

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

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

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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

0	Product background, regulatory context and GAP information	5
0.1	Introduction.....	5
0.1.1	Reason for application	6
0.1.2	Details of RMS(s) and concerned MS	6
0.1.3	Regulatory history of the active(s).....	6
0.1.4	Regulatory history of the product	7
0.2	zRMS conclusion	8
Appendix 1	ALL intended uses	10

zRMS comments:

The text highlighted in grey was provided by the zRMS.

0 Product background, regulatory context and GAP information

0.1 Introduction

This document describes the product background, the regulatory context and GAP information for the re-authorisation of the plant protection product Cervacol Extra in the Central European zone.

Cervacol Extra (code XNJ25; alternative code ASU 98890P (obsolete) is a paste formulation containing 251 g/kg of active substance quartz sand. Quartz sand is a low-risk active substance; it consists largely of mineral quartz, the major constituent of which is silicon dioxide (IUPAC).

The renewal dossier for quartz sand was submitted by the Task force of Avenarius Agro GmbH and Cheminova GmbH & Co. KG in February 2018 to Latvia and Romania acting as the Rapporteur Member state (RMS) and Co-Rapporteur Member State, respectively. The initial evaluation of the dossier on quartz sand was provided by the RMS in the renewal assessment report (RAR), and subsequently, a peer review of the pesticide risk assessment on the RMS evaluation was conducted by EFSA in accordance with Article 13 of Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The renewal report was issued on 25th May 2023¹. The approval of quartz sand was renewed for 15 years following Commission Implementing Regulation (EU) 2023/1488, which applies from 01 September 2023.

Cervacol Extra was a representative formulation reviewed as part of the renewal of active substance quartz sand. The representative uses evaluated on EU level comprise field applications as 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. Full details of the good agricultural practices (GAPs) can be found in the list of end points in EFSA conclusion on the peer review of the pesticide risk assessment of the active substance quartz sand (EFSA Journal 2022;20(9):7552).

For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on quartz sand, and in particular Appendices I and II thereof, shall be taken into account.

Conditions of use shall include risk mitigation measures, where appropriate.

The impurity crystalline silica with a particle diameter $\leq 10 \mu\text{m}$ is of toxicological concern and shall not exceed a level of 0,1 % of particles in the technical material.

The information provided in Cervacol Extra Registration Report, Part B, Sections 1-10 and Part C only reviews data and additional information that has not previously been considered within the EU review process, as part of the Annex I inclusion or renewal evaluation of Quartz Sand. New data included are considered essential for the evaluation and, in this case, a full study summary is provided.

¹ 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; PLAN/2022/2457 RR Rev 2

0.1.1 Reason for application

This draft Registration Report dossier is submitted to support an application for the re-authorisation of Cervacol Extra, under Article 43 of Regulation (EC) No 1107/2009 following the renewal of approval of the low-risk active substance quartz sand. The draft Registration Report dossier is prepared according to SANTE/6895/2009 rev. 1 (07 October 2016).

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

0.1.2 Details of RMS(s) and concerned MS

An overview of applications and authorisations of Cervacol Extra is presented in **Table 0.1-1**.

Table 0.1-1: Overview of RMS and MS

	RMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Northern zone	Latvia: Cervacol Extra, Reg.-no.: 0337	Estonia: Cervacol Extra, 0619/13.06.16 Lithuania: Cervacol extra, Reg.-No.: AS2-46R/2022 for professional use, Reg. No AS2-47R(2017) for non-professional use
Central zone	Poland: Cervacol Extra PA, Reg.-No.: R-85/2014	Austria: Cervacol Plus, Reg.No.: 3755-0 Czech Republic: Cervacol Extra, Reg.-No.: 4156-2 Hungary: Cervacol Extra, Reg.-No.: 6700/1059-1/2023 NÉBIH Romania: Cervacol Extra, Reg.-No.: 1725 Germany: Cervacol Extra, Reg.-No.: 042409-00/00 Slovakia: Cervacol Extra, Reg.-No.: 20-00959-AU
Southern zone	Not planned	Not planned
Inter-zonal	Not planned	Not planned

0.1.3 Regulatory history of the active(s)

Table 0.1-2: Summary of regulatory history of Quartz sand

Status	
Approved in EU	Yes
Commission Implementing Regulation	Commission Implementing Regulation (EU) No 2023/1488
RMS	Latvia
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.09.2023
Date of deadline for renewal of authorization (renewal)	01.12.2023

Status	
Current expiration of approval	31.08.2038
Low risk substance or Candidate for Substitution?	Yes, low-risk a.s.

The EFSA Conclusion on the Peer Review of the Pesticide Risk Assessment of Quartz sand (EFSA Journal 2022;20(9):7552), is considered to provide the relevant information on the evaluation or a reference to where such information can be found.

Remaining data gaps not leading to critical areas of concern or issues not finalised but considered relevant in the context of this dossier submission:

- Applicant Task force Avenarius and Cheminova to provide data on the content of the active substance in at least five representative and recent batches of the technical material (relevant for the representative uses evaluated for ‘Cervacol Extra’)
- Applicant Task force Avenarius and Cheminova to provide data on the active substance content in the formulation ‘Cervacol Extra’ before and after accelerated storage, before and after shelflife at ambient temperature and the analytical method used for its determination (relevant for representative uses evaluated for ‘Cervacol Extra’)
- Applicant Task force Avenarius and Cheminova to provide a validated method for the determination of the quartz sand in the active substance as manufactured (relevant for the representative uses evaluated for ‘Cervacol Extra’)
- Applicant Task force Avenarius and Cheminova to provide validation data for the proposed laser granulometry method for the determination of particle size distribution of the technical active substance. It should be noted that a method that can determine particles with a diameter $\leq 10 \mu\text{m}$ is required. Alternatively, any other validated method that can determine particles with a diameter $\leq 10 \mu\text{m}$ can be provided.

Table 0.1-3: Information on minimum purity of Quartz sand

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product/ information on available equivalency report *, **
915 g/kg	N/A (not different)

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

**. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

0.1.4 Regulatory history of the product

The following table provides corresponding information of product codes, product names and authorizations in different EU Member States.

Table 0.1-4: Summary of regulatory history of the product XNJ25 251 g/kg/ Cervacol Extra

Product code	Product name(s)	MS	Authorization No.	Date of initial registration	Date of the last re-registration
Northern zone					
XNJ25 251 g/kg	Cervacol Extra	LV	A1-121	01.02.2007	17.03.2015
XNJ25 251 g/kg	Cervacol Extra	LT	14-3.10/245		
XNJ25 251 g/kg	Cervacol Extra,	EE		still under evaluation	
Central Zone					
XNJ25 251 g/kg	Cervacol Extra	AT	2424	05.07.1989	03.08.2013
XNJ25 251 g/kg	Cervacol Extra PA/ Cervacol Plus	AT	3755-0	14.07.2016	
XNJ25 251 g/kg	Cervacol Extra	DE	042409-00/00	19.06.2006	31.08.2020
XNJ25 251 g/kg	Cervacol Extra	RO	1725		
XNJ25 251 g/kg	Cervacol Extra	HU	04.2/7774-1/2016		
XNJ25 251 g/kg	Cervacol Extra	CZ	4156-1/2019-08		
XNJ25 251 g/kg	Cervacol Extra PA	PL	R-85/2014		
XNJ25 251 g/kg	Cervacol Extra	SK	13-09-1369	31.01.2007	31.08.2019

Cervacol Extra a paste formulation (PA) containing 251 g/kg of the active substance Quartz sand was one of the representative formulations evaluated during the EU Renewal.

0.2 zRMS conclusion

Section 1, 2 and 4. Identity, physical and chemical properties and further information

The two year shelf life is accepted for the PPP.

Section 3. Efficacy

The evaluation of the application of Cervacol Extra PA resulted in the decision to grant re-authorization for use according to the GAP table.

Section 5. Analytical methods

Accepted.

Section 6. Mammalian Toxicology

Not classified for human health.

EUH208: *Contains: 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.*

According to EFSA conclusion (EFSA Journal 2022;20(9):7552): *Paintbrush and gloves application of quartz sand formulated as a paste was not considered to be a source of significant exposure.*

Section 7. Metabolism and Residues

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

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

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 or MRLs are proposed.

Section 8. Environmental Fate

In accordance with proposed pattern use, based on EFSA, 2022 conclusion, an exposure assessment for the formulation Cervacol Extra PA was not required.

Section 9. Ecotoxicology

The evaluation of the application for Cervacol Extra PA resulted in the decision to grant the authorization in deciduous and coniferous trees in forestry (Uses 1,3).

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.

Uses to be considered safe on the basis of EU methodology:

Uses safe for PL -1, 3. Uses 1, 2 to be confirmed by CMSs.

Uses to be considered non-safe on the basis of EU methodology:

None

Appendix 1 ALL intended uses

GAP rev. 1, date: September 2023

PPP (product name/code): Cervacol Extra / ASU 98890P
Active substance 1: Quartz sand
Active substance 2: n.a.
Active substance....: n.a.
Safener: n.a.
Synergist: n.a.
Applicant: FMC Corporation
Zone(s): CEU, NEU ^(d)
Verified by MS: **yes**

Formulation type: PA ^(a, b)
Conc. of as 1: 251 g/kg ^(c)
Conc. of as 2: - ^(c)
Conc. of as: - ^(c)
Conc. of safener: - ^(c)
Conc. of synergist: - ^(c)
Professional use: ☒
Non professional use: ☐

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: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					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	DE, AT, PL, CZ, HU, RO, SK	Deciduous (3FOBC) and conif- erous 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; in DE 4 kg/1000 plants; in CZ 2 kg/1000 plants; in SK 2-4 kg/ 1000 plants b) n.a.	a) 502 – 1255 g/1000 plants; in DE 1004 g/1000 plants; in CZ 502 g/1000 plants; in SK 502-1004 g/1000 plants b) n.a.	n.a.	Not relevant	2-5 kg/1000 plants; in DE 4 kg/1000 plants; in CZ 2 kg/1000 plants; in SK 2-4 kg/ 1000 plants C: DE, AT, CZ, HU RO, SK A: PL

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: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					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		
2	LV, LT, EE	Deciduous (3FOBC) and conif- erous trees (3FOCC) in forestry	F	Deer (CAPRCA) and red deer (CERVEL)(against browsing)	Coating of undiluted product preferably with gloves	-	a) 1 b) 1	a) not applicable b) not applicable	a) 2-3 kg/1000 plants b) 2-3 kg/1000 plants	a) 0.5-0.8 kg a.s./1000 plants b) 0.5-0.8 kg a.s./1000 plants	a) not applicable b) not applicable	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

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