

FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

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/yy

MS Finalisation date: 11/2025

This document is the property of FMC Corporation and contains confidential and trade secret information. Except as required by law, this document should not be partially or fully (i) photocopied or released in any form to an outside party without the prior written consent of FMC Corporation or its affiliates, or (ii) used by a registration authority to support the registration of any other product without the prior written consent of FMC Corporation or its affiliates.

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

Table of Contents

6	Mammalian Toxicology (KCP 7).....	5
6.1	Summary	5
6.2	Toxicological Information on Active Substance(s)	7
6.3	Toxicological Evaluation of Plant Protection Product.....	7
6.4	Toxicological Evaluation of Groundwater Metabolites.....	9
6.5	Dermal Absorption (KCP 7.3)	9
6.6	Exposure Assessment of Plant Protection Product (KCP 7.2).....	9
6.6.1	Selection of critical use(s) and justification	10
6.6.2	Operator exposure (KCP 7.2.1)	10
6.6.2.1	Estimation of operator exposure	10
6.6.3	Worker exposure (KCP 7.2.3)	11
6.6.3.1	Measurement of worker exposure.....	11
6.6.4	Bystander and resident exposure (KCP 7.2.2)	11
6.6.4.1	Estimation of bystander and resident exposure	12
6.6.4.2	Measurement of bystander and/or resident exposure.....	12
6.6.5	Combined exposure	12
Appendix 1	Lists of data considered in support of the evaluation.....	13
Appendix 2	Detailed evaluation of the studies relied upon.....	17
A 2.1	Statement on bridging possibilities.....	17
A 2.2	Acute oral toxicity (KCP 7.1.1)	17
A 2.3	Acute percutaneous (dermal) toxicity (KCP 7.1.2)	17
A 2.4	Acute inhalation toxicity (KCP 7.1.3)	17
A 2.5	Skin irritation (KCP 7.1.4).....	17
A 2.6	Eye irritation (KCP 7.1.5).....	17
A 2.7	Skin sensitisation (KCP 7.1.6).....	18
A 2.8	Supplementary studies on the plant protection product (KCP 7.1.7)	18
A 2.9	Supplementary studies for combinations of plant protection products (KCP 7.1.8)	18
A 2.10	Data on co-formulants (KCP 7.4)	18
A 2.11	Studies on dermal absorption (KCP 7.3)	18
A 2.12	Other/Special Studies.....	19
Appendix 3	Exposure calculations	20
A 3.1	Operator exposure calculations (KCP 7.2.1.1)	20
A 3.2	Worker exposure calculations (KCP 7.2.3.1)	20
A 3.3	Bystander and resident exposure calculations (KCP 7.2.2.1).....	20
A 3.4	Combined exposure calculations for Quartz sand	20
Appendix 4	Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1)	20

zRMS comments:

The text highlighted in grey was provided by the zRMS.

6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on XNJ25 251 g/kg*

Product name and code	XNJ25 251 g/kg/ ASU 98890P/ Cervacol Extra
Formulation type	Paste [Code: PA]
Active substance(s) (incl. content)	Quartz sand; 251 g/kg
Function	Game repellent
Product already evaluated as the 'representative formulation' during the approval of the active substance(s)	Yes
Product previously evaluated in another MS according to Uniform Principles	Yes

* Information on the detailed composition of XNJ25 251 g/kg can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

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 toxicological data is proposed for the preparation:

Table 6.1-2: Justified proposals for classification and labelling for XNJ25 251 g/kg according to Regulation (EC) No 1272/2008

Hazard class(es), categories:	None
Hazard pictograms or Code(s) for hazard pictogram(s):	None
Signal word:	None
Hazard statement(s):	None
Precautionary statement(s):	None
Additional labelling phrases:	Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction. [EUH208]
	Safety data sheet available on request [EUH210]
	To avoid risks to human health and the environment, comply with the instructions for use. [EUH401]

Table 6.1-3: Summary of risk assessment for operators, workers, bystanders and residents for XNJ25 251 g/kg/ Cervacol Extra

	Result	PPE/ Risk mitigation measures
Operators	Acceptable	None Paintbrush or gloves during application.
Workers	Acceptable	None
Bystanders	Acceptable	None

	Result	PPE/ Risk mitigation measures
Residents	Acceptable	None

No unacceptable risk for operators, workers, bystanders and residents was identified when the product is used as intended and provided that the PPE/ risk mitigation measures stated in Table 6.1-3 are applied.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and bystanders/residents is presented in the following table.

Table 6.1-4 Critical uses and overall conclusion of exposure assessment

1	2	3	4	5	6	7	8	9	10			
Use- No.*	Crops and situation (e.g. growth stage of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Application		Application rate		PHI (d)	Remarks: (e.g. safener/synergist (L/ha)) critical gap for operator, worker, bystander or resident exposure based on [Exposure model]	Acceptability of exposure assessment			
			Method/ Kind (incl. application technique ***	Max. number (min. interval between applications) a) per use b) per crop/ season	Max. application rate kg as/ha a) a.s. 1 b) a.s. 2	Water L/ha min/ max			Operator	Worker	Bystander	Residents
1	Deciduous and coniferous trees in forestry	F	Coating of small trees with undiluted product preferably with glove	a)1 b)1	a) n.a. b) n.a. 2-5 kg/1000 plants	n.a.	n.a.	2-5 kg/1000 plants Models not applicable	R	A	A	A
3	Coniferous trees in forestry	F	Coating of 5- 10 years trees with undiluted product preferably with gloves	a) 1 b) 1	a) n.a. b) n.a. 10-14 kg/1000 plants	n.a.	n.a.	10-14 kg/1000 plants Models not applicable	R	A	A	A

* 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

*** e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held

Explanation for column 10 “Acceptability of exposure assessment”

A	Exposure acceptable without PPE/ risk mitigation measures
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable/ Evaluation not possible

Data gaps

Data gaps should be listed in the summary to give an overview (especially for cMS).

Noticed data gaps are:

- data gap 1
- data gap 2
- data gap 3

6.2 Toxicological Information on Active Substance(s)

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in Table 6.2-1.

Table 6.2-1: Information on active substance(s)

	Quartz sand
Common Name	Silicon dioxide Quartz
CAS-No.	7631-86-9 14808-60-7
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: - Code(s) for hazard pictogram(s): - Signal word: - Hazard statement(s): - Precautionary statement(s): -
Additional C&L proposal	Please insert proposal for additional C&L if no (sufficient) harmonized classification is available
Agreed EU endpoints	
AOEL systemic	No data available not required.
Reference	EFSA Journal 2011;9(7):2300 EFSA Journal 2022;20(9):7552 PLAN/2022/2457 RR Rev 2, 25 May 2023 - <i>FINAL Renewal report for the active substance quartz sand finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 25 May 2023 in view of the renewal of the approval of quartz sand as a low-risk substance in accordance with Regulation (EC) No 1107/2009</i>
Conditions to take into account/critical areas of concern with regard to toxicology	
EFSA Conclusion for active substance	None (EFSA Journal 2022;20(9):7552)

Quartz sand is a low risk substance.

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for the representative formulation during EU renewal of quartz sand which is the same as the product assessed in this dRR is given in the following tables.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for XNJ25 251 g/kg/ Cervacol Extra

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat	>2000 mg/kg bw (supplementary information –studies with amorphous silica)	Y	None	EFSA 2022
LD ₅₀ dermal, rat	>2000 mg/kg bw (supplementary information –studies with amorphous silica). (supplementary information –studies with crystalline and amorphous silica)	Y	None	EFSA 2022
LC ₅₀ inhalation, rat	>2,2 mg/L air (supplementary information –studies with amorphous silica)	Y	None	EFSA 2022
Skin irritation	Non irritating (supplementary information –studies with amorphous SiO ₂)	Y	None	EFSA 2022
Eye irritation	Non irritating (supplementary information –studies with amorphous SiO ₂)	Y	None	EFSA 2022
Skin sensitisation	Non sensitising (supplementary information –studies with amorphous SiO ₂)	Y	None	EFSA 2022
Phototoxicity	No data available, not needed.	-	-	EFSA 2022

Table 6.3-2: Additional toxicological information relevant for classification/labelling of XNJ25 251 g/kg/ Cervacol Extra

	Substance (Concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Reg. 1272/2008)
Toxicological properties of active substance(s) (relevant for classification of product)	Quartz sand (25.1 % (w/w))	None	EFSA 2022	None
Toxicological properties of non-active substance(s) (relevant	1,2-benzisothiazol-3(2H)-one	Eye Dam. 1, H318 Acute Tox. 4, H302 Skin Irrit. 2, H315	MSDS* Harmonised classification	EUH 208: Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic

	Substance (Concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Reg. 1272/2008)
for classification of product)	(CAS No. 2634- 33-5, <0.05 % (w/w))*	Skin Sens. 1, H317 Aquatic Acute 1, H400 <i>From 1 Sept. 2025:</i> Acute Tox. 2, H330 Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Skin Sens. 1A, H317: c ≥ 0.036 %	according to CLP: Commission Delegated Regulation (EU) 2024/197	reaction.
Further toxicological information	No data – not required Please refer to dRR Part C			

* see Material safety data sheet by suppliers provided in dRR Part C

6.4 Toxicological Evaluation of Groundwater Metabolites

Metabolites of Quartz sand do not occur, there are no metabolite concentrations, and hence, no groundwater assessment is required.

6.5 Dermal Absorption (KCP 7.3)

zRMS's comment	Accepted.
----------------	-----------

EFSA 2022: Dermal absorption is considered to be negligible due to the intrinsic properties (insoluble and inert) of the active substance. Dermal penetration of crystalline silica also seems minimal, whereas according to current knowledge, inhalation is the major pathway for silica to enter the human body, with the particle size being the most important aspect regarding clearance and deposition in the lung.

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

Table 6.6-1: Product information and toxicological reference values used for exposure assessment

Product name and code	XNJ25 251 g/kg/ Cervacol Extra
Formulation type	PA
Category	Game repellent
Container size(s), short description	PE (LDPE foil, MFR 0.5-0.8, Density at 23 °C 0.92 g/cm ³ approx.); sealed 5kg knead bags stored in 15 kg PP buckets for transport PE bag size approximates to 265 mm x 255 mm
Active substance(s) (incl. content)	Quartz sand 251 g/kg
AOEL systemic	Not applicable

Inhalation absorption	Since Cervacol Extra is a ready for use paste, which is applied directly onto those parts of the plants that should be protected, a danger by inhalation can be excluded*
Oral absorption	Under the experimental conditions, the oral LD ₅₀ of XNJ25 251 g/kg/ Cervacol Extra is higher than 10000 mg/kg bw in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008.*
Dermal absorption	No data on dermal absorption for quartz sand in Cervacol Extra is available. Due to the nature of quartz sand dermal absorption can be considered negligible. No further data are required*

* RAR; CP Volume 3 B6

6.6.1 Selection of critical use(s) and justification

The critical GAP used for the exposure assessment of the plant protection product is shown in Table 6.1-4. A list of all intended uses within the CEU is given in Part B, Section 0.

Justification

The Plant Protection Product XNJ25 251 g/kg/ Cervacol Extra is a game repellent for use on deciduous and coniferous trees in forestry (professional and non-professional use), on orchards, ornamental shrubs and trees (professional and non-professional use) and on seedlings of conifer and deciduous trees in forestry (professional use) by application locally with a brush or gloves. The product is a ready for use paste. The representative GAP for this assessment is based on maximum application rate.

6.6.2 Operator exposure (KCP 7.2.1)

zRMS's comment	Acceptable. According to EFSA conclusion (EFSA Journal 2022;20(9):7552): <i>Paintbrush and gloves application of quartz sand formulated as a paste was not considered to be a source of significant exposure.</i> AOEL - No data available, not required.
----------------	---

6.6.2.1 Estimation of operator exposure

The possibility of user exposure to XNJ25 251 g/kg/ Cervacol Extra is limited to the application, since a mixing procedure is not applicable. The possible risks can be derived from the toxicity of the formulation. The results of the conducted acute toxicity studies with Cervacol Extra are the following:

- Acute oral toxicity: higher than 10000 mg/kg bw in rats
- Acute oral inhalation: higher than 0.2 mg/L air in rats.
- Skin Irritation: not a skin irritant.

Since XNJ25 251 g/kg/ Cervacol Extra is a ready for use paste, which is applied directly onto those parts of the plants that should be protected, a danger by inhalation can be excluded.

The dermal exposure is limited to the hands, since it might be assumed that during the application time autumn until winter the user wears long clothes. Furthermore, the user should apply the product by using a brush according to the user's instruction (1 kg pack). The 15 kg pack contains 3 kneadable 5 kg bags and rubber gloves with which the product should be applied. Therefore, no exposure is possible in this case.

Provided that the product is used according to the user's instruction, a risk for the eyes by splashes or accidentally by already treated twigs can be excluded, because of the high viscosity of the paste and the way of application (from the bottom to the top).

In spite of the slight risks by handling Cervacol Extra, it is recommended to wear suitable protective clothing, at least gloves, protective work clothing with long sleeves and suitable shoes and furthermore maybe safety glasses in order to prevent injuries of the eye caused by twigs during the application process which are however not caused by the product. Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

6.6.3 Worker exposure (KCP 7.2.3)

zRMS's comment	Acceptable. According to EFSA conclusion (EFSA Journal 2022;20(9):7552): <i>Paintbrush and gloves application of quartz sand formulated as a paste was not considered to be a source of significant exposure.</i> Re-entry to the treated area is not expected.
----------------	---

Provided that the product is used according to the user's instruction, the worker applying to trees is not in danger. Therefore, this study is not required and was not conducted.

Cervacol Extra is used in forestry to protect the trees against damaging biting caused by game. To re-enter the application area is usually not necessary, but can be done without risk. The PA formulation dries directly onto the covered parts of the young trees.

There is a second signalling effect, because of the blue colour of the product, which leads to an avoidance of the treated parts of the plants.

EFSA 2022: Paintbrush and gloves application of quartz sand formulated as a paste was not considered to be a source of significant exposure.

6.6.3.1 Measurement of worker exposure

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mention PPE, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

6.6.4 Bystander and resident exposure (KCP 7.2.2)

zRMS's comment	Acceptable. According to EFSA conclusion (EFSA Journal 2022;20(9):7552): <i>Paintbrush and gloves application of quartz sand formulated as a paste was not considered to be a source of significant exposure.</i> Therefore, the exposure to bystander/resident is negligible.
----------------	--

6.6.4.1 Estimation of bystander and resident exposure

An endangering of the bystander is not given because of the technique of application in spread coating.

EFSA 2022: Paintbrush and gloves application of quartz sand formulated as a paste was not considered to be a source of significant exposure.

6.6.4.2 Measurement of bystander and/or resident exposure

Since the bystander and/or resident exposure estimations for a PA ready to use formulation carried out indicate that the acceptable operator exposure level (AOEL) for Quartz sand will not be exceeded under any conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of bystander/resident exposure was not necessary and was therefore not performed.

6.6.5 Combined exposure

Not relevant. The product contains only one active substance.

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

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)
IIIA 7.1.4/01	xxxxxxx	1977	CERVACOL.Prüfung auf Reizwirkung an der Kaninchenhaut (Test for irritant effects on rabbit skin) A 0479/1527.02 xx GLP: No Published: No	Y	N	-	Cheminova Deutschland GmbH & Co. KG	
IIIA 7.1.1/01	xxxxxxxxx	1978a	Bestimmung der LD ₅₀ und Erfassung toxischer Symptome von Cervacol Extra nach 1-maliger Intra-gastraler Applikation an der männlichen und weiblichen, Ratte (Determination of the LD ₅₀ and recording of toxic symptoms of Cervacol Extra after single intragastric) A 0479/1527.01 xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP: No Published: No	Y	N	-	Cheminova Deutschland GmbH & Co. KG	

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)
IIIA 7.1.3/01	xxxxxxxxx	1978b	Akute Inhalationstoxizitätsuntersuchung mit Cervacol an männlichen und weiblichen Ratten (Acute inhalation toxicity study with Cervacol on male and female rats) A 0479/1527.03 xxxxxxxxxxxxxxxxxxxxx GLP: No Published: No	Y	N	-	Cheminova Deutschland 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)
IIIA 7.1.4/01	xxxxxxxxx	1977	CERVACOL.Prüfung auf Reizwirkung an der Kaninchenhaut (Test for irritant effects on rabbit skin) A 0479/1527.02 xxxxxxxxxxxxxxxxxxxx GLP: No Published: No	Y	N	-	Cheminova Deutschland GmbH & Co. KG	
IIIA 7.1.1/01	xxxxxxxxx	1978a	Bestimmung der LD ₅₀ und Erfassung toxischer Symptome von Cervacol Extra nach 1-maliger Intrastraler Applikation an der männlichen und weiblichen, Ratte (Determination of the LD ₅₀ and recording of toxic symptoms of Cervacol Extra after single intragastric) A 0479/1527.01 xxxxxxxxxxxxxxxxxxxx GLP: No Published: No	Y	N	-	Cheminova Deutschland GmbH & Co. KG	
IIIA 7.1.3/01	xxxxxxxxx	1978b	Akute Inhalationstoxizitätsuntersuchung mit Cervacol an männlichen und weiblichen Ratten (Acute inhalation toxicity study with Cervacol on male and female rats) A 0479/1527.03 xxxxxxxxxxxxxxxxxxxx GLP: No Published: No	Y	N	-	Cheminova Deutschland GmbH & Co. KG	

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 studies relied upon

A 2.1 Statement on bridging possibilities

zRMS's comment	Product Cervacol Extra was a representative formulation during the assessment of the active substance Quartz sand (EFSA Journal 2022;20(9):7552, PLAN/2022/2457 RR Rev 2, 25 May 2023). Considering the composition of the product Cervacol Extra and the classification of ingredients, the product does not require classification according to the CLP regulation (details in Doc. C), only the phrase EUH208 should be added on the label: <i>Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.</i> According to EFSA conclusion (EFSA Journal 2022;20(9):7552) the application of the product is locally with a brush or gloves.
----------------	---

No new or additional studies have been submitted.

A 2.2 Acute oral toxicity (KCP 7.1.1)

No new or additional studies have been submitted.

A 2.3 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

zRMS's comment	Accepted.
----------------	-----------

Since animal testing showed a slightly irritating effect to skin (see KCP 7.1.4 or A 2.5.1), the user is recommended to wear gloves. (The 15 kg unit of Cervacol Extra even contains gloves).

With regard to the way of application, the hands are the only part of the body which are exposed to the product. The product does not contain toxic components (refer to the material safety data sheets, which are provided separately in the confidential dRR Part C).

For this reason and for the protection of animals, no other studies were carried out, since no better findings would be shown.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

No new or additional studies have been submitted.

A 2.5 Skin irritation (KCP 7.1.4)

No new or additional studies have been submitted.

A 2.6 Eye irritation (KCP 7.1.5)

zRMS's comment	Accepted.
----------------	-----------

No studies were carried out with the product. Because of the slightly irritating effect to skin (refer to section B.6.1.4) a slightly irritating effect to eyes is to be expected although a study concerning this matter was not carried out. However, an eye exposure is to be almost excluded, because of the way of application with a ready for use paste. Nevertheless, it is recommended to wear protective glasses during the application.

However, an eye exposure is to be almost excluded, because of the way of application with a ready for use paste. Nevertheless, to wear protective glasses is recommended (refer to the safety data sheet of Cervacol Extra).

For this reason and for the protection of animals, no other study was carried out, since no better findings would be shown.

A 2.7 Skin sensitisation (KCP 7.1.6)

zRMS's comment	Accepted.
----------------	-----------

No studies were carried out with the product. Since a slightly irritating effect to skin was observed (refer to section B.6.1.4), the user is recommended to wear gloves. However, since Cervacol Extra contains co-formulant classified as skin sensitizer above threshold for mixture classification, EUH208 phrasing is added: contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.

A 2.8 Supplementary studies on the plant protection product (KCP 7.1.7)

No new or additional studies have been submitted.

A 2.9 Supplementary studies for combinations of plant protection products (KCP 7.1.8)

No new or additional studies have been submitted.

A 2.10 Data on co-formulants (KCP 7.4)

A 2.10.1 Material safety data sheet for each co- formulant

Information regarding material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.10.2 Available toxicological data for each co-formulant

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.11 Studies on dermal absorption (KCP 7.3)

Not applicable

A 2.12 Other/Special Studies

Not applicable

Appendix 3 Exposure calculations

zRMS's comment	Accepted.
----------------	-----------

Since Cervacol Extra is a ready for use paste, which is applied directly onto those parts of the plants that should be protected, a danger by inhalation can be excluded. The dermal exposure is limited to the hands, since it might be assumed that during the application time autumn until winter the user wears long clothes. Furthermore, the user should apply the product by using a brush according to the user's instruction. Therefore, no exposure is possible in this case.

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

No quantitative risk assessment was carried out.

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

No quantitative risk assessment was carried out.

After application of Cervacol Extra no further handling in the treated area is necessary. Furthermore, the plant protection product, applied as paste, will be already dry, after a few hours with no significant dust formation likely. For this reason, the application does not lead to dislodgeable residues, which are the only residues susceptible to contamination when a person re-enters treated areas.

A 3.3 Bystander and resident exposure calculations (KCP 7.2.2.1)

No quantitative risk assessment was carried out.

No driftage is expected due to the way of application (brushing of a highly viscous paste). Considering a distance of 5 to 10 m between bystander and operator as usual for bystander exposure calculations, dermal and inhalative exposure to PA formulation Cervacol Extra is considered to be negligible and not of any specific concern.

A 3.4 Combined exposure calculations for Quartz sand

Not applicable

Appendix 4 Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1)

Not applicable