

# REGISTRATION REPORT

## Part B

### Section 10

#### **Assessment of the relevance of metabolites in groundwater**

Detailed summary of the risk assessment

Product code: CA3301

Product name(s): JOUST 250 EC

Chemical active substance:

Prothioconazole, 250 g/L

Central Zone

Zonal Rapporteur Member State: Poland

#### CORE ASSESSMENT

New Authorisation (Art.33)

Applicant: NUFARM Polska Sp. z o. o.

Submission date: 23/12/2021

MS Finalisation date: September 2022 (initial Core Assessment)

January 2023 (final Core Assessment)

### Version history

When	What
December 2021	First submission
September 2022	Initial ZRMS assessment  The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency.
January 2023	Final report (Core Assessment updated following the commenting period). No additional information or assessments after the commenting period.

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**Reviewer comments:**

This part of dossier has been submitted to support registration of the plant protection product CA3301 – JOUST according art. 33 of 1107/2009.

Document refers data related to the forming of metabolites in the environment (see dRR B8). dRR Part B10 has been reviewed for the purposes of ongoing registration and also checked its compliance with the current guidelines. Information has been considered as sufficient (see point 10.1) and appropriate for concluding.

## **10 Relevance of metabolites in groundwater**

### **10.1 General information**

Prothioconazole degrades in soil to form two metabolites that are present at levels >10% and are therefore potentially relevant in groundwater. The metabolites, prothioconazole-S-methyl and prothioconazole-desthio, were predicted to occur in groundwater at concentrations below 0.001 µg/L in all FOCUS scenarios for all uses in the GAP, according to the models FOCUS-PEARL (v5.5.5), FOCUS-PELMO (v6.6.4) and FOCUS-MACRO (v5.5.4). Please see Part B.8.8 for a full summary of the modelling. No further assessment of the relevance of these metabolites is therefore required, and groundwater risks are acceptable.

## Appendix 1 Lists of data considered in support of the evaluation

### 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
K-CP 9.2.4/01*	Hale, M.	2021	Prothioconazole: Predicted Environmental Concentrations in Groundwater Following Application to Cereals and Oilseed Rape, Using FOCUS-PEARL, FOCUS-PELMO and FOCUS-MACRO Staphyt Regulatory, Report No 21/122 Non-GLP Unpublished	N	Nufarm Europe

\*Summarised in Part B.8.8

### 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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### 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 not submitted by the applicant but necessary for evaluation**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
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