FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

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: 10/2022

MS Finalisation date: 02/2023; 05/2023

Version history

When	What
01/2023	GAP table completed by the Applicant
02/2023	zRMS assessment
05/2023	Final Registration Report

Table of Contents

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

According to the EFSA Journal 2022;20(9):7552 a negligible exposure for the consumers to residues of quartz sand is expected when the representative uses are considered, and a consumer dietary risk assessment can be waived. No MRLs are proposed.

Due to the inert and insoluble properties of its constituents, quartz sand is not expected to degrade or to form other metabolites relevant for the consumers when used in compliance with the representative uses.

Proposed uses are accepted.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation GORZKA KORA are presented in Table 7.1-1. They have been selected from the individual GAPs in the zone for forestry and several minor crops – forest nursery, ornamental trees, pear, plum, sweet cherry, cherry, peach, apricot, hazel, walnut, gooseberry, chokeberry, highbush blueberry, grapevine. A list of all intended uses within the zone is given in Part B, Section 0.

Overall conclusion

GORZKA KORA is to be applied on trees when there is no edible parts (what is more it is used outside the plant growing season – on November/December). Additionally, quartz sand is an inert material, which is poorly absorbed after oral exposure and the toxicological relevance of quartz sand is mainly via inhalative exposure due to dust. No MRLs has been assigned and quartz sand is in Annex IV of Regulation 396/2005. No consumer risk assessment is also required.

According to available data, no specific mitigation measures should apply.

Data gaps

Data gaps should be listed in the summary to give an overview (especially for cMS).

Noticed data gaps are:

- none

Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	Crop and/ or situation **	Zone	Product code	F, Fn, Fpn G, Gn, Gpn or I***	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
1	Deciduous and conifer-ous trees in forestry	PL	GK-4	Fpn	Bark damage caused by: Rumi-nant animals: - deer family - roe family - fallow deer Lagomorphs Squirrel family Beaver family (browsing dam-ages)	PA	251 g/kg	Coating manually with special brush or glove.	Late au-tumn when game starts to damage seedlings	1 per year.	NR	NR	NR	2,5-3,3 ka as/1000 plants	NR	A

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** Use also code numbers according to Annex I of Regulation (EU) No 396/2005
*** 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

Explanation for Column 11 "Conclusion"

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

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

PPP (product name):	GORZKA KORA	Formulation type:	PA [a, b]
Active substance:	quartz sand	Conc. of as:	251 g/kg [c]
Safener:	not relevant	Conc. of safener:	not relevant [c]
Synergist:	not relevant	Conc. of synergist:	not relevant [c]
Applicant:	Przedsiębiorstwo Produkcyjno-Handlowe ADW Sp. z o.o.	Professional use:	☒
Zone(s):	Central Zone [d]	Non professional use:	☒
Verified by MS:	no		

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:**
					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		e.g. g safener/synergist per ha [f]

Zonal uses – Art. 33													
1	PL	Deciduous and coniferous trees in forestry	Fpn	Bark 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 kas/1000 plants	Not relevant.	Not relevant.	A
2	PL	Deciduous and coniferous trees in forestry	Fpn	Browsing damage caused by: Ruminant animals: - deer family - roe family - fallow deer (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.	A
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	A
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	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	A

				Beaver family									
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	A
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	A
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	A
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 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	A
9	PL	Deciduous and coniferous trees in forestry	Fpn	Bark damage caused by: Ruminant animals: - deer family - roe family - fallow deer Lagomorphs	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.	A

				Squirrel family Beaver family (browsing damages)									
Minor uses for which application is submitted - non-professional use													
10	PL	Forest nursery plants, renew-als, afforesta-tion and seed plantations of forest trees; ornamental shrubs and trees; Christ-mas 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 rele-vant	0,02-0,05 kg/10 plants	0.005-0,013 kg as/1000 plants	Not relevant	Not relevant	A
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 rele-vant	0,02-0,05 kg/10 plants	0.005-0,013 kg as/1000 plants	Not relevant	Not relevant	A
12	PL	Gooseberry, choke berry, highbush blue-berry, 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 rele-vant	0,02-0,05 kg/10 plants	0.005-0,013 kg as/1000 plants	Not relevant	Not relevant	A
13	PL	Ornamental trees, Christ-mas trees grown on plantations	Fn	Bark stripping caused by Ruminant animals: - deer family - roe family	Coating manually with special brush or	Late autumn when game starts to dam-age seedlings	1 per year.	Not rele-vant.	0,10-0,13 kg/10 plants	0,25-0,33 ka as/10 plants	Not relevant	Not relevant	A

				- fallow deer	glove								
14	PL	Pear, plum, sweet cherry, sour cherry, peach, apricot, 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 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	A

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.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
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)
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
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.
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.
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
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
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.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
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

7.1.2 Summary of the evaluation

Considering the nature and physico-chemical properties of quartz sand and the negligible exposure from the representative uses, the active substance quartz sand can be considered as toxicologically irrelevant. No ADI and ARfD values were derived during evaluation of this active substance.

7.1.2.1 Summary for quartz sand

No data available in DAR and EFSA Journal 2011;9(7):2300. No new data submitted in the framework of this application. 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 hence no residue studies, processing studies, studies on residues in succeeding crops were submitted. No consumer risk assessment is required.

7.1.2.2 Summary for GORZKA KORA

Table 7.1-2: Information on GORZKA KORA (KCA 6.8)

Crop	PHI for GORZKA KORA proposed by applicant	PHI/ Withholding period* sufficiently supported for quartz sand	PHI for GORZKA KORA proposed by zRMS	zRMS Comments (if different PHI proposed)
forestry	NR	NR	NR	NR
orchard	NR	NR	NR	NR
shrubs	NR	NR	NR	NR
ornamental trees	NR	NR	NR	NR
nursery forestry	NR	NR	NR	NR

NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Table 7.1-3: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for GORZKA KORA
Crop group	Led by quartz sand	
No applicable – product is intended to use in perennial crops.	NR	NR

NR: not relevant

7.2 Quartz sand

General data on quartz sand are summarized in the table below (EFSA Journal 2011;9(7):2300).

Table 7.2-1: General information on quartz sand

Active substance (ISO Common Name)	quartz sand (no ISO name allocated)
IUPAC	quartz, dioxosilane
Chemical structure	
Molecular formula	SiO_2
Molar mass	60.08 g/mol
Chemical group	inorganic compound
Mode of action (if available)	mechanical contact action
Systemic	no
Company	not relevant
Rapporteur Member State (RMS)	Austria
Approval status	Commission Directive 2008/127/EC of 18 December 2008 amending Council Directive 91/414/EEC to include several active substances http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32008L0127 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 http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32011R0540 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 http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32012R0369
Restriction	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. This application concerns only use in forestry hence it is not relevant.
Review Report	Review Report: SANCO/2628/08-rev. 2-3, 9 March 2012 EFSA Conclusion: EFSA Journal 2011;9(7):2300
Current MRL regulation	not relevant
Current MRL applications on intended uses	not relevant

* Notifier in the EU process to whom the a.s. belong(s)

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No data available in DAR and EFSA Journal 2011;9(7):2300. No residues studies for GORZKA KORA was provided so stability of residues during storage of samples is not required. No new data submitted in the framework of this application.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

No data available in DAR and EFSA Journal 2011;9(7):2300. No sample extracts were stored more than 24 hours so stability of residues in sample extracts is not required. No new data submitted in the framework of this application.

7.2.2 Nature of residues in plants, livestock and processed commodities

No data available in DAR and EFSA Journal 2011;9(7):2300. GORZKA KORA is to be applied on trees and bushes and will not be used on edible parts of crops hence no studies on residues in primary crops are required. Additionally, nature of residues in plants, livestock and processed commodities was evaluated as not relevant in DAR. No MRLs were assigned and quartz sand is in Annex IV of Regulation 396/2005. No new data submitted in the framework of this application.

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Not relevant. See point 7.2.2.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Not relevant. See point 7.2.2.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Not relevant. See point 7.2.2.

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Not relevant. See point 7.2.2.

7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Not relevant. See point 7.2.2.

7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Not relevant. See point 7.2.2.

7.2.3 Magnitude of residues in plants (KCA 6.3)

No data available in DAR and EFSA Journal 2011;9(7):2300. GORZKA KORA is to be applied on trees and bushes and will not be used on edible parts of crops hence no studies on residues in primary crops are required. Additionally, magnitude of residues in plants was evaluated as not relevant in DAR. No MRLs were assigned and quartz sand is in Annex IV of Regulation 396/2005. No new data submitted in the framework of this application

7.2.3.1 Summary of European data and new data supporting the intended uses

Not relevant. See point 7.2.3.

7.2.3.2 Conclusion on the magnitude of residues in plants

Not relevant. See point 7.2.3.

7.2.4 Magnitude of residues in livestock

No data available in DAR and EFSA Journal 2011;9(7):2300. GORZKA KORA is to be applied on trees and bushes and will not be used on edible parts of crops hence no residues studies are required. Additionally, magnitude of residues in livestock was evaluated as not relevant in DAR. No new data submitted in the framework of this application.

7.2.4.1 Dietary burden calculation

Not relevant. See point 7.2.5.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Not relevant. See point 7.2.5.

7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

No data available in DAR and EFSA Journal 2011;9(7):2300. GORZKA KORA is to be applied on trees and bushes and no residues expected in edible parts of crops. Additionally, nature and magnitude of residues in plants was evaluated as not relevant in DAR. No MRLs were assigned and quartz sand is in Annex IV of Regulation 396/2005. Hence no processing studies are required. No new data submitted in the framework of this application.

7.2.5.1 Available data for all crops under consideration

Not relevant. See point 7.2.6.

7.2.5.2 Conclusion on processing studies

Not relevant. See point 7.2.6.

7.2.6 Magnitude of residues in representative succeeding crops

Not relevant. No data available in DAR and EFSA Journal 2011;9(7):2300. GORZKA KORA is to be applied on trees and bushes which are perennial crops. No new data submitted in the framework of this application.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Not relevant. See point 7.2.6.

7.2.7 Other / special studies (KCA6.10, 6.10.1)

Not relevant. No other/special studies are provided.

7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

As ADI and ARfD was not deemed necessary, consumer exposure is not required.

7.2.8.1 Input values for the consumer risk assessment

Not relevant. See point 7.2.8.

7.2.8.2 Conclusion on consumer risk assessment

Not relevant. See point 7.2.8.

7.3 Combined exposure and risk assessment

No relevant. Product contains one active substance. Additionally, as ARfD was not deemed necessary, consumer exposure is not required

7.3.1 Acute consumer risk assessment from combined exposure

Please refer to Point 7.3.

7.3.2 Chronic consumer risk assessment from combined exposure

Please refer to Point 7.3.

7.4 References

- Conclusion on the peer review of the pesticide risk assessment of the active substance quartz sand (EFSA Journal 2011;9(7):2300)
- Draft Assessment Report for quartz sand

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
-	-	-	-	-	-

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
-	-	-	-	-	-

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
-	-	-	-	-	-

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
-	-	-	-	-	-

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Quartz sand

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

No new studies were submitted.

A 2.1.1.1.1 Storage stability of residues in plant products

No new studies were submitted.

A 2.1.1.1.2 Storage stability of residues in animal products

No new studies were submitted.

A 2.1.2 Nature of residues in plants, livestock and processed commodities

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

No new studies were submitted.

A 2.1.2.1.2 Nature of residue in rotational crops

No new studies were submitted.

A 2.1.2.1.3 Nature of residues in processed commodities

No new studies were submitted.

A 2.1.2.2 Nature of residues in livestock

No new studies were submitted.

A 2.1.3 Magnitude of residues in plants

No new studies were submitted.

A 2.1.4 Magnitude of residues in livestock

No new studies were submitted.

A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

No new studies were submitted.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new studies were submitted.

A 2.1.7 Other/Special Studies

No new studies were submitted.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

Not relevant. No calculation was submitted.

A 3.2 IEDI calculations

Not relevant. No calculation was submitted.

A 3.3 IESTI calculations - Raw commodities

Not relevant. No calculation was submitted.

A 3.4 IESTI calculations - Processed commodities

Not relevant. No calculation was submitted.

Appendix 4 Additional information provided by the applicant

Not relevant. No additional information is provided.