

FINAL REGISTRATION REPORT

Part B

Section 10

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

Detailed summary of the risk assessment

Product code: SHA 105000 B

Product name: HIERRO

Chemical active substance:

Ferric phosphate, 10 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: SHARDA Cropchem España S.L.

Submission date: November 2020

MS Finalisation date: 2021; 10.2021

Version history

When	What
2021	Assessment by expert
10.2021	The Final Version of the RR

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10 Relevance of metabolites in groundwater

10.1 General information

No metabolites are 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 SAN-CO/221/2000 –rev.10 is therefore not required.

10.2 Relevance assessment of metabolites

Not required, please refer to point 10.1.

10.2.1 STEP 1: Exclusion of degradation products of no concern

Not required, please refer to point 10.1.

10.2.2 STEP 2: Quantification of potential groundwater contamination

Not required, please refer to point 10.1.

10.2.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.2.3.1 STEP 3, Stage 1: screening for biological activity

Not required, please refer to point 10.1.

10.2.3.2 STEP 3, Stage 2: screening for genotoxicity

Not required, please refer to point 10.1.

10.2.3.3 STEP 3, Stage 3: screening for toxicity

Not required, please refer to point 10.1.

10.2.4 STEP 4: Exposure assessment – threshold of concern approach

Not required, please refer to point 10.1.

10.2.5 STEP 5: Refined risk assessment

Not required, please refer to point 10.1.

Comment:

No metabolites are 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
Acceptable

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:	Comment on statement; acceptable or not.
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