

FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: GK-4

Product name: GORZKA KORA

Chemical active substance:

Active substance: quartz sand, 251 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: **Przedsiębiorstwo Produkcyjno-Handlowe**

ADW Sp. z o.o.

Submission date: October 2022

MS Finalisation date: February 2023 May 2023 July 2023

Version history

When	What
February 2023	ZRMS evaluated dRR submitted by Applicant.
May 2023	Final Registration Report
July 2023	ZRMs made corrections in dRR

Table of Contents

3	Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)	4
3.1	Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6).....	4
3.2	Efficacy data (KCP 6)	10
3.2.1	Preliminary tests (KCP 6.1)	12
3.2.2	Minimum effective dose tests (KCP 6.2).....	13
3.2.3	Efficacy tests (KCP 6.2)	14
3.3	Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)	22
3.4	Adverse effects on treated crops (KCP 6.4).....	22
3.4.1	Phytotoxicity to host crop (KCP 6.4.1).....	22
3.4.2	Effect on the yield of treated plants or plant product (KCP 6.4.2)	23
3.4.3	Effects on the quality of plants or plant products (KCP 6.4.3).....	23
3.4.4	Effects on transformation processes (KCP 6.4.4).....	23
3.4.5	Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)	23
Appendix 1	Lists of data considered in support of the evaluation	26

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:	Comments of zRMS are presented in commenting boxes at the end of each chapter. The text of dRR was generally not changed or rewritten (small changes in the document are marked by grey colour). Corrections marked by turquoise.
-------------------	---

3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

Comments of zRMS: Overall summaries are not necessary here. It was provided at the end of each chapter of the dRR.

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

GAP rev. 1, date: 2022-05-04

PPP (product name): GORZKA KORA
Active substance: quartz sand
Safener: not relevant
Synergist: not relevant
Applicant: Przedsiębiorstwo Produkcyjno-Handlowe
ADW Sp. z o.o.
Zone(s): Central Zone ^(d)
Verified by MS: no

Formulation type: PA ^(a, b)
Conc. of as: 251 g/kg ^(c)
Conc. of safener: not relevant ^(c)
Conc. of synergist: not relevant ^(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: developmental 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 – Art. 33													
1	PL	Deciduous and coniferous trees in forestry	Fpn	Bark stripping damage caused by: Ruminant animals: - deer family - roe family - fallow deer Lagomorphs Squirrel family Beaver family	Coating manually with special brush or glove.	Late autumn when game starts to damage seedlings	1 per year.	Not relevant.	10-13 kg/1000 plants	2,5-3,3 ka as/1000 plants	Not relevant.	Not relevant.	Acceptable against ruminant animals. Conditional accepted against lagomorphs Not accepted against squirrel

				(browsing damages)									family and beaver family and lagomorph
2	PL	Deciduous and coniferous trees in forestry	Fpn	Browsing damage caused by: Ruminant animals: - deer family - roe family - fallow deer and lagomorph (bark stripping)	Coating manually with special brush or glove.	Late autumn when game starts to damage seedlings	1 per year	Not relevant	2-5 kg/1000 plants	0.5-1.3 kg as/1000 plants	Not relevant.	Not relevant.	Acceptable for ruminnat animals and conditionally for lagomorphs
Minor uses – Art. 51 Reg. 1107/2009													
3	PL	Forest nursery plants, renewals, afforestation and seed plantations of forest trees, ornamental shrubs and trees, Christmas trees grown on plantations	F	Browsing damage caused by Ruminant animals: - deer family - roe family - fallow deer Lagomorphs Squirrel family Beaver family	Coating manually with special brush or glove	Late autumn when game starts to damage seedlings	1 per year	Not relevant	2-5 kg/1000 plants	0.5-1.3 kg as/1000 plants	Not relevant	Not relevant	Acceptable
4	PL	Pear, plum, sweet cherry, sour cherry, peach, apricot, hazel, walnut, quince	F	Browsing damage caused by Ruminant animals: - deer family - roe family - fallow deer Lagomorphs Squirrel family Beaver family	Coating manually with special brush or glove	Late autumn when game starts to damage seedlings	1 per year	Not relevant	2-5 kg/1000 plants	0.5-1.3 kg as/1000 plants	Not relevant	Not relevant	Acceptable
5	PL	Gooseberry, choke berry, highbush blueberry, vines	F	Browsing damage caused by Ruminant animals: - deer family - roe family	Coating manually with special brush or	Late autumn when game starts to damage seedlings	1 per year	Not relevant	2-5 kg/1000 plants	0.5-1.3 kg as/1000 plants	Not relevant	Not relevant	Acceptable

				- fallow deer Lagomorphs Squirrel family Beaver family	glove								
6	PL	Ornamental trees, Christmas trees grown on plantations	F	Bark stripping caused by Ruminant animals: - deer family - roe family - fallow deer	Coating manually with special brush or glove	Late autumn when game starts to damage seedlings	1 per year.	Not relevant.	10-13 kg/1000 plants	2,5-3,3 ka as/1000 plants	Not relevant	Not relevant	Acceptable
7	PL	Pear, plum, sweet cherry, sour cherry, peach, apricot, hazel, walnut	F	Bark stripping caused by Ruminant animals: - deer family - roe family - fallow deer	Coating manually with special brush or glove	Late autumn when game starts to damage seedlings	1 per year.	Not relevant.	10-13 kg/1000 plants	2,5-3,3 ka as/1000 plants	Not relevant	Not relevant	Acceptable
Non-professional use for which application is submitted													
8	PL	Deciduous and coniferous trees in forestry	Fn	Browsing damage caused by Ruminant animals: - deer family - roe family - fallow deer and Lagomorphs	Coating manually with special brush or glove	Late autumn when game starts to damage seedlings	1 per year	Not relevant	0,02-0,05 kg/10 plants	0,005-0,013 kg as/1000 plants	Not relevant	Not relevant	Acceptable for ruminant animals and lagomorph – conditionally.
9	PL	Deciduous and coniferous trees in forestry	Fn	Bark damage Bark stripping caused by: Ruminant animals: - deer family - roe family - fallow deer Lagomorphs Squirrel family Beaver family (browsing damages)	Coating manually with special brush or glove.	Late autumn when game starts to damage seedlings	1 per year.	Not relevant.	0,10-0,13 kg/10 plants	0,25-0,33 ka as/10 plants	Not relevant.	Not relevant.	Acceptable for ruminant animals
Minor uses for which application is submitted - non-professional use													
10	PL	Forest nursery	Fn	Browsing damage	Coating	Young shoots,	1 per	Not	0,02-0,05	0,005-	Not relevant	Not	Acceptable

		plants, renewals, afforestation and seed plantations of forest trees; ornamental shrubs and trees; Christmas trees grown on plantations,		caused by Ruminant animals: - deer family - roe family - fallow deer Lagomorphs Squirrel family Beaver family	manually with special brush or glove	2-5 years old, autumn (Sept.-Nov.)	year	relevant	kg/10 plants	0,013 kg as/1000 plants		relevant	
11	PL	Pear, plum, sweet cherry, sour cherry, peach, apricot, hazel, walnut, quince	Fn	Browsing damage caused by Ruminant animals: - deer family - roe family - fallow deer Lagomorphs Squirrel family Beaver family	Coating manually with special brush or glove	Young shoots, 2-5 years old, autumn (Sept.-Nov.)	1 per year	Not relevant	0,02-0,05 kg/10 plants	0.005-0,013 kg as/1000 plants	Not relevant	Not relevant	Acceptable
12	PL	Gooseberry, choke berry, highbush blueberry, vines	Fn	Browsing damage caused by Ruminant animals: - deer family - roe family - fallow deer Lagomorphs Squirrel family Beaver family	Coating manually with special brush or glove.	Young shoots, 2-5 years old, autumn (Sept.-Nov.)	1 per year	Not relevant	0,02-0,05 kg/10 plants	0.005-0,013 kg as/1000 plants	Not relevant	Not relevant	Acceptable
13	PL	Ornamental trees, Christmas trees grown on plantations	Fn	Bark stripping caused by Ruminant animals: - deer family - roe family - fallow deer	Coating manually with special brush or glove	Late autumn when game starts to damage seedlings	1 per year.	Not relevant.	0,10-0,13 kg/10 plants	0,25-0,33 ka as/10 plants	Not relevant	Not relevant	Acceptable
14	PL	Pear, plum, sweet cherry, sour cherry, peach, apricot,	Fn	Bark stripping caused by Ruminant animals: - deer family	Coating manually with special	Late autumn when game starts to damage	1 per year.	Not relevant.	0,10-0,13 kg/10 plants	0,25-0,33 ka as/10 plants	Not relevant	Not relevant	Acceptable

		hazel, walnut		- roe family - fallow deer	brush or glove	seedlings							
--	--	---------------	--	-------------------------------	-------------------	-----------	--	--	--	--	--	--	--

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.

** 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

Column 15: zRMS conclusion.

A	Acceptable
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

This is the application for registration plant protection product under the name GORZKA KORA according to Article 33 of Regulation 1107/2009. GORZKA KORA is a plant protection product in the form of paste (PA) containing active substance quartz sand (251 g/kg). Product is intended to use as a repellent in forestry and several minor crops – forest nursery, ornamental trees, pear, plum, sweet cherry, cherry, peach, apricot, hazel, walnut, gooseberry, chokeberry, highbush blueberry, grapevine.

Description of active substances

Mode of action

Quartz sand is an active substance that has mechanical mode of action.

Table 3.2-1: Details of the active substances

Active substance	Quartz sand
Concentration	251 g/kg
Chemical group	inorganic compound
Mode of action	mechanical
Biological action	repellent

Description of the plant protection product

GORZKA KORA is a paste (PA) containing one active substance quartz sand - 251 g/kg of quartz sand. Currently product is not registered in Poland.

Table 3.2-2: Simplified table of currently registered uses and requested uses for the product code.

Uses		Member State	Previously registered rate	Requested rate	Comments / Other relevant details on GAPs
Crop(s)	Target				
Requested uses					
Deciduous and coniferous trees in forestry	Ruminant animals: - deer family - roe family - fallow deer	Poland	N.A.	Bark stripping: 10-13 kg/1000 trees Browsing damage: 2-5 kg/1000 trees	-
Forest nursery plants, renewals, afforestation and seed plantations of forest trees, ornamental shrubs and trees, Christmas trees grown on	Lagomorphs Squirrel family Beaver family				-

Uses		Member State	Previously registered rate	Requested rate	Comments / Other relevant details on GAPs
Crop(s)	Target				
plantations					
Pear, plum, sweet cherry, sour cherry, peach, apricot, hazel, walnut, quince					-
Gooseberry, choke berry, highbush blueberry, vines					-

Further details are in the table “All intended uses” in Part B - Section 0.

Description of the target pests

Table 3.2-3: Glossary of pests mentioned in the dossier.

EPPO code	Scientific name	Common name*
CERVEL	<i>Cervus elaphus</i>	red deer
CAPRCA	<i>Capreolus capreolus</i>	roe deer
DAMADA	<i>Cervus dama</i>	fallow deer
ALCSAL	<i>Alces alces</i>	moose
OVISAM	<i>Ovis gmelinii musimon</i>	muflon

* optional

Table 3.2-4: Major / minor status of intended uses (for all cMS and zRMS).

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	Minor		Major	Minor
Deciduous and coniferous trees in forestry	PL	-	red deer	PL	-
			roe deer	PL	-
			fallow deer	PL	-
			moose	PL	-
			muflon	PL	-
Forest nursery plants, renewals, afforestation and seed plantations of forest trees, ornamental shrubs and trees, Christmas trees grown on plantations	-	PL			

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	Minor		Major	Minor
Pear, plum, sweet cherry, sour cherry, peach, apricot, hazel, walnut, quince	-	PL			
Gooseberry, chokeberry, highbush blueberry, vines	-	PL			

Compliance with the Uniform Principles

All efficacy studies were performed according to uniform principles. Studies were conducted according to EPPO standards as well as GEP. No deviations were reported.

Information on trials submitted (3.1 Efficacy data)

Table 3.2-5: Presentation of efficacy 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)
					North-East zone		
oak– autumn application	red deer roe deer	PL	2021	E	2 (2)	GEP	
pine – autumn application	fallow deer moose muflon	PL	2021	E	3(3)	GEP	
		PL	2022	E	4(4)	GEP	
mix forest – autumn application		PL	2021	E	1 (1)	GEP	
TOTAL			2		10(10)		

* 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 efficacy 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.			
forestry	Cervacol Extra PA	PL	no data	quartz sand	PA	251 g/kg	2-14 kg/1000 trees	2-10 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.).

Comments of zRMS:	This document summarises the information related to the efficacy of the plant
-------------------	---

	<p>protection product – Gorzka Kora (product code: GK-4), according to Article 33 of Regulation 1107/2009.</p> <p>The formulation of this product is a paste (PA) and it is containing one active substances: quartz sand (251 g/kg). For now, quartz sand is on the list of approved active substances. Sand quartz is an inorganic compound with mechanical mode of action, having a property of repelling unwanted species in each location. Their use is classified as biological (ecological) protection methods. Product is intended to use as a repellent in forestry and several minor crops – forest nursery, ornamental trees, pear, plum, sweet cherry, cherry, peach, apricot, hazel, walnut, gooseberry, chokeberry, highbush blueberry, grapevine</p> <p>In Poland 4 repellents with the same active compound – quartz sand at the same formulation (PA) are registered and commonly used for protection trees against browsing (gnawing) and/or bark damage of trees.</p> <p>Poland is a ZRMs. All necessary information's were presented by Applicant in this dRR.</p>
--	--

3.2.1 Preliminary tests (KCP 6.1)

No results of the preliminary range-finding tests were submitted.

Comments of zRMS:	<p>Statement accepted. No results of the preliminary range-finding tests were submitted by the Applicant. The active substances of Gorzka Kora (product code: GK-4) – quartz sand is registered and has been commonly used in forestry practice for many years. Also, a large-scale efficacy trials are available to evaluate the effectiveness of products containing quartz sand as active compound. Therefore, there was no need for preliminary range-finding tests in the opinion of Evaluator.</p>
-------------------	--

3.2.2 Minimum effective dose tests (KCP 6.2)

Forestry

Efficacy of GORZKA KORA depends on accuracy of tree coating not on application rate expressed in amount per hectare. Application rate per hectare depends on trees density and height but has no effect on efficacy, that is why no trials on minimum effective dose were provided with GORZKA KORA.

Summary and conclusions on the minimum effective dose

Not relevant.

The proposed rate of GORZKA KORA of 2-5 kg/1000 trees should be considered the minimum effective dose to deliver broad spectrum control under a wide range of environmental conditions.

Comments of zRMS:	<p>Statement accepted. In order to provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least one lower dose(s) (for example 60–80% of the recommended dose) to that which would be recommended. It is utilized to achieve the desired effect. Also, we should remember that its efficacy depends on accuracy of tree coating not on application rate expressed in amount per hectare. Application rate per hectare depends on trees density and height but has no effect on efficacy. Therefore, the data of minimum effective dose were not required. Al-</p>
-------------------	--

	so, in the literature we can find information's about efficacy of the plant protection products containing quartz sand. Therefore, the lack of minimum effective dose tests can be observed as acceptable in the opinion of Evaluator.
--	--

3.2.3 Efficacy tests (KCP 6.2)

Forestry

A total of 10 trials were carried out to evaluate the efficacy of GORZKA KORA. 7 trials were performed in pine nursery, 2 trials in oak nursery and one trial was performed in mix forest. All trials were performed in different regions of Poland by recognised institute IBL.

Table 3.2-7: Details on trial methodology

Guidelines	General guidelines	PP 1/152(4) PP 1/181(4) PP 1/135(4)
	Specific guidelines	PP 1/200(1)
Experimental design	Plot design	RCB
	Plot size	20 m x 20 m = 400 m ²
	Number of replications	4
Crop	Trials per crop	Pine tree (7 trials) Oak tree (2 trials) Mix forest (1 trials)
	Varieties per crop	Pine tree – <i>Pinus silvestris</i> L Oak tree – <i>Quercus robur</i> L Beech tree – <i>Fagus silvatica</i> L
	Sowing period	Pine tree – 2011-04-06, 2013-04-10, 2018-04-20, 30-03-2016, 27-03-2014, 22-03-2019, 18-03-2020 Oak tree – 1999-04-20, 2013-04-22 Mix forest – 2017-04-19
Application	Crop stage (BBCH)* at application	Not relevant for pest and crop.
	Timing Pest stage at application (1)	Pest stage at application not relevant. Pine tree – 2020-11-11, 2020-11-13, 2020-11-12, 2021-11-16, 2021-11-21, 2021-11-16, 2021-11-21 Oak tree – 2020-11-09, 2020-11-10 Mix forest – 2020-11-13
	Number of applications Intervals between applications	1 -
	Spray volumes	Not relevant
Assessment	Assessment types	Efficacy was evaluated by number of damaged plants. Phytotoxicity was assessed by visual observations.
	Assessment dates	Oak trees – observation of efficacy and phytotoxicity after application at: 2020-11-09: 115 DAA, 191 DAA 2020-11-10: 115 DAA, 190 DAA Pine trees – observation of efficacy and phytotoxicity after application at: 2020-11-11: 116 DAA, 190 DAA 2020-11-13: 117 DAA, 189 DAA 2020-11-12: 117 DAA, 189 DAA 2021-11-16: 36 DA-A, 98 DA-A, 121 DA-A, 160 DA-A

		2021-11-21: 30 DA-A, 95 DA-A, 116; DA-A, 156 DA-A 2021-11-16: 15 DA-A, 57 DA-A, 121 DA-A, 160 DA-A 2021-11-16: 14 DA-A, 53 DA-A, 116 DA-A, 156 DA-A Mix forest – observation of efficacy and phytotoxicity after application at: 2020-11-13: 118 DAA, 189DAA
Other relevant information	Not relevant	Not relevant

Table 3.2-11: Details on trial methodology_2021 trials

Report code	145283-1	145283-2	145283-3	145283-4	145283-5	145283-6
Location	Nadleśnictwo Czarna Białostocka Podlaskie, Białostocki, Czarna Białostocka	Nadleśnictwo Kobiór, Śląskie, Pszczyński, Kobiór	Nadleśnictwo Złoty Potok Śląskie, Częstochowski, Przyrów	Nadleśnictwo Czarna Białostocka, Podlaskie, Białostocki, Czarna Białostocka	Nadleśnictwo Kobiór, Śląskie, Pszczyński, Kobiór	Nadleśnictwo Złoty Potok Śląskie, Częstochowski, Przyrów
Plant/cultivar	Oak tree – <i>Quercus robur</i> L	Pine tree – <i>Pinus silvestris</i> L	Pine tree – <i>Pinus silvestris</i> L	Oak tree – <i>Quercus robur</i> L	Pine tree – <i>Pinus silvestris</i> L	Pine tree – <i>Pinus silvestris</i> L Beech tree – <i>Fagus sylvatica</i> L
Seeding date	1999-04-20	2011-04-06	2013-04-10	2013-04-22	2018-04-20	2017-04-19
Seeding rate	3 000/ha	5 000/ha	5 000/ha	6 000/ha	10 000/ha	Pi 10 000; Fa 6000
Forecrop	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Type of sprayer	Not relevant. Hand application with glove.	Not relevant. Hand application with glove.	Not relevant. Hand application with glove.	Not relevant. Hand application with glove.	Not relevant. Hand application with glove.	Not relevant. Hand application with glove.
Date of treatment	2020-11-09	2020-11-11	2020-11-13	2020-11-10	2020-11-12	2020-11-13
Plant development phase majority	BBCH: 97-100	postemergence / autumn / in the dormancy stage	BBCH: 97-100	BBCH: 97	BBCH: 97	postemergence / autumn / in the dormancy stage
Plant diameter:	No data	No data	No data	No data	No data	No data
Height :	7,0 m	3 m	2 m	1,75 m	0,3 m	Fa 0,4 m, Pi 0,45 m
Height minimum, maximum:	6,41-8,22 m	2,94 – 3,95m	1,7–3,0 m	1,5-2,2 m	0,22-0,35 m	0,3-0,53 m
Soil type	Rust soils	Podzolic rusty soils	Podzolic soils	Stagnogleyic clay-illuvial soils	Stagnogleyic glossic clayilluvial soils	Podzolic rusty soils
Water volume (l/ha)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

Table 3.2-11: Details on trial methodology_2022 trials

Report code	S21-07629-01	S21-07629-02	S21-07630-01	S21-07630-02
Location	Oborniki Wielkopolskie / obornicki / Oborniki	Pęckowo Wielkopolskie / szamotulski / Obrzycko	Oborniki Wielkopolskie / obornicki / Oborniki	Pęckowo Wielkopolskie / szamotulski / Obrzycko
Plant/cultivar	Pine tree – <i>Pinus silvestris</i> L	Pine tree – <i>Pinus silvestris</i> L	Pine tree – <i>Pinus silvestris</i> L	Pine tree – <i>Pinus silvestris</i> L
Seeding date	30-03-2016	27-03-2014	22-03-2019	18.03.2020
Seeding rate	8400/ha	9600/ha	9000/ha	10 000/ha
Forecrop	n.a.	n.a.	n.a.	n.a.
Type of sprayer	Not relevant. Hand application with glove.	Not relevant. Hand application with	Not relevant. Hand application with	Not relevant. Hand application with glove.

Report code	S21-07629-01	S21-07629-02	S21-07630-01	S21-07630-02
		glove.	glove.	
Date of treatment	2021-11-16	22-11-2021	16-11-2021	22-11-2021
Plant development phase majority	BBCH: 97-100	BBCH 97-100	BBCH: 97-100	BBCH: 97-100
Plant diameter:	No data	No data	No data	No data
Height :	2,1 m	2,5 m	0,5 m	0,40 m
Height minimum, maximum:	1,1-2,7 m	1,2 – 2,70 m	0,2-0,7 m	0,15-0,50 m
Soil type	Sand	Sand	Sand	Sand
Water volume (l/ha)	n.a.	n.a.	n.a.	n.a.

Trials were carried out by testing organisations, all of which followed the available EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The design and analysis of results and reporting of the studies were carried out in compliance with the general EPPO Guidelines

Testing units

1. Instytut Badawczy Leśnictwa, Zakład Ekologii Lasu, Sękocin Stary,
ul. Braci Leśnej nr 3, 05-090 Raszyn, Poland
2. Eurofins Agrosience Services Sp. z o.o.
ul. Parkowa 6
64-530 Kaźmierz

Materials and methods

Trials were conducted in different forest districts in Poland. Trials were established on a set of complete randomized blocks in 4 replications.

The testing units have been authorized to conduct research in the field of efficacy of plant protection products and are officially GEP recognized.

Experimental details

The efficacy trials were designed, conducted and reported according to the following EPPO guidelines:

EFFICACY OF GORZKA KORA AGAINST PEELING OF BARK DAMAGE IN FOREST

PP 1/152(4)	Design and analysis of efficacy evaluation trials
PP 1/181(4)	Conduct and reporting of efficacy evaluation trials including GEP
PP 1/135(4)	Phytotoxicity assessment
PP 1/200(1)	Rodent repellents against debarking of trees
PP 1/214(3)	<i>Principles of acceptable efficacy</i>
PP 1/226(2)	<i>Number of efficacy trials</i>

Assessment methods

Statistical Analysis

The dependent variables were the number of bark stripped trees in a row in a given plot. The variable described the type of agent applied or its absence (control). The one-way ANOVA was used to analyse effectiveness, which showed that the applied agent significantly reduced bark stripping.

Assessment of efficacy and phytotoxicity

Evaluation Description
Phytotoxicity as % of total leaf area affected by chlorosis and/or necrosis. Record any other symptom or

plot differences observed using a scale appropriate to symptom (e.g. untimely withering of needles, retarded growth in spring).
Efficacy: Record the total number of affected trees in the plot.
Efficacy: Record the size of the damage done by peeling using a scale from 1-10 (0 = no damage, 1 = smaller than 10 x 10 cm, 10 = 10 x 100 cm).
Special Requirements
Record any observed effect on the incidence of other non-target or beneficial organisms.

The applications were conducted with glove, manual application.

Application pattern:

Product GORZKA KORA was applied according to treatment lists:

No	Treatments	Formulation	Rate	Unit	Rate a.i.	Unit	Appl.code
1	Untreated check						
2	Gorzka kora	PA	13	kg/1000 plants	3,263	kg/1000 plants	A
3	Gorzka kora	PA	10	kg/1000 plants	2,510	kg/1000 plants	A
4	Gorzka kora	PA	6	kg/1000 plants	1,506	kg/1000 plants	A
5	Cervacol Extra PA	PA	10	kg/1000 plants	2,510	kg/1000 plants	A

Total 5 trials were carried out to support the efficacy of product GORZKA KORA against peeling of bark damage in forest. Presented efficacy data have been conducted in 2021 and 2022 in Poland (NE).

GORZKA KORA was applied at target dose rate: 10-13 kg/1000 plants, reference product used in trials: Cervacol Extra PA at dose rate: 10 kg/1000 plants .

Table 3.2-8: Efficacy of GORZKA KORA

Target	Grouping *	Number of trials	Infestation in the untreated control		% control				No of trials where GORZKA KORA is >, <, = com- pared to stand- ard(s)**
					GORZKA KORA at rate:		Cervacol Extra PA at rate:		
			Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	
Autumn application (oak and pine), spring assessment									
oak and pine	-	5	NR	NR	98,26% at 13 kg/1000 trees 96,68% at 10 kg/1000 trees 79,08% at 6.0 kg/1000 trees	91 - 100% at 13 kg/1000 trees 92.6-100% at 10 kg/1000 trees 62-90,1% at 6.0 kg/1000 trees	93,34% 10 kg/1000 trees	85-100% at 10 kg/1000 trees	3 trials > standard 1 trials = standard 1 trials < standard

* A, B, C can be a “trial group” (as defined in page 10, e.g. EPPO climatic zone A) or a specific target (e.g. weed A, weed B...). In order to adapt the table to the data presented, it is possible:

- to add lines or columns,

- to duplicate the table (e.g. one table for “trial group 1”, one table for “trial group 2”, one table for “all”).

** Optional

In 2021 GORZKA KORA was applied at target dose rate: 10-13 kg/1000 plants at single application. Data demonstrated that the efficacy of the GORZKA KORA at target dose rate was higher or identical as used reference product Cervacol Extra PA at dose rate: 10 kg/1000 plants. The mean efficacy was above 90% that indicate that the product GORZKA KORA is highly effective.

EFFICACY OF GORZKA KORA AGAINST PEELING OF BROWSING DAMAGE IN FOREST

PP 1/152(4)	Design and analysis of efficacy evaluation trials
PP 1/181(4)	Conduct and reporting of efficacy evaluation trials including GEP
PP 1/135(4)	Phytotoxicity assessment
PP 1/200(1)	Rodent repellents against debarking of trees
PP 1/214(3)	<i>Principles of acceptable efficacy</i>
PP 1/226(2)	<i>Number of efficacy trials</i>

Assessment methods

Statistical Analysis

The dependent variables were the number of damaged trees saplings in a row in a given plot. The variable described the type of agent applied or its absence (control). The one-way ANOVA was used to analyse effectiveness, which showed that the applied agent significantly reduced browsing of oak saplings by cervids.

Assessment of efficacy and phytotoxicity

Evaluation Description
Phytotoxicity as % of total leaf area affected by chlorosis and/or necrosis. Record any other symptom or plot differences observed using a scale appropriate to symptom (e.g., untimely withering of needles, retarded growth in spring).
Efficacy: Record the total number of affected trees in the plot.
Special Requirements
Record any observed effect on the incidence of other non-target or beneficial organisms.

Applications methods and rates

The applications were conducted with glove, manual application.

Application pattern:

Product GORZKA KORA was applied according to treatment lists:

No	Treatments	Formulation	Rate	Unit	Rate a.i.	Unit	Appl.code
1	Untreated check						
2	Gorzka kora	PA	5,0	kg/1000 plants	1,255	kg/1000 plants	A
3	Gorzka kora	PA	2,0	kg/1000 plants	0,502	kg/1000 plants	A
4	Gorzka kora	PA	1,2	kg/1000 plants	0,301	kg/1000 plants	A
5	Cervacol Extra PA	PA	2	kg/1000 plants	0,502	kg/1000 plants	A

Total 5 trials were carried out to support the efficacy of product GORZKA KORA against peeling of browsing damage in forest. Presented efficacy data have been conducted in 2021 and 2022 in Poland (NE).

GORZKA KORA was applied at target dose rate: 2-5 kg/1000 plants, reference product used in trials: Cervacol Extra PA at dose rate: 2 kg/1000 plants .

Table 3.2-9: Efficacy of GORZKA KORA

Target	Grouping *	Number of trials	Infestation in the untreated control	% control		No of trials where GORZKA KORA is >, <, = com-
				GORZKA KORA at rate:	Cervacol Extra PA at rate:	

			Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	pared to standard(s)**
Spring application (oak and pine), spring assessment									
oak and pine	-	5	NR	NR	95,25% at 5 kg/1000 trees 93,58% at 2 kg/1000 trees 77,75% at 1.2 kg/1000 trees	75-100% at 5 kg/1000 trees 75-100% at 2 kg/1000 trees 65-90% at 1.2 kg/1000 trees	89,69% 2 kg/1000 trees	66%-100% at 2 kg/1000 trees	4 trials > standard 0 trials = standard 1 trials < standard

* A, B, C can be a “trial group” (as defined in page 10, e.g. EPPO climatic zone A) or a specific target (e.g. weed A, weed B...). In order to adapt the table to the data presented, it is possible:

- to add lines or columns,

- to duplicate the table (e.g. one table for “trial group 1”, one table for “trial group 2”, one table for “all”).

** Optional

In 2021 GORZKA KORA was applied at target dose rate: 2-5 kg/1000 plants at single application. Data demonstrated that the efficacy of the GORZKA KORA at target dose rate was higher or identical as used reference product Cervacol Extra PA at dose rate: 2 kg/1000 plants. The mean efficacy was above 90% that indicate that the product GORZKA KORA is highly effective.

Yield (and relevant quality indicators), from efficacy trials (in the presence of challenging pest populations)

Not relevant.

Summary and conclusion

A total of 10 trials were carried out to evaluate the efficacy of GORZKA KORA. The application rates used in trials were in range 2-13 kg/1000 trees. All trials confirmed the efficacy of GORZKA KORA in control deciduous and coniferous trees in forestry. No phytotoxicity effects on protected trees were observed in efficacy trials. GORZKA KORA is a repellent containing 251g/kg of active substance quartz sand. This plant protection product is in the form of paste (PA) and is applied in the forest with a glove (manual application).

Table 3.2-35: Overall average efficacy of GORZKA KORA

Application	Dose	Pest	Average Efficacy %
against peeling of browsing damage in forest	2-5 kg/1000 trees	red deer roe deer	93,58- 95,25
against peeling of bark damage in forest	10-13 kg/1000 trees	fallow deer moose muflon	96,68-98,26

Comments of zRMS:	<p>Trials methodology has been accepted by Evaluator. The field trials were performed in accordance with EPPO guidelines and in all trials GEP rules were recognized: PP 1/135(3) – <i>Phytotoxicity assessment</i>; PP 1/152(4) – <i>Design and analysis of efficacy evaluation trials</i>; PP 1/181(4) – <i>Conduct and reporting of efficacy evaluation trials including GEP</i>; PP 1/214(3) – <i>Principles of acceptable efficacy</i>; PP 1/226(2) – <i>Number of efficacy trials and PP 1/200(1) – Rodent repellents against debarking of trees.</i></p> <p>The field experiments of the repellent – Gorzka Kora (product code: GK-4) were carried out by the recognised institutes. The testing unit has been man-</p>
-------------------	--

dated to conduct research in the field of efficacy of plant protection products by the Chief Inspector of Plant Health and Seed Inspection and are officially GEP recognised.

The Applicant submitted 10 reports (in total) showing the results in research into product efficacy carried out in 2021 and 2022 (7 trials – pine nursery, 2 trials – oak nursey, 1 trial – mix forestry: pine+birch). List of these reports is contained in Appendix of this dossier. What is important, the number of efficacy of the product presented in this dossier is sufficient for registration the tested product in Poland and in accordance with EPPO PP/226 (6–15 trials). For low-risk substances, the required number of tests as agreed in the harmonization meetings is 2-3. So, number of trials submitted by Applicant is acceptable.

The analysis of trial reports proved that the plot size and number of plants in evaluation process as well as the assessment methods were also in accordance with appropriate standards. All trials were performed in different regions of Poland.

Repellents, in the form of ready-to-use paste, applied manually by rubber glove on the apical shoots of trees. Side shoots were left unprotected. Also avoid applying repellents to donuts peak. Before applying the repellents mixed thoroughly. Spring will assess the effectiveness of repellents to protect against gnawing on experimental plots (trees protected repellents) and control where the trees were not protected repellents. Repellents were secured seedlings of major forest-forming tree species like pine and oak. Experiments were in both the natural regeneration and artificial. In the area of forest complexes, which conducted experiments to determine efficacy of Gorzka Kora (product code: GK-4), exists a large population of game animals, locally in a large density: hares, roe deer, deer and elk.

According to EPPO 1/200 – the rodent species used to conduct the experiments should belong to the group of most important pests in a given region, i.e. *Microtus agrestis* in northern Europe, *M. arvalis* or *M. agrestis* in Central European countries, and *Pitymys* in southern Europe. It is advisable the use for experiments of individuals at the age of pre-breeding (not fully mature), as the natural populations of voles in the winter season consist exclusively of such individuals. The method described below, with minor modifications, can also be used for testing rodenticides that control rodents of the order *Lagomorpha* (rabbits, hares).

Studied pests during efficacy trials: Applicant submitted trials only against Ruminant animals (against browsing damage and bark damage stripping of trees). Lack of trials against lagomorphs, squirrel family and beaver family against bark browsing damage and stripping trees. In the opinion of ZRMs, lagomorphs can be also be accepted against browsing damage but conditionally. It will be necessary to submit at least 1-2 studies for these pests performed on pine or oak trees within 1-2 years after granted product. However, oak or other deciduous tree will be preferred for additional studies. ~~Hares have a preference, it is the bark of apple, plum, apricot, hawthorn, hazel. And they hardly pay attention to calla, currants, honeysuckle, wild rose. Hares bite the twigs of trees and shrubs in winter and eat young shoots in early spring. Therefore, it is important to use protection against bark gnawing (damage) also by hares. Spalding is the stripping by deer (mainly deer and elk) of bark from young forest trees (usually pines, spruces, oaks, ash), which causes significant damage. The damage consists of crippling trees and weakening their resistance to infections such as fungal diseases. Fallowing prevention designed to act against ruminant animals.~~

Quartz sand is a low-risk substance. In Poland few plant protection products with quartz sand are already registered against lagomorphs, squirrel family and beaver family. So, its efficacy is already known. According to harmonization meetings and extrapolating results, the possibility of extrapolation of results between coniferous and deciduous trees in the case of deer or hares has been determined. But the possibility of extrapolation between different pest species, e.g., hares/deer, has not been clarified. Therefore, we believe that based on the so-called judgement opinion, it will be possible to at least conditionally registration of this group of animals. Squirrel family and beaver family are not accepted, also they were not submitted in label project by Applicant.

Pests mentioned in efficacy reports:

CERVEL	<i>Cervus elaphus</i>	red deer	Jeleń szlachetny
CAPRCA	<i>Capreolus capreolus</i>	roe deer	Sarna europejska
DAMADA	<i>Cervus dama</i>	fallow deer	Daniel
ALCSAL	<i>Alces alces</i>	moose	Łoś euroazjatycki
OVISAM	<i>Ovis gmelinii musimon</i>	muflon	Muflon śródziemnomorski

Assessment of efficacy: EPPO PP 1/214 (3) Principles of acceptable efficacy does not define specific scale of efficacy. It refers to EC Regulation 1107/2009 concerning the placing of plant protection products on the market (EC, 2009) which expresses this requirement by declaring that any plant protection product should be 'sufficiently effective', but without explaining what is meant by this term. The Applicant did not apply a scale of effectiveness the tested product – Gorzka Kora (product code: GK-4). In accordance with EPPO 1/200 (1) we should take to account only trials with sufficient (> 50%) damage level of the control group. All trials conducted fulfilled this condition.

Efficacy of Gorzka Kora against peeling of bark–stripping damage in forest (5 trials): Oak was studied during one trial and pine –in 4 trials. During those trials following pests were studied: CERVEL (5 trials), ALCSAL (4 trials), DAMADA (3 trials), CAPRCA (2 trials) and OVISAM (2 trials). Presented efficacy data have been conducted in 2021 and 2022 in Poland (NE). Gorzka Kora was applied at target dose rate: 10-13 kg/1000 plants, reference product used in trials: Cervacol Extra PA at dose rate: 10 kg/1000 plants. Data demonstrated that the efficacy of the GORZKA KORA at target dose rate was higher or identical as used reference product Cervacol Extra PA at dose rate: 10 kg/1000 plants. The mean efficacy was above 90% that indicate that the product Gorzka Kora is highly effective.

Efficacy of Gorzka Kora against peeling of browsing damage in forest (5 trials): One trial was carried out on oak, one trial – on mix forestry (pine and birch) and 3 trials on pine. Following pests were studied during those trials: CERVEL (5 trials), ALCSAL (4 trials), CAPRCE (5 trials), DAMADA (3 trials) and OVISAM (2 trials). Presented efficacy data have been conducted in 2021 and 2022 in Poland (NE). Gorzka Kora was applied at target dose rate: 2-5 kg/1000 plants, reference product used in trials: Cervacol Extra PA at dose rate: 2 kg/1000 plants. Data demonstrated that the efficacy of the Gorzka Kora at target dose rate was higher or identical as used reference product Cervacol Extra PA at dose rate: 2 kg/1000 plants. The mean efficacy was above 90% that indicate that the product GORZKA KORA is highly effective.

The effectiveness of tested product at recommended dose was similar or even slightly higher than standard references products. Differences between the ef-

	<p>iciency (observed as fluctuations of effectiveness) of product from field tests were quite substantial, but they were caused by weather conditions (during rainy and windy weather efficacy of product has been decreased). Autumn application is recommended by Evaluator due to high efficiency of tested product.</p> <p>Gorzka Kora (product code: GK-4) should be used in accordance to label project. All minor uses included in GAP table and label project by Applicant are accepted by ZRMs in line to Article 51. Use professional and non-professional are accepted.</p>
--	---

3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

Not relevant. GORZKA KORA contains quartz sand as an active substance that has mechanical mode of action. Neither occurrence of resistance nor development of resistance is probable.

Comments of zRMS:	Statement accepted by Evaluator. The development of resistance is not probable.
-------------------	---

3.4 Adverse effects on treated crops (KCP 6.4)

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

Not relevant. No phytotoxicity studies were performed since GORZKA KORA is a repellent. Phytotoxicity symptoms were evaluated in efficacy trials. No phytotoxic effects on treated plants were observed at application rate 1N.

Table 3.4-1: Phytotoxicity of product

Number of trials		Selectivity trials (0 trials)				Efficacy trials (6 trials)	
		Test product		Standard		Test product	Standards
		N	2N	N	2N	N	N
OAK, PINE							
Maximum of phytotoxicity recorded during the trials	0% to 5%	-	-	-	-	59	59
	>5% to 10%	-	-	-	-	-	-
	>10% to 15%	-	-	-	-	-	-
	>15 %	-	-	-	-	-	-
Mix forest							
Maximum of phytotoxicity recorded during the trials	0% to 5%	-	-	-	-	1	1
	>5% to 10%	-	-	-	-	-	-
	>10% to 15%	-	-	-	-	-	-
	>15 %	-	-	-	-	-	-

No phytotoxicity symptom caused by GORZKA KORA at the proposed dose rate of 2-13 kg/1000 trees was recorded in all trials.

Comments of zRMS:	Statement accepted. No phytotoxicity symptoms were observed during trials at the proposed dose rate of 2-13 kg/1000 trees was recorded. In all (10) submitted trials the phytotoxicity effect was assessed: mix forest (1 trial), oak (2 trials) and pine (7 trials).
-------------------	---

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

Not relevant. GORZKA KORA is to be used in forestry.

Comments of zRMS:	Studies about effect on the yield of treated plants or plant product are not required, due to fact that Gorzka Kora (product code: GK-4) will be used in forestry. In details, will be used on trees and shrubs, outside the plant growing season on November/December so it will not be used on edible parts of crops.
-------------------	---

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

Not relevant. GORZKA KORA is to be applied on trees and shrubs, outside the plant growing season – on November/December so it will not be used on edible parts of crops.

Comments of zRMS:	Studies about effect on the quality of plants or plant product are not required, due to fact that Gorzka Kora (product code: GK-4) will be used in generally in forestry. In details, will be used on trees and shrubs, outside the plant growing season – on November/December so it will not be used on edible parts of crops.
-------------------	--

3.4.4 Effects on transformation processes (KCP 6.4.4)

Comments of zRMS:	Studies about effects on transformation processes are not required, due to fact that Gorzka Kora (product code: GK-4) will be used in forestry. In details, will be used on trees and shrubs, outside the plant growing season – on November/December so it will not be used on edible parts of crops.
-------------------	--

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

Not relevant. GORZKA KORA is to be applied on trees and shrubs, outside the plant growing season – on November/December so it will have no effect on plant propagation.

Summary and conclusion

No phytotoxicity studies were performed since GORZKA KORA is neither herbicide nor regulator. Phytotoxicity was observed in efficacy trials. No phytotoxic effects were recorded at application rate 1N 2-13 kg/1000 trees.

Comments of zRMS:	Studies about impact on treated plants or plant products to be used for propagation are not required, due to fact that Gorzka Kora (product code: GK-4) will be used in forestry. In details, will be used on trees and shrubs, outside the plant growing season – on November/December so it will not be used on edible parts of crops. Also, no phytotoxic effect was observed during efficacy trials against application rate 1N (2-13 kg/1000 trees).
-------------------	---

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 relevant. GORZKA KORA is to be applied on trees and shrubs, outside the plant growing season – on November/December so it will have no impact on succeeding crops.

Comments of zRMS:	Studies about impact on succeeding crops are not required, due to fact that Gorzka Kora (product code: GK-4) will be used in forestry. In details, will be used on trees and shrubs, outside the plant growing season – on November/December so it will not be used on edible parts of crops.
-------------------	---

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

Not relevant. GORZKA KORA is to be used in forestry. The proposed application manner of GORZKA KORA is annual coating hence no drift occurs and there is no risk for adjacent crops.

Comments of zRMS:	Studies about impact on other plants including adjacent crops are not required, due to fact that Gorzka Kora (product code: GK-4) will be used in forestry. In details, will be used on trees and shrubs, outside the plant growing season – on November/December so it will not be used on edible parts of crops. Also, no drift occurs, so there is no risk for adjacent crops
-------------------	--

Tank cleaning

Not relevant. The proposed application manner of GORZKA KORA is annual coating hence no drift occurs and there is no risk for adjacent crops.

Comments of zRMS:	Not relevant. The proposed application manner of Gorzka Kora (product code: GK-4) is annual coating hence no drift occurs and there is no risk for adjacent crops
-------------------	---

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

Not relevant. No studies on the toxicity to non-target organisms have been carried out with quartz sand and GORZKA KORA. Further data on the GORZKA KORA is also not considered essential since it is to be used manually as a coating onto trees. Additionally, quartz sand naturally occurs in the environment and hence exposure of non-target organisms is considered negligible.

Compatibility with current management practices including IPM

Not relevant.

Comments of zRMS:	Not relevant, quartz sand naturally occurs in the environment and hence exposure of non-target organisms is considered negligible
-------------------	---

Summary and conclusion

GORZKA KORA is to be used in forestry and the proposed application manner is annual coating outside the plant growing season, so no impact on succeeding and adjacent crops is expected. The active substance quartz sand naturally occurs in the environment and hence exposure of non-target organisms is considered negligible.

3.6 Other/special studies

Not relevant. No other/special studies are provided.

Comments of zRMS:	Statement accepted.
-------------------	---------------------

3.7 List of test facilities including the corresponding certificates

Table 3.4-2: List of test facilities

Test facility	Address	Certificate (Yes or No)
Instytut Badawczy Leśnictwa Zakład Ekologii Lasu w Sękocinie Starym	Ul. Braci Leśnej 3, 05-090 Raszyn	Yes
Eurofins Agrosience Services Sp. z o.o.	ul. Parkowa 6 64-530 Kaźmierz	Yes

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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
KCP 6.2/01	dr hab. Zbigniew Borowski, prof. IBL	2021	Study of efficacy of Gorzka kora against peeling of bark damage in forest, Czarna Białostocka, Poland 2021 Company Report No.: 145283-1 Source: Instytut Badawczy Leśnictwa GLP Unpublished	N	ADW*
KCP 6.2/02	dr hab. Zbigniew Borowski, prof. IBL	2021	Study of efficacy of Gorzka kora against peeling of bark damage in forest, Kobiór, Poland 2021 Company Report No.: 145283-2 Source: Instytut Badawczy Leśnictwa GLP Unpublished	N	ADW*
KCP 6.2/03	dr hab. Zbigniew Borowski, prof. IBL	2021	Study of efficacy of Gorzka kora against peeling of bark damage in forest, Żłoty Potok, Poland 2021 Company Report No.: 145283-3 Source: Instytut Badawczy Leśnictwa GLP Unpublished	N	ADW*
KCP 6.2/04	dr hab. Zbigniew Borowski, prof. IBL	2021	Study of efficacy of Gorzka kora against peeling of browsing damage in forest, Czarna Białostocka, Poland 2021 Company Report No.: 145283-4	N	ADW*

			Source: Instytut Badawczy Leśnictwa GLP Unpublished		
KCP 6.2/05	dr hab. Zbigniew Borowski, prof. IBL	2021	Study of efficacy of Gorzka kora against peeling of browsing damage in forest, Kobiór, Poland 2021 Company Report No.: 145283-5 Source: Instytut Badawczy Leśnictwa GLP Unpublished	N	ADW*
KCP 6.2/06	dr hab. Zbigniew Borowski, prof. IBL	2021	Study of efficacy of Gorzka kora against peeling of browsing damage in forest, Złoty Potok, Poland 2021 Company Report No.: 145283-6 Source: Eurofins Instytut Badawczy Leśnictwa GLP Unpublished	N	ADW*
KCP 6.2/07	Trzeciak M.	2022	Determination of Efficacy of Gorzka Kora as repellent against peeling of bark damage in Forest, 2 Site Poland 2021/2022 Company Report No.: S21-07629-01 Source: Eurofins Agrosience Services Sp. z o.o. GLP Unpublished	N	ADW*
KCP 6.2/08	Trzeciak M.	2022	Determination of efficacy of Gorzka Kora as repellent against peeling of bark damage in forest, 2 Site Poland 2021/2022 Company Report No.: S21-07629-02 Source: Eurofins Agrosience Services Sp. z o.o. GLP Unpublished	N	ADW*
KCP 6.2/09	Trzeciak M.	2022	Determination of efficacy of Gorzka Kora as repellent against browsing damage in forest, 2 site Poland 2021/2022 Company Report No.: S21-07630-01 Source: Eurofins Agrosience Services Sp. z o.o. GLP Unpublished	N	ADW*
KCP 6.2/10	Trzeciak M.	2022	Determination of efficacy of Gorzka Kora as repellent against browsing damage in forest, 2 site Poland 2021/2022 Company Report No.: S21-07630-02	N	ADW*

			Source: Eurofins Agrosience Services Sp. z o.o. GLP Unpublished		
--	--	--	---	--	--

ADW*- Przedsiębiorstwo Produkcyjno-Handlowe ADW sp. z o.o., ul. Zbożowa 2, 43-175 Wiry, Poland

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	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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 N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

List of data relied on 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 N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner