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| **REGISTRATION REPORT**  Part B  Section 10  Assessment of the relevance of metabolites in  groundwater  Detailed summary of the risk assessment |
| Product name(s): **ULTRACENT 460 EC**  Chemical active substance:  Prothioconazole, 160 g/L  Spiroxamine, 300 g/L |
| Central Zone  Zonal Rapporteur Member State: Poland |
| CORE ASSESSMENT |
| Applicant: XXXX  Submission date: Aug 2023, update Feb 2024  Evaluation date: October 2024  MS Finalisation date: February 2025 |

Version history

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| When | What |
| Aug 2023 | Application acc. to Art 34 of the Regulation 1107/2009 in Poland |
| October 2024 | Version evaluated by zRMS PL |
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# Relevance of metabolites in groundwater

## General information

For Prothioconazole, the metabolites prothioconazole-S-methyl (M01) and prothioconazole-desthio (M04) are not predicted to occur in groundwater at concentrations above 0.1 µg/L.

Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required.

General information on the metabolites are provided in Table 10.1‑1.

Table 10.1‑1: General information on the metabolite(s)

| Name of active substance | Metabolite name and code | Structural formula | Trigger for relevance assessment | |
| --- | --- | --- | --- | --- |
| Prothioconazole | prothioconazole-S-methyl  (M01) |  | Max PECgw | < 0.1 µg/L |
| Prothioconazole | prothioconazole-desthio  (M04) |  | Max PECgw | < 0.1 µg/L |

For Spiroxamine, the only metabolite known to be found in groundwater is [(8-tert-butyl-1,4-dioxaspiro[4.5]dec-2-yl)methyl]ethyl(propyl)amine oxide (Ref: N-oxide spiroxamine). This is defined as a non-relevant metabolite and for this reason, assessment of this metabolite according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required.

ULTRACENT is believed to be identical to the formulation ‘Input 460 EC’ (R-61/2011) by Bayer CropScience Deutschland GmbH, which has been registered in Poland for a long time and is still registered around Europe. All data required for the assessment of the relevance of metabolites in groundwater are believed to be identical to that of ‘Input 460 EC’ (R-61/2011), for which all data protection has now expired.

**zRMS**:

As it have been demonstrated in confidential part C of this report the composition of ULTRACENT 460 EC is comparable with composition of the product INPUT 460 EC, for which ecotoxicological data are no longer protected, therefore in line with article 34 of Regulation (EC) No 1107/2009: “Applicants shall be exempted from supplying the test and study reports referred to in Article 33(3) where the Member State to which an application is made has the test and study reports concerned and …that any data protection period has expired.”

ULTRACENT 460 EC and INPUT 460 EC are applied on cereals in the same maximal dose of 1L/ha, therefore the PECGW calculated for the active substances and their metabolites will be the same for both products.

Prothioconazole

In the registration report for product INPUT 460 EC (2007 and 2011) it was concluded that the concentration of prothioconazole and its metabolites, including prothioconazole-desthio, are predicted to occur in groundwater at concentrations below 0.1 µg/L. Therefore, no stepwise assessment of their relevance according to the EU requirements is needed (Commission Regulation No. 284/2013; Sanco/221/2000 – rev.11; 21 October 2021).

Spiroxamine

In the registration report for product INPUT 460 EC (2007 and 2011) it was concluded that the concentration of prothioconazole and its metabolites, including prothioconazole-desthio, are predicted to occur in groundwater at concentrations below 0.1 µg/L. Therefore, no stepwise assessment of their relevance according to the EU requirements is needed (Commission Regulation No. 284/2013; Sanco/221/2000 – rev.11; 21 October 2021).

Based on these data it is concluded that application of product ULTRACENT 460 EC in line with GAP does not create a health risk for consumers of ground water used as drinking water.

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| **Review Comments – Envirinmental Fate:**  The PECGW calculations for Prothioconazole and its metabolites: Prothioconazole-S-methyl, Prothioconazole-desthio), Spiroxamine and its metabolites: M01, M02, M03, were provided by the Applicant and are considered acceptable.  For active substances and their relevant metabolites PECGW calculations were performed with FOCUS PEARL 5.5.5 and FOCUS PELMO 6.6.4.  The PECGW of Prothioconazole and Spiroxamine (80th percentile), their metabolites, at 1 m depth following uses on cereals at the proposed maximum rates, were less than 0.001 μg/L in all scenarios of three models.  In conclusion, the results 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 and M03 exceeding acceptable levels in groundwater. |

1. Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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 XX | Author | YYYY | Title  Company Report No  Source  GLP/non GLP/GEP/non GEP  Published/Unpublished | Y/N | Owner |

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 |
| --- | --- | --- | --- | --- | --- |
| KCP XX | Author | YYYY | Title  Company Report N  Source  GLP/non GLP/GEP/non GEP  Published/Unpublished | 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 |
| --- | --- | --- | --- | --- | --- |
| KCP XX | Author | YYYY | Title  Company Report N  Source  GLP/non GLP/GEP/non GEP  Published/Unpublished | Y/N | Owner |

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

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

1. Additional information

ULTRALINE is believed to be identical to the formulation ‘Proline 250 EC’ (R-17/2005) by Bayer CropScience Deutschland GmbH, which has been registered in Poland for a long time and is still registered around Europe. All data required for the assessment of the relevance of metabolites in groundwater are believed to be identical to that of ‘Proline 250 EC’ (R-17/2005), for which all data protection has now expired.

For this reason, the applicant fully refers to the data as mentioned in Appendix 1.