|  |
| --- |
| REGISTRATION REPORT  Part A  Risk Management |
| 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 |
| NATIONAL ASSESSMENT  Poland  (post-authorisation requirement) |
| Applicant: XXXX  Submission date: April 2025  MS Finalisation date: June 2025 |

Version history

|  |  |
| --- | --- |
| When | What |
| October 2023 | Initial dRR - XXXX |
| May 2024 | Initial RR - zRMS |
| November 2024 | Updated dRR – after MSs consultation |
| April 2025 | Updated dRR: post-authorisation requirement – XXXX   * Section 3.1 updated to include outcome of a 2 year storage stability * Appendix 4 updated to include 2 year storage stability reference |
| June 2025 | zRMS-PL evaluation – post registration data |

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PART A

RISK MANAGEMENT

# Details of the application

The application was submitted to address the post-authorisation requirement in Poland regarding the submission of the ambient temperature shelf-life study of the plant protection product DIVEXO (BAS 743 03 F), a SC formulation containing 120 g/L Ametoctradin and 451 g/L Propamocarb hydrochloride (=378 g/L Propamocarb) to confirm the product shelf-life of 2 years. For that reason, final zRMS Core Part B Section 1,2 and 4 was updated to include the 2 years shelf-life study of BAS 743 03 F.

The risk assessment conclusions based on the information, data and assessments provided in Registration Report, Part B Sections 1-8 and Part C. The information, data and assessments provided in Registration Report, Parts B include assessments of further data or information as required at national registration. It also includes assessments for the safe use of BAS 743 03, which have been made using endpoints of the EU review of the active substances Ametoctradin and Propamocarb (Propamocarb hydrochloride).

For the active substance Ametoctradin, the RMS finalized a Draft Assessment Report (DAR) and an updated DAR in September 2009 and December 2010, respectively. EFSA conclusion (November 2012) provides the relevant review information or a reference to where such information can be found.

For the active substance Propamocarb, the Draft Assessment Report (DAR) in 2004 and the EFSA conclusions (2006) provide the relevant review information or a reference to where such information can be found.

This document describes the specific conditions of use and labelling required for the authorisation of BAS 743 03 F.

In Appendix 1 of this document a copy of the product authorisation will be inserted by the evaluating member state after the evaluation.

Appendix 2 of this document contains a copy of the draft product label.

Appendix 3 of this document contains copies of the letters of access to the protected data / third party data that was needed for evaluation of the formulation.

Appendix 4 of this document contains the lists of data considered for national authorization.

## Application background

This application was submitted by XXXX in April 2025, represented by the following affiliate:

**Applicant details**

|  |  |
| --- | --- |
| Name: | XXXX |
| Address: | XXXX |
| Person to contact: | |
| Name: | XXXX |
| Phone: | +48 XXXX |
| Mobile: | +48 XXXX |
| Email: | XXXX |

The dossier will be submitted in the central zone to the countries Austria, Belgium, Czech Republic, Germany, Hungary, Ireland, The Netherlands, Romania, Slovenia, Slovakia and Poland whereas Poland is acting as zonal rapporteur member state.

## Letters of Access

Letter of Access to *Propamocarb hydrochloride Annex II and Annex III data package of Propamocarb hydrochloride inclusion into Annex I of Directive 91/414/EEC replaced by Regulation (EC) Nº 1107/2009* belonging to a 3rd Party Company (Bayer) is included in Appendix 3.

## Justification for submission of tests and studies

Testing is conducted according to the data requirements for the authorisation of plant protection products and is conducted in compliance with national and international animal welfare regulations. The testing strategy takes into account methods compliant with the 3R concept for refinement, reduction and replacement of animal testing where applicable and acceptable.

Testing has been conducted in order to fulfil the data requirements for plant protection products and in order to demonstrate an acceptable use of the plant protection product.

## Data protection claims

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

# Details of the authorization decision

## Product identity

|  |  |
| --- | --- |
| Product code | BAS 743 03 F |
| Product name in MS | DIVEXO |
| Authorization number | Not applicable |
| Function | Fungicide |
| Applicant | XXXX |
| Active substance(s)  (incl. content) | Ametoctradin, 120 g/L  Propamocarb hydrochloride, 451 g/L (=378 g/L Propamocarb) |
| Formulation type | Suspension Concentrate (SC) |
| Packaging | See following table, professional user |
| Coformulants of concern for national authorizations | Not applicable |
| Restrictions related to identity | Further information is provided in Part B, Section 1 |
| Mandatory tank mixtures | Not applicable |
| Recommended tank mixtures | DIVEXO was tested in tank-mixture with a broad range of formulation types that are susceptible to be used by the growers. No issues were observed in these test. Therefore DIVEXO is considered as safe product with regard to tank-mixtures with currently registered market standards.  No tank mixes are recommended on the product label. |

BAS 743 03 F is to be marketed in blow moulded high-density polyethylene (HDPE) or fluorinated high-density polyethylene (f-HDPE) containers, with a minimum wall thickness of 0.5 mm. They are sealed by either a foil seal or gasket, protected by a polyethylene screw cap.

**Packaging information for 0.15 litre bottle**

| **Type** | **Description** |
| --- | --- |
| Material: | HDPE or f-HDPE |
| Shape/size: | Cylindrical / approx. 63 mm diameter x 104 mm |
| Opening: | 42 mm inner diameter |
| Closure: | Screw cap |
| Seal: | Induction sealed or gasket |

**Packaging information for 0.25 litre bottle**

| **Type** | **Description** |
| --- | --- |
| Material: | HDPE or f-HDPE |
| Shape/size: | Cylindrical / approx. 63 mm diameter x 127 mm |
| Opening: | 42 mm inner diameter |
| Closure: | Screw cap |
| Seal: | Induction sealed or gasket |

**Packaging information for 0.5 litre bottle**

| **Type** | **Description** |
| --- | --- |
| Material: | HDPE or f-HDPE |
| Shape/size: | Cylindrical / approx. 69 mm diameter x 196 mm |
| Opening: | 42 mm inner diameter |
| Closure: | Screw cap |
| Seal: | Induction sealed or gasket |

**Packaging information for 1 litre bottle**

| **Type** | **Description** |
| --- | --- |
| Material: | HDPE or f-HDPE |
| Shape/size: | Cylindrical / approx. 88.5 mm diameter x 234 mm |
| Opening: | 42 mm inner diameter |
| Closure: | Screw cap |
| Seal: | Induction sealed or gasket |

**Packaging information for 1 litre eco-bottle**

| **Type** | **Description** |
| --- | --- |
| Material: | HDPE or f-HDPE |
| Shape/size: | Cylindrical / approx. 88.5 mm diameter x 234 mm |
| Opening: | 54 mm inner diameter |
| Closure: | Screw cap |
| Seal: | Induction sealed or gasket |

**Packaging information for 5 litre container**

| **Type** | **Description** |
| --- | --- |
| Material: | HDPE or f-HDPE |
| Shape/size: | Rectangular / approx. 190 mm x 140 mm x 313 mm |
| Opening: | 54 mm inner diameter |
| Closure: | Screw cap |
| Seal: | Induction sealed or gasket |

**Packaging information for 5 litre eco-container**

| **Type** | **Description** |
| --- | --- |
| Material: | HDPE or f-HDPE |
| Shape/size: | Rectangular / approx. 185 mm x 136 mm x 313 mm |
| Opening: | 54 mm inner diameter |
| Closure: | Screw cap |
| Seal: | Induction sealed or gasket |

**Packaging information for 10 litre container**

| **Type** | **Description** |
| --- | --- |
| Material: | HDPE or f-HDPE |
| Shape/size: | Rectangular / approx. 230 mm x 165 mm x 375 mm |
| Opening: | 54 mm inner diameter |
| Closure: | Screw cap |
| Seal: | Induction sealed or gasket |

**Packaging information for 10 litre eco-container**

| **Type** | **Description** |
| --- | --- |
| Material: | HDPE or f-HDPE |
| Shape/size: | Rectangular / approx. 230 mm x 187 mm x 358 mm |
| Opening: | 54 mm inner diameter |
| Closure: | Screw cap |
| Seal: | Induction sealed or gasket |

**Packaging information for 15 litre container**

| **Type** | **Description** |
| --- | --- |
| Material: | HDPE or f-HDPE |
| Shape/size: | Rectangular / approx. 265 mm x 215 mm x 400 mm |
| Opening: | 54 mm inner diameter |
| Closure: | Screw cap |
| Seal: | Induction sealed or gasket |

**Packaging information for 20 litre container**

| **Type** | **Description** |
| --- | --- |
| Material: | HDPE or f-HDPE |
| Shape/size: | Rectangular / approx. 290 x 235 x 424 mm |
| Opening: | 52 mm inner diameter |
| Closure: | Screw cap |
| Seal: | Induction sealed or gasket |

**Packaging information for 50 litre container**

| **Type** | **Description** |
| --- | --- |
| Material: | HDPE or f-HDPE |
| Shape/size: | Cylindrical / approx. 380 mm x 618 mm (d x h) |
| Opening: | 52 mm inner diameter |
| Closure: | Screw cap, plug or valve |
| Seal: | Gasket |

**Packaging information for 100 litre container**

| **Type** | **Description** |
| --- | --- |
| Material: | HDPE or f-HDPE |
| Shape/size: | Cylindrical / approx. 380 mm x 618 mm (d x h) |
| Opening: | 52 mm inner diameter |
| Closure: | Screw cap, plug or valve |
| Seal: | Gasket |

**Packaging information for 200 litre container**

| **Type** | **Description** |
| --- | --- |
| Material: | HDPE or f-HDPE |
| Shape/size: | Cylindrical / approx. 581 mm x 935 mm (d x h) |
| Opening: | 52 mm and/or 65 mm inner diameter |
| Closure: | Screw cap, plug or valve |
| Seal: | Gasket |

**Packaging information for 1000 litre container**

| **Type** | **Description** |
| --- | --- |
| Material: | HDPE or f-HDPE |
| Shape/size: | Rectangular / approx. 1200 mm x 1000 x 1150 mm |
| Opening: | 54 mm and 155 mm inner diameter |
| Closure: | Screw cap, plug or valve |
| Seal: | Gasket |

## Conclusion

The evaluation of the application for DIVEXO (BAS 743 03 F) resulted in the decision to grant the authorization. All uses applied for were authorised (see 2.6).

## Substances of concern for national monitoring

Not applicable.

## Classification and labelling

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

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

|  |  |
| --- | --- |
| Hazard class(es), categories: | Skin Sens. 1  Aquatic Chronic 2 |

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

|  |  |
| --- | --- |
| Hazard pictograms: | GHS_POLLUT.WMF **GHS09GHS07** |
| Signal word: | Warning |
| Hazard statement(s): | **H317 May cause an allergic skin reaction**   |  |  | | --- | --- | | **H411** | **Toxic to aquatic life with long lasting effects.** | |  |  | |
| Precautionary statement(s): | |  |  | | --- | --- | | General:  **P101** | **If medical advice is needed, have product container or label at hand.** | | **P102**  **P103**  **P261**  **P272**  **P280** | Keep out of reach of children.  Read label before use.  **Avoid breathing ~~dust/fume/gas~~/mist/vapours/spray**  Contaminated work clothing should not be allowed out of the workplace.  **Wear protective gloves/protective clothing** | | Response:  **P391**  **P302 + P352**  **P333 + P313**  **P362 + P364** | Collect spillage.  **IF ON SKIN: Wash with plenty of soap and water**  **If skin irritation or rash occurs: Get medical advice/attention**  Take off contaminated clothing and wash it before reuse. | | Disposal:  **P501** | **Dispose of contents/container to hazardous or special waste collection point.** | |
| Additional labelling phrases: |  |
| **EUH401** | **To avoid risks to man and the environment, comply with the instructions for use.** |
|  | **Contains Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) and 1,2-benzisothiazol-3-one. ~~May produce an allergic reaction. [EUH208]~~** |

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

|  |  |
| --- | --- |
| SP 1 | Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads). |
|  |  |

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

None.

## Risk management

### Restrictions linked to the PPP

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

|  |  |
| --- | --- |
| Operator protection: | |
|  | Gloves and coveralls during mixing and loading |
| Worker protection: | |
|  | Workwear  Potato: Workwear (arms, body and legs covered) and **gloves**, during reaching, picking |
| Integrated pest management (IPM)/sustainable use: | |
|  | None |
| Environmental protection | |
| SP 1 | Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads). |
| Other specific restrictions | |
|  | None |

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

|  |  |
| --- | --- |
| Integrated pest management (IPM)/sustainable use: | |
|  | Not applicable. |

### Specific restrictions linked to the intended uses

None.

## Intended uses (only NATIONAL GAP)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | |  | | | | | | | |  | | | GAP rev. 2.0, date: 2023-05-15 | | | | |
|  | | | | |  | | | | | | | |  | | |  | | | | |
| PPP (product name/code): | | | | | DIVEXO / BAS 743 03 F | | | | | | | | Formulation type: | | | Suspension concentrate (SC) (a, b) | | | | |
| Active substance 1: | | | | | Ametoctradin\* (Initium) | | | | | | | | Conc. of as 1: | | | 120 g/L (c) | | | | |
| Active substance 2: | | | | | Propamocarb hydrochloride\*\* | | | | | | | | Conc. of as 2: | | | 451 g/L (equivalent to 378 g Propamocarb/L) (c) | | | | |
| Safener: | | | | | None | | | | | | | | Conc. of safener: | | | Not relevant (c) | | | | |
| Synergist: | | | | | None | | | | | | | | Conc. of synergist: | | | Not relvant (c) | | | | |
| Applicant: | | | | | XXXX | | | | | | | | Professional use: | | |  | | | | |
| Zone(s): | | | | | Central (d) | | | | | | | | Non professional use: | | |  | | | | |
| Verified by MS: | | | | | yes | | | | | | | |  | | |  | | | | |
| Field of use: | | | | | Fungicide | | | | | | | |  | | |  | | | | |
| 1 | 2 | | 3 | | 4 | *5* | 6 | 7 | 8 | | | | 9 | 10 | | 11 | 12 | 13 | 14 | |
| **Use-No. (e)** | **Member state(s)** | | **Crop and/ or situation  (crop destination / purpose of crop)** | | **F, Fn, Fpn G, Gn, Gpn or I** | **Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group) | **Application** | | | | | | | **Application rate** | | | | **PHI** (days) | **Remarks:**   e.g. g safener/synergist per ha  (f) | |
| Method / Kind | Timing / Growth stage of crop & season | Max. number  a) per use  b) per crop/ season | | | | Min. interval between applications (days) | 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)** | | | | | | | | | | | | | | | | | | | | |
| 2 | PL | | Potato (including seed potatoes) (SOLTU) | | 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 | |
| 3 | PL | | Onion  (ALLCE), Garlic (ALLSA) | | F | *Peronospora destructor*  (PERODE) | SP | BBCH 14 – 39 ~~49~~ | a) 2  b) 2 | | | | 5 | a) 2  b) 4 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | 300/700 | 7 | Spray interval: 5-10 days  ~~Water volume Poland:~~  ~~200/800 L/ha~~    Applications only every 2nd year | |
| 5 | PL | | Tomato / Aubergine  (LYPES) / (SOLME) | | F | *Phytophthora infestans* (PHYTIN) | SP | ~~BBCH 21 40-89~~  BBCH 70-89 | a) 2  b) 2 | | | | 7 | a) 2  b) 4 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | 500/700 | 1 | Spray interval: 7-10 days | |
| **Minor uses according to Article 51 (zonal uses)** | | | | | | | | | | | | | | | | | | | | |
|  |  | |  | |  |  |  |  |  | | | |  |  | |  |  |  |  | |
| 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 | | | | | | | | | |

# Background of authorization decision and risk management

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a homogeneous white opaque free-flowing liquid. It is not explosive and has no oxidising properties. No flash point was detectable up to a temperature of 125°C. It has an auto-ignition temperature of 430°C. The product has a pH value of 7.5. When diluted 1% with deionized water the pH value is 7.6. When CIPAC D water is used to make a 1% dilution the pH value is 7.3. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 2 weeks at 54°C, neither the active ingredient content nor the technical properties changed. ~~A 2-year storage stability study is ongoing and the final results will be available in Q1 2025.~~ A 2 year storage stability study at 25 °C has been submitted which confirms that the active ingredient content and technical properties were also unchanged following storage in HDPE containers. Its technical characteristics are acceptable for a SC formulation.

The intended concentration of use is 0.17 to 2.00 % v/v.

The active ingredients contents and physical or technical properties remain unchanged after low and high temperature storage (7 days at 0°C and 14 days at 54°C) demonstrating no significant effect of low and high temperatures. Based on accelerated storage, the stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE containers. In the tests of suspensibility and spontaneity of dispersion, only the content of ametoctradin was determined, but it was considered acceptable as propamocarb hydrochloride is fully soluble in water.

~~An ambient temperature shelf life study is required to confirm the proposed shelf life of 2 years for the product BAS 743 03 F.~~

An ambient temperature shelf life study has been provided to confirm the proposed shelf life of 2 years for the product BAS 743 03 F. The formulation is stable during 2 years stability study. No significant changes in content active substances and technical properties is observed.

No change in HDPE packaging was observed after 2-y storage of the product.

The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE packaging.

The f-HDPE containers are supported based on extrapolation of storage data for the product BAS 743 03 F (for details see findings of storage stability tests, fRR B1,2,4).

The phrase ‘shake before use’ should be included on the label of the product due to colourless liquid phase separation observed upon storage (separation was fully reversible after agitation).

No tank mixes are recommended on the product label.

The product is not classified for physical-chemical hazards under CLP Regulation, therefore no labelling is proposed.

## Efficacy (Part B, Section 3)

Efficacy data have been generated in order to support the registration of the fungicide BAS 743 03 F in the Central Registration Zone.

BAS 743 03 F is a fungicide intended for the control of:

* *Phytophthora infestans* in potatoes, tomatoes and aubergines
* *Peronospora destructor* in onions and garlic

BAS 743 03 F contains 120 g ametoctradin/L and 451 g propamocarb-hydrochloride/L, SC formulation.

## Efficacy data

Altogether four formulations of the product were tested in the field trials depending on the crop and are used:

* BAS 743 AA F – tested in 2019
* BAS 743 AT F – tested between 2020 and 2021
* BAS 743 00 F – tested between in 2020-2021 (equivalent to BAS 743 AT F)
* BAS 743 03 F –tested in 2022

Although the formulations used in efficacy trials between 2019 and 2021, namely BAS 743 AA F, BAS 743 AT F and BAS 743 00 F are predecessor formulations of BAS 743 03 F, all are delivering the same active ingredient, amount and ratio, as the final formulation BAS 743 03 F. BAS 743 AA F differs from BAS 743 AT F and 743 00 F formulations in the use of different wetting agent, which has no influence on the selectivity or the products efficacy.

As tested formulation (BAS 743 00 F) exhibited a slight gelling issue of the product after an undisturbed long-term storage (> 20 weeks), reformulation, by changing dispersant and the thickener system was implemented to improve storage stability. The exchange of these compounds does not affect efficacy or crop selectivity.

*Preliminary tests*

In order to justify the most effective ratio of the active ingredients for BAS 743 03 F, different ratios of the two active ingredients were tested. Results showed that the formulation combination of 120 g of Ametoctradin + 451 g of Propamocarb-hydrochloride, meaning a ratio of 1:3.15 showed better control of the diseases tested than the alternative tested ratios.

Between 2020 and 2021, the performance of the solo active ingredients (Ametoctradin and Propamocarb-hydrochloride) was compared to the efficacy of the ready mixture in thirty trials covering the Maritime, the North-East and the South-East EPPO climatic zone. The potatoand onion trial results show that the active ingredients applied separately gave a lower level of performance against Phytophthora infestans and Peronospora destructor than the formulation of the two actives. Therefore, the results confirm the benefit of mixing Ametoctradin and Propamocarb-hydrochloride and that the 1:3.15 ratio provides optimum control of targeted pathogens in all tested crops.

For the formulation bridging, seventeen bridging efficacy trials demonstrate that both formulations BAS 743 00 F and the final BAS 743 03 F formulation performed equivalently and showed good control of the tested diseases in most of the conducted trials for the three EPPO climatic zones.

*Minimum effective dose*

Fifty-one trials conducted on potatoes, onions, and tomatoes are presented to justify the minimum effective dose for intended uses of the product BAS 743 03 F, following the Good Agricultural Practices recommended. In summary, BAS 743 03 F at the targeted dose rate (2.0 L/ha) per individual crop provided the optimum and most consistent control of the targeted pathogens, and consequently this rate should be considered as the minimum effective dose rate in all tested crops under a wide range of environmental conditions.

*Effectiveness*

Seventy-two trials on four different crops demonstrate the efficacy of intended uses of BAS 743 03 F, following the recommended Good Agricultural Practices. Data submitted prove that BAS 743 03 F provides good control of Phytophthora infestans and Peronospora destructor. In addition, dose rate ranges requested for either legal or marketing reasons in countries of the South-East EPPO climatic zone (Hungary, Romania, Slovakia and Slovenia) and the Czech Republic have been justified with data on potatoes.

### Information on the occurrence or possible occurrence of the development of resistance

The risk of any possible occurrence of resistance development has been discussed. Resistance management strategies aim to reduce selection pressure to avoid or delay the occurrence of resistance or to keep the frequency of resistant isolates in a population low. This can be achieved by Good Agricultural Practice, which leads to lower infection pressure (*e.g*., phytosanitary measurements, cultivation of less susceptible varieties, appropriate crop cultivation unfavorable for the target pathogens). Furthermore, limiting the number of sprays is also essential in delaying the build-up of resistant pathogen populations. A further tool is the use of fungicide mixtures. Various studies showed that especially mixtures help in delaying the selection of resistance. BAS 743 03 F is already a mixture of two active ingredients, which are both active against all pathogens.

Since population size of pathogens is lower at disease onset than when already established in the field, selection pressure is less when using preventive applications rather than curative or eradicative spray schemes. Therefore, BAS 743 03 F should be applied in a preventive manner following the recommendations on the label. An optimal timing is also an effective resistance management.

### Adverse effects on treated crops

In all seventy-two efficacy trials, no phytotoxicity symptoms were recorded. Therefore, BAS 743 03 F is deemed fully selective in potatoes, onions, and tomatoes when applied at the target dose rate of 2.0 L/ha, following the recommended Good Agricultural Practices.

Out of seventy-two efficacy trials with disease, assessments on yield and the yield quality parameters are evaluated and presented in fifty trials. In summary, BAS 743 03 F at the proposed rate of 2.0 L/ha showed no adverse, but rather positive effects on the yield and the quality indicators in all tested crops.

### Observations on other undesirable or unintended side-effects

Multiple studies proved that the use of BAS 743 03 F following Good Agricultural Practices does not cause any adverse effects on the treated crops or their products in terms of the quality and taste of harvested and processed products. Likewise, no adverse effects have been observed impacting transformation processes or germination of propagation materials, nor any undesirable or unintended side effects on adjacent or succeeding crops, and beneficial or non-target organisms, have been observed.

BAS 743 03 F is a foliar fungicide containing the active substances ametoctradin (120 g/L) and propamocarb-hydrochloride (451 g/L - equivalent to 378 g Propamocarb/L). It is a new foliar fungicide for the control of *Phytophthora infestans* in potatoes, *Peronospora destructor* on onions and garlic and *Phytophthora infestans* in tomatoes and aubergines. In order to support the proposed use of BAS 743 03 F, data is presented from trials conducted between 2020 and 2022 in countries of the different EPPO climatic zones relevant to the Central Registration Zone, namely the Maritime, the North-East, and the South-East climatic zone.

**Preliminary tests**

The results confirm the benefit of mixing ametoctradin and propamocarb-hydrochloride, with the 1:3.15 ratio providing optimum control of targeted pathogens in all tested crops. The data obtained from 15 bridging efficacy trials (8 trials on potatoes, 3 trials on onions, and 4 trials on tomatoes) demonstrate that both formulations, BAS 743 00 F and the final BAS 743 03 F formulation, perform equivalently.

**Minimum effective dose**

BAS 743 03 F at a dose rate of 2 L/ha provided the optimum and most consistent control of the target pathogens and these rates should be considered as the minimum effective dose rates in potatoes, onions and tomatoes under a wide range of environmental conditions. Reducing the proposed application rate BAS 743 03 F decreased the efficacy of the product against *Phytophthora infestans* and *Peronospora destructor.*

**Efficacy tests**

***Phytophthora infestans* on potato**

It is considered that there is sufficient evidence of efficacy and crop safety to support the use of BAS 743 03 F at 2 L/ha in potatoes across the Maritime, North-East and South-East zones for the control of *Phytophthora infestans*. In addition, for Hungary and Romania, the applicant proposed to authorise the dose rate range of 1.5-2.0 L/ha of BAS 743 03 F.

***Peronospora destructor* on onion**

It is considered that there is sufficient evidence of efficacy and crop safety to support the use of BAS 743 03 F at 2 L/ha on onion in the North-East zone.

In the Maritime zone the data indicates that BAS 743 03 F, at the proposed dose rate of 2.0 L/ha, achieved comparable efficacy to the standard at 1.0 L/ha, providing moderate control of *Peronospora destructor* in onion bulbs. The concerned Member States are kindly asked to decide themselves whether to accept the low efficacy of the applied product against *Peronospora destructor* in bulb onions.

No data were provided for the South-East EPPO climatic zone. The concerned Member States belonging to the southeast EPPO zones are kindly asked to decide themselves whether to accept data from Maritime zone or not.

***Phytophthora infestans* on tomatoes**

It is considered that there is sufficient evidence of efficacy and crop safety to support the use of BAS 743 03 F at 2 L/ha in tomato in the North-East zone. The proposed GAP allows for 2 applications at the maximum rate while the applicant provided data based on 4 to 8 applications. This discrepancy suggests that the data do not fully support the proposed GAP. Based on the data provided, conditional registration is acceptable, but further efficacy data are required as part of the post-registration process. This should include at least two fully supportive trials where the product has only been applied twice or trials as part of an ongoing protection programme where the efficacy is recalculated after two applications.

No data were provided for the South-East EPPO climatic zone. The concerned Member States belonging to the southeast EPPO zones are kindly asked to decide themselves whether to accept data from northeast zone with consideration of the presented potatoes trials or not.

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

The applicant provided a comprehensive overview of the current resistance status and the risk of resistance developing with ametoctradin and propamocarb fungicides.

Ametoctradin belongs to the chemical group of triazolo-pyrimidylamine while propamocarb belongs to the carbamates. Based on FRAC assessment the applicant stated the combined risk of resistance for ametoctradin as medium and for propamocarb as low to medium.

A special resistance management system must be used for the application of the product. It is expected that cMS will implement FRAC recommendations unless their national guidelines indicate more restrictive resistance management measures are required. The zRMS considers that the risk assessment is acceptable.

**Phytotoxicity to host crop**

No phytotoxicity symptoms in potatoes, onion and tomatoes after application of BAS 743 03 F at 2 L/ha were observed in any of the trials reported by the applicant.

**Yield and Quality parameters**

The data summarized across EPPO climatic zones confirmed that BAS 743 03 F was shown to be an effective product for fungicidal control in potatoes, onions and tomatoes. Trials showed that the level of control was equal to or better than the reference standard products tested. In addition, BAS 743 03 F at the recommended label rate of 2.0 L/ha showed no adverse but rather positive effects on yield and quality parameters.

**Adverse effects on succeeding or adjacent crops**

BAS 743 03 F was tested on 10 different crops. No effects were observed on germination and growth with any of crops tested. BAS 743 03 F does not pose a risk to succeeding or adjacent crops and justifies the recommendation of no restrictions on succeeding or adjacent crops when applying BAS 74303 F.

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

### Analytical method for the formulation

The analytical method AFL1028/03 has been developed for the determination of the active substance Propamocarb and Ametoctradin in SC formulations BAS 743 00F, BAS 743 02F and BAS 743 03F. The method has been demonstrated to be suitable for the determination of ametroctradin and Propamocarb in solutions of BAS 743 02 F for the determination of the active substances and for the determination of suspensibility. All validated parameters (identity, specificity, linearity, accuracy & precision etc) are acceptable.

The analytical method AFL1070/01 has been developed for the determination of the impurity amitrole (Reg.No.: 900093) in the BAS 743 03 F. With respect to the conditions described for the analytical method AFL1070/01 all validation parameters (linearity, precision, accuracy, identity, specificity, stability and LOQ) are acceptable. Therefore, the method is valid without restriction in the tested concentration range and is suitable for the determination of amitrole in BAS 743 03 F.

The analytical method AFL1020/01 has been developed for the determination of the impurity o-xylene in formulations containing Ametoctradin and Propamocarb. With respect to the conditions described in the analytical method AFL1073/01 all validation parameters (identity, specificity, linearity, accuracy and precision, stability, LOQ) are acceptable. Therefore, the method is valid without restriction in the tested concentration range and is suitable for the determination of o-xylene in BAS 743 03 F.

### Analytical methods for residues

Suitably validated analytical methods have been submitted for the data submitted with this application.

During the approval process of Ametoctradin and Propamocarb analytical methods were submitted.

As Ametoctradin is not classified as toxic or highly toxic, no method was required for body fluid/tissues at the time of the EU approval process for ametoctradin. A new method was developed (XXXX Method L0347/01) to meet new data requirements. Ametoctradin can be determined by LC-MS/MS with a LOQ of 0.01 mg/kg in blood and urine.

**zRMS**: accepted

## Mammalian toxicology (Part B, Section 6)

### Acute toxicity

BAS 743 03 F is of low acute toxicity when using the calculation method according to Regulation (EC) No 1272/2008. Based on the content of a co-formulant, the formulation is classified for skin sensitisation (H317).

### Operator exposure

The worst case for the operator is given for the highest application rate (maximum individual dose) for each proposed application method.

* The outdoor application of XXXX 743 03 F to potato is presented as the worst case for downward, vehicle mounted spray application to low crops. The highest application rate is 2 L product/ha and using a dermal absorption of 28% for the dilution of propamocarb-HCl. This provides the risk envelope for application to all field crops.
* The outdoor application of XXXX 743 03 F to tomato/aubergine is the worst-case scenario for downward hand-held spray applications. The highest application rate is 2 L product/ha and using a dermal absorption of 1.2% for the dilution of propamocarb-HCl.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | Ametoctradin | | Propamocarb-HCl | |
| Model data | Level of PPE | Total absorbed dose  (mg/kg/day) | % of systemic AOEL | Total absorbed dose  (mg/kg/day) | % of systemic AOEL |
| Tractor mounted boom spray application outdoors to potato/tomato/aubergine/onion/garlic/floriculture crops | | | | | |
| Application rate: | | 2 L product/ha | | | |
| **EFSA Calculator** (75th percentile)  Body weight: 60 kg | Workwear (arms, body and legs covered) ML and A | 0.08 | 4.2 | 0.04 | 13.9 |
| Hand-held (knapsack) spray application outdoors to tomato/aubergine/ onion/garlic /floriculture crops | | | | | |
| Application rate: | | 2 L product/ha | | | |
| **EFSA Calculator** (75th percentile)  Body weight: 60 kg | Workwear (arms, body and legs covered) ML and A | 0.1 | 5.2 | 0.05 | 17.3 |
| Hand-held (manual) spray application outdoors to tomato/aubergine/ onion/garlic /floriculture crops | | | | | |
| Application rate: | | 2 L product/ha | | | |
| **EFSA Calculator** (75th percentile)  Body weight: 60 kg | Workwear (arms, body and legs covered) ML and A | 0.1 | 5.1 | 0.1 | 44.7 |
| Tractor mounted spray application outdoors to high/low ornamentals | | | | | |
| Application rate: | | 2 L product/ha | | | |
| **EFSA**  **Calculator** (75th percentile)  Body weight: 60 kg | Workwear (arms, body and legs covered) ML and A | 0.1 | 4.9 | 0.01 | 4.2 |
| Hand-held (knapsack) spray application outdoors to high/low ornamentals | | | | | |
| Application rate: | | 2 L product/ha | | | |
| **EFSA Calculator** (75th percentile)  Body weight: 60 kg | Workwear (arms, body and legs covered) ML and A | 0.03 | 1.7 | 0.003 | 1.1 |
| Hand-held (manual) spray application outdoors to high/low ornamentals | | | | | |
| **EFSA Calculator** (75th percentile)  Body weight: 60 kg | Workwear (arms, body and legs covered) ML and A | 0.05 | 2.3 | 0.007 | 2.5 |

The predicted systemic exposure following the EFSA Guidance 2022 is within acceptable limits for an operator wearing standard workwear (arms, body and legs covered) during mix/loading and application. The product is classified with regards to human health effects (H317) and therefore gloves and coveralls are required during mix/loading.

### Worker exposure

Worker exposure is defined by the task being undertaken and the amount of active substance that is available to be dislodged. The following exposure scenarios have been presented to cover inspection and harvesting re-entry activities:

* Crop inspection of potatoes represents the worst-case for re-entry activities in field crops. This provides the risk envelope for field crops. The highest application rate is 3 × 2 L product/ha at 5 days interval and using a dermal absorption of 28% for the dilution of propamocarb-HCl.
* Harvesting of tomato/aubergine represents the worst-case re-entry activities in vegetable crops. The highest application rate is 2 × 2 L product/ha at 7 days interval and using a dermal absorption of 7% as the worst-case for propamocarb-HCl.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | Ametoctradin | | Propamocarb-HCl | |
| Model data | Level of PPE | Total absorbed dose (mg/kg/day) | % of systemic AOEL | Total absorbed dose (mg/kg/day) | % of systemic AOEL |
| Number of applications and application rate: | | 3 × 2 L product/ha (potato) | | | |
| Task: Reaching, picking  Work rate: 8 hours/day  Body weight: 60 kg  DT50: 30 days  DFR: 3 µg/cm2/kg a.s./ha  Application interval: 5 days  Dermal absorption:  Ametoctradin 50%  Propamocarb-HCl 28% | Workwear (arms, body and legs covered)  TC: 2500 cm2/person/h | 0.3 | 16.4 | **0.7** | **254** |
| Workwear (arms, body and legs covered) and gloves  TC: 580 cm2/person/h | 0.08 | 3.8 | 0.2 | 58.9 |
| Task: Inspection and irrigation  Work rate: 2 hours/day  Body weight: 60 kg  DT50: 30 days  DFR: 3 µg/cm2/kg a.s./ha  Application interval: 5 days  Dermal absorption:  Ametoctradin 50%  Propamocarb-HCl 28% | Workwear (arms, body and legs covered)  TC: 1400 cm2/person/h | 0.05 | 2.3 | 0.1 | 35.5 |
| Number of applications and application rate: | | 2 × 2 L product/ha (tomato and aubergine) | | | |
| Task: reach and pick  Work rate: 8 hours/day  Body weight: 60 kg  DT50: 30 days  DFR: 3 µg/cm2/kg a.s./ha  Application interval: 7 days  Dermal absorption: Ametoctradin 50%  Propamocarb-HCl ~~7.0%~~ 1.2% | Workwear (arms, body and legs covered)  TC: 2500 cm2/person/h | 0.2 | 11.3 | ~~0.1~~  0.02 | 7.5 |
| Number of applications and application rate: | | 2 × 2 L product/ha (high /low ornamentals) | | | |
| Task: cutting, sorting, bundling and carrying  Work rate: 8 hours/day  Body weight: 60 kg  DT50: 30 days  DFR: 3 µg/cm2/kg a.s./ha  Application interval: 7 days  Dermal absorption: Ametoctradin 50%  Propamocarb-HCl ~~7.0%~~ 1.2% | Workwear (arms, body and legs covered)  TC: 5000 cm2/person/h | 0.5 | **22.6** | 0.04 | 15 |
| Workwear (arms, body and legs covered) and gloves  TC: 1400 cm2/person/h | 0.1 | 6.3 | 0.01 | 4.2 |
| ~~Workwear (arms, body and legs covered) and 3 5 days with gloves~~  ~~TC: 5000 cm~~~~2~~~~/person/h~~ | ~~0.42~~ | ~~21.1~~ | ~~0.23~~ | ~~78.3~~ |

The predicted worker exposure following EFSA guidance 2022 is within acceptable limits for the intended uses for a worker wearing standard workwear (arms, body and legs covered) but no PPE.

### Bystander and resident exposure

The worst case for bystander and resident is given by the number of multiple applications and water volume. For downward spray application, potato (considering a minimum in-use water volume of 100 L/ha and a dermal absorption value of 28%) is presented as the worst case and covers all outdoor crops. The highest application rate 3 × 2 L product/ha at 5-day interval.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | Ametoctradin | | Propamocarb-HCl | |
| Model data | | Total absorbed dose (mg/kg/day) | % of systemic AOEL | Total absorbed dose (mg/kg/day) | % of systemic AOEL |
| Tractor mounted spray application outdoors to low crops  Minimum volume water for application: 100 L/ha  Buffer zone: 2-3 m  Drift reduction technology: not applicable  DT50: 30 days  DFR: 3 µg/cm2/kg a.s./ha  Interval between application: 5 days | | | | | |
| Number of applications and application rate: | | 3 × 2 L product/ha | | | |
| Vapour pressure | | 2.1 x 10-10 Pa at 20 °C  275.4 g/mol | | 1.66 x 10-3 Pa at 25 ºC  224.7 g/mol | |
| Dermal absorption | | 50% for the dilution | | 28% for the dilution | |
| Resident child  Body weight: 10 kg | Drift (75th perc.) | 0.03 | 1.7 | 0.07 | 25.7 |
| Vapour (75th perc.) | 2e-08 | 9E-07 | 0.0008 | 0.3 |
| Deposits (75th perc.) | 0.005 | 0.3 | 0.01 | 4.4 |
| Re-entry (75th perc.) | 0.06 | 2.8 | 0.1 | 42.8 |
| **Sum (mean)** | 0.07 | 3.3 | 0.1 | 51.7 |
| Resident adult  Body weight: 60 kg | Drift (75th perc.) | 0.008 | 0.4 | 0.02 | 6.1 |
| Vapour (75th perc.) | 6e-09 | 3E-07 | 0.0003 | 0.09 |
| Deposits (75th perc.) | 0.002 | 0.1 | 0.005 | 1.7 |
| Re-entry (75th perc.) | 0.03 | 1.5 | 0.07 | 23.8 |
| **Sum (mean**) | 0.03 | 1.5 | 0.06 | 23.2 |
| Tractor mounted spray application outdoors to high ornamentals  Minimum volume water for application: 500 L/ha  Buffer zone: 5 m  Drift reduction technology: not applicable  DT50: 30 days  DFR: 3 µg/cm2/kg a.s./ha  Interval between application: 7 days | | | | | |
| Number of applications and application rate: | | 2 × 2 L product/ha | | | |
| Dermal absorption | | 50% for the dilution | | 1.2% for the dilution | |
| Resident child  Body weight: 10 kg | Drift (75th perc.) | 0.03 | 1.7 | 0.003 | 1.2 |
| Vapour (75th perc.) | 2E-08 | 9E-07 | 0.0008 | 0.3 |
| Deposits (75th perc.) | 0.002 | 0.1 | 0.001 | 0.3 |
| Re-entry (75th perc.) | 0.04 | 1.9 | 0.004 | 1.3 |
| **Sum (mean)** | 0.05 | 2.7 | 0.007 | 2.3 |
| Resident adult  Body weight: 60 kg | Drift (75th perc.) | 0.02 | 0.9 | 0.002 | 0.6 |
| Vapour (75th perc.) | 6E-09 | 3E-07 | 0.0003 | 0.09 |
| Deposits (75th perc.) | 0.0008 | 0.04 | 0.00008 | 0.03 |
| Re-entry (75th perc.) | 0.02 | 1.1 | 0.002 | 0.7 |
| **Sum (mean**) | 0.03 | 1.5 | 0.003 | 1.1 |

In the absence of the acute AOEL (AAOEL) no need for the assessment of specific bystander exposure has been identified. In this case bystanders have been covered by the respective resident exposure assessments. The predicted resident exposure following EFSA guidance 2022 indicated that the acceptable operator exposure level (AOEL) will not be exceeded.

Acute risk assessment from combined exposure

The Hazard Index is < 1. Thus combined exposure to all active substances in BAS 743 03 F is not expected to present a risk for operators, workers, bystanders and residents.

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

**zRMS**: the applicant comments accepted.

### Residues

Ametoctradin

The metabolism of Ametoctradin have been evaluated in context of the active substance approval procedure.

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.

Propamocarb

The metabolism of Propamocarb has been evaluated in context of the active substance approval procedure.

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.

### Consumer exposure

Ametoctradin

|  |  |
| --- | --- |
| 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.

Propamocarb

|  |  |
| --- | --- |
| 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.

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

No new studies are presented; all data were reviewed in the EU reviews of Ametoctradin and propamocarb. Appropriate endpoints from the EU review were used to calculate PEC values, as required, for BAS 743 03 F, active substances and metabolites.

### Predicted environmental concentrations in soil (PECSoil)

~~In the EFSA Conclusion (2012), the degradation endpoint (DT~~~~50~~~~) of 3.2 days (worst-case from laboratory studies) was used for the calculation of PEC~~~~soil~~ ~~for ametoctradin. This value was derived from best-fit kinetics with the biphasic model DFOP. In order to account for biphasic degradation of Ametoctradin in soil, PEC~~~~soil~~ ~~values were calculated with the model ESCAPE v2.0 considering the DFOP degradation parameters k~~~~1~~~~= 0.2361 1/days, k~~~~2~~~~= 0.0052 1/days and g = 0.9361.~~

~~Similar to the parent substance, the degradation endpoint (DT~~~~50~~~~) of 186.5 days (DFOP kinetics; worst-case from field studies) was used for PEC~~~~soil~~ ~~calculations of the metabolite M650F04 in the EFSA Conclusion (2012). For present PEC~~~~soil~~ ~~calculations, degradation of M650F04 in soil was described by DFOP degradation parameters k~~~~1~~~~= 0.001585 1/days, k~~~~2~~~~= 0.072815 1/days and g = 0.6719.~~

The PECsoil calculations for ametoctradin, its metabolites, propamocarb HCl and the formulation BAS 743 03 F were provided by the Applicant and are considered acceptable. The EU agreed endpoints were used for PECsoil calculations. Those values are considered acceptable.

~~No deviation from the EU agreed endpoints were considered for Propamocarb HCl.~~

PECSoil values were used for the ecotoxicological risk assessment.

### Predicted environmental concentrations in groundwater (PECGW)

~~Predicted environmental concentrations in leachate/groundwater (PEC~~~~GW~~~~) were conducted for application uses of Ametoctradin and its metabolites and Propamocarb HCl in BAS 743 03 F on the uses in the GAP.~~~~The PEC~~~~GW~~ ~~following to recommendations in FOCUS Generic Guidance GW (FOCUS, 2021). The PEC~~~~GW~~ ~~simulations were determined using FOCUS PEARL 5.5.5, FOCUS PELMO 6.6.4 and FOCUS MACRO 5.5.4 (if applicable) with the FOCUS groundwater scenarios.~~

~~The PEC~~~~GW~~ ~~for ametoctradin was < 0.001 µg/L in all application uses and all simulated models.~~

~~The PEC~~~~GW~~ ~~values of metabolites M650F01 and M650F02 were below 0.1 µg/L for all application uses and all simulation models. The PEC~~~~GW~~ ~~values for M650F03 and M650F04 were below 0.1 µg/L for all application uses under acidic soil condition. Under alkaline soil condition, the PEC~~~~GW~~ ~~values of metabolites M650F03 and M650F04 may exceed 0.1 µg/L, but below 10 µg/L for all application uses and all simulated models.~~

~~The PEC~~~~GW~~ ~~for Propamocarb HCl was < 0.001 µg/L in all application uses and all simulated models.~~

The PECGW calculations for ametoctradin, its metabolites and for propamocarb HCl were provided by the Applicant and are considered acceptable. To cover all proposed uses, for propamocarb HCl, additional calculations with PUF of 0 were performed by zRMS for the worst-case exposure scenario: use on onion, BBCH 14, 2 × 902 g/ha, every year. The results obtained do not affect the conclusions of the evaluation (PECGW < 0.001 µg/L).

For active substances and relevant metabolites PECGW calculations were performed with FOCUS MACRO 5.5.4 (ametoctradin) and FOCUS PEARL 5.5.5 and FOCUS PELMO 6.6.4. The EU agreed endpoints were used. Geometric mean Kfoc and Kfom (instead of an arithmetic mean Kfoc and Kfom) for all compounds were derived from the datasets presented in the EFSA Journal 2012;10(11):2921 and EFSA Scientific Report (2006) 78, 1-80 for consistency with current FOCUS groundwater recommendation.

The leaching simulation run with FOCUS PELMO, FOCUS PEARL and FOCUS MACRO resulted in PECGW values below 0.1 µg/L for ametoctradin, metabolites M650F01, M650F02 and for M650F03, M650F04 for applications to acidic soil, for all FOCUS scenarios. Under alkaline soil condition, metabolites M650F03 and M650F04 exceed the threshold of 0.1 µg/L, but below 10 µg/L for all application uses and all simulated models. However, these metabolites were subjected to a non-relevance assessment including a consumer exposure assessment according to the Guidance Document1 on the assessment of the relevance of metabolites in groundwater (see section Part B section 10). Based on this assessment metabolites M650F03 and M650F04 are considered non-relevant with regard to groundwater for the proposed uses.

It should be noted that for multiple uses in an onions, the simulations were performed for the application every 2nd year.

All leaching simulation run with FOCUS PELMO, FOCUS PEARL resulted in PECGW values below 0.1 µg/L for propamocarb HCl for all FOCUS scenarios.

In conclusion, the results demonstrate that BAS 743 03 F can be used safely without risk of ametoctradin, its metabolites and for propamocarb HCl exceeding acceptable levels in groundwater.

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

The intended GAPs have been calculated for PECSW/SED following to recommendations in FOCUS (2015).

PEC values were used for the ecotoxicological risk assessment.

### Predicted environmental concentrations in air (PECAir)

The vapour pressure of the active substance Ametoctradin is 2.1 × 10-10 Pa at 20°C and its Henry’s Law constant 4.13 × 10-07 Pa.m3/mol at 20°C. The active substance Ametoctradin is regarded as non-volatile from soil. Furthermore, the estimated photo-chemical oxidative degradation half-life in air was calculated to be 3.3 h (Atkinson method) for Ametoctradin and thus this substance will not persist in the atmosphere.

Propamocarb HCL

In the DAR Vol. B8 following information are given:

“*After 24 hours under standard test conditions Propamocarb HCl, as applied radioactivity, was not observed to volatilise more than 20% from soil or plant (French beans) surfaces. (…)*

*The volatilisation loss of Propamocarb HCl from the soil surface, within a 24-hour period after treatment, was calculated to be <0.001% of the applied amount. The percentage loss for Propamocarb HCl is substantially below the German BBA trigger value of 20%. Therefore, owing to the combination of low volatilisation loss and short persistence in the atmosphere, the PECa of Propamocarb HCl is likely to be low.”*

Conclusion: *“Based on its vapour pressure (3.1 – 4.7 \* 10-5 Pa at 20 ºC and <1.7 \* 10-3 Pa at 25 ºC) and its Henry’s Law constant (<1.7 \* 10-8 Pa m3 mol-1 at 20 ºC and 3.54 \* 10-7 Pa m3 mol-1 at 25 ºC), the volatility of propamocarb hydrochloride can be considered low. This suggestion was further supported following investigation of the volatility of propamocarb hydrochloride from soil (loss <0.001% of the applied amount, calculated with the Dow method) and leaf surfaces. Bimolecular rate constants for atmospheric reactions with photo-generated hydroxyl radicals were calculated to be 9.54 \* 10-11 cm3 molecule-1 s-1 and 2.878322 \* 10-11 cm3 molecule-1 s-1 in two oxidative studies, corresponding to atmospheric DT50 values estimated to be 4.03 hours and 13.4 hours, respectively. All these factors suggested that levels of propamocarb hydrochloride in air following normal agricultural use of the formulated product will be low*.”

No further evaluation is required.

~~Based on vapour pressure 4.21 × 10~~~~-5~~ ~~Pa and its Henry’s Law constant <1.7 × 10~~~~-08~~ ~~Pa.m~~~~3~~~~/mol at 20°C, the volatility of Propamocarb HCl can be considered low. Furthermore, the estimated photo-chemical oxidative degradation half-life in air in two oxidative studies was calculated to be 4.03 h and 13.4 h (Atkinson method). Hence, it could be concluded that levels of Propamocarb HCl in air following normal agricultural use of the formulated product will be low.~~

~~For these reasons, the possibility of a long-term presence of Ametoctradin and Propamocarb HCl in air is unlikely and no PEC calculations are necessary.~~

## Ecotoxicology (Part B, Section 9)

### Effects on terrestrial vertebrates

**Birds**

*Dietary risk assessment*

In the screening step risk assessment, all TERA values and all TERlt values for Ametoctradin exceed the trigger set by Commission Regulation (EU) 546/2011 for acceptability of effects. For the active substance Propamocarb-HCl and the formulation BAS 743 03 F acceptable dietary acute and long-term risk for birds is indicated at Tier 1 level except for the use in fruiting vegetables where an acceptable long-term risk was demonstrated at higher tier level including considerations of combined exposure.

*Drinking water risk assessment*

Following EFSA/2009/1438, the puddle scenario is considered relevant for the proposed use pattern. Since the ratios of the effective application rates to the relevant toxicity endpoints are below the relevant trigger values for both Ametoctradin and Propamocarb-HCl, a quantitative risk assessment for the proposed use pattern of BAS 743 03 F is not necessary for the puddle scenario. In conclusion the proposed use pattern of BAS 743 03 F does not pose a risk to birds via up-take of contaminated drinking water.

*Secondary poisoning and biomagnification*

The log Pow of Propamocarb-HCl does not exceed the trigger value of 3. However, the log Pow of the active substance Ametoctradin was determined to be 4.4, which triggers an assessment of the potential risk from secondary poisoning. According to the tier 1 risk assessment for earthworm- and fish-eating birds, the TER values for Ametoctradin are above the trigger value of 5, indicating an acceptable risk. The potential for bioaccumulation of Ametoctradin and Propamocarb-HCl was considered as low in the respective EU reviews and therefore further evaluation on biomagnification is not necessary.

***Overall conclusion***

**It can be concluded that the risk to birds from the application of BAS 743 03 F according to good agricultural practice is acceptable.**

**Mammals**

*Dietary risk assessment*

In the screening step risk assessment, all TERA values and all TERlt values for Ametoctradin exceed the trigger set by Commission Regulation (EU) 546/2011 for acceptability of effects. For the active substance ~~Propamocarb-HCl, an acceptable dietary acute risk for mammals is indicated at Tier 1 level while an acceptable dietary long-term risk for Propamocarb-HCl is indicated at higher-tier level. For the formulation BAS 743 03 F an acceptable dietary acute risk for mammals is indicated at higher tier level including considerations of combined exposure.~~

All acute TER values exceed the relevant triggers in the Tier 1 risk assessment for propamocarb-HCl.

Based on the higher tier chronic risk assessment for propamocarb-HCl, where the deposition factor and ~~DT~~~~50~~ ~~in plants~~ PD for voles were modified, the TERs exceed the trigger values set by Commission regulation (EU) 546/2011 for acceptability of effects except for multiple applications in onions BBCH ≥ 40 and for uses in fruiting vegetables at BBCH 11-39.

*Drinking water risk assessment*

Following EFSA/2009/1438, the puddle scenario is the one relevant for mammals. Since the ratios of the effective application rates to the relevant toxicity endpoints are below the relevant values for both Ametoctradin and Propamocarb-HCl, a quantitative risk assessment for the proposed use pattern of BAS 743 03 F is not necessary for the puddle scenario. In conclusion the proposed use pattern of BAS 743 03 F does not pose a risk to mammals via uptake of contaminated drinking water.

*Secondary poisoning and biomagnification*

The log Pow of Propamocarb-HCl does not exceed the trigger value of 3. However, the log Pow of the active substance Ametoctradin was determined to be 4.4, which triggers an assessment of the potential risk from secondary poisoning. According to the tier 1 risk assessment for earthworm- and fish-eating mammals, the TER values for Ametoctradin are above the trigger value of 5, indicating an acceptable risk. The potential for bioaccumulation of Ametoctradin and Propamocarb-HCl was considered as low in the respective EU reviews and therefore further evaluation on biomagnification is not necessary.

***Overall conclusion***

**It can be concluded that the risk to mammals from the application of BAS 743 03 F according to good agricultural practice is acceptable.**

### Effects on aquatic species

~~For Ametoctradin, the acute studies conducted with the active substance resulted in endpoints which are greater than the water solubility of the compound under test conditions. However, higher concentrations of the active substance could be achieved by testing the formulated product BAS 650 00 F (nominal content of Ametoctradin: 200 g a.s./L). Therefore, it was decided to include studies with the formulated product BAS 650 00 F, indicating an overall low to moderate toxicity. In the risk assessment, PEC/RAC ratio calculations are based on the endpoints derived with the formulated product (based on the content of the active substance). For Propamocarb, the EU agreed endpoints for acute and long-term toxicity to aquatic organisms are used in the risk assessment. For the formulated product BAS 743 02 F, studies on the acute toxicity to fish and~~ *~~Daphnia magna~~* ~~as well the effects on green algae are available; in addition to measured toxicity data, mixture toxicity is also calculated based on the Concentration Addition (CA) model.~~

For the active substance Ametoctradin, the calculated PEC/RAC ratios are below the trigger of 1 at FOCUS Step 3 for all intended uses indicating an acceptable risk for all groups of aquatic organisms without the necessity of mitigation measures.

For Ametoctradin relevant metabolites, the calculated PEC/RAC ratios are significantly below the trigger of 1 at FOCUS Step 1; they are thus considered not to be of ecotoxicological relevance.

For the active substance Propamocarb-HCl, the calculated PEC/RAC ratios are below the trigger of 1 at FOCUS Step 2 for all intended uses of BAS 743 03 F.

The active substance Ametoctradin contributes by more than 90% to the chronic toxicity of the formulation BAS 743 03 F to fish and aquatic invertebrates; thus the risk assessment for these trophic level is based on the single-substance toxicity data of Ametoctradin. No “driver” of acute mixture toxicity is identified for fish, aquatic invertebrates and algae; thus, any potential risk due to the acute toxicity of BAS 743 03 F is addressed in a mixture risk assessment following the Risk Quotient Approach (RQ). For BAS 743 03 F the calculated RQmix ratios are below the trigger of 1 at FOCUS Step 1 for all intended uses of the formulated product. In addition, the calculated PEC/RAC ratios based on measured formulation endpoints for drift entry are significantly below the trigger of 1 indicating an acceptable risk for all intended uses of BAS 743 03 F.

### Effects on bees

The risk assessment has been performed according to SANCO/10329/2002 rev 2 final~~, since the new EFSA GD~~ *~~“Guidance on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees)”~~* ~~(EFSA Journal 2013; 1187):3295) has not yet been adopted by the Standing Committee on Plants, Animals, Food and Feed.~~

The acute risk to honeybees from the intended uses of BAS 743 03 F is assessed using the maximum single application rate and the relevant LD50 values for the active substances Propamocarb-HCl and Ametoctradin and the formulated product BAS 743 03 F to calculate hazard quotients (HQ) for oral exposure (QHO) and contact exposure (QHC). The hazard quotients for both active substances and the formulated product for acute oral and acute contact exposure of honeybees are below the Commission Regulation (EU) 546/2011 trigger value of 50, indicating an acceptable risk.

In addition, data on chronic oral toxicity to adult honeybees and on oral toxicity to honeybee larvae for the similar formulation BAS 743 02 F (containing 137.1 g/L Ametoctradin and 515.4 g/L Propamocarb-HCl) are available. These studies indicate low toxicity to bees and meet the current data requirements (Commission Regulation (EU) No. 283/2013 and 284/2013).

~~However, under the current risk assessment scheme (SANCO/10329/2002) there is no requirement to conduct a risk assessment with these endpoints.~~

Taking all data together, it can be concluded that the proposed uses of BAS 743 03 F pose no unacceptable risk to honeybees, if applied according to the recommended use patterns.

### Effects on other arthropod species other than bees

The testing and risk assessment strategy used here follow the approach recommended in the ESCORT 2 guidance document, ESCORT 3, and the EC Guidance Document on Terrestrial Ecotoxicology (SANCO/10329, 17 October 2002)*.* The risk assessment for BAS 743 03 F is based on tests with the standard test species *Typhlodromus pyri* and *Aphidius rhopalosiphi*.

An acceptable in- and off-field risk for *Typhlodromus pyri* and *Aphidius rhopalosiphi* was found based on glass plate laboratory data. Therefore, an overall acceptable risk to non-target arthropods for all intended uses of BAS 743 03 F can be concluded.

### Effects on soil organisms

The evaluation of the risk for earthworms, other non-target soil organisms (meso- and macrofauna) and soil microorganisms was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

***Effects on non-target soil meso- and macrofauna***

All TER values ~~for BAS 743 03 F, the active substance Ametoctradin, and relevant metabolites as well as the active substance Propamocarb-HCl~~ for chronic exposure of earthworms and other non-target soil organisms (meso- and macrofauna) are considerably higher than the Commission Regulation (EU) 546/2011 trigger value of 5.

**Therefore, it can be concluded that BAS 743 03 F poses no unacceptable risk to earthworms or other soil meso- and macrofauna when applied according to the proposed uses.**

***Effects on soil microbial activity***

Studies on effects to soil microorganisms have been carried out with the active substance Ametoctradin, the Ametoctradin relevant soil metabolites, the active substance Propamocarb-HCl and with the formulation BAS 743 03 F.

The potential risk to soil micro-organisms was assessed by comparing the maximum PECsoil values with the maximum concentration with effects ≤ 25%. For the formulation BAS 743 03 F, the two active substances Ametoctradin and Propamocarb-HCl, as well as for the relevant Ametoctradin metabolites, the maximum concentrations with effects < 25% (SANCO/10329/2002 trigger) are all by far above the PECsoil values derived from the maximum recommended application rate.

**Therefore, it can be concluded that the use of BAS 743 03 F will not pose an unacceptable risk to non-target soil micro-organisms, if applied according to good agricultural practice.**

### Effects on non-target terrestrial plants

The risk assessment was based on the “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002). BAS 743 03 F is a fungicide and is therefore not expected to have significant herbicidal activity. Hence, a Tier 1 assessment was conducted, using the available screening data.

A study on the effects of BAS 743 03 F exposure on seedling emergence and vegetative vigour of terrestrial higher plants was conducted. The results showed that applications up to a rate of 3.85 L BAS 743 03 F/ha caused no reduced seedling emergence and plant fresh weight, and no symptoms of phytotoxicity were observed for any of the seven terrestrial plant species tested.

The Tier 1 risk assessment based on screening data demonstrates an acceptable risk to non-target terrestrial plants for all intended uses of BAS 743 03 F.

**Based on the risk assessment it can be concluded that the proposed uses of BAS 743 03 F pose no unacceptable risk to non-target plants, if applied according to the recommended use patterns. Particular precautions to reduce the environmental concentrations resulting from BAS 743 03 F applications are not required for the protection of terrestrial non-target plants.**

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

Not relevant.

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

The Ametoctradin metabolites M650F03 and M650F04 are predicted to occur in groundwater at concentrations above 0.1 µg/L.

The relevance of the groundwater metabolites M650F03 and M650650F04 has already been assessed and the assessment agreed at EU level (see DAR of December 2010 and EFSA conclusion 2012), and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (that is the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid also with regard to the PECGW calculated for the GAP and groundwater scenarios considered in this dRR). M650F03 and M650F04 are not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.11.

No Propamocarb metabolites are predicted to occur in groundwater at concentrations above 0.1 µg/L.

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

Not required.

BAS 743 03 F contains the active substances Ametoctradin and Propamocarb which are not approved as candidates for substitution.

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

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

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

1. Copy of the product authorization

Not provided.

1. Copy of the product label

The evaluated project provided separately.

1. Letter of Access

XXXX

1. Lists of data considered for national authorization

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** | **Data protection claimed**  **Y/N** | **Justification if data protection is claimed** | **Owner** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| XXXX | XXXX | XXX | XXXX | XX | XX | XX | XXXX |

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** | **Data protection claimed**  **Y/N** | **Justification if data protection is claimed** | **Owner** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| XXXX | XXXX | XXX | XXXX | XX | XX | XX | 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** |
| --- | --- | --- | --- | --- | --- |
| XXXX | XXXX | XXX | XXXX | XX | XXXX |