

FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

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.

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Version history

When	What
02.2023	First assessment by zRMS.
05.2023	Final Registration Report

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9 Ecotoxicology (KCP 10)

This document reviews the eco-toxicological studies for the product GORZKA KORA, a paste formulation containing 251 g/kg quartz sand for use 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.

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).

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
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: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ synergist per ha	Conclusion						
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber 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			Birds	Mammals	Aquatic organisms	Bees	Non-target arthro-	Soil organisms	Non-target plants
Zonal uses																				
1	PL	Deciduous and coniferous trees in forestry	Fpn	Bark dam-age caused by: Rumi-nant ani- mals: - 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.	10-14 kg/1000 plants	2,5-3,3 ka as/1000 plants	Not rele- vant.	Not relevant.	-	A	A	A	A	A	A	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 – 21 “Conclusion”

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

Remarks table:	<ul style="list-style-type: none">(1) Numeration necessary to allow references(2) Use official codes/nomenclatures of EU(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (<i>e.g.</i> 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 <u>and</u> 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	<ul style="list-style-type: none">(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
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9.1.1 Overall conclusions

9.1.1.1 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

Birds

Effects on birds for quartz sand and GORZKA KORA were not evaluated as part of the EU review of quartz sand. However further data on either GORZKA KORA or quartz sand are not relevant. Further data on GORZKA KORA is not relevant.

No risk assessment for effects on birds was carried since it was assessed that exposure is negligible and there is no unacceptable risk to birds from the proposed use.

Terrestrial vertebrates (other than birds)

Effects on terrestrial vertebrates other than birds for GORZKA KORA were not evaluated as part of the EU review of quartz sand. However further data on GORZKA KORA is not relevant as existing data on toxicity to terrestrial vertebrates other than birds is used and additional formulation data are not considered essential. Therefore all relevant data were assessed in the EU review.

No risk assessment for effects on terrestrial vertebrates other than birds was carried since it was assessed that exposure is negligible and there is no unacceptable risk to terrestrial vertebrates other than birds from the proposed use.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

Effects on aquatic organisms for GORZKA KORA were not evaluated as part of the EU review of quartz sand. Acute toxicity studies for GORZKA KORA were submitted and evaluated in Appendix 2 of this dRR and results were used for classification of the product. GORZKA KORA is not classified as dangerous for aquatic organisms.

No risk assessment for effects on aquatic organisms was carried since it was assessed that exposure is negligible and there is no unacceptable risk to aquatic organisms from the proposed use.

9.1.1.3 Effects on bees (KCP 10.3.1)

Effects on bees for quartz sand and GORZKA KORA were not evaluated as part of the EU review of quartz sand. However further data on GORZKA KORA is not relevant. Therefore all relevant data were assessed in the EU review.

No risk assessment for effects on bees was carried since it was assessed that exposure is negligible and there is no unacceptable risk to bees from the proposed use.

9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)

Effects on arthropods other than bees for quartz sand and GORZKA KORA were not evaluated as part of the EU review of quartz sand. However further data on GORZKA KORA is not relevant. Therefore all relevant data were assessed in the EU review.

No risk assessment for effects on arthropods other than bees was carried since it was assessed that exposure is negligible and there is no unacceptable risk to arthropods other than bees from the proposed use.

9.1.1.5 Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)

Effects on non-target soil meso- and macrofauna as well as soil microbial activity for quartz sand and GORZKA KORA were not evaluated as part of the EU review of quartz sand. However further data on GORZKA KORA is not relevant. Therefore all relevant data were assessed in the EU review.

No risk assessment for non-target soil meso- and macrofauna as well as soil microbial activity was carried since it was assessed that exposure is negligible and there is no unacceptable risk to non-target soil meso- and macrofauna as well as soil microbial activity from the proposed use.

9.1.1.6 Effects on non-target terrestrial plants (KCP 10.6)

Effects on non-terrestrial plants for quartz sand and GORZKA KORA were not evaluated as part of the EU review of quartz sand. However further data on GORZKA KORA is not relevant. Therefore all relevant data were assessed in the EU review.

No risk assessment for effects on non-terrestrial plants was carried since it was assessed that exposure is negligible and there is no unacceptable risk to non-terrestrial plants from the proposed use.

9.1.1.7 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Not relevant.

9.1.2 Grouping of intended uses for risk assessment

Not relevant. The risk assessment for non-target organisms is not required so grouping of uses for risk assessment is not necessary.

9.1.3 Consideration of metabolites

A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of GORZKA KORA is indicated in the table.

Table 9.1-2 Metabolites of quartz sand

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
Not relevant.	Not relevant.	Not relevant.	Not relevant.	Not relevant.

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

No avian toxicity studies have been carried out with quartz sand. However, the provision of further data on either quartz sand or GORZKA KORA is not considered essential, because quartz sand toxicity data for mammals evaluated in EU DAR demonstrated the low toxicity and quartz sand naturally occurs in the environment and birds are not assumed to feed on the treated plant material like the bark and the green parts of the trees and therefore exposure is negligible. Further data on the GORZKA KORA is not considered essential.

9.2.1.1 Justification for new endpoints

Not relevant. No new endpoints were used.

9.2.2 Risk assessment for spray applications

Not relevant. GORZKA KORA is not to be used if a form of spray. Birds are not assumed to feed on the treated plant material like the bark and the green parts of the trees and therefore exposure is negligible. Additionally, GORZKA KORA is a mechanical repellent and this mode of action is also assumed to work for birds. Risk assessment for birds is therefore not required.

9.2.2.1 First-tier assessment (screening/generic focal species)

Not relevant, see point 9.2.2.

9.2.2.2 Higher-tier risk assessment

Not relevant, see point 9.2.2.

9.2.2.3 Drinking water exposure

Not relevant, see point 9.2.2.

9.2.2.4 Effects of secondary poisoning

Not relevant, see point 9.2.2.

9.2.2.1 Biomagnification in terrestrial food chains

Not relevant.

9.2.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.2.4 Overall conclusions

GORZKA KORA is to be applied manually as a coating on trees so the exposure of mammals is negligible. GORZKA KORA is a mechanical repellent so it also repels birds. Quartz sand naturally occurs in several environmental compartments. No further studies with the formulation GORZKA KORA as well as risk assessment is required.

zRMS comment:

No toxicity data and risk assessment calculations for birds 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 the treated plant material generally does not constitute an attractive food item for birds and as it is likely that the product also has a slight repellent effect against birds, the risk for birds after application of quartz sand and GORZKA KORA according to the GAP is considered to be low.

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.

9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with quartz sand and lead formulations. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on mammals of GORZKA KORA were not evaluated as part of the EU assessment of quartz sand. However, the provision of further data on the formulation GORZKA KORA is not considered essential, because it is possible to extrapolate from data for the active substance. Additionally, avoidance of vertebrates studies is recommended.

Table 9.3-1: Endpoints and effect values relevant for the risk assessment for mammals

Species	Substance	Exposure System	Results	Reference
rat	quartz sand	oral, 1 d, acute	Data available of limited validity, no further data needed. LD ₅₀ = 500 mg/kg bw	EFSA Journal 2011;9(7):2300 & DAR for quartz sand, xxx, 1968, Report:-
rat	quartz sand (Cervacol)	oral, 1 d, acute	LD ₅₀ > 10 g/kg bw	EFSA Journal 2011;9(7):2300 & DAR for quartz sand, xxx, 1978a, Report: Report A o479/1527.01
rat	quartz sand (Morsuvin)	oral, 1 d, acute	LD ₅₀ > 2 g/kg bw	EFSA Journal 2011;9(7):2300 &

Species	Substance	Exposure System	Results	Reference
				DAR for quartz sand, xxx, 1998a, Report: 9867

9.3.1.1 Justification for new endpoints

Not relevant. No new endpoints were used.

9.3.2 Risk assessment for spray applications

Not relevant. GORZKA KORA is not to be used if a form of spray. Mammals are not assumed to feed on the treated plant material like the bark and the green parts of the trees and therefore exposure is negligible. Additionally, GORZKA KORA is a mechanical repellent and this mode of action is also assumed to work for mammals. Risk assessment for mammals is therefore not required.

9.3.2.1 First-tier assessment (screening/generic focal species)

Not relevant, see point 9.3.2.

9.3.2.2 Higher-tier risk assessment

Not relevant, see point 9.3.2.

9.3.2.3 Drinking water exposure

Not relevant, see point 9.3.2.

9.3.2.4 Effects of secondary poisoning

Not relevant, see point 9.3.2.

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.3.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.3.4 Overall conclusions

GORZKA KORA is to be applied manually as a coating on trees so the exposure of mammals is negligi-

ble. GORZKA KORA is a mechanical repellent so it also repels mammals. Quartz sand naturally occurs in several environmental compartments. No further studies with the formulation GORZKA KORA as well as risk assessment is required.

zRMS comment:

No risk assessment calculations for mammals 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 the treated plant material generally does not constitute an attractive food item for mammals and as it is likely that the product also has a slight repellent effect against mammals, the risk for mammals after application of quartz sand and GORZKA KORA according to the GAP is considered to be low.

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.

9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

Not relevant. No further data is required.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with lead formulations of quartz sand. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on aquatic organisms of GORZKA KORA were not evaluated as part of the EU assessment of quartz sand. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2. The results of new studies were used for classification of the product.

Endpoints and effect values relevant for the risk assessment for aquatic organisms – quartz sand

Species	Substance	Exposure System	Results	Reference
<i>Oncorhynchus mykiss</i>	quartz sand (Cervacol)	96 h, s	LC ₅₀ > 500 mg preparation/L _{nom} NOEC = 500 mg preparation/L _{nom}	EFSA Journal 2011;9(7):2300 & DAR, xxx, 2007; Report: 07/493-009H
<i>Oncorhynchus mykiss</i>	quartz sand (Wobra)	96 h, s	LC ₅₀ > 100 mg preparation/L _{nom} NOEC = 100 mg preparation/L _{nom}	EFSA Journal 2011;9(7):2300 & DAR, xxx, 1996; Report: FAR49721
<i>Poecilla reticulata</i>	quartz sand (Morsuvin)	96 h, s	LC ₅₀ = 36.9 mg preparation/L _{nom}	EFSA Journal 2011;9(7):2300 & DAR, xxx, 1998;

Species	Substance	Exposure System	Results	Reference
				Report: 76/L
<i>Daphnia magna</i>	quartz sand (Cervacol)	48 h, s	EC ₅₀ > 500 mg preparation/L _{nom} NOEC = 500 mg preparation/L _{nom}	EFSA Journal 2011;9(7):2300 & DAR, Hernadi D, 2007; Report: 07/493-023DA
<i>Daphnia magna</i>	quartz sand (Wobra)	48 h, s	EC ₅₀ > 1000 mg preparation/L _{nom} NOEC = 580 mg preparation/L _{nom}	EFSA Journal 2011;9(7):2300 & DAR, Noack M, 1996; Report: DA149721
<i>Daphnia magna</i>	quartz sand (Morsuvin)	48 h, s	EC ₅₀ = 92.06 mg preparation/L _{nom}	EFSA Journal 2011;9(7):2300 & DAR, Dolezalova, 1998; Report: 76/L
<i>Pseudokirchneriella subcapitata</i>	quartz sand (Cervacol)	72 h, s	E _b C ₅₀ >500 mg preparation/L _{nom} E _r C ₅₀ >500 mg preparation /L _{nom}	EFSA Journal 2011;9(7):2300 & DAR, Hernadi D, 2007; Report: 07/493-022AL
<i>Scenedesmus subspicatus</i>	quartz sand (Wobra)	72 h, s	E _b C ₅₀ >1000 mg preparation/L _{nom} E _r C ₅₀ >1000 mg preparation /L _{nom}	EFSA Journal 2011;9(7):2300 & DAR, Scheerbaum D, 1996; Report: SS049722
<i>Scenedesmus subspicatus</i>	quartz sand (Morsuvin)	72 h, s	E _b C ₅₀ =13.9 mg preparation/L _{nom}	EFSA Journal 2011;9(7):2300 & DAR, Dolezalova, 1998; Report: 76/L
Higher-tier studies (micro- or mesocosm studies)				
Not relevant.				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations

Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – GORZKA KORA

Species	Substance	Exposure System	Results	Reference
<i>Daphnia magna</i>	GORZKA KORA	48 h, s	EC ₅₀ >100* mg preparation /L _{nom}	Domagała J.2021
<i>Pseudokirchneriella subcapitata</i>	GORZKA KORA	72 h, s	EC ₅₀ > 100** mg preparation /L _{nom}	Domagała J.2021
Higher-tier studies (micro- or mesocosm studies)				
Not relevant.				

* due to lack of dose response, all endpoints were assumed as higher than the highest tested concentration >100 mg/L

** defined on the basis of an analysis of the results

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations

9.5.1.1 Justification for new endpoints

Not relevant. No new endpoints were used.

9.5.2 Risk assessment

Not relevant. GORZKA KORA is to be used as a coating onto trees so the exposure of aquatic organisms is considered to be negligible. Additionally, quartz sand naturally occurs in the environment. Risk assessment for aquatic organisms is therefore not required.

9.5.3 Overall conclusions

GORZKA KORA is to be applied manually as a coating on trees so the exposure of aquatic organisms is negligible. Additionally, quartz sand naturally occurs in the environment. Risk assessment for aquatic organisms is therefore not required. Toxicity studies performed for the active substance as well as the formulation is used for classification. GORZKA KORA is not classified as dangerous for aquatic organisms.

zRMS comment:

No risk assessment calculations for aquatic organisms 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).

Only acute aquatic invertebrates – *Daphnia magna* and algae studies – *Peudokirchneriella subcapitata* were available with **GORZKA KORA** formulation. However, all the available studies showed deficiencies (e.g. lack of analytical measurements) and, therefore, were only considered supportive. However, considering the application method and the properties of quartz sand the low risk was concluded for all aquatic organisms for all GORZKA KORA uses in GAP.

No PEC_{sw} calculations 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.

9.6 Effects on bees (KCP 10.3.1)

9.6.1 Toxicity data

No studies on the toxicity to bees have been carried out with quartz sand. Further data on GORZKA KORA is not considered essential since it is to be used manually as a coating onto trees and hence exposure of bees is considered negligible.

9.6.1.1 Justification for new endpoints

Not relevant. No new endpoints were used.

9.6.2 Risk assessment

Not relevant. GORZKA KORA is to be used as a coating onto trees so the exposure of bees is considered to be negligible. Additionally, quartz sand naturally occurs in the environment. Risk assessment for bees is therefore not required.

9.6.2.1 Hazard quotients for bees

Not relevant, see point 9.6.2.

9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

Not relevant, see point 9.6.2.

9.6.3 Effects on bumble bees

Not relevant, see point 9.6.2.

9.6.4 Effects on solitary bees

Not relevant, see point 9.6.2.

9.6.5 Overall conclusions

GORZKA KORA is to be applied manually as a coating on trees so the exposure of bees is negligible. Additionally, quartz sand naturally occurs in the environment. Risk assessment for bees is therefore not required.

zRMS comment:

No risk assessment calculations for bees 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).

The effect on bees of **GORZKA KORA** has not been assessed as the product is non-toxic, will be applied during late autumn when game starts to damage seedlings and vegetation rest and the exposure to the product is deemed of low significance. No studies are required where preparations containing active substances are intended for the exclusive use in situations where bees are not likely to be exposed.

The risk to bees is considered appropriate and no further consideration is required.

The lead formulations GORZKA KORA are used as a coating on trees (manually applied) and hence exposure of bees is considered to be low.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

No studies on the toxicity to non-target arthropods have been carried out with quartz sand. Further data

on GORZKA KORA is also not considered essential since it is to be used manually as a coating onto trees which is not a large-area application. Additionally, quartz sand naturally occurs in the environment and hence exposure of bees is considered negligible.

9.7.1.1 Justification for new endpoints

Not relevant. No new endpoints were used.

9.7.2 Risk assessment

Not relevant. GORZKA KORA is to be used as a coating onto trees so the exposure of non-target arthropods is considered to be negligible. Additionally, quartz sand naturally occurs in the environment. Risk assessment for non-target arthropods is therefore not required.

9.7.2.1 Risk assessment for in-field exposure

Not relevant, see point 9.7.2.

9.7.2.2 Risk assessment for off-field exposure

Not relevant, see point 9.7.2.

9.7.2.3 Additional higher-tier risk assessment

Not relevant, see point 9.7.2.

9.7.2.4 Risk mitigation measures

Not relevant, see point 9.7.2.

9.7.3 Overall conclusions

GORZKA KORA is to be applied manually as a coating on trees so the exposure of non-target arthropods is negligible. Additionally, quartz sand naturally occurs in the environment. Risk assessment for non-target arthropods is therefore not required.

zRMS comment:

No risk assessment calculations for arthropods other than bees 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).

Due to the facts that the formulations are used as a coating on trees, which is not a large-area application, and that quartz sand ubiquitously occurs in the environment, no testing is considered necessary.

The risk to arthropods other than bees is considered appropriate and no further consideration is required.

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

9.8.1 Toxicity data

No studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with quartz sand. 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 earthworms and other non-target soil organisms is considered negligible.

9.8.1.1 Justification for new endpoints

Not relevant. No new endpoints were used.

9.8.2 Risk assessment

Not relevant. GORZKA KORA is to be used as a coating onto trees so the exposure of earthworms and other non-target soil organisms is considered to be negligible. Additionally, quartz sand naturally occurs in the environment. Risk assessment for earthworms and other non-target soil organisms is therefore not required.

9.8.2.1 First-tier risk assessment

Not relevant, see point 9.8.2.

9.8.2.2 Higher-tier risk assessment

Not relevant, see point 9.8.2.

9.8.3 Overall conclusions

GORZKA KORA is to be applied manually as a coating on trees so the exposure of earthworms and other non-target soil organisms is negligible. Additionally, quartz sand naturally occurs in the environment. Risk assessment for earthworms and other non-target soil organisms is therefore not required.

zRMS comment:

No risk assessment calculations for soil meso- and macrofauna 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).

Due to the manual application of the formulations by coating trees with gloves or by brush no entry of the active substance/formulation into soil is expected. Therefore exposure of soil organisms is considered to be low.

The risk to soil meso- and macrofauna (including earthworms) is considered appropriate and no further consideration is required.

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

No studies on effects soil microorganisms have been carried out with quartz sand. 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 for soil microorganisms is considered negligible.

9.9.1.1 Justification for new endpoints

Not relevant. No new endpoints were used.

9.9.2 Risk assessment

Not relevant. GORZKA KORA is to be used as a coating onto trees so the exposure of soil microorganisms is considered to be negligible. Additionally, quartz sand naturally occurs in the environment. Risk assessment for soil microorganisms is therefore not required.

9.9.3 Overall conclusions

GORZKA KORA is to be applied manually as a coating on trees so the exposure of soil microorganisms is negligible. Additionally, quartz sand naturally occurs in the environment. Risk assessment for soil microorganisms is therefore not required.

zRMS comment:

No risk assessment calculations for soil microorganisms 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).

Due to the manual application of the formulations by coating trees with gloves or by brush no entry of the active substance/formulation into soil is expected. Therefore exposure of soil microorganisms is considered to be low.

The risk to soil microorganisms is considered appropriate and no further consideration is required.

9.10 Effects on non-target terrestrial plants (KCP 10.6)

9.10.1 Toxicity data

No studies on the toxicity to non-target terrestrial plants have been carried out with quartz sand. 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 for non-target plants is considered negligible.

9.10.1.1 Justification for new endpoints

Not relevant. No new endpoints were used.

9.10.2 Risk assessment

Not relevant. GORZKA KORA is to be used as a coating onto trees and no drift occurs so the exposure of non-target plants is considered to be negligible. Additionally, quartz sand naturally occurs in the environment. Risk assessment for non-target plants is therefore not required.

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant, see point 9.10.2.

9.10.2.2 Tier-2 risk assessment (based on dose-response data)

Not relevant, see point 9.10.2.

9.10.2.3 Higher-tier risk assessment

Not relevant, see point 9.10.2.

9.10.2.4 Risk mitigation measures

Not relevant, see point 9.10.2.

9.10.3 Overall conclusions

GORZKA KORA is to be applied manually as a coating on trees and no drift occurs so the exposure of non-target plants is negligible. Additionally, quartz sand naturally occurs in the environment. Risk assessment for soil microorganisms is therefore not required.

zRMS comment:

No risk assessment calculations for non-target plants 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 EF-SA 2011).

Due to the facts that the formulations are used as coating on trees, which is not a large-area application, and that quartz sand occurs ubiquitously in the environment, the risk to other non-target plants is considered to be low.

The risk to non-target plants is considered appropriate and no further consideration is required.

9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Not relevant.

9.12 Monitoring data (KCP 10.8)

Not relevant.

9.13 Classification and Labelling

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to ecotoxicological data is proposed for the preparation:

Table 9.13-1: Justified proposals for classification and labelling for GORZKA KORA according to Regulation (EC) No 1272/2008 with regard to ecotoxicological data

Hazard class(es), categories:	-
Hazard pictograms or Code(s) for hazard pictogram(s):	-
Signal word:	-
Hazard statement(s):	-
Precautionary statement(s):	-
Additional labelling phrases:	EUH401 To avoid risks to man and the environment, comply with the instructions for use.
	SP1 Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).

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 2.2.1/02	Domagała J.	2021	Title Daphnia acute immobilization test according to guideline OECD 202 Company Report No 0068/0002/E Source SORBOLAB Research Laboratory LCC GLP Unpublished	N	ADW*
KCP 2.2.1/03	Domagała J.	2021	Title Freshwater algae (Pseudokirchneriella subcapitata) growth inhibition test according to guideline OECD 201 Company Report No Source SORBOLAB Research Laboratory LCC GLP Unpublished	N	ADW*

* Przedsiębiorstwo Produkcyjno-Handlowe ADW Sp. z o.o.

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 10.1.2/01	xxx	1968	Title: no data, information from IUCLID (2002a) Report No.: no data Source: IUCLID GLP: no data Published: no data	Y	No data.
KCP 10.1.2/02	xxx	1978a	Bestimmung der LD50 und Erfassung toxischer Symptome von “Cervacol” nach 1-maliger intragastraler Applikation an der männlichen und weiblichen Ratte Report No.: Report A o479/1527.o1 Source: no data no GLP Unpublished	Y	Stähler International GmbH
KCP 10.1.2/03	xxx	1998a	Acute oral toxicity; unpublished report 9867 Report No.: 9867 Source: no data GLP Unpublished	Y	Nera Agro
KCP 10.2/01	xxx	2007	Fish acute toxicity study with Cervacol Extra on rainbow trout (<i>Oncorhynchus mykiss</i>) Report No.: 07/493-009H Source: no data GLP Unpublished	Y	Stähler International GmbH & Co. KG, Stade, Germany
KCP 10.2/02	xxx	1996	Fish (Rainbow Trout), Acute Toxicity Test (Limit Test), 96 h Report No.: FAR49721 Source: no data GLP Unpublished	Y	Flügel GmbH
KCP 10.2/03	xxx	1998	Test T37– Acute Toxicity Test in Fish	Y	Nera Agro

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
			Výzkumný ústav organických syntéz a.s. Report No.: 76/L Source: Research Institute for Organic Syntheses GLP Published: no data		
KCP 10.2/04	Hernadi D	2007	Acute immobilisation test with Cervacol Extra on Daphnia Magna Report: 07/493-023DA Source: LAB International Research Center Hungary GLP Unpublished	N	Stähler International GmbH & Co. KG, Stade, Germany
KCP 10.2/05	Noack M	1996	Daphnia magna STRAUS Acute Immobilisation Test, 48 h Report: DA149721 Source: Dr. U. Noack-Laboratorium für Angewandte Biologie, Hildesheim, Germany GLP Unpublished	N	Flügel GmbH
KCP 10.2/06	Dolezalova	1998	Test T38 – Daphnia Acute Immobilization Test Výzkumný ústav organických syntéz a.s. Report No.: 76/L Source: Research Institute for Organic Syntheses GLP Published: no data	N	Nera Agro
KCP 10.2/07	Hernadi D	2007	Cervacol Extra. Growth Inhibition test on Algae Report No.: 07/493-022AL Source: LAB International Research Centre Hungary Ltd. GLP Published: no data	N	Stähler International GmbH & Co. KG, Stade, Germany

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 10.2/08	Scheerbaum D	1996	Alga, Growth Inhibition Test Report No.: SS049722 Source: Dr. U. Noack-Laboratorium für Angewandte Biologie, Hildesheim Germany GLP Published: no data	N	Flügel GmbH
KCP 10.2/09	Dolezalova	1998	Test T39 – Algal Growth Inhibition Test Výzkumný ústav organických syntéz a.s. Report No.: 76/L Source: Research Institute for Organic Syntheses GLP Published: no data	N	Nera Agro

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 studies

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

Not relevant. No avian toxicity studies have been carried out with GORZKA KORA. Further data on the GORZKA KORA is not considered essential since the active substance naturally occurs in the environment. Additionally, vertebrates studies should be avoided.

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

Not relevant. See point 2.1.1.1.

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

Not relevant. No mammal toxicity studies have been carried out with GORZKA KORA. Further data on the GORZKA KORA is not considered essential since the active substance naturally occurs in the environment. Additionally, vertebrates studies should be avoided.

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

Not relevant. See point 2.1.2.2.

A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

Not relevant. No vertebrate wildlife toxicity studies have been carried out with GORZKA KORA. Further data on the GORZKA KORA is not considered essential since the active substance naturally occurs in the environment. Additionally, vertebrates studies should be avoided.

A 2.2 KCP 10.2 Effects on aquatic organisms

A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

KCP 10.2.1 Fish

Not relevant. No fish acute toxicity studies have been carried out with GORZKA KORA. Further data on the GORZKA KORA is not considered essential since the active substance naturally occurs in the environment. Additionally, vertebrates studies should be avoided.

KCP 10.2.1 *Daphnia magna*

Comments of zRMS:	<p>Study was carried out according to appropriate OECD 202 and all validity criteria were met.</p> <p>The validity criteria:</p> <ul style="list-style-type: none">❖ in the control the number of immobilized daphnia at the end of the test was 0% (required: $\leq 10\%$)❖ the lowest oxygen concentration at the end of the test in the control and the tested concentrations was 9.73 mg/L (required: ≥ 3 mg/L). <p>Study limitation:</p> <ul style="list-style-type: none">❖ lack of analytical measurements. <p>No measured test concentrations are available and all endpoints are based on nominal values. Therefore, the study should be considered as supportive. However, considering the application method and the properties of quartz sand the low risk was concluded for all aquatic organisms for all GORZKA KORA uses in GAP. Risk assessment calculation or new data for aquatic organisms is not requirement.</p> <p><i>Daphnia magna</i>:</p> <p>Toxicity endpoints as supportive:</p> <p>48h/LC₅₀ > 100 mg formulation/L_{nom}</p> <p>48h/NOEC > 100 mg formulation/L_{nom}</p>
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Reference:	KCP 10.2.1/02
Report	Daphnia acute immobilization test according to guideline OECD 202, Domagała J., 2021, Report No.: 0068/0002/E
Guideline(s):	Yes, OECD 202
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

The study was conducted for daphnia (*Daphnia magna*) collected from own culture of the SORBOLAB Research Laboratory. Culture is conducted in laboratory conditions in temperature 20±2°C, light intensity 1000-1500 lux, daily cycle: 16 h day / 8 h night on M7 medium, pH 6-9. Daphnia are fed with green algae *Raphidocelis subcapitata* originate from own culture of the SORBOLAB Research Laboratory.

In the study the daphnia no older than 24 h, being not the first brood progeny were used, originating from a healthy culture shows no signs of stress such as: high mortality, presence of males, ephippia, delay in the production of the first brood, discoloring.

The test item was directly dissolved in the M7 medium. The remaining concentrations were prepared using the dilution method. Solubility test was not performed.

In the range finding test, the following concentrations of test item were used: 1 mg/L; 10 mg/L; 100 mg/L and control (0 mg/L). All concentrations of the test item and control were prepared in one repetition.

Results and discussions

During the range finding test, the following parameters were observed and recorded:

- The number of immobilized individuals in each test vessel after 24 and 48 hours from the beginning of the test (Table 2.2.1-1).

Table 2.2.1-1: Immobilization of daphnia after 24 h and 48 h– range-finding test

Time	Concentration [mg/L]	Immobilized daphnia [pcs.]	Introduced daphnia [pcs.]	Immobilized daphnia [%]	Statistical significance*)
24 h	control	5	0	0	not applicable
	1	5	0	0	-
	10	5	0	0	-
	100	5	1	20	-
48 h	control	5	0	0	not applicable
	1	5	0	0	-
	10	5	0	0	-
	100	5	1	20	-

- not statistically significant

*) values calculated by ToxRat Professional using the Fisher test after Bonferroni correction at the significance level of $p \geq 0.05$

Based on the data obtained, a statistical analysis was carried out in accordance with OECD guideline 202 using the ToxRat Professional statistical program (version 3.3) and according to OECD 54

The final results of the range-finding test are presented in Table 2.2.1-2

Table 2.2.1-2: Final results – range-finding test

Final results calculated by ToxRat Professional		
Parametr	Time of measurement	
	24 h	48 h
EC10 [mg/L]	80.128 (nd. – nd.)*	80.128 (nd. – nd.)*
EC50 [mg/L]	152.781 (nd – nd.)*	152.781 (nd. – nd.)*
EC95 [mg/L]	349.797 (nd – nd.)*	349.797 (nd. – nd.)*
LOEC [mg/L]	>100,0	>100,0
NOEC [mg/L]	≥100,0	≥100,0

EC10 effective concentration of test item for 10% reduction

EC50 effective concentration of test item for 50% reduction

EC95 effective concentration of test item for 95% reduction

LOEC lowest observe effective concentration cause statistically significant differences in comparison to the control
NOEC highest non observe effective concentration cause no statistically significant differences in comparison to the control
n.d. not determined as no effects were observed (no dose response)
* the lower and upper 95% confidence limits are given in brackets

Conclusion

The tested item did not statistically significantly affect the immobilization of daphnia after 24 h and 48 h of exposure at the concentration of 6,25 mg/L; 12,5 mg/L; 25 mg/L; 50 mg/L; 100 mg/L. Based on the analysis of the results, the EC10, EC50, EC95, NOEC and LOEC (with 95% confidence limits) were determined to be >100 mg/L. According to the Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16th December, 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No. 1907/2006, GORZKA KORA is beyond the classification.

KCP 10.2.1 Algae

Comments of zRMS:	<p>The study was conducted to OECD guideline 201 and according to the principles of GLP. In the definitive test the validity criteria were met.</p> <p>The validity criteria:</p> <ul style="list-style-type: none"> ❖ yield in control during 72 hours of test increased exponentially 109.9 times (requirements according to OECD 201: ≥ 16); ❖ the coefficient of variance for the average specific growth rate for all repetitions of the control culture over the entire time of the test was 4.7% (requirements according to OECD 201: $< 7\%$); ❖ the average coefficient of variance for a specific growth rate day after day (0-24 h, 24-48 h, 48-72 h) for the control culture was 20.5% (requirements according to OECD 201: $< 35\%$). <p>Study limitation:</p> <ul style="list-style-type: none"> ❖ lack of analytical measurements and, therefore, the study was considered as supportive. <p>No measured test concentrations are available and all endpoints are based on nominal values. However, considering the application method and the properties of quartz sand the low risk was concluded for all aquatic organisms for all GORZKA KORA uses in GAP.</p> <p><i>Pseudokirchneriella subcapitata</i> Toxicity endpoints as supportive: 72-h $E_yC_{50} > 100$ mg/L based on nominal concentration 72-h $E_yC_{10} > 100$ mg/L based on nominal concentration 72-h $E_yC_{20} > 100$ mg/L based on nominal concentration 72-h $NOE_yC > 100$ mg/L based on nominal concentration 72-h $E_rC_{50} > 100$ mg/L based on nominal concentration 72-h $E_rC_{10} > 100$ mg/L based on nominal concentration 72-h $E_rC_{20} > 100$ mg/L based on nominal concentration 72-h $NOE_rC > 100$ mg/L based on nominal concentration</p>
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Reference:

KCP 10.2.1/03

Report	Freshwater algae (<i>Pseudokirchneriella subcapitata</i>) growth inhibition test according to guideline OECD 201, Domagała J., 2021, Report No.: 0068/0001/E
Guideline(s):	Yes, OECD 201
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

The study was conducted on algae *Pseudokirchneriella subcapitata*, obtained from culture from Laboratory of Ecotoxicology in SORBOLAB Research Laboratory. Algae are cultured in a laboratory incubator at 21-24°C±2°C, with constant lighting in the range of 4440-8880 lux and shaking at 90 rpm. As a culture medium, the AAP medium is used, pH 7,5±0,1. The culture conditions are in accordance with the recommendations of the OECD Guideline 201. As an inoculum, the algae in the logarithmic growth stage was used to start the test. The following concentrations of the test item were used in the range-finding test: 1 mg/L, 10 mg/L, 100 mg/L and control (0 mg/L). All concentrations of the test item were prepared in two repetitions and the control in four. In addition, one replicate was prepared for each concentration without the addition of algae to measure background absorbance. The flasks were arranged randomly in accordance with SPT-E/55. The inoculum volume was 10000 cells/mL, and the preculture was established 3 days before the study. The experiment was carried out using the static method.

Results and discussions

In the course of the range-finding test, absorbance measurements at wavelength $\lambda 670$ nm were performed on each day for each repeat of the tested concentrations and control with regard to additional repetitions without the addition of algae. Measurements were carried out 3 times for each sample in cuvettes with an optical length of 50 mm. The number of algae cells was determined based on the prepared nomogram. Microscopic observations were made on the day of the end of the experiment to verify the abnormal appearance of the cells at each concentration and control.

On the basis of the obtained data, a statistical analysis was carried out in accordance with the OECD Guideline 201 using the ToxRat Professional statistical program (version 3.3) and according to OECD 54. The final results are presented in Table 2.2.1-3.

Table 2.2.1-3 Final results

Parameter	Yield	Average specific growth rate	Sectional growth rate
EC10 - 72 h [mg/L]	>100*	>100*	>100*
EC20 - 72 h [mg/L]	>100*	>100*	>100*
EC50 - 72 h [mg/L]	>100*	>100*	>100*
LOEC - 72 h [mg/L]	>100*	>100*	>100*
NOEC - 72 h [mg/L]	>100*	>100*	>100*

EC10 effective concentration of test item for 10% reduction

EC20 effective concentration of test item for 20% reduction
EC50 effective concentration of test item for 50% reduction
LOEC lowest observe effective concentration cause statistically significant differences in comparison to the control
NOEC highest non observe effective concentration cause no statistically significant differences in comparison to the control
* defined on the basis of an analysis of the results

Conclusion

In the course of the study the test item did not statistically significantly affect yield, average specific growth rate and sectional growth rate of algae *Pseudokirchneriella subcapitata* after 72 h exposure in concentration 100 mg/L. Based on the obtained results, EC10, EC20, EC50 (with 95% confidence limits) and NOEC and LOEC values were defined as >100 mg/L. According to the Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16th December, 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No. 1907/2006, GORZKA KORA is beyond the classification.

A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

Not relevant. No long term and chronic toxicity studies have been carried out with GORZKA KORA. Further data on the GORZKA KORA is not considered essential since the active substance naturally occurs in the environment. Additionally, vertebrates studies should be avoided.

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

Not relevant. No further studies are provided.

A 2.3 KCP 10.3 Effects on arthropods

A 2.3.1 KCP 10.3.1 Effects on bees

Not relevant. No studies on the toxicity to bees have been carried out with GORZKA KORA. Further data on the GORZKA KORA is not considered essential since it is to be used manually as a coating onto trees and hence exposure of bees is considered negligible.

A 2.3.1.1 KCP 10.3.1.1 Acute toxicity to bees

Not relevant. See point 2.3.1.

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

Not relevant. See point 2.3.1.

A 2.3.1.3 KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

Not relevant. See point 2.3.1.

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

Not relevant. See point 2.3.1.

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

Not relevant. See point 2.3.1.

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

Not relevant. See point 2.3.1.

A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna

Not relevant. See point 2.3.1.

A 2.4.1 KCP 10.4.1 Earthworms

A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

Not relevant. No studies on the toxicity to earthworms have been carried out with 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 earthworms is considered negligible.

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

Not relevant. See point 2.4.1.1.

A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

Not relevant. See point 2.4.1.1.

A 2.4.2.1 KCP 10.4.2.1 Species level testing

Not relevant. No studies on the toxicity to non-target soil organisms (meso- and macrofauna) have been carried out with 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 other non-target soil organisms is considered negligible.

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

Not relevant. See point 2.4.2.1.

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

No studies on effects soil microorganisms have been carried out with GORZKA KORA. Further data on the GORZKA KORA is 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 for soil microorganisms is considered negligible.

A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.6.1 KCP 10.6.1 Summary of screening data

Not relevant. No studies on the toxicity to non-target terrestrial plants have been carried out with GORZKA KORA. Further data on the GORZKA KORA is 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 for non-target plants is considered negligible.

A 2.6.2 KCP 10.6.2 Testing on non-target plants

Not relevant. See point 2.6.1.

A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants

Not relevant. See point 2.6.1.

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

Not relevant. See point 2.6.1.

A 2.8 KCP 10.8 Monitoring data

No monitoring data submitted.