

FINAL REGISTRATION REPORT

Part B

Section 1: Identity

Section 2: Physical and chemical properties

Section 4: Further information

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

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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	Updated after commenting stage by Poland

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zRMS comments:

The text highlighted in grey was provided by the zRMS.

Sufficient data on identity, physical and chemical properties and other information are **not** available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are:

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

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Cheminova GmbH & Co. KG
FMC Agricultural Solutions
Address: Stader Elbstrasse 26
DE-21683 Stade
Germany

1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

1.2.1 Producer(s) of the preparation

Confidential information or data are provided separately (Part C).

1.2.2 Producer(s) of the active substance(s)

Confidential information or data are provided separately (Part C).

1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

1.2.3.1 Quartz sand

Quartz sand min. 915 g/kg

The source of Quartz sand used in Cervacol Extra is the reference source considered for Annex I listing and renewal of the active substance.

Cervacol Extra does not contain any impurity of toxicological/ ecotoxicological concern.

1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: Cervacol Extra, Cervacol, Cervacol Plus

Company code number: XNJ25 251 g/kg

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

One of the representative formulations that were evaluated during the Annex I inclusion of Quartz sand was "Cervacol Extra" a paste formulation, containing 251 g/kg Quartz sand.

Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)

Active substance/ variant	Declared content of the pure active sub- stance/ variant (g/kg)	FAO Limits (min – max)	Technical content* (g/kg)	Technical content (%w/w)
Quartz sand	251	239 – 264 g/kg	274	27.4

* Based on the minimum purity of 915 g/kg of Quartz sand declared for registration in the active substance dossiers

The formulation Cervacol Extra does not contain relevant impurities, safeners or synergists.

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
Max. 0.1% of particles of crystalline silica with particle diameter $\leq$ 10 μ m in the active substance as manufactured	0.274 g/kg

1.4.2 Information on the active substance(s) (KCP 1.4.2)

Table 1.4-3: Information on Quartz sand

Type	Name/Code Number	
ISO common name	Quartz sand	Variant: n.a.
CAS No.	14808-60-7, 7637-86-9	n.a.
EC No.	238-878-4, 231-545-4	n.a.
CIPAC No.	855	n.a.

1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

Cervacol Extra contains no safeners or synergists.

CONFIDENTIAL information is provided separately (Part C).

1.5 Type and code of the plant protection product (KCP 1.5)

Type: Paste

[Code: PA]

1.6 Function (KCP 1.6)

Repellent

2 **Section 2: Physical, chemical and technical properties of the plant protection product**

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a paste of pastel turquoise colour with an alcoholic odour. It is not explosive, has no oxidising properties. The product has a flash point of >53 °C. It has a self-ignition temperature of >400 °C. In aqueous solution, it has a pH value around 9.66. There is no effect of low and high temperature on the stability of the formulation, after 7 days at 0 °C and 12 weeks days at 35°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in *PE*. Its technical characteristics are acceptable for a *PA* formulation.

The product Cervacol Extra is to be used undiluted and neither suitable nor intended to be mixed in the tank together with other products.

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

None

Notifier Proposals for Risk and Safety Phrases (KCP 12)

EUH 208: Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.
EUH 210: Safety data sheet available on request.
EUH 401: To avoid risks to human health and the environment, comply with the instructions for use.

Compliance with FAO specifications:

The product XNJ25 251 g/kg complies with FAO specifications.

Table 2-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used/ deviations	Test material	Findings	GLP Y/N	Reference	Acceptability/ comments
Colour and physical state (KCP 2.1)	Visual, olfactory	Cervacol Extra (Batch No.: 051004/2)	Colour: pastel turquoise, RAL 6034 Odour: alcoholic odour Physical state: viscous paste	Y	EU RAR (2002) Frauen, M. (2005a)	Accepted
Explosive properties (KCP 2.2.1)			Cervacol extra contains no formulants which are expected to have explosive properties. The active substance is nearly inert and doesn't possess any explosive properties.			
Oxidizing properties (KCP 2.2.2)			Considering the structural formula of its ingredients, Cervacol extra does not possess oxidising properties.			
Flash point (KCP 2.3.1)	EEC A.9	Cervacol Extra (Batch No.: 051004/2)		Y	EU RAR (2002) Kiss, G. (2005a)	Not applicable for a PA formulation
Flammability (KCP 2.3.2)	EEC A.10	Cervacol Extra (Batch No.: 051004/2)		Y	EU RAR (2002) Frauen, M. (2005b)	Not applicable for a PA formulation
Self-heating (KCP 2.3.3)	EEC A.15	Cervacol Extra (Batch No.: 051004/2)		Y	EU RAR (2002) Kiss, G. (2005b)	Not applicable for a PA formulation
Acidity or alkalinity and pH (KCP 2.4.1)			Acidity/alkalinity was not determined, because the pH was >4 and <10.			
pH of a 1% aqueous dilution, emulsion or dispersion	CIPAC MT 75.3	Cervacol Extra (Batch No.: 051004/2)	pH: 9.66	Y	EU RAR (2002) Frauen, M. (2005a)	Accepted

Annex point	Method used/ deviations	Test material	Findings	GLP Y/N	Reference	Acceptability/ comments
(KCP 2.4.2)		051004/2)				
Viscosity (KCP 2.5.1)	OECD 114	Cervacol Extra (Batch No.: 051004/2)	10350 mPas (10.7 1/s) 6985 mPas (21.9 1/s)	Y	EU RAR (2002) Frauen, M. (2005a)	Accepted
Surface tension (KCP 2.5.2)			Not applicable for a PA formulation			
Relative density (KCP 2.6.1)	EEC A.3 CIPAC MT 3.2.1	Cervacol Extra (Batch No.: 051004/2)	1.677 ±0.005	Y	EU RAR (2002) Dardemann, J. (2009)	Accepted
Bulk density (KCP 2.6.2)			Not applicable for a PA formulation			
Storage Stability after 14 days at 54° C (KCP 2.7.1)	SANCO 3030/99 rev. 5	Cervacol Extra (Batch No.: 4551700672)	a.i. content after 2 weeks at 54° C: (init) 25.02 % (m/m) (end) 24.88 % (m/m); weight loss of 52 g was observed from 5 kg bags	Y	FMC-59242 Giorgi, S. (2022)	Accepted
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	CIPAC MT 46.3 CIPAC MT 75.3 OECD 114	Cervacol Extra (Batch No.: 051004/2)	After storage at 35 °C for 12 weeks: Appearance unchanged pH (init): 9.66 pH (end): 9.55 Viscosity (at 20. 3 °C): (init) 10.7 1/s: 10350 m Pa s (end): 21300 m Pa s (init) 21.9 1/s: 6985 m Pa s (end): 15150 m Pa s No signs of damages	Y	EU RAR (2002) Frauen, M. (2005a)	Accepted
Minimum content after heat stability testing (KCP 2.7.3)						

Annex point	Method used/ deviations	Test material	Findings	GLP Y/N	Reference	Acceptability/ comments
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	Cervacol Extra (Batch No.: 051004/2)	No separation, sedimentation or gas formation was observed.	Y	EU RAR (2002) Frauen, M. (2005a)	Accepted
Ambient temperature shelf life (KCP 2.7.5)	CIPAC MT 75.3 OECD 114	Cervacol Extra (Batch No.: 051004/2)	After 2 years at ambient temperature: Appearance: Tins (colour, physical state and odour): unchanged Tubes: colour, odour unchanged, incipient separation, no sedimentation and no formation of gas pH (init): 9.66 pH (end): 9.46 (tin), 9.49 (tube) Mean viscosity (at 20.3 °C): (init) 10.7 1/s: 10350 m Pa s (end): 21300 m Pa s (tins), 20725 m Pa s (tubes) (init) 21.9 1/s: 24750 m Pa s (end): 16850 m Pa s (tins), 14250 m Pa s (tubes) No signs of damages of the containments	Y	EU RAR (2002) Dardemann, J. (2006)	Accepted The content of relevant impurity crystalline silica (SiO₂) with a diameter ≤10 µm in product Cervacol Extra was obtained in the following study: Determination of the Active Ingredient Content of the Cervacol Extra, Including Validation of the Analytical Method, Study Number: 21354-01C, FMC-58762, Giorgi, S. (2022a) , the content of the relevant impurity Crystalline silica <10µm was determined with 0% (LOD: 0.24 % w/w LOQ: 0.50 % w/w) for batch number 4551700672.
		Cervacol Extra (Batch no. 4551700672)	Appearance, colour, odour: unchanged Stability of packaging: Intact plastic bags, no leaks, weight loss -31g Active ingredient determination: 24.93%		Giorgi, S. (2024)	

Annex point	Method used/ deviations	Test material	Findings	GLP Y/N	Reference	Acceptability/ comments
						The relevant impurity does not form upon storage of the product or during manufacture of the formulation. Storage stability data are not required respectively.
Shelf life in months (if less than 2 years) (KCP 2.7.6)			Refer to the two year shelf-life study			
Wettability (KCP 2.8.1)			Not applicable for a PA formulation			
Persistence of foaming (KCP 2.8.2)			Not applicable, because the PA formulation is not diluted with water for use			
Suspensibility (KCP 2.8.3.1)			Not applicable for a PA formulation			
Spontaneity of dispersion (KCP 2.8.3.2)			Not applicable for a PA formulation			
Dispersion stability (KCP 2.8.3.3)			Not applicable for a PA formulation			
Degree of dissolution and dilution stability (KCP 2.8.4)			Not applicable for a PA formulation			
Particle size distribution/ nominal size range of granules (KCP 2.8.5.1.1)			Not applicable for a PA formulation Not applicable for a PA formulation			
Wet sieve test (KCP 2.8.5.1.2)			Not applicable for a PA formulation			

Annex point	Method used/ deviations	Test material	Findings	GLP Y/N	Reference	Acceptability/ comments
Dust content (KCP 2.8.5.2.1)			Not applicable for a PA formulation			
Particle size of dust (KCP 2.8.5.2.2)			Not applicable for a PA formulation			
Attrition (KCP 2.8.5.3)			Not applicable for a PA formulation			
Hardness and integrity (KCP 2.8.5.4)			Not applicable for a PA formulation			
Emulsifiability (KCP 2.8.6.1)			Not applicable for a PA formulation			
Emulsion stability (KCP 2.8.6.2)			Not applicable for a PA formulation			
Re-emulsifiability (KCP 2.8.6.3)			Not applicable for a PA formulation			
Flowability (KCP 2.8.7.1)			Not applicable for a PA formulation			
Pourability (KCP 2.8.7.2)			Not applicable for a PA formulation			
Dustability following accelerated storage (KCP 2.8.7.3)			Not applicable for a PA formulation			
Physical compatibility of tank mixes (KCP 2.9.1)			Not applicable, no tank mixing proposed			
Chemical compatibility of tank mixes (KCP 2.9.2)			Not applicable, no tank mixing proposed			
Adhesion to seeds (KCP 2.10.1)			Not relevant as the formulation is not used as a seed treatment			

Annex point	Method used/ deviations	Test material	Findings	GLP Y/N	Reference	Acceptability/ comments
Distribution to seed (KCP 2.10.2)			Not relevant as the formulation is not used as a seed treatment			
Other/special studies (KCP 2.11)			No other studies performed			

3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

Table 4.1-1: Packaging information for 2.5 kg bucket

Type	Description
Material:	PP
Shape/size:	Bucket: Diam. 174 mm, H 130 mm, Vol. 2500 ml
Opening:	-
Closure:	-
Seal:	-
Manner of construction	Bucket
UN/ADR	Food grade

Table 4.1-2: Packaging information for 5 kg knead bags

Type	Description
Material:	PE (LDPE foil, MFR 0.5-0.8, Density at 23 °C 0.92 g/cm3 approx.); sealed 5kg knead bags stored in 15 kg PP buckets for transport
Shape/size:	PE bag size approximates to 265 mm x 255 mm
Opening:	
Closure:	
Seal:	
Manner of construction	Extruded plastic foil material, head sealed during automated packaging
UN/ADR	compliant

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and 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	Relied upon Y/N
KCP 2.7.1/01	Giorgi, S.	2022a	Determination of the Active Ingredient Content of the Cervacol Extra, Including Validation of the Analytical Method FMC-58762 RenoLab S.R.L. GLP: Yes Published: No	N	FMC	
KCP 2.7.1/02	Giorgi, S.	2022b	Determination of the content of the cervacol extra product after accelerated temperature storage at 54 ± 2°C for 2 weeks FMC-59242 RenoLab S.R.L. GLP: Yes Published: No	N	FMC	
KCP 2.7.5/01	Silvia Giorgi	On going 2024	Determination of the Two Years Storage Stability and Shelf Life Data at Ambient Temperature of the Cervacol Extra product FMC-59244 Study plan RenoLab S.R.L. GLP: Yes Published: No	N	FMC	
KCP 2.7.5/02	-	2024	Determination of the Two Years Storage Stability and Shelf Life Data at Ambient Temperature of the Cervacol Extra product, Amendment No. 1 FMC-59242 AMI RenoLab S.R.L. GLP: Yes Published: No	N	FMC	

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 2.1, KCP 2.4.1 KCP 2.5.1 KCP 2.7.2	Frauen, M.	2005a	Determination of the physical-chemical Properties of Cervacol Extra (ASU 98890P) Report-no.: 98890-FO-012 Stähler International GmbH & Co. KG, Stade, Germany GLP: Yes Not published	N	N	-	Cheminova Deutschland GmbH & Co. KG	
KCP 2.3.1	Kiss, G.	2005a	Determination of the flash point of Cervacol Extra in Accordance with the EEC Guideline A.9 Report-no.: 04/939-352AN LAB International Research Center, Hungary GLP: Yes Not published	N	N	-	Cheminova Deutschland GmbH & Co. KG	
KCP 2.3.2	Frauen, M.	2005b	Determination of the Flammability of Cervacol extra (ASU 98890 P) Report-no.: 98890-PC-006 Stähler International GmbH & Co. KG, Stade, Germany GLP: Yes Not published	N	N	-	Cheminova Deutschland GmbH & Co. KG	
KCP 2.3.3	Kiss, G.	2005b	Determination of the Autoignition Temperature of Cervacol Extra in accordance with the EEC Guideline A.15 Report-no.: 04/939-355AN LAB International Research Center, Hungary GLP: Yes Not published	N	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)
KCP 2.6.1	Dardemann, J.	2009	Revision of the final report AB 98890-PC-002. Determination of the relative density of Cervacol extra AB 98890-PC-002 Stähler International GmbH & Co. KG GLP: Yes Published: No	N	N	-	Cheminova Deutschland GmbH & Co. KG	
KCP 2.7.5	Dardemann, J.	2006	Determination of the two years' storage stability of Cervacol extra (ASU98890P) at ambient temperature AB 98890-PC-032 Stähler International GmbH & Co. KG GLP: Yes Published: No	N	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

No vertebrate studies previously submitted

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

List of data relied on and not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Additional data on the physical, chemical and technical properties of the active substance

A 2.1 Quartz sand

No new or additional studies have been submitted