

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: XNJ25 251 g/kg

Chemical active substance:

Quartz sand, 251 g/kg

Poland

NATIONAL ASSESSMENT

(Product re-authorisation; Art. 43)

Applicant: FMC Corporation

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Version history

When	What
November 2023	Original submission, Product re-authorisation; Art. 43
March 2024	Dossier sent for evaluation
June 2025	zRMS evaluation of dRR
November 2025	Final RR
June 2026	Assessment updated in accordance with Commission Delegated Regulation (EU) No 2023/707

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PART A

RISK MANAGEMENT

1 Details of the application

This document describes the acceptable use conditions and the specific conditions of use and labelling required for the re-authorization of the plant protection product Cervacol Extra PA (XNJ25 251 g/kg) in Poland.

Cervacol Extra PA is paste formulation containing the existing EU active substances quartz sand at 251 g/kg for use as a game repellent in forestry.

Cervacol Extra PA was the representative formulation reviewed during the active substance renewal of low-risk active substance quartz sand. Further, the formulated product has previously been evaluated in any EU countries according to the Uniform Principles. Poland is the zRMS for the evaluation of the core assessment. There cMS are Austria, Czech Republic, Germany, Hungary, Romania and Slovakia.

The risk assessment conclusions on Cervacol Extra PA are based on the information, data, and assessments provided in Cervacol Extra PA Registration Report, Part B, Sections 1-10 and Part C, and national addenda when appropriate.

1.1 Application background

The application is prepared for the re-authorization of Cervacol Extra PA in Poland according to Article 43 of Regulation (EC) No 1107/2009. Cervacol Extra PA is a paste formulation containing 251 g/kg of low-risk active substance quartz sand. Quartz sand is the given name for the low-risk active substance; it consists largely of the mineral quartz, the major constituent of which is silicon dioxide (IUPAC).

The low-risk active substance quartz sand was re-evaluated in the EU as per Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The renewal report was issued in June 2023. The approval renewal of quartz sand was published in the Commission Implementing Regulation (EU) 2023/1488, with entry into force set at 01 September 2023.

This application follows the data requirements for the active substances laid down in Regulation (EC) No. 544/2011 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

The intended uses in Germany are summarised in section 2.6.

1.2 Letters of Access

All studies relied upon and referred to are owned or co-owned by FMC Corporation (= Cheminova Deutschland GmbH & co. KG (former Stähler Deutschland GmbH & Co. KG)). Evidence of ownership may be presented upon request.

1.3 Data protection claims

Claims for the protection of active substance and plant protection product data supporting the application for re-authorisation of Cervacol Extra PA will be claimed according to Articles 33.4, 59, and, where applicable, 80.2 of Regulation EC No. 1107/2009.

Task force member Cheminova Deutschland GmbH & Co. KG hereby requests data protection for all information listed in Appendix 1, Part B of each dossier section where data protection claims are made, on the basis that this information is regarded as proprietary. This request takes into account the provision claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4. Furthermore, task force member Cheminova Deutschland GmbH & Co. KG

requests data confidentiality for all information included in Part C of this dRR application.

2 Details of the authorization decision

2.1 Product identity

Product code	ASU 98890P; XNJ25 251 g/kg
Product name in MS	PL: Cervacol Extra PA
Authorization number	R-85/2014
Function	Repellent
Applicant	Cheminova Deutschland GmbH & Co. KG
Active substance(s) (incl. content)	Quartz sand; 251 g/kg
Formulation type	Paste [PA]
Packaging	1 kg Polyethylene (PE) buckets Shape/size: Ø100 mm x 152 mm Closure: PE (Ø 109.9 mm) Packaging also for non-professional use
	3 x 5 kg knead bag in 15 kg Polypropylene (PP) bucket Knead bags: PE-folisbag, weld 390 x 215 mm Shape/size: Ø 26.5cm x 25.5 cm Closure: PP (Ø 26.6 mm)
Coformulants of concern for national authorizations	Not applicable
Restrictions related to identity	Not applicable
Mandatory tank mixtures	Not applicable
Recommended tank mixtures	Not applicable

2.2 Conclusion

Toxicology: With respect to toxicology, an authorisation can be granted for all uses applied for.

Residues: The evaluation of the application for XNJ25 251 g/kg resulted in the decision to grant the authorization.

Fate and Behaviour. The evaluation of the application for XNJ25 251 g/kg resulted in the decision to grant the authorization.

Ecotoxicology: In conclusion of the evaluation of the risk for aquatic organisms the authorization in Deciduous and coniferous trees in forestry can be granted according to critical GAP.

The evaluator also verified whether the co-formulants contained in plant protection product Quartz sand are listed in Annex III to Regulation (EC) No 1107/2009 and/or could be considered unacceptable based on the criteria indicated in the Annex to the Commission Implementing Regulation (EU) 2023/574 of 13 March 2023.

Based on the currently available MSDSs and other information provided by applicant or manufacturer of co-formulant, the product Quartz sand does not contain any unacceptable co-formulant/ingredient listed in the Commission Regulation (EU) 2021/383 of 3 March 2021 amending Annex III to Regulation (EC) No 1107/2009.

According to the current knowledge and available information, none of the co-formulants in the plant protection product Quartz sand meets the Annex to Regulation (EU) 2023/574 criteria for identification of co-formulants that are unacceptable for inclusion in a plant protection products. Taking this into account, none of the co-formulants/ingredients in this product is considered to be a candidate for inclusion in Annex III of Regulation (EU) 1107/2009.

The Applicant submitted the statement that, according to its current understanding, Quartz sand does not require a classification with any of the new EU hazard classes pursuant to Commission Delegated Regulation (EU) 2023/707.

2.3 Substances of concern for national monitoring

Not applicable

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	None
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	None
Signal word:	None
Hazard statement(s):	None
Precautionary statement(s):	None
Additional labelling phrases:	Zawiera 1,2-benzoizotiazol-3(2H)-on. Może powodować wystąpienie reakcji alergicznej. [EUH208]
	Karta charakterystyki dostępna na żądanie. [EUH210]
	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia [EUH401]

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
EUH 208	Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.
EUH210	Safety data sheet available on request

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	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).
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2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None	
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2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
P280	Stosować rękawice ochronne (Wear protective gloves). 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>
Worker protection:	
respective code if available	national PPE requirements
Integrated pest management (IPM)/sustainable use:	
n.a.	
Environmental protection	
n.a.	
Other specific restrictions	
n.a.	

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
NB663	e.g. The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorization is applied.

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
n.a.		1 from GAP table in 2.6
Environmental protection:		Relevant for use no.
n.a.		1 from GAP table in 2.6

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code):	Cervacol Extra / ASU 98890P	Formulation type:	GAP rev. 1, date: September 2023 PA ^(a, b)
Active substance 1:	Quartz sand	Conc. of as 1:	251 g/kg ^(c)
Active substance 2:	n.a.	Conc. of as 2:	- ^(c)
Active substance....:	n.a.	Conc. of as:	- ^(c)
Safener:	n.a.	Conc. of safener:	- ^(c)
Synergist:	n.a.	Conc. of synergist:	- ^(c)
Applicant:	FMC Corporation	Professional use:	☒
Zone(s):	CEU, NEU ^(d)	Non professional use:	☐
Verified by MS:	yes		

Field of use: repellent

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	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/synergis per ha (i)
					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		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL	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) 2-5 kg/1000 plants b) n.a.	a) 502 – 1255 g/1000 plants b) n.a.	n.a.	Not relevant	2-5 kg/1000 plants

2	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
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Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l

(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when 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 equipments (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

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

Cervacol Extra PA is a pastel turquoise, viscous paste with an alcoholic odour, a pH of 9.66 and a flash point of 53 °C a. It is not explosive, oxidizing, or flammable. Its stability allows storage under practical and normal commercial conditions. Cervacol Extra PA and its commercial container materials have been shown to be stable for at least 2 years at ambient temperature. No unacceptable risks due to Cervacol Extra PA's technical properties are expected when used as recommended.

EFSA 2022 identified a data gap to provide data on the active substance content as well as the relevant impurity content in the formulation 'Cervacol Extra PA' before and after accelerated storage and before and after shelf-life at ambient temperature. New studies have been submitted with this dossier accordingly.

3.2 Efficacy (Part B, Section 3)

Cervacol Extra PA has proved to be very effective and displayed good to very strong repellent effects on average. Due to the combination of different modes of action in the formulation an adaptation to these deterrent effects of the game is quite unlikely.

Cervacol Extra PA has confirmed to be very crop tolerant in forest trees.

The product has not any negative impact on wood harvest or wood quality or any processing of timber.

A negative impact on non-target organisms or beneficials was never observed in the efficacy trials or reported from the practical use of the registered product within the last 20 years.

3.3 Efficacy data

Between the years 1999 and 2011, 21 GEP trials were set up in Germany (6), Poland (12) and Latvia (3) to confirm efficacy of Cervacol Extra PA against gnawing by roe and deer in forest trees.

In 6 trials conducted in Germany (Maritime EPPO climatic zone), 3 kg Cervacol Extra PA per 1000 trees achieved good efficacy (79.9 %) superior to that of the registered reference product (62.0 %).

In 12 supporting trials conducted in Poland (North-East EPPO climatic zone), 2 kg Cervacol Extra PA per 1000 trees achieved sufficient efficacy (43.1 %), very similar to the registered reference products (43.0 %). In the same trials, 5 kg Cervacol Extra PA per 1000 trees achieved clearly superior efficacy (72.5 %).

In 3 additional supporting trials conducted in Latvia, 2 kg Cervacol Extra PA per 1000 trees achieved 20.9 % efficacy under harsh winter conditions that was still comparable to the reference product (25.3 %). In one of these trials, an additional application of 3 kg Cervacol Extra PA achieved solid efficacy (31.9 %) under extreme deer pressure (> 50 % gnawing damage in the untreated) that was superior to the reference product (20.7 %).

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

Cervacol Extra PA contains as active ingredient Quartz sand. The product has been a well-known and highly effective game repellent for preventing of gnawing caused by roe, deer and elk in coniferous and deciduous trees for many years. Cervacol Extra PA is based on a grainy substance and is formulated as aqueous paste.

The repellent activity of Cervacol Extra PA is a combination of different effects such as

- optically by the light blue colour
- taste (unusual taste by the grainy substance)
- effects by the sense of touch acting the grainy layer.

The light blue colour of treated plants represents for roe and red deer an atypical colour in their normal pattern of feed selection. The sandy substance firstly leads to a repellent effect by taste; secondly it causes an abnormal feeling to teeth of roe and red deer. Due to the combination of different repellent effects an adaption of the game to these deterrent effects is very unlikely.

It is a good practice in forest management to use different repellents over the years during the protection period to avoid any adaption to certain products.

Cervacol Extra PA is proved to be very effective over a period of more than 20 years in Germany and other countries.

Nevertheless we recommend as a measure of responsible care to alternate the application of Cervacol Extra PA with other products to avoid any habituation of the animals to the product.

Cervacol Extra contains as the active ingredient quartz sand. Resistance to the active substance is unlikely to occur. However, the ZRMS agrees with the Applicant to alternate the application of Cervacol Extra with other products to avoid any habituation of the animals to the product.

3.3.2 Adverse effects on treated crops

Cervacol Extra PA has been used in forestry for more than 20 years. So far, no phytotoxicity has been reported. Based on the facts we can conclude that Cervacol Extra PA shows a very high crop safety and that there is no negative impact on plants or parts of plants used for propagation purposes.

3.3.3 Observations on other undesirable or unintended side-effects

There were no unintended side-effects observed during all the years when applying Cervacol Extra PA to trees in forestry.

The Applicant has not submitted any new data about preliminary range-finding tests, minimum effective dose nor efficacy tests, adverse effects on treated crops. Although no GAP changes have been applied for.

According to the Guidance document on the Renewal of authorizations, Art.43 of Regulation (EC) No 1107/2009 (SANCO/2010/13170 rev. 14, 7 October 2016), no significant changes compared to previous authorizations should be applied for.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

The Product Cervacol Extra PA was the representative formulation considered during the EU evaluation. Therefore, EU evaluated methods of analysis are available for the determination of the active substance in the technical material and in the representative formulations. New studies have been submitted in this dossier in order to address the data gaps identified by EFSA (2022).

Quartz sand is one of the most common forms of naturally occurring crystalline silica (or silicon dioxide SiO₂). Silica occurs either in a crystalline or non-crystalline (amorphous) form. Regarding impurities, crystalline silica with particle size $\leq 10\ \mu\text{m}$ has been identified as a toxicologically relevant impurity with a maximum acceptable level of 1 g/kg (EFSA 2022, Section 1). There is sufficient evidence of carcinogenicity via inhalation for respirable crystalline silica dust. There methods and its validations of active ingredient (Silicon dioxide) and its impurity (crystalline silica $<10\mu\text{m}$) has been submitted.

The new method for assay of active ingredient (Silicon dioxide) and its impurity (crystalline silica $<10\mu\text{m}$) in Cervacol Extra PA is based on analysis by a spectrophotometric method.

The method for determination of silicon dioxide in Cervacol Extra PA was validated for specificity, linearity, repeatability and accuracy, in compliance with SANCO/3030/99 rev.5 (22/03/19). The analytical method developed for the determination of Crystalline silica $<10\mu\text{m}$ in Cervacol Extra PA was validated with respect to specificity, linearity of detector response, precision and accuracy. Square correlation coefficient (r^2) and modified Horwitz values (%RSD) fulfilled the requirements of SANCO/3030/99 rev. 5.

There are no formulating ingredients in Cervacol Extra PA of toxicological or ecotoxicological concern that justify the need for the submission and disclosure of enforcement methods.

3.4.2 Analytical methods for residues

Quartz sand is a naturally occurring mineral. It is insoluble in water and it will also not degrade in the environment. The intended use of “Cervacol Extra PA” is in forestry to prevent damage to young trees caused by game gnawing, when applied on the plants surfaces. Therefore, analytical methods for the determination of residues in food and feed of plant origin, in food of animal origin, body fluids and tissues and in environmental compartments are not required due to the fact that no residue definitions are proposed according to EFSA Conclusion 2022.

3.5 Mammalian toxicology (Part B, Section 6)

Silica occurs in either a crystalline or non-crystalline (amorphous) form. Quartz sand is one of the most common forms of naturally occurring crystalline silica. The risk assessment has been based on published information on different types of silica including risk assessment performed by other institutions for purposes other than the pesticide use. The original studies were not available to the RMS for their own evaluation and also no suitable data are available to establish NOAELs. The limited database indicated that quartz sand may be of low concern by the oral and dermal route of administration; however this could not be confirmed. Considering the inhalation route, during the commenting phase it was raised that for hazard assessment the maximum content of particles with diameter below 50 µm in quartz sand should not exceed 0.1 % due to the association between exposure to respirable silica dust (i.e. particles with diameter lower than 10 µm) and silicosis and increased probability of developing lung cancer (see also section 1). However, during the expert meeting it was agreed that inhalation exposure can be considered negligible and therefore this route of exposure is of low concern for quartz sand considering the type of application and the nature of the formulation (i.e. ready to use paste).

EFSA 2022 concluded, that the uncertainties from the limited database did not affect the risk assessment, as the paintbrush and gloves application of a paste was not considered to be a source of significant exposure based on the unlikely dermal absorption of quartz sand and the negligible inhalation exposure. Considering the representative uses it was agreed that there is no need to set an Acceptable Operator Exposure Level (AOEL), or an Acceptable Daily Intake (ADI) or an Acute Reference Dose (ARfD).

3.5.1 Acute toxicity

Cervacol Extra PA is not systemically toxic after administration by oral, dermal or inhalation routes. It is slightly irritating to skin and is considered to be also slightly irritating to eyes.

3.5.2 Operator exposure

The calculation of the OPEX was not relevant for Cervacol Extra PA.

3.5.3 Worker exposure

The calculation was considered to be not relevant for Cervacol Extra PA.

3.5.4 Bystander and resident exposure

The calculation was considered to be not relevant for Cervacol Extra PA.

3.6 Residues and consumer exposure (Part B, Section 7)

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. 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.

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.

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.

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.

3.6.1 Residues

Not applicable, there is no residue definition for the active ingredient Quartz sand.

3.6.2 Consumer exposure

There is no consumer exposure as these products are not used on edible crops.

3.7 Environmental fate and behaviour (Part B, Section 8)

The EFSA 2011 and 2022 concluded that due to the natural occurrence of Quartz sand (silicon dioxide) in the environment, specific environmental fate studies are not required. In addition PEC values (PEC_{soil} , PEC_{sw} , PEC_{SED} and $PEC_{Groundwater}$) are considered to be not relevant for the environmental exposure assessment. Owing to the manual application by coating forest trees with gloves or brush no entry of the active substance into soil, surface or ground water is expected. Therefore the calculation of the PEC_{soil} , PEC_{sw} , PEC_{SED} and $PEC_{Groundwater}$ values were not considered necessary. Błąd! Nie zdefiniowano zakładek.

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

Not applicable. Please refer to 3.7.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

Not applicable. Please refer to 3.7.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

Not applicable. Please refer to 3.7.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

Not applicable. Please refer to 3.7.

3.8 Ecotoxicology (Part B, Section 9)

The EFSA 2011 and 2022 concluded, that because of the method of application of Cervacol Extra PA (251 g/kg Quartz sand) leading to negligible levels of environmental exposure, the risk can be considered low for birds and mammals, aquatic organisms, bees, non-target arthropods, earthworms, soil macro- and micro- organisms, terrestrial non-target plants and biological methods for sewage treatment plants.¹

3.8.1 Effects on terrestrial vertebrates

The EFSA 2011 and 2022 concluded, that because of the method of application of Cervacol Extra PA (251 g/kg Quartz sand) leading to negligible levels of environmental exposure, the risk can be considered low for birds and mammals.²

3.8.2 Effects on aquatic species

The EFSA 2011 and 2022 concluded, that because of the method of application of Cervacol Extra PA (251 g/kg Quartz sand) leading to negligible levels of environmental exposure, the risk can be considered low for aquatic organisms.²

3.8.3 Effects on bees

Cervacol Extra PA is used as a coating on trees (manually applied) and hence exposure of honey bees is considered to be low. In addition, Cervacol Extra PA is not used as a large-area application, and because of the fact that quartz sand occurs ubiquitously in the environment, no testing is considered necessary.

3.8.4 Effects on other arthropod species other than bees

Cervacol Extra PA is used as a coating on trees (manually applied) and hence exposure of arthropod species other than bees is also considered to be low.

3.8.5 Effects on soil organisms

The exposure of soil organisms is considered to be low, due to the manual application of “Cervacol Extra PA” by coating trees with gloves or by brush no entry of the active substance/formulation into soil is expected.

3.8.6 Effects on non-target terrestrial plants

The active ingredient quartz sand is a naturally substance, occurring ubiquitous in the environment, hence effects on other non-target terrestrial plants are negligible.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

The active ingredient quartz sand is a naturally substance, occurring ubiquitous in the environment, hence effects on other non-target terrestrial organisms are negligible.

3.9 Relevance of metabolites (Part B, Section 10)

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. ²
Metabolites of Quartz sand did not occur and therefore a risk assessment is not applicable.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Cervacol Extra PA contains 251 g/kg Quartz sand which is not approved as a candidate for substitution because it is a naturally and ubiquitous occurring substance mainly consisting of SiO₂, which doesn't meet any of the criteria for such candidates. Therefore a comparative assessment is not necessary.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Appendix 1 Copy of the product authorization

Appendix 2 Copy of the product label

Uwagi do etykiety:

Fizykochemia – brak uwag do etykiety.

Toksykologia – zaktualizowano zwroty EUH208 oraz P280. Wprowadzono zmiany w zakresie Środki ostrożności dla osób stosujących środek.

Pozostałości – brak uwag do etykiety.

Los i zachowanie w środowisku – brak uwag do etykiety.

Ekotoksykologia – brak uwag do etykiety.

Skuteczność działania – dodano zapis „Środek naprzemiennie stosować z innymi produktami, aby uniknąć przyzwyczajenia zwierząt do produktu”.

Posiadacz zezwolenia:

Cheminova Deutschland GmbH & Co.KG, Stader Elbstrasse 26-28, DE-21683 Stade, Republika Federalna Niemiec, tel. +49 (0) 4141 9204-0, fax: +49 (0) 4141 9204-210; email: info@cheminova.de

CERVACOL EXTRA PA

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

piasek kwarcowy (związek z grupy tlenków nieorganicznych) - **251 g/kg (25,1 %)**

**Zezwolenie MRiRW nr R- 85/2014 z dnia 04.06.2014 r.
ostatnio zmienione decyzją MRiRW nr R – /2023d z dnia .01.2023 r.**

EUH 401 – W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia

EUH 208 – Zawiera: 1,2-Benzisothiazol-3(2H)-one; 2-Methyl-2H-isothiazol-3-one; mieszanina z: 5-Chloro-2-methyl-4-isothiazolin-3-one [EC No. 247-500-7] i 2-Methyl-2H-isothiazol-3-one [EC No. 220-239-6] (3:1). Może powodować wystąpienie reakcji alergicznej.

P280 – ~~Nosić~~ Stosować rękawice ochronne

OPIS DZIAŁANIA

Cervacol Extra PA jest repelentem w formie pasty **gotowej do stosowania** o działaniu odstraszającym, przeznaczonym do ochrony sadzonek i drzewek drzew liściastych i iglastych w leśnictwie przed zgryzaniem i spałowaniem przez zwierzynę łowną.

STOSOWANIE ŚRODKA

Sadzonki i młode drzewka drzew liściastych i iglastych (sosna, jodła, dąb, buk i inne)
- zgryzanie i spałowanie przez zwierzynę łowną (jeleniowate).

Maksymalna dawka dla jednorazowego zastosowania:

- sadzonki 2-5 letnich drzew liściastych i iglastych: 5 kg/1000 sadzonek (zgryzanie)
- 5-10 letnie drzewka iglaste: 14 kg/1000 drzewek (spalowanie)

Zalecana dawka dla jednorazowego zastosowania:

- sadzonki 2-5 letnich drzew liściastych i iglastych: 2 - 5 kg/1000 sadzonek (zgryzanie)
- 5-10 letnie drzewka iglaste: 10 - 14 kg/1000 drzewek (spalowanie)

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Środek stosować w okresie jesienno-zimowym (na sadzonki drzew liściastych po opadnięciu liści), kiedy zwierzyzna łowna zaczyna uszkadzać sadzonki. Środek stosować w temperaturze powyżej 0°C.

Przed użyciem środek dokładnie wymieszać a następnie nanosić preparat na suchą powierzchnię pędów.

Sadzonki i młode drzewka smarować równomiernie cienką warstwą środka:

- drzewka iglaste - pęd główny z bieżącego przyrostu,
- drzewka liściaste - cały pęd główny, jeśli jego grubość nie przekracza 1 cm.

Zalecana dawka zależy od wielkości i gatunku chronionych sadzonek i drzewek.

ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA

Środek stosować w dni bezdeszczowe, w temperaturze nie niższej niż 0°C.

Po wyschnięciu preparat jest odporny na zmywanie i utrzymuje się na pędach 5-7 miesięcy.

Środek nanosić od dolnej części ku górze, zaczynając od około 15-10 cm przed szczytowym odrostem.

Środek nanosić na sadzonki i młode drzewka używając pędzla malarskiego.

Środek naprzemiennie stosować z innymi produktami, aby uniknąć przyzwyczajenia zwierząt do produktu.

PRZYGOTOWANIE PASTY

Cervacol Extra PA jest środkiem gotowym do użycia. Plastikową torbę ze środkiem intensywnie wzruszyć, następnie otworzyć i zawartość przenieść do wiadra. Jeśli środek, w wyniku dłuższego przechowywania staje się zbyt gęsty, na każde 5 kg środka zaleca się dodanie nie więcej niż 200-300 ml wody i dokładne wymieszanie.

WARUNKI BEZPIECZNEGO STOSOWANIA ŚRODKA

Środki ostrożności dla osób stosujących środek:

Nie jeść, nie pić oraz nie palić tytoniu podczas stosowania środka.

Stosować rękawice ochronne/ oraz odzież roboczą ~~ochronną~~ zabezpieczającą przed oddziaływaniem środka ochrony roślin w trakcie wykonywania zabiegu.

Unikać zbędnego kontaktu ze środkiem.

Środki ostrożności związane z ochroną środowiska naturalnego:

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta:

Nie wchodzić do czasu całkowitego wyschnięcia środka na powierzchni sadzonek i drzewek.

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

Nie dotyczy

Okres od ostatniego zastosowania środka na rośliny przeznaczone na paszę do dnia, w którym zwierzęta mogą być karmione tymi roślinami (okres karencji dla pasz):

Nie dotyczy

Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie:

Nie dotyczy

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą

Przechowywać w temperaturze nie niższej niż 0°C i nie wyższej niż 30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów.

Opróżnione opakowania po środku zaleca się zwrócić do sprzedawcy środków ochrony roślin lub można je potraktować jako odpady komunalne. W razie wątpliwości dotyczących postępowania z opakowaniami poradzić się sprzedawcy środków ochrony roślin.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

Not applicable

Appendix 4 Lists of data considered for national authorization

List of data submitted by the applicant and relied on

Please refer to the reference list.

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

Please refer to the reference list.