

FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

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: 08/2025

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Version history

When	What
November 2023	Original submission, Product re-authorisation; Art. 43
March 2024	Dossier sent for evaluation
May 2024	Updated GAP table
June 2024	zRMS evaluation of dRR
August 2025	Final RR (changes after commenting round in purple)

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zRMS comments:

This report has been completed by the Applicant.

The text highlighted in grey was provided by zRMS. Changes provide by zRMS after commenting round are marked in purple.

7 Metabolism and residue data (KCA section 6)

7.1 Summary and RMS Conclusion

Quartz sand meets the criteria for low-risk substances set out in point 5 of Annex II to Regulation (EC) No 1107/2009, and can thus be considered a low-risk active substance in accordance with Article 22 of Regulation (EC) No 1107/2009.

Substance fulfilling criteria Annex VI Reg. 2229/2004. Conditions of approval modified by Reg. (EU) No 369/2012.

According to the EFSA Journal 2022;20(9):7552:

Due to the inert and insoluble properties of its constituents, quartz sand is not expected to degrade or to form other metabolites relevant for the consumers when used in compliance with the representative uses. Since data on genotoxicity and general toxicity of this active substance were not submitted, the toxicological profile of quartz sand could not be assessed and toxicological reference values (ADI, ARfD) were not derived. However, as for the uses intended on orchards by painting with brush the trunk of the individual trees, it can reasonably be assumed that residues of quartz sand will not be quantified if the application to the orchard trees is conducted in a way that precludes any contamination of the edible parts of the fruits. A negligible exposure for the consumers to residues of quartz sand is therefore expected when the representative uses are considered, and a consumer dietary risk assessment can be waived. Quartz sand is not expected to be translocated to plant tissues. It is therefore unlikely that residues may be found in pollen and bee products.

It is noted that some of the representative plant protection products contain a co-formulant of potential concern (see Section 2). However, regarding the assessment of potential residues resulting from the co-formulants used in the representative plant protection products, consumer exposure is not expected for the representative uses on orchards, deciduous and coniferous trees in forestry, ornamental shrubs and trees, seedlings of conifer and deciduous trees in forestry.

The review of existing maximum residue levels (MRLs) under Article 12 of Regulation (EC) No 396/2005 is covered by the assessment of the representative uses on orchards and on deciduous and coniferous trees in forestry since the most critical authorised uses from the European Member States consist in a single treatment by coating manually the trunks of the trees with special brush or gloves, at a dose rate covered by the maximum dose rate of application intended in the representative uses.

A negligible exposure for the consumers to residues of quartz sand is expected when the representative uses are considered, and a consumer dietary risk assessment can be waived. According to Reg. (EC) No 839/2008 there is no MRL required for quartz sand (annex IV).

Authorization can be granted.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation Cervacol Extra are presented in Table 7.1-1. They have been selected from the individual GAPs in the central and

northern zone of the EU for deciduous and coniferous trees in forestry. A list of all intended uses within the EU is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. According to Reg. (EU) 396/2005 there is no MRL required; hence an exceedance of the current MRL for Quartz sand is not possible.

There is no residue definition for Quartz sand residues available, chronic and the short-term intakes of Quartz sand are unlikely to present a public health concern.

As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended use(s).

According to available data, no specific mitigation measures should apply.

Data gaps

Noticed data gaps are:

- None

Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8					9			10	11	
GAP number (see part B.0)*	Crop and/ or situation **	Zone	Product code	F, Fn, Fpn, G, Gn, Gpn or I***	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Conclusion Remarks	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max			
1	Deciduous (3FOBC) and coniferous trees (3FOCC) in forestry	Central	XNJ25 251 g/kg	F	Deer (CAPRCA) and red deer (CERVEL)	PA	251 g/kg	Coating of undiluted product preferably with gloves	-	1	not applicable	n.a.	n.a.	a) 502 – 1255 g/1000 plants; in DE 1004 g/1000 plants b) n.a.	Not relevant	2-5 kg/1000 plants	A
2	Deciduous (3FOBC) and coniferous trees (3FOCC) in forestry	North	XNJ25 251 g/kg	F	Deer (CAPRCA) and red deer (CERVEL)	PA	251 g/kg	Coating of undiluted product preferably with gloves	-	1	not applicable	n.a.	n.a.	a) 502 – 1255 g/1000 plants b) n.a.	Not relevant	2-5 kg/1000 plants Non-professional use in LT 3-4 kg/1000 plants	A
3	Coniferous trees in forestry	Central	XNJ25 251 g/kg	F	Deer and red deer	PA	251 g/kg	Coating of 5-10 years trees with undiluted product preferably with gloves	-	1	not applicable	n.a.	n.a.	a) 2510 – 3514 g/1000 plants b) n.	Not relevant	10-14 kg/1000 plants	A

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

** Use also code numbers according to Annex I of Regulation (EU) No 396/2005

*** 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 11 “Conclusion”

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

7.1.2 Summary of the evaluation

XNJ25 251 g/kg and its intended uses in this dossier are similar to what was evaluated at EU level.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of Quartz sand

Reference value	Source	Year	Value	Study relied upon	Safety factor
Quartz sand - Parent compound					
ADI	EFSA 2011, EFSA 2022		No data available, not required.	-	-
ARfD	EFSA 2011, EFSA 2022		No data available, not required.	-	-
AOEL	EFSA 2011, EFSA 2022		No data available, not required.	-	-

As concluded in RAR Volume 3 – B.6 (AS) considering the representative uses there is no need to set an acceptable operator exposure level (AOEL) or an acceptable daily intake (ADI), or an acute reference dose (ARfD) for quartz sand.

Consumer risk assessment

EFSA 2022: Since data on genotoxicity and general toxicity of this substance were not submitted, the toxicological profile of quartz sand could not be assessed and toxicological reference values (ADI, ARfD) were not derived.

However, a negligible exposure for the consumers to residues of quartz sand is expected when the representative uses are considered, and a consumer dietary risk assessment can be waived.

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.

Recommended MRLs

EFSA 2022: Quartz sand has been notified as a game repellent for the uses on deciduous and coniferous trees in forestry, fruit trees in orchards as well as on ornamental shrubs and trees by coating manually with special brush or glove or by painting with brush the trunk of the individual trees.

Based on these representative uses, a negligible exposure for the consumers to residues of quartz sand is expected and a consumer dietary risk assessment can be waived. No MRLs are therefore proposed for the representative uses.

7.1.2.1 Summary for Quartz sand

Table 7.1-3: Summary for Quartz sand

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1,2	Deciduous and coniferous trees in forestry	Not applicable	Not applicable	Yes	No Not applicable	Not applicable	No	No

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

Residues of Quartz sand do not exist, hence they could not exceed the trigger values defined in Reg (EU) No 283/2013, and there is no need to investigate the effect of industrial and/or household processing.

7.1.2.2 Summary for XNJ25 251 g/kg

Table 7.1-4: Information on XNJ25 251 g/kg (KCA 6.8)

Crop	PHI for XNJ25 251 g/kg proposed by applicant	PHI/ Withholding period* sufficiently supported for			PHI for XNJ25 251 g/kg proposed by zRMS	zRMS Comments (if different PHI proposed)
		Quartz sand	Active substance 2	Active substance 3		
Deciduous trees in forestry	NR	NR	n.a.	n.a.	NR	NR
Coniferous trees in forestry	NR	NR	n.a.	n.a.	NR	NR

NR: not relevant

* Purpose of withholding period to be specified

** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

7.2 Quartz sand

General data on Quart sand are summarized in the table below (last updated February 2018).

Table 7.2-1: General information on Quartz sand

Active substance (ISO Common Name)	Quartz sand
IUPAC	1) Silicon dioxide 2) Quartz
Chemical structure	
Molecular formula	SiO ₂
Molar mass	60.08 g/mol
Chemical group	-
Mode of action (if available)	Odor and mechanical repellent (abrasive effect).
Systemic	No
Company (ies)	Cheminova Deutschland GmbH & Co. KG
Rapporteur Member State (RMS)	Latvia
Approval status	Approved Reg. (EU) 2023/1488 Date of approval 01/09/2009 Expiration of approval 31/08/2038
Restriction (e.g. is restricted to use as "...")	Repellent
Review Report	PLAN/2022/2457 RR Rev 225 th May 2023
Current MRL regulation	Regulation (EC) No 2024/1078
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	No
EFSA Journal:: Conclusion on the peer review	Yes, EFSA Journal 2011;9(7):2300 EFSA Journal 2022;20(9):7552
EFSA Journal: conclusion on article 12	No
Current MRL applications on intended uses	No MRL required

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

Not applicable. No new data submitted in the framework of this application.

Conclusion on stability of residues during storage

Not applicable

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

Not applicable

Conclusion on stability of residues in sample extracts

Not applicable

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

EFSA¹ (2011) and EFSA² (2022) concluded that there is no residue definition for the active ingredient Quartz sand. Metabolism studies or the determination of residue were considered to be not appropriate. No new data submitted in the framework of this application.

EFSA Journal (2022;20(9):7552): *Not required - Due to the inert and insoluble properties of its constituents, quartz sand is not expected to degrade or to form other metabolites relevant for the consumers when used in compliance with the representative uses. The uses as coating/painting with brush of the individual trees of orchards are relevant for the consumer exposure assessment. It can reasonably be assumed that residues of quartz sand will not be quantified if the application to the orchards trees is conducted in a way that precludes any contamination of the edible parts of the fruits.*

Summary of plant metabolism studies reported in the EU

Not applicable

Summary of new plant metabolism studies

Not applicable

Conclusion on metabolism in primary crops

Not applicable

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

Not applicable. No new data submitted in the framework of this application.

Summary of plant metabolism studies reported in the EU

Not applicable

¹ EFSA Journal 2011;9(7):2300 and ² EFSA Journal 2022;20(9):7552)

Conclusion on metabolism in rotational crops

Not applicable

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

Not applicable. No new data submitted in the framework of this application.

Conclusion on nature of residues in processed commodities

Not applicable

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.2-2: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Not appropriate. No residue definition.
Rotational crops covered	Not relevant
Metabolism in rotational crops similar to metabolism in primary crops?	Not relevant.
Processed commodities	a.s. is stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Not relevant
Plant residue definition for monitoring	No residue definition. (EFSA 2011/2022)
Plant residue definition for risk assessment	No residue definition. (EFSA 2011/2022)
Conversion factor from enforcement to RA	Not applicable

7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

Not applicable. No new data submitted in the framework of this application.

Summary of plant metabolism studies reported in the EU

Not appropriate. No residue definition.

Quartz sand has been notified as a repellent for use on trees by application with a brush or gloves; other types of manual application have not been assessed. The formulations are used only as a protective coat on the outside of tree trunks or on saplings. Since coating of trees is the only use of quartz sand, no crops are treated directly and therefore no residues on food and/or feed may occur.²

² EFSA Journal 2011;9(7):2300

Conclusion on metabolism in livestock

Not applicable

7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Quartz sand has been notified as a repellent for use on trees by application with a brush or gloves; other types of manual application have not been assessed. The formulations are used only as a protective coat on the outside of tree trunks or on saplings. Since coating of trees is the only use of quartz sand, no crops are treated directly and therefore no residues on food and/or feed may occur.²

7.2.3 Magnitude of residues in plants (KCA 6.3)

7.2.3.1 Summary of European data and new data supporting the intended uses

No new data are submitted in the framework of this application.

Table 7.2-3: Summary of EU reported and new data supporting the intended uses of XNJ25 251 g/kg and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Deciduous and coniferous trees in forestry	EFSA	EU	n.a.	n.a.				
	New trials	EU	n.a.					
	Overall supporting data for cGAP	EU	n.a.	n.a.	n.a.	n.a.	n.a.	No MRL defined*

* Source of EU MRL: Reg. (EU) 2024/1078

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on deciduous and coniferous trees are considered acceptable, for outdoor uses in forestry.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Not appropriate

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

No new data were submitted in the framework of this application.

It is not considered necessary to provide any livestock feeding studies.

7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

Not appropriate

7.2.5.1 Available data for all crops under consideration

No new data were submitted in the framework of this application.

7.2.5.2 Conclusion on processing studies

Not applicable

7.2.6 Magnitude of residues in representative succeeding crops

Crops under evaluation are not expected to be grown in rotation.

Quartz sand is a game repellent and will be used as protection coat on the outer surface of deciduous and coniferous trees in forestry and fruit trees in orchards as well as ornamental shrubs and trees by coating manually with special brush or glove or by painting with brush the trunk of the individual trees.

Further investigation of residues in rotational crops is therefore not required.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Not relevant. No new data submitted in the framework of this application.

7.2.7 Other/special studies (KCA6.10, 6.10.1)

Not relevant.

7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

As ARfD was not deemed necessary, acute risk assessment is not relevant.

7.2.8.1 Input values for the consumer risk assessment

Not applicable, no ADI and no ARfD have been set.

7.2.8.2 Conclusion on consumer risk assessment

Table 7.2-4: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	n.a.
IEDI (% ADI) according to EFSA PRIMo	n.a.
IESTI (% ARfD) according to EFSA PRIMo*	n.a.
NTMDI (% ADI) **	n.a.
NEDI (% ADI)**	n.a.
NESTI (% ARfD) **	n.a.

* include raw and processed commodities if both values are required for PRIMo

** if national model is available

The proposed use of Quartz sand in the PA formulation Cervacol Extra does not represent unacceptable acute and/or chronic risks for the consumer.

7.3 References

EFSA 2022: Conclusion on the peer review of the pesticide risk assessment of the active substance quartz sand, EFSA Journal 2022;20(9): 7552

RAR 2022: Combined Draft (Renewal) Assessment Report prepared according to Regulation (EC) 1107/2009 or Quartz sand (2022)

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 or referred to by the applicant and relied on, but already evaluated at EU peer review

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 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 No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

List of data relied on and 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 No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner