

FINAL REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: SHA 126085 A

Product name: MEPCY

Chemical active substances:

Chlormequat chloride, 345 g/L

Mepiquat chloride, 115 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem Ltd.

Submission date: February 2022

MS Finalisation date: May 2023, August 2023

Version history

When	What
05/2023	ZRMs evaluated updated dRR by Applicant
August 2023	Final version of RR after commenting period.

Table of Contents

10	Relevance of metabolites in groundwater	4
10.1	General information	4
10.1.1	STEP 1: Exclusion of degradation products of no concern	4
10.1.2	STEP 2: Quantification of potential groundwater contamination.....	4
10.1.3	STEP 3: Hazard assessment – identification of relevant metabolites.....	4
10.1.3.1	STEP 3, Stage 1: screening for biological activity	4
10.1.3.2	STEP 3, Stage 2: screening for genotoxicity	4
10.1.3.3	STEP 3, Stage 3: screening for toxicity	4
10.1.4	STEP 4: Exposure assessment – threshold of concern approach.....	4
10.1.5	STEP 5: Refined risk assessment.....	4
Appendix 1	Lists of data considered in support of the evaluation	4
Appendix 2	Additional information	5

10 Relevance of metabolites in groundwater

10.1 General information

Chlormequat chloride nor Mepiquat chloride produce soil metabolites. Therefore no assessment according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is required.

10.1.1 STEP 1: Exclusion of degradation products of no concern

10.1.2 STEP 2: Quantification of potential groundwater contamination

10.1.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.1.3.1 STEP 3, Stage 1: screening for biological activity

10.1.3.2 STEP 3, Stage 2: screening for genotoxicity

10.1.3.3 STEP 3, Stage 3: screening for toxicity

10.1.4 STEP 4: Exposure assessment – threshold of concern approach

10.1.5 STEP 5: Refined risk assessment

ACCEPTED

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

No new or additional data were submitted.

Appendix 2 Additional information

Not relevant