

# 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**

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

**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 Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
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## Appendix 2 Additional information

Comments of zRMS:	Comment on statement; acceptable or not.
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