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| REGISTRATION REPORT  Part B  Section 3  Efficacy Data and Information  Concise summary |
| 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  Evaluation date: May 2024  MS Finalisation date: November 2024 |

Version history

|  |  |
| --- | --- |
| When | What |
| October 2023 | Initial dRR – XXXX Doc ID 2022/2044803 |
| May 2024 | Initial RR - zRMS |
| November 2024 | Updated dRR – after MSs consultation |
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# Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

BAS 743 03 F is a new fungicide developed by XXXX for the control of major diseases in vegetable crops.

BAS 743 03 F contains the following active ingredients:

* Ametoctradin: 120 g/L
* Propamocarb-Hydrochloride: 451 g/L (equivalent to 378 g Propamocarb/L)

Ametoctradin was included into Annex I under Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 200/2013 of 09 March 2013). This active substance belongs to the chemical family of triazolo-pyrimidylamine, group of QoSI fungicides (Quinone outside Inhibitor, stigmatellin binding type), FRAC Code C8.

Propamocarb-Hydrochloride was included into Annex I to Directive (EU) 91/414/EEC (Document 1654/VI/94, rev 7 of 22 April 1998). Propamocarb is a carbamate ester that is the propyl ester of 3- (dimethylamino)propylcarbamic acid. It is a systemic fungicide used (normally as the hydrochloride salt) to control diseases caused by oomycetes in soil, roots, and leaves. Propamocarb could affect the biosynthesis of fatty acid and phospholipid, thus changing the membrane in fungi.

The SANCO reports for ametoctradin (SANCO/12977/2012 rev 2 – 01/02/2013) and propamocarb (SANCO/10057/2006 final – 25/04/2007) are considered to provide the relevant review information or a reference to where such information can be found.

The Annex I Inclusion Regulations for ametoctradin, (EU) No 200/2013, and for propamocarb, Directive (EU) 91/414/EEC, provide specific provisions under Part B, which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorization.

This Biological Assessment Dossier (BAD) contains information relating efficacy for the new registration of BAS 743 03 F in the Central Registration Zone.

Information on the detailed composition of the product can be found in the confidential dossier of this submission (Registration Report - Part C).

## Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

|  |
| --- |
| 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, onion 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 lower 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 other zones 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. No data were provided for that specific use in 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. From analyses, it can therefore be concluded that the overall resistance risk for the fungicide BAS 743 03 has to be regarded as 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, onion 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. |

Table ‑: Acceptability of intended uses (and respective fall-back GAPs, if applicable).

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | |  | | | | | |  | | | | |  | | | | |  | |
| 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/no | | | | | |  | | | | |  | | | | |  | |
|  | | | | |  | | | | | |  | | | | |  | | | | |  | |
| Field of use: | | | | | Fungicide | | | | | |  | | | | |  | | | | |  | |
| 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) | | **Remarks:**  **zRMS Conclusion**  **(Efficacy)** | |
| Method / Kind | Timing / Growth stage of crop & season | Max. number  a) per use  b) per crop/ season | | | Min. interval between applications (days) | | 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) | | 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 | | 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  Dose rate range for HU, RO, SI, SK: 1,5-2 L/ha | |  | |
| 3 | HU, RO, SI, SK AT, CZ, DE | | 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  Dose rate range for HU, RO, SI, SK: 1,5-2 L/ha | |  | |
| 4 | PL | | Onion  (ALLCE), Garlic (ALLSA) | | F | *Peronospora destructor*  (PERODE) | SP | ~~BBCH 14 – 49~~  BBCH 14 - 39 | a) 2  b) 2 | | | 5 | | a) 2  b) 4 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | ~~200/800~~  300/700 | 7 | Spray interval: 5-10 days  Applications only every 2nd year | |  | |
| 5 | BE, IE, NL, RO | | Onion  (ALLCE), Garlic (ALLSA) | | 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: 200/800 L/ha  IE. 200/700 L/ha  Applications only every 2nd year | |  | |
| 6 | AT, CZ, DE, HU, SK, SI | | Onion  (ALLCE), Garlic (ALLSA) | | 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 |  | | DE | |
|  | |
| 7 | PL | | Tomato / Aubergine  (LYPES) / (SOLME) | | F | *Phytophthora infestans* (PHYTIN) | SP | ~~BBCH 21-89~~  BBCH 70-89 | a) 2  b) 2 | | | 7 | | a) 2  b) 4 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | ~~150/500~~  500/700 | 1 | Spray interval: 7-10 days | |  | |
| 8 | HU, RO, SK, SI | | Tomato / Aubergine  (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 | |  | |
| Minor uses according to Article 51 (zonal uses) | | | | | | | | | | | | | | | | | | | | |  | |
| 9 | NL | | Floriculture crops DTG .2)  (unprotected culture) | | F | *Peronospora sp* (PEROSP)  *Phytophthora spp (*PHYTSP) | Foliar treatment | BBCH 12-59 (Apr-Sep) | a) 2  b) 2 | | | 7 | | a) 2  b) 4 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | 500 | NA |  | |  | |
| 10 | NL | | Avenue trees | | F | *Peronospora sp* (PEROSP) | Foliar Treatment | BBCH 12-59 (Apr-Sep) | a) 2  b) 2 | | | 7 | | a) 2  b) 4 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | 500 | NA |  | |  | |
| 11 | NL | | Climbing Plants | | F | *Peronospora sp* (PEROSP) | Foliar Treatment | BBCH 12-59 (Apr-Sep) | a) 2  b) 2 | | | 7 | | a) 2  b) 4 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | 500 | NA |  | |  | |
| 12 | NL | | Conifers (incl. Christmas trees) | | F | *Peronospora sp* (PEROSP) | Foliar Treatment | BBCH-12-59 (Apr-Sep) | a) 2  b) 2 | | | 7 | | a) 2  b) 4 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | 500 | NA |  | |  | |
| 13 | NL | | Ornamental shrubs (incl. roses) | | F | *Peronospora sp* (PEROSP) | Foliar Treatment | BBCH-12-59 (Apr-Sep) | a) 2  b) 2 | | | 7 | | a) 2  b) 4 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | 500 | NA |  | |  | |
| 14 | NL | | Heather | | F | *Phytophthora spp (*PHYTSP) | Foliar Treatment | BBCH-12-59 (Apr-Sep) | a) 2  b) 2 | | | 7 | | a) 2  b) 4 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | 500 | NA |  | |  | |
| 15 | NL | | Forest trees and hedging plants | | F | *Peronospora sp* (PEROSP) | Foliar Treatment | BBCH-12-59 (Apr-Sep) | a) 2  b) 2 | | | 7 | | a) 2  b) 4 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | 500 | NA |  | |  | |
| 16 | NL | | Fruit trees and shrubs | | F | *Peronospora sp* (PEROSP) | Foliar Treatment | BBCH-12-59 (Apr-Sep) | a) 2  b) 2 | | | 7 | | a) 2  b) 4 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | 500 | NA |  | |  | |
| 17 | NL | | Perennial crops | | F | *Peronospora sp* (PEROSP) | Foliar Treatment | BBCH-12-59 (Apr-Sep) | a) 2  b) 2 | | | 7 | | a) 2  b) 4 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | 500 | NA |  | |  | |
| 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 | | | | | | | | | | |

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

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

Column 15: zRMS conclusion.

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

## Efficacy data (KCP 6)

Introduction

This Biological Assessment Dossier summarizes the biological activity of the plant protection product BAS 743 03 F containing two active substances: ametoctradin (120 g/L) and propamocarb-hydrochloride (451 g/L). This new product was developed for the control of *Phytophthora infestans* and *Peronospora destructor.*

This Biological Assessment Dossier contains all information necessary for the efficacy evaluation of BAS 743 03 F against the listed pathogens in potatoes, tomatoes, aubergine, bulb onions, and garlic for the Central Registration Zone in the following countries: Austria, Belgium, Czech Republic, Germany, Hungary, Ireland, the Netherlands, Poland, Romania, Slovakia and Slovenia.

Description of active substances

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).

Mode of action

Ametoctradin is a fungicidal molecule with protective activity belonging to the chemical class of triazolo-pyrimidylamine, and in particular to the group of QoSI fungicides (Quinone outside Inhibitor, Stigmatellin binding type), FRAC Code C8. Ametoctradin is a strong inhibitor of mitochondrial respiration in complex III (cytochrome bc1) of oomycetes fungi, reducing the ATP content in target organisms during their key development stages. Because of its mode of action, fungi treated with ametoctradin have less total ATP and consume less O2, so they have not enough energy to maintain their metabolic processes and finally are severely inhibited in their growth or die. Ametoctradin strongly inhibits zoospore differentiation within the zoosporangium, the release of zoospores from the zoosporangium, the motility of any released zoospores and the germination of the encysted zoospores. All this was shown for *Plasmopara viticola* and *Phytophthora infestans*. In addition, inhibition of the direct germination of sporangia was found in *Phytophthora infestans*. Therefore, ametoctradin is highly effective against *Peronosporomycete* pathogens like *Phytophthora infestans*, with long-lasting preventive control due to its excellent contact properties on plants; in fact, it has an excellent rainfastness due to its high affinity with the waxy layer of plant surfaces and it is not harmful both to beneficials and tested crops.

Propamocarb was first introduced into European markets to control oomycete pathogens in ornamental crops and certain vegetables in 1978. It is widely used as a soil drench against *Phytophthora* and *Pythium* diseases of numerous crops. Specifically, it has been applied successfully to control potato late blight where metalaxyl-resistant populations presented an increasingly severe problem. Propamocarb is a systemic carbamate fungicide used to control diseases caused by oomycetes in soil, roots, and leaves. It has been speculated that the mode of action of propamocarb is through selectively interfering with the biosynthesis of fatty acid and phospholipids in oomycete membranes, although this has not been proven.

Details of the active substances are provided in Table 3.2‑1.

Table ‑: Details of the active substances.

| Active substance | Ametoctradin | Propamocarb-hydrochloride |
| --- | --- | --- |
| Concentration | 120 g/L | 451 g/L - equivalent to 378 g Propamocarb/L |
| Chemical group | Triazolo-pyrimidylamine | Carbamate |
| Mode of action | C8: Inhibitor of mitochondrial respiration in complex III (cytochrome bc1) | Systemic fungicide with protective action absorbed by roots and leaves, translocated.  Lipid synthesis inhibitor |
| Chemical name | 5-ethyl-6-octyl[1,2,4]triazolo[1,5-a]pyrimidin-7-amine | Propyl 3-(dimethylamino) propylcarbamate hydrochloride |

Description of the plant protection product

BAS 743 03 F is formulated as a suspension concentrate (SC) containing active substances ametoctradin (120 g/L) and propamocarb-hydrochloride (451 g/L). BAS 743 03 F is intended for registration against *Phytophthora infestans* in potatoes with a maximum of 2 applications (in PL, HU, RO, SL, SK, AT, CZ, DE) and 3 applications (in FR, BE, IE, NL) with a rate of 2.0 L/ha between growth stages 21 to 89.

For control of *Peronospora destructor* in onions and garlic it is intended for registration with 1 application (in AT, CZ, DE, HU, SK) and with 2 applications (in FR, BE, IE, NL, PL, RO, SI) with a rate of 2.0 L/ha between growth stages 14-49.

BAS 743 03 F is intended for registration against *Phytophthora infestans* in tomatoes and aubergines in open field with a maximum of 2 applications with a rate of 2.0 L/ha between growth stages 21 to 89.

For control of downy mildews in floriculture crops, climbing plants, conifers (incl. Christmas trees), ornamental shrubs and heather a maximum of 2 applications between growth stages 12-59 with a rate of 2.0 L/ha is intended.

For control of downy mildews in avenue trees, forest trees and hedging plants, fruit trees and shrubs and perennial crops a maximum of 2 applications between growth stages 12-59 with a rate of 2.0 L/ha is intended.

A simplified overview of intended uses is provided in Table 3.2‑2.

Table ‑: Simplified table of requested uses for BAS 743 03 F.

| **Uses** | | **Member State** | **Requested rate(s)** | **Comments /**  **Other relevant details on GAPs** |
| --- | --- | --- | --- | --- |
| **Crop(s)** | **Target(s)** |
| Potato | *Phytophthora*  *infestans*  (PHYTIN) | AT, CZ, DE, HU, PL, RO, SL, SK | 2 L/ha | Max. total rate per crop/season - 4 L/ha  Max. 2 applications per season  Min. interval between applications – 5 days |
| BE, IE, NL | Max. total rate per crop/season - 6 L/ha  Max. 3 applications per season  Min. interval between applications – 5 days |
| Onion / Garlic | *Peronospora*  *destructor*  (PERODE) | BE, IE, NL, PL, RO | 2 L/ha | Max. total rate per crop/season - 4 L/ha  Max. 2 applications per season  Min. interval between applications – 5 days |
| Max. total rate per crop/season - 2 L/ha  Max. 1 application per season |
| AT, CZ, DE, HU, SK, SI |
| Tomato /  Aubergine | *Phytophthora*  *infestans*  (PHYTIN) | HU, PL, RO,  SI, SK | 2 L/ha | Max. total rate per crop/season - 4 L/ha  Max. 2 applications per season  Min. interval between applications – 7 days |
| Floriculture crops, avenue trees, climbing plants, conifers (incl. christmas trees), ornamental shrubs, heather, forest trees and hedging plants, fruit trees and shrubs, perennial crops *(via Art. 51)* | Downy mildews  (PEROSP, PHYTSP) | NL | 2 L/ha | Max. total rate per crop/season - 4 L/ha  Max. 2 applications per season  Min. interval between applications – 7 days |

Description of the target pests

Table ‑: Glossary of pests mentioned in the dossier.

| EPPO code | Scientific name |
| --- | --- |
| PHYTIN | *Phytophthora infestans* |
| PERODE | *Peronospora destructor* |
| PEROSP | *Peronospora sp.* |
| PHYTSP | *Phytophthora spp.* |

Table ‑: Major / minor status of intended uses (for all cMS and zRMS).

| Crop and/or  situation | Crop status | | Pests or group of pests controlled | Pest status | |
| --- | --- | --- | --- | --- | --- |
|  | Major | Minor | Major | Minor |
| Potato | AT, BE, CZ, DE, HU, IE, NL, **PL (zRMS)**, RO, SI | SK | Phytophthora infestans  (PHYTIN) | AT, BE, CZ, DE, HU, IE, NL, **PL (zRMS)**, RO, SI | SK |
| Onion & Garlic | NL (onion) | AT, BE, CZ, DE, IE, **PL (zRMS),** NL (garlic) | *Peronospora destructor*  (PERODE) | NL(onion) | AT, BE, CZ, DE, IE, **PL (zRMS),** NL (garlic) |
| Tomato and Aubergine | HU, RO | **PL (zRMS)**, SI, SK | Phytophthora infestans  (PHYTIN) | HU, RO | **PL (zRMS)**, SI, SK |
| Floriculture crops, avenue trees, climbing plants, conifers (incl. christmas trees), ornamental shrubs, heather, forest trees and hedging plants, fruit trees and shrubs, perennial crops (*via Art. 51*) | - | NL | Peronospora sp.  (PEROSP)  *Phytophthora spp.*  (PHYTSP) | - | NL |

**Overview on existing uses of the active ingredient (KCP 6)**

In Europe, BAS 743 03 F is a new product, but the active substances are already authorized in many countries (see Table 3.2‑5 for ametoctradin and Table 3.2‑6 for propamocarb-hydrochloride).

Table ‑: Overview of products containing ametoctradin registered for use in Central Europe.

| **Country** | **Trade name** | **Registration number** | **Crop (commodity)** | **Dose rate** |
| --- | --- | --- | --- | --- |
| Austria | Enervin SC | 4221/0 | POTATOES (*Solanum tuberosum*), GARLIC (*Allium sativum*), LEEKS (*Allium porrum*), SHALLOT (*Allium ascalonicum*), ONIONS (*Allium cepa*) | 1.2 L/ha |
| GRAPES: TABLE (*Vitis vinifera*), GRAPES: WINE (*Vitis vinifera*) | 2.4 L/ ha |
| ONIONS-PEARL/SILVERSKIN (*Allium ampeloprasum holmense*), ONIONS-WELSH (*Allium fistulosum*) | 1.2 L/ ha |
| 4221/1 | POTATOES (*Solanum tuberosum*), GARLIC (*Allium sativum*), LEEKS (*Allium porrum*), SHALLOT (*Allium ascalonicum*), ONIONS (*Allium cepa*) | 1.2 L/ ha |
| GRAPES: TABLE (*Vitis vinifera*), GRAPES: WINE (*Vitis vinifera*) | 2.4 L/ ha |
| ONIONS-PEARL/SILVERSKIN (*Allium ampeloprasum holmense*), ONIONS-WELSH (*Allium fistulosum*) | 1.2 L/ ha |
| Prevint Flow | 4221/901 | POTATOES (*Solanum tuberosum*), GARLIC (*Allium sativum*), LEEKS (*Allium porrum*), SHALLOT (*Allium ascalonicum*), ONIONS (*Allium cepa*) | 1.2 L/ ha |
| GRAPES: TABLE (*Vitis vinifera*), GRAPES: WINE (*Vitis* *vinifera*) | 2.4 L/ ha |
| ONIONS-PEARL/SILVERSKIN (*Allium* *ampeloprasum* *holmense*), ONIONS-WELSH (*Allium* *fistulosum*) | 1.2 L/ ha |
| Belgium | Zampro | 10884P/B | LEEKS (*Allium* *porrum*), POTATOES (*Solanum* *tuberosum*) | 1.2 L/ ha |
| GRAPES: WINE (*Vitis* *vinifera*) | 0.83 L/ ha -LWA |
| POTATOES (*Solanum* *tuberosum*) | 1.2 L/ ha |
| GRAPES: TABLE (*Vitis* *vinifera*) | 0.83 L/ ha -LWA |
| Enervin SC | 11223P/B | LEEKS (*Allium* *porrum*), POTATOES (*Solanum* *tuberosum*) | 1.2 L/ ha |
| GRAPES: WINE (*Vitis* *vinifera*) | 0.83 L/ ha -LWA |
| POTATOES (*Solanum* *tuberosum*) | 1.2 L/ ha |
| GRAPES: TABLE (*Vitis* *vinifera*) | 0.83 L/HA-LWA |
| Czech Republic | Enervin SC | 5561-0 | POTATOES (*Solanum* *tuberosum*), GARLIC (*Allium* *sativum*), ONIONS (*Allium* *cepa*), LEEKS (*Allium* *porrum*) | 1.2 L/ ha |
| GRAPES: TABLE (*Vitis* *vinifera*), GRAPES: WINE (*Vitis* *vinifera*) | 0.9 L/ ha |
| Germany | Enervin SC | 008966-00 | POTATOES (*Solanum* *tuberosum*), LEEKS (*Allium* *porrum*), ONIONS (*Allium* *cepa*) | 1.2 L/ ha |
| GRAPES: TABLE (*Vitis* *vinifera*), GRAPES: WINE (*Vitis* *vinifera*) | 1.2-2.4 L/ ha |
| ONIONS-PEARL/SILVERSKIN (*Allium* *ampeloprasum* *holmense*), GARLIC: FRESH/GREEN-GARLIC (*Allium* *sativum*), ONIONS-WELSH (*Allium* *fistulosum*), GARLIC (*Allium* *sativum*), SHALLOT (*Allium* *ascalonicum*) | 1.2 L/ ha |
| Prevint SC | 008966-60 | POTATOES (*Solanum* *tuberosum*), LEEKS (*Allium* *porrum*), ONIONS (*Allium* *cepa*) | 1.2 L/ ha |
| GRAPES: TABLE (*Vitis* *vinifera*), GRAPES: WINE (*Vitis* *vinifera*) | 1.2-2.4 L/ ha |
| ONIONS-PEARL/SILVERSKIN (*Allium* *ampeloprasum* *holmense*), GARLIC: FRESH/GREEN-GARLIC (*Allium* *sativum*), ONIONS-WELSH (*Allium* *fistulosum*), GARLIC (*Allium* *sativum*), SHALLOT (*Allium* *ascalonicum*) | 1.2 L/ ha |
| Ireland | Enervin SC | 5995 | POTATOES (*Solanum* *tuberosum*), LEEKS (*Allium* *porrum*) | 1.2 L/ ha |
| Netherlands | Enervin SC | 15702 | POTATOES (*Solanum* *tuberosum*) | 1.2 L/ ha |
| GRAPES: TABLE (*Vitis* *vinifera*), GRAPES: WINE (*Vitis* *vinifera*) | 1.5 L/ ha |
| LEEKS (*Allium* *porrum*) | 1.2 L/ ha |
| Poland | Enervin | R-52/2019wu | GRAPES: TABLE (*Vitis* *vinifera*), GRAPES: WINE (*Vitis* *vinifera*) | 1.5 L/ ha |
| LEEKS (*Allium* *porrum*), POTATOES (*Solanum* *tuberosum*) | 1.2 L/ ha |
| Slovakia | Enervin SC | 21-01069-AU | GRAPES: TABLE (*Vitis* *vinifera*), GRAPES: WINE (*Vitis* *vinifera*) | 0.9 L/ ha |
| GRAPES: TABLE (*Vitis* *vinifera*), GRAPES: WINE (*Vitis* *vinifera*) | 1.5 L/ ha |
| POTATOES (*Solanum* *tuberosum*) | 1.2 L/ ha |
| United Kingdom | Enervin SC | 19698 | LEEKS (*Allium* *porrum*), POTATOES (*Solanum* *tuberosum*), POTATOES: SEED (*Solanum* *tuberosum*) | 1.2 L/ ha |

*The presented information is based on a Homologa excerpt, dating from 20.02.2023 and we take no liability of the correctness of the information in this database.*

Table ‑: Overview of products containing propamocarb-hydrochloride registered for use in Central Europe.

| **Country** | **Trade**  **name** | **Registration number** | **Crop (commodity)** | **Dose rate** |
| --- | --- | --- | --- | --- |
| Austria | Rival | 4579/0 | TOMATOES-CHERRY (*Lycopersicon* *esculentum* *cerasiforme*) | 4.5 mL/m2 |
| 300 mL/m3 |
| TOMATOES (*Lycopersicon* *esculentum*) | 4.5 mL/m2 |
| 300 mL/m3 |
| Belgium | Rival | 10863P/B | TOMATOES-CHERRY (*Lycopersicon* *esculentum* *cerasiforme*) | 5 mL/m2 |
| 2 L/ha |
| TOMATOES (*Lycopersicon* *esculentum*) | 5 mL/m2 |
| 2 L/ ha |
| Omix | 10864P/B | TOMATOES-CHERRY (*Lycopersicon* *esculentum* *cerasiforme*) | 5 mL/m2 |
| 2 L/ ha |
| TOMATOES (*Lycopersicon* *esculentum*) | 5 mL/m2 |
| 2 L/HA |
| Proplant | 8672P/B | TOMATOES-CHERRY (*Lycopersicon* *esculentum* *cerasiforme*) | 5 mL/m2 |
| 2 L/ ha |
| ANGELICA: EDIBLE-ROOT (*Angelica* *archangelica*) | 1.5 L/ ha |
| BRUSSELS-SPROUTS (*Brassica* *oleracea* *gemmifera*/*fruticosa*) | 5 L/ ha |
| TOMATOES (*Lycopersicon* *esculentum*) | 5 mL/M2 |
| 2 L/ ha |
| AUBERGINE/AUBERGINE (*Solanum* *melongena*) | 5 mL/m2 |
| 2 L/ ha |
| Edipro | 9986P/B | POTATOES (*Solanum* *tuberosum*) | 1.4 L/ ha |
| Czech  Republic | Proplant | 4518-0 | BRASSICAS-HEAD: OTHERS (*Brassica* sp.) | 0.15-2% |
| BRASSICAS-LEAFY: OTHERS (*Brassica* sp.) | 0.15-2% |
| BRASSICAS-FLOWERING: OTHERS (*Brassica* sp.) | 0.15-2% |
| TOMATOES-CHERRY (*Lycopersicon* *esculentum* *cerasiforme*) | 0.15-2% |
| BRUSSELS-SPROUTS (*Brassica* *oleracea* *gemmifera*/*fruticosa*) | 0.15-2% |
| TOMATOES (*Lycopersicon* *esculentum*) | 0.15-2% |
| 4518-0V | BRASSICAS-HEAD: OTHERS (*Brassica* sp.) | 0.15-2% |
| BRASSICAS-LEAFY: OTHERS (*Brassica* sp.) | 0.15-2% |
| BRASSICAS-FLOWERING: OTHERS (*Brassica* sp.) | 0.15-2% |
| TOMATOES-CHERRY (*Lycopersicon* *esculentum* *cerasiforme*) | 0.15-2% |
| BRUSSELS-SPROUTS (*Brassica* *oleracea* *gemmifera*/*fruticosa*) | 0.15-2% |
| TOMATOES (*Lycopersicon* *esculentum*) | 0.15-2% |
| Germany | Sporax | 00A808-00 | POTATOES (*Solanum* *tuberosum*) | 1.4 L/ ha |
| Ireland | Edipro | 3889 | POTATOES (*Solanum* *tuberosum*) | 1.4 L/ ha |
| Proplant | 3994 | BRUSSELS-SPROUTS (*Brassica* *oleracea* *gemmifera*/*fruticosa*) | 5 ML/m2 |
| Hungary | Proplant | 16451/2003 | LETTUCE-AND-SIMILAR: OTHERS (*Lactuca* *sativa*) | 0.15% |
| POTATOES (*Solanum* *tuberosum*). ONIONS (*Allium* *cepa*), TOMATOES (*Lycopersicon* *esculentum*) | 3 L/ ha |
| TOMATOES (*Lycopersicon* *esculentum*) | 0.3-0.4 L/m3 |
| LETTUCE (*Lactuca* *sativa*) | 0.15% |
| LETTUCE-HEAD-VARIETIES (*Lactuca* *sativa* *capitata*) | 0.15% |
| Netherlands | Rival | 15535 | TOMATOES-CHERRY (*Lycopersicon* *esculentum* *cerasiforme*) | 300 mL/m3 |
| TOMATOES (*Lycopersicon* *esculentum*) | 300 mL/m3 |
| Floriculture crops | 300mL/m3 or 10mL/m3 |
| Edipro | 14280N | POTATOES (*Solanum* *tuberosum*) | 1.4 L/ ha |
| Proplant | 12918N | LETTUCE (*Lactuca* spp) | 1.5 L/ ha |
| TOMATOES (*Lycopersicon* *esculentum*)  AUBERGINE/AUBERGINE (*Solanum* *melongena*) | Drip 1-2 L/ ha |
| Courgette, Cucumber, melon | Drip 1-2L/HA |
| Bulb flower | Dip 0.3% |
| Floriculture crops | 300 ml in 10 L water per m3 potting soil |
| 5-10 ml in 3-6 L water per m2 |
| Drench 0.15% |
| Drip 1-2 L per ha |
| United Kingdom | Proplant | 15422 | TOMATOES-CHERRY (*Lycopersicon* *esculentum* *cerasiforme*)  BRUSSELS-SPROUTS (*Brassica* *oleracea* *gemmifera*/*fruticosa*)  TOMATOES (*Lycopersicon* *esculentum*) | 0.1 L/1000L |
| 50 L/ha |
| 0.25 L/1000L |
| BRUSSELS-SPROUTS (*Brassica* *oleracea* *gemmifera*/*fruticosa*) | 1 L/1000L |
| TOMATOES (*Lycopersicon* *esculentum*)  POTATOES (*Solanum* *tuberosum*)  BRUSSELS-SPROUTS (*Brassica* *oleracea* *gemmifera*/*fruticosa*) | 0.1 L/1000L |
| 1.4 L/ha |
| 50 L/ha |
| Edipro | 15564 | TOMATOES-CHERRY (*Lycopersicon* *esculentum* *cerasiforme*) | 0.25 L/1000L |
| Propamex-I 604 SL | 15901 | BRUSSELS-SPROUTS (*Brassica* *oleracea* *gemmifera*/*fruticosa*) | 0.1 L/1000L |
| Promess | 16008 | BRUSSELS-SPROUTS (*Brassica oleracea gemmifera/fruticosa*)  TOMATOES (*Lycopersicon esculentum*) | 50 L/ha |
| 0.25 L/1000L |
| BRUSSELS-SPROUTS (*Brassica oleracea gemmifera/fruticosa*) | 0.1 L/1000L |
| TOMATOES-CHERRY (*Lycopersicon esculentum cerasiforme*) | 0.3 L/100m3 |
| 50 L/ha |
| Rival | 18177 | TOMATOES (*Lycopersicon esculentum*) | 0.3 L/100m3 |
| 50 L/ha |
| Rival | 18177 | TOMATOES-CHERRY (*Lycopersicon esculentum cerasiforme*) | 0.3 L/100m3 |
| 50 L/ha |
| Propicarb | 19884 | POTATOES (*Solanum tuberosum*)  POTATOES (*Solanum tuberosum*) | 1.4 L/ha |
| 1.4 L/ha |
| Sporax | 20004 | POTATOES (*Solanum tuberosum*) | 1.4 L/ha |
| Raport | 20536 | POTATOES (*Solanum tuberosum*) | 1.4 L/ha |

*The presented information is based on a Homologa excerpt, dating from 20.02.2023 and we take no liability of the correctness of the information in this database.*

Compliance with the Uniform Principles

A total of 54 efficacy trials are evaluated in the Biological Assessment Dossier.

Efficacy trials were 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.

All trials were carried out according to Good Experimental Practice (GEP) standards and accreditations. The relevant GEP and Officially Recognized Testing Organizations are listed in chapter 3.7.

All trials were conducted in compliance with relevant EPPO guidelines. The major general guidelines followed were:

EPPO PP 1/135 (4) Phytotoxicity assessment

EPPO PP 1/152 (4) Design and Analysis of Efficacy Evaluation Trials

EPPO PP 1/181 (5) Conduct and reporting of efficacy evaluation trials including good

experimental practice

EPPO PP 1/207 (2) Effects on succeeding crops

EPPO PP 1/213 (4) Resistance risk analysis

EPPO PP 1/226 (3) Number of efficacy trials

EPPO PP 1/239 (3) Dose expression for plant protection products

EPPO PP 1/242 (2) Taint tests

EPPO PP 1/256 (1) Effects on adjacent crops

EPPO PP 1/278 (1) Principles of zonal data production and evaluation

EPPO PP 1/306 (1) General principles for the development of co-formulated mixture of plant protection

products

Information on trials submitted (3.1 Efficacy data)

The following table (Table 3.2‑7) gives an overview of submitted efficacy trials. The list of all individual trials is detailed at the beginning of each relevant chapter.

Table ‑: Presentation of trials (Potato, Onion, and Tomato).

| **Crop** | **Target** | **Country** | **Years** | **Type of trial\*** | **Number of trials** | | | | **GEP /**  **non-GEP** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Ma**  **zone** | **NE**  **zone** | **SE**  **zone** | **ME**  **zone** |
| **Potato** | PHYTIN | Germany | 2018-2022 | RJ/CF/ BR/ MED/ E | 1/ 3/ 1/ 2/ 7 | - | - | - | GEP |
| The Netherlands | 2021-2022 | RJ/CF/ BR/ MED/ E | 1/ 2/ 1/ 1/ 3 | - | - | - | GEP |
| Ireland | 2020-2022 | RJ/CF/ BR/ MED/ E | 2/ 2/ -/ 4/ 4 | - | - | - | GEP |
| United Kingdom | 2018 | RJ | 1 | - | - | - | GEP |
| Poland | 2020-2022 | RJ/CF/ BR/ MED/ E | - | -/ 2/ 1/ 5/ 9 | - | - | GEP |
| Hungary | 2020-2022 | RJ/CF/ BR/ MED/ E | - | - | -/ 3/ 1/ 3/ 4 | - | GEP |
| Romania | 2020-2022 | RJ/CF/ BR/ MED/ E | - | - | -/ 3/ 2/ 6/ 8 | - | GEP |
| Spain | 2022 | BR | - | - | - | 1 | GEP |
| Italy | 2022 | BR | - | - | - | 1 | GEP |
| **TOTAL** | | **2020-2022** | **RJ/CF/ BR/ MED/ E** | **5/ 7/ 2/ 7/ 14** | **-/ 2/ 1/ 5/ 9** | **- / 6/ 3/ 9/ 12** | **-/ -/ 2 /- /- /** | **5/ 15/ 8/ 21/ 35** |
| **Onion** | ALLCE | Germany | 2020-2022 | CF/ BR/ MED/ E | -/ 1/ 3/ 4 | - | - | - | GEP |
| The Netherlands | 2020-2022 | CF/ BR/ MED/ E | 2/ 1/ 3/ 4 | - | - | - | GEP |
| Poland | 2020-2022 | CF/ BR/ MED/ E | - | 1/ -/ 6/ 6 | - | - | GEP |
| Spain | 2022 | BR | - | - | - | 1 |  |
| **TOTAL** | | **2020-2022** | **CF/ BR/ MED/ E** | **2/ 2/ 6/ 8** | **1/ -/ 6/ 6** | **-** | **1** | **3/ 3/ 12/14** |
| **Tomato** | PHYTIN | Poland | 2020-2022 | BR/ MED/ E | - | 2/ 3/ 5 | - | - | GEP |
| France | 2022 | BR | - | - | - | 1 | GEP |
| Italy | 2022 | BR | - | - | - | 1 | GEP |
| **TOTAL** | | **2020-2022** | **BR/ MED/ E** | **-** | **2/ 3/ 5** | **-** | **2/ -/ -** | **4/ 3/ 5** |

*\* Type of trial: RJ = Ratio-justification trial, CF = Co-formulation trial, BR= Bridging trials, MED = minimum effective dose, E = efficacy*

*trial, GEP = Good Experimental Practices*

* Material and methods

An overview of the trial methodology is given in tabular form separately for each crop. More detailed information on trials is available in Dossier Trial Data Reports with the following Doc ID: 2023/2022462.

* **Trial layout**

Trials were conducted following a randomized design or a randomized block design. For information on the number of replications and the plot size, refer to the respective table, "Details on trial methodology."

Untreated plots were included in the trial layout. Trial sites were chosen according to the disease's presence or probability of appearing on a disease-sensitive variety.

* **Application**

Applications were carried out according to the GAP, mostly preventatively or at onset of disease. Generally, more than the maximum number of applications recommended in the GAP have been carried out in most of the trials. Treatments usually started before the development of the disease as preventive applications and continued season-long as a continuous spray program.

* **Evaluation methods and statistical analyses**

Visual assessments of the infection percentage were made for each crop in each plot. Here below are explained all the assessments evaluation codes used in this dossier.

* INFECT – P%FREQ: frequency of attack evaluated as percentage (%) of infected plant parts
* INFECT – P%INF: intensity of infection on plant parts, reported as percentage (%) of infection
* KR%ABB: frequency of disease attack reported as percentage (%), considering 2 classes (healthy and damage);

PHYTOX – % of crop injury

* YIELD - Most trials were harvested in order to measure yield in terms of quantity (dt/ha) and quality. Calibration (SIB – sieve size in potatoes and onions) was done according to national or local standards and the harvested crops were assigned to two or more classes. The weight of tubers (potatoes) and bulbs (onions) in each class was recorded and each class was expressed as a percentage of the total weight. Moreover, for starch potato varieties the yield of starch (YSTAER) in dt/ha was reported.
* **Statistical analysis**

The statistical analysis was conducted using the program SPEAD MI. The observed or calculated variables were subjected to an analysis of variance (ANOVA) for statistical interpretation. The automatic transformation in the SPEAD database in XXXX considers the optimal transformation according to the distribution of variation in the response. This is conducted independently of the result of the analysis of variance. The choices of transformation available are: a) Untransformed b) Logit c) Arcsin of the square root of the data d) Square root e) Box-Cox. The transformations. a)-d) are well-known. For the Box-Cox transformation, a value of h between -2 and 2 is selected, where the Boxcox function, B(y) is equal to B(y) = (y^h -1)/h, if h is not equal to zero and B(y) = ln(y), (the natural logarithm) where h is equal to zero.

From these five transformations, the transformation is chosen for which the model explains the largest proportion of variation in the response and also for which the Levene test is fulfilled. The Levene test checks the homogeneity of variance between treatment groups. If the variance within each treatment group is not deemed homogeneous to the others, the test fails.

For efficacy data, when the result of the variance analysis is significant, a multiple comparison of treatments is performed by using the Student-Newman-Keuls test (SNK). The yield values were subjected to the analysis of variance and the comparison of treatment is performed by Tukey test. The statistical tests show, which treatments are different with a 95% probability. The averages are divided into homogeneous groups (A, B, C, …). Statistically significant difference exists if the letters beside the results for two treatments are different. Values followed by the same letter are not significantly different (P<0.05).

* **Results layout**

In the efficacy section of the Biological Assessment Dossier, percentage control in relation to the untreated plot is presented in each efficacy table. A data summary is provided for each trial results table with the number of trials shown and the average, minimum, and maximum values.

The infection level is usually rounded to one decimal place. A relative percentage of efficacy is calculated using the Abbott formula for treated plots. The efficacy value is rounded to the closest unit with one decimal place.

Abbott formula:

*C = infection degree in the untreated object,*

*T = infection degree in the treated object*

The trials and assessments with sufficient infestation levels in the untreated plot are considered for evaluation if not stated otherwise.

Unless mentioned differently, the mean threshold considered in this dossier is usually 5% of the intensity of attack for diseases of the field crops.

Phytotoxicity, yield, and yield quality parameters are presented from the efficacy trials.

* **Reference products**

Commercially registered fungicides were used as standards, as listed for each crop in the following subchapters. The standards were applied as per locally approved label rates. The trials have been conducted over several years in multiple countries of the Central Registration Zone, and in each trial, the tested product was compared to one reference product. In the summary tables, orthogonal comparisons to individual standards are provided.

**Potato (*Solanum tuberosum*/SOLTU)**

A total of 35 efficacy trials on potato are included in this Biological Assessment Dossier. In these efficacy trials, the product at the target and the reduced dose rate and the standard were tested with 2 – 12 applications with the spray interval (min-max) of 5-21 days. Details on materials and methods are summarized in the following Table 3.2‑8.

Table ‑: Details on trial methodology, Potato.

|  |  |  |  |
| --- | --- | --- | --- |
| **Guidelines** | General guidelines | EPPO PP 1/135 (4) Phytotoxicity assessment  EPPO PP 1/152 (4) Design and Analysis of Efficacy Evaluation Trials  EPPO PP 1/181 (5) Conduct and reporting of efficacy evaluation trials including good  experimental practice  EPPO PP 1/207 (2) Effects on succeeding crops  EPPO PP 1/213 (4) Resistance risk analysis  EPPO PP 1/226 (3) Number of efficacy trials  EPPO PP 1/239 (3) Dose expression for plant protection products  EPPO PP 1/242 (2) Taint tests  EPPO PP 1/256 (1) Effects on adjacent crops  EPPO PP 1/278 (1) Principles of zonal data production and evaluation  EPPO PP 1/306 (1) General principles for the development of co-formulated mixture of plant protection products | |
| Specific guidelines | EPPO PP 1/002 (4): *Phytophthora infestans* on potato | |
| **Experimental design** | Plot design | RB - randomized block design; RR – randomized design | |
| Plot size | 10-33 m² | |
| Number of replications | 4 | |
| **Crop** | Trials per crop | 35 | |
| Varieties per crop | ROOSTER, MARIS PIPER, BINTJE, FONTANE, IRGA, SATINA, ALBATROS, TAJFUN, ZUZANNA, GALA, LILY, ESZME, BELLAROSA, SORAYA, SANTE, ARIZONA  BALATONI ROZSA, CARERA, ACTRICE, RED SCARLET | |
| **Application** | Crop stage at application | BBCH 17-89 | |
| Number of applications | 2-12 | |
| Intervals between applications | 5-21 days | |
| Spray volumes | 200-500 L/ha | |
| **Assessment** | Assessment types | Disease severity (%)  Phytotoxicity (%)  Yield (dt/ha)  Yield of starch (dt/ha)  Sieve size (%) | P%INF  PHYTOX  ERTRNE  YSTAER  SIB |

Reference product used in potato trials is presented in the following Table 3.2‑9.

Table ‑: Presentation of reference standard used in potato trials.

| **Crop** | **Reference standard** | **Trade name(s)** | **Active substance(s)** | **Formulation** | | **Registered application rate in countries** | **Application rate in trials (per treatment)** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Type** | **Conc. of a.s.** |
| Potato | BAS 9412 0 F | Revus | Mandipropamid | SC | 250 g/L | 0.6 L/ha | 0.6 L/ha |

**Onion (*Allium cepa*** / **ALLCE)**

A total of 14 efficacy trials on onion are included in this Biological Assessment Dossier. In these efficacy trials, the product at the target and the reduced dose rate and the standard were tested with 4 – 11 applications with the spray interval (min-max) of 4-9 days. Details on materials and methods are summarized in the following table.

Table ‑: Details on trial methodology, Onion.

|  |  |  |  |
| --- | --- | --- | --- |
| **Guidelines** | General guidelines | EPPO PP 1/135 (4) Phytotoxicity assessment  EPPO PP 1/152 (4) Design and Analysis of Efficacy Evaluation Trials  EPPO PP 1/181 (5) Conduct and reporting of efficacy evaluation trials including good  experimental practice  EPPO PP 1/207 (2) Effects on succeeding crops  EPPO PP 1/213 (4) Resistance risk analysis  EPPO PP 1/226 (3) Number of efficacy trials  EPPO PP 1/239 (3) Dose expression for plant protection products  EPPO PP 1/242 (2) Taint tests  EPPO PP 1/256 (1) Effects on adjacent crops  EPPO PP 1/278 (1) Principles of zonal data production and evaluation  EPPO PP 1/306 (1) General principles for the development of co-formulated mixture of plant protection products | |
| Specific guidelines | EPPO PP1/065(4): Downy mildews of vegetables  EPPO PP1/120(2): Foliage diseases of Allium crops | |
| **Experimental design** | Plot design | RB - randomized block design | |
| Plot size | 10.8-21.1 m² | |
| Number of replications | 4 | |
| **Crop** | Trials per crop | 14 | |
| Varieties per crop | TONDA MUSONA, DORMO, CENTRO, SUPRA, MAJKA, SOCHACZEWSKA, HOZA, FASTO, OLOROSA MIESZAN | |
| **Application** | Crop stage at application | BBCH 15-47 | |
| Number of applications | 4-11 | |
| Intervals between applications | 4-9 days | |
| Spray volumes | 300 -700 L/ha | |
| **Assessment** | Assessment types | Disease severity (%)  Phytotoxicity (%)  Yield (dt/ha)  Sieve size (%) | P%INF  PHYTOX  ERTRNE  SIB |

Reference product used in onion trials is presented in the following Table 3.2‑11.

Table ‑: Presentation of reference standard used in onion trials.

| **Crop** | **Reference standard** | **Trade name(s)** | **Active substance(s)** | **Formulation** | | **Registered application rate in countries** | **Application rate in trials (per treatment)** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Type** | **Conc. of a.s.** |
| Onion | BAS 9164 4 F | Ortiva | Azoxystrobin | SC | 250 g/L | 1.0 L/ha | 1.0 L/ha |

**Tomato (*Solanum lycopersicum*** / **LYPES)**

A total of 5 efficacy trials on tomato are included in this Biological Assessment Dossier. In these efficacy trials, the product at the target and the reduced dose rate and the standard were tested with 4 – 8 applications with the spray interval (min-max) of 7-13 days. Details on materials and methods are summarized in the following Table 3.2‑12.

Table ‑: Details on trial methodology, Tomato.

|  |  |  |  |
| --- | --- | --- | --- |
| **Guidelines** | General guidelines | EPPO PP 1/135 (4) Phytotoxicity assessment  EPPO PP 1/152 (4) Design and Analysis of Efficacy Evaluation Trials  EPPO PP 1/181 (5) Conduct and reporting of efficacy evaluation trials including good  experimental practice  EPPO PP 1/207 (2) Effects on succeeding crops  EPPO PP 1/213 (4) Resistance risk analysis  EPPO PP 1/226 (3) Number of efficacy trials  EPPO PP 1/239 (3) Dose expression for plant protection products  EPPO PP 1/242 (2) Taint tests  EPPO PP 1/256 (1) Effects on adjacent crops  EPPO PP 1/278 (1) Principles of zonal data production and evaluation  EPPO PP 1/306 (1) General principles for the development of co-formulated mixture of plant protection products | |
| Specific guidelines | EPPO PP1/65 (3): Downy mildews of vegetables | |
| **Experimental design** | Plot design | RB - randomized block design | |
| Plot size | 2-12m² | |
| Number of replications | 4 | |
| **Crop** | Trials per crop | 5 | |
| Varieties per crop | SCOOTER, RUMBA O¿AROWSKA, NUN00507, PIETRAROSSA, DYNO | |
| **Application** | Crop stage at application | BBCH 74-83 | |
| Number of applications | 4-11 | |
| Intervals between applications | 7-13 days | |
| Spray volumes | 500-700 L/ha | |
| **Assessment** | Assessment types | Disease severity (%)  Disease incidence (%)  Phytotoxicity (%)  Yield (dt/ha) | P%INF  P%FREQ  PHYTOX  ERTRNE |

Reference product used in tomato trials is presented in the following Table 3.2‑13.

Table ‑: Presentation of reference standard used in tomato trials.

| **Crop** | **Reference standard** | **Trade name(s)** | **Active substance(s)** | **Formulation** | | **Registered application rate in countries** | **Application rate in trials (per treatment)** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Type** | **Conc. of a.s.** |
| Tomato | **BAS 9412 0 F** | **Revus** | Mandipropamid | SC | 250 g/L | 0.6 L/ha | * 1. L/ha |

### Preliminary tests (KCP 6.1)

In order to justify the ratio for BAS 743 03 F, 5 trials were conducted in 2018 in the Maritime EPPO climatic zone in Germany (1 trial), the Netherlands (1 trial), Ireland (2 trials) and the United Kingdom (1 trial) in potatoes for *Phytophthora infestans.*

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 18 trials – 15 trials on potatoes and 3 trials on bulb onions, covering the Maritime, the North-East and the South-East EPPO climatic zone. In all cases, each compound was applied at the dose rate intended to be delivered with BAS 743 03 F.

For the formulation bridging, 15 trials - 8 trials on potatoes, 3 trials on onions and 4 trials on tomatoes, were evaluated and are presented. These trials were conducted in 2022 in different countries covering the Maritime, the Mediterranean, the North-East, and the South-East EPPO climatic zones.

Justification of co-formulated mixture (KCP 6.1)

* **Rationale for the co-formulation BAS 743 03 F**

BAS 743 03 F is a mixture of ametoctradin and propamocarb-hydrochloride.

The dose rate and ratio defined for this ready-to-use mixture, aim to provide to growers:

* High level control of late blight of potatoes and tomatoes (PHYTIN)
* High level control of downy mildew of onions (PERODE)

Ametoctradin is a fungicidal molecule with protective activity belonging to the chemical class of triazolo-pyrimidylamine, and in particular to the group of QoSI fungicides (Quinone outside Inhibitor, Stigmatellin binding type), FRAC Code C8.

Propamocarb is a systemic carbamate fungicide used to control diseases caused by oomycetes in soil, roots, and leaves. It has been speculated that the mode of action of propamocarb is through selectively interfering with the biosynthesis of fatty acid and phospholipids in oomycete membranes, although this has not been proven.

While both active ingredients target oomycete plant pathogens, the interest of this mixture is to combine a high lipophilic product with the long-lasting preventive activity of treated plant parts with a highly soluble systemic carbamate fungicide - thus providing protection of the new growth systemically and controlling fungicidal activity. At its intended dose rate and ratio, BAS 743 03 F aims to provide optimum control of targeted diseases as well as prevention of resistence development. The complementarity of the active ingredients at the rate and ratio intended to be applied with BAS 743 03 0F was tested in the field against late blight and downy mildew, the main diseases targeted to be controlled by this mixture. The results are presented in the chapters below.

* Layout of field trials

Biological efficacy trials were conducted at different growing locations across Europe between 2018 and 2021. The trials were laid out in a randomized block design with 4 replicates. Applications started preventatively or at onset of disease and continued season-long. Statistical analyses were performed. Percentage disease values were transformed using automatic transformation and multiple mean comparisons were done using Student-Newman-Keuls test.

* **Efficacy of alternative ratios of active ingredients**

To define the ratio of active ingredients within the BAS 743 03 F formulation, preliminary trials were conducted in 2018, in the Maritime zone (1 trial in Germany, 1 trial in the Netherlands, 2 trials in Ireland and 1 trial in the United Kingdom against *Phytophthora infestans* in potato (altogether 5 trials).

In order to determine the most effective ratio of the active ingredients, different ratios of propamocarb-hydrochloride were tested. BAS 743 03 F is a combination of 120 g/L of ametoctradin and 451 g/L of propamocarb-hydrochloride, being equivalent to 378 g/L of propamocarb. Therefore, the intended dose rate of 2.0 L/ha gives 240 g of ametoctradin/ha and 902 g of propamocarb-hydrochloride/ha (equivalent to 756 g of propamocarb/ha). The ratio of ametoctradin : propamocarb in BAS 743 03 F is 1:3.15.

Different combinations of ametoctradin and propamocarb-hydrochloride were tested in tankmix reflecting ratios of 1:1.26, 1:1.89, 1:2.52 and 1:3.15. Results are presented in Table 3.2‑14.

The assessments on leaves/total plants at BBCH ranging 75-92 have been evaluated.

* Summary and conclusions

BAS 743 03 F contains ametoctradin and propamocarb-hydrochloride, both showing good efficacy against the major target disease caused by Phytophthora infestans in potatoes. Combining both compounds leads to superior control compared to single active ingredients. In most trials, the chosen ratio of 240 g/ha ametoctradin and 902 g/ha of propamocarb-hydrochloride proved the better technical solution for potatoes, as the alternative tested ratios performed less effectively. With this target ratio in BAS 743 03 F, a more consistent performance is achieved for Phytophthora infestans in potatoes.

Table ‑: Ratio justification trial summary, Potato, PHYTIN (disease severity and efficacy in %); Details.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **EPPO**  **Zone** | **Trial ID** | **Part**  **Rated** | **Untreated** | | **Ametoctradin: Propamocarb**  **1: 1.26** | | | **Ametoctradin: Propamocarb**  **1: 1.89** | | | **Ametoctradin: Propamocarb**  **1: 2.52** | | | **Ametoctradin: Propamocarb**  **1: 3.15 (target treatment)** | | |
| **P%INF** | **SNK** | **P%INF** | **SNK** | **Efficacy** | **P%INF** | **SNK** | **Efficacy** | **P%INF** | **SNK** | **Efficacy** | **P%INF** | **SNK** | **Efficacy** |
| Maritime | Trial No.1 | LEAF | 93.5 | A | - | - | - | 3.8 | D | 96.0 | 3.8 | D | 96.0 | 4.5 | D | 95.2 |
| Trial No.2 | PLANT,  TOTAL | 65.8 | AB | - | - | - | 27.5 | BC | 58.2 | 38.8 | BC | 41.1 | 20.8 | BC | 68.4 |
| Trial No.3 | PLANT,  TOTAL | 95.5 | A | 1.8 | D | 98.2 | 2.2 | D | 97.7 | - | - | - | 1.9 | D | 98.0 |
| Trial No.4 | PLANT,  TOTAL | 97.8 | A | 9.9 | C | 89.9 | 10.1 | C | 89.6 | - | - | - | 8.5 | C | 91.3 |
| Trial No.5 | PLANT,  TOTAL | 100.0 | A | 20.0 | C | 80.0 | 12.5 | C | 87.5 | - | - | - | 5.6 | D | 94.4 |

* Efficacy of solo active ingredients versus ready-mix

Between 2020 and 2021, 18 trials were conducted in order to evaluate the interaction of the active ingredients, ametoctradin and propamocarb-hydrochloride. The performance of the solo active ingredients was compared to the efficacy of the ready mixture. In all cases, each compound was applied at the dose rate intended to be delivered with BAS 743 03 F.

For all trials the same timing is presented as in the dose justification chapter and efficacy trials. Summary results are presented in Table 3.2‑15 (Potatoes) and Table 3.2‑16 (Onions).

Table ‑: Co-formulation justification; Potato, PHYTIN (disease severity and efficacy in %); Summary.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **EPPO**  **Zone** | | **Untreated** | **BAS 743 03 F**  **2 L/ha** | | **Ametoctradin**  **1.2 L/ha** | | **Propamocarb**  **1.3 L/ha** | |
| **P%INF** | **P%INF** | **Efficacy** | **P%INF** | **Efficacy** | **P%INF** | **Efficacy** |
| Maritime | Mean (n = 7)  (min-max) | 98.4  (93.3-100.0) | 33.9  (6.0-55.0) | 65.7  (44.4-93.8) | 50.3  (7.5-96.5) | 48.8  (3.5-78.0) | 74.0  (52.5-84.0) | 23.1  (3.3-47.5) |
| North-East | Mean (n = 2)  (min-max) | 49.5  (14.0-85.0) | 5.6  (1.4-9.8) | 89.4  (88.5-90.3) | 6.2  (1.4-11.0) | 88.7  (87.1-90.2) | 15.9  (1.8-30.0) | 76.1  (64.7-87.5) |
| South-East | Mean (n = 6)  (min-max) | 53.7  (9.3-96.3) | 15.7  (1.0-30.0) | 69.9  (41.9-98.5) | 18.7  (1.3-35.0) | 63.8  (34.9-89.1) | 17.2  (1.4-35.0) | 65.9  (34.9-94.5) |
| **Total ALL** | **Mean (n = 15)**  **(min-max)** | **74.0**  **(9.3-100.0)** | **22.8**  **(1.0-55.0)** | **70.5**  **(41.9-98.5)** | **31.7**  **(1.3-96.5)** | **60.1**  **(3.5-90.2)** | **43.6**  **(1.4-84.0)** | **47.3**  **(3.3-94.5)** |

Table ‑: Co-formulation justification; Onion, PERODE (disease severity and efficacy in %); Summary.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **EPPO**  **Zone** | | **Untreated** | **BAS 743 03 F**  **2 L/ha** | | **BAS 650 00 F**  **1.2 L/ha** | | **BAS 9068 2 F**  **1.3 L/ha** | |
| **P%INF** | **P%INF** | **Efficacy** | **P%INF** | **Efficacy** | **P%INF** | **Efficacy** |
| Maritime | Mean (n = 2)  (min-max) | 18.8  (5.0-32.5) | 3.4  (2.0-4.8) | 72.7  (60.6-85.4) | 6.3  (2.4-10.3) | 60.5  (52.5-68.5) | 11.6  (2.4-68.5) | 43.8  (36.2-51.3) |
| North-East | Mean (n = 1)  (min-max) | 9.7  (-) | 0.7  (-) | 92.3  (-) | 2.0  (-) | 79.9  (-) | 3.6  (-) | 63.1  (-) |
| **Total ALL** | **Mean (n = 3)**  **(min-max)** | **15.7**  **(5.0-32.5)** | **2.5**  **(0.7-4.8)** | **79.2**  **(60.6-92.3)** | **4.9**  **(2.0-10.3)** | **67.0**  **(52.5-79.9)** | **8.9**  **(2.4-20.8)** | **50.2**  **(36.2-63.1)** |

* **Summary and conclusions**

BAS 743 03 F contains ametoctradin and propamocarb-hydrochloride, which both show medium to good efficacy against the major target diseases caused by Phytophthora infestans and Peronospora destructor in potatoes and onions. Taking the results together, the combination of both compounds leads to superior control compared to the single active ingredients.

**Bridging trials (KCP 6.1)**

* **Introduction**

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

* 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

Overview of all 4 formulations used in this BAD is listed in table below.

Table ‑: Overview of the formulations.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Formulation** | **BAS 743 AA F** | **BAS 743 AT F** | **BAS 743 00 F** | **BAS 743 03 F** |
| **Components** | 120g/L Ametoctradin  378.0 g/L Propamocarb  0.6g/L Texapon K 12G | 120g/L Ametoctradin  451 g/L Propamocarb-hydrochloride (equivalent to 378.0 g/L Propamocarb)  10 g/L Ethylan NS 500 LQ | 120g/L Ametoctradin  451 g/L Propamocarb-hydrochloride (equivalent to 378.0 g/L Propamocarb)  10 g/L Ethylan NS 500 LQ | 120g/L Ametoctradin  451 g/L Propamocarb-hydrochloride (equivalent to  378.0 g/L Propamocarb) |
| **Type** | SC | SC | SC | SC |
| **Tested in Year** | 2019 | 2020-2021 | 2020-2021 | 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.

Detailed information and comparison of both formulations is provided in Part C Chapter 1.2 KCP 1.4.1.

Adverse effects of the change have neither been observed nor are to be expected. Therefore, all formulations are included in this BAD to prove the efficacy and selectivity of the product, as well as to justify the minimum effective dose rate for the uses on potatoes, onion, and tomatoes.

* **Material and Methods**

All trials presented in this chapter were used for efficacy evaluation. Materials and methods are therefore not mentioned here but can be found in chapter 3.2.0.7.

Further details can be found in the Dossier Trial Data Reports included in Part K.

A list of individual bridging trials is presented in Table 3.2‑18. These bridging trials compare the preliminary formulation BAS 743 00 F with the final BAS 743 03 F formulation at the intended dose rate foreseen in the GAP for uses against *Phytophthora infestans* and *Peronospora destructor.*

Table ‑: List of individual bridging trials.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Crop** | **EPPO Zone** | **Trial ID** | **Year** | **Country** | **Variety** | **Pathogen** |
| Potato | Maritime | Trial No.1 | 2022 | DE | BINTJE | PHYTIN |
| Trial No.2 | 2022 | NL | BINTJE |
| North-East | Trial No.1 | 2022 | PL | TAJFUN |
| South-East | Trial No.1 | 2022 | HU | BALATONI ROZSA |
| Trial No.2 | 2022 | RO | BELAROSA |
| Trial No.3 | 2022 | RO | CARRERA |
| Mediterranean | Trial No.1 | 2022 | ES | SPUNTA |
| Trial No.2 | 2022 | IT | COLOMBA |
| Onion | Maritime | Trial No.1 | 2022 | DE | TONDA MUSONA | PERODE |
| Trial No.2 | 2022 | NL | HOZA |
| Mediterranean | Trial No.1 | 2022 | ES | ROCIO |
| Tomato | North-East | Trial No.1 | 2022 | PL | PIETRAROSA | PHYTIN |
| Trial No.2 | 2022 | PL | DYNO |
| Mediterranean | Trial No.1  Trial No.2 | 2022 | FR | RIO GRANDE |
| 2022 | IT | FOKKER |
| **Total ALL** | | | | **Potato**  **Onion**  **Tomato** | **8**  **3**  **4** | |
| **ALL** | **15** | |

* **Results**

Altogether 15 trials - 8 trials on t5rggves, 3 trials on onions and 4 trials on tomatoes - were evaluated and are presented in this chapter. The trials were conducted in 2022 in different countries covering the Maritime, the Mediterranean, the North-East, and the South-East EPPO climatic zones.

A summary of the results is available in Table 3.2‑19, Table 3.2‑20, Table 3.2‑21and Table 3.2‑22.

* **Summary and conclusions**

In fifteen trials, data demonstrate that both formulations performed equivalently and showed good control of the tested diseases. Therefore, based on the results presented in this chapter and for the purpose of this BAD, both formulations are considered biologically comparable and are consequently evaluated and summarized together. The final product code BAS 743 03 F is used in the dossier tables. The individual formulations used are given in respective dossier trials data reports and can also be traced in each list of individual trials for each presented chapter of this BAD.

***Potato Bridging trials:*** *No difference in the efficacy between the two formulations was observed.*

Table ‑: Bridging data, Efficacy, Potato, PHYTIN (disease intensity and efficacy in %); Summary.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **EPPO**  **Zone** | | **Untreated** | **BAS 743 03 F**  **2.0 L/ha** | | **BAS 743 00 F**  **2.0 L/ha** | |
| **P%INF** | **P%INF** | **Efficacy** | **P%INF** | **Efficacy** |
| Maritime | Mean (n = 2)  (min-max) | 14.2  (5.1-23.3) | 0.7  (0.0-1.3) | 97.3  (94.6-100.0) | 0.3  (0.0-0.5) | 98.7  (97.8-99.5) |
| North-East | Mean (n = 1)  (min-max) | 46.3  (-) | 9.0  (-) | 80.5  (-) | 10.0  (-) | 78.4  (-) |
| South-East | Mean (n = 3)  (min-max) | 28.2  (15.7-42.5) | 3.6  (2.4-5.5) | 87.1  (84.7-89.5) | 7.6  (3.5-15.0) | 75.1  (64.7-83.2) |
| Mediterranean | Mean (n = 2)  (min-max) | 61.3  (22.5-100.0) | 7.4  (7.0-7.8) | 80.6  (68.9-92.3) | 9.0  (-) | 75.5  (60.0-91.0) |
| **Total ALL** | **Mean (n = 8)**  **(min-max)** | **35.2**  **(5.1-100.0)** | **4.5**  **(0.0-9.0)** | **87.2**  **(68.9-100.0)** | **6.4**  **(0.0-15.0)** | **81.5**  **(60.0-99.5)** |

***Onion Bridging trials:*** *No difference in the efficacy between the two formulations was observed.*

Table ‑: Bridging data, Efficacy, Onion, PERODE (disease intensity and efficacy in %); Summary.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **EPPO**  **Zone** | | **Untreated** | **BAS 743 03 F**  **2.0 L/ha** | | **BAS 743 00 F**  **2.0 l/ha** | |
| **P%INF** | **P%INF** | **Efficacy** | **P%INF** | **Efficacy** |
| Maritime | Mean (n =2)  (min-max) | 24.5  (11.5-37.5) | 7.1  (2.8-11.3) | 73.1  (70.0-76.1) | 10.5  (3.5-17.5) | 61.5  (53.3-69.6) |
| Mediterranean | Mean (n =1)  (min-max) | 19.3  (-) | 4.8  (-) | 75.3  (-) | 3.8  (-) | 80.5  (-) |
| **Total ALL** | **Mean (n =3)**  **(min-max)** | **22.8**  **(11.5-37.5)** | **6.3**  **(2.8-11.3)** | **73.8**  **(70.0-76.1)** | **8.3**  **(3.5-17.5)** | **67.8**  **(53.3-80.5)** |

***Tomato Bridging trials:*** *No difference in the efficacy between the two formulations was observed.*

Table ‑: Bridging data, Efficacy, Tomato, PHYTIN (disease intensity and efficacy in %); Summary.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **EPPO**  **Zone** | | **Untreated** | **BAS 743 03 F**  **2 L/ha** | | **BAS 743 00 F**  **2.0 l/ha** | |
| **P%INF** | **P%INF** | **Efficacy** | **P%INF** | **Efficacy** |
| North-East | Mean (n = 2)  (min-max) | 14.5  (7.5-21.5) | 1.9  (1.2-2.6) | 85.9  (83.7-88.1) | 1.7  (1.2-2.2) | 86.9  (83.7-90.0) |
| Mediterranean | Mean (n = 2)  (min-max) | 95.0  (89.9-100.0) | 9.1  (3.6-14.5) | 90.8  (85.5-96.0) | 16.3  (3.8-28.8) | 83.5  (71.3-95.8) |
| **Total ALL** | **Mean (n = 4)**  **(min-max)** | **54.7**  **(7.5-100.0)** | **5.5**  **(1.2-14.5)** | **88.3**  **(83.7-96.0)** | **9.0**  **(1.2-28.8)** | **85.2**  **(71.3-95.8)** |

Table ‑: Bridging data, Efficacy, Tomato, PHYTIN (disease incidence and efficacy in %); Summary.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **EPPO**  **Zone** | | **Untreated** | **BAS 743 03 F**  **2 L/ha** | | **BAS 743 00 F**  **2.0 l/ha** | |
| **P%FREQ** | **P%FREQ** | **Efficacy** | **P%FREQ** | **Efficacy** |
| North-East | Mean (n = 2)  (min-max) | 53.0   (31.0-75.0) | 22.0   (6.9-37.0) | 64.3  (50.7-77.8) | 20.3  (6.5-34.0) | 66.9  (54.7-79.0) |
| Mediterranean | Mean (n = 2)  (min-max) | 92.0   (-) | 17.5   (-) | 81.0  (-) | 15.5   (-) | 83.2  (-) |
| **Total ALL** | **Mean (n = 4)**  **(min-max)** | **66.0**  **(31.0-92.0)** | **20.5**  **(6.9-37.0)** | **69.8**  **(50.7-81.0)** | **18.7**  **(6.5-34.0)** | **72.3**  **(54.7-83.2)** |

**Summary and conclusions on preliminary tests (KCP 6.1)**

In order to determine the most effective ratio of the active ingredients, 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, being equivalent to 378 g/L of propamocarb, meaning a ratio of ametoctradin: propamocarb of **1:3.15** showed better control of the diseases tested than the alternative tested ratios.

The potato and 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 of ametoctradin : propamocarb provides 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 and show good control of the tested diseases in most of the conducted trials for the three EPPO climatic zones.

|  |
| --- |
| **Conclusion – Preliminary tests**  The applicant provided combined results from field trials on potato (15) and onion (3), directly comparing the effectiveness of the ready mixture BAS 743 03 F to solo active substances. The findings indicated that control achieved from BAS 743 03 F at 2.0 l/ha, providing 240 g of ametoctradin/ha and 902 g of propamocarb-hydrochloride/ha, was higher than that from solo products applied against *Phytophthora infestans* and *Peronospora destructor*. Therefore, 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 tests (KCP 6.2)

BAS 743 03 F comprises of 120 g/L ametoctradin and 451 g/L propamocarb-hydrochloride, and the proposed registration rate against Phytophthora infestans and Peronospora destructor is 2.0 L/ha. Following the EPPO guideline PP 1/225(2) Minimum effective dose, the efficacy of the target dose rate and a lower dose rate (60% of the recommended dose rate) was tested to justify the recommended dose rate as the minimum effective dose under a wide range of agro-environmental conditions.

* Potato; *Phytophthora infestans* (PHYTIN) (KCP 6.2)

In this chapter, data is presented from 21 potato trials, in which BAS 743 03 F at the target dose rate of 2.0 L/ha was compared to the reduced rate of 1.2 L/ha. The applications started preventatively, and BAS 743 03 F was applied season-long (between 3 and 11 applications).

The methodology for these trials is described in introduction section.

Trials were conducted between 2020 and 2021 in the Maritime EPPO climatic zone in Germany (2 trials), the Netherlands (1 trial) and Ireland (4 trials), in the North-East EPPO climatic zone in Poland (5 trials), and in the South-East EPPO climatic zone in Hungary (3 trials) and Romania (6 trials).

In the trials for presentation of the minimum effective dose, the assessment is chosen mostly at the end of the trial to show that the claimed dose rate of BAS 743 03 F (2.0 L/ha) has a higher level of effectiveness than the lower dose rate (1.2 L/ha) or a longer persistence of action.

List of individual trials for the evaluation of MED is presented in Table 3.2‑23 below.

Table ‑: MED, List of individual potato trials.

| **EPPO**  **Zone** | **Trial ID** | **GEP** | **Year** | **Country** | **Variety** |
| --- | --- | --- | --- | --- | --- |
| Maritime  (7 trials) | Trial No.1\* | YES | 2020 | DE | BINTJE |
| Trial No.2\*\* | YES | 2021 | DE | BINTJE |
| Trial No.3\* | YES | 2020 | NL | BINTJE |
| Trial No.4\*\* | YES | 2021 | IE | ROOSTER |
| Trial No.5\*\* | YES | 2021 | IE | MARIS PIPER |
| Trial No.6\* | YES | 2020 | IE | ROOSTER |
| Trial No.7\* | YES | 2020 | IE | MARIS PIPER |
| North-East  (5 trials) | Trial No.1\* | YES | 2020 | PL | IRGA |
| Trial No.2\* | YES | 2020 | PL | SATINA |
| Trial No.3\*\* | YES | 2021 | PL | ALBATROS |
| Trial No.4\*\* | YES | 2021 | PL | ZUZANNA |
| Trial No.5\*\* | YES | 2021 | PL | GALA |
| South-East  (9 trials) | Trial No.1\* | YES | 2020 | HU | ESZME |
| Trial No.2\* | YES | 2020 | RO | BELLAROSA |
| Trial No.3\* | YES | 2020 | RO | SORAYA |
| Trial No.4\* | YES | 2020 | RO | SANTE |
| Trial No.5\* | YES | 2021 | HU | ARIZONA |
| Trial No.6\*\* | YES | 2021 | RO | ESMEE |
| Trial No.7\* | YES | 2021 | RO | ACTRICE |
| Trial No.8\* | YES | 2021 | RO | RED SCARLET |
| Trial No.9\*\* | YES | 2021 | RO | BELLAROSA |

* *BAS 743 AT F formulation*

*\*\* BAS 743 00 F formulation*

Table 3.2‑24 represents the application summary for MED trials.

Summary results are listed in Table 3.2‑25.

Table ‑: MED, Application summary - Potato trials.

|  |  |  |  |
| --- | --- | --- | --- |
| **EPPO**  **Zone** | **Application details Summary** | | |
| **BBCH**  **at appl.** | **Water volume**  **at appl.** | **Total number**  **of appl.** |
|
| Maritime | 69-92 | 200-400 | 3-11 |
| North-East | 45-81 | 250-400 | 3-5 |
| South-East | 50-89 | 250-500 | 3-6 |

*MED, Disease severity on leaves/total plants*

Higher performance of the full dose rate (2.0 L/ha) in comparison to the reduced dose rate was observed in majority of the trials. In one trial, a slight, numerical but statistically not significant reverse dose response was observed.

Overall, the full dose rate of 2.0 L/ha provided superior levels of control for longer and more consistent control of *Phytophthora infestans* in all EPPO climatic zones 73.0% (full dose) vs 59.7% (lower dose). For the Maritime zone, the results show +18.1 % on average compared to the lower dose rate. The results for the North-east zone, +5.8%, and for the South-east zone, the results show +13.7% on average compared to the lower dose rate.

Table ‑: MED, Potato, PHYTIN (disease severity and efficacy in %); Summary.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **EPPO**  **Zone** | | **Untreated** | **BAS 743 03 F**  **2 L/ha** | | **BAS 743 03 F**  **1.2 L/ha** | |
|
| **P%INF** | **P%INF** | **Efficacy** | **P%INF** | **Efficacy** |
| Maritime | Mean (n = 7)  (min-max) | 95.9  (75.0-100.0) | 38.7  (6.0-55.0) | 58.8  (32.3-93.8) | 56.6  (9.8-82.5) | 40.7  (16.7-90) |
| North-East | Mean (n = 5)  (min-max) | 66.0  (12.5-100.0) | 12.6  (1.3-52.1) | 83.6  (48.0-97.7) | 16.2  (2.3-65.2) | 77.8  (34.8-95.8) |
| South-East | Mean (n = 9)  (min-max) | 49.3  (9.3-96.3) | 12.0  (1.0-31.3) | 78.2  (41.9-98.5) | 17.8  (1.3-36.3) | 64.5  (32.6-86.1) |
| **Total ALL** | **Mean (n = 21)**  **(min-max)** | **68.8**  **(9.3-100.0)** | **21.1**  **(1.0-55.0)** | **73.0**  **(32.3-98.5)** | **30.3**  **(1.3-83.8)** | **59.7**  **(16.3-95.8)** |

*Conclusion minimum effective dose potato, PHYTIN*

According to the presented results, the dose of 2.0 L/ha of BAS 743 03 F provided the optimum overall control and should be considered as effective against *Phytophthora infestans*, for which activity of BAS 743 03 F is claimed. The proposed rate of 2.0 L/ha should be considered the minimum effective dose to deliver optimum control of *Phytophthora infestans* under a wide range of environmental conditions.

* ****Onion****; *Peronospora destructor* (PERODE) (KCP 6.2)

In this chapter, data is presented from 12 onion trials, in which BAS 743 03 F at the target dose rate of 2.0 L/ha was compared to the reduced rate of 1.2 L/ha. The applications started preventatively, and BAS 743 03 F was applied season-long (between 4 and 11 applications).

Data supporting the minimum effective dose of the plant protection product are derived from the same trials and assessments used to determine the efficacy of the target dose rate. Therefore, the evaluations presented in this chapter represent the same infection thresholds in the untreated plots as the assessments in the efficacy chapter.

The methodology for these trials is described in introduction section.

Trials were conducted between 2020 and 2021 in the Maritime EPPO climatic zone in Germany (3 trials), the Netherlands (3 trials), and in the North-East EPPO climatic zone in Poland (6 trials).

In the efficacy chapter, two timing are chosen to evaluate the efficacy of BAS 743 03 F

* The first timing / application was taken when the level of the disease started to rise in the untreated.
* The second timing / application followed normal application timings, depending on the disease pressure, as would be standard agricultural practice.

In the trials evaluating the minimum effective dose in onions, the second timing/ application is presented to show that the claimed dose rate of BAS 743 03 F (2.0 L/ha) has a higher level of effectiveness than the lower dose rate (1.2 L/ha).

List of individual trials used for the evaluation of MED is presented in Table 3.2‑26 below.

Table ‑: MED, List of individual onion trials.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **EPPO**  **Zone** | **Trial ID** | **GEP** | **Year** | **Country** | **Variety** |
| Maritime  (6 trials) | Trial No.1\* | YES | 2020 | DE | TONDA MUSONA |
| Trial No.2\* | YES | 2020 | DE | TONDA MUSONA |
| Trial No.3\* | YES | 2020 | NL | DORMO |
| Trial No.4\* | YES | 2020 | NL | HOZA |
| Trial No.5\*\* | YES | 2021 | DE | HOZA |
| Trial No.6\*\* | YES | 2021 | NL | HOZA |
| North-East  (6 trials) | Trial No.1\* | YES | 2020 | PL | CENTRO |
| Trial No.2\* | YES | 2020 | PL | MAJKA |
| Trial No.3\*\* | YES | 2020 | PL | SOCHACZEWSKA |
| Trial No.4\*\* | YES | 2021 | PL | FASTO |
| Trial No.5\*\* | YES | 2021 | PL | SUPRA |
| Trial No.6\*\* | YES | 2021 | PL | OLOROSA MIESZAN |

* *BAS 743 AT F formulation*

*\*\* BAS 743 00 F formulation*

Table 3.2‑26 represents the application summary for MED trials.

Summary results are listed in Table 3.2‑27.

Table ‑: MED, Application summary – Onion trials.

|  |  |  |  |
| --- | --- | --- | --- |
| **EPPO**  **Zone** | **Application details Summary** | | |
| **BBCH**  **at appl.** | **Water volume**  **at appl.** | **Total number**  **of appl.** |
| Maritime | 15-47 | 300-400 | 5-11 |
| North-East | 18-45 | 400-700 | 4-9 |

*MED, Disease severity on leaves/total plants*

The mean values of intensity of attack (= severity) on untreated leaves were 10.4% in the Maritime EPPO climatic zone and 11.8% in the North-East EPPO climatic zone. The application of the full dose rate resulted in an increase of the disease control on leaves by +10.1% in the Maritime EPPO climatic zone and by +12% in the North-East EPPO climatic zone, compared to the reduced dose rate.

In 11 out of 12 trials, the product rate of 2.0 L/ha achieved a superior fungicidal efficacy compared to the rate of 1.2 L/ha. In one trial, a slight, but statistically not significant numerical reverse dose response was observed.

Overall, higher performance of the full dose rate (2.0 L/ha) in comparison to the reduced dose rate was observed in majority of the trials. The full dose rate resulted in a total mean level of disease control of 72.7% versus 61.7% achieved by the reduced dose rate.

Table ‑: MED, Onion, PERODE (disease severity and efficacy in %); Summary.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **EPPO**  **Zone** | | **Untreated** | **BAS 743 03 F**  **2.0 L/ha** | | **BAS 743 03 F**  **1.2 L/ha** | |
| **P%INF** | **P%INF** | **Efficacy** | **P%INF** | **Efficacy** |
| Maritime | Mean (n =6)  (min-max) | 10.4  (1.5-25.0) | 4.4  (0.0-11.3) | 64.7  (50.0-100.0) | 7.3  (2.4-11.5) | 54.6  (37.0-75.4) |
| North-East | Mean (n = 6)  (min-max) | 11.8  (4.0-40.8) | 2.8  (0.3-13.0) | 80.8  (50.0-96.3) | 5.2  (0.3-27.4) | 68.8  (32.9-87.2) |
| **Total ALL** | **Mean (n = 12)**  **(min-max)** | **11.1**  **(1.5-40.8)** | **3.6**  **(0.0-13.0)** | **72.7**  **(50.0-100.0)** | **6.2**  **(0.3-27.4)** | **61.7**  **(32.9-87.2)** |

*Conclusion minimum effective dose onion, PERODE*

According to the presented results, the dose of 2.0 L/ha of BAS 743 03 F provided the optimum overall control and should be considered as effective against *Peronospora destructor*, for which activity of BAS 743 03 F is claimed. The proposed rate of 2.0 L/ha should be considered the minimum effective dose to deliver optimum control of *Peronospora destructor* under a wide range of environmental conditions.

* Tomato; *Phytophthora infestans* (PHYTIN) (KCP 6.2)

In this chapter, data is presented from 3 tomato trials, in which BAS 743 03 F at the target dose rate of 2.0 L/ha was compared to the reduced rate of 1.2 L/ha. The applications started preventatively, and BAS 743 03 F was applied season-long (between 4 and 6 applications).

Data supporting the minimum effective dose of the plant protection product are derived from the same trials and assessments used to determine the efficacy of the target dose rate. Therefore, the evaluations presented in this chapter represent the same infection thresholds in the untreated plots as the assessments in the efficacy chapter.

The methodology for these trials is described in introduction section 3.2.0.7.

Trials were conducted between 2020 and 2021 in the North-East EPPO climatic zone in Poland (3 trials).

To show that the claimed dose rate of BAS 743 03 F (2.0 L/ha) has a higher level of effectiveness and/or a longer persistence of action than the lower dose rate (1.2 L/ha), the assessments were chosen at the end of the trial.

List of individual trials used for the evaluation of MED is presented in Table 3.2‑29 below.

Table ‑: MED, List of individual tomato trials.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **EPPO**  **Zone** | **Trial ID** | **GEP** | **Year** | **Country** | **Variety** |
| North-East  (3 trials) | Trial No.1\* | YES | 2020 | PL | SCOOTER |
| Trial No.2\* | YES | 2020 | PL | RUMBA O¿AROWSKA |
| Trial No.3\* | YES | 2021 | PL | NUN00507 |

* *BAS 743 AT F formulation*

Table 3.2‑29 represents the application summary for MED trials.

Summary results are listed in Table 3.2‑30.

Table 3.2-0: MED, Application summary – Tomato trials.

|  |  |  |  |
| --- | --- | --- | --- |
| **EPPO**  **Zone** | **Application details Summary** | | |
| **BBCH**  **at appl.** | **Water volume**  **at appl.** | **Total number**  **of appl.** |
| North-East | 75-81 | 600-700 | 4-6 |

*MED, Disease severity on leaves/total plants*

The mean values of intensity of attack (= severity) on untreated leaves were 72.8% in the North-East EPPO climatic zone. The application of the full dose rate resulted in an increase of the disease control on leaves by +5.8%, compared to the reduced dose rate. Data demonstrate that the product target dose rate of 2.0 L/ha achieved a superior fungicidal efficacy compared to the reduced dose rate of 1.2 L/ha.

Overall, higher performance of the full dose rate (2.0 L/ha) in comparison to the reduced dose rate was observed in all trials. The full dose rate resulted in a total mean level of disease control of 90.3% versus 84.5% achieved by the reduced dose rate.

Table ‑: MED, Tomato, PHYTIN (disease severity on leaves/total plants and efficacy in %); Summary.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **EPPO**  **Zone** | | **Untreated** | **BAS 743 03 F**  **2 L/ha** | | **BAS 743 03 F**  **1.2 L/ha** | |
| **P%INF** | **P%INF** | **Efficacy** | **P%INF** | **Efficacy** |
| **North-East** | **Mean (n = 3)**  **(min-max)** | **72.8**  **(21.6-100.0)** | **6.5**  **(2.6-9.0)** | **90.3**  **(88.1-92.2)** | **10.9**  **(3.7-18.3)** | **84.5**  **(81.7-89.1)** |

*Conclusion minimum effective dose tomato, PHYTIN*

According to the presented results, the dose of 2.0 L/ha of BAS 743 03 F provided the optimum overall control and should be considered as effective against *Phytophthora infestans*, for which activity of BAS 743 03 F is claimed. The proposed rate of 2.0 L/ha should be considered the minimum effective dose to deliver optimum control of *Phytophthora infestans* under a wide range of environmental conditions.

Summary and conclusions on the minimum effective dose (KCP 6.2)

The dose response for BAS 743 03 F has been demonstrated with altogether 36 trials conducted in the target crops in which the performances of the target dose rate (2.0 L/ha) and a lower dose rate (1.2 L/ha = 60% of the target) were compared.

In summary, according to the presented results, BAS 743 03 F at the target dose rates per individual crop provided the optimum and most consistent control of the targeted 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.

|  |
| --- |
| **Conclusion – Minimum effective dose**  The presented data correspond with the requirements of the EPPO Standard PP 1/225.  For the evaluation of the minimum effective dose against *Peronospora destructor and Phytophthora infestans* 36 field trials were presented by the applicant in the years 2020 and 2021. Trials were conducted in EPPO zones maritime, northeast and southeast.  *Phytophthora infestans* on potatoes  A total 21 trials on potato were provided, in which BAS 743 03 F at the target dose rate of 2.0 L/ha was compared to the reduced rate of 1.2 L/ha. The applications started preventatively, and BAS 743 03 F was applied season-long (between 3 and 11 applications). The applicant showed a decrease of efficacy as a result of dose reduction by 60%. The dose reduction from 2 L/ha to 1.2 L/ha caused a decrease of disease control by 18.1% in the maritime zone (n=7), 5.8% in the north-eastern zone (n= 5) and 13.7% in the south-eastern zone (n=9). The justification for the proposed dose of 2 L/ha is accepted.  *Peronospora destructor* ononion  A total 12 trials on onion were provided, in which BAS 743 03 F at the target dose rate of 2.0 L/ha was compared to the reduced rate of 1.2 L/ha. The applications started preventatively, and BAS 743 03 F was applied season-long (between 4 and 11 applications). The applicant showed a decrease of efficacy as a result of dose reduction by 60%. The dose reduction from 2 L/ha to 1.2 L/ha caused a decrease of disease control by 10.1% in the maritime zone (n=6) and 12% in the north-eastern zone (n= 6). No data were provided from south-eastern zone. The justification for the proposed dose of 2 L/ha is accepted.  *Phytophthora infestans* on tomatoes  A total of 3 trials on onion were provided from the North-East EPPO climatic zone, in which BAS 743 03 F at the target dose rate of 2.0 L/ha was compared to the reduced rate of 1.2 L/ha. The applications started preventatively, and BAS 743 03 F was applied season-long (between 4 and 6 applications). Overall, a better efficacy is achieved with the application rate of 2 L/ha than with 1.2 L/ha. The proposed dose rate of 2 L/ha can be considered as the minimum effective dose for control *Phytophthora infestans* on tomatoes. No data were provided from maritime and south-eastern zone. |

### Efficacy tests (KCP 6.2)

* Potato, *Phytophthora infestans* (PHYTIN) (KCP 6.2)

A total of 35 field trials were carried out to evaluate the efficacy of the product for the control *Phytophthora infestans* (PHYTIN) in potatoes***.***

BAS 743 03 F was applied in season-long efficacy trials following the GAP. BAS 743 03 F was tested at the claimed dose rate of 2.0 L/ha. Total number of applications was between 2-12.

All presented trials were conducted between 2020 and 2022 in the Maritime EPPO climatic zone in Germany (7 trials), the Netherlands (3 trials), Ireland (4 trials), in the North-East EPPO climatic zone in Poland (9 trials), and in the South-East EPPO climatic zone in Hungary (4 trials) and in Romania (8 trials).

The distribution of the trials per country, year and EPPO climatic zone is provided in Table 3.2‑31.

The reference product Revus (BAS 9412 0 F) at 0.6 L/ha is presented in all efficacy trials.

The GAP has 2 applications in total requested for potato. In order to minimise interference from other chemistry the season-long disease control was done only using BAS 743 03 F and compared to the standard.

To give data for the 2 applications on the GAP the following method was used:

* The first timing / application was taken when the level of disease started to rise in the untreated.
* The second timing / application followed normal application timings depending on the disease pressure as would be normal agricultural practice.

List of individual trials are presented in Table 3.2‑32.

Table 3.2‑33 represents the application summary for potato efficacy trials.

A summary of the results is available in Table 3.2‑34 and Table 3.2‑35.

Table ‑: Distribution of trials by location and year – Potato trials.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Crop** | **EPPO**  **Zone** | **Country** | **Year** | | | **TOTAL**  **per row** |
| **2020** | **2021** | **2022** |
| Potato  (SOLTU) | Maritime | Germany | 1 | 5 | 1 | 7 |
| Netherlands | 1 | 1 | 1 | 3 |
| Ireland | 2 | 2 | - | 4 |
| **Total Maritime zone** | | **4** | **8** | **2** | **14** |
| North-East | Poland | 4 | 4 | 1 | 9 |
| **Total North-East zone** | | **4** | **4** | **1** | **9** |
| South-East | Hungary | 2 | 1 | 1 | 4 |
| Romania | 3 | 3 | 2 | 8 |
| **Total South-East zone** | | **5** | **4** | **3** | **12** |
| **Total** | | | **13** | **16** | **6** | **35** |

Table ‑: Efficacy, List of individual potato trials.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **EPPO**  **Zone** | **Trial ID** | **GEP** | **Year** | **Country** | **Variety** | **Yield** | **Sieve**  **size** | **Yield**  **of**  **Starch** |
| Maritime  (14 trials) | Trial No.1\* | YES | 2020 | DE | BINTJE | YES | YES | - |
| Trial No.2\* | YES | 2020 | NL | BINTJE | YES | YES | - |
| Trial No.3\*\* | YES | 2021 | DE | FONTANE | YES | YES | - |
| Trial No.4\*\* | YES | 2021 | DE | BINTJE | - | - | - |
| Trial No.5\*\* | YES | 2021 | DE | BINTJE | - | - | - |
| Trial No.6\*\* | YES | 2021 | DE | BINTJE | - | - | - |
| Trial No.7\*\* | YES | 2021 | DE | BINTJE | - | - | - |
| Trial No.8\*\* | YES | 2021 | NL | BINTJE | YES | YES | - |
| Trial No.9\*\* | YES | 2022 | DE | BINTJE | - | - | - |
| Trial No.10\*\* | YES | 2022 | NL | BINTJE | YES | YES | - |
| Trial No.11\*\* | YES | 2021 | IE | ROOSTER | YES | YES | - |
| Trial No.12\*\* | YES | 2021 | IE | MARIS PIPER | YES | YES | - |
| Trial No.13\* | YES | 2020 | IE | ROOSTER | YES | YES | - |
| Trial No.14\* | YES | 2020 | IE | MARIS PIPER | YES | YES | - |
| North-East  (9 trials) | Trial No.1\* | YES | 2020 | PL | IRGA | YES | YES | YES |
| Trial No.2\* | YES | 2020 | PL | SATINA | YES | YES | - |
| Trial No.3\* | YES | 2020 | PL | ALBATROS | YES | - | YES |
| Trial No.4\* | YES | 2020 | PL | TAJFUN | YES | YES | - |
| Trial No.5\*\* | YES | 2021 | PL | ALBATROS | YES | - | YES |
| Trial No.6\*\* | YES | 2021 | PL | ZUZANNA | YES | YES | YES |
| Trial No.7\*\* | YES | 2021 | PL | GALA | YES | YES | - |
| Trial No.8\*\* | YES | 2021 | PL | LILY | YES | YES | YES |
| Trial No.9\*\* | YES | 2022 | PL | TAJFUN | YES | YES | - |
| South-East  (12 trials) | Trial No.1\* | YES | 2020 | HU | ESZME | YES | YES | YES |
| Trial No.2\* | YES | 2020 | HU | BELLAROSA | YES | YES | - |
| Trial No.3\* | YES | 2020 | RO | SORAYA | YES | YES | YES |
| Trial No.4\* | YES | 2020 | RO | SANTE | YES | YES | - |
| Trial No.5\* | YES | 2020 | RO | ARIZONA | YES | YES | - |
| Trial No.6\*\* | YES | 2021 | HU | ESMEE | YES | YES | - |
| Trial No.7\*\* | YES | 2021 | RO | ACTRICE | YES | YES | - |
| Trial No.8\*\* | YES | 2021 | RO | RED SCARLET | YES | YES | - |
| Trial No.9\*\* | YES | 2021 | RO | BELLAROSA | YES | YES | YES |
| Trial No.10\*\* | YES | 2022 | HU | BALATONI RÓZSA | YES | YES | - |
| Trial No.11\*\* | YES | 2022 | RO | BELAROSA | YES | YES | - |
| Trial No.12\*\* | YES | 2022 | RO | CARERA | YES | YES | - |

* *BAS 743 AT F formulation*

*\*\* BAS 743 00 F formulation*

Table ‑: Efficacy, Application summary – Potato trials.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **EPPO**  **Zone** | | **Application details Summary** | | |
| **BBCH**  **at appl.** | **Water vol.**  **at appl.** | **Tot number**  **of appl.** |
|
| Maritime | Timing 1  Timing 2 | 17-65  37-79 | 200-400  200-400 | 4-12  4-12 |
| North-East | Timing 1  Timing 2 | 41-71  43-85 | 250-400  250-400 | 3-5  3-5 |
| South-East | Timing 1  Timing 2 | 22-80  45-89 | 250-500  250-500 | 2-6  2-6 |

The mean values of intensity of attack (= severity) on untreated leaves/total plants at ***the application timing 1*** were 11.1% in the Maritime EPPO climatic zone, 13.8% in the North-East EPPO climatic zone and 10.9% in the South-East EPPO climatic zone.

Two trials conducted in the Maritime EPPO climatic zone and one in the South-East EPPO climatic zone showed lower efficacy (below 70%) for both, the tested product and the standard, when compared to the rest of the trials of this zone. Although the reasons for this cannot be fully explained, it was noted that extreme weather and soil conditions were observed during the trial season for these trials.

Taken together, applying the intended dose rate resulted in total mean product efficacy of 89.1% in all EPPO climatic zones together. Data also demonstrated that the overall efficacy of the BAS 743 03 F product at the proposed rate of 2.0 L/ha was equivalent to the efficacy of the standard (89.1% versus 83.6%).

Table ‑: Efficacy, Application Timing 1, Potato, PHYTIN (disease severity and efficacy in %); Summary.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **EPPO**  **Zone** | | **Untreated** | **BAS 743 03 F**  **2.0 L/ha** | | **Revus**  **BAS 9412 0 F**  **0.6 l/ha** | |
| **P%INF** | **P%INF** | **Efficacy** | **P%INF** | **Efficacy** |
| Maritime | Mean (n = 14)  (min-max) | 11.1  (0.8-46.3) | 1.6  (0.0-7.3) | 90.2  (57.4-100.0) | 1.4  (0.0-5.8) | 83.7  (0.0-100) |
| North-East | Mean (n = 9)  (min-max) | 13.8  (1.0-75.0) | 1.3  (0.0-7.3) | 92.5  (73.8-100.0) | 1.1  (0.0-5.8) | 93.5  (75.02-100.0) |
| South-East | Mean (n = 12)  (min-max) | 10.9  (0.0-29.9) | 1.8  (0.0-6.0) | 85.3  (67.4-100.0) | 3.0  (0.0-14.1) | 76.1  (39.0-100.0) |
| **Total ALL** | **Mean (n = 35)**  **(min-max)** | **11.7**  **(0.0-75.0)** | **1.6**  **(0.0-7.3)** | **89.1**  **(57.4-100.0)** | **1.9**  **(0.0-14.1)** | **83.6**  **(0.0-100.0)** |

The mean values of intensity of attack (= severity) on untreated leaves/total plants at ***the application timing 2*** were 53.3% in the Maritime EPPO climatic zone, 32.0% in the North-East EPPO climatic zone and 28.1% in the South-East EPPO climatic zone.

One trial conducted in the Maritime EPPO climatic zone (DEV-F-2021-NL-P02-A-02.0-NL-NL4-406), showed lower efficacy when compared to the standard. In the South-East EPPO climatic zone, two trials (DEV-F-2020-RO-P01-A-01.0-RO-SGS-001 and DEV-F-2022-HU-P01-A-01.0-HU-HU0-KUK) showed lower efficacy levels for both the tested product and the standard. Although the reasons for this variability cannot be fully explained, it was noted that extreme weather was observed during the trial season for these trials.

Applying the intended dose rate resulted in total mean product efficacy of 86.3% in all EPPO climatic zones together. Data also demonstrated that the overall efficacy of the BAS 743 03 F product at the proposed rate of 2.0 L/ha was equivalent to the efficacy of the standard (86.3% versus 84.2%).

Table ‑: Efficacy, Application Timing 2, Potato, PHYTIN (disease severity and efficacy in %); Summary.

| **EPPO**  **Zone** | | **Untreated** | **BAS 743 03 F**  **2.0 L/ha** | | | **Revus**  **BAS 9412 0 F**  **0.6 l/ha** |
| --- | --- | --- | --- | --- | --- | --- |
| **P%INF** | **P%INF** | **Efficacy** | **P%INF** | **Efficacy** |
| Maritime | Mean (n = 14)  (min-max) | 53.3  (5.1-93.3) | 5.0  (0.0-29.0) | 91.5  (58.3-100.0) | 2.9  (0.0-12.4) | 94.9  (23.3-100.0) |
| North-East | Mean (n = 9)  (min-max) | 32.0  (5.6-85.0) | 3.3  (0.3-10.0) | 89.2  (78.4-97.8) | 4.0  (0.4-12.3) | 86.9  (85.1-.96.9) |
| South-East | Mean (n = 12)  (min-max) | 28.1  (3.4-53.8) | 7.6  (0.0-31.3) | 78.1  (41.9-100.0) | 10.1  (0.0-32.5) | 69.7  (39.5-100.0) |
| **Total ALL** | **Mean (n = 35)**  **(min-max)** | **39.2**  **(3.4-93.3)** | **5.4**  **(0.0-31.3)** | **86.3**  **(41.9-100.0)** | **5.6**  **(0.0-32.5)** | **84.2**  **(23.3-100.0)** |

*Conclusion efficacy potato, PHYTIN*

Data demonstrate that the efficacy of BAS 743 03 F product at the proposed dose rate of 2.0 L/ha gives high levels of control of *Phytophthora infestans* in potatoes.

After one application (**Timing 1**) as disease levels start to rise (11.7 % mean), control from BAS 743 03 F was 89.1% (57.4-100.0%) compared to the standard of 83.6% (0.0-100.0%).

After two applications (T**iming 2**) with average disease levels at 39.2 % in the untreated, BAS 743 03 F was still giving 86.3% (41.9-100%) control compared to the standard of 84.2% (23.3-100.0%).

At the proposed usage of two applications, it can be clearly demonstrated that BAS 743 03 F is effective at controlling *Phytophthora infestans*.

The registration of BAS 743 03 F against *Phytophthora infestans* is sought formajor uses in potatoes in all concerned member states*,* except Slovakia, in the Central Registration Zone*.* A total of 35 field trials from the Maritime (14 trials), the North-East (9 trials) and the South-East (12 trials) EPPO climatic zone were carried out to evaluate the efficacy of this product. Therefore, the provided data set is considered sufficient to justify the use of BAS 743 03 F against *Phytophthora infestans* in potatoes in all EPPO climatic zones.

|  |
| --- |
| **Conclusion to *Phytophthora infestans* on potato.**  Maritime zone  The presented data correspond with the requirements of the EPPO Standards PP 1/214, PP 1/223, PP 1/226 and PP 1/ 2 (5).  The severity of *Phytophthora infestans* infection was assessed in 14 efficacy trials with a two application of BAS 743 03 F. After one application (Timing 1) BAS 743 03 F gave good control of *Phytophthora infestans* with an average 90.2% with infection in the untreated ranging from 0.8 to 46.3 % (~11.1%). The efficacy of the product varied from 57.4 to 100%. Standard products performed in average on slightly lower level with an average 83.7%. Following two applications (Timing 2), with average disease levels at 53.3% in the untreated, BAS 743 03 F showed very high efficacy in control 91.5% (ranging from 58.3% to 100.0%), compared to the standard control of 94.9% (ranging from 23.3% to 100.0%).  Northeast zone  The presented data correspond with the requirements of the EPPO Standards PP 1/214, PP 1/223, PP 1/226 and PP 1/ 2 (5).  The severity of *Phytophthora infestans* infection was assessed in 9 efficacy trials with a two application of BAS 743 03 F. After one application (Timing 1) BAS 743 03 F gave good control of *Phytophthora infestans* with an average 92.5% with infection in the untreated ranging from 1.0 to 75.0 % (~13.8%). The efficacy of the product varied from 73.8 to 100%. Standard products performed in average on slightly higher level with an average 93.5%. Following two applications (Timing 2), with average disease levels at 32.0% in the untreated, BAS 743 03 F showed very high efficacy in control 89.2% (ranging from 78.4% to 97.8%), compared to the standard control of 86.9% (ranging from 85.1% to 96.9).  The applicant proposed an application window of BBCH 21–89. However, trials conducted in the northeast zone only covered applications starting from BBCH 41. In this case, the proposed application window can be accepted based on supporting trials conducted in the maritime EPPO zone (Germany). These trials demonstrated high efficacy BAS 743 03 F against Phytophthora infestans with product application beginning at BBCH 17, providing sufficient evidence to support the proposed application window (Table 3.2‑34 -35).  Southeast zone  The presented data correspond with the requirements of the EPPO Standards PP 1/214, PP 1/223, PP 1/226 and PP 1/ 2 (5).  The severity of *Phytophthora infestans* infection was assessed in 12 efficacy trials with a two application of BAS 743 03 F. After one application (Timing 1) BAS 743 03 F gave good control of *Phytophthora infestans* with an average 85.3% with infection in the untreated ranging from 0.0 to 29.9 % (~10.9%). The efficacy of the product varied from 67.4 to 100%. Standard products performed in average on slightly lower level with an average 76.1%. Following two applications (Timing 2), with average disease levels at 28.1% in the untreated, BAS 743 03 F showed very high efficacy in control 78.1% (ranging from 41.9% to 100%), compared to the standard control of 69.7% (ranging from 39.5% to 100). |

* **Onion, *Peronospora destructor* (PERODE) (KCP 6.2)**

A total of 14 trials were carried out to evaluate the efficacy of BAS 743 03 F for the control of *Peronospora destructor* (PERODE) in onions.

BAS 743 03 F was applied in season-long efficacy trials following the GAP. BAS 743 03 F was tested at the claimed dose rate of 2.0 L/ha. Total number of applications was between 4-11.

All presented trials have been conducted between 2020 and 2022 in the Maritime EPPO climatic zone in Germany (4 trials), the Netherlands (4 trials), and in the North-East EPPO climatic zone in Poland (6 trials).

The distribution of the trials per country, year and EPPO zone is provided in Table 3.2‑36.

The reference product Ortiva (BAS 9164 4 F) at 1.0 L/ha dose rate is presented in all efficacy trials.

For Belgium, Ireland, Poland, the Netherlands, Poland and France the maximum number of applications per crop /season is 2, and for Austria, Czech Republic, Germany the maximum intended number of applications is 1. To give data for the 2 applications on the GAP the following method was used:

* The first timing / application was taken when the level of disease started to rise in the untreated.
* The second timing / application followed normal application timings depending on the disease pressure as would be normal agricultural practice

List of individual trials are presented in Table 3.2‑37.

Table 3.2‑38 represents the application summary for onion efficacy trials.

A summary of results is available in Table 3.2‑39 – Timing 1 and Table 3.2‑40 – Timing 2.

Table ‑: Distribution of trials by location and year – Onion trials.

| **Crop** | **EPPO**  **Zone** | **Country** | **Year** | | | **TOTAL**  **per row** |
| --- | --- | --- | --- | --- | --- | --- |
| **2020** | **2021** | **2022** |
| Onion  (ALLCE) | Maritime | DE | 2 | 1 | 1 | **4** |
| NL | 2 | 1 | 1 | **4** |
| **Total Maritime zone** | | **4** | **2** | **2** | **8** |
| North-East | PL | 2 | 4 | **-** | 6 |
|  | **Total North-East zone** | | **2** | **4** | **-** | **6** |
| **TOTAL** | | | **6** | **6** | **2** | **14** |

Table ‑: Efficacy, List of individual onion trials.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **EPPO**  **Zone** | **Trial ID** | **GEP** | **Year** | **Country** | **Variety** | **Yield** | **Sieve**  **size** |
| Maritime  (8 trials) | Trial No.1\* | YES | 2020 | DE | TONDA MUSONA | - | - |
| Trial No.2\* | YES | 2020 | DE | TONDA MUSONA | - | - |
| Trial No.3\* | YES | 2020 | NL | DORMO | - | - |
| Trial No.4\* | YES | 2020 | NL | HOZA | YES | YES |
| Trial No.5\*\* | YES | 2021 | DE | HOZA | - | - |
| Trial No.6\*\* | YES | 2021 | NL | HOZA | YES | YES |
| Trial No.7\*\*\* | YES | 2022 | DE | TONDA MUSONA | - | - |
| Trial No.8\*\*\* | YES | 2022 | NL | HOZA | - | - |
| North-East  (6 trials) | Trial No.1\* | YES | 2020 | PL | CENTRO | YES | - |
| Trial No.2\* | YES | 2020 | PL | MAJKA | YES | - |
| Trial No.3\*\* | YES | 2020 | PL | SOCHACZEWSKA | YES | - |
| Trial No.4\*\* | YES | 2021 | PL | FASTO | YES | - |
| Trial No.5\*\* | YES | 2021 | PL | SUPRA | YES | - |
| Trial No.6\*\* | YES | 2021 | PL | OLOROSA MIESZAN | YES | - |

* *BAS 743 AT F formulation*

*\*\* BAS 743 00 F formulation*

*\*\*\* BAS 743 03 F formulation*

Table ‑: Efficacy, Application summary – Onion trials.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **EPPO**  **Zone** | | **Application details Summary** | | |
| **BBCH**  **at appl.** | **Water volume**  **at appl.** | **Total number**  **of appl.** |
| Maritime | Timing 1 | 15-47 | 300-400 | 5-11 |
| Timing 2 | 18-47 | 300-400 | 5-11 |
| North-East | Timing 1 | 41-43 | 400-700 | 4-9 |
| Timing 2 | 18-45 | 400-700 | 4-9 |

*Disease severity on leaves/total plants*

After first application (**Timing 1**) as disease levels start to rise, the mean values of intensity of attack (= severity) on untreated leaves/total plants was 7.8% in the Maritime EPPO climatic zone, and 2.9% in the North-East EPPO climatic zone. The application of the intended dose rate resulted in total mean product efficacy of 74.4 % across both EPPO climatic zones.

Data also demonstrated that the overall efficacy of the BAS 743 03 F product at the proposed rate of 2.0 L/ha was equivalent to the efficacy of the standard (74.4% versus 73.7%).

Table ‑: Efficacy, Onion, PERODE, (disease severity and efficacy in %); Summary - Timing 1.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **EPPO**  **Zone** | | **Untreated** | **BAS 743 03 F**  **2.0 L/ha** | | **Ortiva**  **BAS 9164 4 F**  **1.0 L/ha** | |
| **P%INF** | **P%INF** | **Efficacy** | **P%INF** | **Efficacy** |
| Maritime | Mean (n =8)  (min-max) | 7.8  (1.5-25.0) | 2.9  (0.0-8.8) | 68.3  (46.8-100.0) | 2.7  (0.0-8.8) | 72.0  (44.4-100.0) |
| North-East | Mean (n = 6)  (min-max) | 2.9  (1.6-4.0) | 0.6  (0.0-1.9) | 82.6  (50.9-100.0) | 0.9  (0.0-3.1) | 76.0  (11.3-100.0) |
| **Total ALL** | **Mean (n = 14)**  **(min-max)** | **5.7**  **(1.6-25.0)** | **1.9**  **(0.0-8.8)** | **74.4**  **(46.8-100.0)** | **1.9**  **(0.0-8.8)** | **73.7**  **(11.3-100.0)** |

After second application (**Timing 2**), the mean values of intensity of attack (= severity) on leaves/total plants in untreated was 19.0% for the Maritime EPPO climatic zone, and 11.8% for the North-East EPPO climatic zone. The application of the intended dose rate resulted in total mean product efficacy on leaves of 71.1 % across both EPPO climatic zones.

Data also demonstrated that the overall efficacy of the BAS 743 03 F product at the proposed rate of 2.0 L/ha was equivalent to the efficacy of the standard (71.1% versus 68.7%).

Table ‑: Efficacy, Onion, PERODE, (disease severity and efficacy in %); Summary - Timing 2.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **EPPO**  **Zone** | | **Untreated** | **BAS 743 03 F**  **2.0 L/ha** | | **Ortiva**  **BAS 9164 4 F**  **1.0 L/ha** | |
| **P%INF** | **P%INF** | **Efficacy** | **P%INF** | **Efficacy** |
| Maritime | Mean (n =8)  (min-max) | 19.0  (5.0-32.55) | 6.5  (2.0-11.3) | 63.8  (38.4-85.4) | 5.2  (1.3-10.3) | 66.0  (32.5-98.0) |
| North-East | Mean (n = 6)  (min-max) | 11.8  (4.1-40.8) | 2.8  (0.3-13.0) | 80.8  (50.0-96.3) | 6.3  (0.2-33.9) | 72.4  (16.9-96.6) |
| **Total ALL** | **Mean (n = 14)**  **(min-max)** | **15.9**  **(4.1-40.8)** | **4.9**  **(0.3-13.0)** | **71.1**  **(38.4-96.3)** | **5.7**  **(0.2-33.9)** | **68.7**  **(16.9-96.6)** |

*Conclusion efficacy onion, PERODE*

Data demonstrated that the mean efficacy of the BAS 743 03 F at the proposed dose rate of 2.0 L/ha was equivalent to the efficacy of the standard at 1.0 L/ha and provided medium level control of *Peronospora destructor* in bulb onionsacross both EPPO climatic zones.

The registration of the BAS 743 03 F plant protection product against *Peronospora destructor* is sought for uses in bulb onions and garlic in all concerned member states, in the Central Registration Zone. A total of 8 trials in the Maritime EPPO climatic zone (4 trials in Germany and 4 trials the Netherlands), and 6 trials in the North-East zone (in Poland) were carried out to evaluate the efficacy of this product. According to the extrapolation tables 14/20180, data generated on any *Allium* crops may be used to extrapolate to all *Allium* crops. Therefore, the applicant suggests that the data originated on onion as indicator crop are used to justify the use of BAS 743 03 F also in garlic, as listed in the GAP.

For the South-East EPPO climatic zone, the applicant suggests but leaves the decision to the competent authorities, using the data set generated on onions in the Maritime EPPO climatic zone to support the registration of BAS 743 03 F in Hungary, Romania, Slovakia, and Slovenia, as listed in the GAP. Although BAS 743 03 F is a new product; both substances (ametoctradin and propamocarb) have already been registered as solo products or in combination with other substances for use in the South-East EPPO climatic zone. BAS 743 03 F combines these two active ingredients, and overall, the data demonstrated that at the proposed rate of 2.0 L/ha, this product provides a medium level but still slightly better control of downy mildew in onions than existing commercially available standards. The presented results support the proposed label claim for the management of downy mildew in bulb onions and garlic. *Peronospora destructor* is an obligate and aggressive pathogen causing heavy yield losses in onions and other crops worldwide. To control downy mildew in bulb onion and garlic, BAS 743 03 F should be applied in a protectant spray program commencing before the appearance of disease symptoms or when the monitoring and forecasting indicated a high risk of infection.

|  |
| --- |
| **Conclusion to** ***Peronospora destructor* on onion**  Maritime zone  The presented data correspond with the requirements of the EPPO Standards EPPO PP 1/65 (3), 1/120 (2), 1/135 (4), 1/152 (4), 1/181 (4)  The severity of *Peronospora destructor* infection was assessed in 8 efficacy trials with a two application of BAS 743 03 F. After one application (Timing 1) BAS 743 03 F gave medium control of *Peronospora destructor* with an average 68.3% with infection in the untreated ranging from 1.5 to 25.0 % (~7.8%). The efficacy of the product varied from 46.8 to 100%. Standard products performed in average on slightly higher level with an average 72.0%. Following two applications (Timing 2), with average disease levels at 19.0% in the untreated, BAS 743 03 F gave lower control 63.8% (ranging from 38.4% to 85.4%), compared to the standard control of 66.0% (ranging from 32.5% to 98.0).  No trials were conducted in garlic. An extrapolation from onion to garlic is possible.  The data suggest that BAS 743 03 F, applied at the proposed dose rate of 2.0 L/ha, achieved efficacy comparable to the standard at 1.0 L/ha. This resulted in moderate control of *Peronospora destructor* under conditions of low to moderate pathogen pressure. The concerned Member States are kindly asked to decide themselves whether to accept the lower efficacy of the applied product against *Peronospora destructor* on bulb onions.  North east zone  The presented data correspond with the requirements of the EPPO Standards EPPO PP 1/65 (3), 1/120 (2), 1/135 (4), 1/152 (4), 1/181 (4).  The severity of *Peronospora destructor* infection was assessed in 14 efficacy trials with a two application of BAS 743 03 F. After one application (Timing 1) BAS 743 03 F gave good control of *Peronospora destructor* with an average 82.6% with inadequate infection in the untreated of 2.9%. The efficacy of the product varied from 50.9 to 100%. Standard products performed in average on slightly lower level with an average 76.0%. Following two applications (Timing 2), with average disease levels at 11.8% in the untreated, BAS 743 03 F gave good control 80.8% (ranging from 50.0% to 96.3%), compared to the standard control of 72.4% (ranging from 16.9% to 96.6%).  No trials were conducted in garlic. An extrapolation from onion to garlic (minor crop) is possible.  It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness against *Peronospora destructor* in onion.  The applicant proposed an application window of BBCH 14–39. However, the trials conducted in the northeast zone only covered applications from BBCH 39 onward. In this case, the proposed application window can be accepted based on supporting trials conducted in the maritime EPPO zone (Germany), where the product application begins at BBCH 15. These trials demonstrated sufficient evidence of efficacy BAS 743 03 F against *Peronospora destructor* providing sufficient evidence to support the proposed application window ( Table 3.2‑39 – 40).  Southeast zone  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 other zones or not. |

* **Tomato, *Phytophthora infestans* (PHYTIN) (KCP 6.2)**

A total of 5 trials were carried out to evaluate the efficacy of BAS 743 03 F for the control of *Phytophthora infestans* in tomatoes.

BAS 743 03 F was applied in season-long efficacy trials following the GAP. BAS 743 03 F was tested at the claimed dose rate of 2.0 L/ha. The total number of applications was between 4-8.

All presented trials have been conducted between 2020 and 2022 in Poland, in the North-East EPPO climatic zone.

The distribution of the trials per country, year and EPPO climatic zone is provided in Table 3.2‑41.

The reference product Revus (BAS 9412 0 F) at 0.6 L/ha dose rate is presented in all efficacy trials.

For each trial, a single assessment of leaves and fruits is chosen at the end of the trial between BBCH 83-89. Results are presented for disease severity on leaves and disease incidence on leaves and fruits.

List of individual trials are presented in Table 3.2‑42.

Table 3.2‑43 represents the application summary for tomato efficacy trials.

A summary of results is available in Table 3.2‑44, Table 3.2‑45 and Table 3.2‑46.

Table ‑: Distribution of trials by location and year – Tomato trials.

| **Crop** | **EPPO**  **Zone** | **Country** | **Year** | | | **TOTAL**  **per row** |
| --- | --- | --- | --- | --- | --- | --- |
| **2020** | **2021** | **2022** |
| Tomato  (LYPES) | North-East | PL | 2 | 1 | 2 | 5 |
| **TOTAL** | | | **2** | **1** | **2** | **5** |

Table ‑: Efficacy, List of individual tomato trials.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **EPPO**  **Zone** | **Trial ID** | **GEP** | **Year** | **Country** | **Variety** | **Yield** |
| North-East  (5 trials) | Trial No.1\* | YES | 2020 | PL | SCOOTER | YES |
| Trial No.2\* | YES | 2020 | PL | RUMBA O¿AROWSKA | - |
| Trial No.3\* | YES | 2021 | PL | NUN00507 | - |
| Trial No.4\*\* | YES | 2022 | PL | PIETRAROSSA | YES |
| Trial No.5\*\* | YES | 2022 | PL | DYNO | YES |

* *BAS 743 AT F formulation*

*\*\* BAS 743 03 F formulation*

Table ‑: Efficacy, Application summary – Tomato trials.

|  |  |  |  |
| --- | --- | --- | --- |
| **EPPO**  **Zone** | **Application details Summary** | | |
| **BBCH**  **at appl.** | **Water volume**  **at appl.** | **Total number**  **of appl.** |
| North-East | 74-83 | 500-700 | 4-8 |

*Disease severity on leaves*

The mean values of intensity of attack (= severity) on untreated leaves were 49.5%. Applying the full dose rate of the tested product decreased the number of affected leaves compared to untreated, reaching the mean product efficacy of 88.6% in the North-East EPPO climatic zone. The data also demonstrated that the overall efficacy of BAS 743 03 F at the proposed rate of 2.0 L/ha was equivalent to the efficacy of the standard (88.6% versus 89.5%).

Table ‑: Efficacy, Tomato, PHYTIN, (disease severity and efficacy in %); Summary – Assessments on leaves.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **EPPO**  **Zone** | | **Untreated** | **BAS 743 03 F**  **2 L/ha** | | **STANDARD**  **BAS 9412 0 F**  **0.6 l/ha** | |
| **P%INF** | **P%INF** | **Efficacy** | **P%INF** | **Efficacy** |
| **Total ALL**  **(North-East)** | **Mean (n = 5)**  **(min-max)** | **49.5**  **(7.5-100.0)** | **4.6**  **(1.2-9.0)** | **88.6**  **(83.7-92.2)** | **3.9**  **(1.1-7.6)** | **89.5**  **(85.3-94.3)** |

*Disease incidence on leaves*

The mean percentage values of frequency of attack (=incidence) on untreated leaves were 67.0%. Applying the full dose rate decreased the number of affected leaves compared to untreated, reaching the mean product efficacy of 62.5% in the North-East EPPO climatic zone. Data also demonstrated that the overall efficacy of BAS 743 03 F at the proposed rate of 2.0 L/ha was equivalent to the efficacy of the standard (62.5% versus 63.9%).

Table ‑: Efficacy, Tomato, PHYTIN, (disease severity and efficacy in %); Summary – Assessments on leaves.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **EPPO**  **Zone** | | **Untreated** | **BAS 743 03 F**  **2 L/ha** | | **STANDARD**  **BAS 9412 0 F**  **0.6 l/ha** | |
| **P%FREQ** | **P%FREQ** | **Efficacy** | **P%FREQ** | **Efficacy** |
| **Total ALL**  **(North-East)** | **Mean (n = 3)**  **(min-max)** | **67.0**  **(31.0-95.0)** | **27.6**  **(6.9-39.0)** | **62.5**  **(50.7-77.8)** | **28.4**  **(4.1-46.0)** | **63.9**  **(51.6-86.7)** |

*Disease incidence on fruits*

The mean percentage values of frequency of attack (=incidence) on untreated fruits were 13.5%. Applying the full dose rate decreased the number of affected fruits compared to untreated, reaching the mean product efficacy of 86.7% in the North-East EPPO climatic zone. The data also demonstrated that the overall efficacy of BAS 743 03 F at the proposed rate of 2.0 L/ha was equivalent to the efficacy of the standard (86.7% versus 89.6%).

Table ‑: Efficacy, Tomato, PHYTIN, (disease severity and efficacy in %); Summary – Assessments on fruits.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **EPPO**  **Zone** | | **Untreated** | **BAS 743 03 F**  **2 L/ha** | | **STANDARD**  **BAS 9412 0 F**  **0.6 l/ha** | |
| **P%FREQ** | **P%FREQ** | **Efficacy** | **P%FREQ** | **Efficacy** |
| **Total ALL**  **(North-East)** | **Mean (n = 3)**  **(min-max)** | **13.5**  **(9.8-17.3)** | **1.9**  **(1.3-2.8)** | **86.7**  **(84.1-88.7)** | **1.5**  **(0.5-2.3)** | **89.6**  **(86.8-94.9)** |

*Summary and conclusion*

Data demonstrated that the efficacy of BAS 743 03 F at the proposed dose rate of 2.0 L/ha was equivalent to the efficacy of standard at a rate of 0.6 L/ha and provided good control of *Phytophthora infestans* in tomatoes*.*

The registration of the BAS 743 03 F plant protection product against *Phytophthora infestans* is sought for uses in tomato(*Solanum lycopersicum*) and aubergine(*Solanum melongena*). A total of five trials conducted in the North-East EPPO climatic zone, in Poland, were carried out to evaluate the efficacy of this product.

For the registration of BAS 743 03 F in Poland, Slovakia, and Slovenia, the extrapolation tables 14/19575 for minor uses allow data generated on tomatoes to be extrapolated to aubergine*.*Thus, the applicant suggests that the data originating from tomatoes as indicator crops for controlling *Phytophthora infestans* are applied to justify these uses also in aubergine.

Since potatoes belong to the same family of *Solanaceae* as tomatoes*,*and*Phytophthora infestans*is one of the primary pathogens for both crops in the agricultural sector; for the registration of BAS 743 03 F in Hungary and Romania, the applicant suggests using the data set generated on potatoes (Section 3.2.3.1) to complement and support theefficacy data conducted on tomatoes. In section 3.2.3.1, the results of 35 potato trials (14 trials in the Maritime zone, 9 trials in the North-East zone, and 12 trials in the South-East zone) are evaluated and presented. The data from 12 trials performed in the South-East EPPO climatic zone demonstrated the mean product efficacy of 85.3% (Timing 1 assessment) resp., 78.1 % (Timing 2 assessment). The overall product efficacy summarized across all three EPPO climatic zones in potatoes was 89.1% (Timing 1 assessment) resp., 86.3% (Timing 2 assessment), which is equivalent to this product's efficacy in tomatoes (88.6%).

The overall results of the tomato trials complemented with the potato trials confirm good efficacy levels of BAS 743 03 F against late blight caused by *Phytophthora infestans*. However, the applicant proposes that the responsible authorities decide if the number of tomato trials (5 trials), with consideration of the presented potatoes trials, would be sufficient for the registration of BAS 743 03 F against *Phytophthora infestans* in Hungary and Romania, in the South-East EPPO climatic zone.

|  |
| --- |
| **Conclusion to *Phytophthora infestans* on tomatoes**  The presented data correspond with the requirements of the EPPO Standards EPPO PP 1/65 (4), 1/135 (4), 1/152 (4), 1/181 (4)  Results from 5 trials against *Phytophthora infestans* on tomatoes in the north-east zone showed a reduction in the number of leaves affected compared to untreated, with average product efficacy of 62.5% (disease incidence) and 88.6% (disease severity). The number of fruit affected compared to untreated reached an average product efficacy of 86.7% (disease incidence). In addition, the data showed that the overall efficacy of BAS 743 03 F at the recommended rate of 2.0 L/ha was comparable to the standard. No data were provided for aubergine. An extrapolation from tomato to aubergine (minor crop) is possible. The proposed GAP allows for 2 applications at the maximum rate while the applicant provided results 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.  **The application window proposed by the applicant, starting from BBCH 21, is insufficiently supported, as the trials conducted in the northeast zone only covered applications beginning at BBCH 74.**  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. |

* **Dose Rate Range (KCP 6.2)**

In certain countries within the EU 26 such as Hungary, Romania, Slovakia and Slovenia, regulations do not allow the farmer to apply lower dose rates than the registered ones, not even in the cases where the use of a lower dose rate might be scientifically justified. Crop variety, disease pressure and the prevailing climatic conditions are all potential factors that could affect the application rate. Therefore, the dose rate range requested for these countries of the South-East EPPO climatic zone will enable farmers to use the product as part of an Integrated Pest Management approach and adapt the application rates of the plant protection product according to their needs.

*Does Rate Range in potatoes*

The dose rate range of 1.5-2.0 L/ha is proposed for Hungary and Romania, the member states of the South-East EPPO climatic zone (Table 3.2‑47).

Table ‑: Dose rate range are proposed for the pathogen in potatoes.

|  |  |  |  |
| --- | --- | --- | --- |
| **Crop** | **Country** | **Disease** | **Dose Rate Range** |
| Potato | Hungary  Romania | *Phytophthora infestans*  (PHYTIN) | 1.5 – 2.0 L/ha |

*Results*

In order to justify the dose rate range in the South-East EPPO climatic zone, 4 efficacy trials in potatoes were performed to test the reduced dose rate of 1.5 L/ha, compared to the dose rate of 2.0 L/ha.

In these trials, the disease severity (assessed in %) was evaluated and compared to the reference product Revus (BAS 9412 0 F) at the dose rate of 0.6 L/ha.

According to GAP, 2 applications in total are requested for potato in the Central Registration Zone. In order to minimise interference from other chemistry, the season long disease control was done only using BAS 743 03 F and compared to the reference product.

To give data for the 2 applications on the GAP, 2 timings/application were considered to evaluate the efficacy of the plant protection product:

* The first timing / application: refer to the time when the level of disease in the untreated plot started to rise.
* The second timing / application: followed normal application timings depending on the disease pressure as would be normal agricultural practice

A summary of results for both timings is available in Table 3.2‑48.

After 1 application (**Timing 1**) as disease levels start to rise (3.6% mean), control from BAS 743 03 F at 1.5 L/ha was 94.0% (75.8-100.0%) compared to the dose rate of 2.0 L/ha, which reached the efficacy of 95.6% (82.4-100%). The mean efficacy of the standard was 92.6%.

After 2 applications (**Timing 2**) with average disease levels at 11.8% in the untreated, BAS 743 03 F at the dose rate of 1.5 L/ha was showing a good efficacy of 73.3% (66.7-84.4%) compared to the higher dose rate of 2.0 L/ha reaching the efficacy of 86.1% (73.9-100%). The mean efficacy of the standard was 55.4%.

Table ‑: Dose Rate Range, Efficacy, Potato, PHYTIN (disease severity and efficacy in %); Summary.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **EPPO**  **Zone** | | | **Untreated** | **BAS 743 03 F**  **1.5 L/ha** | | **BAS 743 03 F**  **2 L/ha** | | **BAS 9412 0 F**  **0.6 l/ha** | |
| **P%INF** | **P%INF** | **Efficacy** | **P%INF** | **Efficacy** | **P%INF** | **Efficacy** |
| **South-East** | **1st Timing** | **Mean (n = 4)**  **(min-max)** | **3.6**  **(0.2-7.5)** | **0.1**  **(0.0-0.2)** | **94.0**  **(75.8-100.0)** | **0.1**  **(0.0-0.2)** | **95.6**  **(82.4-100.0)** | **0.1**  **(0.0-0.3)** | **92.6**  **(70.3-100.0)** |
| **2nd Timing** | **Mean (n = 4)**  **(min-max)** | **11.8**  **(5.3-23.2)** | **3.2**  **(1.8-6.5)** | **73.3**  **(66.7-84.4)** | **1.6**  **(0.9-3.7)** | **86.1**  **(83.7-90.5)** | **4.4**  **(3.8-14.1)** | **55.4**  **(28.7-78.8)** |

*Conclusion*

Taken these results together, it can be demonstrated that BAS 743 03 F gives a good control of *Phytophtora infestans* in the dose rate range of 1.5-2.0 L/ha under the low disease pressure. Therefore, it is proposed to allow the dose rate range of 1.5-2.0 L/ha of BAS 743 03 F for Hungary and Romania, as requested in the GAP. The lower dose should be recommended in situations of less sensitive (to disease) varieties and localities with the lower disease pressure.

|  |
| --- |
| **Conclusion to Dose Rate Range**  The data showed that lower rates than 2 L/ha of BAS 743 03 F can also be effective, as confirmed by trials presented. The proposed dose rate of 1.5 L/ha provided acceptable effectiveness against *Phytophtora infestans* in potato and may be considered as effective under certain agricultural conditions. The lower dose should be recommended in situations of less sensitive (to disease) varieties and localities with the lower disease pressure.  The concerned cMS, based on their national experience, should consider whether the proposals of the applicant may be accepted. |

Yield (and relevant quality indicators), from efficacy trials (in the presence of challenging pest populations)

In the chapter below, the summary of the results on yield and the quality parameters obtained from the efficacy trials are presented. In all presented trials, BAS 743 03 F was applied at the full dose rate of 2.0 L/ha and compared to the reference product.

* Potato (*Solanum tuberosum*/SOLTU) (KCP 6.2)

**YIELD**

A total of 30 of the 35 trials which were conducted between 2020 and 2022 in the Maritime EPPO climatic zone in Germany (2 trials), the Netherlands (3 trials), Ireland (4 trials), in the North-East EPPO climatic zone in Poland (9 trials), and in the South-East EPPO climatic zone in Hungary (4 trials) and in Romania (8 trials) were yielded.

Summary results are presented in Table 3.2‑49.

Across all EPPO climatic zones, BAS 743 03 F recorded yield of 138.5% relative to the untreated and therefore had no adverse effects on yield in potatoes. In fact, the quantity of the yielded crop was significantly enhanced compared to the untreated control.

Table ‑: Yield in potato - efficacy trials (dt and % relative to untreated); Summary.

| **EPPO**  **Zone** | | **Untreated** | **BAS 743 03 F**  **2.0 l/HA** | **Revus**  **BAS 9412 0 F**  **0.6 l/ha** |
| --- | --- | --- | --- | --- |
| Total All | %  Mean  min  max  n | 100.0  313.4  69.9  651.7  30 | 138.5  419.5  119.1  844.4  30 | 142.2  413.9  131.2  824.2  30 |
| Maritime | %  Mean  min  max  n | 100.0  324.5  69.9  568.1  9 | 179.9  532.7  148.3  844.4  9 | 204.5  560.5  267.6  824.2  9 |
| North-East | %  Mean  min  max  n | 100.0  293.4  143.1  501.5  9 | 128.4  366.9  245.2  581.7  9 | 124.7  354.6  237.9  541.9  9 |
| South-East | %  Mean  min  max  n | 100.0  320.2  130.6  651.7  12 | 115.0  374.1  119.1  805.8  12 | 108.6  348.4  131.2  691.7  12 |

**GRADING OF HARVESTED TUBERS**

The grading of the harvested tubers was assessed in 28 out of 35 trials covering the Maritime EPPO climatic zone in Germany (2 trials), Ireland (4 trials), the Netherlands (3 trials), the North-East EPPO climatic zone in Poland (7 trials), and the South-East EPPO climatic zone in Hungary (4 trials) and Romania (8 trials).

Different gradings were used in the trials, according to local standards.

Summary results are presented in Table 3.2‑50, Table 3.2‑51 and Table 3.2‑52.

Regardless the grading class, it is observed that the application of BAS 743 03 F had no detrimental effect on the size of potato tubers, but actually increased the size profile moving more potatoes in the desired saleable range.

Table ‑: Tuber grading (in % and decitons per size class), Potato; Summary.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Grading – North-East Zone** | | | | | | |
| **Sieve**  **Sizes** | **Untreated** | | **BAS 743 03 T**  **2.0 L/HA** | | **BAS 9412 0 F**  **0.6 L/HA** | |
| **%** | **dt** | **%** | **dt** | **%** | **dt** |
| **3 grades** | | | | | | |
| **SIB>55**  **SIB>35**  **SIB<35** | 60  39  1 | 112  73  2 | 68  31  1 | 177  81  3 | 63  36  1 | 161  91  3 |
| **No. of trials** | 1 | 1 | 1 | 1 | 1 | 1 |
| **3 grades** | | | | | | |
| **SIB>75**  **SIB>45**  **SIB>35**  **SIB<35** | 25  26  22  6 | 60  133  67  17 | 30  45  19  5 | 97  147  71  19 | 27  49  17  5 | 83  170  70  19 |
| **No. of trials** | 4 | 4 | 4 | 4 | 4 | 4 |
| **4 grades** | | | | | | |
| **SIB>70**  **SIB>55**  **SIB<35**  **SIB<35** | 30  68  2  0 | 67  149  3  0 | 45  54  1  0 | 139  169  4  0 | 47  52  1  0 | 138  154  4  0 |
| **No. of trials** | 1 | 1 | 1 | 1 | 1 | 1 |
| **4 grades** | | | | | | |
| **SIZHK1**  **SIZHK2**  **SIZHK3**  **SIZHK4** | 31  60  7  0.5 | 76  145  18  1 | 77  58  9  1 | 36  147  24  3 | 34  56  16  1 | 87  144  20  3 |
| **No. of trials** | 1 | 1 | 1 | 1 | 1 | 1 |

Table ‑: Tuber grading (in % and decitons per size class), Potato; Summary.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Grading – Maritime Zone** | | | | | | |
| **Sieve**  **Sizes** | **Untreated** | | **BAS 743 03 F**  **2.0 L/HA** | | **BAS 9412 0 F**  **0.6 L/HA** | |
| **%** | **dt** | **%** | **dt** | **%** | **dt** |
| **3 grades** | | | | | | |
| **SIB>55**  **SIB<55**  **SIB<35** | 38  51  10 | 142  190  39 | 89  6  5 | 609  44  31 | 83  11  6 | 592  82  43 |
| **No. of trials** | 1 | 1 | 1 | 1 | 1 | 1 |
| **3 grades** | | | | | | |
| **SIB>50**  **SIB<50**  **SIB<35** | 15  51  64 | 53  115  51 | 15  67  18 | 78  278  51 | 25  71  11 | 84  302  45 |
| **No. of trials** | 4 | 4 | 4 | 4 | 4 | 4 |
| **4 grades** | | | | | | |
| **SIB>85**  **SIB<85**  **SIB<65**  **SIB<45** | 0  2  52  47 | 0  7  240  173 | 0  4  71  26 | 0  29  443  160 | 0  4  72  25 | 0  24  369  138 |
| **No. of trials** | 4 | 4 | 4 | 4 | 4 | 4 |

Table ‑: Tuber grading (in % and decitons per size class), Potato; Summary

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Grading- South-East Zone** | | | | | | |
| **Sieve**  **Sizes** | **Untreated** | | **BAS 743 03 T**  **2.0 L/HA** | | **BAS 94120 F**  **0.6 L/HA** | |
| **%** | **dt** | **%** | **dt** | **%** | **dt** |
| **3 grades** | | | | | | |
| **SIB>55**  **SIB<55**  **SIB<35** | 55  34  12 | 165  102  35 | 61  32  7 | 203  107  25 | 60  33  8 | 189  104  24 |
| **No. of trials** | 1 | 1 | 1 | 1 | 1 | 1 |
| **4 grades** | | | | | | |
| **SIB>70**  **SIB>50**  **SIB>30**  **SIB<30** | 6  44  38  12 | 19  109  108  33 | 9  45  35  11 | 32  132  113  31 | 7  43  38  12 | 25  119  115  34 |
| **No. of trials** | 6 | 6 | 6 | 6 | 6 | 6 |
| **4 grades** | | | | | | |
| **SIB<85**  **SIB<65**  **SIB>65**  **SIB>45** | 7  45  9  9 | 22  164  34  34 | 8  47  10  10 | 33  207  46  46 | 8  45  10  10 | 29  183  42  42 |
| **No. of trials** | 2 | 2 | 2 | 2 | 2 | 2 |
| **4 grades** | | | | | | |
| **SIB>85**  **SIB<85**  **SIB<65**  **SIB<45** | 0  5  66  29 | 0  19  275  99 | 0  14  65  22 | 0  65  333  69 | 0  8  65  27 | 0  34  290  96 |
| **No. of trials** | 3 | 3 | 3 | 3 | 3 | 3 |

**YIELD OF STARCH**

Yield of starch was assessed in 8 out of 35 efficacy trials in the North-East EPPO climatic zone in Poland (5 trials), and in the South-East EPPO climatic zone in Hungary (1 trial) and in Romania (2 trials).

Summary results are presented in Table 3.2‑53.

Across the trials, no adverse effects on the yield of starch, relative to the untreated was observed. In fact, rather positive effect was seen across the evaluated trials.

Table ‑: Yield of starch (in dt/ha and % of UTC), Potato – Summary.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **EPPO Zone** | | **Untreated** | **BAS 743 03 F**  **2.0 L/HA** | **BAS 9412 0 F**  **0.6 L/HA** |
| Total | % Mean  Mean  min  max  n | 100.0  84.9  27.0  201.1  8 | 131.3  109.3  40.7  238.5  8 | 122.7  101.9  39.4  222.4  8 |
| North-East | % Mean  Mean  min  max  n | 100.0  57.2  27.0  98.0  5 | 135.4  76.7  40.7  116.0  5 | 127.2  71.6  39.4  117.0  5 |
| South-East | % Mean  Mean  min  max  n | 100.0  130.9  38.7  201.1  3 | 124.3  163.8  46.1  238.5  3 | 115.2  152.4  42.1  222.4  3 |

* Onion (*****Allium cepa***** / ****ALLCE****) (KCP 6.2)

**YIELD**

A total of 8 of the 14 trials which were conducted between 2020 and 2021 in the Maritime EPPO climatic zone in the Netherlands (2 trials), and in the North-East EPPO climatic zone in Poland (6 trials) were yielded.

Summary results are presented in Table 3.2‑54.

Across both evaluated EPPO climatic zones, BAS 743 03 F recorded yield of 112.3% relative to the untreated and therefore no adverse effects on yield in onion are observed. In fact, the quantity of the yielded crop was enhanced compared to the untreated control.

Table ‑: Yield in onion - efficacy trials (dt and % relative to untreated); Summary.

| **EPPO**  **Zone** | | **Untreated** | **BAS 743 03 F**  **2.0 L/HA** | **BAS 9164 4 F**  **1.0 L/HA** |
| --- | --- | --- | --- | --- |
| Total All | %  Mean  min  max  n | 100.0  428.8  164.4  696.2  8 | 112.3  471.5  213.0  729.2  8 | 111.7  473.0  185.2  712.3  8 |
| Maritime | %  Mean  min  max  n | 100.0  444.4  192.6  696.2  2 | 107.0  451.0  224.8  677.3  2 | 99.2  448.7  185.5  712.3  2 |
| North-East | %  Mean  min  max  n | 100.0  423.6  164.4  577.6  6 | 114.1  478.3  213.0  729.2  6 | 115.9  481.1  232.0  705.8  6 |

**GRADING OF HARVESTED ONION**

The grading of the harvested onion bulbs was assessed in the Maritime EPPO climatic zone in the Netherlands (2 trials).

Grading in the trials was used according to local standards.

Summary results are presented in Table 3.2‑55.

It can be concluded that the application of BAS 743 03 F had no detrimental effect on size of onion bulbs.

Table ‑: Onion bulbs grading, (in % and decitons per size class); Summary.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Grading- Maritime Zone** | | | | | | |
| **Sieve**  **Sizes** | **Untreated** | | **BAS 743 03 F**  **2.0L/ha** | | **BAS 9164 4 F**  **1.0 L/ha** | |
| **%** | **dt** | **%** | **dt** | **%** | **dt** |
| **3 grades** | | | | | | |
| SIB<40  SIB<60  SIB>60 | 10 | 24 | 9 | 24 | 13 | 29 |
| 54 | 179 | 47 | 165 | 47 | 158 |
| 36 | 242 | 44 | 263 | 39 | 262 |
| **No. of trials** | 2 | 2 | 2 | 2 | 2 | 2 |

* Tomato (*Solanum lycopersicum* / ****LYPES****) (KCP 6.2)

A total of 3 of the 5 trials which were conducted between 2020 and 2022 in the North-East EPPO climatic zone in Poland (3 trials) were yielded.

Summary results are presented in Table 3.2‑56.

BAS 743 03 F recorded yield of 113.0% relative to the untreated and therefore no adverse effects on yield in tomatoes are observed. In fact, the quantity of the yielded crop was enhanced compared to the untreated control.

Table ‑: Yield in tomato - efficacy trials (dt and % relative to untreated); Summary.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **EPPO**  **Zone** | | **Untreated** | **BAS 743 03 F**  **2.0 L/HA** | **BAS 9412 0 F**  **0.6 L/HA** |
| Total ALL | %  Mean  min  max  n | 100.0  297.9  166.8  387.1  3 | 113.0  340.6  178.6  452.0  3 | 111.9  335.3  181.9  438.0  3 |

Summary and conclusion section 3.2 (KCP 6.2)

Data on fungicidal efficacy (54 trials) and impact on yield (41 trials) over efficacy trials presented in this chapter have proven BAS 743 03 F to be an efficient product of fungicidal control in potatoes, onions and tomatoes. Trials proved the level of control equivalent or better than the reference standard products tested. Furthermore, BAS 743 03 F at the proposed label rate of 2.0 L/ha showed no adverse but rather positive effects on the yield and the quality indicators.

|  |
| --- |
| **Conclusion to quality parameters from efficacy trials (in the presence of the specific diseases)**  54 efficacy trials, located in the maritime, northeast and southeast EPPO zones, were harvested in 2020 and 2022. These data correspond with the requirements of the EPPO Standards PP 1/214 and PP 1/223.  In potatoes trials an average yield increase of 38.5% compared to untreated was achieved, therefore no adverse effects on potato yield were observed. BAS 743 03 F had no adverse effect on starch yield or tuber size.  In onion trials an average yield increase of 12.3% compared to untreated was achieved, therefore no adverse effects on onion yield were observed. BAS 743 03 F had no adverse effect on onion size.  In tomatoes trials an average yield increase of 13% compared to untreated was achieved, therefore no adverse effects on tomato yield were observed. BAS 743 03 F had no adverse effect on onion size.  BAS 743 03 F was shown to be an effective product for fungicidal control in potatoes, onion 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.  It can be concluded to accept the data provided by the applicant to demonstrate the effectiveness in crops. |

## Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

BAS 743 03 F is a fungicide intended for the control of *Phytophthora infestans* in potatoes, tomatoes and aubergines and *Peronospora destructor* in onions and garlic. It contains 120 g ametoctradin/L and 451 g propamocarb-hydrochloride/L SC formulation**.**

Detail information on the occurrence or possible occurrence of the development of resistance can be found in part K under Doc ID: 2023/2010683.

* **Mechanisms of resistance**

Ametoctradin: Amino acid substitutions causing resistance to QiIs or to ametoctradin in *Plasmopara viticola* were identified by XXXX and others (Fontaine *et al.* 2019). The mutation S34L was found in field isolates originating from south-western France. *In vivo* and *in vitro* tests have shown that the S34L has a specific impact on ametoctradin but no impact on QiIs, like cyazofamid or amisulbrom. The mutation L201S and the insertion E203-DE-V204 were identified as well in France. *In vivo* and *in vitro* tests have shown that these mutations affect specifically QiIs and have no impact on ametoctradin. In addition, other types of insertion, E203-VE-V204 and E203-E-V204, were detected. Also, for these insertions, *in vivo* and *in vitro* tests have shown that they have no impact on ametoctradin, while they have a strong impact on QiIs. Besides these mutations causing specific resistance towards either ametoctradin or QiIs or QoIs, a general mechanism linked to the overexpression of the alternative oxidase (AOX) enzyme was observed in XXXX monitoring studies and described also by Fehr *et al*. (2015) and Zito *et al.* (2020). *In vivo* and *in vitro* tests confirmed that AOX overexpression affects the efficacy of complex III inhibitors.

Propamocarb: There are various reports about higher EC50 values in different tests systems in isolates of different oomycete species. Resistance to propamocarb has been detected in *Pythium* species (Gisi and Sierotzki 2008), in *Phytophthora infestans* (Samoucha and Cohen 1990) and *Pseudoperonospora cubensis* (Cohen and Samoucha 1984, Urban and Lebeda 2007, Pavelkova *et al.* 2014). However, there are no reports available on the mechanisms of resistance to propamocarb. This is also a result of the lack of knowledge on the mode of action and therefore on the biochemical target and potential target site mutations.

* **Evidence of resistance**

Ametoctradin: Isolates of *Plasmopara viticola* with overexpression of AOX have been identified in trial and commercial sites with intensive use of complex III inhibitors in the last decades. These show reduced sensitivity to ametoctradin and other complex III inhibitors such as QiI and QoI. Such strains have been proved to be less fit in competition experiments with sensitive isolates (Fehr *et al.* 2015).

Additionally, isolates of *Plasmopara viticola* with a reduced sensitivity to ametoctradin and a mutation in the cytochrome *b* gene, leading to the amino acid exchange S34L, have been identified mainly in France (Note Technique Commune Maladies de la Vigne 2016 and later, Zito *et al.* 2020). Such S34L-isolates showed significant fitness penalties when grown together and in competition with sensitive strains The very slight increase in frequency of S34L-isolates since 2016 also strongly indicates that isolates with the S34L amino acid exchange are less competitive in nature compared to wildtype isolates.

Negative effects of the mutation S34L on the complex III activity has been recently described by Mounkoro *et al.* (2019) and fitness penalties by this mutation has also been postulated by Fontaine *et al.* (2019).

No ametoctradin resistance has been reported for *Phytophthora infestans* or any other downy mildews.

Propamocarb: Isolates with reduced sensitivity to propamocarb have been detected for *Phytophthora infestans* in own monitoring studies and have been published in various studies (*e.g.* Samoucha and Cohen 1990, Möller *et al.* 2009). Resistance had also been reported in *Pythium* species (Gisi and Sierotzki 2008) and *Pseudoperonospora cubensis* (Cohen and Samoucha 1984, Urban and Lebeda 2006 and 2007, Pavelkova *et al.* 2014).

* **Cross resistance**

Ametoctradin: Isolates of oomycetes species such as *Plasmopara viticola* with specific resistance to QoI, phenylamides, cymoxanil and CAA-fungicides are fully sensitive to ametoctradin*.* Cross-resistance to other oomycete compounds such as ethaboxam, zoxamide, Al-fosetyl or fluazinam has also not been detected and reported and is unlikely because of the different modes of action. Isolates with AOX overexpression have been found to be less sensitive to all complex III inhibitors such as cyazofamid, amisulbrom and ametoctradin. Such isolates have significant fitness penalties as shown in competition experiments with sensitive isolates in the greenhouse (Fehr *et al.* 2015). Strains of *Plasmopara viticola* with the S34L mutation were resistant to ametoctradin and have also shown to be less competitive than sensitive wildtype strains (Fontaine *et al.* 2019).

Propamocarb: Two other compounds, iodocarb and prothiocarb, are in the same FRAC group # 28 and may be cross resistant to propamocarb. However, there are no reports available on cross resistance of carbamates. Iodocarb is mainly used in wound protection products (*e.g.* Bertsch *et al.* 2013) and prothiocarb is of low importance and low market share nowadays.

Cross-resistance to other oomycete compounds such as QoI, QiI, QoSI, CAAs, ethaboxam, zoxamide, Al-fosetyl or fluazinam has not been detected and reported and this is also unlikely because of the unique mode of action of propamocarb. Studies on phenylamide resistant oomycetes showed that there is no cross-resistance between phenylamides and carbamates (Diriwächter *et al.* 1987, Crute *et al.* 1987, Samoucha and Cohen 1990).

* **Baseline sensitivity / Sensitivity monitoring**

In the following chapter baseline sensitivity data and newest monitoring data are provided.

**A. Sensitivity to ametoctradin**

***A1. Phytophthora infestans* on tomatoes, potatoes and aubergines**

Baseline sensitivity: The baseline sensitivity for *Phytophthora infestans* to ametoctradin was done in 2008 with 95 isolates from Europe from 1993-2008. Such isolates were never exposed to ametoctradin and represent therefore the natural baseline sensitivity.

Literature research was done in Q-knows in March 2023 without any further findings on sensitivity data for *Phytophthora infestans* to ametoctradin. No data of ametoctradin resistance or field failure due to resistance issues have been reported so far for *Phytophthora infestans*.

***A2. Peronospora destructor* on onions and garlic**

There are no reports on the sensitivity of *Peronospora destructor* towards ametoctradin available by using the research programme Q-Knows. Published efficacy studies indicated good efficacy of ametoctradin + dimethomorph on *Peronospora destructor* (Araujo *et al.* 2020) and there is no indication of any resistance development.

**B. Sensitivity to Propamocarb**

***B1. Phytophthora infestans* on potatoes, tomatoes and aubergines**

Monitoring studies were done in 2019, 2020 and 2021 with isolates gained from samples from various European countries, with most isolates from potatoes and some from tomatoes. The test system was a microtiter test. Microtiter tests include mainly the inhibition of mycelial growth, which might be less inhibited by propamocarb (Hu *et al.* 2007). Isolates with EC50 values higher than 100 ppm are seen as less sensitive and these were in 2019 8.3% in 2020 43.9% and in 2021 14.7% of all isolates tested. Data from Möller *et al.* (2009) described a frequency of 13.2% propamocarb-resistant isolates in Germany in 1999.

In a study from Lethinen *et al*. (2007) propamocarb resistance was found in Finland with 1.0% in 1997, 2.5% in 1998, 54% in 1999 and 11.3 % in 2000.

Based on these data it can be stated that propamocarb adaptation is present since more than 20 years in the European population with fluctuating values from year to year.

However, there are no reports on field failure available.

***B2. Peronospora destructor* on onions and garlic**

There are no reports on the sensitivity of *Peronospora destructor* towards propamocarb available by using the research programme Q-Knows. Published efficacy studies indicated good efficacy of fluopicolide+propamocarb on *Peronospora destructor* (Araujo *et al.* 2020) and no indication of any resistance development.

* **Use pattern**

BAS 743 03 F is intended for registration against *Phytophthora infestans* in potatoes with a maximum of 2 applications (in PL, HU, RO, SL, SK, AT, CZ, DE) and 3 applications (in BE, IE, NL) with a rate of 2.0 L/ha between growth stages 21 to 89.

BAS 743 03 F is intended for registration against *Phytophthora infestans* in tomatoes and aubergines in open field with a maximum of 2 applications with a rate of 2.0 L/ha between growth stages 21 to 89.

For control of *Peronospora destructor* in onions and garlic it is intended for registration with 1 application (in AT, CZ, DE, SK, SI) and with 2 applications (in BE, IE, NL, PL, RO) with a rate of 2.0 L/ha between growth stages 14-49.

For control of downy mildews in floriculture crops, climbing plants, conifers (incl. christmas trees), ornamental shrubs and heather a maximum of 2 applications between growth stages 12-59 with a rate of 2.0 L/ha is intended.

For control of downy mildews in avenue trees, forest trees and hedging plants, fruit trees and shrubs and perennial crops a maximum of 2 applications between growth stages 12-59 with a rate of 2.0 L/ha is intended.

For a detailed description of growth stages of the different crops please refer to BBCH-code (BBCH Monograph, 2001).

* **Resistance risk assessment of unrestricted use pattern**

***Fungicide risk***

Ametoctradin: FRAC describes the risk of fungicides as low, medium or high (FRAC 2023) according to the principles described in FRAC Monographs 1 and 2 (Brent 2007, Brent and Hollomon 2007). The resistance risk for ametoctradin is described to be medium to high (FRAC 2023).

Propamocarb: FRAC describes the risk of fungicides as low, medium or high (FRAC 2023) according to the principles described in FRAC Monographs 1 and 2 (Brent 2007, Brent and Hollomon 2007). The resistance risk for propamocarb is described to be low to medium (FRAC 2023).

* ***Pathogen risk***

FRAC classified a high number of pathogens in species with a low, medium and high risk for fungicide resistance. This classification is based on experience and reported resistance claims over the last 50 years. Generally, the risk increases when a pathogen undergoes many and short disease cycles per season, the dispersal through spores over time and space is high and the competitive ability of resistant individuals is high in the absence of selection pressure. Furthermore, the risk is considered as high when resistance evolved already after few years of product use.

Current FRAC classification of the target pathogens of BAS 743 03 F:

* *Phytophthora infestans, Peronospora destructor* and other *Peronospora* species and *Pseudoperonospora* species (others than *Pseudoperonospora cubensis*)are classified as medium-risk pathogens. Other *Phytophthora* species are classified by FRAC as low or medium risk pathogens. For simplification, we classify all *Phytophthora* species, which are addressed in this Resistance Risk Analysis, as species with medium risk, even if the risk is most probably low.
* **The combined resistance risk (under unrestricted use)** **can be described for:**

Ametoctradin

*Phytophthora infestans* and other *Phytophthora species, Peronospora destructor* and other *Peronospora* species, *Pseudoperonospora* spp. (others than *Pseudoperonospora cubensis*): **medium**

Propamocarb

*Phytophthora infestans* and other *Phytophthora species, Peronospora destructor* and other *Peronospora* species, *Pseudoperonospora* spp. (others than *Pseudoperonospora cubensis*): **low to medium**

* ***Agronomic risk***

Besides the “Fungicide Risk” and the “Pathogen risk” the “Overall Resistance Risk” is determined by the “Agronomic Risk” (Figure 8). While the fungicide risk and the pathogen risk are inherent, the agronomic risk comprises environmental factors, especially climatic and topographic conditions that affect the severity and spread of fungal disease. Also integrated pest management, cropping systems, crop rotation, choice of cultivars, nutrition, glasshouse, tunnels, field, sprinkling systems and other farm practices influencing disease development and the use of resistance management strategies based on the use of fungicides influence the agronomic and therefore the overall resistance risk.

Resistance management strategies are part of the agronomic risk and are described in the chapter “Management strategy”.

* **Acceptability of the resistance risk**

The outcome of the resistance risk analysis (pathogens x ametoctradin) was that the combined risk for development of resistance to ametoctradin in *Phytophthora infestans* and other *Phytophthora species, Peronospora destructor* and other *Peronospora* species, *Pseudoperonospora* spp. (others than *Pseudoperonospora cubensis*) is medium under unrestricted use.

The outcome of the combined resistance risk analysis (pathogens x propamocarb) was that the combined risk for development of resistance to propamocarb in *Phytophthora infestans* and other *Phytophthora species, Peronospora destructor* and other *Peronospora* species, *Pseudoperonospora* spp. (others than *Pseudoperonospora cubensis*) is low to medium under unrestricted use.

Therefore, an unrestricted use of ametoctradin or propamocarb without resistance management is not acceptable and management strategies are recommended in order to reduce the risk of resistance development.

The key of resistance management strategies is the reduction of selection pressure to a specific mode of action. Different modifiers that lead to such a reduction will be implemented in the resistance management strategy and are described in the next chapter.

* **Management strategy**

The objective of resistance management strategies is the reduction of 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 less infection pressure (*e.g.* phytosanitary measurements, cultivation of less susceptible varieties, appropriate crop cultivation unfavourable for the target pathogens).

Limiting the number of sprays is also an important factor in delaying the build-up of resistant pathogen populations (van den Berg *et al.* 2016). The number of BAS 743 03 F applications will be restricted as described in the “use pattern”.

A further tool is the use of fungicide mixtures. Various studies showed that especially mixtures help in delaying the selection of resistance (Hobbelen *et al.* 2013, 2014, van den Bosch *et al.* 2014). BAS 743 03 F is already a mixture of two active ingredients, which are both active against all pathogens of this Resistance Risk Analysis.

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 (van den Berg *et al.* 2013).

* **Implementation of the management strategy**

XXXX promotes an awareness of fungicide resistance management in product leaflets and training sessions to sales personnel, distributors and growers’ associations. The latest issues relating to fungicide resistance are discussed with the XXXX technical managers from all regions of the world so that the information from individual countries can be passed on as quickly as possible to the other countries.

Resistance management strategy will be included as a topic in product brochures, labels and training courses. XXXX is a founder member of the FRAC Working Groups. As well as helping to formulate the recommendations for resistance management, it will wherever possible also promote them.

* **Monitoring, reporting and reaction to changes in performance**

Monitoring programmes are running for *Phytophthora infestans* and ametoctradin on a regular basis. For propamocarb the sensitivity for *Phytophthora infestans* will also be further observed.

Any reports from the field that indicate that there may be reduced efficacy of BAS 743 03 F or one of the single components against the target pathogens of this Resistance Risk Analysis will immediately be investigated to analyse if a reduced sensitivity towards ametoctradin or propamocarb can be determined.

Regulatory authorities will be informed at an early stage about all cases of field failure known to be due to resistance. Changes in sensitivity will be communicated and may result in modifications of the recommended resistance management strategies.

**References**

Araujo E.R., Resende R.S., Alves D.P. and Higashikawa F.S. (2020) Field efficacy of fungicides to control downy mildew of onion. *European Journal of Plant Pathology* **156**, 305-309

BBCH Monograph (2001) 2nd edition, edited by U. Meier, published on [*http://www.bba.de/veroeff/bbch/*](http://www.bba.de/veroeff/bbch/)*.*

Beaulieu J., Balzi Y. and Munera J.D.C. (2021) Detection of Oomycide-Insensitive *Phytophthora* Isolates in Maryland Ornamental Nurseries and Mid-Atlantic Landscapes Provide Data for Reconsidering Management Strategies. *Plant Health Progress* **22**, 1-6

Bertsch, C., Ramirez-Suero, Magnin-Robert M., Larignon P., Chong J., Abou-Mansour E., Spagnolo A., Clement C. and Fontaine F. (2013) Grapevine trunk diseases: complex and still poorly understood. *Plant Pathology* **62,** 243-265

Brent, K.J. (2007) Fungicide resistance in crop pathogens: How can it be managed? 2nd revision. *FRAC Monograph* **1**

Brent, K.J. and Hollomon, D.W. (2007) Fungicide Resistance: The assessment of risk. 2nd revision. *FRAC Monograph* **2**

Cohen Y. and Samoucha Y (1984) Cross-resistance to four systemic fungicides in metalaxyl-resistant strains of *Phytophthora infestans* and *Pseudoperonospora cubensis*. *Plant Disease* **71**, 763-767

Crute I.R., Norwood J.M. and Gordon P.L. (1987) The occurrence, characteristics and distribution in the United Kingdom of resistance to phenylamide fungicides in Bremia lactucae (lettuce downy mildew). *Plant Pathology* **36**, 297-315

Diriwächter G., Sozzi D. and Staub T. (1987) Crossresistance in Phytophthora infestans and Plasmopara viticola against different phenylamides and unrelated fungicides. *Crop Protection* **6**, 250-255

Dreinert A., Wolf A., Mentzel T., Meunier B. and Fehr M. (2018) The cytochrome bc 1 complex inhibitor ametoctradin has an unusual binding mode. *Biochimica et Biophysica Acta - Bioenergetics* **1859**, 567-576

EPPO (2015) Efficacy evaluation of plant protection products. Resistance risk analysis PP 1/213 (4). *Bulletin OEPP/EPPO Bulletin* **45**, 371-387

Fehr M., Wolf A. and Stammler, G. (2015) Binding of the respiratory chain inhibitor ametoctradin to the mitochondrial *bc*1 complex. *Pest Management Science* **72**, 591-602.

Fontaine S., Remuson F., Caddoux L. and Barrès B. (2019) Investigation of the sensitivity of *Plasmopara viticola* to amisulbrom and ametoctradin in French vineyards using bioassays and molecular tools. *Pest Management Science* **75**, 2115-2123.

FRAC (2023) Current web page of the Fungicide Resistance Action Committee*.*[*www.frac.info*](http://www.frac.info)

Gilardi G., Garibaldi A. and Gullino M. (2020) Integrated management of downy mildew of basil. *Crop Protection* **137**, doi.org/10.1016/j.cropro.2020.105202

Gisi U. and Sierotzki H. (2008) Fungicide modes of action and resistance in downy mildews. *European Journal of Plant Pathology* **122**, 157-167

Gullino M., Gilardi G. and Garibaldi a. (2009) Chemical control of downy mildew on lettuce and basil under greenhouse. *Communications in Agricultural and Applied Biological Sciences* **74**, 933-940

Hobbelen, P.H.F., Paveley, N.D. and van den Bosch, F. (2014) The emergence of resistance to fungicides. *PLOS ONE* **9**, DOI:10.1371/journal.pone.0091910

Hobbelen, P.H.F., Paveley, N.D., Oliver, R.P. and van den Bosch, F. (2013) The usefulness of fungicide mixtures and alternation for delaying the selection for resistance in populations of *Mycosphaerella graminicola* on winter wheat: A modeling analysis. *Phytopathology* **103,** 690-707

Hu J., Hong C., Stromberg E.L. and Moorman G.W. (2007) Effects of propamocarb hydrochloride on mycelial growth, sporulation and infection by *Phytophthora nicotianae* isolates from Virginia nurseries. *Plant Disease* **91**, 414-420

Lehtinen A., Hannukkala A., Rantanen T. and Jauhiainen L. (2007) Phenotypic and genetic variation in Finnish potato-late blight populations, 1997-2000. *Plant Pathology* **56**, 480-491

Merk M., Gold R.E., Schiffer H., Levy T., Frechen T., and Saramago J. (2011), December). Initium®: A new innovative fungicide of a new chemical class for the control of late blight and downy mildew diseases. *Acta Horticulturae* **917**, 143-148

Möller K., Dilger M., Habermeyer J., Zinkernagel V., Flier W.G. and Hausladen H. (2009) population studies on *Phytophthora infestans* on potatoes and tomatoes in southern Germany. *European Journal of Plant Pathology* **124**, 659-672

Mounkoro P., Michel T., Benhachemi R., Surpateanu G., Iorga B.I., Fisher N. and Meunier B. (2019) Mitochondrial complex III Qi-site inhibitor resistance mutations found in laboratory selected mutants and ﬁeld isolates. *Pest Management Science* **75**, 2107-2114

Note Technique Commune Maladies de la Vigne 2016 (2016) Available at (status 04.10.2016): [*http://www.vignevin-sudouest.com/cartes/temoins/documents/note-mildiou-2015.pdf?PHPSESSID=a5682bc2a86e4a3e4d0628d6064e51b8*](http://www.vignevin-sudouest.com/cartes/temoins/documents/note-mildiou-2015.pdf?PHPSESSID=a5682bc2a86e4a3e4d0628d6064e51b8)

Papavizas G.C., O’Neil N.R. and Lewis J.A. (1978) Fungistatic activity of propyl-N-(adimethylaminopropyl)-carbamate on *Pythium* spp. and its reversal by sterols. *Phytopathology* **68**, 1667-1671

Pavelkova J., Lebeda A. and Sedlakova B. (2014) Efficacy of fosetyl-AL, propamocarb, dimethomorph, cymoxanil, metalaxyl and metalaxyl-M in Czech *Pseudoperonospora cubensis* populations during the years 2005 through 2010. *Crop Protection* **60**, 9-19

Pieroh E.A., Krass W. and Hemmen C. (1978) Propamocarb, ein neues Fungizid zur Abwehr von Oomyceten im Zierpflanzen- und Gemüsebau. *Meded. Fac. Landbouw. Rijksuniv. Gent* **43**, 933-942

Samoucha Y. and Cohen Y. (1990) Toxicity of propamocarb to the late blight fungus on potato. *Phytoparasitica* **18**, 27-40

Urban J. and Lebeda A. (2006) Fungicide resistance in cucurbit downy mildew – methodological, biological and population aspects. *Annals of Applied Biology* **149**, 63-75

Urban J. and Lebeda A. (2007) Variation of fungicide resistance in Czech populations of *Pseudoperonospora cubensis*. *Journal of Phytopathology* **155**, 143-151

Van den Berg, F., van den Bosch and Pavely, N. (2013) Optimal fungicide application timings for disease control are also an effective anti-resistance strategy: a case study for *Zymoseptoria tritici (Mycosphaerella graminicola)* on wheat. *Phytopathology* **103**, 1209-1219

Van den Berg, F., Paveley, N and van den Bosch (2016) Dose and number of applications that maximize fungicide effective life exemplified by *Zymoseptoria tritici* on wheat - a model analysis. *Plant Pathology* **65**, 1380-1389

Van den Bosch, F., Paveley, N., van den Berg, F., Hobbelen, P. and Oliver, R. (2014) Mixtures as a fungicide resistance management tactic. *Phytopathology* **104**, 1264-1273

Wu P., Guo Q. and Qin Z. (2016) The fungicide propamocarb increases lignin by activating the phenylpropanoid pathway in *Cucumis sativus* L. *Horticultural and Environmental Biotechnology* **57**, 511-518

Zhang G., babadoost M., de Young A., Johnson E.T. and Schisler D.A. (2018) evaluation of selected fungicide application regimes and biotic agents for the management of basil downy mildew. *Horttechnology* **28**, 822-829

Zhu X., Zhang M., Liu J., Ge J. and Yang G. (2015) Ametoctradin is a potent Qo site inhibitor of the mitochondrial respiration complex III. *Journal of Agricultural and Food Chemistry* **63**, 3377-3386.

Zito R., Meyer l., Aumont C., Fehr M. and Stammler G. (2020) State of knowledge on molecular mechanisms leading to a reduced sensitivity of *P. viticola* towards ametoctradin and complex III inhibitors. *19th International Reinhardsbrunn Symposium 2019, Modern Fungicides and Antifungal Compounds*

|  |
| --- |
| **Conclusion to Resistance**  **Ametoctradin** is an effective fungicide that disrupts the energy production of fungi, and it is part of the QoSI group (FRAC code 45), distinct from other fungicides in terms of its specific binding site within the mitochondrial respiratory chain.  **Propamocarb-Hydrochloride** is a systemic fungicide that targets the lipid biosynthesis pathway in oomycete fungi, disrupting their cell membranes and leading to their death. It is classified under FRAC code 28, indicating its specific mode of action as a phospholipid biosynthesis inhibitor.  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. From the above analyses, it can therefore be concluded that the overall resistance risk for the fungicide BAS 743 03 has to be regarded as 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. |

## Adverse effects on treated crops (KCP 6.4)

### Information on trials submitted, Material and methods (KCP 6.4)

Assessing the phytotoxicity of a plant protection product to a crop plant is an essential element in its efﬁcacy evaluation. Therefore, a phytotoxicity assessment was carried out in 54 efficacy trials, between 2020 and 2022, in accordance with the EPPO guideline PP 1/135(4). All trials were conducted in the countries of the Central Registration Zone covering the Maritime, the North-East and the South-East EPPO climatic zone.

### Phytotoxicity to host crop (KCP 6.4.1)

**Potato (*Solanum tuberosum*/SOLTU) (KCP 6.4.1)**

A phytotoxicity assessment was conducted in all 35 efficacy trials in the Maritime zone in Germany (7 trials), the Netherlands (3 trials), Ireland (4 trials), in the North-East zone in Poland (9 trials), and in the South-East EPPO climatic zone in Hungary (4 trials) and in Romania (8 trials).

Altogether 20 different varieties were tested and are presented in Table 3.4‑1.

Table ‑: Varieties tested in efficacy trials – Potato.

| **Varieties tested in potato** | | | | |
| --- | --- | --- | --- | --- |
| ROOSTER  MARIS PIPER  BINTJE  FONTANE | IRGA  SATINA  ALBATROS | TAJFUN  ZUZANNA  GALA | LILY  ESZME  BELLAROSA  SORAYA  SANTE | ARIZONA  BALATONI ROZSA  CARERA  ACTRICE  RED SCARLET |

The phytotoxicity assessments of BAS 743 03 F at the full dose rate are summarized in Table 3.4‑2.

Table ‑: Phytotoxicity in efficacy trials; Potato.

| **Number of trials with phytotoxicity** | | **Efficacy trials (35)** | |
| --- | --- | --- | --- |
| **BAS 743 03 F** | **Standard** |
| **2.0 L/ha** |
| **Phytotoxicity** | 0% | **35** | **35** |
| **recorded during the trials** | >0% to 5% | **-** | **-** |
|  | >5% to 10% | **-** | **-** |
|  | >10% to 15% | **-** | **-** |
|  | >15 % | **-** | **-** |
| **Level of symptoms** | 0% | **35** | **35** |
| **at the last assessments** | >0% to 5% | **-** | **-** |
|  | >5% to 10% | **-** | **-** |
|  | >10% to 15% | **-** | **-** |
|  | >15 % | **-** | **-** |

**Across the efficacy trials, no sign of phytotoxicity was recorded at all.**

**Onion (*Allium cepa* / ALLCE) (KCP 6.4.1)**

A phytotoxicity assessment was conducted in 14 efficacy trials in the Maritime zone in Germany (4 trials), the Netherlands (4 trials), and in the North-East EPPO climatic zone in Poland (6 trials).

Altogether 9 different varieties were tested and are presented in Table 3.4‑3.

Table ‑: Varieties tested in efficacy trials – Onion

| **Varieties tested in onion** | | |
| --- | --- | --- |
| TONDA MUSONA  DORMO  CENTRO | SUPRA  MAJKA  SOCHACZEWSKA | HOZA  FASTO  OLOROSA MIESZAN |

The phytotoxicity assessments of BAS 743 03 F at the full dose rate are summarized in Table 3.4‑4.

Table ‑: Phytotoxicity in efficacy trials; Onion.

| **Number of trials with phytotoxicity** | | **Efficacy trials (14)** | |
| --- | --- | --- | --- |
| **BAS 743 03 F** | **Standard** |
| **2.0 L/ha** |
| **Phytotoxicity** | 0% | **14** | **14** |
| **recorded during the trials** | >0% to 5% | **-** | **-** |
|  | >5% to 10% | **-** | **-** |
|  | >10% to 15% | **-** | **-** |
|  | >15 % | **-** | **-** |
| **Level of symptoms** | 0% | **14** | **14** |
| **at the last assessments** | >0% to 5% | **-** | **-** |
|  | >5% to 10% | **-** | **-** |
|  | >10% to 15% | **-** | **-** |
|  | >15 % | **-** | **-** |

**Across the efficacy trials, no sign of phytotoxicity was recorded at all.**

**Tomato (*Solanum lycopersicum* / LYPES) (KCP 6.4.1)**

A phytotoxicity assessment was conducted in 5 efficacy trials in the North-East EPPO climatic zone in Poland.

Altogether 5 different varieties were tested and are presented in Table 3.4‑5.

Table ‑: Varieties tested in efficacy trials – Tomato.

| **Varieties tested in onion** | |
| --- | --- |
| SCOOTER  RUMBA O¿AROWSKA  NUN00507 | PIETRAROSSA  DYNO |

The phytotoxicity assessments of BAS 743 03 F at the full dose rate are summarized in Table 3.4‑6.

Across the efficacy trials, no sign of phytotoxicity was recorded at all.

Table ‑: Phytotoxicity in efficacy trials; Tomato.

| **Number of trials with phytotoxicity** | | **Efficacy trials (5)** | |
| --- | --- | --- | --- |
| **BAS 743 03 F** | **Standard** |
| **2.0 L/ha** |
| **Phytotoxicity** | 0% | **5** | **5** |
| **recorded during the trials** | >0% to 5% | **-** | **-** |
|  | >5% to 10% | **-** | **-** |
|  | >10% to 15% | **-** | **-** |
|  | >15 % | **-** | **-** |
| **Level of symptoms** | 0% | **5** | **5** |
| **at the last assessments** | >0% to 5% | **-** | **-** |
|  | >5% to 10% | **-** | **-** |
|  | >10% to 15% | **-** | **-** |
|  | >15 % | **-** | **-** |

**Across the efficacy trials, no sign of phytotoxicity was recorded at all.**

**Summary and conclusions on Phytotoxicity to host crop (KCP 6.4.1)**

Across all efficacy trials, no sign of phytotoxicity was recorded. Therefore, it can be concluded, that BAS 743 03 F is fully selective in potatoes, onions, and tomatoes when applied at the target dose rate of 2.0 L/ha.

|  |
| --- |
| **Conclusion – Phytotoxicity**  BAS 743 03 F was fully selective in potato, onion and tomato crops. It is therefore maintained that this fungicide is safe when used as proposed. |

### Effect on the yield of treated plants or plant product (KCP 6.4.2)

The summary of the results on yield and the quality parameters obtained from the efficacy trials in the presence of challenging pest populations is presented in chapter 3.2.3. No information on yield from trials without disease is provided here.

Based on the fact, that no adverse effects on the yield and the quality indicators were observed in all efficacy trials in the presence of disease, no negative impact is expected on crops in the trials without the disease.

|  |
| --- |
| **Conclusion –**  **Effect on the yield of treated plants or plant product**  No yield data has been supplied by the applicant. EPPO standard PP1/135(4) phytotoxicity assessment table 1 shows no specific selectivity trials for yield. The case presented by the applicant is acceptable and no further data are required. |

### Effects on the quality of plants or plant products (KCP 6.4.3)

No information is provided here.

|  |
| --- |
| **Conclusion –**  **Effects on the quality of plants or plant products**  No quality data has been supplied by the applicant. EPPO standard PP1/135(4) phytotoxicity assessment table 1 shows no specific selectivity trials for yield. The case presented by the applicant is acceptable and no further data are required. |

### Effects on transformation processes (KCP 6.4.4)

For certain types of treatments with plant protection products, it may be necessary to provide evidence that the use of the product does not give a taint (unpleasant taste or smell) to the harvested or processed plant product. This is described under EPPO PP1/242 (2) – Taint tests.

Many crops such as potatoes, onions, and tomatoes are usually produced for fresh consumption, and no transformation processes are performed. When processing occurs, it consists of baking, freezing, canning, juicing, or in the elaboration of purees and dicing. These processes are physical or chemical and do not depend on the biological activity that might be affected by the product.

Effects on transformation processes were tested in potatoes. While the full study report is available under Doc ID: 2021/2000057, the following subchapter briefly summarizes this study.

Potato (*Solanum tuberosum*/SOLTU) (KCP 6.4.4)

Sensory evaluation of potatoes treated with the fungicide was conducted using the Triangle Test Method TES-S-001. Prior to sensory testing, the potatoes (treated and untreated) were processed into quick-frozen potato chips by the Product Innovation Team at Campden BRI (Chipping Campden).

* **Methods and References**

**Method reference**: EPPO Guideline PP 1-242 (2): Taint Tests

Efficacy Guideline Taint Tests with Pesticides 301

Triangle Test No. TES-S-001 (British Standard, Sensory Analysis – Methodology –

Triangle Test, BS EN ISO 4120: 2007)

**Deviations from method**: A panel of sensory assessors conducted triangle tests for sensory difference at CRD and the client’s request. NOTE: Due to Covid-19 restrictions, 12 assessors each completed two replications, thereby providing a total of 24 evaluations (judgements) per test

* **Sample Information**

**Date samples received**: 28/09/2020

**Stored:** Prior to sensory testing, the treated and untreated potato chip samples were stored in the Product Innovation Team Freezer (quick-frozen)

**Date samples tested**: Sample 1 - 26/10/2020

Sample 2 and Sample 3 – 04/11/2020

* **Preparation**

The potato chips (four packs each of untreated and treated) were deep fried separately in vegetable oil using a temperature- controlled twin compartment deep fat fryer. The chips were fried in separate labelled compartments, at 190°C for 7-9 minutes until golden brown in colour and tender. Once drained on paper towel, the samples were transferred into two coded labelled glass dishes, placed on a heated tray and covered loosely with foil to maintain the temperature of the samples. Each assessor received two chips per coded container presented following the experimental design of the test.

* **Sensory Testing**

The samples were evaluated using the Triangle Test Procedure (TES-S-001). In the triangle test each assessor is presented with a set of three coded samples, two of which are the same and one of which is different. The sets of samples are presented equally often in each of the six possible orders; this experimental design minimises any possible order and carryover effects. Twelve trained assessors are used for each test, six receiving ‘Treated/Test’ as the ‘different’ sample and six receiving ‘Untreated/Control’ as the ‘different’ sample. After tasting the three samples in the designated order, each assessor is asked to select the different sample and to describe the difference(s) perceived.

* **Test Conditions**

The test was carried out in a purpose-built testing room. Each assessor was required to undertake the tests in an individual sensory booth. The room was positively pressurised to minimise the entrance of external odours. Coloured lighting was used to mask any colour difference between the samples. The panel were instructed to use plain crackers and industrially filtered cold water (served at room temperature) as palate cleansers to minimise any sample carry-over.

* **Triangle Test Results**

For a triangle test with 24 judgements, a minimum of 13 correct judgements are required to establish a significant difference between samples at the 5% (α) level of significance (British Standard, Sensory Analysis – Methodology – Triangle Test, BS EN ISO 4120: 2007). For each test, 24 evaluations (12 assessors x 2 replications) were performed by the panel. Results of the test are in Table 3.4‑7.

The test results above show that in Test Ref. No: 150727/44T/QF there was a significant difference perceived between the control and test samples at the 5% alpha (α) significance level but no taint. Whereas the test results for Test Ref. No: 150727/47T/QF and 150727/48T/QF show there was no significant difference perceived between the control and test samples at the 5% alpha (α) significance level and no taint.

*ND = No significant difference at the 5% level of significance*

*NT = Significantly different at the 5% level of significance but no taint*

*ND(T) = No significant difference at the 5% level of significance, but a taint detected by two or more panel members*

*T = Significantly different at the 5% level of significance, and a taint*

*T(P) = Significantly different at the 5% level of significance, and a potential taint detected by two or more panel members*

Table ‑: Summary of the results.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Test Reference No.** | **No.**  **of**  **Assessors** | **No.**  **of**  **Evaluations** | **No. Correctly**  **Identifying**  **the Different**  **Sample** | **Significance** |
| Sample 1 Potatoes, Frozen Chipped | 12 | 24 | 18 | NT |
| Sample 2 Potatoes, Frozen Chipped | 12 | 24 | 10 | ND |
| Sample 3 Potatoes, Frozen Chipped | 12 | 24 | 9 | ND |

* **Summary**

**Test Ref No: Sample 1.** There was a statistically significant difference, at the 5% significance level, detected between the treated and untreated Potato Chips in Test Ref No: Sample 1. One assessor described the treated potato chip sample as having a slightly stronger earthy note. However, this was an isolated comment and no further potential taint descriptors were perceived; this test has therefore been reported as statistically significant but not tainted (NT).

**Test Ref No: Sample 2.** There was no statistically significant difference, at the 5% significance level, detected between the treated and untreated potato chips in Test Ref No: Sample 2. No potential taint descriptors were recorded for the treated potato chip sample; this test has therefore been reported as not tainted (ND).

**Test Ref No: Sample 3.** There was no statistically significant difference, at the 5% significance level, detected between the treated and untreated potato chips in Test Ref No: Sample 3. One assessor described the treated potato chip sample as having a metallic, earthy flavour. However, this was an isolated comment and no further potential taint descriptors were perceived, this test has therefore been reported as not tainted (ND).

Summary and conclusions on the effects on transformation processes (KCP 6.4.4)

In one of the tests conducted, a statistically significant difference, at the 5% significance level, was detected between the treated and untreated Potato Chips (Test Ref No: Sample 1). Although one assessor described the treated potato chip sample as having a slightly stronger earthy note, this was an isolated comment. Therefore, this test, as well as the other two, were reported as not tainted. In conclusion, BAS 743 03 applied at the target dose rate of 2.0 L/ha, has no adverse effect on the transformation processes in potatoes.

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| **Conclusion – Effects on transformation processes**  A sensory evaluation of the potatoes treated with the fungicide showed that no potential taint descriptors were recorded for the chip samples treated with BAS 743 03 F compared to the untreated samples. These results confirm that the product has no adverse effect on potato quality or processing. |

### Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

The product BAS 743 03 F has demonstrated to be highly selective on a wide range of crops and varieties. Although, no adverse effects are expected from the use of BAS 743 03 F on plants or plant parts used for propagating purposes when the product is applied following the Good Agricultural Practice proposed, in accordance with EPPO standard PP 1/135 (4), 3 germination studies were conducted between 2020 and 2021 in the United Kingdom. The full study reports are available under Doc IDs: 2022/2026296, 2022/2046728 and 2022/2046727. The following subchapter briefly summarizes the results of these studies.

Potato (*Solanum tuberosum*/SOLTU) (KCP 6.4.5)

Three germination studies were conducted in the United Kingdom in 2020 (1 trial) and 2021 (2 trials). Tests were conducted on harvested potato tubers treated with 2.0 L/ha of BAS 743 AT F/ BAS 743 BJ F (the older formulations of BAS 743 03 F delivering the same active ingredients, amount, and ratio) and compared to untreated samples and a reference standard product.

Details on tests are provided in Table 3.4‑8.

Table ‑: Germination tests; Potato.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Doc ID** | **Variety** | **EPPO zone** | **Product** | **GS at application** | **Product Rate** | **Spray interval** |
| 2022/2026296 | Rocket | Maritime (UK) | BAS 743 AT F  (BAS 743 00 F) | BBCH 75-89 | 2.0 L/ha | 7 days |
| Revus  (BAS 94120 F) | BBCH 61-71 | 0.6 L/ha | 7 days |
| 2022/2046727 | Rocket | Maritime (UK) | BAS 743 BJ F  (new name BAS 743 03 F) | BBCH 75-89 | 2.0 L/ha | 7 days |
| Revus  (BAS 94120 F) | BBCH 55-65 | 0.6 L/ha | 7 days |
| 2022/2046728 | Maris Piprer | Maritime (UK) | BAS 743 BJ F  (new name BAS 743 03 F) | BBCH 71-89 | 2.0 L/ha | 7 days |
| Revus  (BAS 94120 F) | BBCH 35-69 | 0.6 L/ha | 7 days |

The test items were applied as a spray application. No problems were encountered during mixing or application of any of the product formulations mixtures under test. No phytotoxic symptoms or treatment related crop vigour differences were observed on the trial at any of the assessment timings. No effects on other pest or non-target organisms were noted during trial conduct

Summary and conclusions on the effects on the impact on treated plants or plant products to be used for propagation

Based on the presented results it can be concluded that BAS 743 03 F from all 3 trials, over 2 years, at the recommended dose rate of 2.0 L/ha did not negatively influence the germination behaviour, shoot length or tuber weight of harvested and stored potatoes.

|  |
| --- |
| **Conclusion –**  **Impact on treated plants or plant products to be used for propagation**  BAS 743 03 F applied at the proposed maximum label rate of 2.0 l/ha and according to other label recommendations on claimed uses would not be expected to have an adverse impact on treated plants or plant products to be used for propagation. |

## Observations on other undesirable or unintended side-effects (KCP 6.5)

### Impact on succeeding crops (KCP 6.5.1)

The adverse effects on rotational or replacement crops are evaluated following “EPPO PP 1/135 (4) Phytotoxicity assessment and PP1/207 (2) Effects on succeeding crops”. Details on the fate and behaviour of the active ingredients and results from a glasshouse study are presented to show the nature of the biological activity. More information can be found in the trial report in Part K and Part B Section 9.10 - Ecotoxicological studies.

A succeeding crop study was carried out in 2021 (Doc ID: 2020/2078640), where the influence of substrate contamination with the formulation BAS 743 01 F on the germination and growth of different crops was tested in pot trials in the greenhouse. Although no BAS 743 03 F formulation trials were conducted, BAS 743 01 F and BAS 743 03 F deliver the same active ingredients. The comparison of BAS 743 01 F and BAS 743 03 F is in Table 3.5-1 below. Furthermore, in the study summarized below, where BAS 743 01 F was tested at a much higher dose rate (7.0 L/ha = 960 g active ingredient [a.i.] /ha Ametoctradin + 3024 g a.i./ha Propamocarb) compared to an intended dose rate of BAS 743 03 F (2.0 L/ha), no negative effects on germination rate or the presence of phytotoxicity were observed. Therefore, no adverse effects on succeeding crops are expected from using BAS 743 03 F when the product is applied following the recommended Good Agricultural Practice.

Table 3.5-: Comparison of the formulations: BAS 743 01 F vs BAS 743 03 F.

|  |  |  |
| --- | --- | --- |
| **Formulation** | **BAS 743 01 F** | **BAS 743 03 F** |
| **Components** | 137.14 g/L ametoctradin  515 g/L Propamocarb  (equivalent to 432 g propamocarb/L)  10g/L Ethylan NS 500 LQ | 120g/L ametoctradin  451g/L Propamocarb  (equivalent to 378 g Propamocarb/L) |
| **Type** | Suspension concentrate | Suspension concentrate |

Guidelines covered by the study were the following:

* EPPO Guideline PP 1/207 (2)
* EPPO Guideline PP 1/135 (4)
* ISTA method, 2004, chapter 5
* BBCH scale 2nd Edition 1997
* XXXX SOP Succeeding Crops AUG 2014.docx

The following 10 species were tested (Table 3.5-2)

Table 3.5-: Crops tested in succeeding crops study.

| ***Crop (Scientific name)*** | ***Crop (common name)*** | ***Variety*** |
| --- | --- | --- |
| *Beta vulgaris* | Sugar beet | Danicia |
| *Brassica napus* | Oilseed rape | Licapo |
| *Oaucus carota* | Carrot | Tozresis F1 |
| *Helianthus annuus* | Sunflower | Sunrich Orange F1 |
| *Hordeum vulgare* | Winter barley | Astrid |
| *Pisum sativum* | Pea | Livioletta |
| *Solanum tuberosum* | Potato | Bintje |
| *Triticum aestivum* | Winter wheat | Monopol |
| *Vicia faba* | Broad bean | Taifun |
| *Zea mays* | Maize | Ronaldinio |

Before cultivation of the crops, BAS 743 01 F was incorporated into the substrate. According to the PEC soil calculation, a dose rate of 7.0 L/ha BAS 743 01 F (= 960 g active ingredient [a.i.]/ha Ametoctradin + 3024 g a.i./ha Propamocarb) was applied. This is the 4- fold targeted registration rate.

PEC soil of Ametoctradin and Propamocarb after yearly, multi-year application of BAS 743 01 F to various crops and maximum concentration after application in the succeeding crop experiment at four times elevated application rate (SOP 4) (Table 3.5-3).

Table 3.5-: PEC soil calculated for ametoctradin and propamocarb.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Substance** | **GAP-L scenario** | | | **SOP 2 scenario** |
| **PEC soil, plateau**  **[mg/kg]**  **(20 cm tillage)** | **PEC soil, max**  **[mg/kg]** | **PEC soil, acc**  **[mg/kg]** | **PEC soil, act**  **[mg/kg]** |
| Ametoctradin | 0.273 | 0.462 | 0.735 | 0.738 |
| Propamocarb | 0.072 | 1.486 | 1.557 | 2.326 |

Assessments carried out were as follows:

• Phytotoxicity was assessed as a percentage of injured plants at GS 12.

• Germination was evaluated by counting the seedlings according ISTA at GS 12.

• Plant height in cm (for monocots) and plant weight (fresh matter) in g/plant for all crops were measured at GS 12.

Results showed that none of the tested crops showed crop injury when grown in substrate treated with BAS 743 01 F, moreover none of the tested crops grown in substrate treated exhibited a negative influence on germination rate in relation to the untreated substrate. No negative effect on plant weight or plant height was observed.

Therefore, it can be concluded that there are no indications for expecting a risk of damage to following crops due to application of BAS 743 01 F. There is no necessity for restrictions in the choice of following crops, even in the event of crop failure on a field which has been treated with BAS 743 01 F.

|  |
| --- |
| **Conclusion to Impact on succeeding crops**  The trials carried out are only in conformity with the established experimental design of the EPPO Standard PP 1/207 *Effects on succeeding crops* and EPPO PP 1/135 (4) *Phytotoxicity assessment*. The applicant submitted data from germination and growth test to support this section. No negative effects were observed in any of the 10 different crops.  It can be concluded to accept the data provided by the applicant to demonstrate no negative impacts for succeeding crops. |

### Impact on other plants including adjacent crops (KCP 6.5.2)

One study on seedling emergence and one study on vegetative vigour on non-target terrestrial plants were conducted with the formulation of BAS 743 02 F (137.14 g/L of ametoctradin, 515 g/L Propamocarb-hydrochloride = equivalent to 432 g Propamocarb/ L) by Agro-check in 2023 to demonstrate the lack of adverse effects of ametoctradin and propamocarb in other plants including adjacent crops. Although no BAS 743 03 F formulation trials were performed, BAS 743 02 F delivers the same active ingredients as BAS 743 03 F. The comparison of BAS 743 02 F and BAS 743 03 F components is in Table 3.5-4 below. As the BAS 743 02 F product applied pre- and post-emergence with a rate of 3.85 L/ha did not cause any adverse effects, no negative impact on adjacent crops is expected from using BAS 743 03 F at the intended dose rate of 2.0 L/ha when the product is applied following the recommended Good Agricultural Practice.

Table 3.5-: Comparison of the formulations: BAS 743 02 F vs BAS 743 03 F.

|  |  |  |
| --- | --- | --- |
| **Formulation** | **BAS 743 02 F** | **BAS 743 03 F** |
| **Components** | 137.14 g/L ametoctradin  515 g/L Propamocarb  (equivalent to 432 g propamocarb/L) | 120g/L ametoctradin  451g/L Propamocarb  (equivalent to 378 g Propamocarb/L) |
| **Type** | Suspension concentrate | Suspension concentrate |

Guidelines covered by the studies were:

* Ecological Effects Test Guidelines OCSPP 850.4150: Vegetative Vigor (EPA 712-C-011) January 2012
* EPA, Ecological Effects Test Guidelines: OCSPP 850.4150: Vegetative Vigour (adopted January 2012)
* OECD Guidelines for the Testing of Chemicals; Test No. 208 Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test, 19 July 2006
* Ecological Effects Test Guidelines OCSPP 850.4100: Seedling Emergence and Seedling Growth (EPA 712-C-012) January 2012

Table 3.5-: Studies on the impact on other plants, including adjacent crops.

| **Doc ID** | **Study title** | **Testing facility** | **GLP** |
| --- | --- | --- | --- |
| 2022/2033722 | Effect of BAS 743 02 F on seedling emergence and seedling growth of several species of terrestrial plants under greenhouse conditions | Agro-check | YES |
| 2022/2033723 | Effect of BAS 743 02 F on vegetative vigour of several species of terrestrial plants under greenhouse conditions |

Summary of the conclusion are included below, while study reports are included in Part K (study files), confidential information. For more details refer to Part B Section 9.10 - Ecotoxicological studies.

* ***Effect of BAS 743 02 F on seedling emergence and seedling growth of several species of terrestrial plants under greenhouse conditions***

**Objective**

The effect of BAS 743 02 F on seedling emergence and seedling growth of ten species of terrestrial plants was assessed in a greenhouse study (limit test).

Ten different crops were chosen to represent a broad range of non-target plants, namely: carrot (Daucus carota L.); lettuce (*Lactuca sativa L*.); oilseed rape (Brassica napus L. ssp. napus); cucumber (*Cucumis sativus L.*); soybean (*Glycine max L*.); tomato (*Solanum lycopersicum L.*); onion (*Allium cepa L.*); ryegrass (*Lolium multiflorum L*.); wheat (*Triticum aestivum L*.); corn (*Zea mays L*.)

**Results**

Based on the results of this study, conducted under greenhouse conditions, it can be concluded that the fungicide BAS 743 02 F applied pre-emergence with a rate of 3.85 L/ha did not cause effects to the seedling emergence, plant survival, visual phytotoxicity, plant development (BBCH), plant length and plant dry biomass of the tested plant species. For all tested species an ER50 > 3.85 L/ha was detected. For all tested species an ER50 > 3.85 L/ha was detected.

* ***Effect of BAS 743 02 F on vegetative vigour of several species of terrestrial plants under greenhouse conditions***

**Objective**

The effect of BAS 743 02 F on vegetative vigour of ten species of terrestrial plants was assessed in a greenhouse study (limit test).

Ten different crops were chosen to represent a broad range of non-target plants, namely: carrot (Daucus carota L.); lettuce (*Lactuca sativa L*.); oilseed rape (Brassica napus L. ssp. *napus*); cucumber (*Cucumis sativus L.*); soybean (*Glycine max L*.); tomato (*Solanum lycopersicum L.*); onion (*Allium cepa L.*); ryegrass (*Lolium multiflorum L*.); wheat (*Triticum aestivum L*.); corn (*Zea mays L*.)

**Results**

Based on the results of this study, conducted under greenhouse conditions, it can be concluded that BAS 743 02 F applied post emergence with a rate of 3.85 L/ha did not cause effects to visual plant phytotoxicity, plant survival, plant length and plant dry biomass for all tested plant species. For all tested species an ER50 > 3.85 L/ha was detected.

|  |
| --- |
| **Conclusion – Impact on other plants including adjacent crops**  The data demonstrates an acceptable risk to non-target terrestrial plants for all intended uses of BAS 743 03 F. 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.  It can be concluded to accept the data provided by the applicant to demonstrate no negative impacts for adjacent crops. |

### Effects on beneficial and other non-target organisms (KCP 6.5.3)

No adverse effects on beneficial or non-target organisms were recorded in efficacy trials during the development phase of BAS 743 03 F. In laboratory as in field, testing never revealed another effect of the product than a fungicide activity on diseases listed.

For detailed studies on the possible adverse effects to beneficial organisms see Part B, Section 9 (Ecotoxicology).

|  |
| --- |
| **Conclusion –**  **Effects on beneficial and other non-target organisms**  No adverse effects on beneficial or non-target organisms were recorded in efficacy trials during the development phase of BAS 743 03 F . The case presented by the applicant is acceptable and no further data are required. |

### Summary and conclusion (KCP 6.5)

Considering the studies mentioned above, no adverse effects on treated crops are expected from using BAS 743 03 F at the intended dose rate of 2.0 L/ha when the product is applied following the Good Agricultural Practice.

## Other/special studies (KCP 6.6)

### Physical and chemical compatibility

The physical and chemical compatibility of BAS 743 AT F (the older formulation of BAS 743 03 F) and the formulation BAS 743 03 F was tested in mixture with 11 mixtures (Table 3.6-1) and 9 mixtures (Table 3.6-2). The full study reports are available under Doc ID: 2021/2000190 and 2022/2004497 and the following subchapter briefly summarizes the results of this study.

Table 3.6-: Mix partners in compatibility study for BAS 743 AT F.

| **Test**  **Mixture** | **Trade name(s)** | **Active ingredient(s)** | **Formulation type** |
| --- | --- | --- | --- |
| 1 | Belanty Fungicide | 75 g/L Mefentrifluconazole | SC |
| BAS 750 11 F |
| 2 | Dithane NeoTec | 75 % Mancozeb | WG |
| BAS 266 10 F |
| 3 | Decis Protech | 15 g/L Deltamethrin | EW |
| BAS 9034 5 I |
| 4 | Narita | 250 g/L Difenoconazole | EC |
| BAS 9150 8 F |
| 5 | Signum 33 WG | 26,7 % Boscalid + 6,7 % Pyraclostrobin | WG |
| BAS 516 07 F |
| 6 | Mospilan 20 SG | 20 % Acetamiprid | SG |
| BAS 9111 9 I |
| 7 | No Tradename | 120 g/L Dimpropyridaz-N-ethyl-5-methyl-1-[(2RS)-3-  methylbutan-2-yl]-N-(pyridazin-4-yl)-1H-pyrazole-4- carboxamide | SL |
| BAS 550 01 I |
|
| 8 | Teppeki | 50 % Floricamid | WG |
| BAS 9146 0 I |
| 9 | Movento 150 OD | 150 g/L Spirotetramat | OD |
| BAS 9220 1 I |
| 10 | Spintor | 480 g/L Spinosad | SC |
| BAS 9153 2 I |
| 11 | Para Sommer | 654 g/L Paraffin oil ( = 75 %) | EW |
| BAS 9008 7 S |

*Physical compatibility according to Regulation (EU) No. 284/2013, Part B 2.9.1*

In total 11 mixtures of BAS 743 AT F with other plant protection products were tested. All mixtures were determined to be physically compatible and can be used in spray applications. In all mixtures no lumping and no flocculation occurred. The mixtures appeared to be homogeneous.

*Therefore, BAS 743 AT F is apparently physically compatible with the tested products.*

*Chemical compatibility according to Regulation (EU) No. 284/2013, Part B 2.9.1*

Ametoctradin and propamocarb, the active substances of BAS 743 AT F, are stable in diluted aqueous conditions. Therefore, none of the functional groups are likely to react under normal tank mix conditions. The tank mix partners described in Table 3.6-1 are approved commercial products for applications in various tank mixtures as they are sufficiently stable in aqueous conditions. No indication of any chemical reaction between the mixed products was observed.

*Therefore BAS, 743 AT F is apparently chemically compatible with the tested products.*

* **Conclusion**

The tank mixture of BAS 743 AT F with the other plant protection products described in the report was found to be a homogeneous emulsion with good physical user properties at the recommended use rates. BAS 743 AT F is therefore physical compatible with the other plant protection products described in the report under normal tank mix conditions. The physicochemical data of each mixing component, the chemical stability of the active ingredients and the stable pH of the mixture indicate that BAS 743 AT F is apparently chemically compatible with the other plant protection products described in this study.

Table 3.6-: Mix partners in compatibility study for BAS 743 03 F.

| **Test**  **Mixture** | **Trade name(s)** | **Active ingredient(s)** | **Formulation type** |
| --- | --- | --- | --- |
| 1 | Signum 33 WG | 26.7 % Boscalid + 6.7 % Pyraclostrobin | WG |
| BAS 516 07 F |
| 2 | Axalion | 120 g/L Reg.Nr. 5845955 | SL |
| BAS 550 01 I |
| 3 | Belanty Fungicide | 75 g/L Mefentrifluconazole | SC |
| BAS 750 11 F |
| 4 | Decis Protech | 15 g/L Deltamethrin | EW |
| BAS 9034 5 I |
| 5 | Mospilan 20 SG | 20 % Acetamiprid | SG |
| BAS 9111 9 I |
| 6 | Teppeki | 50 % Flonicamid | WG |
| BAS 9146 0 I |
| 7 | Narita | 250 g/L Difenoconazole | EC |
| BAS 9150 8 F |
|
| 8 | Spintor | 480 g/L Spinosad | SC |
| BAS 9153 2 I |
| 9 | Movento 150 OD | 150 g/L Spirotetramat | OD |
| BAS 9220 1 I |

*Physical compatibility according to Regulation (EU) No. 284/2013, Part B 2.9.1*

In total 9 mixtures of BAS 743 03 F with other plant protection products were tested. All mixtures were determined to be physically compatible and can be used in spray applications. In all mixtures no lumping and no flocculation occurred. The mixtures appeared to be homogeneous.

*Therefore, BAS 743 03 F is apparently physically compatible with the tested products.*

*Chemical compatibility according to Regulation (EU) No. 284/2013, Part B 2.9.1*

Ametoctradin and propamocarb, the ingredients of BAS 743 03 F, are stable in diluted aqueous conditions. Therefore, none of the functional groups are likely to react under normal tank mix conditions. The tank mix partners described in Table 3.6-2 are approved commercial products for applications in various tank mixtures as they are sufficiently stable in aqueous conditions. No indication of any chemical reaction between the mixed products was observed.

*Therefore BAS 743 03 F is apparently chemically compatible with the tested products.*

* **Conclusion**

The tank mixtures of BAS 743 03 F with the other plant protection products described in this report were found to be homogeneous with good physical properties at the recommended use rates. BAS 743 03 F is therefore physically compatible with the other plant protection products described in this report under normal tank mix conditions. The physicochemical data of each mixing component, the chemical stability of the ingredients and the stable pH of the mixtures indicate that BAS 743 03 F is apparently chemically compatible with the other plant protection products described in this study.

|  |
| --- |
| **Conclusion –**  **Physical and chemical compatibility**  The case presented by the applicant is acceptable. |

## List of test facilities including the corresponding certificates.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Country** | | **Institute** | | **Street 1** | **Town** | **GEP** |
| DE | | BASF SE | | SPEYERER STR. 2 | LIMBURGERHOF | 2018/1238674 |
| IE | | Eurofins Agroscience Serv | | Slade Lane | Melbourne | 2020/2099466 |
| IE | | Eurofins Agroscience Serv | | Slade Lane | Melbourne | 2020/2099466 |
| NL | | BASF Nederland BV | | Groningensingel 1 | Arnhem | 2019/2047841 |
| DE | | BASF SE | | Speyererstr.2 | Limburgerhof | 2020/2095366 |
| DE | | BASF SE | | Speyererstr.2 | Limburgerhof | 2020/2095366 |
| DE | | BASF SE | | Speyererstr.2 | Limburgerhof | 2020/2095366 |
| NL | | BASF Nederland BV | | Groningensingel 1 | Arnhem | 2019/2047841 |
| DE | | BASF SE | | Repker Damm 11 | Bühren | 2020/2095366 |
| IE | | Eurofins Agroscience Serv | | Slade Lane | Melbourne | 2021/2034664 |
| IE | | Eurofins Agroscience Serv | | Slade Lane | Melbourne | 2021/2034664 |
| DE | | BASF SE | | Speyerer Strasse 2 | Limburgerhof | 2018/1238674 |
| NL | | BASF Nederland BV | | Groningensingel 1 | Arnhem | 2019/2047841 |
| PL | | Staphyt Sp. z o.o | | ul. Ziębicka 2 | Poznan / Poland | 2011/1269209 |
| PL | | Lab. of phytopathology | | Konstytucji 3 Maja 1/3 | Skierniewice | 2017/1226923 |
| PL | | Agreco Sp. z o.o. | | Gac 64A | Olawa | 2018/1181238 |
| PL | | IHAR-PIB, Oddział Bonin | | Bonin 3 | Bonin | 2011/1288614 |
| PL | | IOR-PIB Poznań | | Władysława Węgorka 20 | POZNAŃ | 2011/1269209 |
| PL | | SGS Polska Sp z o.o. | | Jana Kazimierza 3 | Warszawa | 2016/1350127 |
| PL | | Staphyt Sp. z o.o | | ul.Poznańska 62/53 | Poznań / Poland | 2011/1239203 |
| PL | | Agreco Sp. z o.o. | | Gac 64A | Olawa | 2021/2039159 |
| PL | | IOR-PIB POZNAŃ | | WŁ.WĘGORKA 20 | POZNAŃ | 2011/1269209 |
| RO | | EUROFINS AGROSCIENCE SERV | | Muntele mic No 20 | Giarmata | 2015/1174500 |
| RO | | AgroProspect SRL | | Principala No.1 | FANTANA | 2013/1399864 |
| RO | | SGS | | Bucovinei 56 | Timisoara | 2019/2038531 |
| HU | | SGS Hungária KFT | | Sirály u.4. | Budapest | 2019/2039376 |
| HU | | SZSZBMKH NYHJH ÉBNTF NTO | | Kotaji ut 33. | Nyiregyhaza | 2019/2039378 |
| RO | | BASF | | Str.Morii Nr.21 | Tamadau Mare | 2016/1135081 |
| RO | | BASF | | Str.Morii Nr.21 | Tamadau Mare | 2016/1135081 |
| RO | | SGS | | Bucovinei 56 | Timisoara | 2019/2038531 |
| HU | | SGS Hungária KFT | | Sirály u.4 | Budapest | 2019/2075561 |
| RO | | BASF | | Str.Morii Nr.21 | Tamadau Mare | 2016/1135081 |
| RO | | BASF | | Str.Morii Nr.21 | Tamadau Mare | 2016/1135081 |
| HU | | AGROPASS Hungária Kft. | | Napóleon utca 10. | Győr | 2019/2039801 |
| NL | BASF NL | | GRONINGENSINGEL 1 | | ARNHEM | 2019/2047841 |
| NL | BASF NL | | GRONINGENSINGEL 1 | | ARNHEM | 2019/2047841 |
| DE | BASF SE | | SPEYERER STR. 2 | | LIMBURGERHOF | 2013/1412362 |
| DE | BASF SE | | SPEYERER STR. 2 | | LIMBURGERHOF | 2013/1412362 |
| DE | ARS LIMBURGERHOF | | SPEYERER STR. 2 | | LIMBURGERHOF | 2020/2095366 |
| NL | BASF NL | | GRONINGENSINGEL 1 | | ARNHEM | 2019/2047841 |
| DE | BASF SE | | SPEYERER STR. 2 | | LIMBURGERHOF | 2020/2095366 |
| NL | BASF NL | | GRONINGENSINGEL 1 | | ARNHEM | 2019/2047841 |
| PL | Staphyt Sp. z o.o | | ul. Ziębicka 2 | | Poznan / Poland | 2011/1239203 |
| PL | Lab. of phytopathology | | Konstytucji 3 Maja 1/3 | | Skierniewice | 2017/1226923 |
| PL | Staphyt | | ul. Poznańska 62/53 | | Poznan / Poland | 2011/1239203 |
| PL | Lab. of Phytopathology | | Konstytucji 3 Maja 1/3 | | Skierniewice | 2021/2043748 |
| PL | Agreco Sp. z o.o. | | Gac 64A | | Olawa | 2021/2039159 |
| PL | Lab. of Phytopathology | | Konstytucji 3 Maja 1/3 | | Skierniewice | 2021/2043748 |
| PL | Lab. of phytopathology | | Konstytucji 3 Maja 1/3 | | Skierniewice | 2017/1226923 |
| PL | Agreco Sp. z o.o. | | Gac 64A | | Olawa | 2018/1181238 |
| PL | Lab. of Phytopathology | | Konstytucji 3 Maja 1/3 | | Skierniewice | 2021/2043748 |
| PL | Agreco Sp. z o.o. | | Gac 64A | | Olawa | 2021/2039159 |
| PL | Staphyt Sp. z o.o | | ul. Poznanska 62/53 | | Poznan / Poland | 2011/1239203 |

1. Lists of data considered in support of the evaluation

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
| KCP 6/1 | Gaspar, L |  | Biological Assessment Dossier - BAS 743 03 F - Core C  2023/2022544  XXXX  no  Unpublished | No | XXXX |
| KCP 6.2/1 | Anonymous | 2023 | Dossier Trial Data Reports to the Central Zone Biological Assessment Dossier of BAS 743 03 F - Efficacy trials  2023/2022462  <none>  no  Unpublished | No | XXXX |
| KCP 6.2/2 | Anonymous | 2023 | Dossier Trial Data Reports to the Central Zone Biological Assessment Dossier of BAS 743 03 F - Efficacy trials  2023/2026133  <none>  no  Unpublished | No | XXXX |
| KCP 6.3/1 | Stammler, G. | 2023 | BAS 743 03 F - Resistance Risk Analysis  2023/2010683  XXXX  no  Unpublished | No | XXXX |
| KCP 6.4.4/1 | Rogers, S. | 2020 | Sensory Evaluation of Potatoes (Quick Frozen) Treated with either BAS 743 ATF or BAS 743 AUF (a.i Propamocarb, Initium)  2021/2000057  Campden BRI Ltd., Chipping Campden Gloucestershire GL55 6LD, United Kingdom  yes  Unpublished | No | XXXX |
| KCP 6.4.5/1 | Edmonds M. | 2022 | BAS 743 00 F - Potato Germination Study, 2020  2022/2026296  Eurofins Agroscience Services Ltd., Melbourne Derbyshire DE73 8AG, United Kingdom  yes  Unpublished | No | XXXX |
| KCP 6.4.5/2 | Fordham, R. | 2022 | Potato germination Study (early variety) 2021 - BAS 743 00 F and BAS 743 01 F J94  2022/2046728  Eurofins Agroscience Services Ltd., Melbourne Derbyshire DE73 8AG, United Kingdom  yes  Unpublished | No | XXXX |
| KCP 6.4.5/3 | Fordham, R. | 2022 | Potato germination Study (Maris Piper Variety) 2021 - BAS 743 00 F and BAS 743 01 F J95  2022/2046727  Eurofins Agroscience Services Ltd., Melbourne Derbyshire DE73 8AG, United Kingdom  yes  Unpublished | No | XXXX |
| KCP 6.5.1/1 | Brahm, L. | 2021 | Cultivation of different crops in substrate treated with 743 01 F (Succeeding crops study)  2020/2078640  XXXX  no  Unpublished | No | XXXX |
| KCP 6.5.2/1 | Maleck, A. | 2023 | Effect of BAS 743 02 F on seedling emergence and seedling growth of several species of terrestrial plants under greenhouse conditions  2022/2033722  Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Germany Fed.Rep.  yes  Unpublished | No | XXXX |
| KCP 6.5.2/2 | Maleck, A. | 2023 | Effect of BAS 743 02 F on vegetative vigour of several species of terrestrial plants under greenhouse conditions  2022/2033723  Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Germany Fed.Rep.  yes  Unpublished | No | XXXX |
| KCP 6.6/1 | Anonymous | 2019 | GEP Certificate - XXXX Nederland BV Arnhem 2019  2019/2047841  XXXX  no  Unpublished | No | XXXX |
| KCP 6.6/2 | Anonymous | 2011 | GEP Certificate - Institut of Plant Protection - National Research Institute - Department of Plant Protection Products - Team for Fungicide Investigation, Poznan, Poland  2011/1269209  Institute of Plant Protection - National Research Institute, Poznan, Poland  no  Unpublished | No | XXXX |
| KCP 6.6/3 | Anonymous | 2010 | GEP Certificate: Instytut Hodowli i Aklimatyzacji Roslin - Zaklad nasiennictwa i Ochrony Ziemniaka w Boninie, Bonin, Poland  2011/1288614  <none>  no  Unpublished | No | XXXX |
| KCP 6.6/4 | Anonymous | 2013 | GEP Certificate - SC AgroProspect SRL Brasov, Romania, 2013  2013/1399864  SC AgroProspect Srl, Brasov, Romania  no  Unpublished | No | XXXX |
| KCP 6.6/5 | Anonymous | 2013 | GEP Certificate: XXXX  2013/1412362  XXXX  no  Unpublished | No | XXXX |
| KCP 6.6/6 | Anonymous | 2015 | GEP Certificate: S.C. Eurofins Agroscience Services SRL, Timisoara, Romania, 2015  2015/1174500  Eurofins Agroscience Services SRL, Timisoara, Romania  no  Unpublished | No | XXXX |
| KCP 6.6/7 | Anonymous | 2016 | GEP Certificate - S.C. XXXX - 2016  2016/1135081  S.C. XXXX,  no  Unpublished | No | XXXX |
| KCP 6.6/8 | Laczynski, T. | 2016 | GEP Certificate - SGS Polska Sp. zo.o Warswa Poland - Translation  2016/1350127  SGS Polska Sp. zo.o., Warsaw, Poland  no  Unpublished | No | XXXX |
| KCP 6.6/9 | Anonymous | 2017 | GEP Certificate: Instytut Ogrodnictwa Zaklad Fitopatologii Warzywnictwo Skierniewice, Poland 2017  2017/1226923  Instytut Ogrodnictwa Zaklad Fitopatologii, Skierniewice, Poland  no  Unpublished | No | XXXX |
| KCP 6.6/10 | Anonymous | 2018 | GEP Certificate: AGRECO Sp. z o.o., Wroclaw, Poland 2018  2018/1181238  AGRECO Sp. z o.o., Wroclaw, Poland  no  Unpublished | No | XXXX |
| KCP 6.6/11 | Anonymous | 2018 | GEP Certificate - XXXX - 2018  2018/1238674  XXXX.  no  Unpublished | No | XXXX |
| KCP 6.6/12 | Anonymous | 2018 | GEP Certificate - SGS Romania SA - AFL seed & Crop - 2018  2019/2038531  SGS Romania SA - AFL seed & Crop, Timisoara, Romania  no  Unpublished | No | XXXX |
| KCP 6.6/13 | Anonymous | 2014 | GEP Certificate: SGS Hungaria Kft., Budapest, Hungary  2019/2039376  SGS Hungaria Kft., Budapest, Hungary  no  Unpublished | No | XXXX |
| KCP 6.6/14 | Anonymous | 2018 | GEP Certificate: Szabolcs-Szatmar-Bereg Megyei KH, Nyiregyhaza, Hungary  2019/2039378  no  Unpublished | No | XXXX |
| KCP 6.6/15 | Anonymous | 2018 | GEP Certificate - Agropass Hungaria Kft Gyoer Hungaria - 2018  2019/2039801  Agropass Hungaria Kft., Gyoer, Hungary  no  Unpublished | No | XXXX |
| KCP 6.6/16 | Anonymous | 2019 | GEP Certificate - SGS Hungaria Kft. Hungary - 2019  2019/2075561  SGS Hungaria Kft., Budapest, Hungary  no  Unpublished | No | XXXX |
| KCP 6.6/17 | Anonymous | 2020 | GEP Certificate - XXXX - 2020  2020/2095366  XXXX  no  Unpublished | No | XXXX |
| KCP 6.6/18 | Anonymous | 2020 | Trail Permit Certificate - Eurofins AgroScience Services, Carlow Ireland - 2020  2020/2099466  Eurofins AgroScience Services, Carlow, Ireland  no  Unpublished | No | XXXX |
| KCP 6.6/19 | Anonymous | 2021 | GEP Certificate - Eurofins AgroScience Services, Unit 2 Southcourt, Wexford Road Business Park, Wexford Road, Carlow, R93 HR65, lreland  2021/2034664  Eurofins AgroScience Services, Carlow, Ireland  no  Unpublished | No | XXXX |
| KCP 6.6/20 | Anonymous | 2021 | GEP Certificate - Agreco Sp Warszawa Poland 2021  2021/2039159  AGRECO Sp. z o.o., Wroclaw, Poland  no  Unpublished | No | XXXX |
| KCP 6.6/21 | Anonymous | 2021 | GEP Certificate - Instytut Ogrodnictwa - Panstwowy Instytut Badawczy, Skierniewice, Poland - 2021  2021/2043748  Instytut Ogrodnictwa - Panstwowy Instytut Badawczy, Skierniewice, Poland  no  Unpublished | No | XXXX |

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

There are no studies already evaluated submitted with this section.

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

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