

FINAL REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: Protiokonazol 300 EC

Product name(s): HERA 300 EC

Chemical active substance:

prothioconazole, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Pestila Spółka z ograniczoną odpowiedzialnością

Submission date: October 2023

MS Finalisation date: February 2024; July 2024

Version history

When	What
February 2024	ZRMs evaluated dRR submitted by Applicant.
July 2024	The final Registration Report

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10 Relevance of metabolites in groundwater

10.1 General information

Metabolites of prothioconazole are predicted to occur in groundwater at concentration below 0.1 µg/L (see dRR Part B8). 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.

10.2 Relevance assessment

10.2.1 STEP 1: Exclusion of degradation products of no concern

Not relevant.

10.2.2 STEP 2: Quantification of potential groundwater contamination

Not relevant.

10.2.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.2.3.1 STEP 3, Stage 1: screening for biological activity

Not relevant.

10.2.3.2 STEP 3, Stage 2: screening for genotoxicity

Not relevant.

10.2.3.3 STEP 3, Stage 3: screening for toxicity

Not relevant.

10.2.4 STEP 4: Exposure assessment – threshold of concern approach

Not relevant.

10.2.5 STEP 5: Refined risk assessment

ACCEPTED

Appendix 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
-	-	-	-	-	-

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 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

Appendix 2 Additional information

Not relevant.