

FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

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: 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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9 Ecotoxicology (KCP 10)

Review Comments:

This application was submitted by FMC Corporation for approval of the paste formulation Cervacol Extra (code XNJ25; alternative code ASU 98890P) containing 252 g/kg quartz sand for use as a game repellent for use on deciduous and coniferous trees in forestry.

This Part B document only reviews data (Annex III) and additional information that has not previously been considered within the EU review process.

Since this document is based on the information provided by the Applicant, all review comments, additions, and corrections have been made using commenting boxes or highlighted in grey. Any incorrect data or text not evaluated by the zRMS has been crossed out.

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use-No. *	Member state(s)	Crop and/or situation (crop destination/ purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha	Conclusion						
					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			Birds	Mammals	Aquatic organisms	Bees	Non-target arthro-	Soil organisms	Non-target plants
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 preferably with gloves	-	a) 1 b) 1	a) n.a. b) n.a. a) I b) I	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 preferably with gloves	-	a) 1 b) 1	a) n.a. b) n.a. a) I b) I	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 preferably 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 – 21 “Conclusion”

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

Remarks table:

- (1) Numeration necessary to allow references
- (2) Use official codes/nomenclatures of EU
- (3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
- (4) 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
- (5) Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (*e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named
- (6) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
- (7) Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (8) The maximum number of application possible under practical conditions of use must be provided
- (9) Minimum interval (in days) between applications of the same product.
- (10) For specific uses other specifications might be possible, *e.g.*: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products
- (11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ ha).
- (12) If water volume range depends on application equipment (*e.g.* ULVA or LVA) it should be mentioned under "application: method/kind".
- (13) PHI - minimum pre-harvest interval
- (14) Remarks may include: Extent of use/economic importance/restrictions

Review Comments:

GAP presented in the Table 9.1-1 of this document is revised with consideration of the outcome of the evaluation performed in area of ecotoxicology.

9.1.1 Overall conclusions

Cervacol Extra is a ready to use game repellent paste which is intended to be applied to trees via coating with a brush. All applications are carried out manually to the terminal shoot of young trees.

The formulation reviewed at EU level during renewal of approval of the active substance is the same as applied for in this dRR.

Valid toxicity data with the active substance were not available for any group of non-target organisms. Therefore, an assessment of the compliance of the material tested with the specifications was not required.

Only acute fish and aquatic invertebrates and algae studies were available with each of the representative formulations. However, all the available studies showed deficiencies (e.g. lack of analytical measurements) and, therefore, were only considered supportive.

Quartz sand is intended to be used by manually coating deciduous and coniferous trees in forestry, orchards, ornamental shrubs and trees in forestry and seedlings of conifer and deciduous trees in forestry with special brush or glove to act as repellent preventing browsing damage.

Given the type of application and the properties of the active substance, the representative uses are expected to result in exposure levels which are too low to measure in the environment. In addition, it is anticipated that the exposure through food items relevant for non-target organisms would be low, considering the application method and the properties of quartz sand. Therefore, low risk was concluded for all nontarget organisms for all the representative uses.¹

9.1.2 Grouping of intended uses for risk assessment

Not applicable.

9.1.3 Consideration of metabolites

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

Quartz sand does not form any metabolites of environmental concern. And therefore a consideration of metabolites for risk assessment is not applicable.

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

However, the provision of further data on the Cervacol Extra is not considered essential, because “the treated plant material generally does not constitute an attractive food item for birds and as it is likely that the product also has a slight repellent effect against birds, the risk for birds after application of quartz sand according to the representative uses is considered to be low.”²

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

² Combined Draft (Renewal) Assessment Report prepared according to Regulation (EC) N° 1107/2009 - Quartz sand, July 2022, Vol. 3 - B.8 (PPP)

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process. Justifications are provided below.

No studies with active ingredient Quartz sand have been submitted. Cervacol Extra was one of the representative formulations which were tested in acute toxicity studies on mammals and were demonstrated to be of low toxicity. Birds are not assumed to feed on the treated plant material like the bark and the needles of the trees and therefore exposure is considered to be negligible. Moreover, the active ingredient “Quartz sand” acts as a mechanical repellent. This mode of action is also assumed to work for birds.²

9.2.1.1 Justification for new endpoints

Not applicable

9.2.2 Risk assessment for spray applications

The risk assessment based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438) was considered to be not applicable for Cervacol Extra.

Review comments:

Not relevant since quartz sand is intended to be used by manually coating deciduous and coniferous trees in forestry, orchards, ornamental shrubs and trees in forestry and seedlings of conifer and deciduous trees in forestry with special brush or glove to act as repellent preventing browsing damage.

9.2.2.1 First-tier assessment (screening/generic focal species)

Not applicable

9.2.2.2 Higher-tier risk assessment

Not applicable

9.2.2.3 Drinking water exposure

When necessary, the assessment of the risk for birds due to uptake of contaminated drinking water is conducted for a small granivorous bird with a body weight of 15.3 g (*Carduelis cannabina*) and a drinking water uptake rate of 0.46 L/kg bw/d (cf. Appendix K of EFSA/2009/1438).

Leaf scenario

Since Cervacol Extra is not a product for spray applications/ not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorp-

tive substances ($K_{oc} < 500 \text{ L/kg}$) or 3000 in the case of more sorptive substances ($K_{oc} \geq 500 \text{ L/kg}$).

Quartz sand is a biologically inert substance, which belongs to the group of less sorptive substances, there is no $K(f)_{oc}$ value available.

9.2.2.4 Effects of secondary poisoning

Quartz sand is insoluble in water; hence no $\log P_{ow}$ exists and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

Risk assessment for earthworm-eating birds via secondary poisoning

Not required.

Risk assessment for fish-eating birds via secondary poisoning

Not required.

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.2.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.2.4 Overall conclusions

As the treated plant material generally does not constitute an attractive food item for birds and as it is likely that the product also has a slight repellent effect against birds, the risk for birds after application of Quartz sand according to the representative uses is considered to be low.²

Review comments:

No avian studies have been performed with quartz sand. Toxicity data were submitted for mammals and demonstrated the low toxicity. Full details of these studies are provided in the EU DAR no additional data on the use of XNJ25 251 g/kg are considered necessary.

Birds are not assumed to feed on the treated plant material like the bark and the green parts of the trees and therefore exposure is negligible.

No risk assessment for effects on birds was carried since it was assessed that exposure is negligible and there is no unacceptable risk to birds from the proposed use.

9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

9.3.1 Toxicity data

Mammalian acute toxicity studies have been carried out with Cervacol Extra (251 g/kg Quartz sand). Full details of these studies are provided in the respective EU RAR² and related documents.

Effects on mammals of Cervacol Extra and SiO₂ were evaluated as part of the EU assessment of Quartz sand.

Moreover, the available data on mammalian toxicity for the formulations Cervacol Extra indicate a low risk to mammals via acute exposure.²

Table 9.3-1: Endpoints and effect values relevant for the risk assessment for mammals

Species	Substance	Exposure System	Results	Reference
Rat	251 g/kg Quartz sand	Oral 1 d Acute	LD ₅₀ >10.000 mg/kg bw	Hackenberg, U., 1978, A0479/1527.01
Rat	SiO ₂ (crystalline; CAS: 14808-60-7)	no information available		
	SiO ₂ (amorphous, CAS: 7631-86-9)	Dietary Reproductive toxicity Multi-generation study	NOAEL: n.a. Neither malformation nor any other adverse effects were noted in the offspring.	EU RAR ²
Rats, mice	SiO ₂ (crystalline; CAS: 14808-60-7): no information available	no information available		
	SiO ₂ (amorphous, CAS: 7631-86-9)	Oral Developmental toxicity	NOAEL 1350 mg/kg bw (rat) NOAEL 1340 mg/kg bw (mice) (parental/ no adverse effect could be found)	EU RAR ²

9.3.1.1 Justification for new endpoints

Not applicable

9.3.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Mammals and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

A concise risk assessment is not applicable for Cervacol Extra; it is not intended for the use as spray solution, but to be applied undiluted as coating on trees by brushing.

9.3.2.1 First-tier assessment (screening/generic focal species)

Not applicable

9.3.2.2 Higher-tier risk assessment

Not applicable

9.3.2.3 Drinking water exposure

When necessary, the assessment of the risk for mammals due to uptake of contaminated drinking water is conducted for a small omnivorous mammal with a body weight of 21.7 g (*Apodemus sylvaticus*) and a drinking water uptake rate of 0.24 L/kg bw/d (cf. Appendix K of EFSA/2009/1438).

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances ($K_{oc} < 500$ L/kg) or 3000 in the case of more sorptive substances ($K_{oc} \geq 500$ L/kg).

Quartz sand is not a sorptive substance therefore a concise risk assessment with risk envelope approach is not applicable.

9.3.2.4 Effects of secondary poisoning

Quartz sand is insoluble in water; hence no $\log P_{ow}$ exists and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

Risk assessment for earthworm-eating mammals via secondary poisoning

Not required.

Risk assessment for fish-eating mammals via secondary poisoning

Not required.

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.3.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.3.4 Overall conclusions

Quartz sand is a biologically inert substance and therefore no tendency for bioaccumulation is expected. As the treated plant material generally does not constitute an attractive food item for birds and as it is likely that the product also has a slight repellent effect against birds, the risk for birds after application of quartz sand according to the representative uses is considered to be low. Cervacol Extra is used as a coating of trees (manually applied) and hence exposure of mammals is considered negligible. Moreover, the available data on mammalian toxicity for the formulation Cervacol Extra[®] indicate a low risk to mammals via acute exposure.¹

Review comments:

XNJ25 251 g/kg is intended to be used by manually coating deciduous and coniferous trees in forestry, orchards, ornamental shrubs and trees in forestry and seedlings of conifer and deciduous trees in forestry with special brush or glove to act as repellent preventing browsing damage.

XNJ25 251 g/kg is a mechanical repellent so it repels mammals.

No risk assessment for effects on terrestrial vertebrates other than birds was carried since it was assessed that, taking to consideration type of application and the properties of the active substance, exposure is negligible and there is no unacceptable risk to terrestrial vertebrates other than birds from the proposed use. No further studies with the formulation as well as risk assessment is required.

9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

Not relevant

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with Quartz sand. Full details of these studies are provided in the respective section of the EU RAR² and related documents.

Effects on aquatic organisms of Cervacol Extra were evaluated as part of the EU assessment of Quartz sand.

No studies about acute or chronic toxicity were available for the active substance Quartz sand. As SiO₂ is commonly found in all environmental compartments (water, soil, and is also found in plants and algae) no further testing is considered necessary.² Hence only data with the formulation were available.

Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms –Quartz sand

Species	Substance	Exposure System	Results	Reference
Not applicable				EU RAR ²
Higher-tier studies (micro- or mesocosm studies)				
Not relevant				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations

Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – Cervacol Extra

Species	Substance	Exposure System	Results	Reference
<i>Oncorhynchus mykiss</i>	Cervacol Extra	96 h, s	LC ₅₀ >500 mg/L _{nom}	xxxxxxxxxxx D./2007a/07/493-009H

Species	Substance	Exposure System	Results	Reference
<i>Daphnia magna</i>	Cervacol Extra	48 h, s	EC ₅₀ >500 mg/L _{nom}	Hernádi, D./2007b/07/493-023DA
<i>Pseudokirchneriella subcapitata</i>	Cervacol Extra	72 h, s	E _r C ₅₀ >500 mg/L _{nom} E _y C ₅₀ >500 mg/L _{nom} E _b C ₅₀ >500 mg/L _{nom}	Hernádi, D./2007c/07/493-022AL
Higher-tier studies (micro- or mesocosm studies)				
Not relevant				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations

9.5.1.1 Justification for new endpoints

Not applicable

9.5.2 Risk assessment

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the “Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009”, as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

The relevant global maximum FOCUS Step 1, 2 and 3 PEC_{SW} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios were regarded to be not relevant for the environmental exposure assessment.

9.5.3 Overall conclusions

Owing to the manually performed application by coating trees with gloves or brush no entry of the active substance into soil and water will be expected. Therefore, the calculation of PEC_{SW} and PEC_{ED} is not considered necessary.²

Review comments:

Taking to consideration type of application and the properties of the active substance, no risk assessment for effects on aquatic organisms was carried since it was assessed that exposure is negligible and there is no unacceptable risk to aquatic organisms from the proposed use.

9.6 Effects on bees (KCP 10.3.1)

9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out with Quartz sand. Full details of these studies are provided in the respective EU RAR² and related documents.

Effects of Cervacol Extra on bees were evaluated as part of the EU assessment of Quartz sand and the exposure of bees is considered negligible, because PA formulation Cervacol Extra is intended for an ex-

clusive use in situations where bees are not likely to be present or exposed.²

9.6.1.1 Justification for new endpoints

Not applicable

9.6.2 Risk assessment

The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SAN-CO/10329/2002 rev.2 (final), October 17, 2002).

The PA formulation Cervacol Extra is used as a coating onto trees (manually applied) and hence exposure of bees is considered negligible. Cervacol Extra is intended for an exclusive use in situations where bees are not likely to be exposed.²

9.6.2.1 Hazard quotients for bees

Not applicable

9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

Not relevant

9.6.3 Effects on bumble bees

Not applicable

9.6.4 Effects on solitary bees

Not applicable

9.6.5 Overall conclusions

The PA formulation Cervacol Extra is used as a coating onto trees (manually applied) and hence exposure of bees is considered negligible. Cervacol Extra is intended for an exclusive use in situations where bees are not likely to be exposed.²

Review comments:

Taking to consideration type of application and the properties of the active substance no risk assessment for effects on bees was carried since it was assessed that exposure is negligible and there is no unacceptable risk to bees from the proposed use.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

Studies on the toxicity to non-target arthropods have been carried out with Quartz sand. Full details of these studies are provided in the respective EU RAR and related documents.

Effects on non-target arthropods of Cervacol Extra were evaluated as part of the EU assessment of Quartz sand.

Due to the fact that Cervacol Extra is used as a coating onto trees and not as a large-area application, together with the fact that Quartz sand ubiquitously occurs in the environment, no testing is considered necessary.²

9.7.1.1 Justification for new endpoints

Not relevant

9.7.2 Risk assessment

The evaluation of the risk for non-target arthropods in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SAN-CO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2 was regarded to be not relevant for Quartz sand.

9.7.2.1 Risk assessment for in-field exposure

Not applicable

9.7.2.2 Risk assessment for off-field exposure

Not applicable

9.7.2.3 Additional higher-tier risk assessment

Not relevant.

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

Due to the fact that Cervacol Extra is used as a coating onto trees and not as a large-area application, together with the fact that Quartz sand ubiquitously occurs in the environment, no testing is considered necessary.²

Review comments:

Taking to consideration type of application and the properties of the active substance no risk assessment for effects on arthropods other than bees was carried since it was assessed that exposure is negligible and there is no unacceptable risk to arthropods other than bees from the proposed use.

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

9.8.1 Toxicity data

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have not been carried out with Quartz sand. Full details are provided in the respective EU RAR² and related documents.

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of Cervacol Extra were evaluated as part of the EU assessment of Quartz sand and were considered to be not relevant.

9.8.1.1 Justification for new endpoints

Not relevant

9.8.2 Risk assessment

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

9.8.2.1 First-tier risk assessment

No relevant PEC_{soil} for risk assessments covering the proposed use pattern exists for Cervacol Extra (refer to Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3). According to the assessment of environmental-fate data, multi-annual accumulation in soil does not need to be considered for Quartz sand.

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of Cervacol Extra were evaluated as part of the EU assessment of Quartz sand and were considered to be not relevant.

Review comments:

Taking to consideration type of application and the properties of the active substance no risk assessment for non-target soil meso- and macrofauna was carried since it was assessed that exposure is negligible and there is no unacceptable risk to non-target soil meso- and macrofauna from the proposed use.

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

Studies on effects soil microorganisms have been carried out with Quartz sand. Full details of these studies are provided in the respective EU RAR².

Effects on soil microorganisms of Cervacol Extra were evaluated as part of the EU assessment of Quartz sand and were considered to be not relevant.²

9.9.1.1 Justification for new endpoints

Not applicable

9.9.2 Risk assessment

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

No relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see Section 9.8).

9.9.3 Overall conclusions

Due to the manual application by coating trees with gloves or by brush no entry of the active substance/formulation into soil is expected. Therefore, exposure of soil non-target micro or macro-organisms is considered negligible.²

Review comment:

Taking to consideration type of application and the properties of the active substance no risk assessment for soil microbial activity was carried since it was assessed that exposure is negligible and there is no unacceptable risk to soil microbial activity from the proposed use.

9.10 Effects on non-target terrestrial plants (KCP 10.6)

9.10.1 Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with Quartz sand. Full details of these studies are provided in the respective EU RAR and related documents.

Effects on non-target terrestrial plants of Cervacol Extra were evaluated as part of the EU assessment of Quartz sand.

It was concluded that because of the method of application leading to negligible levels of environmental exposure, the risk can be considered low for terrestrial non-target plants.²

9.10.1.1 Justification for new endpoints

Not relevant

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

9.10.2.2 Tier-2 risk assessment (based on dose-response data)

The risk assessment based on the “Guidance Document on Terrestrial Ecotoxicology”, (SAN-CO/10329/2002 rev.2 final, 2002) was considered to be not relevant. It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.

9.10.2.3 Higher-tier risk assessment

Not relevant.

9.10.2.4 Risk mitigation measures

No risk mitigation needed.

9.10.3 Overall conclusions

The endpoints of aquatic toxicity data are given in Table 9.5-1 and Table 9.5-2. There was no classification from the acute aquatic toxicity studies done with Cervacol Extra.

Effects on birds, bees, earthworms or arthropods are not relevant, since Cervacol Extra is a ready to use formulation which is used as game repellent on trees.

Review comment:

Taking to consideration type of application and the properties of the active substance no risk assessment for effects on non-terrestrial plants was carried since it was assessed that exposure is negligible and there is no unacceptable risk to non-terrestrial plants from the proposed use.

9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Due to the fact that Cervacol Extra is used as a coating onto trees and not as a large-area application, together with the fact that Quartz sand ubiquitously occurs in the environment, the risk for other non-target organisms (flora and fauna) is considered to be acceptable.²

9.12 Monitoring data (KCP 10.8)

Not relevant

9.13 Classification and Labelling

There was no classification from the acute aquatic toxicity studies done with Cervacol Extra.

Review comments:

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to ecotoxicological data formulation XNJ25 251 g/kg and according to good agricultural practice poses no unacceptable risk to non-target species.

Hazard class(es), categories:	-
Hazard pictograms or Code(s) for hazard pictogram(s):	-
Signal word:	-
Hazard statement(s):	-
Precautionary statement(s):	-
Additional labelling phrases:	EUH401 To avoid risks to man and the environment, comply with the instructions for use.
	SP1 Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).

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

Data Requirement No., Reference No.	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Relied Upon (Y/N)
KCP 10.2.1/001	xxxxxxxxx	2007a	Fish acute toxicity study with Cervacol Extra on rainbow trout (<i>Oncorhynchus Mykiss</i>) 07/493-009H xxxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	N	-	FMC/ Cheminova Deutsch- land GmbH & Co. KG	
KCP 10.2.1/002	Hernádi, D.	2007b	Acute immobilisation test with Cervacol Extra on <i>Daphnia Magna</i> 07/493-023DA Lab International Research Centre Hungary GLP: Yes Published: No	N	N	-	FMC/ Cheminova Deutsch- land GmbH & Co. KG	
KCP 10.2.1/003	Hernádi, D.	2007c	Cervacol Extra. Growth Inhibition test on Algae 07/493-022AL Lab International Research Centre Hungary GLP: Yes Published: No	N	N	-	FMC/ Cheminova Deutsch- land GmbH & Co. KG	

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

Data Requirement No., Reference No.	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Relied Upon (Y/N)
KCP 10.2.1/001	xxxxxxx	2007a	Fish acute toxicity study with Cervacol Extra on rainbow trout (<i>Oncorhynchus Mykiss</i>) 07/493-009H xxxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP: Yes Published: No	Y	N	-	FMC/ Cheminova Deutsch- land GmbH & Co. KG	

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 studies

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

Review comments:

Not relevant. No bird toxicity studies have been carried out with XNJ25 251 g/kg. Further data on the XNJ25 251 g/kg is not considered essential since the active substance naturally occurs in the environment

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

Review comments:

Not relevant. No bird toxicity studies have been carried out with XNJ25 251 g/kg. Further data on the XNJ25 251 g/kg is not considered essential since the active substance naturally occurs in the environment

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

Review comments:

Not relevant. No mammal toxicity studies have been carried out with XNJ25 251 g/kg. Further data on the XNJ25 251 g/kg is not considered essential since the active substance naturally occurs in the environment

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

Review comments:

Not relevant. No mammal toxicity studies have been carried out with XNJ25 251 g/kg. Further data on the XNJ25 251 g/kg is not considered essential since the active substance naturally occurs in the environment

A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

A 2.2 KCP 10.2 Effects on aquatic organisms

Review comments:

Not relevant. No aquatic toxicity studies have been carried out with XNJ25 251 g/kg. Further data on the XNJ25 251 g/kg is not considered essential since the active substance naturally occurs in the environment

A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

Not relevant. See point 2.2

A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

Not relevant. See point 2.2

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

Not relevant. See point 2.2

A 2.3 KCP KCP 10.3 Effects on arthropods

Review comments:

Not relevant. No studies on the toxicity to arthropods other than bees have been carried out with XNJ25 251 g/kg. Further data on the XNJ25 251 g/kg is not considered essential since it is to be used manually as a coating onto deciduous and coniferous trees in forestry and hence exposure of arthropods other than bees is considered negligible.

A 2.3.1 10.3.1 Effects on bees

Review comments:

Not relevant. No studies on the toxicity to bees have been carried out with XNJ25 251 g/kg. Further data on the XNJ25 251 g/kg is not considered essential since it is to be used manually as a coating onto deciduous and coniferous trees in forestry and hence exposure of bees is considered negligible.

A 2.3.1.1 KCP 10.3.1.1 Acute toxicity to bees

Not relevant. See point 2.3.1.

A 2.3.1.1.1 KCP 10.3.1.1.1 Acute oral toxicity to bees

Not relevant. See point 2.3.1.

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Not relevant. See point 2.3.1.

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

Not relevant. See point 2.3.1.

A 2.3.1.3 KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

Not relevant. See point 2.3.1.

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

Not relevant. See point 2.3.1.

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

Not relevant. See point 2.3.1.

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

Not relevant. See point 2.3.1.

A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna

A 2.4.1 KCP 10.4.1 Earthworms

Review comments:

Not relevant. No studies on the toxicity to earthworms have been carried out with XNJ25 251 g/kg. Further data on the XNJ25 251 g/kg is also not considered essential since it is to be used manually as a coating onto deciduous and coniferous trees in forestry. Additionally, quartz sand naturally occurs in the environment and hence exposure of earthworms is considered negligible.

A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

Not relevant. See point 2.4.1.

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

Not relevant. See point 2.4.1.1

A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

Review comments:

Not relevant. No studies on the toxicity to non-target soil meso- and macrofauna (other than earthworms) have been carried out with XNJ25 251 g/kg. Further data on the XNJ25 251 g/kg is also not considered essential since it is to be used manually as a coating onto deciduous and coniferous trees in forestry. Additionally, quartz sand naturally occurs in the environment and hence exposure of non-target soil meso- and macrofauna (other than earthworms) is considered negligible.

A 2.4.2.1 KCP 10.4.2.1 Species level testing

Not relevant. See point 2.4.2.

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

Review comments:

Not relevant. No studies on effects soil microorganisms have been carried out with XNJ25 251 g/kg. Further data on the XNJ25 251 g/kg is also not considered essential since it is to be used manually as a coating onto deciduous and coniferous trees in forestry. Additionally, quartz sand naturally occurs in the environment and hence exposure on effects of soil microorganisms is considered negligible.

A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.6.1 KCP 10.6.1 Summary of screening data

Review comments:

Not relevant. No studies on the toxicity to non-target terrestrial plants have been carried out with XNJ25 251 g/kg. Further data on the XNJ25 251 g/kg is also not considered essential since it is to be used manually as a coating onto deciduous and coniferous trees in forestry. Additionally, quartz sand naturally occurs in the environment and hence exposure on effects of soil microorganisms is considered negligible.

A 2.6.2 KCP 10.6.2 Testing on non-target plants

Not relevant. See point 2.6.1

A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants

Not relevant. See point 2.6.1

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

Not relevant. No studies on other terrestrial organism were submitted.

A 2.8 KCP 10.8 Monitoring data