

REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: GLOB2011I

Product name(s): SANKARI

Chemical active substance(s):

Pelargonic acid, 650 g/L

Central

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Globachem NV

Submission date: 31/07/2023

RMS Assessment: 15/01/2024

After commenting period: 05/05/2024

Update list studies: 28/05/2024

Version history

| When | What |
|--------------|-------------------------|
| January 2024 | RMS Assessment |
| May 2024 | After commenting period |
| May 2024 | Update list studies |
| | |

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10 Relevance of metabolites in groundwater

RMS comment: No metabolite(s) are predicted to occur in groundwater at concentrations above 0.1 µg/L. Assessment of the relevance of metabolite(s) according to the stepwise procedure according to the EC guidance document SANCO/221/2000 –rev.11 is therefore not required.

10.1 General information

Pelargonic acid is a naturally occurring product (part of fatty acids C7-C18) and the residue definition in groundwater is “fatty acids C7-C18 salts and methyl esters”. No groundwater metabolites of toxicological concern are expected. (cf. EFSA Journal 2013;11(1):3023)

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 |
|------------|-----------|------|---|-------------------------|-------|
| None | | | | | |

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| KCP XX | Author | YYYY | Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished | 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| KCP XX | Author | YYYY | Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished | Y/N | Owner |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