

Product name: Cervacol Extra PA

Product code: XNJ25 251 g/kg

Active Substance: Quartz sand 251 g/kg

REGISTRATION REPORT – POLAND

Part B, Sec. 1 to 9

Reference List

Application for re-authorisation (Article 43)

Applicant: FMC Corporation

Date: 11/2025

Section 1, 2, 4

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	Data protection claimed Y/N	Used for Evaluation Y/N	Owner
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	Y	Y	FMC
KCP 2.7.1/02	Giorgi, S.	2022b	Determination of the content of the cervacol extra product after accelerated temperature storage at $54 \pm 2^{\circ}\text{C}$ for 2 weeks FMC-59242 RenoLab S.R.L. GLP: Yes Published: No	Y	Y	FMC
KCP 2.7.5/01	Silvia Giorgi	2024	Determination of the Two Years Storage Stability and Shelf Life Data at Ambient Temperature of the Cervacol Extra product FMC-59244 RenoLab S.R.L. GLP: Yes Published: No	Y	Y	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 AM1 RenoLab S.R.L. GLP: Yes Published: No	Y	Y	FMC

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data protection claimed Y/N	Used for Evaluation Y/N	Owner
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	Y	Cheminova Deutschland GmbH & Co. KG

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data protection claimed Y/N	Used for Evaluation Y/N	Owner
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	Y	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	Y	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	Y	Cheminova Deutschland GmbH & Co. KG
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	Y	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	Y	Cheminova Deutschland GmbH & Co. KG

Section 3

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data protection claimed Y/N	Used for Evaluation Y/N	Owner
KCP 6.3/01	Landwirtschaftskammer Westfalen-Lippe	2000	Zulassungsprüfung nach GEP im Forst Wildschadenverhütungsmittel (Winterwildverbißschutzmitte) <u>Reported trial</u> : PFWA2000-001 GEP: Yes Published: No	N	Y	Cheminova
KCP 6.3/02	Landwirtschaftskammer Rheinland	2000	Wildschadenverhütungsmittel: Wildverbißschutzmittel ASU 99 810 P Reported trials: Abt. 302, Abt. 129, Abt. 247C, Abt. 762 GEP: Yes Published: No	N	Y	Cheminova
KCP 6.3/03	Niesar, N.	2000	Wildschadenverhütungsmittel ASU 99810 P gegen Wildverbiß an Laubholz Reported trial: 990430 GEP: Yes Published: No	N	Y	Cheminova
KCP 6.3/04	Tomek, A.	2011	Assessment of Cervacol Extra PA efficacy in the protection of coniferous and deciduous trees against gnawing and protecting coniferous trees against tapping by deer in Southern Poland. Reported trials: Krynica/Fir, Krynica/Beech, Wisla/Fir, Wisla/Beech GEP: Yes Published: No	N	Y	Cheminova
KCP 6.3/05	Lapanowski, G.	2011	Efficacy of CERVACOL Extra PA in the prevention of gnawing of coniferous and deciduous trees and tapping of coniferous trees by game – deer (Cervus elaphus) and roe (Capreolus capreolus) Reported trials: HRI Trial 1 to 8 GEP: Yes Published: No	N	Y	Cheminova
KCP 6.3/06	Cinitis, R. Ozolina, L.	2007	Efficacy evaluation of the repellent Cervacol Extra as deer, elk and roe browse deterrent on pine nursery Reported trial: R-07-1-81-IAp-487 GEP: Yes Published: No	N	Y	Cheminova

KCP 6.3/0 7	Apenite, I. Ozolina-Pole, L.	2009	Efficacy evaluation of the repellent Cervacol Extra as deer, elk and roe browse deterrent on pine nursery Reported trial: R-07-3-81-IA-788 GEP: Yes Published: No	N	Y	Cheminov a
KCP 6.3/0 8	Apenite, I. Ozolina-Pole, L.	2008	Efficacy evaluation of the repellent Cervacol Extra as deer, elk and roe browse deterrent on pine nursery Reported trial: R-07-2-81-IA616 GEP: Yes Published: No	N	Y	Cheminov a

Section 5

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	Data protection claimed Y/N	Used for Evaluation Y/N	Owner
KCP 5.1.1/01	Giorgi, S.	2022	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	Y	Y	FMC
KCP 5.2./01	Giorgi, S.	2022	Determination of silica and impurities, including validation of the analytical method, in five batches of quartz sand technical FMC-58761 RenoLab S.R.L. GLP: Yes Published: No	Y	Y	FMC

Section 6

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data protection claimed Y/N	Used for Evaluation Y/N	Owner
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 xxxxxxxxxxxxxxxxxxxxx GLP: No Published: No	N	Y	Cheminova Deutschland GmbH & Co. KG
IIIA 7.1.1/01	xxxxxxx	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 xxxxxxxxxxxxx GLP: No Published: No	N	Y	Cheminova Deutschland GmbH & Co. KG
IIIA 7.1.3/01	xxxxxxx	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	N	Y	Cheminova Deutschland GmbH & Co. KG
IIIA 7.1.4/01	xxxxxx	1977	CERVACOL.Prüfung auf Reizwirkung an der Kaninchenhaut (Test for irritant effects on rabbit skin) A 0479/1527.02 xxxxxxxxxxxxxxxxxxxxx GLP: No Published: No	N	Y	Cheminova Deutschland GmbH & Co. KG

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IIIA 7.1.1/01	xxxxxxx	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 xxxxxxxxxxxxxxxxxxxxxx GLP: No Published: No	N	Y	Cheminova Deutschland GmbH & Co. KG
IIIA 7.1.3/01	xxxxxxx	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 xxxxxxxxxxxxxxxxxxxxxx GLP: No Published: No	N	Y	Cheminova Deutschland GmbH & Co. KG

Section 7

List of data submitted by the applicant and relied on

No studies submitted.

Section 8

List of data submitted by the applicant and relied on

No studies submitted.

Section 9

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

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