

# FINAL REGISTRATION REPORT

## Part B

### Section 10

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

Detailed summary of the risk assessment

Product code: SHA 6800 A

Product name: DUKES

Chemical active substance:

Dithianon, 700 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

#### CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: September 2020

MS Finalisation date: May 2021; December 2021

## Version history

When	What
May 2021	Assessment by expert
December 2021	Final registration report after commenting period

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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.

#### **10.1.1 STEP 1: Exclusion of degradation products of no concern**

Not relevant

#### **10.1.2 STEP 2: Quantification of potential groundwater contamination**

Not relevant

#### **10.1.3 STEP 3: Hazard assessment – identification of relevant metabolites**

##### **10.1.3.1 STEP 3, Stage 1: screening for biological activity**

Not relevant

##### **10.1.3.2 STEP 3, Stage 2: screening for genotoxicity**

Not relevant

##### **10.1.3.3 STEP 3, Stage 3: screening for toxicity**

Not relevant

#### **10.1.4 STEP 4: Exposure assessment – threshold of concern approach**

Not relevant

#### **10.1.5 STEP 5: Refined risk assessment**

Not relevant

**Comment**

**According to the Peer Review of the pesticide risk assessment of the active substance dithianon EF-SA Journal 2010;8(11):1904 Metabolism in animals:”Extensive metabolism leading to the formation of mostly polar products. The metabolic reactions included oxidation of the sulphur atoms, cleavage of the dithiine ring, reduction of the 1,4-naphthoquinone moiety, glucuronidation as well as substitution of the carbonitrile moieties by amino and carboxy groups. The only predominant metabolite in quantitative terms was M216F020, detected mainly in urine (up to 10%) and secondly in kidney and plasma”**

**No metabolite is predicted to occur in groundwater at concentrations above 0.1 µg/L. Assessment of the relevance of this metabolite is not required.**

## 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

No new or additional data were submitted.

### 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
None					

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
None					

<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>
None					

## **Appendix 2    Additional information**

Not relevant