FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

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: October 2022

MS Finalisation date: January 2023; May 2023

Version history

When	What
01.2023	First assessment by zRMS.
05.2023	Final Registration Report

Table of Contents

8 Fate and behaviour in the environment (KCP 9)

This document reviews the environmental fate studies and modelling for the product This document reviews the environmental fate studies and modelling for the product GORZKA KORA, a paste formulation containing 251 g/kg quartz sand for use in forestry and several minor crops – forest nursery, ornamental trees, pear, plum, sweet cherry, cherry, peach, apricot, hazel, walnut, gooseberry, chokeberry, highbush blueberry, grapevine. Quartz sand was first included in Annex I to Directive 91/414/EEC by Commission Directive 2008/127/EC of 18 December 2008.

A risk assessment according to Uniform Principles is provided which demonstrates that the product is safe for the environment.

Where appropriate this document refers to the conclusions of the EU review of 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 additional data/information should be considered at national re-registration.

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

The Commission Implementing Regulation for quartz sand (540/2011) provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on quartz sand (SANCO/2628/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.
Conditions of use shall include, where appropriate, risk mitigation measures.

Information on the detailed composition of GORZKA KORA can be found in the confidential dossier of this submission (Registration Report - Part C).

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the formulated product

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, 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	**Conclusion**
					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			Groundwater
Zonal uses														
1	Deciduous and coniferous trees in forestry	PL	GK-4	Fpn	Bark damage caused by: Ruminant animals: - deer family - roe family - fallow deer Lagomorphs Squirrel family Beaver family (browsing damages)	PA	251 g/kg	Coating manually with special brush or glove.	Late autumn when game starts to damage seedlings	1 per year.	NR	NR	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

** 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 15 “Conclusion”

A	Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

8.2 Metabolites considered in the assessment

Table 8.2-1: Metabolites of quartz sand potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
Not relevant.	Not relevant.	Not relevant.	Not relevant.	Not relevant.

8.3 Rate of degradation in soil (KCP 9.1.1)

Not relevant. Due to the naturally occurrence of quartz sand in the environment, specific environmental fate studies are not required.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

Not relevant. See point 8.3.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Not relevant. See point 8.3.

8.4 Field studies (KCP 9.1.1.2)

Not relevant. Due to the naturally occurrence of quartz sand in the environment, specific environmental fate studies are not required.

8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

Not relevant. See point 8.4.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Not relevant. See point 8.4.

8.5 Mobility in soil (KCP 9.1.2)

Not relevant. Due to the naturally occurrence of quartz sand in the environment, specific environmental fate studies are not required.

8.5.1 Column leaching (KCP 9.1.2.1)

Not relevant. See point 8.5.

8.5.2 Lysimeter studies (KCP 9.1.2.2)

Not relevant. See point 8.5.

8.5.3 Field leaching studies (KCP 9.1.2.3)

Not relevant. See point 8.5.

8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

Not relevant. Due to the naturally occurrence of quartz sand in the environment, specific environmental fate studies are not required.

8.7 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

8.7.1 Justification for new endpoints

Not relevant. No new endpoints were used.

8.7.2 Active substance(s) and relevant metabolite(s)

Not relevant for the environmental exposure assessment. Silicon dioxide naturally occurs in the environment. Taking into account application method (manually coating trees with gloves or brush) no entry of the active substance into soil is expected. PECs calculation is not considered necessary.

zRMS comment:

No calculations of PECs are deemed necessary and a calculation has not been done upon inclusion in Annex I (see DAR Quartz sand, September 2008 and Peer Review document EFSA 2011).
As no metabolites of toxicological concern are built during degradation no environmental exposure for metabolites is considered.
Quartz sand is a naturally occurring mineral mainly composed of silicon dioxide which is highly abundant in the earth's crust. Quartz is the main component of many rock types (granites, sandstones, etc), sands and soils.

8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

8.8.1 Justification for new endpoints

Not relevant. No new endpoints were used.

8.8.2 Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1)

Not relevant for the environmental exposure assessment. Silicon dioxide naturally occurs in the environ-

ment. Taking into account application method (manually coating trees with gloves or brush) no entry of the active substance into ground water is expected. PECgw calculation is not considered necessary.

zRMS comment:

No studies were performed. The amount of product dislocated by surface run off water is considered negligible as the product dries off to a water insoluble-coat. In addition, the active ingredient quartz sand is a naturally occurring mineral and would be indistinguishable from sediments. The active ingredient does not pose any harm to ground water.

8.9 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

8.9.1 Justification for new endpoints

Not relevant. No new endpoints were used.

8.9.2 Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5)

Not relevant for the environmental exposure assessment. Silicon dioxide naturally occurs in the environment. Taking into account application method (manually coating trees with gloves or brush) no entry of the active substance into surface water is expected. PECsw calculation is not considered necessary.

zRMS comment:

No studies were performed. The active substance quartz sand does not pose environmental harm. Application method by coating reduces exposure to surface water to negligible levels.
The active substance quartz sand does not pose environmental harm, no metabolites of harm are built.

8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

Not relevant for the environmental exposure assessment. Quartz sand is not a volatile compound so PECair calculation is not considered necessary.

zRMS comment:

Application will be done by brushing. The product will be coated onto barks of individual tree boles. The product dries off to a protective, water-insoluble film.

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 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 new Annex II studies

No new studies are submitted.

Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)

No additional information is submitted.