

REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: XNJ25 251 g/kg

Chemical active substance:

Quartz sand, 251 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Product re-authorisation; Art. 43)

Applicant: FMC Corporation

Submission date: 24/11/2023

MS Finalisation date: dd/mm/yyyy

Version history

When	What
November 2023	Original submission

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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 (see dRR Part B, Section 8, Point 8.2). Assessment of the relevance of metabolite(s) according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required.

General information on the metabolites are provided in Table 10.1-1. The impact of the relevance assessment on whether a particular GAP use leads to acceptable risk or not is presented in the summary of the cGAP evaluation in chapter 8.1 of the dRR Part B, Section 8 (Environmental fate and behaviour).

According to EFSA, 2022¹ a consumer exposure assessment through drinking water resulting from groundwater metabolite(s) according to SANCO/221/2000 rev.10 Final (25/02/2003) is not required.

Table 10.1-1: General information on the metabolite(s)

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
Quartz sand	No metabolites	n.a.	Max PEC _{gw}	n.a.
XNJ25			Based on:	n.a.

10.2 Relevance assessment of metabolite 1

Summary:

The relevance of the groundwater metabolites has already been assessed and the assessment was agreed at EU level. It applies as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at the EU-level are valid also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR). There are no metabolites considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in Table 10.1-1.

10.2.1 STEP 1: Exclusion of degradation products of no concern

Quartz sand does not have metabolites and meets the criteria for products of no concern as defined in step 1 of the guidance.

Quartz sand is a substance is an inorganic compound without containing heavy metals and which is known to be of no toxicological or ecotoxicological concern, and which is naturally occurring at much higher concentrations in the respective compartment and therefore needs not further assessment.

Due to the natural occurrence of silicon dioxide in the environment, specific environmental fate studies are not required.¹

¹ EFSA, Peer review of the pesticide risk assessment of the active substance quartz sand, EFSA 2022; 20(9):7552

10.2.2 STEP 2: Quantification of potential groundwater contamination

Not applicable

10.2.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.2.3.1 STEP 3, Stage 1: screening for biological activity

Not applicable

10.2.3.2 STEP 3, Stage 2: screening for genotoxicity

Not applicable

10.2.3.3 STEP 3, Stage 3: screening for toxicity

Not applicable

10.2.4 STEP 4: Exposure assessment – threshold of concern approach

Not applicable

10.2.5 STEP 5: Refined risk assessment

Not applicable

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 – all documents

No studies submitted

List of data submitted by the applicant and relied on – vertebrate studies

No vertebrate studies submitted

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review – all documents

No studies previously submitted and relied upon

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review – vertebrate studies

No vertebrate studies previously submitted

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
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