

# FINAL REGISTRATION REPORT

## Part B

### Section 0

Product Background, Regulatory Context and  
GAP information

Product code: -

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 corrected dRR (eff.section)

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## 0 Product background, regulatory context and GAP information

### 0.1 Introduction

This document presents the product background, regulatory context and GAP information for the product GORZKA KORA, a paste formulation containing 251 g/kg quartz sand for use mainly in forestry. Quartz sand was first included in Annex I to Directive 91/414/EEC by Commission Directive 2008/127/EC of 18 December 2008.

Where appropriate this document refers to the conclusion of the EU review for quartz sand. This will be where:

- The active substance data are relied upon in the risk assessment of the formulation; or when
- the EU review concluded that the additional data/information should be considered at national re-registration.

This product was not the representative formulation and has not been previously evaluated according to the Uniform Principles.

The EFSA Scientific report for quartz sand (EFSA Journal ~~2011;9(7):2300~~ 2022;20(9):7552) is considered to provide the relevant review information or a reference to where such information can be found.

#### 0.1.1 Reason for application

This application is made for the authorisation of GORZKA KORA in accordance with Article 33 of Regulation (EC) No. 1107/2009. This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

#### 0.1.2 Details of zRMS(s) and concerned MS

**Table 0.1-1: Overview of zRMS and cMS**

	<b>zRMS, product name and authorization no. (if relevant)</b>	<b>(if relevant) Concerned MS, MS' product name and authorization number (if applicable)</b>
<b>Central zone</b>	zRMS: Poland Authorization No.: not available, product is not authorised	cMS: not applicable, the application for authorisation is submitted only in Poland

#### 0.1.3 Regulatory history of the active(s)

##### 0.1.3.1 Quartz sand

**Table 0.1-2: Summary of regulatory history of CAS No: 14808-60-7**

<b>Status</b>	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2008/127/EC of 18 December 2008 amending Council Directive 91/414/EEC to include several active substances <a href="http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32008L0127">http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32008L0127</a> Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances <a href="http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011R0540">http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011R0540</a> Commission Implementing Regulation (EU) No 369/2012 of 27 April 2012 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances blood meal, calcium carbide, calcium carbonate, limestone, pepper and quartz sand <a href="http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32012R0369">http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32012R0369</a>
RMS	Austria
Date of Approval	01/09/2009
Current expiration of approval	<del>31/08/2022</del> 31/08/2023
Low risk substance or Candidate for Substitution?	NA

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

In assessing applications to authorise plant protection products containing quartz sand for uses other than on trees in forestry, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorization is granted.

The SANCO report for quartz sand (SANCO/2628/08 – rev. 2-3, 9 March 2012) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on ~~2011~~ 2022.

**Table 0.1-3: Table 0.1-4: Information on minimum purity of quartz sand**

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
minimum purity of quartz sand is 915 g/kg	minimum purity of quartz sand 990 g/kg Equivalence report available: Y RMS: Latvia

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

\*\*. If the specification of the active substance is different to that used as reference specification for EU approval then please

refer to the equivalency document from the RMS.

#### 0.1.4 Regulatory history of the product

Not relevant as the product has not yet been authorised.

#### 0.2 zRMS conclusion

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

Efficacy section: 1-14  
Residues section: 1-14  
Environmental fate and behavior section: 1-14  
Ecotoxicology section: 1-14

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

Efficacy section: none  
Residues section: none  
Environmental fate and behavior section: none  
Ecotoxicology section: none

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant CMS:

Residues section: none

~~All uses/ GAPs are covered by established MRLs except for use in crop. An application for amending the MRL has been submitted by MS to EFSA EFSA Project Number (if applicable).~~  
Residues section: No MRLs are proposed.

zRMS main conclusions:

**Physical-chemical properties section:** 2-years ambient storage stability data is ongoing.

**Analytical methods section:** No data gaps.

**Efficacy section:** Gorzka Kora can be granted, in line to accepted GAP table against ruminant animals (against bark **damage stripping** and browsing **damages**). Squirrel family and beaver family is not accepted. Lagomorphs are accepted **only** conditionally against **bark browsing** damages of trees. All minor uses included in GAP table and label project are accepted.

**Mammalian toxicology section:** GORZKA KORA is not classified and is not subject to operator, employee and bystander / resident. According to the EFSA Journal 2011;9(7):2300 Paintbrush and gloves application of quartz sand formulated as a paste was not considered to be a source of significant exposure

**Fate section:** no risk to groundwater after application product according to the GAP.

**Ecotoxicology section:** No data gaps. All minor uses in line to GAP table are accepted.

## Appendix 1 ALL intended uses

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 <sup>(d)</sup>  
Verified by MS: no

Formulation type: PA <sup>(a, b)</sup>  
Conc. of as: 251 g/kg <sup>(c)</sup>  
Conc. of safener: not relevant <sup>(c)</sup>  
Conc. of synergist: not relevant <sup>(c)</sup>  
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. <sup>(e)</sup>	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: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safen- er/synergist per ha <sup>(f)</sup>
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val 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 (browsing damages)	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 kg/1000 plants	Not relevant.	Not relevant.	- Eff. section: accepted only ruminant animals and lagomorphs (conditionally Squirrel family, lagomorph, and beaver family – not accepted.
2	PL	Deciduous and coniferous trees in forestry	Fpn	Browsing damage by: Ruminant animals: - deer family - roe family - fallow deer (bark stripping) and Lagomorph	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/1000 plants	Not relevant.	Not relevant.	-Eff section. Lagomorph is accepted conditionally
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/1000 plants	Not relevant	Not relevant	-
4	PL	Pear, plum, sweet cherry, sour cherry,	F	Browsing damage caused by Ruminant animals:	Coating manually with	Late autumn when game starts to	1 per year	Not relevant	2-5 kg/1000 plants	0.5-1.3 kg/1000 plants	Not relevant	Not relevant	-



		peach, apricot, hazel, walnut, quince		- deer family - roe family - fallow deer Lagomorphs Squirrel family Beaver family	special brush or glove	damage seedlings				plants			
5	PL	Gooseberry, choke berry, highbush blueberry, vines	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	-
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	-
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	
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	Coating manually with special brush or	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	<b>Eff. section:</b> lagomorph is accepted conditionally

				- fallow deer and Lagomorphs	glove								
9	PL	Deciduous and coniferous trees in forest- ry	Fpn	Bark stripping damage 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 kg/10 plants	Not relevant.	Not relevant.	Eff. section: only ruminant animals - accepted
Minor uses for which application is submitted - non-professional use													
10	PL	Forest nursery plants, renewals, afforestation and seed plantations of forest trees; ornamental shrubs and trees; Christmas trees grown on plantations,	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/1000 plants	Not relevant	Not 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/1000 plants	Not relevant	Not relevant	
12	PL	Gooseberry,	Fn	Browsing damage	Coating	Young	1 per	Not relevant	0,02-0,05	0,005-	Not relevant	Not	

		choke berry, highbush blueberry, vines		caused by Ruminant animals: - deer family - roe family - fallow deer Lagomorphs Squirrel family Beaver family	manually with special brush or glove.	shoots, 2-5 years old, autumn (Sept.-Nov.)	year	vant	kg/10 plants	0,013 kg as/1000 plants	vant	relevant	
13	PL	Ornamental trees, Christ- mas 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 seed- lings	1 per year.	Not rele- vant.	0,10-0,13 kg/10 plants	0,25- 0,33 ka as/10 plants	Not rele- vant	Not relevant	
14	PL	Pear, plum, sweet cherry, sour cherry, peach, apri- cot, hazel, walnut	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 seed- lings	1 per year.	Not rele- vant.	0,10-0,13 kg/10 plants	0,25- 0,33 ka as/10 plants	Not rele- vant	Not relevant	

**Remarks table heading:**

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  
(b) Catalogue of pesticide formulation types and international coding system CropLife  
International Technical Monograph n°2, 6th Edition Revised May 2008  
(c) g/kg or g/l

(d) Select relevant  
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1  
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

<b>Remarks columns:</b>	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
		13	PHI - minimum pre-harvest interval	
		14	Remarks may include: Extent of use/economic importance/restrictions	