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| --- |
| FINAL REGISTRATION REPORT  Part A  Risk Management |
| Product code: GK-4  Product name: GORZKA KORA / Biały Płaszcz Extra  Chemical active substance:  Active substance: quartz sand, 251 g/kg |
| Central Zone  Zonal Rapporteur Member State: Poland |
| NATIONAL ASSESSMENT Poland  (authorization, renewal of authorisation Art. 43) |
| Applicant: Przedsiębiorstwo Produkcyjno-Handlowe  ADW Sp. z o.o.  Submission date: ~~October 2022~~ November 2023  MS Finalisation date: February 2023; May 2023; October 2024; December 2024, March 2025; January 2026 |

Version history

|  |  |
| --- | --- |
| When | What |
| February 2023 | ZRMS evaluated dRR submitted by Applicant. |
| May 2023 | Final Registration Report. |
| October 2023 | Additional packaging. |
| November 2023 | Art. 43 renewal |
| October 2024 | ZRMs assessed dRR submitted for renewal. |
| December 2024 | zRMS assessment of Applicant’s update (2-years storage stability study, effect of low temperatures on stability, label). Also, efficacy section assessed compliance with the conditional registration rules agianst hares. |
| March 2025 | Verification of the lists of data and labels |
| January 2026 | The Final Registration Report |

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PART A

RISK MANAGEMENT

# Details of the application

## Application background

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. Quartz sand approval was renewed in 2023 and it was approved as a low risk active substance (Commission Implementing Regulation (EU) 2023/1488 of 6 July 2023 renewing the approval of the low-risk active substance quartz sand in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011).

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~~ EFSA Journal 2022;20(9):7552) 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.~~

For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on quartz sand, and in particular Appendices I and II thereof, shall be taken into account. Conditions of use shall include risk mitigation measures, where appropriate.

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

## Letters of Access

Not relevant.

## Justification for submission of tests and studies

This application for registration of Gorzka Kora is submitted according to ~~Art. 33~~ Art 43 of Reg. 1107/2009. All studies or tests submitted with this application are data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

## Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

# Details of the authorization decision

## Product identity

|  |  |
| --- | --- |
| Product code | GK-4 |
| Product name in MS | GORZKA KORA |
| Authorization number | not relevant |
| Function | Repellent |
| Applicant | Przedsiębiorstwo Produkcyjno-Handlowe  ADW Sp. z o.o. |
| Active substance(s)  (incl. content) | quartz sand, 251 g/kg |
| Formulation type | paste [PA] |
| Packaging | 5 kg LLDPE/EVOH/LLDPE bag, professional and non-professional user  5 kg, 7kg, PP bucket, professional and non-professional user |
| Coformulants of concern for national authorizations | not relevant |
| Restrictions related to identiy | not relevant |
| Mandatory tank mixtures | not relevant |
| Recommended tank mixtures | not relevant |

## Conclusion

The evaluation of the application for product name resulted in the decision to grant the authorization.

**Physical-chemical properties section:** 2-years ambient storage stability study ~~is ongoing.~~ results were provided and accepted.

The Applicant proposed the changes to the label regarding the temperatures of formulation storage and use (see comment to the label in Appendix 2). The proposed changes were accepted.

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

**Efficacy section:** **Previous evaluation**: Gorzka Kora can be granted, in line to accepted GAP table. Ruminant animals are accepted against bark damage and browsing. Squirrel family and beaver family are not accepted. Lagomorphs are accepted conditionally against bark damage. All minor uses in line to GAP table are accepted. **Evaluation for renewal:** Gorzka Kora can be renewal for professional use and minor uses and Biały Płaszcz can be renewal for unprofessional use in line to Article 43. Gorzka Kora (R-136/2023) and Biały Płaszcz (R-135/2023) are identical. **Evaluation for compliance with the conditional registration rules:** The applicant complied with the rules for conditional approval and, with-in 24 months of obtaining the authorization submitted two additional efficacy field trials carried out in Poland and conducted on deciduous trees against hare crab gnawing. Those trials were assessed as a valid by ZRMs. So, the entry on conditional registration of this use has been removed from the GAP table and label.

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

**Metabolism and residues:** The assessment of the Metabolism and residues section is still valid for renewal.

**Ecotoxicology section:** No data gaps. All minor uses in line to GAP table are accepted. The assessment of the ecotoxicology section is still valid for renewal.

**Identity section:** The evaluators also verified whether the co-formulants contained in the plant protection product Gorzka Kora are listed in Annex III to Regulation (EC) No 1107/2009 and/or could be considered unacceptable based on the criteria indicated in the Annex to the Commission Implementing Regulation (EU) 2023/574 of 13 March 2023.

Based on the currently available MSDSs and other information provided by the applicant on co-formulants, the product Gorzka Kora does not contain any unacceptable co-formulant/ingredient listed in the Commission Regulation (EU) 2021/383 amending Annex III to Regulation (EC) No 1107/2009.

According to the current knowledge and available information none of the co-formulants in the plant protection product Gorzka Kora meets the Annex to Regulation (EU) 2023/574 criteria for identification of co-formulants that are unacceptable for inclusion in plant protection products. Taking this into account, none of the co-formulants/ingredients in this product is considered to be a candidate for inclusion in Annex III of Regulation (EU) 1107/2009.

Detailed assessment of co-formulants according to Article 3 of Regulation (EU)2023/574 can be found in RR Part C of this submission (section 1.2.2).

## Substances of concern for national monitoring

Quartz sand is not a substance of concern.

## Classification and labelling

### Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

|  |  |
| --- | --- |
| Hazard class(es), categories: | not relevant |

The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold:**

|  |  |
| --- | --- |
| Hazard pictograms: | not relevant |
| Signal word: | not relevant |
| Hazard statement(s): | not relevant |
| Precautionary statement(s): | not relevant |
| Additional labelling phrases: | not relevant |

|  |  |
| --- | --- |
| Special rule for labelling of plant protection product (PPP): | |
| EUH401 | To avoid risks to man and the environment, comply with the instructions for use. |
| Further labelling statements under Regulation (EC) No 1272/2008: | |
| not relevant | not relevant |

**See Part C for justifications of the classification and labelling proposals.**

### Standard phrases under Regulation (EU) No 547/2011

|  |  |
| --- | --- |
| SP 1 | 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). |

### Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

|  |  |
| --- | --- |
| not relevant | not relevant |

## Risk management

### Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

|  |  |
| --- | --- |
| Operator protection: | |
| respective code if available | Gloves during application. |
| Worker protection: | not relevant |
| not relevant | not relevant |
| Integrated pest management (IPM)/sustainable use: | |
| not relevant | not relevant |
| Environmental protection | |
| not relevant | not relevant |
| Other specific restrictions | |
| not relevant | not relevant |

The authorization of the PPP is linked to the following conditions (voluntary labelling):

|  |  |
| --- | --- |
| Integrated pest management (IPM)/sustainable use: | |
| not relevant | not relevant |

### Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

|  |  |  |
| --- | --- | --- |
| Integrated pest management (IPM)/sustainable use: | | Relevant for use no. |
| not relevant | not relevant | not relevant |
| Environmental protection: | | Relevant for use no. |
| not relevant | not relevant | not relevant |

## Intended uses (only NATIONAL GAP)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | |  | | | | | |  | | | GAP rev. 1, date: 2022-05-04 | | | | |
|  | | |  | | | | | |  | | |  | | | | |
| PPP (product name): | | | GORZKA KORA (professional and minor uses) and Biały Płaszcz (only non professiioal uses) | | | | | | 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:   e.g. g safener/synergist per ha  (f) |
| 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 |
| Zonal uses – Art. 33 | | | | | | | | | | | | | | | | |
| 1 | PL | Deciduous and coniferous trees in forestry | | Fpn | Bark damage stripping 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 ka as/1000 plants | Not relevant. | Not relevant. | **Eff.section:** squirrel family and beaver family are not accepted. Lagomorph is accepted only coditionally. Acceptable against ruminant animals. |
| 2 | PL | Deciduous and coniferous trees in forestry | | Fpn | Browsing damage caused by: Ruminant animals:  - deer family  - roe family  - fallow deer  (bark stripping)  and lagomorph | Coating manually with special brush or glove. | Late autumn when game starts to damage seedlings | 1 per year | | Not relevant | 2-5 kg/1000 plants | | 0.5-1.3 kg as/1000 plants | Not relevant. | Not relevant. | - **Eficacy section**: acceptable for ruminant animals and lagomprphs |
| Minor uses – Art. 51 Reg. 1107/2009 for proffesional uses in Gorzka KORA | | | | | | | | | | | | | | | | |
| 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 | - |
| 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  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 | - |
| 5 | PL | Gooseberry, choke berry, highbush blueberry, vines | | F | Browsing damage caused by  Ruminant animals:  - deer family  - roe family  - fallow deer  Lagomorphs  Squirrel family  Beaver family | Coating manually with special brush or glove | Late autumn when game starts to damage seedlings | 1 per year | | Not relevant | 2-5 kg/1000 plants | | 0.5-1.3 kg as/1000 plants | Not relevant | Not relevant | - |
| 6 | PL | Ornamental trees, Christmas trees grown on plantations | | F | Bark stripping caused by  Ruminant animals:  - deer family  - roe family  - fallow deer | Coating manually with special brush or glove | Late autumn when game starts to damage seedlings | 1 per year. | | Not relevant. | 10-13 kg/1000 plants | | 2,5-3,3 ka as/1000 plants | Not relevant | Not relevant | - |
| 7 | PL | Pear, plum, sweet cherry, sour cherry, peach, apricot, hazel, walnut | | F | Bark stripping caused by  Ruminant animals:  - deer family  - roe family  - fallow deer | Coating manually with special brush or glove | Late autumn when game starts to damage seedlings | 1 per year. | | Not relevant. | 10-13 kg/1000 plants | | 2,5-3,3 ka as/1000 plants | Not relevant | Not relevant |  |
| Non-professional use for which application is submitted in Biały Płaszcz | | | | | | | | | | | | | | | | |
| 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 |  |
| 9 | PL | Deciduous and coniferous trees in forestry | | Fpn | Bark damage striping caused by: Ruminant animals:  - deer family  - roe family  - fallow deer  Lagomorphs  Squirrel family  Beaver family  (browsing damages) | Coating manually with special brush or glove. | Late autumn when game starts to damage seedlings | 1 per year. | | Not relevant. | 0,10-0,13 kg/10 plants | | 0,25-0,33 ka as/10 plants | Not relevant. | Not relevant. |  |
| Minor uses for which application is submitted - non-professional use | | | | | | | | | | | | | | | | |
| 10 | PL | Forest nursery plants, renewals, afforestation and seed plantations of forest trees; ornamental shrubs and trees; Christmas trees grown on plantations, | | Fn | Browsing damage caused by  Ruminant animals:  - deer family  - roe family  - fallow deer  Lagomorphs  Squirrel family  Beaver family | Coating manually with special brush or glove | Young shoots, 2-5 years old, autumn (Sept.-Nov.) | 1 per year | | Not relevant | 0,02-0,05 kg/10 plants | | 0.005-0,013 kg as/1000 plants | Not relevant | Not relevant | **Efficacy section:** Minor uses were registered only for professional use in Gorzka Kora, so renewal for those uses in Biały Płaszcz is not possible. |
| 11 | PL | Pear, plum, sweet cherry, sour cherry, peach, apricot, hazel, walnut, quince | | Fn | Browsing damage caused by  Ruminant animals:  - deer family  - roe family  - fallow deer  Lagomorphs  Squirrel family  Beaver family | Coating manually with special brush or glove | Young shoots, 2-5 years old, autumn (Sept.-Nov.) | 1 per year | | Not relevant | 0,02-0,05 kg/10 plants | | 0.005-0,013 kg as/1000 plants | Not relevant | Not relevant | **Efficacy section:** Minor uses were registered only for professional use in Gorzka Kora, so renewal for those uses in Biały Płaszcz is not possible. |
| 12 | PL | Gooseberry, choke berry, highbush blueberry, 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 relevant | 0,02-0,05 kg/10 plants | | 0.005-0,013 kg as/1000 plants | Not relevant | Not relevant | **Efficacy section:** Minor uses were registered only for professional use in Gorzka Kora, so renewal for those uses in Biały Płaszcz is not possible. |
| 13 | PL | Ornamental trees, Christmas trees grown on plantations | | Fn | Bark stripping caused by  Ruminant animals:  - deer family  - roe family  - fallow deer | Coating manually with special brush or glove | Late autumn when game starts to damage 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 | **Efficacy section:** Minor uses were registered only for professional use in Gorzka Kora, so renewal for those uses in Biały Płaszcz is not possible. |
| 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 | **Efficacy section:** Minor uses were registered only for professional use in Gorzka Kora, so renewal for those uses in Biały Płaszcz is not possible. |

|  |  |  |  |
| --- | --- | --- | --- |
| 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 |

# Background of authorization decision and risk management

## Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is ivory opaque dense paste with characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. It hasn’t got self-ignition temperature (no Auto-Ignition at 600 °C). In aqueous solution, it has a pH value around 7,42 at 24 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. Its technical characteristics are acceptable for a paste formulation.

~~The 2 years stability study is ongoing.~~ The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in intact plastic bag made of LLDPE/EVOH/LLDPE. Storage of the product for seven days at a temperature above 0°C (+2°C) shows that under those conditions product doesn’t solidifies and it is ready to use. The technical characteristics of the product are acceptable for a paste formulation.

Justified Proposals for Classification and Labelling for physical chemical properties

Not relevant. No classification is proposed.

## Efficacy (Part B, Section 3)

### Efficacy data

**Previous evaluation**: A total of 10 trials were carried out to evaluate the efficacy of GORZKA KORA. The application rates used in trials were in range 2-13 kg/1000 trees. All trials confirmed the efficacy of GORZKA KORA in control deciduous and coniferous trees in forestry. No phytotoxicity effects on protected trees were observed in efficacy trials.

No preliminary tests and minimum effective dose tests were performed. The proposed application rate is known of its effectiveness. Effectiveness of the product depends on concentration of the active ingredient in the formulation and the thoroughness of application. Application rate expressed in amount per ha depends on density of trees.

Trials methodology has been accepted by Evaluator.The field trials were performed in accordance with EPPO guidelines and in all trials GEP rules were recognized: PP 1/135(3) – *Phytotoxicity assessment*; PP 1/152(4) – *Design and analysis of efficacy evaluation trials*; PP 1/181(4) – *Conduct and reporting of efficacy evaluation trials including GEP*; PP 1/214(3) – *Principles of acceptable efficacy*;PP 1/226(2) – *Number of efficacy trials and* PP 1/200(1)– *Rodent repellents against debarking of trees.*

The field experiments of the repellent – Gorzka Kora (product code: GK-4) were carried out by the by recognised institutes. The testing unit has been mandated to conduct research in the field of efficacy of plant protection products by the Chief Inspector of Plant Health and Seed Inspection and are officially GEP recognised.

According to EPPO 1/200 – the rodent species used to conduct the experiments should belong to the group of most important pests in a given region, i.e. *Microtus agrestis* in northern Europe, *M. arvalis* or *M. agrestis* in Central European countries, and *Pitymys* in southern Europe. It is advisable the use for experiments of individuals at the age of pre-breeding (not fully mature), as the natural populations of voles in the winter season consist exclusively of such individuals. The method described below, with minor modifications, can also be used for testing rodenticides that control rodents of the order *Lagomorpha* (rabbits, hares).

Studied pests during efficacy trials: Applicant submitted trials only against Ruminant animals (against browsing damage and bark damage stripping of trees). Lack of trials against lagomorphs, squirrel family and beaver family against bark browsing damage and stripping trees. In the opinion of ZRMs, lagomorphs can be also accepted against browsing damage but conditionally. It will be necessary to submit at least 1-2 studies for these pests performed on pine or oak trees within 1-2 years after granted product. However, oak or other deciduous tree will be preferred for additional studies. Hares have a preference, it is the bark of apple, plum, apricot, hawthorn, hazel. And they hardly pay attention to calla, currants, honeysuckle, wild rose. Hares bite the twigs of tress and shrubs in winter and eat young shoots in early spring. Therefore, it is important to use protection against bark gnawing (damage) also by hares. Spalding is the stripping be deer (mainly deer and elk) of bark from young forest trees (usually pines, spruces, oaks, ash), which cause significant damage. The damage consists of crippling trees and weakening their resistance to infections such as fungal diseases. Fallowing prevention designed to act against ruminant animals.

Quartz sand is a low-risk substance. In Poland few plant protection products with quart sand are already registered against lagomorphs, squirrel family and beaver family. So, its efficacy is already known. According to harmonization meetings and extrapolating results, the possibility of extrapolation of results between coniferous and deciduous trees in the case of deer or hares has been determined. But the possibility of extrapolation between different pest species, e.g., hares/deer, has not been clarified. Therefore, we believe that based on the so-called judgement opinion, it will be possible to at least conditionally registration of this group of animals. Squirrel family and beaver family are not accepted, also they were not submitted in label project by Applicant.

Pests mentioned in efficacy reports:

|  |  |  |  |
| --- | --- | --- | --- |
| CERVEL | *Cervus elaphus* | red deer | Jeleń szlachetny |
| CAPRCA | *Capreolus capreolus* | roe deer | Sarna europejska |
| DAMADA | *Cervus dama* | fallow deer | Daniel |
| ALCSAL | *Alces alces* | moose | Łoś euroazjatycki |
| OVISAM | *Ovis gmeliniii musimon* | muflon | Muflon śródziemnomorski |

**Assessment of efficacy:** EPPO PP 1/214 (3) Principles of acceptable efficacy does not define specific scale of efficacy. It refers to EC Regulation 1107/2009 concerning the placing of plant protection products on the market (EC, 2009) which expresses this requirement by declaring that any plant protection product should be ‘sufficiently effective’, but without explaining what is meant by this term. The Applicant did not apply a scale of effectiveness the tested product – Gorzka Kora (product code: GK-4). In accordance with EPPO 1/200 (1) we should take to account only trials with sufficient (> 50%) damage level of the control group. All trials conducted fulfilled this condition.

**Efficacy of Gorzka Kora against peeling of bark stripping damage in forest** (5 trials): Oak was studied during one trial and pine –in 4 trials. During those trials following pests were studied: CERVEL (5 trials), ALCSAL (4 trials), DAMADA (3 trials), CAPRCA (2 trials) and OVISAM (2 trials). Presented efficacy data have been conducted in 2021 and 2022 in Poland (NE). Gorzka Kora was applied at target dose rate: 10-13 kg/1000 plants, reference product used in trials: Cervacol Extra PA at dose rate: 10 kg/1000 plants. Data demonstrated that the efficacy of the GORZKA KORA at target dose rate was higher or identical as used reference product Cervacol Extra PA at dose rate: 10 kg/1000 plants. The mean efficacy was above 90% that indicate that the product Gorzka Kora is highly effective.

**Efficacy of Gorzka Kora against peeling of browsing damage in forest** (5 trials): One trial was carried out on oak, one trial – on mix forestry (pine and birch) and 3 trials on pine. Following pests were studded during those trials: CERVEL (5 trials), ALCSAL (4 trials), CAPRCE (5 trials), DAMADA (3 trials) and OVISAM (2 trials). Presented efficacy data have been conducted in 2021 and 2022 in Poland (NE). Gorzka Kora was applied at target dose rate: 2-5 kg/1000 plants, reference product used in trials: Cervacol Extra PA at dose rate: 2 kg/1000 plants. Data demonstrated that the efficacy of the Gorzka Kora at target dose rate was higher or identical as used reference product Cervacol Extra PA at dose rate: 2 kg/1000 plants. The mean efficacy was above 90% that indicate that the product GORZKA KORA is highly effective.

The effectiveness of tested product at recommended dose was similar or even slightly higher than standard references products. Differences between the efficiency (observed as fluctuations of effectiveness) of product from field tests were quite substantial, but they were caused by weather conditions (during rainy and windy weather efficacy of product has been decreased). Autumn application is recommended by Evaluator due to high efficiency of tested product.

**Gorzka Kora (product code: GK-4) should be used in accordance to label project. All minor uses included in GAP table and label project by Applicant are accepted by ZRMs in line to Article 51. Use professional and non-professional are accepted.**

**Evaluation for renewal:** This information’s are still valid for renewal registration of Gorzka Kora (product code: GK-4) in line to Article 43. Gorzka Kora can be renewal for professional use and minor uses and Biały Płaszcz can be renewal for unprofessional use. Gorzka Kora (R-136/2023) and Biały Płaszcz (R-135/2023) are identical.

**Evaluation for compliance with the conditional registration rules:** ZRMs has assessed compliance with the conditional registration rules. Two additional trials carried out in Poland (N-E EPPO zone) against the gnawing of trees by hares in the forest was presented by Applicant. Those studies started in 2023 and ended in 2024.

**Report (145283-1)** – oak was studied and control of gnawing of threes by LEPUEU (Lepus europaeus). Regardless of the dose, the use of Gorzka kora significantly reduced the number of damaged plants on the plots treated with this repellent. This translated into the calculated effectiveness of the test product, which ranged from 90 % to 100%. It can be concluded that the test product was highly efficient at all rates.

**Report (145283-2)** – oak was studied and control of gnawing of threes by LEPUEU (Lepus europaeus). The use of Gorzka kora, regardless of the dose, significantly reduced the number of damaged plants on the plots treated with this repellent. This translated into the test product's calculated effectiveness, ranging from 84.7 % to 100%. It can be concluded that the test product was highly efficient at all rates.

**The applicant complied with the rules for conditional approval and, with-in 24 months of obtaining the authorization submitted two additional effi-cacy field trials carried out in Poland and conducted on deciduous trees against hare crab gnawing. Those trials were assessed as a valid by ZRMs. So, the entry on conditional registration of this use has been removed from the GAP table and label**.

### Information on the occurrence or possible occurrence of the development of resistance

**Previous evaluation:** Not relevant. GORZKA KORA contains quartz sand as an active substance that has mechanical mode of action. Neither occurrence of resistance nor development of resistance is probable.

**Evaluation for renewal:** This information’s are still valid for renewal registration of Gorzka Kora (product code: GK-4) in line to Article 43. Gorzka Kora can be renewal for professional use and minor uses and Biały Płaszcz can be renewal for unprofessional use. Gorzka Kora (R-136/2023) and Biały Płaszcz (R-135/2023) are identical.

Sand quartz is often used in various repellents and coatings to deter animals from damaging trees. However, the effectiveness can vary based on several factors.

Ruminant animals (like deer) and lagomorphs can be persistent, especially if they are accustomed to a particular food source. Their behavioural adaptability might allow them to overcome mild deterrents over time.

Sand quartz may create a rough texture that animals find unpleasant, but its effectiveness can diminish if it washes away with rain or is applied unevenly.

Weather conditions, like heavy rain or snow, can reduce the effectiveness of repellents by washing them off the tree bark.

If there are alternative food sources available, animals are more likely to avoid treated bark. But in extreme conditions, limited food availability might drive them to strip bark despite repellents.

Regular and through application is required for repellents to work effectively. Inconsistencies can lead to parts of the bark remaining exposed and vulnerable.

During certain seasons, animals might be more desperate for food (eg. winter), leading them to ignore repellents that they might otherwise avoid.

While sand quartz can serve as a deterrent, it may not be entirely effective on its own. The use of combination strategies, such as physical barriers (fencing), other repellents, or habitat management, might be necessary for more robust protection. Considering the varying persistence and adaptability of ruminants and lagomorphs, relying solely on sand quartz result in inconsistent protection. Resistance in the form of behavioural adaptation by the animals is possible but not guaranteed.

### Adverse effects on treated crops

**Previous evaluation:** No phytotoxicity studies were performed since GORZKA KORA is neither herbicide not regulator. Phytotoxicity was observed in efficacy trials. No phytotoxic effects were recorded at application rate 1N.

**Evaluation for renewal:** This information’s are still valid for renewal registration of Gorzka Kora (product code: GK-4) in line to Article 43. Gorzka Kora can be renewal for professional use and minor uses and Biały Płaszcz can be renewal for unprofessional use. Gorzka Kora (R-136/2023) and Biały Płaszcz (R-135/2023) are identical.

**Evaluation for compliance with the conditional registration rules:** Phytotoxicity assessment was also made in two additional trials (Report 145283-1 and Report 145283-2.Those trials were submitted in line to condi-tional registration of use against hares, No phytotoxic symptoms were ob-served at any of the assessment timings on the crop. Also, no negative im-pact of the tested item on wildlife has been observed during the experiment.

### Observations on other undesirable or unintended side-effects

**Previous evaluation:** GORZKA KORA is to be used in forestry and several minor crops. Although the proposed application manner is annual coating and time of application so no impact on succeeding and adjacent crops is expected. The active substance quartz sand naturally occurs in the environment and hence exposure of non-target organisms is also considered negligible.

**Evaluation for renewal:** This information’s are still valid for renewal registration of Gorzka Kora (product code: GK-4) in line to Article 43. Gorzka Kora can be renewal for professional use and minor uses and Biały Płaszcz can be renewal for unprofessional use. Gorzka Kora (R-136/2023) and Biały Płaszcz (R-135/2023) are identical.

## Methods of analysis (Part B, Section 5)

### Analytical method for the formulation

Active substance

Test item was a GK-4, a product formulated as a paste containing 251 g/kg of quartz sand. Silicon diox-ide was determined spectrophotometrically. Molybdenum blue complex was obtained from a solution prepared by fusion of the quartz sample with sodium hydroxide, the yellow silico-molybdate complex was reduced to molybdenum blue complex. The absorption measurements were acquired by a single beam UV/visible spectroscopy system at wavelength 816±2 nm with a 1 cm cell path length.The specificity of the method was demonstrated on the basis of a parallel analysis of the test material and placebo. Silica is not detected in the placebo. It confirms the ability of the method to the determination of an analyte in a formulation without interference from other components. The validation parameters (linearity, precision and accuracy) are within the acceptance range and fulfil EU requirements given in SANCO /3030 /99 rev.5.

Relevant impurities

According to EFSA Conclusions (EFSA Journal 2022;20(9):7552), crystalline silica with a diameter <10 µm is considered the relevant impurity of active substance quartz sand.

The requirement for methods of analysis for monitoring the respirable crystalline silica in the representative formulations has been waived due to negligible inhalation exposure predicted for the proposed uses.

The 5-batch analysis assessed in the equivalence report (RMS Latvia, 2022) indicates that the source of active substance to be used for Gorzka Kora production does not contain any crystalline silica of a diameter <50 µm so also <10 µm. In the report, validation of an analytical method for quantification of crystalline silica with particles <10 μm as an impurity in quartz sand technical (Giorgi S. 2022) was assessed and found acceptable in terms of specificity, linearity, recovery and precision criteria specified under SANCO/3030/99 (rev.5, 22 March 2019).

Therefore, the lack of an analytical method for the determination of crystalline silica with a diameter <10 μm should not be considered as a data gap.

### Analytical methods for residues

The assessment is still valid for renewal.

Methods are not required.

Noticed data gaps are:

* No data gap identified

| Commodity/crop | Supported/ Not supported |
| --- | --- |
| Not relevant |  |

## Mammalian toxicology (Part B, Section 6)

### Acute toxicity

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.

According to the ~~EFSA Journal 2011;9(7):2300~~ EFSA Journal 2022;20(9):7552 Paintbrush and gloves application of quartz sand formulated as a paste was not considered to be a source of significant exposure.

Accepted.

### Worker exposure

As quartz sand in GORZKA KORA is immobilised in the paste it is unlikely that exposure to the aerosolic form can occur. Paintbrush and gloves application of quartz sand formulated as a paste is not considered to be a source of significant exposure. Furthermore dermal and inhalation absorption is assumed to be negligible; therefore no systemic exposure of the active substance occurs and no possible risk for the worker can be identified. A study to provide measurements of worker exposure is also not necessary and was therefore not performed.

According to the ~~EFSA Journal 2011;9(7):2300~~ EFSA Journal 2022;20(9):7552 Paintbrush and gloves application of quartz sand formulated as a paste was not considered to be a source of significant exposure.

Accepted.

### Bystander and resident exposure

As quartz sand in GORZKA KORA is immobilised in the paste it is unlikely that exposure to the aerosolic form can occur. Quartz sand is also not volatile. Paintbrush and gloves application of quartz sand formulated as a paste is not considered to be a source of significant exposure. Furthermore dermal and inhalation absorption is assumed to be negligible; therefore no systemic exposure of the active substance occurs and no possible risk for the bystander and resident can be identified. A study to provide measurements of bystander and resident exposure is also not necessary and was therefore not performed.

According to the ~~EFSA Journal 2011;9(7):2300~~ EFSA Journal 2022;20(9):7552 Paintbrush and gloves application of quartz sand formulated as a paste was not considered to be a source of significant exposure.

Accepted.

## Residues and consumer exposure (Part B, Section 7)

### Residues

The assessment is still valid for renewal

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.

### Consumer exposure

Not required.

## Environmental fate and behaviour (Part B, Section 8)

### Predicted environmental concentrations in soil (PECsoil)

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. The assessment is still valid for renewal

### Predicted environmental concentrations in groundwater (PECgw)

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 ground water is expected. PECgw calculation is not considered necessary. The assessment is still valid for renewal

### Predicted environmental concentrations in surface water (PECsw)

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.

### Predicted environmental concentrations in air (PECair)

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

PECair calculation is not considered necessary. The assessment is still valid for renewal

## Ecotoxicology (Part B, Section 9)

### Effects on terrestrial vertebrates

**Birds**

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~~ RAR Quartz sand, ~~September 2008~~ November 2020 and Peer Review document ~~EFSA 2011~~ EFSA Journal 2022;20(9):7552).

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.

The assessment of the ecotoxicology section is still valid for renewal.

**Terrestrial vertebrates (other than birds)**

No risk assessment calculations for mammals are deemed necessary and a calculation has not been done upon inclusion in Annex I (see ~~DAR~~ RAR Quartz sand, ~~September 2008~~ November 2020 and Peer Review document ~~EFSA 2011~~ EFSA Journal 2022;20(9):7552).

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 birds, the risk for mammals after application of quartz sand and GORZKA KORA according to the GAP is considered to be low.

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.

The assessment of the ecotoxicology section is still valid for renewal.

### Effects on aquatic species

No risk assessment calculations for aquatic organisms are deemed necessary and a calculation has not been done upon inclusion in Annex I (see ~~DAR~~ RAR Quartz sand, ~~September 2008~~ November 2020 and Peer Review docu-ment ~~EFSA 2011~~ EFSA Journal 2022;20(9):7552).

Only acute aquatic invertebrates – *Daphnia magna* and algae studies – *Peudokirchneriella subcapitata* were available with GORZKA KORA formulation. However, all the available studies showed deficien-cies (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 PECsw 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.

The assessment of the ecotoxicology section is still valid for renewal.

### Effects on bees

No risk assessment calculations for bees are deemed necessary and a calculation has not been done upon inclusion in Annex I (see ~~DAR~~ RAR Quartz sand, ~~September 2008~~ November 2020 and Peer Review document ~~EFSA 2011~~ EFSA Journal 2022;20(9):7552).

The effect on bees of GORZKA KORA has not been assessed as the product is non-toxic, will be ap-plied 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.

The assessment of the ecotoxicology section is still valid for renewal.

### Effects on other arthropod species other than bees

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~~ RAR Quartz sand, ~~September 2008~~ November 2020 and Peer Review document ~~EFSA 2011~~ EFSA Journal 2022;20(9):7552).

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.

The assessment of the ecotoxicology section is still valid for renewal.

### Effects on soil organisms

No risk assessment calculations for soil meso- and macrofauna as well as soil microorganisms are deemed necessary and a calculation has not been done upon inclusion in Annex I (see ~~DAR~~ RAR Quartz sand, ~~September 2008~~ November 2020 and Peer Review document ~~EFSA 2011~~ EFSA Journal 2022;20(9):7552).

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) and soil microorganisms is considered appropriate and no further consideration is required.

The assessment of the ecotoxicology section is still valid for renewal.

### Effects on non-target terrestrial plants

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~~ RAR Quartz sand, ~~September 2008~~ November 2020 and Peer Review document ~~EFSA 2011~~ EFSA Journal 2022;20(9):7552).

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.

The assessment of the ecotoxicology section is still valid for renewal.

### Effects on other terrestrial organisms (Flora and Fauna)

Not relevant.

## Relevance of metabolites (Part B, Section 10)

Not relevant. There are no groundwater metabolites that could occur in groundwater at concentrations above 0.1 µg/L so assessment of the relevance of groundwater metabolites is therefore not required.

# Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Not relevant. Quartz sand is not CfS.

# Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

NA

1. Copy of the product authorization

Not relevant.

1. Copy of the product label

|  |
| --- |
| ***Sekcja skuteczności:*** brak uwag do etykiety śor Gorzka Kora i Biały Płaszcz.  ***Sekcja fiz-chem:*** Ponieważ po przechowywaniu w temperaturze 0°C produkt ulega zamrożeniu, proponuje się dodanie w sekcji WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA sformułowania „W przypadku przechowywania w temperaturze zbliżonej do 0°C odczekać 4 godziny przed zastosowaniem”.  W 2024 roku Wnioskodawca przedstawił badania środka w temperaturze +2°C, których wyniki wskazują, że w tej temperaturze środek nie ulega zamrożeniu. Wnioskodawca przedstawił propozycje następujących zmian w etykiecie:  1. W punkcie ŚRODKI OSTROŻNOŚCI ORAZ SZCZEGÓLNE WARUNKI STOSOWANIA zapis „Środek stosować w dni bezdeszczowe, w temperaturze otoczenia, nie niższej niż 0°C” zmienić na „Środek stosować w dni bezdeszczowe, w temperaturze otoczenia, powyżej 0°C”.  Wykreślić zapis „Przed zastosowaniem, w przypadku przechowywania w temperaturze zbliżonej do 0°C, należy przetrzymywać środek w temperaturze pokojowej przez 4 godziny”.  2. W punkcie WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA zapis podpunktu „w temperaturze 0°C - 30°C” zmienić na „w temperaturze powyżej 0°C, do maksymalnie 30°C”.  Proponowane zmiany zostały zakceptowane.  ***Sekcja toksykologii:*** bez komentarza  ***Sekcja pozostałości:*** bez komentarza  ***Sekcja losu:*** bez komentarza  ***Sekcja ekotoksykologii:*** bez komentarza. |

*Etykieta środka ochrony roślin GORZKA KORA*

Posiadacz zezwolenia:

Przedsiębiorstwo Produkcyjno-Handlowe ADW Sp. z o.o., ul. Zbożowa 2, 43-175 Wyry, tel: 32 218-71-85, fax: 32 323-00-85, e-mail:sekretariat@adw.com.pl

**GORZKA KORA**

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

piasek kwarcowy (związek z grupy tlenków nieorganicznych) - 251 g/kg (25,1%)

**Zezwolenie MRiRW nr R-136/2023 z dnia 03 sierpnia 2023 r.**

|  |  |
| --- | --- |
| EUH 401 | W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia |
| P280 | Stosować rękawice ochronne/odzież ochronną. |

**OPIS DZIAŁANIA**

GORZKA KORA jest środkiem o działaniu odstraszającym w formie pasty do bezpośredniego stosowania przeznaczonym do ochrony sadzonek i drzewek w leśnictwie, drzew ozdobnych, drzewek bożonarodzeniowych uprawianych na plantacjach, gruszy, śliwy, czereśni wiśni, brzoskwini, moreli, leszczyny i orzecha włoskiego przed zgryzaniem i spałowaniem przez zwierzynę łowną a także w ochronie rośliny szkółkarskich leśnych, odnowień, zalesień oraz plantacji nasiennych drzew leśnych, krzewów ozdobnych, pigwy pospolitej, agrestu, aronii, borówki wysokiej oraz winorośli przed zgryzaniem.

**STOSOWANIE ŚRODKA**

Środek przeznaczony do stosowania przy użyciu pędzla lub rękawicy.

**ZAPOBIEGANIE ZGRYZANIU**

**Drzewa iglaste i liściaste**

*Zapobieganie zgryzaniu przez jeleniowate i zającowate.*

Maksymalna dawka dla jednorazowego zastosowania: 5 kg/1000 sztuk 2-5 letnich drzewek.

Zalecana dawka dla jednorazowego zastosowania: 2 - 5 kg/1000 sztuk 2-5 letnich drzewek. Zalecana dawka zależy od wielkości i gatunku chronionych sadzonek i drzewek.

Termin stosowania środka: Środek stosować w okresie jesienno-zimowym (na sadzonki drzew liściastych po opadnięciu liści), kiedy zwierzyna łowna zaczyna uszkadzać sadzonki. Środek stosować w temperaturze powyżej 0°C.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

**ZAPOBIEGANIE SPAŁOWANIU**

**Drzewa iglaste i liściaste**

*Zapobieganie spałowaniu kory z drzew przez jeleniowate.*

Maksymalna dawka dla jednorazowego zastosowania: 13 kg/1000 sztuk 2-5 letnich drzewek.

Zalecana dawka dla jednorazowego zastosowania: 10-13 kg/1000 sztuk 2-5 letnich drzewek. Zalecana dawka zależy od wielkości i gatunku chronionych sadzonek i drzewek.

Termin stosowania środka: Środek stosować w okresie jesienno-zimowym (na sadzonki drzew liściastych po opadnięciu liści), kiedy zwierzyna łowna zaczyna uszkadzać sadzonki. Środek stosować w temperaturze powyżej 0°C.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

**STOSOWANIE ŚRODKA OCHRONY ROŚLIN W UPRAWACH**

**I ZASTOSOWANIACH MAŁOOBSZAROWYCH**

***Odpowiedzialność za skuteczność działania i fitotoksyczność środka ochrony roślin stosowanego w uprawach małoobszarowych ponosi wyłącznie jego użytkownik***

**ZAPOBIEGANIE ZGRYZANIU**

**Rośliny szkółkarskie leśne, odnowienia, zalesienia oraz plantacje nasienne drzew leśnych, krzewy i drzewa ozdobne, drzewka bożonarodzeniowe uprawiane na plantacjach**

*Zapobieganie zgryzaniu pędów wierzchołkowych siewek i sadzonek wraz z liśćmi i pączkami przez jeleniowate, zającowate, wiewiórki pospolite i bobry.*

Maksymalna dawka dla jednorazowego zastosowania: 5 kg/1000 sztuk 2-5 letnich drzewek / krzewów.

Zalecana dawka dla jednorazowego zastosowania: 2 - 5 kg/1000 sztuk 2-5 letnich drzewek / krzewów. Zalecana dawka zależy od wielkości i gatunku chronionych sadzonek i drzewek.

Termin stosowania środka: Środek stosować w okresie jesienno-zimowym (na sadzonki drzew liściastych po opadnięciu liści), kiedy zwierzyna łowna zaczyna uszkadzać sadzonki. Środek stosować w temperaturze powyżej 0°C.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

**Grusza, śliwa, czereśnia, wiśnia, brzoskwinia, morela, leszczyna, orzech włoski, pigwa pospolita**

*Zapobieganie zgryzaniu pędów wierzchołkowych siewek i sadzonek wraz z liśćmi i pączkami przez jeleniowate, zającowate, wiewiórki pospolite i bobry.*

Maksymalna dawka dla jednorazowego zastosowania: 5 kg/1000 sztuk 2-5 letnich drzewek / krzewów.

Zalecana dawka dla jednorazowego zastosowania: 2 - 5 kg/1000 sztuk 2-5 letnich drzewek / krzewów. Zalecana dawka zależy od wielkości i gatunku chronionych sadzonek i drzewek.

Termin stosowania środka: Środek stosować w okresie jesienno-zimowym (na sadzonki drzew liściastych po opadnięciu liści), kiedy zwierzyna łowna zaczyna uszkadzać sadzonki. Środek stosować w temperaturze powyżej 0°C.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

**Agrest, aronia, borówka wysoka, winorośl**

*Zapobieganie zgryzaniu pędów wierzchołkowych siewek i sadzonek wraz z liśćmi i pączkami przez jeleniowate, zającowate, wiewiórki pospolite i bobry.*

Maksymalna dawka dla jednorazowego zastosowania: 5 kg/1000 sztuk 2-5 letnich drzewek / krzewów.

Zalecana dawka dla jednorazowego zastosowania: 2 - 5 kg/1000 sztuk 2-5 letnich drzewek / krzewów. Zalecana dawka zależy od wielkości i gatunku chronionych sadzonek i drzewek.

Termin stosowania środka: Środek stosować w okresie jesienno-zimowym (na sadzonki drzew liściastych po opadnięciu liści), kiedy zwierzyna łowna zaczyna uszkadzać sadzonki. Środek stosować w temperaturze powyżej 0°C.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

**ZAPOBIEGANIE SPAŁOWANIU**

**Drzewa ozdobne; drzewka bożonarodzeniowe uprawiane na plantacjach**

*Zapobieganie spałowaniu kory z drzew przez jeleniowate.*

Maksymalna dawka dla jednorazowego zastosowania: 13 kg/1000 sztuk drzew.

Zalecana dawka dla jednorazowego zastosowania: 10 - 13 kg/1000 sztuk drzew. Zalecana dawka zależy od wielkości i gatunku chronionych sadzonek i drzewek.

Termin stosowania środka: Termin stosowania środka: Środek stosować w okresie jesienno-zimowym (na sadzonki drzew liściastych po opadnięciu liści), kiedy zwierzyna łowna zaczyna uszkadzać sadzonki. Środek stosować w temperaturze powyżej 0°C.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

**Grusza, śliwa, czereśnia, wiśnia, brzoskwinia, morela, leszczyna, orzech włoski.**

*Zapobieganie spałowaniu kory z drzew przez jeleniowate.*

Maksymalna dawka dla jednorazowego zastosowania: 13 kg/1000 sztuk drzew.

Zalecana dawka dla jednorazowego zastosowania: 10 - 13 kg/1000 sztuk drzew. Zalecana dawka zależy od wielkości i gatunku chronionych sadzonek i drzewek.

Termin stosowania środka: Środek stosować w okresie jesienno-zimowym (na sadzonki drzew liściastych po opadnięciu liści), kiedy zwierzyna łowna zaczyna uszkadzać sadzonki. Środek stosować w temperaturze powyżej 0°C.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

**SPOSÓB STOSOWANIA**

Zapobieganie zgryzaniu: Przed zabiegiem środek dokładnie wymieszać aż do uzyskania konsystencji półpłynnej zawiesiny. Zaleca się również mieszanie w trakcie nanoszenia środka.

Zabieg wykonać za pomocą pędzla lub ręką zabezpieczoną gumową rękawicą:

Na drzewa iglaste środek nanosić na tegoroczny przyrost pędu drzew, na drzewa liściaste środek nanosić na cały pęd główny, gdy jego grubość nie przekracza 2 cm, a wysokość 60-80 cm.

Zapobieganie spałowaniu: Przed zabiegiem środek dokładnie wymieszać aż do uzyskania konsystencji półpłynnej zawiesiny. Zaleca się również mieszanie w trakcie nanoszenia środka.

Zabieg wykonać za pomocą pędzla lub ręką zabezpieczoną gumową rękawicą.

Środek nanosić na pnie drzew.

**ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WRAUNKI STOSOWANIA**

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

Nie dotyczy.

Środek stosować w dni bezdeszczowe, w temperaturze ~~nie niższej niż~~ otoczenia, powyżej 0°C.

Po wyschnięciu środek utrzymuje się na pędach do 7 miesięcy.

**ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH**

Nie jeść, nie pić ani nie palić podczas używania produktu.

Stosować rękawice ochronne oraz odzież roboczą w trakcie wykonywania zabiegu.

Wyprać zanieczyszczoną odzież przed ponownym użyciem.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):

Nie wchodzić do czasu wyschnięcia środka na powierzchni roślin.

**ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO**

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.

Nie myć aparatury w pobliżu wód powierzchniowych.

Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

**WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA**

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

* w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
* w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
* w temperaturze powyżej 0°C, do maksymalnie 30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zaleca się zwrócić do sprzedawcy środków ochrony roślin lub można je potraktować jako odpady komunalne. W razie wątpliwości dotyczących postępowania z opakowaniami poradź się sprzedawcy środków ochrony roślin.

**PIERWSZA POMOC**

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W przypadku kontaktu ze skórą umyć dużą ilością wody/mydłem.

W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

*Etykieta środka ochrony roślin BIAŁY PŁASZCZ EXTRA*

***Sekcja skuteczności:*** brak uwag do etykiety śor Gorzka Kora i Biały Płaszcz.

***Sekcja fiz-chem:*** Ponieważ po przechowywaniu w temperaturze 0°C produkt ulega zamrożeniu, proponuje się dodanie w sekcji WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA sformułowania „W przypadku przechowywania w temperaturze zbliżonej do 0°C odczekać 4 godziny przed zastosowaniem”.

W 2024 roku Wnioskodawca przedstawił badania środka w temperaturze +2°C, których wyniki wskazują, że w tej temperaturze środek nie ulega zamrożeniu. Wnioskodawca przedstawił propozycje następujących zmian w etykiecie:

1. W punkcie ŚRODKI OSTROŻNOŚCI ORAZ SZCZEGÓLNE WARUNKI STOSOWANIA zapis „Środek stosować w dni bezdeszczowe, w temperaturze otoczenia, nie niższej niż 0°C” zmienić na „Środek stosować w dni bezdeszczowe, w temperaturze otoczenia, powyżej 0°C”.

Wykreślić zapis „Przed zastosowaniem, w przypadku przechowywania w temperaturze zbliżonej do 0°C, należy przetrzymywać środek w temperaturze pokojowej przez 4 godziny”.

2. W punkcie WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA zapis podpunktu „w temperaturze 0°C - 30°C” zmienić na „w temperaturze powyżej 0°C, do maksymalnie 30°C”.

Proponowane zmiany zostały zakceptowane.

***Sekcja toksykologii:*** bez komentarza

***Sekcja ekotoksykologii:*** bez komentarza.

Posiadacz zezwolenia:

Przedsiębiorstwo Produkcyjno-Handlowe ADW Sp. z o.o., ul. Zbożowa 2, 43-175 Wyry, tel: 32 218-71-85, fax: 32 323-00-85, e-mail:sekretariat@adw.com.pl

**BIAŁY PŁASZCZ EXTRA**

Środek przeznaczony do stosowania przez użytkowników nieprofesjonalnych

Zawartość substancji czynnej:

piasek kwarcowy (związek z grupy tlenków nieorganicznych) - 251 g/kg (25,1%).

**Zezwolenie MRiRW nr R-135/2023 z dnia 03 sierpnia 2023 r**

|  |  |
| --- | --- |
| EUH 401 | W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia |
| P280 | Stosować rękawice ochronne. |

**OPIS DZIAŁANIA**

BIAŁY PŁASZCZ EXTRA jest środkiem o działaniu odstraszającym w formie pasty do bezpośredniego stosowania przeznaczonym do ochrony sadzonek i drzewek w leśnictwie przed zgryzaniem i spałowaniem przez zwierzynę leśną.

**STOSOWANIE ŚRODKA**

Środek przeznaczony do stosowania przy użyciu pędzla lub rękawicy.

**ZAPOBIEGANIE ZGRYZANIU**

**Drzewa iglaste i liściaste**

*Zapobieganie zgryzaniu przez jeleniowate i zającowate.*

Maksymalna dawka dla jednorazowego zastosowania: 0,05 kg/10 sztuk 2-5 letnich drzewek.

Zalecana dawka dla jednorazowego zastosowania: 0,02 – 0,05 kg/10 sztuk 2-5 letnich drzewek.

Środek stosować w okresie jesienno-zimowym (na sadzonki drzew liściastych po opadnięciu liści), kiedy zwierzyna łowna zaczyna uszkadzać sadzonki. Środek stosować w temperaturze powyżej 0°C.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

**ZAPOBIEGANIE SPAŁOWANIU**

**Drzewa iglaste i liściaste**

*Zapobieganie spałowaniu kory z drzew przez jeleniowate.*

Maksymalna dawka dla jednorazowego zastosowania: 0,13 kg/10 sztuk 2-5 letnich drzewek.

Zalecana dawka dla jednorazowego zastosowania: 0,10 – 0,13 kg/10 sztuk 2-5 letnich drzewek.

Środek stosować w okresie jesienno-zimowym (na sadzonki drzew liściastych po opadnięciu liści), kiedy zwierzyna łowna zaczyna uszkadzać sadzonki. Środek stosować w temperaturze powyżej 0°C.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

**SPOSÓB STOSOWANIA**

Zapobieganie zgryzaniu: Przed zabiegiem środek dokładnie wymieszać aż do uzyskania konsystencji półpłynnej zawiesiny. Zaleca się również mieszanie w trakcie nanoszenia środka.

Zabieg wykonać za pomocą pędzla lub ręką zabezpieczoną gumową rękawicą:

Na drzewa iglaste środek nanosić na tegoroczny przyrost pędu drzew, na drzewa liściaste środek nanosić na cały pęd główny, gdy jego grubość nie przekracza 2 cm, a wysokość 60-80 cm.

Zapobieganie spałowaniu: Przed zabiegiem środek dokładnie wymieszać aż do uzyskania konsystencji półpłynnej zawiesiny. Zaleca się również mieszanie w trakcie nanoszenia środka.

Zabieg wykonać za pomocą pędzla lub ręką zabezpieczoną gumową rękawicą.

Środek nanosić na pnie drzew.

**ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WRAUNKI STOSOWANIA**

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

Nie dotyczy.

Środek stosować w dni bezdeszczowe, w temperaturze ~~nie niższej niż~~ otoczenia, powyżej 0°C.

Po wyschnięciu środek utrzymuje się na pędach do 7 miesięcy.

**ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH**

Nie jeść, nie pić ani nie palić podczas używania produktu.

Stosować rękawice ochronne (nitrylowe).

Wyprać zanieczyszczoną odzież przed ponownym użyciem.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):

Nie wchodzić do czasu wyschnięcia środka na powierzchni roślin.

**ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO**

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.

Nie myć aparatury w pobliżu wód powierzchniowych.

Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

**WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA**

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

* w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
* w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
* w temperaturze powyżej 0°C, do maksymalnie 30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów. Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zaleca się zwrócić do sprzedawcy środków ochrony roślin lub można je potraktować jako odpady komunalne. W razie wątpliwości dotyczących postępowania z opakowaniami poradź się sprzedawcy środków ochrony roślin.

**PIERWSZA POMOC**

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W przypadku kontaktu ze skórą umyć dużą ilością wody/mydłem.

W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

1. Letter of Access

Not relevant. No Letter of Access submitted.

1. Lists of data considered for national authorization

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** | **Verte-brate study**  **Y/N** | **Data protection claimed**  **Y/N** | **Justification if data protection is claimed** | **Owner** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| KCP 2.1  KCP 2.3.1  KCP 2.3.3  KCP 2.4.2  KCP 2.6.1  KCP 2.7.1  KCP 2.7.3  KCP 2.7.4  KCP 2.8.5.1.2  KCP 2.11 | Giorgi S., | 2022 | Determination of the Physical-Chemical Properties of the GK-4 Product  (batch: 01 10 09 2021) Before and After Accelerated Storage for 14 Days at  54±2 °C and Cold Storage for 7 Days at 0±2 °C  Company Report No 21326-02C  Renolab S.r.l.  GLP  Unpublished | N | N | Data/study report submitted for first registration in Poland. | ADW Sp. z o.o.\* |
| KCP 5.1.1/01 | Giorgi S. | 2022 | Determination of the Active Ingredient Content in GK-4 (Batch: 01 10 09 2021) Product, Including Validation of an Analytical Method and Emission of an Analytical Certificate  Study code: 21326-01C  Renolab S.r.l.  GLP  Unpublished | N | N | Data/study report submitted for first registration in Poland. | ADW Sp. z o.o.\* |
| KCP 2.7.5 | Giorgi S. | 2024 | Determination of the Two years Storage Stability and Shelf-Life Data of the GK-4 Product (batch: 01 10 09 2021)  Study code: 21326-03C  Renolab S.r.l.  GLP  Unpublished | N | Y | Data/study report never submitted before to Poland. | ADW Sp. z o.o.\* |
| KCP 2.7.4 | Budniok A, | 2024 | Stabilność w niskich temperaturach Gorzka Kora  Study code: -  Consbridge Chemicals sp. z o.o.  No-GLP  Unpublished | N | Y | Data/study report never submitted before to Poland. | ADW Sp. z o.o.\* |
| ~~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~~ | ~~Y~~ | ~~Data/study report submitted for first registration in Poland.~~ | ~~ADW Sp. z o.o.\*~~ |
| ~~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~~ | ~~Y~~ | ~~Data/study report submitted for first registration in Poland.~~ | ~~ADW Sp. z o.o.\*~~ |
| KCP 6.2/01 | Borowski Z | 2021 | Study of efficacy of Gorzka kora  against peeling of bark damage in forest, Czarna Białostocka, Poland 2021  Company Report No.: 145283-1  Source: Instytut Badawczy Leśnictwa  GLP  Unpublished | N | Y | Data/study report never submitted before to Poland. | ADW Sp. z o.o.\* |
| KCP 6.2/02 | Borowski Z | 2021 | Study of efficacy of Gorzka kora  against peeling of bark damage in forest, Kobiór, Poland 2021  Company Report No.: 145283-2  Source: Instytut Badawczy Leśnictwa  GLP  Unpublished | N | Y | Data/study report never submitted before to Poland. | ADW Sp. z o.o.\* |
| KCP 6.2/03 | Borowski Z | 2021 | Study of efficacy of Gorzka kora  against peeling of bark damage in forest, Złoty Potok, Poland 2021  Company Report No.: 145283-3  Source: Instytut Badawczy Leśnictwa  GLP  Unpublished | N | Y | Data/study report never submitted before to Poland. | ADW Sp. z o.o.\* |
| KCP 6.2/04 | Borowski Z | 2021 | Study of efficacy of Gorzka kora  against peeling of browsing damage in forest, Czarna Białostocka, Poland 2021  Company Report No.: 145283-4  Source: Instytut Badawczy Leśnictwa  GLP  Unpublished | N | Y | Data/study report never submitted before to Poland. | ADW Sp. z o.o.\* |
| KCP 6.2/05 | Borowski Z | 2021 | Study of efficacy of Gorzka kora  against peeling of browsing damage in forest, Kobiór, Poland 2021  Company Report No.: 145283-5  Source: Instytut Badawczy Leśnictwa  GLP  Unpublished | N | Y | Data/study report submitted for first registration in Poland. | ADW Sp. z o.o.\* |
| KCP 6.2/06 | Borowski Z | 2021 | Study of efficacy of Gorzka kora  against peeling of browsing damage in forest, Złoty Potok, Poland 2021  Company Report No.: 145283-6  Source: Instytut Badawczy Leśnictwa  GLP  Unpublished | N | Y | Data/study report submitted for first registration in Poland. | ADW Sp. z o.o.\* |
| KCP 6.2/11 | dr hab. Zbigniew Borowski, prof. IBL | 2024 | Study of the efficacy of Gorzka kora against tree browsing by hares in the forest, Czarna Białostocka, Poland 2024.  Company Report No.: 145283-1  Source: Instytut Badawczy Leśnictwa  GLP  Unpublished | N | Y | Data/study report never submitted before to Poland. | ADW Sp. z o.o.\* |
| KCP 6.2/12 | dr hab. Zbigniew Borowski, prof. IBL | 2024 | Study of the efficacy of Gorzka kora against tree browsing by hares in the forest, Supraśl, Poland 2024.  Company Report No.: 145283-2  Source: Instytut Badawczy Leśnictwa  GLP  Unpublished | N | Y | Data/study report never submitted before to Poland. | ADW Sp. z o.o.\* |

\* 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** | **Verte-brate study**  **Y/N** | **Data protection claimed**  **Y/N** | **Justification if data protection is claimed** | **Owner** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| KCP 5.1.1/02 | Giorgi S. | 2022 | Determination of the Crystalline silica <10μm in 5 batches of Quartz sand Technical, Including Validation of the Analytical Method  Renolab S.r.l., Italy  Study No: 21321-02C  GLP: Yes  Published: No | N | N | No relevant. | ADW Sp. z o.o.\* |

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** | **Verte-brate study**  **Y/N** | **Data protection claimed**  **Y/N** | **Justification if data protection is claimed** | **Owner** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| KCP 10.2/09 | 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 | Y | Data/study report submitted for first registration in Poland. | ADW Sp. z o.o.\* |
| KCP 10.2/10 | 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 | Y | Data/study report submitted for first registration in Poland. | ADW Sp. z o.o.\* |

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** | **Verte-brate study**  **Y/N** | **Data protection claimed**  **Y/N** | **Justification if data protection is claimed** | **Owner** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| KCP XX | Author | YYYY | Title  Company Report No  Source  GLP/non GLP/GEP/non GEP  Published/Unpublished | Y/N | Y/N | Data/study report never submitted before to <insert MS>  If previously submitted in **this** MS:  Data protection started with: <insert authorization number of first authorization> | Owner |
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