

FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: XNJ25 251 g/kg

Chemical active substance:

Quartz sand, 251 g/kg

Central Zone

Rapporteur Member State: Poland

CORE ASSESSMENT

(Product re-authorisation; Art. 43)

Applicant: FMC Corporation

Submission date: dd/mm/yyyy

MS Finalisation date: 11/2025

Version history

When	What
November 2023	Original submission
March 2024	Dossier sent for evaluation
16 May 2025	This document has been updated per zRMS Poland request New information highlighted in green
June 2025	zRMS evaluation of dRR
November 2025	Final RR

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zRMS comments:

The text highlighted in grey was provided by the zRMS.

8 Fate and behaviour in the environment (KCP 9)

EFSA Journal 2022;20(9):7552:

Sand/silicon dioxide is a major component of nearly all mineral soils and many aquatic sediments.

In some regions, it is the solid material of groundwater aquifers. After application (by brush or glove), the formulation dries and forms a protective coating. Quartz sand is not water soluble. Because of the method of application, environmental concentrations of the quartz sand being added (except on the treated trees/shrubs) are expected to be too low to measure. Considering the natural presence of quartz sand in soils and aquatic sediments and sand being a groundwater aquifer material, further consideration of its fate and behaviour in the environment was concluded to be unnecessary.

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the formulated product

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/or situation (crop destina- tion/ purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ synergist per ha	Conclusion
					Method/ Kind	Timing/ Growth stage of crop & season	Max. num- ber a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	DE, AT, PL, CZ, HU, RO, SK	Deciduous (3FOBC) and coniferous trees (3FOCC) in forestry	F	Deer (CAPRCA) and red deer (CERVEL)	Coating of undiluted product prefer- ably with gloves	-	a) 1 b) 1	a) n.a. b) n.a. a) 1 b) 1	a) 2-5 kg/ 1000 plants; in DE 4 kg/1000 plants b) n.a.	a) 502 – 1255 g/1000 plants; in DE 1004 g/1000 plants b) n.a.	a) n.a. b) n.a.	Not relevant	2-5 kg/1000 plants	
2	LV, LT, EE	Deciduous (3FOBC) and coniferous trees (3FOCC) in forestry	F	Deer (CAPRCA) and red deer (CERVEL)	Coating of undiluted product prefer- ably with gloves	-	a) 1 b) 1	a) n.a. b) n.a. a) 1 b) 1	a) 2-5 kg/1000 plants b) n.a.	a) 502 – 1255 g/1000 plants b) n.a.	a) n.a. b) n.a.	Not relevant	2-5 kg/1000 plants, Non- professional use in LT 3-4 kg/1000 plants	
3	PL	Coniferous trees in forestry	F	Deer and red deer	Coating of 5-10 years trees with undiluted product prefer- ably with gloves	-	a) 1 b) 1	a) n.a. b) n.a.	a) 10-14 kg/1000 plants b) 10-14 kg/1000 plants	a) 2510-3514 g a.s./1000 plants b) 2510-3514 g a.s./1000 plants	n.a.	Not relevant	10-14 kg/1000 plants	

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 “Conclusion”

A	Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

Table 8.1-2: Assessed (critical) uses during approval of Quartz sand concerning the Section Environmental Fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. *	Member state(s)	Crop and/or situation (crop destina- tion/ purpose of crop)	F, Fn, G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method/ Kind	Timing/ Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
		Deciduous (3FOBC) and coniferous trees (3FOCC) in forestry	F	Deer (CAPRCA) and red deer (CERVEL)	Coating of undiluted product prefer- ably with gloves	-	a) 1 b) 1	a) n.a. b) n.a. a) 1 b) 1	a) 10-14 kg/1000 plants b) 10-14 kg/1000 plants	a) 2510-3514 g a.s./1000 plants b) 2510-3514 g a.s./1000 plants	a) n.a. b) n.a.	Not relevant	2-5 kg/1000 plants; 10-14 kg/1000 plants Non-professional use in LT 3-4 kg/1000 plants

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

8.2 Metabolites considered in the assessment

Quartz sand is a stable inorganic compound with the main component silicon dioxide. It is practically insoluble and known to be inert to most mineral acids and bases.¹

Metabolites of Quartz sand do not occur and therefore a risk assessment is not applicable.

8.3 Rate of degradation in soil (KCP 9.1.1)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

Not relevant. Due to the naturally occurrence of Silicon dioxide in the environment, specific environmental fate studies are not required.

8.3.1.1 Quartz sand and its metabolites

Not applicable

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Not relevant. Due to the naturally occurrence of Silicon dioxide in the environment, specific environmental fate studies are not required.

8.4 Field studies (KCP 9.1.1.2)

Not relevant

8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

Not applicable

8.4.1.1 Quartz sand and its metabolites

Not applicable

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Not applicable

¹ EFSA Journal 2011;9(7):2300

8.5 Mobility in soil (KCP 9.1.2)

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

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

8.5.1 Quartz sand and its metabolites

Not applicable

8.5.2 Column leaching (KCP 9.1.2.1)

Not applicable

8.5.3 Lysimeter studies (KCP 9.1.2.2)

Not applicable

8.5.4 Field leaching studies (KCP 9.1.2.3)

Not applicable

8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

Not relevant

8.6.1 Quartz sand and its metabolites

Not applicable

8.7 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

zRMS Comments:	The submitted justification considering the application of Cervacol Extra was accepted. The Use No 1 and 2 is covered by the use (No 3) evaluated at the EU level. No further assessment is required. Considering the natural presence of quartz sand in soils further consideration of its fate and behaviour in the environment was concluded to be unnecessary (EFSA, 2022).
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8.7.1 Justification for new endpoints

Not relevant

8.7.2 Active substance(s) and relevant metabolite(s)

Not relevant

8.7.2.1 Quartz sand and its metabolites

Not relevant

8.7.2.2 PEC_{soil} of Cervacol Extra

Not relevant for the environmental exposure assessment. Owing to the manually application by coating trees with gloves or brush no entry of the active substance into soil is expected. Therefore, the calculation of PEC_s is not considered necessary. Because of the method of application leading to negligible levels of environmental exposure and the natural presence of quartz sand in soils, further consideration of its fate and behaviour in the environment was concluded to be unnecessary.

8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

zRMS Comments:	The submitted justification considering the application of Cervacol Extra was accepted. The Use No 1 and 2 is covered by the use (No 3) evaluated at the EU level. No further assessment is required. Considering the natural presence of quartz sand being a groundwater aquifer material, further consideration of its fate and behaviour in the environment was concluded to be unnecessary (EFSA, 2022).
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Not relevant for the environmental exposure assessment. Owing to the manually application by coating trees with gloves or brush no significant entry of the active substance or formulation into soil is expected. Because of the method of application leading to negligible levels of environmental exposure and the natural presence of quartz sand in soils, further consideration of its fate and behaviour in the environment was concluded to be unnecessary.

8.8.1 Justification for new endpoints

Not relevant

8.8.2 Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1)

Not applicable

8.8.2.1 Quartz sand and its metabolites

Not applicable

8.9 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

zRMS Comments:	The submitted justification considering the application of Cervacol Extra was accepted. The Use No 1 and 2 is covered by the use (No 3) evaluated at the EU level. No further assessment is required. Considering the natural presence of quartz sand in aquatic sediments, further consideration of its fate and behaviour in the environment was concluded to be unnecessary (EFSA, 2022).
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8.9.1 Justification for new endpoints

Not relevant

8.9.2 Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5)

8.9.2.1 Quartz sand and its metabolites

Not applicable

8.9.2.2 PEC_{sw/sed} of Cervacol Extra

Not relevant for the environmental exposure assessment. Owing to the manually application by coating trees with gloves or brush no significant entry of the active substance into soil and water will be expected. The amount of product dislocated by surface run off water is considered negligible. Because of the method of application leading to negligible levels of environmental exposure and the natural presence of quartz sand in soils and aquatic sediments, further consideration of its fate and behaviour in the environment was concluded to be unnecessary.

8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

Table 8.10-1: Summary of atmospheric degradation and behaviour

Compound	Quartz sand
Direct photolysis in air	Not relevant EFSA 2011 ² and EFSA 2022 ³
Quantum yield of direct phototransformation	N.a.
Photochemical oxidative degradation in air	Not relevant EFSA 2022
Volatilisation	Quartz is not a volatile compound EFSA 2022
Metabolites	No metabolites

Data from the active substance are considered to be applicable to the formulation. Therefore, as it is possible to extrapolate from data provided for the active substance, no additional data is provided on the preparation. Silicon dioxide is not a volatile compound and therefore, it is not reasonable to perform assessment of PEC_{AIR}. No relevant exposure of air is therefore to be expected.

² EFSA Journal 2011;9(7):2300

³ EFSA Journal 2022;20(9):7552

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

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

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

Appendix 2 Detailed evaluation of the new Annex II studies

No studies available

Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)

No additional information