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| REGISTRATION REPORT  Part B  Section 7  Metabolism and Residues  Detailed summary of the risk assessment |
| Product code: BAS 743 03 F  Product name(s): **DIVEXO**  Chemical active substance(s):  Ametoctradin 120 g/L  Propamocarb hydrochloride 451 g/L |
| Central Zone  Zonal Rapporteur Member State: Poland |
| CORE ASSESSMENT |
| Applicant: XXXX  Submission date: October 2023 (update April 2024)  Evaluation date: (March) May 2024  Finalisation date: November 2024 |

Version history

|  |  |
| --- | --- |
| When | What |
| October 2023 | Initial dRR – XXXX Doc ID 2023/2029344 |
| April 2024 | zRMS RR version update – XXXX Doc ID 2024/2012944   * Appendix 3 update: unreadable PRIMo outputs replaced |
| May 2024 | Initial RR - zRMS |
| November 2024 | fRR by zRMS after comments. |

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# Metabolism and residue data (KCA section 6)

## Summary and zRMS Conclusion

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

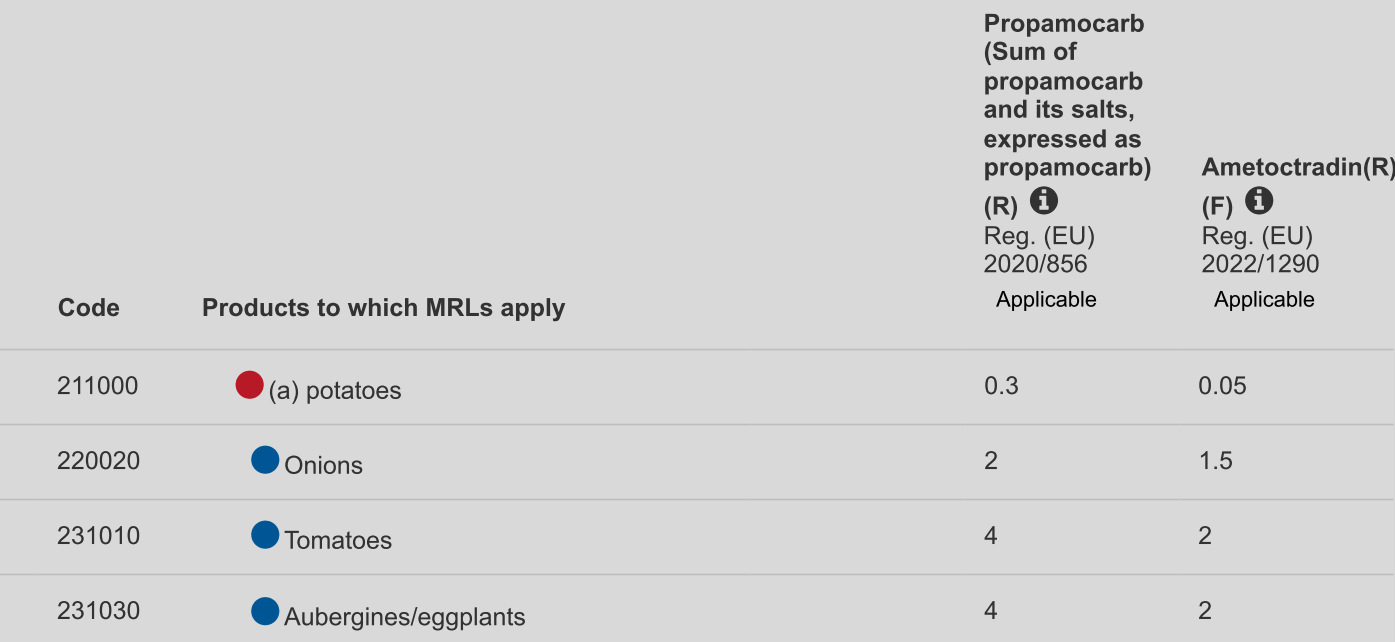
### Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation BAS 743 03 F are presented in Table 7.1‑1. A list of all intended uses within the zone is given in Part B, Section 0. It is noted that uses ~~9 - 17~~ 6-14 are not relevant for a residue assessment, as the crops are not destined for animal or human consumption. Therefore, these uses were avoided in Table 7.1‑1.

Overall conclusion

The data available are considered sufficient for risk assessment. No exceedance of the existing EU MRLs (0.05 mg/kg for potatoes; 1.5 mg/kg for onion and garlic; and 2 mg/kg for tomatoes and aubergines) for ametoctradin is expected. No exceedance of the existing EU MRLs (0.3 mg/kg for potatoes; 2 mg/kg for onion and garlic; and 4 mg/kg for tomatoes and aubergines) for propamocarb is expected.



The propamocarb MRL in honey of 15 mg/kg is now in force (Reg. (EU) 2024/1439).

The chronic (long-term) and acute (short-term) intakes of ametoctradin and propamocarb residues are unlikely to present a public health concern.

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

Data gaps

Noticed data gaps are: none

Table ‑: 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 | 15 |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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) | **Conclusion** |
| Method / Kind | Timing / Growth stage of crop & season | Max. number  a) per use  b) per crop/ season | Min. interval between applications (days) | | | kg or L product / ha  a) max. rate per appl.  b) max. total rate per crop/season | g or kg as/ha  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 | BE, IE, NL | | Potato (including seed potatoes) (SOLTU)  0211000 | F | *Phytophthora infestans* (PHYTIN) | SP | BBCH 21-89 | a) 3  b) 3 | 5 | | | a) 2  b) 6 | a) 0.24(\*) + 0.902(\*\*)  b) 0.72(\*) + 2.706(\*\*) | 100/1000 | 7 | Spray interval: 5-10 days  Water volume:  NL: 150/400 L/ha  IE: 200/400 L/ha  Applications only every 2nd year |  |
| 2 | PL HU, RO, SI, SK AT, CZ, DE | | Potato (including seed potatoes) (SOLTU)  0211000 | F | *Phytophthora infestans* (PHYTIN) | SP | BBCH 21-89 | a) 2  b) 2 | 5 | | | a) 2  b) 4 | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | 200/400 | 7 | Spray interval: 5-10 days  Dose rate range for HU, RO, SI, SK: 1,5-2 L/ha |  |
| 3 | BE, IE, NL, PL, RO | | Onion  0220020  (ALLCE), Garlic (ALLSA)  0220010 | F | *Peronospora destructor*  (PERODE) | SP | BBCH 14 - 49 | a) 2  b) 2 | 5 | | | a) 2  b) 4 | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | 200/1000 | 7 | Spray interval: 5-10 days  Water volume:  NL, PL: 200/800 L/ha  IE. 200/700 L/ha  Applications only every 2nd year |  |
| 4 | AT, CZ, DE, HU, SK, SI | | Onion 0220020  (ALLCE), Garlic (ALLSA)  0220010 | F | *Peronospora destructor*  (PERODE) | SP | BBCH 14 - 49 | a) 1  b) 1 | NA | | | a) 2  b) 2 | a) 0.24(\*) + 0.902(\*\*)  b) 0.24(\*) + 0.902(\*\*) | 200/1000 | 7 |  |  |
| 5 | PL,  HU, RO, SK, SI | | Tomato / 0231010 Aubergine 0231030 (LYPES) / (SOLME) | F | *Phytophthora infestans* (PHYTIN) | SP | BBCH 21-89 | a) 2  b) 2 | 7 | | | a) 2  b) 4 | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | 150/500 | 1 | Spray interval: 7-10 days |  |
| Remarks  table heading: | | | (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  (b) Catalogue of pesticide formulation types and international coding system CropLife  International Technical Monograph n°2, 6th Edition Revised May 2008  (c) g/kg or g/l | | | | | | | |  | (d) Select relevant  (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1  (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use. | | | | | | | |
| Remarks  columns: | | | 1 Numeration necessary to allow references  2 Use official codes/nomenclatures of EU Member States  3 For crops, the EU and Codex classifications (both) should be used; when relevant, the  use situation should be described (e.g. fumigation of a structure)  4 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  5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.  6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated. | | | | | | | |  | 7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3‑8263-3152-4), including where relevant, information on season at time of application  8 The maximum number of application possible under practical conditions of use must be provided.  9 Minimum interval (in days) between applications of the same product  10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.  11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).  12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.  13 PHI - minimum pre-harvest interval  14 Remarks may include: Extent of use/economic importance/restrictions | | | | | | | |

\* Ametoctradin

\*\* Propamocarb-hydrochloride

Explanation for Column 15 “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 BAS 743 03 F is composed of the active substance ametoctradin and propamocarb hydrochloride (the HCl salt of propamocarb).

Table ‑: Toxicological reference values for the dietary risk assessment of ametoctradin and propamocarb / propamocarb hydrochloride

| **Reference value** | **Source** | **Year** | **Value** | **Study relied upon** | | | **Safety factor** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Ametoctradin | | | | | | | |
| ADI | EFSA | 2012 | 10 mg/kg bw/d | Overall NOAEL of 1000 mg/kg bw per day  2 year rat | | | 100 |
| ARfD | EFSA | 2012 | Not required | | | | |
| Propamocarb hydrochloride | | | | | | | |
| ADI | EFSA | 2006 | 0.29 mg/kg bw/d | | 1 year rat | 100 | |
| ARfD | EFSA | 2006 | 1 mg/kg bw | | 28 day rat | 100 | |
| Propamocarb[1] | | | | | | | |
| ADI | EFSA | 2006 | 0.224 mg/kg bw/d | | - | - | |
| ARfD | EFSA | 2006 | 0.84 mg/kg bw | | - | - | |

[1] Reference values re-calculated for propamocarb by applying a molecular weight conversion factor 0.84 to the toxicological reference values derived for propamocarb hydrochloride (EFSA, 2013)

#### Summary for ametoctradin

Table ‑: Summary for ametoctradin

| 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, 2 | Potato | Yes | Yes (12 NEU) | Yes | Yes | Yes | No | No |
| 3, 4 | Onion / Garlic | Yes | Yes (13 NEU) | Yes | Yes | Yes | No | No |
| 5 | Tomato / Aubergine | Yes | Yes (12 NEU) | Yes | Yes | Yes | No | No |

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

New residue trials are provided to support the intended uses. The effects of processing on the nature of residues and data on effects of processing on the amount of residue have been EU reviewed.

Data on residues in succeeding crops are provided. It is very unlikely that residues will be present in succeeding crops, except rotated cereals and rotated strawberry, which are included in the risk assessments.

No significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

No MRL exceedance or consumer risk has been identified for the intended uses.

#### Summary for propamocarb

Table ‑: Summary for propamocarb

| 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, 2 | Potato | Yes | Yes (12 NEU) | Yes | Yes | Yes | No | No |
| 3, 4 | Onion / Garlic | Yes | Yes (13 NEU) | Yes | Yes | Yes | No | No |
| 5 | Tomato / Aubergine | Yes | Yes (12 NEU) | Yes | Yes | Yes | No | No |

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

New residue trials are provided to support the intended uses. The effects of processing on the nature of residues are available and data on effects of processing on the amount of residue have been EU reviewed.

Data on residues in succeeding crops have been EU reviewed. It is very unlikely that residues will be present in succeeding crops.

No significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

No MRL exceedance or consumer risk has been identified for the intended uses.

#### Summary for active substance 3

Not relevant

#### Summary for BAS 743 03 F

Table ‑: Information on BAS 743 03 F (KCA 6.8)

| Crop | PHI for BAS 743 03 F  proposed by applicant | PHI/ Withholding period sufficiently supported for | | PHI for BAS 743 03 F proposed by zRMS | zRMS Comments  (if different PHI proposed) |
| --- | --- | --- | --- | --- | --- |
| Ametoctradin | Propamocarb |
| Potato | 7 | Yes | Yes | none | |
| Onion | 7 | Yes | Yes |
| Garlic | 7 | Yes | Yes |
| Tomato | 1 | Yes | Yes |
| Aubergine | 1 | Yes | Yes |

Table ‑: Waiting periods before planting succeeding crops

|  |  |  |  |
| --- | --- | --- | --- |
| Waiting period before planting succeeding crops | | | Overall waiting period proposed by zRMS for  BAS 743 03 F |
| Crop group | Led by ametoctradin | Led by propamocarb |
| Potato | NR | NR | none |
| Onion | NR | NR |
| Garlic | NR | NR |
| Tomato | NR | NR |
| Aubergine | NR | NR |

NR: not relevant

Assessment

## Ametoctradin

General data on ametoctradin are summarised in the table below.

Table ‑: General information on ametoctradin

|  |  |
| --- | --- |
| Active substance (ISO Common Name) | Ametoctradin |
| IUPAC | 5-ethyl-6-octyl[1,2,4]triazolo[1,5-a]pyrimidin-7-amine |
| Chemical structure |  |
| Molecular formula | C15H25N5 |
| Molar mass | 275.40 g/mol |
| Chemical group | Triazol-Pyrimidylamine |
| Mode of action (if available) | Ametoctradin inhibits mitochondrial respiration by binding to the stigmatellin subsite in the respiratory complex III within the cells of fungi. |
| Systemic | No |
| Company (ies) \* | XXXX |
| Rapporteur Member State (RMS) | Germany (the original RMS were The Netherlands) |
| Approval status | Reg. (EU) 2023/918  Approved (date of approval 01/08/2013; date of expiration of approval 31/07/2023)  [Commission Implementing Regulation (EU) No 200/2013](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R0200&from=EN) of 8 March 2013 approving active substance in accordance with Regulation (EC) 1107/2009 and amending Commission Implementing Regulation (EU) No 540/2011.  [Commission Implementing Regulation (EU) 2018/155](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0155&from=EN) of 31 January 2018 amending implementing Regulation (EC) No 5686/2012. |
| Restriction | None |
| Review Report | SANCO/12977/2012 – rev.2  01/02/2013 |
| Current MRL regulation | Commission Regulation (EU) 2024/1439 amending Regulation (EC) No 396/2005 |
| Peer review of MRLs according to Article 12 of Regulation (EC) No 396/2005 performed | Yes (EFSA, 2020) |
| EFSA Journal: Conclusion on the peer review | Yes (EFSA, 2012b) |
| Current MRL applications on intended uses | None |

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

### Stability of Residues (KCA 6.1)

#### Stability of residues during storage of samples

Available data

New data are submitted in the framework of this application. Freezer storage stability data for ame-toctradin and metabolites M650F03 and M650F04 were evaluated and accepted during the first EU approval (The Netherlands, 2010, 2012; EFSA, 2012b) and were summarised in the Article 12 review (EFSA, 2020). These EU reviewed data originated from a selection of metabolism studies and storage stability studies. New data are also available on the storage of ametoctradin and metabolites M650F03 and M650F04 in plant commodities. Available studies are summarised in Table 7.2‑2

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

| **Matrix** | **Characteristics of the matrix** | **Acceptable Maximum Storage duration** | **Reference** |
| --- | --- | --- | --- |
| **Data relied on in EU** | | | |
| **Plant products** | | | |
| Tomato | High water content | 24 months, -20°C  (ametoctradin, metabolism study)  36 months, -20°C  (ametoctradin, stability study)  24 months, -20°C  (M650F03, M650F04, stability study) | The Netherlands, 2010, 2012  EFSA, 2012b  EFSA, 2020 |
| Lettuce | High water content | 36 months, -20°C  (ametoctradin, metabolism study)  24 months, -20°C  (ametoctradin, M650F03, M650F04, stability study) |
| Wheat forage | High water content | 24 months, -20°C  (ametoctradin, M650F03, M650F04, stability study) |
| Pea | High protein content | 24 months, -20°C  (ametoctradin, M650F03, M650F04, stability study) |
| Potato | High starch content | 24 months, -20°C  (ametoctradin, M650F03, M650F04, stability study) |
| Wheat grain | High starch content | 24 months, -20°C  (ametoctradin, M650F03, M650F04, stability study) |
| Grape | High acid content | 16 months, -20°C  (ametoctradin, stability study)  24 months, -20°C  (M650F03, M650F04, stability study) |
| Wheat straw | Other | 24 months, -20°C  (ametoctradin, M650F03, M650F04, stability study) |
| **New data** | | | |
| **Plant products** | | | |
| Melon | High water content | 24 months, -18°C (ametoctradin) | Yozgatli, H. & Ereretevwe, K., 2023  Doc ID: 2020/2036187 |
| Leek | High water content | 24 months, -18°C (ametoctradin) |
| Potato | High starch content | 24 months, -18°C (ametoctradin) |
| Grape | High acid content | 24 months, -18°C (ametoctradin) |
| Strawberry | High acid content | 24 months, -18°C (ametoctradin) |
| Rapeseed | High-oil content | 24 months, -18°C (ametoctradin, M650F003, M650F004) † |
| Hops (green cones) | Difficult matrix | 12 months, -18°C (ametoctradin) |

† It is noted that the metabolite name M650F03 and M650F003 are the same compound. Likewise, M650F04 and M650F004.

Conclusion on stability of residues during storage

Ametoctradin has been demonstrated to be stable for at least 24 months in at least 3 diverse high water commodities and for at least 24 months in potato. The residue data included in this submission stored samples for the following maximum time periods:

Potatoes: 262 days (*ca.* 9 months)

Onions: 210 days (*ca.* 7 months)

Tomatoes: 286 days (*ca.* 9 months)

The available storage stability data are sufficient to support the residue data on potato (high starch commodity), onion and tomato (high water commodities). No further data are required or submitted in the framework of this application.

**zRMS:** accepted.

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

Conclusion on stability of residues in sample extracts

Procedural recoveries obtained during residue analysis demonstrate the stability of ametoctradin residues in sample extracts and fully support the residue data presented in the submission.

No further information on the stability of residues in sample extracts is required or submitted.

**zRMS:** accepted.

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

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

Available data

No new data are submitted in the framework of this application. Metabolism data were evaluated and accepted during the first EU approval (The Netherlands, 2010, 2012; EFSA, 2012b) and were summarised in the Article 12 review (EFSA, 2020). Metabolism of ametoctradin was investigated for foliar application on fruits and fruiting vegetables (tomato), on leafy vegetables (lettuce) and on root and tuber vegetables (potato) using both [2,7-14C] labelled and [2,5,7-13C] labelled ametoctradin. Available studies are summarised in Table 7.2‑3.

Table ‑: Summary of plant metabolism studies

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Crop Group** | **Crop** | **Label position** | **Application and sampling details** | | | | | **Reference** |
| **Method,**  **F or G (a)** | **Rate**  **(kg a.s./ha)** | **No** | **Sampling (DAT)** | **Remarks** |
| **EU data** | | | | | | | | |
| **Fruits and fruiting**  **vegetable** | Tomato | Mixture of [2,7-14C] ametoctradin and [2,5,7-13C] ametoctradin | Foliar treatment,  G | 0.3 | 3 (7 days) | 1 day |  | The Netherlands, 2010, 2012  EFSA, 2012b  EFSA, 2020 |
| **Leafy**  **vegetables** | Lettuce | 0.223 | 3  (7-10 days) | 7 days |  |
| **Root and tuber vegetables** | Potato | 0.44 | 3  (14 days) | After 2nd application (14 DBLA) and 7 DALA (maturity) |  |
| **New data** | | | | | | | | |
| No new data |  |  |  |  |  |  |  |  |

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

DAT = days after last treatment

DBLA = days before last application

DALA = days after last application

Summary of plant metabolism studies reported in the EU

Reference: EFSA, 2020

“metabolic pathway was not proposed for ametoctradin because it remained the only compound found in treated commodities, besides metabolites M650F03 and M650F04 which were found in tuber however not in directly treated leaves or fruits. It was therefore assumed that these two metabolites would be taken up from the soil (Netherlands, 2010, 2012).

It can therefore be concluded in line with the peer review that the metabolism of ametoctradin was similar in all three crops, with the parent being hardly taken up and not translocated via leaves or fruits of plants and poorly metabolised following foliar applications. In root crops, uptake of soil metabolites M650F03 and M650F04 was evident.”

Summary of new plant metabolism studies

No new studies have been conducted.

Conclusion on metabolism in primary crops

The intended uses on potato, onion, garlic, tomato and aubergine are covered by the existing metabolism data package. Considering the maximum seasonal rate in this submission (root and tuber veg at 720 g a.s./ha and fruiting veg. at 480 g a.s./ha), the metabolism studies were conducted at 1.8N (root and tuber veg.) and 1.9N (fruiting veg.), and in accordance with the intended PHIs. Therefore the existing data accommodate the intended uses and no further data are required.

Based on the crop metabolism studies evaluated during the first EU approval (The Netherlands, 2010, 2012; EFSA, 2012b), the following residue definitions are applicable to this product submission and were confirmed in the EFSA Article 12 review (EFSA, 2020):

Residue definition for monitoring and risk assessment: Ametoctradin.

**zRMS:** accepted.

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

Available data

No new data are submitted in the framework of this application. Data were evaluated and accepted during the first EU approval (The Netherlands, 2010, 2012; EFSA, 2012b) and were summarised in the Article 12 review (EFSA, 2020).

Metabolism of ametoctradin in rotational crops was investigated on leafy vegetables (lettuce), root and tuber vegetables (white radish) and cereals (spring wheat) using both [2,7-14C] labelled and [2,5,7-13C] labelled ametoctradin. This study is summarised in Table 7.2‑4.

**Table 7.2‑4: Summary of metabolism studies in rotational crops**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Crop group** | **Crop** | **Label position** | **Application and sampling details** | | | | | | **Reference** |
| **Method,**  **F or G \*** | **Rate**  **(kg a.s./ha)** | **Sowing intervals**  **(DAT)** | **Harvest**  **Intervals (DAT)** | **Remarks** |  | |
| **EU reviewed data** | | | | | | | | | |
| **Leafy**  **vegetables** | Lettuce | BAS 650 F, 2,7-14C and 2,5,7-13C | G | 1.44 | 30 | 58, 76 | - | The Netherlands, 2010, 2012  EFSA, 2012b  EFSA, 2020 | |
| 120 | 150, 176 |
| 365 | 400, 428 |
| **Root and tuber vegetables** | White radish | 30 | 119 | - |
| 120 | 211 |
| 365 | 454 |
| **Cereals** | Spring wheat | 30 | 140 | - |
| 120 | 168, 245 |
| 365 | 421, 483 |
| **New data** | | | | | | | | | |
| No new data |  |  |  |  |  |  |  |  | |

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

Summary of rotational crop metabolism studies reported in the EU

Reference: EFSA, 2020

“Crops were planted at nominal plant back intervals (PBI) of 30, 120 and 365 days after treatment (DAT). Crops planted at each interval consisted of leafy vegetable (lettuce), roots (white radish) and cereals (spring wheat).

Residues in lettuce, radish roots and spring wheat declined over time. Highest levels of radioactivity were observed in unripe (0.097 mg eq/kg) and ripe lettuce (0.064 mg eq/kg) 120 DAT which declined to 0.016–0.025 mg/kg at PBI 365 DAT. In radish roots and tops, the TRR decreased from a PBI of 30 DAT (2.4 and 0.66 mg eq/kg, respectively) to a PBI of 365 DAT (0.062 and 0.018 mg eq/kg, respectively). In wheat straw and grain, the TRR decreased from a PBI 30 DAT (6.04 mg eq/kg and 1.83 mg eq/kg, respectively) to a PBI 365 DAT (1.239 mg eq/kg and 0.843 mg eq/kg, respectively). In wheat forage, the TRR at a PBI of 120 DAT (1.71 mg eq/kg) declined to 0.356 mg eq/kg at a PBI of 365 DAT.

Ametoctradin was only detected in lettuce at a PBI of 30 DAT (0.009 mg eq/kg; 15.2% TRR) and wheat forage and straw (0.005 mg eq/kg; 0.3% TRR and 0.044 mg eq/kg; 0.7% TRR).

Significant residues of metabolites M650F03 and M650F04 were observed up to a PBI of 120 DAT in lettuce (0.005 mg eq/kg and 0.019 mg eq/kg) and in radish roots (0.029 mg eq/kg and 0.010 mg eq/kg). However, at a PBI of 365 DAT residues were below LOQ of 0.01 mg eq/kg. On the other hand, metabolites M650F03 and M650F04 were reported in wheat straw (0.121 mg eq/kg (9.8% TRR) and 0.547 mg eq/kg (44.2% TRR), in wheat forage (0.039 mg eq/kg (11% TRR) and 0.215 mg eq/kg (60.5% TRR)) and grain (0.008 mg eq/kg (0.9% TRR) and 0.672 mg eq/kg (79.7% TRR)), respectively, at a PBI of 365 DAT.

Therefore, even one year after soil treatment significant residues of ametoctradin can be detected in edible parts of small grain cereals and field rotational crop studies are triggered.

The metabolism and distribution of ametoctradin in rotational crops is dissimilar to the metabolic pathway observed in primary crops where the parent was the main residue, whereby in rotational crops, main soil metabolites M650F03 and M650F04 were found with occasional detection of the parent.”

Summary of rotational crop metabolism studies

No new data submitted in the framework of this application.

Conclusion on metabolism in rotational crops

The intended uses may be rotated. Ametoctradin is not persistent in soil (DT90 <100 days), but me-tabolites M650F03 and M650F04 are considered persistent in soil, with a DT90 of 420 days and >365 days, respectively (EFSA, 2012b). The metabolism of ametoctradin was investigated in rotational crops (wheat, lettuce and radish and significant residues of the soil metabolites M650F03 and M65F04 were observed at various plant back intervals in all crop groups. EFSA concluded that the metabolites M650F03 and M650F04 were relevant for the risk assessment of rotational crops.

Residue definition for risk assessment for rotational crops: Sum of ametoctradin, M650F03 and M650F04 expressed as ametoctradin.

**zRMS:** accepted.

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

Available data

No new data submitted in the framework of this application. Metabolism data were evaluated and accepted during the first EU approval (The Netherlands, 2010, 2012; EFSA, 2012b) and were summarised in the Article 12 review (EFSA, 2020). Available studies are summarised in Table 7.2- 5.

Table ‑: Nature of the residues in processed commodities

| **Conditions (Duration, Temperature, pH)** | **Identified compound(s) (%)** | **Reference** |
| --- | --- | --- |
| **EU data** | | |
| **Pasteurisation** (20 minutes, 90°C, pH 4) | Parent: 109 | The Netherlands, 2010, 2012  EFSA, 2012b  EFSA, 2020 |
| **Baking, boiling, brewing**  (60 minutes, 100°C, pH 5) | Parent: 96 |
| **Sterilisation** (20 minutes, 120°C, pH 6) | Parent: 97 |

Conclusion on nature of residues in processed commodities

Ametoctradin was shown to remain stable under standard hydrolytic conditions representative of pasteurization, baking, boiling, brewing and sterilization (EFSA, 2012b).

It is noted that EFSA concluded no further processing data on the metabolites was required (EFSA, 2020): “metabolites M650F03 and M650F04 are proposed to be included in the rotational crop residue definition, and therefore, information on their fate during processing would be in principle required however noting the very low acceptable daily intake (ADI) which is well below 10% even below 1% this is considered as desirable”.

**zRMS:** accepted.

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

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

|  |  |
| --- | --- |
| **Endpoints** | |
| Plant groups covered | Root and tuber vegetables (potatoes), leafy vegetables (lettuce), fruiting vegetables (tomatoes) |
| Rotational crops covered | Cereals (wheat), leafy vegetables (lettuce), root and tuber vegetables (radish) |
| Metabolism in rotational crops similar to metabolism in primary crops? | No |
| Processed commodities | a.s. is stable under standard hydrolysis conditions |
| Residue pattern in processed commodities similar to pattern in raw commodities? | Yes |
| Plant residue definition for monitoring | Ametoctradin (Reg. (EU) 2022/1290) |
| Plant residue definition for risk assessment | Primary crops: ametoctradin  Rotational crops: Sum of ametoctradin, M650F03, M650F04, expressed as ametoctradin  (EFSA, 2020) |
| Conversion factor from enforcement to RA | EFSA, 2020:  none, except for small grain cereals (tentatively derived from limited dataset):  grain (N-EU): 3.0  straw (N-EU): 6.6  forage (N-EU): 4.9  grain (S-EU): 5.3  straw (S-EU): 16.8  forage (S-EU): 4.9 |

**zRMS:** accepted.

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

Available data

No new studies are submitted in the framework of this submission. Livestock metabolism data were evaluated and accepted during the first EU approval (The Netherlands, 2010, 2012; EFSA, 2012b) and were summarised in the Article 12 review (EFSA, 2020). Available studies are summarised in Table 7.2‑7.

Table ‑: Summary of animal metabolism studies

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** | **Species** | **Label position** | **No of animal** | **Application details** | | **Sample details** | | **Reference** |
| **Rate**  **(mg/kg bw/d)** | **Duration**  **(days)** | **Commodity** | **Time of samp­ling** |
| **EU data** | | | | | | | | |
| **Lactating ruminants** | Goat | BAS 650 F, 2,7-14C and 2,5,7-13C | 2 | 0.51  and 0.49 | 10 days | Milk | Twice daily | EFSA 2012b, EFSA 2020 |
| Urine and faeces | Once daily |
| Tissues (liver, kidney fat, intra-peritoneal fat, muscle) | At sacrifice |
| **Laying poultry** | Hens | BAS 650 F, 2,7-14C and 2,5,7-13C | 9 | 0.81  (mean) | 10 days | Eggs | Twice daily | EFSA 2012b, EFSA 2020 |
| Excreta | Once daily |
| Tissues (muscle, liver, adipose tissue, GI tract, GI tract contents, blood) | At sacrifice |

Summary of animal metabolism studies reported in the EU

Reference: EFSA, 2012b

“Metabolism studies in ruminants and poultry indicate ametoctradin is metabolised by repeated oxidation of the fatty acid side chain. The most abundant residues in poultry edible matrices were ametoctradin and metabolite M650F01, while in goat edible matrices ametoctradin was not detect-ed, but metabolites M650F01 and M650F06 were the major residues. The animals were dosed with parent ametoctradin, while rotational crop residues in the form of metabolites M650F03 and M650F04 can be a significant source of livestock exposure. It was concluded that due to the structural similarity of these metabolites with parent and the major animal metabolites M650F01 and M650F06 the behavior of M650F03 and M650F04 could be addressed by the available animal metabolism data. No new metabolism studies with M650F03 and M650F04 are deemed necessary.”

EFSA confirmed the residue definition in the Article 12 review (EFSA, 2020): “EFSA concludes during this Art. 12 review that the metabolism of ametoctradin in livestock is adequately elucidated, and parent and metabolites M650F01 and M650F06 are the most relevant components of the residues in livestock commodities. As the parent compound and metabolites M650F01 and M650F06 were found to be a suitable marker in livestock commodities, the residue definition for enforcement and for risk assessment is proposed as ‘sum of ametoctradin, M650F01 and M650F06, expressed as ametoctradin’.”

Conclusion on metabolism in livestock

The metabolism of ametoctradin in livestock is sufficiently addressed to support the proposed uses of the product BAS 743 03 F.

Based on the livestock metabolism studies evaluated during the first EU approval (The Netherlands, 2010, 2012; EFSA, 2012b), the following residue definitions are applicable to this product submission and were confirmed in the EFSA Article 12 review (EFSA, 2020):

Residue definition for monitoring and risk assessment in animal commodities (except for honey and other apiculture products): Sum of ametoctradin, M650F01 and M650F06, expressed as ametoctradin.

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

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

|  |  |
| --- | --- |
| **Endpoints** | |
| Animals covered | Lactating goats, Laying hens |
| Time needed to reach a plateau concentration | 5 - 8 days in milk  7 days in eggs |
| Animal residue definition for monitoring | Sum of ametoctradin, M650F01, M650F06, expressed as ametoctradin (Reg. (EU) 2022/1290) |
| Animal residue definition for risk assessment | Sum of ametoctradin, M650F01, M650F06, expressed as ametoctradin (EFSA, 2020) |
| Conversion factor | None (EFSA, 2020) |
| Metabolism in rat and ruminant similar | Yes |
| Fat soluble residue | Yes (ametoctradin detected in egg and hen fat)  Log Pow: 4.4 at pH 7.1 |

**zRMS:** accepted.

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

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

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

Table ‑: Summary of EU reported and new data supporting the intended uses of BAS 743 03 F and conformity to existing MRL

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Commodity | Source | Residue zone (N-EU, S-EU) | Evaluation GAP Residue levels (mg/kg)(a) | STMR (mg/kg) | HR (mg/kg) | Unrounded OECD calculator MRL (mg/kg) | Current EU MRL  (mg/kg)  (Reg. (EU) 2022/1290) | MRL compliance |
| Potato  cGAP: 3 x 240 g a.s./ha, RTI 5 days, PHI 7 days | New data | N-EU | Trials GAP: 3 x 240 g a.s./ha, RTI 4-6 days, 7 day PHI  E/RA: 12x <0.01 | 0.01 | 0.01 | 0.01 | 0.05 | Yes |
| Onion 🡪 extrapolated to garlic  cGAP: 2 x 240 g a.s./ha, RTI 5 days, PHI 7 days | New data | N-EU | Trials GAP: 2 x 240 g a.s./ha, RTI 4-5 days, 7 day PHI  E/RA: 2x <0.01, 0.015, 0.026, 0.030, 0.033, 0.046, 0.052, 0.056, 0.059, 2x 0.098, 0.11 | 0.046 | 0.11 | 0.186 | 1.5 | Yes |
| Tomato 🡪 extrapolated to aubergine  cGAP: 2 x 240 g a.s./ha, RTI 7 days, PHI 1 days | New data | N-EU | Trials GAP: 2 x 240 g a.s./ha, RTI 6-9 days, 1 day PHI  E/RA: 0.043, 0.081, 0.11, 3x 0.14, 0.15, 0.19, 0.24, 0.27, 0.33, 0.35 | 0.15 | 0.35 | 0.568 | 2 | Yes |

* + - * 1. Definition of residue for enforcement: Ametoctradin

Definition of residues for risk assessment: Ametoctradin

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

*Potato*

Potato is a major crop in northern Europe. The intended critical GAP (cGAP) is for three applications at 240 g ametoctradin/ha, with a re-treatment interval of 5 days and a PHI of 7 days. To support the cGAP twelve NEU potato trials have been provided at the cGAP. No exceedance of the current EU MRL will occur following application of BAS 743 03 F at the intended cGAP and the uses are considered acceptable.

*Onion and garlic*

Onion is a major crop and garlic a minor crop in northern Europe. The intended cGAP is for two application at 240 g ametoctradin/ha, with a re-treatment interval of 5 days and a PHI of 7 days. To support the cGAP thirteen NEU onion trials have been provided at the cGAP. In accordance with SANTE/2019/12752 data on onion can be extrapolated to garlic, which is the case here. No exceedance of the current ametoctradin EU MRLs will occur following application of BAS 743 03 F at the intended cGAP and the uses are considered acceptable.

*Tomato and aubergine*

Tomato is a major crop and aubergine a minor crop in northern Europe. The intended cGAP is for two applications at 240 g ametoctradin/ha, with a retreatment interval of 7 days and a PHI of 1 day. To support the cGAP twelve NEU tomato trials have been provided at the cGAP. In accordance with SANTE/2019/12752 data on tomato can be extrapolated to aubergine, which is the case here. No exceedance of the current ametoctradin EU MRLs will occur following application of BAS 743 03 F at the intended cGAP and the uses are considered acceptable.

**zRMS:** accepted.

### Magnitude of residues in livestock

The intended use of BAS 743 03 F on potato may result in residues of ametoctradin in animal feed items, therefore the possible transfer of residues to animal matrices should be considered.

#### Dietary burden calculation

The dietary burden of ametoctradin was recently assessed in the Article 12 MRL review (EFSA, 2020). Of the intended uses included in this submission, only potato are used as animal feed. Endpoints for potato derived in this submission are less critical than those previously evaluated during the Article 12 process. Therefore, the intended uses will not impact the previously conducted animal dietary burden or existing EU animal MRLs. Nonetheless a new dietary burden calculation has been presented. It is noted that head cabbage has been excluded from the dietary burden calculation as the use is an import tolerance and imported cabbages are unlikely to be used as animal feed. The input values are shown in the table below.

Table ‑: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)

| **Feed Commodity** | **Median dietary burden** | | **Maximum dietary burden** | |
| --- | --- | --- | --- | --- |
| **Input value (mg/kg)** | **Comment** | **Input value (mg/kg)** | **Comment** |
| Risk assessment residue definition: Ametoctradin | | | | |
| Potato, culls | 0.01 | STMR (EFSA, 2020) | 0.04 | HR (EFSA, 2020) |
| 0.01 | STMR (This submission, within EFSA, 2020 input) | 0.01 | HR (This submission, within EFSA, 2020 input) |
| Potato, process waste | 0.20 | STMR (0.01) x default PF (20) (EFSA, 2020) | 0.20 | STMR (0.01) x default PF(20) (EFSA, 2020) |
| Potato, dried pulp | 0.38 | STMR (0.01) x default PF (38) (EFSA, 2020) | 0.38 | STMR (0.01) x default PF (38) (EFSA, 2020) |
| Cassava/tapioca, roots | 0.01 | STMR (EFSA, 2020) | 0.04 | HR (EFSA, 2020) |
| Risk assessment residue definition for rotational crops: sum of ametoctradin, M650F03 and M650F04,  expressed as ametoctradin | | | | |
| All rotated crops | see EFSA, 2020 | | | |

The results of the calculations are reported in Table 7.2‑13. The previous animal dietary burden conducted in the Article 12 MRL review (EFSA, 2020) and on which the existing EU animal MRLs were set, is not impacted by the intended uses in this submission. Therefore, the existing EU animal MRLs are sufficient to accommodate the intended uses of BAS 743 03 F.

Table ‑: Results of the dietary burden calculation

| **Animal species** | **Median  dietary  burden (mg/kg bw/d)** | **Maximum  dietary burden**  **(mg/kg bw/d)** | **Highest  contributing  commodity** | **Max  dietary burden (mg/kg DM)** | **Trigger  exceeded (Y/N)** | **Article 12 max. dietary burden**  **(mg/kg bw/d) (EFSA, 2020)** |
| --- | --- | --- | --- | --- | --- | --- |
| Risk assessment residue definition: Ametoctradin | | | | | | |
| Beef cattle\* | 0.0178 | 0.019 | Potato, process waste | 0.78 | Yes | 0.407 |
| Dairy cattle\* | 0.0223 | 0.024 | Potato, process waste | 0.62 | Yes |
| Ram/ewe | 0.0260 | 0.026 | Potato, process waste | 0.8 | Yes | 0.230 |
| Lamb | 0.0195 | 0.021 | Potato, process waste | 0.49 | Yes |
| Breeding swine | 0.009 | 0.011 | Potato, process waste | 0.48 | Yes | 0.126 |
| Finishing swine\* | 0.007 | 0.009 | Wheat, milled by-products | 0.31 | Yes |
| Broiler poultry | 0.009 | 0.010 | Potato, dried pulp | 0.14 | Yes | 0.181 |
| Layer poultry\* | 0.010 | 0.011 | Wheat, milled by-products | 0.16 | Yes |
| Turkey | 0.009 | 0.011 | Wheat, milled by-products | 0.16 | Yes |

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

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

Available data

The requested uses do not modify the theoretical maximum daily intake for animals so there is no risk for the existing animal MRLs to be exceeded. In the Article 12 MRL review (EFSA, 2020) animal MRLs were tentatively set based on metabolism studies. However, a data gap was set for a cattle feeding study.

*Reference: EFSA, 2020*

*“*Based on the available metabolism studies, tentative MRLs and risk assessment values were derived for all animal commodities in compliance with the latest recommendations on this matter (FAO, 2009). It is noted that significant levels of ametoctradin are only expected in cattle liver, while for all other animal tissues, milk and eggs MRLs are proposed at the LOQ of 0.03 mg/kg. Hence, with exception of cattle liver, MRLs and risk assessment values for the relevant commodities in poultry, swine and sheep can be established at the LOQ level. It is noted that the contribution considered for wheat from rotational crops had no impact on the tentatively proposed MRLs for livestock. A livestock feeding study is needed, however, for cattle (data gap).*”*

To address this data gap a dairy cow feeding study (2011/1036848) is available and has been submitted as part of the AIR5 renewal dossier (XXXX, 2020) and will also be submitted as Article 12 confirmatory data (submission before 07 July 2023). The data are not EU peer reviewed, therefore, a summary is included in this submission. However, it is noted that the most appropriate framework for the evaluation of these data is the AIR5 or Article 12 confirmatory data evaluation, to obtain a EU peer reviewed conclusion.

**Summary of new animal feeding studies (2011/1036484)**

In a dairy cow feeding study, ametoctradin (BAS 650 F) was administered via gelatine capsule orally to groups of 3 Holstein lactating female dairy cows (with one control group of 3, fed empty gelatine capsules only) for 28 days. The highest dose group included 2 animals for depuration testing. The nominal daily doses per animal were 50 mg for the 1x level, 150 mg for the 3x level, and 500 mg for the 10x level. The actual dose levels were 3.11 mg/kg, 7.83 mg/kg and 30.3 mg/kg feed (DM) for the 1x, 3x and 10x dose level, respectively, equivalent to 0.0864, 0.218 and 0.862 mg/kg bw/day, respectively.

Milk samples from each animal were collected twice daily for 28 days and combined as one pooled sample. On day 21, milk was also separated into cream and skim milk. Animals were sacrificed within 25 h after the final morning dose and tissue samples were taken, except for two cows of the 10x group, which were sacrificed two and seven days after the final morning dose to determine residue decline. All samples were stored and shipped frozen and remained frozen until analysis.

The samples were analysed for residues of ametoctradin and metabolites M650F01 and M650F06 using XXXX method No. L0104.

No residues above the limit of quantitation (LOQ; 0.03\* mg/kg) were found in milk, muscle, and fat at any dose level.

Residues above the limit of quantification (LOQ) were only detected in liver of the middle and high dose level (Groups 3 and 4) and in kidney of the highest dose level (Group 4) but these declined to <LOQ within 2 days of withdrawal of the test item.

**zRMS:** accepted.

Table ‑: Overview of the values derived from livestock feeding studies

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Commodity** | **Dietary burden** | | **Results of the livestock feeding study** | | | | | | **Median residue**  **(mg/kg)(a)** | **Highest residue**  **(mg/kg)(a)** | **Calculated MRL**  **(mg/kg)** | **CF for RA(b)** |
| **Med. (mg/kg bw/d)** | **Max. (mg/kg bw/d)** | **Dose Level (mg/kg bw/d)** | **No** | **Result for enforcement** | | **Result for RA** | |
| **Mean (mg/kg)** | **Max. (mg/kg)** | **Mean (mg/kg)** | **Max. (mg/kg)** |
| **New data (XXXX 2011, XXXX Doc ID. 2011/1036848)** | | | | | | | | | | | | |
| **Ruminant muscle** | 0.026 | 0.026 | 0.086 | 3 | <0.03 | <0.03 | <0.03 | <0.03 | 0.03 | 0.03 | 0.03\* | - |
| 0.218 | 3 | <0.03 | <0.03 | <0.03 | <0.03 |
| 0.862 | 3 | <0.03 | <0.03 | <0.03 | <0.03 |
| **Ruminant fat** | 0.086 | 3 | <0.03 | <0.03 | <0.03 | <0.03 | 0.03 | 0.03 | 0.03\* | - |
| 0.218 | 3 | <0.03 | <0.03 | <0.03 | <0.03 |
| 0.862 | 3 | <0.03 | <0.03 | <0.03 | <0.03 |
| **Ruminant liver** | 0.086 | 3 | <0.03 | <0.03 | <0.03 | <0.03 | 0.03 | 0.03 | 0.03\* | - |
| 0.218 | 3 | 0.032 | 0.035 | 0.032 | 0.035 |
| 0.862 | 3 | 0.073 | 0.097 | 0.073 | 0.097 |
| **Ruminant kidney** | 0.086 | 3 | <0.03 | <0.03 | <0.03 | <0.03 | 0.03 | 0.03 | 0.03\* | - |
| 0.218 | 3 | <0.03 | <0.03 | <0.03 | <0.03 |
| 0.862 | 3 | 0.039 | 0.048 | 0.039 | 0.048 |
| **Ruminant milk** | 0.086 | 3 | <0.03 | N/A | <0.03 | N/A | 0.03 | 0.03 | 0.03\* | - |
| 0.218 | 3 | <0.03 | N/A | <0.03 | N/A |
| 0.862 | 3 | <0.03 | N/A | <0.03 | N/A |

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

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

(a): Median and highest residue values according to the EFSA 2017 animal dieatry burden calculator

(b): The median conversion factor for enforcement to risk assessment.

The maximum ruminant dietary burden was 0.026 mg/kg bw/day for Ram/ewes. Based on the results of the new ruminant feeding study the existing EU ruminant MRLs are considered sufficient to accommodate the intended uses.

**Table 7.2‑13:** **MRL proposals derived from the new ruminant feeding study**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Animal commodity** | **Residues at the closet feeding level** (mg/kg) | | **Estimated value at 1N level** | | **MRL proposal** (mg/kg) | **CF** | **STMR** (mg/kg) | **HR** (mg/kg) | **Existing EU MRL**  **Reg. (EU) 2022/1290**  (mg/kg) |
|  |
| STMRMo(mg/kg) | HRMo (mg/kg) |  |
| Mean | Highest |  |
| **Cattle (all diets)** |  |  |  |  |  |  |  |  |  |  |
| Closest feeding level: | 0.086 | mg/kg bw | 3.6 | N Dairy cattle (highest diet) | | |  |  |  |
| Muscle | 0.03 | 0.03 | 0.03 | 0.03 | 0.03\* | n.c. | 0.03 | 0.03 | 0.03\* |  |
| Fat | 0.03 | 0.03 | 0.03 | 0.03 | 0.03\* | n.c. | 0.03 | 0.03 | 0.03\* |  |
| Liver | 0.03 | 0.03 | 0.03 | 0.03 | 0.03\* | n.c. | 0.03 | 0.03 | 0.04 |  |
| Kidney | 0.03 | 0.03 | 0.03 | 0.03 | 0.03\* | n.c. | 0.03 | 0.03 | 0.03\* |  |
| **Cattle (dairy only)** |  |  |  |  |  |  |  |  |  |  |
| Closest feeding level: | 0.086 | mg/kg bw | 3.6 | N Dairy cattle | |  |  |  |  |  |
| Milk | 0.03 | 0.03 | 0.03 | 0.03 | 0.03\* | n.c. | 0.03 | 0.03 | 0.03\* |  |
| **Sheep (all diets)** |  |  |  |  |  |  |  |  |  |  |
| Closest feeding level: | 0.086 | mg/kg bw | 3.3 | N Ram/Ewe (highest diet) | |  |  |  |  |  |
| Muscle | 0.03 | 0.03 | 0.03 | 0.03 | 0.03\* | n.c. | 0.03 | 0.03 | 0.03\* |  |
| Fat | 0.03 | 0.03 | 0.03 | 0.03 | 0.03\* | n.c. | 0.03 | 0.03 | 0.03\* |  |
| Liver | 0.03 | 0.03 | 0.03 | 0.03 | 0.03\* | n.c. | 0.03 | 0.03 | 0.03\* |  |
| Kidney | 0.03 | 0.03 | 0.03 | 0.03 | 0.03\* | n.c. | 0.03 | 0.03 | 0.03\* |  |
| **Sheep (dairy only)** |  |  |  |  |  |  |  |  |  |  |
| Closest feeding level: | 0.086 | mg/kg bw | 3.3 | N Ewe |  |  |  |  |  |
| Milk | 0.03 | 0.03 | 0.03 | 0.03 | 0.03\* | n.c. | 0.03 | 0.03 | 0.03\* |  |
| **Swine** |  |  |  |  |  |  |  |  |  |  |
| Closest feeding level: | 0.086 | mg/kg bw | 7.8 | N Breeding (highest diet) | |  |  |  |  |  |
| Muscle | 0.03 | 0.03 | 0.03 | 0.03 | 0.03\* | n.c. | 0.03 | 0.03 | 0.03\* |  |
| Fat | 0.03 | 0.03 | 0.03 | 0.03 | 0.03\* | n.c. | 0.03 | 0.03 | 0.03\* |  |
| Liver | 0.03 | 0.03 | 0.03 | 0.03 | 0.03\* | n.c. | 0.03 | 0.03 | 0.03\* |  |
| Kidney | 0.03 | 0.03 | 0.03 | 0.03 | 0.03\* | n.c. | 0.03 | 0.03 | 0.03\* |  |

n.c. not calculated

Conclusion on feeding studies

The requested uses do not modify the theoretical maximum daily intake for animals assessed in the Article 12 MRL review (EFSA, 2020). To address the data gap for a cattle feeding study set in EFSA, 2020, a new feeding study in dairy cows is available and summarised in this submission. The feeding study confirms no residues above the current EU MRLs are expected as a result of the intended usesrota.

**zRMS:** accepted.

### 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 are submitted in the framework of this application. Data were evaluated and accepted during the first EU approval (The Netherlands, 2010, 2012; EFSA, 2012b) and summarised in the Article 12 review (EFSA, 2020). The data are summarised in.Table 7.2‑14

Table ‑: Overview of the available processing studies

| **Processed commodity** | **Number of studies** | **Median PF \*** | **Median CF \*\*** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| **EU data** | | | | | |
| Enforcement residue definition: Ametoctradin | | | | | |
| Grapes (for rose wine preparation) | 4 | 1 | - | Total ametoctradin\*\*\* | The Netherlands, 2010, 2012  Germany, 2019  EFSA, 2020 |
| Grape, must naturally cloudy | 4 | 0.67 | - | Total ametoctradin\*\*\* |
| Grape, wet pomace | 4 | 2.64 | - | Total ametoctradin\*\*\* |
| Grape, must deposit | 4 | 4.57 | - | Ametoctradin |
| Grape, must separated | 4 | 0.37 | - | Ametoctradin |
| Grape, juice pasteurised | 4 | 0.24 | - | Total ametoctradin\*\*\* |
| Grape, yeast deposit | 4 | 2.08 | - | Ametoctradin |
| Grape, rose wine | 4 | 0.0075 | - | Total ametoctradin\*\*\* |
| Grape (for red wine preparation) | 4 | 1 | - | Total ametoctradin\*\*\* |
| Grape, stalks | 4 | 1.74 | - | Ametoctradin |
| Grape crush | 4 | 1.09 | - | Ametoctradin |
| Grape, must naturally cloudy | 4 | 0.13 | - | Total ametoctradin\*\*\* |
| Grape, wet pomace | 4 | 4.55 | - | Total ametoctradin\*\*\* |
| Grape, must deposit | 4 | 0.87 | - | Ametoctradin |
| Grape, must separated | 4 | 0.36 | - | Ametoctradin |
| Grape, juice pasteurised | 4 | 0.37 | - | Total ametoctradin\*\*\* |
| Grape, yeast deposit | 4 | 2.02 | - | Ametoctradin† |
| Grape, red wine | 4 | 0.025 | - | Total ametoctradin\*\*\* |
| Grapes (for raisin preparation) | 4 | 1 | - | Total ametoctradin\*\*\* |
| Grape, raisins | 4 | 3.35 | - | Total ametoctradin\*\*\* |
| Potato chips | 4 | 1 | - | Total ametoctradin\*\*\* |
| Potato flakes | 4 | 1 | - | Total ametoctradin\*\*\* |
| Potato, microwave boiled | 4 | 1.04 | - | Total ametoctradin\*\*\* |
| Potato, peeled | 4 | 1 | - | Total ametoctradin\*\*\* |
| Potato, fried | 4 | 1 | - | Total ametoctradin\*\*\* |
| Potato, cooked | 4 | 1 | - | Total ametoctradin\*\*\* |
| Potato, peel | 4 | 1.28 | - | Total ametoctradin\*\*\* |
| Onions, dried | 4 | 0.16 |  | Ametoctradin |
| Onions, peeled | 4 | 0.12 |  | Ametoctradin |
| Onion peel | 4 | 12.3 |  | Ametoctradin |
| Tomato juice, raw | 4 | 0.18 | - | Ametoctradin⁑ |
| Tomato, canned | 4 | 0.015 | - | Ametoctradin⁑ |
| Tomato, peeled | 4 | 0.015 | - | Ametoctradin⁑ |
| Tomato, peel | 4 | 9.6 | - | Ametoctradin⁑ |
| Tomato, ketchup | 4 | 0.39 | - | Ametoctradin⁑ |
| Tomato, purree | 4 | 0.87 | - | Ametoctradin⁑ |
| Tomato, pomace wet | 4 | 0.79 | - | Ametoctradin⁑ |
| Tomatoes, washed | 4 | 0.23 | - | Ametoctradin⁑ |
| Wash water (tomatoes) | 4 | 0.64 | - | Ametoctradin⁑ |
| Gherkins, washed | 4 | 0.68 | - | Total ametoctradin\*\*\* |
| Wash water | 4 | 0.51 | - | Total ametoctradin\*\*\* |
| Gherkins, canned | 4 | 0.62 | - | Total ametoctradin\*\*\* |
| Vegetable stock | 4 | 0.31 | - | Total ametoctradin\*\*\* |
| Hops, dried cones | 3 | 1 | - | Ametoctradin⁑ |
| Beer | 3 | 0.0005 | - | Ametoctradin⁑ |
| Brewer’s yeast | 3 | 0.02 | - | Ametoctradin⁑ |
| Extracted hops | 3 | 0.34 | - | Ametoctradin⁑ |
| Hops draff | 3 | 0.27 | - | Ametoctradin⁑ |

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

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

\*\*\* Total ametoctradin: sum ametoctradin, M650F03 and M650F04 expressed as ametoctradin.

† The value of 0.09 was considered as an outlier

⁑  For metabolites M650F03 and M650F04 residues were all below LOQ of 0.01 mg/kg in tomato processed fractions and hop green and dried cones.

#### Conclusion on processing studies

The residue data in this submission demonstrate that residues of ametoctradin in tomatoes (extrapolated to aubergine) and onions (extrapolated to garlic) may be >0.1 mg/kg.

The only category 1 processes relevant to these commodities is preparation of vegetable juice (VII), for which data on tomatoes can be extrapolated to all vegetables in accordance with OECD 508. Data are available on the processing of grapes, tomato, potato, onion, gherkins and hops from the Article 12 review (EFSA, 2020). Furthermore, reliable ametoctradin processing factors are reported in the EU database of processing factors for pesticide residues[[1]](#footnote-1). No further information is required as part of this product submission.

**zRMS:** accepted.

### Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Data dealing with magnitude of residues in succeeding crops are available/have been submitted and are summarised hereafter.

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

Available data

Data were evaluated and accepted during the first EU approval (The Netherlands, 2010, 2012; EF-SA, 2012b) and summarised in the Article 12 review (EFSA, 2020). The data are summarised in Table 7.2- 15.

New data are available and have been submitted in the context of the AIR5 renewal dossier (XXXX, 2020) and will also be submitted as Article 12 confirmatory data (submission before 07 July 2023). The data are not EU peer reviewed, therefore, a summary is included in this submission. However, it is noted that the most appropriate framework for the evaluation of these data is the AIR5 or Article 12 confirmatory data evaluation, to obtain a EU peer reviewed conclusion.

Table ‑: Summary of available studies in field rotational crops

| **Primary crop** | **Rate (kg a.s./ha)**  **(GS at application or PHI)** | **Residue levels in succeeding crops** | | | |
| --- | --- | --- | --- | --- | --- |
| **Succeeding crop group** | **Succeeding crop** | **Sowing intervals**  **(DAT)** | **Reference /**  **Remarks** |
| **EU reviewed data** | | | | | |
| Application to bare soil | 0.96 (n.a.) | Leafy vegetables | Lettuce | 30  120  365 | The Netherlands, 2010, 2012  EFSA, 2012b  EFSA, 2020 |
| Root and tuber vegetables | Carrot | 30  120  365 |
| Cauliflower | 30  120  365 |
| Cereals | Wheat | 30  120  365 |
| Application to bare soil | 0.96 (n.a.) | Cereals | Winter wheat | 120 | The Netherlands, 2010, 2012  EFSA, 2012b  EFSA, 2020 |
| **New Data** | | | | | |
| Application to bare soil | 0.96 (n.a.) | Berries and small fruits | Strawberry | 30  120 | Erdmann, H-P., 2020  Doc ID:  2020/2030949 |
| Fruiting vegetables | Tomato | 30  120 |
| Stem vegetables | Leek | 30  120 |
| Oilseed and oil fruits | Oilseed rape seed | 30  120 |

n.a. growth stage is not applicable

*Reference: EFSA 2020*

“In both rotational field crop trials, ametoctradin was applied at 960 g a.s./ha to bare soil representing 0.8N of the authorised cGAP on potatoes (NEU) of this Art. 12 review. With regard to the expected crop interception, this may be estimated equivalent to 1.2N for this Art. 12 review. Notably, details on soil characteristics (soil type, organic carbon) were not reported in both studies (Netherlands, 2010, 2012). Reported soil concentrations (0–20 cm) in both studies indicate metabolite M650F04 was still present at 360 DAT (< 0.01–0.019 mg/kg) (Netherlands, 2010, 2012).

With the available information, it cannot be concluded whether the available field rotational crop studies cover the predicted plateau concentration of the most critical GAP on potato (NEU) of this review. However, since in normal crop rotation potatoes are grown only once every 3 years, accumulation of ametoctradin residues in soil is not expected.

Metabolites M650F03 and M650F04 were the only residues observed in significant concentrations in the mature crops. The data from the available field crop trials indicate that at plant back intervals of 120 days or beyond crop parts for human consumption are not expected to contain residues above the LOQ with exception of cereal grains. In grains, a total residue of M650F03 and M650F04 up to 0.33 mg/kg was found after treatment of the bare soil. In all studies, significant residue levels were also found in potential animal feed items (EFSA, 2012b). Considering the available data from two available rotational crop field studies on small grain cereals at a PBI of 120 DAT, it was possible to derive tentative MRLs and risk assessment values for wheat which were extrapolated to barley, oat and

rye considered in the assessment. Data from one study on other rotated crops were considered insufficient to derive MRLs or risk assessment values (Table B.1.2.2.(b)).

However, it is noted that detectable amounts of metabolite M650F04 can be expected in soil at periods longer than 360 DAT. In addition, in one rotational field crop trial, data for a PBI of 360 DAT in carrot roots and wheat grain reported a maximum residue of 0.03 mg/kg and in cauliflower 0.036 mg/kg whereby for lettuce, residues were below the LOQ of 0.03 mg/kg (see Table B.1.2.2.(b)). Nevertheless, since less than two residue values were reported, these data could not be considered quantitatively, however, qualitatively to support recommendations for risk mitigation option.

Furthermore, the group of fruits and fruiting vegetables is not covered. Considering that in brassica vegetables (cauliflower) and small cereal grain residues at or slightly above the LOQ of 0.03 mg/kg at a PBI of 360 days were reported, a requirement for further studies may need to be considered at national level. This information should be considered by risk managers for deriving and for the adoption of possible mitigation measures.”

It is noted that a data gap was set in EFSA, 2020 for

* a representative field rotational crop studies reporting soil characteristics to allow a conclusion as to whether the plateaus for soil metabolites M650F03 and M650F04 are covered and including additional crop groups such as fruits and fruiting vegetables

This data gap has been addressed in the AIR5 renewal dossier (XXXX, 2020) and the Article 12 confirmatory data submission, by provision of a new magnitude of residue in rotational crop study (2020/2030949) and a calculation demonstrating plateau levels are covered. The following extract is reproduced from the AIR5 renewal dossier (XXXX, 2020):

Residues of ametoctradin and its metabolites in rotational crops were investigated in two studies which have already been evaluated during the previous active substance inclusion process (The Netherlands, 2010).

In both studies, BAS 650 00 F, a SC formulation containing 200 g/L ametoctradin (BAS 650 F), was sprayed onto bare soil in a single application at a nominal rate of 0.960 kg a.s./ha using a target water volume of 300 L/ha. Representative succeeding crops (wheat, carrot, cauliflower and lettuce) were planted at different plant back intervals (30, 120 and 360 days) and analysed for residues of parent ametoctradin and its major metabolites M650F003 and M650F004 in succeeding crops and soil.

The application rate of 0.960 kg a.s./ha in these studies is considered to cover the plateau level for the metabolites M650F003 and M650F004 as justified in the following paragraphs.

For parent BAS 650 F accumulation in soil does not need to be considered, while for the metabolites M650F03 and M650F04, accumulation needs to be accounted for (see MCA Section 7.1.2 for degradation behaviour in soil).

A formation rate of 57.0% M650F003 and 54.9% M650F004 from parent was observed. The input parameters for the PECsoil calculations and the resulting PEC values for metabolites M650F003 and M650F004 are summarized below. For details please refer to MCP Section 9.00 – 9.01.03.

The relevant critical GAP with regard to crop rotation is the N-EU GAP for potatoes (foliar application of 3 x 0.240 kg a.s./ha, interval 5 days, PHI 7 days).

| **Table 7.2‑16: PECsoil values for metabolites M650F003 and M650F004 following application of 3 x 240 g/ha to potatoes** | | |
| --- | --- | --- |
| **PECsoil [mg kg-1]** | **M650F003** | **M650F004** |
| Initial concentration (PECact) | 0.169 | 0.158 |
| Plateau concentration (20 cm)  after 10 years (PECsoil plateau) | 0.003 | 0.087 |

Using these values, the PECsoil values (mg/kg soil) were transformed to hypothetical application rates for the metabolites and correspondingly for equivalents of parent ametoctradin (in g/ha) assuming the soil parameters described above using the following formula:

g/ha = (PECsoil plateau, 20 cm x depth x density x area) + (PECact, 5 cm x depth x density x area)

The results of these calculations are summarized in the table below. These calculations represent worst case assumptions with considering high PECact values in the upper soil layer of 5 cm and plateau PECsoil values for the soil layer 0-20 cm.

| **Table 7.2‑17:** **PECsoil values for metabolites M650F003 and M650F004 expressed as application rates for parent Ametoctradin equivalents** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **PEC (mg/kg)** | | **Depth (m)** | **Density (g/cm3)** | **Area**  **(m2)** | **Metabolite equivalent**  **(g/ha)** | **Formation rate**  **(%)** | **Ametoctradin equivalent**  **(g/ha)** |
| **M650F003** | | | | | | | |
| PECact, 5 cm | 0.169 | 0.05 | 1.5 | 10000 | 126.75 | 57.0 | 222.37 |
| PECsoil plateau, 20 cm | 0.003 | 0.2 | 1.5 | 10000 | 9.00 | 57.0 | 15.79 |
| Total | | | | | 135.75 | 57.0 | 238.16 |
| **M650F004** | | | | | | | |
| PECact, 5 cm | 0.158 | 0.05 | 1.5 | 10000 | 118.50 | 54.9 | 215.85 |
| PECsoil, 20 cm | 0.087 | 0.2 | 1.5 | 10000 | 261.00 | 54.9 | 475.41 |
| Total | | | | | 379.50 | 54.9 | 691.26 |
| Combined Total | | | | | 515.25 | -- | 929.41 |

From these calculations it can be seen that residue concentrations of metabolites M650F003 and M650F004 expected from multiple year applications (plateau concentrations of metabolites) are covered by the application rates of parent ametoctradin in the available field studies. Moreover, it is noted that the above PEC calculations represent a worst-case scenario since no interception is considered.

**Summary of new data (2020/2030949)**

One new field rotational crop study investigated the residues of ametoctradin, M650F003 and M650F004 in rotational crops: strawberries, leek, oilseed rape and tomato, after one application of BAS 650 00 F to bare soil 30 and 120 days prior to planting/seeding in Northern and Southern Europe.

The results from these trials show that at a PBI of 30 days, ametoctradin residues in all crop samples were not detected (<LOD). Residues of M650F003 and M650F004 ranged from <LOD – 0.30 mg/kg and <LOD – 0.017 mg/kg, respectively. At a PBI of 120 days, residues of ametoctradin were not detected (<LOD) in all crop samples. Residues of M650F003 and M650F004 ranged from <LOD – 0.079 mg/kg and <LOD – 0.054 mg/kg, respectively.

Residues in accordance with the risk assessment residue definition ranged from <0.035 –0.053 mg/kg in leek, <0.035 mg/kg in oilseed rape seed, <0.035 – 0.088 mg/kg in strawberry and <0.035 – 0.040 mg/kg in tomato.

Conclusion on rotational crops studies

Calculations have been presented to demonstrate that the application rate of 960 g ametoctradin/ha in the rotational crop field trials covers the plateau concentrations of the metabolites M650F003 and M650F004.

Furthermore, a new rotational crop field study has been provided to address the magnitude of residues of ametoctradin, M650F003 and M650F004 in additional rotated super crop groups; oilseeds (oilseed rape), bulb and stem vegetable (leeks), fruits and fruiting vegetables (strawberry and tomato). These results confirm that no residues of parent ametoctradin are expected in rotated oilseeds, bulb and stem vegetable or fruits and fruiting vegetables. Hence it is not necessary to set MRLs for rotated crops. For risk assessment purposes, the additional super crop groups have been assessed in the table below.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Commodity** | **Region** | **PBI** | **Residue levels†** | **Calculated MRL** | **Median CF** | **Comments** |
| Leek (BBCH 41) | NEU | 30 | Mo: <0.01, <0.01  RA: 0.037, 0.048 | 0.01\* | 3.6 | Immature leek stems not used for risk assessment / extrapolation to super crop group. |
| SEU | Mo: <0.01, <0.01  RA: <0.035, <0.035 |
| Leek (BBCH 41) | NEU | 120 | Mo: <0.01, <0.01  RA: 0.036, <0.035 | 0.01\* | 3.6 |
| SEU | Mo: <0.01, <0.01  RA: 0.053, <0.035 |
| Leek (BBCH 49) | NEU | 30 | Mo: <0.01, <0.01  RA: <0.035, 0.036 | 0.01\* | 3.5 | In accordance with ENV/JM/MONO(2018)9, trials on leek can be extrapolated to rotated bulb and stem vegetables.  Residues expected in rotated mature leeks are insignificant (<25%) compared to primary crop residues in leek (STMR=1.06 mg/kg; EFSA, 2020) and bulb vegetables (garlic, onion, shallots, spring onions) (STMR=0.22 to 4.3 mg/kg; EFSA, 2020).  Therefore, no further consideration of rotated residues in stem or bub vegetables is required for risk assessment. |
| SEU | Mo: <0.01, <0.01  RA: <0.035, <0.035 |
| Leek (BBCH 49) | NEU | 120 | Mo: <0.01, <0.01  RA: <0.035, <0.035 | 0.01\* | 3.5 |
| SEU | Mo: <0.01, <0.01  RA: <0.035, <0.035 |
| Oilseed rape seed | NEU | 30 | Mo: <0.01, <0.01  RA: <0.035, <0.035 | 0.01\* | Not required; all residues <LOQ | All residues are <LOQ in rotated oilseeds. Therefore, no further consideration of rotated residues in oilseeds is required for risk assessment. |
| SEU | 30 | Mo: <0.01, <0.01  RA: <0.035, <0.035 |
| Oilseed rape seed | NEU | 120 | Mo: <0.01, <0.01  RA: <0.035, <0.035 | 0.01\* | Not required; all residues <LOQ |
| SEU | 120 | Mo: <0.01, <0.01  RA: <0.035, <0.035 |
| Strawberry | NEU | 30 | Mo: <0.01, <0.01  RA: 0.042, 0.057 | 0.01\* | 3.9 | Residues expected in rotated strawberries are significant (>25%) as there is no primary crop use. Therefore, the worst-case CF (4.0) is used in the risk assessment for strawberries. |
| SEU | Mo: <0.01, <0.01  RA: 0.035, <0.035 |
| Strawberry | NEU | 120 | Mo: <0.01, <0.01  RA: 0.044, 0.088 | 0.01\* | 4.0 |
| SEU | Mo: <0.01, <0.01  RA: <0.035, <0.035 |
| Tomato | NEU | 30 | Mo: <0.01, <0.01  RA: 0.040, <0.035 | 0.01\* | 3.7 | Residues expected in rotated tomatoes are insignificant (<25%) compared to primary crop residues in fruiting vegetables (cucumber, tomatoes, peppers, aubergines, okra, courgette, gherkins) (STMR=0.155 to 0.54 mg/kg; EFSA, 2020). Therefore, no further consideration of rotated residues in fruiting vegetables is required for risk assessment. |
| SEU | Mo: <0.01, <0.01  RA: <0.035, 0.039 |
| Tomato | NEU | 120 | Mo: <0.01, <0.01  RA: <0.035, <0.035 | 0.01\* | 3.5 |
| SEU | Mo: <0.01, <0.01  RA: <0.035, <0.035 |

† Mo: Ametoctradin

RA: Sum of ametoctradin, M650F003 and M650F004, expressed as ametoctradin

Of the additional super crop groups, only rotated strawberry contain residues that need to be included in the consumer risk assessment. It is noted that EFSA, 2020 concluded that the previously evaluated rotational crop field data justified the inclusion of cereal residues in the livestock dietary burden and the consumer risk assessment, though no use of ametoctradin is proposed for cereal crops.

**zRMS:** accepted.

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

Of the intended uses, aubergine and floriculture are considered melliferous (SANTE/11956/2016).

Residues of ametoctradin and metabolites M650F003 and M650F004 in honey have previously been evaluated following three applications of ametoctradin to buckwheat at a rate of 390 g a.s./ha (total 1.17 kg as/ha), with one application before flowering and two applications during flowering (EFSA, 2021). On the basis of these data an MRL of 5 mg/kg was set in honey (EFSA, 2021; Regulation 2022/1290). These data were conducted at approximately 2.4N the worst case intended rate on melliferous crops in this submission and therefore, the existing EU MRL on honey is sufficient to support the intended uses of BAS 743 03 F.

### 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 Section 7.1.2).

Due to the low toxicity in context of the chronic risk assessments only the TMDI calculation was considered necessary. The MRLs used are from EU reg 2022/1290, with the exception of barley, oat, rye and wheat grain where the rotational crop STMRs, determined in the EFSA Article 12 review, are used (EFSA, 2020).

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

#### Input values for the consumer risk assessment

Table ‑: Input values for the consumer risk assessment

| **Commodity** | **Chronic risk assessment** | |
| --- | --- | --- |
| **Input value (mg/kg)** | **Comment** |
| Risk assessment residue definition: ametoctradin | | |
| All crops (except rotational crops barley, oat, rye, wheat) | Existing MRLs as specified in EU Reg 2022/1290 | |
| Risk assessment residue definition: sum of ametoctradin, M650F03 and M650F04, expressed as ametoctradin | | |
| Barley, oat, rye, wheat grain | 0.053 | STMR (EFSA, 2020) |
| Risk assessment residue definition: sum of ametoctradin, M650F01 and M650F06, expressed as ametoctradin | | |
| All commodities of animal origin | Existing MRLs as specified in EU Reg 2022/1290 | |

#### Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table ‑: Consumer risk assessment

|  |  |
| --- | --- |
| TMDI (% ADI) according to EFSA PRIMo | 0.9% (Based on NL toddler) |
| IEDI (% ADI) according to EFSA PRIMo | Not conducted, TMDI <<100% |
| IESTI (% ARfD) according to EFSA PRIMo | Not applicable (no ARfD) |

The proposed uses of ametoctradin in BAS 743 03 F do not represent unacceptable chronic risks for the consumer.

**zRMS:** accepted.

PRIMo reports included in Appendix 3 are unreadable. Please replace them with the clear ones.

**Applicant comments**:

The two unreadable PRIMo outputs in Appendix 3 have been replaced as requested by the zRMS.

## Propamocarb

General data on propamocarb are summarised in the table below.

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

|  |  |
| --- | --- |
| Active substance (ISO Common Name) | Propamocarb |
| IUPAC | propyl *N*-[3-(dimethylamino)propyl]carbamate (propamocarb)  propyl *N*-[3-(dimethylamino)propyl]carbamate hydrochloride (propamocarb hydrochloride) |
| Chemical structure | (propamocarb)    (propamocarb hydrochloride) |
| Molecular formula | C9H20N2O2 (propamocarb)  C9H21ClN2O2 (propamocarb hydrochloride) |
| Molar mass | 188.27 g/mol (propamocarb)  224.7 (propamocarb hydrochloride) |
| Chemical group | Carbamate fungicide |
| Mode of action (if available) | Propamocarb interferes with the synthesis of phospholipids and fatty acids, effecting several stages of the pathogen life cycle, limiting spore production |
| Systemic | Yes |
| Company (ies) \* | Bayer |
| Rapporteur Member State (RMS) | Portugal (the original RMS were Ireland) |
| Approval status | Reg. (EU) 2023/918  Approved (date of approval 01/10/2007; date of expiration of approval 15/06/2025)  [Commission Implementing Regulation (EU) No 540/2011](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0540&from=EN) of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved substances.  [Commission Implementing Regulation (EU) 2022/708](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R0708&from=EN) of 5 May 2022 amending implementing Regulation (EC) 540/201.. |
| Restriction | Only uses as a fungicide may be authorised |
| Review Report | SANCO/10057/2006 final  25/04/2008 |
| Current MRL regulation | Commission Regulation (EU) 2020/856 amending Regulation (EC) No 396/2005 |
| Peer review of MRLs according to Article 12 of Regulation (EC) No 396/2005 performed | Yes (EFSA, 2013) |
| EFSA Journal: Conclusion on the peer review | Yes (EFSA, 2006) |
| Current MRL applications on intended uses | MRLs in honey (EFSA-Q-2022-00427) |

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

### Stability of Residues (KCA 6.1)

#### Stability of residues during storage of samples

Available data

New data are submitted in the framework of this application. Freezer storage stability data for propamocarb and propamocarb hydrochloride were evaluated and accepted during the first EU approval (Ireland, 2004; EFSA, 2006) and the Article 12 review (EFSA, 2013). Additional data, of relevance to this product submission, were submitted as part of the ongoing renewal of approval of propamocarb (Portugal, 2017), for which the applicant (XXXX) has a Letter of Access. Available studies are summarised in Table 7.3‑2

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

| **Category** | **Analyte(s)** | **Commodity** | **Stability period** | **Reference** |
| --- | --- | --- | --- | --- |
| **Data relied on in EU** | | | | |
| **Plant products** | | | | |
| High water content | Propamocarb HCl | Tomatoes | 26 months  (-18°C) | Ireland, 2004  EFSA, 2006  Moede J., 1990, Report No. A85300  Sutton, A. L.; Charter, G. E., 1999, Re-port No. C003740  Wrede-Rücker, A., 1990, Report No. A85303 |
| Propamocarb HCl | Lettuce | 14 months  (-20°C) |
| Propamocarb | Lettuce | 24 months  (-18°C) | Ireland, 2004  EFSA, 2006  Pigeon, O., 2002, Report No. 20018  Pigeon, O., 2003, Report No. RE 20044/2000  Pigeon, O., 2002, Report No. 20042 / 2000 |
| Propamocarb | Cucumber | 12 months  (-18°C) |
| Propamocarb | Brussel sprouts | 12 months  (-18°C) |
| **New Data** | | | | |
| High starch | Propamocarb HCl | Potatoes | 26 months (-18°C) | Everitt, S. L.; Charter, G. E.; 1999; M-167991-02-1† |
| **Animal products** | | | | |
| No new data |  |  |  |  |

† XXXX has a Letter of Access allowing them to rely on this study include in Part A. Data are being evaluated as part of renewal of approval of propamocarb (Portugal, 2017).

Conclusion on stability of residues during storage

Propamocarb has been demonstrated to be stable for at least 12 months in high water and 26 months in high starch commodities. The residue data included in this submission stored samples for the following maximum time periods:

Potatoes: 249 days (*ca.* 8 months)

Onions: 179 days (*ca.* 6 months)

Tomatoes: 275 days (*ca.* 9 months)

The available storage stability data are sufficient to support the residue data on potato (high starch commodity), onion and tomato (high water commodities). No further data are required or submitted in the framework of this application.

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

Conclusion on stability of residues in sample extracts

Procedural recoveries obtained during residue analysis demonstrate the stability of propamocarb residues in sample extracts and fully support the residue data presented in the submission.

No further information on the stability of residues in sample extracts is required or submitted.

**zRMS:** accepted.

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

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

Available data

No new data are submitted in the framework of this application. Metabolism data were evaluated and accepted during the first EU approval (Ireland, 2004; EFSA, 2006) and the Article 12 review (EFSA, 2013). Metabolism of propamocarb hydrochloride was investigated for foliar application on fruits and fruiting vegetables (tomato and cucumber), on leafy vegetables (lettuce and spinach) and on root and tuber vegetables (potato) and for soil application on fruiting vegetables (tomato and cucumber) and on leafy vegetables (lettuce) using [diamino-propyl-1-14C] and [diamino-propyl-2-14C] labelled propamocarb. Available studies are summarised in Table 7.3‑3.

Table ‑: Summary of plant metabolism studies

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Crop Group** | **Crop** | **Label position** | **Application and sampling details** | | | | **Source** |
| **Method,**  **F or G(a)** | **Rate** | **No** | **Sampling (DAT)** |
| **EU reviewed data** | | | | | | | |
| **Fruits and fruiting vegetable** | Tomato | [diamino-propyl-2-14C] | Soil, G | 72.2 kg a.s./ha | 4 | 14, 21, 28, 35 | Ireland, 2004  EFSA, 2006  Goodyear, A., 2001, Report No. CLE 1669/3-D2149 |
| 361 kg a.s./ha | 4 |
| Foliar, G | 2.166 kg a.s./ha | 1 | 7, 14, 21, 28 |
| Cucumber | [diamino-propyl-1-14C] | Foliar(b) | 2.9 kg a.s./ha | 1 | 30 | Ireland, 2004  EFSA, 2006  Rupprecht K.J.,  Feyerabend M., 1998, Report No. A85149 |
| Soil (hydroponic)(b) | 53.4 mg/plant (aqueous) | 1 | 21 |
| **Leafy vegetables** | Spinach | [diamino-propyl-1-14C] | Foliar, F | 2.53 kg a.s./ha | 2 | 0 DAA1, 3 DAA2 | Ireland, 2004  EFSA, 2006  Rupprecht K. J.,  Daniel L. E., 2000, Report No. B002936 |
| Lettuce | [diamino-propyl-2-14C] | Soil (drench), G | 72.2 kg a.s./ha | 3 | 38 | Ireland, 2004  EFSA, 2006  Goodyear, A., 2002, Report No. CLE 1669/6-D2149 |
| Foliar, G | 1.083 kg a.s./kg | 3 | 21 |
| **Root and tuber vegetables** | Potato | [diamino-propyl-1-14C] | Foliar, F | 2.45 kg a.s./ha | 3 | 42 | Ireland, 2004  EFSA, 2006  Foertsch, A., 1991, Report No. A85140  Foertsch, A., 1993, Report No. A85141 |
| [diamino-propyl-2-14C] | Foliar, F | 2.166 kg a.s./ha | 6 | 7 | Ireland, 2004  EFSA, 2006  Goodyear, A., 2002, Report No. CLE 1669/5-D2149 |
| 10.83 kg a.s.ha | 6 |

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

(b): F or G not stated

\* Identification of metabolites in sample extracts further investigated in study CLE 1669/10-D2149

DAA1 – Days after application 1

DAA2 – Days after application 2

Summary of plant metabolism studies reported in the EU

*Reference: EFSA, 2013*

“The metabolism of propamocarb hydrochloride in the crops under consideration is sufficiently addressed and the residue definition for enforcement purposes and risk assessment in all plant commodities is defined as the sum of propamocarb and its salts, expressed as propamocarb since the identified metabolites in all crops were recovered as a low proportion (<10% TRR) and no significant contribution to the toxicological burden is expected. Validated analytical methods for enforcement of the proposed residue definition are available. The conclusions reached by EFSA reflect the views of the RMS and are also in line with those of the HMPR (FAO, 2006a) even if the wording used by JMPR is slightly different (the residues is defined as propamocarb (free base)).”

Conclusion on metabolism in primary crops

The intended uses on potato, onion, garlic, tomato and aubergine are covered by the existing metabolism data package. Considering the maximum seasonal rate in this submission (root and tuber veg at 2.706 kg propamocarb hydrochloride/ha (2.268 kg propamocarb/ha) and fruiting veg. at 1.804 kg propamocarb hydrochloride/ha (1.512 kg propamocarb/ha)), the foliar metabolism studies were conducted at 3.2-28.7N (root and tuber veg.) and 1.4-1.9N (fruiting veg). and in accordance with the intended PHIs. Therefore the existing data accommodate the intended uses and no further data are required.

Based on the crop metabolism studies evaluated during the first EU approval (Ireland, 2004; EFSA, 2006), the following residue definitions are applicable to this product submission and were confirmed in the EFSA Article 12 review (EFSA, 2013):

Residue definition for monitoring and risk assessment: Sum of propamocarb and its salts, expressed as propamocarb.

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

Available data

No new data are submitted in the framework of this application. Data were evaluated and accepted during the first EU approval (Ireland, 2004; EFSA, 2006) and the Article 12 review (EFSA, 2013). Furthermore, propamocarb hydrochloride is not persistent in soil, with a DT90 value in the range 58-78 days, which is below the trigger value of 100 days. Nevertheless, the metabolism of propamocarb in rotational crops (lettuce, radish and wheat) has been investigated. This study is summarised in Table 7.3‑4

Table ‑: Summary of metabolism studies in rotational crops

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Crop group** | **Crop** | **Label position** | **Application and sampling details** | | | | **Source** |
| **Method,**  **F or G(a)** | **Rate**  **(kg a.s./ha)** | **Sowing intervals**  **(DAT)** | **Harvest**  **Intervals (DAT)** |
| **EU reviewed data** | | | | | | | |
| **Leafy vegetables** | Lettuce | 14C-aminopropyl | Bare soil, G | 5.96 – 6.16 | 30, 120, 365 | n.r. | Ireland, 2004  EFSA, 2006  Meyer, B. N., 1999, Report No. B002934 |
| **Root and tuber vegetables** | Radish |
| **Cereals** | Wheat |

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

n.r. Not reported

Summary of rotational crop metabolism studies reported in the EU

*Reference: EFSA, 2013*

“In crops planted in the 30 day aged soil, total residues ranged from 0.36 (radish roots) to 2.33 mg/kg (wheat straw), and declined rapidly in crops planted in soil aged 120 days and 365 days to a maximum of 0.09 mg eq/kg. Propamocarb was found in all acidic methanol sample extracts from the 30 day aged soil and was the major component (15.4 % TRR (0.36 mg/kg) in wheat straw to 67.4 % TRR (0.91 mg/kg) in radish tops), except in wheat grain, where the main compound was the oxazolidine metabolite representing 19.9 % TRR (0.13 mg/kg). 2-hydroxy propamocarb, N-oxide and desmethyl propamocarb (wheat only) were not present in any sample at levels exceeding 10 % TRR. The remaining residue was a complex mixture of highly polar components. Residues released after acid and base hydrolysis (< 10 % TRR) indicated a similar pattern of metabolites.

Consequently, metabolism in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary. Although the oxazolidine metabolite was recovered in significant amounts in wheat straw, this metabolism study was carried out with plants grown in pots with an overdosed application rate. Consequently, it is expected that this metabolite will not be present in significant amounts following realistic application conditions (<0.01 mg eq/kg).”.

Conclusion on metabolism in rotational crops

The intended uses may be rotated. Propamocarb hydrochloride is not persistent in soil (DT90 <100 days) therefore, studies are not strictly required. However, data are available that demonstrate the metabolism in primary and rotational crops was similar and it was concluded that a specific residue definition for rotational crops was not necessary.

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

Available data

New data are submitted in the framework of this application. No high temperature hydrolysis data were evaluated during the first EU approval (Ireland, 2004; EFSA, 2006). However, data were submitted as part of the ongoing renewal of approval of propamocarb (Portugal, 2017), for which the applicant (XXXX) has a Letter of Access. A study summary based on the publicly available RAR has been included in A 2.2.2.1.3. Available studies are summarised in Table 7.3‑5

Table ‑: Nature of the residues in processed commodities

| **Conditions** | **Identified compound(s) (%)** | **Source** |
| --- | --- | --- |
| **New data** | | |
| Pasteurisation (20 minutes, 90°C, pH 4) | Propamocarb hydrochloride (100.7%) | Justus, K.; Kuhnke, G.; 2008; MEF-08/173† |
| Baking, boiling, brewing (60 minutes, 100°C, pH 5) | Propamocarb hydrochloride (100.8%) |
| Sterilisation (20 minutes, 120°C, pH 6) | Propamocarb hydrochloride (101.2%) |

† XXXX has a Letter of Access allowing them to rely on this study included in Part A. Data are being evaluated as part of renewal of approval of propamocarb (Portugal, 2017).

**Summary of new studies**

No hydrolysis products of [1-C14]propamocarb-hydrochloride was resistant to hydrolysis under conditions representative of pasteurization (pH 4, 90°C, 20 min), baking, boiling, brewing (pH 5, 100°C, 60 min) and sterilization (pH 6, 120°C, 20 min).

**Conclusion on nature of residues in processed commodities**

Propamocarb hydrochloride is hydrolytically stable under the representative processing conditions and the same residue definitions as for raw agricultural commodities apply. No further data are required.

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

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

|  |  |
| --- | --- |
| **Endpoints** | |
| Plant groups covered | Foliar treatment: Root vegetables (potato), Fruit crops (tomato, cucumber), Leafy crops (spinach, lettuce)  Soil treatment: Fruit crops (tomato, cucumber), Leafy crops (lettuce) |
| Rotational crops covered | Leafy crops (lettuce), Root & tuber vegetables (radish), Cereals (wheat) |
| Metabolism in rotational crops similar to metabolism in primary crops? | Yes |
| Processed commodities | a.s. is stable under standard hydrolysis conditions |
| Residue pattern in processed commodities similar to pattern in raw commodities? | Yes |
| Plant residue definition for monitoring | Sum of propamocarb and its salts expressed as propamocarb (Reg. (EU) 2020/856) |
| Plant residue definition for risk assessment | Sum of propamocarb and its salts expressed as propamocarb (EFSA, 2013) |
| Conversion factor from enforcement to RA | n.a. |

n.a. not applicable

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

Available data

No new data are submitted in the framework of this application. Livestock metabolism data were evaluated during the first EU approval (Ireland, 2004; EFSA, 2006) and the Article 12 review (EFSA, 2013). Metabolism of propamocarb hydrochloride was investigated in lactating cows and laying hens. Available studies are summarised in Table7.3‑7.

Table7.3‑7: Summary of animal metabolism studies

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** | **Species** | **Label position** | **No of animal** | **Application details** | | **Sample details** | | **Report reference** | **Reference** |
| **Rate**  **(mg/kg bw/d)** | **Duration**  **(days)** | **Commodity** | **Time of samp­ling** |
| **EU reviewed data** | | | | | | | | | |
| **Lactating ruminants** | Cow | [Diaminopropyl-1-14C] | 1 | 2 | 7 | Milk | Twice daily | XXXX  1998, Report No. B002935 | Ireland, 2004  EFSA, 2006  EFSA, 2013 |
| Urine & faeces | Twice daily |
| Tissues | After sacrifice |
| **Laying poultry** | Hens | [Diaminopropyl-1-14C] | 12 | 1.02 | 14 | Eggs | Daily | 2010, MERPX029 | Ireland, 2012 EFSA, 2013† |
| Excreta | Not reported |
| Tissues | After sacrifice |

† XXXX has a Letter of Access allowing them to rely on these data included in Part A.

Summary of animal metabolism studies reported in the EU

*Reference: EFSA, 2013*

“In cow, over 80 % of the administered dose was excreted in urine and faeces while only 0.7% and 0.46% of the AR remained in tissues and milk, respectively. No quantifiable residues (<0.01 mg/kg) were recovered in fat and no further metabolites identification was attempted. The highest total radioactive residues were found in liver (0.415 mg eq/kg) and in kidney (0.107 mg eq/kg) and to a minor extent in muscle (0.02 mg eq/kg) and in milk (0.057 mg eq/kg). Propamocarb accounted for 24.6 % TRR in muscle (0.005 mg/kg), 23.5 % TRR in kidney (0.025 mg/kg), 6.2 % TRR in liver (0.026 mg/kg) and 6.0 % TRR in milk (0.003 mg/kg). Parent compound was either oxidized to form Review of the existing MRLs for propamocarb EFSA Journal 2013;11(4):321433N-oxide propamocarb, or hydroxylated at the propyl side chain to form the 2-hydroxy-propamocarb17followed by a cyclisation to form the oxazolidine-2-one propamocarb metabolite. Another route of degradation consisted of demethylation of the parent molecule into the N-desmethyl propamocarb. Metabolite N-oxide propamocarb was the predominant metabolite of the total residues found in kidney (41 % TRR – 0.044 mg/kg), liver (49 % TRR – 0.203 mg/kg), muscle (40.5 % TRR – 0.008 mg/kg) and also in milk (21 % TRR – 0.012 mg/kg). Oxazolidine-2-one propamocarb occurred in significant amounts in kidney, liver and milk (14 – 23 % TRR; 0.014 – 0.09 mg/kg). 2-hydroxy propamocarb was the major metabolite of the total residues in milk (37.5 % TRR – 0.022 mg/kg) but was also identified at a lower level in liver (5 % TRR) and kidney (13 % TRR). N-desmethyl propamocarb was either not detected (kidney, liver) or identified at a trace level in milk and muscle (up to 0.002 mg/kg).

In hens, the majority of the residues (92 to 99 % TRR) in the egg and tissues was extractable. The total radioactive residues accounted for 0.254 mg/kg in eggs, 0.492 mg/kg in liver, 0.117 – 0.135 mg/kg in muscle and 0.042– 0.065 mg/kg in fat. The predominant compound of the total residues was the N-desmethyl propamocarb in eggs (45 % TRR), liver (22 % TRR), muscle (29 % TRR) and to a minor extend in fat (6 % TRR) whilst the parent compound occurred at a lower level in all matrices (2– 12 % TRR). Bis desmethyl propamocarb18 and N-oxide propamocarb accounted for less than 10% TRR. It is noted that a significant fraction of the radioactive residues remained uncharacterized in liver and muscle (32 % and 41 % TRR, respectively).

With an additional route of degradation of propamocarb through hydroxylation of the parent molecule at the propyl side chain with further cyclisation of the side chain, the metabolic degradation of propamocarb in cows appears to be more extensive compared to the metabolism depicted in hens. All the major metabolites identified in cow and hens were also observed in the rat metabolism and are therefore assumed to have similar toxicological properties as the parent compound. The general metabolic pathways of propamocarb in rodents and ruminants were found to be comparable; the findings in ruminants can therefore be extrapolated to pigs.

Based on these studies, EFSA proposes to limit the residue definition to the best marker compound and to define the residue for enforcement in pig and ruminant tissues and milk as N-oxide propamocarb only and in poultry tissues and eggs as N-desmethyl propamocarb. For risk assessment, EFSA proposes to define the residue in milk, pig and ruminant tissues as the sum of propamocarb, N-oxide propamocarb, oxazolidine-2-one propamocarb and 2-hydroxypropamocarb expressed as propamocarb. For poultry tissues, EFSA proposes to define the residue as the sum of propamocarb and N-desmethyl propamocarb, expressed as propamocarb.

Theoretical conversion factors could also be derived as follow: 1.3 for all poultry tissues and eggs, 4.25 for milk, 2.2 for ruminant kidney, 1.7 for ruminant liver and muscle, 1 for ruminant fat. Analytical methods for enforcement of the proposed residue definition are not available (see also section 1.2). The conclusions reached by EFSA are not in line with those of the JMPR (FAO, 2006a) who set a residue definition by default as propamocarb (free base) because the dietary burden was not triggered.”.

Conclusion on metabolism in livestock

The metabolism of propamocarb in livestock is sufficiently addressed to support the proposed uses of the product BAS 743 03 F.

Based on the livestock metabolism studies evaluated during the first EU approval (Ireland, 2004; EFSA, 2006), the following residue definitions are applicable to this product submission and were confirmed in the EFSA Article 12 review (EFSA, 2013):

Residue definition for monitoring swine, ruminant tissues and milk: N-oxide propamocarb

Residue definition for monitoring poultry tissues and eggs: N-desmethyl propamocarb

Residue definition for risk assessment swine, ruminant tissues and milk: Sum of propamocarb, N-oxide propamocarb, oxazolidin-2-one propamocarb and 2-hydroxypropamocarb expressed as propamocarb

Residue definition for risk assessment poultry tissues and eggs: Sum of propamocarb and N-desmethyl propamocarb, expressed as propamocarb

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

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

|  |  |
| --- | --- |
| **Endpoints** | |
| Animals covered | Lactating goats, laying hens |
| Time needed to reach a plateau concentration | Not reported in EFSA, 2013 |
| Animal residue definition for monitoring | Swine, ruminant tissues and milk: N-oxide propamocarb (Reg. (EU) 2020/856)  Poultry tissues and eggs: N-desmethyl propamocarb  (Reg. (EU) 2020/856) |
| Animal residue definition for risk assessment | Swine, ruminant tissues and milk: Sum of propamocarb, N-oxide propamocarb, oxazolidin-2-one propamocarb and 2-hydroxypropamocarb expressed as propamocarb (EFSA, 2013)  Poultry tissues and eggs: Sum of propamocarb and N-desmethyl propamocarb, expressed as propamocarb (EFSA, 2013) |
| Conversion factor | Ruminant kidney: 2.2  Ruminant liver and muscle: 1.7  Ruminant fat: 1  Poultry tissues and eggs: 1.3  Milk: 4.25  (EFSA, 2013) |
| Metabolism in rat and ruminant similar | Yes |
| Fat soluble residue | No |

**zRMS:** accepted.

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

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

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

Table ‑: Summary of EU reported and new data supporting the intended uses of BAS 743 03 F and conformity to existing MRL

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Commodity | Source | Residue zone (N-EU, S-EU) | Evaluation GAP Residue levels (mg/kg)(a) | STMR (mg/kg) | HR (mg/kg) | Unrounded OECD calculator MRL (mg/kg) | Current EU MRL  (mg/kg)  (Reg. (EU) 2020/856) | MRL compliance |
| Potato  cGAP: 3 x 902 g a.s./ha, RTI 5 days, PHI 7 days | New data | N-EU | Trials GAP: 3 x 902 g a.s./ha propamocarb hydrochloride, RTI 4-6 days, 7 day PHI  E/RA: 12x <0.01 | 0.01 | 0.01 | 0.01 | 0.3 | Yes |
| Onion 🡪 extrapolated to garlic  cGAP: 2 x 902 g a.s./ha, RTI 5 days, PHI 7 days | New data | N-EU | Trials GAP: 2 x 902 g a.s./ha propamocarb hydrochloride, RTI 4-5 days, 7 day PHI  E/RA: 0.011, 0.029, 0.038, 0.082, 0.083, 0.092, 0.10, 0.13, 0.14, 0.18, 0.31, 0.48, 0.51 | 0.10 | 0.51 | 0.824 | 2 | Yes |
| Tomato 🡪 extrapolated to aubergine  cGAP: 2 x 902 g a.s./ha, RTI 7 days, PHI 1 days | New data | N-EU | Trials GAP: 2 x 902 g a.s./ha propamocarb hydrochloride, RTI 6-9 days, 1 day PHI  E/RA: 0.076, 0.20, 0.23, 0.27, 0.32, 0.39, 0.40, 0.61, 0.72, 0.81, 1.3, 2.1 | 0.40 | 2.1 | 2.919 | 4 | Yes |

* + - * 1. E: Definition of residue for enforcement: sum of propamocarb and its salts, expressed as propamocarb

RA: Definition of residues for risk assessment: sum of propamocarb and its salts, expressed as propamocarb

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

*Potato*

Potato is a major crop in northern Europe. The intended critical GAP (cGAP) is for three applications at 902 g propamocarb hydrochloride/ha (756 g propamocarb/ha), with a re-treatment interval of 5 days and a PHI of 7 days. To support the cGAP twelve NEU potato trials have been provided at the cGAP. No exceedance of the current propamocarb EU MRL will occur following application of BAS 743 03 F at the intended cGAP and the uses are considered acceptable.

*Onion and garlic*

Onion is a major crop and garlic a minor crop in northern Europe. The intended cGAP is for two applications at 902 g propamocarb hydrochloride/ha (756 g propamocarb/ha), with a re-treatment interval of 5 days and a PHI of 7 days. To support the cGAP thirteen NEU onion trials have been provided at the cGAP. In accordance with SANTE/2019/12752 data on onion can be extrapolated to garlic, which is the case here. No exceedance of the current propamocarb EU MRLs will occur following application of BAS 743 03 F at the intended cGAP and the uses are considered acceptable.

*Tomato and aubergine*

Tomato is a major crop and aubergine a minor crop in northern Europe. The intended cGAP is for two applications at 902 g propamocarb hydrochloride/ha (756 g propamocarb/ha), with a re-treatment interval of 7 days and a PHI of 1 day. To support the cGAP twelve NEU tomato trials have been provided at the cGAP. In accordance with SANTE/2019/12752 data on tomato can be extrapolated to aubergine, which is the case here. No exceedance of the current propamocarb EU MRLs will occur following application of BAS 743 03 F at the intended cGAP and the uses are considered acceptable.

**zRMS:** accepted.

### Magnitude of residues in livestock

The intended use of BAS 743 03 F on potato may result in residues of propamocarb in animal feed items, therefore the possible transfer of residues to animal matrices should be considered.

#### Dietary burden calculation

The dietary burden of propamocarb was assessed in the propamocarb Article 12 review (EFSA, 2013). A new propamocarb dietary burden calculation has been conducted using the 2017 EFSA model[[2]](#footnote-2), taking into account the uses included in the Article 12 review and the intended uses. Where the new data represent a more critical endpoint, these are used in the dietary burden calculation. Input values are summarized in Table 7.3‑10. It is noted that this is an identical calculation to the one conducted as part of the ongoing renewal of approval of propamocarb (Portugal, 2017).

Table ‑: Input values for the dietary burden calculation (considering the uses evaluated in the Art. 12 review and the intended uses)

| **Feed Commodity** | **Median dietary burden** | | **Maximum dietary burden** | |
| --- | --- | --- | --- | --- |
| **Input value (mg/kg)** | **Comment** | **Input value (mg/kg)** | **Comment** |
| Risk assessment residue definition: sum of propamocarb and its salts, expressed as propamocarb | | | | |
| Cabbage | 0.20 | STMR (EFSA, 2013) | 0.36 | HR (EFSA, 2013) |
| Kale | 4.00 | STMR (EFSA, 2013) | 11.80 | HR (EFSA, 2013) |
| Potato, culls | 0.01 | STMR (EFSA, 2013) | 0.03 | HR (EFSA, 2013) |
| 0.01 | STMR (This submission, within EFSA, 2013 input) | 0.014 | HR (This submission, within EFSA, 2013 input) |
| Potato, process waste | 0.20 | STMR (0.01) x default PF (20) (EFSA, 2013) | 0.20 | STMR (0.01) x default PF(20) (EFSA, 2013) |
| Potato, dried pulp | 0.38 | STMR (0.01) x default PF (38) (EFSA, 2013) | 0.38 | STMR (0.01) x default PF (38) (EFSA, 2013) |

The results of the calculations are reported in Table 7.3‑11

Table ‑: Results of the dietary burden calculation

| **Animal species** | **Median**  **dietary burden (mg/kg bw/d)** | **Maximum dietary burden**  **(mg/kg bw/d)** | **Highest contributing commodity** | **Max dietary burden (mg/kg DM)** | **Trigger exceeded (Y/N)** | **Previous Max. (mg/kg bw/d)**  **EFSA, 2013** |
| --- | --- | --- | --- | --- | --- | --- |
| Risk assessment residue definition: Sum of propamocarb and its salts, expressed as propamocarb | | | | | | |
| Beef cattle\* | 0.1444 | 0.395 | Kale leaves | 16.45 | Y | 1.269 |
| Dairy cattle\* | 0.2249 | 0.626 | Kale leaves | 16.28 | Y | 1.075 |
| Ram/ewe | 0.1116 | 0.286 | Kale leaves | 8.6 | Y | - |
| Lamb | 0.1279 | 0.350 | Kale leaves | 8.23 | Y | - |
| Breeding swine | 0.070 | 0.191 | Kale leaves | 8.28 | Y | 0.510 |
| Finishing swine\* | 0.003 | 0.005 | Potato dried pulp | 0.16 | Y |
| Broiler poultry | 0.006 | 0.007 | Potato dried pulp | 0.10 | Y | 0.269 |
| Layer poultry\* | 0.009 | 0.014 | Cabbage, heads leaves | 0.20 | Y |
| Turkey | 0.001 | 0.002 | Potato culls | 0.03 | N |

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

The maximum dietary burdens calculated in this submission are well within those used to set the existing animal EU MRLs (EFSA, 2013). Therefore, the BAS 743 03 F GAPs are within the risk envelope already assessed at EU level and no further consideration of livestock exposure to propamocarb is required.

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

Available data

No new data were submitted in the framework of this application. The requested uses do not modify the theoretical maximum daily intake for animals so there is no risk for the existing animal MRLs to be exceeded. No further data are required as part of this submission.

One dairy cow (2003, Report No. B004276) and one poultry feeding study (2011, Report No. RAPRX068) were evaluated in the Article 12 review and used to set tentative animal MRLs (EFSA, 2013). XXXX have a Letter of Access allowing them to rely on these data included in Part A.

*Reference: EFSA, 2013*

“The RMS also reported a livestock feeding study on lactating cows which was underdosed; no reliable conclusion can be drawn on the magnitude of residues in ruminants and pigs. A representative feeding study for ruminants is therefore required and tentative MRLs and risk assessment values were derived from the available metabolism study on cows. Regarding poultry, a feeding study in hens demonstrated that significant residues of propamocarb in edible matrices of poultry are expected but separate results for propamocarb and N-desmethyl propamocarb are still required; tentative MRLs and risk assessment values were derived.”

These data gaps have been addressed as part of the ongoing renewal of approval of propamocarb (Portugal, 2017). An additional ruminant feeding study (2015, Report No. RAPRN023) was submitted, for which the applicant (XXXX) has a Letter of Access included in Part A. It was also clarified that the original poultry feeding study reported the analytes separately and therefore this remains relevant for MRL setting.

Conclusion on feeding studies

Data are available and were used to set the existing EU MRLs for animal matrices (EFSA, 2013). The requested uses do not modify the theoretical maximum daily intake for animals so there is no risk for the existing animal MRLs to be exceeded. No further data are required as part of this submission.

**zRMS:** accepted.

### 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 are submitted in the framework of this application. Data were evaluated and accepted during the Article 12 review (EFSA, 2013). It was noted in the Article 12 review that the processing factors were indicative as the nature of residues were not investigated. However, nature of residues data are now available (7.3.2.3) so these processing factors can be considered reliable. The data are summarised in Table 7.3‑12.

Table ‑: Overview of the available processing studies

| **Processed commodity** | **Number of studies** | **Median PF \*** | **Median CF \*\*** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| **EU data** | | | | | |
| Residue definition: Sum of propamocarb and its salts, expressed as propamocarb | | | | |  |
| Tomatoes, peeled and canned | 4 | 0.30 | 1.00 | - | EFSA, 2013†  Billian. P.; 2008; M-307290-01-1  Schulte, G.; Bauer, J.; 2011; M-406443-02-1  Billian, P.; Krusell, L.; 2010; M-397716-01-1 |
| Tomoatoes, paste | 4 | 3.10 | 1.00 | - |
| Tomatoes, ketchup | 4 | 0.70 | 1.00 | - |
| Tomatoes, juice | 4 | 0.45 | 1.00 | - |
| Head cabbage, cooked | 4 | 0.17 | 1.00 | - |
| Head cabbage, sauerkraut | 4 | 0.19 | 1.00 | - |
| Head cabbage, sauerkraut juice | 4 | 0.39 | 1.00 | - |
| Spinach, cooked | 4 | 0.88 | 1.00 | - |

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

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

† XXXX has a Letter of Access allowing them to rely on these data included in Part A.

#### Conclusion on processing studies

The residue data in this submission demonstrate that residues of propamocarb (in accordance with the residue definition for risk assessment) in tomatoes (extrapolated to aubergine) and onions (extrapolated to garlic) may be >0.1 mg/kg.

The only category 1 processes relevant to these commodities is preparation of vegetable juice (VII), for which data on tomatoes can be extrapolated to all vegetables in accordance with OECD 508. Data are available on the processing of tomato, cabbage and spinach from the Article 12 review (EFSA, 2013). Furthermore, reliable propamocarb processing factors are reported in the EU database of processing factors for pesticide residues[[3]](#footnote-3). No further information is required as part of this product submission.

**zRMS:** accepted.

### Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

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

Available data

No new data are submitted in the framework of this application. Data were evaluated during the first EU approval (Ireland, 2004; EFSA, 2006) and the Article 12 review (EFSA, 2013). Available studies are summarised in Table 7.3‑13

Table ‑: Summary of available studies in field rotational crops

| **Primary crop** | **Rate (kg a.s./ha)** | **Residue levels in succeeding crops** | | | **Source** |
| --- | --- | --- | --- | --- | --- |
| **Succeeding crop group** | **Succeeding crop** | **Sowing intervals**  **(DAT)** |
| **EU reviewed data** | | | | | |
| Application to bare soil | 4 x 1.68  propamocarb | Root and tuber vegetables | Sugar beet | 30, 60, 365 | Ireland, 2004  EFSA, 2006  Singer S.S. 1999, Report No. C003451 |
| Table beet |
| Cereals | Wheat |
| Oilseed, pulses | Soybean |
| Dry beans |
| Cabbage | 1 x 72.2(a) + 1 x 36.1(a) + 2 x 3.61(a)  propamocarb hydrochloride | Leafy vegetables | Lamb’s lettuce | 52-59 | EFSA, 2013†  Klein, E. H. J., 2004, Report No. C039190 |
| Cereals | Wheat | 81-102 |
| Lettuce | 3 x 1.325(b)  propamocarb | Leafy vegetables | Lettuce | 30 | EFSA, 2013†  Melrose, I.; Portet, M., 2009, Report No. 08-2504  Melrose, I.; Portet, M., 2009, Report No.: 08-2505  Melrose, I.; Portet, M., 2010, Report No.: 08-2506  Melrose, I.; Portet, M., 2009, Report No. 08-2507 |
| Root and tuber vegetables | Carrot |
| Cereals | Wheat |
| Barley |

(a) 1 x 72.2 kg a.s./ha drench application to primary crop directly after sowing (BBCH 00-11) + 1 x 36.1 kg a.s./ha drench application, 14 days after (BBCH 10-12) + 2 x 3.61 kg a.s./ha foliar applications after transplanting (BBCH 15-19 and BBCH 41-45). Total application equivalent to 60.8 kg propamocarb/ha

(b) First application at BBCH 14-42, final application at BBCH 19-48

n.a. growth stage is not applicable

† XXXX has a Letter of Access allowing them to rely on these data included in Part A.

*Reference: EFSA, 2013*

“Rotational crop field trials were evaluated in the framework of the peer review (Ireland, 2004). Propamocarb was applied on bare soil at 4 x 1.68 kg a.s./ha (1 N) and the magnitude of residues was investigated on several succeeding crops (wheat, soybean, sugar beet, table beet and dry beans) sown at three different plant-back intervals (30, 60 and 365 days) following application of the active substance. Wheat was the only crop grown on 30 days aged soils which contained parent residues at or above LOQ. Further rotational crop field trials were submitted where propamocarb was applied on white cabbage with 2 drench applications at a dose rate of 72.2 kg a.s./ha followed by 2 foliar applications at 3.61 kg a.s./ha (1 N) and the magnitude of residues was investigated on wheat and lamb’s lettuce sown at two different plant-back intervals (81 – 102 days for wheat and 52 – 59 days for lamb’s lettuce) (Ireland, 2012). No residue was detected (<LOQ of the method) in any of the following crops. In a third set of rotational crop field trials, propamocarb was sprayed on lettuce as the primary crop at 3 x 1.33 kg a.s./ha (1.8 N) and the magnitude of propamocarb residues was investigated in lettuce, carrot, winter wheat and barley sown at the 30 day plant-back interval. Residues were < 0.01 mg/kg in all the edible parts of the rotated crops and < 0.05 mg/kg for straw.

Based on the rotational crop field studies and considering that the application rate of propamocarb within the EU ranges between 0.84 – 1.85 kg a.s./ha and the fact that propamocarb was applied to a bare soil (interception of propamocarb by the plants is expected in practice), it can be concluded that propamocarb residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that propamocarb is applied in compliance with the GAPs reported in Appendix A. EFSA is of the opinion that the label restriction proposed during the peer review (EFSA, 2006) can be cancelled.”

Conclusion on rotational crops studies

Data already evaluated at EU level are available on the magnitude of residues in rotated crops. Considering the total application rates applied, the field trials were conducted at exaggerated rates compared to the critical intended GAP (3 x 0.756 propamocarb kg/ha), equivalent to 1.8-27N. The critical intended GAPs are within those evaluated by EFSA in the Article 12 review, therefore the conclusions of EFSA, 2013 remain relevant. The data indicate residues in rotational crops are not expected to exceed 0.01 mg/kg and no label restriction is necessary.

**zRMS:** accepted.

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

Of the intended uses, aubergine and floriculture are considered melliferous (SANTE/11956/2016).

The transfer of propamocarb residues to honey has been investigated and data submitted (Appeltauer, A., 2021, Report No. S20-01996) as part of an ongoing MRL application (EFSA-Q-2022-00427). The applicant, XXXX, has a Letter of Access for these data. A study summary based on the publicly available IUCLID dossier has been included in A 2.2.7.

The semi-field trials were conducted on *Phacelia tanacetifolia* with a total application rate of 6 kg propamocarb/ha and a MRL of 15 mg/kg was proposed. These data accommodate the intended GAPs in this submission and residues exceeding the proposed MRL are not expected as a result of the GAPs in this submission. No further information is required or submitted.

The MRL has changed by Reg. (EU) 2024/1439 and now is applicable.

### 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 Section 7.1.2).

For calculating the propamocarb chronic exposure, the intended uses in this submission and the current EU MRLs as listed in Regulation 2020/856 were used as input values, alongside the proposed MRL on honey (EFSA-Q-2022-00427).

For calculating the propamocarb acute exposure, only the crops under consideration were taken into account.

The input values used for the propamocarb dietary exposure calculations are summarised below.

#### Input values for the consumer risk assessment

Table ‑: Input values for the consumer risk assessment

| **Commodity** | **Chronic risk assessment** | | **Acute risk assessment** | |
| --- | --- | --- | --- | --- |
| **Input value (mg/kg)** | **Input value (mg/kg)** | **Input value (mg/kg)** | **Comment** |
| Risk assessment residue definition: sum of propamocarb and its salts, expressed as propamocarb | | | | |
| Potato | 0.01 | STMR this submission | 0.01 | HR this submission |
| Tomato | 0.40 | STMR this submission | 2.1 | HR this submission |
| Aubergine | 0.40 | STMR this submission | 2.1 | HR this submission |
| Onion | 0.10 | STMR this submission | 0.51 | HR this submission |
| Garlic | 0.10 | STMR this submission | 0.51 | HR this submission |
| Honey | 15 | Proposed MRL (EFSA-Q-2022-00427) | Not relevant | |
| All other plant commodities | Existing EU MRL (Reg. 2020/856) | | Not relevant | |
| Risk assessment residue definition: sum of propamocarb, N-oxide propamocarb, oxazolidin-2-one propamocarb and 2-hydroxypropamocarb expressed as propamocarb | | | | |
| Ruminant and swine tissues and milk | Existing EU MRL (Reg. 2020/856)x CF (EFSA, 2013) | | Not relevant | |
| Risk assessment residue definition: sum of propamocarb and N-desmethyl propamocarb, expressed as propamocarb | | | | |
| Poultry meat, fat, liver and Birds’ eggs | Existing EU MRL (Reg. 2020/856) x CF (EFSA, 2013) | | Not relevant | |

#### Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table ‑: Consumer risk assessment

|  |  |
| --- | --- |
| TMDI (% ADI) according to EFSA PRIMo | Not conducted |
| IEDI (% ADI) according to EFSA PRIMo | 23 % (based on NL toddler) |
| IESTI RAC (% ARfD) according to EFSA PRIMo\* | Child  14.5% Tomatoes (based on BE toddler)  6.3% Aubergines/egg plants (based on UK 4-6 yr)  1.4% Onions (based on BE toddler)  0.2% Garlic (based on IE child)  0.2% Potatoes (based on UK infant)  Adult  6.8% Aubergines/egg plants (based on NL general)  4.0% Tomatoes (based on LT adult)  0.9% Onions (based on UK vegetarian)  0.04% Garlic (based on vegetarian)  0.04% Potatoes (based on UK vegetarian) |
| IESTI Processed (&ARfD) according to EFSA PRIMo rev 3.1 | Child  0.9% Tomatoes / juice (based on DE child)  0.4% Tomatoes / sauce/puree (based on NL child)  0.1% Potatoes / fried (based on NL toddler)  0.1% Potatoes / dried (flakes) (based on DE child)  Adult  0.6% Onions / boiled (based on NL general)  0.4% Tomatoes / sauce/puree (based on NL general)  0.01% Potatoes / chips (based on NL general)  0.01% Potatoes / dried (flakes) (based on NL general) |

The proposed uses of propamocarb in BAS 743 03 F do not represent unacceptable chronic or acute risks for the consumer.

## Combined exposure and risk assessment

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised “scientific methods accepted by the Authority to assess such effects are available.”

Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

The product is a mixture of two active substances, but for only one of them has an acute reference dose been allocated.

**zRMS:** accepted.

PRIMo reports included in Appendix 3 are unreadable. Please replace them with the clear ones.

**Applicant comments**:

The two unreadable PRIMo outputs in Appendix 3 have been replaced as requested by the zRMS

## References

|  |
| --- |
| XXXX, 2020. AIR5 renewal dossier for the active substance BAS 650 F (ametoctradin) submitted by XXXX to Germany. Submitted 20th Oct 2020. Update submitted 24th Sep 2021. |
| EFSA (European Food Safety Authority), 2006. Conclusion on the peer review of the pesticide risk assessment of the active substance propamocarb. EFSA Journal 2006;4(7):78r, 80 pp. https://doi.org/10.2903/j.efsa.2006.78r |
| EFSA (European Food Safety Authority), 2012a. Reasoned opinion on the modification of the existing MRLs for ametoctradin in various commodities. EFSA Journal 2012;10(6):2771. |
| EFSA (European Food Safety Authority), 2012b. Conclusion on the peer review of the pesticide risk assessment of the active substance ametoctradin (BAS 650 F). EFSA Journal 2012;10(11):2921. |
| EFSA (European Food Safety Authority), 2013. Review of the existing maximum residue levels for propamocarb according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(4):3214, 72 pp. https://doi.org/10.2903/j.efsa.2013.3214 |
| EFSA (European Food Safety Authority), 2020. Reasoned Opinion on the review of the existing maximum residue levels for ametoctradin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(1):5990 |
| EFSA (European Food Safety Authority), 2021. Modification of the existing maximum residue level for ametoctradin in honey. EFSA Journal 2021;19(11):6943 |
| Germany, 2019. Evaluation report prepared under Article 12.1 of Regulation (EC) No 396/2005. Review of the existing MRLs for ametoctradin, 26 February 2019 revised on July 2019. |
| Ireland, 2004. Draft assessment report on the active substance propamocarb prepared by the rapporteur Member State Ireland in the framework of Council Directive 91/414/EEC, September 2004. |
| Ireland, 2012. Evaluation report on the review of the existing EU MRLs for propamocarb prepared by the rapporteur Member State Ireland in the framework of Article 12 of Regulation (EC) No 396/2005, April 2012. |
| Portugal, 2017. Propamocarb draft Renewal Assessment Report prepared according to the Commission Implementing Regulation (EU) No 844/2012. RMS Portugal, June 2017. |
| The Netherlands, 2010. Draft Assessment Report (DAR) on the active substance BAS 650 F prepared by the rapporteur Member State The Netherlands in the framework of Directive 91/414/EEC, December 2010. |
| The Netherlands, 2012. Final Addendum to Draft Assessment Report on ametoctradin, compiled by EFSA, September 2012. |

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 6.1/1 | Yozgatli, H. | 2023 | Storage Stability of BAS 650 F, M650F003 and M650F004 in plant matrices under Deep Frozen Conditions  XXXX DocID 2020/2036187  Eurofins Agroscience Services Chem GmbH, Hamburg, Germany Fed.Rep.  yes  Unpublished | No | XXXX |
| KCA 6.3.1/1 | Gabriel, E. | 2021 | Residues of Ametoctradin (BAS 650 F) and Propamocarb (Reg.No. 4628172) in Potato after Treatment with BAS 743 00 F under Field Conditions in Northern Europe, 2020  XXXX DocID 2021/2017109  SGS Institut Fresenius GmbH, Taunusstein, Germany Fed.Rep.  yes  Unpublished | No | XXXX |
| KCA 6.3.1/2 | Plier, S. | 2022 | Study on the residue behaviour of Propamocarb (Reg.No. 4628172) and Ametoctradin (BAS 650 F) in potato after three applications of BAS 743 00 F under field conditions in Northern Europe, 2021  XXXX DocID 2022/2011022  BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep.  yes  Unpublished | No | XXXX |
| KCA 6.3.1/3 | Plier, S. | 2023 | Study on the residue behaviour of Ametoctradin (BAS 650 F) and Propamocarb (Reg.No. 4628172) in potato after applications of either BAS 743 00 F or BAS 743 03 F under field conditions in Northern Europe, 2022  XXXX DocID 2022/2041761  BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Machern OT Gerichshain, Germany Fed.Rep.  yes  Unpublished | No | XXXX |
| KCA 6.3.3/1 | Loriau, P. | 2021 | Study on the residue behaviour of Ametoctradin (BAS 650 F) and Propamocarb (Reg.No. 4628172) in onion after two foliar applications of BAS 743 00 F under open field conditions in Northern Europe, 2020.  2021/2025103  Redebel SA, Saint-Amand, Belgium  yes  Unpublished | No | XXXX |
| KCA 6.3.3/2 | Erdmann, H. | 2022 | Study on the residue behaviour of Propamocarb (Reg.No. 4628172) and Ametoctradin (BAS 650 F) in onions after two applications of BAS 743 00 F under field conditions in Northern Europe, 2021  2022/2003268  Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Germany Fed.Rep.  yes  Unpublished | No | XXXX |
| KCA 6.3.3/3 | Loriau, P. | 2023 | Study on the residue behaviour of Ametoctradin (BAS 650 F) and Propamocarb (Reg.No. 4628172) in onions after application of either BAS 743 00 F or BAS 743 03 F under field conditions in Northern Europe, 2022  2022/2041763  Redebel SA, Saint-Amand, Belgium  yes  Unpublished | No | XXXX |
| KCA 6.3.4/1 | Schneider, E. | 2021 | Study on the residue behaviour of Propamocarb (Reg.No. 4628172) and Ametoctradin (BAS 650 F) in Tomato after treatment with BAS 743 00 F under field conditions in Northern Europe in 2020  2021/2020563  ANADIAG, Haguenau, France  yes  Unpublished | No | XXXX |
| KCA 6.3.4/2 | Schneider, E. | 2023 | Study on the residue behaviour of Propamocarb (Reg.No. 4628172) and Ametoctradin (BAS 650 F) in Tomato after two applications of BAS 743 00 F under field conditions in Northern Europe in 2021  2022/2041755  ANADIAG, Haguenau, France  yes  Unpublished | No | XXXX |
| KCA 6.3.4/3 | Plier, S. | 2022 | Study on the residue behaviour of Propamocarb (Reg.No. 4628172) and Ametoctradin (BAS 650 F) in tomato after two applications of BAS 743 00 F under field conditions in Northern Europe, 2021  2022/2011021  BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Machern OT Gerichshain, Germany Fed.Rep.  yes  Unpublished | No | XXXX |
| KCA 6.3.4/4 | Plier, S. | 2023 | Study on the residue behaviour of Ametoctradin (BAS 650 F) and Propamocarb (Reg.No. 4628172) in tomato after application of either BAS 743 00 F or BAS 743 03 F under field conditions in Northern Europe, 2022  2022/2041764  BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Machern OT Gerichshain, Germany Fed.Rep.  yes  Unpublished | No | XXXX |
| KCA 6.4.2/1 | XXXX | 2011 | Report Amendment 1: Magnitude of residues in milk and tissues of dairy cows following multiple oral administrations of BAS 650 F  XXXX  yes  Unpublished | Yes | XXXX |
| KCA 6.6.2/1 | Erdmann, H. | 2022 | Study on the residue behaviour of BAS 650 F (Ametoctradin) on the rotational crops: strawberries, leek, oilseed rape and tomato after one application of BAS 650 00 F to bare soil 30 and 120 days prior planting/seeding under field conditions in Northern and Southern Europe, 2020-2021  2020/2030949  Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Germany Fed.Rep.  yes  Unpublished | No | XXXX |
| KCA 6.1/2 | Everitt, S. L.;  Charter, G. E. | 1999 | Potatoes tubers: Stability during deep freeze storage up to 26 months propamocarb hydrochloride active substance  Report No C003683  Document No. M-167991-02-1 | No |  |
| KCA 6.5.1 | Justus, K.;  Kuhnke, G. | 2008 | [1-14C] propamocarb hydrochloride: Aqueous hydrolysis under conditions of processing studies  Report No MEF-08/173  Document No. M-300710-01-1 | No |  |
| KCA 6.10.1 | Appeltauer, A. | 2021 | Determination of Residues of Propamocarb in Honey after Four Ap-plications of Fluopicolide + Propamocarb SC 687.5 in Phacelia tanacetifolia at 4 Sites in Northern and Southern Europe in 2020  Report No. S20-01996  ***The study submitted as part of an ongoing MRL application (EFSA-Q-2022-00427). The applicant, XXXX, has a Letter of Access for these data. The study mentioned here.*** | No | - |

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

**Ametoctradin**

| **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 6.1 | Lehmann A.,  Mackenroth  C. | 2008 | Interim report: Investigation of the storage stability of BAS 650 F, M650F03 and M650F04 in plant matrices  BASF SE; Limburgerhof; Germany Fed.Rep.  GLP  Unpublished  XXXX DocID 2008/1022126 | N | XXXX |
| KCA 6.1 | Gordon, B. | 2008 | Storage stability of BAS 650 F in samples from metabolism studies  BASF SE; Limburgerhof; Germany Fed.Rep.  GLP  Unpublished  XXXX DocID 2008/1043913 | N | XXXX |
| KCA 6.1 | Lehmann A.,  Mackenroth  C. | 2009 | Final report: Investigation of the storage stability of BAS 650 F, M650F03 and M650F04 in plant matrices  BASF SE; Limburgerhof; Germany Fed.Rep.  GLP  Unpublished  XXXX DocID 2009/1072418 | N | XXXX |
| KCA 6.1 | Lehmann A.,  Mackenroth  C. | 2009 | Amendment no.1: Investigation of the storage stability of BAS 650 F, M650F03 and M650F04 in plant matrices  BASF SE; Limburgerhof; Germany Fed.Rep.  GLP  Unpublished  XXXX DocID 2009/1031703 | N | XXXX |
| KCA 6.2.1 | Rabe U.,  Labib S. | 2008 | Metabolism of BAS 650 F in lettuce  BASF SE; Limburgerhof; Germany Fed.Rep.  GLP  Unpublished  XXXX DocID 2007/1043389 | N | XXXX |
| KCA 6.2.1 | Rabe U.,  Labib S. | 2009 | Metabolism of BAS 650 F in potatoes  BASF SE; Limburgerhof; Germany Fed.Rep.  GLP  Unpublished  XXXX DocID 2009/7006608 (includes: 2007/1048105 and 2009/1122278) | N | XXXX |
| KCA 6.2.1 | Rabe U.,  Labib S. | 2008 | Metabolism of BAS 650 F in tomatoes  BASF SE; Limburgerhof; Germany Fed.Rep.  GLP  Unpublished  XXXX DocID 2008/1006293 | N | XXXX |
| KCA 6.2.3 | XXXX | 2008 | Metabolism of 14C-BAS 650 F (14C-Reg. No. 49993353) in lactating goat  XXXX  GLP  Unpublished  XXXX DocID 2008/1004313 | Y | XXXX |
| KCA 6.2.3 | XXXXX | 2007 | 14C-BAS 650 F – Absorption, Distribution and Excretion after Repeated Oral Administration in Lactating Goats  Experimental Toxicology and Ecology, 67056 Ludwigshafen/Rhein, Germany  GLP  Unpublished  XXXX DocID 2006/1037726 | Y | XXXX |
| KCA 6.2.2 | XXXX | 2008 | The metabolism of 14C-BAS 650 F in laying hens  XXXX  GLP  Unpublished  XXXX DocID 2008/1009285 | Y | XXXX |
| KCA 6.2.2 | XXXX | 2007 | 14C-BAS 650 F – Absorption, Distribution and Excretion after Repeated Oral Administration in Laying Hens  XXXX  GLP  Unpublished  XXXX DocID 2007/1016301 | Y | XXXX |
| KCA 6.5.1 | Hassink, J. | 2008 | Hydrolysis of BAS 650 F at 90°C, 100°C and 120°C  BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep.  GLP  Unpublished  XXXX DocID 2007/1057705 | N | XXXX |
| KCA 6.5.3 | Braun D. | 2008 | Determination of residues of BAS 650 F in potatoes and their processed products after six applications of  BAS 650 00 F in Germany  BioChem agrar Labor fuer biologische und chemische Analytik GmbH; Gerichshain; Germany Fed.Rep.  GLP  Unpublished  XXXX DocID 2008/1022149 | N | XXXX |
| KCA 6.5.3 | Braun D. | 2008 | Determination of residues of BAS 650 F in tomatoes and their processed products after three applications  of BAS 650 00 F in Germany  BioChem agrar Labor fuer biologische und chemische Analytik GmbH; Gerichshain; Germany Fed.Rep.  GLP  Unpublished  XXXX DocID 2008/1022150 | N | XXXX |
| KCA 6.5.3 | Harant, H. | 2010 | Determination of residues of BAS 650 F and BAS 550 F (Dimethomorph) in onion and its processed products after two applications of BAS 651 00 F in Germany  BioChem agrar Labor fuer biologische und chemische Analytik GmbH; Gerichshain; Germany Fed.Rep.  GLP  Unpublished  XXXX DocID 2010/1093126 | N | XXXX |
| KCA 6.6.1 | Rabe U.,  Labib S. | 2008 | Confined rotational crop study with 14C-BAS 650 F  BASF SE; Limburgerhof; Germany Fed.Rep.  GLP  Unpublished  XXXX DocID 2008/1013139 | N | XXXX |
| KCA 6.6.2 | Klimmek S. | 2008 | Study on the residue behaviour of BAS 650 F on rotational crops: wheat, carrots, cauliflower and  lettuce after application to the bare soil of BAS 650 00 F under field conditions in Germany, Italy, The  Netherlands and Southern France, 2007  Eurofins Analytik GmbH; Hamburg; Germany  Fed.Rep.  Interim report  GLP  Unpublished  XXXX DocID 2008/1004862 | N | XXXX |
| KCA 6.6.2 | Klimmek S. | 2009 | Study on the residue behaviour of BAS 650 F on rotational crops: wheat, carrots, cauliflower and  lettuce after application to the bare soil of BAS 650 00 F under field conditions in Germany, Italy, The  Netherlands and Southern France, 2007  Eurofins Analytik GmbH; Hamburg; Germany  Fed.Rep.  Final report  GLP  Unpublished  XXXX DocID 2008/1110621 | N | XXXX |
| KCA 6.6.2 | Klimmek S. | 2010 | Study on the residue behaviour of BAS 650 F on rotational crop winter wheat after application to the  bare soil of BAS 650 00 F under field conditions in Germany, Italy, The Netherlands and Southern  France, 2008/2009  Eurofins Analytik GmbH; Hamburg; Germany  Fed.Rep.  GLP  Unpublished  XXXX DocID 2010/1022763 | N | XXXX |
| KCA 6.10.1 | Elze, M. | 2021 | Determination of residues of BAS 650 F (Ametoctradin) and BAS 181 S (Phosphonic Acid) in buckwheat and buckwheat honey after three applications of BAS 657 00 F under semi-field conditions in Northern Europe, 2020  BioChem agrar Labor fuer biologische und chemische Analytik GmbH; Gerichshain; Germany  GLP  Unpublished  XXXX DocID 2020/2031155 | N | XXXX |

**Propamocarb**

| **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 6.1 | Moede J. | 1990 | STABILITY OF PROPAMOCARB x HCl IN TOMATOES DURING DEEP FREEZE STORAGE  Schering AG, Berlin, Germany  Document No: A85300  Non-GLP  Unpublished | N | XXXX |
| KCA 6.1 | Sutton, A. L.; Charter, G. E. | 1999 | Tomatoes: Stability during deep freeze storage up to 26 months - Propamocarb hydrochloride active substance Code: AE B066752  AgrEvo UK Crop Protection Ltd., Chesterford Park, United Kingdom  Report No.: C003740,  Edition Number: M-186706-01-1  GLP  Unpublished | N | XXXX |
| KCA 6.1 | Wrede-Rücker  A. | 1990 | STABILITY OF PROPAMOCARB x HCl IN LETTUCE DURING DEEP FREEZE STORAGE  Generated by: Schering AG, Berlin, Germany  Document No: A85303  Non-GLP  Unpublished | N | XXXX |
| KCA 6.2.1 | Rupprecht, J. K. | 1998 | Metabolism of [14C]-Propamocarb Hydrochloride in Spinach (Amended Report Replacing Report AV97E519, Document A89868)  AgrEvo USA Company, USA  Report No.: B002936,  Edition Number: M-165542-02-1  GLP  Unpublished | N | XXXX |
| KCA 6.2.1 | Foertsch, A. | 1991 | The fate of Propamocarb x HCl in potato tubers  Schering AG, Berlin, Germany  Report No.: A85140,  Edition Number: M-157333-01-1  GLP  Unpublished | N | XXXX |
| KCA 6.2.1 | Foertsch, A. | 1993 | The fate of Propamocarb hydrochloride in potato tubers addendum to report UPSR 14/91  Schering AG, Berlin, Germany  Report No.: A85141,  Edition Number: M-157334-01-1  GLP  Unpublished | N | XXXX |
| KCA 6.2.1 | Rupprecht, J. K.; Feyerabend, M. | 1998 | Metabolism of propamocarb HCL in cucumber grown in soil and hydroculture propamocarb hydrochloride  Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany  Report No.: A85149,  Edition Number: M-157342-01-1  GLP  Unpublished | N | XXXX |
| KCA 6.2.2 | XXXX | 2010 | Metabolism of [14c]-propamocarb hydrochloride in the laying hen;  Report No.: MEPRX029  Edition Number: M-366633-01-1  GLP  Unpublished | Y | XXXX |
| KCA 6.2.3 | XXXX | 1998 | PROPAMOCARB: RUMINANT (Cow) - METABOLISM, DISTRIBUTION AND NATURE OF THE RESIDUES IN MILK AND EDIBLE TISSUES (Amended Report Replacing Report AV97E521, Document A91204)  XXXX  Document No: B002935  GLP  Unpublished | Y | XXXX |
| KCA 6.4.1 | XXXX | 2011 | Propamocarb - Magnitude of the residue in laying hens;  Report No.: RAPRX068,  Edition Number: M-409874-01-1  GLP  Unpublished | Y | XXXX |
| KCA 6.4.2 | XXXX | 2015 | Propamocarb: Magnitude of residues in dairy cows  Report No.: RAPRN023,  Edition Number: M-507614-01-1  GLP  Unpublished | Y | XXXX |
| KCA 6.4.2 | XXXX | 2003 | Propamocarb: Magnitude of Residues in Dairy Cow Milk and Tissues;  Report No.: B004276,  Edition Number: M-240879-02-1  GLP  Unpublished | Y | XXXX |
| KCA 6.5.3 | Billian. P. | 2008 | Determination of the residues of AE C638206 and propamocarb hydrochloride in/on tomato fruit and fruit for processing and the processed fractions (raw juice; washings; fruit, washed; juice; peel; preserve; fruit, peeled; peeling water.  Report No.: RA-3639/07,  Edition Number: M-307290-01-1  GLP  Unpublished | N | XXXX |
| KCA 6.5.3 | Schulte, G.;  Bauer, J. | 2011 | Amendment no. 0001 to report no. 09-3235 - Determination of the residues of fenamidone and propamocarb hydrochloride in/on tomato and the processed fractions (whole fruit, washed; washings; strain rest; raw juice; juice; peel; peeling water; fruit peeled; preserve; raw puree and puree) after spraying of AE B066752 03 SC40 A1 in the field in the Netherlands, Italy and Germany  Report No.: 09-3235,  Edition Number: M-406443-02-1  GLP  Unpublished | N | XXXX |
| KCA 6.6.1 | Meyer B.N. | 2000 | UPTAKE OF [14C]-PROPAMOCARB HYDROCHLORIDE RESIDUES IN SOIL BY ROTATIONAL CROPS UNDER CONFINED CONDITIONS (Amended Report Replacing Report AV96E518,  Document A91264)  Aventis CropScience, Environmental Chemistry Department, USA  Document No: B002934  GLP  Unpublished | N | XXXX |
| KCA 6.6.2 | Singer S.S. | 1999 | AT HARVEST PROPAMOCARB HYDROCHLORIDE DERIVED RESIDUES IN ROTATIONAL CROPS FOLLOWING SEQUENTIAL APPLICATIONS OF BANOL® TO BARE SOIL AT THE MAXIMUM PROPOSED RATE AND THE SHORTEST ROTATIONAL INTERVAL, USA, 1997  Schering AG, Ecochemistry Berlin, Germany  Document No: C003451  GLP  Unpublished | N | XXXX |
| KCA 6.6.2 | Klein, E. H-J. | 2004 | Decline of residues in white cabbage, lamb's lettuce and wheat field rotation crop study European Union (Northern zone) 2002 propamocarb hydrochloride, AE B066752 water soluble concentrate (SL) 66.5% (722 g/L), Code: AE B066752 00 SL67 A219;  Report No. C039190 (M-226597-01-1)  GLP  Unpublished | N | XXXX |
| KCA 6.6.2 | Melrose, I. and Portet, M. | 2010 | Determination of the residues of Fosetyl and propamocarb in/on carrot, lettuce and wheat (winter) after spraying of Fosetyl & propamocarb SL 840 in the Field in Netherlands;  Study: 08-2504 (M-349882-02-1)  GLP  Unpublished | N | XXXX |
| KCA 6.6.2 | Melrose, I. and Portet, M. | 2010 | Determination of the residues of Fosetyl and propamocarb in/on carrot, lettuce and barley (winter) after spraying of Fosetyl & propamocarb SL 840 in the Field in France (North);  Study: 08-2505 (M-349137-02-1)  GLP  Unpublished | N | XXXX |
| KCA 6.6.2 | Melrose, I. and Portet, M. | 2010 | Determination of the residues of Fosetyl and propamocarb in/on carrot, lettuce and wheat (winter) after spraying of Fosetyl & propamocarb SL 840 in the Field in Spain;  Study: 08-2506 (M-361470-01-1)  GLP  Unpublished | N | XXXX |
| KCA 6.6.2 | Melrose, I. and Portet, M. | 2010 | Determination of the residues of Fosetyl and propamocarb in/on carrot, lettuce and wheat (winter) after spraying of Fosetyl & propamocarb SL 840 in the Field in Italy;  Study: 08-2507 (M-349147-02-1)  GLP  Unpublished | N | XXXX |

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

2020/2036187

|  |  |
| --- | --- |
| Comments of zRMS: | The study has been accepted. The study is very well documented.  The study report provides the results for the freezer storage stability of BAS 650 F in plant matrices (melon, leek, hops, potato, grape, strawberry, and rapeseed) and of its metabolites M650F003 and M650F004 in rapeseed. The study was performed over a period of two years.  For the analysis, the validated XXXX Method No. L0117/01 (for BAS 650 F), and the validated XXXX Method no. L0078/01 (for BAS 650 F, M650F003, and M650F004) were used. The analytes were finally determined by means of LC-MS/MS. As in case of the metabolites M650F003 and M650F004 a second mass transition was not available (sensitivity of the detection system) an independent LC-MS/MS run was to be applied for confirmation purposes. All LOQs could be set at 0,01.  However, modifications to the original method L0117/01 for hops and rapeseed (to L0078/01) were made to adapt them for the present study needs. 5 fortifications at the LOQ and 5 fortifications at 10xLOQ were made in separate analytical sets for each matrix. For each analyte, 2 mass transitions were evaluated.  The stored samples were analysed in duplicate (except day 0, 5x). For BAS 650 F, M650F003, and M650F004 the mean recovery for all samples extracted at day 0 was in range 70 – 110 %. RSDs were ≤ 20 %. For duplicate analysis of storage samples from the same time point (6 points) the difference between highest and lowest recovery did not exceed 20 %. Such values demonstrate satisfying analytical performance for all analytes and matrices.  **Results**:  **BAS 650 F:** after about 730 days, the mean recovery results in plant matrices (melon (fruit), leek, potato (tuber), grape (fruit) and strawberry (fruit)) were above 70% and therefore show stability under the applied storage conditions. For hops (green cones) were above 70% after 365 days and were below 70 % after 566 - 756 days and therefore, show stability for a maximum storage period of 365 days under the applied storage conditions. For rapeseed (seed) the mean recovery results were above 70% after about 730 days and therefore show stability under the applied storage conditions.  **M650F003**: after about 730 days, the mean recovery results in rapeseed (seed) were above 70% and therefore show stability under the applied storage conditions.  **M650F004**: after about 730 days, the mean recovery results in rapeseed (seed) were above 70% and therefore show stability under the applied storage conditions.  Thus, the results demonstrate that **BAS 650 F** is stable in high-starch, high-water, high-acid, and high-oil matrices after at least 730 days and in hops (representing a difficult matrix) for at least 365 days at ‑18 C. BAS 650 F metabolites **M650F003** and **M650F004** are stable in high-oil matrices at least 730 days at ‑18 C. |

|  |  |
| --- | --- |
| Reference: | CA 6.1/1 |
| Report | Storage Stability of BAS 650 F, M650F003 and M650F004 in plant matrices under Deep Frozen Conditions  Yozgatli, H. & Ereretevwe, K., 2023  XXXX Study ID 897460, Study No. S20-03582 (BAS-2014L)  XXXX DocID 2020/2036187 |
| Guideline(s): | EPA 860.1380, OECD 506 (2007), SANCO 3029/99 Rev.4 |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes | |

**Materials and methods**

The purpose of this study was to determine the freezer storage stability of residues of ametoctradin (BAS 650 F) in high-starch (potato (tuber)), high-water (melon (fruit), leek), high-acid (grape (fruit), strawberry (fruit)), high-oil (rapeseed (seed)) and hops (green cones) (representing a difficult ma-trix) matrices and its metabolites M650F003 and M650F004 in high-oil matrices (rapeseed (seed)) for 24 months. The results reported herein reflect the results of frozen storage up to 728-729 days for melon (fruit), leek, potato (tuber), grape (fruit) and strawberry (fruit) and 756 days for hops (green cones) and 731 days for rapeseed (seed). Plant samples fortified with standard solutions of ametoctradin (melon (fruit), leek, hops (green cones), potato (tuber), grape (fruit), rapeseed (seed) and strawberry (fruit)), M650F003 and M650F004 (rapeseed (seed) only) at 0.1 mg/kg were stored frozen (approximately -18 °C) for durations of 0, 60, 90, 180, 365, 545 and 730 days (approximately 0, 2, 3, 6, 12, 18 and 24 months).

For the day 0 time point, for melon (fruit), leek, hops (green cones), potato (tuber), grape (fruit) and strawberry (fruit), 8 samples were prepared. Five samples were fortified with 0.10 mg/kg (10×LOQ) individually for BAS 650 F, one sample was used for control and for procedural recoveries two samples were freshly fortified with 0.10 mg/kg (10×LOQ) using a standard solution containing BAS 650 F.

For all other sampling dates, for melon (fruit), leek, hops (green cones), potato (tuber), grape (fruit) and strawberry (fruit), 5 samples were prepared. Two samples were fortified with 0.10 mg/kg (10×LOQ) individually for BAS 650 F, one sample was used for control and for procedural recov-eries two samples were freshly fortified with 0.10 mg/kg (10×LOQ) using a standard solution con-taining BAS 650 F.

For the day 0 time point, for rapeseed (seeds), 18 samples were prepared. Each five samples were fortified with 0.10 mg/kg (10×LOQ) individually for BAS 650 F, M650F003 and M650F004, one sample was used for control and for procedural recoveries two samples were freshly fortified with 0.10 mg/kg (10×LOQ) using a standard solution containing all analytes.

For all other sampling dates, for rapeseed (seeds), 9 samples were prepared. Each two samples were fortified with 0.10 mg/kg (10×LOQ) individually for BAS 650 F, M650F003 and M650F004, one sample was used for control and for procedural recoveries two samples were freshly fortified with 0.10 mg/kg (10×LOQ) using a standard solution containing all analytes.

All fortified samples and controls were immediately stored in a freezer (approximately 18 °C) until analysis.

Analyses were performed after 0 days (“time-zero”), 60 - 67, 90 - 104, 179 - 209, 364 – 365, 544 – 545 and 728 – 756 days of frozen storage (approximately 0, 2, 3, 6, 12, 18 and 24 months). On the day of analysis, for each time interval, a minimum of two replicates of each treated plant matrix sample were analyzed along with one untreated control sample and two procedural fortification samples. Thus, each sample set consisted of one control, two untreated control samples freshly fortified with BAS 650 F (and M650F003 and M650F004 for rapeseed (seed)), and two “stored-fortified” samples fortified with BAS 650 F (and M650F003 and M650F004 for rapeseed (seed)) (except for 0-day in which case five “freshly-fortified” were analyzed).

The plant samples were analyzed for the analytes of interest using XXXX Analytical Method No. L0078/01.

Specimens of melon (fruit), leek, hops (green cones), potato (tuber), grape (fruit) and strawberry (fruit) were analyzed with XXXX method no. L0117/01 which allows the quantitation of BAS 650 F residues to a limit of quantitation 0.010 mg/kg in all matrices. Specimens were extracted with meth-anol/water (50:50, v/v). An aliquot of the extract was centrifuged and partitioned against dichloro-methane.

Specimens of rapeseed (seed) were analyzed with XXXX method no. L0078/01 which allows the quantitation of BAS 650 F and its metabolites M650F003 and M650F004 residues to a limit of quantitation 0.010 mg/kg. Specimens were extracted twice with methanol/water (50:50, v/v). An aliquot of the combined extracts was centrifuged.

Residues of BAS 650 F and its metabolites M650F003 and M650F004 are determined by LC-MS/MS monitoring in the positive mode ion transition m/z 276→176. The results are calculated by direct comparison of the sample peak responses to those of external standards.

The method was the subject of a separate, successful method validation study for BAS 650 F and its metabolites M650F003 and M650F004 in the investigated matrices: The validated limit of quantitation (LOQ) for BAS 650 F and its metabolites M650F003 and M650F004 was 0.01 mg/kg in all matrices, and the method limit of detection (LOD) was 0.003 mg/kg. The lowest level of method verification in the subject study - also the spiking level used for stored-fortified samples - was 10X the validated LOQ for each analyte/matrix combination.

**Results and discussions**

A summary of the freezer stability of each analyte fortified in the various plant matrices, together with the method (procedural) recovery data for this study, are summarized below. Acceptable concurrent recovery data (70 – 110 %) were obtained for all tested matrices during the storage stability study, sufficiently demonstrating the acceptability of the method (Table A 1 and Table A 2). Recovery rates of fortified samples stored up to 756 days are shown in

Table A **3** and Table A 4.

The data indicate that after about 728-756 days, the mean recovery results of the nominal of BAS 650 F in plant matrices investigated (melon (fruit), leek, potato (tuber), grape (fruit) and strawberry (fruit)) were above 70% and therefore show stability under the applied storage conditions.

For hops (green cones) the mean recovery results of the nominal of BAS 650 F were above 70% after 365 days and therefore show stability under the applied storage conditions

For rapeseed (seed) the mean recovery results of the nominal of BAS 650 F, M650F003 and M650F004 were above 70% after 731 days and therefore show stability under the applied storage conditions.

**Table A 1: Summary of concurrent recoveries of ametoctradin from plant matrices**

| **Matrix** | **Spike level (mg/kg)** | **Storage**  **Interval (days)** | **Sample size (n)** | **Individual procedural recoveries (%)** | **Mean ± RSD (%)** |
| --- | --- | --- | --- | --- | --- |
| BAS 650 F | | | | | |
| Melon (fruit) | 0.1 | 0 | 2 | 102, 95.8 | 98.9±N/A |
|  |  | 60 | 2 | 97.3, 101 | 99.2±N/A |
|  |  | 104 | 2 | 96.0, 93.6 | 94.8±N/A |
|  |  | 180 | 2 | 101, 100 | 101±N/A |
|  |  | 365 | 2 | 107, 103 | 105±N/A |
|  |  | 545 | 2 | 105, 103 | 104±N/A |
|  |  | 729 | 2 | 99.3, 94.3 | 96.8±N/A |
| Leek | 0.1 | 0 | 2 | 90.0, 91.7 | 90.9±N/A |
|  |  | 60 | 2 | 105, 101 | 103±N/A |
|  |  | 104 | 2 | 109, 97.4 | 103±N/A |
|  |  | 180 | 2 | 102, 99.5 | 101±N/A |
|  |  | 365 | 2 | 100, 91.8 | 95.9±N/A |
|  |  | 545 | 2 | 99.6, 99.3 | 99.5±N/A |
|  |  | 729 | 2 | 87.0, 91.8 | 89.4±N/A |
| Potato (tuber) | 0.1 | 0 | 2 | 86.2, 95.6 | 90.9±N/A |
|  |  | 60 | 2 | 98.1, 98.3 | 98.2±N/A |
|  |  | 104 | 2 | 99.2, 98.4 | 98.8±N/A |
|  |  | 180 | 2 | 103, 98.1 | 100±N/A |
|  |  | 365 | 2 | 99.2, 97.5 | 98.4±N/A |
|  |  | 545 | 2 | 103, 101 | 102±N/A |
|  |  | 729 | 2 | 102, 101 | 101±N/A |
| Grape (fruit) | 0.1 | 0 | 2 | 98.3, 98.3 | 98.3±N/A |
|  |  | 60 | 2 | 97.7, 101 | 99.4±N/A |
|  |  | 104 | 2 | 105, 98.5 | 102±N/A |
|  |  | 180 | 2 | 103, 100 | 102±N/A |
|  |  | 365 | 2 | 96,1, 93.4 | 94.8±N/A |
|  |  | 545 | 2 | 101, 96.7 | 98.9±N/A |
|  |  | 728 | 2 | 91.8, 88.1 | 90.0±N/A |
| Strawberry (fruit) | 0.1 | 0 | 2 | 91.3, 95.0 | 93.2±N/A |
|  |  | 67 | 2 | 109, 107 | 108±N/A |
|  |  | 103 | 2 | 92.5, 91.7 | 92.1±N/A |
|  |  | 179 | 2 | 105, 103 | 104±N/A |
|  |  | 364 | 2 | 103, 98.5 | 101±N/A |
|  |  | 544 | 2 | 96.8, 101 | 98.9±N/A |
|  |  | 729 | 2 | 95.2, 90.5 | 92.9±N/A |
| Hops (green cones) | 0.1 | 0 | 2 | 79.8, 69.0 | 74.4±N/A |
|  |  | 60 | 2 | 92.0, 85.7 | 88.9±N/A |
|  |  | 90 | 2 | 92.3, 92.1 | 92.2±N/A |
|  |  | 209 | 2 | 79.6, 103 | 91.3±N/A |
|  |  | 365 | 2 | 94.8, 89.5 | 92.2±N/A |
|  |  | 566-572 | 2 | 80.5\*, 79.8\*  87.5\*\*, 88.3\*\* | 80.2±N/A\*  87.9±N/A\*\* |
|  |  | 749-756 | 2 | 78.9\*, 95.5\*  88.6\*\*, 76.7\*\* | 84.7±N/A\*  82.7±N/A\*\* |

RSD Relative Standard Deviation

n Number of results included in calculation

N/A Not applicable

\* Initial analysis

\*\* Re-analysis

**Table A 2: Summary of concurrent recoveries of ametoctradin and its metabolites from rapeseed (seed)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Matrix** | **Spike level (mg/kg)** | **Storage**  **Interval (days)** | **Sample size (n)** | **Individual procedural recoveries (%)** | **Mean ± RSD (%)** |
| BAS 650 F | | | | | |
| Rapeseed (seed) | 0.1 | 0 | 2 | 75.7, 74.3 | 75.0±N/A |
| 60 | 2 | 99.0, 94.7 | 96.9±N/A |
| 88 | 2 | 78.0, 74.8 | 76.4±N/A |
| 180 | 2 | 76.0, 71.7 | 73.9±N/A |
| 367 | 2 | 103, 106 | 105±N/A |
| 545 | 2 | 85.4, 85.6 | 85.5±N/A |
| 731 | 2 | 92.2. 93.1 | 87.7±N/A |
| M650F003 | | | | | |
| Rapeseed (seed) | 0.1 | 0 | 2 | 94.1, 93.1 | 93.6±N/A |
| 60 | 2 | 99.6, 99.9 | 99.8±N/A |
| 88 | 2 | 92.1, 88.3 | 90.2±N/A |
| 180 | 2 | 85.4, 84.2 | 84.8±N/A |
| 367 | 2 | 106, 112 | 109±N/A |
| 545 | 2 | 89.7, 91.3 | 90.5±N/A |
| 731 | 2 | 110, 110 | 110±N/A |
| M650F004 | | | | | |
| Rapeseed (seed) | 0.1 | 0 | 2 | 95.0, 94.5 | 94.8±N/A |
| 60 | 2 | 102, 102 | 102±N/A |
| 88 | 2 | 95.5, 99.0 | 97.3±N/A |
| 180 | 2 | 89.4, 94.9 | 92.2±N/A |
| 367 | 2 | 102, 109 | 106±N/A |
| 545 | 2 | 89.1, 89.9 | 89.5±N/A |
| 731 | 2 | 86.1, 87.6 | 86.9±N/A |

**Table A 3: Stability of BAS 650 F residues in plant matrices following storage at ‑18 °C**

| **Matrix** | **Spike level (mg/kg)** | **Storage interval (days)** | **Storage interval (months)** | **Individual  recovered residues (mg/kg)** | **Uncorrected individual recoveries**  **[mean recovery]**  **(%)** | **Relative recovery (%)1** |
| --- | --- | --- | --- | --- | --- | --- |
| BAS 650 F | | | | | | |
| Melon (fruit) | 0.1 | 0 | 0 | 0.0939, 0.0915, 0.0921, 0.0930, 0.0958 | 93.9, 91.5, 92.1, 93.0, 95.8 (93.3) | 94.3 |
|  |  | 60 | 2 | 0.0909, 0.0891 | 90.9, 89.1 (90.0) | 90.8 |
|  |  | 104 | 3 | 0.0895, 0.0927 | 89.5, 92.7 (91.1) | 96.1 |
|  |  | 180 | 6 | 0.0914, 0.0891 | 91.4, 89.1 (90.3) | 89.8 |
|  |  | 365 | 12 | 0.0992, 0.0992 | 99.2, 99.2 (99.2) | 94.5 |
|  |  | 545 | 18 | 0.0863, 0.0910 | 86.3, 91.0 (88.7) | 85.2 |
|  |  | 729 | 24 | 0.0892, 0.0960 | 89.2, 96.0 (92.6) | 95.7 |
| Leek | 0.1 | 0 | 0 | 0.0850, 0.0926, 0.0891, 0.0917, 0.0900 | 85.0, 92.6, 89.1, 91.7, 90.0 (89.7) | 98.7 |
| 60 | 2 | 0.0955, 0.0902 | 95.5, 90.2 (92.9) | 90.1 |
| 104 | 3 | 0.0917, 0.0933 | 91.7, 93.3 (92.5) | 89.6 |
| 180 | 6 | 0.0882, 0.0877 | 88.2, 87.7 (88.0) | 87.3 |
| 365 | 12 | 0.0893, 0.0864 | 89.3, 86.4 (90.6) | 94.4 |
| 545 | 18 | 0.0851, 0.0860 | 85.1, 86.0 (85.6) | 86.0 |
| 729 | 24 | 0.0857, 0.0775 | 85.7, 77.5 (81.6) | 91.3 |
| Potato (tuber) | 0.1 | 0 | 0 | 0.0948, 0.102, 0.100, 0.0996, 0.0917 | 94.8, 102, 100, 99.6, 91.7 (97.6) | 107 |
| 60 | 2 | 0.0913, 0.0894 | 91.3, 89.4 (90.4) | 92.0 |
| 104 | 3 | 0.0888, 0.0925 | 88.8, 92.5 (90.7) | 91.8 |
| 180 | 6 | 0.0822, 0.0893 | 82.2, 89.3 (85.8) | 85.4 |
| 365 | 12 | 0.102, 0.107 | 102, 107 (104) | 106 |
| 545 | 18 | 0.0875, 0.0868 | 87.5, 86.8 (87.2) | 85.4 |
| 729 | 24 | 0.101, 0.0950 | 101, 95.0 (98.0) | 96.7 |
| Grape (fruit) | 0.1 | 0 | 0 | 0.0927, 0.101, 0.0935, 0.0920, 0.0975 | 92.7, 101, 93.5, 92.0, 97.5 (95.3) | 97.0 |
| 60 | 2 | 0.0936, 0.0889 | 93.6, 88.9 (91.3) | 91.8 |
| 104 | 3 | 0.0993, 0.0985 | 99.3, 98.5 (98.9) | 97.2 |
| 180 | 6 | 0.0851, 0.0905 | 85.1, 90.5 (87.8) | 86.5 |
| 365 | 12 | 0.114, 0.0958 | 114, 95.8 (105) | 111 |
| 545 | 18 | 0.0849, 0.0902 | 84.9, 90.2 (87.6) | 88.6 |
| 728 | 24 | 0.0896, 0.0874 | 89.6, 87.4 (88.5) | 98.4 |
| Strawberry (fruit) | 0.1 | 0 | 0 | 0.0935, 0.0965, 0.0890, 0.0890, 0.0905 | 93.5, 96.5, 89.0, 89.0, 90.5 (91.7) | 98.4 |
| 67 | 2 | 0.0968, 0.0941 | 96.8, 94.1 (95.5) | 88.4 |
| 103 | 3 | 0.0991, 0.0966 | 99.1, 96.6 (97.9) | 106 |
| 179 | 6 | 0.0983, 0.0924 | 98.3, 92.4 (95.4) | 91.7 |
| 364 | 12 | 0.105, 0.102 | 105, 102 (104) | 103 |
| 544 | 18 | 0.0931, 0.0893 | 93.1, 89.3 (91.2) | 92.2 |
| 729 | 24 | 0.0929, 0.0952 | 92.9, 95.2 (94.1) | 101 |
| Hops (green cones) | 0.1 | 0 | 0 | 0.0854, 0.0843, 0.0697, 0.0785, 0.0897 | 85.4, 84.3, 69.7, 78.5, 89.7 (81.5) | 110 |
| 60 | 2 | 0.0795, 0.0803 | 79.5, 80.3 (79.9) | 89.9 |
| 90 | 3 | 0.0743, 0.0745 | 74.3, 74.5 (74.4) | 80.7 |
| 209 | 6 | 0.0730, 0.0741 | 73.0, 74.1 (73.6) | 80.6 |
| 365 | 12 | 0.0768, 0.0763 | 76.8, 76.3 (76.6) | 83.1 |
| 566-572 | 18 | 0.0633\*, 0.0700\*  0.0746\*\*, 0.0606\*\* | 63.3\*, 70.0\* (66.7\*)  74.6\*\*, 60.6\*\* (67.6\*\*) | 80.2\*  87.9\*\* |
| 749-756 | 24 | 0.0716\*, 0.0607\*  0.0485\*\*, 0.0626\*\* | 71.6\*, 60.7\* (66.2\*)  48.5\*\*, 62.6\*\* (55.6\*\*) | 84.7\*  82.7\*\* |

1. Corrected for concurrent-recoveries.

\* Initial analysis

\*\* Re-analysis

**Table A 4: Stability of BAS 650 F, M650F003 and M650F004 residues in rapeseed(seed) following storage at ‑18 °C**

| **Matrix** | **Spike level (mg/kg)** | **Storage interval (days)** | **Storage interval (months)** | **Individual  recovered residues (mg/kg)** | **Uncorrected individual recoveries**  **[mean recovery]**  **(%)** | **Relative recovery (%)1** |
| --- | --- | --- | --- | --- | --- | --- |
| BAS 650 F | | | | | | |
| Rapeseed (seed) | 0.1 | 0 | 0 | 0.0776, 0.0804, 0.0790, 0.0799, 0.0776 | 77.6, 80.4, 79.0, 79.9, 77.6 (78.9) | 105 |
| 60 | 2 | 0.0929, 0.0892 | 92.9, 89.2 (91.1) | 94.0 |
| 88 | 3 | 0.0799, 0.0842 | 79.9, 84.2 (82.1) | 107 |
| 180 | 6 | 0.0734, 0.0764 | 73.4, 76.4 (74.9) | 101 |
| 367 | 12 | 0.101, 0.100 | 101, 100 (101) | 96.2 |
| 545 | 18 | 0.0780, 0.0804 | 78.0, 80.4 (79.2) | 92.6 |
| 731 | 24 | 0.0868, 0.0829 | 86.8, 82.9 (84.9) | 96.8 |
| M650F003 | | | | | | |
| Rapeseed (seed) | 0.1 | 0 | 0 | 0.100, 0.0995, 0.100, 0.0963, 0.102 | 100, 99.5, 100, 96.3, 102 (99.6) | 106 |
|  | 60 | 2 | 0.103, 0.105 | 103, 105 (104) | 104 |
| 88 | 3 | 0.0960, 0.0990 | 96.0, 99.0 (97.5) | 108 |
| 180 | 6 | 0.0871, 0.0877 | 87.1, 87.7 (87.4) | 103 |
| 367 | 12 | 0.111, 0.107 | 111, 107 (109) | 100 |
| 545 | 18 | 0.0900, 0.0876 | 90.0, 87.6 (88.8) | 98.1 |
| 731 | 24 | 0.0993, 0.100 | 99.3, 100 (99.7) | 90.6 |
| M650F004 | | | | | | |
| Rapeseed (seed) | 0.1 | 0 | 0 | 0.0950, 0.0979, 0.100, 0.0970, 0.0970 | 95.0, 97.9, 100, 97.0, 97.0 (97.5) | 103 |
| 60 | 2 | 0.102, 0.100 | 102, 100 (101) | 99.0 |
| 88 | 3 | 0.0918, 0.0902 | 91.8, 90.2 (91.0) | 93.6 |
| 180 | 6 | 0.0921, 0.0888 | 92.1, 88.8 (90.5) | 98.2 |
| 367 | 12 | 0.103, 0.0969 | 103, 96.9 (100) | 94.7 |
| 545 | 18 | 0.0842, 0.0850 | 84.2, 85.0 (84.6) | 94.5 |
| 731 | 24 | 0.0836, 0.0936 | 83.6, 93.6 (88.6) | 102 |

**Conclusion**

The results obtained in this study demonstrate that BAS 650 F is stable in high-starch (potato (tuber)), high-water (melon (fruit), leek), high-acid (grape (fruit), strawberry (fruit)) and high-oil matrices (rapeseed (seed)) matrices after a storage period of at least 24 months and in hops (green cones) (representing a difficult matrix) for at least 12 months, following storage at ‑18 C. BAS 650 F metabolites M650F003 and M650F004 are stable in high-oil matrices (rapeseed (seed)) for a storage period of at least 24 months at ‑18 C.

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

No new data submitted in the framework of this application.

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

No new data submitted in the framework of this application.

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

No new data submitted in the framework of this application.

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

No new data submitted in the framework of this application.

* + - 1. Nature of residues in livestock

No new data submitted in the framework of this application.

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

**Table A 5: Comparison of intended and critical EU GAPs**

| **Type of GAP** | Number of applica­tions | **Application rate per treatment**  (g a.s./ha) | Interval between application | Growth stage at last application | PHI (days) |
| --- | --- | --- | --- | --- | --- |
| cGAP NEU (DAR, The Netherlands, 2012) | 4 | 240 | 7-10 days | 19-89 | 7 |
| cGAP NEU (Art. 12, EFSA, 2020) | 5 | 240 | 5 days | - | 7 |
| Intended cGAP (1)\* | 3 | 240 | 5 days | 21-89 | 7 |
| Intended GAP (2)\*† | 2 | 240 | 5 days | 21-89 | 7 |

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

† This GAP is less critical and within the risk envvelope of intended use 1 (cGAP)

* + - * 1. 2021/2017109

|  |  |
| --- | --- |
| Comments of zRMS: | The study has been accepted.  In 2020 four field trials in potato were conducted in NEU to determine residues of ametoctradin (BAS 650 F) and its metabolites M650F003 and M650F004 as well as propamocarb (BAS 9068 F) in potatoes after treatment with BAS 743 00 F SC formulation under field conditions.  The application rates, frequency and spray interval were covered the critical GAP. Plots were treated 3 times with 2.0 L/ha of BAS 743 00 F (0.240 kg/ha of ametoctradin and 0.756 kg/ha of propamocarb) with a water volume of 200 L/ha for each application. The first application took place at BBCH 44 – 47, the second one at BBCH 46 – 48 and the third application at BBCH 47 – 48.  The used and adapted for the study XXXX analytical methods were Method L0450/01 for propamocarb and Method L0078/01 for ametoctradin and its metabolites M650F003 and M650F004. The final determinations of analytes were performed by LC-MS/MS. The validation of both methods was performed on plant matrices in a separate study.  The LOQ of 0.01 mg/kg was set for each analyte. However, for ametoctradinmetabolites M650F003 and M650F004, the LOQ expressed as the parent equivalent [mg/kg] was at 0,012 (CF: 1,2450) and at 0.013 (CF: 1,3292), respectively. Overall and average recoveries were all in the range of 70 – 110 % and RSDs were < 20 %.  No residues of Ametoctradin and its metabolites above the LOQs were present in any of the control samples, but for Propamocarb, residues ≥0.010 mg/kg were present in shoot samples L2002980001, L2003000001 and L2005410001. For L2005410001 a spray drift from a neighbour farmer who applied twice propamocarb hydrochloride was found as a reason of the contamination. For trial L200298 and L200230 no reason could be found to explain the contaminated control samples. However, potato shoot specimens were only relevant to demonstrate that the applications in the field were done successfully. |

|  |  |
| --- | --- |
| Reference: | CA 6.3.1/1 |
| Report | Residues of Ametoctradin (BAS 650 F) and Propamocarb (Reg.No. 4628172) in Potato after Treatment with BAS 743 00 F under Field Conditions in Northern Europe, 2020  Gabriel, E., 2021  XXXX Study ID 890061, Study No. IF20-05289908  XXXX DocID 2021/2017109 |
| Guideline(s): | * European Community Guideline 7029/VI/95 - rev.5, 22/07/97: General recommendations for the design, preparation and realization of residue trials * European Community Guideline 7525/VI/95 - rev.10.3, 13/06/17: Comparability, extrapolation, group tolerances and data requirements for setting MRLs. * OECD Guideline for the Testing of Chemicals No. 509. Crop Field Trial,07 September 2009 |
| Deviations: | Yes, none that affect the validity of the study |
| GLP: | Yes |
| Acceptability: | Yes | |

**Materials and methods**

In 2020, four independent field trials were conducted in NEU (Germany, northern France, the Netherlands and Poland) to support the use of BAS 650 F (ametoctradin) and BAS 9068 F (propamocarb) in potatoes. BAS 743 00 F (120 g/L of ametoctradin and 378 g/L of propamocarb) a suspension concentrate (SC) formulation, was foliar applied three times on potatoes at a nominal rate of 2.0 L/ha, corresponding to 240 g/ha of ametoctradin and 756 g/ha of propamocarb. The first application was made 16-18 days before harvest (DBH) (BBCH 44 – 47), the second application at 10-13 DBH (BBCH 46 – 48) and the final application 6-7 DBH (BBCH 47 – 48). Potato shoots were collected 0 days after last application (DALA) and potato tubers were collected 3, 6 – 7 and 13 – 14 DALA.

All samples were maintained frozen (≤ -18°C) at the testing facility, during shipping to the laboratory, and were stored frozen prior to analysis. The maximum storage interval for samples between harvest and analysis was 262 days (*ca* 9 months). Residues of ametoctradin, M650F003 and M650F004 have been shown to be stable in high water content and high starch content crops for at least 24 months.

Residues of ametoctradin, M650F003 and M650F004 were determined using XXXX method no. L0078/01, a LC-MS/MS method. Acceptable concurrent recoveries were reported for potato shoots and potato tubers, thus demonstrating the suitability of the methods. The limit of quantification (LOQ) was 0.01 mg/kg per analyte. For metabolites M650F03 and M650F04 this is equivalent to 0.012 mg/kg and 0.013 mg/kg, respectively, expressed as parent (ametoctradin). Conversion factors of 1.2450 and 1.3292 are applied to M650F003 and M650F004 to convert residues to ametoctradin.

**Table A 6: Summary of recoveries of ametoctradin, M650F003 and M650F004 in potato**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Matrix** | **Fortification Level  [mg/kg]** | **Summary Recoveries** | | | |
| **Method No. L0078/01** | | **Mean  [%]** | **SD1)  [±]** | **RSD2) [%]** | **n3)** |
| Ametoctradin | | | | | |
| Potato Shoot | 0.010, 0.10 and 100 | 91.8 | 5.6 | 6.1 | 5 |
| Potato Tuber | 0.010, 0.10 and 100 | 86.3 | 11 | 12 | 6 |
| Overall | | 88.8 | 8.9 | 10 | 11 |
| M650F003 | | | | | |
| Potato Shoot | 0.010 and 0.10 | 95.6 | 4.0 | 4.2 | 3 |
| Potato Tuber | 0.010 and 0.10 | 89.3 | 2.3 | 2.6 | 3 |
| Overall | | 92.5 | 4.5 | 4.9 | 6 |
| M650F004 | | | | | |
| Potato Shoot | 0.010 and 0.10 | 89.9 | 1.7 | 1.9 | 3 |
| Potato Tuber | 0.010 and 0.10 | 83.9 | 2.5 | 3.0 | 3 |
| Overall | | 86.9 | 3.8 | 4.3 | 6 |

1) SD: Standard deviation

2) RSD: Relative standard deviation

3) n: Number of results included in calculations

**Table A 7: Summary of the study 2021/2017109 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) expressed as parent\*** | | | **PHI (days)** | **Details on trial** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **g a.s./ ha** | **Water (l/ha)** | **g a.s./hl** | **BAS 650 F** | **M650F003** | **M650F004** |
|  | (a) | (b) |  |  |  | (c) |  |  |  |  |  | (d) | (e) |
| L200298 / 79206 Breisach, Germany / NEU / 2020 | Potato / Colombia | 1. 18.03.2020  2. 18.05 – 03.06.2020  3. 23.07.2020 | 240  240  245 | 200  200  204 | 120  120  120 | 30.06.2020  06.07.2020  10.07.2020 | 48 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 31  <0.01  <0.01  <0.01 | <0.012  <0.012  <0.012  <0.012 | 0.013  <0.013  <0.013  <0.013 | 0  3  6  12 | XXXX method No. L0078/01 for BAS 650 F, M650F003, M650F004  LOQ = 0.01 mg/kg per analyte  Maximum storage interval (days): 262 |
| L200299 / 51110 Auménancourt. France (North) / NEU / 2020 | Potato / Rose de France | 1. 08.04.2020  2. 08.06 – 22.06.2020  3. 17.07 – 23.07.2020 | 232  232  244 | 193  193  203 | 120  120  120 | 30.06.2020  06.07.2020  10.07.2020 | 48 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 11  <0.01  <0.01  <0.01 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  3  7  13 |
| L200300 / 9695 Bellingwolde, Netherlands / NEU / 2020 | Potato / Cilena | 1. 07.04.2020  2. 15.06 – 16.07.2020  3. 24.08 – 31.08.2020 | 240  243  243 | 200  202  202 | 120  120  120 | 06.08.2020  11.08.2020  17.08.2020 | 47 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 4.5  <0.01  <0.01  <0.01 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  3  7  14 |
| L200541 / 89-430 Zamarte, Poland / NEU / 2020 | Potato / Vineta | 1. 05.05.2020  2. 30.06 – 15.07.2020  3. 04.09.2020 | 230  249  231 | 191  207  193 | 120  120  120 | 12.08.2020  17.08.2020  21.08.2020 | 48 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 28  <0.01  <0.01  <0.01 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  3  7  14 |

(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

\* Conversion factor for calculation of M650F003 to parent BAS 650 F is 1.2450. Conversion factor for calculation of M650F004 to parent BAS 650 F is 1.3292

* + - * 1. 2022/2011022

|  |  |
| --- | --- |
| Comments of zRMS: | The study has been accepted.  4 field trials were conducted in NEU to determine the magnitude of residues of Ametoctradin and its metabolites M650F003 and M650F004 as well as of Propamocarb in potatoes after thrice treatment with BAS 743 00 F (378.0 g/L Propamocarb and 120.0 g/L Ametoctradin), a suspension concentrate (SC), at 17±1 days before harvest, 12±1 days before harvest and 7±1 days before harvest on plot 2 at a target rate of 2.0 L/ha (0,24 kg/ha Ametoctradin and 0,756 kg/ha Propamocarb). The water volume used was 200 L/ha (within ≤ 10 % of variation).  The same methods as in 2021/2017109 study were employed. The final determinations of analytes were performed by LC-MS/MS. The validation of both methods was performed on plant matrices in a separate study.  For recovery, the mean value of each measured concentration was within 70 % and 110 %. The precision of each concentration level was ≤ 20 % of the relative standard deviation. The LOQ of 0.01 mg/kg was set for each analyte. However, for ametoctradinmetabolites M650F003 and M650F004, the LOQ expressed as the parent equivalent [mg/kg] was at 0,012 (CF: 1,2450) and at 0.013 (CF: 1,3292), respectively. All validation parameters required were in the acceptable range.  The similar contamination of the samples as previously (2021/2017109) took place during the study - in the shoot samples L2100330001 8.7 mg/kg and L2100340001 1.2 mg/kg of Propamocarb were found. |

|  |  |
| --- | --- |
| Reference: | CA 6.3.1/2 |
| Report | Study on the residue behaviour of Propamocarb (Reg.No. 4628172) and Ametoctradin (BAS 650 F) in potato after three applications of BAS 743 00 F under field conditions in Northern Europe, 2021  Plier, S. & Eysoldt M-B., 2022  XXXX Study ID 890062, Study No. 21 47 GRU 0003  XXXX DocID 2022/2011022 |
| Guideline(s): | * European Commission Guideline SANTE/2019/12752 : Technical Guidelines on Data Requirements for Setting Maximum Residue Levels, Comparability of Residue Trials and Extrapolation of Residue Data on Products from Plant and Animal Origin (former 7525/VI/95 rev. 10.3) * OECD Guidelines for the Testing of Chemicals, Number 509 (2009): Crop Field Trial. * Working document of the Commission of the European Communities, Directorate General for Agriculture, VI B II-1, Appendix B, 7029/VI/95 rev. 5 of 22.07.1997 |
| Deviations: | Yes, none that affect the validity of the study |
| GLP: | Yes |
| Acceptability: | Yes | |

**Materials and methods**

In 2021, four independent field trials were conducted in NEU (Germany, northern France, Belgium and Poland) to support the use of BAS 650 F (ametoctradin) and BAS 9068 F (propamocarb) in potatoes. BAS 743 00 F (120 g/L of ametoctradin and 378 g/L of propamocarb) a suspension concentrate (SC) formulation, was foliar applied three times on potatoes at a nominal rate of 2.0 L/ha, corresponding to 240 g/ha of ametoctradin and 756 g/ha of propamocarb. The first application was made 16-18 days before harvest (DBH) (BBCH 45 – 47), the second application at 11-13 DBH (BBCH 46 – 47) and the final application 7-8 DBH (BBCH 47 – 49). Potato shoots were collected 0 days after last application (DALA) and potato tubers were collected 3, 7 – 8 and 14 – 15 DALA.

All samples were maintained frozen (≤ -18°C) at the testing facility, during shipping to the laboratory, and were stored frozen prior to analysis. The maximum storage interval for samples between harvest and analysis was 147 days (*ca* 5 months). Residues of ametoctradin, M650F003 and M650F004 have been shown to be stable in high water content and high starch content crops for at least 24 months.

Residues of ametoctradin, M650F003 and M650F004 were determined using XXXX method no. L0078/01, a LC-MS/MS method. Acceptable concurrent recoveries were reported for potato shoots and potato tubers, thus demonstrating the suitability of the methods. The limit of quantification (LOQ) was 0.01 mg/kg per analyte. For metabolites M650F003 and M650F004 this is equivalent to 0.012 mg/kg and 0.013 mg/kg, respectively, expressed as parent (ametoctradin). Conversion factors of 1.245 and 1.3292 are applied to M650F003 and M650F004 to convert residues to ametoctradin.

**Table A 8: Summary of recoveries of ametoctradin, M650F003 and M650F004 in potato**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Matrix** | **Fortification Level  [mg/kg]** | **Summary Recoveries** | | | |
| **Method No. L0078/01** | | **Mean  [%]** | **SD1)  [±]** | **RSD2) [%]** | **n3)** |
| Ametoctradin | | | | | |
| Potato Shoot | 0.010, 0.10 and 50 | 92.4 | 4.7 | 5.1 | 7 |
| Potato Tuber | 0.010 and 0.10 | 104 | 2.6 | 2.5 | 8 |
| Overall | | 98.7 | 7.1 | 7.2 | 15 |
| M650F003 | | | | | |
| Potato Shoot | 0.010 and 0.10 | 106 | 1.9 | 1.8 | 6 |
| Potato Tuber | 0.010 and 0.10 | 106 | 1.9 | 1.8 | 8 |
| Overall | | 106 | 1.9 | 1.8 | 14 |
| M650F004 | | | | | |
| Potato Shoot | 0.010 and 0.10 | 104 | 1.8 | 1.8 | 6 |
| Potato Tuber | 0.010 and 0.10 | 105 | 2.8 | 2.7 | 8 |
| Overall | | 105 | 2.4 | 2.3 | 14 |

1) SD: Standard deviation

2) RSD: Relative standard deviation

3) n: Number of results included in calculations

**Table A 9: Summary of the study 2022/2011022 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) expressed as parent\*** | | | **PHI (days)** | **Details on trial** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **g a.s./ ha** | **Water (l/ha)** | **g a.s./hl** | **BAS 650 F** | **M650F003** | **M650F004** |
|  | (a) | (b) |  |  |  | (c) |  |  |  |  |  | (d) | (e) |
| L210032 / 67245 Lambsheim, Germany / NEU / 2021 | Potato / Gala | 1. 11.04.2021  2. 02.07 – 19.07.2021  3. 30.07.2021 | 240  230  240 | 200  195  200 | 120  118  120 | 14.07.2021  19.07.2021  23.07.2021 | 47 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 26  <0.01  <0.01  <0.01 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  3  7  14 | XXXX method No. L0078/01 for BAS 650 F, M650F003, M650F004  LOQ = 0.01 mg/kg per analyte  Maximum storage interval (days): 147 |
| L210033 / 49350 Saint Georges le Spets Voies, France (North) / NEU / 2021 | Potato / Bintje | 1. 29.03.2021  2. 10.07 – 27.07.2021  3. 02.08.2021 | 230  260  240 | 193  213  197 | 119  122  122 | 15.07.2021  20.07.2021  26.07.2021 | 49 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 15  <0.01  <0.01  <0.01 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  3  7  14 |
| L210034 / 3470 Kortenaken, Belgium / NEU / 2021 | Potato / Friesländer | 1. 30.03.2021  2. 04.06 – 18.06.2021  3. 19.07.2021 | 250  250  240 | 204  206  200 | 123  121  120 | 02.07.2021  08.07.2021  12.07.2021 | 47-48 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 15  <0.01  <0.01  <0.01 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  3  7  14 |
| L220035 / 64-600, Berdychowo, Poland / NEU / 2021 | Potato / Queen Anne | 1. 22.04.2021  2. 20.06 – 18.06.2021  3. 06.09.2021 | 220  230  240 | 184  190  196 | 120  121  122 | 20.08.2021  25.08.2021  29.08.2021 | 48 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 23  <0.01  <0.01  <0.01 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  3  8  15 |

(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

\* Conversion factor for calculation of M650F003 to parent BAS 650 F is 1.2450. Conversion factor for calculation of M650F004 to parent BAS 650 F is 1.3292

* + - * 1. 2022/2041761

|  |  |
| --- | --- |
| Comments of zRMS: | The study has been accepted.  In 2022 4 field trials were conducted in NEU to determine the magnitude of residues of Ametoctradin and its metabolites M650F003 and M650F004 as well as of Propamocarb in potatoes after treatment with BAS 743 00 F or BAS 743 03 F under field conditions.  The test item BAS 743 00 F was applied as foliar application thrice on potatoes (plot 2) at 16-17, 11 and 6-7 days before harvest at a target rate equal to 0.24 kg/ha Ametoctradin and 0.756 kg/ha Propamocarb. Another test item BAS 743 03 F (378.0 g/L Propamocarb and 120.0 g/L Ametoctradin), a suspension concentrate (SC), was applied as foliar application thrice on potatoes (plot 3) at 16-17, 11 and 6-7 days before harvest at a rate equal to 0.24 kg/ha Ametoctradin and 0.756 kg/ha Propamocarb. The water volume used was 200 L/ha (within ≤ 10 % of variation).  The determination of Ametoctradin and its metabolites M650F003 and M650F004 was also performed according to method No. L0078/01. The LOQ of the method is 0.010 mg/kg for Ametoctradin and its metabolites M650F003 and M650F004. The determination of Propamocarb was performed using the method L0450/01. The LOQ of the method also is 0.010 mg/kg. LC-MS/MS was used for the final determination of residues of Ametoctradin and its metabolites M650F003 and M650F004 as well as Propamocarb. In all cases 2 transition were used.  For the recoveries, the mean values were within the acceptable range of 70 % and 110 %, with a relative standard deviation (RSD) ≤ 20 %. All validation parameters required were in the acceptable range.  No residues in control samples were found except in one shoot sample L2200910001 - 0.58 mg/kg of Propamocarb were found (an unknown contamination). |

|  |  |
| --- | --- |
| Reference: | CA 6.3.1/3 |
| Report | Study on the residue behaviour of Ametoctradin (BAS 650 F) and Propamocarb (Reg.No. 4628172) in potato after application of either BAS 743 00 F or BAS 743 03 F under field conditions in Northern Europe, 2022  Plier, S. & Eysoldt, M-B., 2023  XXXX Study ID 921987, Study No. 22 47 GRU 0005  XXXX DocID 2022/2041761 |
| Guideline(s): | * SANTE/2020/12830 rev. 1 (24. February 2021) * OPPTS 860.1340 * OECD ENV/JM/MONO(2007)17 |
| Deviations: | ~~None~~ Yes, none that affect the validity of the study |
| GLP: | Yes |
| Acceptability: | Yes | |

**Materials and methods**

In 2022, four independent field trials were conducted in NEU (Germany, northern France, Belgium and Poland) to support the use of BAS 650 F (ametoctradin) and BAS 9068 F (propamocarb) in potatoes. In each trial two plots were treated with different products. In plot 2, BAS 743 00 F (120 g/L of ametoctradin and 378 g/L of propamocarb), a suspension concentrate (SC) formulation was applied; in plot 3 BAS 743 03 F (120 g/L of ametoctradin and 378 g/L of propamocarb), a SC formulation, was applied. In both plots the products were foliar applied three times on potatoes at a nominal rate of 2.0 L/ha, corresponding to 240 g/ha of ametoctradin and 756 g/ha of propamocarb. The first application was made 16-17 days before harvest (DBH) (BBCH 45 – 47), the second application at 11 DBH (BBCH 46 – 48) and the final application 6 - 7 DBH (BBCH 47 – 49). Potato shoots were collected 0 days after last application (DALA) and potato tubers were collected 3, 6 – 7 and 13 – 15 DALA.

All samples were maintained frozen (≤ -18°C) at the testing facility, during shipping to the laboratory, and were stored frozen prior to analysis. The maximum storage interval for samples between harvest and analysis was 124 days (*ca* 4 months). Residues of ametoctradin, M650F003 and M650F004 have been shown to be stable in high water content and high starch content crops for at least 24 months.

Residues of ametoctradin, M650F003 and M650F004 were determined using XXXX method no. L0078/01, a LC-MS/MS method. Acceptable concurrent recoveries were reported for potato shoots and potato tubers, thus demonstrating the suitability of the methods. The limit of quantification (LOQ) was 0.01 mg/kg per analyte. For metabolites M650F003 and M650F004 this is equivalent to 0.012 mg/kg and 0.013 mg/kg, respectively, expressed as parent (ametoctradin). Conversion factors of 1.245 and 1.3292 are applied to M650F003 and M650F004 to convert residues to ametoctradin.

**Table A 10: Summary of recoveries of ametoctradin, M650F003 and M650F004 in potato**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Matrix** | **Fortification Level  [mg/kg]** | **Summary Recoveries** | | |
| **Method No. L0078/01** | | **Mean  [%]** | **RSD1) [%]** | **n2)** |
| Ametoctradin | | | | |
| Potato Shoot | 0.010, 0.10 and 50 | 92.7 | 6.8 | 7 |
| Potato Tuber | 0.010 and 0.10 | 92.4 | 3.3 | 12 |
| Overall | | 92.5 | 4.7 | 19 |
| M650F003 | | | | |
| Potato Shoot | 0.010 and 0.10 | 91.0 | 4.7 | 6 |
| Potato Tuber | 0.010 and 0.10 | 101 | 4.9 | 11 |
| Overall | | 97.7 | 7.0 | 17 |
| M650F004 | | | | |
| Potato Shoot | 0.010 and 0.10 | 93.5 | 1.2 | 6 |
| Potato Tuber | 0.010 and 0.10 | 94.5 | 3.1 | 12 |
| Overall | | 94.2 | 2.7 | 18 |

1) RSD: Relative standard deviation

2) n: Number of results included in calculations

**Table A 11: Summary of the study 2022/2041761 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) expressed as parent\*** | | | **PHI (days)** | **Details on trial** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **g a.s./ ha** | **Water (l/ha)** | **g a.s./hl** | **BAS 650 F** | **M650F003** | **M650F004** |
|  | (a) | (b) |  |  |  | (c) |  |  |  |  |  | (d) | (e) |
| L220091 / 55262 Ingelheim am Rhein – Heidesheim, Germany / NEU / 2022 (Plot 2) | Potato / Bernina | 1. 21.04.2022  2. 21.06 – 05.07.2022  3. 08.08.2022 | 220  250  250 | 187  205  208 | 120  120  120 | 22.07.2022  18.07.2022  01.08.2022 | 48 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 15  <0.01  <0.01  <0.01 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  3  7  14 | XXXX method No. L0078/01 for BAS 650 F, M650F003, M650F004  LOQ = 0.01 mg/kg per analyte  Maximum storage interval (days): 124 |
| L220091 / 55262 Ingelheim am Rhein – Heidesheim, Germany / NEU / 2022 (Plot 3) | Potato / Bernina | 1. 21.04.2022  2. 21.06 – 05.07.2022  3. 08.08.2022 | 240  240  260 | 203  203  213 | 120  120  120 | 22.07.2022  18.07.2022  01.08.2022 | 48 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 20  <0.01  <0.01  <0.01 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  3  7  14 |
| L220092 / 49650 Allonnes, France (North) / NEU / 2022 (Plot 2) | Potato / Spunta | 1. 01.04.2022  2. 30.05 – 17.06.2022  3. 04.07.2022 | 230  220  220 | 193  187  180 | 120  120  120 | 17.06.2022  23.06.2022  27.06.2022 | 48 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 20  <0.01  <0.01  <0.01 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  3  7  15 |
| L220092 / 49650 Allonnes, France (North) / NEU / 2022 (Plot 3) | Potato / Spunta | 1. 01.04.2022  2. 30.05 – 17.06.2022  3. 04.07.2022 | 240  240  240 | 193  187  180 | 120  120  120 | 17.06.2022  23.06.2022  27.06.2022 | 48 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 21  <0.01  <0.01  <0.01 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  3  7  15 |
| L220093 / 3470 Kortenaken, Belgium / NEU / 2022 (Plot 2) | Potato / Friesländer | 1. 01.04.2022  2. 01.06 – 14.06.2022  3. 08.07.2022 | 250  250  250 | 208  208  210 | 120  120  120 | 21.06.2022  27.06.2022  01.07.2022 | 47-48 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 22  <0.01  <0.01  <0.01 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  3  7  13 |
| L220093 / 3470 Kortenaken, Belgium / NEU / 2022 (Plot 3) | Potato / Friesländer | 1. 01.04.2022  2. 01.06 – 14.06.2022  3. 08.07.2022 | 250  240  240 | 210  202  198 | 120  120  120 | 21.06.2022  27.06.2022  01.07.2022 | 47-48 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 17  <0.01  <0.01  <0.01 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  3  7  13 |
| L220094 / 64-600, Berdychowo, Poland / NEU / 2022 (Plot 2) | Potato / Queen Anne | 1. 18.04.2022  2. 27.06 – 09.07.2022  3. 12.08.2022 | 230  240  240 | 186  196  196 | 120  120  120 | 27.07.2022  01.08.2022  06.08.2022 | 49 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 16  <0.01  <0.01  <0.01 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  3  6  13 |
| L220094 / 64-600, Berdychowo, Poland / NEU / 2022 (Plot 3) | Potato / Queen Anne | 1. 18.04.2022  2. 27.06 – 09.07.2022  3. 12.08.2022 | 230  240  240 | 186  196  196 | 120  120  120 | 27.07.2022  01.08.2022  06.08.2022 | 49 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 13  <0.01  <0.01  <0.01 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  3  6  13 |  |

(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

\* Conversion factor for calculation of M650F003 to parent BAS 650 F is 1.2450. Conversion factor for calculation of M650F004 to parent BAS 650 F is 1.3292

* + - 1. Onion, garlic

**Table A 12: Comparison of intended and critical EU GAPs**

| **Type of GAP** | **Number of applica­tions** | **Application rate per treatment**  **(g a.s./ha)** | **Interval between application** | **Growth stage at last application** | **PHI (days)** |
| --- | --- | --- | --- | --- | --- |
| cGAP NEU (DAR, The Netherlands, 2012) | - | - | - | - | - |
| cGAP NEU (Art. 12, EFSA, 2020) | 2 | 240 | 7 days | 15-48 | 7 |
| Intended cGAP (3)\* | 2 | 240 | 5 days | 14-49 | 7 |
| Intended GAP (4)\* † | 1 | 240 | - | 14-49 | 7 |

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

† This GAP is less critical and within the risk envelope of intended use 1 (cGAP)

* + - * 1. 2021/2025103

|  |  |
| --- | --- |
| Comments of zRMS: | The study has been accepted.  The objective of the study was to determine the magnitude of residues of Ametoctradin, M650F003, M650F004 and Propamocarb in onion growing under field conditions after treatment with BAS 743 00 F containing 120 g/L of Ametoctradin and 378g/L of Propamocarb. 4 trials were conducted in Northern Europe. At each site, there was one untreated plot in addition to the treated plot. BAS 743 00 F was applied 2 times (at 10-13 DBH and 6-8 DBH) at a rate of 2.0 L/ha (240 g/ha Ametoctradin and 756 g/ha Propamocarb).  For the determination of Propamocarb method L0450/01 was used. For the determination of Ametoctradin, M650F003, and M650F004 method L0078/01 was used. Matrix-matched standards in both cases were used. In both cases high performance liquid chromatography with ESl tandem mass spectrometry was employed for final compounds determination. 2 mass transitions were monitored. The methods have a LOQ of 0.010 mg/kg for each analyte. No residues above LOQs were found in any of the control samples. The validation parameters required were within the acceptable range. |

|  |  |
| --- | --- |
| Reference: | CA 6.3.3/1 |
| Report | Study on the residue behaviour of Ametoctradin (BAS 650 F) and Propamocarb (Reg.No. 4628172) in onion after two foliar applications of BAS 743 00 F under open field conditions in Northern Europe, 2020  Loriau, P., 2021  XXXX Study ID 890065, Study No. BAS-G119TO122-20  XXXX DocID 2021/2025103 |
| Guideline(s): | EC 1607/VI/97 rev.2, EEC 7029/VI/95 (22 July 1997), EEC 7525/VI/95 rev. 10.3, SANCO/3029/99, ENV/JM/MONO(2011)50/Rev1, OECD 509 |
| Deviations: | Yes, none that affect the validity of the study |
| GLP: | Yes |
| Acceptability: | Yes | |

**Materials and methods**

In 2020, four independent field trials were conducted in NEU (Germany, northern France, Belgium and Poland) to support the use of BAS 650 F (ametoctradin) and BAS 9068 F (propamocarb) in onions. BAS 743 00 F (120 g/L of ametoctradin and 378 g/L of propamocarb) a suspension concentrate (SC) formulation, was foliar applied twice to onions at a nominal rate of 2.0 L/ha, corresponding to 240 g/ha of ametoctradin and 756 g/ha of propamocarb. The first application was made 10-13 days before harvest (DBH) (BBCH 45 – 48) and the second application at 6 – 8 DBH (BBCH 45 – 48). Onion bulbs were collected 0, 2 – 3, 6 – 8 and 14 – 15 days after last application (DALA).

All samples were maintained frozen (≤ -18°C) at the testing facility, during shipping to the laboratory, and were stored frozen prior to analysis. The maximum storage interval for samples between harvest and analysis was 210 days (*ca* 7 months). Residues of ametoctradin, M650F003 and M650F004 have been shown to be stable in high water content crops for at least 24 months.

Residues of ametoctradin, M650F003 and M650F004 were determined using XXXX method no. L0078/01, a LC-MS/MS method. Acceptable concurrent recoveries were reported for onion bulbs, thus demonstrating the suitability of the methods. The limit of quantification (LOQ) was 0.01 mg/kg per analyte. For metabolites M650F003 and M650F004 this is equivalent to 0.012 mg/kg and 0.013 mg/kg, respectively, expressed as parent (ametoctradin). Conversion factors of 1.245 and 1.32924 are applied to M650F003 and M650F004 to convert residues to ametoctradin.

**Table A 13: Summary of recoveries of ametoctradin, M650F003 and M650F004 in onion**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Matrix** | **Fortification Level  [mg/kg]** | **Summary Recoveries** | | | |
| **Method No. L0078/01** | | **Mean  [%]** | **SD1)  [±]** | **RSD2) [%]** | **n3)** |
| Ametoctradin | | | | | |
| Onion bulbs | 0.010, 0.10 and 1.0 | 94.5 | 7.0 | 7.4 | 10 |
| M650F003 | | | | | |
| Onion bulbs | 0.010 and 0.10 | 93.3 | 9.2 | 9.8 | 6 |
| M650F004 | | | | | |
| Onion bulbs | 0.010 and 0.10 | 92.3 | 5.4 | 5.9 | 6 |

1) SD: Standard deviation

2) RSD: Relative standard deviation

3) n: Number of results included in calculations

**Table A 14: Summary of the study 2021/2025103 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) expressed as parent\*** | | | **PHI (days)** | **Details on trial** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **g a.s./ ha** | **Water (l/ha)** | **g a.s./hl** | **BAS 650 F** | **M650F003** | **M650F004** |
|  | (a) | (b) |  |  |  | (c) |  |  |  |  |  | (d) | (e) |
| L200302 / 46359 Heiden Germany / NEU / 2020 | Onion / Dormo F1 | 1. 03.04.2020  2. -  3. 27.08.2020 | 259  229 | 215.6  191.1 | 120  120 | 14.08.2020  19.08.2020 | 47-48 | Onion / bulb  Onion / bulb  Onion / bulb  Onion / bulb | 0.073  0.088  0.052  0.042 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  2  8  15 | XXXX method No. L0078/01 for BAS 650 F, M650F003, M650F004  LOQ = 0.01 mg/kg per analyte  Maximum storage interval (days): 210 |
| L200303 / 08300 Avançon, France (North) / NEU / 2020 | Onion / Hytune | 1. 23.03.2020  2. -  3. 15.09.2020 | 230  240 | 192.0  200.0 | 120  120 | 04.09.2020  08.09.2020 | 47 | Onion / bulb  Onion / bulb  Onion / bulb  Onion / bulb | 0.045  <0.01  <0.01  <0.01 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  3  7  14 |
| L200304 / 1450 Ittre, Belgium / NEU / 2020 | Onion / Centro 2 | 1. 31.03.2020  2. -  3. 13.08.2020 | 240  236 | 200.0  197.3 | 120  120 | 31.07.2020  05.08.2020 | 45-47 | Onion / bulb  Onion / bulb  Onion / bulb  Onion / bulb | 0.1  0.13  0.046  <0.01 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  2  8  14 |
| L200305 / 64-560 Szczepankowo, Poland / NEU / 2020 | Onion / Majka | 1. 06.04.2020  2. -  3. 07.08.2020 | 260  234 | 217.0  195.0 | 120  120 | 27.07.2020  31.07.2020 | 47 | Onion / bulb  Onion / bulb  Onion / bulb  Onion / bulb | 0.24  0.071  0.11  0.022 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  3  6  14 |

(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

\* Conversion factor for calculation of M650F003 to parent BAS 650 F is 1.2450. Conversion factor for calculation of M650F004 to parent BAS 650 F is 1.32924

* + - * 1. 2022/2003268

|  |  |
| --- | --- |
| Comments of zRMS: | The study has been accepted.  The objective of the study was to determine the magnitude of residues of Ametoctradin and its metabolites (M650F003, M650F004) as well as of Propamocarb in onions after treatment with BAS 743 00 F in 4 trials in onions conducted under field conditions in Northern Europe. At each site BAS 743 00 F was applied 2 times at a rate of 2.0 L/ha (240 g/ha Ametoctradin and 756 g/ha Propamocarb).  For the determination of Propamocarb method L0450/01 was used. For the determination of Ametoctradin, M650F003, and M650F004 method L0078/01 was used. In both cases high performance liquid chromatography with ESl tandem mass spectrometry was employed for final compounds determination. 2 mass transitions were monitored. The methods have a LOQ of 0.010 mg/kg for each analyte. No residues above LOQs were found in any of the control samples. The validation parameters required were within the acceptable range. |

|  |  |
| --- | --- |
| Reference: | CA 6.3.3/2 |
| Report | Study on the residue behaviour of Propamocarb (Reg.No. 4628172) and Ametoctradin (BAS 650 F) in onions after two applications of BAS 743 00 F under field conditions in Northern Europe, 2021  Erdmann, H-P., 2022  XXXX Study ID 890066, Study No. AC/XXXX/21/03  XXXX DocID 2022/2003268 |
| Guideline(s): | * + European Community Guideline 7029/VI/95 - rev.5, 22/07/97: General recommendations for the design preparation and realization of residue trials.   + European Community SANTE/2019/12752 Technical Guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin (former SANCO 7525/VI/95 – Rev. 10.3)   + OECD Guideline for the testing of chemicals – Crop Field Trials: OECD/OCDE 509. Adopted 7 September 2009 |
| Deviations: | None |
| GLP: | Yes |
| Acceptability: | Yes | |

**Materials and methods**

In 2021, four independent field trials were conducted in NEU (Germany, northern France, The Netherlands and Poland) to support the use of BAS 650 F (ametoctradin) and BAS 9068 F (propamocarb) in onions. BAS 743 00 F (120 g/L of ametoctradin and 378 g/L of propamocarb) a suspension concentrate (SC) formulation, was foliar applied twice to onions at a nominal rate of 2.0 L/ha, corresponding to 240 g/ha of ametoctradin and 756 g/ha of propamocarb. The first application was made 12 – 13 days before harvest (DBH) (BBCH 47 – 48) and the second application at 7 – 8 DBH (BBCH 47 – 48). Onion whole plants (no roots) were collected at 0 days after last application (DALA). Onion bulbs were collected 2 – 3, 7 – 8 and 14 – 15 DALA.

All samples were maintained frozen (≤ -18°C) at the testing facility, during shipping to the laboratory, and were stored frozen prior to analysis. The maximum storage interval for samples between harvest and analysis was 137 days (*ca* 5 months). Residues of ametoctradin, M650F003 and M650F004 have been shown to be stable in high water content crops for at least 24 months.

Residues of ametoctradin, M650F003 and M650F004 were determined using XXXX method no. L0078/01, a LC-MS/MS method. Acceptable concurrent recoveries were reported for onion whole plant (no roots) and onion bulbs, thus demonstrating the suitability of the methods. The limit of quantification (LOQ) was 0.01 mg/kg per analyte. For metabolites M650F003 and M650F004 this is equivalent to 0.012 mg/kg and 0.013 mg/kg, respectively, expressed as parent (ametoctradin). Conversion factors of 1.245 and 1.32924 are applied to M650F003 and M650F004 to convert residues to ametoctradin.

**Table A 15: Summary of recoveries of ametoctradin, M650F003 and M650F004 in onion**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Matrix** | **Fortification Level  [mg/kg]** | **Summary Recoveries** | | | |
| **Method No. L0078/01** | | **Mean  [%]** | **SD1)  [±]** | **RSD2) [%]** | **n3)** |
| Ametoctradin | | | | | |
| Onion whole plant (no roots) | 0.010, 0.10 and 10 | 109 | 2.0 | 1.8 | 7 |
| Onion bulbs | 0.010 and 0.10 | 109 | 1.5 | 1.4 | 8 |
| Overall | | 109 | 1.7 | 1.5 | 15 |
| M650F003 | | | | | |
| Onion whole plant (no roots) | 0.010 and 0.10 | 109 | 2.5 | 2.3 | 6 |
| Onion bulbs | 0.010 and 0.10 | 109 | 1.4 | 1.3 | 8 |
| Overall | | 109 | 1.9 | 1.7 | 14 |
| M650F004 | | | | | |
| Onion whole plant (no roots) | 0.010 and 0.10 | 107 | 3.1 | 2.9 | 6 |
| Onion bulbs | 0.010 and 0.10 | 107 | 2.4 | 2.3 | 8 |
| Overall | | 107 | 2.6 | 2.4 | 14 |

1) SD: Standard deviation

2) RSD: Relative standard deviation

3) n: Number of results included in calculations

**Table A 16: Summary of the study 2022/2003268 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) expressed as parent\*** | | | **PHI (days)** | **Details on trial** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **g a.s./ ha** | **Water (l/ha)** | **g a.s./hl** | **BAS 650 F** | **M650F003** | **M650F004** |
|  | (a) | (b) |  |  |  | (c) |  |  |  |  |  | (d) | (e) |
| L220037 / 16883 Lentzke, Germany / NEU / 2021 | Onion / Hylander | 1. 30.03.2021  2. -  3. 07.09.2021 | 225  253 | 188  211 | 120  120 | 19.08.2021  24.08.2021 | 48 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | 2.0  0.063  0.011  0.015 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  3  7  14 | XXXX method No. L0078/01 for BAS 650 F, M650F003, M650F004  LOQ = 0.01 mg/kg per analyte  Maximum storage interval (days): 137 |
| L210038 / 67240 Bischwiller, France (North) / NEU / 2021 | Onion / Redspark | 1. 17.03.2021  2. -  3. 10.09 – 20.08.2021 | 232  244 | 192  203 | 120  120 | 29.07.2021  02.08.2021 | 48 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | 1.8  0.078  0.059  0.018 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  3  8  14 |
| L220039 / 6562 LT Groesbeek, The Netherlands / NEU / 2021 | Onion / Red Tide F1 | 1. 02.04.2021  2. -  3. 01.09 – 07.09.2021 | 253  253 | 211  194 | 120  120 | 19.08.2021  24.08.2021 | 47-48 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | 2.5  0.051  0.056  0.041 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  2  8  14 |
| L210040 / 63-140 Maslow o, Poland / NEU / 2020 | Onion / Centro | 1. 25.03.2021  2. -  3. 09.09.2021 | 262  244 | 218  203 | 120  120 | 04.08.2021  09.08.2021 | 47 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | 1.2  0.074  0.098  <0.01 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  3  7  15 |

(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

\* Conversion factor for calculation of M650F003 to parent BAS 650 F is 1.2450. Conversion factor for calculation of M650F004 to parent BAS 650 F is 1.3292

* + - * 1. 2022/2041763

|  |  |
| --- | --- |
| Comments of zRMS: | The study has been accepted.  The objective of the study was to determine the magnitude of residues of Ametoctradin and its metabolites (M650F003, M650F004) as well as of Propamocarb in onions after treatment with either BAS 743 00 F or BAS 743 03 F in 5 trials in onions conducted under field conditions in Northern Europe. At each trial site, there was one untreated plot in addition to 2 treated plots. At each site the test item was applied 2 times at a rate of 2.0 L/ha (240 g/ha Ametoctradin and 756 g/ha Propamocarb) in plot 2. Treated plot 2 was treated with BAS 743 00 F and treated plot 3 was treated with BAS 743 03 F.  For the determination of Propamocarb method L0450/01 was used. For the determination of Ametoctradin, M650F003, and M650F004 method L0078/01 was used. In both cases high performance liquid chromatography with ESl tandem mass spectrometry was employed for final compounds determination. 2 mass transitions were monitored.  For the recoveries, the mean values were within the acceptable range of 70 % and 110 %, with a relative standard deviation (RSD) ≤ 20 %. No residues ≥ 0.010 mg/kg (LOQ) were found in any of the untreated control samples. The results prove that no interferences of the samples material with the analytical procedure occurred. The methods have a LOQ of 0.010 mg/kg for each analyte. The validation parameters required were within the acceptable range. |

|  |  |
| --- | --- |
| Reference: | CA 6.3.3/3 |
| Report | Study on the residue behaviour of Ametoctradin (BAS 650 F) and Propamocarb (Reg.No. 4628172) in onions after application of either BAS 743 00 F or BAS 743 03 F under field conditions in Northern Europe, 2022  Loriau, P., 2023  XXXX Study ID 921989, Study No. BAS-G205TO208-22  XXXX DocID 2022/2041763 |
| Guideline(s): | * FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials, Rome 1990 * EC working document 1607/VI/97, [rev. 2] (10/06/1999) * EC working document 7029/VI/95 - Appendix B, [rev. 5] (22/07/1997) * EC working document SANTE/2019/12752 * EC working document SANTE/2020/12830 rev.1 (24/02/2021) *(risk assessment part)* * OECD Guidance document on Crop Field Trials [ENV/JM/MONO(2011)50/Rev1] (07/09/2016)   OECD Guideline for the testing of chemicals n°509, Crop Field Trial, June 2021 |
| Deviations: | Yes, none that affect the validity of the study |
| GLP: | Yes |
| Acceptability: | Yes | |

**Materials and methods**

In 2022, five independent field trials were conducted in NEU (Germany, northern France, Belgium, Poland) to support the use of BAS 650 F (ametoctradin) and BAS 9068 F (propamocarb) in onions. In plot 2, BAS 743 00 F (120 g/L of ametoctradin and 378 g/L of propamocarb), a suspension concentrate (SC) formulation was applied; in plot 3, BAS 743 03 F (120 g/L of ametoctradin and 378 g/L of propamocarb), an SC formulation, was applied. In both plots the products were foliar applied twice on onions at a nominal rate of 2.0 L/ha, corresponding to 240 g/ha of ametoctradin and 756 g/ha of propamocarb. The first application was made 11 – 14 days before harvest (DBH) (BBCH 45 – 48) and the second application at 6 – 8 DBH (BBCH 47 – 48). Onion whole plants (no roots) were collected at 0 days after last application (DALA), with the exception of trial L220101 where no whole plant samples were collected. Onion bulbs were collected from all trials 2 – 3, 6 – 8 and 14 DALA.

All samples were maintained frozen (≤ -18°C) at the testing facility, during shipping to the laboratory, and were stored frozen prior to analysis. The maximum storage interval for samples between harvest and analysis was 133 days (4.4 months). Residues of ametoctradin, M650F003 and M650F004 have been shown to be stable in high water content crops for at least 24 months.

Residues of ametoctradin, M650F003 and M650F004 were determined using XXXX method no. L0078/01, an LC-MS/MS method. Acceptable concurrent recoveries were reported for onion whole plant (no roots) and onion bulbs, therefore demonstrating the suitability of the method. The limit of quantification (LOQ) was 0.01 mg/kg per analyte. For metabolites M650F003 and M650F004 this is equivalent to 0.012 mg/kg and 0.013 mg/kg, respectively, expressed as parent equivalents (ametoctradin). Conversion factors of 1.245 and 1.32924 are applied to M650F003 and M650F004 to convert residues to ametoctradin.

**Table A 17: Summary of recoveries of ametoctradin, M650F003 and M650F004 in onion**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Matrix** | **Fortification Level  [mg/kg]** | **Summary Recoveries** | | |
| **Method No. L0078/01** | | **Mean  [%]** | **RSD1) [%]** | **n2)** |
| Ametoctradin | | | | |
| Onion whole plant (no roots) | 0.010, 0.10 and 10 | 95.5 | 8.4 | 9 |
| Onion bulbs | 0.010, 0.10 and 1.0 | 90.7 | 3.9 | 13 |
| Overall | | 92.7 | 6.6 | 22 |
| M650F003 | | | | |
| Onion whole plant (no roots) | 0.010 and 0.10 | 104 | 3.3 | 8 |
| Onion bulbs | 0.010 and 0.10 | 100 | 10 | 10 |
| Overall | | 102 | 8.0 | 18 |
| M650F004 | | | | |
| Onion whole plant (no roots) | 0.010 and 0.10 | 99.9 | 3.4 | 8 |
| Onion bulbs | 0.010 and 0.10 | 96.0 | 5.5 | 12 |
| Overall | | 97.6 | 5.0 | 20 |

1) RSD: Relative standard deviation

2) n: Number of results included in calculations

Table A 18: Summary of the study 2022/2041763 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) expressed as parent\*** | | | **PHI (days)** | **Details on trial** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **g a.s./ ha** | **Water (l/ha)** | **g a.s./hl** | **BAS 650 F** | **M650F003** | **M650F004** |
|  | (a) | (b) |  |  |  | (c) |  |  |  |  |  | (d) | (e) |
| L220099 / 67063, Ludwigshafen, Friesenheim, Germany / NEU / 2022 / (plot 2) | Onion / Hybelle | 1. 22.02.2022  2. -  3. 22.08.2022 | 232  232 | 193  193 | 120  120 | 10.08.2022  15.08.2022 | 47  47-48 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | 1.3  0.029  0.026  0.011 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  2  7  14 | XXXX method No. L0078/01 for BAS 650 F, M650F003, M650F004  LOQ = 0.01 mg/kg per analyte  Maximum storage interval (days): 133 |
| L220099 / 67063, Ludwigshafen, Friesenheim, Germany / NEU / 2022 / (plot 3) | Onion / Hybelle | 1. 22.02.2022  2. -  3. 22.08.2022 | 240  244 | 200  203 | 120  120 | 10.08.2022  15.08.2022 | 47  47-48 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | 1.1  0.022  0.026  0.011 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  2  7  14 |
| L220100 / 80170, Beauforten-Santerre, northern France / NEU / 2022 (plot 2) | Onion / Stardust | 1. 19.04.2022  2. -  3. 04.10.2022 | 180  178 | 211  208 | 85  85 | 20.09.2022  28.09.2022 | 45  47 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | 1.1  0.011  <0.01  <0.01 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  2  6  14 |
| L220100 / 80170, Beauforten-Santerre, northern France / NEU / 2022 (plot 3) | Onion / Stardust | 1. 19.04.2022  2. -  3. 04.10.2022 | 226  229 | 188  191 | 120  120 | 20.09.2022  28.09.2022 | 45  47 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | 0.90  0.023  <0.01  <0.01 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  2  6  14 |
| L220101 / 6221, Saint-Amand, Belgium / NEU / 2022 (plot 2) | Onion / Sturon | 1. 28.03.2022  2. -  3. 01.08.2022 | 245  244 | 203  203 | 120  120 | 20.07.2022  25.07.2022 | 48  48 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | -†  0.13  0.024  <0.01 | -†  <0.012  <0.012  <0.012 | -†  <0.013  <0.013  <0.013 | 0  3  7  14 |
| L220101 / 6221, Saint-Amand, Belgium / NEU / 2022 (plot 3) | Onion / Sturon | 1. 28.03.2022  2. -  3. 01.08.2022 | 250  244 | 207  203 | 121  120 | 20.07.2022  25.07.2022 | 48  48 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | -†  0.065  0.025  0.033 | -†  <0.012  <0.012  <0.012 | -†  <0.013  <0.013  <0.013 | 0  3  7  14 |
| L220102 / 64-560, Szczepankowo, Poland / NEU / 2022 (plot 2) | Onion / Rijnsburger 5 | 1. 03.05.2022  2. -  3. 26.09.2022 | 232  224 | 193  187 | 120  120 | 13.09.2022  18.09.2022 | 48  48 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | 1.3  0.11  0.076  0.067 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  3  8  14 |
| L220102 / 64-560, Szczepankowo, Poland / NEU / 2022 (plot 3) | Onion / Rijnsburger 5 | 1. 03.05.2022  2. -  3. 26.09.2022 | 232  224 | 193  187 | 120  120 | 13.09.2022  18.09.2022 | 48  48 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | 0.97  0.13  0.098  0.078 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  3  8  14 |
| L220391 / 6230, Rosseignies, Belgium / NEU / 2022 (plot 2) | Onion / Red Ray F1 | 1. 17.03.2022  2. -  3. 09.09.2022 | 259.6  254.7 | 216  212 | 120  120 | 29.08.2022  02.09.2022 | 47  47 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | 1.8  0.053  0.026  0.026 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  3  7  14 |
| L220391 / 6230, Rosseignies, Belgium / NEU / 2022 (plot 3) | Onion / Red Ray F1 | 1. 17.03.2022  2. -  3. 09.09.2022 | 235.1  244.9 | 196  204 | 120  120 | 29.08.2022  02.09.2022 | 47  47 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | 1.0  0.027  0.030  0.023 | <0.012  <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013  <0.013 | 0  3  7  14 |

(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

\* Conversion factor for calculation of M650F003 to parent BAS 650 F is 1.2450. Conversion factor for calculation of M650F004 to parent BAS 650 F is 1.3292

† Samples of whole plant (no roots) not collected

* + - 1. Tomato, aubergine

**Table A 19: Comparison of intended and critical EU GAPs**

| **Type of GAP** | **Number of applica­tions** | **Application rate per treatment**  **(g a.s./ha)** | **Interval between application** | **Growth stage at last application** | **PHI (days)** |
| --- | --- | --- | --- | --- | --- |
| cGAP NEU (DAR, The Netherlands, 2012) | 3 | 240 | 7-10 days | 10-89 | 1 |
| cGAP NEU (Art. 12, EFSA, 2020) | 3 | 240 | 7 days | - | 1 |
| Intended cGAP (5\*) | 2 | 240 | 7 days | 21-89 | 1 |

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

* + - * 1. 2021/2020563 & 2022/2041755

|  |  |
| --- | --- |
| Comments of zRMS: | Both studies have been accepted.  **1.** In 2020 4 field trials were conducted in NEU to determine residues of Propamocarb, Ametoctradin, M650F003, and M650F004 in tomatoes after treatment with BAS 743 00 F which was applied twice in each trial on plot 2 at 8 (±1) DBH and at 1 DBH respectively, at a rate of 2.0 L/ha (equal to 0.756 kg/ha of Propamocarb and 0.240 kg/ha of Ametoctradin) with a water volume of 300 L/ha.  Collected samples were analysed for Propamocarb according to the XXXX method L0450/01. The limit of quantitation (LOQ) of the method is 0.010 mg/kg. For Ametoctradin, M650F003, and M650F004 samples were analysed according to the XXXX method L0078/01. The LOQ of the method is 0.010 mg/kg.  Matrix-matched standards were used for quantitation in both methods. The final determinations were performed by LC-MS/MS. 2 transitions were monitored. For the recoveries, the mean values were within the acceptable range of 70 % and 120 %, with a relative standard deviation (RSD) ≤ 20 %. The validation parameters required were within the acceptable range.  In control samples only for trial L200282 contamination with residues of propamocarb were found above the LOQ in a range of 0.050 – 0.059 mg/kg. This trial therefore was repeated.  2. The repeated trial: In 2021, one trial L210194 in tomatoes was conducted in NEU. The procedural details as above. 2 applications were done at 1 and 8 days before harvest. The analytical methods applied to determine relevant residues were the same. The course of the study was very similar. For the recoveries, the mean values were within the acceptable range of 70 % and 120 %, with a relative standard deviation (RSD) ≤ 20 %. The validation parameters required were within the acceptable range. |

|  |  |
| --- | --- |
| Reference: | CA 6.3.4/1 |
| Report | Study on the residue behaviour of Propamocarb (Reg.No. 4628172) and Ametoctradin (BAS 650 F) in Tomato after treatment with BAS 743 00 F under field conditions in Northern Europe, 2020  Schneider, E., 2021  XXXX Study ID 890058, Study No. C0075  XXXX DocID 2021/2020563 |
| Guideline(s): | * European Community Guideline 7525/VI/95 - rev.10.3, 13 June 2017: Comparability, extrapolation, group tolerances and data requirements for setting MRLs * 7029/VI/95 rev. 5: Appendix B- General Recommendations for the design, preparation and realization of residue trials * OECD – guideline for the testing of chemicals, 509; Crop field trial, 07/09/2009 * OECD ENV/JM/MONO(2007)17 – Guidance Document on Pesticide Residue Analytical Methods * EU Guidance Document SANCO/3029/99 re. 4 for generating and reporting methods of analysis in support of pre-registration data requirements |
| Deviations: | Yes. During trial L200282 a product containing propamocarb was mistakenly applied to the untreated plot, distance between plots and half of the treated plot. This trial has been repeated in study 890058\_1 (2022/2041755) |
| GLP: | Yes |
| Acceptability: | Yes | |

|  |  |
| --- | --- |
| Reference: | CA 6.3.4/2 |
| Report | Study on the residue behaviour of Propamocarb (Reg.No. 4628172) and Ametoctradin (BAS 650 F) in Tomato after two applications of BAS 743 00 F under field conditions in Northern Europe in 2021  Schneider, E., 2023  XXXX Study ID 890058\_1, Study No. C1066  XXXX DocID 2022/2041755 |
| Guideline(s): | * + European Commission guideline SANTE/2019/12752: Technical guidelines on Data Requirements for Setting Maximum Residue Levels, Comparability of Residue Trials and Extrapolation of Residue Data on Products from Plant and Animal Origin (Repealing and replacing SANCO 7525/VI/95 – Rev. 10.3)   + OECD Guideline for the testing of chemicals – Crop Field Trials: OECD/OCDE 509. Adopted 7 September 2009   + SANTE/2020/12830, Rev. 1   + OECD ENV/JM/MONO(2007)17 |
| Deviations: | Yes, none that affect the validity of the study |
| GLP: | Yes |
| Acceptability: | Yes | |

**Materials and methods**

In 2020, four independent field trials were conducted in NEU (Germany, northern France, Poland and Hungary) to support the use of BAS 650 F (ametoctradin) and BAS 9068 F (propamocarb) in tomato. BAS 743 00 F (120 g/L of ametoctradin and 378 g/L of propamocarb) a suspension concentrate (SC) formulation, was foliar applied twice to tomatoes at a nominal rate of 2.0 L/ha, corresponding to 240 g/ha of ametoctradin and 756 g/ha of propamocarb. The first application was made 8 – 9 days before harvest (DBH) (BBCH 81 – 87) (except for trial L200281 where the first application was made 10 DBH) and the second application was made 1 DBH (BBCH 83 – 89). Tomato (fruit) samples were collected at 0, 1 and 3 - 4 days after the last application (DALA).

Due to the incorrect application of propamocarb to one trial in 2020 an additional independent trial was conducted in NEU (Poland) to support the use of BAS 650 F (ametoctradin) and BAS 9068 F (propamocarb) in tomato. BAS 743 00 F (120 g/L of ametoctradin and 378 g/L of propamocarb) a suspension concentrate (SC) formulation, was foliar applied twice to tomatoes at a nominal rate of 2.0 L/ha, corresponding to 240 g/ha of ametoctradin and 756 g/ha of propamocarb. The first application was made 8 DBH (BBCH 81 – 85) and the second application was made 1 DBH (BBCH 85 – 87). Tomato (fruit) samples were collected at 0, 1 and 2 days after the last application (DALA).

All samples were maintained frozen (≤ -18°C) at the testing facility, during shipping to the laboratory, and were stored frozen prior to analysis. The maximum storage interval for samples between harvest and analysis was 273 days (*ca* 9 months). Residues of ametoctradin, M650F003 and M650F004 have been shown to be stable in high water content crops for at least 24 months.

Residues of ametoctradin, M650F003 and M650F004 were determined using XXXX method no. L0078/01, a LC-MS/MS method. Acceptable concurrent recoveries were reported for tomato fruit, therefore demonstrating the suitability of the methods. The limit of quantification (LOQ) was 0.01 mg/kg per analyte. For metabolites M650F003 and M650F004 this is equivalent to 0.012 mg/kg and 0.013 mg/kg, respectively, expressed as parent (ametoctradin). Conversion factors of 1.245 and 1.32924 are applied to M650F003 and M650F004 to convert residues to ametoctradin.

**Table A 20: Summary of recoveries of ametoctradin, M650F003 and M650F004 in tomato**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Matrix** | **Fortification Level  [mg/kg]** | **Summary Recoveries** | | | |
| **Method No. L0078/01** | | **Mean  [%]** | **SD1)  [±]** | **RSD2) [%]** | **n3)** |
| Ametoctradin | | | | | |
| Tomato fruit\* | 0.010, 0.10 and 1.0 | 94.2 | 7.8 | 8.3 | 10 |
| Tomato fruit† | 0.010, 0.10 and 10 | 94.0 | - | 5.8 | 7 |
| M650F003 | | | | | |
| Tomato fruit\* | 0.010, 0.10 and 1.0 | 91.4 | 3.7 | 4.1 | 6 |
| Tomato fruit† | 0.010, 0.10 and 10 | 94.1 | - | 4.2 | 7 |
| M650F004 | | | | | |
| Tomato fruit\* | 0.010, 0.10 and 1.0 | 93.3 | 3.3 | 3.5 | 6 |
| Tomato fruit† | 0.010, 0.10 and 10 | 95.9 | - | 2.9 | 7 |

1) SD: Standard deviation

2) RSD: Relative standard deviation

3) n: Number of results included in calculations

\* Procedural recoveries from study 2021/2020563

† Procedural recoveries from study 2022/2041755

**Table A 21: Summary of the study 2021/2020563 & 2022/2041755 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) expressed as parent\*** | | | **PHI (days)** | **Details on trial** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **g a.s./ ha** | **Water (l/ha)** | **g a.s./hl** | **BAS 650 F** | **M650F003** | **M650F004** |
|  | (a) | (b) |  |  |  | (c) |  |  |  |  |  | (d) | (e) |
| L200280 / 79227 Schallstadt, Germany / NEU / 2020 | Tomato / Matina | 1. 19.05.2020  2. 10.06.2020 – 15.07.2020  3. - | 261  251 | 327  313 | 80  80 | 10.08.2020  18.08.2020 | 87-89 | Fruit  Fruit  Fruit | 0.29  0.27  0.12 | <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013 | 0  1  3 | XXXX method No. L0078/01 for BAS 650 F, M650F003, M650F004  LOQ = 0.01 mg/kg per analyte  Maximum storage interval (days): 273 |
| L200281 / Thorée les Pins, France / NEU / 2020 | Tomato / Tribeca | 1. 15.05.2020  2. 10.06.2020 – 20.08.2020  3. 01.09.2020 – 20.09.2020 | 229  235 | 287  293 | 80  80 | 26.08.2020  04.09.2020 | 86 | Fruit  Fruit  Fruit | 0.14  0.081  0.061 | <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013 | 0  1  3 |
| L200283 / H-2921 Komarom, Hungary / NEU / 2020 | Tomato / Mobil F1 | 1. 02.06.2020  2. 20.06.2020 – 20.07.2020  3. - | 228  242 | 302  303 | 80  80 | 17.08.2020  24.08.2020 | 83-84 | Fruit  Fruit  Fruit | 0.16  0.068  0.14 | <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013 | 0  1  3 |
| L210194 / 99-122 Góra Św iętej Małgorzaty, Poland / NEU / 2021 | Tomato / Hector | 1. 14.05.2021  2. 07.06.2021 – 30.07.2021  3. 27.08.2021 | 245  240 | 306  300 | 80  80 | 18.08.2021  25.08.2021 | 85-87 | Fruit  Fruit  Fruit | 0.063  0.039  0.043 | <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013 | 0  1  2 |

(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

\* Conversion factor for calculation of M650F003 to parent BAS 650 F is 1.2450. Conversion factor for calculation of M650F004 to parent BAS 650 F is 1.3292

* + - * 1. 2022/2011021

|  |  |
| --- | --- |
| Comments of zRMS: | The study has been accepted.  In 2021 4 field trials were conducted in NEU to determine residues of Propamocarb, Ametoctradin, M650F003, and M650F004 in tomatoes after treatment with BAS 743 00 F which was applied twice in each trial on plot 2 at 7-8 DBH and at 1 DBH respectively, at a rate of 2.0 L/ha (equal to 0.756 kg/ha of Propamocarb and 0.240 kg/ha of Ametoctradin) with a water volume of 300 L/ha.  Collected samples were analysed for Propamocarb according to the XXXX method L0450/01. The limit of quantitation (LOQ) of the method is 0.010 mg/kg. For Ametoctradin, M650F003, and M650F004 samples were analysed according to the XXXX method L0078/01. The LOQ of the method is 0.010 mg/kg.  Matrix-matched standards were used for quantitation in both methods. The final determinations were performed by LC-MS/MS. 2 transitions were monitored. For the recoveries, the mean values were within the acceptable range of 70 % and 120 %, with a relative standard deviation (RSD) ≤ 20 %. The validation parameters required were within the acceptable range. No residues at or above the LOQ were found in any of the control samples. |

|  |  |
| --- | --- |
| Reference: | CA 6.3.4/3 |
| Report | Study on the residue behaviour of Propamocarb (Reg.No. 4628172) and Ametoctradin (BAS 650 F) in tomato after two applications of BAS 743 00 F under field conditions in Northern Europe, 2021  Plier, S. and Eysoldt, M., 2022  XXXX Study ID 890060, Study No. 21 47 GRU 0002  XXXX DocID 2022/2011021 |
| Guideline(s): | * + European Community Guideline 7029/VI/95 - rev.5, 22/07/97: General recommendations for the design preparation and realization of residue trials.   + European Commission guideline SANTE/2019/12752: Technical guidelines on Data Requirements for Setting Maximum Residue Levels, Comparability of Residue Trials and Extrapolation of Residue Data on Products from Plant and Animal Origin (Repealing and replacing SANCO 7525/VI/95 – Rev. 10.3)   + OECD Guideline for the testing of chemicals – Crop Field Trials: OECD/OCDE 509. Adopted 7 September 2009 |
| Deviations: | Yes, none that affect the validity of the study |
| GLP: | Yes |
| Acceptability: | Yes | |

**Materials and methods**

In 2021, four independent field trials were conducted in NEU (Germany, northern France, Poland and Belgium) to support the use of BAS 650 F (ametoctradin) and BAS 9068 F (propamocarb) in tomato. BAS 743 00 F (120 g/L of ametoctradin and 478 g/L of propamocarb) a suspension concentrate (SC) formulation, was foliar applied twice to tomatoes at a nominal rate of 2.0 L/ha, corresponding to 240 g/ha of ametoctradin and 756 g/ha of propamocarb. The first application was made 7 - 8 days before harvest (DBH) (BBCH 81 - 85) and the second application was made 1 DBH (BBCH 82 – 87). Tomato (fruit) samples were collected at 0, 1 and 3 - 4 days after last application (DALA).

All samples were maintained frozen (≤ -18°C) at the testing facility, during shipping to the laboratory, and were stored frozen prior to analysis. The maximum storage interval for samples between harvest and analysis was 286 days (*ca* 9 months). Residues of ametoctradin, M650F003 and M650F004 have been shown to be stable in high water content crops for at least 24 months.

Residues of ametoctradin, M650F003 and M650F004 were determined using XXXX method no. L0078/01, a LC-MS/MS method. Acceptable concurrent recoveries were reported for tomato fruit, therefore demonstrating the suitability of the methods. The limit of quantification (LOQ) was 0.01 mg/kg per analyte. For metabolites M650F003 and M650F004 this is equivalent to 0.012 mg/kg and 0.013 mg/kg, respectively, expressed as parent (ametoctradin). Conversion factors of 1.245 and 1.32924 are applied to M650F003 and M650F004 to convert residues to ametoctradin.

**Table A 22: Summary of recoveries of ametoctradin, M650F003 and M650F004 in tomato**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Matrix** | **Fortification Level  [mg/kg]** | **Summary Recoveries** | | |
| **Method No. L0078/01** | | **Mean  [%]** | **RSD1) [%]** | **n2)** |
| Ametoctradin | | | | |
| Tomato fruit | 0.010, 0.10 and 10 | 91.0 | 5.9 | 11 |
| M650F003 | | | | |
| Tomato fruit | 0.010, 0.10 and 10 | 91.5 | 5.1 | 11 |
| M650F004 | | | | |
| Tomato fruit | 0.010, 0.10 and 10 | 92.6 | 3.1 | 11 |

1) RSD: Relative standard deviation

2) n: Number of results included in calculations

**Table A 23: Summary of the study 2022/2011021 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) expressed as parent\*** | | | **PHI (days)** | **Details on trial** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **g a.s./ ha** | **Water (l/ha)** | **g a.s./hl** | **BAS 650 F** | **M650F003** | **M650F004** |
|  | (a) | (b) |  |  |  | (c) |  |  |  |  |  | (d) | (e) |
| L210028 / 04827 Machem OT, Gerichshain, Germany / NEU / 2021 | Tomato / Hoffmanns Rentita | 1. 24.05.2021  2. 01.06.2021 – 19.07.2021  3. 18.08.2021 | 240  250 | 300  310 | 80  80 | 10.08.2021  17.08.2021 | 87 | Fruit  Fruit  Fruit | 0.10  0.15  0.091 | <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013 | 0  1  3 | XXXX method No. L0078/01 for BAS 650 F, M650F003, M650F004  LOQ = 0.01 mg/kg per analyte  Maximum storage interval (days): 286 |
| L210029 / 71570 La Chapelle de Guinchay, France / NEU / 2021 | Tomato / Fandango | 1. 09.06.2021  2. 12.07.2021 – 20.08.2021 | 250  230 | 313  290 | 79  79 | 31.08.2021  07.09.2021 | 82 | Fruit  Fruit  Fruit | 0.13  0.14  0.048 | <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013 | 0  1  3 |
| L210030 / 64-606 Wychowaniec, Poland / NEU / 2021 | Tomato / Dyno | 1. 16.05.2021  2. 25.06.2021 – 05.08.2021  3. 31.08.2021 | 240  230 | 304  290 | 80  80 | 24.08.2021  30.08.2021 | 83 | Fruit  Fruit  Fruit | 0.28  0.11  0.084 | <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013 | 0  1  3 |
| L210031 / 3470 Kortenaken, Belgium / NEU / 2021 | Tomato / Pannovy | 1. 28.06.2021  2. 15.07.2021 – 20.08.2021  3. 16.09.2021 | 250  230 | 313  293 | 80  78 | 08.09.2021  15.09.2021 | 85 | Fruit  Fruit  Fruit | 0.44  0.30  0.35 | <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013 | 0  1  4 |

(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

\* Conversion factor for calculation of M650F003 to parent BAS 650 F is 1.2450. Conversion factor for calculation of M650F004 to parent BAS 650 F is 1.3292

* + - * 1. 2022/2041764

|  |  |
| --- | --- |
| Comments of zRMS: | The study has been accepted.  The objective of the study was to determine the magnitude of residues of Ametoctradin and its metabolites (M650F003, M650F004) as well as of Propamocarb in tomatoes after treatment with either BAS 743 00 F or BAS 743 03 F in 4 trials conducted under field conditions in Northern Europe. At each trial site, there was one untreated plot in addition to 2 treated plots. At each site the test item was applied 2 times 7-8 DBH and 1 DBH at a rate of 2.0 L/ha (240 g/ha Ametoctradin and 756 g/ha Propamocarb). Plot 2 was treated with BAS 743 00 F and plot 3 was treated with BAS 743 03 F.  For the determination of Propamocarb method L0450/01 was used. For the determination of Ametoctradin, M650F003, and M650F004 method L0078/01 was used. In both cases HPLC with tandem mass spectrometry was employed for final compounds determination. 2 mass transitions were monitored.  For the recoveries, the mean values were within the acceptable range of 70 % and 110 %, with a relative standard deviation (RSD) ≤ 20 %. No residues ≥ LOQ were found in any of the untreated control samples. The validation parameters required were within the acceptable range. |

|  |  |
| --- | --- |
| Reference: | CA 6.3.4/4 |
| Report | Study on the residue behaviour of Ametoctradin (BAS 650 F) and Propamocarb (Reg.No. 4628172) in tomato after application of either BAS 743 00 F or BAS 743 03 F under field conditions in Northern Europe, 2022  Plier, S. & Eysoldt, M., 2023  XXXX Study ID 921990, Study No. 22 47 GRU 0006  XXXX DocID 2022/2041764 |
| Guideline(s): | * + European Community Guideline 7029/VI/95 - rev.5, 22/07/97: General recommendations for the design preparation and realization of residue trials.   + European Commission guideline SANTE/2019/12752: Technical guidelines on Data Requirements for Setting Maximum Residue Levels, Comparability of Residue Trials and Extrapolation of Residue Data on Products from Plant and Animal Origin (Repealing and replacing SANCO 7525/VI/95 – Rev. 10.3)   + OECD Guideline for the testing of chemicals – Crop Field Trials: OECD/OCDE 509. Adopted 7 September 2009   + SANTE/2020/12830, Rev. 1   + OECD ENV/JM/MONO(2007)17 |
| Deviations: | Yes, none that affect the validity of the study |
| GLP: | Yes |
| Acceptability: | Yes | |

**Materials and methods**

In 2022, four independent field trials were conducted in NEU (Germany, northern France, Poland and The Netherlands) to support the use of BAS 650 F (ametoctradin) and BAS 9068 F (propamocarb) in tomato. In treatment plot 2, BAS 743 00 F (120 g/L of ametoctradin and 378 g/L of propamocarb) a suspension concentrate (SC) formulation, was foliar applied twice to tomatoes at a nominal rate of 2.0 L/ha, corresponding to 240 g/ha of ametoctradin and 756 g/ha of propamocarb. The first application was made 7 – 8 days before harvest (DBH) and the second application was made 1 DBH. In treatment plot 3, BAS 743 03 F (120 g/L of ametoctradin and 378 g/L of propamocarb) a suspension concentrate (SC) formulation, was foliar applied twice to tomatoes at a nominal rate of 2.0 L/ha, corresponding to 240 g/ha of ametoctradin and 756 g/ha of propamocarb. The first application was made 7 – 8 DBH and the second application was made 1 DBH. Tomato (fruit) samples were collected at 0, 1 and 2 – 4 days after the last application (DALA).

All samples were maintained frozen (≤ -18°C) at the testing facility, during shipping to the laboratory, and were stored frozen prior to analysis. The maximum storage interval for samples between harvest and analysis was 121 days (*ca* 4 months). Residues of ametoctradin, M650F003 and M650F004 have been shown to be stable in high water content crops for at least 24 months.

Residues of ametoctradin, M650F003 and M650F004 were determined using XXXX method no. L0078/02, a LC-MS/MS method. Acceptable concurrent recoveries were reported for tomato fruit, therefore demonstrating the suitability of the methods. The limit of quantification (LOQ) was 0.01 mg/kg per analyte. For metabolites M650F003 and M650F004 this is equivalent to 0.012 mg/kg and 0.013 mg/kg, respectively, expressed as parent (ametoctradin). Conversion factors of 1.245 and 1.32924 are applied to M650F003 and M650F004 to convert residues to ametoctradin.

**Table A 24: Summary of recoveries of ametoctradin, M650F003 and M650F004 in tomato**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Matrix** | **Fortification Level  [mg/kg]** | **Summary Recoveries** | | |
| **Method No. L0078/02** | | **Mean  [%]** | **RSD1) [%]** | **n2)** |
| Ametoctradin | | | | |
| Tomato fruit | 0.010, 0.10 and 1.0 | 80.8 | 5.1 | 18 |
| M650F003 | | | | |
| Tomato fruit | 0.010, 0.10 and 1.0 | 86.3 | 4.6 | 19 |
| M650F004 | | | | |
| Tomato fruit | 0.010, 0.10 and 1.0 | 86.9 | 7.4 | 19 |

1) RSD: Relative standard deviation

2) n: Number of results included in calculations

**Table A 25: Summary of the study 2022/2041764 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) expressed as parent\*** | | | **PHI (days)** | **Details on trial** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **g a.s./ ha** | **Water (l/ha)** | **g a.s./hl** | **BAS 650 F** | **M650F003** | **M650F004** |
|  | (a) | (b) |  |  |  | (c) |  |  |  |  |  | (d) | (e) |
| L220103 / 04827 Machern OT Gerichshain, Germany / NEU / 2022  (Plot 2) | Tomato / Hoffmanns Rentita | 1. 16.05.2022  2. 18.05.2022 – 02.08.2022  3. 21.07.2022 | 230  240 | 290  294 | 80  80 | 13.07.2022  20.07.2022 | 85 | Fruit  Fruit  Fruit | 0.073  0.099  0.061 | <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013 | 0  1  2 | XXXX method No. L0078/02 for BAS 650 F, M650F003, M650F004  LOQ = 0.01 mg/kg per analyte  Maximum storage interval (days): 121 |
| L220103 / 04827 Machern OT Gerichshain, Germany / NEU / 2022  (Plot 3) | Tomato / Hoffmanns Rentita | 1. 16.05.2022  2. 18.05.2022 – 02.08.2022  3. 21.07.2022 | 240  240 | 296  302 | 81  79 | 13.07.2022  20.07.2022 | 85 | Fruit  Fruit  Fruit | 0.070  0.14  0.065 | <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013 | 0  1  2 |
| L220104 / 5110 Aumenancourt, France / NEU / 2022  (Plot 2) | Tomato / Supersteak | 1. 27.05.2022  2. 15.07.2022 – 17.08.2022  3. 18.08.2022 | 230  230 | 287  283 | 80  80 | 09.08.2022  16.08.2022 | 84 | Fruit  Fruit  Fruit | 0.28  0.32  0.22 | <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013 | 0  1  2 |
| L220104 / 5110 Aumenancourt, France / NEU / 2022  (Plot 3) | Tomato / Supersteak | 1. 27.05.2022  2. 15.07.2022 – 17.08.2022  3. 18.08.2022 | 230  230 | 289  287 | 80  80 | 09.08.2022  16.08.2022 | 84 | Fruit  Fruit  Fruit | 0.28  0.33  0.29 | <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013 | 0  1  3 |
| L220105 / 64-606 Wychowaniec, Poland / NEU / 2022  (Plot 2) | Tomato / Dyno | 1. 15.05.2022  2. 15.06.2022 – 03.08.2022  3. 07.09.2022 | 260  250 | 326  316 | 80  80 | 30.08.2022  06.09.2022 | 84 | Fruit  Fruit  Fruit | 0.24  0.19  0.15 | <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013 | 0  1  3 |
| L220105 / 64-606 Wychowaniec, Poland / NEU / 2022  (Plot 3) | Tomato / Dyno | 1. 15.05.2022  2. 15.06.2022 – 03.08.2022  3. 07.09.2022 | 260  250 | 326  316 | 80  80 | 30.08.2022  06.09.2022 | 84 | Fruit  Fruit  Fruit | 0.19  0.11  0.083 | <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013 | 0  1  3 |
| L220106 / 6599 AV Ven-Zelerheide, The Netherlands / NEU / 2022  (Plot 2) | Tomato / Pannovy | 1. 16.05.2022  2. 10.06.2022 – 25.06.2022  3. 09.08.2022 | 240  250 | 293  310 | 80  80 | 01.08.2022  08.08.2022 | 85 | Fruit  Fruit  Fruit | 0.15  0.16  0.24 | <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013 | 0  1  4 |
| L220106 / 6599 AV Ven-Zelerheide, The Netherlands / NEU / 2022  (Plot 3) | Tomato / Pannovy | 1. 16.05.2022  2. 10.06.2022 – 25.06.2022  3. 09.08.2022 | 250  250 | 310  317 | 80  80 | 01.08.2022  08.08.2022 | 85 | Fruit  Fruit  Fruit | 0.17  0.17  0.21 | <0.012  <0.012  <0.012 | <0.013  <0.013  <0.013 | 0  1  4 |

(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

\* Conversion factor for calculation of M650F003 to parent BAS 650 F is 1.2450. Conversion factor for calculation of M650F004 to parent BAS 650 F is 1.3292

* + 1. Magnitude of residues in livestock
       1. Livestock feeding studies
          1. 2011/1036848

|  |  |
| --- | --- |
| Comments of zRMS: | The study has been accepted.  The study is extremely detailed allowing to trace all procedures. It was designed to determine BAS 650 F and its metabolites (M650F01 and M650FO6) residues in dairy cow tissues (liver, kidney, muscle, and fat), and milk, cream that occur after dietary exposure to the compound following oral administration to dairy cows for 28 consecutive days. The dairy cow was selected as the model animal for ruminants. The cows were subject to a veterinary exam and acceptance prior to acceptance on to study. The appearance and behaviour of the cows were assessed at least twice daily, and any abnormal details recorded. Only cows of normal health and non-pregnant were used on this study.  Appropriately labelled gelatine capsules were used to prepare the dose capsules. There was capsule for each animal per day, for 28 days. The dose amount had been calculated assuming each animal would consume 20 kg of feed a day (on a dry weight basis).  All 14 animals received one single dose capsule daily for 28 consecutive days, except for cow 10, which was sacrificed on Day 25, therefore only received 25 dose capsules. The appropriate capsule for each animal was placed in an appropriate dosing gun. There was a separate dosing gun for each group with a different dose level (the study according to the requirements should allow to test realistic (1x) and exaggerated (to 10x) modes of feeding). Animals were monitored briefly, to ensure the capsule had been swallowed.  The feed consumption for each group, over the dosing phase remained consistent. Animal weights remained stable over the course of the study. There was no evidence of any treatment effect on body weight. Milk yields observed during the study were summarized on a weekly basis in the study.  The concentrations of BAS 650 F in dose capsules were measured using Charles River Method No. 1718A. The mean recovery for found concentration vs weighed amount for all dose groups over the 4 weeks ranged from 86.7 - 113%. This confirms animals were accurately dosed at the target levels. LC-UV analytical method No. 1718A was validated in terms of suitability, accuracy, and precision as part of the study and it is suitable for the concentration determination of BAS 650 F in dose capsule.  To collect the samples all animals were sacrificed. All terminal procedures were also recorded in detail. Following sacrifice, samples of liver, kidney, fat (combined mesenterial, perirenal, and subcutaneous), and muscle (combined loin, flank, and diaphragm) were collected. Each tissue sample was chopped where necessary, weighed and the weight recorded to an accuracy of one gram. Tissue samples were placed in storage pails, labelled with study number, treatment group, animal number, matrix, and day. All tissue samples were frozen immediately at ca -20°C.  Milk was already collected twice daily. Whole milk, skim milk, and cream samples were stored frozen at approximately -20°C until analysis. All details of sampling procedure were recorded.  Then collected samples of milk, skim milk, cream, and tissues were analysed with LC-MS/MS based method L0104 (with recorded deviations) to determine BAS 650 F and the metabolites M650F01 and M650F06. 2 mass transitions were used for determination and confirmation. The method L0104 detailed procedure and conditions are presented within the study report.  During sampling and extraction, samples were stored at approximately -20 °C or lower. Storage stability was investigated in milk for a storage period of 41 days for BAS 650 F and M650F01 (34 days for M650F06) covering the longest interval between sampling and extraction of a sample observed in this feeding study.  The performed analysis of collected samples from cows that had been dosed with BAS 650 F for 28 days was shown no residues >LOQ for any dose group for milk, skim milk or cream.  At a realistic dose level (1x), residues were not detected for liver. One liver sample had a found residue >LOQ in the 3x dose group. No residues >LOQ were detected in kidney at the 3x dose level and in muscle and fat at the 10x dose level.  At an exaggerated dose level (10x) residues were found in liver and kidney, with highest residue levels in liver. Parent compound (BAS 650 F) accounted for none of the residues detected >LOQ with M650F01 and M650F06 detectable in both liver and kidney.  All results were expressed as parent equivalents and were not corrected for recovery. Recoveries were generally acceptable with average values ranging from 69.1 % for BAS 650 F. The average recovery for liver fortified at the LOQ (0.01 mg/kg) was <70%. The individual results were 68.6, 70.0, 70.3 and 67.3%. The data was considered acceptable as the overall mean over both fortified levels of liver was 71.0% and the RSD was low at 3.9%.  The recoveries for M650F01 were acceptable with average values ranging from 83.2 % to 96:8 %. Recoveries of M650F06 were acceptable with average values ranging from 80.6 % to 97.9%. The relative standard deviation was below +/-20% for all analytes indicating good performance of the method.  The fat content of cream samples was determined and ranged from 44.7% to 49.9%. The fat content of muscle samples was determined and ranged from 2.29% to 5.60% (with 1 exception of 0.501%).  The determination of total fat content in cream and muscle samples was performed according to Charles River Analytical Method No. 1718B. This analytical method was based on ISO 1443. This method is presented in the study. The principle of this method is a gravimetric determination of the fat obtained by soxhlet extraction with petroleum ether after acid hydrolysis.  As no residues >LOQ occurred in muscle or cream samples, no conclusion on the influence of fat content on residue levels could be drawn.  As it was mentioned already, residues were only detectable >LOQ in liver and kidney samples, consisted of the metabolites (M650F01 and M650F06) with the parent molecule not being detected >LOQ, but at the 10x dose level no residues >LOQ were detected after seven days, it can be concluded that BAS 650 F and its metabolites were eliminated rapidly from the liver and kidney. |

|  |  |
| --- | --- |
| Reference: | CA 6.4.2/1 |
| Report | XXXX (2011). Report Amendment 1: Magnitude of residues in milk and tissues of dairy cows following multiple oral administrations of BAS 650 F  Report Amendment 1 should be regarded as revised final report; with respect to the content it replaces the orginal find report XXXX DocID 2010/1201201593, December 2010.  CRL Report No. EU-31383, CRL Study No. EU-217180  XXXX Doc ID. 2011/1036848 |
| Guideline(s): | EEC 91/414, EEC 7031/VI/95 Appendix G, EPA 860.1460, OECD 505 (Jan. 2007), OECD ENV/JM/TG (2007) 1: Residue Analytical Methods, OECD Guidance Document: Overview for Residue Chemistry Studies (2006), SANCO/3029/99 rev. 4 (11 July 2000), SANCO/825/00 rev. 7 (17 March 2004) |
| Deviations: | No major deviation according to OECD 505 |
| GLP: | Yes  (certified by Department of Health of the Government of the United Kingdom, United Kingdom) |
| Acceptability: | Yes | |

**Executive summary**

In a dairy cow feeding study, Ametoctradin (BAS 650 F) was administered via gelatine capsule orally to groups of 3 Holstein lactating female dairy cows (with one control group of 3, fed empty gelatine capsules only) for 28 days. The highest dose group included 2 animals for depuration testing. The nominal daily doses per animal were 50 mg for the 1x level, 150 mg for the 3x level, and 500 mg for the 10x level. The actual dose levels were 3.11 mg/kg, 7.83 mg/kg and 30.3 mg/kg feed (DM) for the 1x, 3x and 10x dose level, respectively, equivalent to 0.0864, 0.218 and 0.862 mg/kg bw/day, respectively.

Milk samples from each animal were collected twice daily for 28 days and combined as one pooled sample. On day 21, milk was also separated into cream and skim milk. Animals were sacrificed within 25 h after the final morning dose and tissue samples were taken, except for two cows of the 10x group, which were sacrificed two and seven days after the final morning dose to determine residue decline. All samples were stored and shipped frozen and remained frozen until analysis.

The samples were analyzed for residues of Ametoctradin and metabolites M650F001 and M650F006 using XXXX method No L0104.

No residues above the limit of quantitation (LOQ; 0.03\* mg/kg) were found in milk, muscle, and fat at any dose level.

Residues above the limit of quantification (LOQ) were only detected in liver of the middle and high dose level (Groups 3 and 4) and in kidney of the highest dose level (Group 4) but these declined to <LOQ within 2 days of withdrawal of the test item.

**I. MATERIAL AND METHODS**

**A. MATERIALS**

**1. Test Material:**

**Description:** Ametoctradin (BAS 650 F)

**Lot/batch #:** COD-000748

**Purity:** 99.3%

**CAS#:**  865318-97-4

**Development code:** Not reported

**Spiking levels:** 0.01-0.1 mg/kg

**2. Test Commodity:** Bovine

**Species:** *Bos primigenius taurus*; Holstein/Friesian

**Gender:** Female

**Age:** Approx. 2-10 years

**Weight at dosing:** 420-728 kg

**Number of animals:** 11 treated, 3 control group

**Acclimation period:** 7 days

**Diet:** Meadow hay *ad libitum* (ca 12 kg/cow/day)

1x8.0 kg/cow/day concentrate ration

**Water:** Domestic mains quality water**,** *ad libitum*

**Housing:** Individual pens (5.3 m2), bedding of straw

**Husbandry:** A & A S Dunlop, Nether Southbar Farm, Inchinnan, UK, PA4 9NA

**Environmental conditions:**

**Temperature:** 11-27°C

**Humidity:** 41-98%

**Air changes:** Natural ventilation

**Photoperiod:** Natural photocycle

**B. STUDY DESIGN AND METHODS**

1. **Dosing regime:** Oral, by gelatin capsule, once daily

**Amount of dose:** Group I (3 animals): control group

Group II (3 animals): 3.11 mg/kg feed

0.0864 mg/kg bw/d Group III (3 animals): 7.83 mg/kg feed

0.218 mg/kg bw/dGroup IV (5 animals): 30.3 mg/kg feed

0.862 mg/kg bw/d

**Food consumption: ~**20 kg/day

**Vehicle:** Gelatin capsules

**Timing:** Once daily

**Duration:** 28 days

**Observations:** Appearance and behavior were observed at least twice daily. No health observations were thought to be as a result from receiving the test item. Cow 10 (group IV, 10x) was sacrificed on day 25 on welfare grounds (not associated with Ametoctradin feeding)

1. **Sample collection:**

**Milk collection:** Twice daily, -1, 1, 3, 5, 7, 10, 14, 17, 21, 24, 28, 30, 32 and 35- pooled on a daily basis

Skim milk/cream prepared from day 21

**Interval from last**

**Dose to sacrifice:** 23-25 hours

**Tissues collected and**

**Analyzed:** Liver (from distal portions of each lobe), kidney (entire organs), composite muscle (loin, hind leg, diaphragm), fat (perirenal, mesenteric, subcutaneous)

1. **Storage of samples:** Milk and tissue samples were stored frozen at or below -20°C and analyzed within 19 days
2. **Extraction and**

**Characterization**

**Analytical method & type:** XXXX method No L0104

(determination ofAmetoctradin and its metabolites M650F001 and M650F006. LOQ is 0.01 mg/kg for each analyte)

**5. Test procedure**

The purpose of the study was to determine the concentration of Ametoctradin and its metabolites M650F001 and M650F006 residues in dairy cow tissues (liver, kidney, muscle and fat, milk and cream) that occur after dietary exposure to the compound Ametoctradin.

The residue of Ametoctradin and its metabolites in dairy cattle was determined following repeated oral administration at three dose level. The in‑life phase of this study were performed by Charles River. For 28 days, lactating dairy cows were administered Ametoctradin at dose levels of 3.11 mg/kg (1x), 7.83 mg/kg (3x) and 30.3 mg/kg (10x) feed (DM). The daily dose was calculated assuming a feed intake of 20 kg dry matter each cow per day.

The analytical part of the study was performed by Charles River.

All samples were stored frozen at ‑20ºC.

**6. Description of analytical procedures**

Analysis of the samples was carried out according to XXXX method No L0104, which underwent Independent Laboratory Validation in Charles River.

Principle of the method: An aliquot of the sample was extracted with methanol/water (50/50, v/v). An aliquot thereof was taken for further work-up. The methanol extract was added to a portion of water/hydrochloric acid (100/0.2, v/v) before clean up on SPE (Strata X-C). The final elution solvent of acetonitrile/ammonia solution (95/5, v/v) was evaporated to dryness and reconstituted with methanol/water/formic acid (50/50/0.1, v/v/v). The final determination of the analytes Ametoctradin, M650F001 and M650F006 was performed by HPLC/MS/MS.

The limit of quantification (LOQ) of the method was 0.01 mg/kg for each analyte in all matrices.

**II. RESULTS AND DISCUSSION**

The efficiency of the method was determined by fortifying control samples of each matrix with Ametoctradin, M650F001 and M650F006. Results are shown in the table below.

| **Table A 26: Accuracy and precision data obtained during the study (procedural recoveries of freshly spiked samples)** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Analyte** | **Matrix** | **Fortification level (mg/kg)** | **Recovery** | | | |
| **Result/range (%)** | **Mean** | **RSD (%)** | **n** |
| BAS 650 F | Milk | 0.01 | 81.5, 116, 144\*, 99.9, 97.5, 86.5, 78.3, 68.3,94.3, 90.5, 124, 108, 119, 120, 80.6,106, 87.3, 85.3, 88.6, 162\* | 96.2 | 16.8 | 18 |
| 0.1 | 80.4, 85.9, 95.9, 75.8, 79.6, 88.9, 93.0, 78.6, 70.1, 81.2, 68.0, 78.9, 74.6, 74.6, 84.1, 93.5, 96.1, 85.1, 89.9, 93.5 | 83.4 | 10.3 | 20 |
| Overall | 68.0-120 | 89.8 | 13.6 | 38 |
| Cream | 0.01 | 68.3, 74.4 | 71.4 | N/A | 2 |
| 0.1 | 71.1, 73.9 | 72.5 | N/A | 2 |
| Overall | 68.3-74.4 | 72.0 | 3.9 | 4 |
| Skim milk | 0.01 | 82.3, 100, 78.2, 70.8 | 82.8 | 15.0 | 4 |
| 0.1 | 93.4, 62.9, 83.6, 79.2 | 79.8 | 15.9 | 4 |
| Overall | 62.9-100 | 81.3 | 14.4 | 8 |
| Muscle | 0.01 | 69.6, 71.9 | 70.8 | N/A | 2 |
| 0.1 | 74.4, 78.2 | 76.3 | N/A | 2 |
| Overall | 69.6-78.2 | 73.5 | 5.0 | 4 |
| Fat | 0.01 | 72.3, 77.4 | 74.9 | N/A | 2 |
| 0.1 | 79.2, 31.3\* | 79.2 | N/A | 1 |
| Overall | 72.3-79.2 | 76.3 | 4.7 | 3 |
| Liver | 0.01 | 68.6, 70.0, 70.3, 67.3 | 69.1 | 2.0 | 4 |
| 0.1 | 76.1, 72.8, 70.0, 72.6 | 72.9 | 3.4 | 4 |
| Overall | 67.3-76.1 | 71.0 | 3.9 | 8 |
| Kidney | 0.01 | 70.0, 71.2 | 70.6 | N/A | 2 |
| 0.1 | 78.5, 69.3 | 73.9 | N/A | 2 |
| Overall | 69.3-78.5 | 72.3 | 5.9 | 4 |
| M650F001 | Milk | 0.01 | 80.5, 81.9, 95.2, 82.0, 85.9, 104, 98.1, 78.3, 73.3, 70.0, 74.9, 85.6, 103, 73.7, 84.2, 84.8, 91.0, 95.2, 96.3, 107 | 87.2 | 12.6 | 20 |
| 0.1 | 91.7, 83.6, 106, 84.1, 86.6, 93.7, 93.5, 82.9, 61.6, 84.1, 60.4, 83.3, 97.4, 72.4, 86.3, 87.7, 91.0, 81.9, 88.4, 89.6 | 85.3 | 12.0 | 20 |
| Overall | 60.4-107 | 86.4 | 12.5 | 40 |
| Cream | 0.01 | 99.4, 94.1 | 96.8 | N/A | 2 |
| 0.1 | 92.8, 91.5 | 92.2 | N/A | 2 |
| Overall | 91.5-99.4 | 94.5 | 3.7 | 4 |
| Skim milk | 0.01 | 88.8, 95.9 | 92.4 | N/A | 2 |
| 0.1 | 95.1, 93.0 | 94.1 | N/A | 2 |
| Overall | 88.8-95.9 | 93.2 | 3.4 | 4 |
| Muscle | 0.01 | 84.2, 85.7 | 85.0 | N/A | 2 |
| 0.1 | 84.4, 89.7 | 87.1 | N/A | 2 |
| Overall | 84.2-89.7 | 86.0 | 3.0 | 4 |
| Fat | 0.01 | 89.6, 85.2 | 87.4 | N/A | 2 |
| 0.1 | 86.3, 36.7\* | 86.3 | N/A | 1 |
| Overall | 85.2-89.6 | 87.0 | 2.6 | 3 |
| Liver | 0.01 | 91.5, 90.3, 98.5, 94.2 | 93.6 | 3.9 | 4 |
| 0.1 | 91.5, 89.8, 88.8, 90.6 | 90.2 | 1.3 | 4 |
| Overall | 88.8-98.5 | 91.9 | 3.4 | 8 |
| Kidney | 0.01 | 83.6, 82.8 | 83.2 | N/A | 2 |
| 0.1 | 89.4, 79.8 | 84.6 | N/A | 2 |
| Overall | 79.8-89.4 | 83.9 | 4.8 | 4 |
| M650F006 | Milk | 0.01 | 78.1, 95.9, 86.4, 79.0, 87.9, 93.1, 86.8, 88.9, 80.0, 70.0, 80.1, 81.8, 86.4, 76.7, 84.5, 75.8, 88.5, 88.2, 91.3, 84.8 | 84.2 | 7.6 | 20 |
| 0.1 | 75.1, 85.7, 107, 89.1, 89.5, 100, 96.5, 85.8, 62.7, 75.3, 64.9, 83.8, 83.5, 78.9, 80.6, 82.5, 86.7, 83.4, 89.7, 94.7 | 84.8 | 12.6 | 20 |
| Overall | 62.7-107 | 84.5 | 10.3 | 40 |
| Cream | 0.01 | 96.5, 92.4 | 94.5 | N/A | 2 |
| 0.1 | 98.7, 97.0 | 97.9 | N/A | 2 |
| Overall | 92.4-98.7 | 96.2 | 2.8 | 4 |
| Skim milk | 0.01 | 96.4, 90.0 | 93.2 | N/A | 2 |
| 0.1 | 100, 88.9 | 94.5 | N/A | 2 |
| Overall | 88.9-100 | 93.8 | 5.6 | 4 |
| Muscle | 0.01 | 80.6, 83.5 | 82.1 | N/A | 2 |
| 0.1 | 80.7, 86.6 | 83.7 | N/A | 2 |
| Overall | 80.6-86.6 | 82.9 | 3.4 | 4 |
| Fat | 0.01 | 88.3, 83.8 | 86.1 | N/A | 2 |
| 0.1 | 84.7, 35.5\* | 84.7 | N/A | 1 |
| Overall | 83.8-88.3 | 87.0 | 2.6 | 3 |
| Liver | 0.01 | 91.4, 87.3, 100, 87.8 | 91.6 | 6.4 | 4 |
| 0.1 | 90.4, 86.9, 92.1, 86.1 | 88.9 | 3.2 | 4 |
| Overall | 86.1-100 | 91.9 | 3.4 | 8 |
| Kidney | 0.01 | 79.6, 83.5 | 81.6 | N/A | 2 |
| 0.1 | 86.0, 75.1 | 80.6 | N/A | 2 |
| Overall | 75.1-86.0 | 83.9 | 4.8 | 4 |

RSD Relative standard deviation

n Number of analysis

\* Excluded from all mean calculations

N/A Not applicable

Animals were dosed once daily by administering the target amounts in capsules. The dose levels for the study were set based on dietary burden calculations at the time of study conduct considering residues in grapes (grape pomace) from Australian residue trials, resulting in a dose level of approx. 44 mg/animal/day.

Based on these calculations, the dose levels in this study were set at a feeding level of 2.5 mg/kg feed (dry matter), corresponding to 50 mg/animal/day as 1x level, and 7.5 mg/kg feed (dry matter) for the 3x level and 25 mg/kg feed (dry matter) for the highest (10x) dose level (corresponding to 150 mg/animal in the 3x and 500 mg/animal in the 10x dose group). Actual dose levels are depicted in the table below.

| **Table A 27: Calculation of the actual dose levels of Ametoctradin** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Group** | **Cow** | **Nominal dose: mg/animal/day** | **Actual dose of BAS 650 F: mg/animal/day** | **Actual dose level: mg/kg bw** | **Actual dose level: mg/kg feed1** |
| I | 1 | 0 | 0 | 0 | 0 |
| 2 | 0 | 0 | 0 | 0 |
| 3 | 0 | 0 | 0 | 0 |
| **Average** | **0** | **0** | **0** | **0** |
| II | 4 | 50.0 | 50.6 | 0.0866 | 3.11 |
| 5 | 50.0 | 50.5 | 0.0875 | 3.11 |
| 6 | 50.0 | 50.5 | 0.0852 | 3.11 |
| **Average** | **50.0** | **50.5** | **0.0864** | **3.11** |
| III | 7 | 150.0 | 153 | 0.236 | 7.83 |
| 8 | 150.0 | 153 | 0.216 | 7.83 |
| 15 | 150.0 | 153 | 0.202 | 7.83 |
| **Average** | **150.0** | **153** | **0.218** | **7.83** |
| IV | 10 | 500.0 | 504 | 0.772 | 30.7 |
| 11 | 500.0 | 504 | 0.739 | 30.2 |
| 12 | 500.0 | 504 | 0.727 | 30.2 |
| 13 | 500.0 | 504 | 1.07 | 30.2 |
| 14 | 500.0 | 503 | 1.00 | 30.1 |
| **Average** | **500.0** | **504** | **0.862** | **30.3** |

1 Not corrected for purity of test item (99.3%)

Residues in milk, skim milk and cream

Residues in milk, skim milk and cream are summarized in the table below. No residues greater than the LOQ were detected in these matrices in any of the dose groups.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Table A 28: Summary of group mean residues in milk, skim milk and cream of Ametoctradin and its metabolites for dose level groups I and II** | | | | | | | | | |
|  | **Group mean (and maximum individual) BAS 650 F residues in milk1 (mg/kg)** | | | | | | | | |
| **Study day** | **Group I (control)** | | | | **Group II 1x (3.11 mg/kg)** | | | | |
| **BAS 650 F** | **M650F0012** | **M650F0063** | **Total residue4** | **BAS 650 F** | **M650F0012** | **M650F0063** | | **Total residue4** |
| **(mg/kg)** | **(mg/kg)** | **(mg/kg)** | **(mg/kg)** | **(mg/kg)** | **(mg/kg)** | **(mg/kg)** | | **(mg/kg)** |
| -1 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | | <0.01 (<0.01) | <0.03 (<0.03) |
| 1 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | | <0.01 (<0.01) | <0.03 (<0.03) |
| 3 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | | <0.01 (<0.01) | <0.03 (<0.03) |
| 5 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | | <0.01 (<0.01) | <0.03 (<0.03) |
| 7 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | | <0.01 (<0.01) | <0.03 (<0.03) |
| 10 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | | <0.01 (<0.01) | <0.03 (<0.03) |
| 14 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | | <0.01 (<0.01) | <0.03 (<0.03) |
| 17 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | | <0.01 (<0.01) | <0.03 (<0.03) |
| 21 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | | <0.01 (<0.01) | <0.03 (<0.03) |
| 24 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | | <0.01 (<0.01) | <0.03 (<0.03) |
| 28 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | | <0.01 (<0.01) | <0.03 (<0.03) |
| 305 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | | <0.01 (<0.01) | <0.03 (<0.03) |
| 325 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | | <0.01 (<0.01) | <0.03 (<0.03) |
| 355 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | | <0.01 (<0.01) | <0.03 (<0.03) |
| Skim milk (21 d) | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | | <0.01 (<0.01) | <0.03 (<0.03) |
| Cream (21 d) | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | | <0.01 (<0.01) | <0.03 (<0.03) |

1 As Ametoctradin equivalent

2 Factor for converting M650F001 residues in parent equivalents is 1.10

3 Factor for converting M650F006 residues in parent equivalents is 0.993

4 Sum of Ametoctradin and its metabolites after conversion to parent equivalent

5 Day of withdrawal (DOW) (depuration), 30 = 2 DOW, 32 = 4 DOW, 35 = 7 DOW

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Table A 29: Summary of group mean residues in milk, skim milk and cream of Ametoctradin and its metabolites for dose level groups III and IV** | | | | | | | | |
|  | **Group mean (and maximum individual) BAS 650 F residues in milk1 (mg/kg)** | | | | | | | |
| **Study day** | **Group III 3x (7.83 mg/kg)** | | | | **Group IV 10x (30.0 mg/kg)** | | | |
| **BAS 650 F** | **M650F0012** | **M650F0063** | **Total residue4** | **BAS 650 F** | **M650F0012** | **M650F0063** | **Total residue4** |
| -1 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (<0.03) |
| 1 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (<0.03) |
| 3 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (<0.03) |
| 5 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (<0.03) |
| 7 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (<0.03) |
| 10 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (<0.03) |
| 14 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (<0.03) |
| 17 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (<0.03) |
| 21 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (<0.03) |
| 24 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (<0.03) |
| 28 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (<0.03) |
| 305 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (<0.03) |
| 325 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (<0.03) |
| 355 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (<0.03) |
| Skim milk (21 d) | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (<0.03) |
| Cream (21 d) | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (0.03) | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (<0.03) |

1 As Ametoctradin equivalent

2 Factor for converting M650F001 residues in parent equivalents is 1.10

3 Factor for converting M650F006 residues in parent equivalents is 0.993

4 Sum of Ametoctradin and its metabolites after conversion to parent equivalent

5 Day of withdrawal (DOW) (depuration), 30 = 2 DOW, 32 = 4 DOW, 35 = 7 DOW

Residues in tissues (muscle, liver, fat and kidney)

A summary of residues in samples of muscle, liver, kidney and fat are depicted in Table A 38.

Muscle:

Group IV samples were analyzed (10x) and no residues above LOQ were detected. As no residues above LOQ occurred in group IV, samples from group I-III and from depuration were not analyzed.

Liver:

No residues were detected at the 1x dose level. In the 3x dose level group M650F006 was found in only one sample (0.0152 mg/kg). Total residues ranged from <0.03-0.0351 mg/kg with an average of 0.0317 mg/kg. In dose level group IV (10x), M650F001 and M650F006 were found at an average of 0.0208 and 0.0405 mg/kg, respectively. The mean total residue in dose group IV accounted for 0.0731 mg/kg. After two and seven days of withdrawal, the residues were below LOQ or none detected.

Kidney:

No residues were detected in dose level group III (3x), thus samples of the low dose group II (1x) were not analyzed. The residues in dose level group IV (10x) of metabolites M650F001 and M650F006 ranged from <0.01-0.0105 mg/kg and 0.0118-0.0270 mg/kg, respectively. Total residues ranged from 0.0333-0.0478 mg/kg with an average of 0.0389 mg/kg. After two and seven days of withdrawal, the residues were below LOQ or none detected.

Fat:

Only Group IV samples were analyzed (10x) and no residues above LOQ were detected.

| **Table A 30: Summary of group mean tissue results (1x, 3x, 10x dose groups and depuration)** | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Matrix** | **Dose**  **group** | **Number of animals in group** | **Actual dose level** | | **Mean residue (and maximum individual) (mg/kg)1** | | | |
| **mg/kg in dry feed** | **mg/kg**  **b.w./day** | **BAS 650 F** | **M650F0012** | **M650F0063** | **Total residue4** |
| **Muscle** | I (control) | 1 | 0 | 0 | n.a. | n.a. | n.a. | n.a. |
| II (1x) | 3 | 3.11 | 0.0864 | n.a. | n.a. | n.a. | n.a. |
| III (3x) | 3 | 7.83 | 0.218 | n.a. | n.a. | n.a. | n.a. |
| IV (10x) | 3 | 30.3 | 0.862 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (<0.03) |
| **Fat** | I (control) | 1 | 0 | 0 | n.a. | n.a. | n.a. | n.a. |
| II (1x) | 3 | 3.11 | 0.0864 | n.a. | n.a. | n.a. | n.a. |
| III (3x) | 3 | 7.83 | 0.218 | n.a. | n.a. | n.a. | n.a. |
| IV (10x) | 3 | 30.3 | 0.862 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (<0.03) |
| **Liver** | I (control) | 1 | 0 | 0 | <0.01 | n.d. | n.d. | <0.03 |
| II (1x) | 3 | 3.11 | 0.0864 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (<0.03) |
| III (3x) | 3 | 7.83 | 0.218 | <0.01 (<0.01) | <0.01 (<0.01) | 0.0117 (0.0152) | 0.0317 (0.0351) |
| IV (10x) | 3 | 30.3 | 0.862 | <0.01 (<0.01) | 0.0208 (0.0399) | 0.0405 (0.0474) | 0.0731 (0.0965) |
| IV (depuration) | 1 | 30.3 | 0.862 | <0.01 | <0.01 | <0.01 | <0.03 |
| 1 | 30.3 | 0.862 | <0.01 | n.d. | n.d. | <0.03 |
| **Kidney** | I (control) | 1 | 0 | 0 | n.a. | n.a. | n.a. | n.a. |
| II (1x) | 3 | 3.11 | 0.0864 | n.a. | n.a. | n.a. | n.a. |
| III (3x) | 3 | 7.83 | 0.218 | <0.01 (<0.01) | <0.01 (<0.01) | <0.01 (<0.01) | <0.03 (<0.03) |
| IV (10x) | 3 | 30.3 | 0.862 | <0.01 (<0.01) | 0.0102 (0.0105) | 0.0182 (0.0270) | 0.0389 (0.0478) |
| IV (depuration) | 1 | 30.3 | 0.862 | <0.01 | <0.01 | <0.01 | <0.03 |
| 1 | 30.3 | 0.862 | <0.01 | n.d. | n.d. | <0.03 |

1 As Ametoctradin equivalent

2 Factor for converting M650F001 residues in parent equivalents is 1.10

3 Factor for converting M650F006 residues in parent equivalents is 0.993

4 Sum of Ametoctradin and its metabolites after conversion to parent equivalent

n.a. Not analyzed. Since no residues were detected in group IV, group I-III and IV (depuration) were not analyzed

n.d. Not detected

**Storage stability of samples**

Storage stability was investigated in milk for a storage period of 41 days, covering the longest interval between sampling and extraction of a sample. The maximum time interval from sampling to extraction in cream, skim milk, muscle, liver, kidney and fat was ≤19 days. As trial samples were always analyzed within 30 days of their storage in frozen conditions, conducting a freezer storage stability study was not mandatory.

During the course of this study, set of milk samples were fortified individually with each reference item and stored frozen for a period of 41 days for Ametoctradin and M650F001 and for a period of 34 days for M650F006. Each set consisted of 2 unfortified controls and 3 fortified at 0.1 mg/kg. Under the chosen conditions, no noticeable change in the stability of the analytes could be observed.

**III. CONCLUSION**

Milk and tissue samples from cows that had been dosed for a period of 28 days with Ametoctradin (BAS 650 F) were analyzed according to XXXX method No L0104. In milk, skim milk and cream no residues of Ametoctradin or its metabolites M650F001 and M650F006 were found above LOQ.

In liver for the 3x and 10x dose level groups mean values were detected with 0.0317 and 0.0731 mg/kg, respectively. Mean values of 0.0389 mg/kg for the 10x dose level group were determined in kidney.

**Assessment and conclusion**

|  |
| --- |
| **Assessment and conclusion by applicant:**  The study assessing the residue of Ametoctradin and its metabolites in bovine (dairy cattle) milk and tissues (fat, muscle, liver, kidney) has been performed under GLP and has not been previously evaluated at EU level. The study is considered to be acceptable for determining the level of Ametoctradin and its metabolites M650F001 and M650F006 residue that may transfer from bovine diet to milk and edible bovine tissues. The study is deemed to comply with current requirements as laid down in Reg (EU) No 283/2013 and OECD Guideline for Testing of Chemicals, 505 and OECD Guidance Document on Residues in Livestock (Series on Pesticides No. 73) with a minor deficit in the time of sacrifice after the last administered dose, which exceed the maximum time by <1 h (47 min).  Nevertheless, this study is considered valid and acceptable. |

* + 1. Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)
       1. Distribution of the residue in peel/pulp

No new data submitted in the framework of this application.

* + - 1. Processing studies on a core set of representative processes

No new data submitted in the framework of this application.

* + 1. Magnitude of residues in representative succeeding crops
       1. 2020/2030949

|  |  |
| --- | --- |
| Comments of zRMS: | The study has been accepted.  During the growing season of 2020 - 2021 4 trials were conducted. 2 in NEU and 2 in SEU. The objective was to determine the magnitude of residues of Ametoctradin in the field rotational crops (strawberries, leek, oilseed rape and tomato) after one application of BAS 650 00 F to bare soil 30 ±1 and 120 ±3 days before seeding/planting. The metabolites (M650F003 and M650F004) were also determined. Furthermore, bare soil specimens (0-20 cm) were analysed for BAS 650 F, M650F001, M650F002, M650F003 and M650F004. Application verification specimens (Petri dishes) were analysed for BAS 650 F.  For the analysis of BAS 650 F, M650F003 and M650F004 in plant matrices the method No. L0078/01 was used which determines the analytes by means of LC-MS/MS. Validation of method L0078/01 was performed on plant matrices in a separate study. For the analysis of BAS 650 F, M650F001, M650F002, M650F003 and M650F004 in soil was the method L0091/03 used. The residues are determined using LC-MS/MS. Validation of method L0091/03 was performed in a separate study.  The validation parameters in the study were within the acceptable range. |

|  |  |
| --- | --- |
| Reference: | CA 6.6.2 / 01 |
| Report: | Erdmann, H-P. (2022); Study on the residue behaviour BAS 650 F (Ametoctradin) on the rotational crops: strawberries, leek, oilseed rape, and tomato after one application of BAS 650 00 F to bare soil 30 and 120 days prior planting/seeding under field conditions in Northern and Southern Europe, 2020-2021  XXXX Study ID. 897458  Lab Study No. AC/XXXX/20/11  XXXX Doc ID. 2020/2030949 |
| Guideline(s): | 7029/VI/95 – rev.5  SANCO 7525/VI/95 – Rev. 10.3  OECD 509 (2009)  OECD 504 (2007)  ENV/JM/MONO(2018)9 |
| Deviations: | Yes, None that impact the validity of the study |
| GLP: | Yes |
| Validity of the study: | The study is considered scientifically acceptable and is considered acceptable and reliable. |
| Acceptability: | Yes |

*Materials and methods*

|  |  |
| --- | --- |
| **Test Material** | BAS 650 00 F (Suspension concentrate formulation containing ametoctradin) |
| **Lot/Batch #:** | FRE-001902  FRE-001964 |
| **Active substance content (%):** | Ametoctradin 200 g/L |

**Study Design and Methods**

Test facility: SGS INSTITUT FRESENIUS GmbH, Tannustein, Germany

Study start date: 13 Mar 2020

Study end date: 11 Aug 2022

Fourfield trials for ametoctradin on rotational crops were conducted: two trials in Northern Europe (Germany and The Netherlands) and two trials in Southern Europe (Italy and Spain) during the 2020 – 2021 growing season. All trials are independent.

In each trial, a single application of ametoctradin was made using a suspension concentrate (SC) formulation (BAS 605 00 F) containing 200 g ametoctradin per L to bare soil. The application was at a nominal rate of 960 g a.s/ha. No adjuvant was used in any of the applications.

Two representative fruit and fruiting vegetables (strawberries and tomatoes), a bulb and stem vegetable (leek) and an oilseed (oilseed rape seed) were planted as rotated crops. All crops were planted into a treated plot at plant-back intervals (PBIs) of 29-30 and 117-121 days. The rotational crops were grown under field conditions and harvested at immature (leek and oilseed rape only) and mature growth stages. Crops harvested at immature stages were leek (whole plant no roots) at BBCH 41 and oilseed rape (whole plant no roots) at BBCH 55-59. All crops were harvested at maturity: strawberry (fruits) at BBCH 85-87, leek (whole plant no roots) at BBCH 49, oilseed rape (seeds and rest of plant no roots) at BBCH 89, and tomato (fruits) at BBCH 81-83.

Soil samples were collected at 0 DALA and at seeding/planting.

Further details are presented in the following tables.

**Crop information**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Trial Location (City, Province or State Country /Year)** | **Crop/crop group** | **Variety** | **Growth stage at harvest**  **(BBCH code)** | **Harvested RAC** |
| Trial No. L200258  (Brandenburg, Germany/2020-2021) | Strawberry/fruits and fruiting vegetables | Darselect / Rumba | BBCH 85-87 | Fruits |
| Tomato/fruits and fruiting vegetables | Pannovy / Super Sweet | BBCH 81-83 | Fruits |
| Leek/bulb and stem vegetables | Krypton / Vitaton | BBCH 41 | Whole plant no roots |
| BBCH 49 | Whole plant no roots |
| Oilseed rape/oilseeds | Mirakel / SY Florida | BBCH 55-59 | Whole plant no roots |
| BBCH 89 | Seeds, rest of plant no roots |
| Trial No. L200259  (Limburg/Gennep, The Netherlands/2020-2021) | Strawberry/fruits and fruiting vegetables | Elsanta A+ | BBCH 85-87 | Fruits |
| Tomato/fruits and fruiting vegetables | Pannovy | BBCH 81-83 | Fruits |
| Leek/bulb and stem vegetables | Krypton | BBCH 41 | Whole plant no roots |
| BBCH 49 | Whole plant no roots |
| Oilseed rape/oilseeds | ABILITY | BBCH 57-59 | Whole plant no roots |
| BBCH 89 | Seeds, rest of plant no roots |
| Trial No. L200260  (Piedmont/Cuneo, Italy/2020-2021) | Strawberry/fruits and fruiting vegetables | Portola / Aprica | BBCH 85-87 | Fruits |
| Tomato/fruits and fruiting vegetables | Roma Ovale Diabolik / Heinz 3406 F1 | BBCH 81-83 | Fruits |
| Leek/bulb and stem vegetables | F1 Columbus / Porro Lungo di Riviera | BBCH 41 | Whole plant no roots |
| BBCH 49 | Whole plant no roots |
| Oilseed rape/oilseeds | Delight / Golden KWS | BBCH 55-59 | Whole plant no roots |
| BBCH 89 | Seeds, rest of plant no roots |
| Trial No. L200261  (Andalusia/Sevilla, Spain /2020-2021) | Strawberry/fruits and fruiting vegetables | San Andreas | BBCH 87 | Fruits |
| Tomato/fruits and fruiting vegetables | H-1015 | BBCH 83 | Fruits |
| Leek/bulb and stem vegetables | Duraton / Lexton | BBCH 41 | Whole plant no roots |
| BBCH 49 | Whole plant no roots |
| Oilseed rape/oilseeds | PR45H73 | BBCH 55-57 | Whole plant no roots |
| BBCH 89 | Seeds, rest of plant no roots |

**Trial site conditions**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Trial Location (City, Province or State Country /Year)** | **Soil characteristics** | | | | **Meteorological data** | |
| **Type** | **% TOC** | **pH** | **CEC (mval Ba/100g)** | **Average monthly rainfall1 (mm)** | **Average temperature1 (°C)** |
| Trial No. L200258  (Brandenburg, Germany/2020-2021) | S12 poor loamy sand | 0.8 | 6.24 | 6.5 | Min. 8.4  Max. 95.0 | Min. 0.5  Max. 20.9 |
| Trial No. L200259  (Limburg/Gennep, The Netherlands/2020-2021) | S12 poor loamy sand | 2.0 | 6.35 | 12.9 | Min. 6.2  Max. 93.0 | Min. 3.0  Max. 21.2 |
| Trial No. L200260  (Piedmont/Cuneo/Italy/2020-2021) | UIs sandy loamy silt | 1.7 | 7.66 | 16.4 | Min. 4  Max. 150 | Min. 0.8  Max. 24.3 |
| Trial No. L200261  (Andalusia/Sevilla, Spain/2020-2021) | St2 poor clay sand | 0.6 | 7.63 | 4.7 | Min. 0.0  Max. 96.4 | Min. 9.5  Max. 26.7 |
| 1 Between 03/2020 and 08/2021 | | | | | | |

**Application and use pattern of end-use product A8637C**

|  |  |  |  |
| --- | --- | --- | --- |
| **Trial Location (City, Province or State Country /Year)** | **Method/ Timing** | **Actual Rate**  **(kg ai/ha)** | **Tank mix adjuvants** |
| Trial No. L200258  (Brandenburg, Germany/2020-2021) | Spray/Pre-planting | Plot 2/subplot 1,4: 0.937 | None |
| Plot 2/subplot 2,3: 0.953 |
| Plot 4/subplot 1: 0.868 |
| Plot 4/subplot 2: 0.953 |
| Plot 4/subplot 3: 0.937 |
| Plot 4/subplot 4: 0.868 |
| Trial No. L200259  (Limburg/Gennep, The Netherlands/2020-2021) | Spray/Pre-planting | Plot 2/subplot 1,4: 0.973 | None |
| Plot 2/subplot 2,3: 1.037 |
| Plot 4/subplot 1, 2: 0.980 |
| Plot 4/subplot 3: 0.979 |
| Plot 4/subplot 4: 0.976 |
| Trial No. L200260  (Piedmont/Cuneo, Italy/2020-2021) | Spray/Pre-planting | Plot 2/subplot 1: 0.898 | None |
| Plot 2/subplot 2: 1.008 |
| Plot 2/subplot 3: 0.869 |
| Plot 2/subplot 4: 0.949 |
| Plot 4/subplot 1: 0.911 |
| Plot 4/subplot 2: 0.976 |
| Plot 4/subplot 3: 1.048 |
| Plot 4/subplot 4: 0.976 |
| Trial No. L200261  (Andalusia/Sevilla, Spain/2020-2021) | Spray/Pre-planting | Plot 2/subplot 1: 0.924 | None |
| Plot 2/subplot 2: 0.915 |
| Plot 2/subplot 3: 0.988 |
| Plot 2/subplot 4: 0.915 |
| Plot 4/subplot 1, 2, 3: 0.937 |
| Plot 4/subplot 4: 0.960 |

**Sowing/planting details**

|  |  |  |
| --- | --- | --- |
| **Trial Location (City, Province or State Country /Year)** | **Date** | **Crop** |
| Trial No. L200258  (Brandenburg, Germany/2020-2021) | 19/05/2020 (PBI 29 days)  13/07/2020 (PBI 120 days) | Strawberry |
| 15/04/2020 (PBI 29 days)  13/07/2020 (PBI 118 days) | Leek |
| 15/04/2020 (PBI 29 days)  19/08/2020 (PBI 121 days) | Oilseed rape |
| 19/05/2020 (PBI 29 days)  25/05/2021 (PBI 119 days) | Tomato |
| Trial No. L200259  (Limburg/Gennep, The Netherlands/2020-2021) | 13/05/2020 (PBI 29 days)  28/07/2020 (PBI 120 days) | Strawberry |
| 28/04/2020 (PBI 29 days)  28/07/2020 (PBI 120 days) | Leek |
| 28/04/2020 (PBI 29 days)  29/03/2021 (PBI 117 days) | Oilseed rape |
| 13/05/2020 (PBI 29 days)  17/05/2021 (PBI 119 days) | Tomato |
| Trial No. L200260  (Piedmont/Cuneo, Italy/2020-2021) | 16/04/2020 (PBI 30 days)  27/08/2020 (PBI 120 days) | Strawberry |
| 21/05/2020 (PBI 29 days)  10/05/2021 (PBI 117 days) | Leek |
| 11/04/2020 (PBI 29 days)  28/09/2020 (PBI 117 days) | Oilseed rape |
| 22/05/2020 (PBI 30 days)  10/05/2021 (PBI 117 days) | Tomato |
| Trial No. L200261  (Andalusia/Sevilla, Spain/2020-2021) | 16/10/2020 (PBI 30 days)  16/10/2020 (PBI 120 days) | Strawberry |
| 14/04/2020 (PBI 29 days)  16/10/2020 (PBI 120 days) | Leek |
| 16/10/2020 (PBI 30 days)  16/10/2020 (PBI 120 days) | Oilseed rape |
| 14/04/2020 (PBI 29 days)  21/03/2021 (PBI 120 days) | Tomato |

All samples were maintained frozen (-18°C) at the testing facility, during shipping to the laboratory, and were stored frozen for a maximum of *ca.* 13 months until analysis (one sample of oilseed rape whole plant was re-analysed after 18 months of storage). Storage stability of ametoctradin, M650F003 and M650F004 under these conditions has been demonstrated for a period of at least 24 months in high-water commodities and at least 16 months in high-acid commodities (EFSA, 2020). New storage stability data in high oil commodities are included in study 2022/2006182 (see Appendix C.3.5), which demonstrates ametoctradin, M650F003 and M65F004 are stable for at least 12 months under frozen conditions (-18°C). Adequate storage stability data are therefore available to support the storage conditions and intervals for these rotational crop samples.

Samples were analysed using XXXX method L0078/01, an LC-MS/MS method to determine residues of ametoctradin, M650F003 and M650F004. Acceptable concurrent recoveries were reported for strawberry (fruits), leek (whole plant no roots), oilseed rape (whole plant no roots, rest of plant no roots and seeds) and tomato (fruits) at fortification levels of 0.01 mg/kg and 0.10 mg/kg. Additionally, acceptable recoveries were reported for oilseed rape (rest of plant no roots) at a fortification level of 1.0 mg/kg. Thus validating the method. The limit of quantification (LOQ) was 0.01 mg/kg, 0.012 mg/kg and 0.013 mg/kg for ametoctradin, M650F003 and M65F004, respectively.

Soil specimens were analysed for ametoctradin, M650F001, M650F002, M65F003 and M650F004 using XXXX analytical method L0091/03. Acceptable concurrent recoveries were reported at 0.01 mg/kg and 0.10 mg/kg. Thus validating the method. The limit of quantification (LOQ) was 0.01 mg/kg per analyte.

**Fortification and recovery**

**Ametoctradin**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Matrix** | **Fortification level (mg/kg)** | **Sample size (n)** | **Recoveries (%)** | **Mean recovery (%)** | **RSD (%)** |
| Strawberry (fruit) | 0.01 | 7 | 95.7, 96.7, 97.0, 99.3, 99.3, 100, 101 | - | - |
| 0.10 | 7 | 94.6, 95.4, 97.1, 97.9, 97.8, 98.2, 98.3 | - | - |
| Overall | 14 |  | 97.8 | 1.9 |
| Leek (whole plant no roots) | 0.01 | 5 | 89.1, 91.1, 95.0, 96.0, 96.3 | - | - |
| 0.10 | 5 | 90.4, 91.5, 91.9, 92.2, 93.5 | - | - |
| Overall | 10 |  | 92.7 | 2.6 |
| Oilseed Rape (whole plant no roots) | 0.01 | 6 | 83.2, 83.9, 85.2, 85.9, 87.2, 99.0 | - | - |
| 0.10 | 6 | 87.9, 90.2, 90.8, 90.9, 92.2, 92.4 | - | - |
| Overall | 12 |  | 89.1 | 5.0 |
| Oilseed Rape (seed) | 0.01 | 6 | 78.8, 78.9, 79.9, 80.4, 82.1, 85.9 | - | - |
| 0.10 | 6 | 84.0, 84.4, 84.4, 85.4, 85.7, 85.8 | - | - |
| Overall | 12 |  | 83.0 | 3.4 |
| Oilseed Rape (rest of plant no roots) | 0.01 | 7 | 80.8, 83.2, 83.6, 83.9, 84.8, 86.6, 87.3 | - | - |
| 0.10 | 6 | 90.7, 91.1, 91.3, 92.2, 92.5, 94.7 | - | - |
| 1.0 | 1 | 85.6 | - | - |
| Overall | 14 |  | 87.7 | 4.9 |
| Tomato (fruit) | 0.01 | 6 | 85.6, 87.6, 88.5, 92.3, 93.4, 95.3 | - | - |
| 0.10 | 6 | 91.4, 91.9, 92.4, 93.0, 93.3, 94.5 | - | - |
| Overall | 12 |  | 91.6 | 3.2 |
|  | | | | | |

**M650F003**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Matrix** | **Fortification level (mg/kg)** | **Sample size (n)** | **Recoveries (%)** | **Mean recovery (%)** | **RSD (%)** |
| Strawberry (fruit) | 0.01 | 7 | 89.0, 94.6, 95.2, 97.1, 98.8, 100, 109 | - | - |
| 0.10 | 7 | 95.5, 97.3, 97.6, 98.8, 99.1, 101, 101 | - | - |
| Overall | 14 |  | 98.2 | 4.6 |
| Leek (whole plant no roots) | 0.01 | 5 | 86.7, 89.1, 89.2, 98.9, 108 | - | - |
| 0.10 | 5 | 93.7, 94.5, 95.0, 98.4 | - | - |
| 1.0 | 1 | 91.4 | - | - |
| Overall | 10 |  | 94.5 | 6.6 |
| Oilseed Rape (whole plant no roots) | 0.01 | 6 | 86.7, 86.9, 87.7, 87.9, 90.6, 92.7 | - | - |
| 0.10 | 6 | 93.3, 93.4, 94.0, 95.1, 95.5, 95.7 | - | - |
| Overall | 12 |  | 91.6 | 3.8 |
| Oilseed Rape (seed) | 0.01 | 6 | 89.0, 89.2, 92.0, 92.1, 98.1, 99.2 | - | - |
| 0.10 | 6 | 94.4, 95.3, 95.8, 97.2, 97.4, 98.5 | - | - |
| Overall | 12 |  | 94.8 | 3.8 |
| Oilseed Rape (rest of plant no roots) | 0.01 | 7 | 91.5, 93.1, 94.3, 94.9, 96.6, 101, 104 | - | - |
| 0.10 | 6 | 90.3, 95.4, 96.1, 96.4, 98.2, 100 | - | - |
| 1.0 | 1 | 78.4 | - | - |
| Overall | 14 |  | 95.0 | 6.3 |
| Tomato (fruit) | 0.01 | 6 | 85.2, 85.6, 87.0, 88.0, 88.1, 94.0 | - | - |
| 0.10 | 6 | 93.9, 94.4, 94.7, 95.5, 96.1, 97.5 | - | - |
| Overall | 14 |  | 91.7 | 4.9 |
|  | | | | | |

**M650F004**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Matrix** | **Fortification level (mg/kg)** | **Sample size (n)** | **Recoveries (%)** | **Mean recovery (%)** | **RSD (%)** |
| Strawberry (fruit) | 0.01 | 7 | 81.6, 94.5, 94.6, 96.5, 96.6, 98.1, 107 | - | - |
| 0.10 | 7 | 96.6, 97.3, 98.9, 98.9, 99.0, 100, 101 | - | - |
| Overall | 14 |  | 97.2 | 5.6 |
| Leek (whole plant no roots) | 0.01 | 5 | 90.9, 91.0, 98.0, 98.4, 98.7 | - | - |
| 0.10 | 5 | 94.5, 94.8, 94.9, 95.1, 97.1 | - | - |
| Overall | 10 |  | 95.3 | 2.9 |
| Oilseed Rape (whole plant no roots) | 0.01 | 6 | 83.4, 84.5, 86.7, 88.0, 89.5, 90.8 | - | - |
| 0.10 | 6 | 92.6, 95.2, 95.6, 96.8, 97.9, 98.5 | - | - |
| Overall | 12 |  | 91.6 | 5.7 |
| Oilseed Rape (seed) | 0.01 | 6 | 91.5, 96.7, 97.7, 98.4, 100, 106 | - | - |
| 0.10 | 6 | 92.8, 94.4, 95.3, 97.1, 97.3, 101 | - | - |
| Overall | 12 |  | 97.3 | 4.0 |
| Oilseed Rape (rest of plant no roots) | 0.01 | 7 | 86.0, 87.2, 88.9, 90.0, 93.9, 99.8, 106 | - | - |
| 0.10 | 6 | 94.1, 94.1, 96.4, 98.8, 98.9, 101 | - | - |
| 1.0 | 1 | 96.4 | - | - |
| Overall | 14 |  | 95.1 | 5.9 |
| Tomato (fruit) | 0.01 | 6 | 81.6, 84.6, 90.3, 91.5, 92.0, 99.7 | - | - |
| 0.10 | 6 | 95.2, 95.7, 95.8, 95.8, 96.6, 99.0 | - | - |
| Overall | 12 |  | 93.2 | 5.9 |
|  | | | | | |

**Recoveries in soil**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Matrix** | **Fortification level (mg/kg)** | **Sample size (n)** | **Recoveries (%)** | **Mean recovery (%)** | **RSD (%)** |
| Ametoctradin | 0.01 | 5 | 99.3, 105, 106, 107, 109 |  |  |
| 0.10 | 5 | 96.2, 96.4, 97.2, 99.0, 99.0 |  |  |
| Overall | 10 |  | 101 | 4.7 |
| M650F001 | 0.01 | 5 | 92.5, 94.8, 95.9, 102, 109 |  |  |
| 0.10 | 5 | 95.0, 97.0, 98.0, 103, 104 |  |  |
| Overall | 10 |  | 99.1 | 5.3 |
| M650F002 | 0.01 | 5 | 87.2, 88.5, 90.2, 91.2, 94.8 |  |  |
| 0.10 | 5 | 95.0, 95.0, 97.6, 103, 106 |  |  |
| Overall | 10 |  | 94.8 | 6.4 |
| M650F003 | 0.01 | 5 | 88.4, 89.7, 91.4, 96.1, 96.2 |  |  |
| 0.10 | 5 | 95.7, 95.8, 98.5, 100, 109 |  |  |
| Overall | 10 |  | 96.1 | 6.1 |
| M650F004 | 0.01 | 5 | 82.5, 86.2, 91.2, 92.4, 100 |  |  |
| 0.10 | 5 | 92.3, 94.6, 96.1, 104, 107 |  |  |
| Overall |  |  | 94.7 | 8.1 |

**Results**

Details of the trials, the individual samples and the analytical residue results obtained are summarised in the following table.

**Residues of ametoctradin in rotational crops**

| **Trial No./**  **Location/**  **Year** | **Commodity** | **PBI** | **Harvest** | | **Portion analysed** | **Residues (mg/kg)** | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Days** | **DALA** | **BBCH** | **Ametoctradin** | **M650F003**  **(expressed as parent)(a)** | **M650F004**  **(expressed as parent)(b)** | |
| Trial No. L200258  (Brandenburg, Germany/2020-2021) | Strawberry | 29 | 79 | BBCH 85-87 | Fruits | ND | 0.019 | <0.013 | |
| 120 | 162 | BBCH 85-87 | Fruits | ND, ND, ND | 0.022, 0.025, 0.024 | 0.052, 0.056, 0.054 | |
| Leek | 29 | 84 | BBCH 41 | Whole plant no roots | ND | 0.014 | <0.013 | |
| 29 | 105 | BBCH 49 | Whole plant no roots | ND | <0.012 | <0.013 | |
| 118 | 155 | BBCH 41 | Whole plant no roots | ND | 0.013 | 0.023 | |
| 118 | 209 | BBCH 49 | Whole plant no roots | ND | ND | <0.013 | |
| Oilseed rape | 29 | 80 | BBCH 55-59 | Whole plant no roots | ND | ND | ND | |
| 29 | 136 | BBCH 89 | Seeds | ND | ND | ND | |
| 29 | 136 | BBCH 89 | Rest of plant no roots | ND | 0.021 | ND | |
| 121 | 359 | BBCH 55-57 | Whole plant no roots | ND | <0.012 | ND | |
| 121 | 451 | BBCH 89 | Seeds | ND | ND | ND | |
| 121 | 451 | BBCH 89 | Rest of plant no roots | ND | 0.017 | 0.027 | |
| Tomato | 29 | 109 | BBCH 81-83 | Fruits | ND | 0.017 | ND | |
| 119 | 191 | BBCH 81-83 | Fruits | ND | <0.012 | ND | |
| Trial No. L200259  (Limburg/Gennep, The Netherlands/2020-2021) | Strawberry | 29 | 77 | BBCH 85-87 | Fruits | ND | 0.034 | <0.013 | |
| 120 | 165 | BBCH 85-87 | Fruits | ND | 0.021 | <0.013 | |
| Leek | 29 | 77 | BBCH 41 | Whole plant no roots | ND | 0.025 | ND | |
| 29 | 112 | BBCH 49 | Whole plant no roots | ND | 0.013 | ND | |
| 120 | 172 | BBCH 41 | Whole plant no roots | ND | <0.012 | <0.013 | |
| 120 | 235 | BBCH 49 | Whole plant no roots | ND | ND | ND | |
| Oilseed rape | 29 | 77 | BBCH 59 | Whole plant no roots | ND | 0.041 | ND | |
| 29 | 148 | BBCH 89 | Seeds | ND | ND | ND | |
| 29 | 148 | BBCH 89 | Rest of plant no roots | ND, ND, ND | 0.27, 0.31, 0.32 | 0.016, 0.017, 0.017 | |
| 117 | 180 | BBCH 57 | Whole plant no roots | ND | <0.012 | ND | |
| 117 | 259 | BBCH 89 | Seeds | ND | ND | ND | |
| 117 | 259 | BBCH 89 | Rest of plant no roots | ND | 0.079 | <0.013 | |
| Tomato | 29 | 118 | BBCH 81-83 | Fruits | ND | <0.012 | ND | |
| 119 | 214 | BBCH 81-83 | Fruits | ND | <0.012 | ND | |
| Trial No. L200260  (Piedmont/Cuneo, Italy/2020-2021) | Strawberry | 30 | 118 | BBCH 85-87 | Fruits | ND | 0.012 | ND | |
| 120 | 386 | BBCH 85-87 | Fruits | ND | ND | ND | |
| Leek | 29 | 119 | BBCH 41 | Whole plant no roots | ND | ND | <0.013 | |
| 29 | 194 | BBCH 49 | Whole plant no roots | ND | ND | ND | |
| 117 | 197 | BBCH 41 | Whole plant no roots | ND | <0.012 | 0.031 | |
| 117 | 268 | BBCH 49 | Whole plant no roots | ND | ND | <0.013 | |
| Oilseed rape | 29 | 75 | BBCH 55-57 | Whole plant no roots | ND | 0.048 | ND | |
| 29 | 132 | BBCH 89 | Seeds | ND | ND | ND | |
| 29 | 132 | BBCH 89 | Rest of plant no roots | ND | 0.12 | 0.017 | |
| 117 | 308 | BBCH 55-59 | Whole plant no roots | ND | ND | ND | |
| 117 | 395 | BBCH 89 | Seeds | ND | ND | ND | |
| 117 | 395 | BBCH 89 | Rest of plant no roots | ND | 0.031 | 0.018 | |
| Tomato | 30 | 112 | BBCH 82 | Fruits | ND | <0.012 | ND | |
| 117 | 198 | BBCH 81-83 | Fruits | ND | ND | ND | |
| Trial No. L200261  (Andalusia/Sevilla, Spain/2020-2021) | Strawberry | 30 | 197 | BBCH 87 | Fruits | ND | <0.012 | ND | |
| 120 | 287 | BBCH 87 | Fruits | ND | ND | ND | |
| Leek | 29 | 67 | BBCH 41 | Whole plant no roots | ND | <0.012 | <0.013 | |
| 29 | 107 | BBCH 49 | Whole plant no roots | ND | ND | ND | |
| 120 | 174 | BBCH 41 | Whole plant no roots | ND | <0.012 | <0.013 | |
| 120 | 279 | BBCH 49 | Whole plant no roots | ND | ND | ND | |
| Oilseed rape | 30 | 148 | BBCH 55-57 | Whole plant no roots | ND | <0.012 | ND | |
| 30 | 267 | BBCH 89 | Seeds | ND | ND | ND | |
| 30 | 267 | BBCH 89 | Rest of plant no roots | ND | 0.040 | 0.014 | |
| 120 | 238 | BBCH 55-57 | Whole plant no roots | ND | ND | ND | |
| 120 | 357 | BBCH 89 | Seeds | ND | ND | ND | |
| 120 | 357 | BBCH 89 | Rest of plant no roots | ND | 0.022 | <0.013 | |
| Tomato | 29 | 107 | BBCH 83 | Fruits | ND | 0.016 | ND | |
| 120 | 210 | BBCH 83 | Fruits | ND | <0.012 | ND | |
| ND Not detected (<LOD; <0.003 mg/kg for all analytes (expressed as parent: 0.0036 mg/kg (M650F003) and 0.0039 mg/kg (M650F004))  DALA – Days after last application; PBI – Plant-back interval  (a) Conversion factor for calculation of M650F003 to ametoctradin is 1.2450  (b) Conversion factor for calculation of M650F004 to ametoctradin is 1.3292 | | | | | | | | |
|  | | | | | | | | |

**Summary of residues in rotational crops in accordance with the residue definition for risk assessment**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Sub Plot No.** | **Crop** | **Portion analyzed** | **Growth Stage [BBCH]** | **n** | **Sum of BAS 650 F, M650F003 and M650F004, expressed as BAS 650F 1)**  **(mg/kg)** | |
| **PBI 30 days** | **PBI 120 days** |
| 1 | Strawberry | Fruits | 85 – 87 | 4 | < 0.035 – 0.057 | < 0.035 – 0.088 |
| 2 | Leek | Whole plant no roots | 41 | 4 | < 0.035 – 0.048 | < 0.035 – 0.053 |
| 49 | 4 | < 0.035 – 0.036 | < 0.035 |
| 3 | Oilseed Rape | Whole plant no roots | 55 – 59 | 4 | < 0.035 – 0.071 | < 0.035 |
| Seeds | 89 | 4 | < 0.035 | < 0.035 |
| Rest of plant no roots | 89 | 4 | 0.044 – 0.33 | 0.045 – 0.10 |
| 4 | Tomato | Fruits | 81 – 83 | 4 | < 0.035 – 0.040 | < 0.035 |

DALA = days after last application n = number of specimens

1. For calculation of sum; residues of < 0.010 is set to 0.010 mg/kg for BAS 650 F, residues of < 0.012 is set to 0.012 mg/kg for M650F003 and residues of < 0.013 is set to 0.013 mg/kg for M650F004. Where all residues are < LOQ, the total sum residues is given as < 0.035 mg/kg.

**Residues of ametoctradin in soil**

| **Trial No./**  **Location/**  **Year** | **Commodity** | **DALA** | **Residues (mg/kg)** | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Ametoctradin** | **M650F001** | **M650F002** | **M650F003** | **M650F004** |
| Trial No. L200258  (Brandenburg, Germany/2020-2021) | Bare soil | 29 | 0.11 | 0.032 | < 0.010 | ND | ND |
| 29 | 0.17 | ND | ND | ND | ND |
| 29 | 0.15 | ND | ND | ND | ND |
| 29 | 0.10 | 0.027 | ND | ND | ND |
| 120 | ND | ND | ND | 0.022 | 0.043 |
| 118 | 0.014 | 0.045 | < 0.010 | 0.022 | 0.026 |
| 121 | < 0.010 | 0.028 | ND | < 0.010 | 0.016 |
| 119 | ND | ND | ND | 0.019 | 0.031 |
| Trial No. L200259  (Limburg/Gennep, The Netherlands/2020-2021) | 29 | 0.22 | 0.062 | 0.010 | 0.035 | < 0.010 |
| 29 | 0.37 | ND | ND | ND | ND |
| 29 | 0.36 | ND | ND | ND | ND |
| 29 | 0.29 | < 0.010 | ND | < 0.010 | ND |
| 120 | 0.011 | 0.013 | ND | 0.036 | 0.030 |
| 120 | 0.012 | 0.010 | ND | 0.070 | 0.056 |
| 117 | ND | ND | ND | 0.012 | < 0.010 |
| 119 | < 0.010 | ND | ND | 0.054 | 0.037 |
| Trial No. L200260  (Piedmont/Cuneo, Italy/2020-2021) | 30 | 0.12 | < 0.010 | ND | ND | ND |
| 29 | 0.059 | 0.022 | < 0.010 | 0.075 | 0.021 |
| 30 | 0.15 | < 0.010 | ND | ND | ND |
| 29 | 0.011 | < 0.010 | < 0.010 | 0.054 | 0.019 |
| 120 | ND | ND | ND | 0.016 | 0.030 |
| 120 | ND | ND | ND | 0.023 | 0.10 |
| 120 | ND | ND | ND | 0.030 | 0.036 |
| 120 | ND | ND | ND | 0.015 | 0.081 |
| Trial No. L200261  (Andalusia/Sevilla, Spain/2020-2021) | 30 | < 0.010 | 0.030 | < 0.010 | 0.021 | < 0.010 |
| 29 | 0.024 | < 0.010 | ND | 0.037 | 0.011 |
| 30 | 0.079 | 0.021 | < 0.010 | 0.012 | < 0.010 |
| 29 | 0.033 | 0.012 | ND | 0.028 | < 0.010 |
| 120 | < 0.010 | < 0.010 | ND | 0.015 | 0.010 |
| 120 | < 0.010 | < 0.010 | ND | 0.015 | < 0.010 |
| 120 | < 0.010 | < 0.010 | ND | 0.019 | 0.014 |
| 120 | ND | ND | ND | 0.019 | 0.015 |
| ND Not detected, <LOD; <0.003 mg/kg for all analytes  DALA – Days after last application; PBI – Plant-back interval | | | | | | | |

**Conclusion**

Fourfield trials for ametoctradin on rotational crops were conducted; two trials in Northern Europe (Germany and The Netherlands) and two trials in Southern Europe (Italy and Spain) during the 2020 – 2021 growing season. All trials are independent.

In each trial, a single application of ametoctradin was made using a suspension concentrate (SC) formulation (BAS 605 00 F) containing 200 g ametoctradin per L formulation by spraying to bare soil. The application was at a nominal rate of 960 g a.s/ha. No adjuvant was used in any of the applications.

The results from these trials show that at a PBI of 30 days, ametoctradin residues in all crop samples were <LOD. Residues of M650F003 and M650F004 ranged from <0.012 – 0.048 mg/kg and <0.013 – 0.017 mg/kg, respectively. At a PBI of 120 days, residues of ametoctradin were <LOD in all crop samples. Residues of M650F003 and M650F004 ranged from <0.012 – 0.079 mg/kg and <0.013 – 0.054 mg/kg, respectively.

Residues of ametoctradin in soil at a PBI of 30 days ranged from <0.010 – 0.37 mg/kg. Residues of M650F001 ranged from <0.01 – 0.062 mg/kg. Residues of M650F002 ranged from <0.01 – 0.01 mg/kg. Residues of M650F003 ranged from <0.01 – 0.075 mg/kg. Residues of M650F004 ranged from <0.01 – 0.021 mg/kg.

Residues in accordance with the risk assessment residue definition ranged from <0.035 – 0.053 mg/kg in leek, <0.035 mg/kg in oilseed rape seed, <0.035 – 0.088 mg/kg in strawberry and <0.035 – 0.040 mg/kg in tomato.

* + 1. Other/Special Studies (KCA 6.10, KCA 6.10.1)

No new data submitted in the framework of this application.

* 1. Propamocarb
     1. Stability of residues
        1. Stability of residues during storage of samples
           1. Storage stability of residues in plant products

M-167991-02-1

|  |  |
| --- | --- |
| Comments of zRMS: | XXXX has a Letter of Access included in Part A allowing them to rely on this study. Data are being evaluated as part of renewal of approval of propamocarb (Portugal, 2017). The data were used in the evaluation.  No comments. |

|  |  |
| --- | --- |
| Reference: | CA 6.1/2 |
| Report | Potatoes tubers: Stability during deep freeze storage up to 26 months propamocarb hydrochloride active substance  Everit, S. L., Charter, G. E., 1999  report No C003683  M-167991-02-1 |
| Guideline(s): | Not specified |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes | |

**Material and methods**:

The study was designed to determine the stability of residues of propamocarb hydrochloride in potato tubers during storage under deep freeze conditions for 26 months.

Potato tubers samples (10 g) were fortified with propamocarb hydrochloride at a concentration equivalent to 0.5 mg/kg propamocarb (free base) and stored in deep freeze at about –18°C. Samples were removed at intervals of up to 26 months (Day 0, 3, 8, 13, 17 and 26 months) with three replicates per interval for immediate residue analysis.

Test substance:

Common name: propamocarb hydrochloride

Chemical name [IUPAC]: propyl 3-(dimethylamino) propylcarbamate hydrochloride

CAS No.: 25606-41-1

Purity: 96.8 %

Batch No.: 27948-058

Test commodity:

The sample of potatoes used in this study was purchased locally and their history is unknown.

Residues of propamocarb hydrochloride were extracted from the samples using acidified methanol, followed by different clean-up steps of the extract. The free base formed by alkali hydrolysis was quantitatively determined by GC / MSD (Chambers J.G., Charter G.E., Prangley P.J.; 1997; propamocarb hydrochloride active ingredient analytical grade; Code: AE B066752; Validation of analytical method; leeks, onions, brassicas, tomatoes, potatoes and melons; gas chromatography mass selective detection, Doc. No.: A84070 – M-156283-01-1).

To check the analytical methods for efficiency, recovery experiments were run at levels between 0.05 and 0.5 mg/kg equivalent propamocarb. Residues were determined and expressed as propamocarb.

**Findings:**

Apparent residues in control potato samples were all below the LOQ (0.05 mg/kg).

The mean recovery for propamocarb hydrochloride at levels between 0.05 and 0.50 mg/kg equivalent propamocarb was 85 %, with a RSD of 13 %.

No decline could be detected for propamocarb hydrochloride in potato tubers during a storage interval of 26 months. The mean recoveries of propamocarb hydrochloride of the stored samples are summarized in the tables below.

**Table A 31:** **Recovery efficiency of analysis of propamocarb hydrochloride in potato tubers**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Matrix** | **Compound added** | **Storage interval**  **[months]** | **Fortification level**  **(a)**  **[mg/kg]** | **Single recoveries**  **[%]** | **Mean recovery**  **[%]** | **RSD**  **(b)**  **[%]** | **n** |
| Potato tuber | propamocarb HCl  (AE B066752) | 3 | 0.50 | 90;96 | 93 | - | 2 |
| 8 | 0.20 | 71;73 | 72 | - | 2 |
| 13 | 0.50 | 72;89 | 81 | - | 2 |
| 17 | 0.05 | 89;77 | 83 | - | 2 |
| 26 | 0.50 | 79;84 | 82 | - | 2 |
|  | **Overall mean** | | **85** | **13** | **12** |

a) fortified with propamocarb hydrochloride, but fortification level equivalent propamocarb (free base)

b) RSD: relative standard deviation RSD = SD / Mean recovery x 100 %

**Table A 32:** **Storage stability of propamocarb hydrochloride in potato tubers**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Storage interval**  **[months]** | **Fortification level**  **[mg/kg] (a)** | **Recovered residues in stored samples** | | | | |
| **Single recoveries uncorrected**  **[%]** | **Mean recovery uncorrected**  **[%]** | **Mean recovery corrected (b)**  **[%]** | **RSD**  **(c)** | **n** |
| 0 | 0.50 | 96;96;100 | 97 | 97 | 2.4 | 3 |
| 3 | 0.50 | 102;104;106 | 104 | 112 | 1.9 | 3 |
| 8 | 0.50 | 74;80;78 | 77 | 107 | 4.0 | 3 |
| 13 | 0.50 | 104;96;92 | 97 | 120 | 6.3 | 3 |
| 17 | 0.50 | 92;94 | 93 | 112 | 1.5 | 2 |
| 26 | 0.50 | 82;82;86 | 83 | 102 | 2.8 | 3 |

a) fortified with propamocarb hydrochloride, but fortification level equivalent propamocarb (free base)

b) Corrected for procedural recovery efficiency

c) RSD: relative standard deviation RSD = SD / Mean recovery x 100 %

**Conclusion:**

At the final stability interval of 26 months, 102% (83% uncorrected) of the nominal fortification level remained extractable and quantifiable by the analytical method. This indicates that residues of propamocarb hydrochloride in potato tubers are stable for a period of at least 26 months when stored deep frozen.

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

No new data submitted in the framework of this application.

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

No new data submitted in the framework of this application.

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

No new data submitted in the framework of this application.

* + - * 1. Nature of residues in processed commodities
        2. MEF-08/173

|  |  |
| --- | --- |
| Comments of zRMS: | XXXX has a Letter of Access included in Part A allowing them to rely on this study. Data are being evaluated as part of renewal of approval of propamocarb (Portugal, 2017). The data were used in the evaluation.  No comments. |

|  |  |
| --- | --- |
| Reference: | CA 6.5.1 |
| Report | [1-14C] propamocarb hydrochloride: Aqueous hydrolysis under conditions of processing studies,  Justus, K.; Kuhnke, G., 2008  Report No MEF-08/173, Document No. M-300710-01-1 |
| Guideline(s): | EU 91/414/EEC amended by 96/68/EC Section 6.5.1; OECD 507 |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes | |

**Material and methods:**

This study was performed to investigate the degradation behaviour of propamocarb hydrochloride in buffered drinking water. The experiments were carried out under laboratory conditions which are reprensentative for processing operations of raw agricultural commodities.

The experiments were performed with a concentration of 1 mg [1-14C] propamocarb hydrochloride/L.



The test systems were incubated at three representative sets of hydrolysis conditions (pasteurisation: 90°C at pH 4 for 20 min.; baking, brewing, boiling: 100°C at pH 5 for 60 min. and sterilisation: 120°C at pH 6 for 20 min). At zero-time (test start) and at test termination, the content of radioactivity was determined in the samples by Liquid Scintillation Counting (LSC) to establish the material balances. Potential hydrolysis was investigated by High Performance Liquid Chromaotgraphy (RP18 column 250 x 4.6 mm, 5μm particle size,operated with a gradient mixture of water/25% aqueous ammonia solution 99/1 and acetonitrile/25% ammonia solution 99/1 at 40°C) equipped with a radiomonitor (radio-HPLC profiling) at the beginning and termination of the incubation.

**Findings:**

The applied radioactivity was defined as the amount of radioactivity measured in the samples at the beginning of the incubation period. Based on the results of LSC measurements immediately after test termination, a radioactivity balance was established for each experiment.

The material balances were complete; no radioactivity and no volatile substance dissipated from the test system. Detailed recoveries are shown in the table below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Substrate** | **Temperature**  **(˚C)** | **Incubation time**  **(min.)** | **Simulation of** | **Mean % of applied radioactivity determined as propamocarb hydrochloride\*** |
| pH 4 buffer | 90 | 20 | pasteurisation | 100.7 |
| pH 5 buffer | 100 | 60 | baking, brewing or boiling | 100.8 |
| pH 6 buffer | 120 | 20 | sterilisation | 101.2 |

\* Mean value of three replicates

**Conclusion:**

No hydrolysis products of [1-14C] propamocarb hydrochloride were found under the conditions of processing tested: pH 4/90°C (20 min); pH 5/100°C (60 min) and pH 6/120°C (20min).

The test item propamocarb hydrochloride was stable under all conditions of processing (pasteurization, baking, brewing, boiling and sterilization) tested.

* + - 1. Nature of residues in livestock

No new data submitted in the framework of this application.

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

**Table A 33: Comparison of intended and critical EU GAPs**

| **Type of GAP** | **Number of applica­tions** | **Application rate per treatment**  **(g a.s./ha)** | **Interval between application** | **Growth stage at last application** | **PHI (days)** |
| --- | --- | --- | --- | --- | --- |
| cGAP NEU (DAR, Ireland, 2005) | 6 | 1083 g propamocarb hydrochloride/ha | 7 days | - | 14 |
| cGAP NEU (Art. 12, EFSA, 2013) | 4 | 840 g propamocarb/ha | 7-10 days | 20-95 | 7 |
| Intended cGAP (1)\* | 3 | 902 g propamocarb hydrochloride/ha (756 g propamocarb)/ha 240 | 5 days | 21-89 | 7 |
| Intended GAP (2)\*† | 2 | 902 g propamocarb hydrochloride/ha (756 g propamocarb)/ha | 5 days | 21-89 | 7 |

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

† This GAP is less critical and within the risk envvelope of intended use 1 (cGAP)

* + - * 1. 2021/2017109

|  |  |
| --- | --- |
| Comments of zRMS: | The study has been accepted.  In 2020 four field trials in potato were conducted in NEU to determine residues of **ametoctradin (BAS 650 F)** and its metabolites M650F003 and M650F004 as well as **propamocarb (BAS 9068 F)** in potatoes after treatment with BAS 743 00 F SC formulation under field conditions.  The application rates, frequency and spray interval were covered the critical GAP. Plots were treated 3 times with 2.0 L/ha of BAS 743 00 F (0.240 kg/ha of ametoctradin and 0.756 kg/ha of propamocarb) with a water volume of 200 L/ha for each application. The first application took place at BBCH 44 – 47, the second one at BBCH 46 – 48 and the third application at BBCH 47 – 48.  The used and adapted for the study XXXX analytical methods were Method L0450/01 for propamocarb and Method L0078/01 for ametoctradin and its metabolites M650F003 and M650F004. The final determinations of analytes were performed by LC-MS/MS. The validation of both methods was performed on plant matrices in a separate study.  The LOQ of 0.01 mg/kg was set for each analyte. However, for ametoctradinmetabolites M650F003 and M650F004, the LOQ expressed as the parent equivalent [mg/kg] was at 0,012 (CF: 1,2450) and at 0.013 (CF: 1,3292), respectively. Overall and average recoveries were all in the range of 70 – 110 % and RSDs were < 20 %.  No residues of Ametoctradin and its metabolites above the LOQs were present in any of the control samples, but for Propamocarb, residues ≥0.010 mg/kg were present in shoot samples L2002980001, L2003000001 and L2005410001. For L2005410001 a spray drift from a neighbour farmer who applied twice propamocarb hydrochloride was found as a reason of the contamination. For trial L200298 and L200230 no reason could be found to explain the contaminated control samples. However, potato shoot specimens were only relevant to demonstrate that the applications in the field were done successfully. |

|  |  |
| --- | --- |
| Reference: | CA 6.3.1/1 |
| Report | Residues of Ametoctradin (BAS 650 F) and Propamocarb (Reg.No. 4628172) in Potato after Treatment with BAS 743 00 F under Field Conditions in Northern Europe, 2020  Gabriel, E., 2021  report No 890061, IF20-05289908  2021/2017109 |
| Guideline(s): | * European Community Guideline 7029/VI/95 - rev.5, 22/07/97: General recommendations for the design, preparation and realization of residue trials * European Community Guideline 7525/VI/95 - rev.10.3, 13/06/17: Comparability, extrapolation, group tolerances and data requirements for setting MRLs. * OECD Guideline for the Testing of Chemicals No. 509. Crop Field Trial,07 September 2009 |
| Deviations: | Yes, none that affect the validity of the study |
| GLP: | yes |
| Acceptability: | Yes | |

**Materials and methods**

In 2020, four independent field trials were conducted in NEU (Germany, northern France, the Netherlands and Poland) to support the use of BAS 650 F (ametoctradin) and BAS 9068 F (propamocarb) in potatoes. BAS 743 00 F (120 g/L of ametoctradin and 378 g/L of propamocarb) a suspension concentrate (SC) formulation, was foliar applied three times on potatoes at a nominal rate of 2.0 L/ha, corresponding to 240 g/ha of ametoctradin and 756 g/ha of propamocarb. The first application was made 16-18 days before harvest (DBH) (BBCH 44 – 47), the second application at 10-13 DBH (BBCH 46 – 48) and the final application 6-7 DBH (BBCH 47 – 48). Potato shoots were collected 0 days after last application (DALA) and potato tubers were collected 3, 6 – 7 and 13 – 14 DALA.

All samples were maintained frozen (≤ -18°C) at the testing facility, during shipping to the laboratory, and were stored frozen prior to analysis. The maximum storage interval for samples between harvest and analysis was 249 days (*ca* 8 months). Residues of propamocarb have been shown to be stable in high water content and high starch content crops for at least 26 months.

Residues of propamocarb were determined using XXXX method no. L0450/01, a LC-MS/MS method. Acceptable concurrent recoveries were reported for potato shoots and potato tubers, thus demonstrating the suitability of the methods. The limit of quantification (LOQ) was 0.01 mg/kg.

**Table A 34: Summary of recoveries of propamocarb in potato**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Matrix** | **Fortification Level  [mg/kg]** | **Summary Recoveries** | | | |
| **propamocarb** | | | |
| **Method No. L0450/01** | | **Mean  [%]** | **SD1)  [±]** | **RSD2) [%]** | **n3)** |
| Potato Shoot | 0.010, 0.10 and 100 | 91.4 | 3.3 | 3.6 | 3 |
| Potato Tuber | 0.010, 0.10 and 100 | 94.4 | 8.4 | 8.8 | 8 |
| overall | | 93.6 | 7.3 | 7.8 | 11 |

1) SD: Standard deviation

2) RSD: Relative standard deviation

3) n: Number of results included in calculations

**Table A 35: Summary of the study 2021/2017109 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 a.s./ ha** | **Water (l/ha)** | **g a.s./hl** | **Propamocarb** |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| L200298 / 79206 Breisach, Germany / NEU / 2020 | Potato / Colombia | 1. 18.03.2020  2. 18.05 – 03.06.2020  3. 23.07.2020 | 756  756  773 | 200  200  204 | 378  378  379 | 30.06.2020  06.07.2020  10.07.2020 | 48 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 97  ND  ND  ND | 0  3  6  12 | XXXX method No. L0450/01 for propamocarb  LOQ = 0.01 mg/kg  Maximum storage interval (days): 249 |
| L200299 / 51110 Auménancourt. France (North) / NEU / 2020 | Potato / Rose de France | 1. 08.04.2020  2. 08.06 – 22.06.2020  3. 17.07 – 23.07.2020 | 731  731  769 | 193  193  203 | 379  379  379 | 30.06.2020  06.07.2020  10.07.2020 | 48 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 95  <0.01  <0.01  ND | 0  3  7  13 |
| L200300 / 9695 Bellingwolde, Netherlands / NEU / 2020 | Potato / Cilena | 1. 07.04.2020  2. 15.06 – 16.07.2020  3. 24.08 – 31.08.2020 | 756  764  764 | 200  202  202 | 378  378  378 | 06.08.2020  11.08.2020  17.08.2020 | 47 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 87  ND  <0.01  ND | 0  3  7  14 |
| L200541 / 89-430 Zamarte, Poland / NEU / 2020 | Potato / Vineta | 1. 05.05.2020  2. 30.06 – 15.07.2020  3. 04.09.2020 | 723  784  728 | 191  207  193 | 379  379  377 | 12.08.2020  17.08.2020  21.08.2020 | 48 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 72  ND  ND  ND | 0  3  7  14 |

(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

ND Not detected (<LOD; <0.003 mg/kg)

* + - * 1. 2022/2011022

|  |  |
| --- | --- |
| Comments of zRMS: | The study has been accepted.  4 field trials were conducted in NEU to determine the magnitude of residues of Ametoctradin and its metabolites M650F003 and M650F004 as well as of Propamocarb in potatoes after thrice treatment with BAS 743 00 F (378.0 g/L Propamocarb and 120.0 g/L Ametoctradin), a suspension concentrate (SC), at 17±1 days before harvest, 12±1 days before harvest and 7±1 days before harvest on plot 2 at a target rate of 2.0 L/ha (0,24 kg/ha Ametoctradin and 0,756 kg/ha Propamocarb). The water volume used was 200 L/ha (within ≤ 10 % of variation).  The same methods as in 2021/2017109 study were employed. The final determinations of analytes were performed by LC-MS/MS. The validation of both methods was performed on plant matrices in a separate study.  For recovery, the mean value of each measured concentration was within 70 % and 110 %. The precision of each concentration level was ≤ 20 % of the relative standard deviation. The LOQ of 0.01 mg/kg was set for each analyte. However, for ametoctradinmetabolites M650F003 and M650F004, the LOQ expressed as the parent equivalent [mg/kg] was at 0,012 (CF: 1,2450) and at 0.013 (CF: 1,3292), respectively. All validation parameters required were in the acceptable range.  The similar contamination of the samples as previously (2021/2017109) took place during the study - in the shoot samples L2100330001 8.7 mg/kg and L2100340001 1.2 mg/kg of Propamocarb were found. |

|  |  |
| --- | --- |
| Reference: | CA 6.3.1/2 |
| Report | Study on the residue behaviour of Propamocarb (Reg.No. 4628172) and Ametoctradin (BAS 650 F) in potato after three applications of BAS 743 00 F under field conditions in Northern Europe, 2021  Plier, S. & Eysoldt M-B., 2022  report No 890062, 21 47 GRU 0003  2022/2011022 |
| Guideline(s): | * European Commission Guideline SANTE/2019/12752 : Technical Guidelines on Data Requirements for Setting Maximum Residue Levels, Comparability of Residue Trials and Extrapolation of Residue Data on Products from Plant and Animal Origin (former 7525/VI/95 rev. 10.3) * OECD Guidelines for the Testing of Chemicals, Number 509 (2009): Crop Field Trial. * Working document of the Commission of the European Communities, Directorate General for Agriculture, VI B II-1, Appendix B, 7029/VI/95 rev. 5 of 22.07.1997 |
| Deviations: | Yes, none that affect the validity of the study |
| GLP: | yes |
| Acceptability: | Yes | |

**Materials and methods**

In 2021, four independent field trials were conducted in NEU (Germany, northern France, Belgium and Poland) to support the use of BAS 650 F (ametoctradin) and BAS 9068 F (propamocarb) in potatoes. BAS 743 00 F (120 g/L of ametoctradin and 378 g/L of propamocarb) a suspension concentrate (SC) formulation, was foliar applied three times on potatoes at a nominal rate of 2.0 L/ha, corresponding to 240 g/ha of ametoctradin and 756 g/ha of propamocarb. The first application was made 16-18 days before harvest (DBH) (BBCH 45 – 47), the second application at 11-13 DBH (BBCH 46 – 47) and the final application 7-8 DBH (BBCH 47 – 49). Potato shoots were collected 0 days after last application (DALA) and potato tubers were collected 3, 7 – 8 and 14 – 15 DALA.

All samples were maintained frozen (≤ -18°C) at the testing facility, during shipping to the laboratory, and were stored frozen prior to analysis. The maximum storage interval for samples between harvest and analysis was 246 days (*ca* 8 months). Residues of propamocarb have been shown to be stable in high water content and high starch content crops for at least 26 months.

Residues of propamocarb were determined using XXXX method no. L0450/01, a LC-MS/MS method. Acceptable concurrent recoveries were reported for potato shoots and potato tubers, thus demonstrating the suitability of the methods. The limit of quantification (LOQ) was 0.01 mg/kg.

**Table A 36: Summary of recoveries of propamocarb in potato**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Matrix** | **Fortification Level  [mg/kg]** | **Summary Recoveries** | | | |
| **Propamocarb** | | | |
| **Method No. L0450/01** | | **Mean  [%]** | **SD1)  [±]** | **RSD2) [%]** | **n3)** |
| Potato Shoot | 0.010, 0.10 and 70 | 86.5 | 6.2 | 7.2 | 7 |
| Potato Tuber | 0.010 and 0.10 | 99.5 | 10 | 10 | 8 |
| overall | | 93.4 | 11 | 11 | 15 |

1) SD: Standard deviation

2) RSD: Relative standard deviation

3) n: Number of results included in calculations

**Table A 37: Summary of the study 2022/2011022 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 a.s./ ha** | **Water (l/ha)** | **g a.s./hl** | **Propamocarb** |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| L210032 / 67245 Lambsheim, Germany / NEU / 2021 | Potato / Gala | 1. 11.04.2021  2. 02.07 – 19.07.2021  3. 30.07.2021 | 756  737  756 | 200  195  200 | 378  378  378 | 14.07.2021  19.07.2021  23.07.2021 | 47 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 62  <0.01  <0.01  <0.01 | 0  3  7  14 | XXXX method No. L0450/01 for propamocarb  LOQ = 0.01 mg/kg  Maximum storage interval (days): 246 |
| L210033 / 49350 Saint Georges le Spets Voies, France (North) / NEU / 2021 | Potato / Bintje | 1. 29.03.2021  2. 10.07 – 27.07.2021  3. 02.08.2021 | 730  806  745 | 193  213  197 | 378  378  378 | 15.07.2021  20.07.2021  26.07.2021 | 49 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 70  <0.01  <0.01  <0.01 | 0  3  7  14 |
| L210034 / 3470 Kortenaken, Belgium / NEU / 2021 | Potato / Friesländer | 1. 30.03.2021  2. 04.06 – 18.06.2021  3. 19.07.2021 | 772  780  756 | 204  206  200 | 378  378  378 | 02.07.2021  08.07.2021  12.07.2021 | 47-48 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 45  <0.01  <0.01  <0.01 | 0  3  7  14 |
| L220035 / 64-600, Berdychowo, Poland / NEU / 2021 | Potato / Queen Anne | 1. 22.04.2021  2. 20.06 – 18.06.2021  3. 06.09.2021 | 696  718  741 | 184  190  196 | 378  378  378 | 20.08.2021  25.08.2021  29.08.2021 | 48 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 51  <0.01  <0.01  <0.01 | 0  3  8  15 |

(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

* + - * 1. 2022/2041761

|  |  |
| --- | --- |
| Comments of zRMS: | The study has been accepted.  In 2022 4 field trials were conducted in NEU to determine the magnitude of residues of Ametoctradin and its metabolites M650F003 and M650F004 as well as of Propamocarb in potatoes after treatment with BAS 743 00 F or BAS 743 03 F under field conditions.  The test item BAS 743 00 F was applied as foliar application thrice on potatoes (plot 2) at 16-17, 11 and 6-7 days before harvest at a target rate equal to 0.24 kg/ha Ametoctradin and 0.756 kg/ha Propamocarb. Another test item BAS 743 03 F (378.0 g/L Propamocarb and 120.0 g/L Ametoctradin), a suspension concentrate (SC), was applied as foliar application thrice on potatoes (plot 3) at 16-17, 11 and 6-7 days before harvest at a rate equal to 0.24 kg/ha Ametoctradin and 0.756 kg/ha Propamocarb. The water volume used was 200 L/ha (within ≤ 10 % of variation).  The determination of Ametoctradin and its metabolites M650F003 and M650F004 was also performed according to method No. L0078/01. The LOQ of the method is 0.010 mg/kg for Ametoctradin and its metabolites M650F003 and M650F004. The determination of Propamocarb was performed using the method L0450/01. The LOQ of the method also is 0.010 mg/kg. LC-MS/MS was used for the final determination of residues of Ametoctradin and its metabolites M650F003 and M650F004 as well as Propamocarb. In all cases 2 transition were used.  For the recoveries, the mean values were within the acceptable range of 70 % and 110 %, with a relative standard deviation (RSD) ≤ 20 %. All validation parameters required were in the acceptable range.  No residues in control samples were found except in one shoot sample L2200910001 - 0.58 mg/kg of Propamocarb were found (an unknown contamination). |

|  |  |
| --- | --- |
| Reference: | CA 6.3.1/3 |
| Report | Study on the residue behaviour of Ametoctradin (BAS 650 F) and Propamocarb (Reg.No. 4628172) in potato after application of either BAS 743 00 F or BAS 743 03 F under field conditions in Northern Europe, 2022  Plier, S. & Eysoldt, M-B., 2023  report No 921987, 22 47 GRU 0005  2022/2041761 |
| Guideline(s): | * SANTE/2020/12830 rev. 1 (24. February 2021) * OPPTS 860.1340 * OECD ENV/JM/MONO(2007)17 |
| |  |  | | --- | --- | | Deviations: | ~~None~~ Yes, none that affect the validity of the study | | |  |  | | --- | --- | |  | ~~None~~ Yes, none that affect the validity of the study | |
| GLP: | yes |
| Acceptability: | Yes | |

**Materials and methods**

In 2022, four independent field trials were conducted in NEU (Germany, northern France, Belgium and Poland) to support the use of BAS 650 F (ametoctradin) and BAS 9068 F (propamocarb) in potatoes. BAS 743 00 F (120 g/L of ametoctradin and 378 g/L of propamocarb), a suspension concentrate (SC) formulation, or BAS 743 03 F (120 g/L of ametoctradin and 378 g/L of propamocarb), a SC formulation, was foliar applied three times on potatoes at a nominal rate of 2.0 L/ha, corresponding to 240 g/ha of ametoctradin and 756 g/ha of propamocarb. The first application was made 16-17 days before harvest (DBH) (BBCH 45 – 47), the second application at 11 DBH (BBCH 46 – 48) and the final application 6 - 7 DBH (BBCH 47 – 49). Potato shoots were collected 0 days after last application (DALA) and potato tubers were collected 3, 6 – 7 and 13 – 15 DALA.

All samples were maintained frozen (≤ -18°C) at the testing facility, during shipping to the laboratory, and were stored frozen prior to analysis. The maximum storage interval for samples between harvest and analysis was 125 days (*ca* 4 months). Residues of propamocarb have been shown to be stable in high water content and high starch content crops for at least 26 months.

Residues of propamocarb were determined using XXXX method no. L0450/01, a LC-MS/MS method. Acceptable concurrent recoveries were reported for potato shoots and potato tubers, thus demonstrating the suitability of the methods. The limit of quantification (LOQ) was 0.01 mg/kg.

**Table A 38: Summary of recoveries of propamocarb in potato**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Matrix** | **Fortification Level  [mg/kg]** | **Summary Recoveries** | | |
| **propamocarb** | | |
| **Method No. L0078/01** | | **Mean  [%]** | **RSD1) [%]** | **n2)** |
| Potato Shoot | 0.010, 0.10, 70 and 110 | 104 | 4.0 | 12 |
| Potato Tuber | 0.010 and 0.10 | 97.2 | 3.6 | 12 |
| overall | | 101 | 5.2 | 24 |

1) RSD: Relative standard deviation

2) n: Number of results included in calculations

**Table A 39: Summary of the study 2022/2041761 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 a.s./ ha** | **Water (l/ha)** | **g a.s./hl** | **Propamocarb** |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| L220091 / 55262 Ingelheim am Rhein – Heidesheim, Germany / NEU / 2022 (Plot 2) | Potato / Bernina | 1. 21.04.2022  2. 21.06 – 05.07.2022  3. 08.08.2022 | 378  378  378 | 187  205  208 | 707  775  786 | 22.07.2022  18.07.2022  01.08.2022 | 48 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 48  <0.01  <0.01  <0.01 | 0  3  7  14 | XXXX method No. L0450/01 for propamocarb  LOQ = 0.01 mg/kg  Maximum storage interval (days): 125 |
| L220091 / 55262 Ingelheim am Rhein – Heidesheim, Germany / NEU / 2022 (Plot 3) | Potato / Bernina | 1. 21.04.2022  2. 21.06 – 05.07.2022  3. 08.08.2022 | 378  378  378 | 203  203  213 | 767  767  805 | 22.07.2022  18.07.2022  01.08.2022 | 48 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 69  <0.01  <0.01  <0.01 | 0  3  7  14 |
| L220092 / 49650 Allonnes, France (North) / NEU / 2022 (Plot 2) | Potato / Spunta | 1. 01.04.2022  2. 30.05 – 17.06.2022  3. 04.07.2022 | 378  378  378 | 193  187  180 | 730  707  680 | 17.06.2022  23.06.2022  27.06.2022 | 48 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 68  <0.01  <0.01  <0.01 | 0  3  7  15 |
| L220092 / 49650 Allonnes, France (North) / NEU / 2022 (Plot 3) | Potato / Spunta | 1. 01.04.2022  2. 30.05 – 17.06.2022  3. 04.07.2022 | 378  378  378 | 193  187  180 | 745  756  767 | 17.06.2022  23.06.2022  27.06.2022 | 48 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 82  <0.01  <0.01  <0.01 | 0  3  7  15 |
| L220093 / 3470 Kortenaken, Belgium / NEU / 2022 (Plot 2) | Potato / Friesländer | 1. 01.04.2022  2. 01.06 – 14.06.2022  3. 08.07.2022 | 378  378  378 | 208  208  210 | 788  788  795 | 21.06.2022  27.06.2022  01.07.2022 | 47-48 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 98  <0.01  <0.01  <0.01 | 0  3  7  13 |
| L220093 / 3470 Kortenaken, Belgium / NEU / 2022 (Plot 3) | Potato / Friesländer | 1. 01.04.2022  2. 01.06 – 14.06.2022  3. 08.07.2022 | 378  378  378 | 210  202  198 | 795  764  748 | 21.06.2022  27.06.2022  01.07.2022 | 47-48 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 74  <0.01  <0.01  <0.01 | 0  3  7  13 |
| L220094 / 64-600, Berdychowo, Poland / NEU / 2022 (Plot 2) | Potato / Queen Anne | 1. 18.04.2022  2. 27.06 – 09.07.2022  3. 12.08.2022 | 378  378  378 | 186  196  196 | 703  740  740 | 27.07.2022  01.08.2022  06.08.2022 | 49 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 107  <0.01  <0.01  <0.01 | 0  3  6  13 |
| L220094 / 64-600, Berdychowo, Poland / NEU / 2022 (Plot 3) | Potato / Queen Anne | 1. 18.04.2022  2. 27.06 – 09.07.2022  3. 12.08.2022 | 378  378  378 | 186  196  196 | 728  763  764 | 27.07.2022  01.08.2022  06.08.2022 | 49 | Potato / Shoot  Potato / Tuber  Potato / Tuber  Potato / Tuber | 97  <0.01  <0.01  <0.01 | 0  3  6  13 |  |

(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

* + - 1. Onion, garlic

**Table A 40: Comparison of intended and critical EU GAPs**

| **Type of GAP** | **Number of applica­tions** | **Application rate per treatment**  **(g a.s./ha)** | **Interval between application** | **Growth stage at last application** | **PHI (days)** |
| --- | --- | --- | --- | --- | --- |
| cGAP NEU (DAR, Ireland, 2005) | - | - | - | - | - |
| cGAP NEU (Art. 12, EFSA, 2013) | 3 | 840 g propamocarb/ha | - | 13-49 | 7 |
| Intended cGAP (3)\* | 2 | 902 g propamocarb-hydrochloride/ha (756 g propamocarb)/ha | 5 days | 14-49 | 7 |
| Intended GAP (4)\* † | 1 | 902 g propamocarb-hydrochloride/ha (756 g propamocarb)/ha | - | 14-49 | 7 |

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

† This GAP is less critical and within the risk envelope of intended use 1 (cGAP)

* + - * 1. 2021/2025103

|  |  |
| --- | --- |
| Comments of zRMS: | The study has been accepted.  The objective of the study was to determine the magnitude of residues of Ametoctradin, M650F003, M650F004 and Propamocarb in onion growing under field conditions after treatment with BAS 743 00 F containing 120 g/L of Ametoctradin and 378g/L of Propamocarb. 4 trials were conducted in Northern Europe. At each site, there was one untreated plot in addition to the treated plot. BAS 743 00 F was applied 2 times (at 10-13 DBH and 6-8 DBH) at a rate of 2.0 L/ha (240 g/ha Ametoctradin and 756 g/ha Propamocarb).  For the determination of Propamocarb method L0450/01 was used. For the determination of Ametoctradin, M650F003, and M650F004 method L0078/01 was used. Matrix-matched standards in both cases were used. In both cases high performance liquid chromatography with ESl tandem mass spectrometry was employed for final compounds determination. 2 mass transitions were monitored. The methods have a LOQ of 0.010 mg/kg for each analyte. No residues above LOQs were found in any of the control samples. The validation parameters required were within the acceptable range. |

|  |  |
| --- | --- |
| Reference: | CA 6.3.2/1 |
| Report | Study on the residue behaviour of Ametoctradin (BAS 650 F) and Propamocarb (Reg.No. 4628172) in onion after two foliar applications of BAS 743 00 F under open field conditions in Northern Europe, 2020  Loriau, P., 2021  report No 890065, BAS-G119TO122-20  2021/2025103 |
| Guideline(s): | EC 1607/VI/97 rev.2, EEC 7029/VI/95 (22 July 1997), EEC 7525/VI/95 rev. 10.3, SANCO/3029/99, ENV/JM/MONO(2011)50/Rev1, OECD 509 |
| Deviations: | Yes, none that affect the validity of the study |
| GLP: | yes |
| Acceptability: | Yes | |

**Materials and methods**

In 2020, four independent field trials were conducted in NEU (Germany, northern France, Belgium and Poland) to support the use of BAS 650 F (ametoctradin) and BAS 9068 F (propamocarb) in onions. BAS 743 00 F (120 g/L of ametoctradin and 378 g/L of propamocarb) a suspension concentrate (SC) formulation, was foliar applied twice to onions at a nominal rate of 2.0 L/ha, corresponding to 240 g/ha of ametoctradin and 756 g/ha of propamocarb. The first application was made 10-13 days before harvest (DBH) (BBCH 45 – 48) and the second application at 6 – 8 DBH (BBCH 45 – 48). Onion bulbs were collected 0, 2 – 3, 6 – 8 and 14 – 15 days after last application (DALA).

All samples were maintained frozen (≤ -18°C) at the testing facility, during shipping to the laboratory, and were stored frozen prior to analysis. The maximum storage interval for samples between harvest and analysis was 179 days (*ca* 6 months). Residues of propamocarb have been shown to be stable in high water content crops for at least 26 months.

Residues of propamocarb were determined using XXXX method no. L0450/01, a LC-MS/MS method. Acceptable concurrent recoveries were reported for onion bulbs, thus demonstrating the suitability of the methods. The limit of quantification (LOQ) was 0.01 mg/kg.

**Table A 41: Summary of recoveries of propamocarb in onion**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Matrix** | **Fortification Level  [mg/kg]** | **Summary Recoveries** | | | |
| **Method No. L0078/01** | | **Mean  [%]** | **SD1)  [±]** | **RSD2) [%]** | **n3)** |
| Ametoctradin | | | | | |
| Onion bulbs | 0.010, 0.10 and 1.0 | 95.2 | 5.7 | 6.0 | 9 |

1) SD: Standard deviation

2) RSD: Relative standard deviation

3) n: Number of results included in calculations

**Table A 42: Summary of the study 2021/2025103 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 a.s./ ha** | **Water (l/ha)** | **g a.s./hl** | **Propamocarb** |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| L200302 / 46359 Heiden Germany / NEU / 2020 | Onion / Dormo F1 | 1. 03.04.2020  2. -  3. 27.08.2020 | 815  722 | 215.6  191.1 | 378  378 | 14.08.2020  19.08.2020 | 47-48 | Onion / bulb  Onion / bulb  Onion / bulb  Onion / bulb | 0.15  0.15  0.082  0.061 | 0  2  8  15 | XXXX method No. L0450/01 for propamocarb  LOQ = 0.01 mg/kg  Maximum storage interval (days): 179 |
| L200303 / 08300 Avançon, France (North) / NEU / 2020 | Onion / Hytune | 1. 23.03.2020  2. -  3. 15.09.2020 | 726  756 | 192.0  200.0 | 378  378 | 04.09.2020  08.09.2020 | 47 | Onion / bulb  Onion / bulb  Onion / bulb  Onion / bulb | 0.17  0.022  0.011  <0.01 | 0  3  7  14 |
| L200304 / 1450 Ittre, Belgium / NEU / 2020 | Onion / Centro 2 | 1. 31.03.2020  2. -  3. 13.08.2020 | 756  746 | 200.0  197.3 | 378  378 | 31.07.2020  05.08.2020 | 45-47 | Onion / bulb  Onion / bulb  Onion / bulb  Onion / bulb | 0.36  0.38  0.083  0.040 | 0  2  8  14 |
| L200305 / 64-560 Szczepankowo, Poland / NEU / 2020 | Onion / Majka | 1. 06.04.2020  2. -  3. 07.08.2020 | 820  737 | 217.0  195.0 | 378  378 | 27.07.2020  31.07.2020 | 47 | Onion / bulb  Onion / bulb  Onion / bulb  Onion / bulb | 0.88  0.29  0.18  0.059 | 0  3  6  14 |

(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

* + - * 1. 2022/2003268

|  |  |
| --- | --- |
| Comments of zRMS: | The study has been accepted.  The objective of the study was to determine the magnitude of residues of Ametoctradin and its metabolites (M650F003, M650F004) as well as of Propamocarb in onions after treatment with BAS 743 00 F in 4 trials in onions conducted under field conditions in Northern Europe. At each site BAS 743 00 F was applied 2 times at a rate of 2.0 L/ha (240 g/ha Ametoctradin and 756 g/ha Propamocarb).  For the determination of Propamocarb method L0450/01 was used. For the determination of Ametoctradin, M650F003, and M650F004 method L0078/01 was used. In both cases high performance liquid chromatography with ESl tandem mass spectrometry was employed for final compounds determination. 2 mass transitions were monitored. The methods have a LOQ of 0.010 mg/kg for each analyte. No residues above LOQs were found in any of the control samples. The validation parameters required were within the acceptable range. |

|  |  |
| --- | --- |
| Reference: | CA 6.3.2/2 |
| Report | Study on the residue behaviour of Propamocarb (Reg.No. 4628172) and Ametoctradin (BAS 650 F) in onions after two applications of BAS 743 00 F under field conditions in Northern Europe, 2021  Erdmann, H-P., 2022  report No 890066, AC/XXXX/21/03  2022/2003268 |
| Guideline(s): | * + European Community Guideline 7029/VI/95 - rev.5, 22/07/97: General recommendations for the design preparation and realization of residue trials.   + European Community SANTE/2019/12752 Technical Guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin (former SANCO 7525/VI/95 – Rev. 10.3)   + OECD Guideline for the testing of chemicals – Crop Field Trials: OECD/OCDE 509. Adopted 7 September 2009 |
| Deviations: | None |
| GLP: | yes |
| Acceptability: | Yes | |

**Materials and methods**

In 2021, four independent field trials were conducted in NEU (Germany, northern France, The Netherlands and Poland) to support the use of BAS 650 F (ametoctradin) and BAS 9068 F (propamocarb) in onions. BAS 743 00 F (120 g/L of ametoctradin and 378 g/L of propamocarb) a suspension concentrate (SC) formulation, was foliar applied twice to onions at a nominal rate of 2.0 L/ha, corresponding to 240 g/ha of ametoctradin and 756 g/ha of propamocarb. The first application was made 12 – 13 days before harvest (DBH) (BBCH 47 – 48) and the second application at 7 – 8 DBH (BBCH 47 – 48). Onion whole plants (no roots) were collected at 0 days after last application (DALA). Onion bulbs were collected 2 – 3, 7 – 8 and 14 – 15 DALA.

All samples were maintained frozen (≤ -18°C) at the testing facility, during shipping to the laboratory, and were stored frozen prior to analysis. The maximum storage interval for samples between harvest and analysis was 141 days (*ca* 5 months). Residues of propamocarb have been shown to be stable in high water content and high starch content crops for at least 26 months.

Residues of propamocarb were determined using XXXX method no. L0450/01, a LC-MS/MS method. Acceptable concurrent recoveries were reported for onion bulbs, thus demonstrating the suitability of the methods. The limit of quantification (LOQ) was 0.01 mg/kg.

**Table A 43: Summary of recoveries of propamocarb in onion**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Matrix** | **Fortification Level  [mg/kg]** | **Summary Recoveries** | | | |
| **Method No. L0450/01** | | **Mean  [%]** | **SD1)  [±]** | **RSD2) [%]** | **n3)** |
| Propamocarb | | | | | |
| Onion whole plant (no roots) | 0.010, 0.10 and 10 | 106 | 6.1 | 5.7 | 7 |
| Onion bulbs | 0.010, 0.10 and 10 | 105 | 6.6 | 6.3 | 9 |
| overall | | 105 | 6.2 | 5.9 | 16 |

1) SD: Standard deviation

2) RSD: Relative standard deviation

3) n: Number of results included in calculations

**Table A 44: Summary of the study 2022/2003268 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 a.s./ ha** | **Water (l/ha)** | **g a.s./hl** | **Propamocarb** |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| L220037 / 16883 Lentzke, Germany / NEU / 2021 | Onion / Hylander | 1. 30.03.2021  2. -  3. 07.09.2021 | 710  798 | 188  211 | 378  378 | 19.08.2021  24.08.2021 | 48 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | 5.2  0.085  0.021  0.038 | 0  3  7  14 | XXXX method No. L0450/01 for propamocarb  LOQ = 0.01 mg/kg  Maximum storage interval (days): 141 |
| L210038 / 67240 Bischwiller, France (North) / NEU / 2021 | Onion / Redspark | 1. 17.03.2021  2. -  3. 10.09 – 20.08.2021 | 731  769 | 192  203 | 378  378 | 29.07.2021  02.08.2021 | 48 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | 5.2  0.17  0.14  0.052 | 0  3  8  14 |
| L220039 / 6562 LT Groesbeek, The Netherlands / NEU / 2021 | Onion / Red Tide F1 | 1. 02.04.2021  2. -  3. 01.09 – 07.09.2021 | 798  735 | 211  194 | 378  378 | 19.08.2021  24.08.2021 | 47-48 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | 10  0.29  0.31  0.13 | 0  2  8  14 |
| L210040 / 63-140 Maslow o, Poland / NEU / 2020 | Onion / Centro | 1. 25.03.2021  2. -  3. 09.09.2021 | 825  769 | 218  203 | 378  378 | 04.08.2021  09.08.2021 | 47 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | 9.6  0.41  0.48  0.17 | 0  3  7  15 |

(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

* + - * 1. 2022/2041763

|  |  |
| --- | --- |
| Comments of zRMS: | The study has been accepted.  The objective of the study was to determine the magnitude of residues of Ametoctradin and its metabolites (M650F003, M650F004) as well as of Propamocarb in onions after treatment with either BAS 743 00 F or BAS 743 03 F in 5 trials in onions conducted under field conditions in Northern Europe. At each trial site, there was one untreated plot in addition to 2 treated plots. At each site the test item was applied 2 times at a rate of 2.0 L/ha (240 g/ha Ametoctradin and 756 g/ha Propamocarb) in plot 2. Treated plot 2 was treated with BAS 743 00 F and treated plot 3 was treated with BAS 743 03 F.  For the determination of Propamocarb method L0450/01 was used. For the determination of Ametoctradin, M650F003, and M650F004 method L0078/01 was used. In both cases high performance liquid chromatography with ESl tandem mass spectrometry was employed for final compounds determination. 2 mass transitions were monitored.  For the recoveries, the mean values were within the acceptable range of 70 % and 110 %, with a relative standard deviation (RSD) ≤ 20 %. No residues ≥ 0.010 mg/kg (LOQ) were found in any of the untreated control samples. The results prove that no interferences of the samples material with the analytical procedure occurred. The methods have a LOQ of 0.010 mg/kg for each analyte. The validation parameters required were within the acceptable range. |

|  |  |
| --- | --- |
| Reference: | CA 6.3.2/3 |
| Report | Study on the residue behaviour of Ametoctradin (BAS 650 F) and Propamocarb (RE.No. 4628172) in onions after application of either BAS 743 00 F or BAS 743 03 F under field conditions in Northern Europe, 2022  Loriau, P., 2023  XXXX Study ID 921989, Study No. BAS-G205TO208-22  XXXX DocID 2022/2041763 |
| Guideline(s): | * FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials, Rome 1990 * EC working document 1607/VI/97, [rev. 2] (10/06/1999) * EC working document 7029/VI/95 - Appendix B, [rev. 5] (22/07/1997) * EC working document SANTE/2019/12752 * EC working document SANTE/2020/12830 rev.1 (24/02/2021) *(risk assessment part)* * OECD Guidance document on Crop Field Trials [ENV/JM/MONO(2011)50/Rev1] (07/09/2016)   OECD Guideline for the testing of chemicals n°509, Crop Field Trial, June 2021 |
| Deviations: | Yes, none that affect the validity of the study |
| GLP: | Yes |
| Acceptability: | Yes | |

**Materials and methods**

In 2022, five field trials were conducted in NEU (Germany, northern France, Belgium, Poland) to support the use of BAS 650 F (ametoctradin) and BAS 9068 F (propamocarb) in onions. In plot 2, BAS 743 00 F (120 g/L of ametoctradin and 378 g/L of propamocarb), a suspension concentrate (SC) formulation was applied; in plot 3 BAS 743 03 F (120 g/L of ametoctradin and 378 g/L of propamocarb), an SC formulation, was applied. In both plots the products were foliar applied twice on onions at a nominal rate of 2.0 L/ha, corresponding to 240 g/ha of ametoctradin and 756 g/ha of propamocarb. The first application was made 11 – 14 days before harvest (DBH) (BBCH 45 – 48) and the second application at 6 – 8 DBH (BBCH 47 – 48). Onion whole plants (no roots) were collected at 0 days after last application (DALA), with the exception of trial L220101 where no whole plant samples were collected. Onion bulbs were collected from all trials 2 – 3, 6 – 8 and 14 DALA.

All samples were maintained frozen (≤ -18°C) at the testing facility, during shipping to the laboratory, and were stored frozen prior to analysis. The maximum storage interval for samples between harvest and analysis was 132 days (4.4 months). Residues of propamocarb have been shown to be stable in high water content crops for at least 26 months.

Residues of propamocarb were determined using XXXX method no. L0450/01, an LC-MS/MS method. Acceptable concurrent recoveries were reported for onion bulbs and whole plant (no roots), thus demonstrating the suitability of the methods. The limit of quantification (LOQ) was 0.01 mg/kg.

**Table A 45: Summary of recoveries of propamocarb in onion**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Matrix** | **Fortification Level  [mg/kg]** | **Summary Recoveries** | | |
| **Method No. L0450/01** | | **Mean  [%]** | **RSD1) [%]** | **n2)** |
| Ametoctradin | | | | |
| Onion whole plant (no roots) | 0.010, 0.10 and 10 | 102 | 4.2 | 9 |
| Onion bulbs | 0.010, 0.10 and 1.0 | 102 | 2.5 | 15 |
| Overall | | 102 | 3.1 | 24 |

1) RSD: Relative standard deviation

2) n: Number of results included in calculations

**Table A 46: Summary of the study 2022/2041763 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) expressed as parent** | **PHI (days)** | **Details on trial** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **g a.s./ ha** | **Water (l/ha)** | **g a.s./hl** | **Propamocarb** |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| L220099 / 67063, Ludwigshafen, Friesenheim, Germany / NEU / 2022 (plot 2) | Onion / Hybelle | 1. 22.02.2022  2. -  3. 22.08.2022 | 731  731 | 193  193 | 378  378 | 10.08.2022  15.08.2022 | 47  47-48 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | 3.7  0.023  0.029  <0.01 | 0  2  7  14 | XXXX method No. L0450/01 for propamocarb  LOQ = 0.01 mg/kg  Maximum storage interval (days): 132 |
| L220099 / 67063, Ludwigshafen, Friesenheim, Germany / NEU / 2022 (plot 3) | Onion / Hybelle | 1. 22.02.2022  2. -  3. 22.08.2022 | 756  768 | 200  203 | 378  378 | 10.08.2022  15.08.2022 | 47  47-48 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | 2.9  0.024  0.013  <0.01 | 0  2  7  14 |
| L220100 / 80170, Beauforten-Santerre, northern France / NEU / 2022 (plot 2) | Onion / Stardust | 1. 19.04.2022  2. -  3. 04.10.2022 | 567  561 | 211  208 | 269  269 | 20.09.2022  28.09.2022 | 45  47 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | 4.3  0.060  0.036  0.043 | 0  2  6  14 |
| L220100 / 80170, Beauforten-Santerre, northern France / NEU / 2022 (plot 3) | Onion / Stardust | 1. 19.04.2022  2. -  3. 04.10.2022 | 711  720 | 188  191 | 378  378 | 20.09.2022  28.09.2022 | 45  47 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | 3.1  0.26  0.017  0.092 | 0  2  6  14 |
| L220101 / 6221, Saint-Amand, Belgium / NEU / 2022 (plot 2) | Onion / Sturon | 1. 28.03.2022  2. -  3. 01.08.2022 | 772  769 | 203  203 | 379  378 | 20.07.2022  25.07.2022 | 48  48 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | -†  0.35  0.053  0.037 | 0  3  7  14 |
| L220101 / 6221, Saint-Amand, Belgium / NEU / 2022 (plot 3) | Onion / Sturon | 1. 28.03.2022  2. -  3. 01.08.2022 | 788  769 | 207  203 | 381  378 | 20.07.2022  25.07.2022 | 48  48 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | -†  0.25  0.10  0.074 | 0  3  7  14 |
| L220102 / 64-560, Szczepankowo, Poland / NEU / 2022 (plot 2) | Onion / Rijnsburger 5 | 1. 03.05.2022  2. -  3. 26.09.2022 | 731  706 | 193  187 | 378  378 | 13.09.2022  18.09.2022 | 48  48 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | 4.5  0.54  0.34  0.51 | 0  3  8  14 |
| L220102 / 64-560, Szczepankowo, Poland / NEU / 2022 (plot 3) | Onion / Rijnsburger 5 | 1. 03.05.2022  2. -  3. 26.09.2022 | 731  706 | 193  187 | 378  378 | 13.09.2022  18.09.2022 | 48  48 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | 2.9  0.91  0.48  0.39 | 0  3  8  14 |
| L220391 / 6230, Rosseignies, Belgium / NEU / 2022 (plot 2) | Onion / Red Ray F1 | 1. 17.03.2022  2. -  3. 09.09.2022 | 818  802 | 216  212 | 378  378 | 29.08.2022  02.09.2022 | 47  47 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | 5.9  0.27  0.13  0.092 | 0  3  7  14 |
| L220391 / 6230, Rosseignies, Belgium / NEU / 2022 (plot 3) | Onion / Red Ray F1 | 1. 17.03.2022  2. -  3. 09.09.2022 | 741  771 | 196  204 | 378  378 | 29.08.2022  02.09.2022 | 47  47 | Whole plant (no roots)  Onion / bulb  Onion / bulb  Onion / bulb | 4.1  0.10  0.074  0.071 | 0  3  7  14 |

(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

† Samples of whole plant (no roots) not collected

* + - 1. Tomato, aubergine

**Table A 47: 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)** |
| --- | --- | --- | --- | --- | --- |
| cGAP NEU (DAR, Ireland, 2005) | No NEU representative use | | | | |
| cGAP SEU (DAR, Ireland, 2005) | 2 x drench + 2 x nutrient solution | Drench: 72.2 kg propamcarb-hydrochloride /ha  Nutrient solution: 2.166 kg propamcarb-hydrochloride/ha | T1: 0 –10 d  after seeding  T2: 7-10d  before  transplanting  T3: maturing  T4: T3 + 7-10d | - | 3 |
| cGAP NEU (Art. 12, EFSA, 2013) | 3 | 1050 g propamocarb/ha | - | 20-89 | 3 |
| Intended cGAP (5\*) | 2 | 902 g propamocarb-hydrochloride/ha (756 g propamocarb)/ha | 7 days | 21-89 | 1 |

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

* + - * 1. 2021/2020563 & 2022/2041755

|  |  |
| --- | --- |
| Comments of zRMS: | Both studies have been accepted.  **1.** In 2020 4 field trials were conducted in NEU to determine residues of Propamocarb, Ametoctradin, M650F003, and M650F004 in tomatoes after treatment with BAS 743 00 F which was applied twice in each trial on plot 2 at 8 (±1) DBH and at 1 DBH respectively, at a rate of 2.0 L/ha (equal to 0.756 kg/ha of Propamocarb and 0.240 kg/ha of Ametoctradin) with a water volume of 300 L/ha.  Collected samples were analysed for Propamocarb according to the XXXX method L0450/01. The limit of quantitation (LOQ) of the method is 0.010 mg/kg. For Ametoctradin, M650F003, and M650F004 samples were analysed according to the XXXX method L0078/01. The LOQ of the method is 0.010 mg/kg.  Matrix-matched standards were used for quantitation in both methods. The final determinations were performed by LC-MS/MS. 2 transitions were monitored. For the recoveries, the mean values were within the acceptable range of 70 % and 120 %, with a relative standard deviation (RSD) ≤ 20 %. The validation parameters required were within the acceptable range.  In control samples only for trial L200282 contamination with residues of propamocarb were found above the LOQ in a range of 0.050 – 0.059 mg/kg. This trial therefore was repeated.  **2.** **The repeated trial:** In 2021, one trial L210194 in tomatoes was conducted in NEU. The procedural details as above. 2 applications were done at 1 and 8 days before harvest. The analytical methods applied to determine relevant residues were the same. The course of the study was very similar. For the recoveries, the mean values were within the acceptable range of 70 % and 120 %, with a relative standard deviation (RSD) ≤ 20 %. The validation parameters required were within the acceptable range. |

|  |  |
| --- | --- |
| Reference: | CA 6.3.3/1 |
| Report | Study on the residue behaviour of Propamocarb (Reg.No. 4628172) and Ametoctradin (BAS 650 F) in Tomato after treatment with BAS 743 00 F under field conditions in Northern Europe, 2020  Schneider, E., 2021  XXXX Study ID 890058, Study No. C0075  XXXX DocID 2021/2020563 |
| Guideline(s): | * European Community Guideline 7525/VI/95 - rev.10.3, 13 June 2017: Comparability, extrapolation, group tolerances and data requirements for setting MRLs * 7029/VI/95 rev. 5: Appendix B- General Recommendations for the design, preparation and realization of residue trials * OECD – guideline for the testing of chemicals, 509; Crop field trial, 07/09/2009 * OECD ENV/JM/MONO(2007)17 – Guidance Document on Pesticide Residue Analytical Methods * EU Guidance Document SANCO/3029/99 re. 4 for generating and reporting methods of analysis in support of pre-registration data requirements |
| Deviations: | Yes. During trial L200282 a product containing propamocarb was mistakenly applied to the untreated plot, distance between plots and half of the treated plot. This trial has been repeated in study 890058\_1 (20222041755) |
| GLP: | Yes |
| Acceptability: | Yes | |

|  |  |
| --- | --- |
| Reference: | CA 6.3.3/2 |
| Report | Study on the residue behaviour of Propamocarb (Reg.No. 4628172) and Ametoctradin (BAS 650 F) in Tomato after two applications of BAS 743 00 F under field conditions in Northern Europe in 2021  Schneider, E., 2023  XXXX Study ID 890058\_1, Study No. C1066  XXXX DocID 2022/2041755 |
| Guideline(s): | * + European Commission guideline SANTE/2019/12752: Technical guidelines on Data Requirements for Setting Maximum Residue Levels, Comparability of Residue Trials and Extrapolation of Residue Data on Products from Plant and Animal Origin (Repealing and replacing SANCO 7525/VI/95 – Rev. 10.3)   + OECD Guideline for the testing of chemicals – Crop Field Trials: OECD/OCDE 509. Adopted 7 September 2009   + SANTE/2020/12830, Rev. 1   + OECD ENV/JM/MONO(2007)17 |
| Deviations: | Yes, none that affect the validity of the study |
| GLP: | Yes |
| Acceptability: | Yes | |

**Materials and methods**

In 2020, four independent field trials were conducted in NEU (Germany, northern France, Poland and Hungary) to support the use of BAS 650 F (ametoctradin) and BAS 9068 F (propamocarb) in tomato. BAS 743 00 F (120 g/L of ametoctradin and 378 g/L of propamocarb) a suspension concentrate (SC) formulation, was foliar applied twice to tomatoes at a nominal rate of 2.0 L/ha, corresponding to 240 g/ha of ametoctradin and 756 g/ha of propamocarb. The first application was made 8 – 9 days before harvest (DBH) (BBCH 81 – 87) (except for trial L200281 where the first application was made 10 DBH) and the second application was made 1 DBH (BBCH 83 – 89). Tomato (fruit) samples were collected at 0, 1 and 3 - 4 days after the last application (DALA).

Due to the incorrect application of propamocarb to one trial in 2020 an additional independent trial was conducted in NEU (Poland) to support the use of BAS 650 F (ametoctradin) and BAS 9068 F (propamocarb) in tomato. BAS 743 00 F (120 g/L of ametoctradin and 378 g/L of propamocarb) a suspension concentrate (SC) formulation, was foliar applied twice to tomatoes at a nominal rate of 2.0 L/ha, corresponding to 240 g/ha of ametoctradin and 756 g/ha of propamocarb. The first application was made 8 DBH (BBCH 81 – 85) and the second application was made 1 DBH (BBCH 85 – 87). Tomato (fruit) samples were collected at 0, 1 and 2 days after the last application (DALA).

All samples were maintained frozen (≤ -18°C) at the testing facility, during shipping to the laboratory, and were stored frozen prior to analysis. The maximum storage interval for samples between harvest and analysis was 271 days (*ca* 9 months). Residues of propamocarb have been shown to be stable in high water content crops for at least 26 months.

Residues of propamocarb were determined using XXXX method no. L0450/01, a LC-MS/MS method. Acceptable concurrent recoveries were reported for tomato fruit, therefore demonstrating the suitability of the methods. The limit of quantification (LOQ) was 0.01 mg/kg.

**Table A 48: Summary of recoveries of propamocarb in tomato**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Matrix** | **Fortification Level  [mg/kg]** | **Summary Recoveries** | | | |
| **Method No. L0450/01** | | **Mean  [%]** | **SD1)  [±]** | **RSD2) [%]** | **n3)** |
| Propamocarb | | | | | |
| Tomato fruit\* | 0.010, 0.10 and 1.0 | 100 | 6.3 | 6.3 | 10 |
| Tomato fruit† | 0.010, 0.10 and 10 | 101 | - | 2.6 | 7 |

1) SD: Standard deviation

2) RSD: Relative standard deviation

3) n: Number of results included in calculations

\* Procedural recoveries from study 2021/2020563

† Procedural recoveries from study 2022/2041755

**Table A 49: Summary of the study 2021/2020563 & 2022/2041755 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 a.s./ ha** | **Water (l/ha)** | **g a.s./hl** | **Propamocarb** |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| L200280 / 79227 Schallstadt, Germany / NEU / 2020 | Tomato / Matina | 1. 19.05.2020  2. 10.06.2020 – 15.07.2020  3. - | 823  790 | 327  313 | 252  252 | 10.08.2020  18.08.2020 | 87-89 | Fruit  Fruit  Fruit | 0.71  0.61  0.47 | 0  1  3 | XXXX method No. L0450/01 for propamocarb  LOQ = 0.01 mg/kg  Maximum storage interval (days): 271 |
| L200281 / Thorée les Pins, France / NEU / 2020 | Tomato / Tribeca | 1. 15.05.2020  2. 10.06.2020 – 20.08.2020  3. 01.09.2020 – 20.09.2020 | 722  739 | 287  293 | 252  252 | 26.08.2020  04.09.2020 | 86 | Fruit  Fruit  Fruit | 0.35  0.27  0.24 | 0  1  3 |
| L200283 / H-2921 Komarom, Hungary / NEU / 2020 | Tomato / Mobil F1 | 1. 02.06.2020  2. 20.06.2020 – 20.07.2020  3. - | 717  762 | 284  302 | 252  252 | 17.08.2020  24.08.2020 | 83-84 | Fruit  Fruit  Fruit | 0.45  0.23  0.19 | 0  1  3 |
| L210194 / 99-122 Góra Św iętej Małgorzaty, Poland / NEU / 2021 | Tomato / Hector | 1. 14.05.2021  2. 07.06.2021 – 30.07.2021  3. 27.08.2021 | 771  756 | 306  300 | 252  252 | 18.08.2021  25.08.2021 | 85-87 | Fruit  Fruit  Fruit | 0.30  0.16  0.20 | 0  1  2 |

(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

* + - * 1. 2022/2011021

|  |  |
| --- | --- |
| Comments of zRMS: | The study has been accepted.  In 2021 4 field trials were conducted in NEU to determine residues of Propamocarb, Ametoctradin, M650F003, and M650F004 in tomatoes after treatment with BAS 743 00 F which was applied twice in each trial on plot 2 at 7-8 DBH and at 1 DBH respectively, at a rate of 2.0 L/ha (equal to 0.756 kg/ha of Propamocarb and 0.240 kg/ha of Ametoctradin) with a water volume of 300 L/ha.  Collected samples were analysed for Propamocarb according to the XXXX method L0450/01. The limit of quantitation (LOQ) of the method is 0.010 mg/kg. For Ametoctradin, M650F003, and M650F004 samples were analysed according to the XXXX method L0078/01. The LOQ of the method is 0.010 mg/kg.  Matrix-matched standards were used for quantitation in both methods. The final determinations were performed by LC-MS/MS. 2 transitions were monitored. For the recoveries, the mean values were within the acceptable range of 70 % and 120 %, with a relative standard deviation (RSD) ≤ 20 %. The validation parameters required were within the acceptable range. No residues at or above the LOQ were found in any of the control samples. |

|  |  |
| --- | --- |
| Reference: | CA 6.3.3/3 |
| Report | Study on the residue behaviour of Propamocarb (Reg.No. 4628172) and Ametoctradin (BAS 650 F) in tomato after two applications of BAS 743 00 F under field conditions in Northern Europe, 2021  Plier, S and Eysoldt, M, 2022  XXXX Study ID 890060, Study No. 21 47 GRU 0002  XXXX DocID 2022/2011021 |
| Guideline(s): | * + European Community Guideline 7029/VI/95 - rev.5, 22/07/97: General recommendations for the design preparation and realization of residue trials.   + European Commission guideline SANTE/2019/12752: Technical guidelines on Data Requirements for Setting Maximum Residue Levels, Comparability of Residue Trials and Extrapolation of Residue Data on Products from Plant and Animal Origin (Repealing and replacing SANCO 7525/VI/95 – Rev. 10.3)   + OECD Guideline for the testing of chemicals – Crop Field Trials: OECD/OCDE 509. Adopted 7 September 2009 |
| Deviations: | Yes, none that affect the validity of the study |
| GLP: | Yes |
| Acceptability: | Yes | |

**Materials and methods**

In 2021, four independent field trials were conducted in NEU (Germany, northern France, Poland and Belgium) to support the use of BAS 650 F (ametoctradin) and BAS 9068 F (propamocarb) in tomato. BAS 743 00 F (120 g/L of ametoctradin and 478 g/L of propamocarb) a suspension concentrate (SC) formulation, was foliar applied twice to tomatoes at a nominal rate of 2.0 L/ha, corresponding to 240 g/ha of ametoctradin and 756 g/ha of propamocarb. The first application was made 7 - 8 days before harvest (DBH) (BBCH 81 - 85) and the second application was made 1 DBH (BBCH 82 – 87). Tomato (fruit) samples were collected at 0, 1 and 3 - 4 days after last application (DALA).

All samples were maintained frozen (≤ -18°C) at the testing facility, during shipping to the laboratory, and were stored frozen prior to analysis. The maximum storage interval for samples between harvest and analysis was 275 days (*ca* 9 months). Residues of propamocarb have been shown to be stable in high water content crops for at least 26 months.

Residues of propamocarb were determined using XXXX method no. L0450/01, a LC-MS/MS method. Acceptable concurrent recoveries were reported for tomato fruit, therefore demonstrating the suitability of the methods. The limit of quantification (LOQ) was 0.01 mg/kg.

**Table A 50: Summary of recoveries of propamocarb in tomato**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Matrix** | **Fortification Level  [mg/kg]** | **Summary Recoveries** | | |
| **Method No. L0450/01** | | **Mean  [%]** | **RSD1) [%]** | **n2)** |
| Propamocarb | | | | |
| Tomato fruit | 0.010, 0.10 and 10 | 102 | 5.1 | 9 |

1) RSD: Relative standard deviation

2) n: Number of results included in calculations

**Table A 51: Summary of the study 2022/2011021 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 a.s./ ha** | **Water (l/ha)** | **g a.s./hl** | **Propamocarb** |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| L210028 / 04827 Machem OT, Gerichshain, Germany / NEU / 2021 | Tomato / Hoffmanns Rentita | 1. 24.05.2021  2. 01.06.2021 – 19.07.2021  3. 18.08.2021 | 756  781 | 300  310 | 252  252 | 10.08.2021  17.08.2021 | 87 | Fruit  Fruit  Fruit | 0.39  0.39  0.14 | 0  1  3 | XXXX method No. L0450/01 for propamocarb  LOQ = 0.01 mg/kg  Maximum storage interval (days): 275 |
| L210029 / 71570 La Chapelle de Guinchay, France / NEU / 2021 | Tomato / Fandango | 1. 09.06.2021  2. 12.07.2021 – 20.08.2021 | 790  731 | 131  290 | 252  252 | 31.08.2021  07.09.2021 | 82 | Fruit  Fruit  Fruit | 0.37  0.32  0.13 | 0  1  3 |
| L210030 / 64-606 Wychowaniec, Poland / NEU / 2021 | Tomato / Dyno | 1. 16.05.2021  2. 25.06.2021 – 05.08.2021  3. 31.08.2021 | 766  731 | 304  290 | 252  252 | 24.08.2021  30.08.2021 | 83 | Fruit  Fruit  Fruit | 0.71  0.076  0.071 | 0  1  3 |
| L210031 / 3470 Kortenaken, Belgium / NEU / 2021 | Tomato / Pannovy | 1. 28.06.2021  2. 15.07.2021 – 20.08.2021  3. 16.09.2021 | 790  739 | 313  293 | 252  252 | 08.09.2021  15.09.2021 | 85 | Fruit  Fruit  Fruit | 2.6  2.0  2.1 | 0  1  4 |

(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

* + - * 1. 2022/2041764

|  |  |
| --- | --- |
| Comments of zRMS: | The study has been accepted.  The objective of the study was to determine the magnitude of residues of Ametoctradin and its metabolites (M650F003, M650F004) as well as of Propamocarb in tomatoes after treatment with either BAS 743 00 F or BAS 743 03 F in 4 trials conducted under field conditions in Northern Europe. At each trial site, there was one untreated plot in addition to 2 treated plots. At each site the test item was applied 2 times 7-8 DBH and 1 DBH at a rate of 2.0 L/ha (240 g/ha Ametoctradin and 756 g/ha Propamocarb). Plot 2 was treated with BAS 743 00 F and plot 3 was treated with BAS 743 03 F.  For the determination of Propamocarb method L0450/01 was used. For the determination of Ametoctradin, M650F003, and M650F004 method L0078/01 was used. In both cases HPLC with tandem mass spectrometry was employed for final compounds determination. 2 mass transitions were monitored.  For the recoveries, the mean values were within the acceptable range of 70 % and 110 %, with a relative standard deviation (RSD) ≤ 20 %. No residues ≥ LOQ were found in any of the untreated control samples. The validation parameters required were within the acceptable range. |

|  |  |
| --- | --- |
| Reference: | CA 6.3.3/4 |
| Report | Study on the residue behaviour of Ametoctradin (BAS 650 F) and Propamocarb (Reg.No. 4628172) in tomato after application of either BAS 743 00 F or BAS 743 03 F under field conditions in Northern Europe, 2022  Plier, S. & Eysoldt, M., 2023  XXXX Study ID 921990, Study No. 22 47 GRU 0006  XXXX DocID 2022/2041764 |
| Guideline(s): | * + European Community Guideline 7029/VI/95 - rev.5, 22/07/97: General recommendations for the design preparation and realization of residue trials.   + European Commission guideline SANTE/2019/12752: Technical guidelines on Data Requirements for Setting Maximum Residue Levels, Comparability of Residue Trials and Extrapolation of Residue Data on Products from Plant and Animal Origin (Repealing and replacing SANCO 7525/VI/95 – Rev. 10.3)   + OECD Guideline for the testing of chemicals – Crop Field Trials: OECD/OCDE 509. Adopted 7 September 2009   + SANTE/2020/12830, Rev. 1   + OECD ENV/JM/MONO(2007)17 |
| Deviations: | Yes, none that affect the validity of the study |
| GLP: | Yes |
| Acceptability: | Yes | |

**Materials and methods**

In 2022, four independent field trials were conducted in NEU (Germany, northern France, Poland and The Netherlands) to support the use of BAS 650 F (ametoctradin) and BAS 9068 F (propamocarb) in tomato. In treatment plot 2, BAS 743 00 F (120 g/L of ametoctradin and 378 g/L of propamocarb) a suspension concentrate (SC) formulation, was foliar applied twice to tomatoes at a nominal rate of 2.0 L/ha, corresponding to 240 g/ha of ametoctradin and 756 g/ha of propamocarb. The first application was made 7 – 8 days before harvest (DBH) and the second application was made 1 DBH. In treatment plot 3, BAS 743 03 F (120 g/L of ametoctradin and 378 g/L of propamocarb) a suspension concentrate (SC) formulation, was foliar applied twice to tomatoes at a nominal rate of 2.0 L/ha, corresponding to 240 g/ha of ametoctradin and 756 g/ha of propamocarb. The first application was made 7 – 8 DBH and the second application was made 1 DBH. Tomato (fruit) samples were collected at 0, 1 and 2 – 4 days after the last application (DALA).

All samples were maintained frozen (≤ -18°C) at the testing facility, during shipping to the laboratory, and were stored frozen prior to analysis. The maximum storage interval for samples between harvest and analysis was 121 days (*ca* 4 months). Residues of propamocarb have been shown to be stable in high water content and high starch content crops for at least 26 months.

Residues of propamocarb were determined using XXXX method no. L0450/01, a LC-MS/MS method. Acceptable concurrent recoveries were reported for tomato fruit, thus demonstrating the suitability of the methods. The limit of quantification (LOQ) was 0.01 mg/kg.

**Table A 52: Summary of recoveries of propamocarb**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Matrix** | **Fortification Level  [mg/kg]** | **Summary Recoveries** | | |
| **Method No. L0450/01** | | **Mean  [%]** | **RSD1) [%]** | **n2)** |
| Propamocarb | | | | |
| Tomato fruit | 0.010, 0.10, 1.0 and 10 | 99.8 | 10 | 21 |

1) RSD: Relative standard deviation

2) n: Number of results included in calculations

**Table A 53: Summary of the study 2022/2041764 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 a.s./ ha** | **Water (l/ha)** | **g a.s./hl** | **Propamocarb** |
|  | (a) | (b) |  |  |  | (c) |  |  |  | (d) | (e) |
| L220103 / 04827 Machern OT Gerichshain, Germany / NEU / 2022  (Plot 2) | Tomato / Hoffmanns Rentita | 1. 16.05.2022  2. 18.05.2022 – 02.08.2022  3. 21.07.2022 | 731  741 | 290  294 | 252  252 | 13.07.2022  20.07.2022 | 85 | Fruit  Fruit  Fruit | 0.26  0.27  0.096 | 0  1  2 | XXXX method No. L0450/01 for propamocarb  LOQ = 0.01 mg/kg  Maximum storage interval (days): 121 |
| L220103 / 04827 Machern OT Gerichshain, Germany / NEU / 2022  (Plot 3) | Tomato / Hoffmanns Rentita | 1. 16.05.2022  2. 18.05.2022 – 02.08.2022  3. 21.07.2022 | 746  761 | 296  302 | 252  252 | 13.07.2022  20.07.2022 | 85 | Fruit  Fruit  Fruit | 0.25  0.40  0.14 | 0  1  2 |
| L220104 / 5110 Aumenancourt, France / NEU / 2022  (Plot 2) | Tomato / Supersteak | 1. 27.05.2022  2. 15.07.2022 – 17.08.2022  3. 18.08.2022 | 723  713 | 287  283 | 252  252 | 09.08.2022  16.08.2022 | 84 | Fruit  Fruit  Fruit | 0.87  0.73  0.65 | 0  1  2 |
| L220104 / 5110 Aumenancourt, France / NEU / 2022  (Plot 3) | Tomato / Supersteak | 1. 27.05.2022  2. 15.07.2022 – 17.08.2022  3. 18.08.2022 | 728  723 | 289  287 | 252  252 | 09.08.2022  16.08.2022 | 84 | Fruit  Fruit  Fruit | 1.0  0.81  0.66 | 0  1  3 |
| L220105 / 64-606 Wychowaniec, Poland / NEU / 2022  (Plot 2) | Tomato / Dyno | 1. 15.05.2022  2. 15.06.2022 – 03.08.2022  3. 07.09.2022 | 822  796 | 326  316 | 252  252 | 30.08.2022  06.09.2022 | 84 | Fruit  Fruit  Fruit | 1.0  0.72  0.19 | 0  1  3 |
| L220105 / 64-606 Wychowaniec, Poland / NEU / 2022  (Plot 3) | Tomato / Dyno | 1. 15.05.2022  2. 15.06.2022 – 03.08.2022  3. 07.09.2022 | 822  796 | 326  316 | 252  252 | 30.08.2022  06.09.2022 | 84 | Fruit  Fruit  Fruit | 0.65  0.42  0.18 | 0  1  3 |
| L220106 / 6599 AV Ven-Zelerheide, The Netherlands / NEU / 2022  (Plot 2) | Tomato / Pannovy | 1. 16.05.2022  2. 10.06.2022 – 25.06.2022  3. 09.08.2022 | 739  781 | 293  310 | 252  252 | 01.08.2022  08.08.2022 | 85 | Fruit  Fruit  Fruit | 1.1  1.1  1.3 | 0  1  4 |
| L220106 / 6599 AV Ven-Zelerheide, The Netherlands / NEU / 2022  (Plot 3) | Tomato / Pannovy | 1. 16.05.2022  2. 10.06.2022 – 25.06.2022  3. 09.08.2022 | 781  798 | 310  317 | 252  252 | 01.08.2022  08.08.2022 | 85 | Fruit  Fruit  Fruit | 1.1  1.0  1.3 | 0  1  4 |

(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

* + 1. Magnitude of residues in livestock
       1. Livestock feeding studies

No new data submitted in the framework of this application.

* + 1. Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)
       1. Distribution of the residue in peel/pulp

No new data submitted in the framework of this application.

* + - 1. Processing studies on a core set of representative processes

No new data submitted in the framework of this application.

* + 1. Magnitude of residues in representative succeeding crops

No new data submitted in the framework of this application.

* + 1. Other/Special Studies (KCA 6.10, KCA 6.10.1)

|  |  |
| --- | --- |
| Comments of zRMS: | zRMS decided that the data provided can be used for the purpose of this submission. This is new data submitted by XXXX a as part of an ongoing MRL application (EFSA-Q-2022-00427).  Of the intended uses, aubergine and floriculture are considered melliferous (SANTE/11956/2016) and the applicant informs that the transfer of propamocarb residues to honey has been investigated and new data submitted (Appeltauer, A., 2021, Report No. S20-01996) as part of an ongoing MRL application (EFSA-Q-2022-00427). The applicant, XXXX, has a Letter of Access for these data. A study summary based on the publicly available IUCLID dossier has been included in A 2.2.7.  The semi-field trials were conducted on *Phacelia tanacetifolia* with a total application rate of 6 kg propamocarb/ha and a MRL of 15 mg/kg was proposed. These data accommodate the intended GAPs in this submission and residues exceeding the proposed MRL are not expected as a result of the GAPs in this submission. |

|  |  |
| --- | --- |
| Reference: | CA 6.10.1 |
| Report | Determination of Residues of Propamocarb in Honey after Four Applications of Fluopicolide + Propamocarb SC 687.5 in Phacelia tanacetifolia at 4 Sites in Northern and Southern Europe in 2020,  Appeltauer, A., 2021  Report No. S20-01996 |
| Guideline(s): | OECD 509  SANTE/11956/2016 rev. 9 |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes | |

**Materials and methods**

Four residue trials were conducted in Europe (2 in northern Europe and 2 in southern Europe) on *Phacelia tanacetifolia* in order to determine the magnitude of residues of propamocarb in honey after application of propamocarb under semi-field conditions. The fungicide Fluopicolide + Propamocarb SC 687.5, a suspension concentrate formulation containing 625 g propamocarb/L, was applied to plots with *Phacelia tanacetifolia* by spraying four times with spray intervals of 5-7 days. The amount of propamocarb was 3.0 kg/ha for the first application and 0.9-1.1 kg/ha for the second, third and fourth application.

On each trial site one tunnel confining the bees was established on the control and the treated plot. One bee hive was set up per tunnel for the control and treated plot each. Colony assessments were performed before set-up of the hives in the tunnels and after sampling of the honey.

Honey was collected from initially empty combs which were introduced in the hive shortly before the third application. Honey was collected once mature at the end of flowering or if the water content was < 20% or after comb closure – whatever occurred first - for subsequent residue analysis.

Residues of propamocarb in honey were determined according to method 01642 by HPLC-MS/MS. Procedural recoveries at 0.01 mg/kg, 0.10 mg/kg and 7.0 mg/kg propamocarb in honey were acquired thus verifying the performance of the method. The LOQ was 0.01 mg/kg. The maximum storage interval from sampling to last extraction was 132 days, which is covered by available storage stability studies.

**Recovery data for propamocarb in honey**

| **Matrix** | **Spike level (mg/kg)** | **Individual recoveries (%)** | **Sample size (n)** | **Mean recovery (%)** | **RSD (%)** |
| --- | --- | --- | --- | --- | --- |
| Honey | 0.01 | 99, 98, 99, 101, 104, 102 | 6 | 101 | 2.2 |
| 0.10 | 101, 101, 99, 100, 101, 102 | 6 | 101 | 1.0 |
| 7.0 | 100, 99, 99, 100, 101 | 5 | 100 | 0.8 |
| **Overall** | | 17 | 100 | 1.5 |

**Results and discussions**

Residues collected according to the intended GAP are summarized in the table below.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trial No. Country** | **C/T** | **Crop growth stage at sampling [BBCH[** | **DALT** | **Honey fresh or dried** | **Residues [mg/kg]** |
| **a.s. propamocarb** |
| S20-01996-01  Germany | C | 67 | 3 | Fresh | <0.01 |
| T | 67 | 3 | Fresh | 1.8  1.7\*  1.7\*\* |
| S20-01996-02  Germany | C | 69 | 9 | Fresh | <0.01 |
| T | 69 | 9 | Fresh | 6.1  5.6\*  5.5\*\* |
| S20-01996-03  France | C | 67 | 11 | Fresh | <0.01 |
| T | 67 | 11 | Fresh | 1.5  1.5\*  1.5\*\* |
| S20-01996-04  Spain | C | 67-69 | 8 | Fresh | <0.01 |
| T | 67-69 | 8 | Fresh | 0.14  0.14\*  0.14\*\* |

DALT = Days after last treatment

C = Control

T = Treated

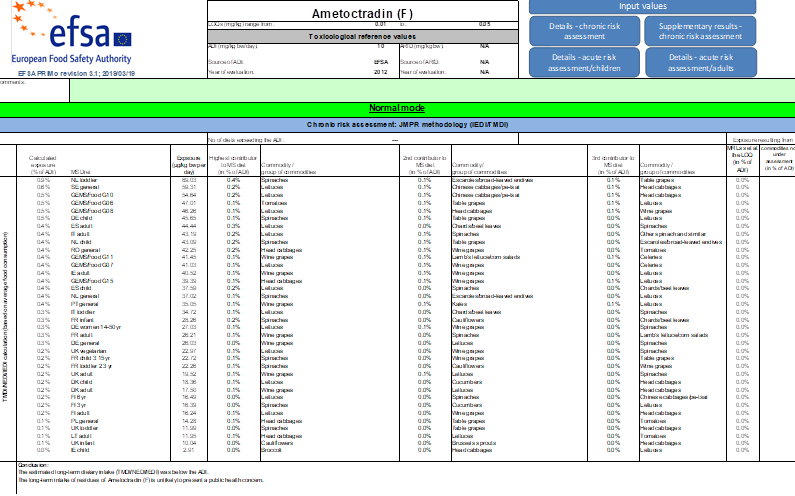
\* 2nd verification samples/ \*\* 3rd verifications samples

**Conclusion**

In honey, the potential residues of propamocarb were determined after application of propamocarb to Phacelia tanacetifolia as a surrogate crop under semi-field conditions. Based on the residue definitions for monitoring (propamocarb and its salts, expressed as propamocarb) in honey, an MRL of 15 mg/kg is proposed for propamocarb in honey.

1. Pesticide Residue Intake Model (PRIMo)
   1. Ametoctradin TMDI calculations





* 1. IEDI calculations

Not conducted.

* 1. IESTI calculations - Raw commodities

Not conducted.

* 1. IESTI calculations - Processed commodities

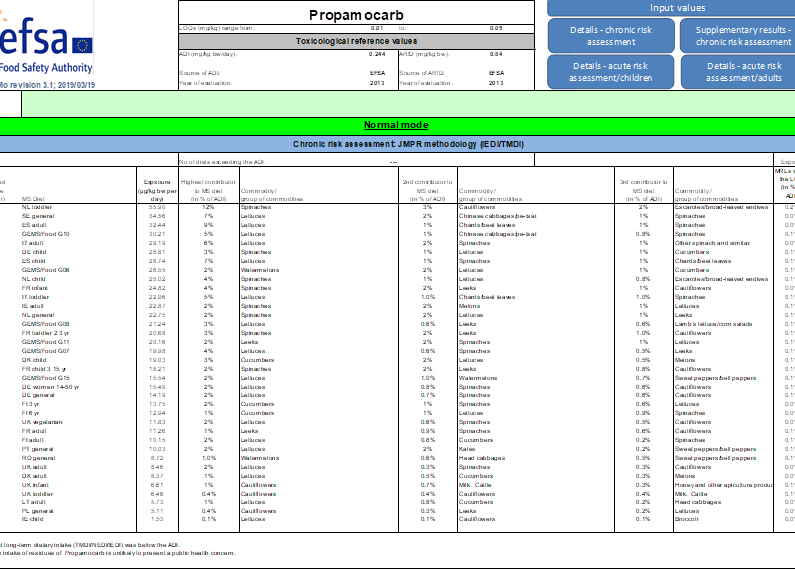
Not conducted.

* 1. Propamocarb TMDI calculations

Not conducted

* 1. Propamocarb IEDI calculations





* 1. IESTI calculations - Raw commodities



* 1. IESTI calculations - Processed commodities

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Processed commodities** | **Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI): | |  | --- | **Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI): | |  | --- |
| **IESTI** |  |  |  | **IESTI** |  |  |  |
| Highest % of ARfD/ADI | Processed commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Processed commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) |
| 0.9% | Tomatoes / juice | 4 / 0.4 | 7.52 | 0.6% | Onions / boiled | 2 / 0.51 | 4.80 |
| 0.4% | Tomatoes / sauce/puree | 4 / 0.4 | 3.77 | 0.39% | Tomatoes / sauce/puree | 4 / 0.4 | 3.24 |
| 0.1% | Potatoes / fried | 0.3 / 0.01 | 0.93 | 0.01% | Potatoes / chips | 0.3 / 0.01 | 0.08 |
| 0.1% | Potatoes / dried (flakes) | 0.3 / 0.05 | 0.59 | 0.01% | Potatoes / dried (flakes) | 0.3 / 0.05 | 0.06 |
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1. Additional information provided by the applicant

None

1. Zincke F, Fischer A, Kittelmann A, Kraus C, Scholz R and Michalski B, 2022. Doi:10.5281/zenodo.6827098 [↑](#footnote-ref-1)
2. Pesticides\_mrl\_guidelines\_animal\_model\_2017.xls http://ec.europa.eu/food/plant/pesticides/max\_residue\_levels/guidelines/index\_en.htm [↑](#footnote-ref-2)
3. Zincke F, Fischer A, Kittelmann A, Kraus C, Scholz R and Michalski B, 2022. Doi:10.5281/zenodo.6827098 [↑](#footnote-ref-3)