

FINAL REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: SHA 8500 A

Product name: MEPISHA

Chemical active substances:

Mepiquat chloride, 50 g/L
(Mepiquat 38 g/L)

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Authorization)

Applicant: Sharda Cropchem España S.L.

Submission date: February 2021

MS Finalisation date: 04/2021, 02/2022

Version history

When	What
April 2021	Assessment by expert
February 2022	Final version of RR

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10 Relevance of metabolites in groundwater

10.1 General information

Assessment of the relevance of metabolite is not required. No major and significant metabolites of mepiquat / mepiquat chloride were found during the EU Review of mepiquat / mepiquat chloride.

10.2 Relevance assessment of metabolites

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:

Assessment of the relevance of metabolite is not required. It is acceptable

No major and significant metabolites of mepiquat / mepiquat chloride were found during the EU Review of mepiquat / mepiquat chloride.

According to the EFSA Scientific Report (2008) 146, 1-73, Conclusion on the peer review of mepiquat “ 4-hydroxy mepiquat chloride: LD50 of > 464 mg/kg bw negative in the Salmonella typhimurium and Escherichia coli reverse mutation assays using the standard plate and pre-incubation methods. „

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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