|  |
| --- |
| REGISTRATION REPORT  Part A  Risk Management |
| Product code: IN233C1560  Product name: AVTAR  Chemical active substances:  Prothioconazole, 250 g/L Difenoconazole, 130 g/L |
| Central Zone: PL, DE, AT, IE, NL, BE, CZ, SL, SK, HUN, RO  Zonal Rapporteur Member State: Poland |
| NATIONAL ASSESSMENT - Poland  (Authorisation – Article 33) |
| Applicant: INDOFIL Industries (Netherlands) B.V.  Submission date: January 2022  Evaluation date: June 2023  MS Finalisation date: February 2024 |

Version history

|  |  |
| --- | --- |
| When | What |
| January 2022 | First version of the document according to Article 33 of Regulation (EC) 1107/2009 |
| June 2023 | Version evaluated by zRMS PL |
| November 2023 | Version updated following the availability of additional data and zRMS reply of the commenting table |
| February 2024 | RR finalized by zRMS |

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PART A

RISK MANAGEMENT

# Details of the application

## Application background

The dossier is submitted for the authorisation of the product IN233C1560 according to Article 33 of Regulation (EC) 1107/2009 in the Central zone. This part A is written for the registration of IN233C1560 in Poland.

The product IN233C1560 is an Emulsifiable Concentrate [EC] formulation containing 250 g/L prothioconazole and 130 g/L difenoconazole. This product is a fungicide intended to be used outdoor in cereals and oilseed rape.

The dossier is submitted in Poland which is a cMS of the Central zone. The relevant GAP is presented in Part A and in Part B0.

The risk assessment conclusions are based on the information, data and assessments provided in Draft Registration Report, Part B Sections 0 to 10 and Part C. The information, data and assessments provided in Draft Registration Report, Parts B includes assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to IN233C1560 where that data has not been considered in the EU review. Otherwise assessments for the safe use of IN233C1560 have been made using endpoints agreed in the EU review of prothioconazole and difenoconazole.

This document describes the specific conditions of use and labelling required for the registration of Poland IN233C1560.

## Letters of Access

Studies conducted on the formulated product IN233C1560 are owned by INDOFIL Industries (Netherlands) B.V.

Regarding the access of the data on the active substance prothioconazole, INDOFIL Industries (Netherlands) B.V. does not have access to studies. However, INDOFIL’s supplier of the active substance prothioconazole provided a certificate for the said active substance which can be referred to INDOFIL Industries (Netherlands) B.V.

Regarding the access of the data on the active substance difenoconazole, INDOFIL Industries (Netherlands) B.V. does not have access to studies. However, INDOFIL’s supplier of the active substance difenoconazole provided a certificate for the said active substance which can be referred to INDOFIL Industries (Netherlands) B.V.

## Justification for submission of tests and studies.

IN233C1560 is a new formulation. The following tests have been generated with IN233C1560 and submitted within the current application: product data on physical and chemical properties, analytical methods, acute toxicity and dermal absorption and ecotoxicological data.

These new tests have been generated as IN233C1560 is a new formulation

## Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

# Details of the authorization decision

## Product identity

|  |  |
| --- | --- |
| Product code | IN233C1560 |
| Product name in MS | Avtar |
| Authorization number | xxxx – xx |
| Function | fungicide |
| Applicant | INDOFIL Industries (Netherlands) B.V. |
| Active substance(s)  (incl. content) | Prothioconazole, 250 g/L  Difenoconazole, 130 g/L |
| Formulation type | Emulsifiable Concentrate [Code : EC] |
| Packaging | Packaging type : PA/HDPE  Size: 1, 3, 5 and 10 liters  Use: Professional user |
| Coformulants of concern for national authorizations | None |
| Restrictions related to identiy | None |
| Mandatory tank mixtures | Not applicable |
| Recommended tank mixtures | Not applicable |

## Conclusion

The evaluation of the application for product IN233C1560 / AVTAR resulted in the decision to grant the authorization for all uses except oilseed rape.

## Substances of concern for national monitoring

Both active substances of the product IN233C1560 (i.e. prothioconazole and difenoconazole) are not concerned by a national monitoring.

## Classification and labelling

### Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

|  |  |
| --- | --- |
| Hazard class(es), categories: | Eye irritation (Category 2)  Skin irritation ( Category 2)  Carcinogenicity (Category 2)  Aquatic Chronic (~~Category 3~~ Category 1) |

The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold:**

|  |  |
| --- | --- |
| Hazard pictograms: | **GHS07, GHS08, GHS09** |
| Signal word: | **Warning** |
| Hazard statement(s): | **H315:** Causes skin irritation  **H319:** Causes serious eye irritation.  **H351:** Suspected of causing cancer  **~~H412:~~** ~~Harmful to aquatic life with long lasting effects~~  **H410:** Very toxic to aquatic life with long lasting effects |
| Precautionary statement(s): | **P201:** Obtain special instructions before use.  **P202:** Do not handle until all safety precautions have been read and understood  **~~P261:~~** ~~Avoid breathing mist/vapours~~  **~~P271:~~** ~~Use only outdoors or in a well-ventilated area~~.  **~~P273:~~** ~~Avoid release to the environment, if this is not the intended use~~  **P264:** Wash face and hands thoroughly after handling.  **P280:** Wear protective gloves/protective clothing/eye protection/face protection.  **~~P304 + P340: IF INHALED:~~** ~~Remove person to fresh air and keep comfortable for breathing~~.  **~~P311~~**~~: Call a POISON CENTER/doctor/...~~  **~~P321:~~** ~~Specific treatment (see … on this label~~)  **P302 + P352:** IF ON SKIN: Wash with plenty of water  **P332 + P313:** If skin irritation occurs: Get medical advice/attention  **P362 + P364:** Take off contaminated clothing and wash it before reuse  **P308 + P313:** IF exposed or concerned: Get medical advice /attention.  **~~P321:~~** ~~Specific treatment (see … on this label)~~  **P305+P351+P338:** IF IN EYES: Rinse cautiously with water for several minutes. Rem contact lenses, if present and easy to do. Continue rinsing. **P337+P313:** If eye irritation persists: Get medical advice/attention.  **P391**: Collect spillage  **P405:** Store locked up.  **P501:** Dispose of contents/ container in accordance with local/ regional/ national/international regulation |
| Additional labelling phrases: | To avoid risks to man and the environment, comply with the instructions for use. [**EUH401**] |

|  |  |
| --- | --- |
| Special rule for labelling of plant protection product (PPP): | |
| EUH401 | To avoid risks to man and the environment, comply with the instructions for use. |
| Further labelling statements under Regulation (EC) No 1272/2008: | |
| - | - |

**See Part C for justifications of the classification and labelling proposals.**

### Standard phrases under Regulation (EU) No 547/2011

|  |  |
| --- | --- |
| SP 1 | Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads). |
| SPe3 | To protect aquatic organisms respect 10 m vegetative filter strip including 5 m an unspraywed buffer zone to water bodies. |
| - | - |

### Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

|  |  |
| --- | --- |
| - | - |

## Risk management

### Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

|  |  |
| --- | --- |
| Operator protection: | |
| - | Vehicle-mounted application with a drift reduction nozzle.  Use gloves during handling, mixing and loading. |
| Worker protection: |  |
| - | none |
| Integrated pest management (IPM)/sustainable use: | |
| - | none |
| Environmental protection | |
| - | **Cereals**: To protect aquatic organisms respect 10 m vegetative filter strip including 5 m an unspraywed buffer zone to water bodies.  To protect birds and soil organisms, application in cereals is limited to the range BBCH 30 to 69. |
| - | **Oilseed rape**: To protect aquatic organisms respect 10 m vegetative filter strip including 5 m an unspraywed buffer zone to water bodies.  To protect birds and soil organisms, application in oilseed rape is limited to the two following application schemes:   * + One application in autumn/winter at 0.6 L/ha at BBCH 20 to 69 and one application in spring at BBCH 20 to 69   + Only one split application per crop at 0.3 + 0.3 L/ha at BBCH 14 to 69. |
| Other specific restrictions | |
| - | - |

The authorization of the PPP is linked to the following conditions (voluntary labelling):

|  |  |
| --- | --- |
| Integrated pest management (IPM)/sustainable use: | |
| - | - |

### Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

|  |  |  |
| --- | --- | --- |
| Integrated pest management (IPM)/sustainable use: | | Relevant for use no. |
| - | none | - |
| Environmental protection: | | Relevant for use no. |
| - | none | - |

## Intended uses (only NATIONAL GAP)

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  | GAP rev. 8.0, date: January 2022 |
| PPP (product name/code): | IN233C1560 | Formulation type: | EC (a, b) |
| Active substance 1: | Prothioconazole | Conc. of as 1: | 250 g/L (c) |
| Active substance 2: | Difenoconazole | Conc. of as 2: | 130 g/L (c) |
|  |  |  |  |
| Safener: | - | Conc. of safener: | - (c) |
| Synergist: | - | Conc. of synergist: | - (c) |
| Applicant: | INDOFIL Industries (Netherlands) B.V. | Professional use: |  |
| Zone(s): | Central zone (d) PL | Non professional use: |  |
| Verified by MS: | yes |  |  |
|  |  |  |  |
| Field of use: | Fungicide |  |  |

| **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **14** | **15** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Use-No.\*** | **Member state(s)** | **Crop and/or situation** | **F, Fn, Fpn G, GN, Gpn or  I\*\*** | **Pests or Group of pests controlled** | **Application** | | | | **Application rate** | | | **PHI (days)** | **Remarks** | **zRMS  Conclusion (efficacy)** |
| Method / Kind | Timing / Growth stage of crop & season | Max number a) per use b) per crop/season | Min. interval between applications (days) | L product/ha a) max per appl b) max total per crop/season | g as/ha a) max per appl b) max total per crop/season | water L/ha min/max |
| **Zonal uses (field or outdoor uses, certain types of protected crops)** | | | | | | | | | | | | | | |
| 1 | PL | Wheat | F | Septoria leaf spot (*Septoria tritici/Mycosphaerella gramincola*),  Ear blight (*Fusarium* spp.) | foliar spray | BBCH 39-69 | 2 | 14 | a) 0,7 b) 1,4 | a) Prothioconazole 175 + Difenoconazole 91 b) Prothioconazole 350 + Difenoconazole 182 | 200-300 | NA | 0,6 - 0,7 L/ha  0,6 L/ha = Prothioconazole 150 g as/ha + Difenoconazole 78 g as/ha 0,7 L/ha = Prothioconazole 175 g as/ha + Difenoconazole 91 g as/ha |  |
| 2 | ~~CEU:~~  PL, ~~DE, AT, UK, IE, NL, BE, CZ, SI,   SK, HU, RO~~ | Wheat | F | Brown Rust (*Puccinia triticina*), Yellow Rust (*Puccinia striiformis*), Powdery mildew (*Erysiphe graminis*) Eyespot (*Oculimacula* spp.) Tan Spot (*Drechslera tritici-repentis*) *Septoria nodorum* | foliar spray | BBCH 39-69 | 2 | 14 | a) 0,7 b) 1,4 | a) Prothioconazole 175 + Difenoconazole 91 b) Prothioconazole 350 + Difenoconazole 182 | 200-300 | NA | 0,6 - 0,7 L/ha  0,6 L/ha = Prothioconazole 150 g as/ha + Difenoconazole 78 g as/ha 0,7 L/ha = Prothioconazole 175 g as/ha + Difenoconazole 91 g as/ha |  |
| 3 | PL | Barley | F | Net blotch (*Pyrenophora teres*) | foliar spray | BBCH 32-52 | 2 | 14 | a) 0,7 b) 1,4 | a) Prothioconazole 175 + Difenoconazole 91 b) Prothioconazole 350 + Difenoconazole 182 | 200-300 | NA | 0,6 - 0,7 L/ha  0,6 L/ha = Prothioconazole 150 g as/ha + Difenoconazole 78 g as/ha 0,7 L/ha = Prothioconazole 175 g as/ha + Difenoconazole 91 g as/ha |  |
| 4 | PL | Barley | F | Leaf blotch (*Rhynchosporium secalis*) Ramularia (*Ramularia collo-cygni*) Dwarf Rust (*Puccinia hordei*) Spot blotch (*Helminthosporium*) Powdery mildew (*Erysiphe graminis*) *Fusarium* spp. | foliar spray | BBCH 32-52 | 2 | 14 | a) 0,7 b) 1,4 | a) Prothioconazole 175 + Difenoconazole 91 b) Prothioconazole 350 + Difenoconazole 182 | 200-300 | NA | 0,6 - 0,7 L/ha  0,6 L/ha = Prothioconazole 150 g as/ha + Difenoconazole 78 g as/ha 0,7 L/ha = Prothioconazole 175 g as/ha + Difenoconazole 91 g as/ha |  |
| 5 | ~~CEU~~:  PL, ~~DE, AT, UK, IE, NL, BE, CZ, SI,   SK, HU, RO~~ | Triticale | F | Leaf Spot (*Mycosphaerella graminicola*) Brown Rust (*Puccinia recondita*) Septoria (*Septoria tritici*) Powdery mildew (*Erysiphe graminis*) Groundbreak Disease (*Pseudocercosporella herpotrichoides*) | foliar spray | BBCH 32-69 | 2 | 14 | a) 0,7 b) 1,4 | a) Prothioconazole 175 + Difenoconazole 91 b) Prothioconazole 350 + Difenoconazole 182 | 200-300 | NA | 0,6 - 0,7 L/ha  0,6 L/ha = Prothioconazole 150 g as/ha + Difenoconazole 78 g as/ha 0,7 L/ha = Prothioconazole 175 g as/ha + Difenoconazole 91 g as/ha |  |
| 6 | ~~CEU~~:  PL, ~~DE, AT, UK, IE, NL, BE, CZ, SI,   SK, HU, RO~~ | Rye | F | Leaf Blotch (*Rhynchosporium* *secalis*) Brown Rust (*Puccinia* *recondita*) Powdery mildew (*Erysiphe* *graminis*) Eyespot (*Oculimacula* spp.) Glume Blotch (*Leptosphaeria* (syn. *Septoria*) *nodorum*) Leaf Spot (*Mycosphaerella* *graminicola*) | foliar spray | BBCH 32-69 | 2 | 14 | a) 0,7 b) 1,4 | a) Prothioconazole 175 + Difenoconazole 91 b) Prothioconazole 350 + Difenoconazole 182 | 200-300 | NA | 0,6 - 0,7 L/ha  0,6 L/ha = Prothioconazole 150 g as/ha + Difenoconazole 78 g as/ha 0,7 L/ha = Prothioconazole 175 g as/ha + Difenoconazole 91 g as/ha |  |
| 7 | ~~CEU:~~  PL, ~~DE, AT, UK, IE, NL, BE, CZ, SI,   SK, HU, RO~~ | Oats | F | Leaf Spot (*Mycosphaerella* *graminicola*) Brown Rust (*Puccinia* *recondita*) *Septoria* spp. Powdery mildew (*Erysiphe graminis*)  Groundbreak Disease (*Pseudocercosporella herpotrichoides*) | foliar spray | BBCH 32-69 | 2 | 14 | a) 0,7 b) 1,4 | a) Prothioconazole 175 + Difenoconazole 91 b) Prothioconazole 350 + Difenoconazole 182 | 200-300 | NA | 0,6 - 0,7 L/ha  0,6 L/ha = Prothioconazole 150 g as/ha + Difenoconazole 78 g as/ha 0,7 L/ha = Prothioconazole 175 g as/ha + Difenoconazole 91 g as/ha |  |
| 8 | ~~PL~~ | ~~OilSeed Rape~~ | ~~F~~ | ~~Sclerotinia stem rot (~~*~~Sclerotinia sclerotiorum~~*~~) Phoma leaf spot / Stem canker (~~*~~Leptosphaeria~~**~~maculans~~* ~~/~~ *~~L. biglobosa~~*~~)~~ *~~Alternaria brassicae~~* ~~Powdery mildew (~~*~~Erysiphe~~**~~cruciferarum~~*~~)~~ *~~Mycosphaerella~~* ~~Cylindrosporiose Light leaf spot (~~*~~Pyrenopeziza brassicae~~*~~)~~ | ~~foliar spray~~ | ~~Spring : just before mid-flowering (anticipating any significant petal fall)  Autumn: At the first sign of disease~~  ~~Until BBCH 69~~  ~~or~~  ~~BBCH 14 20 – 69~~  ~~Split~~  ~~BBCH14-69~~  **~~Up to BBCH 69 or BBCH 14-69~~** | ~~2~~ | ~~14 90~~  ~~Split 14~~ | ~~a) 0,6 b) 1,2~~ | ~~a) Prothioconazole 150 + Difenoconazole 78 b) Prothioconazole 300 + Difenoconazole 156~~ | ~~200-500~~ | ~~NA~~ | ~~1 application in autumn and/or 1 in spring  or 2 in autumn (repeat application in late autumn/winter when disease symptoms reoccur - spray interval 14-28 d or longer) or 2 applications in spring (Split applications: 1st = from yellow bud to early flowering; 2nd = 3 weeks after 1st ap)  0,3 L/ha f. by 0,3 L/ha if 2 applications in autumn OR 2 applications in spring~~ |  |

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

\*\* 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

Column 15: zRMS conclusion.

|  |  |
| --- | --- |
| A | Acceptable |
| R | Acceptable with further restriction |
| C | To be confirmed by cMS |
| N | Not acceptable / evaluation not possible |
| n.r. | Not relevant for section 3 |

# Background of authorization decision and risk management

## Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of light-yellow liquid, with an aromatic odour. It is not explosive and has no oxidising properties. The product is not flammable liquid and has a flash point of 102°C. It has a self-ignition temperature of 375°C. In aqueous solution, it has a pH value around 5.2 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 8 weeks at 40°C, neither the active ingredient content nor the technical properties were changed. The shelf life study showed that the product is stable for 2 years at ambient temperature when stored in PA/HDPE packaging material. Its technical characteristics are acceptable for a EC formulation.

**Implication for labelling resulting from technical properties assessment:**

**Recommended storage temperature: <40°C.**

The intended concentration of use is 0.12%v/v to 0.7%v/v.

However, in case of split application 2 x 0.3 l/ha (use 13-15) the lowest application concentration is 0.06%v/v.

The product is not classified for physical hazards of CLP regulation.

## Efficacy (Part B, Section 3)

IN233C1560 is a emulsifiable concentrate (EC) containing 250 g/L prothioconazole and 130 g/L difenoconazole. It is a new foliar fungicide treatment for use wheat, barley, triticale, rye, oat and oilseed rape. The proposed maximum rate of the product is 0.7 L/ha with a maximum of two applications for cereals and one application at 0.6 L/ha for oilseed rape. Data is presented from trials conducted in the Maritime (France, Germany and United Kingdom), the North-East (Poland) and the South-East (Bulgaria and Romania) EPPO zones during seasons 2020 and 2021.

**Preliminary tests:**

Preliminary range-finding tests are not required since IN233C1560 contains prothioconazole and difenoconazole which are existing active substances. However, justification of the co-formulation of these substances in a single product is required. The applicant provided data to compare the efficacy of IN233C1560 to already approved products only containing a single active substance. Based on presented trials, the applicant stated that efficacy was better, faster and longer-lasting control than the single active substance products. The applicant claims the ratio of 150 g a.s./ha of prothioconazole and 78 g a.s./ha of difenoconazole is the best compromise of active substances selected.

**Minimum effective dose**

The presented data correspond with the requirements of the EPPO Standard PP 1/225 (Minimum effective dose).

Data was presented in wheat, barley and oilseed rape conducted across the maritime, northeast and southeast EPPO climatic zones. The data demonstrated that the different dose reductions for all intended uses show a decrease of efficacy in cereals and oilseed rape diseases.

The results of MED tests demonstrated a dose rate of 0.6 L/ha as the minimum effective dose in wheat, barley and oilseed rape regardless of EPPO zone.

**EFFICACY**

Based on data provided, the following intended uses may be accepted:

**For Maritime EPPO zone:**

* *Septoria tritici* (SEPTTR), *Fusarium spp.* on winter wheat,
* *Puccinia hordei* (PUCCHD) on barley,
* *Sclerotinia sclerotiorum* (SCLESC) on oilseed rape (spring application).

**For South-East EPPO zone :**

* *Septoria tritici* (SEPTTR) on winter wheat
* *Pyrenophora teres* (PYRNTE) on barley

The concerned Member States of SE, based on national experiences, may consider whether data from the Maritime EPPO zone is appropriate to support the registration of IN233C1560 against *Fusarium spp*. on wheat and *Puccinia hordei* (PUCCHD) on barley.

**For North-East EPPO zone:**

* *Septoria tritici* (SEPTTR), *Fusarium spp*on winter wheat**,**
* *Pyrenophora teres* (PYRNTE) on barley.

For IN233C1560, an insufficient number of trials have been submitted, as specified in EPPO PP1/226, and because major crops and diseases are requested, specific data is required. EPPO PP1/226 states that 10 (range 6-15) trials are required for each EPPO zone (especially if it concerns a product with a new combination of active substances). Therefore, the following intended uses cannot be recommended for authorisation for the professional product:

**Wheat:**

*Puccinia triticina* (PUCCRT), *Puccinia recondita* (PUCCRE), *Puccinia striiformis* (PUCCST), *Puccinia striiformis* f. sp. tritici (PUCCSI), ***Fusarium sp\*.* (FUSASP) ,** *Erysiphe graminis* (ERYSGR), *Oculimacula spp*. (OLIMSP), *Drechslera tritici-repentis* (PYRNTR), *Septoria nodorum* (LEPTNO), and *Helminthosporium* (HELMSP).

**Barley**

*Rhynchosporium secalis* (RHYNSE), *Ramularia collo-cygni* (RAMUCC), *Helminthosporium* (HELMSP), *Erysiphe graminis* (ERYSGR), *Fusarium sp.* (FUSASP), ***Pyrenophora teres\*\**** (PYRNTE), ***Puccinia hordei*\*\*\*** (PUCCHD)**.**

**Triticale**

*Mycosphaerella graminicola* (SEPTTR), *Puccinia recondita* (PUCCRE), *Septoria sp.* (SEPTSP), *Erysiphe graminis* (ERYSGR), and *Pseudocercosporella herpotrichoides* (PSDCHE)

**Rye**

*Puccinia recondita* (PUCCRE), *Rhynchosporium secalis* (RHYNSE), *Erysiphe graminis* (ERYSGR), *Oculimacula spp.* (OLIMSP), *Leptosphaeria (syn. Septoria) nodorum* (LEPTNO), and *Mycosphaerella graminicola* (SEPTTR).

**Oat**

*Mycosphaerella graminicola* (SEPTTR), *Puccinia recondita (PUCCRE), Septoria spp. (SEPTSP), Erysiphe graminis (ERYSGR), Pseudocercosporella herpotrichoides (PSDCHE)*

**Oilseed rape**

***Sclerotinia sclerotiorum***(SCLESC)\*\*\*\* (), Plenodomus lingam / Plenodomus biglobosus (LEPTMA), *Alternaria brassicae* (ALTEBA), *Erysiphe cruciferarum* (ERYSCR), Mycosphaerella (1MYCOG), and *Cylindrosporiose/Pyrenopeziza brassicae* (CYLSSP/PYRPBR).

**\* insufficient for SE**

**\*\* insufficient for Maritime**

**\*\*\* insufficient for NE and SE**

**\*\*\*\*** **insufficient for NE and SE**

**Yield and Yield parameters:**

Based on the results presented, it can be concluded that IN233C1560 has no adverse effect on the quantitative and qualitative parameters of wheat, barley and oilseed rape yield if used according to label recommendations.

**Information on possible occurrence of the development of resistance:**

The applicant addresses all points of the EPPO Standard PP 1/213 *(Resistance risk analysis)* to evaluate the possible actual resistance risk of prothioconazole and difenoconazole.

Based on FRAC assessment the applicant stated the risk for the development of pathogen resistance against IN233C1560 as a medium. Overall, zRMS considers that the risk of developing resistance to prothioconazole and difenoconazole as a result of the proposed use of IN233C1560 is medium to high. A special resistance management system must be used for the application of the product.

**Phytotoxicity to host crop:**

No specific crop selectivity trials have been conducted in support of IN233C1560. All selectivity data have been generated from efficacy trials. Phytotoxicity was assessed in all efficacy trials in accordance with EPPO PP 1/135(4), evaluating the percentage of general phytotoxicity (% PHYGEN) at various assessment timings and describing symptoms when observed (% PHYCHL for chlorosis and % PHYCOL for discolouration). No phytotoxicity was recorded for any of these IN233C1560 treatments at any of the assessment timings in any of the trials in the Maritime, North-east or South-east climate zones. Based on the substantial evidence showing a lack of significant effects across the crops tested, it is considered that the proposed use on cereals and oilseed rape is unlikely to result in any significant adverse effects.

**Adverse effects on succeeding or adjacent crops:**

No trials were carried out to specifically investigate the possible adverse effects of IN233C1560 on succeeding crops. Data submitted within the ecotoxicology section demonstrating safety to non-target plants provide the necessary evidence of a lack of adverse effects to succeeding crops from the use of IN233C1560. Neither active substance has demonstrated ‘herbicidal activity’. Therefore, it is unlikely that applications of IN233C1560 will have any negative effects on adjacent and succeeding crops.

## Methods of analysis (Part B, Section 5)

### Analytical method for the formulation

The analytical methods for the determination of the active substances prothioconazole and difeno-conazole and their relevant impurities toluene and prothioconazole-desthio in the plant protection product IN233C1560 have been validated according to the Guidance Document SANCO/3030/99 rev. 5. Therefore, the analytical methods can be considered as acceptable.

### Analytical methods for residues

***For Prothioconazole:***

Methods for food and feed of plant origin:

Methods for determination of prothioconazole-desthio have been validated in High water content, High oil content, High acid content and High protein/high starch content (dry). Independent Laboratory Validation (ILV) ~~are ongoing~~ have been validated in High water content, High oil content, High acid content and High protein/high starch content (dry).

Methods for animal matrices:

*Will be covered by data that would be available/generated/finalised at the time of the renewal of the a.s.*

According to the commenting table, an overview on the acceptable methods and possible data gaps for analysis of prothioconazole in animal matrices is given.

Furthermore, regarding method for the monitoring residue in animal commodities, this was a data GAP of the active ingredient and it is currently under evaluation in the renewal process. This data point will be suitably addressed by the Applicant during the product renewal (Art 43). No additional data need to be provided by the applicant in the framework of the authorisation of the product.

Methods for soil:

Methods for determination of prothioconazole-desthio and its metabolite (prothioconazole-S-methyl) have been validated in soil.

Methods for water:

Methods for determination of prothioconazole and prothioconazole-desthio have been validated in drinking water.

Methods for determination of prothioconazole and prothioconazole-desthio and PCBA have been validated in surface water.

Methods for air:

Methods for determination of prothioconazole and prothioconazole-desthio have been validated in air.

Methods for body fluids and tissues:

*Will be covered by data that would be available/generated/finalised at the time of the renewal of the a.s.*

To argue the italic sentence, the applicant commented this data point during the commenting table. So, the applicant’s comment is:

“*A fully validated method for the determination of residues of difenoconazole in animal tissue is available at EU level and it is considered suitable for body tissues as well.*

*A method for the determination of residues of Difenoconazole in body fluids is currently handled at EU level in the process of renewal of the active substance This data point will be suitably addressed by the Applicant during the product renewal (Art 43).*

*No additional data need to be provided by the applicant in the framework of the authorisation of the product*.”

Method for honey:

Method for determination of prothioconazole and prothioconazole-desthio have been validated in the honey. ILV have also been validated in the honey.

***For Difenoconazole:***

Methods for food and feed of plant origin:

Methods for determination of difenoconazole have been validated in High water content, High oil content and High protein/high starch content (dry). Independent Laboratory Validation (ILV) ~~are ongoing~~ have been validated in High water content, High oil content, High acid content and High protein/high starch content (dry).

Methods for animal matrices:

*Will be covered by data that would be available/generated/finalised at the time of the renewal of the a.s.*

As stipulated in the commenting table, an overview on the acceptable methods and possible data gaps for analysis of Difenoconazole in animal matrices is given. No new/additional studies presented. Indeed, regarding method for the monitoring residue in animal commodities, this was a data GAP of the active ingredient and it is currently under evaluation in the renewal process.

A fully validated method for the determination of residues of difenoconazole in animal tissue is available at EU level and it is considered suitable for body tissues as well.

A method for the determination of residues of Difenoconazole in body fluids is required and this issue is currently handled at EU level in the process of renewal of the a.i.

No additional data need to be provided by the applicant in the framework of the authorisation of the product.

Methods for soil:

Methods for determination of difenoconazole (and its metabolite CGA205375) have been validated in soil.

Methods for water:

*Will be covered by data that would be available/generated/finalised at the time of the renewal of the a.s.*

As stipulated in the commenting table, an overview on the acceptable methods and possible data gaps for analysis of Difenoconazole in surface and drinking water is given. No new/additional studies presented. Indeed, regarding method for the monitoring residue in water, this was a data GAP of the active ingredient and it is currently under evaluation in the renewal process.

No additional data need to be provided by the applicant in the framework of the authorisation of the product.

Methods for air:

A method of analysis for air is not required because the active substance is not a volatile substance.

Methods for body fluids and tissues:

A method of analysis for body fluids and tissues is not required because the active substance is not classified as toxic or very toxic.

**zRMS**:

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

Method for honey:

Method for determination of difenoconazole have been validated in the honey. ILV have also been validated in the honey.

|  |  |
| --- | --- |
| Comments of zRMS: | It has been finally accepted. |

## Mammalian toxicology (Part B, Section 6)

Table 3.4‑1: Summary of risk assessment for operators, workers, residents and bystanders for product IN233C1560/ AVTAR

|  | Result | PPE / Risk mitigation measures |
| --- | --- | --- |
| Operators | Acceptable | Vehicle-mounted application.  Work wear covering arms, body and legs during mixing/loading and application, protective gloves, eye protection/face protection during mixing/loading operations or when directly contacting surface of equipment contaminated with concentrated product.  ~~Vehicle-mounted application with a drift reduction nozzle.~~  ~~Use gloves during handling, mixing and loading.~~ |
| Workers | Acceptable | None |
| Residents | Acceptable | None |
| Bystanders | Acceptable | None |

No unacceptable risk for operators, workers, residents and bystanders was identified when the product is used as intended and provided that the PPE/ risk mitigation measures stated in Table 3.4‑1 are applied.

### Acute toxicity

A summary of the toxicological evaluation for AVTAR is given in the following tables. Full summaries of studies on the product that have not been previously considered within an EU peer review process are described in detail in Appendix 2 of Part B Section 6.

Table 3.4‑2: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for AVTAR

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of test, species, model system (Guideline) | Result | Acceptability | Classification  (acc. to the criteria in Reg. 1272/2008) | Reference |
| LD50 oral | N/A | Yes | None | Classification by calculation |
| LD50 dermal | N/A | Yes | None | Classification by calculation |
| LC50 inhalation | N/A | Yes | None  ~~Acute Tox. Inhalation Category 3 (H331)~~) | Classification by calculation |
| Skin irritation, Reconstructed Human Epidermis  (OECD 439) | Irritant | Yes | Skin Irr, Cat 2 (H315) | Cattaneo A., 2021  KCP 7.1.4/01 |
| Skin corrosion, Reconstructed Human Epidermis  (OECD 431) | Non corrosive | Yes | None | Cattaneo A., 2021  KCP 7.1.4/02 |
| Eye irritation, Bovine  (OECD 437) | Irritant | Yes | Eye Irr, Cat 2 (H319) | Cattaneo A., 2021  KCP 7.1.5/01 |
| Eye irritation & corrosion | None | Yes | None | Cattaneo A., 2021  KCP 7.1.5/02 |
| Skin sensitisation | N/A | Yes | None | Classification by calculation |
| Supplementary studies for combinations of plant protection products | Not required |  |  |  |

N/A = not applicable

Additional toxicological information relevant for classification/labelling of AVTAR

|  | Substance (concentration in product, % w/w) | Classification of the  substance  (acc. to the criteria in Reg. 1272/2008) | Reference | Classification of product (acc. to the criteria in Reg. 1272/2008) |
| --- | --- | --- | --- | --- |
| Toxicological properties of active substance(s) (relevant for classification of product) | Difenoconazole  (CAS No. 119446-68-3, ≈11.40% (w/w)) | H302 Acute Tox. 4  H319 Eye Irritation 2 | MSDS\*\* | H319 Eye Irrit. 2  ~~H302 Acute tox. 4~~ |
| Difenoconazole  (CAS No. 119446-68-3, ≈11.40% (w/w)) | Carc. 2, H351  Acute Tox. 4; H302  Eye Irrit. 2, H319 | RAC opinion adopted on  10 June 2021 | Eye Irrit. 2, H319  Carc. 2; H351 Suspected of causing cancer |
| Prothioconazole  (CAS No. 178928-70-6, ≈ 21.94%(w/w)) | None | MSDS\*\* | None |
| Toxicological properties of non-active substance(s) (relevant for classification of product) | Geronol TE 777  (20-30% (w/w)) | H315: Causes skin irritation. | MSDS\*\* | H315: Causes skin irritation according to in vitro studies performed on the product |
| H318: Causes serious eye damage. | MSDS\*\* | ~~H318: Causes serious eye damage according to in vitro studies performed on the product~~  Eye Irrit. 2, H319 Causes serious eye irritation -  based on calculation and in vitro studies |
| Further toxicological information | No data – not required | / | / | / |

### Operator exposure

Table 3.4‑3: Exposure models for intended uses

|  |  |
| --- | --- |
| Critical use(s) | Cereal (max 0.7 L of AVTAR/ha per application)  Oilseed rape (max 0.6 L of AVTAR/ha per application) |
| Model(s) | Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874  calculator version: 30/03/2015 |

***Assuming 50% conversion from the parent prothioconazole to the metabolite prothioconazole-desthio:***

**Operators.** The application of a product IN233C1560 / AVTAR does not pose an unacceptable risk to the health of operator using tractor-mounted/trailed boom sprayer without drift reduction technology for application of the product in line with its intended use within good agricultural practice providing that he is wearing a work wear (with arms, body and legs covered) and protective gloves during M/L. It is noted that the product is classified as Skin Irrit. 2 and Eye Irrit 2 thus the operator should wear a work wear covering arms, body and legs during mixing/loading and application, protective gloves, eye protection/face protection during mixing/loading operations or when directly contacting surface of equipment contaminated with concentrated product (see part B6).

Table 3.4‑4: Estimated operator exposure (acute exposure)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | ~~Difenoconazole~~ | | ~~Prothioconazole~~ | | ~~Prothioconazole-desthio~~ | |
| ~~Model data~~ | ~~Level of PPE~~ | ~~Total absorbed dose  (mg/kg/day)~~ | ~~% of systemic AAOEL~~ | ~~Total absorbed dose  (mg/kg/day)~~ | ~~% of systemic AAOEL~~ | ~~Total absorbed dose  (mg/kg/day)~~ | ~~% of systemic AAOEL~~ |
| ~~Tractor mounted with drift reduction boom spray application outdoors to low crops~~ | | | | | | | |
| ~~Cereals~~ | | | | | | | |
| ~~Application rate~~ | | ~~0.091 kg a.s./ha~~ | | ~~0.175 kg a.s./ha~~ | | ~~0.159 kg a.s./ha~~ | |
| **~~Spray application outdoor~~** ~~(AOEM~~**~~;~~** ~~95~~~~th~~ ~~percentile)~~  ~~Body weight: 60 kg~~ | ~~Potential exposure~~ | ~~0.0954~~ | ~~59.63~~ | ~~0.0182~~ | **~~182.06~~** | ~~0.0064~~ | ~~63.69~~ |
| ~~Work wear (arms, body and legs covered) M/L and A~~ | ~~0.0377~~ | ~~23.59~~ | ~~0.0117~~ | **~~116.96~~** | ~~0.0061~~ | ~~61.52~~ |
| ~~Work wear (arms, body and legs covered) M/L and A + gloves during M/L~~ | ~~0.0083~~ | ~~5.18~~ | ~~0.0073~~ | ~~72.81~~ | ~~0.0061~~ | ~~61.52~~ |
| ~~Oilseed rape~~ | | | | | | | |
| ~~Application rate~~ | | ~~0.078 kg a.s./ha~~ | | ~~0.150 kg a.s./ha~~ | | ~~0.136 kg a.s./ha~~ | |
| **~~Spray application outdoor~~** ~~(AOEM~~**~~;~~** ~~95~~~~th~~ ~~percentile)~~  ~~Body weight: 60 kg~~ | ~~Potential exposure~~ | ~~0.0887~~ | ~~55.43~~ | ~~0.0167~~ | **~~166.70~~** | ~~0.0057~~ | ~~57.26~~ |
| ~~Work wear (arms, body and legs covered) M/L and A~~ | ~~0.0335~~ | ~~20.96~~ | ~~0.0105~~ | **~~104.65~~** | ~~0.0055~~ | ~~55.40~~ |
| ~~Work wear (arms, body and legs covered) M/L and A + gloves during M/L~~ | ~~0.0074~~ | ~~4.63~~ | ~~0.0065~~ | ~~65.47~~ | ~~0.0055~~ | ~~55.40~~ |

NR = not required

Table 3.4‑5: Estimated operator exposure (longer term exposure)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Difenoconazole | | Prothioconazole | | Prothioconazole-desthio | |
| Model data | Level of PPE | Total absorbed dose  (mg/kg/day) | % of systemic AOEL | Total absorbed dose  (mg/kg/day) | % of systemic AOEL | Total absorbed dose  (mg/kg/day) | % of systemic AOEL |
| Tractor mounted boom spray application outdoors to low crops | | | | | | | |
| Cereals | | | | | | | |
| Application rate | | 0.091 kg a.s./ha | | 0.175 kg a.s./ha | | 0.159 kg a.s./ha | |
| **Spray application** (AOEM**;** 75th percentile)  Body weight: 60 kg | Potential exposure | 0.0149 | 9.33 | 0.0037 | 1.86 | 0.0015 | 14.74 |
| Work wear (arms, body and legs covered) M/L and A | 0.0094 | 5.89 | 0.0027 | 1.35 | 0.0013 | 12.60 |
| Work wear (arms, body and legs covered) M/L and A + gloves during M/L | 0.0014 | 0.88 | 0.0015 | 0.75 | 0.0013 | 12.60 |
| **Spray application** (AOEM**;** 75th percentile)  Body weight: 60 kg | Potential exposure taking dermal absorption of prothioconazole from the concentrate 0.3% and from dilution 15% | - | - | 0.0039 | 1.98 |  |  |
|  | Work wear (arms, body and legs covered) M/L and A + gloves during M/L |  |  | 0.0016 | 0.80 |  |  |
|  |  |  |  |  |  |  |  |
| Oilseed rape | | | | | | | |
| Application rate | | 0.078 kg a.s./ha | | 0.150 kg a.s./ha | | 0.136 kg a.s./ha | |
| **Spray application outdoor** (AOEM**;** 95th percentile)  Body weight: 60 kg | Potential exposure | 0.1327 | 8.30 | 0.0033 | 1.63 | 0.0013 | 12.76 |
| Work wear (arms, body and legs covered) M/L and A | 0.0083 | 5.21 | 0.0024 | 1.18 | 0.0011 | 10.92 |
| Work wear (arms, body and legs covered) M/L and A + gloves during M/L | 0.0012 | 0.77 | 0.0013 | 0.65 | 0.0011 | 10.92 |
| Potential exposure taking dermal absorption of prothioconazole from the concnetrate 0.3% and from dilution 15% |  |  | 0.0035 | 1.74% |  |  |
| Work wear (arms, body and legs covered) M/L and A + gloves during M/L |  |  | 0.0014 | 0.69 |  |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | ~~Difenoconazole~~ | | ~~Prothioconazole~~ | | ~~Prothioconazole-desthio~~ | |
| ~~Model data~~ | ~~Level of PPE~~ | ~~Total absorbed dose  (mg/kg/day)~~ | ~~% of systemic AOEL~~ | ~~Total absorbed dose  (mg/kg/day)~~ | ~~% of systemic AOEL~~ | ~~Total absorbed dose  (mg/kg/day)~~ | ~~% of systemic AOEL~~ |
| ~~Tractor mounted boom spray application outdoors to low crops~~ | | | | | | | |
| ~~Cereals~~ | | | | | | | |
| ~~Application rate~~ | | ~~0.091 kg a.s./ha~~ | | ~~0.175 kg a.s./ha~~ | | ~~0.159 kg a.s./ha~~ | |
| **~~Spray application~~** ~~(AOEM~~**~~;~~** ~~75~~~~th~~ ~~percentile)~~  ~~Body weight: 60 kg~~ | ~~Potential exposure~~ | ~~0.0149~~ | ~~9.33~~ | ~~0.0037~~ | ~~1.86~~ | ~~0.0015~~ | ~~14.74~~ |
| ~~Work wear (arms, body and legs covered) M/L and A~~ | ~~0.0094~~ | ~~5.89~~ | ~~0.0027~~ | ~~1.35~~ | ~~0.0013~~ | ~~12.60~~ |
| ~~Work wear (arms, body and legs covered) M/L and A + gloves during M/L~~ | ~~0.0014~~ | ~~0.88~~ | ~~0.0015~~ | ~~0.75~~ | ~~0.0013~~ | ~~12.60~~ |
| ~~Oilseed rape~~ | | | | | | | |
| ~~Application rate~~ | | ~~0.078 kg a.s./ha~~ | | ~~0.150 kg a.s./ha~~ | | ~~0.136 kg a.s./ha~~ | |
| **~~Spray application outdoor~~** ~~(AOEM~~**~~;~~** ~~95~~~~th~~ ~~percentile)~~  ~~Body weight: 60 kg~~ | ~~Potential exposure~~ | ~~0.1327~~ | ~~8.30~~ | ~~0.0033~~ | ~~1.63~~ | ~~0.0013~~ | ~~12.76~~ |
| ~~Work wear (arms, body and legs covered) M/L and A~~ | ~~0.0083~~ | ~~5.21~~ | ~~0.0024~~ | ~~1.18~~ | ~~0.0011~~ | ~~10.92~~ |
| ~~Work wear (arms, body and legs covered) M/L and A + gloves during M/L~~ | ~~0.0012~~ | ~~0.77~~ | ~~0.0013~~ | ~~0.65~~ | ~~0.0011~~ | ~~10.92~~ |

NR = not required

**zRMS**:

The estimation of potential exposure of operator and of operator wearing a work wear (with arms, body and legs covered) and protective gloves to both active substances of a product IN233C1560 / AVTAR applied on a field of cereals at dose of 0.7 L product/ha, using tractor-mounted/trailed boom sprayer with drift reduction technology, calculated with the EFSA AOEM demonstrates that a potential exposure of operator and an exposure of operator wearing a work wear (with arms, body and legs covered) and gloves is equal respectively to 9.33% and to 0.88% of AOEL for Difenconazole, and to 1.98% and to 0.80 % of AOEL for Prothioconazole, and to 14.74 % and 12.60 % of ARfD for Prothioconazole used as AOEL for Prothioconazole-desthio an environmental metabolite of Prothioconazole. The sum of potential exposure of operator and exposure of operator wearing a work wear (with arms, body and legs covered) to both active substances and to metabolite Prothioconazole-desthio expressed as percentage of their AOELs is below 100%, therefore the application of product IN233C1560 / AVTAR does not pose an unacceptable risk to the health of operator applying a product IN233C1560 / AVTAR on a field of cereals according to its intended use on cereals within good agricultural practice.

The estimation of potential exposure of operator and of operator wearing a work wear (with arms, body and legs covered) and protective gloves to both active substances of a product IN233C1560 / AVTAR applied on a field of oilseed rape at dose of 0.6 L product/ha, using tractor-mounted/trailed boom sprayer with drift reduction technology, calculated with the EFSA AOEM demonstrates that a potential exposure of operator and an exposure of operator wearing a work wear (with arms, body and legs covered) and gloves is equal respectively to 8.30% and to 0.0012% of AOEL for Difenconazole, and to 1.74% and to 0.69 % of AOEL for Prothioconazole, and to 12.76 % and 10.92 % of ARfD for Prothioconazole used as surrogate AOEL for Prothioconazole-desthio an environmental metabolite of Prothioconazole. The sum of potential exposure of operator and exposure of operator wearing a work wear (with arms, body and legs covered) to both active substances and to metabolite Prothioconazole-desthio expressed as percentage of their AOELs is below 100%, therefore the application of product IN233C1560 / AVTAR does not pose an unacceptable risk to the health of operator applying a product IN233C1560 / AVTAR on a field of oilseed rape according to its intended use on cereals within good agricultural practice.

No operator acute exposure estimation for Difenconazole and for Prothioconazole is required since no acute acceptable operator exposure value (AAOEL) has be set for any of this active substance nor for metabolite Prothioconazole-desthio. Therefore, as indicated in the EU guidance (SANTE-10832-2015 rev. 1.7; 24 January 2017), no unacceptable risk is expected for operator due to short-term single exposure to Difenconazole and to Prothioconazole, and to metabolite Prothioconazole-desthio as a result of application of a product IN233C1560 / AVTAR with accordance with intended use within good agricultural practice.

Summing up the application of a product IN233C1560 / AVTAR does not pose an unacceptable risk to the health of operator using tractor-mounted/trailed boom sprayer with drift reduction technology for application of the product in line with its intended use within good agricultural practice. Since the product classified as Skin Irrit. 2 and Eye Irrit 2 the operator should wear a work wear covering arms, body and legs during mixing/loading and application, protective gloves, eye protection/face protection during mixing/loading operations or when directly contacting surface of equipment contaminated with concentrated product.

### Worker exposure

***Assuming 50% conversion from the parent prothioconazole to the metabolite prothioconazole-desthio:***

**Workers:**

The application of a product IN233C1560 / AVTAR on a field of cereals at dose of 0.7 L product/ha or on a field of oilseed rape at dose of 0.6 L product/ha, using tractor-mounted/trailed boom sprayer without drift reduction technology in line with GAP does not pose an unacceptable health risk for worker wearing a work wear (with arms, body and legs covered) and entering a treated field for 2hrs inspection after a spray has dried up ( see part B6).

Table 3.4‑6: Exposure models for intended uses

|  |  |
| --- | --- |
| Critical use(s) | Cereal (max 0.7 L of AVTAR/ha per application)  Oilseed rape (max 0.6 L of AVTAR/ha per application) |
| Model | Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874  calculator version: 30/03/2015 |

Table 3.4‑7: Estimated worker exposure

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Difenoconazole | | Prothioconazole | | Prothioconazole-desthio | |
| **Model data** | Level of PPE | Total absorbed dose (mg/kg bw/day) | % of systemic AAOEL | Total absorbed dose (mg/kg bw/day) | % of systemic AAOEL | Total absorbed dose (mg/kg bw/day) | % of systemic AAOEL |
| Inspection, Irrigation  Outdoor  Work rate: 2 hours/day  DT50: 30 days  DFR: 3 µg/cm2/kg a.s./ha | | | | | | | |
| Cereals | | | | | | | |
| Application rate | | 0.091 kg a.s./ha | | 0.175 kg a.s./ha | | 0.159 kg a.s./ha | |
| Body weight: 60 kg | Potential  TC:12500cm2/person/h | 0.0431 | 26.96 | 0.0528 | 26.39 | 0.0445 | **445.34** |
| Work wear (arms, body and legs covered)  TC: 1400 cm2/person/h | 0.0048 | 3.02 | 0.0059 | 2.96 | 0.0050 | 49.88 |
| Potential  TC:12500cm2/person/h assuming dermal absorption of prothioconazole from concentrate 0.3% and from dilution 15% | - | - | 0.0565 | 28.28% |  |  |
| Work wear (arms, body and legs covered)  TC: 1400 cm2/person/h  assuming dermal absorption of prothioconazole from concentrate 0.3% and from dilution 15% | - | - | 0.0063 | 3.17% |  |  |
| Oilseed rape | | | | | | | |
| Application rate | | 0.078 kg a.s./ha | | 0.150 kg a.s./ha | | 0.136 kg a.s./ha | |
| Body weight: 60 kg | Potential  TC:12500cm2/person/h | 0.0370 | 23.11 | 0.0452 | 22.62 | 0.0381 | **380.92** |
| Work wear (arms, body and legs covered)  TC: 1400 cm2/person/h | 0.0041 | 2.59 | 0.0051 | 2.53 | 0.0043 | 42.66 |
| Potential  TC:12500cm2/person/h assuming dermal absorption of prothioconazole from concentrate 0.3% and from dilution 15% | - | - | 0.0485 | 24.24% |  |  |
| Work wear (arms, body and legs covered)  TC: 1400 cm2/person/h  assuming dermal absorption of prothioconazole from concentrate 0.3% and from dilution 15% | - | - | 0.0054 | 2.71% |  |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | ~~Difenoconazole~~ | | ~~Prothioconazole~~ | | ~~Prothioconazole-desthio~~ | |
| **~~Model data~~** | ~~Level of PPE~~ | ~~Total absorbed dose (mg/kg bw/day)~~ | ~~% of systemic AAOEL~~ | ~~Total absorbed dose (mg/kg bw/day)~~ | ~~% of systemic AAOEL~~ | ~~Total absorbed dose (mg/kg bw/day)~~ | ~~% of systemic AAOEL~~ |
| ~~Inspection, Irrigation~~  ~~Outdoor~~  ~~Work rate: 2 hours/day~~  ~~DT~~~~50~~~~: 30 days~~  ~~DFR: 3 µg/cm~~~~2~~~~/kg a.s./ha~~ | | | | | | | |
| ~~Cereals~~ | | | | | | | |
| ~~Application rate~~ | | ~~0.091 kg a.s./ha~~ | | ~~0.175 kg a.s./ha~~ | | ~~0.159 kg a.s./ha~~ | |
| ~~Body weight: 60 kg~~ | ~~Potential~~  ~~TC:12500cm~~~~2~~~~/person/h~~ | ~~0.0431~~ | ~~26.96~~ | ~~0.0528~~ | ~~26.39~~ | ~~0.0445~~ | **~~445.34~~** |
| ~~Work wear (arms, body and legs covered)~~  ~~TC: 1400 cm~~~~2~~~~/person/h~~ | ~~0.0048~~ | ~~3.02~~ | ~~0.0059~~ | ~~2.96~~ | ~~0.0050~~ | ~~49.88~~ |
| ~~Oilseed rape~~ | | | | | | | |
| ~~Application rate~~ | | ~~0.078 kg a.s./ha~~ | | ~~0.150 kg a.s./ha~~ | | ~~0.136 kg a.s./ha~~ | |
| ~~Body weight: 60 kg~~ | ~~Potential~~  ~~TC:12500cm~~~~2~~~~/person/h~~ | ~~0.0370~~ | ~~23.11~~ | ~~0.0452~~ | ~~22.62~~ | ~~0.0381~~ | **~~380.92~~** |
| ~~Work wear (arms, body and legs covered)~~  ~~TC: 1400 cm~~~~2~~~~/person/h~~ | ~~0.0041~~ | ~~2.59~~ | ~~0.0051~~ | ~~2.53~~ | ~~0.0043~~ | ~~42.66~~ |

**zRMS**:

The estimation of potential exposure of worker and of worker wearing a work wear (with arms, body and legs covered) to both active substances of a product IN233C1560 / AVTAR applied on a field of cereals at dose of 0.7 L product/ha, using tractor-mounted/trailed boom sprayer with drift reduction technology, calculated with the EFSA AOEM demonstrates that a potential exposure of worker and an exposure of worker wearing a work wear (with arms, body and legs covered) is equal respectively to 29.96% and to 3.02% of AOEL for Difenconazole, and to 28.28% and to 3.17 % of AOEL for Prothioconazole, and to 445.34% and 49.88% of ARfD for Prothioconazole used as AOEL for Prothioconazole-desthio an environmental metabolite of Prothioconazole. The sum of exposures of worker wearing a work wear (with arms, body and legs covered) to both active substances and to metabolite Prothioconazole-desthio expressed as percentage of their AOELs is below 100%, therefore the application of product IN233C1560 / AVTAR does not pose an unacceptable risk to the health of worker entering for 2hrs inspection a field of cereals treated with a product IN233C1560 / AVTAR according to its intended use on cereals within good agricultural practice.

The estimation of potential exposure of worker and of worker wearing a work wear (with arms, body and legs covered) to both active substances of a product IN233C1560 / AVTAR applied on a field of oilseed rape at dose of 0.6 L product/ha, using tractor-mounted/trailed boom sprayer with drift reduction technology, calculated with the EFSA AOEM demonstrates that a potential exposure of worker and an exposure of worker wearing a work wear (with arms, body and legs covered) is equal respectively to 23.11% and to 2.59% of AOEL for Difenconazole, and to 24.24 % and to 2.71 % of AOEL for Prothioconazole, and to 380.92% and 42.66% of ARfD for Prothioconazole used as AOEL for Prothioconazole-desthio an environmental metabolite of Prothioconazole. The sum of exposures of worker wearing a work wear (with arms, body and legs covered) to both active substances and to metabolite Prothioconazole-desthio expressed as percentage of their AOELs is below 100%, therefore the application of product IN233C1560 / AVTAR does not pose an unacceptable risk to the health of worker entering for 2hrs inspection a field of oilseed rape treated with a product IN233C1560 / AVTAR according to its intended use on oilseed rape within good agricultural practice.

Summing up application of a product IN233C1560 / AVTAR on a field of cereals at dose of 0.7 L product/ha or on a field of oilseed rape at dose of 0.6 L product/ha, using tractor-mounted/trailed boom sprayer with drift reduction technology in line with GAP does not pose an unacceptable health risk for worker entering a treated field for 2hrs inspection after a spray has dried up.

### Bystander and resident exposure

***Assuming 50% conversion from the parent prothioconazole to the metabolite prothioconazole-desthio:***

**Residents:**

The application of application of a product IN233C1560 / AVTAR on a field of cereals at dose of 0.7 L product/ha or on a field of oilseed rape at dose of 0.6 L product/ha, using tractor-mounted/trailed boom sprayer without drift reduction technology in line with GAP does not pose an unacceptable health risk for residents and bystanders.

Table 3.4‑8: Exposure models for intended uses

|  |  |
| --- | --- |
| Critical use(s) | Cereal (max 0.7 L of AVTAR/ha per application)  Oilseed rape (max 0.6 L of AVTAR/ha per application) |
| Model | Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874  calculator version: 30/03/2015 |

Table 3.4‑9: Estimated resident exposure (long term exposure)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Difenoconazole | | Prothioconazole | | **Prothioconazole-desthio** | |
| Model data |  | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL |
| Tractor mounted boom spray application outdoors to low crops  Buffer zone: 2-3 (m)  Drift reduction technology: yes  DT50: 30 days  DFR: 3 µg/cm2/kg a.s./ha  Interval between treatments: 14 days | | | | | | | |
| Cereals | | | | | | | |
| Number of applications and application rate | | 2 x 0.091kg a.s./ha | | 2 x 0.175 kg a.s./ha | | 2 x 0.159 kg a.s./ha | |
| Resident child  Body weight: 10 kg | Drift (75th perc.) | 0.0027 | 1.68 | 0.0033 | 1.65 | 0.0007 | 6.97 |
| Vapour (75th perc.) | 0.0010 | 0.67 | 0.0011 | 0.54 | 0.0011 | 10.70 |
| Deposits (75th perc.) | 0.0003 | 0.20 | 0.0004 | 0.21 | 0.0004 | 3.71 |
| Re-entry (75th perc.) | 0.0058 | 3.64 | 0.0071 | 3.56 | 0.0060 | 60.12 |
| **Sum (mean)** | 0.0074 | 4.64 | 0.0089 | 4.44 | 0.0065 | 65.20 |
| **Sum (mean) taking dermal absorption of prothioconazole 0.3% for concentrate and 15% for dilution** |  |  | 0.0079 | 3.99% |  |  |
| Resident adult  Body weight: 60 kg | Drift (75th perc.) | 0.0006 | 0.40 | 0.0008 | 0.39 | 0.0002 | 1.66 |
| Vapour (75th perc.) | 0.0002 | 0.14 | 0.0002 | 0.12 | 0.0002 | 2.30 |
| Deposits (75th perc.) | 0.0001 | 0.07 | 0.0001 | 0.07 | 0.0001 | 1.21 |
| Re-entry (75th perc.) | 0.0032 | 2.02 | 0.0040 | 1.98 | 0.0033 | 33.40 |
| **Sum (mean)** | 0.0032 | 2.00 | 0.0039 | 1.93 | 0.0031 | 30.61 |
| **Sum (mean) taking dermal absorption of prothioconazole 0.3% for concentrate and 15% for dilution** |  |  | 0.0038 | 1.91% |  |  |
| Oilseed rape | | | | | | | |
| Number of applications and application rate | | 2 x 0.078 kg a.s./ha | | 2 x 0.150 kg a.s./ha | | 2 x 0.136 kg a.s./ha | |
| Resident child  Body weight: 10 kg | Drift (75th perc.) | 0.0023 | 1.44 | 0.0028 | 1.42 | 0.0006 | 5.96 |
| Vapour (75th perc.) | 0.0011 | 0.67 | 0.0011 | 0.54 | 0.0011 | 10.70 |
| Deposits (75th perc.) | 0.0003 | 0.17 | 0.0004 | 0.18 | 0.0003 | 3.17 |
| Re-entry (75th perc.) | 0.005 | 3.12 | 0.0061 | 3.05 | 0.0051 | 51.42 |
| **Sum (mean)** | 0.0065 | 4.08 | 0.0078 | 3.89 | 0.0057 | 57.31 |
|  | **Sum (mean) taking dermal absorption of prothioconazole 0.3% for concentrate and 15% for dilution** |  |  | 0.0069 | 3.45 |  |  |
| Resident adult  Body weight: 60 kg | Drift (75th perc.) | 0.0006 | 0.34 | 0.0007 | 0.34 | 0.0001 | 1.42 |
| Vapour (75th perc.) | 0.00023 | 0.14 | 0.0002 | 0.12 | 0.0002 | 2.30 |
| Deposits (75th perc.) | 0.0001 | 0.06 | 0.0001 | 0.06 | 0.0001 | 1.04 |
| Re-entry (75th perc.) | 0.0027 | 1.73 | 0.0034 | 1.70 | 0.0029 | 28.57 |
| **Sum (mean)** | 0.0028 | 1.74 | 0.0033 | 1.67 | 0.0027 | 26.52 |
|  | **Sum (mean) taking dermal absorption of prothioconazole 0.3% for concentrate and 15% for dilution** |  |  | 0.0033 | 1.65 |  |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | ~~Difenoconazole~~ | | ~~Prothioconazole~~ | | **~~Prothioconazole-desthio~~** | |
| ~~Model data~~ |  | ~~Total absorbed dose (mg/kg bw/day)~~ | ~~% of systemic AOEL~~ | ~~Total absorbed dose (mg/kg bw/day)~~ | ~~% of systemic AOEL~~ | ~~Total absorbed dose (mg/kg bw/day)~~ | ~~% of systemic AOEL~~ |
| ~~Tractor mounted boom spray application outdoors to low crops~~  ~~Buffer zone: 2-3 (m)~~  ~~Drift reduction technology: yes~~  ~~DT~~~~50~~~~: 30 days~~  ~~DFR: 3 µg/cm~~~~2~~~~/kg a.s./ha~~  ~~Interval between treatments: 14 days~~ | | | | | | | |
| ~~Cereals~~ | | | | | | | |
| ~~Number of applications and application rate~~ | | ~~2 x 0.091kg a.s./ha~~ | | ~~2 x 0.175 kg a.s./ha~~ | | ~~2 x 0.159 kg a.s./ha~~ | |
| ~~Resident child~~  ~~Body weight: 10 kg~~ | ~~Drift (75~~~~th~~ ~~perc.)~~ | ~~0.0027~~ | ~~1.68~~ | ~~0.0033~~ | ~~1.65~~ | ~~0.0007~~ | ~~6.97~~ |
| ~~Vapour (75~~~~th~~ ~~perc.)~~ | ~~0.0010~~ | ~~0.67~~ | ~~0.0011~~ | ~~0.54~~ | ~~0.0011~~ | ~~10.70~~ |
| ~~Deposits (75~~~~th~~ ~~perc.)~~ | ~~0.0003~~ | ~~0.20~~ | ~~0.0004~~ | ~~0.21~~ | ~~0.0004~~ | ~~3.71~~ |
| ~~Re-entry (75~~~~th~~ ~~perc.)~~ | ~~0.0058~~ | ~~3.64~~ | ~~0.0071~~ | ~~3.56~~ | ~~0.0060~~ | ~~60.12~~ |
| **~~Sum (mean)~~** | ~~0.0074~~ | ~~4.64~~ | ~~0.0089~~ | ~~4.44~~ | ~~0.0065~~ | ~~65.20~~ |
| ~~Resident adult~~  ~~Body weight: 60 kg~~ | ~~Drift (75~~~~th~~ ~~perc.)~~ | ~~0.0006~~ | ~~0.40~~ | ~~0.0008~~ | ~~0.39~~ | ~~0.0002~~ | ~~1.66~~ |
| ~~Vapour (75~~~~th~~ ~~perc.)~~ | ~~0.0002~~ | ~~0.14~~ | ~~0.0002~~ | ~~0.12~~ | ~~0.0002~~ | ~~2.30~~ |
| ~~Deposits (75~~~~th~~ ~~perc.)~~ | ~~0.0001~~ | ~~0.07~~ | ~~0.0001~~ | ~~0.07~~ | ~~0.0001~~ | ~~1.21~~ |
| ~~Re-entry (75~~~~th~~ ~~perc.)~~ | ~~0.0032~~ | ~~2.02~~ | ~~0.0040~~ | ~~1.98~~ | ~~0.0033~~ | ~~33.40~~ |
| **~~Sum (mean)~~** | ~~0.0032~~ | ~~2.00~~ | ~~0.0039~~ | ~~1.93~~ | ~~0.0031~~ | ~~30.61~~ |
| ~~Oilseed rape~~ | | | | | | | |
| ~~Number of applications and application rate~~ | | ~~2 x 0.078 kg a.s./ha~~ | | ~~2 x 0.150 kg a.s./ha~~ | | ~~2 x 0.136 kg a.s./ha~~ | |
| ~~Resident child~~  ~~Body weight: 10 kg~~ | ~~Drift (75~~~~th~~ ~~perc.)~~ | ~~0.0023~~ | ~~1.44~~ | ~~0.0028~~ | ~~1.42~~ | ~~0.0006~~ | ~~5.96~~ |
| ~~Vapour (75~~~~th~~ ~~perc.)~~ | ~~0.0011~~ | ~~0.67~~ | ~~0.0011~~ | ~~0.54~~ | ~~0.0011~~ | ~~10.70~~ |
| ~~Deposits (75~~~~th~~ ~~perc.)~~ | ~~0.0003~~ | ~~0.17~~ | ~~0.0004~~ | ~~0.18~~ | ~~0.0003~~ | ~~3.17~~ |
| ~~Re-entry (75~~~~th~~ ~~perc.)~~ | ~~0.005~~ | ~~3.12~~ | ~~0.0061~~ | ~~3.05~~ | ~~0.0051~~ | ~~51.42~~ |
| **~~Sum (mean)~~** | ~~0.0065~~ | ~~4.08~~ | ~~0.0078~~ | ~~3.89~~ | ~~0.0057~~ | ~~57.31~~ |
| ~~Resident adult~~  ~~Body weight: 60 kg~~ | ~~Drift (75~~~~th~~ ~~perc.)~~ | ~~0.0006~~ | ~~0.34~~ | ~~0.0007~~ | ~~0.34~~ | ~~0.0001~~ | ~~1.42~~ |
| ~~Vapour (75~~~~th~~ ~~perc.)~~ | ~~0.00023~~ | ~~0.14~~ | ~~0.0002~~ | ~~0.12~~ | ~~0.0002~~ | ~~2.30~~ |
| ~~Deposits (75~~~~th~~ ~~perc.)~~ | ~~0.0001~~ | ~~0.06~~ | ~~0.0001~~ | ~~0.06~~ | ~~0.0001~~ | ~~1.04~~ |
| ~~Re-entry (75~~~~th~~ ~~perc.)~~ | ~~0.0027~~ | ~~1.73~~ | ~~0.0034~~ | ~~1.70~~ | ~~0.0029~~ | ~~28.57~~ |
| **~~Sum (mean)~~** | ~~0.0028~~ | ~~1.74~~ | ~~0.0033~~ | ~~1.67~~ | ~~0.0027~~ | ~~26.52~~ |

Table 3.4‑10: Estimated bystander exposure (acute exposure)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | ~~Difenoconazole~~ | | ~~Prothioconazole~~ | | ~~Prothioconazole-desthio~~ | |
| ~~Model data~~ |  | ~~Total absorbed dose (mg/kg bw/day)~~ | ~~% of systemic AAOEL~~ | ~~Total absorbed dose (mg/kg bw/day)~~ | ~~% of systemic AAOEL~~ | ~~Total absorbed dose (mg/kg bw/day)~~ | ~~% of systemic AAOEL~~ |
| ~~Tractor mounted boom spray application outdoors to low crops~~  ~~Buffer zone: 2-3(m)~~  ~~Drift reduction technology: yes~~  ~~DFR: 3 µg/cm~~~~2~~~~/kg a.s./ha~~ | | | | | | | |
| ~~Cereals~~ | | | | | | | |
| ~~Application rate:~~ | | ~~2 x 0.091 kg a.s./ha~~ | | ~~2 x 0.175 kg a.s./ha~~ | | ~~2 x 0.159 kg a.s./ha~~ | |
| ~~Bystander child~~  ~~Body weight: 10 kg~~ | ~~Drift (95~~~~th~~ ~~perc.)~~ | ~~0.0613~~ | ~~3.83~~ | ~~0.0075~~ | ~~75.31~~ | ~~0.0016~~ | ~~15.90~~ |
| ~~Vapour (95~~~~th~~ ~~perc.)~~ | ~~0.0011~~ | ~~0.67~~ | ~~0.0011~~ | ~~10.70~~ | ~~0.0011~~ | ~~10.70~~ |
| ~~Deposits (95~~~~th~~ ~~perc.)~~ | ~~0.0009~~ | ~~0.58~~ | ~~0.0011~~ | ~~12.54~~ | ~~0.0011~~ | ~~10.79~~ |
| ~~Re-entry (95~~~~th~~ ~~perc.)~~ | ~~0.0058~~ | ~~3.64~~ | ~~0.0071~~ | ~~71.26~~ | ~~0.0060~~ | ~~60.12~~ |
| ~~Bystander adult~~  ~~Body weight: 60 kg~~ | ~~Drift (95~~~~th~~ ~~perc.)~~ | ~~0.0017~~ | ~~1.04~~ | ~~0.0020~~ | ~~20.33~~ | ~~0.0004~~ | ~~4.29~~ |
| ~~Vapour (95~~~~th~~ ~~perc.)~~ | ~~0.0002~~ | ~~0.14~~ | ~~0.0002~~ | ~~2.30~~ | ~~0.0002~~ | ~~2.30~~ |
| ~~Deposits (95~~~~th~~ ~~perc.)~~ | ~~0.0003~~ | ~~0.22~~ | ~~0.0004~~ | ~~4.34~~ | ~~0.0004~~ | ~~3.66~~ |
| ~~Re-entry (95~~~~th~~ ~~perc.)~~ | ~~0.0032~~ | ~~2.02~~ | ~~0.0036~~ | ~~39.59~~ | ~~0.0033~~ | ~~33.40~~ |
| ~~Oilseed rape~~ | | | | | | | |
| ~~Application rate:~~ | | ~~2 x 0.078 kg a.s./ha~~ | | ~~2 x 0.150 kg a.s./ha~~ | | ~~2 x 0.136 kg a.s./ha~~ | |
| ~~Bystander child~~  ~~Body weight: 10 kg~~ | ~~Drift (95~~~~th~~ ~~perc.)~~ | ~~0.0052~~ | ~~3.28~~ | ~~0.0065~~ | ~~64.55~~ | ~~0.0014~~ | ~~13.60~~ |
| ~~Vapour (95~~~~th~~ ~~perc.)~~ | ~~0.0011~~ | ~~0.67~~ | ~~0.0011~~ | ~~10.70~~ | ~~0.0011~~ | ~~10.70~~ |
| ~~Deposits (95~~~~th~~ ~~perc.)~~ | ~~0.0008~~ | ~~0.50~~ | ~~0.0011~~ | ~~10.75~~ | ~~0.0009~~ | ~~9.23~~ |
| ~~Re-entry (95~~~~th~~ ~~perc.)~~ | ~~0.0050~~ | ~~3.12~~ | ~~0.0061~~ | ~~61.08~~ | ~~0.0051~~ | ~~51.42~~ |
| ~~Bystander adult~~  ~~Body weight: 60 kg~~ | ~~Drift (95~~~~th~~ ~~perc.)~~ | ~~0.0014~~ | ~~0.89~~ | ~~0.0017~~ | ~~17.43~~ | ~~0.0004~~ | ~~3.67~~ |
| ~~Vapour (95~~~~th~~ ~~perc.)~~ | ~~0.0002~~ | ~~0.14~~ | ~~0.0002~~ | ~~2.30~~ | ~~0.0002~~ | ~~2.30~~ |
| ~~Deposits (95~~~~th~~ ~~perc.)~~ | ~~0.0003~~ | ~~0.19~~ | ~~0.0004~~ | ~~3.72~~ | ~~0.0003~~ | ~~3.13~~ |
| ~~Re-entry (95~~~~th~~ ~~perc.)~~ | ~~0.0028~~ | ~~1.73~~ | ~~0.0034~~ | ~~33.93~~ | ~~0.0029~~ | ~~28.57~~ |

**zRMS**:

The exposure estimation of resident (adult and child) to both active substances of a product IN233C1560 / AVTAR applied on a field of cereals at dose of 0.7 L product/ha, using tractor-mounted/trailed boom sprayer with drift reduction technology, calculated with the EFSA AOEM demonstrates that such a exposure for adult and child resident is equal respectively to 2.00% and to 4.64% of AOEL for Difenconazole, and to 1.91% and to 3.99% of AOEL for Prothioconazole, and to 30.61% and 65.2% of ARfD for Prothioconazole used as AOEL for Prothioconazole-desthio an environmental metabolite of Prothioconazole. The sum of exposures of adult or child resident to both active substances and to metabolite Prothioconazole-desthio expressed as percentage of their AOELs is also below 100%, therefore the application of product IN233C1560 / AVTAR does not pose an unacceptable risk to the health of adult and child resident for its intended use on cereals within good agricultural practice.

The exposure estimation of resident (adult and child) to both active substances of a product IN233C1560 / AVTAR applied on a field of oilseed rape at dose of 0.6 L product/ha, using tractor-mounted/trailed boom sprayer with drift reduction technology, calculated with the EFSA AOEM demonstrates that such a exposure for adult and child resident is equal respectively to 1.74% and to 4.08% of AOEL for Difenconazole, and to 1.65% and to 3.45% of AOEL for Prothioconazole, and to 26.52% and 57.31% of ARfD for Prothioconazole used as AOEL for Prothioconazole-desthio, an environmental metabolite of Prothioconazole. The sum of exposures of adult or child resident to both active substances and to metabolite Prothioconazole-desthio expressed as percentage of their AOELs is also below 100%, therefore the application of product IN233C1560 / AVTAR does not pose an unacceptable risk to the health of adult and child resident for its intended use on oilseed rape within good agricultural practice.

No bystander acute exposure estimation for Difenconazole and for Prothioconazole is required since no acute acceptable operator exposure value (AAOEL) has be set for any of this active substance nor for metabolite Prothioconazole-desthio. Therefore, as indicated in the EU guidance (SANTE-10832-2015 rev. 1.7; 24 January 2017), no unacceptable risk is expected for bystanders due to short-term single exposure to Difenconazole and to Prothioconazole, and to metabolite Prothioconazole-desthio as a result of application of a product IN233C1560 / AVTAR with accordance with intended use within good agricultural practice.

Summing up application of a product IN233C1560 / AVTAR on a field of cereals at dose of 0.7 L product/ha or on a field of oilseed rape at dose of 0.6 L product/ha, using tractor-mounted/trailed boom sprayer with drift reduction technology in line with GAP does not pose an unacceptable health risk for residents and bystanders.

## Residues and consumer exposure (Part B, Section 7)

**zRMS**:

An exceedance of the current MRLs for prothioconazole and difenoconazole as laid down in Reg. (EU) 396/2005 is not expected. The chronic and the short-term intakes of prothioconazole, difenoconazole and TDMs residues are unlikely to present a public health concern. ~~The approval can be granted for the intended uses with the provisional timing change for oilseed rape to “up to BBCH 60 or BBCH 14-60” due to the lack of the relevant residue data in honey.~~

~~The applicant should (after approval) complete the ongoing stability studies and complete the necessary honey trials for oilseed rape~~. The ongoing residue data in honey were completed, provided by the applicant and then evaluated.

For details, please see the section B7.

|  |  |
| --- | --- |
| Comments of zRMS: | Entire paragraph 3.5 after updating by the applicant the relevant agreed data has been in general accepted unless otherwise was noted. This means that in the context of the residue data and the required residue analytical methods (see B7&5 for details) the requested for the authorization intended GAP can be authorized except the use in oilseed rape regarding the insufficient information on residues in honey. No honey residue data for systemic actives for a crop treatment before blossom. |

### Residues

***Prothioconazole:***

The EU MRLs for prothioconazole are published in the Commission Regulation (EU) No 2019/552 of 4 April 2019, based on the European Food Safety Authority Reasoned opinion on the review of the existing maximum residue levels (MRLs) for prothioconazole according to Article 12 of Regulation (EC) No 396/2005 (ESFA Journal 2020;18(2):5999).

NATURE OF RESIDUES IN

* PLANT:
  + The metabolism of prothioconazole was investigated in sugar beet, in peanut and wheat after foliar application of JAU6476 in primary crops.
  + The metabolism of prothioconazole in rotational crops was investigated in Swiss chard, turnip and wheat after foliar application of JAU6476 in rotational crops.
  + Plant residue definition for monitoring according to Regulation (EC) 396/2005 is prothioconazole-desthio. In addition, the RAR (United Kingdom, 2018) states that a more specific definition for cereal straws should be taken into account. Thus, plant residue definition for cereals straws is prothioconazole-desthio-3-hydroxy, prothioconazole-desthio-4-hydroxy, prothioconazole-desthio-5-hydroxy, prothioconazole-desthio-6-hydroxy, prothioconazole-desthio-alpha-hydroxy
  + As the active substance belongs to the triazole family, the metabolites of this family (TRZ, TA, TLA and TAA ) were also studied for the intended uses.
* ANIMAL:
  + The metabolism of difenoconazole was investigated in lactating ruminants and laying hens.
  + Animal residue definition for monitoring according to Regulation (EC) 396/2005 is prothioconazole.

MAGNITUDE OF RESIDUES IN PLANTS

Wheat, barley and oilseed rape are the three crops grown in the field for the residues trials in the Northern and in the Southern zones of EU.

16 NEU trials and 16 SEU trials on wheat and barley are available to support the use of cereals while 8 NEU trials and 8 SEU trials on oilseed rape are also available to support the use of oilseed rape.

Available data fully support the intended use on wheat (2x 175 g prothioconazole/ha), application between BBCH 25-69). They also fully support the intended use on barley (2x 175 g prothioconazole/ha),, application between BBCH 30-61). Moreover, available extrapolated data support the intended use on triticale, rye and oats (2x 175 g prothioconazole/ha), application between BBCH 25-69).

Concerning the oilseed rape, available data fully support the intended use on this crop (2x 175 g prothioconazole/ha), application between BBCH 14-69 or until BBCH 69).

Regarding the magnitude of residues in cereals crops, since only the grains are consumed for rye, oat and triticale, the data submitted show that no exceedance of the MRL will occur:

* for rye in the Northern zone,
* for oat in the Northern zone,
* for triticale in both zones

These uses are therefore considered acceptable.

Regarding the magnitude of residues in oilseed rape, since only seeds and pods are consumed for oilseed rape, the data submitted show that no exceedance of the MRL will occur.

The uses are therefore considered acceptable.

In addition, as no MRL exists for these metabolites, no unrounded OECD have been calculated. However, to assess the potential risk following ingestion of these molecules, a consumer risk assessment has been performed for each metabolite.

MAGNITUDE OF RESIDUES IN LIVESTOCK

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

MAGNITUDE OF RESIDUES IN PROCESSED COMMODITIES

Twelve processing studies were conducted for wheat, oilseed rape and barley (four studies per crops) from the samples of the trials of magnitude of residues. The processed commodities for wheat were white flour and white bread. As the residues were below the LOQ, no processing factors could be derived from the studies.

Four studies were performed to process oilseed rape seeds in crude oil and refined oil. As all the residues in processed commodities were below the LOQ, it was not possible to derive a processing factors.

Four studies were performed in order to investigate the processing of barley, the following processed commodities were analyzed: Malt Sprout, Brewing malt, Spent grain, Brewing yeast and beer. Based on the residues level in raw and processed commodities, the following processing factors were calculated: 0.160 in brewing malt. For the other processed commodities, as the residues were below the LOQ or LOD, no processing factors could be derived.

Regarding the wheat processed commodities, processed factors could be derived for TA and TAA for both processed commodities. Regarding TA, the PF were for white flour and white bread respectively 0.34 and 0.86. For TAA, the PF were for white flour and white bread respectively, 0.176 and 0.51. For the other metabolites, as the residues were below the LOQ or LOD, no PF could be derived.

Regarding the barley processed commodities, the following processing factors could be calculated: for TA, 13.57 for malt sprout, 0.817 for brewing malt, 0.19 for spent grain, 0.22 for brewing yeast and 0.25 for beer. For TLA, 13.71 for malt sprout and 2.25 for brewing malt. For TAA, 5.95 for malting sprout, 1.15 for brewing malt, 0.10 for spent grain, 0.17 for brewing yeast and 0.16 for beer. For the others couple metabolite/processed commodities, as the results were below the LOQ, no PF could be derived.

MAGNITUDE OF RESIDUES IN REPRESENTATIVE SUCCEEDING CROPS

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues, no study dealing with magnitude of residues in succeeding crops is needed.

MAGNITUDE OF RESIDUES IN HONEY

Four residue trials have been provided: 1 in northern Europe and 3 in southern Europe. The aim of these trials is to determine the magnitude of residues of prothioconazole, its metabolite prothioconazole-desthio and the triazole-derivative metabolites (TDMs): triazole-alanine (TA), 1,2,4-triazole (1,2,4-T), triazole lactic acid (TLA), triazole acetic acid (TAA) in honey after one application of IN233C1560 380 EC on flowering Phacelia crop under semi-field conditions (tunnels). One application of the formulated product IN233C1560 380 EC was carried out at crop full flowering (BBCH 65) at a rate of 1.0 L f.p./ha (250 g prothioconazole + 130 g difenoconazole/ha).

In these residue trials, residues for prothioconazole, its metabolite prothioconazole-desthio and the triazole-derivative metabolites (TDMs) (TA, 1,2,4-T, TLA, TAA) are found below 0.01 mg/kg.

According to the data submitted, no exceedance of the in force MRL on honey for prothioconazole (Reg EU No 2019/552) is observed.

According to SANTE/11956/2016 rev. 9 “*The highest total application rate defines the most critical scenario. For non-systemic substances only, the application rate to be tested can be limited to the use rates applied during flowering”.*

In this case all actives are systemic, thus when applied before flowering may be present in the aerial parts of the intended crop during flowering and then consequently in nectar and pollen. Therefore, for systemic actives it is absolutely crucial to test treatments before flowering.

In zRMS’s opinion the information obtained from one treatment during the flowering is insufficient to approve the proposed GAP for oilseed rape. This is indicated clearly in guidelines - the intended use in oilseed rape cannot be authorized (see the B7).

***Difenoconazole:***

The EU MRLs for difenoconazole are published in the Commission Regulation (EU) No 2019/552 of 4 April 2019, based on the European Food Safety Authority Reasoned opinion on the review of the existing maximum residue levels (MRLs) for prothioconazole according to the conclusion on the peer review (ESFA Journal 2011;9(1):1967).

NATURE OF RESIDUES IN

* PLANT:
  + The metabolism of difenoconazole in primary crops was investigated in in tomato, grape and oilseed rape after foliar application of CGA169374.
  + The metabolism of difenoconazole in primary crops was investigated in in lettuce, sugar beet, turnip, mustard, maize and wheat (winter and sprint).
  + Plant residue definition for monitoring according to Regulation (EC) 396/2005 is difenoconazole.
  + As the active substance belongs to the triazole family, the metabolites of this family (TRZ, TA, TLA and TAA ) were also studied for the intended uses.
* ANIMAL:
  + The metabolism of difenoconazole was investigated in lactating ruminants and laying hens.
  + Animal residue definition for monitoring according to Regulation (EC) 396/2005 is difenoconazole.

MAGNITUDE OF RESIDUES IN PLANTS

Wheat, barley and oilseed rape are the three crops grown in the field for the residues trials in the Northern and in the Southern zones of EU.

16 NEU trials and 16 SEU trials on wheat and barley are available to support the use of cereals while 8 NEU trials and 8 SEU trials on oilseed rape are also available to support the use of oilseed rape.

Available data fully support the intended use on wheat (2x 91 g difenoconazole/ha), application between BBCH 40-69). They also fully support the intended use on barley (2x 91 g difenoconazole/ha), application between BBCH 30-61). Moreover, available extrapolated data support the intended use on triticale, rye and oats (2x 91 g difenoconazole/ha), application between BBCH 30-69).

Concerning the oilseed rape, available data fully support the intended use on this crop (2x 78 g difenoconazole/ha), application between BBCH 14-69 or until BBCH 69).

Regarding the magnitude of residues in cereals crops, since only the grains are consumed for rye, oat and triticale, the data submitted show that no exceedance of the MRL will occur:

* for rye in both zones,
* for oat in the Northern zone,
* for triticale in both zones

These uses are therefore considered acceptable.

Regarding the magnitude of residues in oilseed rape, since only seeds and pods are consumed for oilseed rape, the data submitted show that no exceedance of the MRL will occur.

The uses are therefore considered acceptable.

In addition, as no MRL exists for these metabolites, no unrounded OECD have been calculated. However, to assess the potential risk following ingestion of these molecules, a consumer risk assessment has been performed for each metabolite.

MAGNITUDE OF RESIDUES IN LIVESTOCK

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

MAGNITUDE OF RESIDUES IN PROCESSED COMMODITIES

Twelve processing studies were conducted for wheat, oilseed rape and barley (four studies per crops) from the samples of the trials of magnitude of residues. The processed commodities for wheat were white flour and white bread. As the residues were below the LOQ, no processing factors could be derived from the studies.

Four studies were performed to process oilseed rape seeds in crude oil and refined oil. As all the residues in processed commodities were below the LOQ, it was not possible to derive a processing factors.

Four studies were performed in order to investigate the processing of barley, the following processed commodities were analysed: Malt Sprout, Brewing malt, Spent grain, Brewing yeast and beer. Based on the residues level in raw and processed commodities, the following processing factors were calculated: 0.940 for malt sprout, 0.602 for brewing malt and 0.47 for spent grain.

The magnitude of residues in processing studies was also studied for the triazole metabolites. As these metabolites are common to prothioconazole and difenoconazole, the results are presented and discussed under the prothioconazole section.

MAGNITUDE OF RESIDUES IN REPRESENTATIVE SUCCEEDING CROPS

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues, no study dealing with magnitude of residues in succeeding crops is needed.

MAGNITUDE OF RESIDUES IN HONEY

Four residue trials have been provided: 1 in northern Europe and 3 in southern Europe. The aim of these trials is to determine the magnitude of residues of difenoconazole and the triazole-derivative metabolites (TDMs): triazole-alanine (TA), 1,2,4-triazole (1,2,4-T), triazole lactic acid (TLA), triazole acetic acid (TAA) in honey after one application of IN233C1560 380 EC on flowering Phacelia crop under semi-field conditions (tunnels). One application of the formulated product IN233C1560 380 EC was carried out at crop full flowering (BBCH 65) at a rate of 1.0 L f.p./ha (250 g prothioconazole + 130 g difenoconazole/ha).

In these residue trials, residues for difenoconazole and the triazole-derivative metabolites (TDMs) (TA, 1,2,4-T, TLA, TAA) are found below 0.01 mg/kg.

According to the data submitted, no exceedance of the in force MRL on honey for difenoconazole (Reg EU No 2019/552) is observed.

In zRMS’s opinion the information obtained from one treatment during the flowering is insufficient to approve the proposed GAP for oilseed rape. The intended use in oilseed rape cannot be authorized (see more details above and in the B7).

### Consumer exposure

***Prothioconazole:***

Table: Consumer risk assessment – PRIMo version 3.1

|  |  |
| --- | --- |
| TMDI (% ADI) according to EFSA PRIMo | 23 % (based on NL toddler) |
| IEDI (% ADI) according to EFSA PRIMo | Not relevant, since TMDI does not exceed ADI |
| IESTI (% ARfD) according to EFSA PRIMo\*/\*\* | Unprocessed commodities:  Lentils: 67 % (based on children)  Lentils: 62 % (based on adults)  Processed commodities:  Lentils/ boiled: 81 % (based on children)  Beetroots/ boiled: 39 % (based on adults) |

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

\*\*The ESFA model indicates that a division by zero takes place and therefore does not indicate the results for IESTI for children (unprocessed commodities). This problem comes from the crop Herbs and edible flowers (Code No. 256000). In order to solve this problem, the MRL of this crop has been removed. This choice can be justified by the fact that the children considered in this model do not yet have the capacity to ingest this crop Herbs and edible flowers (Code No. 256000).

Moreover, this modification does not change the results already obtained, except for solving the problem of division by zero. The spreadsheets from before and after solving this problem are therefore presented in Appendix 3.

***Conclusion:***

The proposed uses of prothioconazole in the formulation IN233C1560 do not represent unacceptable acute and chronic risks for the consumer.

***Difenoconazole:***

Table: Consumer risk assessment – PRIMo version 3.1

|  |  |
| --- | --- |
| TMDI (% ADI) according to EFSA PRIMo | ~~54 % (based on GEMS/FoodG06)~~  100 % (based on NL toddler)  ~~Rice: 47 % (based on GEMS/FoodG06)~~  ~~Wheat: 7 % (based on GEMS/FoodG06)~~  ~~Barley: 0.2 % (based on GEMS/FoodG06)~~  Apples: 17% (based on NL toddler)  Beans (with pods): 8%(based on NL toddler)  Table grapes: 8% (based on NL toddler) |
| IEDI (% ADI) according to EFSA PRIMo | Not relevant, since TMDI does not exceed ADI |
| IESTI (% ARfD) according to EFSA PRIMo\* | Unprocessed commodities:  ~~24% Rice (based on children)~~  ~~16% Rice (based on adults)~~  1% Barley (based on children)  0.9% Barley (based on adults)  Processed commodities:  ~~Rice/milling (polishing): 11 % (based on children)~~  ~~Rice/milling (polishing): 7 % (based on adults)~~  Wheat/milling (flour): 0.8% (based on children)  Barley/beer: 1% (based on adults) |

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

***Conclusion:***

The proposed uses of difenoconazole in the formulation IN233C1560 do not represent unacceptable chronic and acute risks for the consumer.

***TRZ:***

Table: Consumer risk assessment – PRIMo version 3.1

|  |  |
| --- | --- |
| TMDI (% ADI) according to EFSA PRIMo | 0.4 % (based on DK child) |
| IEDI (% ADI) according to EFSA PRIMo | Not relevant, since TMDI does not exceed ADI |
| IESTI (% ARfD) according to EFSA PRIMo | Unprocessed commodities:  Wheat: 0.1 % (based on children)  Wheat: 0.08% (based on adults)  Processed commodities:  Wheat/milling (flour): 0.1% (based on children)  Barley (beer): 0.1% (based on adults) |

***Conclusion:***

The metabolites TRZ resulting the proposed used of the prothioconazole and the difenoconazole in the formulation IN233C1560 do not represent unacceptable acute and chronic risks for the consumer.

***For TA:***

Table: Consumer risk assessment – PRIMo version 3.1

|  |  |
| --- | --- |
| TMDI (% ADI) according to EFSA PRIMo | 2% (based on DK child) |
| IEDI (% ADI) according to EFSA PRIMo | Not relevant, since TMDI does not exceed ADI |
| IESTI (% ARfD) according to EFSA PRIMo | Unprocessed commodities:  Wheat: 3% (based on children)  Wheat: 2% (based on adults)  Processed commodities:  Wheat/ milling (flour): 3% (based on children)  Wheat/ bread/pizza: 1% (based on adults) |

***Conclusion:***

The metabolites TA resulting the proposed used of the prothioconazole and the difenoconazole in the formulation IN233C1560 do not represent unacceptable acute and chronic risks for the consumer.

***For TLA:***

Table: Consumer risk assessment – PRIMo version 3.1

|  |  |
| --- | --- |
| TMDI (% ADI) according to EFSA PRIMo | 0.1 % (based on DK child) |
| IEDI (% ADI) according to EFSA PRIMo | Not relevant, since TMDI does not exceed ADI |
| IESTI (% ARfD) according to EFSA PRIMo | Unprocessed commodities:  Wheat: 0.07% (based on children)  Wheat: 0.04% (based on adults)  Processed commodities:  Wheat/ milling (flour): 0.1% (based on children)  Wheat/bread/pizza: 0.02% (based on adults) |

***Conclusion:***

The metabolites TLA resulting the proposed used of the prothioconazole and the difenoconazole in the formulation IN233C1560 do not represent unacceptable acute and chronic risks for the consumer.

***For TAA:***

Table: Consumer risk assessment – PRIMo version 3.1

|  |  |
| --- | --- |
| TMDI (% ADI) according to EFSA PRIMo | 0.2 % (based on DK child) |
| IEDI (% ADI) according to EFSA PRIMo | Not relevant, since TMDI does not exceed ADI |
| IESTI (% ARfD) according to EFSA PRIMo | Unprocessed commodities:  Wheat: 0.3% (based on children)  Wheat: 0.2% (based on adults)  Processed commodities:  Wheat/milling (flour): 0.2% (based on children)  Barley beer: 0.1% (based on adults) |

***Conclusion:***

The metabolites TAA resulting the proposed used of the prothioconazole and the difenoconazole in the formulation IN233C1560 do not represent unacceptable acute and chronic risks for the consumer.

|  |  |
| --- | --- |
| Comments of zRMS: | The honey residue data, animal dietary burden and PRIMo data was updated. Entire paragraph 3.5 has been accepted unless otherwise was noted. |

## Environmental fate and behaviour (Part B, Section 8)

### Predicted environmental concentrations in soil (PECsoil)

There was no deviation from EU-agreed endpoints.

**Prothioconazole and its metabolites:**

PECsoil for prothioconazole on cereals and oilseed rape were calculated. The maximum PECsoil were 0.1867 mg/kg on cereals and 0.1200 mg/kg on oilseed rape. A refinement was therefore necessary because the regulatory acceptable concentration of Prothioconazole at Tier I is 0.104 mg/kg.

PECsoil of metabolites of prothioconazole were also calculated:

Prothioconazole-s-methyl (M01) on cereals: maximum PEC was 0.0301 mg/kg.

Prothioconazole-s-methyl (M01) on oilseed rape: maximum PEC was 0.0209 mg/kg.

Prothioconazole-desthio (M04) on cereals: maximum PEC was 0.1088 mg/kg. A refinement was necessary because the regulatory acceptable concentration of M04 at Tier I is 0.1 mg/kg.

Prothioconazole-desthio (M04) on oilseed rape: maximum PEC was 0.0751 mg/kg.

**Difenoconazole and its metabolites:**

PECsoil for difenoconazole on cereals and oilseed rape were calculated. The maximum PECsoil were 0.1178 mg/kg (PECs accum of 0.1915 mg/kg) on cereals and 0.0810 mg/kg (PECs accum of 0.1317 mg/kg) on oilseed rape. A refinement was therefore necessary because the regulatory acceptable concentration of Difenoconazole at Tier I is 0.05 mg/kg.

PECsoil of metabolites of difenoconazole were also calculated:

CGA 205375 on cereals: maximum PEC was 0.0118 mg/kg (PECs accum of 0.0135 mg/kg);

CGA 205375 on oilseed rape: maximum PEC was 0.0080 mg/kg (PECs accum of 0.0092 mg/kg).

1,2,4-triazole on cereals: maximum PEC was 0.0048 mg/kg (PECs accum of 0.0213 mg/kg);

1,2,4-triazole on cereals: maximum PEC was 0.0033 mg/kg (PECs accum of 0.0147 mg/kg)

**PECsoil of prothioconazole, M04 and difenoconazole - refined application scheme on cereals BBCH 30+**

A restriction of the application pattern on cereals is applied, with application at or after BBCH 30 (instead of BBCH 25 in the risk envelope). According to AppDate software (M. Klein), in the FOCUS crop calendars for Châteaudun, Hamburg, Kremsmünster and Okehampton, the mean interval between BBCH 30 and BBCH 41 (BBCH 40 is not listed) is 13.75 d. Therefore, the condition to make the second application at or after BBCH 40 is implicit due to the minimum spray interval of 14 d. Results are presented below:

Refined PECsoil for prothioconazole on cereals (applic. at or after BBCH 30): 0.0467 mg/kg.

Refined PECsoil for M04 on cereals (applic. at or after BBCH 30): 0.0332 mg/kg.

Refined PECsoil for difenoconazole on cereals (applic. at or after BBCH 30): 0.0355 mg/kg (PECs accum of 0.0411 mg/kg).

The PECSOIL of M01, CGA 205375 and 1,2,4-triazole were calculated for a risk envelope pattern and do not require refinement.

**PECsoil of prothioconazole and difenoconazole - refined application scheme on oilseed rape - one split application at BBCH 14+**

A restriction of the application pattern on oilseed rape is applied down to a single split application at or after BBCH 14. This is the first out of two refined application schemes which are considered for oilseed rape. According to AppDate software (M. Klein), in the FOCUS crop calendars for Châteaudun, Hamburg, Kremsmünster and Okehampton, the mean interval between BBCH 14 and BBCH 20 for oilseed rape is 7.6 d. Therefore, the condition to make the second application at or after BBCH 20 is implicit due to the minimum spray interval of 14 d. Results are presented below:

Refined PECsoil for prothioconazole on OSR (1 split applic. at or after BBCH 14): 0.0600 mg/kg. The maximum PECis reached at first application, due to a combination of a short DT50 and a higher crop interception on second application.

Refined PECsoil for difenoconazole on OSR (1 split applic. at or after BBCH 14): 0.0405 mg/kg.

The PECSOIL of M01, M04, CGA205375 and 1,2,4-triazole were calculated for a risk envelope pattern on OSR and do not require refinement for this crop.

**PECsoil of prothioconazole and difenoconazole - refined application scheme on oilseed rape - 2 applications at BBCH 20+**

A restriction of the application pattern on oilseed rape is applied down to 2 applications at or after BBCH 20 (instead of BBCH 14). This is the second out of two refined application schemes which are considered for oilseed rape.

Refined PECsoil for prothioconazole on OSR (2 applications at BBCH 20+): 0.0412 mg/kg

Refined PECsoil for difenoconazole on OSR (2 applications at BBCH 20+): 0.0409 mg/kg

The PECSOIL of M01, M04, CGA205375 and 1,2,4-triazole were calculated for a risk envelope pattern on OSR and do not require refinement for this crop.

### Predicted environmental concentrations in groundwater (PECgw)

There was no deviation from EU-agreed endpoints. However, formation fractions were set to 1 when no EU-agreed endpoint was available. Endpoints for 1,2,4-triazole were revised by EFSA in 2011-2013 following the submission of confirmatory data.

The recommended FOCUS models were used: FOCUS PELMO, FOCUS PEARL and FOCUS MACRO.

~~Table 3.6-1: PEC~~~~gw~~ ~~for Prothioconazole and metabolite(s) on Winter Cereals (BBCH 25, case a)~~

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ~~Crop~~ | ~~Scenario~~ | ~~80~~~~th~~ ~~Percentile PEC~~~~gw~~ ~~at 1 m Soil Depth (μg/L)~~ | | |
| ~~Prothioconazole~~ | ~~M01~~ | ~~M04~~ |
| ~~Winter Cereals, BBCH 25 and BBCH 25 + 14 d~~ | ***~~PEARL 5.5.5~~*** | | | |
| ~~Châteaudun~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Hamburg~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Kremsmünster~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Jokioinen~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Okehampton~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Piacenza~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Porto (January)~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Porto (March)~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Sevilla (January)~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Sevilla (March)~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Thiva (Dec/Jan)~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Thiva (March)~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ***~~PELMO 6.6.4~~*** | | | |
| ~~Châteaudun~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Hamburg~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Kremsmünster~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Jokioinen~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Okehampton~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Piacenza~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Porto (January)~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Porto (March)~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Sevilla (January)~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Sevilla (March)~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Thiva (January)~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Thiva (March)~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ***~~MACRO 5.2 (in FOCUS MACRO 5.5.4)~~*** | | | |
| ~~Châteaudun~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |

~~Results for Spring Cereals at BBCH 25 (case b) are identical to those obtained for Winter cereals for all 3 models.~~

~~Results for Winter or Spring cereals at BBCH 69 (cases c and d) are identical to those obtained for Winter cereals, with PEARL.~~

~~Table 3.7-2: PEC~~~~gw~~ ~~for Prothioconazole and metabolite(s) on Winter oilseed Rape (BBCH 14 + BBCH 69, case f)~~

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ~~Crop~~ | ~~Scenario~~ | ~~80~~~~th~~ ~~Percentile PEC~~~~gw~~ ~~at 1 m Soil Depth (μg/L)~~ | | |
| ~~Prothioconazole~~ | ~~M01~~ | ~~M04~~ |
| ~~Winter Oilseed Rape, BBCH 14 + BBCH 69~~ | ***~~PEARL 5.5.5~~*** | | | |
| ~~Châteaudun~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Hamburg~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Kremsmünster~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Jokioinen~~ | ~~n.d.~~  ~~Spring OSR: < 0.001~~ | ~~n.d.~~  ~~Spring OSR: < 0.001~~ | ~~n.d.~~  ~~Spring OSR: < 0.001~~ |
| ~~Okehampton~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Piacenza~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Porto~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Sevilla~~~~1~~ | ~~< 0.001~~~~1~~ | ~~< 0.001~~~~1~~ | ~~< 0.001~~~~1~~ |
| ~~Thiva²~~ | ~~< 0.001²~~ | ~~< 0.001²~~ | ~~< 0.001²~~ |
| ***~~PELMO 6.6.4~~*** | | | |
| ~~Châteaudun~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Hamburg~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Kremsmünster~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Jokioinen~~ | ~~n.d.~~  ~~Spring OSR: < 0.001~~ | ~~n.d.~~  ~~Spring OSR: < 0.001~~ | ~~n.d.~~  ~~Spring OSR: < 0.001~~ |
| ~~Okehampton~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Piacenza~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Porto~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Sevilla~~~~1~~ | ~~< 0.001~~~~1~~ | ~~< 0.001~~~~1~~ | ~~< 0.001~~~~1~~ |
| ~~Thiva²~~ | ~~< 0.001²~~ | ~~< 0.001²~~ | ~~< 0.001²~~ |
| ***~~MACRO 5.2 (in FOCUS MACRO 5.5.4)~~*** | | | |
| ~~Châteaudun~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |

~~Results for Spring OSR at BBCH 14 (case h) are identical to those obtained for Winter OSR at BBCH 14+69 for all 3 models for scenarios.~~

~~Results with PEARL for the remaining cases related to oilseed rape (cases e, g, i) are identical to those obtained with PEARL for Winter OSR at BBCH 14+69.~~

~~Table 3.7-3: PEC~~~~gw~~ ~~for Difenoconazole and metabolite(s) on Winter Cereals (BBCH 25, case a)~~

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| ~~Crop~~ | ~~Scenario~~ | ~~80~~~~th~~ ~~Percentile PEC~~~~gw~~ ~~at 1 m Soil Depth (μg/L)~~ | | | | |
| ~~Difenoconazole~~ | ~~CGA205375~~ | ~~1,2,4-triazole formed from CGA 205375~~ | ~~1,2,4-triazole applied as a parent substance~~ |
| ~~Winter Cereals, BBCH 25 and BBCH 25 + 14 d~~ | ***~~PEARL 5.5.5~~*** | | | |  |
| ~~Châteaudun~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0121~~ | ~~0.0084~~ |
| ~~Hamburg~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0615~~ | ~~0.0523~~ |
| ~~Kremsmünster~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0413~~ | ~~0.0383~~ |
| ~~Jokioinen~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0210~~ | ~~0.0175~~ |
| ~~Okehampton~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0610~~ | ~~0.0536~~ |
| ~~Piacenza~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0352~~ | ~~0.0241~~ |
| ~~Porto (January)~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0331~~ | ~~0.0308~~ |
| ~~Porto (March)~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0332~~ | ~~0.0170~~ |
| ~~Sevilla (January)~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Sevilla (March)~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Thiva (January)~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0073~~ | ~~0.0047~~ |
| ~~Thiva (March)~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0073~~ | ~~0.0030~~ |
| ***~~PELMO 6.6.4~~*** | | | | | |
| ~~Châteaudun~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0085~~ | ~~0.0055~~ |
| ~~Hamburg~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0575~~ | ~~0.0520~~ |
| ~~Kremsmünster~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0395~~ | ~~0.0365~~ |
| ~~Jokioinen~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0225~~ | ~~0.0180~~ |
| ~~Okehampton~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0570~~ | ~~0.0490~~ |
| ~~Piacenza~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0390~~ | ~~0.0255~~ |
| ~~Porto (January)~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0575~~ | ~~0.0550~~ |
| ~~Porto (March)~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0580~~ | ~~0.0345~~ |
| ~~Sevilla (January)~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Sevilla (March)~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ |
| ~~Thiva (January)~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0040~~ | ~~0.0025~~ |
| ~~Thiva (March)~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0040~~ | ~~0.0010~~ |
| ***~~MACRO 5.2 (in FOCUS MACRO 5.5.4)~~*** | | | | | |
| ~~Châteaudun~~ | ~~<0.001~~ | ~~<0.001~~ | ~~n.c.~~ | ~~n.c.~~ |

~~Table 3.7-4: PEC~~~~gw~~ ~~for Difenoconazole and metabolite(s) on Spring Cereals (BBCH 25, case b)~~

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ~~Crop~~ | ~~Scenario~~ | ~~80~~~~th~~ ~~Percentile PEC~~~~gw~~ ~~at 1 m Soil Depth (μg/L)~~ | | | |
| ~~Difenoconazole~~ | ~~CGA205375~~ | ~~1,2,4-triazole formed from CGA 205375~~ | ~~1,2,4-triazole applied as a parent substance~~ |
| ~~Spring Cereals, BBCH 25 and BBCH 25 + 14 d~~ | ***~~PEARL 5.5.5~~*** | | | | |
| ~~Châteaudun~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0099~~ | ~~0.0067~~ |
| ~~Hamburg~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0699~~ | ~~0.0607~~ |
| ~~Kremsmünster~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0428~~ | ~~0.0397~~ |
| ~~Jokioinen~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0200~~ | ~~0.0184~~ |
| ~~Okehampton~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0575~~ | ~~0.0495~~ |
| ~~Piacenza~~ | ~~Crop not defined. Winter cereals is the surrogate crop, see previous Table.~~ | | | |
| ~~Porto~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0347~~ | ~~0.0199~~ |
| ~~Sevilla~~ | ~~n.d.~~ | ~~n.d.~~ | ~~n.d.~~ | ~~n.d.~~ |
| ~~Thiva~~ | ~~n.d.~~ | ~~n.d.~~ | ~~n.d.~~ | ~~n.d.~~ |
| ***~~PELMO 6.6.4~~*** | | | | |
| ~~Châteaudun~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0060~~ | ~~0.0040~~ |
| ~~Hamburg~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0630~~ | ~~0.0535~~ |
| ~~Kremsmünster~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0400~~ | ~~0.0380~~ |
| ~~Jokioinen~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0200~~ | ~~0.0170~~ |
| ~~Okehampton~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0540~~ | ~~0.0470~~ |
| ~~Piacenza~~ | ~~Crop not defined. Winter cereals is the surrogate crop, see previous Table.~~ | | | |
| ~~Porto~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0505~~ | ~~0.0270~~ |
| ~~Sevilla~~ | ~~n.d.~~ | ~~n.d.~~ | ~~n.d.~~ | ~~n.d.~~ |
| ~~Thiva~~ | ~~n.d.~~ | ~~n.d.~~ | ~~n.d.~~ | ~~n.d.~~ |
| ***~~MACRO 5.2 (in FOCUS MACRO 5.5.4)~~*** | | | | |
| ~~Châteaudun~~ | ~~<0.001~~ | ~~<0.001~~ | ~~n.c.~~ | ~~n.c.~~ |

~~Table 3.7-5: PEC~~~~gw~~ ~~for Difenoconazole and metabolite(s) on Winter Oilseed Rape (BBCH 14 + BBCH 69, case f)~~

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ~~Crop~~ | ~~Scenario~~ | ~~80~~~~th~~ ~~Percentile PEC~~~~gw~~ ~~at 1 m Soil Depth (μg/L)~~ | | | |
| ~~Difenoconazole~~ | ~~CGA205375~~ | ~~1,2,4-triazole formed from CGA 205375~~ | ~~1,2,4-triazole applied as a parent substance~~ |
| ~~Winter OSR BBCH 14 & BBCH 69~~ | ***~~PEARL 5.5.5~~*** | | | | |
| ~~Châteaudun~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0102~~ | ~~0.0125~~ |
| ~~Hamburg~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0396~~ | ~~0.0459~~ |
| ~~Kremsmünster~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0258~~ | ~~0.0281~~ |
| ~~Jokioinen~~ | ~~n.d.~~ | ~~n.d.~~ | ~~n.d.~~ | ~~n.d.~~ |
| ~~Okehampton~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0364~~ | ~~0.0386~~ |
| ~~Piacenza~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0181~~ | ~~0.0226~~ |
| ~~Porto~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0228~~ | ~~0.0328~~ |
| ~~Sevilla~~ | ~~n.d.~~ | ~~n.d.~~ | ~~n.d.~~ | ~~n.d.~~ |
| ~~Thiva~~ | ~~n.d.~~ | ~~n.d.~~ | ~~n.d.~~ | ~~n.d.~~ |
| ***~~PELMO 6.6.4~~*** | | | | |
| ~~Châteaudun~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0060~~ | ~~0.0070~~ |
| ~~Hamburg~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0355~~ | ~~0.0430~~ |
| ~~Kremsmünster~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0235~~ | ~~0.0260~~ |
| ~~Jokioinen~~ | ~~n.d.~~ | ~~n.d.~~ | ~~n.d.~~ | ~~n.d.~~ |
| ~~Okehampton~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0370~~ | ~~0.0390~~ |
| ~~Piacenza~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0195~~ | ~~0.0245~~ |
| ~~Porto~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0395~~ | ~~0.0495~~ |
| ~~Sevilla~~ | ~~n.d.~~ | ~~n.d.~~ | ~~n.d.~~ | ~~n.d.~~ |
| ~~Thiva~~ | ~~n.d.~~ | ~~n.d.~~ | ~~n.d.~~ | ~~n.d.~~ |
| ***~~MACRO 5.2 (in FOCUS MACRO 5.5.4)~~*** | | | | |
| ~~Châteaudun~~ | ~~<0.001~~ | ~~<0.001~~ | ~~n.c.~~ | ~~n.c.~~ |

~~Table 3.7-6: PEC~~~~gw~~ ~~for Difenoconazole and metabolite(s) on Spring Oilseed Rape (BBCH 14, case h) (with FOCUS PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.2)~~

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ~~Crop~~ | ~~Scenario~~ | ~~80~~~~th~~ ~~Percentile PEC~~~~gw~~ ~~at 1 m Soil Depth (μg/L)~~ | | | |
| ~~Difenoconazole~~ | ~~CGA205375~~ | ~~1,2,4-triazole formed from CGA 205375~~ | ~~1,2,4-triazole applied as a parent substance~~ |
| ~~Spring OSR BBCH 14~~ | ***~~PEARL 5.5.5~~*** | | | | |
| ~~Châteaudun~~~~1~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0088~~ | ~~0.0069~~ |
| ~~Hamburg~~~~1~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0222~~ | ~~0.0187~~ |
| ~~Kremsmünster~~~~1~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0143~~ | ~~0.0125~~ |
| ~~Jokioinen~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0072~~ | ~~0.0060~~ |
| ~~Okehampton~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0231~~ | ~~0.0189~~ |
| ~~Piacenza~~~~2~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0191~~ | ~~0.0149~~ |
| ~~Porto~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0139~~ | ~~0.0077~~ |
| ~~Sevilla~~~~1~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0009~~ | ~~0.0005~~ |
| ~~Thiva²~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0067~~ | ~~0.0067~~ |
| ***~~PELMO 6.6.4~~*** | | | | |
| ~~Châteaudun~~~~1~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0065~~ | ~~0.0055~~ |
| ~~Hamburg~~~~1~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0225~~ | ~~0.0190~~ |
| ~~Kremsmünster~~~~1~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0145~~ | ~~0.0130~~ |
| ~~Jokioinen~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0075~~ | ~~0.0065~~ |
| ~~Okehampton~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0240~~ | ~~0.0205~~ |
| ~~Piacenza~~~~2~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0215~~ | ~~0.0210~~ |
| ~~Porto~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0220~~ | ~~0.0140~~ |
| ~~Sevilla~~~~1~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0005~~ | ~~0.0005~~ |
| ~~Thiva²~~ | ~~<0.001~~ | ~~<0.001~~ | ~~0.0040~~ | ~~0.0045~~ |
| ***~~MACRO 5.2 (in FOCUS MACRO 5.5.4)~~*** | | | | |
| ~~Châteaudun~~~~1~~ | ~~<0.001~~ | ~~<0.001~~ | ~~n.c.~~ | ~~n.c.~~ |

~~1~~ ~~Surrogate crop cabbage / leafy vegetable~~

~~2~~ ~~Surrogate crop sugar beet~~

The 80th percentile of predicted concentration in groundwater at 1 m depth does not exceed 0.1 µg/L for the uses of product IN233C1560 on cereals and oilseed rape in every FOCUS scenario relevant to the Central zone for the following substances: Prothioconazole, prothioconazole-S-methyl (M01), prothioconazole-desthio (M04), difenoconazole, CGA 205375 and 1,2,4-triazole.

### Predicted environmental concentrations in surface water (PECsw)

*Prothioconazole:*

In accordance with the core zone guidance document, refined endpoints can be used if a safe use cannot be concluded on the basis of current EU agreed endpoints. In this case, new kinetic endpoints were presented in the RAR (2015, Chapple A. and Hoerold C. in RAR Vol. 3 CA B8) based on legacy soil and water/sediment studies already presented in the DAR (2001, Gilges M. and Babczinski in DAR Vol. 3 B8). Thus RAR endpoints were used as a refinement of original endpoints presented in the EFSA conclusions of 2007.

*Difenoconazole:*

There is no deviation from EU-agreed endpoints

**PECsw/sed for Prothioconazole and its metabolites**

The RAC for the most sensitive aquatic organisms for the prothioconazole is 4.7 µg/L. The PECsw calculated following application to cereals and oilseed rape are below the RAC value for the scenarios of FOCUS STEP2.

The RAC for the most sensitive aquatic organisms for the metabolite 1,2,4-triazole (M13) is 320 µg/L. All PECsw values are below the RAC for all simulations with FOCUS STEP2.

The RAC for the most sensitive aquatic organisms for the prothioconazole-S-methyl (M01) is 18 µg/L.

All PECsw values are below the RAC for all simulations with FOCUS STEP2.

The metabolite prothioconazole-desthio (M04) required further modelling to reduce the PECsw below the RAC of 0.334 µg/L. The STEP 3 calculations were run for prothioconazole-desthio with the more recent RAR endpoints since a safe use could not be demonstrated with the endpoints from the EFSA conclusion (please refer to dRR B8 for more details). The RAR endpoints are based on the re-assessment of DAR data with guideline-compliant kinetic evaluation. PECsw values calculated in STEP3 were below the RAC value except for some scenarios for which STEP4 was investigated. Therefore, the following measures apply for these scenarios:

* Vegetative buffer strips of 10 m and 20 m;
* Non-sprayed buffer strips of 5 m, 10 m and 20 m.

~~Table 3.7-7: Global maximum PEC~~~~sw~~ ~~values for Prothioconazole-desthio, following single/multiple application(s) of the product IN233C1560 according to the central EU zone GAP according to surface water Step 4~~

| **~~PEC~~~~sw~~ ~~(µg/L)~~** | **~~Scenario~~** | **~~STEP 4~~** | | |
| --- | --- | --- | --- | --- |
| **~~Nozzle~~**  **~~reduction~~** | **~~Vegetative strip (m)~~** | **~~None~~** | **~~10~~** | **~~20~~** |
| **~~No spray buffer (m)~~** | **~~5~~** | **~~10~~** | **~~20~~** |
| ~~Winter cereals, 2 app., BBCH25 and onwards, 175 g a.s./ha~~ | | | | |
| ~~None~~ | ~~R1 stream~~ | **~~0.9502~~** | **~~0.4316~~** | ~~0.2259~~ |
| ~~None~~ | ~~R3 stream~~ | **~~0.9041~~** | **~~0.4125~~** | ~~0.2164~~ |
| ~~None~~ | ~~R4 stream~~ | **~~1.150~~** | **~~0.5231~~** | ~~0.2740~~ |
| ~~Winter cereals, 1 app., BBCH25 and onwards, 175 g a.s./ha~~ | | | | |
| ~~None~~ | ~~R3 stream~~ | **~~0.3897~~** | ~~0.1778~~ | ~~-~~ |
| ~~None~~ | ~~R4 stream~~ | **~~0.4867~~** | ~~0.2214~~ | ~~-~~ |
| ~~Winter cereals, 2 app., Late application before BBCH69, 175 g a.s./ha~~ | | | | |
| ~~None~~ | ~~R1 stream~~ | **~~0.6632~~** | ~~0.3015~~ | ~~-~~ |
| ~~None~~ | ~~R3 stream~~ | **~~0.7105~~** | ~~0.3195~~ | ~~-~~ |
| ~~None~~ | ~~R4 stream~~ | **~~0.5668~~** | ~~0.2579~~ | ~~-~~ |
| ~~Winter cereals, 1 app., Late application before BBCH69, 175 g a.s./ha~~ | | | | |
| ~~None~~ | ~~R3 stream~~ | **~~0.3726~~** | ~~0.1676~~ | ~~-~~ |
| ~~None~~ | ~~R4 stream~~ | **~~0.5667~~** | ~~0.2578~~ | ~~-~~ |
| ~~Spring cereals, 2 app., BBCH25 and onwards, 175 g a.s./ha~~  *~~In italics: Surrogate Crop: Winter cereals, 2 app., BBCH25~~* | | | | |
| *~~None~~* | *~~R1 stream~~* | ***~~0.9502~~*** | ***~~0.4316~~*** | *~~0.2259~~* |
| *~~None~~* | *~~R3 stream~~* | ***~~0.9041~~*** | ***~~0.4125~~*** | *~~0.2164~~* |
| ~~None~~ | ~~R4 stream~~ | **~~1.128\*~~** | **~~0.5076\*~~** | ~~0.2647\*~~ |
| ~~Spring cereals, 1 app., BBCH25 and onwards, 175 g a.s./ha~~  *~~In italics: Surrogate Crop: Winter cereals, 1 app., BBCH25~~* | | | | |
| ~~None~~ | ~~R3 stream~~ | **~~0.3726~~** | ~~0.1778~~ | ~~-~~ |
| *~~None~~* | *~~R4 stream~~* | ***~~0.5958~~*** | *~~0.2689~~* | *~~-~~* |
| ~~Winter OSR, 2 app., one app. after BBCH14 and one in March, 150 g a.s./ha~~  *~~In italics: Surrogate Crop: Winter cereals, 2 app., BBCH00~~* | | | | |
| ~~None~~ | ~~R3 stream~~ | **~~0.6051~~** | ~~0.2754~~ | ~~-~~ |
| *~~None~~* | *~~R4 stream~~* | ***~~-~~*** | *~~0.2756~~* | *~~-~~* |
| ~~Winter OSR, 1 app., one app. BBCH14 and onwards, 150 g a.s./ha~~  *~~In italics: Surrogate Crop:~~* *~~Winter cereals, 1 app., BBCH00~~* | | | | |
| ~~None~~ | ~~R3 stream~~ | **~~0.6051~~** | ~~0.2754~~ | ~~-~~ |
| *~~None~~* | *~~R4 stream~~* | ***~~-~~*** | *~~0.2785~~* | *~~-~~* |
| ~~Spring OSR, 1 app., BBCH14 and onwards, 150 g a.s./ha~~  *~~In italics: Surrogate Crop: Leafy vegetables, 1 app., BBCH14~~* | | | | |
| ~~None~~ | ~~R1 stream~~ | **~~0.3503~~** | ~~0.1590~~ | ~~-~~ |
| *~~None~~* | *~~R3 stream~~* | ***~~-~~*** | *~~0.1737~~* | *~~-~~* |
| *~~None~~* | *~~R4 stream~~* | ***~~-~~*** | *~~0.3122~~* | *~~-~~* |

**Restriction based on a later crop development stage (BBCH40)**

For scenarios for which PEC/RAC values are still >1, further refinement was investigated with a restriction based on a later crop development stage (BBCH 40). The PECsw were calculated with FOCUS STEP3 for these scenarios. Some of them were still exceeding the RAC, therefore FOCUS STEP4 was conducted to refine to an acceptable risk:

Table 3.7-8: Global maximum PECsw values for prothioconazole-desthio, following single/multiple application(s) of the product IN233C1560 according to surface water Step 4

| **PECsw (µg/L)** | **Scenario** | **STEP 4** |
| --- | --- | --- |
| **Nozzle**  **reduction** | **Vegetative strip (m)** | **10** |
| **No spray buffer (m)** | **None** |
| Winter cereals, 2 app., BBCH40 and onwards, 175 g a.s./ha | | |
| None | R1 stream | 0.3015 |
| None | R3 stream | 0.3121 |
| None | R4 stream | 0.3121 |
| Winter cereals, 1 app., BBCH40 and onwards,175 g a.s./ha | | |
| None | R3 stream | 0.1881 |
| Spring cereals, 2 app., BBCH40 and onwards, 175 g a.s./ha | | |
| None | R4 stream | 0.2752 |

**Additional STEP4 calculations with VFSmod**

In some member states, VFSmod is accepted as a mitigation for the PECsw. Here is an overview of the impact of mitigations with VFSmod on PECSW.

Table 3.7‑9: Global maximum PECsw values for Prothioconazole-desthio, following single/multiple application(s) of the product IN233C1560 according to the central EU zone GAP according to surface water Step 4

| **PECsw (µg/L)** | **Scenario** | **STEP 4** | | | |
| --- | --- | --- | --- | --- | --- |
| **Nozzle**  **reduction** | **Vegetative strip (m)** | **1** | **2** | **5** | **10** |
| Winter cereals, 2 app., BBCH25 and onwards, 175 g a.s./ha | | | | | |
| None | R1 stream | 0.3329 | - | - | - |
| None | R3 stream | **0.5508** | **0.5002** | **0.3755** | 0.2350 |
| None | R4 stream | **0.5060** | 0.3372 | - | - |
| Winter cereals, 1 app., BBCH25 and onwards, 175 g a.s./ha | | | | | |
| None | R3 stream | 0.2385 | - | - | - |
| None | R4 stream | 0.2140 | - | - | - |
| Winter cereals, 2 app., Late application before BBCH69, 175 g a.s./ha | | | | | |
| None | R1 stream | 0.2498 | - | - | - |
| None | R3 stream | 0.2615 | - | - | - |
| None | R4 stream | 0.2555 | - | - | - |
| Winter cereals, 1 app., Late application before BBCH69, 175 g a.s./ha | | | | | |
| None | R3 stream | 0.1052 | - | - | - |
| None | R4 stream | 0.2555 | - | - | - |
| Spring cereals, 2 app., BBCH25 and onwards, 175 g a.s./ha  *In italics: Surrogate Crop: Winter cereals, 2 app., BBCH25* | | | | | |
| *None* | R1 stream | *0.3329* | *-* | *-* | *-* |
| *None* | R3 stream | ***0.5508*** | ***0.5002*** | ***0.3755*** | *0.2350* |
| None | R4 stream | **0.7874** | **0.6679** | **0.4381** | 0.1561 |
| Spring cereals, 1 app., BBCH25 and onwards, 175 g a.s./ha  *In italics: Surrogate Crop: Winter cereals, 1 app., BBCH25* | | | | | |
| None | R3 stream | *0.2385* | - | - | - |
| *None* | *R4 stream* | 0.2581 | - | - | - |
| **Bold**: exceeding 0.334 µg/L | | | | |  |

The 2 m VFS in general is not accepted at zonal level. It could be decided at cMS level.

It is recommended to apply 5 m VFS (Poland).

**PECsw/sed for Difenoconazole and its metabolites**

The RAC for the most sensitive aquatic organisms for the Difenoconazole is 0.56 µg/L for surface water and 5.25 µg/kg for sediment. This required further modelling with STEP3 to reduce the PECsw below this RAC value. PECsw values calculated in STEP3 were below the RAC value except for some scenarios for which STEP4 was investigated. Therefore, the following measures apply for these scenarios:

Table 3.7‑10: Global maximum PECsw values for Difenoconazole, following single/multiple application(s) of the product IN233C1560 according to the central EU zone GAP according to surface water Step 4

| **PECsw (µg/L)** | **Scenario** | **STEP 4** | | |
| --- | --- | --- | --- | --- |
| **Nozzle**  **reduction** | **Vegetative strip (m)** | **None** | **10** | **20** |
| **No spray buffer (m)** | **5** | **None** | **None** |
| Winter cereals, 1 app., BBCH25 and onwards, 91 g a.s./ha | | | | |
| None | D3 ditch | 0.1545 | - | - |
| Winter cereals, 1 app., Late application before BBCH69, 91 g a.s./ha | | | | |
| None | D3 ditch | 0.1551 | - | - |
| Spring cereals, 1 app., BBCH25 and onwards, 91 g a.s./ha | | | | |
| None | D3 ditch | 0.1546 | - | - |

Table 3.7‑11: Global maximum PECsed values for Difenoconazole, following single/multiple application(s) of the product IN233C1560 according to the central EU zone GAP according to surface water Step 4

| **PECsed (µg/kg)** | **Scenario** | **STEP 4** | | |
| --- | --- | --- | --- | --- |
| **Nozzle**  **reduction** | **Vegetative strip (m)** | **None** | **10** | **20** |
| **No spray buffer (m)** | **5** | **None** | **None** |
| Winter cereals, 2 app., Late application before BBCH69, 91 g a.s./ha | | | | |
| None | R1 stream | **5.858** | 1.014 | - |
| None | R4 stream | **9.814** | 1.586 | - |
| Spring cereals, 2 app., BBCH25 and onwards, 91 g a.s./ha | | | | |
| None | R4 stream | **10.13** | 1.729 | - |
| Winter OSR, 2 app., one app. after BBCH14 and one in March, 78 g a.s./ha | | | | |
| None | R3 stream | **7.101** | 1.182 | - |
| Spring OSR, 1 app., BBCH14 and onwards, 78 g a.s./ha  *In italics = SC: Leafy vegetables, 2 app., BBCH14* | | | | |
| None | R3 stream | ***12.83*** | *2.023* | - |
| **Bold**: exceeding 5.25 µg/L | | | | |

**Additional STEP4 calculations with VFSmod**

In some member states, VFSmod is accepted as a mitigation for the PECsw. Here is an overview of the impact of mitigations with VFSmod on PECSW.

Table 3.7‑12: Global maximum PECsed values for Difenoconazole, following single/multiple application(s) of the product IN233C1560 according to the central EU zone GAP according to surface water Step 4

| **PECsed (µg/kg)** | **Scenario** | **STEP 4** | |
| --- | --- | --- | --- |
| **Nozzle**  **reduction** | **Vegetative filter strip (m)** | **1** | **2** |
| Winter cereals, 2 app., Late application before BBCH69, 91 g a.s./ha | | | |
| None | R1 stream | 1.740 | - |
| None | R4 stream | **5.683** | 4.696 |
| Spring cereals, 2 app., at BBCH25, 91 g a.s./ha | | | |
| None | R4 stream | **5.713** | 4.667 |
| **Bold**: exceeding 5.25 µg/kg | | | |

The 2 m VFS in general is not accepted at zonal level. It could be decided at cMS level.

It is recommended to apply 5 m VFS (Poland).

The RAC for the most sensitive aquatic organisms for the metabolite CGA 205375 is 7.4 µg/L. All PECsw values are below the RAC for all simulations with FOCUS STEP2.

The RAC for the most sensitive aquatic organisms for the metabolite 1,2,4-Triazole (CGA 71019) is 320 µg/L. All PECsw values are below the RAC for all simulations with FOCUS STEP2.

**PECsw of the formulation**

The PECsw are based on the Ganzelmeier/Rautmann drift values, no degradation and the cumulated application rate of 2 applications.

Table 8.9‑26: PECsw for formulation on cereals and oilseed rape

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Crop** | **# App.** | **App. rate (L/ha)** | **Density (g/L)** | **App. rate (g/ha)** | **App. rate cumulated (g/ha)** | **Portion reaching the target (%)** | **Application rate reaching water surface (µg/m2)** | **Depth (cm)** | **PECsw (µg/L)** |
| Cereals | 2 | 0.7 | 1155 | 808.5 | 1617 | 2.38 | 3848.46 | 30 | 12.83 |
| Oilseed rape | 2 | 0.6 | 693 | 1386 | 3298.68 | 11.00 |

The calculation with a 5m buffer zone is realised according to the formula Rautmann, 1999 [[1]](#footnote-1) on field crops with 2 applications. This formula is giving the % of the application rate that is reaching the soil or the water expressed in % of a distance x in m. Therefore, by applying a 5 m buffer zone, the new drift value is 0.47 % at the place of 2.38% without buffer zone.

Table 8.9‑27: PECsw for formulation on cereals and oilseed rape with a drift mitigation of 5m buffer zone

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Crop** | **# App.** | **App. rate (L/ha)** | **Density (g/L)** | **App. rate (g/ha)** | **App. rate cumulated (g/ha)** | **Portion reaching the target (%)** | **Application rate reaching water surface (µg/m2)** | **Depth (cm)** | **PECsw (µg/L)** |
| Cereals | 2 | 0.7 | 1155 | 808.5 | 1617 | 0.47 | 759.99 | 30 | 2.53 |
| Oilseed rape | 2 | 0.6 | 693 | 1386 | 651.42 | 2.17 |

The long-term PECSW of the formulation are not relevant, mainly because prothioconazole degrades quickly in water (DT50, WATER < 1 day).

### Predicted environmental concentrations in air (PECair)

The vapour pressure at 20 °C of the active substances Prothioconazole and Difenoconazole are < 10‑5 Pa. Hence these active substances are regarded as non-volatile.

## Ecotoxicology (Part B, Section 9)

### Effects on terrestrial vertebrates

**Birds**

IN233C1560 contains two active substances. Therefore, as requested in EFSA/2009/1438, the risk assessment for dietary exposure (both acute and long-term) was carried out for each substance separately as well as the combined exposure.

The toxicity to mammals of the metabolite prothioconazole-desthio (M04) (NOEL = 14.8 mg/kg bw/d) is higher than the parent (prothioconazole; NOEL = 78 mg/kg bw/d). Furthermore, the conversion from the parent is fast and, as a first (worst-case) approach, can be considered as equal to 100%. In consequence, the endpoint values related to that metabolite have been considered in the risk assessment. In the combined exposure risk assessment, the risk assessment is based on the mixture of difenoconazole and prothioconazole-desthio. That assessment is covering the risk related to the mixture difenoconazole and prothioconazole.

**Risk assessment for active substances and relevant metabolite**

Both the acute and long-term risk to birds is low following the exposure to difenoconazole, prothioconazole and prothioconazole-desthio (considered separately) for all uses of the intended GAP (cereals and OSR).

Regarding the exposure to contaminated water, the leaf scenario is not relevant. For the puddle scenario, since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed the critical value of 3000, a quantitative risk assessment (calculation of TER values) was not necessary and a low risk was identified with regards to difenoconazole, prothioconazole and prothioconazole-desthio.

The risk for earthworm-eating and fish-eating birds via secondary poisoning has been assessed as low. All the calculated TER were above the trigger.

**Combined exposure**

With regards to the combined exposure to difenoconazole and prothioconazole-desthio, for both cereals and oilseed rape (OSR), the acute risk is acceptable. For both cereals and OSR, the long-term risk is not acceptable for one of the assessed scenarios.

For cereals, the scenario: “Early (shoots) autumn-winter BBCH 10-29 - Large herbivorous bird (*goose*) Grass + cereals 100% cereal shoots” is leading to a high risk. ~~As indicated in the DAR and confirmed in EFSA conclusion for prothioconazole (2007), residues data (from 8 trials) are available to refine the mean RUD and the residue half-life for cereals. When the refined RUD value is used (in combination with the default DT~~~~50~~~~) in the risk assessment a low risk can be demonstrated (TER~~~~LT~~ ~~= 10.4).~~

Due to an unacceptable chronic risk assessment for earthworms exposed to difenoconazole. prothioconazole or prothioconazole-desthio at BBCH 25, the further refinements for the scenario: “Early (shoots) autumn-winter BBCH 10-29 - Large herbivorous bird (*goose*) Grass + cereals 100% cereal shoots” is not required.

The resulting TERlt is above the trigger of 5 indicating a low chronic risk to birds when AVTAR is applied (2 applications, 14 days interval) in cereals with first application at or after BBCH 30.

For OSR, with the application rate of 2 x 0.6L/ha and 90 days interval (option 1), the reproductive risk from combined exposure is low for all the scenarios ~~but~~ except scenario “BBCH 10 – 19 - Medium herbivorous/granivorous bird "pigeon" Non-grass herbs 100% crop shoots” where high risk is identified. When the application rate of 2 x 0.3 L/ha and 14 days interval (options 2 and 3) is considered, all the TERLT calculated at Tier I are above the trigger. A low risk can therefore be concluded.

~~Based on expert statements and data presented in Northern Zone B&M GD (2020; version 2.1), the PT value has been refined for the scenario with the focal species “pigeon”. The radio-tracking data considered to determine the new PT values are derived from British studies and were therefore considered relevant for the Central Zone. The highest relevant PT value for “pigeon” in OSR field is equal to 0.84. The new TER~~~~LT~~ ~~value obtained is above the trigger of 5 (TER~~~~LT~~ ~~= 5.75). In consequence, the long-term risk to birds following the application of 2 x 0.6L product/ha in OSR can be regarded as acceptable.~~

Due to an unacceptable chronic risk assessment for earthworms exposed to difenoconazole. prothioconazole or prothioconazole-desthio at BBCH 14, the further refinements for the scenario: “BBCH 10 – 19 - Medium herbivorous/granivorous bird "pigeon" Non-grass herbs 100% crop shoots” is not required.

The resulting TERlt is above the trigger of 5 indicating a low chronic risk to birds when AVTAR is applied in OSR with first application at or after BBCH 20.

**Mammals**

IN233C1560 contains two active substances. Therefore, as requested in EFSA/2009/1438, the risk assessment for dietary exposure (both acute and long-term) was carried out for each substance separately as well as the combined exposure.

The toxicity to mammals of the metabolite prothioconazole-desthio (M04) (NOEL = 10 mg/kg bw/d) is higher than the parent (prothioconazole; NOEL = 95.6 mg/kg bw/d). Furthermore, the conversion from the parent is fast and, as a first (worst-case) approach, can be considered as equal to 100%. In consequence, the endpoint values related to that metabolite have been considered in the risk assessment. In the combined exposure risk assessment, the risk assessment is based on the mixture of difenoconazole and prothioconazole-desthio. That assessment is covering the risk related to the mixture difenoconazole and prothioconazole.

**Risk assessment for active substances and relevant metabolite**

The acute risk to mammals is low following the exposure to difenoconazole, prothioconazole and prothioconazole-desthio (considered separately) for all uses of the intended GAP (cereals and OSR).

The long-term risk to mammals is low as well, except for the exposure to prothioconazole-desthio after application of IN233C1560 in cereals (group 1). A high risk was identified for the scenario: “Cereals BBCH ≥ 40 - Small herbivorous mammal *vole* Grass + cereals 100% grass”. ~~As indicated in the DAR and confirmed in EFSA conclusion for prothioconazole (2007), residues data (from 8 trials) are available to refine the mean RUD and the residue half-life for cereals. When the refined RUD value (3.7 mg/kg instead of 54.2 mg/kg for M04 residues) is considered, the resulting TER~~~~LT~~ ~~is equal to 58.4 (above the trigger of 5), which is indicating a low long-term risk for mammals.~~

The refined DF values of 0.1 (cereals BBCH ≥40), for grass under the crop, can was used based on the interception values in the more recent FOCUS groundwater guidance (version 2.2; May 2014)

When the refined DF value is considered, the resulting TERLT is above the trigger of 5, which is indicating a low long-term risk for mammals.

Regarding the exposure to contaminated water, the leaf scenario is not relevant. For the puddle scenario, since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed the critical value of 3000, a quantitative risk assessment (calculation of TER values) was not necessary and a low risk was identified with regards to difenoconazole, prothioconazole and prothioconazole-desthio.

The risk for earthworm-eating and fish-eating mammals via secondary poisoning has been assessed as low. All the calculated TER were above the trigger.

**Combined exposure**

With regards to the combined exposure to difenoconazole and prothioconazole-desthio, for both cereals and oilseed rape (OSR), the acute risk is acceptable. For OSR, the long-term risk is acceptable as well, at Tier I, all TERlt values are above the trigger of 5. For cereals, the long-term risk is not acceptable for only one scenario: “Cereals BBCH ≥ 40 - Small herbivorous mammal *vole* Grass + cereals 100% grass”. ~~The kind of refinement as that used for the exposure to prothioconazole-desthio alone was used in a refined risk assessment (RUD = 3.7 mg/kg instead of 54.2 mg/kg). The related TER~~~~LT~~ ~~is equal to 7.3 (above the trigger of 5) indicating a low long-term risk for mammals for the combined exposure in cereals.~~

The refined DF values of 0.1 (cereals BBCH ≥40), for grass under the crop, can was used based on the interception values in the more recent FOCUS groundwater guidance (version 2.2; May 2014)

When the refined DF value is considered, the resulting TERLT is above the trigger of 5, which is indicating a low long-term risk for mammals.

### Effects on aquatic species

The relevant metabolites in water for ecotoxicological risk assessment are triazolyl-alcohol (CGA-205375) and 1, 2, 4 triazole (CGA-71019) for the active substance difenoconazole and prothioconazole-desthio (M04) and 1, 2, 4 triazole (M13) for the active substance prothioconazole. In the risk assessment, the two sources of 1, 2, 4 triazole were combined. The sum of the concentrations was used and only the highest toxicity endpoints were considered.

As requested by the EFSA Guidance (SANTE-2015-00080, 15 January 2015) the risk assessment was conducted for both (1) the relevant substances considered separately and (2) the mixture (use of the decision scheme from the Guidance).

The risk assessment was based on the PECsw calculated for cereals (group 1) and OSR (group 2). PECsw values are available for both single and multiple applications and various timing of application have been considered for the FOCUS modelling (see B8) (i.e. spring and winter, various timing of application). In the aquatic risk assessment, only the highest PECsw values have been taken into account for each FOCUS scenario.

Risk assessment for the a.s., relevant metabolites and the formulation considered separately

For difenoconazole, at Tier I, a high chronic risk was detected for fish (RAC = 0.36 µg/L), aquatic invertebrate (RAC = 0.56 µg/L) in cereals ~~(group 1)~~. It was also the case for sediment-dwelling invertebrate (RAC = 5.25 µg/L) ~~but for both group 1 and group 2~~.

For M04, a high chronic risk was detected only for fish (chronic) for both group 1 and group 2 (RAC = 0.334 µg/L).

For prothioconazole and the other relevant metabolites, the Tier I risk assessment based on FOCUS step 2 concentrations does not indicate any unacceptable risk towards aquatic organisms. Regarding the formulation (IN233C1560), the exposition through drift was assessed and no unacceptable risk was identified for both group 1 and group 2.

Mitigation measures were implemented. The implementation of vegetative filter strips and modifications of the initial intended GAP were assessed. The adjustment of the GAP considering a later application at BBCH 40 and onward is not necessary anymore (risk acceptable while applying the product at BBCH 25 and onward with adequate mitigation measures) after the 2023 update. The results obtained can summarized as follow (only relevant for Poland scenarios D3, D4 and R1):

**~~Cereals (group 1)~~**

| **~~Focus scenario~~** | **~~BBCH 25 and onward~~** | **~~BBCH 40 and onward~~~~1~~** | **~~BBCH 25+ with VFSmod~~~~2~~** |
| --- | --- | --- | --- |
| ~~Difenoconazole~~ | | | |
| ~~D3 ditch~~ | ~~5 m NSB~~ | ~~No mitigation required~~ | ~~Not calculated~~ |
| ~~D4 pond~~ | ~~No mitigation required~~ | | |
| ~~D5 pond~~ |
| ~~D5 stream~~ |
| ~~R1 pond~~ |
| ~~R1 stream~~ | ~~10 m VBS~~  ~~No mitigation required~~ | ~~Not calculated~~ | |
| ~~R3 stream~~ | ~~10 m VBS~~ |
| ~~R4 stream~~ | ~~10 m VBS~~ |
| ~~Prothioconazole-desthio~~ | | | |
| ~~D3 ditch~~ | ~~No mitigation required~~ | | |
| ~~D4 pond~~ |
| ~~D5 pond~~ |
| ~~D5 stream~~ |
| ~~R1 pond~~ |
| ~~R1 stream~~ | ~~20 m NSB + 20 m VBS~~ | ~~10 m VBS~~ | ~~1 m VBS~~ |
| ~~R3 stream~~ | ~~20 m VBS~~ | ~~10 m VBS~~ | ~~10 m VBS~~ |
| ~~R4 stream~~ | ~~20 m VBS~~ | ~~10 m VBS~~ | ~~10 m VBS~~ |

~~NSB: no spray buffer zone. VBS: vegetative buffer (filter) strip.~~

~~1: Restriction of the GAP based on a later crop developmental stage (BBCH 40) for the 1~~~~st~~ ~~possible application.~~

~~2: Use of the VFSmod to calculate the effect of a vegetated buffer strip, instead of fixed FOCUS values from Landcape and Mitigation guidance (which was used for the two previous columns)~~

~~In consequence, the following mitigation measures are required when the product IN233C1560 is applied in cereals (all the application patterns are covered under the risk envelope):~~

* ~~Scenarios FOCUS D3 ditch: 5 m unsprayed buffer zone;~~
* ~~Scenarios FOCUS R1, R3 and R4 stream: 20 m Vegetative strip (lowered to 10 m if 1~~~~st~~ ~~application at BBCH 40 and onward instead of BBCH 25);~~
* ~~Scenarios FOCUS R1, R3 and R4 stream with VFSmod: For the original risk envelope at BBCH 25, vegetative buffer strip is lowered to 1 m for the scenario R1 stream and 10 m with R3 and R4 scenarios.~~

As Poland accepts the VFSmod for mitigation measures, and considering that D3, D4 and R1 are the representative scenarios for Poland, the following mitigation measures apply:

* Scenarios FOCUS D3, D4: 5 m unsprayed buffer zone;
* Scenarios FOCUS R1 with VFSmod: ~~For the original risk envelope at BBCH 25,~~ vegetative buffer strip is lowered to 10 m for the scenario R1 stream.

**~~OSR (group 2)~~**

| **~~Focus scenario~~** | **~~BBCH 25 and onward~~** |
| --- | --- |
| ~~Difenoconazole~~ | |
| ~~D3 ditch~~ | ~~No mitigation required~~ |
| ~~D4 pond~~ |
| ~~D5 pond~~ |
| ~~D5 stream~~ |
| ~~R1 pond~~ |
| ~~R1 stream~~ |
| ~~R3 stream~~ | ~~10 m VBS~~ |
| ~~R4 stream~~ | ~~No mitigation required~~ |
| ~~Prothioconazole-desthio~~ | |
| ~~D3 ditch~~ | ~~No mitigation required~~ |
| ~~D4 pond~~ |
| ~~D5 pond~~ |
| ~~D5 stream~~ |
| ~~R1 pond~~ |
| ~~R1 stream~~ | ~~10 m NSB + 10 m VBS~~ |
| ~~R3 stream~~ | ~~10 m VBS~~ |
| ~~R4 stream~~ | ~~10 m VBS~~ |

~~VBS: vegetative buffer (filter) strip with fixed FOCUS values from Landcape and Mitigation guidance.~~

~~In consequence, the following mitigation measures are required when the product IN233C1560 is applied in OSR (all the application patterns are covered under the risk envelope):~~

* ~~Scenario FOCUS R1, R3 and R4 stream: 10 m NSB + 10 m Vegetative strip.~~
* ~~Scenarios FOCUS R1 stream with VFSmod: vegetative buffer strip is lowered to 1 m for the scenario R1 stream~~

Risk assessment for the mixture toxicity

Prothioconazole has a low DT50 in water and M04 is rapidly formed. Besides, the toxicity of M04 is significantly higher than the parent for algae and aquatic invertebrate (chronic exposure). Therefore, the mixture considered in the risk assessment is different depending on the group of organisms and exposure duration. The selected mixture and the result of the assessment are presented in the following table. The outcome of the results is the same for cereals and OSR. No unacceptable risk is to be expected for all tested groups of organisms.

|  |  |  |  |
| --- | --- | --- | --- |
| **~~Group of organisms~~** | **~~Exposure~~** | **~~Mixture considered in the RA~~** | **~~RA results~~** |
| ~~Fish~~ | ~~acute~~ | ~~difenoconazole + prothioconazole~~ | ~~Low risk :~~  ~~PECmix / ECx~~~~PPP~~ ~~< 0.01~~ |
| ~~Aquatic invertebrate~~ | ~~acute~~ | ~~difenoconazole + prothioconazole~~ | ~~Low risk:~~  ~~PECmix / ECx~~~~mix~~**~~-CA~~**~~< 0.01~~ |
| ~~Algae~~ | ~~sub-chronic~~ | ~~difenoconazole + prothioconazole-desthio~~ | ~~Low risk:~~  ~~PECmix / ECx~~~~mix~~**~~-CA~~**~~< 0.1~~ |
| ~~Aquatic invertebrate~~ | ~~chronic~~ | ~~difenoconazole + prothioconazole-desthio~~ | ~~toxicity of the mixture is explained by the sole difenoconazole. See RA for the single a.s. (Low risk)~~ |

|  |  |  |  |
| --- | --- | --- | --- |
| **Group of organisms** | **Exposure** | **Mixture considered in the RA** | **RA results** |
| Fish | acute | difenoconazole + prothioconazole | Low risk :  PECmix / ECxPPP < 0.01 |
| Aquatic invertebrate | acute | difenoconazole + prothioconazole | Low risk:  PECmix / ECxmix**-CA** < 0.01 |
| Algae | sub-chronic | difenoconazole + prothioconazole-desthio | Low risk:  PECmix / ECxmix**-CA** < 0.1  RMM\*:  Cereals: 5 m no spray buffer  OSR: none |
| difenoconazole + prothioconazole | Low risk:  PECmix / ECxmix**-CA** < 0.1 |
| Aquatic invertebrate | chronic | difenoconazole + prothioconazole-desthio | toxicity of the mixture is explained by the sole difenoconazole. See RA for the single a.s. (Low risk) |
| difenoconazole + prothioconazole | toxicity of the mixture is explained by the sole difenoconazole. See RA for the single a.s. (Low risk) |

### Effects on bees

The honeybee risk assessment has been performed according to the **current guidance: SANCO/10329/2002 rev.2 – final**. Hazard quotients have been calculated for the two active substances and the formulation for both oral and contact exposure of honeybees. All the values obtained are below the trigger of 50 indicating an acceptable risk for honeybees when the formulation IN233C1560 is applied on cereals (group 1) in accordance with the intended GAP. The use in OSR (group 2) is covered under the risk envelope.

Data is available for the acute toxicity of the formulation (IN233C1560) to bumblebees. Data is also available regarding the chronic toxicity to honeybee adults and larvae. That kind of data is not available for the active substances. ~~An assessment of the risk based on those data has been performed in accordance with the~~ **~~EFSA Bee Guidance 2013~~**~~.~~

~~For group 1 (cereals), the results obtained are indicating an acceptable risk (for bumblebees as well as honeybee adults and larvae, for all scenarios) when the product is applied according to the intended GAP (2 x 0.7 L product/ha).~~

~~For group 2 (OSR), the risks associated to the acute exposure of bumblebees and the chronic exposure of honeybee larvae are acceptable (HQ and ETR values are all below the EFSA guidance’s triggers). However, the risk associated to the chronic exposure of honeybee adults is high at Tier I for the~~ *~~treated crop~~* ~~scenario (other scenarios are leading to an acceptable risk). However, it can be noted that the ETR value is close to the trigger (ETR = 0.035; trigger = 0.03). It can be reasonably assumed that a risk assessment based on more realistic conditions would lead to an acceptable risk. A semi-field study is planned in order to demonstrate it and will be submitted as soon as available.~~

~~On the other hand, when split applications are used as described in the intended GAP (2 x 0.3 L product/ha), the chronic risk towards adults honeybee is low.~~

### Effects on other arthropod species other than bees

The risk assessment has been performed in accordance with the Guidance SANCO/10329/2002 rev.2 (final) for group 1 (cereals). The results are covering the use from group 2 (OSR) under the risk envelope.

No unacceptable risk to *T. pyri* and *A. rhopalosiphi* has been identified in the assessment for both the in-field and off-field areas. The calculated HQ values are below the trigger of 2 when IN233C1560 is applied according to the intended GAP (2 x 0.7 L product/ha for cereals and 2 x 0.6 L/ha for OSR).

### Effects on soil organisms

At Tier I, a high chronic risk was identified for earthworms when exposed to difenoconazole and prothioconazole-desthio. The risk due to prothioconazole was not evaluated due to the absence of laboratory study but a field study is available. With regards to the exposure to the metabolite CGA 205375, CGA 71019 and prothioconazole-S-methyl, a low risk was identified for earthworms. The chronic risk for earthworms exposed to the formulation (IN233C1560) is low as well.

The higher-tier risk assessment for **difenoconazole** is based on a refinement of the application scenarios. In cereal (group 1), the product (IN233C1560) is applied for the 1st time at BBCH 30 instead of 25 and BBCH ≥ 40 for the 2nd application (due to the spray interval of 14 d). The new PECs (accumulation) value is equal to 0.0411 mg/kg. The NOECcorr is equal to 0.25 mg/kg. Therefore, the refined TERlt value is equal 6.08 (above the trigger of 5) indicating an acceptable risk.

In OSR, the original risk envelope of 2 applications of 0.6 L/ha at BBCH 14-69 has been refined into 2 sub-uses as follows:

- 2 applications at 0.6 L/ha at or after BBCH 20, 1 in autumn and/or 1 in spring (each can be split towards 0.3 L + 0.3 L/ha). In this application scenario the new PECs (accumulation) value is equal to 0.0472 mg/kg

OR

- only 1 split application per crop at or after BBCH 14 (0.3 + 0.3 L/ha) In this application scenario the new PECs (accumulation) value is equal to 0.0468 mg/kg

The refined TERlt values are above the trigger of 5~~)~~ indicating an acceptable risk.

The higher-tier risk assessment for **prothioconazole** and **prothioconazole-desthio** is based both on field endpoints and on application scenario refinement.

The higher Tier endpoints for prothioconazole and M04 are based on the result of the field study (i.e. study of Lechelt-Kuntze, 2002) carried out with various species of earthworm. No adverse effects were observed on earthworms 5 months after 1st application. Considering the low DT50 of prothioconazole in soil (longest 1st order: 2.8 days), that active substance is rapidly transformed into prothioconazole-desthio (M04). Therefore, it can be assumed that the possible long-term effects on earthworm reproduction are mainly due to the M04 toxicity. The maximum PECs for M04 is equal to 0.1088 mg/kg, which is below the maximum measured concentration of M04 in the field study (i.e. 0.212 mg/kg, value over the 5 cm depth).

In consequence, the higher-tier risk assessment for prothioconazole-desthio based on the field study (see below) is indicating a low chronic risk for earthworms. Therefore, it can be reasonably stated that the chronic risk to earthworm following the application of IN233C1560 according to the intended GAP is acceptable.

The risk assessment for prothioconazole also required the use of refined application scenarios for both cereals and oilseed rape, the same as for the other a.s. Applying these refined application scenarios also reduced the PECSOIL of M04 to such extent that the refined endpoint of 0.212 mg/kg for M04 is not absolutely required.

The following Table summarizes the effect of the applications scenario refinements for difenoconazole, M04 and prothioconazole:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Substance** | **RAC1**  **(mg/kg)** | **Tier I PECSOIL**  **(mg/kg)**  **risk envelop cereals**  **(BBCH 25+)** | **PECSOIL with refined applic. scenario cereals (BBCH 30+)** | **Tier I PECSOIL**  **(mg/kg)**  **risk envelope OSR**  **(BBCH 14+, 2 app.)** | **PECSOIL with refined applic. scenario OSR (BBCH 20+, 2 app.)** | **PECSOIL with refined applic. scenario OSR (BBCH 14+, 1 split app.)** |
| Difenoconazole2 | Laboratory:  0.05  (= 0.25 / 5) | **0.1363** | 0.0411 | **0.0936** | 0.0472 | 0.0468 |
| Prothioconazole | Field:  0.104 | **0.1867** | 0.0467 | **0.1200** | 0.0412 | 0.0600 |
| M04 | Laboratory:  0.1 (= 0.5 / 5)  Field:  0.212 | 0.1088 | 0.0332 | 0.0751 | not required | not required |

1 Regulatory acceptable concentration in soil considering the most critical endpoint and the TER trigger

2 PECACCUMULATION since a plateau concentration of difenoconazole develops over successive years

The refined TERlt values are above the trigger of 5 (or 1, for field endpoints) indicating an acceptable risk.

The chronic risk assessment for soil organisms other than earthworms does not indicate any unacceptable risk. All calculated TERlt were above the trigger of 5.

**Soil micro-organisms**

The results are covering the use from group 2 (OSR) under the risk envelope. The PECsoil values considered in the risk assessment are based on a GAP where applications start at BBCH 25.

The maximum concentration with less than 25% effects on soil micro-organisms is above the calculated PECsoil values for the formulation, the two active substances and the relevant metabolites. Therefore, the risk can be considered low when the product IN233C1560 is applied according to the intended GAP.

### Effects on non-target terrestrial plants

For both seedling emergence and vegetative vigour, at the end of the laboratory tests no phytotoxic effect was shown in tested species (1.4 L/ha is the highest tested dose). In consequence, a low risk to non-target terrestrial plant can be concluded when IN233C1560 is applied according to the intended GAP (2 x 808.5 g product/ha at 14 days interval in cereals).

The risk assessment has been conducted for group 1 (cereal uses). The use on OSR (group 2) is covered under the risk envelope.

### Effects on other terrestrial organisms (Flora and Fauna)

No further data is available.

## Relevance of metabolites (Part B, Section 10)

None of the metabolites predicted to occur in groundwater at concentrations above 0.1 µg/L. Therefore, they are not deemed relevant and no relevance assessment is presented.

# Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Avtar contains difenoconazole which is approved as a candidate for substitution because it meets two of the PBT criteria (persistence and toxicity).

As a conclusion of the comparative assessment, use 1 from GAP table in 2.6 is not suitable for substitution because, for every pest assessed, either no data was available or there are only 4 or less suitable alternative mode(s) of action available amongst alternative products and thus the chemical diversity remaining is not sufficient to minimise the occurrence of resistance.

As a conclusion of the comparative assessment, use 2 from GAP table in 2.6 is not suitable for substitution because, for every pest assessed, either no data was available or there are only 4 or less suitable alternative mode(s) of action available amongst alternative products and thus the chemical diversity remaining is not sufficient to minimise the occurrence of resistance.

As a conclusion of the comparative assessment, use 3 from GAP table in 2.6 is not suitable for substitution because, for every pest assessed, either no data was available or there are only 4 or less suitable alternative mode(s) of action available amongst alternative products and thus the chemical diversity remaining is not sufficient to minimise the occurrence of resistance.

As a conclusion of the comparative assessment, use 4 from GAP table in 2.6 is not suitable for substitution because, for every pest assessed, either no data was available or there are only 3 or less suitable alternative mode(s) of action available amongst alternative products and thus the chemical diversity remaining is not sufficient to minimise the occurrence of resistance.

As a conclusion of the comparative assessment, no data was available for use 5 from GAP table in 2.6 and as a consequence, the comparative assessment was stopped.

As a conclusion of the comparative assessment, use 6 from GAP table in 2.6 is not suitable for substitution because, for every pest assessed, either no data was available or there are only 3 or less suitable alternative mode(s) of action available amongst alternative products and thus the chemical diversity remaining is not sufficient to minimise the occurrence of resistance.

It can also be stated that the product IN233C1560 presents benefits for the farmer in term of practical use and economics. It is also a greener and safer solution to similar products on the market. The relevance of the product IN233C1560 on the plant protection market has been demonstrated and the concerned product should not be substituted.

# Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Insert any data that the notifier needs to submit following authorization. As a rule, this is restricted to storage stability and monitoring data.

Insert the data that is still required for the evaluation of the product in the case where the product authorization is not granted.

1. Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

1. Copy of the product label

MS assessor to present a copy of the approved product label for MS country.

1. Letter of Access

Not required as no Letter of Access is within this dossier.

1. Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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** | **Verte-brate study**  **Y/N** | **Data protection claimed**  **Y/N** | **Justification if data protection is claimed** | **Owner** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| KCP 2.1 | Urbani, M. | 2021 | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560 : Determination of the Physico-chemical Properties  Report No. : CH – 0323/2021  + Amendment report No. 1 to final report (Amdm1\_KCP 2.1)  ChemService S.r.l. Controlli e Ricerche, Novate Milanese - Italy  GLP : Yes  Unpublished | N | Y | ~~Data/study report never submitted before to Poland~~  Data/study report submitted first time in Poland for new authorisation under Article 33 | INDOFIL industries (Netherlands) B.V |
| KCP 2.7.2 | Urbani, M. | 2021 | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560 : Determination of the Accelerated Storage Stability and Corrosion Characteristics  Report No. : CH – 0327/2021  + Amendment report No.1 to final report (Amdm1\_KCP 2.7.2)  ChemService S.r.l. Controlli e Ricerche, Novate Milanese - Italy  GLP : Yes  Unpublished | N | Y | ~~Data/study report never submitted before to Poland~~  Data/study report submitted first time in Poland for new authorisation under Article 33 | INDOFIL industries (Netherlands) B.V |
| KCP 2.7.2 | Urbani, M. | 2023 | Statement to the Final report – Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560 : Determination of the Accelerated Storage Stability and Corrosion Characteristics  Report No. : CH – 0327/2021  GLP : No  Unpublished | N | Y | ~~Data/study report never submitted before to Poland~~  Data/study report submitted first time in Poland for new authorisation under Article 33 | INDOFIL industries (Netherlands) B.V |
| KCP 2.7.5 | ~~Urbani, M.~~  Nichetti, S. | ~~2021~~  2023 | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560: Two Years Storage Stability and Corrosion Characteristics  Report No. : CH-0328/2021  ~~STUDY PLAN AMENDEMENT No. 1~~  ChemService S.r.l. Controlli e Ricerche, Novate Milanese - Italy  GLP : Yes  Unpublished | N | Y | ~~Data/study report never submitted before to Poland~~  Data/study report submitted first time in Poland for new authorisation under Article 33 | INDOFIL industries (Netherlands) B.V |
| KCP 2.11 | Devos, M. | 2023 | Evaluation of tank cleaning procedure for IN233C1560 (AVTAR) – Autumn 2022  Report No. : R001-23F  Redebel s.a., Saint-Amand, Belgium  GEP : Yes  Unpublished | N | Y | ~~Data/study report never submitted before to Poland~~  Data/study report submitted first time in Poland for new authorisation under Article 33 | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/01 KCP 6.2 KCP 6.4.1 | Crepin D. | 2020 | Evaluate the efficacy of IN233C1560 against Septoria on wheat - 2020 ESSAIS+  FR20-IBV-106-01  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/02 KCP 6.2 KCP 6.4.1 | Crepin D. | 2020 | Evaluate the efficacy of IN233C1560 against Puccinia striiformis and Fusarium graminum on winter wheat - 2020 ESSAIS+  FR20-IBV-106-02  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/03 KCP 6.2 KCP 6.4.1 | Negrini P. | 2020 | EVALUATE THE EFFICACY OF IN233C1560 AGAINST FOLIAR AND EAR DISEASES ON WHEAT - 2020 ANTEDIS  FR20-IBV-106-03  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/04 KCP 6.2 KCP 6.4.1 | Barou J. L. | 2020 | EVALUATE THE EFFICACY OF IN233C1560 AGAINST FOLIAR AND EAR DISEASES ON WHEAT - 2020. Agrotest France  FR20-IBV-106-04  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/05 KCP 6.2 KCP 6.4.1 | Dudman S. | 2020 | TO EVALUATE THE EFFICACY OF THE TEST PRODUCT IN233C1560 AGAINST FOLIAR AND EAR DISEASES ON WHEAT-2020 AGROCHEMEX  UK20-IBV-106-07  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/06 KCP 6.2 KCP 6.4.1 | Haigh I. | 2020 | EVALUATE THE EFFICACY OF IN233C1560 AGAINST FOLIAR AND EAR DISEASES ON WHEAT – 2020 FIELD ARM  UK20-IBV-106-08  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/07 KCP 6.2 KCP 6.4.1 | Haigh I. | 2020 | EVALUATE THE EFFICACY OF IN233C1560 AGAINST FOLIAR AND EAR DISEASES ON WHEAT – 2020 FIELD ARM  UK20-IBV-106-09  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/08 KCP 6.2 KCP 6.4.1 | Maßmann K. W. | 2020 | EVALUATE THE EFFICACY OF IN233C1560 AGAINST FOLIAR AND EAR DISEASES ON WHEAT - 2020 BIOCHEM AGRAR  GE20-IBV-106-10  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/09 KCP 6.2 KCP 6.4.1 | Hetterich A. | 2020 | EVALUATE THE EFFICACY OF IN233C1560 AGAINST FOLIAR AND EAR DISEASES ON WHEAT - 2020 HETTERICH  GE20-IBV-106-11  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/10 KCP 6.2 KCP 6.4.1 | Wöllmann S. | 2020 | EVALUATE THE EFFICACY OF IN233C1560 AGAINST FOLIAR AND EAR DISEASES ON WHEAT - 2020 AGROCHECK  GE20-IBV-106-12  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/11 KCP 6.2 KCP 6.4.1 | Negrini P. | 2020 | EVALUATE THE EFFICACY OF IN233C1560 AGAINST FOLIAR AND EAR DISEASES ON WHEAT - 2020 ANTEDIS  FR20-IBV-106-05  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/12 KCP 6.2 KCP 6.4.1 | Voisin J. F. | 2020 | EVALUATE THE EFFICACY OF IN233C1560 AGAINST FOLIAR AND EAR DISEASES ON WHEAT - 2020. Agrotest france  FR20-IBV-106-06  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/13 KCP 6.2 KCP 6.4.1 | Altissimo A. | 2020 | EVALUATE THE EFFICACY OF IN233C1560 AGAINST FOLIAR AND EAR DISEASES ON WHEAT - 2020 LANDLAB  IT20-IBV-106-21  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/14 KCP 6.2 KCP 6.4.1 | Altissimo A. | 2020 | EVALUATE THE EFFICACY OF IN233C1560 AGAINST FOLIAR AND EAR DISEASES ON WHEAT - 2020 LANDLAB  IT20-IBV-106-22  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/15 KCP 6.2 KCP 6.4.1 | Caballero J. R. | 2020 | EVALUATE THE EFFICACY OF IN233C1560 AGAINST FOLIAR AND EAR DISEASES ON WHEAT - 2020 FTS  SP20-IBV-106-25  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/16 KCP 6.2 KCP 6.4.1 | Moreno S. | 2020 | EFFICACY OF IN233C1560 AGAINST FOLIAR AND EAR DISEASES ON WHEAT AYE  SP20-IBV-106-24  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/17 KCP 6.2 KCP 6.4.1 | Forte G. | 2020 | EVALUATE THE EFFICACY OF IN233C1560 AGAINST FOLIAR AND EAR DISEASES ON WHEAT – 2020. AGRIGEOS  IT20-IBV-106-23  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/18 KCP 6.2 KCP 6.4.1 | Kolditz M. | 2020 | EVALUATE THE EFFICACY OF IN233C1560 AGAINST FOLIAR AND EAR DISEASES ON WHEAT 2020 BioChem agrar GmbH  PL20-IBV-106-13 GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/19 KCP 6.2 KCP 6.4.1 | Kolditz M. | 2020 | EVALUATE THE EFFICACY OF IN233C1560 AGAINST FOLIAR AND EAR DISEASES ON WHEAT 2020 BioChem agrar GmbH  PL20-IBV-106-14 GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/20 KCP 6.2 KCP 6.4.1 | Rusek K. | 2020 | EVALUATE THE EFFICACY OF IN233C1560 AGAINST FOLIAR AND EAR DISEASES ON WHEAT 2020 Fertico Sp. z o.o.  PL20-IBV-106-15 GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/21 KCP 6.2 KCP 6.4.1 | Rusek K. | 2020 | EVALUATE THE EFFICACY OF IN233C1560 AGAINST FOLIAR AND EAR DISEASES ON WHEAT 2020 Fertico Sp. z o.o.  PL20-IBV-106-16 GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/22 KCP 6.2 KCP 6.4.1 | Botoman G. | 2020 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on winter wheat - 2020 AGROPROSPECT  RO20-IBV-106-17 GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/23 KCP 6.2 KCP 6.4.1 | Ciprian F. G. | 2020 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2020 AGROTEST ROMANIA  RO20-IBV-106-18 GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/24 KCP 6.2 KCP 6.4.1 | Viglione P. | 2020 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2020 SAGEA  BG20-IBV-106-19 GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/25 KCP 6.2 KCP 6.4.1 | Viglione P. | 2020 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2020 SAGEA  BG20-IBV-106-20 GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/26 KCP 6.2 KCP 6.4.1 | Crepin D. | 2020 | Evaluate the efficacy of IN233C1560 against Pyrenophora teres on winter barley - 2020 ESSAIS+  FR20-IBV-107-01  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/27 KCP 6.2 KCP 6.4.1 | Haigh I. | 2020 | Evaluate the efficacy of IN233C1560 against foliar disease on barley - 2020 FIELD ARM  UK20-IBV-107-04  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/28 KCP 6.2 KCP 6.4.1 | Maßmann K. W. | 2020 | Evaluate the efficacy of IN233C1560 against foliar disease on barley - 2020 BioChem agrar GmbH  GE20-IBV-107-05  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/29 KCP 6.2 KCP 6.4.1 | Wöllmann S. | 2020 | Evaluate the efficacy of IN233C1560 against foliar disease on barley - 2020 agro-check  GE20-IBV-107-06  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/30 KCP 6.2 KCP 6.4.1 | Negrini P. | 2020 | Evaluate the efficacy of IN233C1560 against foliar disease on barley - 2020 ANTEDIS  FR20-IBV-107-02 GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/31 KCP 6.2 KCP 6.4.1 | Negrini P. | 2020 | Evaluate the efficacy of IN233C1560 against foliar disease on barley - 2020 ANTEDIS  FR20-IBV-107-03 GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/32 KCP 6.2 KCP 6.4.1 | Forte G. | 2020 | Evaluate the efficacy of IN233C1560 against foliar disease on barley - 2020 AGRIGEOS  IT20-IBV-107-09 GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/33 KCP 6.2 KCP 6.4.1 | Kolditz M. | 2020 | Evaluate the efficacy of IN233C1560 against foliar disease on barley - 2020 BioChem agrar GmbH G7 PL20-IBV-107-07 GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/34 KCP 6.2 KCP 6.4.1 | Rusek K. | 2020 | Evaluate the efficacy of IN233C1560 against foliar disease on barley - 2020 Fertico Sp. z o.o. G7 PL20-IBV-107-08 GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/01 KCP 6.4.1 | Crepin D. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 ESSAIS+  FR21-IBV-101-05  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/02 KCP 6.4.1 | Rivet J. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 ESSAIS+  FR21-IBV-101-06  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/03 KCP 6.4.1 | Crepin D. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 ESSAIS+  FR21-IBV-101-07  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/04 KCP 6.4.1 | Biaunier M. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 Qualiphyt  FR21-IBV-101-08  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/05 KCP 6.4.1 | Seifert M. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 BIOCHEM AGRAR  GE21-IBV-101-09  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/06 KCP 6.4.1 | Seifert M. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 BIOCHEM AGRAR  GE21-IBV-101-10  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/07 KCP 6.4.1 | Hetterich A. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 HETTERICH  GE21-IBV-101-11  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/08 KCP 6.4.1 | Hetterich A. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 HETTERICH  GE21-IBV-101-12  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/09 KCP 6.4.1 | Hetterich A. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 HETTERICH  GE21-IBV-101-13  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/10 KCP 6.4.1 | Kull S. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 CropTrials  GE21-IBV-101-14  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/11 KCP 6.4.1 | Deutsch D. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 CropTrials  GE21-IBV-101-15  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/12 KCP 6.4.1 | Deutsch D. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 CropTrials  GE21-IBV-101-16  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/13 KCP 6.4.1 | Waite K. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 NIAB  UK21-IBV-101-21  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/14 KCP 6.4.1 | Waite K. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 NIAB  UK21-IBV-101-22  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/15 KCP 6.4.1 | Haigh I. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 FIELD ARM  UK21-IBV-101-23  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/16 KCP 6.4.1 | Haigh I. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 FIELD ARM  UK21-IBV-101-24  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/17 KCP 6.4.1 | Negrini P. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on Durum Wheat - 2021 ANTEDIS  FR21-IBV-102-01  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/18 KCP 6.4.1 | Grasso S. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on durum wheat - 2021 LANDLAB  IT21-IBV-102-02  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/19 KCP 6.4.1 | Toninello A. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on durum wheat - 2021 SAGEA  IT21-IBV-102-03  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/20 KCP 6.4.1 | Vargas M. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on durum wheat - 2021 FTS  SP21-IBV-102-04  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/21 KCP 6.4.1 | Negrini P. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on Wheat - 2021 ANTEDIS  FR21-IBV-101-01  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/22 KCP 6.4.1 | Negrini P. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on Wheat - 2021 ANTEDIS  FR21-IBV-101-02  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/23 KCP 6.4.1 | Negrini P. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on Wheat - 2021 ANTEDIS  FR21-IBV-101-04  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/24 KCP 6.4.1 | Cioni F. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 SAGEA  IT21-IBV-101-03  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/25 KCP 6.4.1 | Cioni F. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 SAGEA  IT21-IBV-101-25  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/26 KCP 6.4.1 | Cioni F. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 SAGEA  IT21-IBV-101-26  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/27 KCP 6.4.1 | Altissimo A. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 LANDLAB  IT21-IBV-101-27  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/28 KCP 6.4.1 | Altissimo A. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 LANDLAB  IT21-IBV-101-28  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/29 KCP 6.4.1 | Toninello A. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 SAGEA  IT21-IBV-101-31  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/30 KCP 6.4.1 | Moreno S. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 AYE  SP21-IBV-101-29  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/31 KCP 6.4.1 | Moreno S. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 AYE  SP21-IBV-101-30  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/32 KCP 6.4.1 | Vargas M. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 FTS  SP21-IBV-101-32  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/33 KCP 6.4.1 | Rusek K. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 Fertico Sp. z o.o.  PL21-IBV-101-17  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/34 KCP 6.4.1 | Rusek K. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 Fertico Sp. z o.o.  PL21-IBV-101-18  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/35 KCP 6.4.1 | Rusek K. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 Fertico Sp. z o.o.  PL21-IBV-101-19  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/36 KCP 6.4.1 | Kolditz M. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 BioChem agrar GmbH  PL21-IBV-101-20  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/37 KCP 6.4.1 | Aleksiev N. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 SAGEA  BG21-IBV-101-33  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/38 KCP 6.4.1 | Aleksiev N. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 SAGEA  BG21-IBV-101-34  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/39 KCP 6.4.1 | Aleksiev N. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 SAGEA  BG21-IBV-101-35  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/40 KCP 6.4.1 | Aleksiev N. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 SAGEA  BG21-IBV-101-36  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/41 KCP 6.4.1 | Fora G. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 AGROTEST ROMANIA  RO21-IBV-101-37  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/42 KCP 6.4.1 | Fora G. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 AGROTEST ROMANIA  RO21-IBV-101-38  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/43 KCP 6.4.1 | Fora G. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 AGROTEST ROMANIA  RO21-IBV-101-39  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/44 KCP 6.4.1 | Botoman G. | 2021 | Evaluate the efficacy of IN233C1560 against foliar and ear diseases on wheat - 2021 AGROPROSPECT  RO21-IBV-101-40  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/45 KCP 6.4.1 | Crepin D. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on winter barley - 2021 ESSAIS+  FR21-IBV-103-05  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/46 KCP 6.4.1 | Gilet G. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on winter barley - 2021 VITA CONSULT  FR21-IBV-103-06  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/47 KCP 6.4.1 | Teresiak H. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on winter barley - 2021 agro-check  GE21-IBV-103-07  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/48 KCP 6.4.1 | Kull S. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on winter barley - 2021 CropTrials GmbH  GE21-IBV-103-08  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/49 KCP 6.4.1 | Zickart U. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on winter barley - 2021 BioChem agrar GmbH  GE21-IBV-103-09  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/50 KCP 6.4.1 | Hetterich A. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on winter barley - 2021 HETTERICH  GE21-IBV-103-10  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/51 KCP 6.4.1 | Teresiak H. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on spring barley - 2021 agro-check  GE21-IBV-104-02  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/52 KCP 6.4.1 | Haigh I. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on barley - 2020 FIELD ARM  UK21-IBV-103-16  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/53 KCP 6.4.1 | Livingstone K. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on spring barley - 2021 Scottish Agri Trials Service  UK21-IBV-104-01  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/54 KCP 6.4.1 | Livingstone K. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on spring barley - 2021 Scottish Agri Trials Service  UK21-IBV-104-04  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/55 | Negrini P. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on Winter Barley - 2021 ANTEDIS  FR21-IBV-103-01  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/56 KCP 6.4.1 | Toninello A. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on winter barley - 2021 SAGEA  IT21-IBV-103-02  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/57 KCP 6.4.1 | Toninello A. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on winter barley - 2021 SAGEA  IT21-IBV-103-03  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/58 KCP 6.4.1 | Zappalà P. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on winter barley - 2021 AGRIGEOS  IT21-IBV-103-04  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/59 KCP 6.4.1 | Zappalà P. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on winter barley - 2021 AGRIGEOS  IT21-IBV-103-17  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/60 KCP 6.4.1 | Altissimo A. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on winter barley - 2021 LANDLAB  IT21-IBV-103-18  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/61 KCP 6.4.1 | Altissimo A. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on winter barley - 2021 LANDLAB  IT21-IBV-103-19  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/62 KCP 6.4.1 | Zappalà P. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on spring barley - 2021 AGRIGEOS  IT21-IBV-104-05  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/63 KCP 6.4.1 | Moreno S. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on winter barley - 2021 Agricultura y Ensayo S.L.  SP21-IBV-103-20  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/64 KCP 6.4.1 | Vargas M. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on winter barley - 2021 Field Trials Services SL  SP21-IBV-103-21  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/65 KCP 6.4.1 | Vargas M. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on winter barley - 2021 Field Trials Services SL  SP21-IBV-103-22  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/66 KCP 6.4.1 | Vargas M. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on spring barley - 2021 Field Trials Services SL  SP21-IBV-104-06  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/67 KCP 6.4.1 | Rusek K. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on winter barley - 2021 Fertico Sp. z o.o.  PL21-IBV-103-11  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/68 KCP 6.4.1 | Rusek K. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on winter barley - 2021 Fertico Sp. z o.o.  PL21-IBV-103-12  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/69 KCP 6.4.1 | Kolditz M. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on winter barley - 2021 BioChem agrar GmbH  PL21-IBV-103-13  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/70 KCP 6.4.1 | Rusek K. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on spring barley - 2021 Fertico Sp. z o.o.  PL21-IBV-104-03  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/71 KCP 6.4.1 | Aleksiev N. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on winter barley - 2021 SAGEA OOD  BG21-IBV-103-23  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/72 KCP 6.4.1 | Aleksiev N. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on winter barley - 2021 SAGEA OOD  BG21-IBV-103-24  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/73 KCP 6.4.1 | Aleksiev N. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on winter barley - 2021 SAGEA OOD  BG21-IBV-103-25  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/74 KCP 6.4.1 | Aleksiev N. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on spring barley - 2021 SAGEA OOD  BG21-IBV-104-07  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/75 KCP 6.4.1 | Fora G. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on winter barley - 2021 S.C. AGROTEST ROMANIA SRL  RO21-IBV-103-26  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/76 KCP 6.4.1 | Botoman G. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on winter barley - 2021 AgroProspect SRL  RO21-IBV-103-27  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/77 KCP 6.4.1 | Botoman G. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on winter barley - 2021 AgroProspect SRL  RO21-IBV-103-28  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/78 KCP 6.4.1 | Fora G. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on spring barley - 2021 S.C. AGROTEST ROMANIA SRL  RO21-IBV-104-08  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/79 KCP 6.4.1 | Barou J.-C. | 2021 | Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. AGROTEST FRANCE  FR21-IBV-105-04  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/80 KCP 6.4.1 | Camuñez S. | 2020 | Efficacy of Prothio + Difeno RMIX against Sclerotinia on OSR.  STAPHYT  SCZ-20-44463-FR01 v2  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/81 KCP 6.4.1 | Camuñez S. | 2020 | Efficacy of Prothio + Difeno RMIX against Sclerotinia on OSR.  STAPHYT  SCZ-20-44463-FR02  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/82 KCP 6.4.1 | Crepin D. | 2021 | Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. ESSAIS +  FR21-IBV-105-02  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/83 KCP 6.4.1 | Hetterich A. | 2021 | Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. Hetterich Fieldwork GbR  GE21-IBV-105-08  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/84 KCP 6.4.1 | Hetterich A. | 2021 | Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. Hetterich Fieldwork GbR  GE21-IBV-105-09  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/85 KCP 6.4.1 | Hetterich A. | 2021 | Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. Hetterich Fieldwork GbR  GE21-IBV-105-12  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/86 KCP 6.4.1 | Hetterich A. | 2021 | Evaluate the efficacy of IN233C1560 and IN005B1560 against Phoma and Sclerotinia on OSR. Hetterich Fieldwork GbR  GE21-IBV-107-10  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/87 KCP 6.4.1 | Hetterich A. | 2021 | Evaluate the efficacy of IN233C1560 and IN005B1560 against Phoma and Sclerotinia on OSR. Hetterich Fieldwork GbR  GE21-IBV-107-11  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/88 KCP 6.4.1 | Rivet J. | 2021 | Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. ESSAIS+  FR21-IBV-105-01  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/89 KCP 6.4.1 | Teresiak H. | 2021 | Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. agro-check  GE21-IBV-105-05  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/90 KCP 6.4.1 | Zickart U. | 2021 | Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. BioChem agrar GmbH  GE21-IBV-105-07  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/91 KCP 6.4.1 | Camuñez S. | 2020 | Efficacy of Prothio + Difeno RMIX against Sclerotinia on OSR. GEP Trial, POLAND, 2020 FINAL REPORT STAPHYT  SCZ-20-44463-PL06  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/92 KCP 6.4.1 | Kolditz M. | 2021 | Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. -2021 Poland – Trial season 2021 EPPO Zone North-East BioChem agrar GmbH  PL21-IBV-105-13  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/93 KCP 6.4.1 | Rusek K. | 2021 | Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. -2021 Poland – Trial season 2021 EPPO Zone North-East Fertico  PL21-IBV-105-14  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/94 KCP 6.4.1 | Aleksiev N. | 2021 | Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. SAGEA OOD  BG21-IBV-105-15  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/95 KCP 6.4.1 | Aleksiev N. | 2021 | Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. SAGEA OOD  BG21-IBV-105-16  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/96 KCP 6.4.1 | Camuñez S. | 2020 | Efficacy of Prothio + Difeno RMIX against Sclerotinia on OSR.  STAPHYT  SCZ-20-44463-BG08  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/97 KCP 6.4.1 | Camuñez S. | 2020 | Efficacy of Prothio + Difeno RMIX against Sclerotinia on OSR.  STAPHYT  SCZ-20-44463-RO07  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/98 KCP 6.4.1 | George F. | 2021 | Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. SC Agrotest Romania SRL  RO21-IBV-105-17  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/99 KCP 6.4.1 | Teresiak-Baumgart | 2021 | Evaluate the efficacy of IN233C1560 and IN005B1570 against Phoma on OSR. agro-check  GE21-IBV-106-02  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/100 KCP 6.4.1 | Haigh I. | 2021 | Evaluate the efficacy of IN233C1560 and IN005B1560 against Phoma on OSR. Fieldarm Limited  UK21-IBV-106-05  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/101 KCP 6.4.1 | Camuñez S. | 2021 | Efficacy of Prothio + Difeno RMIX against Phoma on OSR GEP Trial, FRANCE, 2020 STAPHYT  SCZ-20-45428-FR01  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/102 KCP 6.4.1 | Kolditz M. | 2021 | Evaluate the efficacy of IN233C1560 and IN005B1560 against Phoma on OSR. BioChem agrar Polska Spolka z o.o.  PL21-IBV-106-03  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/103 KCP 6.4.1 | Fora G. | 2021 | Evaluate the efficacy of IN233C1560 and IN005B1560 against Phoma on OSR. SC Agrotest Romania SRL  RO21-IBV-106-07  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.2/104 KCP 6.4.1 | Camuñez S. | 2021 | Efficacy of Prothio + Difeno RMIX against Phoma on OSR GEP Trial, ROMANIA, 2020 FINAL REPORT STAPHYT  SCZ-20-45428-RO07  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.4.1/01 KCP 6.4.3 | Crepin D. | 2021 | Field part of bread making tests of cereals fungicide IN233C1560 on wheat - 2021, France – Trial season 2021, EPPO Zone Maritime ESSAIS+  FR21-IBV-108-01  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.4.1/02 KCP 6.4.3 | Crepin D. | 2021 | Field part of bread making tests of cereals fungicide IN233C1560 on wheat - 2021, France – Trial season 2021, EPPO Zone Maritime ESSAIS+  FR21-IBV-108-02  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.4.1/03 | Waite K. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on winter barley - 2021 NIAB  UK21-IBV-103-14  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.4.1/04 | Waite K. | 2021 | Evaluate the efficacy of IN233C1560 against foliar disease on winter barley - 2021 NIAB  UK21-IBV-103-15  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.4.1/05 | McCabe T. | 2021 | Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. Prime Crop Research  UK21-IBV-105-18  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.4.1/06 | McCabe T. | 2021 | Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. Prime Crop Research  UK21-IBV-105-19  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.4.1/07 | Negrini P. | 2021 | Evaluate the efficacy of IN233C1560 and IN005B1560 against Phoma, Sclerotinia on OSR. ANTEDIS  FR21-IBV-106-01  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.4.1/08 | Pralea M. | 2021 | Evaluate the efficacy of IN233C1560 and IN005B1560 against Phoma on OSR. Agrochemex Environmental LTD  UK21-IBV-106-04  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.4.1/09 | Camuñez S. | 2021 | Efficacy of Prothio + Difeno RMIX against Phoma on OSR GEP Trial, GERMANY, 2020 STAPHYT  SCZ-20-45428-DE03  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.4.1/10 | Camuñez S. | 2021 | Efficacy of Prothio + Difeno RMIX against Phoma on OSR GEP Trial, GERMANY, 2020 STAPHYT  SCZ-20-45428-DE04  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.4.1/11 | Camuñez S. | 2021 | Efficacy of Prothio + Difeno RMIX against Phoma on OSR. GEP Trial, UNITED KINGDOM, 2020 STAPHYT  SCZ-20-45428-GB05  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.4.1/12 | Camuñez S. | 2021 | Efficacy of Prothio + Difeno RMIX against Phoma on OSR. GEP Trial, POLAND, 2020 STAPHYT  SCZ-20-45428-PL06  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.4.1/13 | Aleksiev N. | 2021 | Evaluate the efficacy of IN233C1560 and IN005B1560 against Phoma on OSR. SAGEA  BG21-IBV-106-06  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.4.4/01 | Schmitt M. | 2021 | STUDY OF UNINTENTIONAL EFFECTS OF PLANT PROTECTION PRODUCT IN233C1560 ON QUALITY OF WINTER AND SPRING SOFT WHEAT AND ON BAKING I.F.B.M.  21/2520-E1195  GEP Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.1/01 | Urbani, M. | 2021a | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560: Validation of the Analytical Method for the Determination of Toluene as Relevant Impurity Content  Report No. : CH – 0325/2021  + Amendment report No.1 to final report (Amdm1\_KCP 5.1.1/01)  ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy  GLP : Yes  Unpublished | N | Y | ~~Data/study report never submitted before to Poland~~  Data/study report submitted first time in Poland for new authorisation under Article 33 | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.1/02 | Urbani, M. | 2021b | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560: Validation of the Analytical Method for the Determination of Prothioconazole-desthio as Relevant Impurity Content  Report No. : CH – 0326/2021  + Amendment report No.1 to final report (Amdm1\_KCP 5.1.1/02)  ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy  GLP : Yes  Unpublished | N | Y | ~~Data/study report never submitted before to Poland~~  Data/study report submitted first time in Poland for new authorisation under Article 33 | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.1/03 | Urbani, M. | 2021c | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560: Validation of the Analytical Method for the Determination of Active Ingredients Content  Report No. : CH – 0324/2021  + Amendment report No.1 to final report (Amdm1\_KCP 5.1.1/03)  ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy  GLP : Yes  Unpublished | N | Y | ~~Data/study report never submitted before to Poland~~  Data/study report submitted first time in Poland for new authorisation under Article 33 | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.2/01 | Garagna, D. | 2021a | Validation of the Analytical Method for the Determination of Difenoconazole and Prothioconazole residues in soil samples of Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560 coming from the Ecotoxicological tests  Report No. : CH – 0235/2021  + Amendment report No.1 to final report (Amdm1\_KCP 5.1.2/01)  ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.2/02 | Longhi, D. | 2021a | Validation of an analytical method for the quantification of Difenoconazole and Prothioconazole-desthio in wheat, barley, oilseed rape and processed commodities  Report No. : 21-31  LabAnalysis s.r.l., Casanova Lonati – Italy  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.2/03 | Garagna, D. | 2021b | Validation of the Analytical Method for the Determination of Difenoconazole and Prothioconazole residues in aqueous samples of Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560 coming from the Ecotoxicological tests  Report No. : CH – 0227/2021  + Amendment report No.1 to final report (Amdm1\_KCP 5.1.2/03)  ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.2/04 | Garagna, D. | 2021c | Validation of the Analytical Method for the Determination of Difenoconazole and Prothioconazole content in stock solutions of Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560 coming from the Ecotoxicological tests  Report No. : CH – 0232/2021  + Amendment report No.1 to final report (Amdm1\_KCP 5.1.2/04)  ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.2/05 | Garagna, D. | 2021d | Validation of the Analytical Method for the Determination of Difenoconazole and Prothioconazole content in feeding solutions of Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560 coming from the Ecotoxicological tests  Report No. : CH – 0232/2021  + Amendment report No.1 to final report (Amdm1\_KCP 5.1.2/05)  ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.2/06 | Noè, F. | 2021a | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560: Acute Toxicity to *Daphnia magna* in a 48-hour Immobilization Test under Semi-Static Exposure  Report No. : CH-0229/2021  + Amendment report No.1 to final report (Amdm1\_KCP 5. 1.2/06)  ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.2/07 | Noè, F. | 2021b | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560: Toxicity to Green Algae *Pseudokirchneriella subcapitata* in a Growth Inhibition Study  Report No. : CH-0230/2021  + Amendment report No.1 to final report (Amdm1\_KCP 5.1.2/07)  ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.2/08 | Noè, F. | 2021c | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560: Acute Toxicity to Zebrafish (*Brachydanio rerio*) in a 96-hour Study under Semi-Static Exposure  Report No. : CH-0228/2021  + Amendment report No.1 to final report (Amdm1\_KCP 5.1.2/08)  ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy  GLP : Yes  Unpublished | Y | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.2/09 | Dini, R. | 2021a | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560: Effects on Reproduction of Earthworm *Eisenia fetida* in an Artificial Soil Study  Report No. : CH-0239/2021  ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.2/10 | Dini, R. | 2021b | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560: Effects on Collembolan Reproduction in an Artificial Soil Study  Report No. : CH-0240/2021  ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.2/11 | Ponti, B. | 2021a | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560: Acute Oral and Contact Toxicity to adult worker bumblebees *Bombus terrestris* L.  Report No. : CH-0234/2021  ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy  GLP : Yes  Unpublished | Y | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.2/12 | Dini, R. | 2021c | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560: Effects on *Hypoaspis (Geolaelaps) aculeifer* Reproduction in an Artificial Soil Study  Report No. : CH-0241/2021  ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.2/13 | Ponti, B. | 2021b | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560: Chronic Oral Toxicity to adult worker honeybees *Apis mellifera* L. (10-day feeding)  Report No. : CH-0669/2021  ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy  GLP : Yes  Unpublished | Y | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.2/14 | Longhi, D. | 2021b | Validation of an analytical method for the quantification of Triazole Derivative Metabolites (TDMs) in wheat, barley, oilseed rape and processed commodities  Report No. : 21-108  LabAnalysis s.r.l., Casanova Lonati – Italy  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.2/15 | Longhi, D. | 2021c | Validation of an analytical method for the quantification of prothioconazole-desthio-3-hydroxy, prothioconazole-desthio-4-hydroxy, prothioconazole-desthio-5-hydroxy, prothioconazole-desthio-6-hydroxy and prothioconazole-desthio-alpha-hydroxy in cereal straw  Report No. : 21-120  + Amendment report No.1 to stduy plan (Amdm1\_KCP 5.1.2/15)  LabAnalysis s.r.l., Casanova Lonati – Italy  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| ~~KCP 5.1.2/16~~ | ~~Rigamonti, E.~~ | ~~2022a~~ | ~~Independent Laboratory Validation (ILV) of the Analytical Method for the Determination of Difenoconazole and Prothio-desthio in Rapeseed seeds~~  ~~Study plan No. : CH-1083/2021~~  ~~ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy~~  ~~GLP : Yes~~  ~~Unpublished~~ | ~~N~~ | ~~Y~~ | ~~Data/study report never submitted before to Poland~~ | ~~INDOFIL industries (Netherlands) B.V~~ |
| ~~KCP 5.1.2/17~~ | ~~Rigamonti, E.~~ | ~~2022b~~ | ~~Independent Laboratory Validation (ILV) of the Analytical Method for the Determination of Difenoconazole and Prothio-desthio in Whole Plant (Rapeseed)~~  ~~Study plan No. : CH-1084/2021~~  ~~ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy~~  ~~GLP : Yes~~  ~~Unpublished~~ | ~~N~~ | ~~Y~~ | ~~Data/study report never submitted before to Poland~~ | ~~INDOFIL industries (Netherlands) B.V~~ |
| ~~KCP 5.1.2/18~~ | ~~Rigamonti, E.~~ | ~~2022c~~ | ~~Independent Laboratory Validation (ILV) of the Analytical Method for the Determination of Difenoconazole and Prothio-desthio in Grain (Wheat)~~  ~~Study plan No. : CH-1082/2021~~  ~~ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy~~  ~~GLP : Yes~~  ~~Unpublished~~ | ~~N~~ | ~~Y~~ | ~~Data/study report never submitted before to Poland~~ | ~~INDOFIL industries (Netherlands) B.V~~ |
| ~~KCP 5.1.2/19~~ | ~~Rigamonti, E.~~ | ~~2022d~~ | ~~Independent Laboratory Validation (ILV) of the Analytical Method for the Determination of Difenoconazole and Prothio-desthio in Straw (wheat)~~  ~~Study plan No. : CH-1081/2021~~  ~~ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy~~  ~~GLP : Yes~~  ~~Unpublished~~ | ~~N~~ | ~~Y~~ | ~~Data/study report never submitted before to Poland~~ | ~~INDOFIL industries (Netherlands) B.V~~ |
| KCP 5.1.2/16 | Nichetti, S. | 2022a | Independent Laboratory Validation (ILV) of the Analytical Method for the Determination of Difenoconazole and Prothio-desthio in Straw (wheat)  Report No. : CH-1081/2021  ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.2/17 | Nichetti, S. | 2022b | Independent Laboratory Validation (ILV) of the Analytical Method for the Determination of Difenoconazole and Prothio-desthio in Grain (Wheat)  Report No.: CH-1082/2021  ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.2/18 | Nichetti, S. | 2022c | Independent Laboratory Validation (ILV) of the Analytical Method for the Determination of Difenoconazole and Prothio-desthio in Rapeseed seeds  Report No.: CH-1083/2021  ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.2/19 | Nichetti, S. | 2022d | Independent Laboratory Validation (ILV) of the Analytical Method for the Determination of Difenoconazole and Prothio-desthio in Whole Plant (Rapeseed)  Report No.: CH-1084/2021  ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.2/20 | ~~Rigamonti, E.~~  Nichetti, S. | 2022e | Independent Laboratory Validation (ILV) of the Analytical Method for the Determination of Prothio-desthio metabolites in Cereal straw  ~~Study plan~~ Report No. : CH-1091/2021  ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.2/21 | ~~Rigamonti, E.~~  Nichetti, S. | 2022f | Independent Laboratory Validation (ILV) of the Analytical Method for the Determination of TDM in Rapeseed seeds  ~~Study plan~~ Report No. : CH-1090/2021  ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.2/22 | ~~Rigamonti, E.~~  Nichetti, S. | 2022g | Independent Laboratory Validation (ILV) of the Analytical Method for the Determination of TDM in Whole Plant (Rapeseed)  ~~Study plan~~ Report No. : CH-1085/2021  ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.2/23 | ~~Rigamonti, E.~~  Nichetti, S. | 2022h | Independent Laboratory Validation (ILV) of the Analytical Method for the Determination of TDM in Grain (wheat)  ~~Study plan~~ Report No. : CH-1087/2021  ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.2/24 | ~~Rigamonti, E.~~  Nichetti, S. | 2022i | Independent Laboratory Validation (ILV) of the Analytical Method for the Determination of TDM in Straw (wheat)  ~~Study plan~~ Report No. : CH-1086/2021  ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.2/25 | Garagna, D. | 2022a | Validation of the Analytical Method for the Determination of Prothioconazole-desthio Residues in Aqueous Samples coming from the Ecotoxicological tests  Report No.: CH-0949/2021  ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.2/26 | Garagna, D. | 2022b | Difenconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560 Validation of the Analytical Method for the Determination of Difenoconazole and Prothioconazole Residues in Pollen and Nectar from Ecotoxicological Study  Report No.: CH-0223/2022  ChemService S.r.l. Controlli e Ricerche, Novate Milanese – Italy  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.1.2/27 | Garagna, D. | 2022c | Difenconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560: Effects on Honey Bee Brood (Apis mellifera L.) under Semi-field Conditions – Tunnel Test (Analytical Phase)  Report No.: 168191033  Report No test site study.: CH-0695/2022  Ibacom gmBH, Rossdorf - Germany  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.3.2.8/01 | Longhi, D. | 2023a | Validation of an analytical method for the quantification of Difenoconazole, Prothioconazole and Prothioconazole-desthio in honey  Report No.: LBN-0092-2023  LabAnalysis s.r.l., Casanova Lonati – Italy  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.3.2.8/02 | Longhi, D. | 2023b | Validation of an analytical method for the quantification of Triazole Derivative Metabolites (TDMs) in honey  Report No.: LBN-0093-2023  LabAnalysis s.r.l., Casanova Lonati – Italy  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.3.2.8/03 | Mattioli, B. | 2023 | Independent Laboratory Validation (ILV) of the Analytical Method fo the Determination of Difenoconazole, Prothioconazole, Prothioconazole-desthio and Triazole Derivatives Metabolites (TDMs) residue in Honey  Report No.: CH-0859-2023  ChemService S.r.l. Controlli e Ricerche, Novate Milanese (MI) – Italy  GLP: Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 5.3.2.8/04 | Rovetto, I. | 2023 | Analytical phase report - Magnitude of the residue of difenoconazole, prothioconazole, prothioconazole-desthio and triazole-derivative-metabolites (TDMs) in honey after one application of IN233C1560 380 EC on Phacelia crop under semi field conditions in four trials in Northern Europe and Southern Europe – 2023  Multisite study: 1111.4F.SAG23  Report No.: LBN-0108-2023  LabAnalysis s.r.l., Casanova Lonati – Italy  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/35 | Longhi, D. | ~~2021e~~  2022a | Storage stability of prothioconazole-desthio in forage, wheat grain, rapeseed seeds, wheat straw  ~~Study plan~~ Report No. : GLP-STUDY-21-123  LabAnalysis s.r.l., Casanova Lonati -Italy  GLP :Yes  Unpublished  ~~Ongoing~~ | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/36 | Longhi, D. | ~~2021f~~  2022b | Storage stability of Triazole Derivative Metabolites (TDM) in wheat forage, wheat grain, rapeseed seeds, wheat straw, apple, tomato, carrot  ~~Study plan~~ Report No. : GLP-STUDY-21-124  LabAnalysis s.r.l., Casanova Lonati -Italy  GLP :Yes  Unpublished  ~~Ongoing~~ | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| Amendment1\_KCP 6.1/36 | Longhi, D. | 2023 | Final report amendment No. 1 : Storage stability of Triazole Derivative Metabolites (TDM) in wheat forage, wheat grain, rapeseed seeds, wheat straw, apple, tomato, carrot  Report No. : GLP-STUDY-21-124-A-01  LabAnalysis s.r.l., Casanova Lonati -Italy  GLP :Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.1/37 | Longhi, D. | ~~2021g~~  2022c | Storage stability of prothioconazole-desthio-3-hydroxy, prothioconazole-desthio-4-hydroxy, prothioconazole-desthio-5-hydroxy, prothioconazole-desthio-6-hydroxy and prothioconazole-desthio-alpha-hydroxy in cereal straw  ~~Study plan~~ Report No. : GLP-STUDY-21-125  LabAnalysis s.r.l., Casanova Lonati -Italy  GLP :Yes  Unpublished  ~~Ongoing~~ | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.3/01 | Longhi, D. | 2021d | Determination of difenoconazole, prothioconazoldesthio and Triazole Derivative Metabolites (TDMs) residues in raw agricultural commodity of oilseed rape and processed (oilseed rape oil) following two applications of the formulated products IN233C1560 and IN005B1570 (Northern and Southern Europe – 16 trials + processed, year 2021 – open field)  Report No. : GLP-study-21-26  Staphyt, Inchy en Artois – France  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.3/02 | Sala, A. | 2021a | Determination of difenoconazole and prothioconazole residues in winter or spring wheat raw and processed commodities (white flour and white bread) following two applications of IN233C1560 380 EC  (Prothioconazole 250 g/L + Difenoconazole 130 g/L)  Northern and Southern Europe – 16 trials  Report No. : GLP-study-21-24  Staphyt, Inchy en Artois – France  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.3/03 | Sala, A. | 2021b | Determination of difenoconazole, prothioconazole-desthio and Triazole Derivative Metabolites (TDMs) residues in Barley raw and processed commodities (brewing malt and malt sprout, brewers grain, brewers yeast, beer) following two applications of IN233C1560 380 EC  (Prothioconazole 250 g/L + Difenoconazole 130 g/L)  (Northern and Southern Europe – 16 trials)  Multisite study  Report No. : GLP-study-21-~~24~~ 25  Staphyt, Inchy en Artois – France  GLP : Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 6.10/01 | Rovetto, I. | 2023 | Magnitude of the residue of difenoconazole, prothioconazole, prothioconazole-desthio and triazole-derivative metabolites (TDMs) in honey after one application of IN233C1560 380 EC on Phacelia crop under semi field conditions in four trials in Northern Europe and Southern Europe – 2023  Multisite study  Report No. : 1111.4F.SAG23  LabAnalysis s.r.l., Casanova Lonati -Italy  GLP :Yes  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V. |
| KCP 7.1.4/01 | Cattaneo A. | 2021 | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560: *In vitro* Skin Irritation Test with the EpiDermTM Model  Final Report CH – 0245/2021ChemService S.r.l. Controlli e RicercheGLP Unpublished | N | Y | ~~Data/study report never submitted before to Poland~~  Data/study report submitted first time in Poland for new authorisation under Article 33 | INDOFIL industries (Netherlands) B.V |
| KCP 7.1.4/02 | Cattaneo A. | 2021 | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560: *In vitro* Skin Corrosion Test with the EpiDermTM Model  Final Report CH – 0246/2021ChemService S.r.l. Controlli e RicercheGLP Unpublished | N | Y | ~~Data/study report never submitted before to Poland~~  Data/study report submitted first time in Poland for new authorisation under Article 33 | INDOFIL industries (Netherlands) B.V |
| KCP 7.1.5/01 | Cattaneo A. | 2021 | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560: *In vitro* Ocular Irritation Test with the EpiOcularTM Model  Final Report CH – 0247/2021ChemService S.r.l. Controlli e RicercheGLP Unpublished | N | Y | ~~Data/study report never submitted before to Poland~~  Data/study report submitted first time in Poland for new authorisation under Article 33 | INDOFIL industries (Netherlands) B.V |
| KCP 7.1.5/02 | Cattaneo A. | 2021 | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560: *In vitro* Eye Irritation and Corrosion with the BCOP Test  Final Report CH – 0248/2021ChemService S.r.l. Controlli e RicercheGLP Unpublished | N | Y | ~~Data/study report never submitted before to Poland~~  Data/study report submitted first time in Poland for new authorisation under Article 33 | INDOFIL industries (Netherlands) B.V |
| KCP 7.3/01 | Nagane, R. | 2022a | IN VITRO DERMAL ABSORPTION OF DIFENOCONAZOLE FROM DIFENOCONAZOLE 130 G/L + PROTHIOCONAZOLE 250 G/L EC - IN233C1560 USING HUMAN SPLIT-THICKNESS SKIN IN A FLOW THROUGH DIFFUSION SYSTEM  Report No.: 617-1-06-29169  JAI RESEARCH FOUNDATION  GLP Unpublished | N | Y | ~~Data/study report never submitted before to Poland~~  Data/study report submitted first time in Poland for new authorisation under Article 33 | INDOFIL industries (Netherlands) B.V |
| KCP 7.3/02 | Nagane, R. | 2022b | IN VITRO DERMAL ABSORPTION OF PROTHIOCONAZOLE FROM DIFENOCONAZOLE 130 G/L + PROTHIOCONAZOLE 250 G/L EC - IN233C1560 USING HUMAN SPLIT-THICKNESS SKIN IN A FLOW THROUGH DIFFUSION SYSTEM  Report No.: 617-1-06-29234  JAI RESEARCH FOUNDATION  GLP Unpublished | N | Y | ~~Data/study report never submitted before to Poland~~  Data/study report submitted first time in Poland for new authorisation under Article 33 | INDOFIL industries (Netherlands) B.V |
| KCP 7.3/03 | Nagane, R. | 2022c | IN VITRO DERMAL ABSORPTION OF PROTHIOCONAZOLE-DESTHIO FROM DIFENOCONAZOLE 130 G/L + PROTHIOCONAZOLE 250 G/L EC - IN233C1560 USING HUMAN SPLIT-THICKNESS SKIN IN A FLOW THROUGH DIFFUSION SYSTEM  Report No.: 617-1-06-29977  JAI RESEARCH FOUNDATION  GLP Unpublished | N | Y | ~~Data/study report never submitted before to Poland~~  Data/study report submitted first time in Poland for new authorisation under Article 33 | INDOFIL industries (Netherlands) B.V |
| KCP 9.2.4.1/01 | Ooms D. | 2021 | Predicted environmental concentrations in groundwater of prothioconazole, difenoconazole and metabolites, following application of product IN233C1560 on cereals and oilseed rape in Central EU using FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3 and FOCUS MACRO 5.5.4.  Company Report No 2021-IND-PECGW01  Eric Neumans Consulting s.r.l.  non GLP  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 9.2.4.1/02 | Rifflart M. | 2023 | Predicted environmental concentrations in groundwater of prothioconazole, difenoconazole and metabolites, following application of product AVTAR on cereals and oilseed rape in Central EU using FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3 and FOCUS MACRO 5.5.4.  Company Report No 2023-IND-PECGW01  Eric Neumans Consulting s.r.l.  no GLP  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V. |
| KCP 9.2.5/01 | Rifflart M. and Ooms D. | 2021 | Predicted environmental concentrations in Surface water of prothioconazole, difenoconazole and metabolites, following application of product IN233C1560 on cereals and oilseed rape in Central EU using STEPs 1-2 in FOCUS, SPIN 2.2, SWASH v5.3, MACRO v5.5.4, PRZM v4.3.1, TOXSWA v5.5.3 and SWAN v5.0.0.  Company Report No R2021-IND-PECSW01  Eric Neumans Consulting s.r.l.  non GLP  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 9.2.5/02 | Rifflart M. | 2023 | Predicted environmental concentrations in Surface water of prothioconazole, difenoconazole and metabolites, following application of product AVTAR on cereals and oilseed rape in Central EU using STEPs 1-2 in FOCUS, SPIN 2.2, SWASH v5.3, MACRO v5.5.4, PRZM v4.3.1, TOXSWA v5.5.3 and SWAN v5.0.0.  Company Report No R2023-IND-PECSW01  Eric Neumans Consulting s.r.l.  non GLP  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V. |
| KCP 9.2.5/03 | Anonymous | 2023 | Predicted environmental concentrations in Surface water of metabolite prothioconazole-S-methyl (M01), following application of product AVTAR on cereals and oilseed rape in using STEPs 1-2 in FOCUS.  Modelling output files  Eric Neumans Consulting s.r.l.  non GLP  Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V. |
| KCP 10.2.1/01 | Noè F. | 2021a | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560:  Acute Toxicity to Zebrafish (*Brachydanio rerio*) in a 96-hour Study under Semi-Static Exposure  Study CH-0228/2021  Source : ChemService S.r.l. Controlli e Ricerche GLP Studies Department, Novate Milanese (MI), Italy.  GLP, Unpublished | Y | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 10.2.1/02 | Noè F. | 2021b | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560:  Acute Toxicity to *Daphnia magna* in a 48-hour Immobilization Test under Semi-Static Exposure  Study CH-0229/2021  Source : ChemService S.r.l. Controlli e Ricerche GLP Studies Department, Novate Milanese (MI), Italy.  GLP, Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 10.2.1/03 | Noè F. | 2021c | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560:  Toxicity to Green Algae *Pseudokirchneriella subcapitata* in a Growth Inhibition Study  Study CH-0230/2021  Source : ChemService S.r.l. Controlli e Ricerche GLP Studies Department, Novate Milanese (MI), Italy.  GLP, Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 10.2.2/01 | Noè F. | 2021d | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560:  *Daphnia magna* Reproduction Test under Semi-static Conditions  Study CH-0231/2021  Source : ChemService S.r.l. Controlli e Ricerche GLP Studies Department, Novate Milanese (MI), Italy.  GLP, Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 10.3.1.1.1/01 | Ponti B. | 2021a | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560:  Acute Contact and Oral Toxicity to adult worker honeybees *Apis mellifera* L.  Study CH-0233/2021  Source : ChemService S.r.l. Controlli e Ricerche GLP Studies Department, Novate Milanese (MI), Italy.  GLP, Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 10.3.1.1.1/02 | Ponti B. | 2021b | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560:  Acute Oral and Contact Toxicity to adult worker bumblebees *Bombus terrestris* L.  Study CH-0234/2021  Source : ChemService S.r.l. Controlli e Ricerche GLP Studies Department, Novate Milanese (MI), Italy.  GLP, Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 10.3.1.2/01 | Ponti B. | 2021c | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC - IN233C1560:  Chronic Oral Toxicity to adult worker honeybees *Apis mellifera* L. (10-day feeding)  Study CH-0669/2021  Source : ChemService S.r.l. Controlli e Ricerche GLP Studies Department, Novate Milanese (MI), Italy.  GLP, Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 10.3.1.3/01 | Noè F. | 2021e | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560:  Honey bees (*Apis mellifera* L.) Larval Toxicity Test with Repeated Exposure  Study CH-0236/2021  Source : ChemService S.r.l. Controlli e Ricerche GLP Studies Department, Novate Milanese (MI), Italy.  GLP, Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 10.3.2.1/01 | Dini R. | 2021a | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560:  Effects on the Parasitoid *Aphidius rhopalosiphi* De Stefani Perez (Hymenoptera, Braconidae) under laboratory conditions  Study CH-0238/2021  Source : ChemService S.r.l. Controlli e Ricerche GLP Studies Department, Novate Milanese (MI), Italy.  GLP, Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 10.3.2.1/02 | Dini R. | 2021b | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560:  Effects on the predatory mite *Typhlodromus pyri* Scheuten (Acari: Phytoseiidae) under laboratory conditions  Study CH-0237/2021  Source : ChemService S.r.l. Controlli e Ricerche GLP Studies Department, Novate Milanese (MI), Italy.  GLP, Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 10.4.1.1/01 | Dini R. | 2021c | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560:  Effects on Reproduction of Earthworm *Eisenia fetida* in an Artificial Soil Study  Study CH-0239/2021  Source : ChemService S.r.l. Controlli e Ricerche GLP Studies Department, Novate Milanese (MI), Italy.  GLP, Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 10.4.2.1/01 | Dini R. | 2021d | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560:  Effects on Collembolan Reproduction in an Artificial Soil Study  Study CH-0240/2021  Source : ChemService S.r.l. Controlli e Ricerche GLP Studies Department, Novate Milanese (MI), Italy.  GLP, Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 10.4.2.1/02 | Dini R. | 2021e | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560:  Effects on *Hypoaspis (Geolaelaps) aculeifer* Reproduction in an Artificial Soil Study  Study CH-0241/2021  Source : ChemService S.r.l. Controlli e Ricerche GLP Studies Department, Novate Milanese (MI), Italy.  GLP, Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 10.5/01 | Tediosi E. | 2021 | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560:  Effects on Soil Microorganisms -Nitrogen Transformation Test  Study CH-0242/2021  Source : ChemService S.r.l. Controlli e Ricerche GLP Studies Department, Novate Milanese (MI), Italy.  GLP, Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 10.6.2/01 | Noè F. | 2021f | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560:  Seedling Emergence and Seedling Growth Test of Terrestrial Plants  Study CH-0243/2021  Source : ChemService S.r.l. Controlli e Ricerche GLP Studies Department, Novate Milanese (MI), Italy.  GLP, Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |
| KCP 10.6.2./02 | Noè F. | 2021g | Difenoconazole 130 g/L + Prothioconazole 250 g/L EC – IN233C1560:  Vegetative Vigour Test of Terrestrial Plants  Study CH-0244/2021  Source : ChemService S.r.l. Controlli e Ricerche GLP Studies Department, Novate Milanese (MI), Italy.  GLP, Unpublished | N | Y | Data/study report never submitted before to Poland | INDOFIL industries (Netherlands) B.V |

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

| **Data point** | **Author(s)** | **Year** | **Title Company Report No.  Source (where different from company)**  **GLP or GEP status**  **Published or not** | **Verte-brate study**  **Y/N** | **Data protection claimed**  **Y/N** | **Justification if data protection is claimed** | **Owner** |
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| ~~CP 5.2~~ | ~~Anft & Bardel~~ | ~~2005~~ | ~~Modification M001 of method 00731 for the determination of residues of JAU 6476-desthio (SXX 0665) in air by HPLCMS/ MS~~  ~~Bayer CropScience,~~  ~~Report No.: 00731/M001~~  ~~GLP~~  ~~Unpublished~~ | ~~N~~ | ~~N~~ |  | ~~Bayer CropScience~~  ~~AG~~ |
| CP 5.2 | Scharmel, O. | 2006 | Report No.: M-041798-01-1  EU agreed, DAR, United Kingdom, 2004.  GLP  Unpublished | N | N |  | Bayer CropScience  AG |
| CP 5.2 | Steinhauer, S. | 2001 | Report No. : M-067970-01-1  EU agreed, DAR, United Kingdom, 2004.  GLP  Unpublished | N | N |  | Bayer CropScience  AG |
| CP 5.2 | Sommer, H | 2001 | Report No.: M-079449-01-1  EU agreed, DAR, United Kingdom, 2004.  GLP  Unpublished | N | N |  | Bayer CropScience  AG |
| CP 5.2 | Massfeld | 2002 | Report No. : M-032554-01-1  EU agreed, DAR, United Kingdom, 2004.  GLP  Unpublished | N | N |  | Bayer CropScience  AG |
| ~~CP 5.2~~ | ~~Weeren & Pelz~~ | ~~2000~~ | ~~Report No. : M-027637-01-1~~  ~~EU agreed, DAR, United Kingdom, 2004~~  ~~GLP~~  ~~Unpublished~~ | ~~N~~ | ~~N~~ |  | ~~Bayer CropScience~~  ~~AG~~ |
| ~~CP 5.2~~ | ~~Class, T.~~ | ~~2001~~ | ~~Report No. : M-033019-01-1~~  ~~EU agreed, DAR, United Kingdom, 2004~~  ~~GLP~~  ~~Unpublished~~ | ~~N~~ | ~~N~~ |  | ~~Bayer CropScience~~  ~~AG~~ |
| CP 5.2 | Heinemann, O. | 2001a | Analytical determination of residues of JAU6476-3-hydroxy-desthio,JAU6476-4-hydroxy-desthio, and JAU6476-desthio in/on matrices of animal origin by HPLC-MS/MS  Bayer AG,  Report No.: 00655  GLP  Unpublished  EU agreed, DAR, United Kingdom, 2004 | N | N |  | Bayer CropScience  AG |
| CP 5.2 | Heinemann, O. | 2001c | Analytical determination of residues of JAU6476-3-hydroxy-desthio, JAU6476-4-hydroxy-desthio, and JAU6476-desthio in milk by HPLCMS/MS (00655/M001)  Bayer AG,  Report No.: 00655/M001  GLP  Unpublished  EU agreed, DAR, United Kingdom, 2004 | N | N |  | Bayer CropScience  AG |
| CP 5.2 | Dubey, L. | 2001 | Independent laboratory validation ofbayer methods 00655 and 00655/M001 for the determination of residues of JAU6476-3-hydroxydesthio,JAU6476-4-hydroxy-desthio, and JAU6476-desthio in/on matreces of animal origin by HPLC-MS/MS  Battelle, Geneva Research Centres, Carouge/Geneva, SwitzerlandBayer AG,  Report No.: A-14-01-01  GLP  Unpublished  EU agreed, DAR, United Kingdom, 2004 | N | N |  | Bayer CropScience  AG |
| KCA 6.1/01 | Heinemann, O. | 2001 | 18 months storage stability of residues of JAU 6476 and JAU6476-Desthio during frozen storage in/on wheat matrices  Report No. : MR-282/00  Bayer CropScience  GLP : Yes  Unpublished | N | N |  | Bayer CropScience |
| KCA 6.1 | Murphy, I. | 2008 | Stability of 1,2,4-Triazole, Tiazole-alanine, and Triazolyl acetic acid in Various Crop Matrices and Processed Commodities during Frozen Storage  Report No. : RAJAY006  ESFA technical report (10 August 2016)  GLP : Yes  Unpublished | N | N |  | Bayer CropScience |
| KCA 6.2.1/01 | Hass, M. | 2000 | Metabolism of JAU6476 in spring wheat (after foliar application)  Report No. : MR-198/99  Bayer CropScience  GLP : Yes  Unpublished | N | N |  | Bayer CropScience |
| KCA 6.2.1/04 | Vogeler, K. | 1993 | Metabolism of SXX0665 in summer wheat  Report No. : PF3906  Bayer CropScience  GLP : Yes  Unpublished | N | N |  | Bayer CropScience |
| KCA 6.2.1/05 | Hass, M. | 2001 | Metabolism of [phenyl-UL-14C]JAU6476 in peanuts  Report No. : MR-193/01  Bayer CropScience  GLP : Yes  Unpublished | N | N |  | Bayer CropScience |
| KCA 6.2.1/07 | Beedle, E.C. | 2004 | The metabolism of [phenyl-UL-14C]JAU6476 in sugar beets  Report No. : 200466  Bayer CropScience  GLP : Yes  Unpublished | N | N |  | Bayer CropScience |
| KCA 6.2.2/01 | XXXX | 2001 | [Phenyl-UL-14C]JAU6476 – Absroption, distribution, excretion, and metabolism in laying hens  Report No. : MR-309/01  XXXXX  GLP : Yes  Unpublished | Y | N |  | Bayer CropScience |
| KCA 6.2.2/02 | XXXX | 2003 | [Triazole-UL-14C]JAU6476 – Absroption, distribution, excretion, and metabolism in laying hens  Report No. : MEF-005/03  Bayer CropScience  GLP : Yes  Unpublished | Y | N |  | Bayer CropScience |
| KCA 6.2.3/01 | XXXX | 2001 | [Phenyl-UL-14C]JAU6476 – Absroption, distribution, excretion, and metabolism in lactating goat  Report No. : MR-092/01  Bayer CropScience  GLP : Yes  Unpublished | Y | N |  | Bayer CropScience |
| KCA 6.2.3/02 | XXXX | 2003 | [Triazole -UL-14C]JAU6476 – Absroption, distribution, excretion, and metabolism in lactating goat  Report No. : MR-448/02  Bayer CropScience  GLP : Yes  Unpublished | Y | N |  | Bayer CropScience |
| KCA 6.2.3/03 | XXXX | 2002 | [Phenyl-UL-14C]JAU6476-desthio – Absroption, distribution, excretion, and metabolism in lactating goat  Report No. : MR-091/01  Bayer CropScience  GLP : Yes  Unpublished | Y | N |  | Bayer CropScience |
| KCA 6.2.3/04 | XXXX | 2006 | [Phenyl-UL-14C]JAU6476-desthio – Absroption, distribution, excretion, and metabolism in lactating goat – Subsequent identification of metabolite hydrolisis products  Bayer CropScience  Report No. : MR-091/01  GLP : Yes  Unpublished | Y | N |  | Bayer CropScience |
| KCA 6.3.1/05 | Heinemann, O. | 2001 | Determination of residues of JAU6476-desthio on spring wheat after spray application of JAU646 FS and spray application of JAU6476 250 EC in France, Spain, and Italy  Bayer CropScience  Report No. : RA-2104/00  GLP/GEP : Yes  Unpublished | N | N |  | Bayer CropScience |
| KCA 6.3.1/07 | Heinemann, O. | 2001 | Determination of residues of JAU6476-desthio in/on wheat and triticale after spray application of JAU6476 250 EC in Spain and France  Bayer CropScience  Report No. : RA-2105/00  GLP/GEP : Yes  Unpublished | N | N |  | Bayer CropScience |
| KCA 6.3.2/03 | Heinemann, O. | 2001 | Determination of residues of JAU6476-desthio on spring barley after spray application of JAU6476 250 EC in Sweden, Germany, Northern France and Great Britain  Bayer CropScience  Report No. : RA-2101/00  GLP/GEP : Yes  Unpublished | N | N |  | Bayer CropScience |
| KCA 6.3.2/05 | Heinemann, O. | 2001 | Determination of residues of JAU6476-desthio in/on winter barley after spray application of JAU6476 250 EC in France, Italy and Portugal  Bayer CropScience  Report No. : RA-2144/98  GLP/GEP : Yes  Unpublished | N | N |  | Bayer CropScience |
| KCA 6.3.2/06 | Heinemann, O. | 2001 | Determination of residues of JAU6476-desthio in/on spring barley after spray application of JAU6476 250 EC in Spain, Italy and Southern France  Bayer CropScience  Report No. : RA-2103/00  GLP/GEP : Yes  Unpublished | N | N |  | Bayer CropScience |
| KCA 6.4.2/01 | XXXX | 2001 | JAU 6476-desthio – Dairy cattle feeding study  Bayer CropScience  Report No. : MR-535/00  GLP : Yes  Unpublished | Y | N |  | Bayer CropScience |
| KCA 6.6.1/01 | Haas, M. | 2001 | Confined rotational crop study with JAU6476  Bayer CropScience  Report No. : MR-159/00  GLP : Yes  Unpublished | N | N |  | Bayer CropScience |
| KCA 6.6.1/02 | Duah & Kraai | 2004 | The accumulation of [triazole-3,5-14C]JAU6476 in confined rotational crops  Bayer CropScience  Report No. : 200623  GLP : Yes  Unpublished | N | N |  | Bayer CropScience |

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

| **Data point** | **Author(s)** | **Year** | **Title Company Report No.  Source (where different from company)**  **GLP or GEP status**  **Published or not** | **Verte-brate study**  **Y/N** | **Data protection claimed**  **Y/N** | **Justification if data protection is claimed** | **Owner** |
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| CP 5.2 | Crook, S. | 2004 | Residue Method for the Determination of Difenoconazole (CGA169374) in Various Crops and Processed Crop Fractions. Final Determination by LC-MS/MS  Syngenta Crop Protection AG, Basel, Switzerland  Syngenta, Jealott’s Hill, United Kingdom,  Report No.: REM147.08  Not GLP  not published | N | N |  | Syngenta |
| CP 5.2 | Benazeraf, L. | 2004 | EU agreed, DAR, Sweden, 2006.  Unpublished | N | N |  | Syngenta |
| CP 5.2 | Wurrx R.E.M. | 1994 | EU agreed, DAR, Sweden, 2006.  Unpublished | N | N |  | Syngenta |
| CP 5.2 | Tribolet, R. | 2000 | EU agreed, DAR, Sweden, 2006.  Unpublished | N | N |  | Syngenta |
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| CP 5.2 | Tribolet, R. | 1999a | EU agreed, DAR, Sweden, 2006.  Unpublished | N | N |  | Syngenta |
| CP 5.2 | Tribolet, R. | 1992 | Sampling of air and determination of residues of parent compound by gas chromatography  Novartis Crop Protection AG, Basel, Switzerland  Ciba-Geigy Ltd., Basel, Switzerland,  Report No REM-147-02  Not GLP  Not Published | N | N |  | Syngenta |
| CP 5.2 | Tribolet, R. | 1996 | Report on Special Study 102/96. Validation of method REM 147.02 in air, Validation by analysis of fortified specimens and determination of recoveries  Novartis Crop Protection AG, Basel, Switzerland  Ciba-Geigy Ltd., Basel, Switzerland,  Report No 102/96  GLP  Not Published | N | N |  | Syngenta |
| KCA 6.1/02 | Beidler WT. | 1991a | Stability of CGA169374 residues in potatoes under freezer storage conditions for 2 years.  Novartis Crop Protection AG, Basel, Switzerland.  Ciba-Geigy Corp., Greensboro, United States  Report No ABR-90070.  Syngenta File No CGA 169374/0453  GLP :Yes  Unpublished. | N | N |  | Syngenta |
| KCA 6.1/03 | Beidler WT. | 1991b | Stability of CGA169374 residues in potatoes under freezer storage conditions for 2 years.  Novartis Crop Protection AG, Basel, Switzerland.  Ciba-Geigy Corp., Greensboro, United States  Report No ABR-90069.  Syngenta File No CGA 169374/0452  GLP :Yes  Unpublished. | N | N |  | Syngenta |
| KCA 6.1/04 | Beidler WT. | 1992 | Stability of CGA169374 residues in lettuce, soybeans and wheat forage under freezer storage conditions for one year.  Syngenta Crop Protection AG, Basel, Switzerland.  Ciba-Geigy Corp., Greensboro, United States  Report No ABR-91024.  Syngenta File No CGA 169374/0617  GLP :Yes  Unpublished | N | N |  | Syngenta |
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The following tables are to be completed by MS

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** | **Verte-brate study**  **Y/N** | **Data protection claimed**  **Y/N** | **Justification if data protection is claimed** | **Owner** |
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List of data relied on and not submitted by the applicant but necessary for evaluation

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