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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: -  Product name(s): **ULTRACENT 460 EC**  Chemical active substance(s):  Prothioconazole, 160 g/L Spiroxamine, 300 g/L |
| Central Zone  Zonal Rapporteur Member State: Poland |
| CORE ASSESSMENT  (authorization) |
| Applicant: XXXX  Submission date: August 2023, update December 2023  Evaluation date: October 2024  MS Finalisation date: February 2025 |

Version history

|  |  |
| --- | --- |
| When | What |
| August 2023 | First submission – application according to Article 33 in connection with Article 34 of Regulation (EC) No. 1107/2009 with reference to unprotected data of the product INPUT 460 EC authorized in Poland |
| December 2023 | The dossier was updated to include available information on the unprotected data of the reference product INPUT 460 EC (R-61/2011). |
| October 2024 | Version evaluated by zRMS PL |
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Table of Contents

[1 Section 1: Identity of the plant protection product 5](#_Toc175131482)

[1.1 Applicant (KCP 1.1) 5](#_Toc175131483)

[1.2 Producer of the plant protection product and of the active substances (KCP 1.2) 5](#_Toc175131484)

[1.2.1 Producer(s) of the preparation 5](#_Toc175131485)

[1.2.2 Producer(s) of the active substance(s) 5](#_Toc175131486)

[1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s) 5](#_Toc175131487)

[1.2.3.1 Prothioconazole 5](#_Toc175131488)

[1.2.3.2 Spiroxamine 5](#_Toc175131489)

[1.3 Trade names and producer’s development code numbers for the preparation (KCP 1.3) 6](#_Toc175131490)

[1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4) 6](#_Toc175131491)

[1.4.1 Composition of the plant protection product (KCP 1.4.1) 6](#_Toc175131492)

[1.4.2 Information on the active substance(s) (KCP 1.4.2) 6](#_Toc175131493)

[1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3) 6](#_Toc175131494)

[1.5 Type and code of the plant protection product (KCP 1.5) 7](#_Toc175131495)

[1.6 Function (KCP 1.6) 7](#_Toc175131496)

[2 Section 2: Physical, chemical and technical properties of the plant protection product 8](#_Toc175131497)

[3 Section 3 is presented as a separate document 20](#_Toc175131498)

[4 Section 4: Further information on the plant protection product 20](#_Toc175131499)

[4.1 Packaging and Compatibility with the Preparation (KCP 4.4) 20](#_Toc175131500)

[4.2 Safety intervals and other precautions to protect humans, animals and the environment (KCP 4.1) 21](#_Toc175131501)

[4.3 Recommended methods and precautions (KCP 4.2) 22](#_Toc175131502)

[4.3.1 Procedures for Cleaning Application Equipment 22](#_Toc175131503)

[4.3.2 Statement of the Risks Arising and the Recommended Methods and Precautions and Handling Procedures to Minimise Those Risks 22](#_Toc175131504)

[4.3.2.1 Warehouse storage and User level storage 22](#_Toc175131505)

[4.3.2.2 Transport 22](#_Toc175131506)

[4.3.2.3 Fire 23](#_Toc175131507)

[4.3.2.4 Nature of protective clothing proposed 23](#_Toc175131508)

[4.3.2.5 Characteristics of protective clothing proposed 23](#_Toc175131509)

[4.3.2.6 Suitability and effectiveness of protective clothing and equipment 24](#_Toc175131510)

[4.3.2.7 Procedures to minimise the generation of waste 24](#_Toc175131511)

[4.3.2.8 Combustion products likely to be generated in the event of fire 24](#_Toc175131512)

[4.4 Emergency measures in the case of an accident (KCP 4.3) 24](#_Toc175131513)

[4.5 Procedures for destruction or decontamination of the plant protection product and its packaging (KCP 4.5) 25](#_Toc175131514)

[4.5.1 Neutralisation procedure 25](#_Toc175131515)

[4.5.2 Disposal Procedures for the Plant Protection Product 25](#_Toc175131516)

[Appendix 1 Lists of data considered in support of the evaluation 26](#_Toc175131517)

[Appendix 2 Additional data on the physical, chemical and technical properties of the active substance 31](#_Toc175131518)

[A 2.1 Prothioconazole 31](#_Toc175131519)

[A 2.2 Spiroxamine 31](#_Toc175131520)

State whether or not submitted data are sufficient for evaluation. Data gaps and conditions for registration should be listed, if appropriate.

Sufficient data on identity, physical and chemical properties and other information are ~~not~~ available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are: none.

* ~~data gap 1~~
* ~~data gap 2~~
* ~~data gap 3~~

# Section 1: Identity of the plant protection product

## Applicant (KCP 1.1)

Name: XXXX

Address: XXXX,

XXXX

XXXX

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

### Producer(s) of the preparation

Confidential information or data are provided separately (Part C).

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

Confidential information or data are provided separately (Part C).

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

#### Prothioconazole

|  |  |
| --- | --- |
| Prothioconazole | min. 985 g/kg |

#### Spiroxamine

|  |  |
| --- | --- |
| Spiroxamine | min. 970 g/kg |

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

|  |  |
| --- | --- |
| Trade name: | ULTRACENT 460 EC |
| Company code number: | - |

## 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 or g/kg) | FAO Limits  (min – max) | Technical content\*  (g/L or g/kg) | Technical content\*\*  (%w/w) |
| --- | --- | --- | --- | --- |
| Prothioconazole | 160 g/L | Not available | 160 g/L | 16.3 % |
| Spiroxamine | 300 g/L | none | 300 g/L | 30.6 % |

\* Based on the minimum purity of the active substance declared for registration in the active substance dossiers

\*\* Based on the density of the formulation = 0.98 g/cm³ (Note: only applies if a liquid formulation – delete this comment if not needed)

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

Table 1.4‑4: Information on Prothioconazole

| Type | Name/Code Number | |
| --- | --- | --- |
| ISO common name | Prothioconazole |  |
| CAS No. | 178928-70-6 |  |
| EC No. | Not allocated |  |
| CIPAC No. | 745 |  |

Table 1.4‑4: Information on Spiroxamine

| Type | Name/Code Number | |
| --- | --- | --- |
| ISO common name | Spiroxamine |  |
| CAS No. | 118134-30-8 |  |
| EC No. | Not allocated |  |
| CIPAC No. | 572 |  |

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

CONFIDENTIAL information is provided separately (Part C).

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

|  |  |
| --- | --- |
| Type: Emulsifiable concentrate | [Code: EC] |

## Function (KCP 1.6)

ULTRACENT 460 EC is a fungicide.

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

For the support of the application for authorisation of ULTRACENT 460 EC, reference is made to the unprotected data and dossier of the reference product INPUT 460 EC (R-61/2011). Additional studies on physical-chemical properties conducted for ULTRACENT 460 EC are submitted in Poland to support the application and are submitted here as well for reasons of completeness.

All additional 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 yellowish brown liquid, with a mild aromatic odour. In aqueous solution, it has a pH value around 7.08 at 25 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE/PA containers. Its technical characteristics are acceptable for an EC formulation.

**RMS comment on use of the art. 34 of the 1107/2009 to support ULTRACENT 460 EC registration in Poland**

From physicochemical perspective ULTRACENT 460 EC is considered equivalent/ comparable to already registered INPUT 460 EC in Poland under Composition’s comparison in accordance with Article 34 of Regulation 1107/2009. So, unprotected physicochemical data taken from INPUT 460 EC can be used to support ULTRACENT 460 EC registration in Poland.

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

Please refer to the data for INPUT 460 EC (R-61/2011).

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Please refer to the data for INPUT 460 EC (R-61/2011).

Compliance with FAO specifications:

FAO specifications have not been allocated for the active substances contained in ULTRACENT 460 EC. Neither for prothioconazole, nor for spiroxamine, FAO specifications are described in the respective SANCO documents.

Formulation used for tests

The product used in the tests has the same composition as the one cited in Part C.

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

*The following highlighted information can be found in the evaluation reports that were compiled for the authorization of INPUT 460 EC (R-61/2011) in Poland:*

| Annex point | Method used /  deviations | Test material | Findings | GLP Y/N | Reference | Acceptability /  comments |
| --- | --- | --- | --- | --- | --- | --- |
| Colour and  physical state  (KCP 2.1) | Visual assessment | INPUT 460 EC | Appearance:  Color: brown  Odor: armotaic  Physical state: liquid, transparent |  | Gueldner, 2001 | Non protected data can be used to support Ultracent 460 EC registration in Poland under art. 34 of reg.1107/2009. |
| Colour and  physical state  (KCP 2.1) | OCSPP 830.6302  OCSPP 830.6304  OCSPP 830.6303 | Prothioconazole 160 g/L + Spiroxamine 300 g/L EC,  Batch no. JMG22X03A | Appearance:  Color: Yellowish brown, 2.5Y 8/4  Odor: Mild aromatic  Physical state: Liquid | Y | Kishora, K. S., 2023a, Report no. AG-G1571 | Accepted |
| Explosive properties  (KCP 2.2.1) | EEC A14 | INPUT 460 EC | It is not explosive under the influence of shock mechanical shock. | Y | Heitkamp, 2001 | Non protected data can be used to support Ultracent 460 EC registration in Poland under art. 34 of reg.1107/2009. |
| Oxidizing properties  (KCP 2.2.2) | Not tested | INPUT 460 EC | Due to the chemical structure of the active substances and additives, oxidising properties are not expected. |  |  | Non protected data can be used to support Ultracent 460 EC registration in Poland under art. 34 of reg.1107/2009. |
| Flash point  (KCP 2.3.1) | EEC A9  DIN EN 22719 | INPUT 460 EC | 152 °C | Y | Heitkamp, 2001 | Non protected data can be used to support Ultracent 460 EC registration in Poland under art. 34 of reg.1107/2009. |
| Flammability  (KCP 2.3.2) |  | INPUT 460 EC | not relevant, liquid product |  |  |  |
| Self-heating  (KCP 2.3.3) | EEC A15  DIN51794 | INPUT 460 EC | 245 °C | Y | Heitkamp, 2001 | Non protected data can be used to support Ultracent 460 EC registration in Poland under art. 34 of reg.1107/2009. |
| Acidity or alkalinity and pH  (KCP 2.4.1) | Not tested | INPUT 460 EC | 4< pH < 10 |  |  |  |
| pH of a 1% aqueous dilution, emulsion or dispersion  (KCP 2.4.2) | CIPAC MT 75.3 | INPUT 460 EC | pH = 7.8 | Y | Gueldner, 2001 | Non protected data can be used to support Ultracent 460 EC registration in Poland under art. 34 of reg.1107/2009. |
| pH of a 1% aqueous dilution, emulsion or dispersion  (KCP 2.4.2) | CIPAC MT 75.3  OCSPP 830.7000 | Prothioconazole 160 g/L + Spiroxamine 300 g/L EC,  Batch no. JMG22X03A | pH of 1 % w/v aqueous emulsion: 7.08 ± 0.01 at 25 °C ± 1 °C  pH of neat sample: 6.73 ± 0.02 at 25 °C ± 1 °C | Y | Kishora, K. S., 2023a, Report no. AG-G1571 | Accepted |
| Viscosity  (KCP 2.5.1) | Kinematic viscosity | INPUT 460 EC | Not relevant, not used as ULV |  |  |  |
| Viscosity  (KCP 2.5.1) | OECD 114, Dynamic viscosity | INPUT 460 EC | Ŋ = 63.9 x 10-3 Pa s at 20 °C, rotations 100 s-1 | Y | Gueldner, 2001 | The study doesn’t meet the current requirements. So it’s not considered for evaluation |
| Viscosity  (KCP 2.5.1) | OECD 114  CIPAC MT 192 | Prothioconazole 160 g/L + Spiroxamine 300 g/L EC,  Batch no. JMG22X03A | Determination of mean viscosity by rotational viscometer at 20 ± 0.2 °C:   |  |  | | --- | --- | | Shear rates (1/s) | Apparent viscosity (cP/mPa.s) | | 20 | 60.32 ± 0.31 | | 40 | 60.79 ± 0.10 | | 60 | 60.81 ± 0.03 | | 40 | 60.59 ± 0.17 | | 20 | 59.93 ± 0.30 |   Determination of mean viscosity by rotational viscometer at 40 ± 0.2 °C:   |  |  | | --- | --- | | Shear rates (1/s) | Apparent viscosity (cP/mPa.s) | | 20 | 22.64 ± 0.12 | | 40 | 22.15 ± 0.06 | | 60 | 22.11 ± 0.07 | | 40 | 22.01 ± 0.21 | | 20 | 21.91 ± 0.12 | | Y | Kishora, K. S., 2023b, Report no. AG-G2167 | Accepted  The PPP doesn’t meet the requirement to classify under ASP. TOX CAT. 1. |
| Surface tension  (KCP 2.5.2) | OECD 115 | INPUT 460 EC | 29.7 mN/m  0.63 % at 20 °C | Y | Gueldner, 2001 | Non protected data can be used to support Ultracent 460 EC registration in Poland under art. 34 of reg.1107/2009. |
| Surface tension  (KCP 2.5.2) | OECD 115  EEA A.5 | Prothioconazole 160 g/L + Spiroxamine 300 g/L EC,  Batch no. JMG22X03A | The surface tension of 1.25 % v/v (12.5 mL product/L water) of Prothioconazole 160 g/L + Spiroxamine 300 g/L EC was determined to be 39.395 ± 0.063 dynes/cm at sample mean temperature of 20.10 ºC.  The surface tension of test item Prothioconazole 160 g/L + Spiroxamine 300 g/L EC as such (neat) was determined to be 34.882 ± 0.031 dynes/cm at neat sample mean temperature of 20.10 ºC. | Y | Kishora, K. S., 2023c, Report no. AG-G2166 | Accepted |
| Relative density  (KCP 2.6.1) | OECD 109 | INPUT 460 EC | D420 = 0.985 | Y | Gueldner, 2001 | Non protected data can be used to support Ultracent 460 EC registration in Poland under art. 34 of reg.1107/2009. |
| Relative density  (KCP 2.6.1) | OECD 109  CIPAC MT 3 | Prothioconazole 160 g/L + Spiroxamine 300 g/L EC,  Batch no. JMG22X03A | The density of test item, Prothioconazole 160 g/L + Spiroxamine 300 g/L EC at 20.1 °C were found to be 0.989 ± 0.000 g/mL and relative density of the test item was 0.989 ± 0.000. | Y | Kishora, K. S., 2023d, Report no. AG-G1570 | Accepted |
| Bulk density  (KCP 2.6.2) | Not tested | INPUT 460 EC | not relevant for EC formulations |  |  |  |
| Storage Stability after 14 days at 54º C  (KCP 2.7.1) | CIPAC MT 46  CIPAC MT 46.3 | INPUT 460 EC | The active ingredient content has not decreased to below 95%. The phys-chem properties have not changed to an extent that affects the use and safety of the product.  The product is stable after 14 days at 54°C. |  | Gueldner, 2004a,  Gueldner 2004b, Gueldner 2004c | Non protected data can be used to support Ultracent 460 EC registration in Poland under art. 34 of reg.1107/2009. |
| Storage Stability after 14 days at 54º C  (KCP 2.7.1) | CIPAC MT 46.4/OCSSPP 830.6317  SANCO 3030/99 rev.5  OCSPP 830.6302  OCSPP 830.6304  OCSPP 830.6303  CIPAC MT 75.3  CIPAC MT 47.3  CIPAC MT 36.3  OCSPP 830.6320 | Prothioconazole 160 g/L + Spiroxamine 300 g/L EC,  Batch no. JMG22X03A | |  |  |  |  | | --- | --- | --- | --- | | Parameter | Guideline | Results (mean ± SD) | | | Ambient sample | Stored at 54 ± 2 °C for 14 days | | Active Ingredient (A.I.) Content, g/L  - Prothioconazole  - Spiroxamine | SANCO 3030/99 rev.5  HPLC Method  GC Method | 161.2 ± 0.7  300.6 ± 0.7 | 160.9 ± 0.4  299.4 ± 0.7 | | Impurity content, % m/m  - Deschloro Prothioconazole (Impurity-1)  - Desthio Prothioconazole (Impurity-2)  - Toluene (Impurity-3) | SANCO 3030/99 rev.5  LCMS Method  GCHS Method | 0.00646 ± 0.00006  0.00642 ± 0.00012  0.0166 ± 0.0004 | 0.00660 ± 0.00018  0.00629 ± 0.00008  0.0160 ± 0.0004 | | Appearance  - Color  - Odor  - Physical state | OCSPP 830.6302  OCSPP 830.6304  OCSPP 830.6303 | Yellowish brown  2.5Y 8/4  Mild aromatic  Liquid | Yellowish brown  2.5Y 8/4  Mild aromatic  Liquid | | pH of  - 1% w/v aqueous emulsion  - Neat sample | CIPAC MT 75.3 | 7.08 ± 0.01  6.73 ± 0.02 | 6.90 ± 0.02  6.69 ± 0.01 | | Persistent foam, mL  @ 0.1875 %v/v (Low use rate)  - after 1 min ± 10 sec  - after 12 min ± 10 sec  @1.25 %v/v (High use rate)  - after 1 min ± 10 sec  - after 12 min ± 10 sec | CIPAC MT 47.3 | Nil  Nil  10.0 ± 0.0  8.0 ± 0.0 | Nil  Nil  10.0 ± 0.0  8.0 ± 0.0 | | Emulsion characteristics and  Re-emulsification | CIPAC MT 36.3 | Complies | Complies | | Packing Stability/Corrosion  Characteristics | OCSPP 830.6320,  Visual | No perforation, leakage, discoloration or darkening and no corrosion to the packaging material | No perforation, leakage, discoloration or darkening and no corrosion to the packaging material | | Y | Kishora, K. S., 2023a, Report no. AG-G1571 | Accepted |
| Stability after storage for other periods and/or temperatures  (KCP 2.7.2) | Not tested | INPUT 460 EC | The product is stable after 14 days at 54 °C. |  |  | Not required |
| Minimum content after heat stability testing  (KCP 2.7.3) | Not tested | INPUT 460 EC | The product is stable after 14 days at 54 °C. |  |  | Not required |
| Effect of low temperatures on stability  (KCP 2.7.4) | CIPAC 39.3 | INPUT 460 EC | 0 ml separation into liquid or solid fractions at 7 days at 0 °C |  | Gueldner, 2004a,  Gueldner 2004b, Gueldner 2004c | The study doesn’t meet the current requirements. So it’s not considered for evaluation |
| Effect of low temperatures on stability  (KCP 2.7.4) | CIPAC MT 39.3  CIPAC MT 36.3 | Prothioconazole 160 g/L + Spiroxamine 300 g/L EC,  Batch no. JMG22X03A | Results before and after storage for 7 days at 0 ± 2 °C:   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Parameter | Result of analyis | | | Method of analysis | |  | Initial at ambient condition | | After 7 days storage at 0 ± 2 °C |  | | Low temperature stabilitly | | The test item was homogeneous and there were no separated materials | | CIPAC MT 39.3 | | Emulsion Stability and Re-emulsification | | Complies | Complies | CIPAC MT 36.3 | | Y | Kishora, K. S., 2023e, Report no. AG-G1572 | Accepted |
| Ambient temperature shelf life  (KCP 2.7.5) |  |  | Please refer to the data of the reference product INPUT 460 EC (R-61/2011). |  |  | Non protected physicochemical data taken from INPUT 460 EC can be used to support Ultracent 460 EC registration in Poland under art. 34 of reg.1107/2009. |
| Shelf life in months (if less than 2 years)  (KCP 2.7.6) |  |  | Please refer to the data of the reference product INPUT 460 EC (R-61/2011). |  |  | Non protected physicochemical data taken from INPUT 460 EC can be used to support Ultracent 460 EC registration in Poland under art. 34 of reg.1107/2009. |
| Wettability  (KCP 2.8.1) | Not tested | INPUT 460 EC | Not relevant for an EC product. |  |  |  |
| Persistence of foaming  (KCP 2.8.2) | CIPAC MT 47.2 | INPUT 460 EC | 3 mL foam after 10 sec;  0 ml foam after 1 min;  0 mL foam after 3 min;  0 mL foam after 12 min |  | Gueldner, 2001 | Non protected physicochemical data taken from INPUT 460 EC can be used to support Ultracent 460 EC registration in Poland under art. 34 of reg.1107/2009.  Nevertheless, the newer study using the adequate cipac method is presented below. |
| Persistence of foaming  (KCP 2.8.2) | CIPAC MT 47.3 | Prothioconazole 160 g/L + Spiroxamine 300 g/L EC,  Batch no. JMG22X03A | Persistent foam, mL  @ 0.1875 % v/v (Low use rate)  - after 1 min ± 10 sec: Nil  - after 12 min ± 10 sec: Nil  @1.25 % v/v (High use rate)  - after 1 min ± 10 sec: 10.0 ± 0.0  - after 12 min ± 10 sec 8.0 ± 0.0 | Y | Kishora, K. S., 2023a, Report no. AG-G1571 | Accepted |
| Suspensibility  (KCP 2.8.3.1) |  | INPUT 460 EC | Not relevant for an EC product. |  |  |  |
| Spontaneity of dispersion  (KCP 2.8.3.2) |  | INPUT 460 EC | Not relevant for an EC product. |  |  |  |
| Dispersion stability  (KCP 2.8.3.3) |  | INPUT 460 EC | Not relevant for an EC product. |  |  |  |
| Degree of dissolution and dilution stability  (KCP 2.8.4) |  | INPUT 460 EC | Not relevant for an EC product. |  |  |  |
| Particle size distribution / nominal size range of granules  (KCP 2.8.5.1.1) |  | INPUT 460 EC | Not relevant for an EC product. |  |  |  |
| Wet sieve test  (KCP 2.8.5.1.2) |  | INPUT 460 EC | Not relevant for an EC product. |  |  |  |
| Dust content  (KCP 2.8.5.2.1) |  | INPUT 460 EC | Not relevant for an EC product. |  |  |  |
| Particle size of dust  (KCP 2.8.5.2.2) |  | INPUT 460 EC | Not relevant for an EC product. |  |  |  |
| Attrition  (KCP 2.8.5.3) |  |  | Please refer to the data of the reference product INPUT 460 EC (R-61/2011). |  |  | Not applicable |
| Hardness and integrity  (KCP 2.8.5.4) |  |  | Please refer to the data of the reference product INPUT 460 EC (R-61/2011). |  |  | Not applicable |
| Emulsifiability  (KCP 2.8.6.1) | CIPAC MT 36.1 | INPUT 460 EC | Water A  30 min. - 0 ml  2 hrs - 0 ml  24 hrs - 0 ml  Water D  30 min. - 0 ml  2 hrs - 0 ml  24 hrs - 0 ml |  | Gueldner, 2001 | Non protected data can be used to support Ultracent 460 EC registration in Poland under art. 34 of reg.1107/2009. |
| Emulsion stability  (KCP 2.8.6.2) |  | INPUT 460 EC | Not relevant for an EC product. |  |  |  |
| Emulsion stability  (KCP 2.8.6.2) | CIPAC MT 36.3 | Prothioconazole 160 g/L + Spiroxamine 300 g/L EC,  Batch no. JMG22X03A | It was observed that there was no formation of froth, free oil, cream, and solid matter for both doses (with standard water D and A). The volume of emulsion was found to be 100 mL. | Y | Kishora, K. S., 2023a, Report no. AG-G1571 | Accepted |
| Emulsion stability  (KCP 2.8.6.2) | CIPAC MT 36.3 | Prothioconazole 160 g/L + Spiroxamine 300 g/L EC,  Batch no. JMG22X03A | It was observed that there was no formation of froth, free oil, cream, and solid matter for both doses (with standard water D and A) for low temperature stability samples. The volume of emulsion was found to be 100 mL. | Y | Kishora, K. S., 2023e, Report no. AG-G1572 | Accepted |
| Re-emulsifiability  (KCP 2.8.6.3) | CIPAC MT 36.1 | INPUT 460 EC | Reemulsifiability  24 hrs. - completely (water A and D)  24.5 hrs - 0 ml (water A and D) |  | Gueldner, 2001 | Non protected data can be used to support Ultracent 460 EC registration in Poland under art. 34 of reg.1107/2009. |
| Re-emulsifiability  (KCP 2.8.6.3) | CIPAC MT 36.3 | Prothioconazole 160 g/L + Spiroxamine 300 g/L EC,  Batch no. JMG22X03A | It was observed that there was no formation of froth, free oil, cream, and solid matter for both doses (with standard water D and A). The volume of emulsion was found to be 100 mL. | Y | Kishora, K. S., 2023a, Report no. AG-G1571 | Accepted |
| Re-emulsifiability  (KCP 2.8.6.3) | CIPAC MT 36.3 | Prothioconazole 160 g/L + Spiroxamine 300 g/L EC,  Batch no. JMG22X03A | It was observed that there was no formation of froth, free oil, cream, and solid matter for both doses (with standard water D and A). The volume of emulsion was found to be 100 mL. | Y | Kishora, K. S., 2023e, Report no. AG-G1572 | Accepted |
| Flowability  (KCP 2.8.7.1) |  | INPUT 460 EC | Not relevant for an EC product. |  |  |  |
| Pourability  (KCP 2.8.7.2) |  |  | Please refer to the data of the reference product INPUT 460 EC (R-61/2011). |  |  | Not applicable |
| Dustability following accelerated storage  (KCP 2.8.7.3) |  | INPUT 460 EC | Not relevant for an EC product. |  |  |  |
| Physical compatibility of tank mixes  (KCP 2.9.1) |  | INPUT 460 EC | Not relevant. On labelling, it is not recommended to mix the contents of the containers. |  |  |  |
| Chemical compatibility of tank mixes  (KCP 2.9.2) |  | INPUT 460 EC | Not relevant. On labelling, it is not recommended to mix the contents of the containers. |  |  |  |
| Adhesion to seeds  (KCP 2.10.1) |  | INPUT 460 EC | Not relevant for an EC product. |  |  |  |
| Distribution to seed  (KCP 2.10.2) |  | INPUT 460 EC | Not relevant for an EC product. |  |  |  |
| Other/special studies  (KCP 2.11) |  |  | Please refer to the data of the reference product INPUT 460 EC (R-61/2011). |  |  | Non protected data can be used to support Ultracent 460 EC registration in Poland under art. 34 of reg.1107/2009. |

# 

# 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

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

**RMS comment on use of the art. 34 of the 1107/2009 to support ULTRACENT 460 EC registration in Poland**

From physicochemical perspective ULTRACENT 460 EC is considered equivalent/ comparable to already registered INPUT 460 EC in Poland under Composition’s comparison in accordance with Article 34 of Regulation 1107/2009. So, unprotected physicochemical data taken from INPUT 460 EC can be used to support ULTRACENT 460 EC registration in Poland. In summary, the packaging material accepted for INPUT 460 EC can be accepted for ULTRACENT 460 EC.

Table 4.1‑1: Packaging information for 1 liter bottle

| Type | Description |
| --- | --- |
| Material: | HDPE/PA & HDPE/EVOH Co-EX |
| Shape/size: | 1 L, cylinder, 234 mm x 88.5 mm |
| Opening: | 45 mm |
| Closure: | HDPE |
| Seal: | Induction |
| Manner of construction | Extruded |
| UN/ADR | Yes |

Table 4.1‑2: Packaging information for 3 liter jerry can

| Type | Description |
| --- | --- |
| Material: | HDPE/PA & HDPE/EVOH Co-EX |
| Shape/size: | 3 L, rectangular, 257 mm x 115 mm x 160 mm |
| Opening: | 63 mm |
| Closure: | HDPE |
| Seal: | Induction |
| Manner of construction | Extruded |
| UN/ADR | Yes |

Table 4.1‑2: Packaging information for 5 liter jerry can

| Type | Description |
| --- | --- |
| Material: | HDPE/PA & HDPE/EVOH Co-EX |
| Shape/size: | 5 L, rectangular, 298.5 mm x 142 mm x 193 mm |
| Opening: | 63mm |
| Closure: | HDPE |
| Seal: | Induction |
| Manner of construction | Extruded |
| UN/ADR | Yes |

Table 4.1‑2: Packaging information for 15 liter jerry can

| Type | Description |
| --- | --- |
| Material: | HDPE/PA & HDPE/EVOH Co-EX |
| Shape/size: | 15 L, jerry can, 320 mm x 245 mm x 293 mm |
| Opening: | 63mm |
| Closure: | HDPE |
| Seal: | Induction |
| Manner of construction | Extruded |
| UN/ADR | Yes |

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

**Pre-harvest interval (in days) for each relevant crop**

|  |  |
| --- | --- |
| **For use in** | **PHI** |
| Winter wheat | 35 |
| Spring wheat | 35 |
| Spring barley | 35 |
| Winter barley | 35 |
| Winter triticale | 35 |

**Re-entry period (in days) for livestock, to areas to be grazed**

ULTRACENT 460 EC will be applied on the following representative crops: winter wheat, spring wheat, spring barley and winter barley.

None of the crops are intended for grazing by cattle shortly after treatment. Exposure of livestock in this way is highly unlikely. Therefore, the establishment of a withholding period for the protection of livestock is not necessary.

**Re-entry period (in hours or days) for man to crops, building or spaces treated**

Do not enter until the spray has completely dried on the plant surface.

**Withholding period (in days) for animal feeding stuffs**

Not relevant.

**Waiting period (in days) between application and handling of treated products**

There are no specific waiting periods as there is no specific risk for humans. It can be expected that handling of the treated products is without risk, if the spray dilution has dried.

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

Not relevant.

**Information on specific conditions under which the preparation may or may not be used**

None of the test results or observations obtained so far indicate that any restrictions should be imposed. ULTRACENT 460 EC, when used according to label directions and precautions, will produce the expected results in controlling the target pests.

## Recommended methods and precautions (KCP 4.2)

### Procedures for Cleaning Application Equipment

**Procedures for cleaning application equipment and protective clothing**

Before use, start with clean, well-maintained equipment. Clean all sprayers thoroughly immediately after use to reduce the risk of hardened deposits forming, which can be difficult to remove. Drain spray-equipment. Thoroughly rinse sprayer and flush hoses, booms, and nozzles with clean water. Also clean all other associated application equipment. Take all necessary safety precautions when cleaning equipment. Do not clean near wells, water sources or desirable vegetation. Dispose of the rinse water in accordance with local regulations.

**Effectiveness of the cleaning procedures**

The procedures proposed for the cleaning of application equipment are considered to be effective.

### Statement of the Risks Arising and the Recommended Methods and Precautions and Handling Procedures to Minimise Those Risks

#### Warehouse storage and User level storage

Store in the original packaging . Keep containers tightly closed in a dry and well­ ventilated place at a temperature between 0 °C and 30 °C, also for quality reasons. Store in a place accessible only to authorized persons. Protect against freezing. Protect against direct sunlight. Keep away from children. Keep away from food, drink and animal feed.

#### Transport

**Land transport (ADR)**

|  |  |
| --- | --- |
| **ADR UN number** | 3082 |
| **UN proper shipping name:** | Environmentally hazardous substance, liquid, N.O.S. (spiroxamine solution) |
| **Transport hazard class(es):** | 9 |
| **Packing group:** | III |
| **Environmental hazards:** | yes |
| **Special precautions for user:** | Avoid contact with released product or contaminated surfaces. Use personal protective equipment. In the recommended conditions of use and handling , please observe the notes in the instructions for use. |

**Air transport (IATA\_C)**

|  |  |
| --- | --- |
| **IATA/ICAO UN number:** | 3082 |
| **UN proper shipping name:** | Environmentally hazardous substance, liquid, N.O.S. (spiroxamine solution) |
| **Transport hazard class(es):** | 9 |
| **Packing group:** | III |
| **Environmental hazards:** | yes |
| **Special precautions for user:** | Avoid contact with released product or contaminated surfaces. Use personal protective equipment. In the recommended conditions of use and handling , please observe the notes in the instructions for use. |

**Sea transport**

|  |  |
| --- | --- |
| **IMDG UN number:** | 3082 |
| **UN proper shipping name:** | Environmentally hazardous substance, liquid, N.O.S. (spiroxamine solution) |
| **Transport hazard class(es):** | 9 |
| **Packing group:** | III |
| **Environmental hazards:** | yes  Marine pollutant: YES |
| **Special precautions for user:** | Avoid contact with released product or contaminated surfaces. Use personal protective equipment. In the recommended conditions of use and handling , please observe the notes in the instructions for use. |

This classification is generally not approved for inland waterway transport in tankers. Contact the manufacturer for more information.

**Carriage in bulk in accordance with Annex II of MARPOL 73/78 and the IBC Code.**

There is no bulk transport.

#### Fire

**Extinguishing media:**

Suitable extinguishing media: water spray, alcohol-resistant foam, extinguishing powders or carbon dioxide.

Unsuitable extinguishing media for safety reasons: Avoid full water jet.

**Special hazards arising from the substance or mixture:**

In the event of fire, the following may be released: hydrogen chloride (HCI), hydrogen cyanide (hydrocyanic acid), carbon monoxide (CO), sulfur oxides, nitrogen oxides (NOx).

**Advice for fire-fighters:**

In case of fire and/or explosion, do not breathe fumes. In case of fire, wear self-contained breathing apparatus.

**Further information:**

Limit the spread of extinguishing agents. Do not allow liquids from fire extinguishing to run off into water systems or drains.

#### Nature of protective clothing proposed

In the recommended conditions of use and handling , please observe the notes on the instruction label. Otherwise, follow the instructions provided.

#### Characteristics of protective clothing proposed

**Respiratory protection**

Use respirator with mask and filter against organic vapours and gases (protection factor 10) in accordance with EN 140 or equivalent.

Respiratory protective equipment should only be used to control residual risk, during short duration activities, when all reasonable and possible measures to reduce exposure at source have already been applied, e.g. containment and/or local exhaust ventilation. Manufacturers' instructions for wearing and maintaining respiratory protective equipment should always be followed.

**Hand protection**

Please follow the permeability and breakthrough time instructions provided by the glove supplier. Also take into account the specific local conditions of use of the product, such as the danger of cutting, abrasion and contact time.

Wash the gloves if contaminated. Remove them if they are contaminated on the inside, perforated or the contamination on the outside cannot be removed. Wash hands frequently and always before eating, drinking, smoking or using the toilet.

Material Nitrile rubber

Permeation rate > 480 min

Glove thickness >0.4 mm

Protection index Class 6

Standard Protective gloves conforming to EN374.

**Eye protection**

Wear goggles (according to EN166, field of vision = 5 or equivalent).

**Skin and body protection**

Wear standard protective suit and category 3 type 6 protective clothing.

Wear two layers of clothing if possible. Polyester/cotton or cotton protective clothing should be worn under the chemical-resistant suit and should be cleaned frequently at a professional laundry.

If a chemical protective suit is splashed, sprayed or heavily soiled, it should be cleaned immediately and then carefully removed and disposed of according to the manufacturer's recommendations.

#### Suitability and effectiveness of protective clothing and equipment

Please refer to point 4.3.2.4.

No additional information provided, general advice for all plant protection products should be followed.

#### Procedures to minimise the generation of waste

Buy and store only the quantity of product needed in the short term. Do not open larger containers than required for immediate use. Do not mix a larger quantity of spray solution than is required for immediate use.

#### Combustion products likely to be generated in the event of fire

In the event of fire, the following may be released: hydrogen chloride (HCI), hydrogen cyanide (hydrocyanic acid), carbon monoxide (CO), sulfur oxides, nitrogen oxides (NOx).

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

Accidental release measures:

Avoid contact with spilled product or contaminated surfaces. Wear personal protective equipment. Do not allow to enter drains, surface water or groundwater. Do not use when weather conditions allow runoff or drift. Do not contaminate surface water or groundwater through equipment washing or waste disposal (including water after equipment washing). Avoid release to the environment contrary to the identified use.

First aid measures:

Remove from the danger zone. Position and transport affected person in a stable position (laterally fixed). Immediately remove all contaminated clothing and dispose of safely. In case of accident or if you feel unwell, seek medical advice immediately (show the label if possible).

If inhaled:

Move to fresh air. Keep affected person warm and calm. Contact a poison centre or doctor immediately.

In case of skin contact:

Wash off thoroughly with plenty of soapy water, if possible with polyethylene glycol 400, then rinse with water. If symptoms persist, call a doctor.

In case of eye contact:

Rinse immediately with plenty of water, also under the eyelids for at least 15 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue flushing the eyes. Contact a poison centre or doctor immediately.

If swallowed:

DO NOT induce vomiting. Rinse out mouth. Contact a poison centre or doctor immediately.

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

### Neutralisation procedure

Absorb in an inert adsorbent material (e.g. sand, silica gel, acid absorber, universal absorber, sawdust). Thoroughly clean contaminated floors and objects in accordance with environmental regulations. Store in suitable, closed containers until disposal.

### Disposal Procedures for the Plant Protection Product

**Product**

In accordance with current legislation and, if necessary, after consultation with the operator and local authorities, the product may be disposed of in a landfill or waste incineration plant. Do not dispose with municipal waste. Do not dispose of residues into wastewater.

**Contaminated packaging**

Add water to the remaining suspension. Rinse the containers three times. Return empty containers to the point of sale where this product was purchased. Incomplete empty containers should be disposed of as hazardous waste. Do not reuse empty containers.

1. Lists of data considered in support of the evaluation

No data other than the one cited below is submitted in support of the application for authorization of ULTRACENT 460 EC. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, approval holder Bayer AG), in accordance with Article 34 of Regulation 1107/2009/EC. It was not considered necessary to submit additional data and the evaluator is referred to the registration report of INPUT 460 EC.

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  Also submitted under:  KCP 2.4.2 KCP 2.7.1  KCP 2.8.2  KCP 2.8.6.2  KCP 2.8.6.3 | Kishora, K. S. | 2023a | Accelerated Storage Stability Test by Heating at 54 ± 2°C of Prothioconazole 160 g/L + Spiroxamine 300 g/L EC  Report No. AG-G1571  Eurofins Advinius Agrosciences Services India Private Limited, Karnataka, India  GLP  Unpublished | N | XXXX |
| KCP 2.4.2  Also submitted under:  KCP 2.1  KCP 2.7.1  KCP 2.8.2  KCP 2.8.6.2  KCP 2.8.6.3 | Kishora, K. S. | 2023a | Accelerated Storage Stability Test by Heating at 54 ± 2°C of Prothioconazole 160 g/L + Spiroxamine 300 g/L EC  Report No. AG-G1571  Eurofins Advinius Agrosciences Services India Private Limited, Karnataka, India  GLP  Unpublished | N | XXXX |
| KCP 2.5.1 | Kishora, K. S. | 2023b | Determination Viscosity of Prothioconazole 160 g/L + Spiroxamine 300 g/L EC  Report No. AG-G2167  Eurofins Advinius Agrosciences Services India Private Limited, Karnataka, India  GLP  Unpublished | N | XXXX |
| KCP 2.5.2 | Kishora, K. S. | 2023c | Determination of Surface Tension of Prothioconazole 160 g/L + Spiroxamine 300 g/L EC  Report No. AG-G2166  Eurofins Advinius Agrosciences Services India Private Limited, Karnataka, India  GLP  Unpublished | N | XXXX |
| KCP 2.6.1 | Kishora, K. S. | 2023d | Determination of Relative Density of Prothioconazole 160 g/L + Spiroxamine 300 g/L EC  Report No. AG-G1570  Eurofins Advinius Agrosciences Services India Private Limited, Karnataka, India  GLP  Unpublished | N | XXXX |
| KCP 2.7.1  Also submitted under:  KCP 2.1  KCP 2.4.2  KCP 2.8.2  KCP 2.8.6.2  KCP 2.8.6.3 | Kishora, K. S. | 2023a | Accelerated Storage Stability Test by Heating at 54 ± 2°C of Prothioconazole 160 g/L + Spiroxamine 300 g/L EC  Report No. AG-G1571  Eurofins Advinius Agrosciences Services India Private Limited, Karnataka, India  GLP  Unpublished | N | XXXX |
| KCP 2.7.4  Also submitted under:  KCP 2.8.6.2  KCP 2.8.6.3 | Kishora, K. S. | 2023e | Low Temperature Stability of Prothioconazole 160 g/L + Spiroxamine 300 g/L EC  Report No. AG-G1572  Eurofins Advinius Agrosciences Services India Private Limited, Karnataka, India  GLP  Unpublished | N | XXXX |
| KCP 2.8.2  Also submitted under:  KCP 2.1  KCP 2.4.2  KCP 2.7.1  KCP 2.8.6.2  KCP 2.8.6.3 | Kishora, K. S. | 2023a | Accelerated Storage Stability Test by Heating at 54 ± 2°C of Prothioconazole 160 g/L + Spiroxamine 300 g/L EC  Report No. AG-G1571  Eurofins Advinius Agrosciences Services India Private Limited, Karnataka, India  GLP  Unpublished | N | XXXX |
| KCP 2.8.6.2  Also submitted under:  KCP 2.1  KCP 2.4.2  KCP 2.7.1  KCP 2.8.2  KCP 2.8.6.3 | Kishora, K. S. | 2023a | Accelerated Storage Stability Test by Heating at 54 ± 2°C of Prothioconazole 160 g/L + Spiroxamine 300 g/L EC  Report No. AG-G1571  Eurofins Advinius Agrosciences Services India Private Limited, Karnataka, India  GLP  Unpublished | N | XXXX |
| KCP 2.8.6.2  Also submitted under:  KCP 2.7.4  KCP 2.8.6.3 | Kishora, K. S. | 2023e | Low Temperature Stability of Prothioconazole 160 g/L + Spiroxamine 300 g/L EC  Report No. AG-G1572  Eurofins Advinius Agrosciences Services India Private Limited, Karnataka, India  GLP  Unpublished | N | XXXX |
| KCP 2.8.6.3  Also submitted under:  KCP 2.1  KCP 2.4.2  KCP 2.7.1  KCP 2.8.2  KCP 2.8.6.2 | Kishora, K. S. | 2023a | Accelerated Storage Stability Test by Heating at 54 ± 2°C of Prothioconazole 160 g/L + Spiroxamine 300 g/L EC  Report No. AG-G1571  Eurofins Advinius Agrosciences Services India Private Limited, Karnataka, India  GLP  Unpublished | N | XXXX |
| KCP 2.8.6.3  Also submitted under:  KCP 2.7.4  KCP 2.8.6.2 | Kishora, K. S. | 2023e | Low Temperature Stability of Prothioconazole 160 g/L + Spiroxamine 300 g/L EC  Report No. AG-G1572  Eurofins Advinius Agrosciences Services India Private Limited, Karnataka, India  GLP  Unpublished | N | 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 |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

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 |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

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 |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

1. Additional data on the physical, chemical and technical properties of the active substance
   1. Prothioconazole

No new data on physical and chemical data on the active substance prothioconazole is submitted with this application.

* 1. Spiroxamine

No new data on physical and chemical data on the active substance spiroxamine is submitted with this application.