|  |
| --- |
| **REGISTRATION REPORT**  Part B  Section 0  Product Background, Regulatory Context and  GAP information |
| 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  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 authorised in Poland |
| October 2024 | Version evaluated by zRMS PL |
| February 2025 | Final revision after dossier reconstruction. |
|  |  |

Table of Contents

[0 Product background, regulatory context and GAP information 4](#_Toc190249365)

[0.1 Introduction 4](#_Toc190249366)

[0.1.1 Reason for application 4](#_Toc190249367)

[0.1.2 Details of zRMS(s) and concerned MS 5](#_Toc190249368)

[0.1.3 Regulatory history of the active(s) 5](#_Toc190249369)

[0.1.3.1 Prothioconazole 5](#_Toc190249370)

[0.1.3.2 Spiroxamine 6](#_Toc190249371)

[0.1.4 Regulatory history of the product 7](#_Toc190249372)

[0.2 zRMS conclusion 7](#_Toc190249373)

[Appendix 1 ALL intended uses 9](#_Toc190249374)

# Product background, regulatory context and GAP information

## Introduction

This application is submitted by XXXX to Poland for the first authorization of ULTRACENT 460 EC. ULTRACENT 460 EC is an emulsifiable concentrate containing 160 g/L prothioconazole and 300 g/L spiroxamine and is used as a fungicide in cereals. This application is based on the comparability with the reference product INPUT 460 EC of the authorization holder Bayer AG.

The application submitted herewith also relies on Article 34, in the form of an article 33 application. In the authorization procedure applied for herewith, Poland acts as zonal rapporteur member state (zRMS). There are no other concerned member states. Reference is made to the unprotected data and dossier submitted for INPUT 460 EC (R-61/2011, authorization holder Bayer AG) in Poland. Hence, exemption from the submission of studies is requested in accordance with Article 34 of Regulation (EC) No. 1107/2009. Additionally, data demonstrating the efficacy of the product as well as new studies on its physical-chemical properties is submitted in support of the application for authorization of ULTRACENT 460 EC.

The requested uses for ULTRACENT 460 EC are covered by those of the Polish reference product INPUT 460 EC. Formulation related data requirements are met by access to data previously submitted to the ministry for the identical and similar product INPUT 460 EC, reference to published data, and citing access to both Polish and EU review data now out of protection. The formulation of ULTRACENT 460 EC is supposed to be identical to that previously approved for INPUT 460 EC. For this reason, all formulation related data submitted by the original authorization holder for INUT 460 EC and held by the Polish ministry are cited as unprotected data in support of this current application. Therefore, except for the additionally submitted studies performed with ULTRACENT 460 EC, no new data nor risk assessment are required and thus are not presented in the current dossier.

This application refers to data and risk assessments performed in accordance with the Uniform Principles of Regulation (EC) No. 1107/2009 provided for the product INPUT 460 EC.

### Reason for application

This application is submitted by XXXX to Poland for the first authorization of ULTRACENT 460 EC.

Exemption from the submission of studies is requested in accordance with Article 34 of Regulation (EC) No. 1107/2009. Reference is made to the unprotected data and dossier of INPUT 460 EC (R-61/2011, authorization holder Bayer AG).

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

In addition to the submission of studies as listed in section(s) 1-2-4 and 3, exemption from the submission of studies is requested in accordance with Article 34 of Regulation (EC) No. 1107/2009.

### Details of zRMS(s) and concerned MS

Table 0.1‑1: Overview of zRMS and cMS

|  | zRMS, product name and authorization no. (if relevant) | (if relevant) Concerned MS, MS’ product name and authorization number (if applicable) |
| --- | --- | --- |
| Northern zone | - | - |
| Central zone | PL, ULTRACENT 460 EC | - |
| Southern zone | - | - |
| Inter-zonal | - | - |

### Regulatory history of the active(s)

#### Prothioconazole

Table 0.1‑2: Summary of regulatory history of CAS No: 178928-70-6

| Status |  |
| --- | --- |
| Approved in EU | Y |
| Original Inclusion Directive  or  Commission Implementing Regulation | Commission Directive 08/44/EC  or  Commission Implementing Regulation (EU) No 540/2011 |
| RMS | PL (The original RMS was UK.) |
| Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied) | 01.08.2008 |
| Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal) | - |
| Date of final Commission (re-registration) deadline (Step 2) | - |
| Current expiration of approval | 15.08.2025 |
| Low risk substance or Candidate for Substitution? | N |

Issues that need to be considered as part of the EU approval are listed below.

- The operator safety in spray applications. Conditions of use should include adequate protective measures;

- The protection of aquatic organisms. Risk mitigation measures such as buffer zones should be applied, where appropriate;

- The protection of birds and small mammals. Risk mitigation measures should be applied, where appropriate.

The SANCO report for prothioconazole (SANCO/3923/07) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 12 July 2007.

**Table 0.1‑3: Information on minimum purity of prothioconazole**

| EU agreed minimum purity from Inclusion Directive or Implementing regulation | (if different) Minimum purity of active substance used in the product / information on available equivalency report \*, \*\* |
| --- | --- |
| ≥ 970 g/kg | 985 g/kg  Equivalence report available: Y  RMS: France |

\* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

\*\*. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

#### Spiroxamine

Table 0.1‑2: Summary of regulatory history of CAS No: 118134-30-8

| Status |  |
| --- | --- |
| Approved in EU | Y |
| Original Inclusion Directive  or  Commission Implementing Regulation | Commission Directive 99/73/EC  or  Commission Implementing Regulation (EU) No 540/2011 |
| RMS | AT |
| Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied) | 01.01.2012 |
| Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal) | - |
| Date of final Commission (re-registration) deadline (Step 2) | - |
| Current expiration of approval | ~~31.12.2023~~  31.05.2026 |
| Low risk substance or Candidate for Substitution? | N |

Issues that need to be considered as part of the EU approval are listed below.

- the risk to operators and workers and shall ensure that conditions of use include the application of adequate personal protective equipment;

- the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;

- the risk to aquatic organisms.

Conditions of authorization shall include risk mitigation measures, where appropriate.

The SANCO report for spiroxamine (SANCO/10889/2011 Rev 2) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available in 22 October 2010.

**Table 0.1‑3: Information on minimum purity of spiroxamine**

| EU agreed minimum purity from Inclusion Directive or Implementing regulation | (if different) Minimum purity of active substance used in the product / information on available equivalency report \*, \*\* |
| --- | --- |
| 940 g/kg | 970 g/kg  Equivalence report available: Y  RMS: Czech Republic |

\* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

\*\*. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

### Regulatory history of the product

Not relevant as the product has not yet been authorized. The product was not evaluated as the ‘representative formulation’ during the EU review of the active substances.

## zRMS conclusion

Physicochemical properties:

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

Efficacy:

The registration is Ultracent 460 EC was considered according to Art. 33 of Regulation (EC) No 1107/2009, using Art. 34 of this Regulation, which allows the use of "non-protected" data of one product for registration of another product if they have a similar composition, activity, and intended use. To support the registration, the applicant submitted data from 8 efficacy trials carried out in Poland and also referred to out-of-protection efficacy data of identical product Input 460 EC, already registered in cereals. The results have shown good efficacy of Ultracent 460 EC, its selectivity towards wheat and barley, and no negative effects on yield and its quality as well as succeeding and adjacent crops. The scope of intended registration of Ultracent 460 EC corresponds to the currently applicable uses of Input 460 EC.

The evaluation of the application for the use of Ultracent 460 EC in wheat and barley in Poland resulted in the decision to grant the authorization.

Toxicology:

The application of a product ULTRACENT 460 EC does not pose an unacceptable risk to the health of operator using tractor-mounted/trailed boom sprayer without drift reduction technology for application of the product at maximal dose of 1L/ha in line with its intended use within good agricultural practice providing that he is wearing a work wear (with arms, body and legs covered) during M/L and A, and protective gloves during M/L. It is noted that the product is classified as Skin Irrit. 2 and Eye Irrit 2 thus the operator should wear a work wear covering arms, body and legs during mixing/loading and application, protective gloves, eye protection/face protection during mixing/loading operations or when directly contacting surface of equipment contaminated with concentrated product.

The application of product ULTRACENT 460 EC does not pose an unacceptable risk to health of adult and child resident and health of worker wearing a work wear (with arms, body and legs covered) entering for 2hrs inspection a field of cereals treated with a product ULTRACENT 460 EC according to its intended use on cereals within good agricultural practice.

Residues:

Since the relevant registration report of INPUT 460 EC was not provided, the inconsistency of spiroxamine MRL for the barley was identified within INPUT 460 EC residue data and in the context of prothioconazole the triazoles data submission requirement was not met, the authorization for ULTRACENT 460 EC cannot be granted.

**February 2025**: the applicant reconstructed the B7 clearly providing all required data consistently with the current requirements. The data available are now considered sufficient for risk assessment. An exceedance of the current MRLs is not expected to be exceeded. The chronic and the short-term intakes of the actives are unlikely to present a public health concern. The approval for the intended GAP of Ultracent 460 EC can be granted.

Fate and behaviour:

The results of leaching simulation run with FOCUS PELMO and FOCUS PEARL demonstrate that ULTRACENT 460 EC can be applied safely according to the recommended use patterns without risk of Prothioconazole, Prothioconazole-S-methyl and Prothioconazole-desthio, Spiroxamine, M01, M02, M03 exceeding acceptable levels in groundwater. The exposure of adjacent surface waters and terrestrial ecosystems by both active substances due to volatilization with subsequent deposition is considered to be low.

Ecotoxicology:

Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed uses of ULTRACENT 460 EC poses acceptable risk to non-target organisms, if applied according to the recommended use pattern. Particular precautions to reduce the environmental concentrations resulting from ULTRACENT 460 EC applications are required for aquatic organisms.

Uses to be considered safe on the basis of EU methodology:

|  |
| --- |
| 1-4 |

Uses to be considered non-safe on the basis of EU methodology:

|  |
| --- |
| None |

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant cMS:

|  |
| --- |
|  |

The following text is to be shortened or to be amended as necessary.

All uses/ GAPs are covered by established MRLs except for use in crop. An application for amending the MRL has been submitted by MS to EFSA EFSA Project Number (if applicable).

1. ALL intended uses

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | |  | | | | | |  | | | GAP rev. 0, date: 2023-08 | | | | |
| PPP (product name/code): | | | | ULTRACENT 460 EC | | | | | | Formulation type: | | | EC | | | | |
| Active substance 1: | | | | prothioconazole | | | | | | Conc. of as 1: | | | 160 g/L | | | | |
| Active substance 2: | | | | spiroxamine | | | | | | Conc. of as 2: | | | 300 g/L | | | | |
| Safener: | | | | - | | | | | | Conc. of safener: | | | - | | | | |
| Synergist: | | | | - | | | | | | Conc. of synergist: | | | - | | | | |
| Applicant: | | | | XXXX | | | | | | Professional use: | | |  | | | | |
| Zone(s): | | | | central | | | | | | Non professional use: | | |  | | | | |
| Verified by MS: | | | | no | | | | | |  | | |  | | | | |
| Field of use: | | | | fungicide | | | | | |  | | |  | | | | |
| 1 | 2 | 3 | | 4 | 5 | 6 | 7 | 8 | | 9 | 10 | | 11 | 12 | 13 | 14 | |
| **Use-No. (e)** | **Member state(s)** | **Crop and/ or situation  (crop destination / purpose of crop)** | | **F, Fn, Fpn G, Gn, Gpn or I** | **Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group) | **Application** | | | | | **Application rate** | | | | **PHI** (days) | **Remarks:**   e.g. g safener/synergist per ha  (f) | |
|  |  |  | |  |  | Method / Kind | Timing / Growth stage of crop & season | Max. number  a) per use  b) per crop/ season | | Min. interval between applications (days) | L product / ha  a) max. rate per appl.  b) max. total rate per crop/season | | g as/ha  a) max. rate per appl.  b) max. total rate per crop/season | Water L/ha  min / max |  |  | |
| **Zonal uses (field or outdoor uses, certain types of protected crops)** | | | | | | | | | | | | | | | | | |
| 1 | PL | Wheat (winter) | | F | Eyespot (PSDCHE), Fusarium sp. (FUSASP), Powdery mildew (ERYSGR) | Foliar spray | BBCH 30-31 | 1. 1 2. 1 | | - | 1. 0.75 2. 0.75 | | 1. 0.12 kg prothioconazole/ha + 0.225 kg spiroxamine/ha 2. 0.12 kg prothioconazole/ha + 0.225 kg spiroxamine/ha | 200-400 | 35 |  | |
| 2 | PL | Wheat (winter) | | F | Eyespot (PSDCHE), Fusarium sp. (FUSASP), Powdery mildew (ERYSGR) | Foliar spray | BBCH 31-37 | 1. 1 2. 1 | | - | 1. 1.0 2. 1.0 | | 1. 0.16 kg prothioconazole/ha + 0.3 kg spiroxamine/ha 2. 0.16 kg prothioconazole/ha + 0.3 kg spiroxamine/ha | 200-400 | 35 |  | |
| 3 | PL | Wheat (winter and spring) | | F | Rust species (PUCCSP),  Brown rust (PUCCRE)  Powdery mildew (ERYSGR)  Septoria leaf spot(SEPTTR)  Glume blotch (LEPTNO)  Tan spot(PYRNTR) | Foliar spray | BBCH 30-59 | 1. 1 2. 1 | | - | 1. 1.0 2. 1.0 | | 1. 0.16 kg prothioconazole/ha + 0.3 kg spiroxamine/ha 2. 0.16 kg prothioconazole/ha + 0.3 kg spiroxamine/ha | 200-400 | 35 |  | |
| 4 | PL | Barley (winter and spring) | | F | Eyespot (PSDCHE)  Brown rust (PUCCHD)  Powdery mildew (ERYSGR)  Rhynchosporium (RHYNSE)  Net blotch (PYRNTE)  Fusarium stem blight(FUSASP*)* | Foliar spray | BBCH 30-51 | 1. 1 2. 1 | | - | 1. 1.0 2. 1.0 | | 1. 0.16 kg prothioconazole/ha + 0.3 kg spiroxamine/ha 2. 0.16 kg prothioconazole/ha + 0.3 kg spiroxamine/ha | 200-400 | 35 |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| Remarks  table heading: | (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  (b) Catalogue of pesticide formulation types and international coding system CropLife  International Technical Monograph n°2, 6th Edition Revised May 2008  (c) g/kg or g/l |  | (d) Select relevant  (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1  (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use. |
| Remarks  columns: | 1 Numeration necessary to allow references  2 Use official codes/nomenclatures of EU Member States  3 For crops, the EU and Codex classifications (both) should be used; when relevant, the  use situation should be described (e.g. fumigation of a structure)  4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application  5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.  6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated. |  | 7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3‑8263-3152-4), including where relevant, information on season at time of application  8 The maximum number of application possible under practical conditions of use must be provided.  9 Minimum interval (in days) between applications of the same product  10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.  11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).  12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.  13 PHI - minimum pre-harvest interval  14 Remarks may include: Extent of use/economic importance/restrictions |