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| REGISTRATION REPORT  **Part B**  Section 1: Identity Section 2: Physical and chemical properties Section 4: Further information  Detailed summary of the risk assessment |
| Product code: BAS 743 03 F  Product name(s): **DIVEXO**  Chemical active substance(s):  Ametoctradin 120 g/L Propamocarb Hydrochloride 451 g/L |
| Central Zone  Zonal Rapporteur Member State: Poland |
| CORE ASSESSMENT  (post-authorisation requirement) |
| Applicant: XXXX  Submission date: April 2025  MS Finalisation date: ~~June 2025~~ August 2025 |

Version history

|  |  |
| --- | --- |
| When | What |
| October 2023 | Initial dRR – XXXX |
| May 2024 | zRMS-PL evaluation |
| November 2024 | Updated dRR – after MSs consultation |
| April 2025 | Updated dRR: post-authorisation requirement – XXXX  KCP 2.7.5 Long term storage stability study added (2 years at 25 °C, HDPE containers) New data added as Table 2-3 Study added to reference list  KCP 4.4/1 Commentary added to signpost the availability of the 2 year storage stability study | |
| June 2025 | zRMS-PL evaluation – post registration data | |
| August 2025 | Updated after MSs consultation | |

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Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substances.

Noticed data gaps are: none

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

# Section 1: Identity of the plant protection product

## Applicant (KCP 1.1)

XXXX

XXXX

XXXX

XXXX

Contact person: XXXX

Tel.No.: +XXXX

e-mail: XXXX

## Producer of the plant protection product and of the active substances (KCP 1.2)

### Producer(s) of the preparation

XXXX

XXXX

XXXX

XXXX

Contact person: XXXX

Tel.No.: +XXXX

e-mail: XXXX

### Producer(s) of the active substance(s)

#### Ametoctradin

XXXX

XXXX

XXXX

XXXX

Contact person: XXXX

Tel.No.: +XXXX

e-mail: XXXX

#### Propamocarb Hydrochloride

XXXX

XXXX

XXXX

XXXX

### Statement of purity (and detailed information on impurities) of the active substance(s)

#### Ametoctradin

|  |  |
| --- | --- |
| Ametoctradin | min. 980 g/kg |

Impurities of toxicological, ecotoxicological or environmental concern:

|  |  |
| --- | --- |
| Amitrole | max. 50 mg/kg |
| o-Xylene | max. 2 g/kg |

according to Review report for the active substance ametoctradin (BAS 650 F) (SANCO/ 12977/2012 rev. 2; 01 February 2013)

Further information is provided in Part C.

#### Propamocarb hydrochloride

Propamocarb hydrochloride (~~salt variant of propamocarb base~~)

min. 690g/kg (TK: technical concentrate) – FAO specification 399.601/TK May 2013 and Review report for the active substance propamocarb (SANCO/10057/2006 final; 25 April 2007)

equivalent to a minimum of purity 92% TC water free material.

The water free material does not exist as an isolated one therefore any composition has to be expressed using the TK purity.

Propamocarb free base is derived from propamocarb hydrochloride with a minimum purity of 690 g/kg (expressed as TK).

Propamocarb hydrochloride does not contain impurities of toxicological, ecotoxicological or environ-mental concern.

Further information is provided in Part C.

## Trade names and producer’s development code numbers for the preparation (KCP 1.3)

|  |  |
| --- | --- |
| Trade name: | Please refer to Registration Report Part A for the relevant country (or) |
| Trade name: | DIVEXO  MAGNUM PRO  ENERVIN DUO  SUPROVA  BAS 743 BJ F (former development code) |
| Company code number: | BAS 743 03 F |

## Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

### Composition of the plant protection product (KCP 1.4.1)

Table 1.4‑1: Active substance(s) and variant(s) of the active substance(s)

| Active substance / variant | Declared content of the pure active substance / variant (g/L) | FAO Limits  (min – max, g/L) | Technical content  (g/L) | Technical  content\*\*\*  (%w/w) |
| --- | --- | --- | --- | --- |
| Ametoctradin | 120 | 112.8 – 127.2 | 122.4\* | 11.44 |
| Propamocarb | 378 | 359.1 – 396.9 | N/A\*\* | N/A\*\* |
| Propamocarb hydrochloride | 451 | 428.5 – 473.6 | 554.1\*\*\*\* | 51.79 |

*\* Based on the minimum purity of the active substance declared for registration in the active substance dossiers (98%)*

*\*\* Because technical propamocarb (base) does not exist in aqueous form, it is not necessary to calculate its hypothetical content in the product*

*\*\*\* Based on the relative density of the formulation = 1.07*

*\*\*\*\* Based on the nominal purity of Propamocarb Hydrochloride TK active substance of 81.4%*

*Note : Molecular weight of propamocarb (base) = 188.3 g/mol  
 Molecular weight of propamocarb (.HCl) = 224.7 g/mol  
 Base to salt conversion factor = 224.7/188.3 = 1.193*

The formulation is not the representative formulation.

Table 1.4‑2: Relevant impurities

| Relevant impurity | Maximum content (g/L or g/kg) 1) |
| --- | --- |
| amitrole | 6.12 mg/L, 5.71 mg/kg |
| o-xylene | 0.245 g/L, 0.23 g/kg |

1) Based on the specified limit of 50 mg/kg amitrole and 2 g/kg o-xylene in TG ametoctradin (see 1.2.3.1) and relative density of the formulation = 1.071.

### Information on the active substance(s) (KCP 1.4.2)

Table 1.4‑3: Information on Ametoctradin

| Type | Name/Code Number |
| --- | --- |
| ISO common name | Ametoctradin |
| CAS No. | 865318-97-4 |
| EC No. | 688-188-6 |
| CIPAC No. | 818 |

Table 1.4‑4: Information on Propamocarb hydrochloride

| Type | Name/Code Number | |
| --- | --- | --- |
| ISO common name | Propamocarb (base) | Propamocarb hydrochloride (salt) |
| CAS No. | 24579-73-5 | 25606-41-1 |
| EC No. | 607-406-2 | 247-125-9 |
| CIPAC No. | 399 | 399.601 |

### Information on safeners, synergists and co-formulants (KCP 1.4.3)

The formulation does not contain any safeners or synergists.

CONFIDENTIAL information is provided separately (Part C).

## Type and code of the plant protection product (KCP 1.5)

|  |  |
| --- | --- |
| Type: Suspension concentrate | [Code: SC] |

## Function (KCP 1.6)

Fungicide

# Section 2: Physical, chemical and technical properties of the plant protection product

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

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

Studies regarding the combination of BAS 743 03 F with other commercial plant protection products were submitted and the application as tank mixture is acceptable.

**zRMS comments**:

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

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

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

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

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

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

No tank mixes are recommended on the product label.

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

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

|  |  |  |
| --- | --- | --- |
| **Classification according to** | **DPD (Directive 67/845/EEC)** | **CLP (Regulation (EC) No 1272/2008)** |
| **Hazard symbol(s)** | **Pictograms** |
| Not required to be provided | None |
| **Indications of danger** | **Signal word** |
| Not required to be provided | None |
| **Hazard class and hazard category** |
| None |

No implication for labelling

Notifier Proposals for Risk and Safety Phrases (KCP 12)

|  |  |  |
| --- | --- | --- |
| With respect to physical/chemical data | **Risk phrases:** | **Hazard statements:** |
| Not required to be provided | Not classified |
| **Safety phrases:** | **Precautionary statements** |
| Not required to be provided | None |

Hazard Statement: None.

Compliance with FAO specifications:

The product BAS 743 03 F complies with FAO specifications of the respective formulation type.

Formulation used for tests

All tests have been conducted with the preparation BAS 743 03 F (or BAS 743 BJ F which is the same formulation by a different formulation code number).

Table 2-1: Physical, chemical and technical properties of the plant protection product

| Annex point | Method used /  deviations | Test material | Findings | GLP Y/N | Reference | Acceptability /  comments |
| --- | --- | --- | --- | --- | --- | --- |
| Colour and  physical state  (KCP 2.1) | Colour and  physical state:  EPA OPPTS 830.6302 (colour), OPPTS 830.6303 (physical state) | BAS 743 03 F  Ametoctradin/Propamocarb 120/378 g/L  Batch FRE-002223 | Colour and physical state:  Homogeneous white opaque free flowing, low viscosity liquid. No supernatant or sediment | Y | 2022/2046342,  Hopley, W., 2022 | Acceptable |
| Explosive properties  (KCP 2.2.1) | OECD 113 | BAS 743 03 F  Ametoctradin/Propamocarb 120/378 g/L  Batch FRE-002223 | The overall exothermic decomposition energy determined by DSC does not go beyond the threshold value of -500 J/g given in the UN-MTC Appendix 6 screening procedures. Therefore, classification procedure for explosives need not be applied to the the test substance and the test substance is not classified as explosive. | Y | 2022/2018332 Dreisch, S. 2022 | Acceptable  Explosive properties of the formulation can be excluded based on UN RTDG criteria and no further test is necessary |
| Oxidizing properties  (KCP 2.2.2) | UN O.2 | BAS 743 03 F  Ametoctradin/Propamocarb 120/378 g/L  Batch FRE-002223 | The test substance shows no oxidizing properties according to the directive. | Y | 2022/2018332 Dreisch, S. 2022 | Acceptable  The formulation is ‘not an oxidizing liquid’ according to the UN Test O.2: “Test for oxidizing liquids” criteria. |
| Flash point  (KCP 2.3.1) | EEC A.9 | BAS 743 03 F  Ametoctradin/Propamocarb 120/378 g/L  Batch FRE-002223 | The test item BAS 743 03 F has no flash point up to a temperature of 125 °C. | Y | 2022/2018332 Dreisch, S. 2022 | Acceptable  The formulation is not classified as flammable liquid (flash point >60°C) according to criteria of CLP reg. |
| Flammability  (KCP 2.3.2) |  |  | Not applicable for liquid formulations |  |  | - |
| Self-heating  (KCP 2.3.3) | EEC A.15 | BAS 743 03 F  Ametoctradin/Propamocarb 120/378 g/L  Batch FRE-002223 | The test item BAS 743 03 F has an auto-ignition  temperature of 430 °C. | Y | 2022/2018332 Dreisch, S. 2022 | Acceptable  The self-heating properties for liquids cannot be determined based on the auto-ignition temperature (Method A.15).  However the formulation is not considered as self-heating based on CLP criteria (under section 2.11.4.2 of Guidance on the Application of the CLP Criteria): ‘*In general, the phenomenon of self-heating applies only to solids. The surface of liquids is not large enough for reaction with air and the test method (UN RTDG test N.4) is not applicable to liquids. Therefore liquids are not classified as self-heating.*’ |
| Acidity or alkalinity and pH  (KCP 2.4.1) |  |  | Acidity/alkalinity not required for pH range between pH 4 and pH 10 |  |  | - |
| pH of a 1% aqueous dilution, emulsion or dispersion  (KCP 2.4.2) | CIPAC MT 75.3 | BAS 743 03 F  Ametoctradin/Propamocarb 120/378 g/L  Batch FRE-002223 | |  |  | | --- | --- | | **Solution** | **pH value (temperature)** | | Neat product | 7.5 (15.4 °C) | | deionised water | 8.4 (18.2 °C) | | 1 % suspension of product in deionised water | 7.6 (18.2 °C) | | CIPAC water D | 6.9 (19.3 °C) | | 1 % suspension of product in CIPAC water D | 7.3 (19.3 °C) | | Y | 2022/2046342,  Hopley, W., 2022 | Acceptable |
| Viscosity  (KCP 2.5.1) | CIPAC MT 192 (OECD 114)  Rotational viscometry | BAS 743 03 F  Ametoctradin/Propamocarb 120/378 g/L  Batch FRE-002223 | |  |  |  |  |  | | --- | --- | --- | --- | --- | | Test Temperture (°C) | Shear Rate (s-1) | Dynamic Viscosity (mPa.s) | Kinematic viscosity (mm2/s) - calculated | Flow behaviour | | 20.0 | 100 | 45 | 42 | Non-Newtonian, Thixotropic | | 10 | 78 | 73 | | 40.0 | 100 | 34 | 32 | Non-Newtonian, Thixotropic | | 10 | 62 | 58 | | Y | 2022/2046342,  Hopley, W., 2022 | Acceptable  The product does not contain hydrocarbons or co-formulants classified for Asp. Tox. 1, thus is not considered as hazardous after aspiration. |
| Surface tension  (KCP 2.5.2) | EC A.5 (OECD 115) | BAS 743 03 F  Ametoctradin/Propamocarb 120/378 g/L  Batch FRE-002223 | Neat: 33.7 mN/m at 25.1 °C 2.00 %w/v dilution: 34.9 mN/m at 20.2 °C | Y | 2022/2046342,  Hopley, W., 2022 | Acceptable  The surface tension of the highest in use-concentration measured at 20°C is below the limit 60 mN/m. Therefore the formulation is considered as surface active. |
| Relative density  (KCP 2.6.1) | EC A.3 (OECD 109) | BAS 743 03 F  Ametoctradin/Propamocarb 120/378 g/L  Batch FRE-002223 | D204 at 20 °C = 1.071 | Y | 2022/2046342,  Hopley, W., 2022 | Acceptable |
| Bulk density  (KCP 2.6.2) |  |  | Not applicable for liquid formulations |  |  | - |
| Storage Stability after 14 days at 54º C  (KCP 2.7.1) | CIPAC MT 46.4 | BAS 743 03 F  Ametoctradin/Propamocarb 120/378 g/L  Batch FRE-002223 | The storage stability of BAS 743 03 F stored in 1 L HDPE bottles was evaluated.  No significant decrease in active substance content or increase in relevant impurities\* was observed following the 2 week storage period at 54ºC ± 2ºC.  No significant variations in any of the technical characteristics of the product, or in the appearance of the packaging, were observed following the 2 week storage period at 54ºC± 2ºC.  Results for individual parameters are presented in Table 2-2 below.  \* Determined in 2022/2046320, Kroehl, T., 2022, stored in 250 mL HDPE bottles. Amitrole only. The content of the relevant ametoctradin impurity o-xylene was not determined. O-xylene is a solvent and is not a decomposition product. It cannot be generated from the active ingredient, the related impurities or arise during the formulation process or storage of BAS 743 03 F. Further information is provided in Part C (KCP 1.4.3). | Y | 2022/2046342,  Hopley, W., 2022  &  2022/2046320, Kroehl, T., 2022  (for determination of amitrole content on storage) | Acceptable  The formulation is considered to be physically and chemically stable for 14 days at 54˚C in HDPE packaging material.  The analytical method used for the determination of the active substances (method AFL 1028) and impurity - amitrole (method AFL1070/01) in the formulation are fully validated according to SANCO/3030/99 rev. 5 and are provided in the dRR part B.5.  The phrase ‘shake before use’ should be included on the label of the product due to colourless liquid phase separation observed upon storage (separation was fully reversible after agitation). |
| Stability after storage for other periods and/or temperatures  (KCP 2.7.2) |  |  | Not applicable because the product is stable at 54 °C for two weeks. Please refer to KCP 2.7.1. |  |  | - |
| Minimum content after heat stability testing  (KCP 2.7.3) |  |  | Not applicable, since the active substance content did not decrease >5% during accelerated storage for 2 weeks at 54 °C. |  |  | No loss of both active substances >5% after storage. |
| Effect of low temperatures on stability  (KCP 2.7.4) | CIPAC MT 39.3 | BAS 743 03 F  Ametoctradin/Propamocarb 120/378 g/L  Batch FRE-002223 | Storage period: 7 days at 0 ºC.  Trace (<0.05 mL) of clear liquid supernatant and trace (<0.05 mL) of sediment was present. The sample was stored for a further 24 hours at 23 ºC. After 1 inversion the sample was homogeneous. Wet sieve test was performed and no material was retained on the 75 µm sieve.  Suspensibility (ametoctradin only) provided in KCP 2.8.3.1 below was found to be acceptable (102 % for 0.10 %w/v dilution and 104 % for 2.00 %w/v dilution).  Spontaneity of dispersion (ametoctradin only) provided in KCP 2.8.3.2 below was found to be acceptable (103 %).  After low storage stability, there were no significant change of the physical properties of the test substance.  Therefore, BAS 743 03 F is considered to be stable at low temperatures. | Y | 2022/2046342 Hopley, W., 2022 | Acceptable  The formulation is considered to be stable for 7 days at 0°C.  However, if a clear liquid supernatant and trace (<0.05 mL) of sediment was found after storage the phrase “shake before use” is recommended on the label. |
| Ambient temperature shelf life  (KCP 2.7.5) |  |  | ~~This study is ongoing and will be provided on completion (estimated end of Q1 2025, XXXX)~~  The storage stability of BAS 743 03 F stored in 1 L HDPE bottles was evaluated.  No significant decrease in active substance content was observed following the 104 week storage period at 25ºC.  No significant variations in any of the technical characteristics of the product, or in the appearance of the packaging, were observed following the 104 week storage period at 25ºC.  Results for individual parameters are presented in Table 2-3 below. | Y | 2022/2048389  Hopley, W., 2024 | The 2-year stability study is required to support the proposed shelf life of 2 years for the product BAS 743 03 F.  **Acceptable**  The formulation is stable during 2 years stability study. No significant changes in content active substances and technical properties observed at ambient temperature in shelf life study.  No change in HDPE packaging was observed after 2-y storage of the product. There was no significant change in weight of unopened container (-0.2%). |
| Shelf life in months (if less than 2 years)  (KCP 2.7.6) |  |  | Please refer to KCP 2.7.5 |  |  | Not applicable. The formulation is stable for 2 years at 25°C |
| Wettability  (KCP 2.8.1) |  |  | Not applicable for liquid formulations |  |  | - |
| Persistence of foaming  (KCP 2.8.2) | CIPAC MT 47.3 | BAS 743 03 F  Ametoctradin/Propamocarb 120/378 g/L  Batch FRE-002223 | 2.00 % dilution in CIPAC water D (Temp 18.2 ºC)   |  |  | | --- | --- | |  | **Volume of foam [mL]** | | after 1 min | 0 | | after 12 min | - | | Y | 2022/2046342 Hopley, W., 2022 | Acceptable  The test was performed at the highest use-concentration |
| Suspensibility  (KCP 2.8.3.1) | CIPAC MT 184.1  AFL1028/02 | BAS 743 03 F  Ametoctradin/Propamocarb 120/378 g/L  Batch FRE-002223 | Suspensibility % (ametoctradin only\*)   |  |  |  | | --- | --- | --- | | Storage period | 0.10 %w/v | 2.00 %w/v | | Initial | 102 | 102 | | 7 days @ 0 ºC | 102 | 104 |   \* Suspensibility test was intentionally performed for Ametocradin (only). It is not necessary to perform the test for Propamocarb as this is not suspended (it is already dissolved in solution). | Y | 2022/2046342 Hopley, W., 2022 | Acceptable  Suspensibility is within acceptable limits (60 - 105%)  Test was performed covering the lowest and the highest use-concentration.  The analytical method used for the determination of suspensibility (ametoctradin only, as propamocarb is fully soluble in the product and water) -method AFL 1028 in dilutions is fully validated according to SANTE/2020/12830 rev.1 and are provided in the dRR part B.5. |
| Spontaneity of dispersion  (KCP 2.8.3.2) | CIPAC MT 160  AFL1028/02 | BAS 743 03 F  Ametoctradin/Propamocarb 120/378 g/L  Batch FRE-002223 | 5 % dilution in CIPAC water D at 25 °C (ametoctradin only\*)   |  |  | | --- | --- | | Storage period | **Suspensibility [%]** | | **5 % dilution** | | Initial | 101 | | 7 days @ 0 ºC | 103 |   \* Spontaneity of dispersion test was intentionally performed for Ametocradin (only). It is not necessary to perform the test for Propamocarb as this is not suspended (it is already dissolved in solution). | Y | 2022/2046342 Hopley, W., 2022 | Acceptable  spontaneity of dispersion is within acceptable limits (60 - 105%) |
| Dispersion stability  (KCP 2.8.3.3) |  |  | Not applicable for SC formulations |  |  | - |
| Degree of dissolution and dilution stability  (KCP 2.8.4) |  |  | Not applicable for SC formulations |  |  | - |
| Particle size distribution / nominal size range of granules  (KCP 2.8.5.1.1) | CIPAC MT 187 | BAS 743 03 F  Ametoctradin/Propamocarb 120/378 g/L  Batch FRE-002223 | Dispersed in deionised water   |  |  | | --- | --- | |  | **Particle size [µm]** | | D10: 10 % of total particle volume are smaller than | 0.9 | | D50: 50 % of total particle volume are smaller than | 2.2 | | D90: 90 % of total particle volume are smaller than | 5.5 | | Y | 2022/2046342 Hopley, W., 2022 | Acceptable |
| Wet sieve test  (KCP 2.8.5.1.2) | CIPAC MT 185 | BAS 743 03 F  Ametoctradin/Propamocarb 120/378 g/L  Batch FRE-002223 | |  |  | | --- | --- | | **Residue on 75 µm sieve** | 0.01 % | | Y | 2022/2046342 Hopley, W., 2022 | Acceptable |
| Dust content  (KCP 2.8.5.2.1) |  |  | Not applicable for SC formulations |  |  | - |
| Particle size of dust  (KCP 2.8.5.2.2) |  |  | Not applicable for SC formulations |  |  | - |
| Attrition  (KCP 2.8.5.3) |  |  | Not applicable for SC formulations. |  |  | - |
| Hardness and integrity  (KCP 2.8.5.4) |  |  | Not applicable for SC formulations |  |  | - |
| Emulsifiability  (KCP 2.8.6.1) |  |  | Not applicable for SC formulations |  |  | - |
| Emulsion stability  (KCP 2.8.6.2) |  |  | Not applicable for SC formulations |  |  | - |
| Re-emulsifiability  (KCP 2.8.6.3) |  |  | Not applicable for SC formulations |  |  | - |
| Flowability  (KCP 2.8.7.1) |  |  | Not applicable for SC formulations |  |  | - |
| Pourability  (KCP 2.8.7.2) | CIPAC MT 148.1 | BAS 743 03 F  Ametoctradin/Propamocarb 120/378 g/L  Batch FRE-002223 | |  |  | | --- | --- | | **Pour residue [%]** | 1.14 | | **Rinsed residue [%]** | Not required (pour residue <5%) | | Y | 2022/2046342 Hopley, W., 2022 | Acceptable |
| Dustability following accelerated storage  (KCP 2.8.7.3) |  |  | Not applicable for SC formulations |  |  |  |
| Physical compatibility of tank mixes  (KCP 2.9.1) | ASTM method  E 1518-05 | BAS 743 BJ F\*  Ametoctradin/Propamocarb 120/378 g/L  Batch FD-210902-1005 | Studies combining BAS 743 BJ F with 9 other commercial plant protection products were performed and the application as a tank mixture was acceptable.  In all mixtures no lumping and no flocculation occurred. The mixtures appeared to be homogeneous.  Therefore, BAS 743 BJ F is considered physically compatible with the tested products.  The applicant does not require specific tank mixture recommendation on the product label. | N | 2022/2004497 Gilbert, S. &  Schlotterbeck, U., 2021 | No tank mixes are recommended on the product label, thus no data is required. |
| Chemical compatibility of tank mixes  (KCP 2.9.2) | ASTM method  E 1518-05 | BAS 743 BJ F\*  Ametoctradin/Propamocarb 120/378 g/L  Batch FD-210902-1005 | Ametoctradin and propamocarb, the active substances of BAS 743 BJ F, are stable in diluted aqueous conditions. Therefore, none of the functional groups are likely to react under normal tank mix conditions.  Belanty Fungicide, Decis Protech, Narita, Signum 33WG, Mospilan 20 SG, Axalion, Teppeki, Movento 150 OD and Spintor 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 BJ F is considered chemically compatible with the tested products.  The applicant does not require specific tank mixture recommendation on the product label. | N | 2022/2004497  Gilbert, S. &  Schlotterbeck, U., 2021 | No tank mixes are recommended on the product label, thus no data is required. |
| Adhesion to seeds  (KCP 2.10.1) |  |  | Not applicable for SC formulations |  |  | - |
| Distribution to seed  (KCP 2.10.2) |  |  | Not applicable for SC formulations |  |  | - |
| Other/special studies  (KCP 2.11) |  |  | Not required |  |  | - |

\* BAS 743 BJ F is an old interim/developmental phase formulation code. The formulation is identical to BAS 743 03 F.

Table 2-2: KCP 2.7.1 - Result overview of the accelerated storage stability study (2 weeks at 54°C in 1 L HDPE containers, Doc ID 2022/2046342, Hopley, W., 2022) for BAS 743 03 F (120 g/L ametoctradin + 378 g/L propamocarb (base))   
(N.B Amitrole content determined in DocID 2022/2046320, Kroehl, T., 2022)

| **Test or study & Data point** | **Method** | **Initial** | **After 2 weeks at 54°C** |
| --- | --- | --- | --- |
| Colour and  physical state  (KCP 2.1) | Colour and  physical state:  EPA OPPTS 830.6302 (colour), OPPTS 830.6303 (physical state), | Colour and physical state:  Homogeneous white opaque free flowing, low viscosity liquid. No supernatant or sediment | Colour and physical state:  At 0 inversions –  Non-homogeneous, trace <0.5% clear colourless liquid supernatant present with no sediment.  After 3 inversions –  Homogeneous white opaque free-flowing, low viscosity liquid. No supernatant or sediment.  No change in appearance or physical state was observed after 2 weeks at 54°C. |
| pH of a 1% aqueous dilution, emulsion or dispersion  (KCP 2.4.2) | CIPAC MT 75.3 | |  |  | | --- | --- | | **Solution** | **pH value (temperature)** | | Neat product | 7.5 (15.4 °C) | | deionised water | 8.4 (18.2 °C) | | 1 % suspension of product in deionised water | 7.6 (18.2 °C) | | CIPAC water D | 6.9 (19.3 °C) | | 1 % suspension of product in CIPAC water D | 7.3 (19.3 °C) |   Free acidity test was not performed as pH was not outside pH 4-10 | |  |  | | --- | --- | | **Solution** | **pH value(temperature)** | | Neat product | 7.6 (15.4 °C) | | deionised water | 8.3 (18.4 °C) | | 1 % suspension of product in deionised water | 7.6 (18.4 °C) | | CIPAC water D | 7.0 (19.5 °C) | | 1 % suspension of product in CIPAC water D | 7.2 (19.5 °C) |   Free acidity test was not performed as pH was not outside pH 4-10  There were no significant changes in pH on storage for 2 weeks at 54°C. |
| Viscosity  (KCP 2.5.1) | CIPAC MT 192 (OECD 114)  Rotational viscometry | |  |  |  |  | | --- | --- | --- | --- | | Test Temperture (°C) | Shear Rate (s-1) | Viscosity (mPa.s) | Flow behaviour | | 20.0 | 100 | 45 | Non-Newtonian, Thixotropic | | 10 | 78 | | 40.0 | 100 | 34 | Non-Newtonian, Thixotropic | | 10 | 62 | | |  |  |  |  | | --- | --- | --- | --- | | Test Temperture (°C) | Shear Rate (s-1) | Viscosity (mPa.s) | Flow behaviour | | 20.0 | 100 | 52 | Non-Newtonian, Thixotropic | | 10 | 92 | | 40.0 | 100 | 48 | Non-Newtonian, Thixotropic | | 10 | 91 | |
| Relative density  (KCP 2.6.1) | EC A.3 (OECD 109) | D204 at 20 °C = 1.071 | D204 at 20 °C = 1.071  There were no significant changes in relative density on storage for 2 weeks at 54°C. |
| Persistence of foaming  (KCP 2.8.2) | CIPAC MT 47.3 | 2.00 % dilution in CIPAC water D (Temp 18.2 ºC)   |  |  | | --- | --- | |  | **Volume of foam [mL]** | | after 1 min | 0 | | after 12 min | - | | 2.00 % dilution in CIPAC water D (Temp 18.2 ºC)   |  |  | | --- | --- | |  | **Volume of foam [mL]** | | after 1 min | 0 | | after 12 min | - |   No change in foaming after storage for 2 weeks at 54 °C. Foaming level acceptable. |
| Suspensibility  (KCP 2.8.3.1) | CIPAC MT 184.1  AFL1028/02 | 0.10 % and 2.00 % dilutions in CIPAC water D at 25 °C   |  |  |  | | --- | --- | --- | |  | **Suspensibility [%]** | | |  | **0.10 %** | **2.00 %** | | Ametoctradin | 102 | 102 | | 0.10 % and 2.00 % dilutions in CIPAC water D at 25 °C   |  |  |  | | --- | --- | --- | |  | **Suspensibility [%]** | | |  | **0.10 %** | **2.00 %** | | Ametoctradin | 103 | 103 |   No significant change in suspensibility after storage for 2 weeks at 54 °C. Suspensibility is at acceptable levels (60-105%) |
| Spontaneity of dispersion  (KCP 2.8.3.2) | CIPAC MT 160  AFL1028/02 | 5 % dilution in CIPAC water D at 25 °C (ametoctradin only):  Spontaneity = 101% | 5 % dilutions in CIPAC water D at 25 °C (ametoctradin only)  Spontaneity = 102%  No significant change in suspensibility after storage for 2 weeks at 54 °C. Suspensibility is at acceptable levels (60-105%) |
| Particle size distribution / nominal size range of granules  (KCP 2.8.5.1.1) | CIPAC MT 187 | Dispersed in deionised water   |  |  | | --- | --- | |  | **Particle size [µm]** | | D10: 10 % of total particle volume are smaller than | 0.9 | | D50: 50 % of total particle volume are smaller than | 2.2 | | D90: 90 % of total particle volume are smaller than | 5.5 | | Dispersed in deionised water   |  |  | | --- | --- | |  | **Particle size [µm]** | | D10: 10 % of total particle volume are smaller than | 1.0 | | D50: 50 % of total particle volume are smaller than | 2.4 | | D90: 90 % of total particle volume are smaller than | 6.1 |   The particle size is comparable to initial after storage for 2 weeks at 54°C and not thought to be significant. |
| Wet sieve test  (KCP 2.8.5.1.2) | CIPAC MT 185 | |  |  | | --- | --- | | **Residue on 75 µm sieve** | 0.01 % | | |  |  | | --- | --- | | **Residue on 75 µm sieve** | 0.01 % |   No change in wet sieve result after storage for 2 weeks at 54 °C.  Residue level acceptable (< 2 %) |
| Pourability  (KCP 2.8.7.2) | CIPAC MT 148.1 | |  |  | | --- | --- | | **Pour residue [%]** | 1.14 | | **Rinsed residue [%]** | Not required (pour residue <5%) | | |  |  | | --- | --- | | **Pour residue [%]** | 1.17 | | **Rinsed residue [%]** | Not required (pour residue <5%) |   No significant change in pourability after storage for 2 weeks at 54 °C. Pour residue acceptable (<5%). |
| Other studies  (KCP 2.7.1) | AFL1028/02  analytical assay using GC-FID for the determination of ametoctradin and propamocarb (base)  AFL1070/01  analytical assay using HPLC-MS for the determination of amitrole | Active ingredient content:   |  |  | | --- | --- | |  | **Content** | | Ametoctradin | 122 g/L | | Propamocarb (base) | 367 g/L | | Amitrole\* | 0.791 mg/kg product (=7.1 mg/kg related to ametoctradin) |   \* determined in 2022/2046320, Kroehl, T., 2022, stored in 250 mL HDPE bottles, method LOQ: 0.02 mg/L (= 0.2 mg/kg in product)  The content of the relevant ametoctradin impurity o-xylene was not determined. O-xylene is a solvent and is not a decomposition product. It cannot be generated from the active ingredient, the related impurities or arise during the formulation process or storage of BAS 743 03 F. Further information is provided in Part C (KCP 1.4.3). | Active ingredient content:   |  |  | | --- | --- | |  | **Content** | | Ametoctradin | 122 g/L | | Propamocarb (base) | 368 g/L | | Amitrole\* | 0.811 mg/kg product (=7.3 mg/kg related to ametoctradin) |   \* determined in 2022/2046320, Kroehl, T., 2022, stored in 250 mL HDPE bottles, method LOQ: 0.02 mg/L (= 0.2 mg/kg in product)  Changes in active ingredient after storage are not significant; a.i. contents remain above 95% of the initial values. |
|  | SOP/HAV.3053 | Pack appearance /weight change:  Yellow opaque 1 L HDPE cylindrical ribbed bottle approx. 24 cm high, 8.5 cm diameter with an approx. 7.0 cm ratchet cap. There was no deformation, corrosion, swelling/cracking/crazing of pack walls, external odour, visual contamination, label staining or leakage. The weight of the empty pack, induction seal and if the pack had been nitrogen purged was unknown. The seal integrity of the ratchet cap was visually intact.  Pack weight = 1165 g | Pack appearance /weight check:  As initial.  Pack weight = 1164g (pack weight change after storage = -0.1%)  There was no significant change in the pack after storage |

**Table 2-3: Long Term Storage Stability - 104 weeks storage at 25°C (Hopley, W., 2024, DocID 2022/2048389)**

**Test article**BAS 743 03 F (Batch FRE-002223), Suspension Concentrate (SC)  
Ametoctradin 120 g/L / Propamocarb 378 g/L(=451 g/L as Propamocarb hydrochloride)  **Time point Pack**12, 26 & 78 weeks (at 25 °C) Yellow 250 mL HDPE bottles  
52 weeks (at 25 °C) Yellow 1L HDPE bottles

| **Test or study** | **Method** | **Initial** | **After 12 weeks at 25 °C** | **After 26 weeks  at 25 °C** | **After 52 weeks  at 25 °C** | **After 78 weeks  at 25 °C** | **After 104 weeks  at 25 °C** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Active content  (% of value at initial) | AFL1028/02 GC-FID method for detn. of ametoctradin and propamocarb (base) | Ametoctradin: 122 g/L | Ametoctradin: 122 g/L (100%) | Ametoctradin: 123 g/L (101%) | Ametoctradin: 120 g/L (98.4%) | Ametoctradin: 126 g/L (103%) | Ametoctradin: 125 g/L (102%) |
| Propamocarb: 367 g/L (438 g/L as the hydrochloride) | Propamocarb:  380 g/L (454 g/L as the hydrochloride) (104%) | Propamocarb:  361 g/L (431 g/L as the hydrochloride) (98.4%) | Propamocarb:  387 g/L (462 g/L as the hydrochloride) (105%) | Propamocarb:  384 g/L (458 g/L as the hydrochloride) (105%) | Propamocarb:  386 g/L (461 g/L as the hydrochloride) (105%) |
| Colour and  physical state | Visual assessment  Colour: OPPTS 830.6302  Physical state:  OPPTS 830.6303  Odour: OPPTS 830.6304 | Homogeneous white opaque free flowing, low viscosity liquid. No supernatant or sediment present.  Fruity odour. |  |  | Non homogeneous white opaque free flowing, low viscosity liquid. 1.6% Hazy Colourless Liquid supernatant.  Nil sediment present.  Homogeneous after 3 inversions  Fruity odour. |  | Non homogeneous white opaque free flowing, low viscosity liquid. 5.3% Hazy Colourless Liquid supernatant.  Nil sediment present.  Homogeneous after 3 inversions  Fruity odour. |
| Pack Appearance / Weight Change | SOP/ HAV.3053 | Pack appearance /weight check:  Yellow opaque 1L HDPE, cylindrical, ribbed bottle with 24cm height, 8.5cm diameter & 7.0cm rachet cap.  Nil deformation, corrosion, swelling, cracking, crazing of pack walls, external odour, visual contamination, label staining or leakage. Seal integrity: visually intact. |  |  | Pack appearance /weight check:  The pack appearance did not change on storage for 52 weeks at 25°C.  Pack weight (change): -0.1 % |  | Pack appearance /weight check:  The pack appearance did not change on storage for 104 weeks at 25°C.  Pack weight (change): ~~-0.02%~~ -0.2% |
| pH of a 1% aqueous dilution, emulsion or dispersion | CIPAC MT 75.3 | pH of 1 % dilutions in pure water and CIPAC water D  **Neat:** pH = 7.5 (15.4 °C)  **1% d.i. water:** Water alone, pH=8.4 1% dilution, pH=7.6 (18.2 °C)  **1% Water D:** Water alone, pH=6.9 1% dilution, pH=7.3 (19.3 °C) |  |  | pH of 1 % dilutions in pure water and CIPAC water D  **Neat:** pH = 7.3 (25.7 °C)  **1% d.i. water:** Water alone, pH=8.0 1% dilution, pH=7.5 (26.3 °C)  **1% Water D:** Water alone, pH=7.0 1% dilution, pH=7.3 (24.8 °C) |  | pH of 1 % dilutions in pure water and CIPAC water D  **Neat:** pH = 7.5 (20.3 °C)  **1% d.i. water:** Water alone, pH=7.1 1% dilution, pH=7.4 (20.6 °C)  **1% Water D:** Water alone, pH=6.0 1% dilution, pH=7.3 (19.3 °C) |
| Viscosity | CIPAC  MT 192 (OECD 114) Rotational viscometry | 20 °C: Shear rate 100 s-1: Viscosity = 45 mPa.s Shear rate 10 s-1: Viscosity = 78 mPa.s  40 °C: Shear rate 100 s-1: Viscosity = 34 mPa.s Shear rate 10 s-1: Viscosity = 62 mPa.s |  |  | 20 °C: Shear rate 100 s-1: Viscosity = 44 mPa.s Shear rate 10 s-1: Viscosity = 76 mPa.s  40 °C: Shear rate 100 s-1: Viscosity = 32 mPa.s Shear rate 10 s-1: Viscosity = 58 mPa.s |  | 20 °C: Shear rate 100 s-1: Viscosity = 46 mPa.s Shear rate 10 s-1: Viscosity = 79 mPa.s  40 °C: Shear rate 100 s-1: Viscosity = 33 mPa.s Shear rate 10 s-1: Viscosity = 60 mPa.s |
| Relative density | EC A.3 (OECD 109) | D204 at 20 °C  = 1.071 | D204 at 20 °C  = 1.071 | D204 at 20 °C  = 1.072 | D204 at 20 °C  = 1.070 | D204 at 20 °C  = 1.072 | D204 at 20 °C  = 1.069 |
| Persistence of foaming | CIPAC 47.3 | 2.00 %w/v dilution in CIPAC water D @18.2 °C:  Foam volume after  1 minute: Nil Foam volume after 12 minutes: N/A |  |  | 2.00 %w/v dilution in CIPAC water D @22.6 °C:  Foam volume after  1 minute: Nil Foam volume after 12 minutes: N/A |  | 2.00 %w/v dilution in CIPAC water D @21.6 °C:  Foam volume after  1 minute: Nil Foam volume after 12 minutes: N/A  0.04 %w/v dilution in CIPAC water D @21.0 °C:  Foam volume after  1 minute: Nil Foam volume after 12 minutes: N/A  18.75 %w/v dilution in CIPAC water D @20.9 °C:  Foam volume after  1 minute: Nil Foam volume after 12 minutes: N/A |
| Suspensibility | CIPAC MT 184.1  AFL1028/02 | 0.10 %w/v dilution in CIPAC water D  at 25 °C: Ametoctradin: 102%  2.00 %w/v dilution in CIPAC water D  at 25 °C: Ametoctradin: 102%  Suspensibility was not measured for Propamocarb because it is water soluble. |  |  | 0.10 %w/v dilution in CIPAC water D  at 25 °C: Ametoctradin: 100%  2.00 %w/v dilution in CIPAC water D  at 25 °C: Ametoctradin: 101%  Suspensibility was not measured for Propamocarb because it is water soluble. |  | 0.10 %w/v dilution in CIPAC water D  at 25 °C: Ametoctradin: 96.9%  2.00 %w/v dilution in CIPAC water D  at 25 °C: Ametoctradin: 99.5%  10.0 %w/v dilution in CIPAC water D  at 25 °C: Ametoctradin: 100%  Suspensibility was not measured for Propamocarb because it is water soluble. |
| Spontaneity of dispersion | CIPAC  MT 160 AFL1028/02 | 5 %w/v dilution in CIPAC water D  at 25 °C: Ametoctradin: 101%  Not determined for Propamocarb because it is water soluble. |  |  | 5 %w/v dilution in CIPAC water D  at 25 °C: Ametoctradin: 100%  Not determined for Propamocarb because it is water soluble. |  | 5 %w/v dilution in CIPAC water D  at 25 °C: Ametoctradin: 99.4%  Not determined for Propamocarb because it is water soluble. |
| Particle size distribution / nominal size range of granules | CIPAC  MT 187 | Dispersed in water  D10: 0.9 µm  D50: 2.2 µm  D90: 5.5 µm |  |  | Dispersed in water  D10: 0.99 µm  D50: 2.38 µm  D90: 5.86 µm |  | Dispersed in water  D10: 0.98 µm  D50: 2.29 µm  D90: 5.40 µm |
| Wet sieve test | CIPAC MT 185 | Residue on 75 µm sieve: 0.01 % |  |  | Residue on 75 µm sieve: 0.01 % |  | Residue on 75 µm sieve: 0.00 % |
| Pourability | CIPAC  MT 148.1 | Pour residue: 1.14%  Rinsed residue: N/A (pour residue <5%) |  |  | Pour residue: 0.95%  Rinsed residue: N/A (pour residue <5%) |  | Pour residue: 0.88%  Rinsed residue: N/A (pour residue <5%) |

# Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

# Section 4: Further information on the plant protection product

**Safety intervals and other precautions to protect humans, animals and the environment (KCP 4.1)**

**Waiting period (in days) between last application and sowing or planting succeeding crops**

Within a common crop rotation, no special waiting periods are required before common crops can be replanted. Some restrictions and recommendations need to be applied in case of emergence replanting in regard of waiting period and soil preparation. Further details are given in Section 3.5 of this submission

**Recommended methods and precautions (KCP 4.2)**

|  |  |
| --- | --- |
| Reference: | CP 4.2/1 |
| Report | Effectiveness of Procedures for Cleaning Application Equipment and Protective Clothing BAS 743 03 F  Langknecht, T. & Popp, C., 2023  Report No 866951  XXXX  Authority registration No |
| Guideline(s): | EPPO PP 1/292 (1), DIN EN ISO 16119-2. |
| Deviations: | No |
| GLP: | No, not subject to GLP regulation |
| Acceptability: | Yes | |

Instead of a large-scale test, a calculation was carried out with a high safety margin for all relevant parameters. A “double rinse procedure” was assumed for the calculation.

The result of the calculation, based on the recommendation for the use of the formulation, the parameters of the proposed cleaning procedure and application equipment, is within the expected range. Although small amounts of the active ingredients Ametoctradin and Propamocarb remain in the spray tank, a risk from this low concentration can be excluded. A more complex cleaning procedure is not necessary, water is sufficient for cleaning sprayers to prevent damage to plants. It is not necessary to add cleaning agents.

Protective clothing will be cleaned effectively when washed with usual laundry detergents, as agrochemical formulations are designed for being readily miscible with water.

**Emergency measures in the case of an accident (KCP 4.3)**

|  |  |
| --- | --- |
| Reference: | CP 4.3/1 |
| Report | Safety data sheet – BAS 743 03 F  Anonymous, 2023  report No EU-version 1.0  XXXX  ID no. 1076232/SDS\_CPA\_EU/EN  Authority registration No |
| Guideline(s): | EEC 1907/2006 |
| Deviations: | No |
| GLP: | No, not subject to GLP regulation |
| Acceptability: | Yes | |

The safety data sheet contains advice for emergency measures in case of an accident with BAS 743 03 F, based on scientific tests.

## Packaging and Compatibility with the Preparation (KCP 4.4)

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

**Table 4.1‑1: Packaging information for 0.15 litre bottle**

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

**Table 4.1‑2: Packaging information for 0.25 litre bottle**

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

**Table 4.1‑3: Packaging information for 0.5 litre bottle**

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

**Table 4.1‑4: Packaging information for 1 litre bottle**

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

**Table 4.1‑5: Packaging information for 1 litre eco-bottle**

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

**Table 4.1‑6: Packaging information for 5 litre container**

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

**Table 4.1‑7: Packaging information for 5 litre eco-container**

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

**Table 4.1‑8: Packaging information for 10 litre container**

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

**Table 4.1‑9: Packaging information for 10 litre eco-container**

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

**Table 4.1‑10: Packaging information for 15 litre container**

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

**Table 4.1‑11: Packaging information for 20 litre container**

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

**Table 4.1‑12: Packaging information for 50 litre container**

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

**Table 4.1‑13: Packaging information for 100 litre container**

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

**Table 4.1‑14: Packaging information for 200 litre container**

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

**Table 4.1‑15: Packaging information for 1000 litre container**

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

The pack complies with ADR/RID regulations. It was tested according to the pack type, material, classification of the contents as specified in ADR regulations. An appropriate UN certificate has been issued. They are labelled individually with all the use instructions.

**zRMS**: The f-HDPE containers are supported based on accelerated and 2-years ambient shelf life storage data for the product BAS 743 03 F packaged in HDPE containers (for details see findings of storage stability tests, Table 2-2 and 2-3, above). The results of the study no.: 2022/2046342 and 2022/2048389 demonstrate that HDPE packaging material is stable after storage (14 days at 54°C and 104 weeks at 25°C) of test item. According to the guidelines of SANCO/10473/2003 –rev.5, for aqueous based formulations such as SC, extrapolation between any plastic material types is acceptable.

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| --- | --- |
| Reference: | CP 4.4/1 |
| Report | BAS 743 02 F, EU-Performance-Test  Maurer, 2022  Report No 222.0084.0009 TB01  XXXX  Authority registration No |
| Guideline(s): | ADR/RID |
| Deviations: | No |
| GLP: | No, not subject to GLP regulations |
| Acceptability: | Yes | |

The chemical compatibility of HDPE was determined using a closely related formulation, BAS 743 02 F, which contains 432.0 g/L propamocarb and 137.1 g/L ametocradin and the same co-formulants. The composition of BAS 743 02 F is given in the confidential section (Part C). The chemical compatibility of HDPE comparison with Model liquid Pfl-Fr 2344 is verified. The permeation rate is less than 0.008 g/L·h.

BAS 743 03 F can be packed in packaging made of HDPE, in case there is an UN-approval for these packaging for Model liquid Pfl-Fr 2344 and there is no conflict on other transport regulations. The maximum allowable values of vapour pressure and density, given in the certificate of approval, may not be exceeded.

The ambient shelf life study is ~~ongoing and data will be available Q1 2025.~~ provided in KCP 2.7.5. HDPE packaging used in the study showed no significant changes from the initial timepoint following storage at 25°C for 2 years.

The 2-y storage data show that the formulation BAS 743 02 F is compatible with HDPE tested packaging material.

## Procedures for the destruction or decontamination of the plant protection product and its packaging (KCP 4.5)

|  |  |
| --- | --- |
| Reference: | CP 4.5/1 |
| Report | Safety data sheet – BAS 743 03 F  Anonymous, 2023  report No EU-version 1.0  XXXX  ID no. 1076232/SDS\_CPA\_EU/EN  Authority registration No |
| Guideline(s): | EEC 1907/2006 |
| Deviations: | No |
| GLP: | No, not subject to GLP regulation |
| Acceptability: | Yes | |

The safety data sheet contains advice for the destruction or decontamination of the plant protection product and its packaging.

### Neutralisation procedure (KCP 4.5.1)

Chemical neutralization is not recommended for spillage of this product. It is easier and simpler to contain and absorb spillages as explained in the safety data sheet. Final destruction of contaminated adsorbent/product will then be in a properly licensed, high temperature incinerator.

### Controlled incineration (KCP 4.5.2)

For purposes of disposal, combustion of BAS 743 03 F in a licensed incinerator is recommended. This method of disposal applies also to contaminated packages, which cannot be cleaned or reused. Although it is possible to incinerate the product at lower temperatures, combustion at approx. 1100°C with a residence time of about 2 sec. is advised. By doing so, i.e., operating the incinerator according to the conditions laid down in council directive 94/67/EEC resp. directive 2000/76/EC of the European Parliament, one will achieve complete combustion and minimize the formation of undesired by-products in the off-gases.

1. Lists of data considered in support of the evaluation

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

List of data submitted by the applicant and relied on

| **Data point** | **Author(s)** | **Year** | **Title Company Report No.  Source (where different from company) GLP or GEP status Published or not** | **Vertebrate study**  **Y/N** | **Owner** |
| --- | --- | --- | --- | --- | --- |
| KCP 2.1/1 | Hopley, W. | 2022 | Physical and Chemical Properties of BAS 743 03 F: Accelerated Storage Stability for up to 2 weeks at 54°C and up to 7 Days at 0°C  2022/2046342  Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom  yes  Unpublished | No | XXXX |
| KCP 2.2.1/1 | Dreisch, S. | 2022 | BAS 743 03 F, Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008)  2022/2018332  consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep.  yes  Unpublished | No | XXXX |
| KCP 2.2.2/1 | Dreisch, S. | 2022 | BAS 743 03 F, Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008)  2022/2018332  consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep.  yes  Unpublished | No | XXXX |
| KCP 2.3.1/1 | Dreisch, S. | 2022 | BAS 743 03 F, Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008)  2022/2018332  consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep.  yes  Unpublished | No | XXXX |
| KCP 2.3.3/1 | Dreisch, S. | 2022 | BAS 743 03 F, Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008)  2022/2018332  consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep.  yes  Unpublished | No | XXXX |
| KCP 2.4.2/1 | Hopley, W. | 2022 | Physical and Chemical Properties of BAS 743 03 F: Accelerated Storage Stability for up to 2 weeks at 54°C and up to 7 Days at 0°C  2022/2046342  Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom  yes  Unpublished | No | XXXX |
| KCP 2.5.1/1 | Hopley, W. | 2022 | Physical and Chemical Properties of BAS 743 03 F: Accelerated Storage Stability for up to 2 weeks at 54°C and up to 7 Days at 0°C  2022/2046342  Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom  yes  Unpublished | No | XXXX |
| KCP 2.5.2/1 | Hopley, W. | 2022 | Physical and Chemical Properties of BAS 743 03 F: Accelerated Storage Stability for up to 2 weeks at 54°C and up to 7 Days at 0°C  2022/2046342  Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom  yes  Unpublished | No | XXXX |
| KCP 2.6.1/1 | Hopley, W. | 2022 | Physical and Chemical Properties of BAS 743 03 F: Accelerated Storage Stability for up to 2 weeks at 54°C and up to 7 Days at 0°C  2022/2046342  Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom  yes  Unpublished | No | XXXX |
| KCP 2.7.1/1 | Hopley, W. | 2022 | Physical and Chemical Properties of BAS 743 03 F: Accelerated Storage Stability for up to 2 weeks at 54°C and up to 7 Days at 0°C  2022/2046342  Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom  yes  Unpublished | No | XXXX |
| KCP 2.7.1/2 | Kroehl, T. | 2022 | Content of Active ingredients and Content of the relevant impurity Amitrole (Reg.No. 900093) in BAS 743 03 F before and after storage for 2 weeks at 54°C  2022/2046320  BASF SE, Limburgerhof, Germany Fed.Rep.  yes  Unpublished | No | XXXX |
| KCP 2.7.4/1 | Hopley, W. | 2022 | Physical and Chemical Properties of BAS 743 03 F: Accelerated Storage Stability for up to 2 weeks at 54°C and up to 7 Days at 0°C  2022/2046342  Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom  yes  Unpublished | No | XXXX |
| KCP 2.7.5/1 | Hopley, W. | 2024 | Physical and Chemical Properties of BAS 743 03 F: Storage Stability for up to 104 weeks at 25°C  2022/2048389  Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom  yes  Unpublished | No | XXXX |
| KCP 2.8.2/1 | Hopley, W. | 2022 | Physical and Chemical Properties of BAS 743 03 F: Accelerated Storage Stability for up to 2 weeks at 54°C and up to 7 Days at 0°C  2022/2046342  Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom  yes  Unpublished | No | XXXX |
| KCP 2.8.3.1/1 | Hopley, W. | 2022 | Physical and Chemical Properties of BAS 743 03 F: Accelerated Storage Stability for up to 2 weeks at 54°C and up to 7 Days at 0°C  2022/2046342  Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom  yes  Unpublished | No | XXXX |
| KCP 2.8.3.2/1 | Hopley, W. | 2022 | Physical and Chemical Properties of BAS 743 03 F: Accelerated Storage Stability for up to 2 weeks at 54°C and up to 7 Days at 0°C  2022/2046342  Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom  yes  Unpublished | No | XXXX |
| KCP 2.8.5.1.1/1 | Hopley, W. | 2022 | Physical and Chemical Properties of BAS 743 03 F: Accelerated Storage Stability for up to 2 weeks at 54°C and up to 7 Days at 0°C  2022/2046342  Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom  yes  Unpublished | No | XXXX |
| KCP 2.8.5.1.2/1 | Hopley, W. | 2022 | Physical and Chemical Properties of BAS 743 03 F: Accelerated Storage Stability for up to 2 weeks at 54°C and up to 7 Days at 0°C  2022/2046342  Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom  yes  Unpublished | No | XXXX |
| KCP 2.8.7.2/1 | Hopley, W. | 2022 | Physical and Chemical Properties of BAS 743 03 F: Accelerated Storage Stability for up to 2 weeks at 54°C and up to 7 Days at 0°C  2022/2046342  Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom  yes  Unpublished | No | XXXX |
| KCP 2.9.1/1 | Gilbert, S. | 2021 | Physical and Chemical Compatibility in Aqueous Tank Mixtures of BAS 74303 F  2022/2004497  BASF SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished | No | XXXX |
| KCP 2.9.2/1 | Gilbert, S. | 2021 | Physical and Chemical Compatibility in Aqueous Tank Mixtures of BAS 74303 F  2022/2004497  BASF SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished | No | XXXX |
| KCP 4.2/1 | Langknecht, T. | 2023 | Effectiveness of Procedures for Cleaning Application Equipment and Protective Clothing BAS 743 03 F  2023/2033336  BASF SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished | No | XXXX |
| KCP 4.3/1 | Anonymous | 2023 | Safety Data Sheet - BAS 743 03 F  2023/2025904  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  no  Unpublished | No | XXXX |
| KCP 4.4/1 | Maurer, B. | 2022 | BAS 743 02 F, EU Performance Test in HDPE  2022/2018336  BASF SE, Limburgerhof, Germany Fed.Rep.  no  Unpublished | No | XXXX |
| KCP 4.5/1 | Anonymous | 2023 | Safety Data Sheet - BAS 743 03 F  2023/2025904  BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep.  no  Unpublished | No | XXXX |

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

| 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 |
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The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
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List of data relied on and 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 |
| --- | --- | --- | --- | --- | --- |
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1. Additional data on the physical, chemical and technical properties of the active substance
   1. Ametoctradin

None

* 1. Propamocarb hydrochloride

None