

FINAL REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: -

Product name(s): Repentol 6 PA / Repentol 6 PA Bis

Chemical active substance(s):

quartz sand, 300 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(renewal of authorisation)

Applicant: DCR ~~Sp. z o.o.~~ S.A.

Submission date: 27/11/2023

MS Finalisation date: 05/2025 ; 09/2025

Version history

When	What
15/11/2023	Update of dRR/RR for renewal of PPP authorisation acc. to Art. 43 Reg. 1107/2023.
05/2025	ZRMS assessment
09/2025	The final Registration Report

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10 Relevance of metabolites in groundwater

10.1 General information

There are no metabolites that occur in groundwater at concentrations above 0.1 µg/L. Assessment of the relevance of metabolites according to the stepwise procedure of the EC guidance document SAN-CO/221/2000 –rev.10 is therefore not required.

10.2 Relevance assessment of metabolite

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

Not relevant.

Comment:

Accepted. There are no metabolites that occur in groundwater at concentrations above 0.1 µg/L

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

Comments of zRMS:	
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Not relevant. No additional information provided.