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| REGISTRATION REPORT  Part B  Section 7  Metabolism and Residues  Detailed summary of the risk assessment |
| Product code: **FRE 001/08/2020**  Product name: **FUNABEN® 018 PA**  Chemical active substance:  **Thiabendazole, 18 g/kg (1,8 %)** |
| Central Zone  Zonal Rapporteur Member State: Poland |
| CORE ASSESSMENT/Poland  (authorization) |
| Applicant: XXXX  Submission date: 07/07/2023  Evaluation date: 12/2023  MS Finalisation date: 03/2024 |

Version history

|  |  |
| --- | --- |
| When | What |
| December 2023 | Initial RR |
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# Metabolism and residue data (KCA section 6)

## Summary and zRMS Conclusion

The applicant's dRR text was not rewritten by the zRMS. In the resulting RR all comments /corrections/add-ons were placed on the grey background.

### Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation FUNABEN® 018 PA are presented in Table 7.1‑1. They have been selected from the individual GAPs in the Central EU. A list of all intended uses within the Central EU is given in Part B, Section 0.

**Overall conclusion**

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs of for Thiabendazole as laid down in Reg. (EU) 2023/377 is not expected as no residues in the proposed crops were determined in the submitted trials consistent with the intended GAP. According to the specific method of the application PRIMo estimation is not necessary - chronic and the short-term intakes of Thiabendazole residues are unlikely to present a public health concern.

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

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

Data gaps

Noticed data gaps are: none

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

| 1 | 2 | 3 | | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | Conclusions |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Use-No. (e)** | **Member state(s)** | **Crop and/ or situation  (crop destination / purpose of crop)** | | **F, Fn, Fpn G, Gn, Gpn or I** | **Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group) | **Application** | | | | **Application rate** | | | **PHI** (days) | **Remarks:**   e.g. g safener/synergist per ha  (f) |  |
| Method / Kind | Timing / Growth stage of crop & season | Max. number  a) per use  b) per crop/ season | Min. interval between applications (days) | g product / m2  a) max. rate per appl.  b) max. total rate per crop/season | g as/m2  a) max. rate per appl.  b) max. total rate per crop/season | Water L/ha  min / max |
|  | | | **Zonal uses (field or outdoor uses, certain types of protected crops)** | | | | | | | | | | | |  |
| 1 | PL | Peach | | Fpn | Leucostoma sp. | painting of wounds with brush | NR | a) 1/each wound  b) 1 / each wound | NR | a) 555,6\*  b) 555,6\* | a) 10\*  b) 10\* | NR | NR | \*dose per m2 of wound area resulting from the cutting and cleaning of infected places of trees |  |
| 2 | PL | Apple | | Fpn | Pezicula malicorticis  Pezicula alba  Nectria galligena | painting of wounds with brush | NR | a) 1/each wound  b) 1 / each wound | NR | a) 555,6\*  b) 555,6\* | a) 10\*  b) 10\* | NR | NR | \*dose per m2 of wound area resulting from the cutting and cleaning of infected places of trees |  |
|  | | | Minor uses according to Article 51 (zonal uses) | | | | | | | | | | | | |
| 3 | PL | Pear, Asian pear, European crab apple | | F | Pezicula malicorticis  Pezicula alba  Nectria galligena | painting of wounds with brush | NR | a) 1/each wound  b) 1 / each wound | NR | a) 555,6\*  b) 555,6\* | a) 10\*  b) 10\* | NR | NR | \*dose per m2 of wound area resulting from the cutting and cleaning of infected places of trees |  |
| 4 | PL | Apricot, Plum, Cherry, Sweet cherry, Nectarine | | F | Leucostoma sp.  Nectria galligena | painting of wounds with brush | NR | a) 1/each wound  b) 1 / each wound | NR | a) 555,6\*  b) 555,6\* | a) 10\*  b) 10\* | NR | NR | \*dose per m2 of wound area resulting from the cutting and cleaning of infected places of trees |  |
| 5 | PL | Ornamental plants (deciduous and coniferous trees and bushes),  Nursery ornamental plants | | F | Pezicula malicorticis  Pezicula alba  Nectria galligena | painting of wounds with brush | NR | a) 1/each wound  b) 1 / each wound | NR | a) 555,6\*  b) 555,6\* | a) 10\*  b) 10\* | NR | NR | Ornamental plants (deciduous and coniferous trees and bushes),  Nursery ornamental plants |  |
| 6 | PL | Forest nurseries plants, restockings, afforestations and forest trees’ seed orchards;  Christmas trees grown on plantations | | F | Pezicula malicorticis  Pezicula alba  Nectria galligena | painting of wounds with brush | NR | a) 1/each wound  b) 1 / each wound | NR | a) 555,6\*  b) 555,6\* | a) 10\*  b) 10\* | NR | NR | \*dose per m2 of wound area resulting from the cutting and cleaning of infected places of trees |  |
| 7 | PL | Peach, Chaenomeles | | F | Nectria galligena | painting of wounds with brush | NR | a) 1/each wound  b) 1 / each wound | NR | a) 555,6\*  b) 555,6\* | a) 10\*  b) 10\* | NR | NR | \*dose per m2 of wound area resulting from the cutting and cleaning of infected places of trees |  |
| 8 | PL | Bird cherry, Mahaleb cherry | | F | Leucostoma sp.  Pezicula malicorticis  Pezicula alba  Nectria galligena | painting of wounds with brush | NR | a) 1/each wound  b) 1 / each wound | NR | a) 555,6\*  b) 555,6\* | a) 10\*  b) 10\* | NR | NR | \*dose per m2 of wound area resulting from the cutting and cleaning of infected places of trees |  |
| 9 | PL | Chokeberry, Blackberry, Raspberry | | F | Pezicula malicorticis  Pezicula alba | painting of wounds with brush | NR | a) 1/each wound  b) 1 / each wound | NR | a) 555,6\*  b) 555,6\* | a) 10\*  b) 10\* | NR | NR | \*dose per m2 of wound area resulting from the cutting and cleaning of infected places of trees |  |

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

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

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

Explanation for Column 11 “Conclusion”

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

### Summary of the evaluation

The preparation FRE 001/08/2020 is composed of Thiabendazole.

Table 7.1‑2: Toxicological reference values for the dietary risk assessment of Thiabendazole

| Reference value | Source | Year | Value | Study relied upon | Safety factor |
| --- | --- | --- | --- | --- | --- |
| Thiabendazole | | | | | |
| ADI | EFSA (Conclusion on pesticide peer review) | 2014 | 0.1 mg/kg bw per day | 2 year rat | 100 |
| AOEL | EFSA (Conclusion on pesticide peer review) | 2014 | 0.070 mg/kg bw per day | 2 year rat | 100 |
| ARfD | EFSA (Conclusion on pesticide peer review) | 2014 | 0.10 mg/kg bw | Rat developmental study | 100 |

#### Summary for Thiabendazole

Table 7.1‑3: Summary for Thiabendazole

| Use-No.\* | Crop | Plant metabolism covered? | Sufficient residue trials? | PHI sufficiently supported? | Sample sto­rage covered by stability data? | MRL compliance | Chronic risk for consumers identified? | Acute risk for consumers identified? |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 | Peach | Yes | Yes (4 trials from 2 seasons) | NR | Yes | Yes | No | No |
| 2 | Apple | Yes | Yes (4 trials from 2 seasons) | NR | Yes | Yes | No |

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

#### Summary for FRE 001/08/2020

Table 7.1‑4: Information on FRE 001/08/2020 (KCA 6.8)

| Crop | PHI for FRE 001/08/2020  proposed by applicant | PHI/ Withholding period\* sufficiently supported for | PHI for FRE 001/08/2020  proposed by zRMS | zRMS Comments  (if different PHI proposed) |
| --- | --- | --- | --- | --- |
| Thiabendazole |
| Peach | NR | NR | No comments | |
| Apple | NR | NR |
| Pear, Asian pear, European crab apple | NR | NR |
| Apricot, Plum, Cherry, Sweet cherry, Nectarine | NR | NR |
| Ornamental plants (deciduous and conif-erous trees and bushes),  Nursery orna-mental plants | NR | NR |
| Forest nurse-ries plants, restockings, afforestations and forest trees’ seed orchards;  Christmas trees grown on plantations | NR | NR |
| Chaenomelex | NR | NR |
| Bird cherry, Mahaleb cherry | NR | NR |
| Chokeberry, Blackberry, Raspberry | NR | NR |

NR: not relevant

\* Purpose of withholding period to be specified

\*\* F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Assessment

All performed studies of the residues of thiabendazole in peach and apple can be considered as representative of respective crops and indicate, that the values of the residue are below quantification limits in all cases.

Taking into account also specific mode of application: painting of wounds on trees with brush (locally) and form of product (thick paste, not used in case of rain; additionally, the present polyvinyl acetate creates an impermeable and indelible coating on the wound surface, which prevents from getting through of active substance and other co-formulants), there is no need to propose any PHI.

## Thiabendazole

General data on Thiabendazole are summarized in the table below:

**Table 7.2‑1: General information on Thiabendazole**

|  |  |
| --- | --- |
| Active substance (ISO Common Name) | Thiabendazole |
| IUPAC | 2-(thiazol-4-yl)benzimidazole |
| Chemical structure | N  N  S  N |
| Molecular formula | C10H7N3S |
| Molar mass | 201,3 g/mol |
| Chemical group | Benzimidazole |
| Mode of action (if available) | Fungicide |
| Systemic | Yes |
| Company | Syngenta Crop Protection AG |
| Rapporteur Member State (RMS) | Spain |
| Approval status | Approved  Date of (05/03/2001) - COMMISSION DIRECTIVE 2001/21/EC <https://eur-lex.europa.eu/legal-content/PL/TXT/PDF/?uri=CELEX:32001L0021>  Date of (30/01/2017) – COMMISSION IMPLEMENTING REGULATION (EU) No 2017/157  <https://eur-lex.europa.eu/legal-content/PL/TXT/PDF/?uri=CELEX:32017R0157> |
| Restriction | see Approval Directive / Regulation |
| Review Report | SANTE/10315/2015 Rev . 3  7 December 2016 |
| Current MRL regulation | Commission Regulation (EU) 2023/377 of 15 February 2023  <https://eur-lex.europa.eu/legal-content/PL/TXT/PDF/?uri=CELEX:32023R0377> |
| Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed | Yes |
| EFSA Journal : Conclusion on the peer review | Yes, EFSA, 2022  <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7212>  EFSA, 2014  <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2014.3880> |
| EFSA Journal: conclusion on article 12 | Yes, EFSA, 2022  <https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2022.7539> |
| Current MRL applications on intended uses | N/A |

\* Notifier in the EU process to whom the a.s. belong(s)

\*\* If yes: EFSA, YYYY - see list of references

### Stability of Residues (KCA 6.1)

#### Stability of residues during storage of samples

Not relevant **–** specimens collected from field trials were storage within 3-4 month until the analyses of residues were performed. Please refer to point 7.2.3.

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

Not relevant – samples were analysed within 24 hours after extraction.

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

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

No new data submitted in the framework of this application.

Information is provided in the dossier for the active substance by Syngenta Crop Protection AG, based on Letter of Access.

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

Not relevant due to specific mode of application: painting of wounds on trees with brush (locally) and form of product (thick paste; additionally, the present polyvinyl acetate creates an impermeable and indelible coating on the wound surface, which prevents from getting through of active substance and other co-formulants). It should also be considered, that apples, peaches and other indicated trees and shrubs (minor uses) are multiyears plants, therefore term "rotational crop" is not relevant in this case.

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

No new data submitted in the framework of this application. Please refer to dossier for active substance provided by Syngenta Crop Protection AG, based on Letter of Access.

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

No new data submitted in the framework of this application. Please refer to dossier for active substance provided by Syngenta Crop Protection AG, based on Letter of Access.

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

Not relevant due to specific mode of application: painting of wounds on trees with brush (locally) and form of product (thick paste, not used in case of rain; additionally, the present polyvinyl acetate creates an impermeable and indelible coating on the wound surface, which prevents from getting through of active substance and other co-formulants). Therefore there is no possibility to expect the exposure for FUNABEN® 018 PA in case of livestock.

For other information please refer to dossier for active substance provided by Syngenta Crop Protection AG, based on Letter of Access.

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

No new data submitted in the framework of this application. Please refer to dossier for active substance provided by Syngenta Crop Protection AG, based on Letter of Access.

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

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

Four new stability studies have been submitted by the applicant in the framework of this application. Results are summarized in the Table below. The detailed assessment of these studies are presented in Appendix 2.

For current MRL, please refer to Commission Regulation (EU) 2023/377 of 15 February 2023 amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benzalkonium chloride (BAC), chlorpropham, didecyldimethylammonium chloride (DDAC), flutriafol, metazachlor, nicotine, profenofos, quizalofop-P, sodium aluminium silicate, thiabendazole and triadimenol in or on certain products (Text with EEA relevance)

<https://eur-lex.europa.eu/legal-content/PL/TXT/PDF/?uri=CELEX:32023R0377>

Table 7.2‑3: Summary of new data supporting the intended uses of FRE 001/08/2020 and conformity to existing MRL

| Crop (matrix) | No of trials | Thiabendazole residues content [mg/kg] | Current MRL [mg/kg] | Acceptability [Yes/No] | Reference (Author/Year/Report no) |
| --- | --- | --- | --- | --- | --- |
| **New data** | | | | | |
| Apple | 2 | <0,003 (<LOD) | 4 | Yes | K.Felczak, R.Figurski, M. Kozmana, 2021, report D-2020-44  K.Felczak, D.Gąszczyk, E. Markiewicz, 2022, report PB-2022-01 |
| Peach | 2 | <0,003 (<LOD) | 0,01 | Yes | K.Felczak, R.Figurski, M. Kozmana, 2021, report 21FRT-04PRUPETHIA  K.Felczak, D.Gąszczyk, E. Markiewicz, 2022, report PB-2022-02 |
| Apple | 2 | <0,003 (<LOD) | 4 | Yes | K.Felczak, M. Kozmana, M.Tartanus, 2022, Report 21FRT-54MABSDFRE  K.Felczak, D.Gąszczyk, E. Markiewicz, 2023, report PB-2023-25 |
| Peach | 2 | <0,003 (<LOD) | 0,01 | Yes | K.Felczak, M. Kozmana, M.Tartanus, 2022, report  2~~1~~2FRT-54MABSDFRE  K.Felczak, D.Gąszczyk, E. Markiewicz, 2023, report PB-2023-26 |
| ~~Apple~~ | ~~N/A (validation)~~ | ~~N/A (validation)~~ | ~~N/A (validation)~~ | ~~Yes~~ | ~~K.Felczak, M. Kozmana, M.Tartanus, 2022, report~~  ~~22FRT-01PRUPETHIA~~  ~~K.Felczak, D.Gąszczyk, E. Markiewicz, 2022, VALIDATION STUDY NUMBER: PW-2021-10~~ |

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

According to the available data (4 trials on Apple and 4 trials on Peach – all results below limit of detection), the intended uses on Apple and Peach are considered acceptable.

Taking into account, that Regulation (EU) No 544/2011 foresees reduction in the number of trials required for “zero residues” (< limit of detection) situations, extrapolation to all minor uses (please refer to GAP table) is possible without performing additional trials. The data submitted show that no exceedance of the MRL will occur. All the intended uses described in the GAP table are considered acceptable.

### Magnitude of residues in livestock

#### Dietary burden calculation

Not relevant due to specific mode of application - painting of wounds on trees with brush (locally). No exposure of livestock animals is expected.

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

Not relevant due to specific mode of application - painting of wounds on trees with brush (locally). No exposure of livestock animals is expected.

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

#### Available data for all crops under consideration

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

#### Conclusion on processing studies

Not relevant - due specific mode of application (painting with brush on wounds of trees, locally) and results of residues (all results below LOD).

### Magnitude of residues in representative succeeding crops

None of the crops under evaluation are expected to be grown in rotation. Further investigation of residues in rotational crops is therefore not required.

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

No new data submitted in the framework of this application. Crops under evaluation are not expected to be grown in rotation. Further investigation of residues in rotational crops is therefore not required.

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

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of FRE 001/08/2020. Therefore, other special studies are not needed.

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

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2). However, taking into account specific mode of application (painting with brush on wounds of trees, locally) and results of residues (all < LOD), no exposure through diet is expected. Therefore no risk assessment for consumers is required.

#### Input values for the consumer risk assessment

Taking into account specific mode of application (painting with brush on wounds of trees, locally) and results of residues (all < LOD), no exposure through diet is expected. Therefore no risk assessment for consumers is required.

#### Conclusion on consumer risk assessment

Taking into account specific mode of application (painting with brush on wounds of trees, locally) and results of residues (all < LOD), no exposure through diet is expected. Therefore no risk assessment for consumers is required.

## Combined exposure and risk assessment

Not relevant. Plant protection product FUNABEN® 018 PA contains only one active substance.

## References

|  |
| --- |
| Commission Regulation (EU) 2023/377 of 15 February 2023 amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benzalkonium chloride (BAC), chlorpropham, didecyldimethylammonium chloride (DDAC), flutriafol, metazachlor, nicotine, profenofos, quizalofop-P, sodium aluminium silicate, thiabendazole and triadimenol in or on certain products. |
| Review report for the active substance thiabendazole finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 7 December 2016 in view of the renewal of the approval of thiabendazole as active substance in accordance with Regulation (EC) No 1107/2009 (SANTE/10315/2015 Rev . 3, 7 December 2016). |
| TECHNICAL GUIDELINES (SANTE/2019/12752): ON DATA REQUIREMENTS FOR SETTING MAXIMUM RESIDUE LEVELS, COMPARABILITY OF RESIDUE TRIALS AND EXTRAPOLATION OF RESIDUE DATA ON PRODUCTS FROM PLANT AND ANIMAL ORIGIN. |
| EFSA (European Food Safety Authority), 2016. Revision of the review of the existing maximum residue  levels for thiabendazole. |
|  |
|  |

1. Lists of data considered in support of the evaluation.

List of data submitted by the applicant and relied on

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
| KCA 6.3 | K.Felczak, R.Figurski, M. Kozmana | 2021 | Magnitute of the residue of thiabendazole (CAS 148-79-8) in apple (Raw Agricultural Commodity – RAC) grown in open field conditions after one application of a formulated product FRE 001/08/2020 – two harvest trials in Northern Europe – Poland (2020)  Report No D-2020-44  Fertico Sp. z o.o.  GLP  Unpublished | N | XXXX |
| KCA 6.3 | K.Felczak, R.Figurski, M. Kozmana | 2021 | Magnitute of the residue of thiabendazole (CAS 148-79-8) in peach (Raw Agricultural Commodity – RAC) grown in open field conditions after one application of a formulated product FRE 001/08/2020 – two harvest trials in Northern Europe – Poland (2020)  Report No 21FRT-04PRUPETHIA  Fertico Sp. z o.o.  GLP  Unpublished | N | XXXX |
| KCA 6.3 | K.Felczak, M. Kozmana, M.Tartanus | 2022 | Magnitute of the residue of thiabendazole (CAS 148-79-8) on apple (Raw Agricultural Commodity – RAC) grown in open field conditions after one application of a formulated product FRE 001/08/2020 – two harvest trials in Northern Europe – Poland (2021)  Report No 21FRT-54MABSDFRE  Fertico Sp. z o.o.  GLP  Unpublished | N | XXXX |
| KCA 6.3 | K.Felczak, M. Kozmana, M.Tartanus | 2022 | Magnitute of the residue of thiabendazole (CAS 148-79-8) in peach (Raw Agricultural Commodity – RAC) grown in open field conditions after one application of a formulated product FRE 001/08/2020 – two harvest trials in Northern Europe – Poland (2022)  Report No 22FRT-01PRUPETHIA  Fertico Sp. z o.o.  GLP  Unpublished | N | XXXX |
| KCA 6.3 | K.Felczak, D.Gąszczyk, E. Markiewicz | 2022 | Quantitative analysis of Thiabendazole residues in apple in field conditions (Raw Agricultural Commodity) after one application of a formulated product FRE 001/08/2020 – two harvest trials in Northern Europe – Poland 2021  Report No PB-2022-01  Fertico Sp. z o.o.  GLP  Unpublished | N | XXXX |
| KCA 6.3 | K.Felczak, D.Gąszczyk, E. Markiewicz | 2022 | Quantitative analysis of Thiabendazole residues in peaches in field conditions (Raw Agricultural Commodity) after one application of a formulated product FRE 001/08/2020 – two harvest trials in Northern Europe – Poland 2021  Report No PB-2022-02  Fertico Sp. z o.o.  GLP  Unpublished | N | XXXX |
| KCA 6.3 | K.Felczak, D.Gąszczyk, E. Markiewicz | 2023 | Quantitative analysis of Thiabendazole residues in apple in field conditions (Raw Agricultural Commodity) after one application of a formulated product FRE 001/08/2020 – two harvest trials in Northern Europe – Poland 2021  Report No PB-2023-25  Fertico Sp. z o.o.  GLP  Unpublished | N | XXXX |
| KCA 6.3 | K.Felczak, D.Gąszczyk, E. Markiewicz | 2023 | Quantitative analysis of Thiabendazole residues in peach in field conditions (Raw Agricultural Commodity) after one application of a formulated product FRE 001/08/2020 – two harvest trials in Northern Europe – Poland 2022  Report No PB-2023-26  Fertico Sp. z o.o.  GLP  Unpublished | N | XXXX |
| KCA 6.3 | K.Felczak, D.Gąszczyk, E. Markiewicz | 2022 | Validation of method for determination of Thiabendazole by Liquid Chromatography (LC-MS/MS)  Report no: PW-2021-10  Fertico Sp. z o.o.  GLP  Unpublished | N | XXXX |

1. Detailed evaluation of the additional studies relied upon
   1. Thiabendazole
      1. Stability of residues

Not relevant.

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

Not relevant.

* + 1. Magnitude of residues in plants
       1. Apple

Table A 1: Comparison of intended and critical EU GAPs

| Type of GAP | Number of applica­tions | Application rate per treatment  (precise unit) | Interval between application | Growth stage at last application | PHI (days) |
| --- | --- | --- | --- | --- | --- |
| GAP EU (EFSA, 2016 Revision of the review of the existing maximum residue  levels for thiabendazole) | 1 | Min. 80 and max 120 g active substance/hL | NR | BBCH 99 | N/A |
| Use no 2 (GAP) | 1 | 555,6 g of product /m2 of wound area | NR | BBCH 97-99 | N/A |

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

* + - * 1. Study no: D-2020-44 (field phase) + Study no: PB-2022-01 (laboratory phase)

|  |  |
| --- | --- |
| Comments of zRMS: | Both parts of the study have been accepted.  The LC-MS/MS method was employed. The method should be described by the applicant below. The qualifying ion and the quantifier ion were monitored. The LOQ was set at 0,01 mg/kg. Recoveries were in the required range. |

|  |  |
| --- | --- |
| Reference: | KCA 6.3 |
| Report | Magnitude of the residue of thiabendazole (CAS 148-79-8) in apple (Raw Agricultural Commodity – RAC) grown in open field conditions after one application of a formulated product FRE 001/08/2020 – two harvest trials in Northern Europe – Poland (2020)  Report No D-2020-44  K. Felczak, R. Figurski, M. Kozmana |
| Guideline(s): | Yes (Reg. (EC) 1107/2009; General recommendations for the design, preparation and realisation of residue trials, 7029/VI/95-rev.5, 22.07.97 and amendments; OECD Principles of Good Laboratory Practice |
| Deviations: | Yes (non-GLP data: weather from weather stations; crop maintenance and pesticide history provided by the farmer; soil characteristic; GPS coordinates; photos |
| GLP: | Yes |
| Acceptability: | Yes |

**Materials and methods**

The field phase happened as anticipated in the study plan and amendments. Two harvest trials were established in central Poland. Trials consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crops at the trial sites to such a degree as to have negatively impacted the integrity and validity of this study. One application of FRE 001/08/2020 was performed on the treated plot at the target dose rate of 100 g\*18 dm-2 (equivalent to 1,8 g a.s.\*dm-2 of thiabendazole). Applications were performed at BBCH 97-99. RAC specimens for analyses were collected at commercial harvest. Quality control measures were taken to maintain integrity and to avoid contamination at the trial site:

- locating untreated plot at least 15 m away from treated plot

- collecting specimens from the inner part of each plot

- harvesting untreated plot before treated and/or different people sampled untreated and treated plots

- using gel packs during transportation of specimens when delay between start of sampling and freezing is more than 12 hours

- wearing disposable gloves

- transporting and storing untreated and treated specimens separately

RAC specimens were put in deep freezing conditions at a target temperature of ≤18°C on the day of sampling, within 12 hours after sampling. All specimens remained deep frozen during storage at the test facility and during shipment to the analytical laboratory.

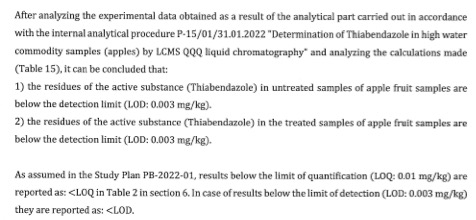
**Results and discussions**

These trials were performed as anticipated, in accordance with the study plan and amendments issued, unless otherwise stated in the deviations. It is therefore considered that the specimens collected were suitable for the purpose of the studies and the residue values can therefore be considered as representative of the crop and of the application timing and rate.

For analytical details please refer to study **PB-2022-01**.

|  |  |
| --- | --- |
| Reference: | KCA 6.3 |
| Report | Quantitative analysis of Thiabendazole residues in apple in field conditions (Raw Agricultural Commodity) after one application of a formulated product FRE 001/08/2020 – two harvest trials in Northern Europe – Poland 2021  Report No PB-2022-01  K. Felczak, D. Gąszczyk, E. Markiewicz |
| Guideline(s): | Yes (OECD Principles of Good Laboratory Practice) |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

**Conclusion**



(pasted by the evaluator).

Table A 2: Summary of the D-2020-44 (field phase) + PB-2022-01 (laboratory phase) trials

| Trial No./  Location/  EU zone/  Year | Commodity/ Variety | Date of  1.Sowing or planting  2.Flowering  3. Harvest | Application rate per treatment | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analyzed | Residues (mg/kg) | | PHI (days) | Details on trial |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| [g of product\*18 dm-2 of wound area]\* | Thiabendazole | |
|  | (a) | (b) |  | (c) |  |  |  | | (d) | (e) |
| D-2020-44-F01 /  09-142 Stare Olszyny, Poland (Mazowieckie) / North Zone / 2021 | 002 Pome fruits / Gala | 1) 10.2015  2) 25.04.2021-13.05.2021  3) 05.09.2021-16.09.2021 | 100,28 | 17.12.2020 | BBCH 97-99 | 2578 g (untreated plot)  3637 g (treated plot) | <0,003\*\* | | NR | \*equivalent to 1,8 g a.s.\*18 dm-2/equivalent to 555,6 g of product per m2  \*\*<LOD |
|  |  |  |  |  |  |  |  |  |  |  |
| D-2020-44-F02 / 05-652 Stary Trakt, Poland (Mazowieckie) / North zone / 2021 | 002 Pome fruits / Szampion | 1) 04.2004  2) 29.04.2021-15.05.2021  3) 24.09.2021-30.09.2021 | 99,992 | 17.12.2020 | BBCH 97-99 | 2712 g (untreated plot)  3275 g (treated plot) | <0,003\*\* | | NR | \*equivalent to 1,8 g a.s.\*18 dm-2/equivalent to 555,6 g of product per m2  \*\*<LOD |
|  |  |  |  |  |  |  |  | |  |  |
|  |  |  |  |  |  |  |  | |  |  |

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

LOD – limit of detection

**All the residue values obtained are < LOD. Analyses were performed using validated method described in report No PW-2021-10. Results are acceptable, “zero residue” situation was obtained.**

* + - * 1. Study no: 21FRT-54-MABSDFRE (field phase) + Study no: PB-2023-25 (laboratory phase)

|  |  |
| --- | --- |
| Comments of zRMS: | Both parts of the study have been accepted.  The LC-MS/MS method was employed. The qualifying ion and the quantifier ion were monitored. The LOQ was set at 0,01 mg/kg. Recoveries were in the required range. |

|  |  |
| --- | --- |
| Reference: | KCA 6.3 |
| Report | Magnitude of the residue of thiabendazole (CAS 148-79-8) on apple (Raw Agricultural Commodity – RAC) grown in open field conditions after one application of a formulated product FRE 001/08/2020 – two harvest trials in Northern Europe – Poland (2021)  Report No 21FRT-54MABSDFRE  K. Felczak, M. Kozmana, M. Tartanus |
| Guideline(s): | Yes (Reg. (EC) 1107/2009; General recommendations for the design, preparation and realisation of residue trials, 7029/VI/95-rev.5, 22.07.97 and amendments; OECD Principles of Good Laboratory Practice |
| Deviations: | Yes (non-GLP data: weather from weather stations; crop maintenance and pesticide history provided by the farmer; soil characteristic; GPS coordinates; photos |
| GLP: | Yes |
| Acceptability: | Yes |

Materials and methods

The field phase happened as anticipated in the study plan and amendments. Two harvest trials were established in central Poland. Trials consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crops at the trial sites to such a degree as to have negatively impacted the integrity and validity of this study. One application of FRE 001/08/2020 was performed on the treated plot at the target dose rate of 100 g\*18 dm-2 (equivalent to 1,8 g a.s.\*dm-2 of thiabendazole). Applications were performed at BBCH 97-99. RAC specimens for analyses were collected at commercial harvest. Quality control measures were taken to maintain integrity and to avoid contamination at the trial site:

- locating untreated plot at least 10 m away from treated plot

- collecting specimens from the inner part of each plot

- harvesting untreated plot before treated and/or different people sampled untreated and treated plots

- using gel packs during transportation of specimens when delay between start of sampling and freezing is more than 12 hours

- wearing disposable gloves

- transporting and storing untreated and treated specimens separately

RAC specimens were put in deep freezing conditions at a target temperature of ≤18°C on the day of sampling, within 12 hours after sampling. All specimens remained deep frozen during storage at the test facility and during shipment to the analytical laboratory.

Results and discussions

These trials were performed as anticipated, in accordance with the study plan and amendments issued, unless otherwise stated in the deviations. It is therefore considered that the specimens collected were suitable for the purpose of the studies and the residue values can therefore be considered as representative of the crop and of the application timing and rate.

For analytical details please refer to study **PB-2023-25**.

|  |  |
| --- | --- |
| Reference: | KCA 6.3 |
| Report | Quantitative analysis of Thiabendazole residues in apple in field conditions (Raw Agricultural Commodity) after one application of a formulated product FRE 001/08/2020 – two harvest trials in Northern Europe – Poland 2021  Report No PB-2023-25  K. Felczak, D. Gąszczyk, E. Markiewicz |
| Guideline(s): | Yes (OECD Principles of Good Laboratory Practice) |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

**Table A 3: Summary of the 21FRT-54MABSDFRE (field phase) + PB-2023-25 (laboratory phase) trials**

| **Trial No./**  **Location/**  **EU zone/**  **Year** | **Commodity/ Variety** | **Date of**  **1.Sowing or planting**  **2.Flowering**  **3. Harvest** | **Application rate per treatment** | **Dates of treatment or no. of treatments and last date** | **Growth stage at last treatment or date** | **Portion analyzed** | **Residues (mg/kg)** | **PHI (days)** | **Details on trial** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **[g of product\*18 dm-2 of wound area]\*** | **Thiabendazole** |
|  | (a) | (b) |  | (c) |  |  |  | (d) | (e) |
| 21FRT-54MABSDFRE-01 /  05-610 Modrzewina, Poland (Mazowieckie) / North Zone / 2022 | 002 Pome fruits / Gala | 1) 05.05.2016  2) 26.04.2022-06.05.2022  3) 10.09.2022-15.09.2022 | 97,76 | 09.02.2022 | BBCH 97-99 | 2185 g (untreated plot)  2225 g (treated plot) | <0,003\*\* | NR | \*equivalent to 1,8 g a.s.\*18 dm-2/equivalent to 555,6 g of product per m2  \*\*<LOD |
|  |  |  |  |  |  |  |  |  |  |
| 21FRT-54MABSDFRE-02 / 96-200 Wólka Babska, Poland (Łódzkie) / North zone / 2022 | 002 Pome fruits / Red Jonaprince | 1) 25.04.2016  2) 23.04.2022-08.05.2022  3) 26.09.2022 | 96,48 | 09.02.2022 | BBCH 97-99 | 2540 g (untreated plot)  2562 g (treated plot) | <0,003\*\* | NR | \*equivalent to 1,8 g a.s.\*18 dm-2/equivalent to 555,6 g of product per m2  \*\*<LOD |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

LOD – limit od detection

**All the residue values obtained are < LOD. Analyses were performed using validated method described in report No PW-2021-10. Results are acceptable, “zero residue” situation was obtained.**

* + - 1. Peach

Table A 4: Comparison of intended and critical EU GAPs

| Type of GAP | Number of applica­tions | Application rate per treatment  (precise unit) | Interval between application | Growth stage at last application | PHI (days) |
| --- | --- | --- | --- | --- | --- |
| Use no 2 (GAP) | 1 | 555,6 g /m2 of wound area | NR | BBCH 97-99 | NR |

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

* + - * 1. Study no: 21FRT-04PRUPETHIA (field phase) + Study no: PB-2022-02 (laboratory phase)

|  |  |
| --- | --- |
| Comments of zRMS: | Both parts of the study have been accepted.  The LC-MS/MS method was employed. The qualifying ion and the quantifier ion were monitored. The LOQ was set at 0,01 mg/kg. Recoveries were in the required range. |

|  |  |
| --- | --- |
| Reference: | KCA 6.3 |
| Report | Magnitude of the residue of thiabendazole (CAS 148-79-8) in peach (Raw Agricultural Commodity – RAC) grown in open field conditions after one application of a formulated product FRE 001/08/2020 – two harvest trials in Northern Europe – Poland (2020)  Report No 21FRT-04PRUPETHIA  K. Felczak, R. Figurski, M. Kozmana |
| Guideline(s): | Yes (Reg. (EC) 1107/2009; General recommendations for the design, preparation and realisation of residue trials, 7029/VI/95-rev.5, 22.07.97 and amendments; OECD Principles of Good Laboratory Practice |
| Deviations: | Yes (non-GLP data: weather from weather stations; crop maintenance and pesticide history provided by the farmer; soil characteristic; GPS coordinates; photos |
| GLP: | Yes |
| Acceptability: | Yes |

**Materials and methods**

The field phase happened as anticipated in the study plan and amendments. Two harvest trials were established in central Poland. Trials consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crops at the trial sites to such a degree as to have negatively impacted the integrity and validity of this study. One application of FRE 001/08/2020 was performed on the treated plot at the target dose rate of 100 g\*18 dm-2 (equivalent to 1,8 g a.s.\*dm-2 of thiabendazole). Applications were performed at BBCH 97-99. RAC specimens for analyses were collected at commercial harvest. Quality control measures were taken to maintain integrity and to avoid contamination at the trial site:

- locating untreated plot at least 10 m away from treated plot

- collecting specimens from the inner part of each plot

- harvesting untreated plot before treated and/or different people sampled untreated and treated plots

- using gel packs during transportation of specimens when delay between start of sampling and freezing is more than 12 hours

- wearing disposable gloves

- transporting and storing untreated and treated specimens separately

RAC specimens were put in deep freezing conditions at a target temperature of ≤18°C on the day of sampling, within 12 hours after sampling. All specimens remained deep frozen during storage at the test facility and during shipment to the analytical laboratory.

**Results and discussions**

These trials were performed as anticipated, in accordance with the study plan and amendments issued, unless otherwise stated in the deviations. It is therefore considered that the specimens collected were suitable for the purpose of the studies and the residue values can therefore be considered as representative of the crop and of the application timing and rate.

For analytical details please refer to study **PB-2022-02**.

|  |  |
| --- | --- |
| Reference: | KCA 6.3 |
| Report | Quantitative analysis of Thiabendazole residues in peaches in field conditions (Raw Agricultural Commodity) after one application of a formulated product FRE 001/08/2020 – two harvest trials in Northern Europe – Poland 2021  Report No PB-2022-02  K. Felczak, D. Gąszczyk, E. Markiewicz |
| Guideline(s): | Yes (OECD Principles of Good Laboratory Practice) |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

Table A 5: Summary of the 21FRT-04PRUPETHIA (field phase) + PB-2022-02 (laboratory phase) trials

| Trial No./  Location/  EU zone/  Year | Commodity/ Variety | Date of  1.Sowing or planting  2.Flowering  3. Harvest | Application rate per treatment | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analyzed | Residues (mg/kg) | PHI (days) | Details on trial |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| [g of product\*18 dm-2 of wound area]\* | Thiabendazole |
|  | (a) | (b) |  | (c) |  |  |  | (d) | (e) |
| 21FRT-04PRUPETHIA-F01 / 05-622 Belsk Mały, Poland (Mazowieckie) / North zone / 2021 | 003 Stone fruits, 003C Peaches / Harnaś | 1) 03.2018  2) 15.04.2021-21.05.2021  3) 10.08.2021-20.08.2021 | 101,5 | 24.03.2021 | BBCH 97-99 | 3096 g (untreated plot)  3178 g (treated plot) | <0,003\*\* | NR | \*equivalent to 1,8 g a.s.\*18 dm-2/equivalent to 555,6 g of product per m2  \*\*<LOD |
|  |  |  |  |  |  |  |  |  |  |
| 21FRT-04PRUPETHIA-F02 / 96-100 Nowy Kałęczyn, Poland (Łódzkie) / North zone / 2021 | 003 Stone fruits, 003C Peaches / Inka | 1) 04.2021  2) 20.04.2021-25.04.2021  3) 20.08.2021-25.08.2021 | 99,2 | 25.03.2021 | BBCH 97-99 | 3292 g (untreated plot)  3428 g (treated plot) | <0,003\*\* | NR | \*equivalent to 1,8 g a.s.\*18 dm-2/equivalent to 555,6 g of product per m2  \*\*<LOD |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

LOD – limit of detection

**All the residue values obtained are < LOD. Analyses were performed using validated method described in report No PW-2021-10. Results are acceptable, “zero residue” situation was obtained.**

* + - * 1. Study no: 22FRT-01PRUPETHIA (field phase) + Study no: PB-2023-26 (laboratory phase)

|  |  |
| --- | --- |
| Comments of zRMS: | Both parts of the study have been accepted.  The LC-MS/MS method was employed. The qualifying ion and the quantifier ion were monitored. The LOQ was set at 0,01 mg/kg. Recoveries were in the required range. |

|  |  |
| --- | --- |
| Reference: | KCA 6.3 |
| Report | Magnitude of the residue of thiabendazole (CAS 148-79-8) in peach (Raw Agricultural Commodity – RAC) grown in open field conditions after one application of a formulated product FRE 001/08/2020 – two harvest trials in Northern Europe – Poland (2022)  Report No 21FRT-04PRUPETHIA  K. Felczak, M. Kozmana, M. Tartanus |
| Guideline(s): | Yes (Reg. (EC) 1107/2009; General recommendations for the design, preparation and realisation of residue trials, 7029/VI/95-rev.5, 22.07.97 and amendments; OECD Principles of Good Laboratory Practice |
| Deviations: | Yes (non-GLP data: weather from weather stations; crop maintenance and pesticide history provided by the farmer; soil characteristic; GPS coordinates; photos |
| GLP: | Yes |
| Acceptability: | Yes |

**Materials and methods**

The field phase happened as anticipated in the study plan and amendments. Two harvest trials were established in central Poland. Trials consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crops at the trial sites to such a degree as to have negatively impacted the integrity and validity of this study. One application of FRE 001/08/2020 was performed on the treated plot at the target dose rate of 100 g\*18 dm-2 (equivalent to 1,8 g a.s.\*dm-2 of thiabendazole). Applications were performed at BBCH 97-99. RAC specimens for analyses were collected at commercial harvest. Quality control measures were taken to maintain integrity and to avoid contamination at the trial site:

- locating untreated plot at least 10 m away from treated plot

- collecting specimens from the inner part of each plot

- harvesting untreated plot before treated and/or different people sampled untreated and treated plots

- using gel packs during transportation of specimens when delay between start of sampling and freezing is more than 12 hours

- wearing disposable gloves

- transporting and storing untreated and treated specimens separately

RAC specimens were put in deep freezing conditions at a target temperature of ≤18°C on the day of sampling, within 12 hours after sampling. All specimens remained deep frozen during storage at the test facility and during shipment to the analytical laboratory.

**Results and discussions**

These trials were performed as anticipated, in accordance with the study plan and amendments issued, unless otherwise stated in the deviations. It is therefore considered that the specimens collected were suitable for the purpose of the studies and the residue values can therefore be considered as representative of the crop and of the application timing and rate.

For analytical details please refer to study **PB-2023-26**.

|  |  |
| --- | --- |
| Reference: | KCA 6.3 |
| Report | Quantitative analysis of Thiabendazole residues in peach in field conditions (Raw Agricultural Commodity) after one application of a formulated product FRE 001/08/2020 – two harvest trials in Northern Europe – Poland 2022  Report No PB-2023-26  K. Felczak, D. Gąszczyk, E. Markiewicz |
| Guideline(s): | Yes (OECD Principles of Good Laboratory Practice) |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

Table A 5: Summary of the 22FRT-01PRUPETHIA (field phase) + PB-2023-26 (laboratory phase) trials

| Trial No./  Location/  EU zone/  Year | Commodity/ Variety | Date of  1.Sowing or planting  2.Flowering  3. Harvest | Application rate per treatment | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analyzed | Residues (mg/kg) | PHI (days) | Details on trial |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| [g of product\*18 dm-2 of wound area]\* | Thiabendazole |
|  | (a) | (b) |  | (c) |  |  |  | (d) | (e) |
| 22FRT-01PRUPETHIA-01 / 05-622 Belsk Mały, Poland (Mazowieckie) / North zone / 2022 | 003 Stone fruits, 003C Peaches / Harnaś | 1) 03.2019  2) 25.04.2022-06.05.2022  3) 18.08.2022-26.08.2022 | 96,8 | 25.03.2022 | BBCH 97-99 | 2476 g (untreated plot)  2594 g (treated plot) | <0,003\*\* | NR | \*equivalent to 1,8 g a.s.\*18 dm-2/equivalent to 555,6 g of product per m2  \*\*<LOD |
|  |  |  |  |  |  |  |  |  |  |
| 22FRT-01PRUPETHIA-02 / 96-100 Nowy Kawęczyn, Poland (Łódzkie) / North zone / 2022 | 003 Stone fruits, 003C Peaches / Inka | 1) 04.2012  2) 29.04.2022-13.05.2022  3) 25.08.2022-01.09.2022 | 98,46 | 25.03.2022 | BBCH 97-99 | 2541 g (untreated plot)  3197 g (treated plot) | <0,003\*\* | NR | \*equivalent to 1,8 g a.s.\*18 dm-2/equivalent to 555,6 g of product per m2  \*\*<LOD |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

LOD – limit of detection

**All the residue values obtained are < LOD. Analyses were performed using validated method described in report No PW-2021-10. Results are acceptable, “zero residue” situation was obtained.**

* + 1. Magnitude of residues in livestock

Not relevant.

* + 1. Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

Not relevant.

* + 1. Magnitude of residues in representative succeeding crops

Not relevant.

* + 1. Other/Special Studies

Not relevant.