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| FINAL REGISTRATION REPORT  Part B  Section 10  Assessment of the relevance of metabolites in  groundwater  Detailed summary of the risk assessment |
| Product code: SHA 5148 A  Product name: PLANET  Chemical active substances:  2,4-D, 275 g/L (in form of DMA salt)  MCPA, 275 g/L (in form of DMA salt) |
| Central Zone  Zonal Rapporteur Member State: Poland |
| CORE ASSESSMENT  (Extension of use) |
| Applicant: Sharda Cropchem Ltd.  Submission date: October 2022  MS Finalisation date: June 2023; May 2024 |

Version history

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| --- | --- |
| When | What |
| 10.2022 | Submition date |
| June 2023 | ZRMs evaluated updated dRR by Applicant. |
| May 2024 | ZRMs prepared fRR after Applicant’s RT comments |
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Table of Contents

[10 Relevance of metabolites in groundwater 4](#_Toc430080177)

[10.1 General information 4](#_Toc430080178)

[10.1.1 STEP 1: Exclusion of degradation products of no concern 4](#_Toc430080179)

[10.1.2 STEP 2: Quantification of potential groundwater contamination 4](#_Toc430080180)

[10.1.3 STEP 3: Hazard assessment – identification of relevant metabolites 4](#_Toc430080181)

[10.1.3.1 STEP 3, Stage 1: screening for biological activity 4](#_Toc430080182)

[10.1.3.2 STEP 3, Stage 2: screening for genotoxicity 4](#_Toc430080183)

[10.1.3.3 STEP 3, Stage 3: screening for toxicity 4](#_Toc430080184)

[10.1.4 STEP 4: Exposure assessment – threshold of concern approach 4](#_Toc430080185)

[10.1.5 STEP 5: Refined risk assessment 4](#_Toc430080186)

[Appendix 1 Lists of data considered in support of the evaluation 5](#_Toc430080187)

[Appendix 2 Additional information 7](#_Toc430080188)

# Relevance of metabolites in groundwater

## General information

No soil metabolites are produced from MCPA and no metabolites from 2,4 D 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.11 is therefore not required.

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

Not relevant

### STEP 2: Quantification of potential groundwater contamination

Not relevant

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

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

Not relevant

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

Not relevant

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

Not relevant

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

Not relevant

### STEP 5: Refined risk assessment

Not relevant

**Comment:**

**No soil metabolites are produced from MCPA and no metabolites from 2,4 D are predicted to occur in groundwater at concentrations above 0.1 µg/L.**

**No metabolites are predicted to occur in groundwater at concentrations above 0.1 μg/L.**

**Assessment of the relevance of these metabolites is therefore not required.**

**Acceptable**

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 |
| --- | --- | --- | --- | --- | --- |
| KCP XX | Author | YYYY | Title  Company Report N  Source  GLP/non GLP/GEP/non GEP  Published/Unpublished | Y/N | Owner |
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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 |
| --- | --- | --- | --- | --- | --- |
| KCP XX | Author | YYYY | Title  Company Report N  Source  GLP/non GLP/GEP/non GEP  Published/Unpublished | Y/N | Owner |
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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 |
| --- | --- | --- | --- | --- | --- |
| KCP XX | Author | YYYY | Title  Company Report N  Source  GLP/non GLP/GEP/non GEP  Published/Unpublished | Y/N | Owner |
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1. Additional information

Not relevant

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