

FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Detailed summary

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	Final RR

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3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

Transformation of the dRR (applicant version) into the RR (zRMS version)

The process chosen by the zRMS to transform the dRR into a RR should be explained. Options are to rewrite the document (with track change or not) or to use commenting boxes such as the following:

Comments of zRMS:	The commenting boxes are filled-in by the zRMS. They are usually placed at the end of each chapter. Commenting boxes should be understandable alone and refer very precisely to the text commented. The main advantage of their use is to distinguish easily between the applicant and the zRMS text.
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3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

The overall assessment was performed according to the uniform principles. ZRMS has proposed uses/conditions should be revised by each involved CMS in accordance with its specific conditions of authorization.

ZRMS considers that the data provided for PL support the following uses: 1, 3.

Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination/ purpose of crop)	F, Fn, G, Gn, Gnp 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/ synergist per ha, other dose rate expression, dose range (min-max)	zRMS Conclusion (efficacy)
					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 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; 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
2	LV, LT, EE	Deciduous (C) and coniferous 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	

Column 15: zRMS conclusion.

A	Acceptable
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R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable/evaluation not possible
n.r.	Not relevant for section 3

3.2 Efficacy data (KCP 6)

Introduction

Description of active substances

Silica (silicon dioxide) occurs in crystalline and amorphous forms. Of the several crystalline polymorphs of silica found in nature, quartz is by far the most common, being abundant in most rock types, notably granites, sandstones, quartzites and in sands and soils. Amorphous silica is found in nature as biogenic silica and as silica glass of volcanic origin. One form of biogenic silica, diatomaceous earth, originates from the skeletons of diatoms deposited on sea floors and contains small amounts of cristobalite and quartz. Fibres of amorphous silica are produced by a variety of plants, such as sugar cane and rice (IARC, 1997a, Doc. No. A0024).

Apart from oxygen (O₂), silicon (Si) is the most abundant element in the earth's crust. Together these two elements form the mineral silica (SiO₂) which is present in most rocks and sands in the earth's crust and accounts for more than 28 % of its total content. Table 3.2-1 shows the approximate content of free silica in some common rocks.

Table 3.2-1: Content (in %) of crystalline silica in some common rocks*

	Content of crystalline silica
Plutonic rocks	
Granite	>20 %
Granodiorite	>20 %
Tonalite (Trondhemite)	>20 %
Quartz (syenite, monzonite, diorite, gabbro)	5 - 20 %
Syenite, Monzonite, Diorite, Gabbro	0 - 5 %
Peridotite, Serpentinite	negligible
Volcanic rocks	
Rhyolite, Dacite	>20 %
Quartz (trachyte, latite)	5 - 20 %
Andesite, Basalt	0 - 20 %
Trachyte, Latite	0 - 5 %
Sedimentary rocks	
Quartzite	>90 %
Sandstones, wide range mostly	>60 %
Mudstone	10 - 30 %
Limestone	negligible
Dolomite	negligible

* In the plutonic and volcanic rocks, the quartz content is calculated as the percentage of the light-coloured minerals (in practice quartz, feldspar and feldspatoids) present in the rock. In the sedimentary rocks, the quartz content is calculated as a percentage of all the minerals present in the rock.

By far the most common form of crystalline silica is α -quartz which is stable at temperatures from 570 to 870 °C. Above 870 °C it transforms to tridymite, which again transforms to cristobalite at approximately 1470 °C. Both α -quartz, tridymite and cristobalite occur in semistable forms below the temperatures at which they transform. When cristobalite is heated beyond 1710 °C it transforms into a viscous glass which, upon cooling, forms a clear glass with an amorphous structure which is stable at all temperatures. The different forms of crystalline silica are named with the prefixes α and β depending on structural and optical properties.

The basic structure of crystalline silica is a SiO₂ tetrahedron where the molecules are linked together by sharing each of their corners with another tetrahedron, thus forming three-dimensional and regular frameworks where every silicon has four oxygens and every oxygen has two silicons as its nearest neighbors.

Sand, clay and rocks containing silica have been used as building materials in most cultures at all times. The quantitatively most important use of silica today is of silica sand for hydraulic fracturing in oil and gas production, sand and gravel in concrete in the building and construction industry, sand in the production of glass, ceramics, porcelain and abrasives and as foundry castings.

In 1984 the world production of silica sand was about 182 million tons with the USA as the greatest producer with 31.8 million tons alone while Canada produced about 2.4 million tons. The leading exporter of silica sand in Europe is Belgium with 2.15 million tons in 1982 (Hilt, B., 1993a, Doc. No. A0022).

As described above silicon dioxide and other silicates occur ubiquitously in the environment. Quartz sand is chemically and biologically inert and practicably insoluble in water. SiO₂ is described to be the major component of nearly all soils and a content of 55.2 % of SiO₂ in the earth's crust can also be found in the literature. Quartz is stable in soil and there will be no transport between environmental compartments, no degradation or biodegradation (IUCLID, 2000a, Doc. No. A0013).

Therefore, it can be concluded that it is not necessary to investigate the fate and behavior of Quartz sand in soil, water or air. Moreover, the definition of a residue for these environmental compartments is not considered relevant.

Mode of Action

Cervacol Extra is based on a grainy substance and is formulated as aqueous paste. The product contains quartz sand as active ingredient.

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

- optical effects (blue color)
- taste
- sense of touch (grainy layer).

The light blue color of treated plant parts differs from the normal pattern of feed selection by roe and deer. The grainy substance of the product leads on one hand to a repellent effect by taste and on the other hand it causes an abnormal feeling to their teeth as well as by touching the grainy layer.

Due to the combination of different repellent effects an adaptation to these deterrent effects of the game is very unlikely.

Table 3.2-2: Spatial distribution of all trials submitted to support the efficacy data in the EPPO climatic zones.

Crop	Use	EPPO zone	Year	Country	Number	Total number
Forestry	Game repellent	Maritime	1999	DE	4	6
			2000	DE	2	
		North-East	2007	LV	1	15
			2008	LV	1	
			2009	LV	1	
			2010	PL	8	
			2011	PL	4	

Intended Use

The product should be applied with a dose rate between 2 and 5 kg per 1000 trees either on the young sprouts/shoots or on the terminal buds/terminal shoots of young coniferous or deciduous trees in forestry plantations.

Applications must be done as brushing method – mainly by using a glove. Furthermore, it is possible to use the product with a brush or a double brush.

Table 3.2-3: Details of the active substances

Active substance	Active substance 1	Active substance 2	Active substance 3
Concentration (Unit: g/kg or g/L..)	251 g/kg Quartz sand	Not applicable	Not applicable
Chemical group	Not applicable		
Mode of action	Not applicable		
Biological action	Not applicable		

Description of the plant protection product

Cervacol extra is a paste (PA) containing XNJ25 251 g/kg Quartz sand, which is a game repellent for the prevention of gnawing caused by roe and deer.

Table 3.2-4: Simplified table of currently registered uses and requested uses for the product code

Uses		Member State	Currently registered rate(s)	Requested rate(s)	Comments/Other relevant details on GAPs
Crop(s)	Target(s)				
Deciduous and coniferous trees in forestry	Deer and red deer (against browsing)	AT, PL, CZ, HU, RO, SK	2-5 kg/1000 trees; in CZ 2 kg/1000 plants; in SK 2-4 kg/1000 plants	2-5 kg/1000 trees; in CZ 2 kg/1000 plants; in SK 2-4 kg/1000 plants	
Deciduous and coniferous trees in forestry	Deer and red deer (against freying)	PL	10-14 kg/1000 plants (5-10 years Coniferous trees); 2-5 kg/1000 plants	10-14 kg/1000 plants (5-10 years Coniferous trees); 2-5 kg/1000 plants	

Uses		Member State	Currently registered rate(s)	Requested rate(s)	Comments/Other relevant details on GAPs
Crop(s)	Target(s)				
			(Deciduous and coniferous trees)	(Deciduous and coniferous trees)	
Deciduous and coniferous trees in forestry	Deer and red deer (against browsing)	LV, EE, DE	3-4 kg/1000 plants	3-4 kg/1000 plants	
Deciduous and coniferous trees in forestry	Deer and red deer (against browsing)	LT	2-3 kg/1000 plants	2-3 kg/1000 plants	Non-professional use 3-4 kg/1000 plants

Compliance with the Uniform Principles

Since no specific EPPO guide lines for field testing of game repellents exist, the trials were conducted according to national guidelines. In Germany, trials were conducted according to the guide line „Richtlinie für amtliche Prüfung von Pflanzenbehandlungsmittel No. 18-4“: „Richtlinie für die Prüfung von Mitteln zur Verhütung von Wildschäden im Forst gegen Wildverbiss, Schälschäden, Fegeschäden und Nageschäden“. In Poland, trials were conducted according to the guideline “SPB – 26: Assessment of the efficacy of repellent action in the protection of forest stands against game (deer)” which was prepared based on EPPO guidelines PP 1/152(2) and PP 1/181(2). In Latvia, trials were conducted according to EPPO guidelines PP 1/135(3), 152(3), 181(3), 199 and 200(1).

Presentation of trials (efficacy trials, preliminary trials..)

A total of 21 trials were carried out to determine efficacy of Cervacol Extra as a game repellent in forestry. An overview of these trials is presented in the table below.

Information on trials submitted (3.1 Efficacy data)

Table 3.2-5: Presentation of trials (efficacy trials, preliminary trials..)

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)		GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime zone	North-east zone		
Forestry	Game repellent	DE	1999	E	4		GEP	
			2000	E	2		GEP	
		LV	2007	E		1	GEP	
			2008	E		1	GEP	
			2009	E		1	GEP	
		PL	2010	E		8	GEP	
			2011	E		4	GEP	
	TOTAL	-	-	-	6	15		

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-6: Presentation of reference standards used in trials (efficacy trials, preliminary trials..)

Crop(s)	Reference standard	Country(ies) where the product is registered (1)	Authorization number	Active substance(s)	Formulation		Registered application rate(3)	Application rate in trials (per treatment)	Remark(4)
					Type(2)	Concentration of a.s.			
	Emol ¹	PL	-	Thiuram 10%	Smearing or spraying	-		5 kg/1000 trees	
	Repentol6PA	PL	R-176/2017	Quartz sand	smearing	300g	10-15 kg/1000 trees	10-14 kg/1000 trees	
	Emol Plus BTX LA ¹	PL	-	Benzoate Denatonium [N-Benzyl-2- (2,6-dimethylphenylamino) -N, N-diethyl-2-on Peroxyaminbenzoat]	Smearing or spraying	0,155 g/l	2 l/1000 trees	2 kg, 5 kg/1000 trees	
	ASU 99810 P ²	DE	ASU 99810 P	Quartz sand	smearing	Not known	3-4 kg/1000 trees	3-3.1 kg/1000 trees	
	Plantskydd	LVA	AS2-61R	Animal protein dried blood 87%, vegetable fat 3%, common salt 5%, water 5%	spraying	990 g/kg	0.8-1.6 kg/1000 trees	0.8 kg/1000 trees	

(1) only on use(s) applied for (with the test product).

(2) e.g. WP (wetttable powder), EC (emulsifiable concentrate), etc.

(3) dose(s)/dose range authorized on that use in the country.

(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application, etc.).

3.2.1 Preliminary tests (KCP 6.1)

Cervacol Extra has been a well-known and highly effective game repellent for more than 20 years. Based on the long experience no preliminary range finding tests were conducted.

3.2.2 Minimum effective dose tests (KCP 6.2)

Cervacol Extra is recommended for an undiluted application. To repel the game over months, it is important that a thick, resistant layer is formed, e.g. on the terminal bud or on the terminal shoot. The appropriate dose rate to be used will depend on:

- the species of trees
- the height of trees
- the type of application (protecting only the terminal bud or more parts of the trees)
- the application equipment/method

From practical experience, it is known that Cervacol Extra is effective at dose rates between 2 – 5 kg per 1000 trees, depending on the size of the trees, local climate conditions and expected level of damage by

¹ The registration of these products has expired. Information regarding authorization number and concentration of active ingredient is therefore not available.

² ASU 99810 P is a test medium that has never been registered, but was used as a reference at that time. No concentration of the active ingredient was given.

deer, roe and elk during winter and early spring. The educated judgment of forestry personnel is needed to determine the suitable dose rate under the given conditions at the site of application, including economic considerations.

3.2.3 Efficacy tests (KCP 6.2)

Between the years 1999 and 2011, a total of 21 GEP trials were set up to confirm the good efficacy of Cervacol Extra in Germany (6), Poland (12) and Latvia (3).

3.2.4 Material and methods

Table 3.2-7: Summary of efficacy results for Cervacol Extra at different dose rates

Dose Rate	No. of results	Average damage in Untreated	Average Efficacy			
			Cervacol Extra [%]		Reference product [%]	
			MEAN	Min-Max	MEAN	Min-Max
Maritime EPPO zone - Germany						
3 kg	6	25.1 %	79.9	29.0 - 100.0	62.0	3.8 - 96.6
North-East EPPO zone - Poland						
2 kg	12	19.7 %	43.1	10.1 - 73.6	43.0	15.7 - 67.9
5 kg	12	19.7 %	72.5	40.9 - 100.0	43.0	15.7 - 67.9
North-East EPPO zone - Latvia						
2 kg	3	36.7 %	20.9	0.0 - 50.5	25.3	5.5 - 49.5
3 kg	1	50.0 %	31.9	-	20.7	-
Overall Means						
2 kg	15	23.1 %	38.7	0.0 - 73.6	39.5	5.6 - 67.9
3 kg	7	28.6 %	73.0	29.0 - 100.0	56.1	3.8 - 96.6
5 kg	12	19.7 %	72.5	40.9 - 100.0	43.0	15.7 - 67.9

Table 3.2-8: Details on trial methodology

Guidelines	General guidelines	(PL): EPPO PP 1/152(2) and PP 1/181(2) (LV): EPPO PP 1/135(3), 152(3), 181(3)
	Specific guidelines	(DE): No. 18-4 (LV): 199 and 200(1)
Experimental design	Plot design	(PL): randomised complete blocks – 5-7 blocks (4 plots each), at least 50 trees per plot or 5 blocks (4 plots each), at least 50 trees per plot
	Plot size	(PL): plot surface 56 m ² (8 x 7 m) to plot surface 121 m ² (11 x 11 m)
	Number of replications	(PL): 5 replicates in the 4 combinations' layout or 4 replicates in the 5 combinations' layout
Crop	Trials per crop	(PL): scots pine (Pinus sylvestris) 4 common fir (Abies alba) 2 european beech (Fagus sylvatica) 2 sessile oak (Quercus petraea) 2

	Varieties per crop	Not applicable
	Sowing period	Not applicable
Application	Crop stage (BBCH)* at application	Not applicable – lead apical shoots of trees (firs, pines, oaks and beeches) were protected with the repellent, which in practice meant protecting the growth of the last growing season
	Timing Pest stage at application (1)	Not applicable
	Number of applications Intervals between applications	(PL): 1 (3 trials)
	Application volumes	(PL): 2 – 5 kg/1000 trees
Assessment	Assessment types	% of damage caused by game at coniferous wood and deciduous wood
	Assessment dates	
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant
	e.g. Natural/artificial inoculation...	Not relevant
	e.g. Field/ Greenhouse..	Forestry

* BBCH for weeds, pre-emergence, preventive/curative application, insect stage...

Summary according to point 3.2 - 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 against gnawing by roe and deer in forest trees.

In 6 trials conducted in Germany (Maritime EPPO climatic zone), 3 kg Cervacol Extra 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 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 per 1000 trees achieved clearly superior efficacy (72.5 %).

In 3 additional supporting trials conducted in Latvia, 2 kg Cervacol Extra 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 achieved solid efficacy (31.9 %) under extreme deer pressure (>50 % gnawing damage in the untreated) that was superior to the reference product (20.7 %).

The trials were carried out by the following research institutes for forestry and hunting:

- LWK Rheinland (Nordrhein-Westfalen, Germany)
- Hessische Landesanstalt für Forsteinrichtung, Waldforschung und Waldökologie (Hessen, Germany)
- Landwirtschaftskammer Westfalen-Lippe (Nordrhein-Westfalen, Germany)
- Horticultural Research Institute (96-100 Skierniewice, Poland)

- DR TOMEK Zakład Badań Naukowych i Ekspertyz Przyrodniczych (31-517 Kraków, Poland)
- Latvian Plant Protection Research Centre, State Ltd. (Riga LV 1006, Latvia)

Cervacol Extra and the reference products were applied from autumn to very early winter (between 18.09 and 01.12.) depending on the conditions at each trial location. The final assessments were done between 5 and 7 months after application.

Details on trial design are summarized in below.

Table 3.2-9: Details of trial design for all efficacy trials

Trial Conductor	Trial ID	Species of tree(s)	Dose rates of Cervacol Extra	Species of game	No. of trees per plot or no. of replications	Reference Product	Date of application	Date of assessment
Maritime EPPO zone - GERMANY (6 trials)								
LWK Rheinland	990430	<i>Fagus sp.</i>	3,1 kg (per 1000 trees)	roe deer	200 trees per plot 4 replications	XNJ25 251 g/kg (3-4 kg/1000 trees)	16.11.1999	14.06.2000 7 months after application
Hessische Landesanstalt für Forsteinrichtung, Waldforschung und Waldökologie*	Abt. 302	<i>Quercus sp.</i> and <i>Fagus sp.</i>	3 kg (per 1000 trees)	roe deer	229 trees were treated 290 trees as untreated control	XNJ25 251 g/kg (3 kg/1000 trees)	29.11.1999	5 months after application
	Abt. 129	<i>Quercus sp.</i> and <i>Tilia cordata</i>	3 kg (per 1000 trees)	roe deer	133 trees were treated 132 trees as untreated control	XNJ25 251 g/kg (3 kg/1000 trees)	25.11.1999	5 months after application
	Abt. 247C	<i>Quercus sp.</i> and <i>Tilia cordata</i>	3 kg (per 1000 trees)	roe deer	100 trees were treated 179 trees as untreated control	XNJ25 251 g/kg (3 kg/1000 trees)	24.11.1999	5 months after application
	Abt.762	<i>Quercus sp.</i> and <i>Tilia cordata</i>	3 kg (per 1000 trees)	roe deer	193 trees were treated 203 trees as untreated control	XNJ25 251 g/kg (3 kg/1000 trees)	01.12.1999	5 months after application
Landwirtschaftskammer Westfalen-Lippe	PFWA2000-001	<i>Fagus sp.</i>	3.1 kg (per 1000 trees)	roe deer red deer	400 trees were treated	XNJ25 251 g/kg (3.6 kg/1000 trees)	20.10.1999	22.05.2000 7 months after application

Trial Conductor	Trial ID	Species of tree(s)	Dose rates of Cervacol Extra	Species of game	No. of trees per plot or no. of replications	Reference Product	Date of application	Date of assessment
North-East EPPO zone - POLAND (12 trials)								
DR TOMEK Zakład Badań Naukowych i Ekspertyz Przyrodniczych	Krynica/Fir	<i>Abies sp.</i>	2 kg, 5 kg (per 1000 trees)	roe deer	5x 50 trees	Emol (5 kg/1000 trees)	06.10.2010	13.04.2011 6 month after application
	Krynica/Beech	<i>Fagus sp.</i>	2 kg, 5 kg (per 1000 trees)	roe deer	5x 50 trees	Emol (5 kg/1000 trees)	06.10.2010	13.04.2011 6 month after application
	Wisla/Beech	<i>Fagus sp.</i>	2 kg, 5 kg (per 1000 trees)	roe deer	5x 50 trees	Emol (5 kg/1000 trees)	18.10.2010	07.04.2011 6 month after application
	Wisla/Fir	<i>Abies sp.</i>	2 kg, 5 kg (per 1000 trees)	roe deer	5x 50 trees	Emol (5 kg/1000 trees)	18.10.2010	07.04.2011 6 month after application
Horticultural Research Institute at Skierniewice	HRI Trial 1	<i>Abies sp.</i>	2 kg, 5 kg (per 1000 trees)	deer and roe	4x 50 trees	Emol Plus BTX LA (2 L/1000 trees)	18.09.2010	7 month after application
	HRI Trial 2	<i>Abies sp.</i>	2 kg, 5 kg (per 1000 trees)	deer and roe	4x 50 trees	Emol Plus BTX LA (2 L/1000 trees)	18.10.2010	7 month after application
	HRI Trial 3	<i>Fagus sp.</i>	2 kg, 5 kg (per 1000 trees)	deer and roe	4x 50 trees	Emol Plus BTX LA (2 L/1000 trees)	18.09.2010	7 month after application
	HRI Trial 4	<i>Fagus sp.</i>	2 kg, 5 kg (per 1000 trees)	deer and roe	4x 50 trees	Emol Plus BTX LA (2 L/1000 trees)	18.10.2010	7 month after application

Trial Conductor	Trial ID	Species of tree(s)	Dose rates of Cervacol Extra	Species of game	No. of trees per plot or no. of replications	Reference Product	Date of application	Date of assessment
	HRI Trial 5	<i>Quercus sp.</i>	2 kg, 5 kg (per 1000 trees)	deer and roe	4x 50 trees	Emol Plus BTX LA (2 L/1000 trees)	30.10.2010	6 month after application
	HRI Trial 6	<i>Quercus sp.</i>	2 kg, 5 kg (per 1000 trees)	deer and roe	4x 50 trees	Emol Plus BTX LA (2 L/1000 trees)	28.10.2010	6 month after application
	HRI Trial 7	<i>Pinus sp.</i>	2 kg, 5 kg (per 1000 trees)	deer and roe	4x 50 trees	Emol Plus BTX LA (2 L/1000 trees)	30.10.2010	6 month after application
	HRI Trial 8	<i>Pinus sp.</i>	2 kg, 5 kg (per 1000 trees)	deer and roe	4x 50 trees	Emol Plus BTX LA (2 L/1000 trees)	28.10.2010	6 month after application
North-East EPPO zone - LATVIA (3 trials)								
Latvian Plant Protection Research Centre, State Ltd	R-07-1-81-IAp-487	<i>Pinus sp.</i>	2 kg (per 1000 trees)	deer, elk and roe	140 trees	Plantskydd (0.8 L/tree)	09.10.2006	17.04.2007 6 month after application
	R-07-2-81-IA-616	<i>Pinus sp.</i>	2 kg (per 1000 trees)	deer, elk and roe	140 trees	Plantskydd (0.8 L/tree)	22.11.2007	12.03.2008 4 month after application
	R-08-3-81-IA-788	<i>Pinus sp.</i>	2 kg, 3 kg (per 1000 trees)	deer, elk and roe	140 trees	Plantskydd (0.8 L/tree)	29.09.2008	14.04.2009 7 month after application

Summary of results

A total of 21 results are presented comparing the efficacy of Cervacol Extra to a registered reference standard. Cervacol Extra was tested at the three different dose rates of 5 kg (12 trials), 3 kg (7 trials) and 2 kg (15 trials) to cover the proposed dose rate range of 2 - 5 kg/1000 trees.

The browsing damage (gnawing) caused by roe and deer ranged from low (1.2 %) to high damage (59.2 %) in the untreated control plots.

6 of these trials were in the maritime EPPO climatic zone (Germany). An average of 25.1 % gnawing damage occurred in the untreated controls of these trials. Application of 3 kg/1000 trees of the test product Cervacol Extra reduced this damage by an average of 79.9 % across 6 trials, while the registered reference products provided an average gnawing reduction of 62.0 %.

Additional ratings of the persistence of the protective layer formed by the test product were done 5 - 7 months after application. Only at one out of six sites, the persistence was found to be insufficient after 7 months.

A total of 15 trials were located in the north-east EPPO climatic zone. 12 of these trials were in Poland where the climatic conditions and forestry practices can be assumed to be very similar to its neighboring country Germany. The data is therefore presented in support of the proposed registration.

In the 12 trials conducted in Poland, Cervacol Extra was applied at the minimum (2 kg/1000 trees) and maximum (5 kg/1000 trees) proposed dose rate. Applications of 2 kg resulted in an average efficacy of 43.1 % for Cervacol Extra and lay within a broad range between 10.1 and 73.6 %. This shows that the appropriate application rate highly depends on the situation and supports the proposal to allow a range of dose rates for forestry experts to choose from according to the individual circumstances.

Applications of 5 kg in the same trials resulted in an average efficacy of 72.5 % (within a range of 40.9 – 100.0 %). The reference products achieved an average efficacy of 43.0 % (within a range of 15.7 – 67.9 %) when applied at the registered dose rate, which is comparable to that of 2 kg Cervacol Extra.

3 additional trials conducted in Latvia (north-east EPPO climatic zone) are also presented here as supporting data. The harsh winter conditions in Latvia may present a worst-case scenario. Due to long lasting snow cover, food alternatives for roe and deer are scarcer than during the usually milder winters in Germany. This often results in higher gnawing damage to young trees (36.7 % on average across 3 trials). Cervacol Extra, applied at the minimum proposed dose rate of 2 kg/1000 trees, provided a 20.9 % decrease of gnawing damage under these conditions, which can be considered similar to the 25.3 % efficacy achieved by the registered standard product. In one of these trials, an additional treatment with 3 kg

Cervacol Extra was tested and provided 31.9 % efficacy under extreme pressure of >50 % gnawing damage in the untreated control. The reference product only achieved 20.7 % efficacy in this trial.

A summary of all efficacy results presented in this dossier is provided in Table 3.2-10. The results from all single trials are summarized in Table 3.2-11 to Table 3.2-12 for each of the tested dose rates of 2, 3 and 5 kg/1000 trees.

Table 3.2-10: Summary of efficacy results for Cervacol Extra at different dose rates

Dose Rate	No. of results	Average damage in Untreated	Average Efficacy			
			Cervacol Extra [%]		Reference product [%]	
			MEAN	Min-Max	MEAN	Min-Max
Maritime EPPO zone - Germany						
3 kg	6	25.1 %	79.9	29.0 - 100.0	62.0	3.8 - 96.6
North-East EPPO zone - Poland						
2 kg	12	19.7 %	43.1	10.1 - 73.6	43.0	15.7 - 67.9
5 kg	12	19.7 %	72.5	40.9 - 100.0	43.0	15.7 - 67.9
North-East EPPO zone - Latvia						
2 kg	3	36.7 %	20.9	0.0 - 50.5	25.3	5.5 - 49.5
3 kg	1	50.0 %	31.9	-	20.7	-
Overall Means						
2 kg	15	23.1 %	38.7	0.0 - 73.6	39.5	5.6 - 67.9
3 kg	7	28.6 %	73.0	29.0 - 100.0	56.1	3.8 - 96.6
5 kg	12	19.7 %	72.5	40.9 - 100.0	43.0	15.7 - 67.9

Table 3.2-11: Efficacy of treatment with 2 kg Cervacol Extra per 1000 plants

Trial Conductor	Trial ID		Species of tree(s)	Untreated (%gnawing)	Cervacol Extra	Reference
					2 kg	
Latvian Plant Protection Research Centre, State Ltd	R-07-1-81-IAp-487		<i>Pinus sp.</i>	>50	50.5	49.5
	R-07-2-81-IA-616		<i>Pinus sp.</i>	<10	0.0	5.6
	R-08-3-81-IA-788		<i>Pinus sp.</i>	~ 50	12.3	20.7
SUMMARY	Latvia		<i>n = 3</i>	36.7	20.9	25.3
DR TOMEK Zakład Badań Naukowych i Ekspertyz Przyrodniczych	Krynica/Fir		<i>Abies sp.</i>	6.6	53.7	52.2
	Krynica/Beech		<i>Fagus sp.</i>	10.3	66.1	46.7
	Wisla/Beech		<i>Fagus sp.</i>	21.5	15.7	32.5
	Wisla/Fir		<i>Abies sp.</i>	2.3	10.1	17.0
Horticultural Research Institute at Skierniewice	HRI Trial 1		<i>Abies sp.</i>	3.4	41.2	58.8
	HRI Trial 2		<i>Abies sp.</i>	20.4	12.7	15.7
	HRI Trial 3		<i>Fagus sp.</i>	9.8	71.4	42.9
	HRI Trial 4		<i>Fagus sp.</i>	1.2	16.7	33.3
	HRI Trial 5		<i>Quercus sp.</i>	25.6	67.2	51.6
	HRI Trial 6		<i>Quercus sp.</i>	54.8	35.8	33.6
	HRI Trial 7		<i>Pinus sp.</i>	21.2	73.6	67.9
	HRI Trial 8		<i>Pinus sp.</i>	59.2	53.4	64.2
SUMMARY	Poland		<i>n = 12</i>	19.7	43.1	43.0
OVERALL SUMMARY		Average		23,1 %	38.7	39.5
		No. of results		15	15	15

Table 3.2-12: Efficacy of treatment with 3 kg Cervacol Extra per 1000 plants

Trial Conductor	Trial ID	Species of tree(s)	Untreated (%gnawing)	Cervacol Extra	Reference
				3 kg	1 N
LWK Rheinland	990430	<i>Fagus sp.</i>	38.8	29.0	48.0
Hessische Landesanstalt für Forstein-richtung, Waldforschung und Waldökologie*	Abt. 302	<i>Quercus sp.</i> <i>Fagus sp.</i>	17.6	85.1	3.8
	Abt. 129	<i>Quercus sp.</i> <i>Tilia cordata</i>	45.5	89.7	62.6
	Abt. 247C	<i>Quercus sp.</i> <i>Tilia cordata</i>	15.6	93.6	80.8
	Abt.762	<i>Quercus sp.</i> <i>Tilia cordata</i>	11.8	100	96.6
Landwirtschafts-kammer West-falen-Lippe	PFWA2000-001	<i>Fagus sp.</i>	21.1	82.0	80.1
SUMMARY	Germany	<i>n = 6</i>	25.1	79.9	62.0
Latvian Plant Protection Research Centre, State Ltd	R-08-3-81-IA-788	<i>Pinus sp.</i>	~ 50	31.9	20.7
SUMMARY	Latvia	<i>n = 1</i>	50.0	31.9	20.7
OVERALL SUMMARY	Average		28.6	73.0	56.1
	No. of results		7	7	7

Table 3.2-13: Efficacy of treatment with 5 kg Cervacol Extra per 1000 plants

Trial Conductor	Trial ID	Species of tree(s)	Untreated (%gnawing)	Cervacol Extra	Reference 1 N
				5 kg	
DR TOMEK Zakład Badań Naukowych i Ekspertyz Przyrodniczych	Krynica/Fir	<i>Abies sp.</i>	6.6	82.4	52.2
	Krynica/Beech	<i>Fagus sp.</i>	10.3	69.4	46.7
	Wisla/Beech	<i>Fagus sp.</i>	21.5	100	32.5
	Wisla/Fir	<i>Abies sp.</i>	2.3	44.5	17.0
Horticultural Research Institute at Skierniewice	HRI Trial 1	<i>Abies sp.</i>	3.4	82.4	58.8
	HRI Trial 2	<i>Abies sp.</i>	20.4	49.0	15.7
	HRI Trial 3	<i>Fagus sp.</i>	9.8	71.4	42.9
	HRI Trial 4	<i>Fagus sp.</i>	1.2	100	33.3
	HRI Trial 5	<i>Quercus sp.</i>	25.6	81.3	51.6
	HRI Trial 6	<i>Quercus sp.</i>	54.8	40.9	33.6
	HRI Trial 7	<i>Pinus sp.</i>	21.2	77.4	67.9
	HRI Trial 8	<i>Pinus sp.</i>	59.2	71.6	64.2
SUMMARY	Poland	<i>n</i> = 12	19.7	72.5	43.0
OVERALL SUMMARY	Average		19.7	72.5	43.0
	No. of results		12	12	12

Persistence of the Cervacol Extra layer on the treated trees

In the 6 trials conducted in Germany, an additional assessment of the persistence of Cervacol Extra was done at the last assessment timing in spring. An overview of the results is presented in the table below.

Table 3.2-14: Persistence of the Cervacol Extra layer on the treated trees

Trial conductor	Species of trees	Date of assessment	Long-term effects and persistence of the layer
Landwirtschaftskammer Rheinland	Fagus	7 months after application	sufficient
Hessisches Landesamt für Forsteinrichtung, Waldforschung und Waldökologie	Quercus and Fagus plot 302	5 months after application	sufficient
	Quercus and Tilia cordata plot 129	5 months after application	sufficient
	Quercus and Tilia cordata plot 247	5 months after application	sufficient
	Quercus and Tilia cordata plot 762	5 months after application	sufficient
Landwirtschaftskammer Westfalen-Lippe	Fagus	7 months after application	not sufficient

In five out of six applications, the persistence of the layer was sufficient at the final assessment. Consequently, Cervacol Extra has excellent weather-resistant properties like rain fastness, which makes sure that the protective layer stays on the plants for months (especially in February and March the pressure by gnawing game is quite high due to the shortage of other fodder plants) during winter time.

Summary according to point 3.2 - 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 against gnawing by roe and deer in forest trees.

In 6 trials conducted in Germany (Maritime EPPO climatic zone), 3 kg Cervacol Extra 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 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 per 1000 trees achieved clearly superior efficacy (72.5 %).

In 3 additional supporting trials conducted in Latvia, 2 kg Cervacol Extra 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 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 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

Cervacol Extra 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 is based on a grainy substance and is formulated as aqueous paste.

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

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

The light blue color of treated plants represents for roe and red deer an atypical color 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 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 with other products to avoid any habituation of the animals to the product.

comments of zRRS: dRR point 3.3	Cervacol Extra contains as the active ingredient quartz sand. Resistance to the active substance is unlikely to occur. However, the ZRRS agrees with the Applicant to alternate the application of Cervacol Extra with other products to avoid any habituation of the animals to the product.
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3.4 Adverse effects on treated crops (KCP 6.4)

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

In forestry, it is not possible to apply a double dosage rate of the ready-to-use repellent Cervacol Extra like requested in current guidelines as EPPO 1/135(2) “Phytotoxicity assessment”, because the dosage rate is depending on:

- the species of trees
- the height of trees
- the type of application
- the application equipment and method

To repel the game over months, it is important to apply a thick layer e.g. on the terminal bud or on the terminal shoot. Applying an abnormally thick layer would only lead to part of the layer to drop off, onto the ground, where it could not have any further phytotoxic effects. Phytotoxicity testing with a double dose rate, as requested by the mentioned EPPO guideline, is therefore not considered appropriate in the case of Cervacol Extra.

Instead, phytotoxicity was assessed with the proposed dose rate in all 21 efficacy trials presented in this dossier. However, no negative effects were reported. Cervacol Extra did not show any phytotoxicity at all.

Furthermore, Cervacol Extra 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 shows a very high crop safety.

3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

In general, Cervacol Extra displayed both, a good efficacy and a high crop safety. Normally, a very long time passes between the application of the game repellent and harvest, which makes it impossible to trace a direct correlation between timber yield and application of the game repellent.

3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

Cervacol Extra demonstrated both a good efficacy and a high crop safety.

Repellents against gnawing are used to protect the young shoots trees which are within the reach of deer. Therefore, the products must be applied only during the first ten years lifetime of the young forest trees. This ensures a strong, vertical growth of the young trees.

Trees which are harvested to serve as timber are normally 80 – 100 years old, an impact of a plant protection application which had taken place so long ago can therefore not be expected.

3.4.4 Effects on transformation processes (KCP 6.4.4)

Not applicable: The most important transformation product for timber is pulp for paper production, any negative impact of repellents on this process can be excluded.

3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

Based on the excellent crop safety over years we can conclude that there is no negative impact on plants or parts of plants used for propagation purposes.

comments of zRMS: dRR point 3.2.1 dRR point 3.2.2 dRR point 3.2.3 dRR point 3.4	The Applicant has not submitted any new data about preliminary range-finding tests, minimum effective dose nor efficacy tests, adverse effects on treated crops. 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. Although no GAP changes have been applied for, it should be checked which uses (crops, pests or group of pests controlled, timing, dose rate, number of applications, water, etc.) are currently authorized in each Member State (CMS). ZRMS proposed uses/conditions should be revised by each involved CMS in accordance with its specific conditions of authorization.
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3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

Not applicable: Any impact on e.g. tree seedling can be excluded, as the product is only applied punctually on the top of plants in small amounts.

3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

Cervacol Extra is only applied by hand and not sprayed. A drift to adjacent or neighbor crops can therefore be excluded.

3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

In none of the 21 efficacy trials, negative effects on beneficials and other non-target organisms were reported.

Summary and conclusion

Cervacol Extra displayed an excellent crop tolerance at dose rates up to 5 kg per 1000 trees. The product did not cause any signs of phytotoxicity or growth alterations. Due to the mode of application as a paste, testing with double dose rates could not be done.

No negative impact on wood harvest or wood quality must be anticipated.

Effects on beneficials and other non-target organisms have never been observed in the efficacy trials or reported during the last 20 years of practical use.

The repellent activity of Cervacol Extra is based on different effects such as optically effects and the unusual taste and feel of the grainy substance. An adaption of the game's behavior to these different modes of active is therefore very unlikely.

3.6 Other/special studies

No other studies are submitted.

3.7 List of test facilities including the corresponding certificates

Table 3.7-1: List of test facilities

Test facility	Address	Certificate (Yes or No)
Latvian Plant Protection Research Centre, State Ltd.	Lielvarde iela 36/38 Riga LV 1006, Latvia	Y
Landwirtschaftskammer Rheinland, Pflanzenschutzamt	Siebenbergstraße 200 53229 Bonn, Germany	Y
Landwirtschaftskammer Westfalen-Lippe, Referat 31, Pflanzenschutz und Landbau, Pflanzenschutzdienst	Nevinghoff 40 48135 Münster, Germany	Y
Hessische Landesanstalt für Forsteinrichtung, Waldforschung und Waldökologie	Prof. Oelkers-Straße 6 34346 Hann. Münden, Germany	Y
DR TOMEK Zakład Badań Naukowych i Ekspertyz Przyrodniczych,	31-517 Kraków ul. Olszańska 21/2, Poland	Y
Horticultural Research Institute	96-100 Skierniewice ul. Konstytucji 3 Maja 1/3, Poland	Y

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on – all documents

No data 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 – all documents

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 6.3/01	Landwirtschaftskammer Westfalen-Lippe	2000	Zulassungsprüfung nach GEP im Forst Wildschadenverhütungsmittel (Winterwildverbißschutzmittel) <u>Reported trial</u> : PFWA2000-001 GEP: Yes Published: No	N	N	-	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	N	-	Cheminova	
KCP 6.3/03	Niesar, N.	2000	Wildschadenverhütungsmittel ASU 99810 P gegen Wildverbiß an Laubholz Reported trial: 990430 GEP: Yes Published: No	N	N	-	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	N	-	Cheminova	

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 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 (<i>Cervus elaphus</i>) and roe (<i>Capreolus capreolus</i>) Reported trials: HRI Trial 1 to 8 GEP: Yes Published: No	N	N	-	Cheminova	
KCP 6.3/06	Cinitis, R. Ozolins, 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	N	-	Cheminova	
KCP 6.3/07	Apenite, I. Ozolins-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	N	-	Cheminova	
KCP 6.3/08	Apenite, I. Ozolins-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	N	-	Cheminova	

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 evaluated and relied upon

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