

FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

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 |
|---------|---------------------------|
| 01/2023 | zRMS assessment of dRR |
| 05/2023 | Final Registration Report |
| | |
| | |

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6 Mammalian Toxicology (KCP 7)

This document reviews the mammalian toxicology for the product GORZKA KORA, a paste formulation containing 251 g/kg quartz sand for use on trees and bushes. 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 difenoconazole. 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.

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).

6.1 Summary

Table 6.1-1: Information on GORZKA KORA *

| | |
|--|-----------------------|
| Product name and code | GORZKA KORA |
| Formulation type | paste [Code:PA] |
| Active substance(s) (incl. content) | quartz sand; 251 g/kg |
| Function | repellent |
| Product already evaluated as the 'representative formulation' during the approval of the active substance(s) | no |
| Product previously evaluated in another MS according to Uniform Principles | no |

* Information on the detailed composition of GORZKA KORA can be found in the confidential dRR Part C.

Justified proposals for 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 toxicological data is proposed for the preparation:

Table 6.1-2: Justified proposals for classification and labelling for GORZKA KORA according to Regulation (EC) No 1272/2008

| | |
|--|---|
| Hazard class(es), categories | - |
| Hazard pictograms or Code(s) for hazard pictogram(s) | - |
| Signal word | - |
| Hazard statement(s) | - |
| Precautionary statement(s) | - |
| Additional labelling phrases | To avoid risks to man and the environment, comply with the instructions for use. [EUH401] |
| | - |

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for GORZKA KORA

| | Result | PPE / Risk mitigation measures |
|------------|------------|--------------------------------|
| Operators | Acceptable | Gloves during application. |
| Workers | Acceptable | None |
| Residents | Acceptable | None |
| Bystanders | Acceptable | None |

No unacceptable risk for operators, workers, bystanders and residents was identified when the product is used as intended and provided that the PPE/ risk mitigation measures stated in Table 6.1 3 are applied i.e. gloves during application.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and residents/bystanders is presented in the following table.

Table 6.1-4 Critical uses and overall conclusion of exposure assessment

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | | | |
|--------------|--|--|--|---|--|-----------------------------------|-----------------|---|--|--------|-----------|-----------|
| Use- No.* | Crops and situation (e.g. growth stage of crop) | F, Fn, Fpn G, Gn, Gpn or I ** | Application | | Application rate | | PHI (d) | Remarks: (e.g. safen- er/synergist (L/ha)) critical gap for operator, worker, resident or by- stander exposure based on [Expo- sure model] | Acceptability of exposure as- sessment | | | |
| | | | Method / Kind (incl. applica- tion technique *** | Max. number (min. interval between applications) a) per use b) per crop/ season | Max. applica- tion rate kg as/ha a) a.s. 1 b) a.s. 2 | Water L/ha min / max | | | Operator | Worker | Residents | Bystander |
| | Deciduous and coniferous trees in forestry | F | Coating manu- ally with special brush or glove. | 1 per year | 2,5-3,3 ka as/1000 plants | Not relevant | Not relevant | Operators, work- ers, bystanders and residents (models: not applicable) | - | - | - | - |

* 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

*** e.g. LC: low crop, HC: high crop, TM: tractor-mounted, HH: hand-held

Explanation for column 10 “Acceptability of exposure assessment”

| | |
|----------|---|
| A | Exposure acceptable without PPE / risk mitigation measures |
| R | Further refinement and/or risk mitigation measures required |
| N | Exposure not acceptable/ Evaluation not possible |

Data gaps

N/A.

6.2 Toxicological Information on Active Substance(s)

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in Table 6.2-1.

Table 6.2-1: Information on active substance(s)

| | quartz sand |
|--|--|
| Common Name | quartz sand |
| CAS-No. | 14808-60-7 |
| Classification and proposed labelling | |
| With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended) | not relevant |
| Additional C&L proposal | not relevant |
| Agreed EU endpoints | |
| AOEL systemic | not relevant |
| Reference | EFSA Journal 2011;9(7):2300 |
| Conditions to take into account/critical areas of concern with regard to toxicology | |
| EFSA Journal 2011;9(7):2300 | maximum 0.1% of particles with diameter below 50 µm Paintbrush and gloves application of quartz sand formulated as a paste was not considered to be a source of significant exposure. |

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for GORZKA KORA is given in the following tables. Full summaries of studies on the product that have not been previously considered within an EU peer review process are described in detail in Appendix 2.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for GORZKA KORA

| Type of test, species, model system (Guideline) | Result | Acceptability | Classification (acc. to the criteria in Reg. 1272/2008) | Reference |
|---|---|---------------|---|-----------|
| LD ₅₀ oral, rat | Not submitted, not necessary. Justification presented in Appendix 2 | | - | - |
| LD ₅₀ dermal, rat | Not submitted, not necessary. Justification presented in Appendix 2 | | - | - |
| LC ₅₀ inhalation, rat | Not submitted, not necessary. Justification presented in Appendix 2 | | - | - |
| Skin irritation | Not submitted, not necessary. Justification presented in Appendix 2 | | - | - |
| Eye irritation | Not submitted, not necessary. Justification presented in Appendix 2 | | - | - |
| Skin sensitisation | Not submitted, not necessary. Justification presented in Appendix 2 | | - | - |
| Supplementary studies for combinations of plant protection products | No data – not relevant. | | | |

Table 6.3-2: Additional toxicological information relevant for classification/labelling of GORZKA KORA

| | Substance (concentration in product, % w/w) | Classification of the substance (acc. to the criteria in Reg. 1272/2008) | Reference | Classification of product (acc. to the criteria in Reg. 1272/2008) |
|--|---|--|-----------|--|
| Toxicological properties of active substance(s) (relevant for classification of product) | Quartz sand (25.1 % (w/w)) | - | - | - |
| Toxicological properties of non-active substance(s) (relevant for classification of product) | Confidential information, see Part C, substance in formulation in amount of ≥ 1 % (w/w)* | - | - | - |
| Further toxicological information | - | - | - | - |

* Please use concentration range or concentration limit (e.g. 1-10% or > 1%) as provided in MSDS.

** Material safety data sheet by the applicant

6.4 Toxicological Evaluation of Groundwater Metabolites

Not relevant. There are no groundwater metabolites.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in GORZKA KORA are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in GORZKA KORA

| | quartz sand | |
|-------------|-------------|-----------------------------|
| | Value | Reference |
| Concentrate | negligible | EFSA Journal 2011;9(7):2300 |
| Dilution | negligible | EFSA Journal 2011;9(7):2300 |

6.5.1 Justification for proposed values - quartz sand

No data on dermal absorption for quartz sand in GORZKA KORA is available. Taking into account quartz sand is an inert and insoluble material. As it is insoluble in water and organic solvents it can be safely assumed that dermal absorption of quartz sand is negligible. No further data are required.

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

Oral, dermal and inhalation exposure to quartz sand in the formulation GORZKA KORA is negligible, no risk to the operator, worker, resident and bystander has been identified.

Quartz sand is an inert material. It is considered poorly absorbed after oral exposure and thus not bioavailable. Further, according to the intended uses of GORZKA KORA and application method (glove/brush application), hand to mouth contact of quartz sand is considered negligible. As it is insoluble in water and organic solvents it can be assumed that dermal absorption of quartz sand is negligible. Quartz sand is immobilised in the paste and therefore it is concluded that exposure to quartz sand for the formulation GORZKA KORA via inhalation route is considered negligible. Therefore, there is no need to consider existing occupational exposure limits for the inhalation risk assessment.

Therefore, it is concluded that exposure to quartz sand for the formulation GORZKA KORA via oral, dermal and inhalation route is considered negligible.

Paintbrush and gloves application of quartz sand formulated as a paste was not considered to be a source of significant exposure.

Table 6.6-1: Product information and toxicological reference values used for exposure assessment

| | |
|--|------------------------------------|
| Product name and code | GORZKA KORA |
| Formulation type | PA |
| Category | repellent |
| Container size(s), short description | LLDPE/EVOH/LLDPE bag with LDPE tap |
| Active substance(s) (incl. content) | quartz sand 251 g/kg |
| AOEL systemic | not allocated |
| Inhalation absorption | negligible |

| | |
|-------------------|---|
| Oral absorption | negligible |
| Dermal absorption | Concentrate: negligible Dilution: negligible |

6.6.1 Selection of critical use(s) and justification

The critical GAP used for the exposure assessment of the plant protection product is shown in Table 6.1-4. A list of all intended uses within the zone is given in Part B, Section 0.

Justification

Not relevant since only one intended use is proposed.

6.6.2 Operator exposure (KCP 7.2.1)

Please refer to Point 6.6.

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.

6.6.2.1 Estimation of operator exposure

Please refer to Point 6.6.

6.6.2.2 Measurement of operator exposure

Please refer to Point 6.6.

6.6.3 Worker exposure (KCP 7.2.3)

Please refer to Point 6.6.

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

6.6.3.1 Estimation of worker exposure

Please refer to Point 6.6.

6.6.3.2 Refinement of generic DFR value (KCP 7.2)

Please refer to Point 6.6.

6.6.3.3 Measurement of worker exposure

Please refer to Point 6.6.

6.6.4 Resident and bystander exposure (KCP 7.2.2)

Please refer to Point 6.6.

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

6.6.4.1 Estimation of resident and bystander exposure

Please refer to Point 6.6.

6.6.4.2 Measurement of resident and/or bystander exposure

Please refer to Point 6.6.

6.6.5 Combined exposure

Not relevant. The product contains only one active substance.

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 studies relied upon

A 2.1 Statement on bridging possibilities

The toxicological evaluation for GORZKA KORA is derived from the classification of the active substance quartz sand and co-formulants. GORZKA KORA has a predicted low oral toxicity and is predicted as not toxic via the oral, dermal or inhalation routes. Details of the co-formulants and their classification and the calculation methodology are presented in the confidential dossier of this submission (Registration Report - Part C).

A 2.2 Acute oral toxicity (KCP 7.1.1)

Acute toxicity studies for GORZKA KORA were not evaluated as part of the EU review of quartz sand. Therefore, all relevant data are provided here and are considered adequate. Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of GORZKA KORA can be found in the confidential dossier of this submission (Registration Report - Part C). **The acute oral toxicity of GORZKA KORA was estimated to be ATEmix > 2000 mg/kg GORZKA KORA therefore does not require classification for this health hazard.**

A 2.3 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

Acute toxicity studies for GORZKA KORA were not evaluated as part of the EU review of quartz sand. Therefore, all relevant data are provided here and are considered adequate. Details of the co-formulants and their classification and the methodology that was used to assess the acute dermal toxicity of GORZKA KORA can be found in the confidential dossier of this submission (Registration Report - Part C). **The acute dermal toxicity of GORZKA KORA was estimated to be ATEmix > 2000 mg/kg GORZKA KORA therefore does not require classification for this health hazard.**

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Acute toxicity studies for GORZKA KORA were not evaluated as part of the EU review of quartz sand. Therefore, all relevant data are provided here and are considered adequate. Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute inhalation toxicity of GORZKA KORA can be found in the confidential dossier of this submission (Registration Report - Part C). **The acute inhalation toxicity of GORZKA KORA was estimated to be ATEmix 5.0 mg/L, GORZKA KORA therefore does not require classification for this health hazard.**

A 2.5 Skin irritation (KCP 7.1.4)

Acute toxicity studies for GORZKA KORA were not evaluated as part of the EU review of quartz sand. Therefore, all relevant data are provided here and are considered adequate. Details of the co-formulants and their classification and the calculation methodology that was used to assess the dermal irritation of GORZKA KORA can be found in an appendix to the can be found in the confidential dossier of this submission (Registration Report - Part C). **GORZKA KORA is not considered a potential dermal irritant and does not require classification for this endpoint. No signal word or hazard statement is required.**

A 2.6 Eye irritation (KCP 7.1.5)

Acute toxicity studies for GORZKA KORA were not evaluated as part of the EU review of quartz sand. Therefore, all relevant data are provided here and are considered adequate. Details of the co-formulants and their classification and the calculation methodology that was used to assess the eye irritation of GORZKA KORA can be found in the confidential dossier of this submission (Registration Report - Part C). **GORZKA KORA is not considered a potential eye irritant and does not require classification for this endpoint. No signal word or hazard statement is required.**

A 2.7 Skin sensitisation (KCP 7.1.6)

Acute toxicity studies for GORZKA KORA were not evaluated as part of the EU review of quartz sand. Therefore, all relevant data are provided here and are considered adequate. Details of the co-formulants and their classification and the calculation methodology that was used to assess the skin sensitisation potential of GORZKA KORA can be found in the confidential dossier of this submission (Registration Report - Part C). **GORZKA KORA is not considered a potential skin sensitiser and does not require classification. No signal word or hazard statement is required.**

A 2.8 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

No supplementary studies are required.

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Material safety data sheet for each co-formulant

Information regarding material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.9.2 Available toxicological data for each co-formulant

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.10 Studies on dermal absorption (KCP 7.3)

Not relevant. No new studies were provided.

A 2.11 Other/Special Studies

Not relevant. No new studies were provided.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

Not relevant. No calculation is provided.

GORZKA KORA is ready to use paste which is applied to trees via coating. Since dermal absorption is assumed to be negligible and no inhalative and systemic exposure is expected it may be assumed that operator exposure is not relevant. Additionally, there are no established European models to estimate exposure via coating. Therefore, no operator exposure was provided.

Accepted

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

Not relevant. No calculation is provided.

GORZKA KORA is ready to use paste which is applied to trees via coating. Since dermal absorption is assumed to be negligible and no worker activity on the treated area is expected it may be assumed that worker exposure is not relevant. Therefore, no worker exposure was provided.

Accepted

A 3.3 Bystander and resident exposure calculations (KCP 7.2.2.1)

Not relevant. No calculation is provided.

GORZKA KORA is not applied in a form of spray and paintbrush and gloves application of paste is not considered to be a source of significant bystander and resident exposure. No possible risk for the bystander and resident can be identified. Therefore, no bystander and resident exposure was provided.

Accepted

Appendix 4 Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1)

Not relevant. No calculation is provided.