | 92, 103 (98) |
| 761/25 | 0.093, 0.095, 0.100 | 93-100 (96) | 104, 104 (104) |
| Soybean | Prothioconazole-α-hydroxy-desthio | 0 | 0.091, 0.093, 0.074, 0.067, 0.074 | 67-93 (80) | --- --- --- |
| 33/1 | 0.101, 0.095, 0.099 | 95-101 (98) | 99, 98 (99) |
| 61/2 | 0.090, 0.096, 0.095 | 90-96 (94) | 94, 96 (95) |
| 93/3 | 0.098, 0.102, 0.103 | 98-103 (101) | 97, 98 (98) |
| 197/6.5 | 0.099, 0.101, 0.100 | 99-101 (100) | 101, 101 (101) |
| 364/12 | 0.114, 0.109, 0.099 | 99-114 (107) | 120, 117 (119) |
| 666/22 | 0.098, 0.099, 0.095 | 95-99 (97) | 95, 100 (98) |
| 761/25 | 0.074, 0.083, 0.088 | 74-88 (82) | 92, 91 (92) |

\*in the study report storage periods are given in days, in order to keep the OECD template requirements the storage period are here recalculated for months with the following assumption: 1 month = 30.5 day.

Table A 9: Storage stability of Prothioconazole-3-hydroxy-desthio

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Commodity** | **Analyte** | **Storage period (days/months)\*** | **Residue Level in**  **Freezer Storage**  **Stability Sample**  **(mg/kg)** | **Residue Level in**  **Freezer Storage**  **Stability Sample (%**  **of nominal spiking**  **level) (range plus**  **mean)** | **Procedural**  **Recovery for**  **Freshly Spiked**  **Control Sample**  **(%)** |
| Rape oil seed | Prothioconazole-3-hydroxy-desthio | 0 | 0.096,0.0 98, 0.100 0.099, 0.099 | 96-100 (98) | ---, --- (---) |
| 33/1 | 0.090, 0.092, 0.093 | 90-93(92) | 87, --- (87) |
| 61/2 | 0.087, 0.090, 0.102 | 87-102 (93) | 88, 88 (88) |
| 93/3 | 0.101, 0.102, 0.104 | 101-104 (102) | 102, 100 (101) |
| 197/6.5 | 0.097, 0.094, 0.098 | 94-98 (96) | 92, 98 (95) |
| 364/12 | 0.082, 0.073, 0.076 | 73-82 (77) | 85, 80 (83) |
| 666/22 | 0.104, 0.103, 0.100 | 100-104 (102) | 105, 105 (105) |
| 761/25 | 0.083, 0.079, 0.079 | 79-83 (80) | 85, 82 (84) |
| Orange fruit | Prothioconazole-3-hydroxy-desthio | 0 | 0.071, 0.073, 0.069, 0.075, 0.073 | 69-75 (72) | ---, --- (---) |
| 33/1 | 0.091, 0.100, 0.091 | 91-100 (94) | 90, --- (90) |
| 61/2 | 0.092, 0.095, 0.100 | 92-100 (96) | 90, 95 (93) |
| 93/3 | 0.100, 0.101, 0.101 | 101-101 (101) | ---, --- (---) |
| 197/6.5 | 0.102, 0.102, 0.096 | 96-102 (100) | 100, 98 (99) |
| 364/12 | 0.081, 0.086, 0.085 | 81-86 (84) | 95, 93 (94) |
| 666/22 | 0.103, 0.102, 0.105 | 102-105 (103) | 109, 111 (110) |
| 761/25 | 0.107, 0.092, 0.096 | 92-107 (98) | 90, 91 (91) |
| Potato tuber | Prothioconazole-3-hydroxy-desthio | 0 | 0.093, 0.092, 0.089, 0.092, 0.090 | 89-93 (91) | ---, --- (---) |
| 33/1 | 0.096, 0.101 | 96-101 (99) | 99, 100 (100) |
| 61/2 | 0.096, 0.097, 0.095 | 95-97 (96) | 97, 99 (98) |
| 93/3 | 0.099, 0.102, 0.100 | 99-102 (100) | ---, --- (---) |
| 197/6.5 | 0.101, 0.094, 0.096 | 94-101 (97) | 97, 93 (95) |
| 364/12 | 0.079, 0.079, 0.080 | 79-80 (79) | 96, 95 (96) |
| 666/22 | 0.103, 0.104, 0.110 | 103-110 (106) | 112, 116 (114) |
| 761/25 | 0.092, 0.092, 0.088 | 88-92 (91) | 103, 99 (101) |
| Tomato fruit | Prothioconazole-3-hydroxy-desthio | 0 | 0.085, 0.082, 0.079 0.074, 0.075 | 74-85 (79) | ---, --- --- |
| 33/1 | 0.095, 0.093, 0.103 | 93-103 (97) | 92, 98 (95) |
| 61/2 | 0.100, 0.100, 0.101 | 100-101 (100) | 111, 98 (105) |
| 93/3 | 0.102, 0.101, 0.101 | 101-102 (101) | 108, 105 (107) |
| 197/6.5 | 0.101, 0.100, 0.099 | 99-101 (100) | 99, 98 (99) |
| 364/12 | 0.086, 0.084, 0.080 | 80-86 (83) | 103, 102 (103) |
| 666/22 | 0.116, 0.116, 0.112 | 112-116 (115) | 106, 115 (111) |
| 761/25 | 0.093, 0.091, 0.100 | 91-100 (95) | 101, 100 (101) |
| Soybean | Prothioconazole-3-hydroxy-desthio | 0 | 0.077, 0.077, 0.064, 0.059, 0.065 | 59-77 (68) | --- --- --- |
| 33/1 | 0.103, 0.097, 0.101 | 97-103 (100) | 102, 103 (103) |
| 61/2 | 0.096, 0.105, 0.100 | 96-105 (100) | 98, 97 (98) |
| 93/3 | 0.096, 0.108, 0.101 | 96-108 (102) | 96, 97 (97) |
| 197/6.5 | 0.102, 0.101, 0.101 | 101-102 (101) | 98, 101 (100) |
| 364/12 | 0.109, 0.108, 0.115 | 108-115 (111) | 110, 110 (110) |
| 666/22 | 0.109, 0.112, 0.106 | 106-112 (109) | 108, 113 (111) |
| 761/25 | 0.073, 0.081, 0.087 | 73-87 (80) | 90, 90 (90) |

\*in the study report storage periods are given in days, in order to keep the OECD template requirements the storage period are here recalculated for months with the following assumption: 1 month = 30.5 day.

Table A 10: Storage stability of Prothioconazole-4-hydroxy-desthio

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Commodity** | **Analyte** | **Storage period (days/months)\*** | **Residue Level in**  **Freezer Storage**  **Stability Sample**  **(mg/kg)** | **Residue Level in**  **Freezer Storage**  **Stability Sample (%**  **of nominal spiking**  **level) (range plus**  **mean)** | **Procedural**  **Recovery for**  **Freshly Spiked**  **Control Sample**  **(%)** |
| Rape oil seed | Prothioconazole-4-hydroxy-desthio | 0 | 0.094, 0.095,0.095, 0.095, 0.095 | 94-95 (95) | ---, --- (---) |
| 33/1 | 0.084, 0.086, 0.086 | 84-86 (85) | 83, --- (83) |
| 61/2 | 0.079, 0.084, 0.090 | 79-90 (84) | 80, 82 (81) |
| 93/3 | 0.093, 0.093, 0.096 | 93-96 (94) | 100, 100 (100) |
| 197/6.5 | 0.084, 0.086, 0.089 | 84-89 (86) | 92, 98 (95) |
| 364/12 | 0.085, 0.081, 0.080 | 80-85 (82) | 80, 76 (78) |
| 666/22 | 0.097, 0.096, 0.092 | 92-97 (95) | 102, 98 (100) |
| 761/25 | 0.085, 0.090, 0.077 | 77-90 (84) | 85, 82 (84) |
| Orange fruit | Prothioconazole-4-hydroxy-desthio | 0 | 0.068, 0.070, 0.064 0.071, 0.071 | 64-71 (69) | ---, --- (---) |
| 33/1 | 0.088, 0.096, 0.089 | 88-96 (91) | 87, --- (---) |
| 61/2 | 0.089, 0.091, 0.094 | 89-94 (91) | 85, 89 (87) |
| 93/3 | 0.094, 0.096, 0.095 | 94-96 (95) | ---, --- (---) |
| 197/6.5 | 0.093, 0.092, 0.085 | 85-93 (90) | 99, 96 (98) |
| 364/12 | 0.092, 0.093, 0.090 | 90-93 (92) | 90, 93 (92) |
| 666/22 | 0.096, 0.096, 0.099 | 96-99 (97) | 103, 106 (105) |
| 761/25 | 0.105, 0.088, 0.117 | 88-117 (103) | 89, 93 (91) |
| Potato tuber | Prothioconazole-4-hydroxy-desthio | 0 | 0.086, 0.085, 0.081, 0.086, 0.083 | 81-86 (84) | ---, --- (---) |
| 33/1 | 0.092, 0.095 | 92-95 (94) | 95, 97 (96) |
| 61/2 | 0.091, 0.091, 0.089 | 89-91 (90) | 94, 93 (94) |
| 93/3 | 0.093, 0.095, 0.094 | 93-95 (94) | ---, --- (---) |
| 197/6.5 | 0.094, 0.084, 0.087 | 84-94 (88) | 97, 93 (95) |
| 364/12 | 0.081, 0.082, 0.076 | 76-82 (80) | 91, 93 (92) |
| 666/22 | 0.091, 0.091, 0.096 | 91-96 (93) | 96, 100 (98) |
| 761/25 | 0.090, 0.091, 0.086 | 86-91 (89) | 102, 101 (102) |
| Tomato fruit | Prothioconazole-4-hydroxy-desthio | 0 | 0.084, 0.083, 0.079, 0.076, 0.076 | 76-84 (80) | --- --- --- |
| 33/1 | 0.090, 0.089, 0.098 | 89-98 (92) | 90, 93 (92) |
| 61/2 | 0.096, 0.097, 0.096 | 96-97 (96) | 104, 93 (99) |
| 93/3 | 0.097, 0.095, 0.096 | 95-97 (96) | 106, 102 (104) |
| 197/6.5 | 0.093, 0.090, 0.091 | 90-93 (91) | 99, 98 (99) |
| 364/12 | 0.094, 0.096, 0.092 | 92-96 (94) | 90, 96 (93) |
| 666/22 | 0.100, 0.101, 0.098 | 98-101 (100) | 89, 98 (94) |
| 761/25 | 0.092, 0.088, 0.098 | 88-98 (93) | 99, 97 (98) |
| Soybean | Prothioconazole-4-hydroxy-desthio | 0 | 0.078, 0.078, 0.065, 0.059, 0.063 | 59-78 (69) | --- --- --- |
| 33/1 | 0.100, 0.095, 0.099 | 95-100 (98) | 98, 97 (98) |
| 61/2 | 0.091, 0.097, 0.095 | 91-97 (94) | 91, 94 (93) |
| 93/3 | 0.090, 0.100, 0.096 | 90-100 (95) | 94, 94 (94) |
| 197/6.5 | 0.093, 0.096, 0.093 | 93-96 (94) | 95, 97 (96) |
| 364/12 | 0.117, 0.114, 0.111 | 111-117 (114) | 113, 115 (114) |
| 666/22 | 0.085, 0.091, 0.082 | 82-91 (86) | 96, 99 (98) |
| 761/25 | 0.071, 0.082, 0.085 | 71-85 (79) | 89, 88 (89) |

\*in the study report storage periods are given in days, in order to keep the OECD template requirements the storage period are here recalculated for months with the following assumption: 1 month = 30.5 day.

Table A 11: Storage stability of Prothioconazole-5-hydroxy-desthio

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Commodity** | **Analyte** | **Storage period (days/months)\*** | **Residue Level in**  **Freezer Storage**  **Stability Sample**  **(mg/kg)** | **Residue Level in**  **Freezer Storage**  **Stability Sample (%**  **of nominal spiking**  **level) (range plus**  **mean)** | **Procedural**  **Recovery for**  **Freshly Spiked**  **Control Sample**  **(%)** |
| Rape oil seed | Prothioconazole-5-hydroxy-desthio | 0 | 0.093, 0.095, 0.098, 0.097, 0.095 | 93-98 (96) | ---, --- (---) |
| 33/1 | 0.083, 0.087, 0.084 | 83-87(85) | 80, --- (80) |
| 61/2 | 0.085, 0.085, 0.098 | 85-98 (89) | 82, 84 (83) |
| 93/3 | 0.100, 0.101, 0.104 | 100-104 (102) | 100, 100 (100) |
| 197/6.5 | 0.097, 0.095, 0.099 | 95-99 (97) | 92, 98 (95) |
| 364/12 | 0.086, 0.080, 0.076 | 76-86 (81) | 76, 75 (76) |
| 666/22 | 0.101, 0.098, 0.096 | 96-101 (98) | 102, 102 (102) |
| 761/25 | 0.086, 0.089, 0.076 | 76-89 (84) | 84, 83 (84) |
| Orange fruit | Prothioconazole-5-hydroxy-desthio | 0 | 0.068, 0.068, 0.065, 0.072, 0.070 | 65-72 (69) | ---, --- (---) |
| 33/1 | 0.089, 0.096, 0.087 | 87-96 (91) | 87, --- (87) |
| 61/2 | 0.090, 0.092, 0.095 | 90-95 (92) | 86, 92 (89) |
| 93/3 | 0.102, 0.101, 0.103 | 101-103 (102) | ---, --- (---) |
| 197/6.5 | 0.104, 0.102, 0.099 | 99-104 (102) | 99, 97 (98) |
| 364/12 | 0.090, 0.094, 0.093 | 90-94 (92) | 97, 90 (94) |
| 666/22 | 0.099, 0.097, 0.101 | 97-101 (99) | 104, 107 (106) |
| 761/25 | 0.101, 0.084, 0.089 | 84-101 (91) | 88, 89 (89) |
| Potato tuber | Prothioconazole-5-hydroxy-desthio | 0 | 0.089, 0.086, 0.084, 0.086, 0.085 | 84-89 (86) | ---, --- (---) |
| 33/1 | 0.093, 0.097 | 93-97 (95) | 97, 97 (97) |
| 61/2 | 0.094, 0.093, 0.092 | 93-94 (93) | 93, 95 (94) |
| 93/3 | 0.102, 0.104, 0.102 | 102-104 (103) | ---, --- (---) |
| 197/6.5 | 0.103, 0.098, 0.101 | 98-103 (101) | 97, 93 (95) |
| 364/12 | 0.086, 0.085, 0.087 | 85-87 (86) | 94, 93 (94) |
| 666/22 | 0.092, 0.094, 0.098 | 92-98 (95) | 96, 101 (99) |
| 761/25 | 0.092, 0.096, 0.091 | 91-96 (93) | 99, 97 (98) |
| Tomato fruit | Prothioconazole-5-hydroxy-desthio | 0 | 0.085, 0.083, 0.082, 0.078, 0.079 | 78-85 (81) | ---, --- (---) |
| 33/1 | 0.092, 0.090, 0.099 | 90-99 (94) | 89, 92 (91) |
| 61/2 | 0.096, 0.097, 0.097 | 96-97 (97) | 106, 95 (101) |
| 93/3 | 0.104, 0.103, 0.103 | 103-104 (103) | 104, 103 (104) |
| 197/6.5 | 0.104, 0.101, 0.100 | 100-104 (102) | 99, 98 (99) |
| 364/12 | 0.092, 0.089, 0.091 | 89-92 (91) | 100, 99 (100) |
| 666/22 | 0.100, 0.102, 0.097 | 97-102 (100) | 90, 100 (95) |
| 761/25 | 0.090, 0.083, 0.095 | 83-95 (89) | 97, 93 (95) |
| Soybean | Prothioconazole-5-hydroxy-desthio | 0 | 0.081, 0.079, 0.064, 0.058, 0.065 | 58-81 (69) | ---, --- (---) |
| 33/1 | 0.100, 0.095, 0.099 | 95-100 (98) | 97, 98 (98) |
| 61/2 | 0.091, 0.095, 0.096 | 91-96 (94) | 93, 96 (95) |
| 93/3 | 0.098, 0.104, 0.102 | 98-104 (101) | 94, 94 (94) |
| 197/6.5 | 0.100, 0.101, 0.101 | 100-101 (101) | 100, 100 (100) |
| 364/12 | 0.111, 0.105, 0.108 | 105-111 (108) | 106, 110 (108) |
| 666/22 | 0.097, 0.099, 0.093 | 93-99 (96) | 96, 99 (98) |
| 761/25 | 0.070, 0.081, 0.086 | 70-86 (79) | 85, 87 (86) |

\*in the study report storage periods are given in days, in order to keep the OECD template requirements the storage period are here recalculated for months with the following assumption: 1 month = 30.5 day.

Table A 12: Storage stability of Prothioconazole-6-hydroxy-desthio

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Commodity** | **Analyte** | **Storage period (days/months)\*** | **Residue Level in Freezer Storage Stability Sample**  **(mg/kg)** | **Residue Level in Freezer Storage Stability Sample (% of nominal spiking level) (range plus mean)** | **Procedural Recovery for Freshly Spiked Control Sample (%)** |
| Rape oil seed | Prothioconazole-6-hydroxy-desthio | 0 | 0.082, 0.086, 0.088, 0.089, 0.087 | 82-89 (86) | ---, --- (---) |
| 33/1 | 0.073, 0.077, 0.070 | 70-77 (73) | 71, --- (71) |
| 61/2 | 0.073, 0.072, 0.092 | 72-92 (79) | 73, 80 (77) |
| 93/3 | 0.088, 0.091, 0.091 | 88-91 (90) | 102, 101 (102) |
| 197/6.5 | 0.087, 0.086, 0.093 | 86-93 (89) | 92, 98 (95) |
| 364/12 | 0.079, 0.068, 0.074 | 68-79 (74) | 81, 68 (75) |
| 666/22 | 0.094, 0.092, 0.085 | 85-94 (90) | 92, 88 (90) |
| 761/25 | 0.070, 0.080, 0.064 | 64-80 (71) | 74, 75 (75) |
| Orange fruit | Prothioconazole-6-hydroxy-desthio | 0 | 0.086, 0.091, 0.086 0.095, 0.093 | 86-95 (90) | ---, --- (---) |
| 33/1 | 0.083, 0.089, 0.079 | 79-89 (84) | 77, --- (77) |
| 61/2 | 0.082, 0.089, 0.092 | 82-92 (88) | 84, 87 (86) |
| 93/3 | 0.098, 0.098, 0.096 | 96-98 (97) | ---, --- (---) |
| 197/6.5 | 0.098, 0.099, 0.094 | 94-99 (97) | 90, 92 (91) |
| 364/12 | 0.081, 0.084, 0.087 | 81-87 (84) | 86, 85 (86) |
| 666/22 | 0.095, 0.095, 0.099 | 95-99 (96) | 98, 101 (100) |
| 761/25 | 0.094, 0.078, 0.081 | 78-94 (84) | 75, 76 (76) |
| Potato tuber | Prothioconazole-6-hydroxy-desthio | 0 | 0.109, 0.109, 0.105, 0.106, 0.105 | 105-109 (107) | ---, --- (---) |
| 33/1 | 0.096, 0.097 | 96-97 (97) | 98, 98 (98) |
| 61/2 | 0.093, 0.096, 0.093 | 93-96 (94) | 97, 96 (97) |
| 93/3 | 0.098, 0.101, 0.100 | 98-101 (100) | ---, --- (---) |
| 197/6.5 | 0.103, 0.094, 0.100 | 94-103 (99) | 97, 93 (95) |
| 364/12 | 0.086, 0.084, 0.095 | 84-95 (88) | 95, 99 (97) |
| 666/22 | 0.087, 0.089, 0.093 | 87-93 (90) | 87, 99 (93) |
| 761/25 | 0.089, 0.092, 0.086 | 86-92 (89) | 92, 91 (92) |
| Tomato fruit | Prothioconazole-6-hydroxy-desthio | 0 | 0.094, 0.092, 0.091, 0.085, 0.088 | 85-94 (90) | --- --- --- |
| 33/1 | 0.089, 0.088, 0.096 | 88-96 (91) | 84, 92 (88) |
| 61/2 | 0.094, 0.096, 0.096 | 94-96 (95) | 105, 93 (99) |
| 93/3 | 0.100, 0.100, 0.099 | 99-100 (100) | 103, 102 (103) |
| 197/6.5 | 0.104, 0.099, 0.095 | 95-104 (99) | 99, 98 (99) |
| 364/12 | 0.097, 0.090, 0.092 | 90-97 (93) | 96, 101 (99) |
| 666/22 | 0.096, 0.095, 0.089 | 89-96 (93) | 86, 93 (90) |
| 761/25 | 0.083, 0.075, 0.084 | 75-84 (81) | 87, 85 (86) |
| Soybean | Prothioconazole-6-hydroxy-desthio | 0 | 0.088, 0.082, 0.070, 0.059, 0.070 | 59-88 (74) | ---, --- (---) |
| 33/1 | 0.099, 0.094, 0.096 | 94-99 (96) | 98, 97 (98) |
| 61/2 | 0.089, 0.092, 0.093 | 89-93 (91) | 89, 92 (91) |
| 93/3 | 0.097, 0.102, 0.100 | 97-102 (100) | 95, 95 (95) |
| 197/6.5 | 0.098, 0.101, 0.101 | 98-101 (100) | 103, 103 (103) |
| 364/12 | 0.111, 0.108, 0.108 | 108-111 (109) | 105, 106 (106) |
| 666/22 | 0.090, 0.091, 0.086 | 86-91 (89) | 89, 91 (90) |
| 761/25 | 0.067, 0.077, 0.081 | 67-81 (75) | 82, 84 (83) |

\*in the study report storage periods are given in days, in order to keep the OECD template requirements the storage period are here recalculated for months with the following assumption: 1 month = 30.5 day.

* + - * 1. Storage stability of residues in animal products

Study 3 (S20-09716)

|  |  |
| --- | --- |
| Comments of zRMS: | The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for CA3301/ Joust (January 2023). This study has not been reassessed in the framework of this application.  The conclusions of the assessment are presented below:  *The study was conducted to check the storage stability of*   * *prothioconazole, prothioconazole-desthio (Group 1),* * *prothioconazole-alpha-hydroxy-desthio, -3-hydroxy-desthio, -4-hydroxy-desthio, -5-hydroxy-desthio and -6-hydroxy-desthio (Group 2),* * *1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid (Group 3)*   *in bee products (honey, nectar and pollen) stored up to 6 months at ≤ -18 °C in the dark.*  *Group 1: The study is deemed sufficient for assessing the stability of prothioconazole-desthio in homogenates of matrices honey, nectar and pollen upon storage at ≤ -18 °C for over 6 months (182 days for honey,183 days for pollen, 198 days for nectar).*  *The study is deemed sufficient for assessing the stability of prothioconazole upon storage at ≤ -18 °C in homogenates of matrices nectar for more than 6 months (198 days) and for pollen for 3 months (91 days).*  *Group 2: The study is deemed sufficient for assessing the stability of prothioconazole-alpha-hydroxy-desthio in homogenates of matrices honey, nectar and pollen upon storage at ≤ -18 °C for 4.5 months (134 days for honey and nectar, 136 days for pollen).*  *The study is deemed sufficient for assessing the stability of prothioconazole-3, -4, -5 and -6-hydroxy-desthio in homogenates of matrices honey, nectar and pollen upon storage at ≤ -18 °C for 5 months (157 days).*  *Group 3: The study is deemed sufficient for assessing the stability of 1,2,4-triazole, triazole alanine, triazole lactic acid and triazole acetic acid in homogenates of matrices honey, nectar and pollen upon storage at ≤ -18 °C for 6 months (182 days for honey and pollen, 185 days for nectar).*  *The study was conducted according to the OECD 506.*  *The study is acceptable.* |

|  |  |
| --- | --- |
| Reference: | KCA 6.1/03 |
| Report | Storage Stability of Prothioconazole and metabolites in different matrices under Deep Frozen Conditions  Kalathoor, R., 2021  Report No S20-09716 |
| Guideline(s): | OECD 506, 2007; OECD Guideline for the Testing of Chemicals – Stability of Pesticide Residues in Stored Commodities |
| Deviations: | None |
| GLP: | Yes |
| Owner: | Nufarm Crop Products UK |
| Acceptability: | Yes |

The storage stability of prothioconazole-desthio (Group 1), prothioconazole-alpha-hydroxy-desthio, -3-hydroxy~~l~~-desthio, -4-hydroxy-desthio, -5-hydroxy-desthio and -6-hydroxy-desthio (Group 2), as well as 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid (Group 3) was investigated in bee products (honey, nectar and pollen) stored at ≤ -18 °C (target) in the dark. The storage stability of prothioconazole was investigated in nectar and pollen only (not analysed in honey).

Materials and methods

The fortification level for storage samples was at ten times the limit of quantification (LOQ) of the method (i.e. 0.1 mg/kg) with all analytes fortified separately on aliquots of homogenised control sample material. Storage samples were kept at ≤ -18 °C in the dark and analysed at different intervals. All testing intervals were accompanied by analysis of a control sample and two procedural recoveries.

Sample extraction and determination of residues was performed according to the analytical methods that was previously validated at Eurofins Agroscience Services EcoChem GmbH according to SANTE/2020/12830, rev. 1 for risk assessment for matrices nectar and pollen and for monitoring for matrix honey in study S20-09747. Additional 5 procedural recoveries at LOQ level were done for prothioconazole-desthio in matrix honey since a minor modification was applied to the method.

In brief, samples of honey and pollen for group 1 and 2 were extracted with acetonitrile and if necessary, after addition of water containing cysteine hydrochloride solution. A salt mixture containing magnesium sulphate, sodium chloride and sodium citrate was added, and the extract was shaken to obtain phase separation after centrifugation.

For pollen, an aliquot of the acetonitrile phase was cleaned by adding primary secondary amine (PSA). For nectar direct dilution with acetonitrile/water was done for group 1 and group 2 samples. In final steps for nectar, samples were diluted with methanol/water, and for pollen and honey the same solvent mixture containing cysteine hydrochloride (in excess) for stabilization of PTZ (group 1). Whereas, for group 2 final dilution of nectar, pollen and honey was done with aqueous solution of ammonium formate.

Group 3 analytes containing 1,2,4-triazole and triazole derivated metabolites, extraction with a mixture of methanol/water was done for pollen. After evaporation of the methanol phase, samples were diluted with HPLC water. All soluble matrices as nectar and honey were directly diluted in HPLC water and analysed.

Fortification was done for recovery samples.

Quantification was performed by use of LC-MS/MS (group 1 and 2) and LC-DMS-MS/MS (group 3) detection using matrix matched calibration.

The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix with a limit of detection (LOD) set at 0.003 mg/kg (defined as the lowest calibration standard, which is 30 % of the LOQ). For group 2 analytes, the LOQ is expressed as prothioconazole-desthio equivalent.

Results and discussions

*Group 1: Prothioconazole (PTZ) and/or Prothioconazole-desthio*

Table A 13: Storage stability of Prothioconazole-desthio in Honey

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Storage Period  (days) | Procedural Recoveries | | Storage Samples | | | | |
| Single Values (%) | Mean (%)a | Residue Level in Storage Samples (mg/kg) | Percentage of analyte found relative to the nominal fortification level (%) | | | Percentage recovered relative to the mean percentage recovered at day 0 |
| Single Values (%) b | Mean  (%)a | |
| Prothioconazole-desthio (PTZ-desthio) Mass Transition 312→125 m/z Nominal Fortification Level: 0.1 mg/kg (10x LOQ) | | | | | | | |
| 0 | 99,101 | 100 | 0.0990,0.0990 | 99,99 | 99 | 100 | |
| 90 | 102,99 | 100 | 0.0930,0.0940 | 93,94 | 94 | 95 | |
| 182 | 97,99 | 98 | 0.0810,0.0885 | 81,89 | 85 | 86 | |

a calculated from unrounded values; b not corrected for procedural recoveries

Table A 14: Storage stability of Prothioconazole and Prothioconazole-desthio in Nectar

| Storage Period  (days) | Procedural Recoveries | | Storage Samples | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Single Values (%) | Mean (%)a | Residue Level in Storage Samples (mg/kg) | Percentage of analyte found relative to the nominal fortification level (%) | | | Percentage recovered relative to the mean percentage recovered at day 0 |
| Single Values (%) b | Mean  (%)a | |
| Prothioconazole-desthio (PTZ-desthio) Mass Transition 312→125 m/z Nominal Fortification Level: 0.1 mg/kg (10x LOQ) | | | | | | | |
| 0 | 103,99 | 101 | 0.102,0.0998 | 102,100 | 101 | 100 | |
| 90 | 105,103 | 104 | 0.0960,0.0958 | 96,96 | 96 | 95 | |
| 198 | 99,100 | 100 | 0.0834,0.0905 | 83,91 | 87 | 88 | |
| Prothioconazole (PTZ) Mass Transition 344→154 m/z Nominal Fortification Level: 0.1 mg/kg (10x LOQ) | | | | | | | |
| 0 | 94,93 | 93 | 0.0911,0.0939 | 91,94 | 93 | 100 | |
| 90 | 99,100 | 99 | 0.0727,0.0782 | 73,78 | 75 | 81 | |
| 198 | 96,92 | 94 | 0.0759,0.0778 | 76,78 | 77 | 83 | |

a calculated from unrounded values; b not corrected for procedural recoveries

Table A 15: Storage stability of Prothioconazole and Prothioconazole-desthio in Pollen

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Storage Period  (days) | Procedural Recoveries | | Storage Samples | | | | |
| Single Values (%) | Mean (%)a | Residue Level in Storage Samples (mg/kg) | Percentage of analyte found relative to the nominal fortification level (%) | | | Percentage recovered relative to the mean percentage recovered at day 0 |
| Single Values (%) b | Mean  (%)a | |
| Prothioconazole-desthio (PTZ-desthio) Mass Transition 312→125 m/zNominal Fortification Level: 0.1 mg/kg (10x LOQ) | | | | | | | |
| 0 | 98,98 | 98 | 0.100,0.100 | 100,100 | 100 | 100 | |
| 90 | 97,97 | 97 | 0.0960,0.0984 | 96,98 | 97 | 97 | |
| 183 | 111,117 | 114 | 0.107,0.103 | 107,103 | 105 | 105 | |
| Prothioconazole (PTZ) Mass Transition 344→154 m/z  Nominal Fortification Level: 0.1 mg/kg (10x LOQ) | | | | | | | |
| 0 | 106,105 | 106 | 0.111,0.103 | 111,103 | 107 | 100 | |
| 50 | 99,89 | 94 | 0.0789,0.0741 | 79,74 | 77 | 72 | |
| 66 | 95,114 | 105 | 0.0768,0.0756 | 77,76 | 77 | 72 | |
| 80 | 101,93 | 97 | 0.0792,0.0864 | 79,86 | 83 | 78 | |
| 91 | 109,113 | 111 | 0.0849,0.0675 | 85,68 | 77 | 72 | |

a calculated from unrounded values; b not corrected for procedural recoveries

*Group 2: Prothioconazole-alpha-OH-,3-OH, 4-OH, 5-OH, 6-OH –Desthio (5 analytes) expressed as prothioconazole-desthio equivalent.*

Table A 16: Storage stability of Prothioconazole-desthio hydroxies in Honey

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Storage Period  (days) | Procedural Recoveries | | Storage Samples | | | | |
| Single Values (%) | Mean (%)a | Residue Level in Storage Samples (mg/kg)\* | Percentage of analyte found relative to the nominal fortification level (%) | | | Percentage recovered relative to the mean percentage recovered at day 0 |
| Single Values (%) b | Mean  (%)a | |
| Prothioconazole-alpha-hydroxy-desthio (alpha-OH) Mass Transition 328→70 m/z Nominal Fortification Level: 0.1 mg/kg (10x LOQ)\* | | | | | | | |
| 0 | 97,97 | 97 | 0.0968,0.0952 | 97,95 | 96 | 100 | |
| 94 | 108,111 | 110 | 0.113,0.109 | 113,109 | 111 | 116 | |
| 134 | 104,102 | 103 | 0.100,0.0980 | 100,98 | 99 | 103 | |
| Prothioconazole-3-hydroxy-desthio (3-OH)Mass Transition 328→70 m/z Nominal Fortification Level: 0.1 mg/kg (10x LOQ)\* | | | | | | | |
| 0 | 94,97 | 95 | 0.101,0.100 | 101,100 | 101 | 100 | |
| 91 | 104,106 | 105 | 0.106,0.100 | 106,100 | 103 | 102 | |
| 156 | 102,107 | 105 | 0.108,0.110 | 108,110 | 109 | 108 | |
| Prothioconazole-4-hydroxy-desthio (4-OH) Mass Transition 328→70 m/z Nominal Fortification Level: 0.1 mg/kg (10x LOQ)\* | | | | | | | |
| 0 | 97,98 | 98 | 0.104,0.102 | 104,102 | 103 | 100 | |
| 91 | 101,102 | 102 | 0.102,0.102 | 102,102 | 102 | 99 | |
| 156 | 104,106 | 105 | 0.110,0.112 | 110,112 | 111 | 108 | |
| Prothioconazole-5-hydroxy-desthio (5-OH)Mass Transition 328→70 m/z Nominal Fortification Level: 0.1 mg/kg (10x LOQ)\* | | | | | | | |
| 0 | 98,96 | 97 | 0.103,0.104 | 103,104 | 104 | 100 | |
| 91 | 102,108 | 105 | 0.0976,0.102 | 98,102 | 100 | 96 | |
| 156 | 104,106 | 105 | 0.112,0.110 | 112,110 | 111 | 107 | |
| Prothioconazole-6-hydroxy-desthio (6-OH)Mass Transition 328→70 m/z Nominal Fortification Level: 0.1 mg/kg (10x LOQ)\* | | | | | | | |
| 0 | 98,97 | 97 | 0.0960,0.0972 | 96,97 | 97 | 100 | |
| 91 | 103,105 | 104 | 0.0996,0.103 | 100,103 | 101 | 104 | |
| 156 | 103,105 | 104 | 0.102,0.0860 | 102,86 | 94 | 97 | |

a calculated from unrounded values; b not corrected for procedural recoveries; \* as prothioconazole-desthio equivalent

Table A 17: Storage stability of Prothioconazole-desthio hydroxies in Nectar

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Storage Period  (days) | Procedural Recoveries | | Storage Samples | | | | |
| Single Values (%) | Mean (%)a | Residue Level in Storage Samples (mg/kg)\* | Percentage of analyte found relative to the nominal fortification level (%) | | | Percentage recovered relative to the mean percentage recovered at day 0 |
| Single Values (%) b | Mean  (%)a | |
| Prothioconazole-alpha-hydroxy-desthio (alpha-OH) Mass Transition 328→70 m/z Nominal Fortification Level: 0.1 mg/kg (10x LOQ)\* | | | | | | | |
| 0 | 98,98 | 98 | 0.0940,0.0984 | 94,98 | 96 | 100 | |
| 94 | 98,98 | 98 | 0.0948,0.0968 | 95,97 | 96 | 100 | |
| 134 | 105,104 | 105 | 0.0980,0.101 | 98,101 | 100 | 104 | |
| Prothioconazole-3-hydroxy-desthio (3-OH) Mass Transition 328→70 m/z Nominal Fortification Level: 0.1 mg/kg (10x LOQ)\* | | | | | | | |
| 0 | 102,108 | 105 | 0.100,0.100 | 100,100 | 100 | 100 | |
| 91 | 92,96 | 94 | 0.0928,0.0924 | 93,92 | 93 | 93 | |
| 157 | 96,97 | 96 | 0.0924,0.0864 | 92,86 | 89 | 89 | |
| Prothioconazole-4-hydroxy-desthio (4-OH) Mass Transition 328→70 m/z Nominal Fortification Level: 0.1 mg/kg (10x LOQ)\* | | | | | | | |
| 0 | 103,107 | 105 | 0.102,0.103 | 102,103 | 103 | 100 | |
| 91 | 94,93 | 94 | 0.0932,0.0940 | 93,94 | 94 | 91 | |
| 157 | 100,102 | 101 | 0.0944,0.0952 | 94,95 | 95 | 92 | |
| Prothioconazole-5-hydroxy-desthio (5-OH)Mass Transition 328→70 m/z Nominal Fortification Level: 0.1 mg/kg (10x LOQ)\* | | | | | | | |
| 0 | 102,107 | 105 | 0.103,0.101 | 103,101 | 102 | 100 | |
| 91 | 93,94 | 94 | 0.0876,0.0896 | 88,90 | 89 | 87 | |
| 157 | 99,100 | 99 | 0.0924,0.0952 | 92,95 | 94 | 92 | |
| Prothioconazole-6-hydroxy-desthio (6-OH)Mass Transition 328→70 m/z Nominal Fortification Level: 0.1 mg/kg (10x LOQ)\* | | | | | | | |
| 0 | 103,104 | 104 | 0.0980,0.0988 | 98,99 | 98 | 100 | |
| 91 | 92,95 | 94 | 0.0912,0.0904 | 91,90 | 91 | 93 | |
| 157 | 101,104 | 103 | 0.0964,0.0972 | 96,97 | 97 | 99 | |

a calculated from unrounded values; b not corrected for procedural recoveries; \* as prothioconazole-desthio equivalent

Table A 18: Storage stability of Prothioconazole-desthio hydroxies in Pollen

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Storage Period  (days) | Procedural Recoveries | | Storage Samples | | | | |
| Single Values (%) | Mean (%)a | Residue Level in Storage Samples (mg/kg)\* | Percentage of analyte found relative to the nominal fortification level (%) | | | Percentage recovered relative to the mean percentage recovered at  day 0 |
| Single Values (%) b | Mean  (%)a | |
| Prothioconazole-alpha-hydroxy-desthio (alpha-OH) Mass Transition 328→70 m/z Nominal Fortification Level: 0.1 mg/kg (10x LOQ)\* | | | | | | | |
| 0 | 101,100 | 101 | 0.0984,0.0945 | 98,95 | 96 | 100 | |
| 94 | 103,102 | 103 | 0.0999,0.101 | 100,101 | 100 | 104 | |
| 136 | 114,107 | 111 | 0.111,0.111 | 111,111 | 111 | 116 | |
| Prothioconazole-3-hydroxy-desthio (3-OH) Mass Transition 328→70 m/z Nominal Fortification Level: 0.1 mg/kg (10x LOQ)\* | | | | | | | |
| 0 | 92,93 | 93 | 0.0927,0.0954 | 93,95 | 94 | 100 | |
| 91 | 99,96 | 97 | 0.0927,0.0936 | 93,94 | 93 | 99 | |
| 157 | 107,101 | 104 | 0.100,0.101 | 100,101 | 101 | 107 | |
| Prothioconazole-4-hydroxy-desthio (4-OH) Mass Transition 328→70 m/z Nominal Fortification Level: 0.1 mg/kg (10x LOQ)\* | | | | | | | |
| 0 | 93,94 | 93 | 0.0960,0.0939 | 96,94 | 95 | 100 | |
| 91 | 99,98 | 98 | 0.0984,0.0978 | 98,98 | 98 | 103 | |
| 157 | 105,100 | 103 | 0.0993,0.0999 | 99,100 | 100 | 105 | |
| Prothioconazole-5-hydroxy-desthio (5-OH) Mass Transition 328→70 m/z Nominal Fortification Level: 0.1 mg/kg (10x LOQ)\* | | | | | | | |
| 0 | 93,93 | 93 | 0.0963,0.0963 | 96,96 | 96 | 100 | |
| 91 | 100,99 | 100 | 0.0918,0.0921 | 92,92 | 92 | 96 | |
| 157 | 103,103 | 103 | 0.0963,0.0996 | 96,100 | 98 | 102 | |
| Prothioconazole-6-hydroxy-desthio (6-OH) Mass Transition 328→70 m/z Nominal Fortification Level: 0.1 mg/kg (10x LOQ)\* | | | | | | | |
| 0 | 91,91 | 91 | 0.0915,0.0933 | 92,93 | 92 | 100 | |
| 91 | 100,99 | 100 | 0.0903,0.0906 | 90,91 | 90 | 98 | |
| 157 | 101,102 | 102 | 0.0906,0.0873 | 91,87 | 89 | 97 | |

a calculated from unrounded values; b not corrected for procedural recoveries; \* as prothioconazole-desthio equivalent

*Group 3: 1,2,4-Triazole (Tz), Triazole Alanine (TA), Triazole Acetic Acid (TAA), Triazole Lactic Acid (TLA)*

Table A 19: Storage stability of Triazole Derivative Metabolite (TDM) in Honey

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Storage Period  (days) | Procedural Recoveries | | Storage Samples | | | | |
| Single Values (%) | Mean (%)a | Residue Level in Storage Samples (mg/kg) | Percentage of analyte found relative to the nominal fortification level (%) | | | Percentage recovered relative to the mean percentage recovered at day 0 |
| Single Values (%) b | Mean  (%)a | |
| 1,2,4-Triazole (Tz) Mass Transition 70→43 *m/z* Nominal Fortification Level: 0.1 mg/kg (10x LOQ) | | | | | | | |
| 0 | 101,93 | 97 | 0.104,0.105 | 104,105 | 105 | 100 | |
| 92 | 94,97 | 96 | 0.0974,0.0950 | 97,95 | 96 | 92 | |
| 182 | 89,97 | 93 | 0.103,0.0926 | 103,93 | 98 | 94 | |
| Triazole Alanine (TA) Mass Transition 157→70 *m/z*  Nominal Fortification Level: 0.1 mg/kg (10x LOQ) | | | | | | | |
| 0 | 96,92 | 94 | 0.0992,0.101 | 99,101 | 100 | 100 | |
| 92 | 98,105 | 102 | 0.0974,0.0932 | 97,93 | 95 | 95 | |
| 182 | 84,98 | 91 | 0.111,0.109 | 111,109 | 110 | 110 | |
| Triazole Acetic Acid (TAA) Mass Transition 128→70 *m/z*  Nominal Fortification Level: 0.1 mg/kg (10x LOQ) | | | | | | | |
| 0 | 101,103 | 102 | 0.103,0.105 | 103,105 | 104 | 100 | |
| 92 | 96,99 | 97 | 0.103,0.103 | 103,103 | 103 | 99 | |
| 182 | 98,90 | 94 | 0.112,0.114 | 112,114 | 113 | 109 | |
| Triazole Lactic Acid (TLA) Mass Transition 158→70 *m/z* Nominal Fortification Level: 0.1 mg/kg (10x LOQ) | | | | | | | |
| 0 | 97,100 | 99 | 0.0922,0.0910 | 92,91 | 92 | 100 | |
| 92 | 94,92 | 93 | 0.0880,0.0912 | 88,91 | 90 | 98 | |
| 182 | 100,97 | 99 | 0.107,0.108 | 107,108 | 108 | 117 | |

a calculated from unrounded values; b not corrected for procedural recoveries

Table A 20: Storage stability of Triazole Derivative Metabolite (TDM) in Nectar

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Storage Period  (days) | Procedural Recoveries | | Storage Samples | | | | |
| Single Values (%) | Mean (%)a | Residue Level in Storage Samples (mg/kg) | Percentage of analyte found relative to the nominal fortification level (%) | | | Percentage recovered relative to the mean percentage recovered at day 0 |
| Single Values (%) b | Mean  (%)a | |
| 1,2,4-Triazole (Tz) Mass Transition 70→43 *m/z*Nominal Fortification Level: 0.1 mg/kg (10x LOQ) | | | | | | | |
| 0 | 100,97 | 98 | 0.0992,0.0972 | 99,97 | 98 | 100 | |
| 90 | 103,100 | 101 | 0.0928,0.0992 | 93,99 | 96 | 98 | |
| 185 | 86,97 | 91 | 0.0928,0.103 | 93,103 | 98 | 100 | |
| Triazole Alanine (TA) Mass Transition 157→70 *m/z*  Nominal Fortification Level: 0.1 mg/kg (10x LOQ) | | | | | | | |
| 0 | 100,99 | 99 | 0.107,0.104 | 107,104 | 106 | 100 | |
| 90 | 102,98 | 100 | 0.107,0.102 | 107,102 | 105 | 99 | |
| 185 | 114,112 | 113 | 0.114,0.108 | 114,108 | 111 | 105 | |
| Triazole Acetic Acid (TAA) Mass Transition 128→70 *m/z*  Nominal Fortification Level: 0.1 mg/kg (10x LOQ) | | | | | | | |
| 0 | 99,98 | 99 | 0.103,0.104 | 103,104 | 104 | 100 | |
| 90 | 104,101 | 103 | 0.102,0.0980 | 102,98 | 100 | 96 | |
| 185 | 104,101 | 103 | 0.111,0.109 | 111,109 | 110 | 106 | |
| Triazole Lactic Acid (TLA) Mass Transition 158→70 *m/z* Nominal Fortification Level: 0.1 mg/kg (10x LOQ) | | | | | | | |
| 0 | 100,98 | 99 | 0.0980,0.0960 | 98,96 | 97 | 100 | |
| 90 | 103,101 | 102 | 0.0976,0.0948 | 98,95 | 96 | 99 | |
| 185 | 99,100 | 99 | 0.100,0.104 | 100,104 | 102 | 105 | |

a calculated from unrounded values; b not corrected for procedural recoveries

Table A 21: Storage stability of Triazole Derivative Metabolite (TDM) in Pollen

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Storage Period  (days) | Procedural Recoveries | | Storage Samples | | | | |
| Single Values (%) | Mean (%)a | Residue Level in Storage Samples (mg/kg) | Percentage of analyte found relative to the nominal fortification level (%) | | | Percentage recovered relative to the mean percentage recovered at day 0 |
| Single Values (%) b | Mean  (%)a | |
| 1,2,4-Triazole (Tz) Mass Transition 70→43 *m/z*Nominal Fortification Level: 0.1 mg/kg (10x LOQ) | | | | | | | |
| 0 | 108,105 | 107 | 0.0880,0.0870 | 88,87 | 88 | 100 | |
| 92 | 109,103 | 106 | 0.0693,0.0743 | 69,74 | 72 | 82 | |
| 182 | 85,77 | 81 | 0.0757,0.0647 | 76,65 | 70 | 80 | |
| Triazole Alanine (TA) Mass Transition 157→70 *m/z*  Nominal Fortification Level: 0.1 mg/kg (10x LOQ) | | | | | | | |
| 0 | 102,104 | 103 | 0.109,0.109 | 109,109 | 109 | 100 | |
| 92 | 94,91 | 92 | 0.0877,0.0873 | 88,87 | 88 | 81 | |
| 182 | 86,97 | 91 | 0.106,0.105 | 106,105 | 106 | 97 | |
| Triazole Acetic Acid (TAA) Mass Transition 128→70 *m/z*  Nominal Fortification Level: 0.1 mg/kg (10x LOQ) | | | | | | | |
| 0 | 109,105 | 107 | 0.111,0.110 | 111,110 | 111 | 100 | |
| 92 | 87,90 | 89 | 0.103,0.0987 | 103,99 | 101 | 91 | |
| 182 | 102,100 | 101 | 0.110,0.106 | 110,106 | 108 | 97 | |
| Triazole Lactic Acid (TLA) Mass Transition 158→70 *m/z* Nominal Fortification Level: 0.1 mg/kg (10x LOQ) | | | | | | | |
| 0 | 106,110 | 108 | 0.101,0.104 | 101,104 | 103 | 100 | |
| 92 | 83,84 | 83 | 0.0883,0.0853 | 88,85 | 87 | 84 | |
| 182 | 97,103 | 100 | 0.0847,0.0870 | 85,87 | 86 | 83 | |

a calculated from unrounded values; b not corrected for procedural recoveries

Conclusion

The stability of Prothioconazole-desthio when stored at ≤ -18 °C is demonstrated for 182 days in honey, 198 days in nectar and 183 days in polle,. The stability of Prothioconazole when stored at ≤ -18 °C is demonstrated for 198 days in nectar and for 91 days in pollen.

The stability of prothioconazole-alpha-hydroxy-desthio when stored at ≤ -18 °C is demonstrated for 134 days in honey, 134 days in nectar and 136 days in pollen.

The stability of prothioconazole-3, -4, -5 and -6-hydroxy-desthio when stored at ≤ -18 °C is demonstrated for 157 days in honey, nectar and pollen.

The stability of 1,2,4-triazole, triazole alanine, triazole lactic acid and triazole acetic acid when stored at ≤ -18 °C is demonstrated for 182 days in honey, 185 days in nectar and 182 days in pollen.

* + - * 1. New storage stability of residues in plant products

Study S22-08287

|  |  |
| --- | --- |
| Comments of zRMS: | The results of the study demonstrate that triazole metabolites 1,2,4-triazole (T), triazole alanine (TA) in homogenates of oilseed rape (grain) as well as of 1,2,4-triazole (T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in homogenates of oilseed rape (straw) are stable under frozen storage at -18 °C or below for 55 days.  The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix.  The mean recoveries over all testing intervals were within 70% - 110% with the relative standard deviations ≤ 20 % for all analytes and matrices (oilseed rape (grain and straw)).  The study is acceptable. |

|  |  |
| --- | --- |
| Reference: | KCA 6.1/04 |
| Report | Storage Stability of the Triazole Derivative Metabolites in Oilseed Rape under Deep Frozen Conditions  Winter, O. *et al.*, 26.05.2023  Report No: S22-08287 (NUK-2201L) |
| Guideline(s): | - EC Guideline 7032/VI/95, rev. 5, July 1997; Appendix H of working document  - 1607/VI/97, rev. 2, June 1999 – Storage Stability of Residue Samples  - OECD 506, 2007; OECD Guideline for the Testing of Chemicals – Stability of Pesticide Residues in Stored Commodities  - ENV/JM/MONO(2007)17 (OECD guidance document on pesticide residue analytical methods) |
| Deviations: | None |
| GLP: | Yes |
| Owner: | Nufarm Crop Products UK |
| Acceptability: | Yes |

Materials and methods

A deep-freezer storage stability study was conducted to obtain data about the storage stability of the triazole metabolites 1,2,4-triazole (T), triazole alanine (TA) in oilseed rape (grain) as well as of 1,2,4-triazole (T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in oilseed rape (straw).

The fortification level for storage samples was at 100 times the limit of quantification (LOQ) of the method (1.0 mg/kg), except for triazole alanine in oilseed rape (grain) where the fortification level was at 200 times the limit of quantification (LOQ) 2.0 mg/kg). All analytes have been fortified separately on aliquots of homogenised control sample material.

The fortified samples were stored in a freezer at about minus 18°C for up to 55 days. Control samples that had not been fortified with triazole metabolites were stored under the same conditions to allow procedural recovery determination from freshly fortified samples.

Samples were analysed after nominal storage periods of 0, 45-47, 55 days.

Sample extraction and determination of analyte levels was performed according to the analytical method as validated in S15-03542[[12]](#footnote-12) and quantification was performed by use of LC-MS/MS detection with isotopically labelled internal standards.

The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ).

The maximum storage interval of final sample extracts at typically 1 °C to 10 °C from extraction until injection to LC-MS/MS was 5 days.

Results and discussions

Accuracy and Precision

For 1,2,4-triazole the mean recovery for samples extracted without any storage (day 0 storage samples and concurrent recoveries) was 87 % for oilseed rape (grain) and 99 % for oilseed rape (straw).

For triazole alanine the mean recovery for samples extracted without any storage (day 0 storage samples and concurrent recoveries) was 94 % for oilseed rape (grain) and 96 % for oilseed rape (straw).

For triazole acetic acid the mean recovery for samples extracted without any storage (day 0 storage samples and concurrent recoveries) was 104 % for oilseed rape (straw).

For triazole lactic acid the mean recovery for samples extracted without any storage (day 0 storage samples and concurrent recoveries) was 84 % for oilseed rape (straw).

Relative standard deviation was ≤ 20 % for all analytes and matrices.

For duplicate analysis of storage samples from the same time point the difference between the highest and lowest recovery did not exceed 20 %.

These values demonstrate satisfying analytical performance for all analytes and matrices while analysing the storage samples. See the following tables.

Applicability/Suitability

For oilseed rape (grain and straw) the applicability/suitability of the method according to SANTE/2020/12830, rev. 1 was demonstrated within this study by a minimum of 3 recoveries at 100x LOQ for all analytes, with the exception of 200x LOQ for triazole alanine in oilseed rape (grain). Furthermore, the applicability/suitability of the method for matrices of oilseed rape (grain and straw) was demonstrated by concurrent recoveries at LOQ (0.01 mg/kg) and 10x LOQ 0.1 mg/kg within the analytical phase of study S22-0257[[13]](#footnote-13).

For all combinations of analytes and matrices the average amount of analyte recovered relative to the initial mean recovery at day 0 was ≥ 70 % at any testing interval.

Table A 22: Storage stability of triazole metabolites in oilseed rape (grain)

| Storage Period  (days) | Concurrent Recoveries | | Storage Samples | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Single Values (%) | Mean (%)a  in brackets: rel. std. deviation % | Residue Level in Storage Samples (mg/kg)  b | Percentage of analyte found relative to the nominal fortification level (%) | | Percentage recovered corrected for the (mean) concurrent recovery of the individual date of extraction a | Percentage recovered relative to the mean percentage recovered at day 0 a |
| Single Values (%) b | Mean  (%)a  in brackets: rel. std. deviation % |
| Analyte: 1,2,4-triazoleNominal Fortification Level: 1.0 mg/kg (100x LOQ) | | | | | | | |
| 0 day | - | - | 0.98, 0.89, 0.96 | 98, 89, 96 | 95 (4.8) | - | - |
| 47 days | 83, 82 | 82 | 0.84, 0.83 | 84, 83 | 83 | 101 | 87 |
| 55 days | 89, 76 | 82 | 0.73, 0.62 | 73, 62 | 67 | 82 | 71 |
| Analyte: triazole alanineNominal Fortification Level: 2.0 mg/kg (100x LOQ) | | | | | | | |
| 0 day | - | - | 0.86 (1.2), 0.88 (1.2), 0.88 (1.2) | 86 (120), 88 (122), 88 (123) | 87 (1.6) | - | - |
| 45 days | 109 (158), 111 (161) | 110 | 0.84 (1.3), 0.96 (1.5) | 84 (133), 96 (146) | 90 | 82 | 103 |
| 55 days | 96 (142), 79 (125) | 88 | 0.84 (1.3), 0.67 (1.1) | 84 (130), 67 (113) | 76 | 86 | 87 |

a calculated from unrounded values; b if corrected for concurrent recoveries, then uncorrected values are shown in brackets

Table A 23: Storage stability of triazole metabolites in oilseed rape (straw)

| Storage Period  (days) | Concurrent Recoveries | | Storage Samples | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Single Values (%) | Mean (%)a  in brackets: rel. std. deviation % | Residue Level in Storage Samples (mg/kg)  b | Percentage of analyte found relative to the nominal fortification level (%) | | Percentage recovered corrected for the (mean) concurrent recovery of the individual date of extraction a | Percentage recovered relative to the mean percentage recovered at day 0 a |
| Single Values (%) b | Mean  (%)a  in brackets: rel. std. deviation % |
| Analyte: 1,2,4-triazoleNominal Fortification Level: 1.0 mg/kg (100x LOQ) | | | | | | | |
| 0 day | - | - | 1.1, 1.0, 1.0 | 108, 100, 100 | 103 (4.4) | - | - |
| 45 days | 95, 93 | 94 | 0.82, 0.86 | 82, 86 | 84 | 89 | 82 |
| 55 days | 92, 102 | 97 | 0.84, 0.92 | 84, 92 | 88 | 91 | 85 |
| Analyte: triazole alanineNominal Fortification Level: 1.0 mg/kg (100x LOQ) | | | | | | | |
| 0 day | - | - | 0.83, 0.84, 0.82 | 83, 84, 82 | 83 (1.3) | - | - |
| 45 days | 114 (117), 104 (107) | 109 | 0.79 (0.82), 0.79 (0.82) | 79 (82), 79 (82) | 79 | 72 | 95 |
| 55 days | 101 (104), 105 (108) | 103 | 0.78 (0.80), 0.79 (0.82) | 78 (80), 79 (82) | 79 | 77 | 95 |
| Analyte: acetic acidNominal Fortification Level: 1.0 mg/kg (100x LOQ) | | | | | | | |
| 0 day | - | - | 1.1, 1.1, 1.1 | 108, 106, 108 | 108 (0.9) | - | - |
| 45 days | 101 (104), 98 (101) | 100 | 0.99 (1.0), 0.88 (0.92) | 99 (102), 88 (92) | 94 | 94 | 87 |
| 55 days | 104 (108), 101 (105) | 103 | 1.0 (1.1), 1.1 (1.1) | 101 (105), 105 (108) | 103 | 100 | 95 |
| Analyte: lactic acidNominal Fortification Level: 1.0 mg/kg (100x LOQ) | | | | | | | |
| 0 day | - | - | 0.96, 0.94, 0.99 | 96, 94, 99 | 96 (2.3) | - | - |
| 47 days | 76 (79), 79 (82) | 78 | 0.77 (0.80), 0.83 (0.85) | 77 (80), 83 (85) | 78 | 100 | 81 |
| 55 days | 73 (75), 74 (76) | 74 | 0.71 (0.72), 0.70 (0.72) | 71 (72), 70 (72) | 71 | 96 | 74 |

a calculated from unrounded values; b if corrected for concurrent recoveries, then uncorrected values are shown in brackets

Conclusion

The results of the study demonstrate the stability of triazole metabolites 1,2,4-triazole (T), triazole alanine (TA) in homogenates of oilseed rape (grain) as well as of 1,2,4-triazole (T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in homogenates of oilseed rape (straw) upon storage at ≤ 18 °C for 55 days.

* + 1. Nature of residues in plants, livestock and processed commodities
       1. Nature of residue in plants
          1. Nature of residue in primary crops

No new data submitted.

* + - * 1. Nature of residue in rotational crops

No new data submitted.

* + - * 1. Nature of residues in processed commodities

No new data submitted.

* + - 1. Nature of residues in livestock

No new data submitted.

* + 1. Magnitude of residues in plants
       1. Barley, Oat

Table A 24: Comparison of intended and critical EU GAPs – Barley & Oat

| Type of GAP | Number of applica­tions | Application rate per treatment  (g a.s./ha) | Interval between application | Growth stage at last application | PHI (days) |
| --- | --- | --- | --- | --- | --- |
| cGAP NEU(DAR, UK, 2007) | 2 | 200 | 14-21 | BBCH 30-61 | 35 |
| cGAP NEU(Art. 12, EFSA, 2020) | 2 | 200 | 14-21 | NEU: BBCH 30-69  SEU: BBCH 32-61 | 28 |
| Intended cGAP CEU | 2 | 150 | 14-21 | BBCH 30-61 | 35 |

* + - * 1. Study 10-2204 – NEU

|  |  |
| --- | --- |
| Comments of zRMS: | It should be noted that the study of Schoening, Bauer and Koester (10-2204) is currently under review in the EU approval renewal process for prothioconazole.  The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for CA3301/ Joust (January 2023). This study has not been reassessed in the framework of this application.  The conclusions of the assessment are presented below:  *Two residue trials on spring barley were conducted in northern Europe to determine residue of prothioconazole-desthio and prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio.*  *Barley was treated twice at application rate of 0.150 kg a.s./ha of prothioconazole with 14 days interval between applications. The time of application was:*  *1. at BBCH 37-39,*  *2. at BBCH 61.*  *Samples were taken at harvest.*  *Analytical method for determination of prothioconazole-desthio - method 01013.*  *Analytical method for determination of prothioconazole -alpha-hydroxy-desthio, -3-hydroxy-desthio, -4-hydroxy-desthio, -5-hydroxy-desthio and -6-hydroxy-desthio – method 00979/M001.*  *Limit of quantitation of 0.01 mg/kg for grain, green material and straw.*  *Mean recoveries in acceptable range (70 - 110%), RSD <20%.*  *Maximum storage period - 387 days.*  *The residues of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio in barley grain at harvest were <0.01 mg/kg. In grain at harvest, the total residue was always <0.06 mg/kg.*  *The study is acceptable.* |

|  |  |
| --- | --- |
| Reference: | KCA 6.3.1/01 |
| Report | Determination of the residues of BYF 00587, HEC 5725 and prothioconazole in/on barley after spray application of bixafen & fluoxastrobin & prothioconazole EC 190 in the field in the Netherlands and Germany  Schoening, R.; Bauer, J.; Koester, P., 28.09.2011  Report No: M-414691-01-1  Reference No: 10-2204 |
| Guideline(s): | EU-Ref: Council Directive 91/414/EEC of July 15, 1991,  Annex II, part A, section 6 and Annex III, part A, section 8  Residues in or on Treated Products, Food and Feed  EC guidance working document 7029/VI/95 rev. 5 (1997-07-22) |
| Deviations: | Not specified |
| GLP: | Yes |
| Owner: | Bayer CropScience AG (Nufarm has a letter of access) |
| Acceptability: | Yes |

The following study is currently under review in the EU approval renewal process for prothioconazole.

Materials and Methods

In the vegetation period of 2010, a set of 2 residue trials on spring barley was conducted in northern Europe. The trials were performed in the Netherlands and Germany.

In each trial, barley was treated twice at a product rate of 1.5 L/ha Bixafen & Fluoxastrobin & Prothioconazole EC 190 corresponding to 0.150 kg a.s./ha of prothioconazole. The water rate was 300 L/ha. The spray interval was 14 days. The time of application was:

1. when the flag leaf is just visible (still rolled) and at the flag leaf stage (flag leaf fully unrolled, ligule just visible) (BBCH 37-39), and

2. at the beginning of flowering (BBCH 61).

Samples were taken at the following intervals:

- prior to and immediately after the final application.

- at a pre-harvest interval of 35 (34) days after the final treatment.

- at harvest (BBCH 89)

Plant material was collected at a pre-harvest interval of 35 days as well as at one later date to obtain harvest values. This additional date was needed to ensure that samples of mature plants were available independent of the growth stage reached following the proposed pre-harvest interval of 35 days.

Residues of prothioconazole-desthio were determined according to method 01013 with a limit of quantitation of 0.01 mg/kg for grain, green material and straw.

Residues of prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio were determined according to method 00979/M001 with a limit of quantitation of 0.01 mg/kg for grain, green material and straw.

Findings

Storage stability:

The maximum storage periods for prothioconazole-desthio in barley samples from the supplementary residue field trials are presented below.

**Table A 25: Maximum storage periods of field samples from supplementary residue trials**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Crops** | **Substance** | **Sample Material** | **Storage period (days)** | **Storage period (months)** | **Study No.** |
| barley | prothioconazole-desthio | grain | 352 | 11.7 | 10-2204  M-414691-01-1 |
| green material | 387 | 12.9 |
| straw | 352 | 11.7 |
| prothioconazole-alpha-hydroxy-desthio  prothioconazole-3-hydroxy-desthio  prothioconazole-4-hydroxy-desthio  prothioconazole-5-hydroxy-desthio  prothioconazole-6-hydroxy-desthio | grain | 281 | 9.4 |
| green material | 301 | 10 |
| straw | 282 | 9.4 |

These storage periods are covered by the storage stability studies*, i.e.* analytes were shown to be stable for a period of at least 24 months.

Sample extracts were measured within 24 hours, or if not, acceptable recoveries measured concurrently with each set of samples ensured integrity of the sample extracts during the period of time between extraction and analysis.

No residue of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio above 30% of the LOQ was found in the control samples.

Method performance:

Recovery rates were determined concurrently with the sample analysis in order to check the accuracy of the residue levels. Recovery means by fortification levels were within the acceptable range of 70-110% except for prothioconazole-desthio in green material at the LOQ level (112%) and for prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio and prothioconazole-6-hydroxy-desthio in straw at 0.50 mg/kg (68%, 69% and 68% respectively). The single and overall mean recoveries are shown in the following tables below. All results of the method validation are in accordance with the general requirements for residue analytical methods, therefore the method was validated successfully.

**Table A 26: 10-2204: Concurrent recoveries for the determination of prothioconazole-desthio in cereal**

| **Analyte** | **Sample Material** | **Fortification level [mg/kg]** | **Recovery rates [%]\*** | | **RSD [%]** | **LOQ [mg/kg]** |
| --- | --- | --- | --- | --- | --- | --- |
| **Single Values** | **Mean** |
| Prothio-conazole-desthio | Cereal grain | 0.01 | 108 | - | - | 0.01 |
| 2.5 | 86 ; 99 | 93 | - |
| **Overall Recovery (n = 3)** | | **98** | **11.3** |
| Cereal green material | 0.01 | 108; 108; 116; 111; 117 | 112a | 3.8 | 0.01 |
| 0.10 | 97 | - | - |
| 2.0 | 84; 104 | 94 | - |
| 2.5 | 92; 95; 94; 89 | 93 | 2.9 |
| **Overall Recovery (n = 12)** | | **101** | **10.7** |
| Cereal straw | 2.5 | 73 | - | - | 0.01 |
| **Overall Recovery (n = 1)** | | **73** | **-** |

RSD = Relative Standard Deviation, LOQ = Practical Limit of Quantification

Fortified with JAU 6476-desthio, determined as JAU 6476-desthio and calculated as JAU 6476-desthio

\*These recoveries were performed with sample material from studies 10-2204, 10-2205, 10-2206 and 10-2207.

Cereal summarises barley and wheat.

aThis value was accepted due to a RSD below 20% and an overall mean in the range of 70-110%.

**Table A 27: 10-2204: Concurrent recoveries for the determination of prothioconazole-alpha-hydroxy-desthio in cereal**

| **Analyte** | **Sample Material** | **Fortification level [mg/kg]** | **Recovery rates [%]\*** | | **RSD [%]** | **LOQ [mg/kg]** |
| --- | --- | --- | --- | --- | --- | --- |
| **Single Values\*\*** | **Mean** |
| prothioconazole-alpha-hydroxy-desthio | Cereal grain | 0.01 | 89; 90; 118; 120; 89; 89; 94; 100; 95; 96 | 98 | 11.9 | 0.01 |
| 0.50 | 89; 98; 89; 95 | 93 | 4.9 |
| **Overall Recovery (n = 14)** | | **97** | **10.6** |
| Cereal green material | 0.01 | 80; 99; 104; 99; 104; 93; 98;  100; 102; 85; 85; 91; 92 | 95 | 8.2 | 0.01 |
| 0.50 | 101; 95; 100; 101; 83; 85 | 94 | 8.7 |
| **Overall Recovery (n = 19)** | | **95** | **8.1** |
| Cereal straw | 0.01 | 77; 79; 88; 97; 81; 84 | 84 | 8.7 | 0.01 |
| 0.50 | 72; 71; 88; 78; 92 | 80 | 11.8 |
| **Overall Recovery (n = 11)** | | **82** | **9.9** |

RSD = Relative Standard Deviation, LOQ = Practical Limit of Quantification

Fortified with JAU 6476-alpha-hydroxy-desthio, determined as JAU 6476-alpha-hydroxy-desthio and calculated as JAU 6476-desthio.

\*These recoveries were performed with sample material from studies 10-2204, 10-2205, 10-2206 and 10-2207.

Cereal summarises barley and wheat.

\*\* : mean of double injection

**Table A 28: 10-2204: Concurrent recoveries for the determination of prothioconazole-3-hydroxy-desthio in cereal**

| **Analyte** | **Sample Material** | **Fortification level [mg/kg]** | **Recovery rates [%]\*** | | **RSD [%]** | **LOQ [mg/kg]** |
| --- | --- | --- | --- | --- | --- | --- |
| **Single Values\*\*** | **Mean** |
| prothioconazole-3-hydroxy-desthio | Cereal grain | 0.01 | 73; 82; 109; 113; 85; 88; 89; 90; 88; 94 | 91 | 13.1 | 0.01 |
| 0.50 | 83; 93; 78; 81 | 84 | 7.8 |
| **Overall Recovery (n =14)** | | **89** | **12.3** |
| Cereal green material | 0.01 | 70; 90; 101; 91; 103; 91; 94; 94;  94; 70; 71; 75; 77 | 86 | 13.8 | 0.01 |
| 0.50 | 85; 82; 98; 104; 70; 74 | 86 | 15.5 |
| **Overall Recovery (n =19)** | | **86** | **14.0** |
| Cereal straw | 0.01 | 80; 80; 83; 86; 98; 107 | 89 | 12.4 | 0.01 |
| 0.50 | 62; 63; 81; 67; 76 | 70 | 12.0 |
| **Overall Recovery (n =11)** | | **80** | **17.2** |

RSD = Relative Standard Deviation, LOQ = Practical Limit of Quantification

Fortified with prothioconazole-3-hydroxy-desthio, determined as prothioconazole-3-hydroxy-desthio and calculated as prothioconazole-desthio

\*These recoveries were performed with sample material from studies 10-2204, 10-2205, 10-2206 and 10-2207.

Cereal summarises barley and wheat.

\*\*: mean of double injection

**Table A 29: 10-2204: Concurrent recoveries for the determination of prothioconazole-4-hydroxy-desthio in cereal**

| **Analyte** | **Sample Material** | **Fortification level [mg/kg]** | **Recovery rates [%]\*** | | **RSD [%]** | **LOQ [mg/kg]** |
| --- | --- | --- | --- | --- | --- | --- |
| **Single Values\*\*** | **Mean** |
| prothioconazole-4-hydroxy-desthio | Cereal grain | 0.01 | 65; 72; 99; 105; 60; 67; 68; 70; 71; 73 | 75 | 19.7 | 0.01 |
| 0.50 | 87; 95; 72; 76 | 83 | 12.7 |
| **Overall Recovery (n = 14)** | | **77** | **17.8** |
| Cereal green material | 0.01 | 68; 80; 99; 79; 83; 65; 66;  73; 74; 63; 64; 74; 76 | 74 | 13.3 | 0.01 |
| 0.50 | 88; 84; 95; 102; 71 ;75 | 86 | 13.7 |
| **Overall Recovery (n = 19)** | | **78** | **14.9** |
| Cereal straw | 0.01 | 67; 64; 67; 77; 77; 81 | 72 | 9.7 | 0.01 |
| 0.50 | 67; 62; 79; 62; 70 | 68\*\*\* | 10.3 |
| **Overall Recovery (n = 11)** | | **70** | **10.0** |

RSD = Relative Standard Deviation, LOQ = Practical Limit of Quantification

Fortified with prothioconazole-4-hydroxy-desthio, determined as prothioconazole-4-hydroxy-desthio and calculated as prothioconazole-desthio

\*These recoveries were performed with sample material from studies 10-2204, 10-2205, 10-2206 and 10-2207.

Cereal summarises barley and wheat.

\*\*: mean of double injection

\*\*\*: This value was accepted due to a RSD below 20% and an overall mean value in the range of 70-110%.

**Table A 30: 10-2204: Concurrent recoveries for the determination of prothioconazole-5-hydroxy-desthio in cereal**

| **Analyte** | **Sample Material** | **Fortification level [mg/kg]** | **Recovery rates [%]\*** | | **RSD [%]** | **LOQ [mg/kg]** |
| --- | --- | --- | --- | --- | --- | --- |
| **Single Values\*\*** | **Mean** |
| prothioconazole-5-hydroxy-desthio | Cereal grain | 0.01 | 74; 77; 108; 108; 75; 83; 86; 88; 78; 86 | 86 | 14.4 | 0.01 |
| 0.50 | 80;86;83;83 | 83 | 3.0 |
| **Overall Recovery (n = 14)** | | **85** | **12.3** |
| Cereal green material | 0.01 | 73; 93; 99; 95; 95; 76; 77; 78; 82; 72; 73; 78; 79 | 82 | 11.7 | 0.01 |
| 0.50 | 90; 85; 92; 98; 70; 73 | 85 | 13.1 |
| **Overall Recovery (n = 19)** | | **83** | **11.9** |
| Cereal straw | 0.01 | 80; 71; 79; 84; 78; 88 | 80 | 7.2 | 0.01 |
| 0.50 | 62; 64; 80; 66; 75 | 69\*\*\* | 11.1 |
| **Overall Recovery (n = 11)** | | **75** | **11.2** |

RSD = Relative Standard Deviation, LOQ = Practical Limit of Quantification

Fortified with prothioconazole-5-hydroxy-desthio, determined as prothioconazole-5-hydroxy-desthio and calculated as prothioconazole-desthio

\*These recoveries were performed with sample material from studies 10-2204, 10-2205, 10-2206 and 10-2207.

Cereal summarises barley and wheat.

\*\*: mean of double injection

\*\*\*: This value was accepted due to a RSD below 20% and an overall mean value in the range of 70-110%.

**Table A 31: Concurrent recoveries for the determination of prothioconazole-6-hydroxy-desthio in cereal**

| **Analyte** | **Sample Material** | **Fortification level [mg/kg]** | **Recovery rates [%]\*** | | **RSD [%]** | **LOQ [mg/kg]** |
| --- | --- | --- | --- | --- | --- | --- |
| **Single Values\*\*** | **Mean** |
| prothioconazole-6-hydroxy-desthio | Cereal grain | 0.01 | 69; 75; 99; 101; 94; 96; 97; 100; 93; 97 | 92 | 11.9 | 0.01 |
| 0.50 | 79;84;79;82 | 81 | 3.0 |
| **Overall Recovery (n = 14)** | | **89** | **11.9** |
| Cereal green material | 0.01 | 73; 102; 103; 92; 99; 87; 93; 95; 99; 69; 75; 77; 77 | 88 | 13.8 | 0.01 |
| 0.50 | 79; 75; 89; 91; 70; 79 | 81 | 10.1 |
| **Overall Recovery (n = 19)** | | **85** | **13.2** |
| Cereal straw | 0.01 | 82; 74; 75; 78; 75; 82 | 78 | 4.7 | 0.01 |
| 0.50 | 68; 68; 80; 60; 62 | 68\*\*\* | 11.5 |
| **Overall Recovery (n = 11)** | | **73** | **10.5** |

RSD = Relative Standard Deviation, LOQ = Practical Limit of Quantification

Fortified with prothioconazole-6-hydroxy-desthio, determined as prothioconazole-6-hydroxy-desthio and calculated as prothioconazole-desthio

\*These recoveries were performed with sample material from studies 10-2204, 10-2205, 10-2206 and 10-2207.

Cereal summarises barley and wheat.

\*\*: mean of double injection

\*\*\*: This value was accepted due to a RSD below 20% and an overall mean value in the range of 70-110%.

Residue results:

The residue results are summarised in the table hereafter.

In the 2 trials conducted in 2010 (report 10-2204), residues of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio in barley grain at harvest were <0.01 mg/kg. In grain at harvest, the total residue was always <0.06 mg/kg.

In straw, the residues at harvest ranged as follows:

* between 0.05 mg/kg and 0.17 mg/kg for prothioconazole-desthio
* <0.01 mg/kg mg/kg for prothioconazole-alpha-hydroxy,
* between 0.04 mg/kg and 0.17 mg/kg for prothioconazole-3-hydroxy-desthio,
* between 0.04 mg/kg and 0.12 mg/kg for prothioconazole-4-hydroxy-desthio,
* between 0.02 mg/kg and 0.08 mg/kg for prothioconazole-5-hydroxy-desthio,
* <0.01 mg/kg mg/kg for prothioconazole-6-hydroxy-desthio,
* between 0.17 mg/kg and 0.56 mg/kg for the total residue.

Conclusion

Two barley residue trials were conducted with Bixafen & Fluoxastrobin & Prothioconazole EC 190 in northern Europe. The product application corresponded to a prothioconazole rate of 2x150 g a.s./ha.

Residues of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio in barley grain at harvest were <0.01 mg/kg. In grain at harvest, the total residue was always <0.06 mg/kg.

In straw, the residues at harvest ranged as follows:

* between 0.05 mg/kg and 0.17 mg/kg for prothioconazole-desthio,
* <0.01 mg/kg mg/kg for prothioconazole-alpha-hydroxy,
* between 0.04 mg/kg and 0.17 mg/kg for prothioconazole-3-hydroxy-desthio,
* between 0.04 mg/kg and 0.12 mg/kg for prothioconazole-4-hydroxy-desthio,
* between 0.02 mg/kg and 0.08 mg/kg for prothioconazole-5-hydroxy-desthio,
* <0.01 mg/kg mg/kg for prothioconazole-6-hydroxy-desthio, between 0.17 mg/kg and 0.56 mg/kg for the total residue.

Table A 32: Summary of the 10-2204 trials

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study Trial No.**  **GLP  Year** | **Crop Variety** | **Country** | **Date of**  **1. Sowing or**  **planting**  **2. Flowering**  **3. Harvest**  **4. Transplanting** | **Application** | | | | | | **Residues (mg/kg)** | | | | | | | | |
| **FL** | **No** | **kg/ha  (a.s.)** | **kg/hL (a.s.)** | **GS** | **Dates of treatment or no. of treatments and last date** | **Portion analysed** | **DALT (days)** | **PTZ-desthio** | **PTZ-alpha-hydroxy-desthio** | **PTZ-3-hydroxy-desthio** | **PTZ-4-hydroxy-desthio** | **PTZ-5-hydroxy-desthio** | **PTZ-6-hydroxy-desthio** | **Total (PTZ-desthio+hydroxy=RD-RA1)\*** |
| 10-2204 10-2204-01  GLP: yes  2010 | Barley, spring  Tipple | Nether-lands 1175 LD Lynden Europe, North | 1) 14.04.2010  3) 01.08.2010  - 20.08.2010 | 190 EC | 2 | 0.150 | 0.050 | 61 | 1)15/06/10  2)29/06/10 | green material | 0(1) 0 | 0.36 0.51 | <0.01 <0.01 | 0.05 0.05 | 0.07 0.08 | 0.03 0.03 | <0.01 <0.01 | 0.53 0.69 |
| grain | 35 43 | <0.01 <0.01 | <0.01 <0.01 | <0.01 <0.01 | <0.01 <0.01 | <0.01 <0.01 | <0.01 <0.01 | <0.06 <0.06 |
| straw | 35 43 | 0.11 0.05 | <0.01 <0.01 | 0.10 0.04 | 0.12 0.04 | 0.06 0.02 | <0.01 <0.01 | 0.41 0.17 |
| 10-2204 10-2204-02  GLP: yes  2010 | Barley, spring  Quench | Germany 51399 Burscheid Europe, North | 1) 06.04.2010  2) 21.06.2010  - 28.06.2010  3) 01.08.2010  - 15.08.2010 | 190 EC | 2 | 0.150 | 0.050 | 61 | 1)07/06/10  2)21/06/10 | green material | 0(1) 0 | 0.53 1.5 | <0.01 <0.01 | 0.09 0.10 | 0.09 0.09 | 0.05 0.06 | <0.01 <0.01 | 0.78 1.8 |
| grain | 34 46 | <0.01 <0.01 | <0.01 <0.01 | <0.01 <0.01 | <0.01 <0.01 | <0.01 <0.01 | <0.01 <0.01 | <0.06 <0.06 |
| straw | 34 46 | 0.54 0.17 | <0.01 <0.01 | 0.32 0.17 | 0.25 0.12 | 0.10 0.08 | 0.01 <0.01 | 1.2 0.56 |

(1): before last treatment \* for the sum, values <0.01 mg/kg were considered to be equal to 0.01 mg/kg, unless all the values were <0.01 mg/kg.  
Residues for PTZ-desthio were determined as PTZ-desthio and calculated as PTZ-desthio

Residues for PTZ-alpha-hydroxy-desthio were determined as PTZ-alpha-hydroxy-desthio and calculated as PTZ-desthio

Residues for PTZ-3-hydroxy-desthio were determined as PTZ-3-hydroxy-desthio and calculated as PTZ-desthio

Residues for PTZ-4-hydroxy-desthio were determined as PTZ-4-hydroxy-desthio and calculated as PTZ-desthio

Residues for PTZ-5-hydroxy-desthio were determined as PTZ-5-hydroxy-desthio and calculated as PTZ-desthio

Residues for PTZ-6-hydroxy-desthio were determined as PTZ-6-hydroxy-desthio and calculated as PTZ-desthio

* + - * 1. Studies 13-2158 & 13-2137 – NEU

|  |  |
| --- | --- |
| Comments of zRMS: | It should be noted that the studies of Bellof and van Berkum (13-2158) and Glaubitz (13-2137) are currently under review in the EU approval renewal process for prothioconazole.  The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for CA3301/ Joust (January 2023). This study has not been reassessed in the framework of this application.  The conclusions of the assessment are presented below:  *Four residue trials on spring and winter barley were conducted in northern Europe to determine residue of prothioconazole-desthio and prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio.*  *Barley was treated twice at application rate of 0.125 kg a.s./ha of prothioconazole with 6-20 days interval between applications. The time of application was*  *1. at BBCH 32-57,*  *2. at BBCH 61.*  *Samples were taken at harvest.*  *Analytical method for determination of prothioconazole-desthio - method 01013.*  *Analytical method for determination of prothioconazole -alpha-hydroxy-desthio, -3-hydroxy-desthio, -4-hydroxy-desthio, -5-hydroxy-desthio and -6-hydroxy-desthio – method 00979/M001.*  *Limit of quantitation of 0.01 mg/kg for grain, green material and straw.*  *Mean recoveries in acceptable range (70 - 110%), RSD <20%.*  *Maximum storage period – 15 months.*  *The residues of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio in barley grain at harvest were <0.01 mg/kg. In grain at harvest, the total residue was always <0.06 mg/kg except for trial 13-2137-02 where the total residue reached 0.061 mg/kg.*  *The study is acceptable.* |

|  |  |
| --- | --- |
| Reference: | KCA 6.3.1/02 |
| Report | Determination of the residues of fluoxastrobin and prothioconazole in/on barley and spring barley after spray application of Fluoxastrobin & Prothioconazole EC 200 in France (North)  Bellof, S.; van Berkum, S., 05.11.2014  Report No: M-501503-01-1  Reference No: 13-2158 |
| Guideline(s): | Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection  products on the market and repealing Council Directives 79/117/EEC and  91/414/EEC  EC Guidance working document 7029/VI/95 rev.5 (1997-07-22)  OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial  US EPA OCSPP Guideline No. 860.1500 |
| Deviations: | None |
| GLP: | Yes |
| Owner: | Bayer CropScience AG (Nufarm has a letter of access) |
| Acceptability: | Yes |

|  |  |
| --- | --- |
| Reference: | KCA 6.3.1/03 |
| Report | Determination of the residues of fluoxastrobin and prothioconazole in/on spring barley after spray application of fluoxastrobin & prothioconazole EC 200 in Germany  Glaubitz, J., 30.01.2015  Report No: M-501711-03-1  Reference No: 13-2137 |
| Guideline(s): | Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC  EC Guidance working document 7029/VI/95 rev.5 (1997-07-22),  OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial  US EPA OCSPP Guideline No. 860.1500 |
| Deviations: | None |
| GLP: | Yes |
| Owner: | Bayer CropScience AG (Nufarm has a letter of access) |
| Acceptability: | Yes |

The following study is currently under review in the EU approval renewal process for prothioconazole.

Materials and Methods

In the vegetation period of 2013, a set of 4 residue trials on spring and winter barley was conducted in northern Europe. The trials were located in northern France and Germany.

In each trial, barley was treated twice at a product rate of 1.25 L/ha fluoxastrobin & prothioconazole EC 200 corresponding to 0.125 kg a.s./ha of prothioconazole. In trial 13-2158-02, the two applications were overdosed by 6.3% and 8.3%, respectively. The water rate was 200-400 L/ha. The spray interval ranged from 6-20 days. The time of application was:

1. when node 2 is at least 2 cm above node 1until 70% of inflorescence emerged (BBCH 32-57), and

2. at the beginning of flowering (BBCH 61).

Samples were taken at the following intervals:

- prior to and immediately after the final application,

- at days 7, 14, 21 and 28 (except for the trial 13-2158-02) after final application,

- at a pre-harvest interval of 35 days (except for the trial 13-2137-02) after the final application,

- at harvest (BBCH 89). Additional samples were taken at days 17 (trial 13-2158-02), 31 (trial 13-2158-01) and 42 (trial 13-2137-02) after final application.

Plant material was collected at a pre-harvest interval of 35 days as well as at one later date to obtain harvest values. This additional date was needed to ensure that samples of mature plants were available independent of the growth stage reached following the proposed pre-harvest interval of 35 days.

Residues of prothioconazole-desthio were determined according to method 01013 with a limit of quantitation of 0.01 mg/kg for grain, green material and straw.

Residues of prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio were determined according to method 00979/M001 with a limit of quantitation of 0.01 mg/kg for grain, green material and straw.

Findings

- Storage stability:

The maximum storage periods for prothioconazole-desthio in barley samples from the supplementary residue field trials are presented below.

**Table A 33: Maximum storage periods of field samples from supplementary residue trials**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Crops** | **Substance** | **Sample Material** | **Storage period (days)** | **Storage period (months)** | **Study No.** |
| barley | prothioconazole-desthio | grain | 337 | 11.2 | 13-2158  M-501503-01-1 |
| green material | 366 | 12.2 |
| straw | 337 | 11.2 |
| prothioconazole-alpha-hydroxy-desthio  prothioconazole-3-hydroxy-desthio  prothioconazole-4-hydroxy-desthio  prothioconazole-5-hydroxy-desthio  prothioconazole-6-hydroxy-desthio | grain | 415 | 13.8 |
| green material | 451 | 15.0 |
| straw | 424 | 14.1 |

These storage periods are covered by the storage stability studies*, i.e.* analytes were shown to be stable for a period of at least 24 months.

Sample extracts were measured within 24 hours, or if not, acceptable recoveries measured concurrently with each set of samples ensured integrity of the sample extracts during the period of time between extraction and analysis.

No residue of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio above 30% of the LOQ was found in the control samples.

- Method performance:

Recovery rates were determined concurrently with the sample analysis in order to check the accuracy of the residue levels. Recovery means by fortification levels were within the acceptable range of 70-110% except for prothioconazole-3-hydroxy-desthio in green material at the LOQ level (68%), for prothioconazole-4-hydroxy-desthio at the LOQ level in grain (68%) and in straw (64%) and prothioconazole-6-hydroxy-desthio in grain at the LOQ level (117% ). The single and overall mean recoveries are shown in the following tables below. All results of the method validation are in accordance with the general requirements for residue analytical methods, therefore the method was validated successfully.

**Table A 34: 13-2158 and 13-2137: Concurrent recoveries for the determination of prothioconazole-desthio in barley**

| **Analyte** | **Study** | **Sample Material** | **Fortification level [mg/kg]** | **Recovery rates [%]** | | **RSD [%]** | **LOQ [mg/kg]** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Single Values** | **Mean** |
| Prothio-conazole-desthio | 13-2158 | barley grain | 0.01 | 103 | - | - | 0.01 |
| 0.10 | 104 | - | - |
| **Overall Recovery (n = 2)** | | **104** | **-** |
| barley green material | 0.01 | 104\* | - | - | 0.01 |
| 0.10 | 113 | - | - |
| 1.0 | 88 | - | - |
| **Overall Recovery (n = 3)** | | **102** | **12.5** |
| barley straw | 0.01 | 107\* | - | - | 0.01 |
| 0.10 | 108 | - | - |
| 1.0 | 91 | - | - |
| **Overall Recovery (n = 3)** | | **102** | **9.4** |
| Prothio-conazole-desthio | 13-2137 | barley grain | 0.01 | 99 | - | - | 0.01 |
| 0.10 | 98 | - | - |
| **Overall Recovery (n = 2)** | | **99** | **-** |
| barley green material | 0.01 | 118 | - | - | 0.01 |
| 0.10 | 100 | - | - |
| **Overall Recovery (n = 2)** | | **109** |  |
| barley straw | 0.01 | 97 | - | - | 0.01 |
| 0.10 | 96 | - | - |
| **Overall Recovery (n = 2)** | | **97** | **-** |

RSD = Relative Standard Deviation, LOQ = Practical Limit of Quantification

Fortified with prothioconazole-desthio, determined as prothioconazole-desthio and calculated as prothioconazole-desthio

\* : corrected for residue level in control sample (29% of the LOQ for green material and 24% of the LOQ for straw). Uncorrected values are 133% (green material) and 132% (straw).

**Table A 35: 13-2158 and 13-2137: Concurrent recoveries for the determination of prothioconazole-alpha-hydroxy-desthio in barley**

| **Analyte** | **Study** | **Sample Material** | **Fortification level [mg/kg]** | **Recovery rates [%]** | | **RSD [%]** | **LOQ [mg/kg]** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Single Values** | **Mean** |
| prothioconazole- alpha -hydroxy-desthio | 13-2158 | barley grain | 0.01 | 81; 82 | 82 | - | 0.01 |
| 0.10 | 76; 80 | 78 | - |
| **Overall recovery (n = 4)** | | **80** | **3.3** |
| barley green material | 0.01 | 78; 80 | 79 | - | 0.01 |
| 0.10 | 95; 99 | 97 | - |
| 0.30 | 99; 100 | 100 | - |
| **Overall recovery (n = 6)** | | **92** | **11.0** |
| barley straw | 0.01 | 63; 69; 76; 81 | 72 | 10.9 | 0.01 |
| 0.10 | 87; 88 | 88 | - |
| 0.60 | 87; 100 | 94 |  |
| **Overall recovery (n = 8)** | | **81** | **14.5** |
| prothioconazole-alpha-hydroxy-desthio | 13-2137 | barley grain | 0.01 | 77 ; 78 | 78 | - | 0.01 |
| 0.10 | 93 ; 93 | 93 | - |
| **Overall Recovery (n = 4)** | | **85** | **10.5** |
| barley green material | 0.01 | 85 ; 94 ; 109 | 96 | 12.6 | 0.01 |
| 0.10 | 85 ; 86 | 86 | - |
| **Overall Recovery (n = 5)** | | **92** | **11.3** |
| barley straw | 0.01 | 85 ; 86 | 86 | - | 0.01 |
| 0.20 | 88 ; 90 ; 97 ; 100 | 94 | 6.1 |
| **Overall Recovery (n = 6)** | | **91** | **6.7** |

RSD = Relative Standard Deviation, LOQ = Practical Limit of Quantification

Fortified with prothioconazole-alpha-hydroxy-desthio, determined as prothioconazole-alpha-hydroxy-desthio and calculated as prothioconazole-desthio

**Table A 36: 13-2158 and 13-2137: Concurrent recoveries for the determination of prothioconazole-3-hydroxy-desthio in barley**

| **Analyte** | **Study** | **Sample Material** | **Fortification level [mg/kg]** | **Recovery rates [%]** | | **RSD [%]** | **LOQ [mg/kg]** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Single Values** | **Mean** |
| prothioconazole-3-hydroxy-desthio | 13-2158 | barley grain | 0.01 | 83; 86 | 85 | - | 0.01 |
| 0.10 | 74; 75 | 75 | - |
| **Overall recovery (n = 4)** | | **80** | **7.4** |
| barley green material | 0.01 | 68; 68 | 68\* | - | 0.01 |
| 0.10 | 88; 91 | 90 | - |
| 0.30 | 96; 97 | 97 | - |
| **Overall recovery (n = 6)** | | **85** | **15.7** |
| barley straw | 0.01 | 67; 67; 78; 86 | 75 | 12.4 | 0.01 |
| 0.10 | 79; 86 | 83 | - |
| 0.60 | 86; 96 | 91 | - |
| **Overall recovery (n = 8)** | | **81** | **12.4** |
| prothioconazole-3-hydroxy-desthio | 13-2137 | barley grain | 0.01 | 86 ; 87 | 87 | - | 0.01 |
| 0.10 | 87 ; 87 | 87 | - |
| **Overall Recovery (n = 4)** | | **87** | **0.6** |
| barley green material | 0.01 | 81 ; 96 ; 108 | 95 | 14.2 | 0.01 |
| 0.10 | 85 ; 93 | 89 | - |
| **Overall Recovery (n = 5)** | | **93** | **11.3** |
| barley straw | 0.01 | 89 ; 89 | 89 | - | 0.01 |
| 0.20 | 85 ; 85 ; 91 ; 97 | 90 | 6.4 |
| **Overall Recovery (n = 6)** | | **89** | **5.0** |

RSD = Relative Standard Deviation, LOQ = Practical Limit of Quantification

Fortified with prothioconazole-hydroxy-desthio, determined as prothioconazole-hydroxy-desthio and calculated as prothioconazole-desthio \* : This value was accepted due to a RSD below 20% and an overall mean value in the range of 70-110%.

**Table A 37: 13-2158 and 13-2137: Concurrent recoveries for the determination of prothioconazole-4-hydroxy-desthio in barley**

| **Analyte** | **Study** | **Sample Material** | **Fortification level [mg/kg]** | **Recovery rates [%]** | | **RSD [%]** | **LOQ [mg/kg]** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Single Values** | **Mean** |
| prothioconazole-4-hydroxy-desthio | 13-2158 | barley grain | 0.01 | 65; 70 | 68\* | - | 0.01 |
| 0.10 | 70; 76 | 73 | - |
| **Overall recovery (n = 4)** | | **70** | **6.4** |
| barley green material | 0.01 | 69; 70 | 70 | - | 0.01 |
| 0.10 | 91; 96 | 94 | - |
| 0.30 | 90; 95 | 93 | - |
| **Overall recovery (n = 6)** | | **85** | **14.5** |
| barley straw | 0.01 | 62; 65; 71 | 66\* | 6.9 | 0.01 |
| 0.10 | 71; 80 | 76 | - |
| 0.60 | 83; 96 | 90 | - |
| **Overall recovery (n = 7)** | | **75** | **15.6** |
| prothioconazole-4-hydroxy desthio | 13-2137 | barley grain | 0.01 | 66 ; 67 | 67 | - | 0.01 |
| 0.10 | 83 ; 85 | 84 | - |
| **Overall Recovery (n = 4)** | | **75** | **13.5** |
| barley green material | 0.01 | 83 ; 95 | 89 | - | 0.01 |
| 0.10 | 76 ; 80 | 78 | - |
| **Overall Recovery (n = 4)** | | **84** | **9.8** |
| barley straw | 0.01 | 63 ; 64 | 64 | - | 0.01 |
| 0.20 | 86 ; 87 ; 84 ; 86 | 86 | 1.5 |
| **Overall Recovery (n = 6)** | | **78** | **14.7** |

RSD = Relative Standard Deviation, LOQ = Practical Limit of Quantification

Fortified with prothioconazole-4-hydroxy-desthio, determined as prothioconazole-4-hydroxy-desthio and calculated as prothioconazole-desthio

\* : This value was accepted due to a RSD below 20% and an overall mean value in the range of 70-110%.

**Table A 38: 13-2158 and 13-2137: Concurrent recoveries for the determination of prothioconazole-5-hydroxy-desthio in barley**

| **Analyte** | **Study** | **Sample Material** | **Fortification level [mg/kg]** | **Recovery rates [%]** | | **RSD [%]** | **LOQ [mg/kg]** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Single Values** | **Mean** |
| prothioconazole-5-hydroxy-desthio | 13-2158 | barley grain | 0.01 | 73; 77 | 75 | - | 0.01 |
| 0.10 | 77; 82 | 80 | - |
| **Overall recovery (n = 4)** | | **77** | **4.8** |
| barley green material | 0.01 | 67; 83 | 75 | - | 0.01 |
| 0.10 | 91; 94 | 93 | - |
| 0.30 | 96; 98 | 97 | - |
| **Overall recovery (n = 6)** | | **88** | **13.2** |
| barley straw | 0.01 | 76; 77; 86 | 80 | 6.9 | 0.01 |
| 0.10 | 81; 87 | 84 | - |
| 0.60 | 81; 94 | 88 | - |
| **Overall recovery (n = 7)** | | **83** | **7.6** |
| prothioconazole-5-hydroxy desthio | 13-2137 | barley grain | 0.01 | 87 ; 87 | 87 | - | 0.01 |
| 0.10 | 85 ; 91 | 88 | - |
| **Overall Recovery (n = 4)** | | **88** | **2.9** |
| barley green material | 0.01 | 79 ; 81 ; 92 | 84 | 8.3 | 0.01 |
| 0.10 | 78 ; 85 | 82 | - |
| **Overall Recovery (n = 5)** | | **83** | **6.9** |
| barley straw | 0.01 | 82 ; 85 | 84 | - | 0.01 |
| 0.20 | 85 ; 86 ; 91 ; 97 | 90 | 6.1 |
| **Overall Recovery (n = 6)** | | **88** | **6.2** |

RSD = Relative Standard Deviation, LOQ = Practical Limit of Quantification

Fortified with prothioconazole-5-hydroxy-desthio, determined as prothioconazole-5-hydroxy-desthio and calculated as prothioconazole-desthio

**Table A 39: 13-2158 and 13-2137: Concurrent recoveries for the determination of prothioconazole-6-hydroxy-desthio in barley**

| **Analyte** | **Study** | **Sample Material** | **Fortification level [mg/kg]** | **Recovery rates [%]** | | **RSD [%]** | **LOQ [mg/kg]** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Single Values** | **Mean** |
| prothioconazole-6-hydroxy-desthio | 13-2158 | barley grain | 0.01 | 115; 118 | 117\* | - | 0.01 |
| 0.10 | 87; 92 | 90 | - |
| **Overall recovery (n = 4)** | | **103** | **15.3** |
| barley green material | 0.01 | 73; 79 | 76 | - | 0.01 |
| 0.10 | 88; 89 | 89 | - |
| 0.30 | 85; 91 | 88 | - |
| **Overall recovery (n = 6)** | | **84** | **8.2** |
| barley straw | 0.01 | 70; 77; 78; 83 | 77 | 7.0 | 0.01 |
| 0.10 | 78; 84 | 81 | - |
| 0.60 | 86; 95 | 91 | - |
| **Overall recovery (n = 8)** | | **81** | **9.1** |
| prothioconazole-6-hydroxy-desthio | 13-2137 | barley grain | 0.01 | 90 ; 92 | 91 | - | 0.01 |
| 0.10 | 83 ; 88 | 86 | - |
| **Overall Recovery (n = 4)** | | **88** | **4.4** |
| barley green material | 0.01 | 93 ; 101 ; 109 | 101 | 7.9 | 0.01 |
| 0.10 | 87 ; 93 | 90 | - |
| **Overall Recovery (n = 5)** | | **97** | **8.8** |
| barley straw | 0.01 | 87 ; 87 | 87 | - | 0.01 |
| 0.20 | 90 ; 93 ; 93 ; 96 | 93 | 2.6 |
| **Overall Recovery (n = 6)** | | **91** | **4.0** |

RSD = Relative Standard Deviation, LOQ = Practical Limit of Quantification

Fortified with prothioconazole-6-hydroxy-desthio, determined as prothioconazole-6-hydroxy-desthio and calculated as prothioconazole-desthio \* : This value was accepted due to a RSD below 20% and an overall mean value in the range of 70-110%

- Residue results:

The residue results are summarised in the tables hereafter.

In the 4 trials conducted in 2013 (reports 13-2137 and 13-2158), residues of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio in barley grain at harvest were < 0.01 mg/kg. In grain at harvest, the total residue was always <0.06 mg/kg except for trial 13-2137-02 where the total residue reached 0.061 mg/kg.

In straw, the residues at harvest ranged as follows:

* between 0.036 mg/kg and 0.81 mg/kg for prothioconazole-desthio
* between < 0.01 mg/kg and 0.023 mg/kg for prothioconazole-alpha-hydroxy
* between 0.020 mg/kg and 0.55 mg/kg for prothioconazole-3-hydroxy-desthio
* between <0.01 mg/kg and 0.55 mg/kg for prothioconazole-4-hydroxy-desthio
* between <0.01 mg/kg and 0.23 mg/kg for prothioconazole-5-hydroxy-desthio
* between < 0.01 mg/kg and 0.042 mg/kg mg/kg for prothioconazole-6-hydroxy-desthio
* between 0.10 mg/kg and 2.2 mg/kg for total residue calc.

Conclusion

Four barley residue trials were conducted with Fluoxastrobin & Prothioconazole EC 200 in northern Europe. The product application corresponded to a prothioconazole rate of 2x125 g a.s./ha with the exception of trial 13-2158-02 where the two applications were overdosed by 6.3% and 8.3%, respectively.

Residues of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio in barley grain at harvest were < 0.01 mg/kg. In grain at harvest, the total residue was always <0.06 mg/kg.

In straw, the residues at harvest ranged as follows:

* between 0.036 mg/kg and 0.81 mg/kg for prothioconazole-desthio
* between < 0.01 mg/kg and 0.023 mg/kg for prothioconazole-alpha-hydroxy
* between 0.020 mg/kg and 0.55 mg/kg for prothioconazole-3-hydroxy-desthio
* between <0.01 mg/kg and 0.55 mg/kg for prothioconazole-4-hydroxy-desthio
* between <0.01 mg/kg and 0.23 mg/kg for prothioconazole-5-hydroxy-desthio
* between < 0.01 mg/kg and 0.042 mg/kg mg/kg for prothioconazole-6-hydroxy-desthio
* between 0.10 mg/kg and 2.2 mg/kg for total residue calc.

Table A 40: Summary of the 13-2137 trials

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study Trial No. GLP  Year** | **Crop Variety** | **Country** | Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting | **Application** | | | | | | **Residues (mg/kg)** | | | | | | | | |
| **FL** | **No** | **kg/ha  (a.s.)** | **kg/hL (a.s.)** | **GS** | **Dates of treatment or no. of treatments and last date** | **Portion analysed** | **DALT (days)** | **PTZ-desthio** | **PTZ-alpha-hydroxy-desthio** | **PTZ-3-hydroxy-desthio** | **PTZ-4-hydroxy-desthio** | **PTZ-5-hydroxy-desthio** | **PTZ-6-hydroxy-desthio** | **Total (PTZ-desthio+hydroxy =RD-RA1)\*** |
| 13-2137 13-2137-01  GLP: yes  2013 | Barley, spring  Conchita | Germany 51399 Burscheid Europe, North | 1) 28.03.2013  2) 14.06.2013  - 21.06.2013  3) 15.08.2013  - 31.08.2013  1) 28.03.2013  2) 14.06.2013  - 21.06.2013  3) 15.08.2013  - 31.08.2013 | 200 EC | 2 | 0.125 | 0.042 | 61 | 1)31/05/13  2)14/06/13 | green material | 0(1) 0 7 14 21 28 35 | 0.27 0.94 0.88 0.42 0.15 0.067 0.049 | <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 | 0.023 0.032 0.062 0.093 0.084 0.074 0.079 | 0.032 0.044 0.075 0.091 0.080 0.066 0.064 | 0.018 0.024 0.044 0.059 0.053 0.039 0.038 | <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 | 0.36 1.1 1.1 0.68 0.39 0.27 0.25 |
| grain | 35 69 | <0.01 <0.01 | <0.01 <0.01 | <0.01 <0.01 | <0.01 <0.01 | <0.01 <0.01 | <0.01 <0.01 | <0.06 <0.06 |
| straw | 35 69 | 0.087 0.036 | <0.01 <0.01 | 0.14 0.029 | 0.12 0.030 | 0.067 0.020 | <0.01 <0.01 | 0.43 0.14 |
| 13-2137 13-2137-02  GLP: yes  2013 | Barley, spring  Grace | Germany 49377 Langförden Europe, North | 1) 09.04.2013  2) 17.06.2013  - 22.06.2013  3) 15.08.2013  - 25.08.2013 | 200 EC | 2 | 0.125 | 0.031-0.042 | 61 | 1)12/06/13  2)18/06/13 | green material | 0(1) 0 7 14 21 28 42 | 0.50 1.1 0.47 0.22 0.098 0.067 0.041 | <0.01 <0.01 0.010 0.013 0.013 0.011 <0.01 | 0.023 0.026 0.070 0.080 0.092 0.078 0.038 | 0.010 0.012 0.025 0.027 0.028 0.025 0.012 | 0.013 0.013 0.030 0.032 0.029 0.024 0.013 | <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 | 0.57 1.2 0.62 0.38 0.27 0.22 0.12 |
| grain | 68 | 0.011 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | 0.061 |
| straw | 68 | 0.044 | <0.01 | 0.020 | <0.01 | <0.01 | <0.01 | 0.10 |

(1): before last treatment \* for the sum, values <0.01 mg/kg were considered to be equal to 0.01 mg/kg, unless all the values were <0.01 mg/kg.  
Residues for PTZ-desthio were determined as PTZ-desthio and calculated as PTZ-desthio

Residues for PTZ-alpha-hydroxy-desthio were determined as PTZ-alpha-hydroxy-desthio and calculated as PTZ-desthio

Residues for PTZ-3-hydroxy-desthio were determined as PTZ-3-hydroxy-desthio and calculated as PTZ-desthio

Residues for PTZ-4-hydroxy-desthio were determined as PTZ-4-hydroxy-desthio and calculated as PTZ-desthio

Residues for PTZ-5-hydroxy-desthio were determined as PTZ-5-hydroxy-desthio and calculated as PTZ-desthio

Residues for PTZ-6-hydroxy-desthio were determined as PTZ-6-hydroxy-desthio and calculated as PTZ-desthio

Table A 41: Summary of the 13-2158 trials

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study Trial No.**  **GLP  Year** | **Crop Variety** | **Country** | Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting | **Application** | | | | | | **Residues (mg/kg)** | | | | | | | | |
| **FL** | **No** | **kg/ha  (a.s.)** | **kg/hL (a.s.)** | **GS** | **Dates of treatment or no. of treatments and last date** | **Portion analysed** | **DALT (days)** | **PTZ-desthio** | **PTZ-alpha-hydroxy-desthio** | **PTZ-3-hydroxy-desthio** | **PTZ-4-hydroxy-desthio** | **PTZ-5-hydroxy-desthio** | **PTZ-6-hydroxy-desthio** | **Total (PTZ-desthio+hydroxy=RD-RA1)\*** |
| 13-2158 13-2158-01  GLP: yes  2013 | Barley  Esterel | France 71150 Fontaines Europe, North | 1) 02.10.2012  3) 09.07.2013 | 200 EC | 2 | 0.125 | 0.063 | 61 | 1)07/05/13  2)27/06/13 | green material | 0(1) 0 7 14 21 28 31 | 0.17 1.5 0.46 0.14 0.078 0.067 0.079 | <0.01 <0.01 0.012 <0.01 <0.01 <0.01 <0.01 | 0.051 0.056 0.076 0.080 0.088 0.057 0.067 | 0.047 0.049 0.068 0.065 0.074 0.046 0.057 | 0.044 0.044 0.065 0.059 0.058 0.039 0.048 | <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 | 0.33 1.7 0.69 0.36 0.32 0.23 0.27 |
| grain | 35 43 | <0.01 <0.01 | <0.01 <0.01 | <0.01 <0.01 | <0.01 <0.01 | <0.01 <0.01 | <0.01 <0.01 | <0.06 <0.06 |
| straw | 35 43 | 0.039 0.15 | <0.01 <0.01 | 0.051 0.11 | 0.036 0.083 | 0.034 0.092 | <0.01 <0.01 | 0.18 0.46 |
| 13-2158 13-2158-02  GLP: yes  2013 | Barley, spring  Sébastian | France 71570 La Chapelle de Guinchay Europe, North | 1) 21.02.2013  3) 23.07.2013 | 200  EC | 2 | 0.133-0.135 | 0.062-0.063 | 61 | 1)03/06/13  2)18/06/13 | green material | 0(1) 0 7 14 21 17 | 0.33 0.89 0.72 0.49 0.40 0.44 | <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 | 0.11 0.13 0.17 0.16 0.15 0.16 | 0.15 0.16 0.21 0.20 0.16 0.17 | 0.078 0.091 0.10 0.082 0.065 0.077 | <0.01 <0.01 <0.01 0.010 0.010 <0.01 | 0.69 1.3 1.2 0.95 0.80 0.87 |
| grain | 35 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.06 |
| straw | 35 | 0.81 | 0.023 | 0.55 | 0.55 | 0.23 | 0.042 | 2.2 |

(1): before last treatment \* for the sum, values <0.01 mg/kg were considered to be equal to 0.01 mg/kg, unless all the values were <0.01 mg/kg.  
Residues for PTZ-desthio were determined as PTZ-desthio and calculated as PTZ-desthio

Residues for PTZ-alpha-hydroxy-desthio were determined as PTZ-alpha-hydroxy-desthio and calculated as PTZ-desthio

Residues for PTZ-3-hydroxy-desthio were determined as PTZ-3-hydroxy-desthio and calculated as PTZ-desthio

Residues for PTZ-4-hydroxy-desthio were determined as PTZ-4-hydroxy-desthio and calculated as PTZ-desthio

Residues for PTZ-5-hydroxy-desthio were determined as PTZ-5-hydroxy-desthio and calculated as PTZ-desthio

Residues for PTZ-6-hydroxy-desthio were determined as PTZ-6-hydroxy-desthio and calculated as PTZ-desthio

* + - * 1. Study 17-2076 – NEU + SEU

|  |  |
| --- | --- |
| Comments of zRMS: | It should be noted that the study of Meklat, Kerkering, Effertz (17-2076) is currently under review in the EU approval renewal process for prothioconazole.  The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for CA3301/ Joust (January 2023). This study has not been reassessed in the framework of this application.  The conclusions of the assessment are presented below:  *Two residue trials on spring and winter barley were conducted in northern Europe to determine residue of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio and TDMs.*  *Barley was treated twice at application rate of 0.140 kg a.s./ha of prothioconazole with 6-20 days interval between applications. The time of application was*  *1. at BBCH 32-49,*  *2. at BBCH 51-61.*  *Samples were taken at harvest.*  *Analytical method for determination of prothioconazole-desthio - method 01013.*  *Analytical method for determination of prothioconazole -alpha-hydroxy-desthio, -3-hydroxy-desthio, -4-hydroxy-desthio, -5-hydroxy-desthio and -6-hydroxy-desthio – method 00979/M02.*  *The residues of 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in/on plant material were analysed according to the method 01062/M004.*  *Limit of quantitation of 0.01 mg/kg for grain, green material and straw.*  *Mean recoveries in acceptable range (70 - 110%), RSD <20%.*  *Maximum storage period – 15 months.*  *Residues of prothioconazole-desthio and hydroxy- derivatives of prothioconazole-desthio, in barley grain at harvest were <0.01 mg/kg. In grain at harvest, the total residue was always <0.06 mg/kg.*  *Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in straw at harvest ranged between <0.06 mg/kg and 2.44 mg/kg.*  *TDMs*  *Residues of 1,2,4-triazole and of triazole lactic acid in barley grain at harvest were < 0.01 mg/kg.*  *Residues of triazole alanine in barley grain at harvest ranged between 0.052 and 0.13 mg/kg.*  *Residues of triazole acetic acid in barley grain at harvest ranged between 0.024 and 0.078 mg/kg.*  *The study is acceptable.* |

|  |  |
| --- | --- |
| Reference: | KCA 6.3.1/04 |
| Report | Determination of the residues of prothioconazole, spiroxamine and trifloxystrobin in/on barley after spray application of PTZ & SPX & TFS EC 280.3 in the Netherlands, Belgium, southern France and Italy  Meklat, N.; Kerkering, S.; Effertz, C., 28.11.2018  Report No: M-641462-01-1  Reference No: 17-2076 |
| Guideline(s): | Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market  OECD Guideline for the Testing of Chemicals on Crop Field Trial  (TG 509 published in September 2009)  US EPA OCSPP 860.1500, Crop Field Trial |
| Deviations: | None |
| GLP: | Yes |
| Owner: | Bayer CropScience AG (Nufarm has a letter of access) |
| Acceptability: | Yes |

The following study is currently under review in the EU approval renewal process for prothioconazole.

Materials and Methods

Four field trials were conducted in/on winter and spring barley during the 2017 growing season. The trials were located in the Netherlands, Belgium, Italy and southern France).

In each trial the emulsifiable concentrate (EC) formulation was applied twice at a nominal rate of prothioconazole of 140 g a.s./ha. The applications were carried out at the growth stages BBCH 32-49 and BBCH 51-61, respectively, using 250-400 L/ha of water. The spray intervals ranged between 7 and 21 days.

Samples of green material were taken for analysis on the day of the last application (day 0) while samples of grain and straw were taken at harvest.

Residues of prothioconazole-desthio were determined according to method 01013 with a limit of quantitation of 0.01 mg/kg for grain, green material and straw. Residues of prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio were determined according to method 00979/M002 with a limit of quantitation of 0.01 mg/kg for grain, green material and straw.

The residues of 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in/on plant material were analysed according to the method 01062/M004.

Findings

- Storage stability:

The maximum storage periods for prothioconazole-desthio and TDMs in barley samples from the supplementary residue field trials are presented in the table below.

Table A 42: Maximum storage periods of field samples from supplementary residue trials

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Crop | Substance | Sample Material | Storage period (days) | Storage period (months) |
| Barley | prothioconazole-desthio | grain | 422 | 14.1 |
| green material | 449 | 15.0 |
| straw | 413 | 13.8 |
| prothioconazole-alpha-hydroxy-desthio  prothioconazole-3-hydroxy-desthio  prothioconazole-4-hydroxy-desthio  prothioconazole-5-hydroxy-desthio  prothioconazole-6-hydroxy-desthio | grain | 400 | 13.3 |
| green material | 440 | 14.7 |
| straw | 411 | 13.7 |
| TAA; 1,2,4-T, TA | grain | 386 | 12.9 |
| green material | 426 | 14.2 |
| straw | 384 | 12.8 |

\* the storage stability of TLA was not investigated in straw, but there is no need, as its stability has been shown for 48 months in representative commodities covering the five categories described in the OECD guideline 506 for the testing of chemicals.

Sample extracts were measured within 24 hours, or if not, acceptable recoveries measured concurrently with each set of samples ensured integrity of the sample extracts during the period of time between extraction and analysis.

No residue above the LOQ was found in the control samples, with the following exceptions:

-triazole alanine: green material: 17-2076-01-0009E (0.019 mg/kg)

grain: 17-2076-01-0023E (0.020 mg/kg)

17-2076-02-0023E (0.010 mg/kg)

17-2076-03-0023E (0.016 mg/kg)

straw: 17-2076-01-0024E (0.017 mg/kg)

-triazole acetic acid: green material: 17-2076-01-0009E (0.010 mg/kg)

grain: 17-2076-01-0023E (0.019 mg/kg)

17-2076-03-0023E (0.012 mg/kg)

straw: 17-2076-01-0024E (0.023 mg/kg)

-triazole lactic acid: green material: 17-2076-01-0009E (0.022 mg/kg)

straw: 17-2076-01-0011E (0.014 mg/kg)

The significant number of control samples showing residues of the triazole derived metabolites is due to the ubiquitous nature of these compounds.

- Method performance:

The apparent residues in the control samples used for the performance of recoveries were below 30% of the LOQ, with some exceptions. Due to the presence of apparent residues at relevant levels in the control samples used for fortification, some of the recoveries for triazole alanine, triazole acetic acid, and triazole lactic acid had to be background corrected. Whenever this is the case both the uncorrected and the corrected recoveries are presented in the result tables. The average recoveries per fortification level were within the range of 70 – 110%.

Remark: For some recovery samples the actual fortification levels (FL) are slightly below the nominal FL of 0.01 mg/kg. To facilitate the calculation of the mean recovery and RSD values, recoveries at 0.009 mg/kg and at 0.01 mg/kg were combined. Note that the calculation of the recovery values is always based on the actual fortification.

Table A 43: 17-2076: Concurrent recoveries for the determination of prothioconazole-desthio in barley

| **Analyte** | **Sample Material** | **Fortification level [mg/kg]** | **Recovery rates [%]** | | **RSD [%]** | **LOQ [mg/kg]** |
| --- | --- | --- | --- | --- | --- | --- |
| **Single Values** | **Mean** |
| Prothio-conazole-desthio | Barley green material | 0.01 | 98, 110, 112 | 107 | 7.1 | 0.01 |
| 0.10 | 103, 105, 107 | 105 | 1.9 |
| 2.5 | 109, 110 | 110 | - |
| **Overall Recovery (n = 8)** | | **107** | **4.3** |
| Barley grain | 0.01 | 90, 93, 98, 102 | 96 | 5.6 | 0.01 |
| 0.10 | 100, 101, 102 | 101 | 1.0 |
| **Overall Recovery (n = 7)** | | **98** | **4.8** |
| Barley straw | 0.01 | 102, 105, 107 | 105 | 2.4 | 0.01 |
| 0.10 | 106, 106, 112 | 108 | 3.2 |
| 2.0 | 109, 111 | 110 | - |
| **Overall Recovery (n = 8)** | | **107** | **3.1** |

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with JAU 6476-desthio, determined as JAU 6476-desthio and calculated as JAU 6476-desthio

Table A 44: 17-2076: Concurrent recoveries for the determination of alpha-hydroxy-prothioconazole-desthio in barley

| Analyte | Sample Material | Fortification level [mg/kg] | Recovery rates [%] | | RSD [%] | LOQ [mg/kg] |
| --- | --- | --- | --- | --- | --- | --- |
| Single Values | Mean |
| Alpha-hydroxy-prothio-conazole-desthio | Barley green material | 0.009 / 0.01 | 94, 102\*, 103 | 100 | 4.9 | 0.01 |
| 0.10 | 104, 105, 107 | 105 | 1.5 |
| **Overall Recovery (n = 6)** | | **103** | **4.4** |
| Barley grain | 0.01 | 95, 99, 99 | 98 | 2.4 | 0.01 |
| 0.10 | 91, 91, 101 | 94 | 6.1 |
| **Overall Recovery (n = 6)** | | **96** | **4.5** |
| Barley straw | 0.01 | 106, 109, 110 | 108 | 1.9 | 0.01 |
| 0.10 | 106, 107, 113 | 109 | 3.5 |
| 0.30 | 101, 104 | 103 | - |
| 1.0 | 96, 101 | 99 | - |
| **Overall Recovery (n = 10)** | | **105** | **4.7** |

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with JAU 6476-alpha-hydroxy-desthio, determined as JAU 6476-alpha-hydroxy-desthio and calculated as JAU 6476-desthio, \* the Fortification Level for this value is 0.009 mg/kg

**Table A 45: 17-2076: Concurrent recoveries for the determination of 3-hydroxy-prothioconazole-desthio in barley**

| Analyte | Sample Material | Fortification level [mg/kg] | Recovery rates [%] | | RSD [%] | LOQ [mg/kg] |
| --- | --- | --- | --- | --- | --- | --- |
| Single Values | Mean |
| 3-hydroxy-prothio-conazole-desthio | Barley green material | 0.009 / 0.01 | 96, 104\*, 105 | 102 | 4.9 | 0.01 |
| 0.10 | 99, 101, 102 | 101 | 1.5 |
| **Overall Recovery (n = 6)** | | **101** | **3.3** |
| Barley grain | 0.01 | 92, 92, 96 | 93 | 2.5 | 0.01 |
| 0.10 | 85, 86, 93 | 88 | 5.0 |
| **Overall Recovery (n = 6)** | | **91** | **4.7** |
| Barley straw | 0.01 | 104, 105, 105 | 105 | 0.6 | 0.01 |
| 0.10 | 98, 98, 101 | 99 | 1.7 |
| 0.30 | 96, 97 | 97 | - |
| 1.0 | 92, 96 | 94 | - |
| **Overall Recovery (n = 10)** | | **99** | **4.4** |

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with JAU 6476-3-hydroxy-desthio, determined as JAU 6476-3-hydroxy-desthio and calculated as JAU 6476-desthio, \* the Fortification Level for this value is 0.009 mg/kg

Table A 46: 17-2076: Concurrent recoveries for the determination of 4-hydroxy-prothioconazole-desthio in barley

| Analyte | Sample Material | Fortification level [mg/kg] | Recovery rates [%] | | RSD [%] | LOQ [mg/kg] |
| --- | --- | --- | --- | --- | --- | --- |
| Single Values | Mean |
| 4-hydroxy-prothio-conazole-desthio | Barley green material | 0.009 / 0.01 | 93, 97\*, 97 | 96 | 2.4 | 0.01 |
| 0.10 | 96, 98, 99 | 98 | 1.6 |
| **Overall Recovery (n = 6)** | | **97** | **2.1** |
| Barley grain | 0.01 | 90, 94, 94 | 93 | 2.5 | 0.01 |
| 0.10 | 87, 87, 97 | 90 | 6.4 |
| **Overall Recovery (n = 6)** | | **92** | **4.5** |
| Barley straw | 0.01 | 100, 102, 102 | 101 | 1.1 | 0.01 |
| 0.10 | 100, 102, 103 | 102 | 1.5 |
| 0.30 | 97, 102 | 100 | - |
| 1.0 | 87, 87 | 87 | - |
| **Overall Recovery (n = 10)** | | **98** | **6.3** |

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with JAU 6476-4-hydroxy-desthio, determined as JAU 6476-4-hydroxy-desthio and calculated as JAU 6476-desthio, \* the Fortification Level for this value is 0.009 mg/kg

Table A 47: 17-2076: Concurrent recoveries for the determination of 5-hydroxy-prothioconazole-desthio in barley

| Analyte | Sample Material | Fortification level [mg/kg] | Recovery rates [%] | | RSD [%] | LOQ [mg/kg] |
| --- | --- | --- | --- | --- | --- | --- |
| Single Values | Mean |
| 5-hydroxy-prothio-conazole-desthio | Barley green material | 0.009 / 0.01 | 93, 98\*, 103 | 98 | 5.1 | 0.01 |
| 0.10 | 98, 102, 105 | 102 | 3.5 |
| **Overall Recovery (n = 6)** | | **100** | **4.4** |
| Barley grain | 0.01 | 91, 92, 95 | 93 | 2.2 | 0.01 |
| 0.10 | 88, 91, 97 | 92 | 5.0 |
| **Overall Recovery (n = 6)** | | **92** | **3.5** |
| Barley straw | 0.01 | 103, 109, 110 | 107 | 3.5 | 0.01 |
| 0.10 | 103, 106, 107 | 105 | 2.0 |
| 0.30 | 100, 101 | 101 | - |
| 1.0 | 93, 95 | 94 | - |
| **Overall Recovery (n = 10)** | | **103** | **5.5** |

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with JAU 6476-5-hydroxy-desthio, determined as JAU 6476-5-hydroxy-desthio and calculated as JAU 6476-desthio, \* the Fortification Level for this value is 0.009 mg/kg

Table A 48: 17-2076: Concurrent recoveries for the determination of 6-hydroxy-prothioconazole-desthio in barley

| Analyte | Sample Material | Fortification level [mg/kg] | Recovery rates [%] | | RSD [%] | LOQ [mg/kg] |
| --- | --- | --- | --- | --- | --- | --- |
| Single Values | Mean |
| Alpha-hydroxy-prothio-conazole-desthio | Barley green material | 0.009 / 0.01 | 97\*, 99, 102 | 99 | 2.5 | 0.01 |
| 0.10 | 101, 103, 105 | 103 | 1.9 |
| **Overall Recovery (n = 6)** | | **101** | **2.8** |
| Barley grain | 0.01 | 90, 93, 93 | 92 | 1.9 | 0.01 |
| 0.10 | 93, 94, 99 | 95 | 3.4 |
| **Overall Recovery (n = 6)** | | **94** | **3.1** |
| Barley straw | 0.01 | 102, 105, 105 | 104 | 1.7 | 0.01 |
| 0.10 | 104, 105, 107 | 105 | 1.5 |
| 0.30 | 97, 104 | 101 | - |
| 1.0 | 85, 86 | 86 | - |
| **Overall Recovery (n = 10)** | | **100** | **8.1** |

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with JAU 6476-6-hydroxy-desthio, determined as JAU 6476-6-hydroxy-desthio and calculated as JAU 6476-desthio

\* the Fortification Level for this value is 0.009 mg/kg

Table A 49: 17-2076: Concurrent recoveries for the determination of 1, 2, 4-Triazole in barley

| Analyte | Sample Material | Fortification level [mg/kg] | Recovery rates [%] | | RSD [%] | LOQ [mg/kg] |
| --- | --- | --- | --- | --- | --- | --- |
| Single Values | Mean |
| 1, 2,4-T | Barley green material | 0.01 | 90, 94, 109 | 98 | 10.3 | 0.01 |
| 0.10 | 101, 112, 118 | 110 | 7.8 |
| **Overall Recovery (n = 6)** | | **104** | **10.4** |
| Barley green material | 0.01 | 86, 94, 100 | 93 | 7.5 | 0.01 |
| 0.10 | 83, 91, 108, 111 | 98 | 13.7 |
| **Overall Recovery (n = 7)** | | **96** | **11.1** |
| Barley straw | 0.01 | 93, 104, 111 | 103 | 8.8 | 0.01 |
| 0.10 | 96, 104, 106 | 102 | 5.2 |
| **Overall Recovery (n = 6)** | | **102** | **6.5** |

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with 1,2,4-triazole, determined as 1,2,4-triazole and calculated as 1,2,4-triazole

Table A 50: 17-2076: Concurrent recoveries for the determination of Triazole Alanine in barley

| Analyte | Sample Material | Fortification level [mg/kg] | Recovery rates [%] | | RSD [%] | LOQ [mg/kg] |
| --- | --- | --- | --- | --- | --- | --- |
| Single Values | Mean |
| TA | Barley green material | 0.01 | 97, 108, 119 | 108 | 10.2 | 0.01 |
| 0.10 | 81, 88, 94 | 88 | 7.4 |
| **Overall Recovery (n = 6)** | | **98** | **14.1** |
| Barley green material | 0.01 | 70 (90)a, 81 (102)a, 93 (113)a | 81 | 14.1 | 0.01 |
| 0.10 | 91, 98, 104 (105)b, 111, 114, 119 (120)a | 106 | 9.9 |
| **Overall Recovery (n = 9)** | | **98** | **16.3** |
| Barley straw | 0.01 | 86, 88, 102 | 92 | 9.5 | 0.01 |
| 0.10 | 82, 92, 95 | 90 | 7.6 |
| **Overall Recovery (n = 6)** | | **91** | **7.8** |

RSD = Relative standard deviation, LOQ = Practical limit of quantification.

a These recoveries were background-corrected since the control sample used for spiking (17-2076-04-0023E) was found to contain (apparent) residues at a level of 0.00203 mg/kg. The uncorrected recovery is shown in brackets.

b These recoveries were background-corrected since the control sample used for spiking (17-2076-04-0023E) was found to contain (apparent) residues at a level of 0.00160 mg/kg. The uncorrected recovery is shown in brackets.

Fortified with triazole alanine, determined as triazole alanine and calculated as triazole alanine

Table A 51: 17-2076: Concurrent recoveries for the determination of Triazole Acetic Acid in barley

| Analyte | Sample Material | Fortification level [mg/kg] | Recovery rates [%] | | RSD [%] | LOQ [mg/kg] |
| --- | --- | --- | --- | --- | --- | --- |
| Single Values | Mean |
| TAA | Barley green material | 0.01 | 88, 96, 98 | 94 | 5.6 | 0.01 |
| 0.10 | 76, 82, 93 | 84 | 10.3 |
| **Overall Recovery (n = 6)** | | **89** | **9.6** |
| Barley green material | 0.01 | 85, 86, 95 | 89 | 6.2 | 0.01 |
| 0.10 | 93, 103, 105 | 100 | 6.4 |
| **Overall Recovery (n = 6)** | | **95** | **8.8** |
| Barley straw | 0.01 | 88, 99, 99 | 95 | 6.7 | 0.01 |
| 0.10 | 93, 100, 103 | 99 | 5.2 |
| **Overall Recovery (n = 6)** | | **97** | **5.6** |

RSD = Relative standard deviation, LOQ = Practical limit of quantification.

Fortified with triazole acetic acid, determined as triazole acetic acid and calculated as triazole acetic acid.

**Table A 52: 17-2076: Concurrent recoveries for the determination of Triazole Lactic acid in barley**

| Analyte | Sample Material | Fortification level [mg/kg] | Recovery rates [%] | | RSD [%] | LOQ [mg/kg] |
| --- | --- | --- | --- | --- | --- | --- |
| Single Values | Mean |
| TLA | Barley green material | 0.01 | 90, 96, 113 | 100 | 12.0 | 0.01 |
| 0.10 | 81, 91, 95 | 89 | 8.1 |
| **Overall Recovery (n = 6)** | | **94** | **11.2** |
| Barley green material | 0.01 | 68, 72, 80 | 73 | 8.3 | 0.01 |
| 0.10 | 77, 85, 104 | 89 | 15.6 |
| **Overall Recovery (n = 6)** | | **81** | **15.7** |
| Barley straw | 0.01 | 90 (103)a, 107 (120)a, 107 (120)a | 101 | 9.7 | 0.01 |
| 0.10 | 96 (98)a, 98 (99)a, 98 (100)a | 97 | 1.2 |
| **Overall Recovery (n = 6)** | | **99** | **6.7** |

RSD = Relative standard deviation, LOQ = Practical limit of quantification.

a These recoveries were background-corrected since the control sample used for spiking (17-2076-04-0024E) was found to contain (apparent) residues at a level of 0.00126 mg/kg.

The uncorrected recovery is shown in brackets. Fortified with triazole lactic acid, determined as triazole lactic acid and calculated as triazole lactic acid.

- Residue results:

The residue results are summarised in the tables in the following pages.

Conclusion

Four barley residue trials were conducted with Prothioconazole & Spiroxamine & Trifloxystrobin EC280.3 in northern and southern Europe. The product application corresponded to a prothioconazole rate of 2x140 g a.s./ha.

Residues of prothioconazole-desthio and hydroxy- derivatives of prothioconazole-desthio, in barley grain at harvest were <0.01 mg/kg.

Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in straw at harvest ranged between <0.06 mg/kg and 2.44 mg/kg.

The results for the TDMs are summarised in the table below.

Table A 53: 17-2076 - Residues of prothioconazole-desthio and metabolites in/on spring and winter barley applied with Prothioconazole & Spiroxamine & Trifloxystrobin EC280.3

| Study Trial No. Plot No.  GLP  Year | Crop Variety | Country | Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting | Application | | | | | | Residues (mg/kg) | | | | | | | |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FL | No | kg/ha  (a.s.) | kg/hL (a.s.) | GS | Dates of treatment / Application interval | Portion analysed | DALT (d) | JAU 6476-desthio | JAU 6476-alpha-OH-desthio | JAU 6476-3-OH-desthio | JAU 6476-4-OH-desthio | JAU 6476-5-OH-desthio | JAU 6476-6-OH-desthio | Total (PTZ-desthio+hydroxy =RD-RA1)\* |
| 17-2076MAN 17-2076-01  17-2076-01-T\*  GLP: yes  2017 | Barley  Kwsirina | Netherlands 1681 ND Zwaagdijk Europe, North | 1) 06.04.2017  2) 27.06.2017  - 11.07.2017  3) 10.08.2017  - 20.08.2017  1) 06.04.2017  2) 27.06.2017  - 11.07.2017  3) 10.08.2017  - 20.08.2017 | 280.3 EC | 2 | 0.140 | 0.0350 | 61 | 08.06.2017/0  27.06.2017/19 | green material | 0 | 0.71 | <0.01 | 0.030 | 0.035 | 0.013 | <0.01 | 0.81 |
| grain | 48 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.06 |
| straw | 48 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.06 |
| 17-2076MAN 17-2076-02  17-2076-02-T\*  GLP: yes  2017 | Barley  Milford | Belgium 6221 Saint-Amand Europe, North | 1) 16.03.2017  2) 02.06.2017  - 07.06.2017  3) 28.07.2017  - 07.08.2017 | 280.3 EC | 2 | 0.140 | 0.0560 | 61 | 26.05.2017/0  02.06.2017/7 | green material | 0 | 1.6 | <0.01 | 0.045 | 0.070 | 0.028 | <0.01 | 1.76 |
| grain | 56 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.06 |
| straw | 56 | 0.14 | <0.01 | 0.056 | 0.080 | 0.043 | <0.01 | 0.34 |
| 17-2076MAN 17-2076-03  17-2076-03-T\*  GLP: yes  2017 | Barley  Platine | France 13103 St Etienne du Gres Europe, South | 1) 15.12.2016  2) 03.05.2017  - 10.05.2017  3) 13.06.2017  - 20.06.2017 | 280.3 EC | 2 | 0.140 | 0.0467 | 61 | 12.04.2017/0  03.05.2017/21 | green material | 0 | 1.6 | <0.01 | 0.043 | 0.060 | 0.034 | <0.01 | 1.76 |
| grain | 43 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.06 |
| straw | 43 | 0.20 | 0.029 | 0.16 | 0.19 | 0.098 | 0.019 | 0.70 |
| 17-2076MAN 17-2076-04  17-2076-04-T\*  GLP: yes  2017 | Barley  Mercur | Italy 01016 Tarquinia (VT) Europe, South | 1) 12.12.2016  2) 26.04.2017  - 05.05.2017  3) 01.06.2017  - 30.06.2017 | 280.3 EC | 2 | 0.140 | 0.0467 | 61 | 05.04.2017/0  26.04.2017/21 | green material | 0 | 2.2 | <0.01 | 0.058 | 0.091 | 0.056 | <0.01 | 2.43 |
| grain | 42 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.06 |
| straw | 42 | 1.4 | 0.031 | 0.030 | 0.68 | 0.24 | 0.061 | 2.44 |

\* for the sum, values <0.01 mg/kg were considered to be equal to 0.01 mg/kg, unless all the values were <0.01 mg/kg.

Table A 54: 17-2076 - Residues of 1,2,4-T and TAA in/on spring and winter barley applied with Prothioconazole & Spiroxamine & Trifloxystrobin EC280.3

| Study Trial No. Plot No.  GLP  Year | Crop Variety | Country | Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting | Application | | | | | | Residues (mg/kg) | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FL | No | kg/ha  (a.s.) | kg/hL (a.s.) | GS | Dates of treatment / Application interval | Portion analysed | DALT (d) | 1,2,4,-T | TAA |
| 17-2076MAN 17-2076-01  17-2076-01-T\*  GLP: yes  2017 | Barley  Kwsirina | Netherlands 1681 ND Zwaagdijk Europe, North | 1) 06.04.2017  2) 27.06.2017  - 11.07.2017  3) 10.08.2017  - 20.08.2017  1) 06.04.2017  2) 27.06.2017  - 11.07.2017  3) 10.08.2017  - 20.08.2017 | 280.3 EC | 2 | 0.140 | 0.0350 | 61 | 08.06.2017/0  27.06.2017/19 | green material | 0 | <0.01 | 0.011/0.010\*\* |
| grain | 48 | <0.01 | 0.078/0.019\*\* |
| straw | 48 | <0.01 | 0.026/0.023\*\* |
| 17-2076MAN 17-2076-02  17-2076-02-T\*  GLP: yes  2017 | Barley  Milford | Belgium 6221 Saint-Amand Europe, North | 1) 16.03.2017  2) 02.06.2017  - 07.06.2017  3) 28.07.2017  - 07.08.2017 | 280.3 EC | 2 | 0.140 | 0.0560 | 61 | 26.05.2017/0  02.06.2017/7 | green material | 0 | <0.01 | <0.01 |
| grain | 56 | <0.01 | 0.024 |
| straw | 56 | <0.01 | 0.010 |
| 17-2076MAN 17-2076-03  17-2076-03-T\*  GLP: yes  2017 | Barley  Platine | France 13103 St Etienne du Gres Europe, South | 1) 15.12.2016  2) 03.05.2017  - 10.05.2017  3) 13.06.2017  - 20.06.2017 | 280.3 EC | 2 | 0.140 | 0.0467 | 61 | 12.04.2017/0  03.05.2017/21 | green material | 0 | <0.01 | <0.01 |
| grain | 43 | <0.01 | 0.077/0.012\*\* |
| straw | 43 | <0.01 | 0.017 |
| 17-2076MAN 17-2076-04  17-2076-04-T\*  GLP: yes  2017 | Barley  Mercur | Italy 01016 Tarquinia (VT) Europe, South | 1) 12.12.2016  2) 26.04.2017  - 05.05.2017  3) 01.06.2017  - 30.06.2017 | 280.3 EC | 2 | 0.140 | 0.0467 | 61 | 05.04.2017/0  26.04.2017/21 | green material | 0 | <0.01 | <0.01 |
| grain | 42 | <0.01 | 0.036 |
| straw | 42 | <0.01 | 0.014 |

\*\* residue in control.

Residues for 1,2,4-triazole (determined as 1,2,4-triazole and calculated as 1,2,4-triazole). Residues for triazole acetic acid (determined as triazole acetic acid and calculated as triazole acetic acid).

Table A 55: 17-2076 - Residues of TA and TLA in/on spring and winter barley applied with Prothioconazole & Spiroxamine & Trifloxystrobin EC280.3

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Study Trial No. Plot No.  GLP  Year | Crop Variety | Country | Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting | Application | | | | | | Residues (mg/kg) | | | |
| FL | No | kg/ha  (a.s.) | kg/hL (a.s.) | GS | Dates of treatment / Application interval | Portion analysed | DALT (d) | TA | TLA |
| 17-2076MAN 17-2076-01  17-2076-01-T\*  GLP: yes  2017 | Barley  Kwsirina | Netherlands 1681 ND Zwaagdijk Europe, North | 1) 06.04.2017  2) 27.06.2017  - 11.07.2017  3) 10.08.2017  - 20.08.2017  1) 06.04.2017  2) 27.06.2017  - 11.07.2017  3) 10.08.2017  - 20.08.2017 | 280.3 EC | 2 | 0.140 | 0.0350 | 61 | 08.06.2017/0  27.06.2017/19 | green material | 0 | 0.021/0.019\*\* | 0.022/0.022\*\* |
| grain | 48 | 0.13/0.020\*\* | <0.01 |
| straw | 48 | 0.030/0.017\*\* | 0.028/0.014\*\* |
| 17-2076MAN 17-2076-02  17-2076-02-T\*  GLP: yes  2017 | Barley  Milford | Belgium 6221 Saint-Amand Europe, North | 1) 16.03.2017  2) 02.06.2017  - 07.06.2017  3) 28.07.2017  - 07.08.2017 | 280.3 EC | 2 | 0.140 | 0.0560 | 61 | 26.05.2017/0  02.06.2017/7 | green material | 0 | 0.021 | 0.018 |
| grain | 56 | 0.052/0.010\*\* | <0.01 |
| straw | 56 | <0.01 | 0.013 |
| 17-2076MAN 17-2076-03  17-2076-03-T\*  GLP: yes  2017 | Barley  Platine | France 13103 St Etienne du Gres Europe, South | 1) 15.12.2016  2) 03.05.2017  - 10.05.2017  3) 13.06.2017  - 20.06.2017 | 280.3 EC | 2 | 0.140 | 0.0467 | 61 | 12.04.2017/0  03.05.2017/21 | green material | 0 | 0.026 | 0.019 |
| grain | 43 | 0.099/0.016\*\* | <0.01 |
| straw | 43 | <0.01 | 0.039 |
| 17-2076MAN 17-2076-04  17-2076-04-T\*  GLP: yes  2017 | Barley  Mercur | Italy 01016 Tarquinia (VT) Europe, South | 1) 12.12.2016  2) 26.04.2017  - 05.05.2017  3) 01.06.2017  - 30.06.2017 | 280.3 EC | 2 | 0.140 | 0.0467 | 61 | 05.04.2017/0  26.04.2017/21 | green material | 0 | 0.017 | 0.013 |
| grain | 42 | 0.041 | <0.01 |
| straw | 42 | <0.01 | 0.050 |

\*\* residue in control.

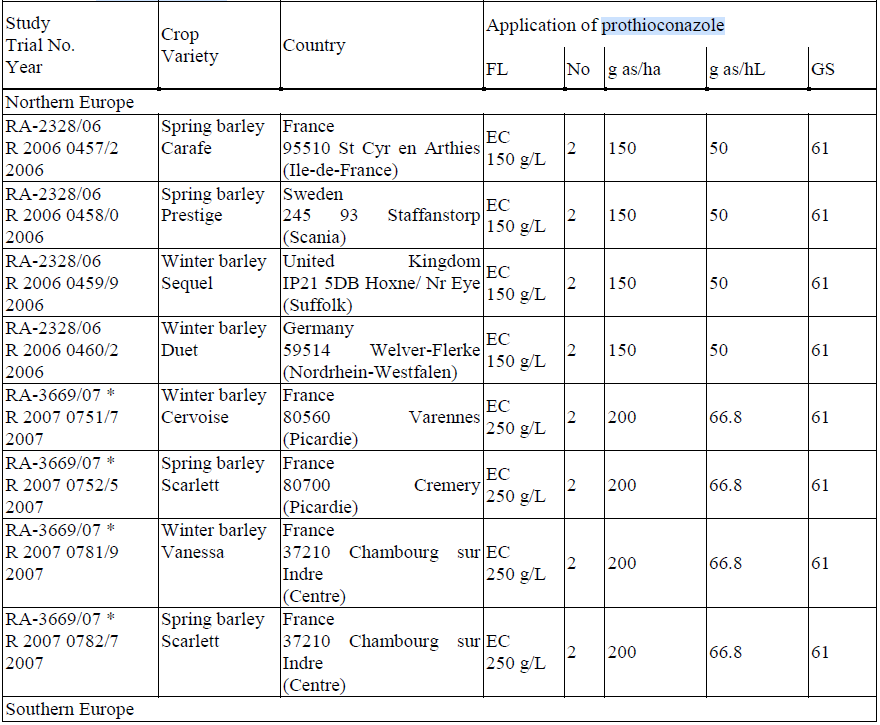
Residues for triazole alanine (determined as triazole alanine and calculated as triazole alanine). Residues for triazole lactic acid (determined as triazole lactic acid and calculated as triazole lactic acid).

* + - * 1. Barley residue trials analysing TDMs

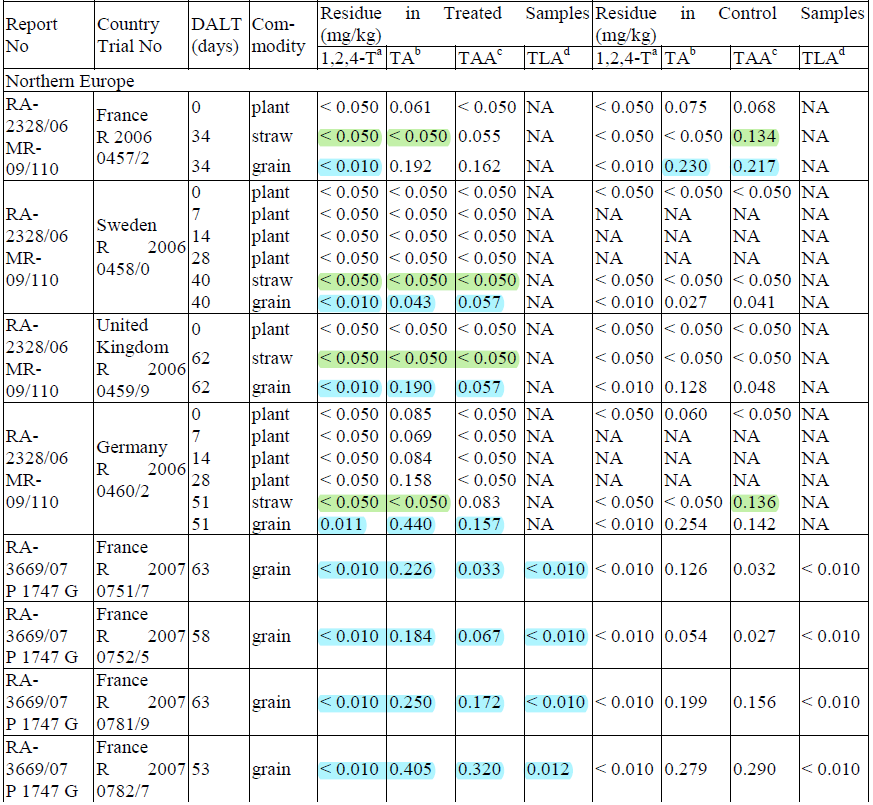
The following tables were extracted from the “Triazole Derivate Metabolites addendum – confirmatory data prepared by the rapporteur Member State, the United Kingdom” Appendix C (UK, 2018).

Only trials performed with prothioconazole were considered and presented hereafter.

**Table A 56: Application summary of residue trials conducted on barley with EC formulations containing prothioconazole**



**Table A 57: Results of residue trials conducted on barley with EC formulations containing prothioconazole**



DALT : Days after last treatment

NA : not analysed

In study MR-09/110:

a 1,2,4-T = Residues determined as 1,2,4-triazole derivative, calculated as 1,2,4-triazole.

b TA = Residues determined as triazole alanine derivative, calculated as triazole alanine.

c TAA = Residues determined as triazole acetic acid derivative, calculated as triazole acetic acid.

d TLA = Triazole lactic acid not analysed.

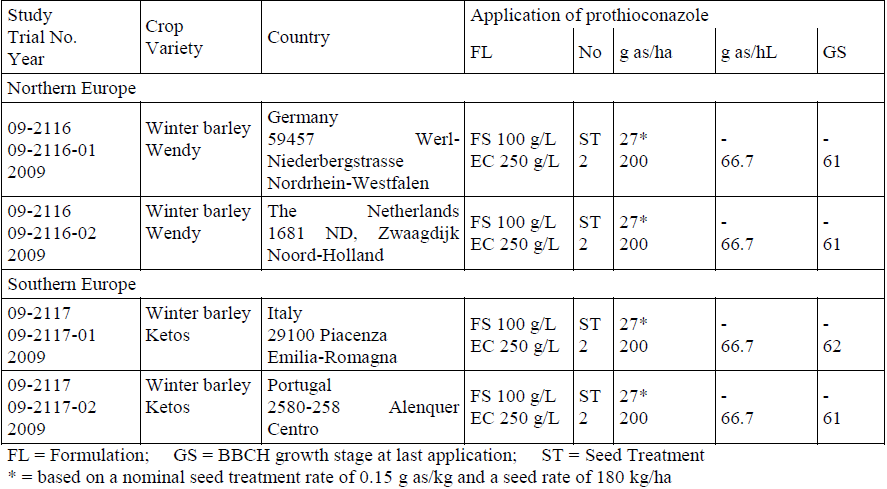
In study P 1747 G:

a 1,2,4-T = Residues determined and calculated as 1,2,4-triazole.

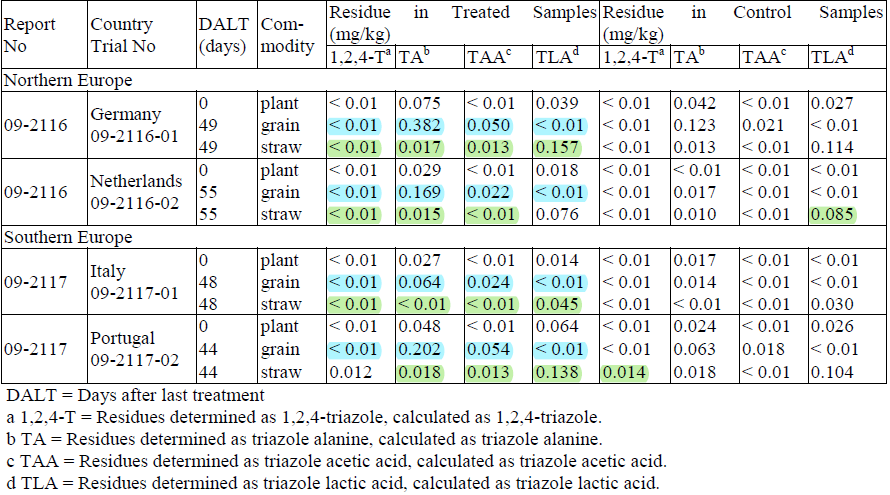
b TA = Residues determined and calculated as triazole alanine.

c TAA = Residues determined and calculated as triazole acetic acid.

d TLA = Residues determined and calculated as triazole lactic acid.

**Table A 58: Application summary of residue trials conducted in/on barley with an EC formulation containing 250 g/L of prothioconazole, after seed treatment with an FS formulation containing 100 g/L of prothioconazole**

**Table A 59: Results of residue trials conducted in/on barley with an EC formulation containing 250 g/L of prothioconazole, after seed treatment with an FS formulation containing 100 g/L of prothioconazole**



Une image contenant table

Description générée automatiquement

* + - 1. Wheat, Rye

Table A 60: Comparison of intended and critical EU GAPs – Wheat & Rye

| Type of GAP | Number of applica­tions | Application rate per treatment  (g a.s./ha) | Interval between application | Growth stage at last application | PHI (days) |
| --- | --- | --- | --- | --- | --- |
| cGAP NEU (DAR, UK, 2007) | 3 | 200 | 14-21 | BBCH 26-69 | 35 |
| cGAP NEU (Art. 12, EFSA, 2020) *Wheat & Rye* | 3 | 200 | 14-21 | BBCH 29-69 | 35 |
| Intended cGAP CEU | 2 | 210 | 14-21 | BBCH 30-69 | 35 |

* + - * 1. Study 17-2015 – NEU

|  |  |
| --- | --- |
| Comments of zRMS: | The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for CA3301/ Joust (January 2023). This study has not been reassessed in the framework of this application.  The conclusions of the assessment are presented below:  *Four residue trials on spring and winter wheat were conducted in northern Europe to determine residue of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio and the triazole-derived metabolites (1,2,4-triazole, triazole alanine, triazole acetic acid, triazole lactic acid).*  *Wheat was treated twice at application rate of 0.200 kg a.s./ha of prothioconazole with 21 day interval between applications. The time of application was:*  *1. at BBCH 45,*  *2. at BBCH 69.*  *Samples were taken at harvest.*  *Analytical method for determination of prothioconazole-desthio - method 01013.*  *Analytical method for determination of prothioconazole-alpha-hydroxy-desthio, -3-hydroxy-desthio, -4-hydroxy-desthio, -5-hydroxy-desthio and -6-hydroxy-desthio – method 00979/M02.*  *The residues of 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in/on plant material were analysed according to the method 01062/M004.*  *Limit of quantitation of 0.01 mg/kg for grain, green material and straw.*  *The average recoveries were within the acceptable range of 70 – 110%, except for prothioconazole-desthio (112%) in sample material wheat, green material at LOQ level. The RSD values were below 20%.*  *Maximum storage period – 524 days.*  *Residues of prothioconazole-desthio and hydroxy- derivatives of prothioconazole-desthio, in wheat grain at harvest were <0.01 mg/kg.*  *Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest were <0.06 mg/kg.*  *Residues of 1,2,4-triazole and triazole lactic acid, in wheat grain at harvest were <0.01 mg/kg.*  *Residues of triazole alanine, in wheat grain at harvest ranged between 0.21 and 0.65 mg/kg.*  *Residues of triazole acetic acid, in wheat grain at harvest ranged between 0.085 and 0.14 mg/kg.*  *The study is acceptable.* |

|  |  |
| --- | --- |
| Reference: | KCA 6.3.2/01 |
| Report | Determination of the residues of prothioconazole and spiroxamine in/on wheat after spray application of JAU 6476 & KWG 4168 EC 460 in Germany, northern France and the Netherlands  Meklat, N.; Kerkering, S., 24.05.2019  Report No: M-659920-01-1  Reference No: 17-2015 |
| Guideline(s): | Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market  OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)  US EPA OCSPP 860.1500, Crop Field Trial |
| Deviations: | None |
| GLP: | Yes |
| Owner: | Bayer CropScience AG (Nufarm has a letter of access) |
| Acceptability: | Yes |

**Text from Bayer: This study has never been submitted to any authority and therefore, no OECD summary is available. Nevertheless, all the relevant information is available / summarised in the following tables.**

Table A 61: GAP Summary of the 17-2015MAN trials

| Trial No. /  Location /  EU zone /  Year | Commodity /  Variety  (a) | Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting  (b) | Application rate per treatment | | | Dates of treatment / Application interval  (c) | Growth stage at last treatment  (d) | Details on trial  (f) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| g a.s./ha | Water (L/ha) | g a.s./hL |
| 17-2015-01 17-2015-01-T Germany 51399 Burscheid Europe, North 2017 | Wheat, winter  Potential | 1) 04.10.2016  2) 30.05.2017  - 06.06.2017  3) 15.07.2017  - 15.08.2017 | 200  200 | 300  300 | 66.7  66.7 | 17.05.2017/0  07.06.2017/21 | 69 | (g) 17-2015MAN(h) EC (prothioconazole 160 g/L ,spiroxamine 300 g/L) (i) Application method: Spraying |
| 17-2015-02 17-2015-02-T Germany 78166 Donaueschingen OT Aasen Europe, North 2017 | Wheat, spring  KWS Chamsin | 1) 28.03.2017  2) 01.07.2017  - 15.07.2017  3) 01.08.2017  - 19.08.2017 | 200  200 | 300  300 | 66.7  66.7 | 21.06.2017/0  12.07.2017/21 | 69 | (g) 17-2015MAN(h) EC (prothioconazole 160 g/L ,spiroxamine 300 g/L) (i) Application method: Spraying |
| 17-2015-03 17-2015-03-T France, north 37310 Chambourg sur Indre Europe, North 2017 | Wheat, winter  Venezio | 1) 12.10.2016  2) 17.05.2017  - 25.05.2017  3) 01.07.2017  - 15.07.2017 | 200  200 | 300  300 | 66.7  66.7 | 02.05.2017/0  23.05.2017/21 | 69 | (g) 17-2015MAN(h) EC (prothioconazole 160 g/L ,spiroxamine 300 g/L) (i) Application method: Spraying |
| 17-2015-04 17-2015-04-T Netherlands 1681 ND Zwaagdijk Europe, North 2017 | Wheat, spring  Tybalt | 1) 06.04.2017  2) 26.06.2017  - 06.07.2017  3) 10.08.2017  - 20.08.2017 | 200  200 | 400  400 | 50.0  50.0 | 15.06.2017/0  06.07.2017/21 | 69 | (g) 17-2015MAN(h) EC (prothioconazole 160 g/L ,spiroxamine 300 g/L) (i) Application method: Spraying |

Table A 62: Analytical part of the 17-2015MAN trials – Part 1

Analyte 1: JAU 6476-desthio (determined as JAU 6476-desthio, calculated as JAU 6476-desthio), Analyte 2: JAU 6476-4-hydroxy-desthio (determined as JAU 6476-4-hydroxy-desthio, calculated as JAU 6476-desthio), Analyte 3: JAU 6476-3-hydroxy-desthio (determined as JAU 6476-3-hydroxy-desthio, calculated as JAU 6476-desthio), Analyte 4: JAU 6476-alpha-hydroxy-desthio (determined as JAU 6476-alpha-hydroxy-desthio, calculated as JAU 6476-desthio), Analyte 5: JAU 6476-6-hydroxy-desthio (determined as JAU 6476-6-hydroxy-desthio, calculated as JAU 6476-desthio), Analyte 6: JAU 6476-5-hydroxy-desthio (determined as JAU 6476-5-hydroxy-desthio, calculated as JAU 6476-desthio)

| Trial No. /  Location /  EU zone /  Year | Commodity /  Variety  (a) | Portion analyzed | Growth stage at sampling  (d) | Residues (mg/kg) | | | | | |  | PHI (days)  (e) | Details on trial  (f) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Analyte 1 | Analyte 2 | Analyte 3 | Analyte 4 | Analyte 5 | Analyte 6 | **Total (PTZ-desthio+hydroxy=RD-RA1)\*** |
| JAU 6476-desthio as JAU 6476-desthio | JAU 6476-4-hydroxy-desthio as JAU 6476-desthio | JAU 6476-3-hydroxy-desthio as JAU 6476-desthio | JAU 6476-alpha-hydroxy-desthio as JAU 6476-desthio | JAU 6476-6-hydroxy-desthio as JAU 6476-desthio | JAU 6476-5-hydroxy-desthio as JAU 6476-desthio |
| 17-2015-01 17-2015-01-T Germany 51399 Burscheid Europe, North F 2017 | Wheat, winter  Potential | green material | 69 69 | 1.5 | 0.11 | 0.13 | 0.092 | 0.024 | 0.14 | 0.50 | 0 0 | (g) 17-2015MAN(j) Analytical method: Analyte 1: 01013 Analyte 2,3,4,5,6: 00979/M002 (k) LOQ: 00979/M002 Analyte 2,3,4,5,6,: 0.01 mg/kg 01013 Analyte 1,: 0.01 mg/kg (l) Method Validation Data: in methods 01013 and 00979/M002 and in study 17-2015 (m) Storage: Analyte 1 straw: 394 days Analyte 2, 3, 4, 5, 6 straw: 402 days Analyte 1 green material: 454 days Analyte 2, 3, 4, 5, 6 green material: 462 days Analyte 1 grain: 394 days Analyte 2, 3, 4, 5, 6 grain: 402 days |
| grain | 89 89 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.06 | 61 61 |
| straw | 89 89 | 0.089 | 0.056 | 0.056 | 0.027 | <0.01 | 0.064 | 0.30 | 61 61 |
| 17-2015-02 17-2015-02-T Germany 78166 Donaueschingen OT Aasen Europe, North F 2017 | Wheat, spring  KWS Chamsin | green material | 69 69 | 1.5 | 0.11 | 0.15 | 0.16 | 0.029 | 0.087 | 0.54 | 0 0 | (g) 17-2015MAN(j) Analytical method: Analyte 1: 01013 Analyte 2,3,4,5,6: 00979/M002 (k) LOQ: 00979/M002 Analyte 2,3,4,5,6,: 0.01 mg/kg 01013 Analyte 1,: 0.01 mg/kg (l) Method Validation Data: in methods 01013 and 00979/M002 and in study 17-2015 (m) Storage: Analyte 1 straw: 394 days Analyte 2, 3, 4, 5, 6 straw: 402 days Analyte 1 green material: 419 days Analyte 2, 3, 4, 5, 6 green material: 427 days Analyte 1 grain: 394 days Analyte 2, 3, 4, 5, 6 grain: 402 days |
| grain | 89 89 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.06 | 26 26 |
| straw | 89 89 | 0.15 | 0.11 | 0.16 | 0.095 | 0.028 | 0.097 | 0.64 | 26 26 |
| 17-2015-03 17-2015-03-T France, north 37310 Chambourg sur Indre Europe, North F 2017 | Wheat, winter  Venezio | green material | 69 69 | 1.3 | 0.051 | 0.055 | 0.030 | <0.01 | 0.034 | 0.18 | 0 0 | (g) 17-2015MAN(j) Analytical method: Analyte 1: 01013 Analyte 2,3,4,5,6: 00979/M002 (k) LOQ: 00979/M002 Analyte 2,3,4,5,6,: 0.01 mg/kg 01013 Analyte 1,: 0.01 mg/kg (l) Method Validation Data: in methods 01013 and 00979/M002 and in study 17-2015 (m) Storage: Analyte 1 straw: 427 days Analyte 2, 3, 4, 5, 6 straw: 435 days Analyte 1 green material: 469 days Analyte 2, 3, 4, 5, 6 green material: 477 days Analyte 1 grain: 427 days Analyte 2, 3, 4, 5, 6 grain: 435 days |
| grain | 89 89 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.06 | 43 43 |
| straw | 89 89 | 0.18 | 0.22 | 0.22 | 0.19 | 0.029 | 0.17 | 1.01 | 43 43 |
| 17-2015-04 17-2015-04-T Netherlands 1681 ND Zwaagdijk Europe, North F 2017 | Wheat, spring  Tybalt | green material | 69 69 | 1.8 | 0.085 | 0.11 | 0.053 | 0.015 | 0.077 | 0.34 | 0 0 | (g) 17-2015MAN(j) Analytical method: Analyte 1: 01013 Analyte 2,3,4,5,6: 00979/M002 (k) LOQ: 00979/M002 Analyte 2,3,4,5,6,: 0.01 mg/kg 01013 Analyte 1,: 0.01 mg/kg (l) Method Validation Data: in methods 01013 and 00979/M002 and in study 17-2015  (m) Storage: Analyte 1 straw: 387 days Analyte 2, 3, 4, 5, 6 straw: 395 days Analyte 1 green material: 425 days Analyte 2, 3, 4, 5, 6 green material: 433 days Analyte 1 grain: 387 days Analyte 2, 3, 4, 5, 6 grain: 395 days |
| grain | 89 89 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.06 | 39 39 |
| straw | 89 89 | 0.041 | 0.064 | 0.076 | 0.022 | 0.010 | 0.063 | 0.28 | 39 39 |

\* for the sum, values <0.01 mg/kg were considered to be equal to 0.01 mg/kg, unless all the values were <0.01 mg/kg.

Table A 63: Analytical part of the 17-2015MAN trials (Part 2)

Analyte 1: 1,2,4-triazole (determined as 1,2,4-triazole, calculated as 1,2,4-triazole), Analyte 2: triazole alanine (determined as triazole alanine, calculated as triazole alanine), Analyte 3: triazole acetic acid (determined as triazole acetic acid, calculated as triazole acetic acid), Analyte 4: triazole lactic acid (determined as triazole lactic acid, calculated as triazole lactic acid)

| Trial No. /  Location /  EU zone /  Year | Commodity /  Variety  (a) | Portion analyzed | Growth stage at sampling  (d) | Residues (mg/kg) | | | | PHI (days)  (e) | Details on trial  (f) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Analyte 1 | Analyte 2 | Analyte 3 | Analyte 4 |
| 1,2,4-triazole as 1,2,4-triazole | triazole alanine as triazole alanine | triazole acetic acid as triazole acetic acid | triazole lactic acid as triazole lactic acid |
| 17-2015-01 17-2015-01-T Germany 51399 Burscheid Europe, North F 2017 | Wheat, winter  Potential | green material | 69 | <0.01 | 0.073/0.011\*\* | 0.036 | 0.029 | 0 | (g) 17-2015MAN(j) Analytical method: 01062/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: in method 01062/M004 and in appendix 5 of study 17-2015 (m) Storage: Analyte 1, 2, 3, 4 straw: 448 days Analyte 1, 2, 3, 4 green material: 509 days Analyte 1, 2, 3, 4 grain: 456 days  \*\*residue in control |
| grain | 89 | <0.01 | 0.21/0.051\*\* | 0.085/0.027\*\* | <0.01 | 61 |
| straw | 89 | <0.01 | <0.01 | 0.010 | <0.01 | 61 |
| 17-2015-02 17-2015-02-T Germany 78166 Donaueschingen OT Aasen Europe, North F 2017 | Wheat, spring  KWS Chamsin | green material | 69 | <0.01 | 0.16 | 0.020 | 0.034 | 0 | (g) 17-2015MAN(j) Analytical method: 01062/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: in method 01062/M004 and in appendix 5 of study 17-2015 (m) Storage: Analyte 1, 2, 3, 4 straw: 448 days Analyte 1, 2, 3, 4 green material: 474 days Analyte 1, 2, 3, 4 grain: 458 days  \*\*residue in control |
| grain | 89 | <0.01 | 0.65/0.035\*\* | 0.092/0.010\*\* | <0.01 | 26 |
| straw | 89 | <0.01 | 0.10 | 0.048 | 0.065 | 26 |
| 17-2015-03 17-2015-03-T France, north 37310 Chambourg sur Indre Europe, North F 2017 | Wheat, winter  Venezio | green material | 69 | <0.01 | 0.052/0.11\*\* | 0.023/0.085\*\* | 0.028/0.095\*\* | 0 | (g) 17-2015MAN(j) Analytical method: 01062/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: in method 01062/M004 and in appendix 5 of study 17-2015 (m) Storage: Analyte 1, 2, 3, 4 straw: 481 days Analyte 1, 2, 3, 4 green material: 524 days Analyte 1, 2, 3, 4 grain: 491 days  \*\*residue in control |
| grain | 89 | <0.01 | 0.42/0.53\*\* | 0.14/0.23\*\* | <0.01 | 43 |
| straw | 89 | <0.01 | 0.016/0.014\*\* | 0.096/0.26\*\* | 0.066/0.11\*\* | 43 |
| 17-2015-04 17-2015-04-T Netherlands 1681 ND Zwaagdijk Europe, North F 2017 | Wheat, spring  Tybalt | green material | 69 | <0.01 | 0.071 | 0.019 | 0.018 | 0 | (g) 17-2015MAN(j) Analytical method: 01062/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: in method 01062/M004 and in appendix 5 of study 17-2015 (m) Storage: Analyte 1, 2, 3, 4 straw: 441 days Analyte 1, 2, 3, 4 green material: 480 days Analyte 1, 2, 3, 4 grain: 449 days  \*\*residue in control |
| grain | 89 | <0.01 | 0.37/0.054\*\* | 0.087/0.020\*\* | <0.01 | 39 |
| straw | 89 | <0.01 | 0.010 | 0.014 | 0.033 | 39 |

* + - * 1. Study S19-01268 – NEU + SEU

|  |  |
| --- | --- |
| Comments of zRMS: | The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for CA3301/ Joust (January 2023). This study has not been reassessed in the framework of this application.  The conclusions of the assessment are presented below:  *Four residue trials on wheat were conducted in northern Europe to determine residue of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio and the triazole-derived metabolites (1,2,4-triazole, triazole alanine, triazole acetic acid, triazole lactic acid).*  *Wheat was treated twice at application rate of 0.200 kg a.s./ha of prothioconazole with 14 days interval between applications. Samples were taken at harvest, 35 days after last application.*  *The analytical methods were validated for the determination of all analytes in wheat (whole plant, grain, straw, ears and rest of plant) according to SANCO/3029/99, rev.4 during analysis.*  *The limit of quantitation for the method is set at 0.01 mg/kg for each analyte for grain, green material and straw.*  *All mean recovery values were within the acceptable range of 70 – 110% in all matrix of wheat with RS<20%.*  *Maximum storage period – 326 days.*  *Residues of prothioconazole-desthio, in wheat grain at harvest were between <0.003 and 0.01 mg/kg.*  *Residues of hydroxy- derivatives of prothioconazole-desthio, in wheat grain at harvest were <0.01 mg/kg.*  *Residues of 1,2,4-triazole and triazole lactic acid, in wheat grain at harvest were between <0.003 and 0.01 mg/kg.*  *Residues of triazole alanine, in wheat grain at harvest ranged between 0. 49 and 1.1 mg/kg.*  *Residues of triazole acetic acid, in wheat grain at harvest ranged between 0.16 and 0.48 mg/kg.*  *The study is acceptable.* |

|  |  |
| --- | --- |
| Reference: | KCA 6.3.2/02 |
| Report | Determination of residues of Prothioconazole-desthio (sum of isomers) after two applications of Prothioconazole in Wheat (outdoor) at 4 sites in Northern Europe and 4 sites in Southern Europe 2019  North, L., 2020  Report No: S19-01268 |
| Guideline(s): | OECD (2009) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32)  OECD Test Guideline 509: Crop field trials  OECD (2016) Guidance Document ENV/JM/MONO (2011)50/REV1 , Second Edition, on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66)  EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials  European Community Guideline SANCO 7525/VI/95, Rev. 10.3, 13/06/17: Comparability, extrapolation, group tolerances and data requirements for setting MRLs) |
| Deviations: | None |
| GLP: | Yes |
| Owner: | Nufarm Crop Products UK |
| Acceptability: | Yes |

Materials and Methods

Eight residue trials were conducted on wheat during 2019, one in the United Kingdom (S19-01268-01), one in Germany (S19-01268-02), one in Northern France (S19-01268-03), one in Hungary (S19-01268-04), one in Spain (S19-01268-05), two in Italy (S19-01268-06 and 08) and one in Southern France (S19-01268-07).

Two application(s) of NUL 3390 Prothioconazole 250 EC (250 g/L prothioconazole) were applied at 200 g ai/ha, diluted with water immediately prior to application to a spray volume of 100-400 L/ha.

Samples of wheat (whole plants) from the untreated and treated plots were taken by hand 0, 7, 14 and 28-29 days after the final application. Samples of wheat (grain and straw) from the untreated and treated plots were taken either by hand or using at plot combine 30-35 days (NCH) after the final application. For trial S19-01268-07 an additional sampling was taken, at 35 days after application ears and rest of plant

with a further sampling of grain and straw at normal commercial harvest.

Wheat samples were analysed for residues of prothioconazole (PTZ)-desthio according to the multi-residue QuEChERS method that was previously validated according to SANCO/30299/99, rev.4 and SANCO/825/00 rev. 8.1 for wheat (grain), grapes, oilseed rape (seed), bean (dry) and cucumber in Eurofins Agroscience Services study S16-04434. The quantitation is done using liquid chromatography with tandem mass spectrometry (LC-MS/MS).

The limit of quantitation for the method is set at 0.01 mg/kg.

Wheat samples were analysed for residues of PTZ-alpha-hydroxy-desthio, PTZ-3-, -4-, -5- and -6-hydroxydesthio according to the analytical method described in Eurofins Agroscience Services study S16-04435 that was previously validated according to SANCO/30299/99, rev.4 and SANCO/825/00 rev. 8.1 for wheat (whole plant, grain and straw) and oilseed rape (seed). The quantitation is done using liquid chromatography with tandem mass spectrometry (LC-MS/MS).

The limit of quantitation for the method is set at 0.01 mg/kg for each analyte. For PTZ-alpha-hydroxy-desthio, PTZ-3-, -4-, -5- and -6-hydroxy-desthio the LOQ is expressed as PTZ-desthio.

Wheat samples were analysed for residues of triazole derivative metabolites (TDMs) 1,2,4-Triazole, triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) according to the analytical method described in S15-03542 that was previously validated according to SANCO/825/00 rev. 8.1 for wheat (grain and straw), barley (grain and straw), grape (bunches) and oilseed rape. The quantitation was done using liquid chromatography with tandem mass spectrometry (LC-MS/MS).

The limit of quantitation for the method is set at 0.01 mg/kg for each analyte.

The maximum storage interval from sampling to extraction was 326 days for wheat (whole plant), 296 days for wheat (grain), 303 days for wheat (straw) and 267 days for wheat (ears and rest of plant). Storage at the Analytical Test Site from sample receipt until lab sample preparation was at ≤ -18 °C.

The maximum interval from extraction to analysis at typically 1 °C to 10 °C with given exceptions (e.g. periods during sample extraction/work-up, periods during transfer to detection instrument and possible minor fluctuations of refrigerator temperatures) was eight days for wheat (whole plant), six days for wheat (straw), and one day for wheat (grain, ears and rest of plant).

The analytical methods were validated for the determination of all analytes in wheat (whole plant, grain, straw, ears and rest of plant) according to SANCO/3029/99, rev.4 during analysis. All mean recovery values (corrected for apparent blank residues, if necessary) at fortification levels of LOQ and 10x LOQ comply with the standard acceptance criteria of the guidance document with evaluation of one (1) mass transition.

Procedural recoveries run concurrently with test sample are summarized in the table below:

Table A 64: Summary of procedural recoveries

| **Analyte** | **Matrix** | **Fortification Levels (mg/kg)** | **Overall Mean Recovery (%)** |
| --- | --- | --- | --- |
| Prothioconazole-desthio | Whole plant | 0.01, 0.1, 1.2 | 97 |
| Grain | 0.01, 0.1 | 93 |
| Straw | 0.01, 0.1, 2.0 | 102 |
| Ears | 0.01, 0.1 | 85 |
| Rest of plant | 0.01, 0.1, 0.2 | 97 |
| Prothioconazole-α-hydroxy-desthio | Whole plant | 0.01, 0.1, 0.2, 1.0 | 102 |
| Grain | 0.01, 0.1 | 89 |
| Straw | 0.01, 0.1, 1.0 | 99 |
| Ears | 0.01, 0.1 | 106 |
| Rest of plant | 0.01, 0.1 | 101 |
| Prothioconazole-3-hydroxy-desthio | Whole plant | 0.01, 0.1, 0.2, 1.0 | 93 |
| Grain | 0.01, 0.1 | 89 |
| Straw | 0.01, 0.1, 1.0 | 89 |
| Ears | 0.01, 0.1 | 101 |
| Rest of plant | 0.01, 0.1 | 93 |
| Prothioconazole-4-hydroxy-desthio | Whole plant | 0.01, 0.1, 0.2, 1.0 | 92 |
| Grain | 0.01, 0.1 | 92 |
| Straw | 0.01, 0.1, 1.0 | 88 |
| Ears | 0.01, 0.1 | 101 |
| Rest of plant | 0.01, 0.1 | 92 |
| Prothioconazole-5-hydroxy-desthio | Whole plant | 0.01, 0.1, 0.2, 1.0 | 87 |
| Grain | 0.01, 0.1 | 86 |
| Straw | 0.01, 0.1, 1.0 | 95 |
| Ears | 0.01, 0.1 | 94 |
| Rest of plant | 0.01, 0.1 | 99 |
| Prothioconazole-6-hydroxy-desthio | Whole plant | 0.01, 0.1, 0.2, 1.0 | 85 |
| Grain | 0.01, 0.1 | 83 |
| Straw | 0.01, 0.1 | 87 |
| Ears | 0.01, 0.1 | 93 |
| Rest of plant | 0.01, 0.1 | 84 |
| 1,2,4-Triazole | Whole plant | 0.01, 0.1 | 107 |
| Grain | 0.01, 0.1 | 103 |
| Straw | 0.01, 0.1 | 103 |
| Ears | 0.01, 0.1 | 105 |
| Rest of plant | 0.01, 0.1 | 106 |
| Triazole alanine | Whole plant | 0.01, 0.1, 1.2 | 97 |
| Grain | 0.01, 0.1, 1.2 | 85 |
| Straw | 0.01, 0.1, 1.2 | 83 |
| Ears | 0.01, 0.1, 1.2 | 82 |
| Rest of plant | 0.01, 0.1 | 82 |
| Triazole acetic acid | Whole plant | 0.01, 0.1, 0.6 | 101 |
| Grain | 0.01, 0.1, 0.6 | 85 |
| Straw | 0.01, 0.1, 0.6 | 96 |
| Ears | 0.01, 0.1, 0.6 | 91 |
| Rest of plant | 0.01, 0.1 | 101 |
| Triazole lactic acid | Whole plant | 0.01, 0.1, 0.4 | 93 |
| Grain | 0.01, 0.1, 0.4 | 76 |
| Straw | 0.01, 0.1, 0.4 | 90 |
| Ears | 0.01, 0.1, 0.4 | 89 |
| Rest of plant | 0.01, 0.1 | 105 |

Findings

The residue levels found in wheat are summarised in the table below.

Table A 65: Summary of the S19-01268 trials

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | NUL 3390 PROTHIOCONAZOLE 250 EC | | | |
| Crop/crop group: | | | | | **Winter wheat** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |
| Country (of trial sites): | | | | | United Kingdom | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | Prothioconazole-desthio (mg/kg) | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | 7 | | 8 | 9 | 10 | 11 | |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | Growth stage at last treatment or date  (e)  BBCH | | Portion analysed  (a) | Residues (mg/kg)  (\*) | PHI (days)  (f) | Remarks  (g) | |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-desthio |
| S19-01268-01  L390HJ, Lancashire, UK | | Winter wheat / TRZAW / Gleam | 1)20 Oct 18  2) na  3) 15 Aug 19 | Overall spray using a boom sprayer | | 67  67 | 300  306 | 200  204 | 27 Jun 19  11 Jul 19 | 71 | | Whole plant  Whole plant  Whole plant  Whole plant  Grain  Straw | 0.90  0.70  0.44  0.16 / 0.01\*\*  <0.01  0.15 / 0.01\*\* | 0  7  14  28  35  35 | No residues >LOQ were found in any untreated samples, except whole plant at 28DAA and straw with a residue of 0.01 mg/kg (LOQ) | |
| (a) | | According to EPPO codes | | | | | | | | (e) | | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*)  \*\* | | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg  Residue in control samples | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |  |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | |  | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | | |
| Crop/crop group: | | | | | **Winter wheat** | | | | Producer of commercial product: | | | | |  | Nufarm UK Limited | | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | |  | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | | |
| Country (of trial sites): | | | | | United Kingdom | | | | Indoor/Glasshouse/Outdoor: | | | | |  | Outdoor | | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | |  | none | | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | |  | Prothioconazole-desthio (mg/kg) | | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | 7 | | | 8 | 9  Residues (mg/kg)  (\*) | | | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | Growth stage at last treatment or date  (e)  BBCH | | | Portion analysed  (a) | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-α-OH-desthio | PTZ-3-OH-desthio | PTZ-4-OH-desthio | PTZ-5-OH-desthio | PTZ-6-OH-desthio | Total (PTZ-desthio+hydroxy=RD-RA1)\* |
| S19-01268-01  L390HJ, Lancashire, UK | | Winter wheat / TRZAW / Gleam | 1)20 Oct 18  2) na  3) 15 Aug 19 | Overall spray using a boom sprayer | | 67  67 | 300  306 | 200  204 | 27 Jun 19  11 Jul 19 | 71 | | | Whole plant  Whole plant  Whole plant  Whole plant  Grain  Straw | 0.09  0.17  0.16  0.08  <0.01  0.06 | 0.06  0.13  0.12  0.07  <0.003  0.10 | 0.05  0.07  0.06  0.03  <0.003  0.04 | 0.04  0.05  0.05  0.03  <0.003  0.03 | 0.01  0.02  0.01  <0.01  <0.003  <0.01 | <0.06  0.39 | 0  7  14  28  35  35 | No residues >LOQ were found in any untreated samples, except whole plant PTZ-3, -4, & -5 with a residue of 0.01-0.02 mg/kg |
| (a) | | According to EPPO codes | | | | | | | | (e) | |  | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | |  | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | |  | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | |  | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | |
| Crop/crop group: | | | | | **Winter wheat** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | |
| Country (of trial sites): | | | | | United Kingdom | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | 1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg) | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | 1,2,4-Triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid |
| S19-01268-01  L390HJ, Lancashire, UK | | Winter wheat / TRZAW / Gleam | 1)20 Oct 18  2) na  3) 15 Aug 19 | Overall spray using a boom sprayer | | 67  67 | 300  306 | 200  204 | 27 Jun 19  11 Jul 19 | | 71 | Whole plant  Whole plant  Whole plant  Whole plant  Grain  Straw | <0.003  <0.003  <0.003  <0.003  <0.003  <0.003 | 0.30  0.42  0.49  0.70  1.10/0.47\*\*  <0.01 | 0.19  0.23  0.31  0.35  0.48/0.34\*\*  0.05/0.03\*\* | 0.14  0.13  0.11  0.02  <0.01  <0.01 | 0  7  14  28  35  35 | No residues >LOQ were found in any 1,2,4 triazole untreated samples, Residues ranged from <0.003-0.47 mg/kg in all other untreateds |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)** | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | PROTIOCONAZOLE 250 EC | | | |
| Crop/crop group: | | | | | **Winter wheat** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |
| Country (of trial sites): | | | | | Germany | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | Prothioconazole-desthio (mg/kg) | | | |
|  | | | | |  | | | |  | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-desthio | |
| S19-01268-02  71706 Markgroningen, Baden Wurttemberg, Germany | | Winter wheat / TRZAW / Spontan | 1) 20 Oct 18  2) 01-21 Jun 19  3) 26 Jul 19 | Overall spray using a boom sprayer | | 67  67 | 289  313 | 193  209 | 07 Jun 19  21 Jun 19 | | 61  73 | Whole plant  Whole plant  Whole plant  Whole plant  Grain  Straw | 0.59  0.19  0.18  0.15  0.01  0.28 | | 0  7  14  28  35  35 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |  |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | |  | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | | |
| Crop/crop group: | | | | | **Winter wheat** | | | | Producer of commercial product: | | | | |  | Nufarm UK Limited | | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | |  | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | | |
| Country (of trial sites): | | | | | Germany | | | | Indoor/Glasshouse/Outdoor: | | | | |  | Outdoor | | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | |  | none | | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | |  | Prothioconazole-desthio (mg/kg) | | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | 7 | | | 8 | 9  Residues (mg/kg)  (\*) | | | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | Growth stage at last treatment or date  (e)  BBCH | | | Portion analysed  (a) | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-α-OH-desthio | PTZ-3-OH-desthio | PTZ-4-OH-desthio | PTZ-5-OH-desthio | PTZ-6-OH-desthio | Total (PTZ-desthio+hydroxy=RD-RA1)\* |
| S19-01268-02  71706 Markgroningen, Baden Wurttemberg, Germany | | Winter wheat / TRZAW / Spontan | 1) 20 Oct 18  2) 01-21 Jun 19  3) 26 Jul 19 | Overall spray using a boom sprayer | | 67  67 | 289  313 | 193  209 | 07 Jun 19  21 Jun 19 | 61  73 | | | Whole plant  Whole plant  Whole plant  Whole plant  Grain  Straw | 0.08  0.21  0.16  0.28  <0.01  0.28 | 0.05  0.10  0.09  0.11  <0.003  0.22 | 0.04  0.08  0.06  0.07  <0.003  0.13 | 0.05  0.10  0.07  0.11  <0.003  0.23 | 0.01  0.03  0.02  0.03  <0.003  0.05 | <0.06  1.19 | 0  7  14  28  35  35 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | |  | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | |  | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | |  | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | |  | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | |
| Crop/crop group: | | | | | **Winter wheat** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | |
| Country (of trial sites): | | | | | Germany | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | 1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg) | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | 1,2,4-Triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid |
| S19-01268-02  71706 Markgroningen, Baden Wurttemberg, Germany | | Winter wheat / TRZAW / Spontan | 1) 20 Oct 18  2) 01-21 Jun 19  3) 26 Jul 19 | Overall spray using a boom sprayer | | 67  67 | 289  313 | 193  209 | 07 Jun 19  21 Jun 19 | | 61  73 | Whole plant  Whole plant  Whole plant  Whole plant  Grain  Straw | <0.003  <0.003  <0.003  <0.003  <0.01  <0.003 | 0.14  0.24  0.29  0.37  0.74/0.05\*\*  0.01 | 0.06  0.07  0.08  0.15  0.23/0.03\*\*  0.12/0.02\*\* | 0.05  0.06  0.05  0.03  <0.01  0.11/0.02\*\* | 0  7  14  28  35  35 | No residues >LOQ were found in any 1,2,4 triazole untreated samples, Residues ranged from <0.003-0.05 mg/kg in all other untreateds |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)** | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | PROTIOCONAZOLE 250 EC | | | |
| Crop/crop group: | | | | | **Winter wheat** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |
| Country (of trial sites): | | | | | France | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | Prothioconazole-desthio (sum of isomers) (mg/kg) | | | |
|  | | | | |  | | | |  | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-desthio | |
| S19-01268-03  91150 Mespuits-91, Essonne, France  N-EU | | Winter wheat / TRZAW / LG Absalom | 1) 26 Oct 18  2) 27 May – 02 Jun 19  3) 17 Jul 19 | Overall spray using a boom sprayer | | 134  133 | 146  152 | 195  202 | 29 May 19  14 Jun 19 | | 56  71 | Whole plant  Whole plant  Whole plant  Whole plant  Grain  Straw | 0.51  0.37  0.19  0.14  <0.003  0.42 | | 0  7  14  28  35  35 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |  |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | |  | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | | | |
| Crop/crop group: | | | | | **Winter wheat** | | | | Producer of commercial product: | | | |  | Nufarm UK Limited | | | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | |  | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | | | |
| Country (of trial sites): | | | | | France | | | | Indoor/Glasshouse/Outdoor: | | | |  | Outdoor | | | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | |  | none | | | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | |  | Prothioconazole-desthio (mg/kg) | | | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | 7 | | 8 | 9  Residues (mg/kg)  (\*) | | | | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | Growth stage at last treatment or date  (e)  BBCH | | Portion analysed  (a) | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-α-OH-desthio | | PTZ-3-OH-desthio | PTZ-4-OH-desthio | PTZ-5-OH-desthio | PTZ-6-OH-desthio | Total (PTZ-desthio+hydroxy=RD-RA1)\* |
| S19-01268-03  91150 Mespuits-91, Essonne, France  N-EU | | Winter wheat / TRZAW / LG Absalom | 1) 26 Oct 18  2) 27 May – 02 Jun 19  3) 17 Jul 19 | Overall spray using a boom sprayer | | 134  133 | 146  152 | 195  202 | 29 May 19  14 Jun 19 | 56  71 | | Whole plant  Whole plant  Whole plant  Whole plant  Grain  Straw | 0.06  0.15  0.13  0.14  <0.003  0.23 | | 0.06  0.12  0.11  0.13  <0.003  0.30 | 0.05  0.10  0.08  0.10  <0.003  0.22 | 0.04  0.09  0.07  0.08  <0.003  0.18 | <0.01  0.02  0.01  0.02  <0.003  0.05 | <0.06  1.4 | 0  7  14  28  35  35 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | |  | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | |  | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | |  | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | |  | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | |
| Crop/crop group: | | | | | **Winter wheat** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | |
| Country (of trial sites): | | | | | France | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | 1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg) | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | 1,2,4-Triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid |
| S19-01268-03  91150 Mespuits-91, Essonne, France  N-EU | | Winter wheat / TRZAW / LG Absalom | 1) 26 Oct 18  2) 27 May – 02 Jun 19  3) 17 Jul 19 | Overall spray using a boom sprayer | | 134  133 | 146  152 | 195  202 | 29 May 19  14 Jun 19 | | 56  71 | Whole plant  Whole plant  Whole plant  Whole plant  Grain  Straw | <0.003  <0.003  <0.003  <0.003  <0.003  <0.003 | 0.07  0.12  0.18  0.17  0.49/0.48\*\*  0.01 | 0.04  0.04  0.05  0.09  0.18/0.35\*\*  0.06/0.04\*\* | 0.05  0.05  0.06  0.07  <0.01  0.21/0.12\*\* | 0  7  14  28  35  35 | No residues >LOQ were found in any 1,2,4 triazole untreated samples, Residues ranged from <0.003-0.48 mg/kg in all other untreateds |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)** | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | PROTIOCONAZOLE 250 EC | | | |
| Crop/crop group: | | | | | **Winter wheat** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |
| Country (of trial sites): | | | | | Hungary | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | Prothioconazole-desthio (mg/kg) | | | |
|  | | | | |  | | | |  | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-desthio | |
| S19-01268-04  H-2476, Pazmand, Fejer, Hungary  N-EU | | Winter wheat / TRZAW / MV Lucilla | 1) 31 Oct 18  2) 22 May – 03 Jun 19  3) 14 Jul 19 | Overall spray using a boom sprayer | | 67  67 | 309  310 | 206  207 | 26 May 19  09 Jun 19 | | 63  73 | Whole plant  Whole plant  Whole plant  Whole plant  Grain  Straw | 1.1  1.1  0.35  0.85  <0.003  0.98 | | 0  7  14  28  35  35 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |  |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | |  | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | | |
| Crop/crop group: | | | | | **Winter wheat** | | | | Producer of commercial product: | | | | |  | Nufarm UK Limited | | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | |  | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | | |
| Country (of trial sites): | | | | | Hungary | | | | Indoor/Glasshouse/Outdoor: | | | | |  | Outdoor | | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | |  | none | | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | |  | Prothioconazole-desthio (mg/kg) | | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | 7 | | | 8 | 9  Residues (mg/kg)  (\*) | | | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | Growth stage at last treatment or date  (e)  BBCH | | | Portion analysed  (a) | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-α-OH-desthio | PTZ-3-OH-desthio | PTZ-4-OH-desthio | PTZ-5-OH-desthio | PTZ-6-OH-desthio | Total (PTZ-desthio+hydroxy=RD-RA1)\* |
| S19-01268-04  H-2476, Pazmand, Fejer, Hungary | | Winter wheat / TRZAW / MV Lucilla | 1) 31 Oct 18  2) 22 May – 03 Jun 19  3) 14 Jul 19 | Overall spray using a boom sprayer | | 67  67 | 309  310 | 206  207 | 26 May 19  09 Jun 19 | 63  73 | | | Whole plant  Whole plant  Whole plant  Whole plant  Grain  Straw | 0.11  0.39  0.28  0.55  <0.01  0.66 | 0.07  0.20  0.15  0.28  <0.003  0.45 | 0.07  0.19  0.13  0.23  <0.003  0.34 | 0.07  0.16  0.11  0.24  <0.003  0.41 | 0.01  0.03  0.02  0.05  <0.003  0.09 | <0.06  2.93 | 0  7  14  28  35  35 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | |  | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | |  | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | |  | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | |  | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | |
| Crop/crop group: | | | | | **Winter wheat** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | |
| Country (of trial sites): | | | | | Hungary | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | 1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg) | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | 1,2,4-Triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid |
| S19-01268-04  H-2476, Pazmand, Fejer, Hungary  N-EU | | Winter wheat / TRZAW / MV Lucilla | 1) 31 Oct 18  2) 22 May – 03 Jun 19  3) 14 Jul 19 | Overall spray using a boom sprayer | | 67  67 | 309  310 | 206  207 | 26 May 19  09 Jun 19 | | 63  73 | Whole plant  Whole plant  Whole plant  Whole plant  Grain  Straw | <0.003  <0.003  <0.003  <0.003  <0.01  <0.003 | 0.12  0.35  0.33  0.17  0.71/0.05\*\*  0.02 | 0.02  0.04  0.05  0.06  0.16/0.03\*\*  0.04 | 0.03  0.04  0.03  0.09  0.01  0.18/0.01\*\* | 0  7  14  28  35  35 | No residues >LOQ were found in any 1,2,4 triazole untreated samples, Residues ranged from <0.003-0.05 mg/kg in all other untreateds |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)** | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | PROTIOCONAZOLE 250 EC | | | |
| Crop/crop group: | | | | | **Winter wheat** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |
| Country (of trial sites): | | | | | Spain | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | Prothioconazole-desthio (mg/kg) | | | |
|  | | | | |  | | | |  | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-desthio | |
| S19-01268-05  41420, Fuentes de Andalucia, Andalucia, Spain | | Winter wheat / TRZAW / Conil | 1) 04 Jan 19  2) Apr to May  3) 29 May 19 | Overall spray using a boom sprayer | | 50  50 | 378  398 | 189  199 | 15 Apr 19  29 Apr 19 | | 61  61 | Whole plant  Whole plant  Whole plant  Whole plant  Grain  Straw | 1.0  0.68  0.50  0.63  <0.01  0.25 | | 0  7  14  28  35  35 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |  |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | |  | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | | |
| Crop/crop group: | | | | | **Winter wheat** | | | | Producer of commercial product: | | | | |  | Nufarm UK Limited | | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | |  | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | | |
| Country (of trial sites): | | | | | Spain | | | | Indoor/Glasshouse/Outdoor: | | | | |  | Outdoor | | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | |  | none | | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | |  | Prothioconazole-desthio (mg/kg) | | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | 7 | | | 8 | 9  Residues (mg/kg)  (\*) | | | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | Growth stage at last treatment or date  (e)  BBCH | | | Portion analysed  (a) | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-α-OH-desthio | PTZ-3-OH-desthio | PTZ-4-OH-desthio | PTZ-5-OH-desthio | PTZ-6-OH-desthio | Total (PTZ-desthio+hydroxy=RD-RA1)\* |
| S19-01268-05  41420, Fuentes de Andalucia, Andalucia, Spain | | Winter wheat / TRZAW / Conil | 1) 04 Jan 19  2) Apr to May  3) 29 May 19 | Overall spray using a boom sprayer | | 50  50 | 378  398 | 189  199 | 15 Apr 19  29 Apr 19 | 61  61 | | | Whole plant  Whole plant  Whole plant  Whole plant  Grain  Straw | 0.15  0.24  0.32  0.37  <0.01  0.08 | 0.11  0.15  0.21  0.28  <0.003  0.13 | 0.08  0.12  0.15  0.19  <0.003  0.11 | 0.07  0.10  0.11  0.14  <0.003  0.07 | 0.01  0.03  0.03  0.05  <0.003  0.03 | <0.06  0.67 | 0  7  14  28  35 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | |  | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | |  | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | |  | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | |  | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | |
| Crop/crop group: | | | | | **Winter wheat** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | |
| Country (of trial sites): | | | | | Spain | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | 1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg) | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | 1,2,4-Triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid |
| S19-01268-05  41420, Fuentes de Andalucia, Andalucia, Spain | | Winter wheat / TRZAW / Conil | 1) 04 Jan 19  2) Apr to May  3) 29 May 19 | Overall spray using a boom sprayer | | 50  50 | 378  398 | 189  199 | 15 Apr 19  29 Apr 19 | | 61  61 | Whole plant  Whole plant  Whole plant  Whole plant  Grain  Straw | <0.003  <0.003  <0.003  <0.003  <0.003  <0.003 | 0.11  0.20  0.25  0.26  0.53/0.06\*\*  0.02 | 0.02  0.03  0.05  0.11  0.14/0.03\*\*  0.03/0.01\*\* | 0.04  0.05  0.06  0.09  <0.01  0.11/0.03\*\* | 0  7  14  28  35  35 | No residues >LOQ were found in any 1,2,4 triazole untreated samples, Residues ranged from <0.003-0.06 mg/kg in all other untreateds |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)** | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | PROTIOCONAZOLE 250 EC | | | |
| Crop/crop group: | | | | | **Winter wheat** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |
| Country (of trial sites): | | | | | Italy | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | Prothioconazole-desthio (mg/kg) | | | |
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| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-desthio | |
| S19-01268-06  40026 Sesto Imolese, Bologna, Italy | | Winter wheat / TRZAW / Bologna | 1) 09 Nov 18  2) 14-24 May 19  3) 21 Jun 19 | Overall spray using a boom sprayer | | 67  67 | 293  284 | 196  190 | 03 May 19  17 May 19 | | 51  65 | Whole plant  Whole plant  Whole plant  Whole plant  Grain  Straw | 1.0  0.44  0.12  0.07  <0.003  0.11 | | 0  7  14  28  35  35 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |  |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | |  | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | | | |
| Crop/crop group: | | | | | **Winter wheat** | | | | Producer of commercial product: | | | |  | Nufarm UK Limited | | | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | |  | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | | | |
| Country (of trial sites): | | | | | Italy | | | | Indoor/Glasshouse/Outdoor: | | | |  | Outdoor | | | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | |  | none | | | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | |  | Prothioconazole-desthio (mg/kg) | | | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | 7 | | 8 | 9 | | | | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | Growth stage at last treatment or date  (e)  BBCH | | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | | | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-α-OH-desthio | | PTZ-3-OH-desthio | PTZ-4-OH-desthio | PTZ-5-OH-desthio | PTZ-6-OH-desthio | Total (PTZ-desthio+hydroxy=RD-RA1)\* |
| S19-01268-06  40026 Sesto Imolese, Bologna, Italy | | Winter wheat / TRZAW / Bologna | 1) 09 Nov 18  2) 14-24 May 19  3) 21 Jun 19 | Overall spray using a boom sprayer | | 67  67 | 293  284 | 196  190 | 03 May 19  17 May 19 | 51  65 | | Whole plant  Whole plant  Whole plant  Whole plant  Grain  Straw | <0.003  <0.01  <0.01  <0.01  <0.003  <0.01 | | 0.03  0.06  0.06  0.07  <0.003  0.10 | 0.04  0.07  0.07  0.07  <0.003  0.08 | 0.08  0.13  0.10  0.11  <0.003  0.13 | <0.01  0.02  0.02  0.02  <0.003  0.02 | <0.06  0.45 | 0  7  14  28  35  35 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | |  | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | |  | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | |  | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | |  | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | |
| Crop/crop group: | | | | | **Winter wheat** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | |
| Country (of trial sites): | | | | | Italy | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | 1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg) | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | 1,2,4-Triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid |
| S19-01268-06  40026 Sesto Imolese, Bologna, Italy | | Winter wheat / TRZAW / Bologna | 1) 09 Nov 18  2) 14-24 May 19  3) 21 Jun 19 | Overall spray using a boom sprayer | | 67  67 | 293  284 | 196  190 | 03 May 19  17 May 19 | | 51  65 | Whole plant  Whole plant  Whole plant  Whole plant  Grain  Straw | <0.003  <0.003  <0.003  <0.003  <0.003  <0.003 | <0.01  0.01  0.01  0.04  0.16/0.07\*\*  0.06/0.03\*\* | <0.003  <0.01  <0.01  0.01  0.03/0.03\*\*  0.03/0.02\*\* | <0.003  <0.01  <0.01  0.01  <0.003  0.03/0.02\*\* | 0  7  14  28  35  35 | No residues >LOQ were found in any 1,2,4 triazole untreated samples, Residues ranged from <0.003-0.07 mg/kg in all other untreateds |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)** | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | PROTIOCONAZOLE 250 EC | | | |
| Crop/crop group: | | | | | **Winter wheat** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |
| Country (of trial sites): | | | | | France | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | Prothioconazole-desthio (mg/kg) | | | |
|  | | | | |  | | | |  | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-desthio | |
| S19-01268-07  82130, Lafrancaise, Tarn et Garonne, France  SEU | | Winter wheat / TRZAW / Nemo | 1) 24 Oct 19  2) na  3) 03 Jul 19 | Overall spray using a boom sprayer | | 100  100 | 215  201 | 215  201 | 10 May 19  23 May 19 | | 59  73 | Whole plant  Whole plant  Whole plant  Whole plant  Ears  Rest of plant  Grain  Straw | 0.69  0.24  0.13  0.10  0.06  0.11  <0.003  0.19 | | 0  7  14  28  35  35  41  41 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |  |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | |  | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | | | |
| Crop/crop group: | | | | | **Winter wheat** | | | | Producer of commercial product: | | | |  | Nufarm UK Limited | | | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | |  | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | | | |
| Country (of trial sites): | | | | | France | | | | Indoor/Glasshouse/Outdoor: | | | |  | Outdoor | | | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | |  | none | | | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | |  | Prothioconazole-desthio (mg/kg) | | | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | 7 | | 8 | 9  Residues (mg/kg)  (\*) | | | | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | Growth stage at last treatment or date  (e)  BBCH | | Portion analysed  (a) | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-α-OH-desthio | | PTZ-3-OH-desthio | PTZ-4-OH-desthio | PTZ-5-OH-desthio | PTZ-6-OH-desthio | Total (PTZ-desthio+hydroxy=RD-RA1)\* |
| S19-01268-07  82130, Lafrancaise, Tarn et Garonne, France  SEU | | Winter wheat / TRZAW / Nemo | 1) 24 Oct 19  2) na  3) 03 Jul 19 | Overall spray using a boom sprayer | | 100  100 | 215  201 | 215  201 | 10 May 19  23 May 19 | 59  73 | | Whole plant  Whole plant  Whole plant  Whole plant  Ears  Rest of plant  Grain  Straw | 0.06  0.11  0.09  0.09  0.05  0.10  <0.003  0.14 | | 0.05  0.09  0.08  0.08  005  0.07  <0.003  0.11 | 0.04  0.09  0.07  0.07  0.03  0.06  <0.003  0.07 | 0.04  0.07  0.07  0.06  0.04  0.06  <0.003  0.07 | <0.01  0.02  0.02  0.01  <0.01  0.01  <0.003  0.02 | <0.06  0.6 | 0  7  14  28  35  35  41  41 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | |  | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | |  | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | |  | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | |  | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | |
| Crop/crop group: | | | | | **Winter wheat** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | |
| Country (of trial sites): | | | | | France | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | 1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg) | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | 1,2,4-Triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid |
| S19-01268-07  82130, Lafrancaise, Tarn et Garonne, France | | Winter wheat / TRZAW / Nemo | 1) 24 Oct 19  2) na  3) 03 Jul 19 | Overall spray using a boom sprayer | | 100  100 | 215  201 | 215  201 | 10 May 19  23 May 19 | | 59  73 | Whole plant  Whole plant  Whole plant  Whole plant  Ears  Rest of plant  Grain  Straw | <0.003  <0.003  <0.003  <0.003  <0.003  <0.003  <0.003  <0.003 | 0.03  0.08  0.07  0.13  0.33  <0.01  0.41/0.01\*\*  0.04 | 0.01  0.01  0.01  0.03  0.08  0.02  0.10/0.01\*\*  0.04 | 0.02  0.02  0.02  0.03  0.02  0.04  <0.01  0.05 | 0  7  14  28  35  35  41  41 | No residues >LOQ were found in any 1,2,4 triazole untreated samples, Residues ranged from <0.003-0.01 mg/kg in all other untreateds |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)** | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | PROTIOCONAZOLE 250 EC | | | |
| Crop/crop group: | | | | | **Winter wheat** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |
| Country (of trial sites): | | | | | Italy | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | Prothioconazole-desthio (mg/kg) | | | |
|  | | | | |  | | | |  | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-desthio | |
| S19-01268-08  40016 San Giorgio Di Piano, Bologna, Italy | | Winter wheat / TRZAW / Ideo | 1) 11 Nov 18  2) 12-25 May  3) 26 Jun 19 | Overall spray using a boom sprayer | | 66  67 | 316  300 | 210  200 | 08 May 19  22 May 19 | | 59  69 | Whole plant  Whole plant  Whole plant  Whole plant  Grain  Straw | 0.84  0.05  0.04  0.06  <0.003  0.08 | | 0  7  14  25  35  35 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |  |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | |  | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | | |
| Crop/crop group: | | | | | **Winter wheat** | | | | Producer of commercial product: | | | | |  | Nufarm UK Limited | | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | |  | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | | |
| Country (of trial sites): | | | | | Italy | | | | Indoor/Glasshouse/Outdoor: | | | | |  | Outdoor | | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | |  | none | | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | |  | Prothioconazole-desthio (mg/kg) | | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | 7 | | | 8 | 9  Residues (mg/kg)  (\*) | | | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | Growth stage at last treatment or date  (e)  BBCH | | | Portion analysed  (a) | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-α-OH-desthio | PTZ-3-OH-desthio | PTZ-4-OH-desthio | PTZ-5-OH-desthio | PTZ-6-OH-desthio | Total (PTZ-desthio+hydroxy=RD-RA1)\* |
| S19-01268-08  40016 San Giorgio Di Piano, Bologna, Italy | | Winter wheat / TRZAW / Ideo | 1) 11 Nov 18  2) 12-25 May  3) 26 Jun 19 | Overall spray using a boom sprayer | | 66  67 | 316  300 | 210  200 | 08 May 19  22 May 19 | 59  69 | | | Whole plant  Whole plant  Whole plant  Whole plant  Grain  Straw | 0.04  0.06  0.05  0.05  <0.01  0.06 | 0.03  0.06  0.05  0.03  <0.003  0.06 | 0.03  0.05  0.04  0.02  <0.003  0.04 | 0.03  0.05  0.04  0.03  <0.003  0.06 | <0.01  0.02  0.01  <0.01  <0.003  0.02 | <0.06  0.32 | 0  7  14  28  35  35 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | |  | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | |  | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | |  | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | |  | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | |
| Crop/crop group: | | | | | **Winter wheat** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | |
| Country (of trial sites): | | | | | Italy | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | 1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg) | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | 1,2,4-Triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid |
| S19-01268-08  40016 San Giorgio Di Piano, Bologna, Italy | | Winter wheat / TRZAW / Ideo | 1) 11 Nov 18  2) 12-25 May  3) 26 Jun 19 | Overall spray using a boom sprayer | | 66  67 | 316  300 | 210  200 | 08 May 19  22 May 19 | | 59  69 | Whole plant  Whole plant  Whole plant  Whole plant  Grain  Straw | <0.003  <0.003  <0.003  <0.003  <0.01  <0.003 | 0.03  0.10  0.11  0.14  0.42/0.08\*\*  0.02 | <0.01  0.01  0.02  0.06  0.14/0.04\*\*  0.05 | <0.01  0.03  0.03  0.03  <0.01  0.07/0.03\*\* | 0  7  14  28  35  35 | No residues >LOQ were found in any 1,2,4 triazole untreated samples, Residues ranged from <0.003-0.08 mg/kg in all other untreateds |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | |

* + - * 1. Study 16-2046 – NEU

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| --- | --- |
| Comments of zRMS: | It should be noted that the study of Meklat, Kerkering (16-2046) is currently under review in the EU approval renewal process for prothioconazole.  The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for CA3301/ Joust (January 2023). This study has not been reassessed in the framework of this application.  The conclusions of the assessment are presented below:  *Four residue trials on spring and winter wheat were conducted in northern Europe to determine residue of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio and TDMs.*  *Wheat was treated twice at application rate of 0.200 kg a.s./ha of prothioconazole with 20-24 days interval between applications. The time of application was*  *1. at BBCH 37-51,*  *2. at BBCH 65-69.*  *Samples were taken at harvest.*  *Analytical method for determination of prothioconazole-desthio - method 01013.*  *Analytical method for determination of prothioconazole -alpha-hydroxy-desthio, -3-hydroxy-desthio, -4-hydroxy-desthio, -5-hydroxy-desthio and -6-hydroxy-desthio – method 00979/M02.*  *The residues of 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in/on plant material were analysed according to the method 01062/M004.*  *Limit of quantitation was 0.01 mg/kg for grain, green material and straw for all substances.*  *Mean recoveries in acceptable range (70 - 110%), RSD <20%.*  *Maximum storage period – 17.5 months.*  *Residues of prothioconazole-desthio and hydroxy- derivatives of prothioconazole-desthio, in wheat grain at harvest were <0.01 mg/kg.*  *Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest was <0.06 mg/kg.*  *Residues of 1,2,4-triazole and triazole lactic acid, in wheat grain at harvest were < 0.01 mg/kg.*  *Residues of triazole alanine, in wheat grain at harvest ranged between 0.11 and 0.26 mg/kg.*  *Residues of triazole acetic acid, in wheat grain at harvest ranged between 0.23 and 0.88 mg/kg.*  *The study is acceptable.* |

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| Reference: | KCA 6.3.2/03 |
| Report | Determination of the residues of prothioconazole and spiroxamine in/on spring wheat and winter wheat after spray application of JAU 6476 & KWG 4168 EC 460 in the United Kingdom, Germany and the Netherlands  Meklat, N.; Kerkering, S., 06.06.2018  Report No: M-626175-01-1  Reference No: 16-2046 |
| Guideline(s): | Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market  OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)  US EPA OCSPP 860.1500, Crop Field Trial |
| Deviations: | None |
| GLP: | Yes |
| Owner: | Bayer CropScience AG (Nufarm Europe has a letter of access) |
| Acceptability: | Yes |

The following study is currently under review in the EU approval renewal process for prothioconazole.

Materials and Methods

Field trials were conducted in/on winter and spring wheat during the 2016 growing season. The trials were located in Germany (2 trials), the Netherlands, and the United Kingdom.

In each trial the emulsifiable concentrate (EC) formulation was applied twice at a nominal rate of prothioconazole of 200 g as/ha. The applications were carried out at the growth stages BBCH 37-51 and BBCH 65-69, respectively, using 200-400 L/ha of water. The spray intervals ranged between 20 and 24 days.

Samples of green material were taken for analysis on the day of the last application (day 0) while samples of grain and straw were taken at harvest.

Residues of prothioconazole-desthio were determined according to method 01013 with a limit of quantitation of 0.01 mg/kg for grain, green material and straw. Residues of prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio were determined according to method 00979/M002 with a limit of quantitation of 0.01 mg/kg for grain, green material and straw (cf. methods part).

The residues of 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in/on plant material were analysed according to the method 01062/M004 (cf, methods part of this summary).

Findings

- Storage stability:

The maximum storage periods for prothioconazole-desthio and TDMs in barley samples from the supplementary residue field trials are presented in the table below.

Table A 66: Maximum storage periods of field samples from supplementary residue trials

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Crop | Substance | Sample Material | Storage period (days) | Storage period (months) |
| Wheat | prothioconazole-desthio | grain | 319 | 10.6 |
| green material | 365 | 12.2 |
| straw | 333 | 11.1 |
| prothioconazole-alpha-hydroxy-desthio  prothioconazole-3-hydroxy-desthio  prothioconazole-4-hydroxy-desthio  prothioconazole-5-hydroxy-desthio  prothioconazole-6-hydroxy-desthio | grain | 476 | 15.9 |
| green material | 524 | 17.5 |
| straw | 476 | 15.9 |
| TAA; 1,2,4-T, TA | grain | 326 | 10.9 |
| green material | 372 | 12.4 |
| straw | 326 | 10.9 |

\* the storage stability of TLA was not investigated in straw, but there is no need, as its stability has been shown for 48 months in representative commodities covering the five categories described in the OECD guideline 506 for the testing of chemicals.

Sample extracts were measured within 24 hours, or if not, acceptable recoveries measured concurrently with each set of samples ensured integrity of the sample extracts during the period of time between extraction and analysis.

No residues above the LOQ were found in the control samples with the following exceptions:

**16-2046:** Triazole alanine: green material in 2 trials (up to 0.079 mg/kg) and in grain, all trials (up to 0.26 mg/kg); Triazole acetic acid: green material, in 2 trials (up to 0.061 mg/kg) and in grain, in 3 trials (up to 0.14 mg/kg) and in straw, in 2 trials (up to 0.062 mg/kg); Triazole lactic acid: green material, in 2 trials (up to 0.063 mg/kg), in straw, one trial (0.079 mg/kg).

- Method performance:

**16-2046**: The average recoveries were within the acceptable range of 70 – 110% and the RSD values were below 20%.

Table A 67: 16-2046: Concurrent recoveries for the determination of prothioconazole-desthio in wheat

| Analyte | Sample Material | Fortification level [mg/kg] | Recovery rates [%] | | RSD [%] | LOQ [mg/kg] |
| --- | --- | --- | --- | --- | --- | --- |
| Single Values | Mean |
| Prothio-conazole-desthio | Wheat grain | 0.01 | 104 | - | - | 0.01 |
| **Overall Recovery (n = 1)** | | **-** | - |
| Wheat green material | 0.01 | 99 | - | - | 0.01 |
| 0.10 | 100 | - | - |
| 3.0 | 102 | - | - |
| **Overall Recovery (n = 3)** | | **100** | **1.5** |
| Wheat straw | 0.01 | 108 | - | - | 0.01 |
| 0.50 | 94 | - | - |
| **Overall Recovery (n = 2)** | | **101** | - |

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with JAU 6476-desthio, determined as JAU 6476-desthio and calculated as JAU 6476-desthio

Table A 68: 16-2046: Concurrent recoveries for the determination of alpha-hydroxy-prothioconazole-desthio in wheat

| Analyte | Sample Material | Fortification level [mg/kg] | Recovery rates [%] | | RSD [%] | LOQ [mg/kg] |
| --- | --- | --- | --- | --- | --- | --- |
| Single Values | Mean |
| alpha-hydroxy-prothio-conazole-desthio | Wheat grain | 0.01 | 84, 93 | 89 | - | 0.01 |
| 0.09 | 86, 89 | 88 | - |
| **Overall Recovery (n = 4)** | | **88** | **4.4** |
| Wheat green material | 0.01 | 96, 104 | 100 | - | 0.01 |
| 0.10 | 92, 96 | 94 | - |
| 0.20 | 101, 104 | 103 | - |
| **Overall Recovery (n = 6)** | | **99** | **5.0** |
| Wheat straw | 0.01 | 106, 110 | 108 | - | 0.01 |
| 0.10 | 87, 103 | 95 | - |
| 0.20 | 102, 116 | 109 | - |
| **Overall Recovery (n = 6)** | | **104** | **9.4** |

RSD = Relative standard deviation, LOQ = Practical limit of quantification.

Fortified with JAU 6476-alpha-hydroxy-desthio, determined as JAU 6476-alpha-hydroxy-desthio and calculated as JAU 6476-desthio

Table A 69: 16-2046: Concurrent recoveries for the determination of 3-hydroxy-prothioconazole-desthio in wheat

| Analyte | Sample Material | Fortification level [mg/kg] | Recovery rates [%] | | RSD [%] | LOQ [mg/kg] |
| --- | --- | --- | --- | --- | --- | --- |
| Single Values | Mean |
| 3-hydroxy-prothio-conazole-desthio | Wheat grain | 0.01 | 86, 88 | 87 | - | 0.01 |
| 0.09 | 75, 86 | 81 | - |
| **Overall Recovery (n = 4)** | | **84** | **7.1** |
| Wheat green material | 0.01 | 104, 106 | 105 | - | 0.01 |
| 0.10 | 85, 93 | 89 | - |
| 0.20 | 95, 97 | 96 | - |
| **Overall Recovery (n = 6)** | | **97** | **7.9** |
| Wheat straw | 0.01 | 102, 116 | 109 | - | 0.01 |
| 0.10 | 79, 100 | 90 | - |
| 0.20 | 99, 104 | 102 | - |
| **Overall Recovery (n = 6)** | | **100** | **12.0** |

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with JAU 6476-3-hydroxy-desthio, determined as JAU 6476-3-hydroxy-desthio and calculated as JAU 6476-desthio

**Table A 70: 16-2046: Concurrent recoveries for the determination of 4-hydroxy-prothioconazole-desthio in wheat**

| Analyte | Sample Material | Fortification level [mg/kg] | Recovery rates [%] | | RSD [%] | LOQ [mg/kg] |
| --- | --- | --- | --- | --- | --- | --- |
| Single Values | Mean |
| 3-hydroxy-prothio-conazole-desthio | Wheat grain | 0.01 | 84, 84 | 84 | - | 0.01 |
| 0.09 | 80, 86 | 83 | - |
| **Overall Recovery (n = 4)** | | **84** | **3.0** |
| Wheat green material | 0.01 | 92, 100 | 96 | - | 0.01 |
| 0.10 | 96, 99 | 98 | - |
| 0.20 | 77, 81 | 79 | - |
| **Overall Recovery (n = 6)** | | **91** | **10.6** |
| Wheat straw | 0.01 | 97, 109 | 103 | - | 0.01 |
| 0.10 | 87, 89 | 88 | - |
| 0.20 | 87, 90 | 89 | - |
| **Overall Recovery (n = 6)** | | **93** | **9.2** |

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with JAU 6476-4-hydroxy-desthio, determined as JAU 6476-4-hydroxy-desthio and calculated as JAU 6476-desthio.

Table A 71: 16-2046: Concurrent recoveries for the determination of 5-hydroxy-prothioconazole-desthio in wheat

| Analyte | Sample Material | Fortification level [mg/kg] | Recovery rates [%] | | RSD [%] | LOQ [mg/kg] |
| --- | --- | --- | --- | --- | --- | --- |
| Single Values | Mean |
| 3-hydroxy-prothio-conazole-desthio | Wheat grain | 0.01 | 91, 97 | 94 | - | 0.01 |
| 0.09 | 90, 92 | 91 | - |
| **Overall Recovery (n = 4)** | | **93** | **3.4** |
| Wheat green material | 0.01 | 106, 111 | 109 | - | 0.01 |
| 0.10 | 87, 91 | 89 | - |
| 0.20 | 92, 94 | 93 | - |
| **Overall Recovery (n = 6)** | | **97** | **9.9** |
| Wheat straw | 0.01 | 104, 115 | 110 | - | 0.01 |
| 0.10 | 93, 97 | 95 | - |
| 0.20 | 99, 100 | 100 | - |
| **Overall Recovery (n = 6)** | | **101** | **7.5** |

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with JAU 6476-5-hydroxy-desthio, determined as JAU 6476-5-hydroxy-desthio and calculated as JAU 6476-desthio

**Table A 72: 16-2046: Concurrent recoveries for the determination of 6-hydroxy-prothioconazole-desthio in wheat**

| Analyte | Sample Material | Fortification level [mg/kg] | Recovery rates [%] | | RSD [%] | LOQ [mg/kg] |
| --- | --- | --- | --- | --- | --- | --- |
| Single Values | Mean |
| 3-hydroxy-prothio-conazole-desthio | Wheat grain | 0.01 | 96, 100 | 98 | - | 0.01 |
| 0.09 | 90, 93 | 92 | - |
| **Overall Recovery (n = 4)** | | **95** | **4.5** |
| Wheat green material | 0.01 | 95, 109 | 102 | - | 0.01 |
| 0.10 | 96, 100 | 98 | - |
| 0.20 | 74, 85 | 80 | - |
| **Overall Recovery (n = 6)** | | **93** | **13.1** |
| Wheat straw | 0.01 | 101, 118 | 110 | - | 0.01 |
| 0.10 | 89, 101 | 95 | - |
| 0.20 | 92, 93 | 93 | - |
| **Overall Recovery (n = 6)** | | **99** | **10.6** |

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with JAU 6476-6-hydroxy-desthio, determined as JAU 6476-6-hydroxy-desthio and calculated as JAU 6476-desthio,

Table A 73: 16-2046: Concurrent recoveries for the determination of 1, 2, 4-Triazole in wheat

| Analyte | Sample Material | Fortification level [mg/kg] | Recovery rates [%] | | RSD [%] | LOQ [mg/kg] |
| --- | --- | --- | --- | --- | --- | --- |
| Single Values | Mean |
| 1, 2,4-T | Wheat grain | 0.01 | 97, 98 | 98 | - | 0.01 |
| 0.10 | 99 | - | - |
| 0.30 | 102 | - | - |
| **Overall Recovery (n = 4)** | | **99** | **2.2** |
| Wheat green material | 0.01 | 91, 93, 97 | 94 | 3.3 | 0.01 |
| 0.10 | 104 | - | - |
| 0.30 | 95 | - | - |
| **Overall Recovery (n = 5)** | | **96** | **5.2** |
| Wheat straw | 0.01 | 103 | - | - | 0.01 |
| 0.10 | 105 | - | - |
| 0.30 | 102 | - | - |
| **Overall Recovery (n = 3)** | | **103** | **1.5** |

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with 1,2,4-triazole, determined as 1,2,4-triazole and calculated as 1,2,4-triazole

**Table A 74: 16-2046: Concurrent recoveries for the determination of Triazole Alanine in wheat**

| Analyte | Sample Material | Fortification level [mg/kg] | Recovery rates [%] | | RSD [%] | LOQ [mg/kg] |
| --- | --- | --- | --- | --- | --- | --- |
| Single Values | Mean |
| TA | Wheat grain | 0.01 | 72 (234)a, 118 (281)a | 95 | - | 0.01 |
| 0.10 | 95 (112)a | - | - |
| 0.30 | 91 (97)a | - | - |
| 1.0 | 86 (87)a, 87 (89)a | 87 | - |
| **Overall Recovery (n = 6)** | | **92** | **16.5** |
| Wheat green material | 0.01 | 96, 98, 113 | 102 | 9.1 | 0.01 |
| 0.10 | 99 | - | - |
| 0.30 | 95 | - | - |
| **Overall Recovery (n = 5)** | | **100** | **7.3** |
| Wheat straw | 0.01 | 100, 109 | 105 | - | 0.01 |
| 0.10 | 87 | - | - |
| 0.30 | 86 | - | - |
| **Overall Recovery (n = 4)** | | **96** | **11.6** |

RSD = Relative standard deviation, LOQ = Practical limit of quantification.

Fortified with triazole alanine, determined as triazole alanine and calculated as triazole alanine. a These recoveries were background-corrected since the control sample used for spiking (16-2046-03-0017E) was found to contain (apparent) residues at a level of 0.0161 mg/kg. The uncorrected recovery is shown in brackets.

Table A 75: 16-2046: Concurrent recoveries for the determination of Triazole Acetic acid in wheat

| Analyte | Sample Material | Fortification level [mg/kg] | Recovery rates [%] | | RSD [%] | LOQ [mg/kg] |
| --- | --- | --- | --- | --- | --- | --- |
| Single Values | Mean |
| TAA | Wheat grain | 0.01 | 88 (138)a, 97 (148)a | 93 | - | 0.01 |
| 0.10 | 84 (90)a | - | - |
| 0.30 | 96 (98)a | - | - |
| **Overall Recovery (n = 4)** | | **91** | **6.9** |
| Wheat green material | 0.01 | 97, 97, 106 | 100 | 5.2 | 0.01 |
| 0.10 | 100 | - | - |
| 0.30 | 97 | - | - |
| **Overall Recovery (n = 5)** | | **99** | **3.9** |
| Wheat straw | 0.01 | 107, 111 | 109 | - | 0.01 |
| 0.10 | 93 | - | - |
| 0.30 | 97 | - | - |
| **Overall Recovery (n = 4)** | | **102** | **8.2** |

RSD = Relative standard deviation, LOQ = Practical limit of quantification

. Fortified with triazole acetic acid, determined as triazole acetic acid and calculated as triazole acetic acid. a These recoveries were background-corrected since the control sample used for spiking (16-2046-03-0017E) was found to contain (apparent) residues at a level of 0.00491 mg/kg. The uncorrected recovery is shown in brackets.

Table A 76: 16-2046: Concurrent recoveries for the determination of Triazole Lactic acid in wheat

| Analyte | Sample Material | Fortification level [mg/kg] | Recovery rates [%] | | RSD [%] | LOQ [mg/kg] |
| --- | --- | --- | --- | --- | --- | --- |
| Single Values | Mean |
| TLA | Wheat grain | 0.01 | 81, 89 | 85 | - | 0.01 |
| 0.10 | 87 | - | - |
| 0.30 | 91 | - | - |
| **Overall Recovery (n = 4)** | | **87** | **5.0** |
| Wheat green material | 0.01 | 94, 97, 111 | 101 | 9.0 | 0.01 |
| 0.10 | 106 | - | - |
| 0.30 | 96 | - | - |
| **Overall Recovery (n = 5)** | | **101** | **7.3** |
| Wheat straw | 0.01 | 96, 108 | 102 | - | 0.01 |
| 0.10 | 93 | - | - |
| 0.30 | 96 | - | - |
| **Overall Recovery (n = 4)** | | **98** | **6.8** |

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with triazole lactic acid, determined as triazole lactic acid and calculated as triazole lactic acid

- Residue results:

The residue results are summarised in the tables below.

Conclusion

Wheat residue trials were conducted with Prothioconazole & Spiroxamine EC 460 in northern Europe. The product application corresponded to a prothioconazole rate of 2x200 g a.s./ha.

Residues of hydroxy- derivatives of prothioconazole-desthio and prothioconazole-desthio, in wheat grain at harvest were <0.01 mg/kg.

Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in straw at harvest ranged between 0.11 mg/kg and 0.60 mg/kg.

The results for the TDMs are summarised in the table below.

Table A 77: 16-2046 - Residues of prothioconazole-desthio and metabolites in/on spring and winter barley applied with Prothioconazole & Spiroxamine EC 460

| Study Trial No. Plot No.  GLP  Year | Crop Variety | Country | Application | | | | | Residues (mg/kg) | | | | | | | |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FL | No | kg/ha  (a.s.) | kg/hL (a.s.) | GS | Portion analysed | DALT (d) | JAU 6476-desthio | JAU 6476-alpha-OH-desthio | JAU 6476-3-OH-desthio | JAU 6476-4-OH-desthio | JAU 6476-5-OH-desthio | JAU 6476-6-OH-desthio | Total (PTZ-desthio+hydroxy=RD-RA1)\* |
| 16-2046MAN 16-2046-01  16-2046-01-T  GLP: yes  2016 | Wheat, winter  Cougar | United Kingdom SG8 8SS Great Chishill, Royston Europe, North | 460 EC | 2 | 0.200 | 0.100 | 69 | green material | 0 | 1.2 | 0.038 | 0.076 | 0.081 | 0.11 | <0.01 | 1.52 |
| grain | 50 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.06 |
| straw | 50 | 0.083 | 0.049 | 0.13 | 0.16 | 0.15 | 0.031 | 0.60 |
| 16-2046MAN 16-2046-04  16-2046-04-T  GLP: yes  2016 | Wheat, spring  Thasos | Germany 59609 Anröchte-Berge Europe, North | 460 EC | 2 | 0.200 | 0.0667 | 69 | green material | 0 | 1.1 | 0.050 | 0.078 | 0.062 | 0.059 | <0.01 | 1.36 |
| grain | 53 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.06 |
| straw | 53 | 0.094 | 0.071 | 0.070 | 0.073 | 0.065 | <0.01 | 0.38 |
| 16-2046MAN 16-2046-03  16-2046-03-T  GLP: yes  2016 | Wheat, spring  Tybalt | Netherlands1606 MG Venhuizen Europe, North | 460 EC | 2 | 0.200 | 0.0500 | 65 | green material | 0 | 1.1 | 0.025 | 0.063 | 0.046 | 0.047 | <0.01 | 1.52 |
| grain | 54 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.06 |
| straw | 54 | 0.046 | 0.013 | 0.012 | 0.024 | 0.019 | <0.01 | 0.12 |
| 16-2046MAN 16-2046-02  16-2046-02-T  GLP: yes  2016 | Wheat, winter  Dekan | Germany 51399 Burscheid Europe, North | 460 EC | 2 | 0.200 | 0.0667 | 69 | green material | 0 | 0.78 | 0.032 | 0.037 | 0.043 | 0.035 | 0.012 | 0.94 |
| grain | 62 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.01 | <0.06 |
| straw | 62 | 0.040 | 0.017 | <0.01 | 0.023 | <0.01 | <0.01 | 0.11 |

\* for the sum, values <0.01 mg/kg were considered to be equal to 0.01 mg/kg, unless all the values were <0.01 mg/kg.

\*\* residue in control. Residues for JAU 6476 -desthio (determined as JAU 6476-desthio and calculated as JAU 6476-desthio). Residues for JAU 6476-alpha-hydroxy-desthio (determined as JAU 6476-alpha-hydroxy-desthio and calculated as JAU 6476-desthio). Residues for JAU 6476-3-hydroxy-desthio (determined as JAU 6476-3-hydroxy-desthio and calculated as JAU 6476-desthio)

\*\* residue in control. Residues for JAU 6476-4-hydroxy-desthio (determined as JAU 6476-4-hydroxy-desthio and calculated as JAU 6476-desthio). Residues for JAU 6476-5-hydroxy-desthio (determined as JAU 6476-5-hydroxy-desthio and calculated as JAU 6476-desthio). Residues for JAU 6476-6-hydroxy-desthio (determined as JAU 6476-6-hydroxy-desthio and calculated as JAU 6476-desthio)

Table A 78: 16-2046 - Residues of 1,2,4-T and TAA in/on spring and winter wheat applied with Prothioconazole & Spiroxamine EC 460

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Study Trial No. Plot No.  GLP  Year | Crop Variety | Country | Application | | | | | Residues (mg/kg) | | | |
| FL | No | kg/ha  (a.s.) | kg/hL (a.s.) | GS | Portion analysed | DALT (d) | 1,2,4,-T | TAA |
| 16-2046MAN 16-2046-01  16-2046-01-T  GLP: yes  2016 | Wheat, winter  Cougar | United Kingdom SG8 8SS Great Chishill, Royston Europe, North | 460 EC | 2 | 0.200 | 0.100 | 69 | green material | 0 | <0.01 | 0.088/0.061\*\* |
| grain | 50 | <0.01 | 0.26/0.14\*\* |
| straw | 50 | <0.01 | 0.097/0.062\*\* |
| 16-2046MAN 16-2046-04  16-2046-04-T  GLP: yes  2016 | Wheat, spring  Thasos | Germany 59609 Anröchte-Berge Europe, North | 460 EC | 2 | 0.200 | 0.0667 | 69 | green material | 0 | <0.01 | 0.037/0.015\*\* |
| grain | 53 | <0.01 | 0.13/0.039\*\* |
| straw | 53 | <0.01 | 0.031/0.013\*\* |
| 16-2046MAN 16-2046-03  16-2046-03-T  GLP: yes  2016 | Wheat, spring  Tybalt | Netherlands 1606 MG Venhuizen Europe, North | 460 EC | 2 | 0.200 | 0.0500 | 65 | green material | 0 | <0.01 | 0.013 |
| grain | 54 | <0.01 | 0.11 |
| straw | 54 | <0.01 | 0.018 |
| 16-2046MAN 16-2046-02  16-2046-02-T  GLP: yes  2016 | Wheat, winter  Dekan | Germany 51399 Burscheid Europe, North | 460 EC | 2 | 0.200 | 0.0667 | 69 | green material | 0 | <0.01 | 0.042 |
| grain | 62 | <0.01 | 0.22/0.027\*\* |
| straw | 62 | <0.01 | 0.036 |

\*\* residue in control.

Residues for 1,2,4-triazole (determined as 1,2,4-triazole and calculated as 1,2,4-triazole). Residues for triazole acetic acid (determined as triazole acetic acid and calculated as triazole acetic acid).

Table A 79: 16-2046 - Residues of TA and TLA in/on spring and winter wheat applied with Prothioconazole & Spiroxamine EC 460

| Study Trial No. Plot No.  GLP  Year | Crop Variety | Country | Application | | | | | Residues (mg/kg) | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FL | No | kg/ha  (a.s.) | kg/hL (a.s.) | GS | Portion analysed | DALT (d) | TA | TLA |
| 16-2046MAN 16-2046-01  16-2046-01-T  GLP: yes  2016 | Wheat, winter  Cougar | United Kingdom SG8 8SS Great Chishill, Royston Europe, North | 460 EC | 2 | 0.200 | 0.100 | 69 | green material | 0 | 0.14/0.079\*\* | 0.094/0.063\*\* |
| grain | 50 | 0.88/0.26\*\* | <0.01 |
| straw | 50 | 0.019 | 0.14/0.079\*\* |
| 16-2046MAN 16-2046-04  16-2046-04-T  GLP: yes  2016 | Wheat, spring  Thasos | Germany 59609 Anröchte-Berge Europe, North | 460 EC | 2 | 0.200 | 0.0667 | 69 | green material | 0 | 0.050/0.018\*\* | 0.033/0.016\*\* |
| grain | 53 | 0.23/0.079\*\* | <0.01 |
| straw | 53 | 0.011 | 0.015 |
| 16-2046MAN 16-2046-03  16-2046-03-T  GLP: yes  2016 | Wheat, spring  Tybalt | Netherlands 1606 MG Venhuizen Europe, North | 460 EC | 2 | 0.200 | 0.0500 | 65 | green material | 0 | 0.023 | 0.011 |
| grain | 54 | 0.36/0.015\*\* | <0.01 |
| straw | 54 | 0.011 | 0.019 |
| 16-2046MAN 16-2046-02  16-2046-02-T  GLP: yes  2016 | Wheat, winter  Dekan | Germany 51399 Burscheid Europe, North | 460 EC | 2 | 0.200 | 0.0667 | 69 | green material | 0 | 0.11 | 0.045 |
| grain | 62 | 0.77/0.042\*\* | <0.01 |
| straw | 62 | 0.063 | 0.021 |

\*\* residue in control.

Residues for triazole alanine (determined as triazole alanine and calculated as triazole alanine). Residues for triazole lactic acid (determined as triazole lactic acid and calculated as triazole lactic acid).

* + - * 1. Wheat residue trials analysing TDMs

The following tables were extracted from the “Triazole Derivate Metabolites addendum – confirmatory data prepared by the rapporteur Member State, the United Kingdom” Appendix C (UK, 2018).

Only trials performed with prothioconazole were considered and presented hereafter.

**Table A 80:** **Application summary of residue trials conducted with an EC formulation containing 150 g/L of prothioconazole**

Une image contenant table

Description générée automatiquement

**Table A 81: Results of residue trials conducted on wheat with an EC formulation containing 150 g/L of prothioconazole**

Une image contenant table

Description générée automatiquement

NA : not analysed

a 1,2,4-T = Residues determined as 1,2,4-triazole derivative, calculated as 1,2,4-triazole.

b TA = Residues determined as triazole alanine derivative, calculated as triazole alanine.

c TAA = Residues determined as triazole acetic acid derivative, calculated as triazole acetic acid.

d TLA = Triazole lactic acid not analysed.

**Table A 82:** **Application summary of residue trials conducted in/on wheat with an EC formulation containing 250 g/L of prothioconazole, after seed treatment with an FS formulation containing 100 g/L of prothioconazole**

Une image contenant table

Description générée automatiquement

Une image contenant table

Description générée automatiquement

**Table A 83:** **Results of residue trials conducted in/on wheat with an EC formulation containing 250 g/L of prothioconazole, after seed treatment with an FS formulation containing 100 g/L of prothioconazole**

Une image contenant table

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Description générée automatiquement

* + - 1. Oilseed rape and other oilseeds

Table A 84: Comparison of intended and critical EU GAPs

| Type of GAP | Number of applica­tions | Application rate per treatment  (g a.s./ha) | Interval between application | Growth stage at last application | PHI (days) |
| --- | --- | --- | --- | --- | --- |
| cGAP NEU (DAR, UK, 2007) | 2 | 175 | 14-28 | Start BBCH 53 | 56 |
| cGAP NEU (Art. 12, EFSA, 2020) *Oilseed rape, Linseeds, Poppy seeds, Mustard seeds* | 2 | 120 | 14 | - | 28 |
| cGAP NEU (Art. 12, EFSA, 2020) *Gold of pleasure* | 2 | 175 | 14 | - | 56 |
| Intended cGAP CEU | 1 | 180 | - | BBCH 69 | 56 |

* + - * 1. Study S19-01269 – NEU + SEU

|  |  |
| --- | --- |
| Comments of zRMS: | The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for CA3301/ Joust (January 2023). This study has not been reassessed in the framework of this application.  The conclusions of the assessment are presented below:  *Six residue trials on oilseed rape were conducted in northern Europe to determine residue of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio and TDMs.*  *Oilseed rape was treated twice at application rate of 0.175 kg a.s./ha of prothioconazole with 14 days interval between applications. The time of application was*  *1. at BBCH 65,*  *2. at BBCH 69.*  *Samples were taken 56 days after the final application at normal commercial harvest.*  *The limit of quantification (LOQ) of the analytical methods were 0.01 mg/kg for each analyte/matrix with a limit of detection (LOD) set at 0.003 mg/kg.*  *The mean recoveries at each fortification level comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, rev. 1.*  *Maximum storage period – 454 days.*  *Residues of prothioconazole-desthio and hydroxy- derivatives of prothioconazole-desthio, in oilseed rape grain at harvest were between <0.003 and 0.03 mg/kg.*  *Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest ranged between <0.06 and 0.08 mg/kg.*  *Residues of 1,2,4-triazole in oilseed rape grain at harvest were < 0.003 mg/kg.*  *Residues of triazole alanine in oilseed rape grain at harvest ranged 1.2 – 2.1 mg/kg.*  *Residues of triazole acetic acid in oilseed rape grain at harvest ranged between <0.01 and 0.1 mg/kg.*  *Residues of triazole lactic acid in oilseed rape grain at harvest were between 0.02 and 0.12 mg/kg.*  *The study is acceptable.* |

|  |  |
| --- | --- |
| Reference: | KCA 6.3.3/01 |
| Report | Determination of residues of Prothioconazole-desthio (sum of isomers) after two applications of Prothioconazole 250EC in Oilseed rape (outdoor) at 4 sites in Northern Europe and 4 sites in Southern Europe 2019  North, L., 2021  Report No: S19-01269 |
| Guideline(s): | OECD (2009) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32)  OECD Test Guideline 509: Crop field trials  OECD (2016) Guidance Document ENV/JM/MONO (2011)50/REV1 , Second Edition, on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66)  EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials  European Community Guideline SANCO 7525/VI/95, Rev. 10.3, 13/06/17: Comparability, extrapolation, group tolerances and data requirements for setting MRLs) |
| Deviations: | None |
| GLP: | Yes |
| Owner: | Nufarm Crop Products UK |
| Acceptability: | Yes |

Materials and Methods

Eight residue trials were conducted on oilseed rape during 2019, three in France (S19-01269-03, 07 and 08), one in the United Kingdom (S19-01269-01), one in Germany S19-01269-02, one in Hungary S19-01269-04, one in Spain S19-01269-05, and one in Italy S19-01269-06.

Two applications of NUL3390 Prothioconazole 250 EC (250g/L, prothioconazole) were applied at 175 g ai/ha, diluted with water immediately prior to application to a spray volume of 100-400 L/ha.

Samples of oilseed rape from the untreated and treated plots were taken by hand at 0, 7, 14, 35 and 56 days after the final application.

Oilseed rape samples were analysed for residues of prothioconazole (PTZ)-desthio according to the multi-residue QuEChERS method that was previously validated according to SANCO/30299/99, rev.4 and SANCO/825/00 rev. 8.1 for wheat (grain), grapes, oilseed rape (seed), bean (dry) and cucumber in Eurofins Agroscience Services study S16-04434. The quantitation is done using liquid chromatography with tandem mass spectrometry (LC-MS/MS).

The limit of quantitation for the method is set at 0.01 mg/kg.

Oilseed rape samples were analysed for residues of PTZ-alpha-hydroxy-desthio, PTZ-3-, -4-, -5- and -6-hydroxy-desthio according to the analytical method described in Eurofins Agroscience Services study S16-04435 that was previously validated according to SANCO/30299/99, rev.4 and SANCO/825/00 rev. 8.1 for wheat (whole plant, grain and straw) and oilseed rape (seed). The quantitation is done using liquid chromatography with tandem mass spectrometry (LC-MS/MS).

The limit of quantitation for the method is set at 0.01 mg/kg for each analyte. The analytes were fortified jointly and quantified separately. For PTZ-alpha-hydroxy-desthio, PTZ-3-, -4-, -5- and -6-hydroxy-desthio the LOQ is expressed as PTZ-desthio.

Oilseed rape samples were analysed for residues of triazole derivative metabolites (TDMs) 1,2,4-Triazole, triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) according to the analytical method described in S15-03542 that was previously validated according to SANCO/825/00 rev. 8.1 for wheat (grain and straw), barley (grain and straw), grape (bunches) and oilseed rape. The quantitation was done using liquid chromatography with tandem mass spectrometry (LC-MS/MS).

The limit of quantitation for the method is set at 0.01 mg/kg for each analyte. The analytes were fortified jointly and quantified separately.

The maximum storage interval from sampling to extraction was 326 days for oilseed rape (whole plant) and 454 days for oilseed rape (seed). Storage at the Analytical Test Site from sample receipt until lab sample preparation was at ≤ -18 °C.

The maximum interval from extraction to analysis at typically 1 °C to 10 °C with given exceptions (e.g. periods during sample extraction/work-up, periods during transfer to detection instrument and possible minor fluctuations of refrigerator temperatures) was six days for oilseed rape (whole plant) and one day for oilseed rape (seed).

The analytical methods were validated for the determination of all analytes in oilseed rape (whole plant and seed) according to SANCO/3029/99, rev.4 during analysis. All mean recovery values (corrected for apparent blank residues, if necessary) at fortification levels of LOQ and 10x LOQ comply with the standard acceptance criteria of the guidance document with evaluation of one (1) mass transition.

Procedural recoveries run concurrently with test sample are summarized in the table below:

Table A 85: Summary of procedural recoveries

| **Analyte** | **Matrix** | **Fortification Levels (mg/kg)** | **Overall Mean Recovery (%)** |
| --- | --- | --- | --- |
| Prothioconazole-desthio | Whole plant | 0.01, 0.1, 4.0 | 91 |
| Seed | 0.01, 0.1 | 90 |
| Prothioconazole-α-hydroxy-desthio | Whole plant | 0.01, 0.1, 0.25 | 109 |
| Seed | 0.01, 0.1 | 102 |
| Prothioconazole-3-hydroxy-desthio | Whole plant | 0.01, 0.1, 0.25 | 107 |
| Seed | 0.01, 0.1 | 96 |
| Prothioconazole-4-hydroxy-desthio | Whole plant | 0.01, 0.1, 0.25 | 108 |
| Seed | 0.01, 0.1 | 93 |
| Prothioconazole-5-hydroxy-desthio | Whole plant | 0.01, 0.1, 0.25 | 109 |
| Seed | 0.01, 0.1 | 97 |
| Prothioconazole-6-hydroxy-desthio | Whole plant | 0.01, 0.1, 0.25 | 97 |
| Seed | 0.01, 0.1 | 85 |
| 1,2,4-Triazole | Whole plant | 0.01, 0.1 | 106 |
| Seed | 0.01, 0.1 | 86 |
| Triazole alanine | Whole plant | 0.01, 0.1, 1.2 | 105 |
| Seed | 0.01, 0.05, 0.1, 0.5, 1.2, 4.0 | 91 |
| Triazole acetic acid | Whole plant | 0.01, 0.1, 0.6 | 104 |
| Grain | 0.01, 0.1, 0.6 | 99 |
| Triazole lactic acid | Whole plant | 0.01, 0.1, 0.4 | 100 |
| Grain | 0.01, 0.1, 0.4 | 92 |

Findings

The residue levels found in oilseed rape are summarised in the table below.

In trial S19-01269-01 residues of **prothioconazole-desthio** above the LOQ were found in seeds from the control plot (0.03 mg/kg). However, no deviations were reported, either for the field phase or for the analytical phase. Therefore, there is no reason to exclude this trial and as a worst case the result in the control sample, which is higher than the one in the treated sample, was considered for MRL compliance and risk assessment.

Table A 86: Summary of the study S19-01269 trials

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | NUL 3390 PROTHIOCONAZOLE 250 EC | | |
| Crop/crop group: | | | | | **Oilseed rape** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | |
| Country (of trial sites): | | | | | UK | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | Prothioconazole-desthio (mg/kg) | | |
|  | | | | |  | | | |  | | | |  | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-desthio |
| S19-01269-01  Ashill, Suffolk, UK, IP257BS | | Oilseed rape / BRSNN / DK Expansion | 1) 15 Aug 18  2) na  3) 12 Jul 19 | Overall spray using a plot sprayer | | 87.7 | 203 | 178 | 2  17 May 19 | | 69 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | 0.72  0.21  0.13  0.04  0.02 / 0.03\*\* | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples, except seed at 56DAA with a residue of 0.03 mg/kg |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |  |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | |  | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | | | |
| Crop/crop group: | | | | | **Oilseed rape** | | | | Producer of commercial product: | | | |  | Nufarm UK Limited | | | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | |  | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | | | |
| Country (of trial sites): | | | | | United Kingdom | | | | Indoor/Glasshouse/Outdoor: | | | |  | Outdoor | | | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | |  | none | | | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | |  | Prothioconazole-desthio (mg/kg) | | | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | 7 | | 8 | 9 | | | | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | Growth stage at last treatment or date  (e)  BBCH | | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | | | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-α-OH-desthio | | PTZ-3-OH-desthio | PTZ-4-OH-desthio | PTZ-5-OH-desthio | PTZ-6-OH-desthio | Total (PTZ-desthio+hydroxy=RD-RA1)\* |
| S19-01269-01  Ashill, Suffolk, UK, IP257BS | | Oilseed rape / BRSNN / DK Expansion | 1) 15 Aug 18  2) na  3) 12 Jul 19 | Overall spray using a plot sprayer | | 87.7 | 203 | 178 | 2  17 May 19 | 69 | | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.003  <0.01  <0.01  <0.01  <0.01 | | 0.03  0.06  0.08  0.09  0.02 | 0.01  0.02  0.03  0.03  0.01 | <0.003  <0.01  <0.01  <0.01  <0.01 | <0.003  <0.003  <0.003  <0.003  <0.003 | 0.77  0.31  0.26  0.18  0.08 | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | |  | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | |  | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | |  | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | |  | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg, | | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | |
| Crop/crop group: | | | | | **Oilseed rape** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | |
| Country (of trial sites): | | | | | United Kingdom | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | 1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg) | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | 1,2,4-Triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid |
| S19-01269-01  Ashill, Suffolk, UK, IP257BS | | Oilseed rape / BRSNN / DK Expansion | 1) 15 Aug 18  2) na  3) 12 Jul 19 | Overall spray using a plot sprayer | | 87.7 | 203 | 178 | 2  17 May 19 | | 69 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.003  <0.003  <0.003  <0.003  <0.003 | 0.30  0.25  0.25  0.37  1.4/0.80\*\* | 0.01  0.01  <0.01  0.01  0.01 | 0.01  0.01  0.01  0.02  0.04/0.04\*\* | 0  7  14  35  56 | No residues >LOQ were found in any 1,2,4 triazole untreated samples, Residues ranged from <0.01-0.80 mg/kg in all other untreateds |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)** | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | NUL 3390 PROTHIOCONAZOLE 250 EC | | | |
| Crop/crop group: | | | | | **Oilseed rape** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |
| Country (of trial sites): | | | | | Germany | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | Prothioconazole-desthio (mg/kg) | | | |
|  | | | | |  | | | |  | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-desthio | |
| S19-01269-02 21737, Wisehnafen, Lower Saxony, Germany | | Oilseed rape / BRSNN / Exception | 1) 03 Sep 18  2) 27 Apr – 20 May 19  3) 24 Jul 19 | Overall spray using a plot sprayer | | 58 | 296 | 173 | 2  16 May 19 | | 68 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | 0.70  0.20  0.12  0.01  <0.01 | | 0  7  14  35  69 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |  |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | |  | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | | | |
| Crop/crop group: | | | | | **Oilseed rape** | | | | Producer of commercial product: | | | |  | Nufarm UK Limited | | | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | |  | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | | | |
| Country (of trial sites): | | | | | Germany | | | | Indoor/Glasshouse/Outdoor: | | | |  | Outdoor | | | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | |  | none | | | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | |  | Prothioconazole-desthio (mg/kg) | | | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | 7 | | 8 | 9  Residues (mg/kg)  (\*) | | | | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | Growth stage at last treatment or date  (e)  BBCH | | Portion analysed  (a) | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-α-OH-desthio | | PTZ-3-OH-desthio | PTZ-4-OH-desthio | PTZ-5-OH-desthio | PTZ-6-OH-desthio | Total (PTZ-desthio+hydroxy=RD-RA1)\* |
| S19-01269-02 21737, Wisehnafen, Lower Saxony, Germany | | Oilseed rape / BRSNN / Exception | 1) 03 Sep 18  2) 27 Apr – 20 May 19  3) 24 Jul 19 | Overall spray using a plot sprayer | | 58 | 296 | 173 | 2  16 May 19 | 68 | | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.003  <0.01  <0.003  <0.003  <0.003 | | 0.03  0.06  0.06  0.04  <0.01 | 0.01  0.02  0.02  0.01  <0.003 | <0.003  <0.01  <0.01  <0.003  <0.003 | <0.003  <0.003  <0.003  <0.003  <0.003 | 0.75  0.30  0.22  0.07  <0.06 | 0  7  14  35  69 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | |  | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | |  | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | |  | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | |  | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | |
| Crop/crop group: | | | | | **Oilseed rape** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | |
| Country (of trial sites): | | | | | Germany | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | 1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg) | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | 1,2,4-Triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid |
| S19-01269-02 21737, Wisehnafen, Lower Saxony, Germany | | Oilseed rape / BRSNN / Exception | 1) 03 Sep 18  2) 27 Apr – 20 May 19  3) 24 Jul 19 | Overall spray using a plot sprayer | | 58 | 296 | 173 | 2  16 May 19 | | 68 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.003  <0.003  <0.003  <0.003  <0.003 | 0.09  0.15  0.23  0.15  1.2/0.39\*\* | <0.003  <0.01  <0.01  <0.01  0.01 | <0.01  <0.01  <0.01  0.01  0.05/0.03\*\* | 0  7  14  35  69 | No residues >LOQ were found in any 1,2,4 triazole untreated samples, Residues ranged from <0.003-0.39 mg/kg in all other untreateds |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)** | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | NUL 3390 PROTHIOCONAZOLE 250 EC | | | |
| Crop/crop group: | | | | | **Oilseed rape** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |
| Country (of trial sites): | | | | | France | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | Prothioconazole-desthio (mg/kg) | | | |
|  | | | | |  | | | |  | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-desthio | |
| S19-01269-03  67140 Statzheim, Bas-Rhin, Alsace, France | | Oilseed rape / BRSNN / Hillier | 1) 25 Aug 19  2) 05 Apr – 10 May  3) 05 Jul 19 | Overall spray using a plot sprayer | | 58.3 | 302 | 176 | 2  10 May 2018 | | 67-69 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | 0.71  0.29  0.12  0.02  0.01 | | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |  |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | |  | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | | | |
| Crop/crop group: | | | | | **Oilseed rape** | | | | Producer of commercial product: | | | |  | Nufarm UK Limited | | | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | |  | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | | | |
| Country (of trial sites): | | | | | France | | | | Indoor/Glasshouse/Outdoor: | | | |  | Outdoor | | | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | |  | none | | | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | |  | Prothioconazole-desthio (mg/kg) | | | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | 7 | | 8 | 9  Residues (mg/kg)  (\*) | | | | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | Growth stage at last treatment or date  (e)  BBCH | | Portion analysed  (a) | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-α-OH-desthio | | PTZ-3-OH-desthio | PTZ-4-OH-desthio | PTZ-5-OH-desthio | PTZ-6-OH-desthio | Total (PTZ-desthio+hydroxy=RD-RA1)\* |
| S19-01269-03  67140 Statzheim, Bas-Rhin, Alsace, France | | Oilseed rape / BRSNN / Hillier | 1) 25 Aug 19  2) 05 Apr – 10 May  3) 05 Jul 19 | Overall spray using a plot sprayer | | 58.3 | 302 | 176 | 2  10 May 2018 | 67-69 | | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.003  <0.01  <0.01  <0.01  <0.01 | | 0.02  0.07  0.08  0.06  0.02 | <0.01  0.03  0.03  0.01  <0.01 | <0.003  <0.01  <0.01  <0.01  <0.003 | <0.003  <0.003  <0.003  <0.003  <0.003 | 0.75  0.41  0.25  0.11  0.06 | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | |  | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | |  | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | |  | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | |  | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | |
| Crop/crop group: | | | | | **Oilseed rape** | | | | Producer of commercial product: | | | Nufarm UK Limited | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | |
| Country (of trial sites): | | | | | France | | | | Indoor/Glasshouse/Outdoor: | | | Outdoor | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | none | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | 1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg) | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | 7 | 8 | 9 | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | 1,2,4-Triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid |
| S19-01269-03  67140 Statzheim, Bas-Rhin, Alsace, France | | Oilseed rape / BRSNN / Hillier | 1) 25 Aug 19  2) 05 Apr – 10 May  3) 05 Jul 19 | Overall spray using a plot sprayer | | 58.3 | 302 | 176 | 2  10 May 2018 | 67-69 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.003  <0.003  <0.003  <0.003  <0.003 | 0.07  0.11  0.12  0.24  1.2/0.74\*\* | <0.003  <0.01  <0.01  <0.01  0.01 | <0.003  <0.01  <0.01  0.02  0.09/0.06\*\* | 0  7  14  35  56 | >LOQ were found in any 1,2,4 triazole untreated samples, Residues ranged from <0.003-0.74 mg/kg in all other untreateds |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)** | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | NUL 3390 PROTHIOCONAZOLE 250 EC | | | |
| Crop/crop group: | | | | | **Oilseed rape** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |
| Country (of trial sites): | | | | | Hungary | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | Prothioconazole-desthio (mg/kg) | | | |
|  | | | | |  | | | |  | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-desthio | |
| S19-01269-04  H-5440 Kunszentmarton, Jasz-Nagykun-Szolnok, Hungary | | Oilseed rape / BRSNN / KWS Gordon | 1)04 Sep 19  2) 16 Apr – 10 May 19  3) 27 Jun 19 | Overall spray using a plot sprayer | | 58.3 | 312 | 182 | 2  02 May 19 | | 69 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | 2.9  0.62  0.16  0.02  <0.01 | | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | | |  |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | |  | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | | | |
| Crop/crop group: | | | | | **Oilseed rape** | | | | Producer of commercial product: | | | | |  | Nufarm UK Limited | | | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | |  | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | | | |
| Country (of trial sites): | | | | | Hungary | | | | Indoor/Glasshouse/Outdoor: | | | | |  | Outdoor | | | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | |  | none | | | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | |  | Prothioconazole-desthio (mg/kg) | | | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | 7 | | | 8 | 9  Residues (mg/kg)  (\*) | | | | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | Growth stage at last treatment or date  (e)  BBCH | | | Portion analysed  (a) | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-α-OH-desthio | | PTZ-3-OH-desthio | PTZ-4-OH-desthio | PTZ-5-OH-desthio | PTZ-6-OH-desthio | Total (PTZ-desthio+hydroxy=RD-RA1)\* |
| S19-01269-04  H-5440 Kunszentmarton, Jasz-Nagykun-Szolnok, Hungary | | Oilseed rape / BRSNN / KWS Gordon | 1)04 Sep 19  2) 16 Apr – 10 May 19  3) 27 Jun 19 | Overall spray using a plot sprayer | | 58.3 | 312 | 182 | 2  02 May 19 | 69 | | | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.01  0.01  <0.01  <0.01  <0.01 | | 0.14  0.21  0.15  0.12  <0.01 | 0.06  0.07  0.06  0.04  <0.003 | 0.02  0.02  0.02  <0.01  <0.003 | <0.003  <0.003  <0.003  <0.003  <0.003 | 3.13  0.93  0.40  0.20  <0.06 | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | |  | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | |  | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | |  | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | |  | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | |
| Crop/crop group: | | | | | **Oilseed rape** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | |
| Country (of trial sites): | | | | | Hungary | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | 1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg) | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | 1,2,4-Triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid |
| S19-01269-04  H-5440 Kunszentmarton, Jasz-Nagykun-Szolnok, Hungary | | Oilseed rape / BRSNN / KWS Gordon | 1)04 Sep 19  2) 16 Apr – 10 May 19  3) 27 Jun 19 | Overall spray using a plot sprayer | | 58.3 | 312 | 182 | 2  02 May 19 | | 69 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.003  <0.003  <0.003  <0.003  <0.003 | 0.07  0.07  0.13  0.35  2.1/2.1\*\* | <0.003  <0.003  <0.003  <0.01  0.02/0.03\*\* | <0.01  <0.003  <0.003  0.01  0.12/0.16\*\* | 0  7  14  35  56 | No residues >LOQ were found in any 1,2,4 triazole untreated samples, Residues ranged from <0.003-2.1 mg/kg in all other untreateds |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)** | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | NUL 3390 PROTHIOCONAZOLE 250 EC | | | |
| Crop/crop group: | | | | | **Oilseed rape** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |
| Country (of trial sites): | | | | | Spain | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | Prothioconazole-desthio (mg/kg) | | | |
|  | | | | |  | | | |  | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-desthio | |
| S19-01269-05 49510 Fonfria, Aragon, Spain | | Oilseed rape / BRSNN / Expression | 1) 05 Sep 18  2) Apr-May  3) 11 Jul 19 | Overall spray using a plot sprayer | | 58 | 314 | 183 | 2  16 May 19 | | 69-71 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | 0.21  0.14  0.08  0.02  <0.01 | | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | | |  |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | |  | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | | | |
| Crop/crop group: | | | | | **Oilseed rape** | | | | Producer of commercial product: | | | | |  | Nufarm UK Limited | | | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | |  | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | | | |
| Country (of trial sites): | | | | | Spain | | | | Indoor/Glasshouse/Outdoor: | | | | |  | Outdoor | | | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | |  | none | | | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | |  | Prothioconazole-desthio (mg/kg) | | | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | 7 | | | 8 | 9  Residues (mg/kg)  (\*) | | | | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | Growth stage at last treatment or date  (e)  BBCH | | | Portion analysed  (a) | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-α-OH-desthio | | PTZ-3-OH-desthio | PTZ-4-OH-desthio | PTZ-5-OH-desthio | PTZ-6-OH-desthio | Total (PTZ-desthio+hydroxy=RD-RA1)\* |
| S19-01269-05 49510 Fonfria, Aragon, Spain | | Oilseed rape / BRSNN / Expression | 1) 05 Sep 18  2) Apr-May  3) 11 Jul 19 | Overall spray using a plot sprayer | | 58 | 314 | 183 | 2  16 May 19 | 69-71 | | | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.003  <0.003  <0.003  <0.003  <0.003 | | 0.06  0.06  0.09  0.08  0.01 | 0.02  0.02  0.03  0.02  <0.003 | <0.01  <0.01  <0.01  <0.01  <0.003 | <0.003  <0.003  <0.003  <0.003  <0.003 | 0.31  0.24  0.22  0.14  0.03 | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | |  | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | |  | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | |  | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | |  | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | |
| Crop/crop group: | | | | | **Oilseed rape** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | |
| Country (of trial sites): | | | | | Spain | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | 1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg) | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | 1,2,4-Triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid |
| S19-01269-05 49510 Fonfria, Aragon, Spain | | Oilseed rape / BRSNN / Expression | 1) 05 Sep 18  2) Apr-May  3) 11 Jul 19 | Overall spray using a plot sprayer | | 58 | 314 | 183 | 2  16 May 19 | | 69-71 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.003  <0.003  <0.003  <0.003  <0.003 | 0.02  0.03  0.05  0.04  0.47/0.12\*\* | <0.003  <0.003  <0.003  <0.003  <0.01 | <0.003  <0.003  <0.01  0.01  0.02/0.01\*\* | 0  7  14  35  56 | No residues >LOQ were found in any 1,2,4 triazole untreated samples, Residues ranged from <0.003-0.12 mg/kg in all other untreateds |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)** | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | NUL 3390 PROTHIOCONAZOLE 250 EC | | | |
| Crop/crop group: | | | | | **Oilseed rape** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |
| Country (of trial sites): | | | | | Italy | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | Prothioconazole-desthio (mg/kg) | | | |
|  | | | | |  | | | |  | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-desthio | |
| S19-01269-06 40068 Idice, Emilia Romagna, Italy | | Oilseed rape / BRSNN / Dariot | 1) 20 Oct 18  2) 02 Apr – 03 May 19  3) 14 Jun 19 | Overall spray using a plot sprayer | | 46.7 | 410 | 179 | 2  19 Apr 19 | | 65 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | 0.58  0.66  0.32  0.10  <0.003 n.d. | | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg, n.d. = not detected | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | | |  |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | |  | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | | | |
| Crop/crop group: | | | | | **Oilseed rape** | | | | Producer of commercial product: | | | | |  | Nufarm UK Limited | | | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | |  | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | | | |
| Country (of trial sites): | | | | | Italy | | | | Indoor/Glasshouse/Outdoor: | | | | |  | Outdoor | | | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | |  | none | | | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | |  | Prothioconazole-desthio (mg/kg) | | | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | 7 | | | 8 | 9  Residues (mg/kg)  (\*) | | | | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | Growth stage at last treatment or date  (e)  BBCH | | | Portion analysed  (a) | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-α-OH-desthio | | PTZ-3-OH-desthio | PTZ-4-OH-desthio | PTZ-5-OH-desthio | PTZ-6-OH-desthio | Total (PTZ-desthio+hydroxy=RD-RA1)\* |
| S19-01269-06 40068 Idice, Emilia Romagna, Italy | | Oilseed rape / BRSNN / Dariot | 1) 20 Oct 18  2) 02 Apr – 03 May 19  3) 14 Jun 19 | Overall spray using a plot sprayer | | 46.7 | 410 | 179 | 2  19 Apr 19 | 65 | | | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.01  0.01  <0.01  <0.01  <0.003 | | 0.04  0.11  0.12  0.12  <0.01 | 0.01  0.04  0.04  0.04  <0.003 | <0.01  <0.01  0.01  <0.01  <0.003 | <0.003  <0.003  <0.003  <0.003  <0.003 | 0.65  0.83  0.50  0.28  <0.06 | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | |  | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | |  | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | |  | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | |  | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | |
| Crop/crop group: | | | | | **Oilseed rape** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | |
| Country (of trial sites): | | | | | Italy | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | 1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg) | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | 1,2,4-Triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid |
| S19-01269-06 40068 Idice, Emilia Romagna, Italy | | Oilseed rape / BRSNN / Dariot | 1) 20 Oct 18  2) 02 Apr – 03 May 19  3) 14 Jun 19 | Overall spray using a plot sprayer | | 46.7 | 410 | 179 | 2  19 Apr 19 | | 65 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.003  <0.01  <0.003  <0.003  <0.003 | 0.10  0.39  0.13  0.15  3.3/1.9\*\* | <0.01  <0.01  <0.01  <0.01  0.04/0.03\*\* | <0.01  0.02  <0.01  <0.01  0.14/0.11\*\* | 0  7  14  35  56 | No residues >LOQ were found in any 1,2,4 triazole untreated samples, Residues ranged from <0.003-1.9 mg/kg in all other untreateds |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)** | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | NUL 3390 PROTHIOCONAZOLE 250 EC | | | |
| Crop/crop group: | | | | | **Oilseed rape** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |
| Country (of trial sites): | | | | | France | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | Prothioconazole-desthio (mg/kg) | | | |
|  | | | | |  | | | |  | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-desthio | |
| S19-01269-07 82700 St Porquier, Tarn et Garonne, France | | Oilseed rape / BRSNN / Trezzor | 1) 26 Sep 18  2) 05-20 Apr 19  3) 25 Jun 19 | Overall spray using a plot sprayer | | 87.2 | 203 | 177 | 2  02 May 19 | | 69-72 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | 0.41  0.38  0.14  0.03  <0.01 | | 0  7  14  35  54 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |  |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | |  | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | | | |
| Crop/crop group: | | | | | **Oilseed rape** | | | | Producer of commercial product: | | | |  | Nufarm UK Limited | | | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | |  | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | | | |
| Country (of trial sites): | | | | | France | | | | Indoor/Glasshouse/Outdoor: | | | |  | Outdoor | | | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | |  | none | | | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | |  | Prothioconazole-desthio (mg/kg) | | | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | 7 | | 8 | 9  Residues (mg/kg)  (\*) | | | | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | Growth stage at last treatment or date  (e)  BBCH | | Portion analysed  (a) | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-α-OH-desthio | | PTZ-3-OH-desthio | PTZ-4-OH-desthio | PTZ-5-OH-desthio | PTZ-6-OH-desthio | Total (PTZ-desthio+hydroxy=RD-RA1)\* |
| S19-01269-07 82700 St Porquier, Tarn et Garonne, France | | Oilseed rape / BRSNN / Trezzor | 1) 26 Sep 18  2) 05-20 Apr 19  3) 25 Jun 19 | Overall spray using a plot sprayer | | 87.2 | 203 | 177 | 2  02 May 19 | 69-72 | | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.01  <0.01  <0.01  <0.003  <0.01 | | 0.05  0.05  0.07  0.08  <0.01 | 0.02  0.02  0.02  0.02  <0.003 | <0.01  <0.01  <0.01  <0.003  <0.003 | <0.003  <0.003  <0.003  <0.003  <0.003 | 0.50  0.47  0.25  0.14  <0.06 | 0  7  14  35  54 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | |  | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | |  | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | |  | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | |  | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | |
| Crop/crop group: | | | | | **Oilseed rape** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | |
| Country (of trial sites): | | | | | France | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | 1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg) | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | 1,2,4-Triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid |
| S19-01269-07 82700 St Porquier, Tarn et Garonne, France | | Oilseed rape / BRSNN / Trezzor | 1) 26 Sep 18  2) 05-20 Apr 19  3) 25 Jun 19 | Overall spray using a plot sprayer | | 87.2 | 203 | 177 | 2  02 May 19 | | 69-72 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.003  <0.003  <0.003  <0.003  <0.003 | 0.28  0.36  0.34  0.41  1.6/1.2\*\* | <0.01  <0.01  <0.01  0.01  0.02/0.01\*\* | 0.01  0.02  0.02  0.04  0.09/0.07\*\* | 0  7  14  35  54 | No residues >LOQ were found in any 1,2,4 triazole untreated samples, Residues ranged from <0.003-1.2 mg/kg in all other untreateds |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)** | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | NUL 3390 PROTHIOCONAZOLE 250 EC | | | |
| Crop/crop group: | | | | | **Oilseed rape** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |
| Country (of trial sites): | | | | | France | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | Prothioconazole-desthio (mg/kg) | | | |
|  | | | | |  | | | |  | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-desthio | |
| S19-01269-08 82200 Moissac, Tarn et Garonne, France | | Oilseed rape / BRSNN / Attletick | 1) 04 Sep 18  2) 05-25 Apr 19  3) 24 Jun 19 | Overall spray using a plot sprayer | | 87.7 | 203 | 178 | 2  02 May 19 | | 78-80 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | 0.49  0.22  0.10  0.04  0.01 | | 0  7  14  35  53 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | | |  |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | |  | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | | | |
| Crop/crop group: | | | | | **Oilseed rape** | | | | Producer of commercial product: | | | | |  | Nufarm UK Limited | | | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | |  | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | | | |
| Country (of trial sites): | | | | | France | | | | Indoor/Glasshouse/Outdoor: | | | | |  | Outdoor | | | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | |  | none | | | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | |  | Prothioconazole-desthio (mg/kg) | | | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | 7 | | | 8 | 9  Residues (mg/kg)  (\*) | | | | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | Growth stage at last treatment or date  (e)  BBCH | | | Portion analysed  (a) | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-α-OH-desthio | | PTZ-3-OH-desthio | PTZ-4-OH-desthio | PTZ-5-OH-desthio | PTZ-6-OH-desthio | Total (PTZ-desthio+hydroxy=RD-RA1)\* |
| S19-01269-08 82200 Moissac, Tarn et Garonne, France | | Oilseed rape / BRSNN / Attletick | 1) 04 Sep 18  2) 05-25 Apr 19  3) 24 Jun 19 | Overall spray using a plot sprayer | | 87.7 | 203 | 178 | 2  02 May 19 | 78-80 | | | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.003  <0.01  <0.003  <0.003  <0.01 | | 0.05  0.06  0.09  0.09  <0.01 | 0.02  0.02  0.02  0.02  <0.003 | <0.01  <0.01  <0.01  <0.01  <0.003 | <0.003  <0.003  <0.003  <0.003  <0.003 | 0.58  0.32  0.23  0.17  <0.06 | 0  7  14  35  53 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EPPO codes | | | | | | | | (e) | |  | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | |  | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | |  | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | (\*) | |  | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **PROTHIOCONAZOLE** | | | | Commercial Product (name): | | | | NUL 3390 PROTHIOCONAZOLE 250 EC | | | | | |
| Crop/crop group: | | | | | **Oilseed rape** | | | | Producer of commercial product: | | | | Nufarm UK Limited | | | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm UK Limited  Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | |  | | | | Wyke Lane  Wyke, Bradford  BD12 9EJ, UK | | | | | |
| Country (of trial sites): | | | | | France | | | | Indoor/Glasshouse/Outdoor: | | | | Outdoor | | | | | |
| Content of active substance nominal (g/kg or g/L): | | | | | 250 | | | | Other active substance in the formulation (common name and content): | | | | none | | | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | Residues calculated as: | | | | 1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg) | | | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | 7 | 8 | 9 | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | 1,2,4-Triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid |
| S19-01269-08 82200 Moissac, Tarn et Garonne, France | | Oilseed rape / BRSNN / Attletick | 1) 04 Sep 18  2) 05-25 Apr 19  3) 24 Jun 19 | Overall spray using a plot sprayer | | 87.7 | 203 | 178 | 2  02 May 19 | | 78-80 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.003  <0.003  <0.003  <0.003  <0.003 | 0.10  0.05  0.07  0.08  0.41/0.48\*\* | <0.01  <0.003  <0.01  <0.01  <0.01 | <0.01  <0.01  <0.01  0.01  0.02/0.04\*\* | 0  7  14  35  53 | No residues >LOQ were found in any 1,2,4 triazole untreated samples, Residues ranged from <0.003-0.48 mg/kg in all other untreateds |
| (a) | | According to EPPO codes | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | | |

* + - * 1. Study S20-01046 – NEU + SEU

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| Comments of zRMS: | The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for CA3301/ Joust (January 2023). This study has not been reassessed in the framework of this application.  The conclusions of the assessment are presented below:  *Four residue trials on oilseed rape were conducted in northern Europe to determine residue of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio and TDMs.*  *Oilseed rape was treated twice at application rate of 0.175 kg a.s./ha of prothioconazole with 14 days interval between applications. The time of application was*  *1. at BBCH 65,*  *2. at BBCH 69.*  *Samples were taken 56-59 days after the final application at normal commercial harvest.*  *The limit of quantification (LOQ) of the analytical methods were 0.01 mg/kg for each analyte/matrix with a limit of detection (LOD) set at 0.003 mg/kg.*  *The mean recoveries at each fortification level comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, rev. 1.*  *Maximum storage period – 420 days.*  *Residues of prothioconazole-desthio and hydroxy- derivatives of prothioconazole-desthio in oilseed rape grain at harvest were between <0.003 and 0.02 mg/kg.*  *Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest ranged between <0.06 and 0.07 mg/kg.*  *Residues of 1,2,4-triazole in oilseed rape grain at harvest were < 0.003 mg/kg.*  *Residues of triazole alanine in oilseed rape grain at harvest ranged between 0.43 and 1.4 mg/kg.*  *Residues of triazole acetic acid in oilseed rape grain at harvest ranged between <0.01 and 0.01 mg/kg.*  *Residues of triazole lactic acid in oilseed rape grain at harvest were between 0.03 and 0.04 mg/kg.*  *The study is acceptable.* |

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| Reference: | KCA 6.3.3/02 |
| Report | Determination of residues of Prothioconazole-desthio (sum of isomers) after two applications of Prothioconazole 250EC in Oilseed rape (outdoor) at 4 sites in Northern Europe and 4 sites in Southern Europe 2020  North, L., 2021  Report No: S20-01046 |
| Guideline(s): | OECD (2009) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32)  OECD Test Guideline 509: Crop field trials  OECD (2016) Guidance Document ENV/JM/MONO (2011)50/REV1 , Second Edition, on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66)  EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials  European Community Guideline SANCO 7525/VI/95, Rev. 10.3, 13/06/17: Comparability, extrapolation, group tolerances and data requirements for setting MRLs) |
| Deviations: | S20-01046-01: seed samples could not be taken as the grower had combined through the trial. Therefore no seeds samples were available for analysis. (No impact on other results) |
| GLP: | Yes |
| Owner: | Nufarm Crop Products UK |
| Acceptability: | Yes |

Materials and Methods

Eight residue trials were conducted on oilseed rape during 2020, two in the United Kingdom (S20-01046-01, -09), one in Germany (S20-01046-02), two in France (S20-01046-03, -05), one in Spain (S20-01046-06) and two in Italy (S20-01046-07, -08). Two applications of NUL 3390 Prothioconazole 250 EC (250 g/L, Prothioconazole) were applied at 175 g ai/ha, diluted with water immediately prior to application to a spray volume of 100-400 L/ha.

Samples of oilseed rape from the untreated and treated plots were taken by hand 0 (0DAA2), 7 (7DAA2), 14 (14DAA2), 35 (35DAA2) and 56/59 (56DAA2 – NCH) days after the final application, with the exception of trial S20-01046-01, where samples at 56DAA2 were not available. Samples were frozen within a maximum of 9 hours after sampling.

Oilseed rape whole plant and seed samples were analysed for residues of prothioconazole (PTZ) and prothioconazole-desthio (PTZ-desthio) using multi-residue method QuEChERS as validated for oilseed rape (seeds) in Eurofins study S16-04434. Quantitation was performed by use of liquid chromatography with tandem mass spectrometry (LC-MS/MS).

The maximum period between sampling and last extraction was 420 days for whole plant samples and 127 days for seed samples. The maximum period between last extraction and last analysus was 1 day for whole plant samples and 2 days for seed samples.

The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ). The analytes were fortified jointly and quantified separately. For prothioconazole the LOQ is expressed as PTZ-desthio.

Oilseed rape whole plant and seed samples were analysed for residues of PTZ-alpha-hydroxy-desthio, PTZ-3-hydroxy-desthio, PTZ-4-hydroxy-desthio, PTZ-5-hydroxy-desthio, and PTZ-6-hydroxy-desthio using Eurofins Agroscience Services method which was validated for oilseed rape (seeds) in study S16-04435. Quantitation was performed by use of liquid chromatography with tandem mass spectrometry (LC-MS/MS).

The maximum period between sampling and last extraction was 420 days for whole plant samples and 126 days for seed samples. The maximum period between last extraction and last analysus was 10 days for whole plant samples and 1 day for seed samples.

The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ). The analytes were fortified jointly and quantified separately. For PTZ-alpha-hydroxy-desthio, PTZ-3-, -4-, -5- and -6-hydroxy-desthio the LOQ is expressed as PTZ-desthio.

Oilseed rape whole plant and seed samples were analysed for residues of 1,2,4-Triazole (T), Triazole Alanine (TA), Triazole Acetic Acid (TAA) and Triazole Lactic Acid (TLA) using Eurofins Agroscience Services method which was validated for oilseed rape (seeds) in study S15-03542. Quantitation was performed by use of liquid chromatography with tandem mass spectrometry and SelexION Differential Mobility Separation (LC-DMS/MS/MS).

The maximum period between sampling and last extraction was 420 days for whole plant samples and 73 days for seed samples. The maximum period between last extraction and last analysus was 3 days for whole plant samples and 4 days for seed samples.

The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ). The analytes were fortified jointly and quantified separately.

Reduced validations of the methods were performed during analysis for oilseed rape (whole plant and seeds). Recovery levels for fortified untreated sub-samples (of each crop matrix) are reported in the table below.

*Procedural Recoveries*

For each analytical set of sample analysis, the method’s applicability in terms of accuracy and repeatability was assessed by fortification of control (untreated) test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the analytical method(s).

Fortifications of prothioconazole and PTZ-desthio were performed at the level of 0.01 mg/kg, 0.1 mg/kg for oilseed rape (whole plant and seeds) and up to 4.0 mg/kg for oilseed rape (whole plant) and were thus at or above the highest residue level found in a sample.

Fortifications of PTZ-alpha-hydroxy-desthio, PTZ-3-, -4-, and -5- and -6-hydroxy-desthio were performed at the level of 0.01 mg/kg, 0.1 mg/kg for oilseed rape (whole plant and seeds) and up to 0.5 mg/kg for oilseed rape (whole plant) and were thus at or above the highest residue level found in a sample.

Fortifications of TDMs 1,2,4-Triazole, TA, TAA and TLA were performed at the level of 0.01 mg/kg, 0.1 mg/kg oilseed rape (whole plant and seeds) and up to 0.5 mg/kg for oilseed rape (whole plant) and up to 2.0 mg/kg for oilseed rape (seeds) and were thus at or above the highest residue level found in a sample.

The accuracy and precision of the method during sample analysis were considered to be acceptable since single recoveries were in the range of 60 ‑ 120 % and the mean recoveries at each fortification level were in the range of 70 – 110 % with relative standard deviation(s) below 20 % for all combinations of matrices and analytes.

Untreated and treated samples received a single assay. The residue levels found in oilseed rape are summarised in the table below.

Table A 87: Summary of the study S20-01046 trials

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | |  | | | |
| Country (of trial sites): | | | | | United Kingdom | | | | | Indoor/Glasshouse/Outdoor: | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | Prothioconazole, PTZ-desthio (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | Prothioconazole | | PTZ-desthio |
| S20-01046-01  L40 6HE, Lathom, Lancashire, United Kingdom  NEU | | Oilseed rape / BRSNN / Ramses | 1. 09 Sep 2019 2. 03 Apr 2020 - 25 May 2020 3. Not taken | Overall foliar with boom plot sprayer | | 58  59 | 315  299 | 184  175 | 20 May 2020  04 Jun 2020 | | | 69-73  75 | Whole plant  Whole plant  Whole plant  Whole plant | 0.68  0.07  0.02  <0.01 | | 1.0  0.36  0.19  0.06 | 0  7  14  35 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | | |  | | | |
| Country (of trial sites): | | | | | United Kingdom | | | | | Indoor/Glasshouse/Outdoor: | | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | | PTZ-α-OH-desthio, PTZ-3-OH-desthio,  PTZ-4-OH-desthio (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-α-OH-desthio | PTZ-3-OH-desthio | | PTZ-4-OH-desthio |
| S20-01046-01  L40 6HE, Lathom, Lancashire, United Kingdom  NEU | | Oilseed rape / BRSNN / Ramses | 1. 09 Sep 2019 2. 03 Apr 2020 - 25 May 2020 3. Not taken | Overall foliar with boom plot sprayer | | 58  59 | 315  299 | 184  175 | 20 May 2020  04 Jun 2020 | | | 69-73  75 | Whole plant  Whole plant  Whole plant  Whole plant | <0.01  <0.01  <0.01  <0.003 n.d. | 0.06  0.09  0.13  0.09 | | 0.03  0.04  0.04  0.02 | 0  7  14  35 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | | |

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|  | | | **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | |  | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | |  | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | | |  | |  | | | |
| Country (of trial sites): | | | | | | United Kingdom | | | | | Indoor/Glasshouse/Outdoor: | | | | | |  | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | |  | | None | | | |
| Formulation (*e.g.* WP): | | | | | | EC | | | | | Residues calculated as: | | | | | |  | | PTZ-5-OH-desthio, PTZ-6-OH-desthio (mg/kg) | | | |
|  | | | | | |  | | | | |  | | | | | |  | |  | | | |
| 1 | | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | | 8 | 9  Residues (mg/kg)  (\*) | | | | | 10 | 11 |
| Report No. Location (region) | | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | | Portion analysed  (a) | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-5-OH-desthio | | PTZ-6-OH-desthio | | Total (PTZ-desthio+hydroxy=RD-RA1)\* |
| S20-01046-01  L40 6HE, Lathom, Lancashire, United Kingdom  NEU | | | Oilseed rape / BRSNN / Ramses | 1. 09 Sep 2019 2. 03 Apr 2020 - 25 May 2020 3. Not taken | Overall foliar with boom plot sprayer | | 58  59 | 315  299 | 184  175 | 20 May 2020  04 Jun 2020 | | | 69-73  75 | | Whole plant  Whole plant  Whole plant  Whole plant | <0.01  0.01  0.01  <0.01 | | <0.003 n.d.  <0.01  <0.01  <0.003 n.d. | | 1.11  0.52  0.39  0.19 | 0  7  14  35 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | | (e) |  | | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | | (f) |  | | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | | (g) |  | | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | | (\*) |  | | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | |  | | | |
| Country (of trial sites): | | | | | United Kingdom | | | | | Indoor/Glasshouse/Outdoor: | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | 1,2,4-Triazole, Triazole alanine (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | 1,2,4-Triazole | | Triazole alanine |
| S20-01046-01  L40 6HE, Lathom, Lancashire, United Kingdom  NEU | | Oilseed rape / BRSNN / Ramses | 1. 09 Sep 2019 2. 03 Apr 2020 - 25 May 2020 3. Not taken | Overall foliar with boom plot sprayer | | 58  59 | 315  299 | 184  175 | 20 May 2020  04 Jun 2020 | | | 69-73  75 | Whole plant  Whole plant  Whole plant  Whole plant | <0.003 n.d.  <0.003 n.d.  <0.003 n.d.  <0.003 n.d. | | 0.16  0.14  0.19  0.21 | 0  7  14  35 | No residues >LOQ were found in any untreated 1,2,4-Triazole samples, triazole alanine samples were 0.17-0.31 mg/kg |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | |  | | | |
| Country (of trial sites): | | | | | United Kingdom | | | | | Indoor/Glasshouse/Outdoor: | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | Triazole acetic acid, Triazole lactic acid (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | Triazole acetic acid | | Triazole lactic acid |
| S20-01046-01  L40 6HE, Lathom, Lancashire, United Kingdom  NEU | | Oilseed rape / BRSNN / Ramses | 1. 09 Sep 2019 2. 03 Apr 2020 - 25 May 2020 3. Not taken | Overall foliar with boom plot sprayer | | 58  59 | 315  299 | 184  175 | 20 May 2020  04 Jun 2020 | | | 69-73  75 | Whole plant  Whole plant  Whole plant  Whole plant | <0.01  <0.01  <0.01  <0.01 | | <0.01  <0.01  <0.01  <0.01 | 0  7  14  35 | No residues >LOQ were found in any untreated samples except 35 DAA 0.01 mg/kg triazole lactic acid |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | |  | | | |
| Country (of trial sites): | | | | | Germany | | | | | Indoor/Glasshouse/Outdoor: | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | Prothioconazole, PTZ-desthio (mg/kg) | | | |
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| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | Prothioconazole | | PTZ-desthio |
| S20-01046-02  21228, Harmstorf, Niedersachsen, Germany  NEU | | Oilseed rape / BRSNN / Alvaro KWS | 1. 11 Sep 2019 2. Not applicable 3. 27 Jul 2020 | Overall foliar with boom plot sprayer | | 59  58 | 294  293 | 172  171 | 15 May 2020  29 May 2020 | | | 65  69 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | 0.36  0.03  0.02  <0.01  <0.003 n.d. | | 0.57  0.27  0.10  0.06  0.02 | 0  7  14  35  59 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | | |  | | | |
| Country (of trial sites): | | | | | Germany | | | | | Indoor/Glasshouse/Outdoor: | | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | | PTZ-α-OH-desthio, PTZ-3-OH-desthio,  PTZ-4-OH-desthio (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-α-OH-desthio | PTZ-3-OH-desthio | | PTZ-4-OH-desthio |
| S20-01046-02  21228, Harmstorf, Niedersachsen, Germany  NEU | | Oilseed rape / BRSNN / Alvaro KWS | 1. 11 Sep 2019 2. Not applicable 3. 07 Jul 2020 | Overall foliar with boom plot sprayer | | 59  58 | 294  293 | 172  171 | 15 May 2020  29 May 2020 | | | 65  69 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.01  <0.01  <0.01  <0.01  <0.01 | 0.04  0.09  0.09  0.14  0.02 | | 0.01  0.03  0.03  0.03  <0.01 | 0  7  14  35  59 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | | |

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|  | | | **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | |  | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | |  | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | | |  |  | | | |
| Country (of trial sites): | | | | | | Germany | | | | | Indoor/Glasshouse/Outdoor: | | | | | |  | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | |  | None | | | |
| Formulation (*e.g.* WP): | | | | | | EC | | | | | Residues calculated as: | | | | | |  | PTZ-5-OH-desthio, PTZ-6-OH-desthio (mg/kg) | | | |
|  | | | | | |  | | | | |  | | | | | |  |  | | | |
| 1 | | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | | 8 | 9  Residues (mg/kg)  (\*) | | | | 10 | 11 |
| Report No. Location (region) | | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | | Portion analysed  (a) | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-5-OH-desthio | PTZ-6-OH-desthio | | Total (PTZ-desthio+hydroxy=RD-RA1)\* |
| S20-01046-02  21228, Harmstorf, Niedersachsen, Germany  NEU | | | Oilseed rape / BRSNN / Alvaro KWS | 1. 11 Sep 2019 2. Not applicable 3. 27 Jul 2020 | Overall foliar with boom plot sprayer | | 59  58 | 294  293 | 172  171 | 15 May 2020  29 May 2020 | | | 65  69 | | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.01  <0.01  <0.01  0.01  <0.01 | <0.003 n.d.  <0.01  <0.003 n.d.  <0.003 n.d.  <0.003 n.d. | | 0.64  0.42  0.24  0.25  0.07 | 0  7  14  35  59 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | | (e) |  | | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | | (f) |  | | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | | (g) |  | | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | | (\*) |  | | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | |  | | | |
| Country (of trial sites): | | | | | Germany | | | | | Indoor/Glasshouse/Outdoor: | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | 1,2,4-Triazole, Triazole alanine (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | 1,2,4-Triazole | | Triazole alanine |
| S20-01046-02  21228, Harmstorf, Niedersachsen, Germany  NEU | | Oilseed rape / BRSNN / Alvaro KWS | 1. 11 Sep 2019 2. Not applicable 3. 27 Jul 2020 | Overall foliar with boom plot sprayer | | 59  58 | 294  293 | 172  171 | 15 May 2020  29 May 2020 | | | 65  69 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.003 n.d.  <0.003 n.d.  <0.003 n.d.  <0.003 n.d.  <0.003 n.d. | | 0.04  0.05  0.06  0.08  0.43/0.28\*\* | 0  7  14  35  59 | No residues >LOQ were found in any untreated 1,2,4-Triazole samples, triazole alanine samples were 0.03-0.28 mg/kg |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | |  | | | |
| Country (of trial sites): | | | | | Germany | | | | | Indoor/Glasshouse/Outdoor: | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | Triazole acetic acid, Triazole lactic acid (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | Triazole acetic acid | | Triazole lactic acid |
| S20-01046-02  21228, Harmstorf, Niedersachsen, Germany  NEU | | Oilseed rape / BRSNN / Alvaro KWS | 1. 11 Sep 2019 2. Not applicable 3. 27 Jul 2020 | Overall foliar with boom plot sprayer | | 59  58 | 294  293 | 172  171 | 15 May 2020  29 May 2020 | | | 65  69 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.003 n.d.  <0.003 n.d.  <0.003 n.d.  <0.01  <0.01 | | <0.003 n.d.  <0.003 n.d.  <0.01  0.01  0.03/0.01\*\* | 0  7  14  35  59 | No residues >LOQ were found in any untreated samples except 0.01 mg/kg triazole lactic acid seed sample |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | |  | | | |
| Country (of trial sites): | | | | | France | | | | | Indoor/Glasshouse/Outdoor: | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | Prothioconazole, PTZ-desthio (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | Prothioconazole | | PTZ-desthio |
| S20-01046-03  67140, Stotzheim,  Bas-Rhin / Alsace,  France  NEU | | Oilseed rape / BRSNN / Exclamation 90% / Ginfizz 10% | 1. 20 Aug 2019 2. 09 Apr 2020 - 27 Apr 2020 3. 02 Jul 2020 | Overall foliar with boom plot sprayer | | 58  70 | 307  236 | 179  165 | 23 Apr 2020  07 May 2020 | | | 67  76 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | 0.63  0.05  0.02  <0.01  <0.003 n.d. | | 0.95  0.32  0.18  0.06  0.01 | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | | |  | | | |
| Country (of trial sites): | | | | | France | | | | | Indoor/Glasshouse/Outdoor: | | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | | PTZ-α-OH-desthio, PTZ-3-OH-desthio,  PTZ-4-OH-desthio (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-α-OH-desthio | PTZ-3-OH-desthio | | PTZ-4-OH-desthio |
| S20-01046-03  67140, Stotzheim,  Bas-Rhin / Alsace,  France  NEU | | Oilseed rape / BRSNN / Exclamation 90% / Ginfizz 10% | 1. 20 Aug 2019 2. 09 Apr 2020 - 27 Apr 2020 3. 02 Jul 2020 | Overall foliar with boom plot sprayer | | 58  70 | 307  236 | 179  165 | 23 Apr 2020  07 May 2020 | | | 67  76 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.01  <0.01  <0.01  <0.01  <0.01 | 0.04  0.08  0.11  0.14  0.02 | | 0.02  0.03  0.04  0.05  <0.01 | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | | |

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|  | | | **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | |  | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | |  | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | | |  |  | | | |
| Country (of trial sites): | | | | | | France | | | | | Indoor/Glasshouse/Outdoor: | | | | | |  | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | |  | None | | | |
| Formulation (*e.g.* WP): | | | | | | EC | | | | | Residues calculated as: | | | | | |  | PTZ-5-OH-desthio, PTZ-6-OH-desthio (mg/kg) | | | |
|  | | | | | |  | | | | |  | | | | | |  |  | | | |
| 1 | | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | | 8 | 9  Residues (mg/kg)  (\*) | | | | 10 | 11 |
| Report No. Location (region) | | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | | Portion analysed  (a) | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-5-OH-desthio | PTZ-6-OH-desthio | | Total (PTZ-desthio+hydroxy=RD-RA1)\* |
| S20-01046-03  67140, Stotzheim,  Bas-Rhin / Alsace,  France  NEU | | | Oilseed rape / BRSNN / Exclamation 90% / Ginfizz 10% | 1. 20 Aug 2019 2. 09 Apr 2020 - 27 Apr 2020 3. 02 Jul 2020 | Overall foliar with boom plot sprayer | | 58  70 | 307  236 | 179  165 | 23 Apr 2020  07 May 2020 | | | 67  76 | | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.01  <0.01  0.01  0.01  <0.01 | <0.003 n.d.  <0.01  <0.01  <0.01  <0.003 | | 1.03  0.46  0.36  0.28  0.06 | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | | (e) |  | | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | | (f) |  | | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | | (g) |  | | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | | (\*) |  | | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | |  | | | |
| Country (of trial sites): | | | | | France | | | | | Indoor/Glasshouse/Outdoor: | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | 1,2,4-Triazole, Triazole alanine (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | 1,2,4-Triazole | | Triazole alanine |
| S20-01046-03  67140, Stotzheim,  Bas-Rhin / Alsace,  France  NEU | | Oilseed rape / BRSNN / Exclamation 90% / Ginfizz 10% | 1. 20 Aug 2019 2. 09 Apr 2020 - 27 Apr 2020 3. 02 Jul 2020 | Overall foliar with boom plot sprayer | | 58  70 | 307  236 | 179  165 | 23 Apr 2020  07 May 2020 | | | 67  76 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.003 n.d.  <0.003 n.d.  <0.003 n.d.  <0.003 n.d.  <0.003 n.d. | | 0.36  0.24  0.26  0.43  1.4/0.97\*\* | 0  7  14  35  56 | No residues >LOQ were found in any untreated 1,2,4-Triazole samples, triazole alanine samples were 0.11-0.97 mg/kg |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | |  | | | |
| Country (of trial sites): | | | | | France | | | | | Indoor/Glasshouse/Outdoor: | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | Triazole acetic acid, Triazole lactic acid (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | Triazole acetic acid | | Triazole lactic acid |
| S20-01046-03  67140, Stotzheim,  Bas-Rhin / Alsace,  France  NEU | | Oilseed rape / BRSNN / Exclamation 90% / Ginfizz 10% | 1. 20 Aug 2019 2. 09 Apr 2020 - 27 Apr 2020 3. 02 Jul 2020 | Overall foliar with boom plot sprayer | | 58  70 | 307  236 | 179  165 | 23 Apr 2020  07 May 2020 | | | 67  76 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | 0.01  <0.01  0.01  0.03  0.01 | | 0.02  0.01  0.02  0.08  0.04/0.02\*\* | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples except <0.01-0.02 mg/kg triazole lactic acid samples |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | |  | | | |
| Country (of trial sites): | | | | | France | | | | | Indoor/Glasshouse/Outdoor: | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | Prothioconazole, PTZ-desthio (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | Prothioconazole | | PTZ-desthio |
| S20-01046-05  82700, Saint-Porquier,  Tarn-et-Garonne, France  SEU | | Oilseed rape / BRSNN / Cadran | 1. 29 Aug 2020 2. 20 Mar 2020 - 20 Apr 2020 3. 25 Jun 2020 | Overall foliar with boom plot sprayer | | 58  58 | 302  293 | 176  171 | 17 Apr 2020  30 Apr 2020 | | | 67-72  69-73 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | 0.55  0.01  <0.01  <0.01  <0.003 n.d. | | 0.80  0.25  0.09  0.06  0.02 | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | | |  | | | |
| Country (of trial sites): | | | | | France | | | | | Indoor/Glasshouse/Outdoor: | | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | | PTZ-α-OH-desthio, PTZ-3-OH-desthio,  PTZ-4-OH-desthio (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-α-OH-desthio | PTZ-3-OH-desthio | | PTZ-4-OH-desthio |
| S20-01046-05  82700, Saint-Porquier,  Tarn-et-Garonne, France  SEU | | Oilseed rape / BRSNN / Cadran | 1. 29 Aug 2020 2. 20 Mar 2020 - 20 Apr 2020 3. 25 Jun 2020 | Overall foliar with boom plot sprayer | | 58  58 | 302  293 | 176  171 | 17 Apr 2020  30 Apr 2020 | | | 67-72  69-73 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.01  <0.01  <0.01  <0.01  <0.01 | 0.03  0.12  0.11  0.21  0.03 | | 0.02  0.05  0.05  0.06  <0.01 | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | | |

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|  | | | **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | |  | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | |  | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | | |  |  | | | |
| Country (of trial sites): | | | | | | France | | | | | Indoor/Glasshouse/Outdoor: | | | | | |  | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | |  | None | | | |
| Formulation (*e.g.* WP): | | | | | | EC | | | | | Residues calculated as: | | | | | |  | PTZ-5-OH-desthio, PTZ-6-OH-desthio (mg/kg) | | | |
|  | | | | | |  | | | | |  | | | | | |  |  | | | |
| 1 | | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | | 8 | 9  Residues (mg/kg)  (\*) | | | | 10 | 11 |
| Report No. Location (region) | | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | | Portion analysed  (a) | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-5-OH-desthio | PTZ-6-OH-desthio | | Total (PTZ-desthio+hydroxy=RD-RA1)\* |
| S20-01046-05  82700, Saint-Porquier,  Tarn-et-Garonne, France  SEU | | | Oilseed rape / BRSNN / Cadran | 1. 29 Aug 2020 2. 20 Mar 2020 - 20 Apr 2020 3. 25 Jun 2020 | Overall foliar with boom plot sprayer | | 58  58 | 302  293 | 176  171 | 17 Apr 2020  30 Apr 2020 | | | 67-72  69-73 | | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.01  0.02  0.01  0.01  <0.01 | <0.003 n.d.  <0.01  <0.01  <0.01  <0.003 n.d. | | 0.87  0.46  0.28  0.36  0.08 | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | | (e) |  | | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | | (f) |  | | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | | (g) |  | | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | | (\*) |  | | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | |  | | | |
| Country (of trial sites): | | | | | France | | | | | Indoor/Glasshouse/Outdoor: | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | 1,2,4-Triazole, Triazole alanine (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | 1,2,4-Triazole | | Triazole alanine |
| S20-01046-05  82700, Saint-Porquier,  Tarn-et-Garonne, France  SEU | | Oilseed rape / BRSNN / Cadran | 1. 29 Aug 2020 2. 20 Mar 2020 - 20 Apr 2020 3. 25 Jun 2020 | Overall foliar with boom plot sprayer | | 58  58 | 302  293 | 176  171 | 17 Apr 2020  30 Apr 2020 | | | 67-72  69-73 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.003 n.d.  <0.003 n.d.  <0.003 n.d.  <0.003 n.d.  <0.003 n.d. | | 0.26  0.46  0.29  0.34  1.8/1.6\*\* | 0  7  14  35  56 | No residues >LOQ were found in any untreated 1,2,4-Triazole samples, triazole alanine samples were 0.29-1.6 mg/kg |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | |  | | | |
| Country (of trial sites): | | | | | France | | | | | Indoor/Glasshouse/Outdoor: | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | Triazole acetic acid, Triazole lactic acid (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | Triazole acetic acid | | Triazole lactic acid |
| S20-01046-05  82700, Saint-Porquier,  Tarn-et-Garonne, France  SEU | | Oilseed rape / BRSNN / Cadran | 1. 29 Aug 2020 2. 20 Mar 2020 - 20 Apr 2020 3. 25 Jun 2020 | Overall foliar with boom plot sprayer | | 58  58 | 302  293 | 176  171 | 17 Apr 2020  30 Apr 2020 | | | 67-72  69-73 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.01  0.01  <0.01  0.02  0.02/0.02\*\* | | <0.01  0.02  0.02  0.05  0.08/0.08\*\* | 0  7  14  35  56 | Residues in untreated samples were 0.01-0.03 mg/kg triazole acetic acid & 0.02-0.08 mg/kg triazole lactic acid |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | |  | | | |
| Country (of trial sites): | | | | | Spain | | | | | Indoor/Glasshouse/Outdoor: | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | Prothioconazole, PTZ-desthio (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | Prothioconazole | | PTZ-desthio |
| S20-01046-06  44492, Fonfria, Aragon,  Spain  SEU | | Oilseed rape / BRSNN / Expression | 1. 01 Oct 2019 2. Not applicable 3. 16 Jul 2020 | Overall foliar with boom plot sprayer | | 87  87 | 206  197 | 180  172 | 07 May 2020  21 May 2020 | | | 65-69  69-71 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | 0.31  0.02  <0.01  <0.003 n.d.  <0.003 n.d. | | 0.54  0.28  0.05  <0.003 n.d.  0.01 | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples except whole plant at 35 DAA <0.01-0.01 mg/kg PTZ & 0.03-0.07 mg/kg PTZ-desthio# |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | |

# The distribution of residue results between treated and untreated samples of sampling S4 (whole plant at 35 DAA2) indicates an incorrect assignment of sample labels. In all earlier samplings, the control samples showed no residues and the residues in treated samples showed a plausible decline. For S4 (35 DAA2) the sample from the control plot showed residues above the level of the treated sample. Therefore, the retain samples S20-01046-06-007R1 and -008R1 were analysed upon request of the study director. Their analysis confirmed the first results.

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | | |  | | | |
| Country (of trial sites): | | | | | Spain | | | | | Indoor/Glasshouse/Outdoor: | | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | | PTZ-α-OH-desthio, PTZ-3-OH-desthio,  PTZ-4-OH-desthio (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-α-OH-desthio | PTZ-3-OH-desthio | | PTZ-4-OH-desthio |
| S20-01046-06  44492, Fonfria, Aragon,  Spain  SEU | | Oilseed rape / BRSNN / Expression | 1. 01 Oct 2019 2. Not applicable 3. 16 Jul 2020 | Overall foliar with boom plot sprayer | | 87  87 | 206  197 | 180  172 | 07 May 2020  21 May 2020 | | | 65-69  69-71 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.01  <0.01  <0.003 n.d.  <0.003 n.d.  <0.01 | 0.06  0.09  0.06  <0.003 n.d.  0.02 | | 0.02  0.04  0.02  <0.003 n.d.  <0.01 | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples, except 35 DAA whole plants, 0.09-0.11 mg/kg PTZ3 & 0.02 mg/kg PTZ 4 |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | | |

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|  | | | **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | |  | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | |  | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | | |  | |  | | | |
| Country (of trial sites): | | | | | | Spain | | | | | Indoor/Glasshouse/Outdoor: | | | | | |  | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | |  | | None | | | |
| Formulation (*e.g.* WP): | | | | | | EC | | | | | Residues calculated as: | | | | | |  | | PTZ-5-OH-desthio, PTZ-6-OH-desthio (mg/kg) | | | |
|  | | | | | |  | | | | |  | | | | | |  | |  | | | |
| 1 | | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | | 8 | 9  Residues (mg/kg)  (\*) | | | | | 10 | 11 |
| Report No. Location (region) | | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | | Portion analysed  (a) | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-5-OH-desthio | | PTZ-6-OH-desthio | | Total (PTZ-desthio+hydroxy=RD-RA1)\* |
| S20-01046-06  44492, Fonfria, Aragon,  Spain  SEU | | | Oilseed rape / BRSNN / Expression | 1. 01 Oct 2019 2. Not applicable 3. 16 Jul 2020 | Overall foliar with boom plot sprayer | | 87  87 | 206  197 | 180  172 | 07 May 2020  21 May 2020 | | | 65-69  69-71 | | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.01  0.01  <0.01  <0.003 n.d.  <0.01 | | <0.003 n.d.  <0.01  <0.003 n.d.  <0.003 n.d.  <0.003 n.d. | | 0.64  0.44  0.15  <0.06  0.06 | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | | (e) |  | | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | | (f) |  | | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | | (g) |  | | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | | (\*) |  | | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | |  | | | |
| Country (of trial sites): | | | | | Spain | | | | | Indoor/Glasshouse/Outdoor: | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | 1,2,4-Triazole, Triazole alanine (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | 1,2,4-Triazole | | Triazole alanine |
| S20-01046-06  44492, Fonfria, Aragon,  Spain  SEU | | Oilseed rape / BRSNN / Expression | 1. 01 Oct 2019 2. Not applicable 3. 16 Jul 2020 | Overall foliar with boom plot sprayer | | 87  87 | 206  197 | 180  172 | 07 May 2020  21 May 2020 | | | 65-69  69-71 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.003 n.d.  <0.003 n.d.  <0.003 n.d.  <0.003 n.d.  <0.003 n.d. | | 0.06  0.05  0.10  0.05  0.76/0.21\*\* | 0  7  14  35  56 | No residues >LOQ were found in any untreated 1,2, triazole samples, triazole alanine samples were 0.04-0.21 mg/kg |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | |  | | | |
| Country (of trial sites): | | | | | Spain | | | | | Indoor/Glasshouse/Outdoor: | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | Triazole acetic acid, Triazole lactic acid (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | Triazole acetic acid | | Triazole lactic acid |
| S20-01046-06  44492, Fonfria, Aragon,  Spain  SEU | | Oilseed rape / BRSNN / Expression | 1. 01 Oct 2019 2. Not applicable 3. 16 Jul 2020 | Overall foliar with boom plot sprayer | | 87  87 | 206  197 | 180  172 | 07 May 2020  21 May 2020 | | | 65-69  69-71 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.003 n.d.  <0.003 n.d.  <0.003 n.d.  <0.01-<0.003 n.d.  <0.01 | | <0.003 n.d.  <0.003 n.d.  <0.01  <0.01  0.02 | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | |  | | | |
| Country (of trial sites): | | | | | Italy | | | | | Indoor/Glasshouse/Outdoor: | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | Prothioconazole, PTZ-desthio (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | Prothioconazole | | PTZ-desthio |
| S20-01046-07  40057, Granarolo Emilia,  Emilia Romagna, Italy  SEU | | Oilseed rape / BRSNN / Sensei | 1. 19 Oct 2019 2. 01 Apr 2020 -29 Apr 2020 3. 10 Jun 2020 | Overall foliar with boom plot sprayer | | 44  44 | 380  363 | 166  159 | 01 Apr 2020  15 Apr 2020 | | | 61  65 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | 0.32  0.03  0.01  <0.003 n.d.  <0.003 n.d. | | 1.0  0.76  0.26  <0.01  <0.003 n.d. | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | | |  | | | |
| Country (of trial sites): | | | | | Italy | | | | | Indoor/Glasshouse/Outdoor: | | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | | PTZ-α-OH-desthio, PTZ-3-OH-desthio,  PTZ-4-OH-desthio (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-α-OH-desthio | PTZ-3-OH-desthio | | PTZ-4-OH-desthio |
| S20-01046-07  40057, Granarolo Emilia,  Emilia Romagna, Italy  SEU | | Oilseed rape / BRSNN / Sensei | 1. 19 Oct 2019 2. 01 Apr 2020 -29 Apr 2020 3. 10 Jun 2020 | Overall foliar with boom plot sprayer | | 44  44 | 380  363 | 166  159 | 01 Apr 2020  15 Apr 2020 | | | 61  65 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.003 n.d.  <0.01  <0.003 n.d.  <0.003 n.d.  <0.003 n.d. | 0.04  0.10  0.07  0.04  <0.003 n.d. | | 0.02  0.04  0.03  <0.01  <0.003 n.d. | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | | |

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|  | | | **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | |  | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | |  | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | | |  | |  | | | |
| Country (of trial sites): | | | | | | Italy | | | | | Indoor/Glasshouse/Outdoor: | | | | | |  | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | |  | | None | | | |
| Formulation (*e.g.* WP): | | | | | | EC | | | | | Residues calculated as: | | | | | |  | | PTZ-5-OH-desthio, PTZ-6-OH-desthio (mg/kg) | | | |
|  | | | | | |  | | | | |  | | | | | |  | |  | | | |
| 1 | | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | | 8 | 9  Residues (mg/kg)  (\*) | | | | | 10 | 11 |
| Report No. Location (region) | | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | | Portion analysed  (a) | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-5-OH-desthio | | PTZ-6-OH-desthio | | Total (PTZ-desthio+hydroxy=RD-RA1)\* |
| S20-01046-07  40057, Granarolo Emilia,  Emilia Romagna, Italy  SEU | | | Oilseed rape / BRSNN / Sensei | 1. 19 Oct 2019 2. 01 Apr 2020 -29 Apr 2020 3. 10 Jun 2020 | Overall foliar with boom plot sprayer | | 44  44 | 380  363 | 166  159 | 01 Apr 2020  15 Apr 2020 | | | 61  65 | | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.01  0.01  <0.01  <0.003 n.d.  <0.003 n.d. | | <0.003 n.d.  <0.003 n.d.  <0.003 n.d.  <0.003 n.d.  <0.003 n.d. | | 1.08  0.92  0.38  0.07  <0.06 | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | | (e) |  | | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | | (f) |  | | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | | (g) |  | | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | | (\*) |  | | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | |  | | | |
| Country (of trial sites): | | | | | Italy | | | | | Indoor/Glasshouse/Outdoor: | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | 1,2,4-Triazole, Triazole alanine (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | 1,2,4-Triazole | | Triazole alanine |
| S20-01046-07  40057, Granarolo Emilia,  Emilia Romagna, Italy  SEU | | Oilseed rape / BRSNN / Sensei | 1. 19 Oct 2019 2. 01 Apr 2020 -29 Apr 2020 3. 10 Jun 2020 | Overall foliar with boom plot sprayer | | 44  44 | 380  363 | 166  159 | 01 Apr 2020  15 Apr 2020 | | | 61  65 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.003 n.d.  <0.003 n.d.  <0.003 n.d.  <0.003 n.d.  <0.003 n.d. | | 0.12  0.15  0.10  0.11  0.45/0.63\*\* | 0  7  14  35  56 | No residues >LOQ were found in any untreated 1,2, triazole samples, triazole alanine samples were 0.10-0.63 mg/kg |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | |  | | | |
| Country (of trial sites): | | | | | Italy | | | | | Indoor/Glasshouse/Outdoor: | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | Triazole acetic acid, Triazole lactic acid (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | Triazole acetic acid | | Triazole lactic acid |
| S20-01046-07  40057, Granarolo Emilia,  Emilia Romagna, Italy  SEU | | Oilseed rape / BRSNN / Sensei | 1. 19 Oct 2019 2. 01 Apr 2020 -29 Apr 2020 3. 10 Jun 2020 | Overall foliar with boom plot sprayer | | 44  44 | 380  363 | 166  159 | 01 Apr 2020  15 Apr 2020 | | | 61  65 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.003 n.d.  <0.01  <0.003 n.d.  <0.01  <0.01 | | <0.01  <0.01  <0.01  <0.01  0.02/0.03\*\* | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples, except 0.03 mg/kg triazole lactic acid seed sample |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | |  | | | |
| Country (of trial sites): | | | | | Italy | | | | | Indoor/Glasshouse/Outdoor: | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | Prothioconazole, PTZ-desthio (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | Prothioconazole | | PTZ-desthio |
| S20-01046-08  48124, Ravenna, Emilia Romagna,  Italy  SEU | | Oilseed rape / BRSNN / PT 200 CL | 1. 20 Sep 2019 2. 06 Apr 2020 - 30 Apr 2020 3. 16 Jun 2020 | Overall foliar with boom plot sprayer | | 44  44 | 392  433 | 171  190 | 06 Apr 2020  21 Apr 2020 | | | 61  65 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | 1.3  0.05  0.03  <0.01  <0.003 n.d. | | 2.6  1.2  0.51  0.15  <0.003 n.d. | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | | |  | | | |
| Country (of trial sites): | | | | | Italy | | | | | Indoor/Glasshouse/Outdoor: | | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | | PTZ-α-OH-desthio, PTZ-3-OH-desthio,  PTZ-4-OH-desthio (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-α-OH-desthio | PTZ-3-OH-desthio | | PTZ-4-OH-desthio |
| S20-01046-08  48124, Ravenna, Emilia Romagna,  Italy  SEU | | Oilseed rape / BRSNN / PT 200 CL | 1. 20 Sep 2019 2. 06 Apr 2020 - 30 Apr 2020 3. 16 Jun 2020 | Overall foliar with boom plot sprayer | | 44  44 | 392  433 | 171  190 | 06 Apr 2020  21 Apr 2020 | | | 61  65 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.01  0.02  0.02  0.02  <0.003 n.d. | 0.10  0.15  0.18  0.33  <0.01 | | 0.05  0.06  0.07  0.08  <0.003 n.d. | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | | |

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|  | | | **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | |  | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | |  | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | | |  | |  | | | |
| Country (of trial sites): | | | | | | Italy | | | | | Indoor/Glasshouse/Outdoor: | | | | | |  | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | |  | | None | | | |
| Formulation (*e.g.* WP): | | | | | | EC | | | | | Residues calculated as: | | | | | |  | | PTZ-5-OH-desthio, PTZ-6-OH-desthio (mg/kg) | | | |
|  | | | | | |  | | | | |  | | | | | |  | |  | | | |
| 1 | | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | | 8 | 9  Residues (mg/kg)  (\*) | | | | | 10 | 11 |
| Report No. Location (region) | | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | | Portion analysed  (a) | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-5-OH-desthio | | PTZ-6-OH-desthio | | Total (PTZ-desthio+hydroxy=RD-RA1)\* |
| S20-01046-08  48124, Ravenna, Emilia Romagna,  Italy  SEU | | | Oilseed rape / BRSNN / PT 200 CL | 1. 20 Sep 2019 2. 06 Apr 2020 - 30 Apr 2020 3. 16 Jun 2020 | Overall foliar with boom plot sprayer | | 44  44 | 392  433 | 171  190 | 06 Apr 2020  21 Apr 2020 | | | 61  65 | | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | 0.01  0.02  0.02  0.03  <0.003 n.d. | | <0.003 n.d.  <0.01  <0.01  <0.01  <0.003 n.d. | | 2.77  1.46  0.81  0.61  <0.06 | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | | (e) |  | | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | | (f) |  | | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | | (g) |  | | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | | (\*) |  | | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | |  | | | |
| Country (of trial sites): | | | | | Italy | | | | | Indoor/Glasshouse/Outdoor: | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | 1,2,4-Triazole, Triazole alanine (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | 1,2,4-Triazole | | Triazole alanine |
| S20-01046-08  48124, Ravenna, Emilia Romagna,  Italy  SEU | | Oilseed rape / BRSNN / PT 200 CL | 1. 20 Sep 2019 2. 06 Apr 2020 - 30 Apr 2020 3. 16 Jun 2020 | Overall foliar with boom plot sprayer | | 44  44 | 392  433 | 171  190 | 06 Apr 2020  21 Apr 2020 | | | 61  65 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.003 n.d.  <0.003 n.d.  <0.003 n.d.  <0.003 n.d.  <0.003 n.d. | | 0.06  0.05  0.06  0.10  0.47/0.63\*\* | 0  7  14  35  56 | No residues >LOQ were found in any untreated 1,2, triazole samples, triazole alanine samples were 0.02-0.63 mg/kg |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | |  | | | |
| Country (of trial sites): | | | | | Italy | | | | | Indoor/Glasshouse/Outdoor: | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | Triazole acetic acid, Triazole lactic acid (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | Triazole acetic acid | | Triazole lactic acid |
| S20-01046-08  48124, Ravenna, Emilia Romagna,  Italy  SEU | | Oilseed rape / BRSNN / PT 200 CL | 1. 20 Sep 2019 2. 06 Apr 2020 - 30 Apr 2020 3. 16 Jun 2020 | Overall foliar with boom plot sprayer | | 44  44 | 392  433 | 171  190 | 06 Apr 2020  21 Apr 2020 | | | 61  65 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.003 n.d.  <0.003 n.d.  <0.003 n.d.  <0.01  <0.01 | | <0.003 n.d.  <0.01  <0.01  0.01  0.02/0.02\*\* | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples, except 0.02 mg/kg triazole lactic acid seed sample |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | |  | | | |
| Country (of trial sites): | | | | | UK | | | | | Indoor/Glasshouse/Outdoor: | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | Prothioconazole, PTZ-desthio (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | Prothioconazole | | PTZ-desthio |
| S20-01046-09  DE73 8BH, Breedon-on-the-Hill, Leicestershire, United Kingdom  NEU | | Oilseed rape / BRSNN / Lumen | 1. 22 Apr 2020 2. Not available 3. 01 Sep 2020 | Overall foliar with boom plot sprayer | | 88  88 | 203  205 | 178  180 | 23 Jun 2020  07 Jul 2020 | | | 59-60  65-71 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | 0.60  0.03  0.01  <0.003 n.d.  <0.003 n.d. | | 1.1  0.33  0.10  0.01  <0.003 n.d. | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | | |  | | | |
| Country (of trial sites): | | | | | UK | | | | | Indoor/Glasshouse/Outdoor: | | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | | PTZ-α-OH-desthio, PTZ-3-OH-desthio,  PTZ-4-OH-desthio (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-α-OH-desthio | PTZ-3-OH-desthio | | PTZ-4-OH-desthio |
| S20-01046-09  DE73 8BH, Breedon-on-the-Hill, Leicestershire, United Kingdom  NEU | | Oilseed rape / BRSNN / Lumen | 1. 22 Apr 2020 2. Not available 3. 01 Sep 2020 | Overall foliar with boom plot sprayer | | 88  88 | 203  205 | 178  180 | 23 Jun 2020  07 Jul 2020 | | | 59-60  65-71 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | 0.02  0.01  <0.01  <0.003 n.d.  <0.003 n.d. | 0.12  0.07  0.04  0.03  <0.003 n.d. | | 0.08  0.04  0.02  0.01  <0.003 n.d. | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | | |

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|  | | | **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | |  | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | |  | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | | |  | |  | | | |
| Country (of trial sites): | | | | | | UK | | | | | Indoor/Glasshouse/Outdoor: | | | | | |  | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | |  | | None | | | |
| Formulation (*e.g.* WP): | | | | | | EC | | | | | Residues calculated as: | | | | | |  | | PTZ-5-OH-desthio, PTZ-6-OH-desthio (mg/kg) | | | |
|  | | | | | |  | | | | |  | | | | | |  | |  | | | |
| 1 | | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | | 8 | 9  Residues (mg/kg)  (\*) | | | | | 10 | 11 |
| Report No. Location (region) | | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | | Portion analysed  (a) | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | PTZ-5-OH-desthio | | PTZ-6-OH-desthio | | Total (PTZ-desthio+hydroxy=RD-RA1)\* |
| S20-01046-09  DE73 8BH, Breedon-on-the-Hill, Leicestershire, United Kingdom  NEU | | | Oilseed rape / BRSNN / Lumen | 1. 22 Apr 2020 2. Not available 3. 01 Sep 2020 | Overall foliar with boom plot sprayer | | 88  88 | 203  205 | 178  180 | 23 Jun 2020  07 Jul 2020 | | | 59-60  65-71 | | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | 0.02  0.01  <0.01  <0.01  <0.003 n.d. | | <0.01  <0.01  <0.003 n.d.  <0.003 n.d.  <0.003 n.d. | | 1.35  0.47  0.18  0.07  <0.06 | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | | (e) |  | | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | | (f) |  | | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | | (g) |  | | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | | (\*) |  | | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | |  | | | |
| Country (of trial sites): | | | | | UK | | | | | Indoor/Glasshouse/Outdoor: | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | 1,2,4-Triazole, Triazole alanine (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | 1,2,4-Triazole | | Triazole alanine |
| S20-01046-09  DE73 8BH, Breedon-on-the-Hill, Leicestershire, United Kingdom  NEU | | Oilseed rape / BRSNN / Lumen | 1. 22 Apr 2020 2. Not available 3. 01 Sep 2020 | Overall foliar with boom plot sprayer | | 88  88 | 203  205 | 178  180 | 23 Jun 2020  07 Jul 2020 | | | 59-60  65-71 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.003 n.d.  <0.003 n.d.  <0.003 n.d.  <0.003 n.d.  <0.003 n.d. | | 0.17  0.14  0.17  0.26  0.84/1.1\*\* | 0  7  14  35  56 | No residues >LOQ were found in any untreated 1,2, triazole samples, triazole alanine samples were 0.18-1.1 mg/kg |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d)  \*\* | | Year must be indicated  Residue level in control samples. | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | |

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| **RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)** | | | | | | | | | | | | | | | | | | | |
| Active substance (common name): | | | | | **Prothioconazole** | | | | | Commercial Product (name): | | | | | NUL 3390 Prothioconazole 250EC | | | |
| Crop/crop group: | | | | | **Oilseed rape / Oilseeds** | | | | | Producer of commercial product: | | | | | Nufarm Australia Limited | | | |
| Responsible body for reporting  (name, address) | | | | | Nufarm SAS, Immeuble West Plaza 11 rue du Débarcadère 92700 Colombes France | | | | |  | | | | |  | | | |
| Country (of trial sites): | | | | | UK | | | | | Indoor/Glasshouse/Outdoor: | | | | | Outdoor | | | |
| Content of active substance nominal (g/L): | | | | | 250 | | | | | Other active substance in the formulation (common name and content): | | | | | None | | | |
| Formulation (*e.g.* WP): | | | | | EC | | | | | Residues calculated as: | | | | | Triazole acetic acid, Triazole lactic acid (mg/kg) | | | |
|  | | | | |  | | | | |  | | | | |  | | | |
| 1 | | 2 | 3 | 4 | | 5 | | | 6 | | | 7 | 8 | 9 | | | 10 | 11 |
| Report No. Location (region) | | Commodity/Variety  (a) | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest  (b) | Method of  Treatment  (c) | | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date  (d) | | | Growth stage at last treatment or date  (e)  BBCH | Portion analysed  (a) | Residues (mg/kg)  (\*) | | | PHI (days)  (f) | Remarks  (g) |
| g as/hL | Water (L/ha) | g a.s./ha | Triazole acetic acid | | Triazole lactic acid |
| S20-01046-09  DE73 8BH, Breedon-on-the-Hill, Leicestershire, United Kingdom  NEU | | Oilseed rape / BRSNN / Lumen | 1. 22 Apr 2020 2. Not available 3. 01 Sep 2020 | Overall foliar with boom plot sprayer | | 88  88 | 203  205 | 178  180 | 23 Jun 2020  07 Jul 2020 | | | 59-60  65-71 | Whole plant  Whole plant  Whole plant  Whole plant  Seeds | <0.003 n.d.  <0.01  <0.01  <0.01  <0.01/0.01\*\* | | <0.01  <0.01  <0.01  0.01  0.04/0.05\*\* | 0  7  14  35  56 | No residues >LOQ were found in any untreated samples, except 0.01 mg/kg triazole acetic acid seed sample and 0.01 mg/kg 35 DAA2 whole plant triazole lactic acid and 0.05 mg/kg triazole lactic acid seed sample |
| (a) | | According to EEC and Codex classifications (both) should be used | | | | | | | | | (e) | BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4 | | | | | | | |
| (b) | | Only if relevant | | | | | | | | | (f) | Minimum number of days after last application (Label pre-harvest interval, PHI, underline) | | | | | | | |
| (c) | | High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated | | | | | | | | | (g) | Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date | | | | | | | |
| (d) | | Year must be indicated | | | | | | | | | (\*) | Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable | | | | | | | |

* + - * 1. Study S21-00259 – NEU

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| Comments of zRMS: | The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for CA3301/ Joust (January 2023). This study has not been reassessed in the framework of this application.  The conclusions of the assessment are presented below:  *One residue trial on oilseed rape were conducted in northern Europe to determine residue of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio and TDMs.*  *Oilseed rape was treated twice at application rate of 0.175 kg a.s./ha of prothioconazole with 14 days interval between applications. The time of application was:*  *1. at BBCH 65,*  *2. at BBCH 69.*  *Samples of oilseed rape from the untreated and treated plots were taken by hand 56 days after the final application at normal commercial harvest.*  *The limit of quantification (LOQ) of the analytical methods were 0.01 mg/kg for each analyte/matrix with a limit of detection (LOD) set at 0.003 mg/kg.*  *The mean recoveries at each fortification level comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, rev. 1.*  *Maximum storage period – 49 days.*  *Residues of prothioconazole-desthio and hydroxy- derivatives of prothioconazole-desthio, in oilseed rape grain at harvest were <0.01 mg/kg.*  *Residues of 1,2,4-triazole in oilseed rape grain at harvest were < 0.003 mg/kg.*  *Residues of triazole lactic acid in oilseed rape grain at harvest were 0.1 mg/kg.*  *Residues of triazole alanine in oilseed rape grain at harvest were 2.3 mg/kg.*  *Residues of triazole acetic acid in oilseed rape grain at harvest were 0.01 mg/kg.*  *The study is acceptable.* |

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| Reference: | KCA 6.3.3/03 |
| Report | Determination of residues of Prothioconazole-desthio (sum of isomers) after two applications of Prothioconazole in Oilseed rape (outdoor) at 1 site in Northern Europe in 2021  North, L., 2021  Report No: S21-00259 |
| Guideline(s): | OECD (2009) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32)  OECD Test Guideline 509: Crop field trials  OECD (2016) Guidance Document ENV/JM/MONO (2011)50/REV1 , Second Edition, on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66)  EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials  European Community Guideline SANCO 7525/VI/95, Rev. 10.3, 13/06/17: Comparability, extrapolation, group tolerances and data requirements for setting MRLs) |
| Deviations: | Trial S21-00259-02 was cancelled due to oversprayed applications.  Trial S21-00259-03 was cancelled due to samples arrived unfrosted to the laboratory.  A new trial was set up for the next season (2022). Report S22-00257 will be available by Q2 2023.  No impact on the current results. |
| GLP: | Yes |
| Owner: | Nufarm Crop Products UK |
| Acceptability: | Yes |

Materials and Methods

One residue trial was conducted on oilseed rape during 2021 in the United Kingdom (S21-00259-01). Trial S21-00259-02 was cancelled due to both the applications being over dosed, Trial S21-00259-03 was cancelled due to the samples arriving at the analytical test site unfrozen.

Two applications of NUL 3390 Prothioconazole 250 EC (250 g/L, Prothioconazole) were applied at 175 g ai/ha, diluted with water immediately prior to application to a spray volume of 100-400 L/ha.

Samples of oilseed rape from the untreated and treated plots were taken by hand 56 days after the final application (Normal Commercial Harvest – NCH). Samples were frozen within 24 hours after sampling.

The analytes were fortified jointly and quantified separately.

Oilseed rape straw and seed samples were analysed for residues of prothioconazole (PTZ) and prothioconazole-desthio (PTZ-desthio) using multi-residue method QuEChERS as validated for oilseed rape (seeds) in Eurofins study S16-04434. Quantitation was performed by use of liquid chromatography with tandem mass spectrometry (LC-MS/MS).

Oilseed rape straw and seed samples were analysed for residues of PTZ-alpha-hydroxy-desthio, PTZ-3-hydroxy-desthio, PTZ-4-hydroxy-desthio, PTZ-5-hydroxy-desthio, and PTZ-6-hydroxy-desthio using Eurofins Agroscience Services method which was validated for oilseed rape (seeds) in study S16-04435. Quantitation was performed by use of liquid chromatography with tandem mass spectrometry (LC-MS/MS).

Oilseed rape whole plant and seed samples were analysed for residues of 1,2,4-Triazole (T), Triazole Alanine (TA), Triazole Acetic Acid (TAA) and Triazole Lactic Acid (TLA) using Eurofins Agroscience Services method which was validated for oilseed rape (seeds) in study S15-03542. Quantitation was performed by use of liquid chromatography with tandem mass spectrometry and SelexION Differential Mobility Separation (LC-DMS/MS/MS).

For all analytes and all matrices, the limit of quantification (LOQ) of the analytical method was 0.01 mg/kg with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ). The analytes were fortified jointly and quantified separately. For prothioconazole the LOQ is expressed as PTZ-desthio.

For PTZ-alpha-hydroxy-desthio, PTZ-3-, -4-, -5- and -6-hydroxy-desthio the LOQ is expressed as PTZ-desthio.

*Procedural Recoveries*

For each analytical set of sample analysis, the method’s applicability in terms of accuracy and repeatability was assessed by fortification of control (untreated) test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the analytical method(s).

Fortifications of all analytes were performed for all matrices at or above the highest residue level found in a sample.

The accuracy and precision of the method during sample analysis were considered to be acceptable since single recoveries were in the range of 60 ‑ 120 % and the mean recoveries at each fortification level were in the range of 70 – 110 % with relative standard deviation(s) below 20 % for all combinations of matrices and analytes.

Findings

No residue of prothioconazole-deshio, alpha-OH, 3-OH, 4-OH 5-OH and 6-OH was found in any untreated samples of all trials.

For triazole derivative metabolites, residues above the LOQ was found in some untreated samples. Triazoles are a common ingredient of numerous pesticides which were widely used by farmers as fungicides in various field crops. Triazole metabolites show a great persistence in the soils and can be uptaken by plants. The residue findings for TA, TAA and TLA were at a similar level in the control and treated samples and most likely origin in former usage of pesticides containing triazoles on the sampling sites or nearby.

The residue levels found in oilseed rape are summarised in the table below.

Table A 88: Summary of the study S21-00259 trials - Prothioconazole-desthio and its hydroxies

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Trial number** | **Country** | **Variety** | **Application date** | **Application rates (g a.s./ha)** | **BBCH at application** | **Timing** | **Matrix** | **Residue of PTZ-Desthio (mg/kg)** | **Residue of alpha-OH  (mg/kg)** | **Residue of 3-OH  (mg/kg)** | **Residue of 4-OH  (mg/kg)** | **Residue of 5-OH (mg/kg)** | **Residue of 6-OH (mg/kg)** | **Total (PTZ-desthio+hydroxy=RD-RA1)\*** |
| S21-00259-01 | Cheshire, CH3 7BF, Waverton, UK | Oilseed Rape,  Click CL | 21 Jun 2021  05 Jul 2021 | 200.28  196.39 | 65  69 | 56 DAA2 (NCH) | Grain | < 0.003 n.d. | <0.01 | <0.01 | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | <0.03 |
| Straw | 0.07 | <0.01 | 0.09 | 0.02 | <0.01 | < 0.003 n.d. | 0.20 |

The limit of quantitation for the method is set at 0.01 mg/kg for each analyte and matrix.

Table A 89: Summary of the study S21-00259 trials - TDMs

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Trial number** | **Country** | **Variety** | **Application date** | **Application rates (g a.s./ha)** | **BBCH at application** | **Timing** | **Matrix** | **Residue in treated samples** | | | | **Residue in control samples** | | | |
| **Residue of Tz (mg/kg)** | **Residue of TA (mg/kg)** | **Residue of TAA (mg/kg)** | **Residue of TLA (mg/kg)** | **Residue of Tz (mg/kg)** | **Residue of TA (mg/kg)** | **Residue of TAA (mg/kg)** | **Residue of TLA (mg/kg)** |
| S21-00259-01 | Cheshire, CH3 7BF, Waverton, UK | Oilseed Rape,  Click CL | 21 Jun 2021  05 Jul 2021 | 200.28  196.39 | 65  69 | 56 DAA2 (NCH) | Grain | < 0.003 n.d. | 2.3 | 0.01 | 0.1 | < 0.003 n.d. | 2.2 | 0.01 | 0.1 |
| Straw | < 0.003 n.d. | 0.07 | 0.03 | 0.05 | < 0.003 n.d. | 0.05 | 0.02 | 0.04 |

The limit of quantitation for the method is set at 0.01 mg/kg for each analyte and matrix.

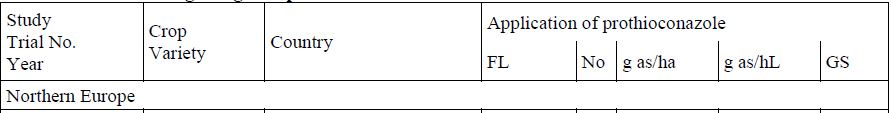
* + - * 1. Oilseed rape residue trials analysing TDMs

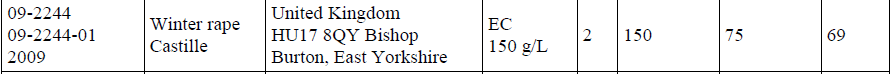
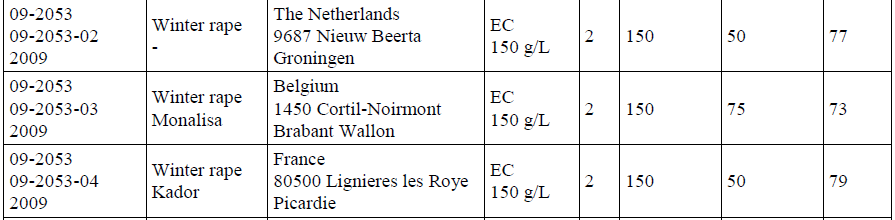
The following tables were extracted from the “Triazole Derivate Metabolites addendum – confirmatory data prepared by the rapporteur Member State, the United Kingdom” Appendix C (UK, 2018).

Only trials performed with prothioconazole were considered and presented hereafter.

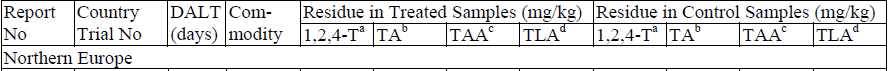
**B.7.3.13.8 Oilseed Rape (Prothioconazole)**

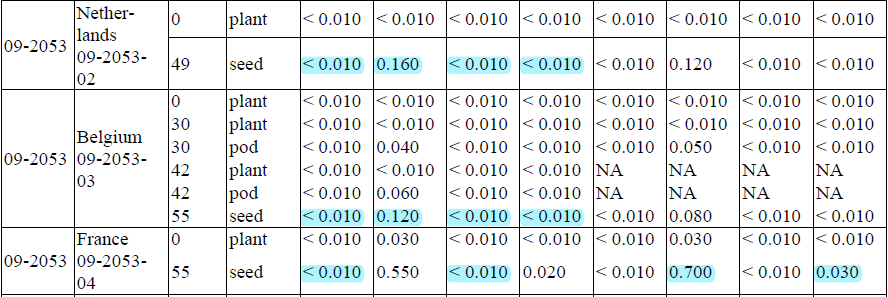
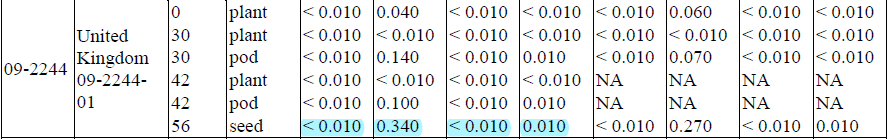
**Table A 90:** **Application summary of residue trials conducted in/on oilseed rape with an EC formulation containing 150 g/L of prothioconazole**





**Table A 91:** **Results of residue trials conducted in/on oilseed rape with an EC formulation containing 150 g/L of prothioconazole**



* + - * 1. New study S22-00257 – NEU

|  |  |
| --- | --- |
| Comments of zRMS: | The study was conducted to determine residue levels of prothioconazole-desthio (sum of isomers) in oilseed rape. Three residue trials were conducted in N-EU on oilseed rape during 2022. Two applications of NUL 3390 (250 g/L, prothioconazole) were applied at 175 g ai/ha (target) at an interval of 14 days with the final application 56 days before harvest.  The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte/matrix  The mean recoveries at each fortification level comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, rev. 1.  Sufficient stability data are available to support the residue data presented in this study.  Residue results in seed of oilseed rape:  Residues of prothioconazole-desthio, PTZ-alpha-hydroxy-desthio and PTZ-4-hydroxy-desthio were below LOQ (0.01 mg/kg) in treated oilseed rape grain samples of all trials.  Residues of PTZ-3-hydroxy-desthio were between < 0.01 mg/kg and 0.02 mg/kg.  No residues of PTZ-5-hydroxy-desthio and PTZ-6-hydroxy-desthio were found in treated oilseed rape grain samples of all trials.  1,2,4-T: 3x <0.003 mg/kg  TAA: 3x 0.01 mg/kg  TA: 0.95, 1.2, 1.5 mg/kg  TLA: 0.04, 0.06, 0.07 mg/kg.  The study is acceptable. |

|  |  |
| --- | --- |
| Reference: | KCA 6.3.3/06 |
| Report | Determination of residues of Prothioconazole-desthio (sum of isomers) after two applications of Prothioconazole in Oilseed rape (outdoor) at 3 sites in Northern Europe in 2022  North, L., 2023  Report No: S22-00257 |
| Guideline(s): | OECD (2009) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32)  OECD Test Guideline 509: Crop field trials  OECD (2016) Guidance Document ENV/JM/MONO (2011)50/REV1 , Second Edition, on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66)  EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials  SANTE/2019/12752 Technical Guidelines on Data Requirements for Setting Maximum Residue Levels, Comparability of Residue Trial and Extrapolation of Residue Data on Products from Plant and Animal Origin (Repealing and replacing the existing Guidance Document SANCO 7525/Vl/95 Rev. 10.3)  SANTE/2020/12830, Rev.1 Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes (Supersedes Guidance Documents SANCO/3029/99 and SANCO/825/00) |
| Deviations: | Some minor deviations during the field phase without impact on the study |
| GLP: | Yes |
| Owner: | Nufarm Crop Products UK |
| Acceptability: | Yes |

Materials and Methods

Three residue trials were conducted on oilseed rape during 2022, one in Germany (S22-00257-01), one in Poland (S22-00257-02) and one in Northern France (S22-00257-03). Two applications of NUL 3390 (250 g/L, prothioconazole) were applied at 175 g ai/ha (target) at an interval of 14 days with the final application 56 days before harvest (target), diluted with water immediately prior to application to a spray volume of 100-400 L/ha (target).

Samples of oilseed rape grain and straw from the untreated and treated plots were taken 56 days after the final application at BBCH 89. Samples were frozen within 24 hours after sampling.

The analytes were fortified jointly and quantified separately.

Oilseed rape straw and seed samples were analysed for residues of prothioconazole (PTZ) and prothioconazole-desthio (PTZ-desthio) using multi-residue method QuEChERS as validated for oilseed rape (seeds) in Eurofins study S16-04434. Quantitation was performed by use of liquid chromatography with tandem mass spectrometry (LC-MS/MS).

Oilseed rape straw and seed samples were analysed for residues of PTZ-alpha-hydroxy-desthio, PTZ-3-hydroxy-desthio, PTZ-4-hydroxy-desthio, PTZ-5-hydroxy-desthio, and PTZ-6-hydroxy-desthio using Eurofins Agroscience Services method which was validated for oilseed rape (seeds) in study S16-04435. Quantitation was performed by use of liquid chromatography with tandem mass spectrometry (LC-MS/MS).

Oilseed rape whole plant and seed samples were analysed for residues of 1,2,4-Triazole (T), Triazole Alanine (TA), Triazole Acetic Acid (TAA) and Triazole Lactic Acid (TLA) using Eurofins Agroscience Services method which was validated for oilseed rape (seeds) in study S15-03542. Quantitation was performed by use of liquid chromatography with tandem mass spectrometry and SelexION Differential Mobility Separation (LC-DMS/MS/MS).

For all analytes and all matrices, the limit of quantification (LOQ) of the analytical method was 0.01 mg/kg with a limit of detection (LOD) set at 0.003 mg/kg (30% of the LOQ). The analytes were fortified jointly and quantified separately. For prothioconazole the LOQ is expressed as PTZ-desthio.

For PTZ-alpha-hydroxy-desthio, PTZ-3-, -4-, -5- and -6-hydroxy-desthio the LOQ is expressed as PTZ-desthio.

*Procedural Recoveries*

For each analytical set of sample analysis, the method’s applicability in terms of accuracy and repeatability was assessed by fortification of control (untreated) test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the analytical method(s).

For PTZ-desthio, PTZ-alpha-hydroxy-desthio, PTZ-3-, -4-, -5- and -6-hydroxy-desthio fortifications were performed at the level of 0.01 mg/kg, and 0.1 mg/kg with additional fortifications for oilseed rape (straw) at 0.2 mg/kg for PTZ-desthio and 0.5 mg/kg for PTZ-3-hydroxy-desthio and were thus at or above the highest residue level found in a sample.

For the triazole metabolites 1,2,4-Triazole, TA, TAA and TLA fortifications were performed at the level of 0.01 mg/kg and 0.1 mg/kg with additional fortifications at 2.0 mg/kg for TA in oilseed rape (grain) and were thus at or above the highest residue level found in a sample.

No residues above 30 % of the LOQ were detected in the control (untreated) test portions used for recovery determinations of PTZ-desthio, PTZ-alpha-hydroxy-desthio, PTZ-3-, -4-, -5- and -6-hydroxy-desthio.

For the triazole metabolites blank values were unavoidable. Control samples with the lowest residues were used for recovery determinations. They were either taken from the current study but also from different origin (e.g. material of the Test Site formerly taken under GLP). The recoveries were corrected by background subtraction and even if they were ≤ 30 % of the LOQ.

The accuracy and precision of all three methods during sample analysis were considered to be acceptable since the following criteria were fulfilled.

For all combinations of analytes and matrices, single recoveries were in the range of 60 % - 120 %.

The mean recoveries at each fortification level comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, rev. 1.

The applicability of all methods for matrices of oilseed rape (grain and straw) was demonstrated by concurrent recoveries at LOQ and higher levels.

For PTZ-desthio the maximum storage interval from sampling to extraction was 45 days and the maximum storage period from extraction to analysis was 3 days.

For PTZ-alpha-hydroxy-desthio, PTZ-3-, -4-, -5- and -6-hydroxy-desthio the maximum storage interval from sampling to extraction was 45 days and the maximum storage period from extraction to analysis was 1 day.

For 1,2,4-Triazole, TA, TAA and TLA the maximum storage interval from sampling to extraction was 50 days and the maximum storage period from extraction to analysis was 1 day.

Results

No residue of prothioconazole-deshio, alpha-OH, 3-OH, 4-OH 5-OH and 6-OH was found in any untreated samples of all trials.

For triazole derivative metabolites, residues above the LOQ was found in some untreated samples. Triazoles are a common ingredient of numerous pesticides which were widely used by farmers as fungicides in various field crops. Triazole metabolites show a great persistence in the soils and can be uptaken by plants. The residue findings for TA, TAA and TLA were at a similar level in the control and treated samples and most likely origin in former usage of pesticides containing triazoles on the sampling sites or nearby.

Details on residue trials are presented in the table thereafter.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Report No.  Location  (region) | Commodity/Variety | Date of  1) Sowing  2) Flowering  3) Harvest | Method of Treatment | Application rate per  treatment | | | Dates of  treatment(s) | Growth stage at last  treatment  BBCH |
| g as/hL | Water  (L/ha) | g as/ha |
| S22-00257-01  16356 Blumberg,  Brandenburg,  Germany  NEU | Oilseed rape  / Ludger | 1) 07/09/2021  2) 19/04/2022 – 22/03/2022  3) 14/07/2022 | Foliar with plot sprayer | 58  58 | 324  306 | 189  178 | 06/05/2022  20/05/2022 | 65  69 |
| S22-00257-02  Ordzin, Wielkopolski  Poland  NEU | Oilseed rape / Derrick | 1) 25/05/2022  2) 7-27/05/2022  3) 21/07/2022 | Foliar with plot sprayer | 44  44 | 432  414 | 189  181 | 12/05/2022  26/05/2022 | 65  69 |
| S22-00257-03  St Hilaine, St Mesmin, Loiret, France  NEU | Oilseed rape / Alessandro | 1) 18/08/2021  2) 05/04/2022– 04/05/2022  3) 28/06/2022 | Foliar with plot sprayer | 58  58 | 304  310 | 177  180 | 19/04/2022  03/05/2022 | 65  69 |

The residue levels found in oilseed rape are summarised in the table below.

Table A 92: Summary of the study S22-00257 trials - Prothioconazole-desthio and its hydroxies

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Report No.**  **Location**  **(region)** | **Commodity /Variety** | **Application date** | **Application rates (g a.s./ha)** | **BBCH at application** | **PHI (days)** | **Matrix** | **Residue of PTZ-Desthio (mg/kg)** | **Residue of alpha-OH  (mg/kg)** | **Residue of 3-OH  (mg/kg)** | **Residue of 4-OH  (mg/kg)** | **Residue of 5-OH (mg/kg)** | **Residue of 6-OH (mg/kg)** | **Total (PTZ-desthio+hydroxy=RD-RA1)\*** |
| S22-00257-01  Blumberg,  Brandenburg,  Germany  NEU | Oilseed rape  / Ludger | 06/05/2022  20/05/2022 | 189  178 | 65  69 | 56 DAA2 (NCH) | Grain | <0.01 | <0.01 | <0.01 | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | <0.04 |
| Straw | 0.14 | 0.02 | 0.25 | 0.09 | 0.03 | <0.01 | 0.54 |
| S22-00257-02  Ordzin, Wielkopolski  Poland  NEU | Oilseed rape / Derrick | 12/05/2022  26/05/2022 | 189  181 | 65  69 | 56 DAA2 (NCH) | Grain | <0.01 | < 0.003 n.d. | 0.01 | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | 0.03 |
| Straw | 0.05 | <0.01 | 0.08 | 0.03 | 0.01 | <0.01 | 0.19 |
| S22-00257-03  St Hilaine, St Mesmin, France  NEU | Oilseed rape / Alessandro | 19/04/2022  03/05/2022 | 177  180 | 65  69 | 56 DAA2 (NCH) | Grain | <0.01 | <0.01 | 0.02 | <0.01 | < 0.003 n.d. | < 0.003 n.d. | 0.06 |
| Straw | 0.15 | 0.01 | 0.14 | 0.05 | 0.02 | <0.01 | 0.38 |

The limit of quantitation for the method is set at 0.01 mg/kg for each analyte and matrix and the limit of detection is 0.003 mg/kg.

NCH = Normal Commercial Harvest

Table A 93: Summary of the study S22-00257 trials - TDMs

| **Report No.**  **Location**  **(region)** | **Variety** | **Application date** | **Application rates (g a.s./ha)** | **BBCH at application** | **Timing** | **Matrix** | **Residue in treated samples** | | | | **Residue in control samples** | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Residue of Tz (mg/kg)** | **Residue of TA (mg/kg)** | **Residue of TAA (mg/kg)** | **Residue of TLA (mg/kg)** | **Residue of Tz (mg/kg)** | **Residue of TA (mg/kg)** | **Residue of TAA (mg/kg)** | **Residue of TLA (mg/kg)** |
| S22-00257-01  Blumberg,  Brandenburg,  Germany  NEU | Oilseed rape  / Ludger | 06/05/2022  20/05/2022 | 189  178 | 65  69 | 56 DAA2 (NCH) | Grain | < 0.003 n.d. | 1.1 | 0.01 | 0.06 | < 0.003 n.d. | 1.5 | 0.01 | 0.07 |
| Straw | < 0.003 n.d. | 0.02 | 0.03 | 0.03 | < 0.003 n.d. | 0.04 | 0.03 | 0.04 |
| S22-00257-02  Ordzin, Wielkopolski  Poland  NEU | Oilseed rape / Derrick | 12/05/2022  26/05/2022 | 189  181 | 65  69 | 56 DAA2 (NCH) | Grain | < 0.003 n.d. | 1.1 | 0.01 | 0.04 | < 0.003 n.d. | 1.2 | 0.01 | 0.06 |
| Straw | < 0.003 n.d. | 0.02 | 0.02 | 0.02 | < 0.003 n.d. | 0.03 | 0.01 | 0.01 |
| S22-00257-03  St Hilaine, St Mesmin, France  NEU | Oilseed rape / Alessandro | 19/04/2022  03/05/2022 | 177  180 | 65  69 | 56 DAA2 (NCH) | Grain | < 0.003 n.d. | 0.48 | < 0.01 | 0.03 | < 0.003 n.d. | 0.95 | 0.01 | 0.04 |
| Straw | < 0.003 n.d. | 0.05 | < 0.01 | < 0.01 | < 0.003 n.d. | 0.07 | 0.03 | 0.02 |

The limit of quantitation for the method is set at 0.01 mg/kg for each analyte and matrix.

* + 1. Magnitude of residues in livestock

No new data submitted.

* + 1. Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

No new data submitted.

* + 1. Magnitude of residues in representative succeeding crops

No new data submitted.

* + 1. Other/Special Studies
       1. Study 1 (S21-00428)

|  |  |
| --- | --- |
| Comments of zRMS: | The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for CA3301/ Joust (January 2023). This study has not been reassessed in the framework of this application.  The conclusions of the assessment are presented below:  *The study was conducted to determine residues of prothioconazole in nectar, pollen and honey collected from honey bees from winter oilseed rape plants after two applications of CA3301 (175 g prothioconazole/ha) under semi-field conditions.*  *The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix.*  *Sufficient stability data are available to support the residue data presented in this study.*  *Honey*  *No residues of prothioconazole-desthio, alpha-OH, 3-OH, 4-OH 5-OH, 6-OH and 1,2,4-triazole were found in treated honey samples of all trials.*  *Residues of triazole alanine (TA) ranged from 0.0131 mg/kg to 0.0298 mg/kg. The highest residues of triazole acetic acid (TAA) was 0.0330 mg/kg in one sample. Residues of triazole lactic acid (TLA) were not detectable in treated honey samples of all trials except trial -04 with values below LOQ.*  *This study complies with the requirements of SANTE / 11956/2016 rev. 9, so the study is acceptable.* |

|  |  |
| --- | --- |
| Reference: | KCA 6.10/01 |
| Report | Determination of Residues of Prothioconazole in Nectar, Pollen and Honey of Winter Oilseed Rape after Two Applications of CA3642 in a Semi-Field Residue Study in Central and Southern Europe in 2021  Knoll, M., 2021  Report No S21-00428 |
| Guideline(s): | Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009  SANTE/11956/2016 rev. 9 |
| Deviations: | None |
| GLP: | Yes |
| Owner: | Nufarm Crop Products UK |
| Acceptability: | Yes |

Materials and methods

Five residue trials, located in Germany (S21-00428-01, -02 and -03), Southern France (S21-00428-04) and Spain (S21-00428-05) were conducted in 2021 with winter oilseed rape as a melliferous source. Trial -01 comprised two plots/tunnels, one control tunnel (C) and one test item treatment tunnel (Ta). Trials -02 to -05 comprised three plots/tunnels, one control tunnel (C) and two test item treatment tunnels (Ta and Tb).

Prothioconazole 250 g/L EC (CA3642) was applied twice, at a nominal application rate of 700 mL product/ha, equivalent to 175 g a.s./ha for each application. The first application (A1) was conducted before flowering and 14 days before the second application (A2) which was conducted at BBCH 61-63.

Forager bees and pollen from pollen traps were collected once in the untreated control (C) and five times in the test item treatment (tunnel Ta) during the study period starting after application A2 (0DAA2) with sampling S1 and up to 8 days after application A2. In trials -02 to -05 honey from combs was sampled from the untreated control (C) tunnel and from the test item treated tunnel Tb. Samples were taken by hand using a spoon. Empty combs were inserted to the bee hive before application and honey was collected from these combs.

For nectar samples, on every sampling day approximately 450 forager bees were tried to collect for the preparation of nectar from their honey stomachs. In addition, forager bees were sampled for the determination of sugar content (at least 50 forager bees) at each sampling day. For pollen samples, on every sampling day a pooled sample of at least 0.6 g was tried to collect using pollen traps or by preparation of the pollen directly from the forager bees.

All samples ((except the honey samples which were transported ambient or on blue ice) for drying in the compartment drier) were transported on dry ice to the test facility/test site and were stored deep frozen (≤ -18 °C) until shipment and/or honey stomach preparation and/or residue analysis.

In the analytical phase of this study, samples of pollen and nectar were analysed for residues of prothioconazole, prothioconazole-desthio (Group 1), prothioconazole-alpha-hydroxy-desthio, -3-hydroxy-desthio, -4-hydroxy-desthio, -5-hydroxy-desthio and -6-hydroxy-desthio (Group 2), as well as 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid (Group 3), with an intended limit of quantification of 0.01 mg/kg. Residues of honey were analysed for residues of prothioconazole-desthio only and analytes of Group 2 and Group 3 for risk assessment with an intended limit of quantification of 0.01 mg/kg.

Quantification was performed by use of LC-MS/MS (group 1 and 2) and LC-DMS-MS/MS (group 3) detection using matrix matched calibration.

The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix with a limit of detection (LOD) set at 0.003 mg/kg (defined as the lowest calibration standard, which is 30 % of the LOQ). For group 2 analytes the LOQ is expressed as prothioconazole-desthio equivalent.

Due to insufficient sample size few samples could not be used for sample preparation and analysis. This includes trial -02 pollen treated samples of sampling 1 and 2.

*Maximum storage period of pollen samples*

The maximum storage interval for pollen tested on residues of Group 1 was 134 days from sampling until extraction and applies only for the sample L21-00428-04-C-S1-P-A. The majority of samples were analysed after 50 days from sampling and the remaining under 78 days from sampling. The maximum storage interval from extraction to analysis was three days.

The maximum storage interval for pollen tested on residues of Group 2 was 134 days from sampling until extraction. The maximum storage interval from extraction to analysis was one day.

The maximum storage interval for pollen tested on residues of Group 3 was 79 days from sampling until extraction. The maximum storage interval from extraction to analysis was five days.

*Maximum storage period of nectar samples*

The maximum storage interval for nectar tested on residues of Group 1 was 77 days from sampling until extraction. The maximum storage interval from extraction to analysis was one day.

The maximum storage interval for nectar tested on residues of Group 2 was 133 days from sampling until extraction. The maximum storage interval from extraction to analysis was one day.

The maximum storage interval for nectar tested on residues of Group 3 was 74 days from sampling until extraction. The maximum storage interval from extraction to analysis was one day.

*Maximum storage period of honey samples*

The maximum storage interval for honey tested on residues of Group 1 was 54 days from sampling until extraction. The maximum storage interval from extraction to analysis was five days.

The maximum storage interval for honey tested on residues of Group 2 was 115 days from sampling until extraction. The maximum storage interval from extraction to analysis was one day.

The maximum storage interval for honey tested on residues of Group 3 was 62 days from sampling until extraction. The maximum storage interval from extraction to analysis was one day.

Results and discussions

No residues of prothioconazole, prothioconazole-desthio, alpha-OH, 3-OH, 4-OH 5-OH, 6-OH and 1,2,4-triazole were found in any untreated samples for any matrix of all trials.

For the metabolite triazole alanine (TA) residues were found in untreated control samples of honey for trial -02, -03 and -04. For untreated nectar samples residues of TA were found for trial -03 and -04 and for pollen residues were found in the control samples of all trials.

Residues of the metabolite triazole acetic acid (TAA) were found in untreated control samples of honey, nectar and pollen of trial -04.

For the metabolite triazole lactic acid (TLA) residues were found in untreated control samples of honey for trial -04 and also in the untreated pollen sample of trial -04.

Triazoles are a common ingredient of numerous pesticides which were widely used by farmers as fungicides in various field crops. Triazole metabolites show a great persistence in the soils and can be uptaken by plants. The residue findings for TA, TAA and TLA were at a similar level in the control and treated samples and most likely origin in former usage of pesticides containing triazoles on the sampling sites or nearby.

*Honey*

No residues of prothioconazole-desthio, alpha-OH, 3-OH, 4-OH 5-OH, 6-OH and 1,2,4-triazole were found in honey samples of all trials.

Residues of the metabolite triazole alanine (TA) were found in the untreated and treated honey samples of trial -02 and trial -04. The values found ranged from 0.0131 mg/kg to 0.0298 mg/kg. Residues of triazole acetic acid (TAA) were also detected in untreated and treated honey samples of trial -04 with values from 0.0330 mg/kg to 0.0646 mg/kg. Residues of the metabolite triazole lactic acid (TLA) were not quantified in treated honey samples of all trials, but was quantified (0.0179 - 0.0194 mg/kg) in untreated honey samples of trial -04.

*Nectar*

Residues of prothioconazole were found in treated nectar samples within a range between not detectable and 0.0649 mg/kg in the nectar samples over all trials at the first two samplings (0DAA2 and 1DAA2). Afterwards prothioconazole was not detectable anymore. The residues of prothioconazole-desthio detected in in treated nectar samples ranged from not detectable to 0.0633 mg/kg over all trials and samplings with no clear pattern. Residues of the metabolite alpha-OH found in treated nectar samples ranged from not detectable to 0.0136 mg/kg over all trials and samplings with no clear pattern. Residues of TA were found in samples of trial -01 to trial -04 of treated nectar and ranged from not detectable to 0.0286 mg/kg. In Trial -05 all samples were below LOD for TA.

No residues of 3-OH, 4-OH, 5-HO and 6-OH, 1,2,4-triazole, triazole lactic acid (TLA) and triazole acetic acid (TAA) were found in nectar samples from treated plots, except trial -04 with findings of TAA in a range from not detectable to 0.0105 mg/kg over all samplings.

*Pollen*

Residues of prothioconazole were detected in treated pollen samples of all trials and were highest at the first sampling with a range of 14.9 to 47.1 mg/kg. Afterwards the residues declined and are within a ranged from below LOQ to 0.0417 mg/kg at the last sampling (6 – 8DAA2). Residues of prothioconazole-desthio were found also in pollen of all trials and the maximum residue values were found at the first sampling (except for trial 05) and ranged between 0.755 mg/kg to 3.65 mg/kg. At the last sampling residues were down to a range of 0.156 mg/kg to 0.672 mg/kg. The residues of the metabolite alpha-OH found in treated pollen sampled ranged between 0.0124 mg/kg and 0.0402 mg/kg over all trials and samplings with no clear increase or decline pattern of the course of the sampling period. Residues of 3-OH found in pollen samples from the treated plots ranged from below LOQ to 0.0121 mg/kg over all trials and samplings with no clear increase or decline pattern of the course of the sampling period. Residues of 4-OH found in pollen samples from the treated plots ranged from not detectable to 0.0123 mg/kg and residues of triazole alanine found in treated pollen samples ranged between 0.0730 mg/kg to 2.22 mg/kg over all trials and samplings with no clear increase or decline pattern of the course of the sampling period.

No residues of 5-OH and 6-OH, 1,2,4-triazole, triazole acetic acid and triazole lactic acid were found in the treated pollen samples of all trials, except the findings in trial -04 of TAA within a range between below LOQ and 0.0143 mg/kg and TLA with findings in trial -04 at below LOQ.

The residue levels of all analytes found in honey, nectar and pollen are summarised in the tables below.

Table A 94: Summary of the study S21-00428 trials – Prothioconazole and metabolites - Honey

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Trial number** | **Country** | **Variety** | **Application date** | **Application rates (g a.s./ha)** | **BBCH at application** | **Timing** | **Matrix** | **Residue of PTZ-Desthio (mg/kg)** | **Residue of alpha-OH  (mg/kg)** | **Residue of 3-OH  (mg/kg)** | **Residue of 4-OH  (mg/kg)** | **Residue of 5-OH (mg/kg)** | **Residue of 6-OH (mg/kg)** |
| S21-00428-02 | 75117, Pforzheim, Baden-Württemberg, Germany | Winter Oilseed Rape, Pionier PX 128 | 13 Apr 2021 08 May 2021 | 177.1 176.7 | 55 63 | 3DAA2 | Honey | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. |
| S21-00428-03 | 75438, Knittlingen, Baden-Würrtemberg, Germany | Winter Oilseed Rape, Raps Ludger | 09 Apr 2021 23 Apr 2021 | 174.0 177.6 | 53 62 | 4DAA2 | Honey | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. |
| S21-00428-04 | 32100, Gers, Larroque-sur-I´Osse, France | Winter Oilseed Rape, DK exception | 05 Mar 2021 22 Mar 2021 | 171.3 172.4 | 57 - 59 61 - 63 | 18DAA2 | Honey | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. |
| n.d. | n.d. | n.d. | n.d. | n.d. | n.d. |
| S21-00428-05 | 02640, Almansa, Albacete, Spain | Winter Oilseed Rape, SY Florida | 31 Mar 2021 14 Apr 2021 | 183.4 170.8 | 57 - 59 63 | 16DAA2 | Honey | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. |
| n.d. | n.d. | n.d. | n.d. | n.d. | n.d. |

DAA2 Days after application 2 (last application)

n.d. Not detected (<0.003 mg/kg)

< LOQ < 0.01 mg/kg

Table A 95: Summary of the study S21-00428 trials – Prothioconazole and metabolites – Nectar

| **Trial number** | **Country** | **Variety** | **Application date** | **Application rates (g a.s./ha)** | **BBCH at application** | **Timing** | **Matrix** | **Residue of PTZ (mg/kg)** | **Residue of PTZ-Desthio (mg/kg)** | **Residue of alpha-OH  (mg/kg)** | **Residue of 3-OH  (mg/kg)** | **Residue of 4-OH  (mg/kg)** | **Residue of 5-OH (mg/kg)** | **Residue of 6-OH (mg/kg)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| S21-00428-01 | 76703, Kraichtal, Baden-Württemberg, Germany | Winter Oilseed Rape, LG Architekt | 09 Apr 2021 23 Apr 2021 | 180.3 175.1 | 55 63 | 0DAA2 | Nectar | 0.0386 | 0.0118 | < LOQ (0.00385) | n.d. | n.d. | n.d. | n.d. |
| 1DAA2 | Nectar | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. |
| 2DAA2 | Nectar | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. |
| 4DAA2 | Nectar | n.d. | n.d. | < LOQ (0.00356) | n.d. | n.d. | n.d. | n.d. |
| 6DAA2 | Nectar | n.d. | < LOQ (0.00362) | n.d. | n.d. | n.d. | n.d. | n.d. |
| S21-00428-02 | 75117, Pforzheim, Baden-Württemberg, Germany | Winter Oilseed Rape, Pionier PX 128 | 13 Apr 2021 08 May 2021 | 177.4 159.2 | 55 63 | 0DAA2 | Nectar | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. |
| 1DAA2 | Nectar | < LOQ (0.00534) | < LOQ (0.00498) | < LOQ (0.00460) | n.d. | n.d. | n.d. | n.d. |
| 2DAA2 | Nectar | n.d. | n.d. | < LOQ (0.00460) | n.d. | n.d. | n.d. | n.d. |
| 5DAA2 | Nectar | n.d. | < LOQ (0.00596) | < LOQ (0.00412) | n.d. | n.d. | n.d. | n.d. |
| 6DAA2 | Nectar | n.d. | < LOQ (0.00397) | < LOQ (0.00404) | n.d. | n.d. | n.d. | n.d. |
| S21-00428-03 | 75438, Knittlingen, Baden-Würrtemberg, Germany | Winter Oilseed Rape, Raps Ludger | 09 Apr 2021 23 Apr 2021 | 175.9 176.7 | 53 62 | 0DAA2 | Nectar | 0.042 | 0.0243 | < LOQ (0.00560) | n.d. | n.d. | n.d. | n.d. |
| 1DAA2 | Nectar | 0.0206 | 0.0633 | < LOQ (0.00572) | n.d. | n.d. | n.d. | n.d. |
| 2DAA2 | Nectar | n.d. | < LOQ (0.00821) | < LOQ (0.00700) | n.d. | n.d. | n.d. | n.d. |
| 4DAA2 | Nectar | n.d. | < LOQ (0.00901) | 0.0103 | n.d. | n.d. | n.d. | n.d. |
| 6DAA2 | Nectar | n.d. | < LOQ (0.00757) | n.d. | n.d. | n.d. | n.d. | n.d. |
| S21-00428-04 | 32100, Gers, Larroque-sur-I´Osse, France | Winter Oilseed Rape, DK exception | 05 Mar 2021 22 Mar 2021 | 169.1 168.2 | 57 - 59 61 - 63 | 0DAA2 | Nectar | 0.0649 | < LOQ (0.00671) | n.d. | n.d. | n.d. | n.d. | n.d. |
| 1DAA2 | Nectar | < LOQ (0.00397) | n.d. | < LOQ (0.00307) | n.d. | n.d. | n.d. | n.d. |
| 2DAA2 | Nectar | n.d. | < LOQ (0.00858) | < LOQ (0.00460) | n.d. | n.d. | n.d. | n.d. |
| 4DAA2 | Nectar | n.d. | < LOQ (0.00610) | < LOQ (0.00748) | n.d. | n.d. | n.d. | n.d. |
| 8DAA2 | Nectar | n.d. | < LOQ (0.00405) | n.d. | < LOQ (0.00468) | n.d. | n.d. | n.d. |
| S21-00428-05 | 02640, Almansa, Albacete, Spain | Winter Oilseed Rape, SY Florida | 31 Mar 2021 14 Apr 2021 | 169.5 172.2 | 57 - 59 63 | 0DAA2 | Nectar | 0.0598 | 0.0218 | n.d. | n.d. | n.d. | n.d. | n.d. |
| 2DAA2 | Nectar | < LOQ (0.00442) | 0.0103 | n.d. | n.d. | n.d. | n.d. | n.d. |
| 3DAA2 | Nectar | n.d. | < LOQ (0.00459) | n.d. | n.d. | n.d. | n.d. | n.d. |
| 4DAA2 | Nectar | n.d. | < LOQ (0.00958) | 0.0136 | n.d. | n.d. | n.d. | n.d. |
| 7DAA2 | Nectar | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. |

DAA2 Days after application 2 (last application)

n.d. Not detected (<0.003 mg/kg)

< LOQ < 0.01 mg/kg

Table A 96: Summary of the study S21-00428 trials – Prothioconazole and metabolites – Pollen

| **Trial number** | **Country** | **Variety** | **Application date** | **Application rates (g a.s./ha)** | **BBCH at application** | **Timing** | **Matrix** | **Residue of PTZ (mg/kg)** | **Residue of PTZ-Desthio (mg/kg)** | **Residue of alpha-OH  (mg/kg)** | **Residue of 3-OH  (mg/kg)** | **Residue of 4-OH  (mg/kg)** | **Residue of 5-OH (mg/kg)** | **Residue of 6-OH (mg/kg)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| S21-00428-01 | 76703, Kraichtal, Baden-Württemberg, Germany | Winter Oilseed Rape, LG Architekt | 09 Apr 2021 23 Apr 2021 | 180.3 175.1 | 55 63 | 0DAA2 | Pollen | 47.1 | 2.19 | 0.0306 | < LOQ (0.00648) | < LOQ (0.00507) | n.d. | n.d. |
| 1DAA2 | Pollen | 1.53 | 0.825 | 0.0273 | < LOQ (0.00624) | < LOQ (0.00711) | n.d. | n.d. |
| 2DAA2 | Pollen | 0.42 | 0.429 | 0.0214 | < LOQ (0.00528) | < LOQ (0.00570) | n.d. | n.d. |
| 4DAA2 | Pollen | 0.0609 | 0.378 | 0.0212 | < LOQ (0.00768) | < LOQ (0.00837) | n.d. | n.d. |
| 6DAA2 | Pollen | 0.0287 | 0.303 | 0.0144 | < LOQ (0.00612) | < LOQ (0.00606) | n.d. | n.d. |
| S21-00428-02 | 75117, Pforzheim, Baden-Württemberg, Germany | Winter Oilseed Rape, Pionier PX 128 | 13 Apr 2021 08 May 2021 | 177.4 159.2 | 55 63 | 2DAA2 | Pollen | 0.248 | 0.435 | 0.0206 | < LOQ (0.00492) | < LOQ (0.00558) | n.d. | n.d. |
| 5DAA2 | Pollen | 0.0202 | 0.256 | 0.0187 | < LOQ (0.00618) | < LOQ (0.00303) | n.d. | n.d. |
| 6DAA2 | Pollen | 0.0219 | 0.221 | 0.017 | < LOQ (0.00498) | n.d. | n.d. | n.d. |
| S21-00428-03 | 75438, Knittlingen, Baden-Würrtemberg, Germany | Winter Oilseed Rape, Raps Ludger | 09 Apr 2021 23 Apr 2021 | 175.9 176.7 | 53 62 | 0DAA2 | Pollen | 45.8 | 3.65 | 0.0399 | 0.0107 | < LOQ (0.00921) | n.d. | n.d. |
| 1DAA2 | Pollen | 3.35 | 1.73 | 0.036 | 0.0123 | 0.0108 | n.d. | n.d. |
| 2DAA2 | Pollen | 0.402 | 0.69 | 0.0402 | 0.0115 | < LOQ (0.00654) | n.d. | n.d. |
| 4DAA2 | Pollen | 0.393 | 0.717 | 0.0384 | 0.012 | < LOQ (0.00855) | n.d. | n.d. |
| 6DAA2 | Pollen | 0.0417 | 0.459 | 0.0233 | 0.0121 | < LOQ (0.00657) | n.d. | n.d. |
| S21-00428-04 | 32100, Gers, Larroque-sur-I´Osse, France | Winter Oilseed Rape, DK exception | 05 Mar 2021 22 Mar 2021 | 169.1 168.2 | 57 - 59 61 - 63 | 0DAA2 | Pollen | 14.9 | 1.7 | 0.0254 | < LOQ (0.00630) | < LOQ (0.00909) | n.d. | n.d. |
| 1DAA2 | Pollen | 1.23 | 1.12 | 0.0241 | < LOQ (0.00603) | < LOQ (0.00927) | n.d. | n.d. |
| 2DAA2 | Pollen | 0.298 | 0.744 | 0.0315 | < LOQ (0.00672) | < LOQ (0.00960) | n.d. | n.d. |
| 4DAA2 | Pollen | 0.0822 | 0.687 | 0.0354 | < LOQ (0.00783) | 0.0103 | n.d. | n.d. |
| 8DAA2 | Pollen | 0.0217 | 0.672 | 0.0241 | < LOQ (0.00849) | 0.0123 | n.d. | n.d. |
| S21-00428-05 | 02640, Almansa, Albacete, Spain | Winter Oilseed Rape, SY Florida | 31 Mar 2021 14 Apr 2021 | 169.5 172.2 | 57 - 59 63 | 0DAA2 | Pollen | 17.7 | 0.755 | 0.0176 | < LOQ (0.00315) | < LOQ (0.00375) | n.d. | n.d. |
| 2DAA2 | Pollen | 2.19 | 1.21 | 0.0124 | n.d. | n.d. | n.d. | n.d. |
| 3DAA2 | Pollen | 0.315 | 0.375 | 0.0227 | n.d. | < LOQ (0.00468) | n.d. | n.d. |
| 4DAA2 | Pollen | 0.0615 | 0.29 | 0.0345 | < LOQ (0.00450) | < LOQ (0.00438) | n.d. | n.d. |
| 7DAA2 | Pollen | < LOQ (0.00783) | 0.156 | 0.0235 | < LOQ (0.00414) | < LOQ (0.00369) | n.d. | n.d. |

DAA2 Days after application 2 (last application)

n.d. Not detected (<0.003 mg/kg)

< LOQ < 0.01 mg/kg

Table A 97: Summary of the study S21-00428 trials – TDMs - Honey

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Trial number** | **Country** | **Variety** | **Application date** | **Application rates (g a.s./ha)** | **BBCH at application** | **Treatment** | **Timing** | **Matrix** | **Residue of Tz (mg/kg)** | **Residue of TA (mg/kg)** | **Residue of TAA (mg/kg)** | **Residue of TLA (mg/kg)** |
| S21-00428-02 | 75117, Pforzheim, Baden-Württemberg, Germany | Winter Oilseed Rape, Pionier PX 128 | - | - | - | C | 3DAA2 | Honey | n.d. | 0.02 | n.d. | n.d. |
| - | - | - | C | 3DAA2 | Honey | n.d. | 0.0198 | n.d. | n.d. |
| 13 Apr 2021 08 May 2021 | 177.1 176.7 | 55 63 | Tb | 3DAA2 | Honey | n.d. | 0.0131 | n.d. | n.d. |
| S21-00428-03 | 75438, Knittlingen, Baden-Würrtemberg, Germany | Winter Oilseed Rape, Raps Ludger | - | - | - | C | 4DAA2 | Honey | n.d. | 0.0192 | n.d. | n.d. |
| 09 Apr 2021 23 Apr 2021 | 174.0 177.6 | 53 62 | Tb | 4DAA2 | Honey | n.d. | n.d. | n.d. | n.d. |
| S21-00428-04 | 32100, Gers, Larroque-sur-I´Osse, France | Winter Oilseed Rape, DK exception | - | - | - | C | 18DAA2 | Honey | n.d. | 0.033 | 0.0638 | 0.0194 |
| - | - | - | C | 18DAA2 | Honey | n.d. | 0.0298 | 0.0646 | 0.0179 |
| 05 Mar 2021 22 Mar 2021 | 171.3 172.4 | 57 - 59 61 - 63 | Tb | 18DAA2 | Honey | n.d. | 0.0256 | 0.033 | < LOQ (0.00692) |
| 05 Mar 2021 22 Mar 2021 | 171.3 172.4 | 57 - 59 61 - 63 | Tb | 18DAA2 | Honey | n.d. | 0.023 | 0.033 | < LOQ (0.00738) |
| S21-00428-05 | 02640, Almansa, Albacete, Spain | Winter Oilseed Rape, SY Florida | - | - | - | C | 19DAA2 | Honey | n.d. | n.d. | n.d. | n.d. |
| - | - | - | C | 19DAA2 | Honey | n.d. | n.d. | n.d. | n.d. |
| 31 Mar 2021 14 Apr 2021 | 183.4 170.8 | 57 - 59 63 | Tb | 16DAA2 | Honey | n.d. | n.d. | n.d. | n.d. |
| 31 Mar 2021 14 Apr 2021 | 183.4 170.8 | 57 - 59 63 | Tb | 16DAA2 | Honey | n.d. | n.d. | n.d. | n.d. |

DAA2 Days after application 2 (last application)

n.d. Not detected (<0.003 mg/kg)

< LOQ < 0.01 mg/kg

Tz 1,2,4-triazole

TA Triazole alanine

TAA Triazole acetic acid

TLA Triazole lactic acid

Table A 98: Summary of the study S21-00428 trials – TDMs – Nectar

| **Trial number** | **Country** | **Variety** | **Application date** | **Application rates (g a.s./ha)** | **BBCH at application** | **Treatment** | **Timing** | **Matrix** | **Residue of Tz (mg/kg)** | **Residue of TA (mg/kg)** | **Residue of TAA (mg/kg)** | **Residue of TLA (mg/kg)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| S21-00428-01 | 76703, Kraichtal, Baden-Württemberg, Germany | Winter Oilseed Rape, LG Architekt | - | - | - | C | 0DAA2 | Nectar | n.d. | n.d. | n.d. | n.d. |
| 09 Apr 2021 23 Apr 2021 | 180.3 175.1 | 55 63 | Ta | 0DAA2 | Nectar | n.d. | < LOQ (0.00496) | n.d. | n.d. |
| 1DAA2 | Nectar | n.d. | n.d. | n.d. | n.d. |
| 2DAA2 | Nectar | n.d. | < LOQ (0.00504) | n.d. | n.d. |
| 4DAA2 | Nectar | n.d. | < LOQ (0.00354) | n.d. | n.d. |
| 6DAA2 | Nectar | n.d. | < LOQ (0.00400) | n.d. | n.d. |
| S21-00428-02 | 75117, Pforzheim, Baden-Württemberg, Germany | Winter Oilseed Rape, Pionier PX 128 | - | - | - | C | 0DAA2 | Nectar | n.d. | n.d. | n.d. | n.d. |
| 13 Apr 2021 08 May 2021 | 177.4 159.2 | 55 63 | Ta | 0DAA2 | Nectar | n.d. | n.d. | n.d. | n.d. |
| 1DAA2 | Nectar | n.d. | < LOQ (0.00976) | n.d. | n.d. |
| 2DAA2 | Nectar | n.d. | n.d. | n.d. | n.d. |
| 5DAA2 | Nectar | n.d. | n.d. | n.d. | n.d. |
| 6DAA2 | Nectar | n.d. | n.d. | n.d. | n.d. |
| S21-00428-03 | 75438, Knittlingen, Baden-Würrtemberg, Germany | Winter Oilseed Rape, Raps Ludger | - | - | - | C | 0DAA2-1DAA2-2DAA2 | Nectar | n.d. | < LOQ (0.00892) | n.d. | n.d. |
| 09 Apr 2021 23 Apr 2021 | 175.9 176.7 | 53 62 | Ta | 0DAA2 | Nectar | n.d. | 0.0134 | n.d. | n.d. |
| 1DAA2 | Nectar | n.d. | < LOQ (0.00812) | n.d. | n.d. |
| 2DAA2 | Nectar | n.d. | < LOQ (0.00604) | n.d. | n.d. |
| 4DAA2 | Nectar | n.d. | < LOQ (0.00848) | n.d. | n.d. |
| 6DAA2 | Nectar | n.d. | < LOQ (0.00464) | n.d. | n.d. |
| S21-00428-04 | 32100, Gers, Larroque-sur-I´Osse, France | Winter Oilseed Rape, DK exception | - | - | - | C | 0DAA2 | Nectar | n.d. | < LOQ (0.00992) | < LOQ (0.00568) | n.d. |
| 05 Mar 2021 22 Mar 2021 | 169.1 168.2 | 57 - 59 61 - 63 | Ta | 0DAA2 | Nectar | n.d. | 0.015 | < LOQ (0.00452) | n.d. |
| 1DAA2 | Nectar | n.d. | 0.0103 | 0.0105 | n.d. |
| 2DAA2 | Nectar | n.d. | 0.0286 | < LOQ (0.00896) | n.d. |
| 4DAA2 | Nectar | n.d. | 0.014 | < LOQ (0.00624) | n.d. |
| 8DAA2 | Nectar | n.d. | 0.0142 | n.d. | n.d. |
| S21-00428-05 | 02640, Almansa, Albacete, Spain | Winter Oilseed Rape, SY Florida | - | - | - | C | 0DAA2 | Nectar | n.d. | n.d. | n.d. | n.d. |
| 31 Mar 2021 14 Apr 2021 | 169.5 172.2 | 57 - 59 63 | Ta | 0DAA2 | Nectar | n.d. | n.d. | n.d. | n.d. |
| 2DAA2 | Nectar | n.d. | n.d. | n.d. | n.d. |
| 3DAA2 | Nectar | n.d. | n.d. | n.d. | n.d. |
| 4DAA2 | Nectar | n.d. | n.d. | n.d. | n.d. |
| 7DAA2 | Nectar | n.d. | n.d. | n.d. | n.d. |

DAA2 Days after application 2 (last application)

n.d. Not detected (<0.003 mg/kg)

< LOQ < 0.01 mg/kg

Tz 1,2,4-triazole

TA Triazole alanine

TAA Triazole acetic acid

TLA Triazole lactic acid

Table A 99: Summary of the study S21-00428 trials – TDMs – Pollen

| **Trial number** | **Country** | **Variety** | **Application date** | **Application rates (g a.s./ha)** | **BBCH at application** | **Treatment** | **Timing** | **Matrix** | **Residue of Tz (mg/kg)** | **Residue of TA (mg/kg)** | **Residue of TAA (mg/kg)** | **Residue of TLA (mg/kg)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| S21-00428-01 | 76703, Kraichtal, Baden-Württemberg, Germany | Winter Oilseed Rape, LG Architekt | - | - | - | C | 0DAA2 | Pollen | n.d. | 0.246 | n.d. | n.d. |
| 09 Apr 2021 23 Apr 2021 | 180.3 175.1 | 55 63 | Ta | 0DAA2 | Pollen | n.d. | 0.61 | n.d. | n.d. |
| 1DAA2 | Pollen | n.d. | 0.727 | n.d. | n.d. |
| 2DAA2 | Pollen | n.d. | 0.773 | n.d. | n.d. |
| 4DAA2 | Pollen | n.d. | 0.987 | n.d. | n.d. |
| 6DAA2 | Pollen | n.d. | 1.02 | n.d. | n.d. |
| S21-00428-02 | 75117, Pforzheim, Baden-Württemberg, Germany | Winter Oilseed Rape, Pionier PX 128 | - | - | - | C | 0DAA2 | Pollen | n.d. | 0.182 | n.d. | n.d. |
| 13 Apr 2021 08 May 2021 | 177.4 159.2 | 55 63 | Ta | 2DAA2 | Pollen | n.d. | 0.37 | n.d. | n.d. |
| 5DAA2 | Pollen | n.d. | 0.24 | n.d. | n.d. |
| 6DAA2 | Pollen | n.d. | 0.251 | n.d. | n.d. |
| S21-00428-03 | 75438, Knittlingen, Baden-Würrtemberg, Germany | Winter Oilseed Rape, Raps Ludger | - | - | - | C | 0DAA2-1DAA2-2DAA2 | Pollen | n.d. | 0.55 | n.d. | n.d. |
| 09 Apr 2021 23 Apr 2021 | 175.9 176.7 | 53 62 | Ta | 0DAA2 | Pollen | n.d. | 0.477 | n.d. | n.d. |
| 1DAA2 | Pollen | n.d. | 0.463 | n.d. | n.d. |
| 2DAA2 | Pollen | n.d. | 0.553 | n.d. | n.d. |
| 4DAA2 | Pollen | n.d. | 0.673 | n.d. | n.d. |
| 6DAA2 | Pollen | n.d. | 0.63 | n.d. | n.d. |
| S21-00428-04 | 32100, Gers, Larroque-sur-I´Osse, France | Winter Oilseed Rape, DK exception | - | - | - | C | 0DAA2 | Pollen | n.d. | 1.57 | 0.0111 | < LOQ (0.00530) |
| 05 Mar 2021 22 Mar 2021 | 169.1 168.2 | 57 - 59 61 - 63 | Ta | 0DAA2 | Pollen | n.d. | 1.7 | 0.01 | < LOQ (0.00503) |
| 1DAA2 | Pollen | n.d. | 1.73 | 0.0143 | < LOQ (0.00767) |
| 2DAA2 | Pollen | n.d. | 1.7 | 0.0133 | < LOQ (0.00810) |
| 4DAA2 | Pollen | n.d. | 2 | 0.0115 | < LOQ (0.00787) |
| 8DAA2 | Pollen | n.d. | 2.22 | < LOQ (0.00800) | < LOQ (0.00407) |
| S21-00428-05 | 02640, Almansa, Albacete, Spain | Winter Oilseed Rape, SY Florida | - | - | - | C | 0DAA2 | Pollen | n.d. | 0.0623 | n.d. | n.d. |
| 31 Mar 2021 14 Apr 2021  31 Mar 2021 14 Apr 2021 | 169.5 172.2  169.5 172.2 | 57 - 59 63  57 - 59 63 | Ta  Ta | 0DAA2 | Pollen | n.d. | 0.066 | n.d. | n.d. |
| 2DAA2 | Pollen | n.d. | 0.067 | n.d. | n.d. |
| 3DAA2 | Pollen | n.d. | 0.0697 | n.d. | n.d. |
| 4DAA2 | Pollen | n.d. | 0.067 | n.d. | n.d. |
| 7DAA2 | Pollen | n.d. | 0.073 | n.d. | n.d. |

DAA2 Days after application 2 (last application)

n.d. Not detected (<0.003 mg/kg)

< LOQ < 0.01 mg/kg

Tz 1,2,4-triazole

TA Triazole alanine

TAA Triazole acetic acid

TLA Triazole lactic acid

* 1. Azoxystrobin
     1. Stability of residues

No new data submitted.

* + 1. Nature of residues in plants, livestock and processed commodities

No new data submitted.

* + - 1. Nature of residues in livestock

No new data submitted.

* + 1. Magnitude of residues in plants
       1. Barley, Oat

Table A 100: Comparison of intended and critical EU GAPs – Barley & Oat

| Type of GAP | Number of applica­tions | Application rate per treatment  (g a.s./ha) | Interval between application | Growth stage at last application | PHI (days) |
| --- | --- | --- | --- | --- | --- |
| cGAP NEU (DAR, UK, 2009) *Barley* | 2 | 250 | 14 | BBCH 31-59 | 35 |
| cGAP NEU (Art. 12, EFSA, 2013) *Barley* | 3 | 250 | - | BBCH 71 | 35 |
| cGAP NEU (Art. 12, EFSA, 2020) *Oat* | 2 | 250 | - | BBCH 71 | 35 |
| Intended cGAP CEU *Barley, Oat* | 2 | 150 | 14-21 | BBCH 30-61 | 35 |

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

* + - * 1. Study ChR-10-8230 – NEU

|  |  |
| --- | --- |
| Comments of zRMS: | The study was conducted to determine residues of azoxystrobin in barley raw agricultural commodity (RAC grain and straw) and processed fractions specimens of summer barley after two applications of NUL 2206. Four residues trials were performed in Poland during 2010.  T1 plot was intended for residue at harvest, treated twice with NUL 2206 at the rate of 1 L/ha. T2 plot was intended for residue in processing fractions, treated at 3 L/ha, representing 750 g/ha of azoxystrobin at each application.  In each trial, two foliar applications were made on T1 and T2 plots. Applications were placed at late stem elongation (BBCH 39 – flag leaf stage) and at end of heading (BBCH 59).  One sampling was taken at harvest in each plot, between 34 to 40 days after last application.  The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each matrix.  Sufficient stability data are available to support the residue data presented in this study.  Barley  Untreated specimens were not contaminated with azoxystrobin or z-isomer. Two trials (PL01 and PL03) were slightly contaminated in the straw specimens (0.019 and 0.038 mg/kg). This contamination was impossible to trace but it may have occurred during field activities. It had no major impact on the study since the grains were not contaminated in both trials concerned.  Residues of azoxystrobin in barley grain ranged from 0.042 mg/kg to 0.13 mg/kg.  In straw, azoxystrobin residues were found up to an average of 2.46 mg/kg, ranging from 1.72 to 3.64 mg/kg.  The study is acceptable.  Remark:  According to the SANTE/2019/12752 four trials from study ChR-10-8230 are not considered independent.  The distance between:  Chwalecin – Chrzan is ~14 km,  Kruczynek – Chrzan is ~15 km,  Michalow – Chrzan is ~13 km,  Kruczynek – Chwalecin is ~ 5 km,  Kruczynek – Michalow is ~ 4 km,  Chwalecin – Michalow is ~ 2 km.  Dates of planting and treatments between trials are close to each other.  According to OECD (2016), the following factors should be considered separately to decide whether supervised residue trials are independent:  - Geographical location and site – Trials at different geographic locations are considered independent. The different sites must be at least 20 km far from one another unless sufficient evidence is available to demonstrate that in shorter-distance sites significant variations occur in relevant conditions e.g. soil types, weather conditions, etc.  - Dates of planting (annual crops) and treatments – Trials involving significantly different planting dates or treatment dates (> 30 days apart) are considered independent.  For those trials being considered as not independent the measured residues should be treated as being replicates. |

|  |  |
| --- | --- |
| Reference: | KCA 6.3.1/08 |
| Report | Magnitude Of The Residues Of Azoxystrobin In Summer Barley (RAC Grain And Straw) And Processed Fractions Following Two Applications Of NUL 2206, Poland, 2010  Roussel, C-H., 2011  Report No.: ChR-10-8230 |
| Guideline(s): | -Guidelines for the generation of data concerning residues as provided in Annex II, part A, section 6 and annex III, part A, section 8 of directive 91/414/EEC concerning the placing of plant protection products on the market. (1607/VI/97 rev. 2).  -General recommendation for the design, preparation and realisation of residue trials (7029/VI/95rev.5)  -Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. Document SANCO 3029/99, 2000.  -Guidance document on residue analytical methods. Document SANCO 825/00, 2004.  -Method validation and quality control procedures for pesticide residues analysis in food and feed. Document SANCO/10684/2009, 2010. |
| Deviations: | None |
| GLP: | Yes |
| Acceptability: | Yes |

Materials and Methods

Four residue trials were conducted in Poland on barley during 2010.

*Field phase*

Three plots were established in each trial: U plot was left untreated. T1 plot was intended for residue at harvest, treated twice with NUL 2206 at the rate of 1 L/ha. T2 plot was intended for residue in processing fractions, treated at 3 L/ha, representing 750 g/ha of azoxystrobin at each application.

In each trial, two foliar applications were made on T1 and T2 plots. Applications were placed at late stem elongation (BBCH 39 – flag leaf stage) and at end of heading (BBCH 59).

One sampling was taken at harvest in each plot, between 34 to 40 days after last application. In plots U and T1, grain and straw specimens were placed into labelled plastic bags, weighed and double bagged. Specimens were frozen within 2 hours after sampling and shipped on freezer truck.

In plots U and T2, grain specimens for processing were collected and stored under ambient conditions before being shipped in cool conditions (about 8°C) to the processing site.

*Processing phase*

Please refer to A 2.2.5.2.

*Analytical phase*

Analysis of specimens were performed at Food Safety Laboratory (FSL). The analytical method was described and validated in FSL report PBBZ-2011/07/DPL separately from this study. For details, please refer to dRR B5.

Limit of quantification (LOQ) achieved was 0.01 mg/kg for azoxystrobin. Limit of determination (LOD) was calculated from analytical procedure. They found to be between 0.001 and 0.004 mg/kg according to the matrices. The determinations of azoxystrobin were performed by LC/MS/MS.

The maximum storage intervals were 343 days for all barley samples between sampling and analysis, and 1 day between extraction and analysis.

Findings

The azoxystrobin levels found in barley are summarised in the table below.

In all untreated specimens, the residue was below LOQ (<0.01 mg/kg), except on two specimens of straw in trials PL01 and PL03 in which slight contaminations were observed.

**Please note that:**

* Trial ChR-10-8233 PL01 at PBI 2 months and trial ChR-10-8230 PL02 (study on primary crops) were performed in similar conditions (location, variety, date and similar application rate on the primary crop barley). The residue level measured in barley grain is the same in both trials (0.058 mg/kg). For straw, the residue level is higher in primary crops ChR-10-8230 PL02 (1.72 mg/kg) compared to rotational crop ChR-10-8233 PL01 (1.64 mg/kg).
* Trial ChR-10-8233 PL02 at PBI 2 months and trial ChR-10-8230 PL04 (study on primary crops) were also performed in similar conditions (location, variety, date and similar application rate on the primary crop barley). The residue level measured in barley grain is higher in primary crops (0.10 mg/kg) compared to rotational crop (0.089 mg/kg). For straw, it is the opposite: the residue level is lower in primary crops (1.93 mg/kg) compared to rotational crop (3.18 mg/kg).

The highest value was considered for the risk assessment.

Table A 101: Summary of the study ChR-10-8230 trials

|  |  |  |  |
| --- | --- | --- | --- |
| Active substance (common name): | **AZOXSYTROBIN** | Commercial Product (name): | NUL 2206 |
| Crop/crop group: | **Barley** | Producer of commercial product: | Nufarm S.A.S |
| Responsible body for reporting  (name, address) | STAPHYT  62860 Inchy en Artois |  |  |
|  |  | Indoor/Glasshouse/Outdoor: | Outdoor |
| Content of active substance nominal (g/kg or g/L): | 250 g/L | Other active substance in the formulation (common name and content): | none |
| Formulation (*e.g.* WP): | SC | Residues calculated as: | Azoxystrobin |

| 1 | 2 | 3 | 4 | 5 | | | 6 | 7 | 8 | 9 | 10 | 11 |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Report No. Location (region) | Commodity/Variety | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest | Method of  Treatment | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date | Growth stage at last treatment or date  BBCH | Portion analysed | Residues (mg/kg)  (\*) | PHI (days) | Remarks |
| kg a.s./ha | Water (L/ha) | kg as/hL | Azoxystrobin |
| Poland  Wielkopolska  63-210  Chrzan  Trial number  ChR-10-8230  PL01 | Summer  barley  Enawa | 1- 15/04/10  2- 18/06/10  3- 25/07/10 | Foliar  broadcast  application | 0.266  0.263 | 307  303 | 0.087  0.087 | 08/06/10  16/06/10 | 39  57 | Grain  Straw | U: <0.01  T: 0.042  U: 0.038  T: 2.54 | 39 | Analytical validation report FSL PBBZ-2011/07/DPL  LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 340 days |
| 0.785  0.785 | 302  302 | 0.260  0.260 | 08/06/10  16/06/10 | 39  59 | Grain  Cleaned grain  De-germinated  Malt  Germs  Spent grain  Wort  Flocs  Young beer  Spent yeast  Beer  Pot barley  Hull | U: <0.01  T: 0.38  U: <0.001  T: 0.069  U: <0.01  T: 0.11  U: <0.004  T: 0.15  U: <0.001  T: 0.047  U: <0.001  T: <0.01  U: <0.001  T: 0.015  U: <0.001  T: <0.01  U: <0.01  T: 0.019  U: <0.001  T: <0.01  U: <0.001  T: 0.10  U: <0.01  T: 3.15 | 39 |
| Poland  Wielkopolska  63-040  Chwalecin  Trial number  ChR-10-8230  PL02 | Summer  barley  Granal | 1- 31/03/10  2- 18/06/10  3- 27/07/10 | Foliar  broadcast  application | 0.260  0.266 | 300  307 | 0.087  0.087 | 08/06/10  16/06/10 | 39  59 | Grain  Straw | U: <0.001  T: 0.058  U: <0.004  T: 1.72 | 40 | Analytical validation report FSL PBBZ-2011/07/DPL  LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and  analysis: 339 days |
| 0.787  0.785 | 303  302 | 0.260  0.260 | 08/06/10  16/06/10 | 39  59 | Grain  De-germinated  Malt  Wort  Beer  Pot barley  Hull | U: <0.001  T: 0.17  U: <0.001  T: 0.068  U: <0.001  T: <0.01  U: <0.001  T: <0.01  U: <0.001  T: 0.031  U: <0.01  T: 1.79 | 40 |
| Poland  Wielkopolska  63-040  Kruczynek  Trial number  ChR-10-8230  PL03 | Summer  barley  Nadek | 1- 07/04/10  2- 19/06/10  3- 22/07/10 | Foliar  broadcast  application | 0.266  0.251 | 307  290 | 0.087  0.087 | 08/06/10  18/06/10 | 39  59 | Grain  Straw | U: <0.01  T: 0.13  U: 0.019  T: 3.64 | 34 | Analytical validation report FSL PBBZ-2011/07/DPL  LOQ: 0.01 mg/kg  Max. Storage  Interval between  sampling and  analysis:  343 days |
| 0.777  0.780 | 299  300 | 0.260  0.260 | 08/06/10  18/06/10 | 39  59 | Grain  De-germinated  Malt  Spent grain  Wort  Beer  Pot barley | U: <0.01  T: 0.29  U: <0.001  T: 0.076  U: <0.001  T: 0.031  U: <0.001  T: <0.01  U: <0.001  T: <0.01  U: <0.001  T: 0.023 | 34 |
| Poland  Wielkopolska  63-040  Michalow  Trial number  ChR-10-8230  PL04 | Summer  barley  Johan | 1- 02/04/10  2- 18/06/10  3- 24/07/10 | Foliar  broadcast  application | 0.266  0.260 | 307  300 | 0.087  0.087 | 08/06/10  16/06/10 | 39  59 | Grain  Straw | U: <0.001  T: 0.10  U: <0.004  T: 1.93(a) | 37 | Analytical validation report FSL PBBZ-  2011/07/DPL  LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 342 days |
| 0.780  0.789 | 300  303 | 0.260  0.260 | 08/06/10  16/06/10 | 39  59 | Grain  De-germinated  Malt  Spent grain  Wort  Beer  Pot barley | U: <0.001  T: 0.81  U: <0.001  T: 0.14  U: <0.001  T: 0.050  U: <0.001  T: 0.010  U: <0.001  T: <0.01  U: <0.001  T: 0.082 | 37 |

U: Untreated, T: Treated

(a): Please refer to the note above in “Findings”.

* + - * 1. Study JCB-11-10126 – NEU + SEU

|  |  |
| --- | --- |
| Comments of zRMS: | The study was conducted to determine residues of azoxystrobin in barley raw agricultural commodity (RAC whole plant, grain and straw) after two applications of NUL 2206.  Twelve trials (4 decline and 8 harvest) were performed in Northern France (2 trials), Germany (2 trials), Italy (2 trials), Spain (4 trials), Southern France (1 trial) and Greece (1 trial) in 2011.  CA2702 (NUL 2206) was applied twice at 1 L/ha on plot T, at BBCH39 and BBCH59  Whole plant specimens were collected on the decline trials at -0, +0, 7 and 21±1 days after  application 2.  Grain and straw specimens were sampled at commercial harvest, 50 days in average after last application.  The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each matrix.  Sufficient stability data are available to support the residue data presented in this study.  Barley  All untreated specimens were found below the LOQ.  Residues of azoxystrobin in barley grain ranged from <0.01 mg/kg to 0.016 mg/kg in N-EU (<0.01, 0.011, 0.015, 0.016 mg/kg).  In straw, azoxystrobin residues ranged from 0.23 to 1.5 mg/kg in N-EU.  The study is acceptable. |

|  |  |
| --- | --- |
| Reference: | KCA 6.3.1/09 |
| Report | Residues Of Azoxystrobin In Barley (RAC Whole Plant, Grain And Straw) Following Two Applications Of CA 2702 (NUL 2206), Northern & Southern Europe – 2011  Boissinot, J-C., 2011  Report No.: JCB-11-10126 |
| Guideline(s): | -Guidelines for the generation of data concerning residues as provided in Annex II, part A, section 6 and annex III, part A, section 8 of directive 91/414/EEC concerning the placing of plant protection products on the market. (1607/VI/97 rev. 2).  -General recommendation for the design, preparation and realisation of residue trials (7029/VI/95rev.5)  -Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. Document SANCO 3029/99, 2000.  -Guidance document on residue analytical methods. Document SANCO 825/00, 2004.  -Method validation and quality control procedures for pesticide residues analysis in food and feed. Document SANCO/10684/2009, 2010. |
| Deviations: | None |
| GLP: | Yes |
| Acceptability: | Yes |

Materials and Methods

Twelve trials (4 decline and 8 harvest) were performed in Northern France, Germany, Italy, Spain, Southern France and Greece in 2011.

*Field phase*

Two plots were established in each trial: U plot was left untreated; T plot was treated twice with CA 2702 (NUL 2206) at the rate of 1.0 L /ha, representing 250 g/ha of azoxystrobin (nominal rate)

at each application..

Applications were made at flag leaf and end of heading stages (respectively BBCH 39 and BBCH 59 (BBCH 39-49 and 55-69/71 on one occasion)).

For the harvest trials, one sample was taken at harvest (straw and grain) in each plot, between 28 and 62 days after last application. For the decline trials, samples were collected at +/- 0, +7 and +21+/-1 days (whole plant) after last application and at harvest (straw and grain), between 42 and 71 days after application.

In plots U and T, whole plant, grain and straw specimens were placed into labelled plastic bags, weighed and double bagged. Specimens were frozen within 7 hours after sampling and shipped on freezer truck/with dry ice.

*Analytical phase*

Analyses of specimens were performed at GIRPA. The analytical method was described and validated in GIRPA report NUFARM/AZO/11.01 and GIR/MET/AZOXYSTR/03V1 separately from this study.

Fortification procedures were conducted to confirm the validity of the analytical method during analysis of the specimens. Recoveries were all in the requested range of 70% to 110 %, RSD <20%.

Limit of quantification (LOQ) achieved was 0.01 mg/kg for azoxystrobin. The determinations of azoxystrobin were performed by LC/MS/MS.

The maximum storage interval was 139 days for barley grain and straw samples between sampling and analysis. The maximum interval was 1 day for barley grain and 18 days for barley straw between extraction and analysis.

Findings

The azoxystrobin levels found in barley are summarised in the table below.

In all untreated specimens, the residue was below LOQ (<0.01 mg/kg).

Table A 102: Summary of the study JCB-11-10126 trials

|  |  |  |  |
| --- | --- | --- | --- |
| Active substance (common name): | **AZOXSYTROBIN** | Commercial Product (name): | NUL 2206 |
| Crop/crop group: | **Barley** | Producer of commercial product: | Nufarm S.A.S |
| Responsible body for reporting  (name, address) | STAPHYT  62860 Inchy en Artois |  |  |
|  |  | Indoor/Glasshouse/Outdoor: | Outdoor |
| Content of active substance nominal (g/kg or g/L): | 250 g/L | Other active substance in the formulation (common name and content): | none |
| Formulation (*e.g.* WP): | SC | Residues calculated as: | Azoxystrobin |

| 1 | 2 | 3 | 4 | 5 | | | 6 | 7 | 8 | 9 | 10 | 11 |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Report No. Location (region) | Commodity/Variety | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest | Method of  Treatment | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date | Growth stage at last treatment or date  BBCH | Portion analysed | Residues (mg/kg)  (\*) | PHI (days) | Remarks |
| kg a.s./ha | Water (L/ha) | kg as/hL | Azoxystrobin |
| France North  Champagne  Ardenne  08190  Houdilcourt  Trial number  JCB-11-10126  FR01 | Spring  Barley  Sebastian | 1- 22/03/11  2- 02/06/11  3- 25/07/11 | Foliar  broadcast  application | 0.246  0.263 | 189  202 | 0.130  0.130 | 12/05/11  01/06/11 | 39  59 | Whole Plant  Grain  Straw | U: <0.01  T: 1.5  U: <0.01  T: 4.2  T: 2.2  T :0.82  U: <0.01  T: 0.016  U: <0.01  T: 0.93 | -0  +0  7  22  54  54 | Analytical report  GIRPA analytical  Phase STAPH/AZO/11.02  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis: 130 days |
| Germany  Herzogtum  Lauenberg  23847  Kastorf  Trial number  JCB-11-10126  DE02 | Spring  Barley  Simba | 1- 08/04/11  2- 13/06/11  3- 24/08/11 | Foliar  broadcast  application | 0.262  0.264 | 302  303 | 0.087  0.087 | 25/05/11  09/06/11 | 39  59 | Whole Plant  Grain  Straw | U: <0.01  T: 0.26  U: <0.01  T: 3.9  T: 3.2  T :0.34  U: <0.01  T: <0.01  U: <0.01  T: 0.23 | -0  +0  7  21  71  71 | Analytical report  GIRPA analytical  Phase STAPH/AZO/11.02  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling  and analysis: 118 days |
| Germany  Thüringen 04603  Taupadel  Trial number  JCB-11-10126  DE03 | Spring  Barley  Tocada | 1- 01/04/11  2- 13/06/11  3- 25/07/11 | Foliar  broadcast  application | 0.269  0.258 | 310  297 | 0.087  0.087 | 24/05/11  10/06/11 | 39  59 | Grain  Straw | U: <0.01  T: 0.015  U: <0.01  T: 0.29 | 45 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.02  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis: 74 days |
| France  Nord Pas-de-Calais  62147  Hermies  Trial number  JCB-11-10126  FR04 | Spring  Barley  Sebastian | 1- 23/03/11  2- 15/06/11  3- 03/08/11 | Foliar  broadcast  application | 0.249  0.256 | 239  246 | 0.104  0.104 | 20/05/11  01/06/11 | 39  59 | Grain  Straw | U: <0.01  T: 0.011  U: <0.01  T: 1.5 | 62 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.02  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis: 66 days |
| Italy  Lombardia  26900  Lodi  Trial number  JCB-11-10126  IT05 | Spring  Barley  Otis | 1- 24/02/11  2- 30/05/11  3- 24/06/11 | Foliar  broadcast  application | 0.265  0.254 | 407  390 | 0.065  0.065 | 10/05/11  27/05/11 | 39  59 | Grain  Straw | U: <0.01  T: <0.01  U: <0.01  T: 0.42 | 28 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.02  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis: 105 days |
| Italy  Lombardia  20090  Caleppio  di Settala  Trial number  JCB-11-10126  IT06 | Spring  Barley  Tunika | 1- 28/02/11  2- 30/05/11  3- 05/07/11 | Foliar  broadcast  application | 0.254  0.259 | 390  398 | 0.065  0.065 | 11/05/11  19/05/11 | 39  59 | Whole Plant  Grain  Straw | U: <0.01  T: <0.01  U: <0.01  T: 2.1  T: 3.9  T : <0.01  U: <0.01  T: <0.01  U: <0.01  T: <0.01 | -0  +0  7  21  47  47 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.02  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis: 139 days |
| Spain  Pais Vasco  01213  Lantaron  Trial number  JCB-11-10126  ES07 | Spring  Barley  Flika | 1- 15/02/11  2- May 2011  3- July 2011 | Foliar  broadcast  application | 0.268  0.273 | 360  367 | 0.074  0.074 | 06/05/11  20/05/11 | 39  59 | Grain  Straw | U: <0.01  T: 0.13  U: <0.01  T: 1.3 | 42 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.02  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis: 98 days |
| Spain  Pais Vasco  01423  Valdegobia  Trial number  JCB-11-10126  ES08 | Spring  Barley  Mane | 1- 10/02/11  2- May/June  2011  3- July 2011 | Foliar  broadcast  application | 0.273  0.261 | 367  350 | 0.074  0.075 | 06/05/11  20/05/11 | 39  59 | Grain  Straw | U: <0.01  T: 0.016  U: <0.01  T: 1.2 | 46 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.02  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis: 94 days |
| Spain  Valencia  46317  Villargordo  del Cabriel  Trial number  JCB-11-10126  ES09 | Spring  Barley  Voley | 1- 20/02/11  2- 31/05/11  3- July 2011 | Foliar  broadcast  application | 0.269  0.274 | 413  420 | 0.065  0.065 | 05/05/11  20/05/11 | 39  59 | Grain  Straw | U: <0.01  T: 0.015  U: <0.01  T: 0.43 | 46 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.02  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis: 94 days |
| Spain  Valencia  46330  Camporrobles  Trial number  JCB-11-10126  ES10 | Spring  Barley  Beca | 1- 05/03/11  2- 31/05/11  3- July 2011 | Foliar  broadcast  application | 0.267  0.267 | 410  410 | 0.065  0.065 | 05/05/11  24/05/11 | 39  59 | Whole plant  Grain  Straw | U: <0.01  T: 0.25  U: <0.01  T: 4.2  T: 4.5  T: 1.1  U: <0.01  T: 0.019  U: <0.01  T: 0.53 | -0  +0  7  21  42  42 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.02  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis: 134 days |
| France South  Rhône-Alpes  01560  Vernoux  Trial number  JCB-11-10126  FR11 | Spring  Barley  Sebastian | 1- 09/03/11  2- 15/06/11  3- 17/08/11 | Foliar  broadcast  application | 0.274  0.265 | 210  204 | 0.130  0.130 | 18/05/11  10/06/11 | 39-49  55-69/71 | Grain  Straw | U: <0.01  T: 0.057  U: <0.01  T: 0.13 | 62 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.02  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis: 57 days |
| Greece  West Macedonia  50100  Polymilos  Trial number  JCB-11-10126  GR12 | Spring  Barley  Mutso | 1- 20/04/11  2- 25/06/11  3- 18/08/11 | Foliar  broadcast  application | 0.261  0.264 | 400  406 | 0.065  0.065 | 10/06/11  23/06/11 | 39  59 | Grain  Straw | U: <0.01  T: 0.11  U: <0.01  T: 2.5 | 55 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.02  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis: 51 days |

U: Untreated, T: Treated

* + - 1. Wheat, Rye

Table A 103: Comparison of intended and critical EU GAPs – Wheat & Rye

| Type of GAP | Number of applica­tions | Application rate per treatment  (g a.s./ha) | Interval between application | Growth stage at last application | PHI (days) |
| --- | --- | --- | --- | --- | --- |
| cGAP NEU (Art. 12, EFSA, 2013) *Wheat* | 3 | 250 | - | BBCH 71 | 35 |
| cGAP NEU (Art. 12, EFSA, 2013) *Rye* | 2 | 250 | - | BBCH 71 | 35 |
| Intended cGAP CEU *Wheat, Rye* | 2 | 210 | 14-21 | BBCH 30-69 | 35 |

* + - * 1. Study ChR-10-8231 – NEU

|  |  |
| --- | --- |
| Comments of zRMS: | The study was conducted to determine residues of azoxystrobin in wheat raw agricultural commodity (RAC grain and straw) and processed fractions specimens of winter wheat after two applications of NUL 2206. Four residues trials were performed in Poland during 2010.  T1 plot was intended for residue at harvest, treated twice with NUL 2206 at the rate of 1 L/ha. T2 plot was intended for residue in processing fractions, treated twice at 3 L/ha.  In each trial, two foliar applications were made on T1 and T2 plots. Applications were placed at late stem elongation (BBCH 39 – flag leaf stage) and at end of flowering (BBCH 69).  One sampling was taken at harvest in each plot, between 40 to 46 days after last application.  The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg.  Sufficient stability data are available to support the residue data presented in this study.  Wheat  The residue found was below LOQ (<0.01 mg/kg) for all untreated specimens.  Residues of azoxystrobin in wheat grain ranged from <0.01 mg/kg to 0.013 mg/kg.  In straw, azoxystrobin residues ranged from 1.50 to 2.29 mg/kg.  The study is acceptable.  Remark:  According to the SANTE/2019/12752 four trials from study ChR-10-8231 are not considered independent.  The distance between:  Dabrowa – Potarzyca is ~6 km,  Dabrowa – Wojciechowo is ~10 km,  Dabrowa – Katy is ~14 km,  Katy – Potarzyca is ~18 km,  Katy – Wojciechowo is ~20 km,  Potarzyca – Wojciechowo – ~10 km.  Dates of planting and treatments between trials are close to each other.  According to OECD (2016), the following factors should be considered separately to decide whether supervised residue trials are independent:  - Geographical location and site – Trials at different geographic locations are considered independent. The different sites must be at least 20 km far from one another unless sufficient evidence is available to demonstrate that in shorter-distance sites significant variations occur in relevant conditions e.g. soil types, weather conditions, etc.  - Dates of planting (annual crops) and treatments – Trials involving significantly different planting dates or treatment dates (> 30 days apart) are considered independent.  For those trials being considered as not independent the measured residues should be treated as being replicates. |

|  |  |
| --- | --- |
| Reference: | KCA 6.3.2/04 |
| Report | Magnitude Of The Residues Of Azoxystrobin In Winter Wheat (RAC Grain And Straw) And Processed Fractions Following Two Applications Of NUL 2206, Poland, 2010  Roussel, C-H., 2011  Report No.: ChR-10-8231 |
| Guideline(s): | -Guidelines for the generation of data concerning residues as provided in Annex II, part A, section 6 and annex III, part A, section 8 of directive 91/414/EEC concerning the placing of plant protection products on the market. (1607/VI/97 rev. 2).  -General recommendation for the design, preparation and realisation of residue trials (7029/VI/95rev.5)  -Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. Document SANCO 3029/99, 2000.  -Guidance document on residue analytical methods. Document SANCO 825/00, 2010. |
| Deviations: | None |
| GLP: | Yes |
| Acceptability: | Yes |

Materials and Methods

Four residue trials were conducted in Poland on wheat during 2010.

*Field phase*

Three plots were established in each trial: U plot was left untreated. T1 plot was intended for residue at harvest, treated twice with NUL 2206 at the rate of 1 L/ha. T2 plot was intended for residue in processing fractions, treated twice at 3 L/ha.

In each trial, two applications were made on T1 and T2 plots. Applications were placed at late stem elongation (BBCH 39 – flag leaf stage) and at end of flowering (BBCH 69).

One sampling was taken at harvest in each plot, between 40 and 46 days after last application.

In plots U and T1, grain and straw specimens were placed into labelled plastic bags, weighed and double bagged. Specimens were frozen within 2 hours after sampling and shipped on freezer truck.

In plots U and T2, grain specimens for processing were collected and stored under ambient conditions before being shipped in cool conditions (about 8°C) to the processing site.

*Processing phase*

Please refer to A 2.2.5.2.

*Analytical phase*

Analysis of specimens were performed at Food Safety Laboratory (FSL). The analytical method was described and validated in FSL report PBBZ-2011/07/DPL separately from this study.

Limit of quantification (LOQ) achieved was 0.01 mg/kg for azoxystrobin. Limit of determination (LOD) was calculated from analytical procedure. They found to be between 0.001 and 0.004 mg/kg according to the matrices. The determinations of azoxystrobin were performed by LC/MS/MS.

The maximum storage intervals were 344 days for all wheat samples between sampling and analysis, and 1 day between extraction and analysis.

Findings

The azoxystrobin levels found in wheat are summarised in the table below.

In all untreated specimens, the residue was below LOQ (<0.01 mg/kg).

Table A 104: Summary of the study ChR-10-8231 trials

|  |  |  |  |
| --- | --- | --- | --- |
| Active substance (common name): | **AZOXSYTROBIN** | Commercial Product (name): | NUL 2206 |
| Crop/crop group: | **Wheat** | Producer of commercial product: | Nufarm S.A.S |
| Responsible body for reporting  (name, address) | STAPHYT  62860 Inchy en Artois |  |  |
|  |  | Indoor/Glasshouse/Outdoor: | Outdoor |
| Content of active substance nominal (g/kg or g/L): | 250 g/L | Other active substance in the formulation (common name and content): | none |
| Formulation (*e.g.* WP): | SC | Residues calculated as: | Azoxystrobin |

| 1 | 2 | 3 | 4 | 5 | | | 6 | 7 | 8 | 9 | 10 | 11 |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Report No. Location (region) | Commodity/Variety | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest | Method of  Treatment | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date | Growth stage at last treatment or date  BBCH | Portion analysed | Residues (mg/kg)  (\*) | PHI (days) | Remarks |
| kg a.s./ha | Water (L/ha) | kg as/hL | Azoxystrobin |
| Poland  Wielkopolska  63-233  Dabrowa  Trial number  ChR-10-8231  PL01 | Winter  wheat  Nowalis | 1- 10/11/09  2- 11/06/10  3- 29/07/10 | Foliar  broadcast  application | 0.271  0.257 | 313  297 | 0.087  0.087 | 26/05/10  15/06/10 | 39  69 | Grain  Straw | U: <0.001  T: 0.013  U: <0.01  T: 2.29 | 41 | Analytical validation  report FSL  PBBZ-2011/07/DPL  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  343 days |
| 0.785  0.783 | 302  301 | 0.260  0.260 | 26/05/10  15/06/10 | 39  69 | Grain  Cleaned  Grain  Steeped  Grain  Steeping  Water  Germs  Middlings  White flour  Bran  Wholemeal  Flour  Wholemeal  Dough  Wholemeal  bread | U: <0.001  T: 0.074  U: <0.001  T: 0.021  U: <0.001  T: < 0.01  U: <0.001  T: < 0.01  U: <0.001  T: 0.024  U: <0.004  T: 0.01  U: <0.001  T: < 0.01  U: <0.01  T: 0.050  U: <0.01  T: 0.021  U: <0.001  T: 0.011  U: <0.001  T: 0.013 | 41 |
| Poland  Wielkopolska  63-233  Wojciechowo  Trial number  ChR-10-8231  PL02 | Winter  wheat  Nadodna | 1- 26/10/09  2- 12/06/10  3- 28/07/10 | Foliar  broadcast  application | 0.266  0.266 | 307  307 | 0.087  0.087 | 26/05/10  15/06/10 | 39  69 | Grain  Straw | U: <0.001  T: 0.01  U: <0.01  T: 2.02 | 40 | Analytical validation  report FSL  PBBZ-2011/07/DPL  LOQ: 0.01 mg/kg  Max. Storage  Interval between  sampling and  analysis:  344 days |
|  |  |  |  | 0.785  0.777 | 302  299 | 0.260  0.260 | 26/05/10  15/06/10 | 39  69 | Grain  Germs  White flour  Bran  Whole  meal flour  Whole  meal bread | U: <0.001  T: 0.051  U: <0.001  T: 0.065  U: <0.001  T: < 0.01  U: <0.001  T: 0.19  U: <0.001  T: 0.040  U: <0.001  T: 0.032 | 40 |
| Poland  Wielkopolska  63-200  Potarzyca  Trial number  ChR-10-8231  PL03 | Winter  wheat  Ostka | 1- 31/10/09  2- 12/06/10  3- 31/07/10 | Foliar  broadcast  application | 0.266  0.266 | 307  307 | 0.087  0.087 | 01/06/10  15/06/10 | 39  69 | Grain  Straw | U: <0.001  T: < 0.01  U: <0.002  T: 1.50 | 46 | Analytical validation  report FSL  PBBZ-2011/07/DPL  LOQ: 0.01 mg/kg  Max. Storage  Interval between  sampling and analysis: 338 days |
| 0.777  0.783 | 299  301 | 0.260  0.260 | 01/06/10  15/06/10 | 39  69 | Grain  Germs  White flour  Bran  Wholemeal  Flour  Wholemeal  bread | U: <0.001  T: 0.027  U: <0.001  T: 0.023  U: <0.001  T: < 0.01  U: <0.001  T: 0.070  U: <0.001  T: 0.023  U: <0.001  T: 0.017 | 46 |
| Poland  Wielkopolska  63-200  Katy  Trial number  ChR-10-8231  PL04 | Winter  wheat  Ismena | 1- 20/10/09  2- 10/06/10  3- 28/07/10 | Foliar  broadcast  application | 0.266  0.269 | 307  310 | 0.087  0.087 | 28/05/10  15/06/10 | 39  69 | Grain  Straw | U: <0.001  T: < 0.01  U: <0.002  T: 2.02 | 42 | Analytical validation  report FSL  PBBZ-2011/07/DPL  LOQ: 0.01 mg/kg  Max. Storage  Interval between  sampling and  analysis:  342 days |
| 0.782  0.789 | 301  303 | 0.260  0.260 | 28/05/10  15/06/10 | 39  69 | Grain  Germs  White flour  Bran  Wholemeal  Flour  Wholemeal  bread | U: <0.001  T: 0.030  U: <0.001  T: 0.023  U: <0.001  T: < 0.01  U: <0.001  T: 0.090  U: <0.001  T: 0.030  U: <0.001  T: 0.015 | 42 |

U: Untreated, T: Treated

* + - * 1. Study JCB-11-10125 – NEU + SEU

|  |  |
| --- | --- |
| Comments of zRMS: | The study was conducted to determine residues of azoxystrobin in wheat raw agricultural commodity (RAC whole plant, grain and straw) after two applications of NUL 2206.  Twelve trials (4 decline and 8 harvest) were performed in Northern Europe (4 trials) and in Southern Europe (8 trials) in 2011.  Two plots were established in each trial: U plot was left untreated; T plot was intended for residue at +/- 0, +7 and +21±1 days after last application (decline trials only) and at harvest (all trials), treated twice with CA 2702 (NUL 2206) at the rate of 1.0 L /ha.  For the harvest trials, one sample was taken at harvest in each plot, between 27 and 58 days after last application. For the decline trials, samples were collected at +/- 0, +7 and +21±1 days after last application and at harvest, between 30 and 66 days after application.  The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg.  Sufficient stability data are available to support the residue data presented in this study.  Wheat  All untreated specimens were found below the LOQ except for one untreated straw specimen, which was found contaminated at harvest with residues of azoxystrobin above the LOQ: 0.029 mg/kg for specimen n°79 (according to the Amendment 1 to final Report).  Residues of azoxystrobin in barley grain ranged from <0.01 mg/kg to 0.028 mg/kg in N-EU <0.01, <0.01, 0.022, 0.028 mg/kg).  In straw, azoxystrobin residues ranged from 0.41 to 10.1 mg/kg in N-EU.  The study is acceptable. |

|  |  |
| --- | --- |
| Reference: | KCA 6.3.2/05 |
| Report | Residues Of Azoxystrobin In Wheat (RAC Whole Plant, Grain And Straw) Following Two Applications Of CA 2702 (NUL 2206), Northern & Southern Europe – 2011, Final report and Amendment 1  Boissinot, J-C. 2011, (2012 amendment)  Report No.: JCB-11-10125 |
| Guideline(s): | -Guidelines for the generation of data concerning residues as provided in Annex II, part A, section 6 and annex III, part A, section 8 of directive 91/414/EEC concerning the placing of plant protection products on the market. (1607/VI/97 rev. 2).  -General recommendation for the design, preparation and realisation of residue trials (7029/VI/95rev.5)  -Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. Document SANCO 3029/99, 2000.  -Guidance document on residue analytical methods. Document SANCO 825/00, 2004.  -Method validation and quality control procedures for pesticide residues analysis in food and feed. Document SANCO/10684/2009, 2010. |
| Deviations: | None |
| GLP: | Yes |
| Acceptability: | Yes |

Materials and Methods

Twelve trials (4 decline and 8 harvest) were performed in Northern France, Germany, Italy, Spain and Greece in 2011.

*Field phase*

Two plots were established in each trial: U plot was left untreated; T plot was treated twice with CA 2702 (NUL 2206) at the rate of 1.0 L /ha, representing 250 g/ha of azoxystrobin (nominal rate) at each application.

Applications were made at flag leaf and end of flowering stages (respectively BBCH39 (BBCH43 on one occasion) and BBCH 69).

For the harvest trials, one sample was taken at (straw and grain) in each plot, between 27 and 58 days after last application. For the decline trials, samples were collected at +/- 0, +7 and +21±1 days (whole plant) after last application and at harvest (straw and grain), between 30 and 66 days after application.

In plots U and T, whole plant, grain and straw specimens were placed into labelled plastic bags, weighed and double bagged. Specimens were frozen within 7 hours after sampling and shipped on freezer truck/with dry ice.

*Analytical phase*

Analyses of specimens were performed at GIRPA. The analytical method was described and validated in GIRPA report NUFARM/AZO/11.01 and GIR/MET/AZOXYSTR/03V1 separately from this study.

Fortification procedures were conducted to confirm the validity of the analytical method during analysis of the specimens. Recoveries were all in the requested range of 70% to 110 %, RSD <20%.

Limit of quantification (LOQ) achieved was 0.01 mg/kg for azoxystrobin. The determinations of azoxystrobin were performed by LC/MS/MS.

The maximum storage interval was 129 days for wheat grain and straw samples between sampling and analysis. The maximum interval was 6 days for wheat grain and 5 days for wheat straw between extraction and analysis.

Findings

The azoxystrobin levels found in wheat are summarised in the table below.

In all untreated specimens, the residue was below LOQ (<0.01 mg/kg), except for two untreated straw specimens in trial ES06, which were found contaminated with residues of azoxystrobin at 0.029 mg/kg.

Table A 105: Summary of the study JCB-11-10125 trials

|  |  |  |  |
| --- | --- | --- | --- |
| Active substance (common name): | **AZOXSYTROBIN** | Commercial Product (name): | NUL 2206 |
| Crop/crop group: | **Wheat** | Producer of commercial product: | Nufarm S.A.S |
| Responsible body for reporting  (name, address) | STAPHYT  62860 Inchy en Artois |  |  |
|  |  | Indoor/Glasshouse/Outdoor: | Outdoor |
| Content of active substance nominal (g/kg or g/L): | 250 g/L | Other active substance in the formulation (common name and content): | none |
| Formulation (*e.g.* WP): | SC | Residues calculated as: | Azoxystrobin |

| 1 | 2 | 3 | 4 | 5 | | | 6 | 7 | 8 | 9 | 10 | 11 |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Report No. Location (region) | Commodity/Variety | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest | Method of  Treatment | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date | Growth stage at last treatment or date  BBCH | Portion analysed | Residues (mg/kg)  (\*) | PHI (days) | Remarks |
| kg a.s./ha | Water (L/ha) | kg as/hL | Azoxystrobin |
| France North  Nord Pas-de-Calais  62860  Inchy en Artois  Trial number  JCB-11-10125  FR01 | Winter  Wheat  Altamira | 1- 15/11/10  2- 17/05/11  3- 31/07/11 | Foliar broadcast application | 0.265  0.264 | 305  305 | 0.087  0.087 | 09/05/11  25/05/11 | 39  69 | Whole Plant  Grain  Straw | U: <0.01  T: 1.4  U: <0.01  T: 3.0  T: 3.3  T :0.84  U: <0.01  T: <0.01  U: <0.01  T: 1.2 | -0  +0  7  21  66  66 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.01  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis: 129 days |
| France North  Champagne  Ardenne  08190  Houdilcourt  Trial number  JCB-11-10125  FR02 | Winter  Wheat  Bermude | 1- 12/10/10  2- 27/05/11  3- 30/07/11 | Foliar broadcast application | 0.262  0.269 | 251  258 | 0.104  0.104 | 10/05/11  01/06/11 | 39  69 | Grain  Straw | U: <0.01  T: <0.01  U: <0.01  T: 1.7 | 58 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.01  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis: 56 days |
| France North  Centre  37110  Azouer  en Touraine  Trial number  JCB-11-10125  FR03 | Winter  Wheat  Premio | 1- 19/10/10  2- 12/05/11  3- 05/07/11 | Foliar broadcast application | 0.241  0.249 | 278  286 | 0.087  0.087 | 04/05/11  20/05/11 | 43  69 | Grain  Straw | U: <0.01  T: 0.028  U: <0.01  T: 10.1 | 47 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.01  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  73 days |
| Germany  Baden  Württenberg  97990  Weikersheim /  Queckbronn  Trial number  JCB-11-10125  DE04 | Winter  Wheat  Mulan | 1- 20/10/10  2- 01/06/11  3- 05/08/11 | Foliar broadcast application | 0.252  0.267 | 290  307 | 0.087  0.087 | 13/05/11  15/06/11 | 39  69 | Whole plant  Grain  Straw | U: <0.01  T: 0.25  U: <0.01  T: 2.6  T: 1.1  T :0.27  U: <0.01  T: 0.022  U: <0.01  T: 0.41 | -0  +0  7  22  36  36 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.01  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  108 days |
| Italy  Lombardia  20060  Bellinzago  Lombardo  Trial number  JCB-11-10125  IT05 | Spring  Wheat  Accor | 1- 04/03/11  2- 31/05/11  3- 30/06/11 | Foliar broadcast application | 0.265  0.271 | 407  417 | 0.065  0.065 | 06/05/11  03/06/11 | 39  69 | Grain  Straw | U: <0.01  T: 0.026  U: <0.01  T: 1.0 | 27 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.01  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  79 days |
| Spain  Teruel  44126  Frias de  Albarracin  Trial number  JCB-11-10125  ES06 | Winter  Wheat  Isingrein | 1- 25/10/10  2- June 2011  3- 03/08/11 | Foliar broadcast application | 0.268  0.251 | 411  386 | 0.065  0.065 | 19/05/11  15/06/11 | 39  69 | Whole plant  Grain  Straw | U: <0.01  T: 0.091  U: <0.01  T: 2.8  T: 0.88  T :0.33  U: <0.01  T: 0.020  U: 0.029  T: 2.4 | -0  +0  7  21  49  49 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.01  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  108 days |
| Spain  Pais Vasco  01213  Lantaron  Trial number  JCB-11-10125  ES07 | Winter  Wheat  Aguila | 1- 25/11/10  2- June 2011  3- 20/07/11 | Foliar broadcast application | 0.271  0.248 | 363  333 | 0.075  0.074 | 06/05/11  08/06/11 | 39  69 | Grain  Straw | U: <0.01  T: 0.13  U: <0.01  T: 6.8 | 29 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.01  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  72 days |
| Spain  Pais Vasco  01230  Iruña de  Oca  Trial number  JCB-11-10125  ES08 | Winter  Wheat  Berdun | 1- 10/11/10  2- June 2011  3- 11/07/11 | Foliar broadcast application | 0.272  0.264 | 365  355 | 0.075  0.074 | 12/05/11  08/06/11 | 39  69 | Whole plant  Grain  Straw | U: <0.01  T: 3.8  U: <0.01  T: 4.1  T: 3.6  T :2.5  U: <0.01  T: 0.27  U: <0.01  T: 7.4 | -0  +0  7  22  30  30 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.01  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  115 days |
| Spain  Teruel  44366  Orihuela del  Tremedal  Trial number  JCB-11-10125  ES09 | Winter  Wheat  Marius | 1- 25/11/10  2- June 2011  3- 27/07/11 | Foliar broadcast application | 0.271  0.254 | 417  390 | 0.065  0.065 | 19/05/11  15/06/11 | 39  69 | Grain  Straw | U: <0.01  T: 0.054  U: <0.01  T: 7.3 | 42 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.01  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  52 days |
| Spain  Alava  01118  Lagran  Trial number  JCB-11-10125  ES10 | Winter  Wheat  Berdun | 1- 15/11/10  2- June 2011  3- 27/07/11 | Foliar broadcast application | 0.247  0.250 | 380  383 | 0.065  0.065 | 17/05/11  08/06/11 | 39  69 | Grain  Straw | U: <0.01  T: 0.20  U: <0.01  T: 5.1 | 44 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.01  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  57 days |
| Greece  West Macedonia  50100  Koilada  Trial number  JCB-11-10125  GR11 | Winter  Wheat  Athos | 1- 06/11/10  2- 15/05/11  3- 13/07/11 | Foliar broadcast application | 0.256  0.262 | 295  302 | 0.087  0.087 | 12/05/11  30/05/11 | 39  69 | Grain  Straw | U: <0.01  T: <0.01  U: <0.01  T: 0.81 | 43 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.01  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  67 days |
| Greece  West Macedonia  53200  Agios  Panteleimonas  Trial number  JCB-11-10125  GR12 | Winter  Wheat  Simeto | 1- 20/01/11  2- 20/05/11  3- 31/06/11 | Foliar broadcast application | 0.257  0.260 | 296  299 | 0.087  0.087 | 12/05/11  26/05/11 | 39  69 | Grain  Straw | U: <0.01  T: 0.1  U: <0.01  T: 2.6 | 34 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.01  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  80 days |

U: Untreated, T: Treated

* + - 1. Oilseed rape, sunflower and other minor oilseeds

Table A 106: Comparison of intended and critical EU GAPs

| Type of GAP | Number of applica­tions | Application rate per treatment  (g a.s./ha) | Interval between application | Growth stage at last application | PHI (days) |
| --- | --- | --- | --- | --- | --- |
| cGAP NEU + SEU (DAR, UK, 2009) | Not a representative use | | | | |
| cGAP NEU (Art. 12, EFSA, 2013) *Oilseed rape, Poppy seeds, Mustard seeds, Gold of pleasure* | 2 | 250 | - | - | 21 |
| cGAP NEU (Art. 12, EFSA, 2013) *Linseed* | Not existing use | | | | |
| Intended cGAP CEU | 1 | 180 | - | BBCH 69 | 56 |

* + - * 1. Study GBU-11-10127 – NEU + SEU

|  |  |
| --- | --- |
| Comments of zRMS: | The study was conducted to determine residues of azoxystrobin in oilseed rape raw agricultural commodity (RAC whole plant, pods, grain) after one application of NUL 2206 (azoxystrobin 250 SC).  Eight trials (4 decline and 4 harvest) were performed in Northern Europe (4 trials) and in Southern Europe (4 trials) in 2011.  Two plots were established in each trial: U plot was left untreated; T plot was intended for residue at harvest and for residue decline treated one with CA 2702 (NUL 2206) at the rate of 1.0 L /ha.  For the harvest trials, one sample was taken at harvest in each plot, between 47 and 66 days after application.  For the decline trials, samples were collected just after application, at +7, +13-14 and +28-29 days after application and at harvest, between 55 and 66 days after application.  The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg.  Sufficient stability data are available to support the residue data presented in this study.  Oilseed rape  No residues were detected (below 0.01 mg/kg) in any untreated specimen.  Residues of azoxystrobin in oilseed rape grain were below 0.01 mg/kg (N-EU).  The study is acceptable. |

|  |  |
| --- | --- |
| Reference: | KCA 6.3.3/04 |
| Report | Residues Of Azoxystrobin In Oilseed Rape, Following One Application Of CA 2702 (NUL 2206), Northern & Southern Europe – 2011, Final report and Amendment 1  Boileau, G., 2011  Report No.: GBU-11-10127 |
| Guideline(s): | -Guidelines for the generation of data concerning residues as provided in Annex II, part A, section 6 and annex III, part A, section 8 of directive 91/414/EEC concerning the placing of plant protection products on the market. (1607/VI/97 rev. 2).  -General recommendation for the design, preparation and realisation of residue trials (7029/VI/95rev.5)  -Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. Document SANCO 3029/99, 2000.  -Guidance document on residue analytical methods. Document SANCO 825/00, 2004.  -Method validation and quality control procedures for pesticide residues analysis in food and feed. Document SANCO/10684/2009, 2010. |
| Deviations: | None |
| GLP: | Yes |
| Acceptability: | Yes |

Materials and Methods

Eight trials were performed in Germany, Spain, Northern and Southern France in 2011.

*Field phase*

Two plots were established in each trial: U plot was left untreated. For half of the trials, T plot was intended for residue at harvest, treated once with CA 2702 (NUL 2206) at the rate of 1.0 L/ha; and for the others, T plot was intended for residue decline treated once with CA 2702 (NUL 2206) at rate dose 1.0 L/ha, representing 250 g/ha of azoxystrobin at application.

In each trial, one application was made on plot T. Application was placed at end of flowering (BBCH 69) except in trial FR08 (BBCH 72 = 20% of pods have reached final size).

For the harvest trials, one sample was taken at harvest in each plot, between 47 and 66 days after application. For the decline trials, samples were collected just after application, at +7, +13-14 and +28-29 days after application and at harvest, between 55 and 66 days after application.

In plots U and T, whole plants, pods and/or grain specimens were placed into labelled plastic bags, weighed and double bagged. Specimens were frozen within 4 hours after sampling and shipped on freezer truck. They were delivered deep-frozen and in good condition to the analytical site.

*Analytical phase*

Analyses of specimens were performed at GIRPA. The analytical method was described and validated in GIRPA reports NUFARM/AZO/11.01 (oilseed rape grain), NUFARM/AZO/11.02 (oilseed rape whole plants) and GIR/MET/AZOXYSTR/03V1 separately from this study.

Fortification procedures were conducted to confirm the validity of the analytical method during analysis of the specimens. Recoveries were all in the requested range of 70% to 110 %, RSD <20%.

Limit of quantification (LOQ) achieved was 0.01 mg/kg for azoxystrobin. The determinations of azoxystrobin were performed by LC/MS/MS.

The maximum storage interval was 152 days for all oilseed rape samples between sampling and analysis. The maximum interval was 6 days for oilseed rape seeds, 22 days for whole plant and 9 days for pods between extraction and analysis.

Extract stability was demonstrated within a separate validation study, PBBZ-2011/07/DPL (for details, please refer to dRR B5). Following storage for 14 days at refrigerator temperature, the average recovery was above 90% for azoxystrobin and its Z-isomer.

Findings

The azoxystrobin levels found in oilseed rape are summarised in the table below.

In all untreated specimens, the residue was below LOQ (<0.01 mg/kg).

Table A 107: Summary of the study GBU-11-10127 trials

|  |  |  |  |
| --- | --- | --- | --- |
| Active substance (common name): | **AZOXSYTROBIN** | Commercial Product (name): | NUL 2206 |
| Crop/crop group: | **Oilseed rape** | Producer of commercial product: | Nufarm S.A.S |
| Responsible body for reporting  (name, address) | STAPHYT  62860 Inchy en Artois |  |  |
|  |  | Indoor/Glasshouse/Outdoor: | Outdoor |
| Content of active substance nominal (g/kg or g/L): | 250 g/L | Other active substance in the formulation (common name and content): | none |
| Formulation (*e.g.* WP): | SC | Residues calculated as: | Azoxystrobin |

| 1 | 2 | 3 | 4 | 5 | | | 6 | 7 | 8 | 9 | 10 | 11 |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Report No. Location (region) | Commodity/Variety | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest | Method of  Treatment | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date | Growth stage at last treatment or date  BBCH | Portion analysed | Residues (mg/kg)  (\*) | PHI (days) | Remarks |
| kg a.s./ha | Water (L/ha) | kg as/hL | Azoxystrobin |
| Germany  Sachsen  08393  Mosel  Trial number  GBU-11-10127  DE01 | Oilseed  rape  Chagall | 1- 04/09/10  2- 18/04/11  3- 12/07/11 | Foliar broadcast application | 0.2571 | 296 | 0.087 | 10/05/11 | 69 | Whole Plants  Pods  Grain | U: <0.01  T: 1.5  T: 0.27  T:0.26  U: <0.01  T: <0.01  U: <0.01  T: <0.01 | 0  7  14  28  60 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.03  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  152 days |
| Germany  Schleswig-  Holstein  23847  Kastorf  Trial number  GBU-11-10127  DE02 | Oilseed  rape  Visby | 1- 04/09/10  2- 10/05/11  3- 28/07/11 | Foliar broadcast application | 0.2636 | 303 | 0.087 | 25/05/11 | 69 | Grain | U: <0.01  T: <0.01 | 64 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.03  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  63 days |
| France  Northern  Champagne-  Ardenne  08310  Juniville  Trial number  GBU-11-10127  FR03 | Oilseed  rape  Alpaga | 1- 01/09/10  2- 11/04/11  3- 11/07/11 | Foliar broadcast application | 0.2696 | 207 | 0.130 | 06/05/11 | 69 | Whole Plants  Pods  Grain | U: <0.01  T: 2.1  T: 1.2  T: 1.2  U: <0.01  T: 0.096  U: <0.01  T: <0.01 | 0  7  14  28  66 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.03  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  132 days |
| France  Northern  Centre  41190  Santenay  Trial number  GBU-11-10127  FR04 | Oilseed  rape  DK  Exquisite | 1- 22/08/10  2- 06/04/11  3- 03/07/11 | Foliar broadcast application | 0.2597 | 399 | 0.0695 | 29/04/11 | 69 | Grain | U: <0.01  T: <0.01 | 66 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.03  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  87 days |
| Spain  Pais Vasco  01213  Lantaron  Trial number  GBU-11-10127  ES05 | Oilseed  rape  Mistral | 1- 17/09/10  2- 20/04/11  3- 01/07/11 | Foliar broadcast application | 0.2443 | 375 | 0.065 | 15/05/11 | 69 | Grain | U: <0.01  T: 0.19 | 47 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.03  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  95 days |
| Spain  Pais Vasco  01520  Arrazua  Trial number  GBU-11-10127  ES06 | Oilseed  rape  Mistral | 1- 24/09/10  2- 25/04/11  3- from  01/07/11 to  10/07/11 | Foliar broadcast application | 0.2503 | 288 | 0.087 | 14/05/11 | 69 | Whole Plants  Pods  Grain | U: <0.01  T: 3.5  T: 0.21  T: <0.01  U: <0.01  T: 0.016  U: <0.01  T: <0.01 | 0  7  13  29  55 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.03  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  133 days |
| France South  Midi-Pyrénées  81630  La Sauzière  Saint Jean  Trial number  GBU-11-10127  FR07 | Oilseed  rape  Facile | 1- 20/09/10  2- 15/04/11  3- 30/06/11 | Foliar broadcast application | 0.2623 | 302 | 0.087 | 03/05/11 | 69 | Whole Plants  Pods  Grain | U: <0.01  T: 3.7  T: 1.9  T: 0.30  U: <0.01  T: 0.14  U: <0.01  T: <0.01 | 0  7  14  28  57 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.03  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  135 days |
| France South  Midi-Pyrénées  82230  Verlhac-Tescou  Trial number  GBU-11-10127  FR08 | Oilseed  rape  Albatros | 1- 30/09/10  2- 03/04/11  3- 28/06/11 | Foliar broadcast application | 0.2644 | 304 | 0.087 | 03/05/11 | 72 | Grain | U: <0.01  T: <0.01 | 57 | Analytical report  GIRPA analytical  phase  STAPH/AZO/11.03  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  92 days |

U: Untreated, T: Treated

* + - * 1. Study ChR-10-8214 – NEU

|  |  |
| --- | --- |
| Comments of zRMS: | The study was conducted to determine residues of azoxystrobin in oilseed rape raw agricultural commodity (RAC grain) and processed fractions specimens of oilseed rape after one application of NUL 2206. Four residues trials were performed in Poland during 2010.  T1 plot was intended for residue at harvest, treated one with NUL 2206 at the rate of 1 L/ha. T2 plot was intended for residue in processing fractions, treated at 3 L/ha.  In each trial, one foliar application was made on T1 and T2 plots. Applications were placed at end of flowering (BBCH 69). One sampling was taken at harvest in each plot, between 48 to 52 days after last application.  The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg.  Sufficient stability data are available to support the residue data presented in this study.  Oilseed rape  The residue found was below LOQ (<0.01 mg/kg) for all untreated specimens.  Residues of azoxystrobin in oilseed rape grain ranged from <0.001 mg/kg to 0.13 mg/kg.  The study is acceptable.  Remark:  According to the SANTE/2019/12752, four trials from study ChR-10-8214 are not considered independent.  The distance between:  Dabrowa – Chwalecin is ~10 km,  Dabrowa – Jaraczewo is ~10 km,  Chwalecin – Jaraczewo is ~9 km,  Chwalecin – Chwalecin is ~0 km,  Dates of planting and treatments between trials are close to each other.  According to OECD (2016), the following factors should be considered separately to decide whether supervised residue trials are independent:  - Geographical location and site – Trials at different geographic locations are considered independent. The different sites must be at least 20 km far from one another unless sufficient evidence is available to demonstrate that in shorter-distance sites significant variations occur in relevant conditions e.g. soil types, weather conditions, etc.  - Dates of planting (annual crops) and treatments – Trials involving significantly different planting dates or treatment dates (> 30 days apart) are considered independent.  For those trials being considered as not independent the measured residues should be treated as being replicates. |

|  |  |
| --- | --- |
| Reference: | KCA 6.3.3/05 |
| Report | Magnitude Of The Residues Of Azoxystrobin In Oilseed Rape (RAC Grain) And Processed Fractions Following One Application Of NUL 2206, Poland, 2010  Roussel, C-H., 2011  Report No.: ChR-10-8214 |
| Guideline(s): | -Guidelines for the generation of data concerning residues as provided in Annex II, part A, section 6 and annex III, part A, section 8 of directive 91/414/EEC concerning the placing of plant protection products on the market. (1607/VI/97 rev. 2).  -General recommendation for the design, preparation and realisation of residue trials (7029/VI/95rev.5)  -Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. Document SANCO 3029/99, 2000.  -Guidance document on residue analytical methods. Document SANCO 825/00, 2010.  -Method validation and quality control procedures for pesticide residues analysis in food and feed. Document SANCO/10684/2009, 2010. |
| Deviations: | None |
| GLP: | Yes |
| Acceptability: | Yes |

Materials and Methods

Four trials were performed in Poland in 2010.

*Field phase*

Three plots were established in each trial: U plot was left untreated. T1 plot was intended for the determination of the residue at harvest and was treated once with NUL 2206 at the rate of 1 L/ha (250 g a.s./ha). T2 plot was intended for the determination of the residue in processed fractions and was treated at 3 L/ha (750 g a.s./ha).

In each trial, one application was made to T1 and T2 plots at end of flowering (BBCH 69).

One sampling was taken at harvest in each plot, between 48 and 52 days after last application.

In plots U and T1, grain specimens were placed into labelled plastic bags, weighed and double bagged. Specimens were frozen within 3 hours after sampling and shipped on freezer truck.

In plots U and T2, grain specimens for processing were collected and stored under ambient conditions before being shipped in cool conditions (about 8°C) to the processing site.

*Processing phase*

Please refer to A 2.2.5.2.

*Analytical phase*

Analyses of specimens were performed at Food Safety Laboratory (FSL). The analytical method was described and validated in FSL report PBBZ-2011/07/DPL separately from this study.

Residues were calculated as the mean of three independent analyses.

Limit of quantification (LOQ) achieved was 0.01 mg/kg for azoxystrobin. Limit of determination (LOD) was found to be 0.001 mg/kg. The determination of azoxystrobin was performed by LC/MS/MS.

The maximum storage interval was 358 days for all oilseed rape samples between sampling and analysis. The maximum interval was 1 day between extraction and analysis.

Extract stability was demonstrated within a separate validation study, PBBZ-2011/07/DPL (for details, please refer to dRR B5). Following storage for 14 days at refrigerator temperature, the average recovery was above 90% for azoxystrobin and its Z-isomer.

Findings

The azoxystrobin levels found in barley are summarised in the table below.

In all untreated specimens, the residue was below LOQ (<0.01 mg/kg).

Table A 108: Summary of the study ChR-10-8214 trials

|  |  |  |  |
| --- | --- | --- | --- |
| Active substance (common name): | **AZOXSYTROBIN** | Commercial Product (name): | NUL 2206 |
| Crop/crop group: | **Oilseed rape** | Producer of commercial product: | Nufarm S.A.S |
| Responsible body for reporting  (name, address) | STAPHYT  62860 Inchy en Artois |  |  |
|  |  | Indoor/Glasshouse/Outdoor: | Outdoor |
| Content of active substance nominal (g/kg or g/L): | 250 g/L | Other active substance in the formulation (common name and content): | none |
| Formulation (*e.g.* WP): | SC | Residues calculated as: | Azoxystrobin |

| 1 | 2 | 3 | 4 | 5 | | | 6 | 7 | 8 | 9 | 10 | 11 |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Report No. Location (region) | Commodity/Variety | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest | Method of  Treatment | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date | Growth stage at last treatment or date  BBCH | Portion analysed | Residues (mg/kg)  (\*) | PHI (days) | Remarks |
| kg a.s./ha | Water (L/ha) | kg as/hL | Azoxystrobin |
| Poland  Wielkopolska  63-233  Dabrowa  Trial number  ChR-10-8214  PL01 | Rapeseed  Kazoar | 1- 14/09/09  2- 14/05/10  3- 20/07/10 | Foliar  broadcast  application | 0.257 | 297 | 0.087 | 01/06/10 | 69 | Grain | U: <0.001  T: 0.13 | 48 | Analytical validation  report FSL  PBBZ-2011/07/DPL  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  357 days |
| 0.780 | 300 | 0.260 | 01/06/10 | 69 | Grain  Cake  Raw oil  Refined oil | U: <0.001  T: 0.035  U: <0.001  T: 0.03  U: <0.001  T: 0.058  U: <0.001  T: 0.057 | 48 |
| Poland  Wielkopolska  63-040  Chwalecin  Trial number  ChR-10-8214  PL02 | Rapeseed  Smart | 1- 25/08/09  2- 10/05/10  3- 16/07/10 | Foliar  broadcast  application | 0.263 | 303 | 0.087 | 26/05/10 | 69 | Grain | U: <0.001  T: < 0.001 | 51 | Analytical validation  report FSL  PBBZ-2011/07/DPL  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  358 days |
| 0.784 | 302 | 0.260 | 26/05/10 | 69 | Grain  Raw oil  Refined oil | U: <0.001  T: 0.1  U: <0.001  T: 0.036  U: <0.001  T: 0.031 | 51 |
| Poland  Wielkopolska  63-040  Chwalecin  Trial number  ChR-10-8214  PL03 | Rapeseed  Nelson | 1- 27/08/09  2- 12/05/10  3- 19/07/10 | Foliar  broadcast  application | 0.260 | 300 | 0.087 | 28/05/10 | 69 | Grain | U: <0.001  T: < 0.01 | 52 | Analytical validation  report FSL  PBBZ-2011/07/DPL  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  355 days |
| 0.789 | 303 | 0.260 | 28/05/10 | 69 | Grain  Raw oil  Refined oil | U: <0.001  T: 0.040  U: <0.001  T: 0.015  U: <0.001  T: 0.016 | 52 |
| Poland  Wielkopolska  63-233  Jaraczewo  Trial number  ChR-10-8214  PL04 | Rapeseed  Ontario | 1- 31/08/09  2- 14/05/10  3- 20/07/10 | Foliar  broadcast  application | 0.266 | 307 | 0.087 | 01/06/10 | 69 | Grain | U: <0.001  T: 0.032 | 48 | Analytical validation  report FSL  PBBZ-2011/07/DPL  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  355 days |
| 0.782 | 301 | 0.260 | 01/06/10 | 69 | Grain  Raw oil  Refined oil | U: <0.001  T: 0.72  U: <0.001  T: 0.081  U: <0.001  T: 0.083 | 48 |

U: Untreated, T: Treated

* + - * 1. Study ~~ongoing~~ S23-100807 – NEU

|  |  |
| --- | --- |
| Comments of zRMS: | Four independent residue trials was conducted on oilseed rape during 2023 in N-EU to determine residue levels and behaviour of azoxystrobin in the raw agricultural commodity oilseed rape and its processed fractions treated with CA2702.  One application of CA2702 (250 g/L azoxystrobin) was applied to plot 2 at 250 g ai/ha and to plot 3 at 750 g ai/ha at BBCH 69.  Samples of oilseed rape seeds from the untreated and treated plot 2 were taken by hand at normal commercial harvest (BBCH 89), 49-60 days after application from trials S23-100807-01, 02, 03 & 04.  Samples of oilseed rape (whole plant, pods and rest of plants) from treated plot 2 were taken by hand at 0, 14, 21 and 35 days after application from trials S23-100807-01 & 02.  Processing samples were taken from treated plot 3 by hand at normal commercial harvest (BBCH 89), 49-60 days after application for trials S23-100807-01, 02 & 03.  Analytical methods  Analytical method has been successfully validated to determine residues of azoxystrobin in samples of oilseed rape (whole plant, pods, rest of plant and seed) as well as its processed fractions (RAC rapeseed, press cake, crude oil, refined oil, meal and extracted oil) for residues of azoxystrobin in accordance with guidance document SANTE/2020/12830, rev. 2 for risk assessment and/or monitoring.  The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each matrix.  Sufficient stability data are available to support the residue data presented in this study.  Oilseed rape  No residues were detected (below 0.01 mg/kg) in any untreated specimen.  Residues of azoxystrobin in oilseed rape grain were below 0.01 mg/kg (N-EU).  The study is acceptable. |

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| Reference: | KCA 6.3.3/07 |
| Report | Determination of residues of Azoxystrobin after a single application of CA2702 in Oilseed rape (outdoor) and its processed fractions at 4 sites in Northern Europe 2023  North, L., ~~ongoing~~ 2024  Report No.: S23-100807 |
| Guideline(s): | OECD (2009) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32)  OECD Test Guideline 509: Crop field trials  OECD (2016) Guidance Document ENV/JM/MONO (2011)50/REV1 , Second Edition, on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66)  EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials  SANTE/2019/12752 Technical Guidelines on Data Requirements for Setting Maximum Residue Levels, Comparability of Residue Trial and Extrapolation of Residue Data on Products from Plant and Animal Origin (Repealing and replacing the existing Guidance Document SANCO 7525/Vl/95 Rev. 10.3)  SANTE/2020/12830, Rev.2 Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes (Supersedes Guidance Documents SANCO/3029/99 and SANCO/825/00) |
| Deviations: | Study ongoing |
| GLP: | Yes |
| Acceptability: | ~~Study ongoping~~ Yes |

Materials and Methods

Four trials were performed in Northern France, Germany, Hungary and the UK in 2023 in oilseed rape (2 DCS and 2 HS).

*Field phase*

In 3 trials, 3 plots were established: U plot was left untreated. T1 plot was intended for the determination of the residue at harvest or for residue decline and was treated once with CA 2702 at the rate of 1 L/ha (250 g a.s./ha). T2 plot was intended for the determination of the residue in processed fractions and was treated at 3 L/ha (750 g a.s./ha).

In the last trial, 2 plots were established: U plot was left untreated. T plot was intended for residue decline and treated once with CA 2702 at the rate of 1.0 L/ha, representing 250 g/ha of azoxystrobin at application

For all trials, 1 application was made at end of flowering (BBCH 69).

In plots U and T1, grain specimens were placed into labelled plastic bags, weighed and double bagged. Specimens were frozen within 3 hours after sampling and shipped on freezer truck.

In plots U and T2, grain specimens for processing were collected and stored under ambient conditions before being shipped in cool conditions (about 8°C) to the processing site.

*Processing phase*

Please refer to **A 2.2.5.2.4**.

*Analytical phase*

Samples of oilseed rape (whole plant, pods, rest of plant and seed) as well as its processed fractions (RAC rapeseed, press cake, crude oil, refined oil, meal and extracted oil) were analysed for residues of azoxystrobin in accordance to guidance document SANTE/2020/12830, rev. 2 for risk assessment and/or monitoring.

~~The analytical phase is ongoing.~~

A validation for the high water content matrix oilseed (whole plant) and for the high oil content matrix oilseed rape (seed) ~~will be~~ was part of this analytical phase.

For matrices oilseed rape (pods, rest of plant, RAC rapeseed, press cake, crude oil, refined oil, meal and extracted oil) the applicability/suitability of the method will be demonstrated by concurrent recoveries within this analytical phase.

Analyses of specimens were performed at Eurofins. The analytical method was described and validated in Eurofins reports Analytical Phase Report S23-100807-L1 (EAS-2311) included in this study.

The method was successfully validated for determination of oilseed rape (whole plant, seed and meal) with an LOQ of 0.01 mg/kg and up to 0.1 mg/kg according to guidance document(s) SANTE/2020/12830, rev. 2.

With regard to selectivity, accuracy and precision, the analytical method was applied successfully for each analytical set for oilseed rape (whole plant, pods, rest of plant and seed) as well as its processed fractions (RAC rapeseed, press cake, crude oil, refined oil, meal and extracted oil) when analysing the samples of the study.

Limit of quantification (LOQ) achieved was 0.01 mg/kg for azoxystrobin. Limit of determination (LOD) was found to be 0.00~~1~~3 mg/kg. The determination of azoxystrobin was performed by LC/MS/MS.

The maximum storage interval was 270 days for all oilseed rape samples between sampling and analysis.

The storage temperature of the samples at the analytical test site was ≤ -18°C with no exceedance.

The maximum storage interval of final sample extracts at typically 1°C to 10°C from extraction until injection to the detection system was 7 days for whole plant, 5 days for RAC rapeseed, one day for press cake, crude oil, refined oil, meal and extracted oil and 0 days for pods, rest of plant and seed.

Extract stability was demonstrated within this study: recoveries are within 70 % - 120 % in all matrix extracts for at least 2 days when considering all matrices (covering all actual storage durations) when stored at typically 1 °C to 10 °C in the dark.

Findings

~~Ongoing~~

The azoxystrobin levels found in oilseed rape are summarised in the table below.

In all untreated specimens, the residue was below LOQ (<0.01 mg/kg).

Table A 109: Summary of the study S23-100807 trials

|  |  |  |  |
| --- | --- | --- | --- |
| Active substance (common name): | **AZOXSYTROBIN** | Commercial Product (name): | CA2702 |
| Crop/crop group: | **Oilseed rape** | Producer of commercial product: | Nufarm S.A.S. |
| Responsible body for reporting  (name, address) | Nufarm Crop Products UK Wyke Lane, Wyke, Bradford, BD12 9EJ,  United Kingdom |  |  |
|  |  | Indoor/Glasshouse/Outdoor: | Outdoor |
| Content of active substance nominal (g/kg or g/L): | 250 g/L | Other active substance in the formulation (common name and content): | none |
| Formulation (*e.g.* WP): | SC | Residues calculated as: | Azoxystrobin (mg/kg) |

| 1 | 2 | 3 | 4 | 5 | | | 6 | 7 | 8 | 9 | 10 | 11 |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Report No. Location (region) | Commodity/Variety | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest | Method of  Treatment | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date | Growth stage at last treatment or date  BBCH | Portion analysed | Residues (mg/kg)  (\*) | PHI (days) | Remarks |
| kg a.s./ha | Water (L/ha) | kg as/hL | Azoxystrobin |
| S23-100807-01  27478, Altenbruch, Niedersachsen, Germany | Oilseed rape / DK Exception | 02 Sep 2022  20 Apr – 22 May 2023  21 Jul 2023 | Foliar with plot sprayer | 0.260 | 291 | 0.089 | 22/05/23 | 69 | Whole plant  Whole plant  Whole plant  Pods  Rest of plant  seed | U: <0.01  T: 2.1  T: 0.05  T: 0.04  U: <0.01  T: 0.01  U: <0.01  T: 0.04  U: <0.01  T: **<0.01** | 0  14  21  35  35  60 | Analytical validation  report S23-100807  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  270 days |
| 0.785 | 293 | 0.268 | 22/05/23 | 69 | Seed  Press cake  Crude oil  Refined oil  Meal  Extracted oil | U: <0.01  T: 0.01/<0.01  U: <0.01  T: 0.01  U: <0.01  T: 0.01  U: <0.01  T: 0.01  U: <0.01  T: 0.03  U: <0.01  T: <0.01 | 60 |
| S23-100807-02  L39 9EN, Bickerstatte, Lancashire, UK | Oilseed rape / Ramses | 15 Aug 2022  Not applicable  20 Jul 2023 | Foliar with plot sprayer | 0.249 | 200 | 0.125 | 01/06/23 | 69 | Whole plant  Whole plant  Whole plant  Pods  Rest of plant  seed | U: <0.01  T: 2.2  T: 0.20  T: 0.07  T: 0.02  T: 0.07  U: <0.01  T: **<0.01** | 0  14  21  35  35  49 | Analytical validation  report S23-100807  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  260 days |
| 0.759 | 202 | 0.376 | 01/06/23 | 69 | Seed  Press cake  Crude oil  Refined oil  Meal  Extracted oil | U: <0.01  T: 0.02/0.02  U: <0.01  T: <0.01  U: <0.01  T:< 0.01  U: <0.01  T: <0.01  U: <0.01  T: 0.01  U: <0.01  T: <0.01 | 49 |
| S23-100807-03  67860, Boofzheim, Bas Rhin, Alsace, France | Oilseed rape / LG Airon | 24 Aug 2022  10 Apr – 10 May 2023  28 Jun 2023 | Foliar with plot sprayer | 0.243 | 243 | 0.100 | 09/05/23 | 69 | seed | U: <0.01  T: **<0.01** | 50 | Analytical validation  report S23-100807  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  226 days |
| 0.744 | 248 | 0.300 | 09/05/23 | 69 | Seed  Press cake  Crude oil  Refined oil  Meal  Extracted oil | U: <0.01  T: 1.9/2.0  U: <0.01  T: 0.05  U: <0.01  T: 0.07  U: <0.01  T: 0.07  U: <0.01  T: 0.05  U: <0.01  T: 0.04 | 50 |
| S23-100807-04  H-2484, Agard, Fejer, Hungary  Plot 2 | Oilseed rape / Dariot | 07 Sep 2022  Mid Apr to start of May  29 Jun 2023 | Foliar with plot sprayer | 0.251 | 352 | 0.071 | 08/05/23 | 69 | seed | U: <0.01  T: **<0.01** | 52 | Analytical validation  report S23-100807  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  232 days |

U: Untreated, T: Treated

* + 1. Magnitude of residues in livestock

No new data submitted.

* + 1. Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)
       1. Distribution of the residue in peel/pulp

No new data submitted.

* + - 1. Processing studies on a core set of representative processes
         1. Study ChR-10-8230

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| --- | --- |
| Comments of zRMS: | The study was conducted to determine residues of azoxystrobin in barley raw agricultural commodity (RAC grain and straw) and processed fractions specimens of summer barley after two applications of NUL 2206. Four residues trials were performed in Poland during 2010.  T1 plot was intended for residue at harvest, treated twice with NUL 2206 at the rate of 1 L/ha. T2 plot was intended for residue in processing fractions, treated at 3 L/ha, representing 750 g/ha of azoxystrobin at each application.  In each trial, two foliar applications were made on T1 and T2 plots. Applications were placed at late stem elongation (BBCH 39 – flag leaf stage) and at end of heading (BBCH 59).  One sampling was taken at harvest in each plot, between 34 to 40 days after last application.  PL01 was conducted as a balance trial. PL02, PL03 and PL04 were conducted as follow up trials.  The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each matrix.  Sufficient stability data are available to support the residue data presented in this study.  Grains used for processing were characterized by a higher azoxystrobin residue level (0.41 mg/kg on average).  In processed fractions, azoxystrobin residue level was reduced in almost all fractions analyzed (cleaned grain, de-germinated malt, germs, spent grain, wort, flocs, yeast, beer and pot barley). Transfer factors were below 0.40.  Azoxystrobin and z-isomer residues were increased in hulls. Average Transfer Factors were 9.41 for azoxystrobin and 8.61 for its Z-isomer respectively.  The study is acceptable. |

|  |  |
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| Reference: | KCA 6.3.1/08 |
| Report | Magnitude Of The Residues Of Azoxystrobin In Summer Barley (RAC Grain And Straw) And Processed Fractions Following Two Applications Of NUL 2206, Poland, 2010  Roussel, C-H., 2011  Report No.: ChR-10-8230 |
| Guideline(s): | Guidelines for the generation of data concerning residues as provided in Annex II, part A, section 6 and annex III, part A, section 8 of directive 91/414/EEC concerning the placing of plant protection products on the market. (1607/VI/97 rev. 2).  -General recommendation for the design, preparation and realisation of residue trials (7029/VI/95rev.5)  -Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. Document SANCO 3029/99, 2000.  -Guidance document on residue analytical methods. Document SANCO 825/00, 2004.  -Method validation and quality control procedures for pesticide residues analysis in food and feed. Document SANCO/10684/2009, 2010. |
| Deviations: | None |
| GLP: | Yes |
| Acceptability: | Yes |

Materials and methods

Please refer to summary made under A 2.2.3 Magnitude of residues in plants for further details on the field and analytical phase.

Four residue trials were conducted in Poland on barley during 2010.

*Processing phase*

Upon arrival, the grains received were cleaned. With clean grain, the following processing were conducted separately: beer (including malting) and pot barley processing. All specimens issued from barley processing were frozen and shipped in freezer truck with dry ice inside the shipment boxes. They were delivered to the analytical site frozen and in good condition.

Malt processing

The malting is composed of three different stages:

- Steeping: barley is passed successively through water (three times) and through air (two times). This at a temperature of 16°C for approximately 42 hours (summer barley).

- Germination: barley is kept at 16°C for approximately 120 hours.

- Kilning: barley passes 6 different stages between 30° and 80°C. This treatment lasts approximately 24 hours.

Germs were removed. De-germinated malt was kept at +5 to +10°C before brewing, for a minimum of eight days (malt maturation).

Brewing method

Malt was ground. Ground malt was mixed with water at approximately 45°C (mashing-in). Wort pH was corrected to approximately 5.5, by addition of lactic acid.

Brewing was composed of different stages: firstly at 45°C for 20 minutes, secondly at 64°C for 20

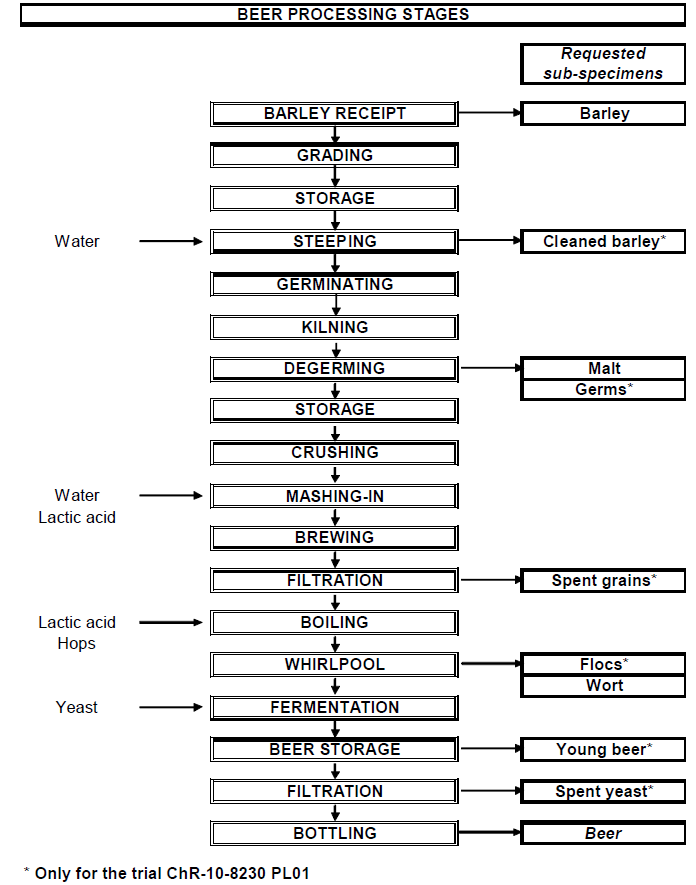
minutes and thirdly at 74°C for 30 minutes. Wort was filtered and cooked at approximately 100°C for 1h30. At the start of the cooking, hops (pellets or CO2 extract) were added to the wort. At the end of the cooking, pH of the wort was corrected to approximately 5.5, by addition of lactic acid.

Suspension particles in the wort was removed by passing through whirlpool stages.

The wort was cooled and put in a fermentation tank thermoregulated at 12°C.

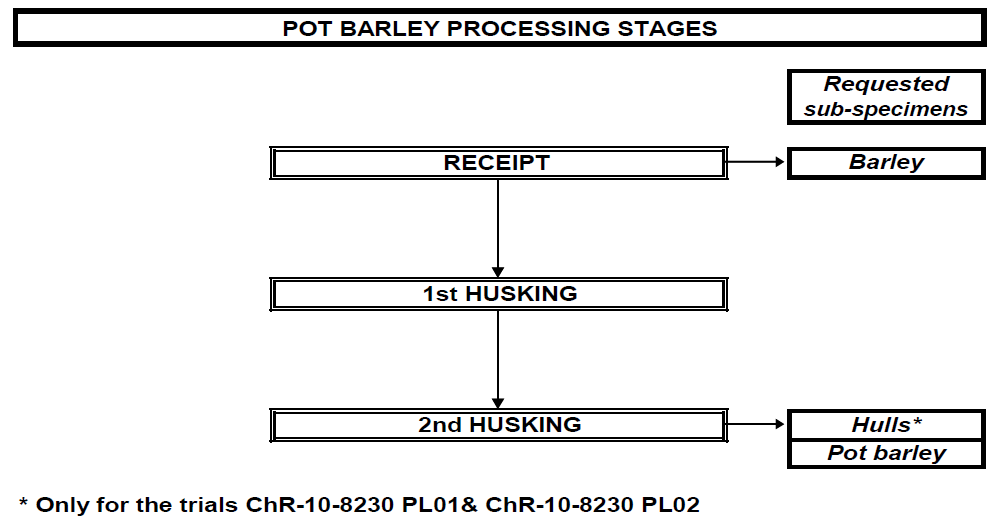
Wort was inoculated with yeast at 12°C. Beer fermentation was monitored on working days measuring the density. The fermentation was regarded as finished when density is remained stable for two consecutive days.

After fermentation, beer was stored for 15 days minimum at 0 to +5°C. Beer was filtrated using a plate filter and then bottled.



Pot barley processing

The barley was introduced in the husker "SATAKE" 100 g at a time until the require quantity was added. The time spent in the husker was determined for each modality. After each passage, the hulls and the pot barley were recovered in plastic bags. The waste and the pot barley was transported at ambient temperature at the STAPHYT processing laboratory to be weighed.



Results

The azoxystrobin levels found in barley are summarised in the table below.

In all untreated specimens, the residue was below LOQ (<0.01 mg/kg).

Processing factors were calculated and presented hereafter.

Table A 110: Residue data from Barley processing study with azoxystrobin

| **Trial number** | **Residues in RAC (unwashed sample, mg/kg)** | **PHI**  **(days)** | **Processed commodity** | **Residue** | **PF\*** |
| --- | --- | --- | --- | --- | --- |
| **(mg/kg)** |
| PL01 | 0.38 | 39 | Cleaned grain | 0.069 | 0.18 |
| De-germinated malt | 0.11 | 0.29 |
| Germs | 0.15 | 0.39 |
| Spent grain | 0.047 | 0.12 |
| Wort | <0.01 | 0.026\*\* |
| Flocs | 0.015 | 0.04 |
| Young beer | <0.01 | 0.026\*\* |
| Beer | <0.01 | 0.026\*\* |
| Pot barley | 0.1 | 0.26 |
| Hull | 3.15 | 8.29 |
| PL02 | 0.17 | 40 | De-germinated malt | 0.068 | 0.40 |
|
| Wort | <0.01 | 0.06\*\* |
| Beer | <0.01 | 0.06\*\* |
| Pot barley | 0.031 | 0.18 |
| Hull | 1.79 | 10.53 |
| PL03 | 0.29 | 34 | De-germinated malt | 0.076 | 0.26 |
|
| Spent grain | 0.031 | 0.11 |
| Wort | <0.01 | 0.03\*\* |
| Beer | <0.01 | 0.03\*\* |
| Pot barley | 0.023 | 0.08 |
| PL04 | 0.81 | 37 | De-germinated malt | 0.14 | 0.17 |
|
| Spent grain | 0.05 | 0.06 |
| Wort | 0.01 | 0.01 |
| Beer | <0.01 | 0.01\*\* |
| Pot barley | 0.082 | 0.10 |

\* Processing factor

\*\* In case residues are < LOQ in the processed commodity, the LOQ value was considered instead for the calculation (worst-case assumption).

* + - * 1. Study ChR-10-8231

|  |  |
| --- | --- |
| Comments of zRMS: | The study was conducted to determine residues of azoxystrobin in wheat raw agricultural commodity (RAC grain and straw) and processed fractions specimens of winter wheat after two applications of NUL 2206. Four residues trials were performed in Poland during 2010.  T1 plot was intended for residue at harvest, treated twice with NUL 2206 at the rate of 1 L/ha. T2 plot was intended for residue in processing fractions, treated twice at 3 L/ha.  In each trial, two foliar applications were made on T1 and T2 plots. Applications were placed at late stem elongation (BBCH 39 – flag leaf stage) and at end of flowering (BBCH 69).  One sampling was taken at harvest in each plot, between 40 to 46 days after last application.  Four trials were processed. PL01 was conducted as a balance trial. PL02, PL03 and PL04 were conducted as follow up trials.  The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg.  Sufficient stability data are available to support the residue data presented in this study.  Grain used for processing were characterized by a higher azoxystrobin residue level (0.05 mg/kg in average).  In processed fractions, azoxystrobin residue level was reduced in most of the fractions analyzed (white flour, whole meal bread or whole meal flour). Transfer factors were below 1.  The azoxystrobin residue was maintained in germs (Transfer factor around 0.8) and increased by concentration on bran (average Transfer Factor was 2.5). Bran was obviously responsible for the higher level in whole meal flour and bread compared to white flour.  The study is acceptable. |

|  |  |
| --- | --- |
| Reference: | KCA 6.3.2/04 |
| Report | Magnitude Of The Residues Of Azoxystrobin In Winter Wheat (RAC Grain And Straw) And Processed Fractions Following Two Applications Of NUL 2206, Poland, 2010  Roussel, C-H., 2011  Report No.: ChR-10-8231 |
| Guideline(s): | -Guidelines for the generation of data concerning residues as provided in Annex II, part A, section 6 and annex III, part A, section 8 of directive 91/414/EEC concerning the placing of plant protection products on the market. (1607/VI/97 rev. 2).  -General recommendation for the design, preparation and realisation of residue trials (7029/VI/95rev.5)  -Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. Document SANCO 3029/99, 2000.  -Guidance document on residue analytical methods. Document SANCO 825/00, 2010. |
| Deviations: | None |
| GLP: | Yes |
| Acceptability: | Yes |

Materials and Methods

Please refer to summary made under A 2.2.3 Magnitude of residues in plants for further details on the field and analytical phase.

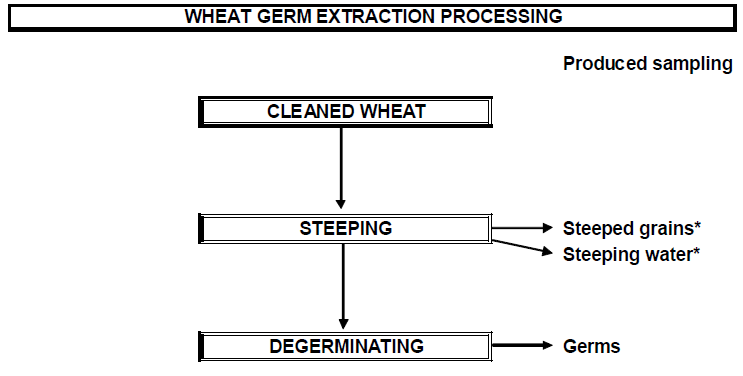
Four residue trials were conducted in Poland on wheat during 2010.

*Processing phase*

The grain specimens were processed under normal conditions into white flour, wholemeal flour, wholemeal bread, wheat germs and semolina (middling). Processing specimens were shipped to the analytical site on a freezer truck with dry ice added inside the shipment boxes. They were delivered to the analytical site frozen and in good condition.

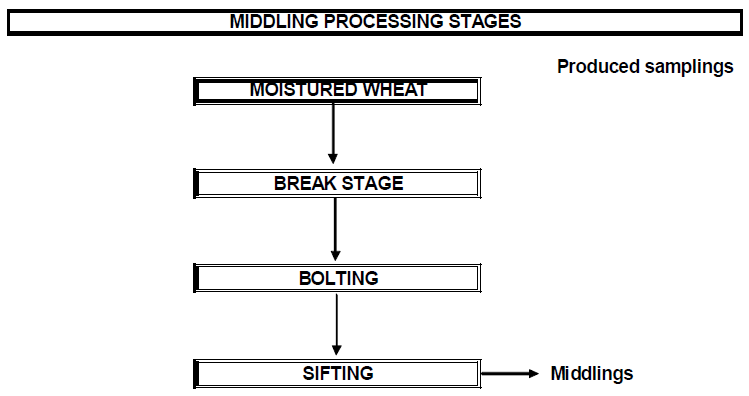
Germ extraction

After cleaning the grains, 1 kg of cleaned grains was placed in a plastic pan filled with 1 kg of water. The steeping duration was a minimum of 12 hours. After straining, a portion of grains was placed on absorbing paper. For the balance trial, two 0.1 kg wheat steeped grain sub-specimens were taken in plastic bags and two 0.1 kg steeping water samples were taken in plastic bottles and frozen (below –18°C). For the other trials, steeping water was discarded. Germs were removed from wheat grains with a cutter.



Middling and flour processing (white flour Type 550 and wholemeal flour)

Middling: the wheat grains were stored in a wet and closed place during minimum 12 hours, to obtain a water content of about 17 %. The moisture wheat grains were placed through a mill consisting of break rolls and screened. The break flour and the bran were weighed and discarded.



White flour (Type 550) processing: The moisture wheat grains were passed through a mill consisting of break rolls and then reduction rolls and screened. After the break stage, coarse bran and break flour were recovered. After the reduction stage, fine bran and reduction flour were recovered. Coarse bran and fine bran were combined to obtain total bran. Break flours and reduction flours were combined to obtain white flour (Type 550).

Wholemeal flour processing: The remaining white flour was mixed to the total bran in proportion to the flour/bran quantity starting (before samplings) to produce wholemeal flour.

Une image contenant table

Description générée automatiquement

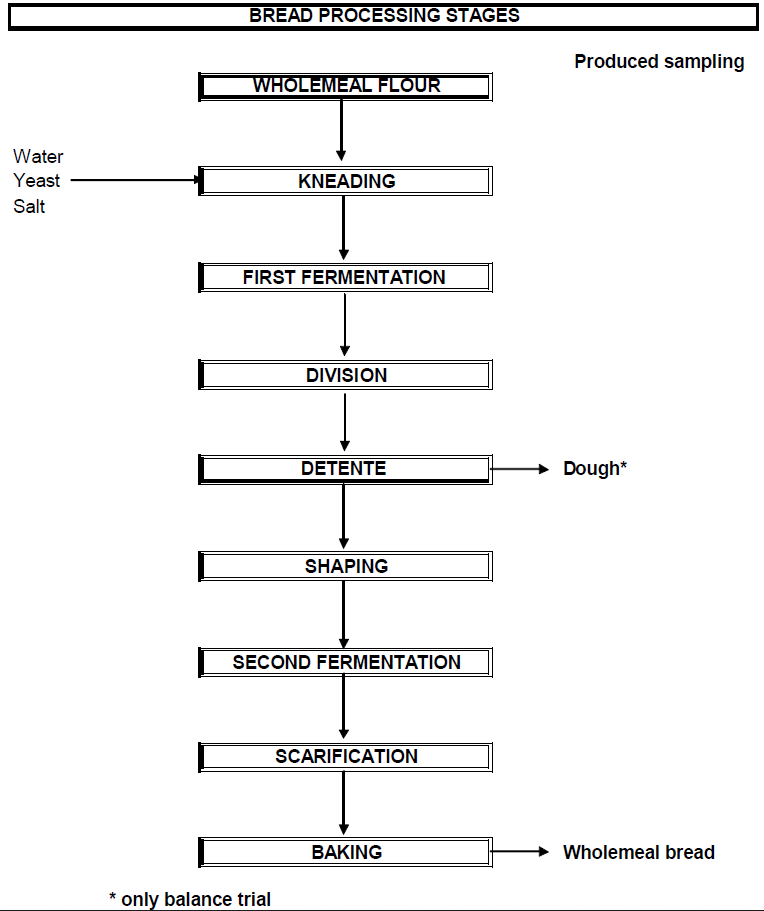
Bread processing

The wholemeal bread was made with the wholemeal flour obtained. Before the bread processing, the flour moisture was measured. According to the flour moisture, the flour quantity was determined and weighed.

The dry baker’s yeast was rehydrated with sugar and water. The water quantity to add was calculated. The flour, water and yeast were put in the kneading machine. The mix was kneaded. Five minutes before the end of the kneading, salt was added.

The obtained dough was placed in a pan at ambient temperature for 45 minutes. The dough was divided into several little dough pieces of approximately 350 grammes. The divided dough was covered and kept at ambient temperature for 15 minutes. The divided dough was shaped into a baguette of approximately 35 centimetres. The baguettes were covered and kept at ambient temperature for 2 hours.

The baguette was notched with a knife three times and baked in an oven at 250°C for approximately 20 minutes. The cooked baguettes were taken out of the oven and put on a aired support for cooling.



Results

The azoxystrobin levels found in wheat are summarised in the table below.

In all untreated specimens, the residue was below LOQ (<0.01 mg/kg).

Processing factors were calculated and presented hereafter.

Table A 111: Residue data from Wheat processing study with azoxystrobin

| **Trial number** | **Residues in RAC (unwashed sample, mg/kg)** | **PHI**  **(days)** | **Processed commodity** | **Residue** | **PF\*** |
| --- | --- | --- | --- | --- | --- |
| **(mg/kg)** |
| PL01 | 0.074 | 41 | Cleaned grain | 0.021 | 0.28 |
| Steeped grain | <0.01 | 0.14\*\* |
| Germs | 0.024 | 0.32 |
| Middlings | 0.01 | 0.14 |
| White flour | <0.01 | 0.14\*\* |
| Bran | 0.050 | 0.68 |
| Wholemeal Flour | 0.021 | 0.28 |
| Wholemeal Dough | 0.011 | 0.15 |
| Wholemeal bread | 0.013 | 0.18 |
| PL02 | 0.051 | 40 | Germs | 0.065 | 1.27 |
| White flour | <0.01 | 0.20\*\* |
| Bran | 0.19 | 3.73 |
| Wholemeal Flour | 0.040 | 0.78 |
| Wholemeal bread | 0.032 | 0.63 |
| PL03 | 0.027 | 46 | Germs | 0.023 | 0.85 |
| White flour | <0.01 | 0.37\*\* |
| Bran | 0.070 | 2.59 |
| Wholemeal Flour | 0.023 | 0.85 |
| Wholemeal bread | 0.017 | 0.63 |
| PL04 | 0.030 | 42 | Germs | 0.023 | 0.77 |
| White flour | <0.01 | 0.33\*\* |
| Bran | 0.090 | 3.00 |
| Wholemeal Flour | 0.030 | 1.00 |
| Wholemeal bread | 0.015 | 0.50 |

\* Processing factor

\*\* In case residues are < LOQ in the processed commodity, the LOQ value was considered instead for the calculation (worst-case assumption).

* + - * 1. Study ChR-10-8214

|  |  |
| --- | --- |
| Comments of zRMS: | The study was conducted to determine residues of azoxystrobin in oilseed rape raw agricultural commodity (RAC grain) and processed fractions specimens of oilseed rape after one application of NUL 2206. Four residues trials were performed in Poland during 2010.  T1 plot was intended for residue at harvest, treated one with NUL 2206 at the rate of 1 L/ha. T2 plot was intended for residue in processing fractions, treated at 3 L/ha.  In each trial, one foliar application was made on T1 and T2 plots. Applications were placed at end of flowering (BBCH 69). One sampling was taken at harvest in each plot, between 48 to 52 days after last application.  The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg.  Sufficient stability data are available to support the residue data presented in this study.  Untreated specimens from the field and from processing were not contaminated with azoxystrobin or its z-isomer.  The grain used for processing had received a higher application rate in the field (NUL 2206 3 L/ha).  Azoxystrobin residue level was slightly reduced in the cake taken in one occasion for the balance trial. In oil, transfer factor (TF) was below 1 for 3 trials out of 4. Average TF was 0.63 for raw oil and 0.61 for refined oil, pointing out a decrease of the residue level during processing. Very close results between raw and refined oil showed a strong reliability of the results.  No azoxystrobin-z-isomer had been detected above 0.01 mg/kg in the specimens generated during processing phase.  The study is acceptable. |

|  |  |
| --- | --- |
| Reference: | KCA 6.3.3/05 |
| Report | Magnitude Of The Residues Of Azoxystrobin In Oilseed Rape (RAC Grain) And Processed Fractions Following One Application Of NUL 2206, Poland, 2010  Roussel, C-H., 2011  Report No.: ChR-10-8214 |
| Guideline(s): | -Guidelines for the generation of data concerning residues as provided in Annex II, part A, section 6 and annex III, part A, section 8 of directive 91/414/EEC concerning the placing of plant protection products on the market. (1607/VI/97 rev. 2).  -General recommendation for the design, preparation and realisation of residue trials (7029/VI/95rev.5)  -Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. Document SANCO 3029/99, 2000.  -Guidance document on residue analytical methods. Document SANCO 825/00, 2010.  -Method validation and quality control procedures for pesticide residues analysis in food and feed. Document SANCO/10684/2009, 2010. |
| Deviations: | None |
| GLP: | Yes |
| Acceptability: | Yes |

Materials and Methods

Please refer to summary made under A 2.2.3 Magnitude of residues in plants for further details on the field and analytical phase.

Four trials were performed in Poland in 2010.

*Processing phase – Oil processing*

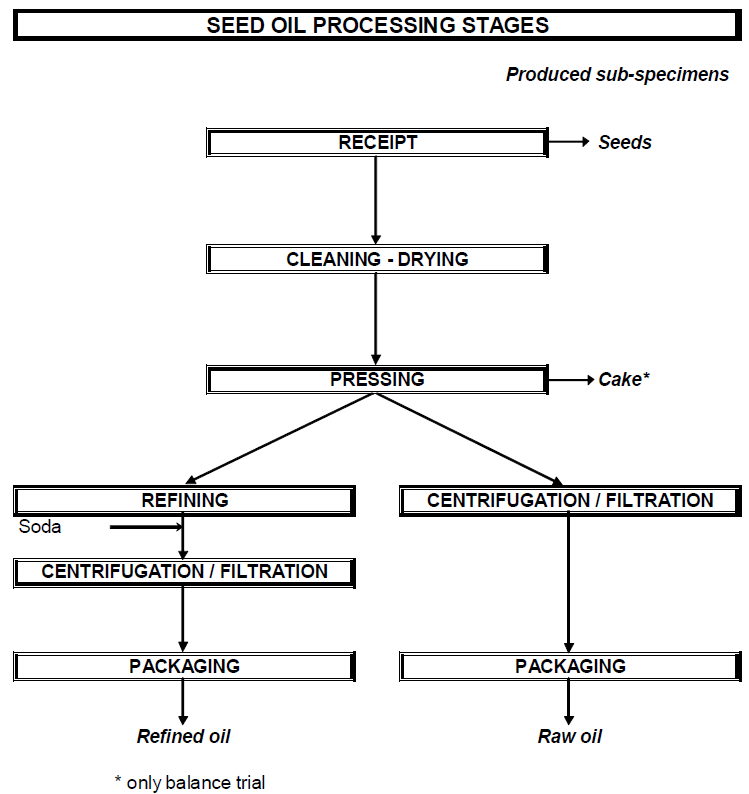
All oilseed rape seed specimens were cleaned with a grading unit. The cleaned oilseed rape seeds were dried in an oven set at 60°C for at least 12 hours before pressing.

The oilseed rape seeds were introduced into the press.

The cake was collected in a plastic container placed at the press head exit and the oil was collected in a plastic bucket placed under the press head. The obtained oil was separated in two parts: one part to produce raw oil and a second part to produce refined oil.

Raw oil production: After settling for 30 minutes, the oil was centrifuged and then filtered to produce raw oil.

Refined oil production: Soda (concentration: 115 g/L) was added to the other part to produce refined oil. The mixing was maintained for approximately 30 minutes in an oven at a temperature of about 80 -90°C. After a settling period of 30 minutes, the oil was centrifuged and then filtered.



Results

The azoxystrobin levels found in oilseed rape are summarised in the table below.

In all untreated specimens, the residue was below LOQ (<0.01 mg/kg).

Processing factors were calculated and presented hereafter.

Table A 112: Residue data from Oilseed rape processing study with azoxystrobin

| **Trial number** | **Residues in RAC (unwashed sample, mg/kg)** | **PHI**  **(days)** | **Processed commodity** | **Residue** | **PF\*** |
| --- | --- | --- | --- | --- | --- |
| **(mg/kg)** |
| PL01 | 0.035 | 48 | Cake | 0.03 | 0.86 |
| Raw oil | 0.058 | 1.66 |
| Refined oil | 0.057 | 1.63 |
| PL02 | 0.1 | 51 | Raw oil | 0.036 | 0.36 |
| Refined oil | 0.031 | 0.31 |
| PL03 | 0.04 | 51 | Raw oil | 0.015 | 0.38 |
| Refined oil | 0.016 | 0.40 |
| PL04 | 0.72 | 48 | Raw oil | 0.081 | 0.11 |
| Refined oil | 0.083 | 0.12 |

* + - * 1. Study ~~ongoing~~ S23-100807 - NEU

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Comments of zRMS: | Please refer to zRMS conclusion in point A 2.2.3.3.3.    Tree residue field trials generated specimens of RAC rapeseed for the processing phase. Rapeseed specimens were sampled for each trial, with two untreated and two treated specimens.  Results:   |  |  | | --- | --- | | **Overall Mean Transfer Factors** | S23-100807-02-011A and -012A & S23-100807-03-005A and -006A | | Press cake | <0.26 | | Crude oil | <0.27 | | Refined oil | <0.27 | | Meal | 0.26 | | Extracted oil | <0.26 |   The study is acceptable. |

|  |  |
| --- | --- |
| Reference: | KCA 6.3.3/07 |
| Report | Determination of residues of Azoxystrobin after a single application of CA2702 in Oilseed rape (outdoor) and its processed fractions at 4 sites in Northern Europe 2023  North, L., ~~ongoing~~ 2024  Report No.: S23-100807 |
| Guideline(s): | OECD (2009) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32)  OECD Test Guideline 509: Crop field trials  OECD (2016) Guidance Document ENV/JM/MONO (2011)50/REV1 , Second Edition, on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66)  EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials  SANTE/2019/12752 Technical Guidelines on Data Requirements for Setting Maximum Residue Levels, Comparability of Residue Trial and Extrapolation of Residue Data on Products from Plant and Animal Origin (Repealing and replacing the existing Guidance Document SANCO 7525/Vl/95 Rev. 10.3)  SANTE/2020/12830, Rev.1 Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes (Supersedes Guidance Documents SANCO/3029/99 and SANCO/825/00) |
| Deviations: | ~~Study ongoing~~  Some deviation during the filed phase and the processing phase but without impact on the study and the residue data. |
| GLP: | Yes |
| Acceptability: | ~~Study ongoping~~ Yes |

Materials and Methods

Please refer to summary made under A 2.2.3 Magnitude of residues in plants for further details on the field and analytical phase.

Three trials were performed in Central administrative zone in 2023.

Processed fractions (RAC rapeseed, press cake, crude oil, refined oil, meal and extracted oil) were analysed for residues of azoxystrobin in accordance to guidance document SANTE/2020/12830, rev. 2 for risk assessment and/or monitoring.

~~Results and details ongoing.~~

*Processing phase – Crude oil processing*

Prior to the start of the processing phase, the sample **“Rape seeds, prior to processing”** was taken.

**Sorting / Cleaning**: the seeds were cleaned using suitable cleaning equipment (sample cleaner SLN3). The grains with a size > 1mm were used for the processing.

When necessary, the cleaned seeds were stored in chilled conditions (target temperature +7°C) until the next process.

**Drying**: The cleaned seeds were dried in a drying oven set at 60°C approximately for at least 12 hours. The drying is completed when the moisture of the seeds is lower than 8%.

**Pressing**: The conditioned seeds were pressed mechanically using suitable equipment - “oil extrusion press”. The sample **“Press cake**” was taken.

**Filtration**: Then the raw oil was filtered using a glass feeding bottle, a funnel, a filter sheet (Whatman) and vacuum pump, to obtain the crude oil. The sample **“Crude oil”** was taken.

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ***Ingredients*** | | |  |  |  |  |  |  |  | ***Fractions*** | | |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | **Rape seed** | | | | |  | ***Rape seeds prior to processing*** | | |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | | |  | **Cleaning**  **(>1mm)** | | | | |  |  |  |  |
|  |  |  |  |  |  | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | **CLEANED SEEDS** | | | | |  |  | | | | |
|  |  |  |  |  |  |  |  |  |  |  | |  | |  |
|  | | |  | **Drying (~ 60°C - > 12 hours - until H% < 8%)** | | | | |  |  | |  | |  |
|  |  |  |  |  |  | | | | |
|  |  |  |  |  |  |  | *Dried seeds* | |  |  | |  | |  |
|  | | |  | **Pressing** | | | | |  |  | | | | |
|  | | |  |  | ***Press cake*** | | | | |
|  |  |  |  |  |  |  | *Raw oil* | |  | |  | |  |  |
|  |  |  |  | **Filtration** | | | | |  |  | |  | |  |
|  |  |  |  |  | ***Crude oil*** | | | | |

*Processing phase – Processing to refined oil*

**Degumming:** About 0.4mL of citric acid solution (at 625g/L) per 100g of crude oil were added to the crude oil. The mixture was stirred continuously and heated at about 95°C, for minimum 35 minutes.

**Neutralisation:** A soda solution (NaOH at 118g/L) was added to the oil (about 1.8mL per 100g of crude oil) (still under continuous stirring, above 95°C). The mixture was stirred continuously and heated at about 95°C, for about 50 minutes.

**Centrifugation:** After cooling down, the oil was centrifuged about 3 minutes to remove the aqueous wastes.

**Cleaning**: About 10% (w/w) of demineralised water was added to the oil and heated to about 95°C for 20 minutes in the oven.

Then, the aqueous wastes were removed with a separator funnel.

**Storage:** The oil was then stored in cool conditions (target +7°C) overnight (for minimum 12 hours).

**Centrifugation:** The oil was centrifuged.

**Deodorisation:** The oil was put into the oven at about 200°C for minimum 75 minutes. The sample “**Refined oil**” was taken.

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ***Ingredients*** | | |  |  |  |  |  |  |  | ***Fractions*** | | |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | **Crude oil** | | | | |  |  | | |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| Citric acid solution at 625g/L | | |  | **Degumming ( ~ 95°C - > 35 minutes)** | | | | |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| Soda solution at 118g/L | | |  | **Neutralisation ( ~ 95°C - ~ 50 minutes)** | | | | |  |  | | |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | **Centrifugation** | | | | |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
| Demineralised water | | |  | **Cleaning (~ 95°C - ~ 20 minutes)** | | | | |  |  | | |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | **Storage (>12 hours - target +7°C)** | | | | |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | **Centrifugation** | | | | |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  | **Deodorisation**  **(~ 200°C - ~ 75 minutes)** | | | | |  | ***Refined oil*** | | |

*Processing phase –Oil after solvent extraction*

**Solvent extraction**: The press cake was “washed” with the solvent (about 1L of hexane (CAS Number 110-54-3) per kg of press cake). The liquid phase was separated from the solid phase (meal) by decantation. The “**Meal**” was sampled.

**Evaporation**: Then the liquid phase was heated until evaporation of the solvent.

The **extracted oil** was produced and sampled.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***Ingredients*** |  |  |  | ***Fractions*** |
|  |  |  |  |  |
|  |  | **Press cake** |  |  |
|  |  |  |  |  |
| *Solvent Hexane* |  | **Solvent extraction** |  | ***Meal*** |
|  |  | Liquid phase oil/solvent |  |  |
|  |  | **Evaporation of the solvent** |  | ***Extracted oil*** |

Results

The azoxystrobin levels found in oilseed rape are summarised in the table below.

In all untreated specimens, the residue was below LOQ (<0.01 mg/kg).

Processing factors were calculated and presented hereafter.

Table A 113: Residue data from Oilseed rape processing study with azoxystrobin

| **Trial number** | **Residues in RAC (unwashed sample, mg/kg)** | **PHI**  **(days)** | **Processed commodity** | **Residue** | **PF\*** |
| --- | --- | --- | --- | --- | --- |
| **(mg/kg)** |
| S23-100807-01 | 0.01 / < 0.01  (Average: <0.01) | 60 | Press cake | 0.01 | Not applicable |
| Crude oil | 0.01 | Not applicable |
| Refined oil | 0.01 | Not applicable |
| Meal | 0.03 | Not applicable |
| Extracted oil | <0.01 | Not applicable |
| S23-100807-02 | 0.02 / 0.02  (Average: 0.02) | 49 | Press cake | <0.01 | Not applicable |
| Crude oil | < 0.01 | Not applicable |
| Refined oil | <0.01 | Not applicable |
| Meal | 0.01 | 0.50 |
| Extracted oil | <0.01 | Not applicable |
| S23-100807-03 | 1.9 / 2.0  (Average: 1.95) | 50 | Press cake | 0.05 | 0.03 |
| Crude oil | 0.07 | 0.04 |
| Refined oil | 0.07 | 0.04 |
| Meal | 0.05 | 0.03 |
| Extracted oil | 0.04 | 0.02 |

\* Processing factor

* + 1. Magnitude of residues in representative succeeding crops
       1. Study ChR-10-8233

|  |  |
| --- | --- |
| Comments of zRMS: | The study was conducted to determine magnitude of residues of azoxystrobin and its z-isomer in rotational crops following two applications of NUL 2206 at 1L/ha on summer barley.  Treated summer barley was sampled at 20 Days After Last Application as green material and at harvest (grain and straw separately), 36 to 40 days after application.  At three different Plant Back Intervals (30 days after last application, 2 months and 10 months), three crops were settled on the trial plots. Replacement or rotational crops were radishes, lettuce and barley (summer or winter according to the season).  PBI 1 was established 28 days after last application and 8 days after summer barley destruction.  PBI 2 was established 2 months after last application, after normal harvest as normal succeeding crops.  PBI 3 was established 10 months after last application as a normal following season.  Untreated specimens were not contaminated with azoxystrobin or azoxystrobin z-isomer.  Residues of azoxystrobin and its z-isomer found in treated summer barley were normal either in green material at 20 days after application or at harvest.  Residues of azoxystrobin in green material were 1.75 mg/kg on average (1.37 – 2.13). Residues in grain were 0.074 mg/kg on average (0.058 – 0.089). Residues in straw were 2.41 mg/kg (1.64 – 3.18).  Residues of z-isomer in green material were 0.071 mg/kg on average (0.061 – 0.081). Residues in straw were 0.172 mg/kg (0.083 – 0.26). No z-isomer residues were found in grain above LOQ.  In rotational crops, neither azoxystrobin nor its z-isomer residue was found above LOQ in any specimen taken in the two trials PL01 and PL02: radishes (roots or leaves), lettuces heads, barley (green material, grain or straw) at any sampling interval.  The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg.  Sufficient stability data are available to support the residue data presented in this study.  The study is acceptable. |

|  |  |
| --- | --- |
| Reference: | KCA 6.6.2/01 |
| Report | Magnitude Of The Residues Of Azoxystrobin In Rotational Crops Following Two Applications Of NUL 2206 On Summer Barley, Poland, 2010-2011  Roussel, C-H., 2011  Report No.: ChR-10-8233 |
| Guideline(s): | OECD Guideline for the Testing of Chemicals on Residues in Rotational Crops (Limited Field Studies) (TG 504 published in January 2007)  General recommendation for the testing of plant protection products in rotational crops (7524/VI/95 rev.2) |
| Deviations: | None |
| GLP: | Yes |
| Acceptability: | Yes |

Materials and Methods

Two trials were performed in Poland in 2010 in a summer barley field.

*Field phase*

Two plots (6 sub-plots in total) were established in each trial: 3 untreated plots (U1, U2 and U3) were left untreated. T1, T2 and T3 plots were intended for 3 Plant Back intervals (PBI), 30 days, 2 months and 10 months respectively. Each treated plot was treated twice with NUL 2206 at the rate of 1 L/ha, representing 250 g/ha of azoxystrobin.

In each trial, two applications were made on T1, T2 and T3 plots. Applications were made at end of stem elongation (BBCH 39) and before flowering (BBCH 59).

20 days after application, summer barley was destroyed on plots PBI 1 (U1 and T1) and 28 days after last application, three types of crops were established (planted or sown) at three different Plant Back Intervals (PBI): radishes, lettuce and summer barley.

On plot U2 and T2, the summer barley was normally harvested at 36 to 40 Days After Last Application (DALA). 2 months after last application three rotational crops were established: radishes, lettuce and winter barley.

On plot U3 and T3, after normal harvest, the soil was left as such during winter and 10 months after last application, actually 300 DALA for summer barley and 314 DALA for radishes and lettuce, the same rotational crops were established.

Two samplings were taken in treated summer barley: green material before destruction in PBI 1 and barley grain and straw separately in PBI 2. In addition, one sampling was taken at normal harvest stage in each individual plot of rotational crops. Exception for summer barley in PBI 1: due to the climate specificity in Poland, this crop was not susceptible to finish its cycle before winter; the sampling was taken as green material just before winter 2010.

The BBCH at sampling for the rotational crops was the following:

* Barley green material: BBCH 59-73
* Barley grain and straw: BBCH 89
* Radish root and leaves: BBCH 49
* Lettuce head: BBCH 18-49

All specimens were placed into labelled plastic bags, weighed and double bagged, frozen within 4 hours after sampling and shipped on freezer truck. They were delivered in frozen, good condition to analytical site.

*Analytical phase*

Analyses of specimens were performed at Food Safety Laboratory (FSL). The analytical method was described and validated in FSL report PBBZ-2011/07/DPL, separately from this study.

The limit of quantification (LOQ) achieved was 0.01 mg/kg for azoxystrobin. Limit of determination (LOD) was found to be between 0.001 and 0.004 mg/kg according to the matrices. The LOD was estimated from the lowest calibration standard concentration used with a signal to noise ratio ≥ 3 The determinations of azoxystrobin were performed by LC/MS/MS.

The maximum storage intervals were 402 days for all samples between sampling and analysis, and 1 day between extraction and analysis.

Findings

The azoxystrobin levels found in summer barley and the rotational crops radish, lettuce and barley are summarised in the table below.

In all untreated specimens, the residue was below LOQ (<0.01 mg/kg).

No azoxystrobin residue above 0.01 mg/kg was found in any succeeding crops at all PBIs.

**Please note that:**

* Trial ChR-10-8233 PL01 at PBI 2 months and trial ChR-10-8230 PL02 (study on primary crops) were performed in similar conditions (location, variety, date and similar application rate on the primary crop barley). The residue level measured in barley grain is the same in both trials (0.058 mg/kg). For straw, the residue level is higher in primary crops ChR-10-8230 PL02 (1.72 mg/kg) compared to rotational crop ChR-10-8233 PL01 (1.64 mg/kg).
* Trial ChR-10-8233 PL02 at PBI 2 months and trial ChR-10-8230 PL04 (study on primary crops) were also performed in similar conditions (location, variety, date and similar application rate on the primary crop barley). The residue level measured in barley grain is higher in primary crops (0.10 mg/kg) compared to rotational crop (0.089 mg/kg). For straw, it is the opposite: the residue level is lower in primary crops (1.93 mg/kg) compared to rotational crop (3.18 mg/kg).

The highest value was considered for the risk assessment.

Table A 114: Rotational trial summary for ChR-10-8233 study

|  |  |  |  |
| --- | --- | --- | --- |
| Preceding crop: | Summer Barley | Analytical method: | FSL PBBZ-2011/07/DPL |
| Succeeding crop: | Radish, lettuce and barley | Limit of Quantification (mg/kg): | 0.001 mg/kg |
| Indoor/Outdoor: | Outdoor |  |  |
| Formulation: | SC | Residues calculated as: | Azoxystrobin |
| Content of active substance (g/kg or g/L): | 250 g/L |  |  |

| 1 | 2 | 3 | 4 | 5 | | | 6 | 7 | 8 | 9 | 10 | 11 |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Report No. Location (region) | Commodity/Variety | Date of 1) Sowing or  Planting 2) Flowering  3) Harvest | Method of  Treatment | Application rate per treatment | | | Dates of treatment(s) or no. of treatment(s) and last date | Growth stage at last treatment or date  BBCH | Portion analysed | Residues (mg/kg)  (\*) | DALA (days) | Remarks |
| kg a.s./ha | Water (L/ha) | kg as/hL | Azoxystrobin |
| Poland  Wielkopolska  63-040  Chlawecin  Trial number  ChR-10-8233  PL01 | Summer  barley  Granal  **(Preceding**  **crop)** | 1- 31/03/10  2- 18/06/10  3- 26/07/10 | Foliar  broadcast  application | 0.260  0.256 | 300  296 | 0.087  0.086 | 09/06/10  16/06/10  **PBI 30 days** | 39  59 | **Barley green**  **Material**  Radishes roots  Radishes leaves  Lettuce  Barley green  material | **U: <0.001**  **T: 1.37**  U: <0.001  T: <0.001  U: <0.001  T: <0.001  U: <0.001  T: <0.01  U: <0.001  T: <0.01 | **20**  68  68  76  106 | U: Untreated  T: Treated  Analytical validation  report FSL  PBBZ-2011/07/DPL  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling and analysis:  402 days |
| 0.262  0.259 | 302  299 | 0.087  0.087 | 09/06/10  16/06/10  **PBI 2 months** | 39  59 | **Barley Grain**  **Barley Straw**  Radishes roots  Radishes  Leaves  Lettuce  Barley grain  Barley straw | **U: <0.001**  **T: 0.058**  **U: <0.004**  **T: 1.64**  U: <0.001  T: <0.001  U: <0.001  T: <0.001  U: <0.001  T: <0.01  U: <0.001  T: <0.001  U: <0.004  T: <0.004 | **40**  **40**  98  98  98  379  379 |
| 0.259  0.258 | 299  298 | 0.087  0.087 | 09/06/10  16/06/10  **PBI 10 months** | 39  59 | Radishes roots  Radishes  Leaves  Lettuce  Barley grain  Barley straw | U: <0.001  T: <0.001  U: <0.001  T: <0.001  U: <0.001  T: <0.001  U: <0.001  T: <0.001  U: <0.004  T: <0.004 | 348  348  371  405  405 |
| Poland  Wielkopolska  63-040  Michalow  Trial number  ChR-10-8233  PL02 | Summer  barley  Johan  **(Preceding**  **crop)** | 1- 02/04/10  2- 18/06/10  3- 22/07/10 | Foliar  broadcast  application | 0.260  0.258 | 300  298 | 0.087  0.087 | 09/06/10  16/06/10  **PBI 30 days** | 39  59 | **Barley green**  **Material**  Radishes roots  Radishes leaves  Lettuce  Barley green  material | **U: <0.001**  **T: 2.13**  U: <0.001  T: <0.001  U: <0.001  T: <0.01  U: <0.001  T: <0.01  U: <0.001  T: <0.001 | **20**  68  68  75  107 | U: Untreated  T: Treated  Analytical validation  report FSL  PBBZ-2011/07/DPL  LOQ: 0.01 mg/kg  Max. Storage Interval  between sampling  and analysis:  402 days |
| 0.258  0.258 | 298  298 | 0.087  0.087 | 09/06/10  16/06/10  **PBI 2 months** | 39  59 | **Barley Grain**  **Barley Straw**  Radishes roots  Radishes  Leaves  Lettuce  Barley grain  Barley straw | **U: <0.001**  **T: 0.089**  **U: <0.004**  **T: 3.18**  U: <0.001  T: <0.001  U: <0.001  T: <0.01  U: <0.001  T: <0.01  U: <0.001  T: <0.001  U: <0.004  T: <0.004 | **36**  **36**  97  97  97  386  386 |
| 0.262  0.260 | 303  300 | 0.086  0.087 | 09/06/10  16/06/10  **PBI 10 months** | 39  59 | Radishes roots  Radishes  Leaves  Lettuce  Barley grain  Barley straw | U: <0.001  T: <0.001  U: <0.001  T: <0.01  U: <0.001  T: <0.001  U: <0.001  T: <0.001  U: <0.004  T: <0.004 | 348  348  371  406  406 |

* + 1. Other/Special Studies

The applicant Nufarm has a letter of co-ownership by the Azoxystrobin Task Force which authorizes Nufarm to access to the studies submitted during the AIR4 renewal of azoxystrobin (process currently ongoing).

For the residue studies on bee products, the applicant kindly asks the zRMS to refer to the studies submitted for the AIR4 renewal of azoxystrobin.

It should be noted that during the AIR4 renewal process, one study (Report No S21-01128) was still ongoing. As the report is now available, the study is summarised hereafter.

* + - 1. Study 1 (S21-01128)

|  |  |
| --- | --- |
| Comments of zRMS: | The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for A22773A/Orondis Evo (June 2023). This study has not been reassessed in the framework of this application.  The conclusions of the assessment are presented below:  *The study contained five field trials (four were performed successfully) on winter oilseed rape was conducted in northern/southern Europe. Azoxystrobin was applied to winter oilseed rape as A12705B, an SC formulation containing nominally 250 g azoxystrobin per litre. Two applications, (applied at growth stage 62-65 BBCH), separated by a 5-7 day interval were made at a nominal rate of 250 g ai/ha for A1 and A2.*  *Treated samples were collected once at maturity (trials -01 and -04) of honey or at the end of flowering (trials -02 and -05) at 2-18 days after the last application (DALA). Untreated samples were collected once at maturity (trials -01 and -04) of honey or at the end of flowering (trials -02 and -05) at 2-18 days after the last application (DALA). In trial -03 no samples could be collected. The samples of trials -02 and -05 were dried in the laboratory to reach the requested sugar content of at least 80%. The sugar content of the honey samples was assessed by performing BRIX analysis.*  *The ranges of residues of azoxystrobin were <0.01 – 0.02 mg/kg and R230310 were <0.01 mg/kg.*  *No residues of azoxystrobin and its metabolite R230310 at or above the limit of quantification of 0.01 mg/kg were found in any of the untreated honey samples.*  *Samples were stored frozen for a maximum period of 76 days from sampling to extraction.*  *Field samples for residue analysis were analysed for azoxystrobin and its metabolite R230310 in honey using method RAM 305/03 as described in Syngenta Report Number: T011298-06-REG. The analytical method has been validated for beer, wheat flour and various crop matrices and honey.*  *Limit of Quantification: 0.01 mg/kg*  *The study is acceptable.* |

|  |  |
| --- | --- |
| Reference: | KCA 6.10/02 |
| Report | Azoxystrobin - Determination of Residues of Azoxystrobin and R230310 (z-isomer) in Honey after Two Applications of A12705B to Winter Oilseed rape at 5 Sites in Northern and Southern Europe in 2021  Appeltauer, A., 2022  Report No S21-01128 |
| Guideline(s): | OECD 509  OECD 506  SANTE/11956/2016 rev. 9  SANTE/2020/12830 rev. 1 |
| Deviations: | None from guidelines |
| GLP: | Yes |
| Owner: | Syngenta Ltd  (Nufarm Crop Products UK has a letter of co-ownership by the Azoxystrobin Task Force) |
| Acceptability: | Yes |

Materials and methods

Four residue trials, located in Germany, Austria and Spain were conducted in 2021 with winter oilseed rape as a melliferous source. A fifth residue trial on winter oilseed rape in Romania was not successfully conducted because it was not possible to sample enough honey for analysis.

A12705B 250 g/L SC was applied twice, at a nominal application rate of 250 g a.s./ha for each application. The applications were conducted during flowering between BBCH 62-65 and separated by a 5–7-day interval.

In each trial, the honeybee hives were installed in tunnel tents (5 m × 40 m with a height of 3.5 m) placed over the winter oilseed rape plots at growth stage BBCH 62. The number of honeybees at the first colony assessment were in the range from 6500 to 15912 bees per colony over all trials. For each trial, the colonies were as homogeneous as possible. The condition of the hives and the brood development were checked once prior to the set-up in the tunnels and once after the sampling of honey.

Treated samples were collected once at maturity (trials -01 and -04) of honey or at the end of flowering (trials -02 and -05) at 2-18 days after the last application (DALA). Untreated samples were collected once at maturity (trials -01 and -04) of honey or at the end of flowering (trials -02 and -05) at 2-18 days after the last application (DALA). The samples of trials -02 and -05 were dried in the laboratory to reach the requested sugar content of at least 80%. The sugar content of the honey samples was assessed by performing BRIX analysis.

All samples were transported on dry ice to the test facility/test site and were stored deep frozen (≤ -18 °C).

Samples were analysed for azoxystrobin and R230310 (Z-isomer) using the Syngenta method RAM 305/03. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte with a limit of detection (LOD) set at 0.003 mg/kg (defined as the lowest calibration standard, which is 30 % of the LOQ).

*Maximum storage period of honey samples and extracts*

Samples were stored frozen for a maximum period of 76 days from sampling to extraction.

The storage stability of azoxystrobin and R230310 (Z-isomer) in honey was investigated within the study. Residues of azoxystrobin and its metabolite R230310 in honey have been shown to be stable under these conditions for at least 81 days.

* Three (3) control samples at Day 0 and two (2) control samples for the end of the storage period (Day X) were fortified for each analyte. A set of pre-weighed control samples was also stored under the same conditions as the fortified samples, to be used for the control and freshly fortified recovery samples analysed with each storage interval.
* One (1) control, two (2) procedural recovery and three (3) fortified storage stability samples were analysed for residues of azoxystrobin and its metabolite R230310 immediately following preparation (i.e. Day 0).
* One (1) control, two (2) procedural recovery and two (2) fortified storage stability samples were analysed for residues of azoxystrobin and its metabolite R230310 at the end of the storage period (i.e. Day 81).
* The control, procedural recovery and fortified storage stability samples were analysed for residues of azoxystrobin and its metabolite R230310 using analytical method RAM 305/03 as described in Syngenta Report Number: T011298-06-REG.

An assessment of the storage stability samples (fortified at 10× LOQ) was made using the quantitation transition only. Samples are said to be stable if the % recovery of each individual fortified sample at the end of the storage period is within 70 - 110% of nominal and if the residue level in the stored samples (% of nominal) is within ± 30% of the initial.

**Table A 115:** **Storage Stability of Azoxystrobin in Honey Samples**

| **Interval Storage Time (Actual)** | **Nominal Fortification Level** | **Procedural Recovery** | | **Mean Procedural Recovery** | **Uncorrected Stored Sample Residue** | **Mean Uncorrected Stored Sample Residue** | **Mean Corrected**  **Stored Sample**  **Residue2** | **Mean Corrected**  **Stored Sample**  **Recovery3** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **days** | **mg/kg** | **mg/kg** | **%** | **mg/kg (%)** | **mg/kg** | **mg/kg (% of nominal)** | **mg/kg** | **% of nominal** |
| **Azoxystrobin** | | | | | | | | |
| 0 | 0.100 | 0.105  0.105 | 105  105 | 0.105 (105) | 0.108  0.108  0.108 | 0.108 (108) | 0.103 | 103 |
| 81 | 0.100 | 0.090  0.093 | 90  93 | 0.092 (92) | 0.096  0.094 | 0.095 (95) | 0.103 | 103 |
| **R230310** | | | | | | | | |
| 0 | 0.100 | 0.105  0.103 | 105  103 | 0.104 (104) | 0.108  0.105  0.106 | 0.106 (106) | 0.102 | 102 |
| 81 | 0.100 | 0.087  0.091 | 87  91 | 0.089 (89) | 0.096  0.090 | 0.093 (93) | 0.104 | 104 |

% recovery and % of nominal fortification level are calculated on rounded data and are not corrected for the residue found in the control samples.

1 [Mean Procedural Recovery Sample Residue (mg/kg) / Nominal Fortification Level (mg/kg)] x 100

2 [Mean Uncorrected Stored Sample Residue (mg/kg) / Mean Procedural Recovery (%)] x 100

3 Based on nominal fortification level = [Mean Corrected Stored Sample Residue (mg/kg) / Nominal Fortification Level (mg/kg)] x 100

Extract solutions were analysed on the same day of extraction for azoxystrobin and its metabolite R230310.

The stability of the analytes in the sample extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the sample extracts.

The stability of azoxystrobin and its metabolite R230310 in in final sample extracts was assessed by storing final extracts fortified at 10x LOQ refrigerated at 1 °C - 10 °C. The samples were then re-analysed by a second measurement after 12 days storage using freshly prepared calibration standards. Results show azoxystrobin and its metabolite R230310 are stable up to 12 days in in final sample extracts.

**Table A 116:** **Recovery Data for Extract Stability Obtained after 12 Days’ Storage at 1 °C to 10 °C for Honey**

| **Storage interval a** | **Fortification level** | **Recoveries Single Values** | | | | | **No. of Analyses** | **Mean** | **Rel. Std. Dev.** | **Range** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **days** | **mg/kg** | **%** | | | | |  | **%** | **%** | **%** |
| **Azoxystrobin** | | | | | | | | | | |
| 0 | 0.10 | 100 | 100 | 102 | 100 | 100 | 5 | 100 | 0.89 | 100-102 |
| 12 | 0.10 | 97 | 97 | 95 | 97 | 97 | 5 | 97 | 0.93 | 95-97 |
| Difference of recoveries after storage to recoveries before storage [%] b | | | | | | | | -3.8 | - | - |
| **R230310** | | | | | | | | | | |
| 0 | 0.10 | 99 | 100 | 100 | 99 | 99 | 5 | 99 | 0.55 | 99-100 |
| 12 | 0.10 | 96 | 95 | 96 | 96 | 96 | 5 | 96 | 0.47 | 95-96 |
| Difference of recoveries after storage to recoveries before storage [%] b | | | | | | | | -3.8 | - | - |

a Time interval between 1st and 2nd injection

b Difference of recoveries after storage to recoveries before storage = (100 % × mean of the 2nd injection / mean of the 1st injection) – 100 %

Results and discussions

No residues of azoxystrobin or R230310 at or above the limit of quantification (0.01 mg/kg) were found in any of the untreated honey samples.

The residue levels of all analytes found in honey are summarised in the table below.

Table A 117: Summary of the study S21-01128 trials

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Trial number** | **Country** | **Variety** | **Application date** | **Application rates (g a.s./ha)** | **BBCH at application** | **Timing** | **Matrix** | **Residue of Azoxystrobin (mg/kg)** | **Residue of R230310 (mg/kg)** |
| S21-01128-01 | 76646, Heidelsheim, Baden-Württemberg, Germany | Winter Oilseed Rape, LG Architect | 22 Apr 2021  27 Apr 2021 | 243.3  247.0 | 62  63 (5DAA1) | 2 DALA | Honey | 0.02 | <0.01 |
| S21-01128-02 | 8263, Großwilfersdorf, Hartberg-Fürstenfeld, Austria | Winter Oilseed Rape, PT 271 | 30 Apr 2021  6 May 2021 | 247.9  249.6 | 62  63 (6DAA1) | 14 DALA | Honey | <0.01 | <0.01 |
| S21-01128-03 | 300645, Timisoara, Timis, Romania | Winter Oilseed Rape, Expower | 19 Apr 2021  26 Apr 2021 | 263.5  270.3 | 62  63 (7DAA1) | Not applicable a | Honey | - | - |
| S21-01128-04 | 02640, Almansa, Albacete, Spain | Winter Oilseed Rape, Florida | 11 Apr 2021  18 Apr 2021 | 251.8  245.0 | 62  63 (7DAA1) | 12 DALA | Honey | <0.01 | <0.01 |
| S21-01128-05 | 02150, Valdeganga, Albacete, Spain | Winter Oilseed Rape, Florida | 6 Apr 2021  12 Apr 2021 | 255.9  245.8 | 62  63-65 (6DAA1) | 18 DALA | Honey | <0.01 | <0.01 |

a No honey could be sampled. There was no honey available on the combs entered before setup of colonies in the tunnels.

1. Pesticide Residue Intake Model (PRIMo)
   1. TMDI calculations

**Prothioconazole-desthio**



**TDMs**

***Triazole alanine***



**Azoxystrobin**



IEDI calculations

**Prothioconazole-desthio**

Not triggered.

**Azoxystrobin**

Not triggered.

* 1. IESTI calculations - Raw commodities

**Prothioconazole-desthio**

**TDMs**

***1,2,4-triazole***

***Triazole alanine***



***Triazole acetic acid***



***Triazole lactic acid***



* 1. IESTI calculations - Processed commodities

**Prothioconazole-desthio**



**TDMs**

***1,2,4-triazole***



***Triazole alanine***



***Triazole acetic acid***



***Triazole lactic acid***



1. Additional information provided by the applicant
   1. Input values for the maximum dietary burden calculation of Triazole alanine considering TDMs EU data and uses under consideration

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1 - Forages** |  | **STMR** | **HR** | **PF** | **CF** | **Default PF** | **STMR by-P** | **HR by-P** |
| Alfalfa | forage (green) | 0.16 | 0.52 | - |  | - | 0.16 | 0.52 |
| Alfalfa | hay (fodder) | 0.16 | 0.52 |  |  | 2.5 | 0.40 | 1.31 |
| Alfalfa | meal | 0.16 | 0.52 |  |  | 2.5 | 0.40 | 1.31 |
| Alfalfa | silage | 0.16 | 0.52 |  |  | 1.1 | 0.18 | 0.576 |
| Barley | straw | 0.12 | 0.65 | - |  | - | 0.12 | 0.65 |
| Beet, mangel | fodder | 0.18 | 0.239 | - |  | - | 0.18 | 0.239 |
| Beet, sugar | tops | 0.04 | 0.218 | - |  | - | 0.04 | 0.218 |
| Cabbage, heads | leaves | 0.17 | 0.500 | - |  | - | 0.17 | 0.50 |
| Clover | forage | 0.16 | 0.524 | - |  | - | 0.16 | 0.524 |
| Clover | hay | 0.16 | 0.52 |  |  | 3 | 0.48 | 1.57 |
| Clover | silage | 0.16 | 0.52 |  |  | 1 | 0.16 | 0.524 |
| Corn, field | stover (fodder) | 0.12 | 0.65 | - |  | - | 0.12 | 0.65 |
| Corn, pop | stover (fodder) | 0.12 | 0.65 | - |  | - | 0.12 | 0.65 |
| Grass | forage (fresh) | 0.16 | 0.524 | - |  | - | 0.16 | 0.524 |
| Grass | hay | 0.16 | 0.524 |  |  | 3.5 | 0.56 | 1.83 |
| Grass | silage | 0.16 | 0.524 |  |  | 1.6 | 0.26 | 0.838 |
| Kale | leaves (forage) | 0.17 | 0.500 | - |  | - | 0.17 | 0.50 |
| Oat | straw | 0.12 | 0.65 | - |  | - | 0.12 | 0.65 |
| Rape | forage | 0.10 | 0.913 | - |  | - | 0.10 | 0.913 |
| Rye | straw | 0.12 | 0.65 | - |  | - | 0.12 | 0.65 |
| Triticale | straw | 0.12 | 0.65 | - |  | - | 0.12 | 0.65 |
| Turnip | tops (leaves) | 0.04 | 0.218 | - |  | - | 0.04 | 0.218 |
| Wheat | straw | 0.12 | 0.65 | - |  | - | 0.12 | 0.65 |
| **2 - Roots & Tubers** |  | **STMR** | **HR** | **-** | **CF** | **-** | **STMR** | **HR** |
| Potato | culls | 0.18 | 0.239 |  |  |  | 0.18 | 0.239 |
| **3 - Cereal grains/Crop seeds** | | **STMR** | **Post-h?** | **HR** | **CF** | **-** | **STMR** | **HR** |
| Barley | grain | 0.621 | N |  |  |  | 0.621 |  |
| Bean | seed (dry) | 0.17 | N |  |  |  | 0.17 |  |
| Corn, field (Maize) | grain | 0.621 | N |  |  |  | 0.621 |  |
| Corn, pop | grain | 0.62 | N |  |  |  | 0.62 |  |
| Cotton | undelinted seed | 1.200 | N |  |  |  | 1.200 |  |
| Cowpea | seed | 0.17 | N |  |  |  | 0.17 |  |
| Lupin | seed | 0.17 | N |  |  |  | 0.17 |  |
| Oat | grain | 0.621 | N |  |  |  | 0.621 |  |
| Rye | grain | 0.621 | N |  |  |  | 0.621 |  |
| Soybean | seed | 1.200 | N |  |  |  | 1.200 |  |
| Triticale | grain | 0.621 | N |  |  |  | 0.621 |  |
| Wheat | grain | 0.621 | N |  |  |  | 0.621 |  |
| **4 - By-products** |  | **STMR** | **-** | **PF** | **CF** | **Default PF** | **STMR by-P** | **-** |
| Apple | pomace, wet | 0.32 |  | 0.52 |  | 5 | 0.167 |  |
| Beet, sugar | dried pulp | 0.18 |  |  |  | 18 | 3.30 |  |
| Beet, sugar | ensiled pulp | 0.18 |  |  |  | 3 | 0.55 |  |
| Beet, sugar | molasses | 0.18 |  |  |  | 28 | 5.1 |  |
| Brewer's grain | dried | 0.62 |  |  |  | 3.3 | 2.0 |  |
| Canola (Rape seed) | meal | 1.200 |  | 1.4 |  | 2 | 1.68 |  |
| Citrus | dried pulp | 0.32 |  | 0.5 |  | 10 | 0.167 |  |
| Corn, field | milled by-pdts | 0.62 |  |  |  | 1 | 0.621 |  |
| Corn, field | hominy meal | 0.62 |  |  |  | 6 | 3.73 |  |
| Corn, field | gluten feed | 0.62 |  |  |  | 2.5 | 1.55 |  |
| Corn, field | gluten, meal | 0.62 |  |  |  | 1 | 0.621 |  |
| Cotton | meal | 1.30 |  | 1.4 |  | 1.3 | 1.68 |  |
| Distiller's grain | dried | 0.62 |  |  |  | 3.3 | 2.0 |  |
| Flaxseed/Linseed | meal | 1.200 |  | 1.4 |  | 2 | 1.68 |  |
| Lupin seed | meal | 0.17 |  |  |  | 1.1 | 0.187 |  |
| Potato | process waste | 0.18 |  |  |  | 20 | 3.68 |  |
| Potato | dried pulp | 0.18 |  |  |  | 38 | 6.99 |  |
| Rape | meal | 1.200 |  | 1.4 |  | 2 | 1.68 |  |
| Safflower | meal | 1.200 |  | 1.4 |  | 2 | 1.68 |  |
| Soybean | meal | 1.200 |  | 1.4 |  | 1.3 | 1.68 |  |
| Soybean | hulls | 1.200 |  |  |  | 13 | 15.6 |  |
| Sugarcane | molasses | 0.18 |  |  |  | 32 | 5.89 |  |
| Sunflower | meal | 1.200 |  | 1.4 |  | 2 | 1.68 |  |
| Wheat gluten | meal | 0.62 |  |  |  | 1.8 | 1.12 |  |
| Wheat | milled by-pdts | 0.62 |  |  |  | 7 | 4.35 |  |

1. Epoxiconazole, penconazole, tebuconazole, fenbuconazole, flutriafol, paclobutrazole, metconazole, fluquiconazole, difenoconazole, tetraconazole, propiconazole, ipconazole. [↑](#footnote-ref-1)
2. M32: 3-chloro-4-[(2RS)-2-(1-chlorocyclopropyl)-2-hydroxy-3-(1H-1,2,4-triazol-1-yl)propyl]cyclohexa-3,5-diene-1,2-diol. [↑](#footnote-ref-2)
3. M28: 3-chloro-2-[2-(1-chlorocyclopropyl)-2-hydroxy-3-(1H-1,2,4-triazol-1-yl)propyl]-6-methoxyphenol [↑](#footnote-ref-3)
4. M34: 3-chloro-4-[2-(1-chlorocyclopropyl)-2-hydroxy-3-(1H-1,2,4-triazol-1-yl)propyl]benzene-1,2-diol [↑](#footnote-ref-4)
5. M35: 4-chloro-5-[(2RS)-2-(1-chlorocyclopropyl)-2-hydroxy-3-(1H-1,2,4-triazol-1-yl)propyl]benzene-1,2-diol [↑](#footnote-ref-5)
6. M01 or prothioconazole-S-methyl: (2RS)-2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-[5-(methylsulfanyl)-2,5-dihydro-1H-1,2,4-triazol-1-yl]propan-2-ol [↑](#footnote-ref-6)
7. M06 or prothioconazole-S-glucuronide: 1-[(2RS)-2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-4,5-dihydro-1H-1,2,4-triazol-5-yl 1-thio-β-D-glucopyranosiduronic acid [↑](#footnote-ref-7)
8. M45: (1RS)-1-(1-chlorocyclopropyl)-2-(1H-1,2,4-triazol-1-yl)ethanol [↑](#footnote-ref-8)
9. Epoxiconazole, metconazole, triticonazole, prothioconazole, prothioconazole-desthio, tebuconazole, fenbuconazole, tetraconazole, propiconazole, difenoconazole, fluquinconazole. [↑](#footnote-ref-9)
10. Metconazole, prothioconazole, tebuconazole, fenbuconazole, propiconazole, difenoconazole. [↑](#footnote-ref-10)
11. Azoxystrobin is currently authorized based on the old data requirements, for which no residue study on honey was required in the DAR 2009. Consequently, the assessment of the present application is based on the same data requirements as for the active substance 2009 re-approval since azoxystrobin is not AIR4 renewed yet. This will avoid any distortion of competition in favour of the previous Art.33 dossiers for which no data on honey was required. Therefore, in the present application, information on honey is considered as informative only. [↑](#footnote-ref-11)
12. “Validation of an Analytical Method for the Determination of Triazole and Triazole-based Metabolites in the Agricultural Commodity Wheat, Barley, Grape and Rape“, Nina Schernikau, Carolina Suaza Colorado, S15-03542 (GAB-1537V), Eurofins Agroscience Services Chem GmbH, 05 Apr 2016 [↑](#footnote-ref-12)
13. “Determination of residues of Prothioconazole-desthio (sum of isomers) after two applications of Prothioconazole in Oilseed rape (outdoor) at 3 sites in Northern Europe in 2022 “, Olga Winter, Hannah Graf, S22-00257 (EAS-2206), Eurofins Agroscience Services Chem GmbH [↑](#footnote-ref-13)