

# FINAL REGISTRATION REPORT

## Part B

### Section 1: Identity

### Section 2: Physical and chemical properties

### Section 4: Further information

Detailed summary of the risk assessment

Product code: GK-4

Product name: GORZKA KORA

Chemical active substance:

Active substance: quartz sand, 251 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

## CORE ASSESSMENT

(authorization)

Applicant: Przedsiębiorstwo Produkcyjno-Handlowe

ADW Sp. z o.o.

Submission date: October 2022

MS Finalisation date: February 2023; May 2023

## Version history

| When          | What                      |
|---------------|---------------------------|
| February 2023 | zRMS assessment of dRR    |
| May 2023      | Final Registration Report |
|               |                           |
|               |                           |

## Table of Contents

|   |  |           |
|---|--|-----------|
| <b>1</b>                                    | <b>Section 1: Identity of the plant protection product.....</b>  | <b>4</b>  |
| 1.1   | Applicant (KCP 1.1) .....  | 4         |
| 1.2   | Producer of the plant protection product and of the active substances<br>(KCP 1.2) .....                   | 4         |
| 1.2.1                                       | Producer(s) of the preparation .....   | 4         |
| 1.2.2                                       | Producer(s) of the active substance(s) .....   | 4         |
| 1.2.3                                       | Statement of purity (and detailed information on impurities) of the active<br>substance(s) .....           | 4         |
| 1.2.3.1                                     | Quartz sand .....  | 4         |
| 1.3   | Trade names and producer's development code numbers for the<br>preparation (KCP 1.3) .....                 | 4         |
| 1.4   | Detailed quantitative and qualitative information on the composition of<br>the preparation (KCP 1.4) ..... | 5         |
| 1.4.1                                       | Composition of the plant protection product (KCP 1.4.1) .....  | 5         |
| 1.4.2                                       | Information on the active substance(s) (KCP 1.4.2) .....   | 5         |
| 1.4.3                                       | Information on safeners, synergists and co-formulants (KCP 1.4.3) .....                                    | 6         |
| 1.5   | Type and code of the plant protection product (KCP 1.5) .....  | 6         |
| 1.6   | Function (KCP 1.6) .....   | 6         |
| <b>2</b>                                    | <b>Section 2: Physical, chemical and technical properties of the plant<br/>protection product .....</b>    | <b>7</b>  |
| <b>3</b>                                    | <b>Section 3 is presented as a separate document .....</b>   | <b>13</b> |
| <b>4</b>                                    | <b>Section 4: Further information on the plant protection product .....</b>                                | <b>14</b> |
| 4.1   | Packaging and Compatibility with the Preparation (KCP 4.4) .....   | 14        |
| <b>Appendix 1</b>                           | <b>Lists of data considered in support of the evaluation .....</b>   | <b>15</b> |
| <b>Appendix 2</b>                           | <b>Additional data on the physical, chemical and technical properties of<br/>the active substance.....</b> | <b>17</b> |
| <b>No additional studies submitted.....</b> |  | <b>17</b> |

Sufficient data on identity, physical and chemical properties and other information are **not** available for the plant protection product and the contained technical active substance.

Noticed data gaps are:

- 2-years ambient storage stability data.

## **1 Section 1: Identity of the plant protection product**

### **1.1 Applicant (KCP 1.1)**

Name: Przedsiębiorstwo Produkcyjno-Handlowe ADW Sp. z o.o.  
Address: ul. Zbożowa 2  
43-175 Wry  
Poland

### **1.2 Producer of the plant protection product and of the active substances (KCP 1.2)**

#### **1.2.1 Producer(s) of the preparation**

Confidential information or data are provided separately (Part C).

#### **1.2.2 Producer(s) of the active substance(s)**

Confidential information or data are provided separately (Part C).

#### **1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)**

##### **1.2.3.1 Quartz sand**

According to Reg. 540/2011:

Purity of quartz sand min. 915 g/kg (acc. to Reg. 540/2011)

Maximum 0.1 % of particles of crystalline silica (with diameter below 50 um).

Information of quartz sand produced by ADW Sp. z o.o. is confidential information and is provided separately (Part C).

### **1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)**

Trade name: Gorzka Kora

Company code number: GK-4

## 1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

### 1.4.1 Composition of the plant protection product (KCP 1.4.1)

**Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)**

| Active substance | Declared content of the pure active substance (g/kg) | FAO Limits (min – max)      | Technical content* (g/kg) | Technical content** (%w/w) |
|------------------|--|-----------------------------|---------------------------|----------------------------|
| Quartz sand      | 251  | <del>NA</del> 238.5 - 263.6 | 253.5                     | 25.35                      |

\* Based on the minimum purity of the active substance declared for registration in the active substance dossiers

**Table 1.4-2: Safener and synergists**

| Safener / synergist | Declared content of the safener / synergist (g/L or g/kg) | FAO Limits (min – max) | Technical content* (g/L or g/kg) | Technical content** (%w/w) |
|---------------------|---|------------------------|----------------------------------|----------------------------|
| NA                  | NA  | NA                     | NA                               | NA                         |

\* Based on the minimum purity of the safener/synergist declared for registration

**Table 1.4-3: Relevant impurities**

| Relevant impurity                            | Maximum content (g/L or g/kg)         |
|--|---------------------------------------|
| Crystalline silica with diameter below 50 µm | maximum <del>0.05 % (LOQ)</del> 0.1 % |

|                   |  |
|-------------------|--|
| Comments of zRMS: | According to EFSA, 2022. Conclusion on the peer review of the pesticide risk assessment of the active substance quartz sand. EFSA Journal 2022;20(9):7552, the specification for relevant impurity was changed to: max. 0.1% of particles of crystalline silica with particle diameter ≤ 10 µm<br>However, at the time of dRR assessment, this change was not yet included in Regulation 540/2011. |
|-------------------|--|

### 1.4.2 Information on the active substance(s) (KCP 1.4.2)

**Table 1.4-4: Information on quartz sand**

| Type            | Name/Code Number          |
|-----------------|---------------------------|
| ISO common name | Quartz sand (no ISO name) |
| CAS No.         | 14808-60-7                |
| EC No.          | 238-878-4                 |
| CIPAC No.       | 855                       |

### **1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)**

**Table 1.4-5: Information on safeners/ synergists / co-formulant**

| <b>Type</b>                      | <b>Name/Code Number</b>                                   |
|----------------------------------|---|
| Safener /synergist/ co-formulant | CONFIDENTIAL information is provided separately (Part C). |
| ISO common name                  | CONFIDENTIAL information is provided separately (Part C). |
| CAS No.                          | CONFIDENTIAL information is provided separately (Part C). |
| EC No.                           | CONFIDENTIAL information is provided separately (Part C). |

CONFIDENTIAL information is provided separately (Part C).

### **1.5 Type and code of the plant protection product (KCP 1.5)**

Type: Paste

[Code: PA]

### **1.6 Function (KCP 1.6)**

Plant protection product is a repellent.

## **2                    Section 2: Physical, chemical and technical properties of the plant protection product**

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.

### **Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only**

Not relevant. No classification and labelling is proposed.

### **Notifier Proposals for Risk and Safety Phrases (KCP 12)**

No applicable.

### **Compliance with FAO specifications:**

Not relevant. No FAO specification available.

### **Formulation used for tests**

The formulation used for tests and studies has the same composition as the one cited in Part C.

**Table 2-1: Physical, chemical and technical properties of the plant protection product**

| Annex point                         | Method used / deviations | Test material                 | Findings   | GLP Y/N | Reference       | Acceptability / comments  |
|-------------------------------------|--------------------------|-------------------------------|--|---------|-----------------|---|
| Colour and physical state (KCP 2.1) | Visual assessment        | GK-4, batch no: 01 10 09 2021 | Ivory opaque dense paste, characteristic odour   | Y       | Giorgi S., 2022 | Accepted.   |
| Explosive properties (KCP 2.2.1)    | -                        | -                             | Not relevant. The product does not contain ingredients that have explosive properties so it can be assumed that it is not explosive. | -       | -               | Considering the composition of the formulation, no further information is required. Accepted.   |
| Oxidizing properties (KCP 2.2.2)    | -                        | -                             | Not relevant. The product does not contain ingredients that have oxidizing properties so it can be assumed that it is not oxidizing. | -       | -               | Considering the composition of the formulation, no further information is required. Accepted.   |
| Flash point (KCP 2.3.1)             | EEC A.9                  | GK-4, batch no: 01 10 09 2021 | No flash point up to 115°C: at 115°C, vapors from the test item turned off the flame.  | Y       | Giorgi S, 2022  | The flash point was determined using a closed cup apparatus according to ASTM D 56 (Flash Point by Tag Closed Tester). The preparation is not flammable Accepted. |
| Flammability (KCP 2.3.2)            | Statement                | GK-4, batch no: 01 10 09 2021 | The test item is not flammable, because the active ingredient contain no “plosophore” groups.  | Y       | Giorgi S., 2022 | Considering the composition of the formulation, no further information is required. Accepted.   |
| Self-heating                        | A15                      | GK-4,                         | No ignition occurred up to maximum instrumental  | Y       | Giorgi S., 2022 | The test was performed  |



| Annex point  | Method used / deviations   | Test material                          | Findings  | GLP Y/N   | Reference       | Acceptability / comments                |                              |  |           |                                 |  |                                  |   |                 |   |
|--|--|--|---|-----------|-----------------|---|------------------------------|--|-----------|---------------------------------|--|----------------------------------|---|-----------------|---|
| (KCP 2.3.3)  |  | batch no:<br>01 10 09<br>2021          | temperature (600°C).  |           |                 | with a Koehler instrument.<br>Accepted. |                              |  |           |                                 |  |                                  |   |                 |   |
| Acidity or alkalinity and pH<br>(KCP 2.4.1)                        | No required.   | -                                      | Required if pH is: pH <4 or >10.  | -         | -               |   |                              |  |           |                                 |  |                                  |   |                 |   |
| pH of a 1% aqueous dilution, emulsion or dispersion<br>(KCP 2.4.2) | CIPAC MT 75.3  | GK-4,<br>batch no:<br>01 10 09<br>2021 | Neat=8.91<br>1%=7.42  | Y         | Giorgi S., 2022 | Accepted.                               |                              |  |           |                                 |  |                                  |   |                 |   |
| Viscosity<br>(KCP 2.5.1)   | -  | -                                      | Not relevant. The product is not a liquid.  | -         | -               |   |                              |  |           |                                 |  |                                  |   |                 |   |
| Surface tension<br>(KCP 2.5.2)                                     | -  | -                                      | Not relevant. The product is not a liquid.  | -         | -               |   |                              |  |           |                                 |  |                                  |   |                 |   |
| Relative density<br>(KCP 2.6.1)                                    | A.3.1  | GK-4,<br>batch no:<br>01 10 09<br>2021 | 1.550   | Y         | Giorgi S., 2022 | Accepted.                               |                              |  |           |                                 |  |                                  |   |                 |   |
| Bulk density<br>(KCP 2.6.2)  | -  | -                                      | Not relevant. The product is not a powder or granulate.   | -         | -               |   |                              |  |           |                                 |  |                                  |   |                 |   |
| Storage Stability after 14 days at 54° C<br>(KCP 2.7.1)            | Visual assessment<br>Visual assessment<br>CIPAC MT 75.3<br>CIPAC MT 185<br>MA CCF 611-1<br>(Validated and determined in the study 21326-01C) | GK-4,<br>batch no:<br>01 10 09<br>2021 | <table><tr><td>Parameter</td><td>Initial product</td><td>After storage at 54°C for 2 weeks</td></tr><tr><td>Appearance, colour and odour</td><td>Ivory opaque dense paste, characteristic odour</td><td>Unchanged</td></tr><tr><td>Packaging appearance and weight</td><td>Intact plastic bag made of LLDPE/EVOH/</td><td>Unchanged;<br/>Weight loss = -2 g</td></tr></table> | Parameter | Initial product | After storage at 54°C for 2 weeks       | Appearance, colour and odour | Ivory opaque dense paste, characteristic odour | Unchanged | Packaging appearance and weight | Intact plastic bag made of LLDPE/EVOH/ | Unchanged;<br>Weight loss = -2 g | Y | Giorgi S., 2022 | The test item was stored in the original container - plastic bag (LLDPE/EVOH/LLDPE). No change to the container after storage.<br>Change of a.s. 0.8%.<br>No significant change the product after the storage.<br>Accepted. |
| Parameter  | Initial product  | After storage at 54°C for 2 weeks      |   |           |                 |   |                              |  |           |                                 |  |                                  |   |                 |   |
| Appearance, colour and odour                                       | Ivory opaque dense paste, characteristic odour   | Unchanged                              |   |           |                 |   |                              |  |           |                                 |  |                                  |   |                 |   |
| Packaging appearance and weight                                    | Intact plastic bag made of LLDPE/EVOH/   | Unchanged;<br>Weight loss = -2 g       |   |           |                 |   |                              |  |           |                                 |  |                                  |   |                 |   |

| Annex point   | Method used / deviations  | Test material                          | Findings  |                                      |   | GLP Y/N | Reference       | Acceptability / comments  |
|---|---|--|---|--------------------------------------|---|---------|-----------------|---|
|   |   |  | change  | LLDPE                                |   |         |                 |   |
|   |   |  | pH as is & 1 % dilution                                   | Neat=8.91<br>1%=7.42                 | Neat=8.80<br>1%= <del>7.30</del> 8.30   |         |                 |   |
|   |   |  | Wet sieve test  | Residues on 75 µm sieve 25.40 %      | Residues on 75 µm sieve 25.51 %   |         |                 |   |
|   |   |  | Active ingredient   | 25.27 %                              | 25.06 %   |         |                 |   |
| Stability after storage for other periods and/or temperatures (KCP 2.7.2) | -   | -                                      | Not relevant. The product was stable at 54°C for 2 weeks. |                                      |   | -       | -               |   |
| Minimum content after heat stability testing (KCP 2.7.3)                  | See KCP 2.7.1   | -                                      | -   |                                      |   | -       | -               |   |
| Effect of low temperatures on stability (KCP 2.7.4)                       | Visual assessment<br>CIPAC MT 75.3<br>CIPAC MT 185<br>MA CCF 611-1<br>(Validated and determined in the study 21326-01C; KCP 5.1.1/01) | GK-4,<br>batch no:<br>01 10 09<br>2021 | Parameter   | Initial product                      | After storage at 0±2 °C for 7 days  | Y       | Giorgi S., 2022 | The product solidifies after storage in low temperatures, but after 4 hours in the ambient temperature there is no change to the properties. The following phrase for the label is proposed by the Applicant: “Store in the temperatures 0°C – 30°C”. However, as after storage in 0°C product is frozen it is proposed to add the phrase “When stored in the temperature close to 0°C, wait 4 hours before application”. Accepted. |
|   |   |  | Appearance, colour and odour                              | Gray-green paste of a specific odor. | Frozen solid, reverts to before storage appearance after 4 hours at ambient temperature |         |                 |   |
|   |   |  | pH as is & 1 % dilution                                   | Neat=8.91<br>1%=7.42                 | Neat=8.87<br>1%=7.74  |         |                 |   |
|   |   |  | Wet sieve test  | Residues on 75 µm sieve 25.40 %      | Residues on 75 µm sieve 25.22 %   |         |                 |   |

| Annex point   | Method used / deviations        | Test material            | Findings   |         |         | GLP Y/N | Reference       | Acceptability / comments   |
|---|---------------------------------|--------------------------|--|---------|---------|---------|-----------------|--|
|   |                                 |                          | Active ingredient  | 25.27 % | 25.17 % |         |                 |  |
| Ambient temperature shelf life (KCP 2.7.5)                                  | In progress.                    |                          |  |         |         |         |                 |  |
| Shelf life in months (if less than 2 years) (KCP 2.7.6)                     | -                               | -                        | Not relevant. Proposed shelf life will be 2 years.   |         |         | -       | -               |  |
| Wettability (KCP 2.8.1)   | -                               | -                        | Not relevant. The product is not to be used as a dilution.   |         |         | -       | -               |  |
| Persistence of foaming (KCP 2.8.2)  | -                               | -                        | Not relevant. The product is not to be used as a dilution.   |         |         | -       | -               |  |
| Suspensibility (KCP 2.8.3.1)  | -                               | -                        | Not relevant. The product is not a water dispersible product.  |         |         | -       | -               |  |
| Spontaneity of dispersion (KCP 2.8.3.2)                                     | -                               | -                        | Not relevant. The product is not a water dispersible product.  |         |         | -       | -               |  |
| Dispersion stability (KCP 2.8.3.3)  | -                               | -                        | Not relevant. The product is not a water dispersible product.  |         |         | -       | -               |  |
| Degree of dissolution and dilution stability (KCP 2.8.4)                    | -                               | -                        | Not relevant. The product is not a water soluble product.  |         |         | -       | -               |  |
| Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1) | -                               | -                        | Not relevant. The product is not in a form of powder or suspension concentrate. However, the results of 5-batch analysis indicate that the quartz sand mixture has no particles of diameter < 50 µm. |         |         | -       | -               | Accepted.  |
| Wet sieve test (KCP 2.8.5.1.2)  | CIPAC MT 185 (Sieve size 75 µm) | GK-4, batch no: 01 10 09 | 25.40%   |         |         | Y       | Giorgi S., 2022 | As the preparation is ready-to-use product and is not diluted with |

| Annex point   | Method used / deviations | Test material | Findings  | GLP Y/N | Reference | Acceptability / comments                          |
|---|--------------------------|---------------|---|---------|-----------|---|
|   |                          | 2021          |   |         |           | water for use the wet sieve test is not required. |
| Dust content (KCP 2.8.5.2.1)                            | -                        | -             | Not relevant. The product is not a granulate.   | -       | -         |   |
| Particle size of dust (KCP 2.8.5.2.2)                   | -                        | -             | Not relevant. The product is not a granulate.   | -       | -         |   |
| Attrition (KCP 2.8.5.3)                                 | -                        | -             | Not relevant. The product is not a granulate.   | -       | -         |   |
| Hardness and integrity (KCP 2.8.5.4)                    | -                        | -             | Not relevant. The product is not a granulate.   | -       | -         |   |
| Emulsifiability (KCP 2.8.6.1)                           | -                        | -             | Not relevant. The product is not in a form of granules or tablets.                      | -       | -         |   |
| Emulsion stability (KCP 2.8.6.2)                        | -                        | -             | Not relevant. The product is not in a form of tablets.                                  | -       | -         |   |
| Re-emulsifiability (KCP 2.8.6.3)                        | -                        | -             | Not relevant. The product is not in a form that exists as a emulsion in the spray tank. | -       | -         |   |
| Flowability (KCP 2.8.7.1)                               | -                        | -             | Not relevant. The product is not in a form that exists as a emulsion in the spray tank. | -       | -         |   |
| Pourability (KCP 2.8.7.2)                               | -                        | -             | Not relevant. The product is not in a form that exists as a emulsion in the spray tank. | -       | -         |   |
| Dustability following accelerated storage (KCP 2.8.7.3) | -                        | -             | Not relevant. The product is not in a form of granules.                                 | -       | -         |   |
| Physical compatibility of tank mixes (KCP 2.9.1)        | -                        | -             | Not relevant. The product is not in a form of suspension.                               | -       | -         |   |
| Chemical compatibility of tank mixes                    | -                        | -             | Not relevant. The product is not in a form of dustable powder.                          | -       | -         |   |

| Annex point                                       | Method used / deviations | Test material                 | Findings                                    | GLP Y/N | Reference       | Acceptability / comments                                       |
|---|--------------------------|-------------------------------|---|---------|-----------------|--|
| (KCP 2.9.2)                                       |                          |                               |   |         |                 |  |
| Adhesion to seeds (KCP 2.10.1)                    | -                        | -                             | Not relevant. No tank-mix is proposed.      | -       | -               |  |
| Distribution to seed (KCP 2.10.2)                 | -                        | -                             | Not relevant. No tank-mix is proposed.      | -       | -               |  |
| Packaging appearance and weight change (KCP 2.11) | Visual assessment        | GK-4, batch no: 01 10 09 2021 | Intact plastic bag made of LLDPE/EVOH/LLDPE | Y       | Giorgi S., 2022 | The packaging was stable during accelerated storage. Accepted. |

### 3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

## 4 Section 4: Further information on the plant protection product

### 4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

|                   |  |
|-------------------|--|
| Comments of zRMS: | During the accelerated storage, the test item was stored in the original container - plastic bag (LLDPE/ EVOH/LLDPE). As there was no change to the container after storage, the proposed packaging is acceptable. |
|-------------------|--|

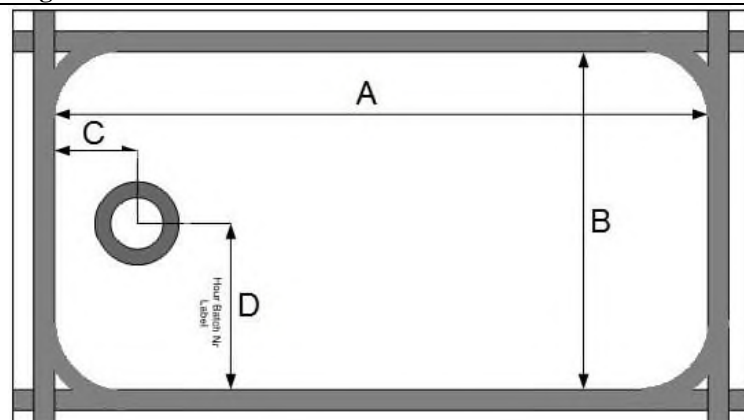
**Table 4.1-1: Packaging information for bags with tap**

| Type            | Description       |
|-----------------|-------------------|
| Material outer: | LLDPE/EVOH/LLDPE  |
| Material inner: | LLDPE             |
| Shape/size:     | Rectangular, 5 kg |
| Spout:          | LDPE              |
| Tap:            | LDPE              |

#### BAG DIMENSIONS

| [mm]  | Size A | Size B | Size C | Size D | Seal | Tolerance | Weight [kg] |
|-------|--------|--------|--------|--------|------|-----------|-------------|
| inner | 315    | 250    | 60     | 125    | 5 mm | ± 8 mm    | ±3%<br>0,04 |
| outer | 330    | 270    | -      | -      |      |           |             |

#### Bag scheme



#### Fitment scheme



## 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<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not   | Vertebrate study<br>Y/N | Owner           |
|--|------------|------|---|-------------------------|-----------------|
| KCP 2.1<br>KCP2.3.1<br>KCP2.3.3<br>KCP 2.4.2<br>KCP 2.6.1<br>KCP 2.7.1<br>KCP 2.7.3<br>KCP 2.7.4<br>KCP 2.8.5.1.2<br>KCP2.11 | 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<br>Company Report No 21326-02C<br>Renolab S.r.l.<br>GLP<br>Unpublished | N                       | 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<br>Study code: 21326-01C<br>Renolab S.r.l.<br>GLP<br>Unpublished                        | N                       | ADW Sp. z o.o.* |
|  |            |      |   |                         |                 |

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**

| <b>Data point</b> | <b>Author(s)</b> | <b>Year</b> | <b>Title<br/>Company Report No.<br/>Source (where different from company)<br/>GLP or GEP status<br/>Published or not</b> | <b>Vertebrate<br/>study<br/>Y/N</b> | <b>Owner</b> |
|-------------------|------------------|-------------|--|-------------------------------------|--------------|
|                   |                  |             |  |                                     |              |

The following tables are to be completed by MS.

**List of data submitted by the applicant and not relied on**

| <b>Data point</b> | <b>Author(s)</b> | <b>Year</b> | <b>Title<br/>Company Report No.<br/>Source (where different from company)<br/>GLP or GEP status<br/>Published or not</b> | <b>Vertebrate<br/>study<br/>Y/N</b> | <b>Owner</b> |
|-------------------|------------------|-------------|--|-------------------------------------|--------------|
|                   |                  |             |  |                                     |              |

**List of data relied on and not submitted by the applicant but necessary for evaluation**

| <b>Data point</b> | <b>Author(s)</b> | <b>Year</b> | <b>Title<br/>Company Report No.<br/>Source (where different from company)<br/>GLP or GEP status<br/>Published or not</b> | <b>Vertebrate<br/>study<br/>Y/N</b> | <b>Owner</b> |
|-------------------|------------------|-------------|--|-------------------------------------|--------------|
|                   |                  |             |  |                                     |              |



## **Appendix 2    Additional data on the physical, chemical and technical properties of the active substance**

**No additional studies submitted.**