

# 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: AKO 600 SC

Product name(s): Tanger 600 SC, Libretto 600 SC

Chemical active substance:

Aclonifen, 600g/L

Central Zone

Zonal Rapporteur Member State: Poland

Co-Rapporteur Member State: Hungary, Slovakia, Germany,  
Romania

## CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: 18.11.2024

zRMS Assessment : 28/06/2025

Following commenting period: 01/10/2025

Final Version:29/06/2026

## Version history

| When         | What                        |
|--------------|-----------------------------|
| June 2025    | zRMS evaluation             |
| October 2025 | Following commenting period |
| June 2026    | Final version               |
|              |                             |

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State whether or not submitted data are sufficient for evaluation. Data gaps and conditions for registration should be listed, if appropriate.

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(s).

Noticed data gaps are:

- data gap 1: The shelf life of at least 2 years at ambient temperature when stored in HDPE package was proposed by applicant based on the 1-year storage stability test at ambient temperature. It is suggested by evaluator to perform 2-years storage stability study at ambient temperature to establish shelf-life for the product. Missing storage stability study at ambient temperature - 2 years storage stability study. It is required to set a shelf-life for the PPP and may be evaluated in post-registration at national level.

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

According to Regulation 1107/2009 data protection for data at European level lasts for 10 years. Due to the fact that the aclonifen annex I was approved on 1/08/2009, data protection has expired 1/08/2019. Therefore, Innvigo can use the European data for aclonifen for the registration of the product AKO 600 SC [Libretto 600 SC, Tanger 600 SC]

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

Name: Innvigo Sp. z o.o.  
Address: Aleje Jerozolimskie 178, 02-486 Warsaw, Poland  
Tel: + 48 22 468 26 70

### **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 Aclonifen**

According to SANCO/161/08 – rev. 2 28 September 2012

Aclonifen – minimum purity: 970 g/kg

The review has established that for the active substance notified by the main data submitters the manufacturing impurity phenol is of toxicological concern and must not exceed maximum level of 5 g/kg in the technical material

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

Trade name: Please refer to Registration Report Part A for the relevant country (or)

Trade name: Tanger 600 SC, Libretto 600 SC

Company code number: CHR/H/AKO 600 SC

### **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 / variant | Declared content of the pure active substance / variant (g/L or g/kg) | FAO Limits (min – max) | Technical content* (g/L or g/kg) | Technical content** (%w/w) |
|----------------------------|-----------------------------------------------------------------------|------------------------|----------------------------------|----------------------------|
| Aclonifen                  | 600                                                                   | 575-625                | 612.25 g/L                       | 50.6% w/w                  |

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

\*\* Based on the density of the formulation = 1.2118 g/ml

**Table 1.4-3: Relevant impurities**

| Relevant impurity | Maximum content (g/kg) |
|-------------------|------------------------|
| Phenol            | 5                      |

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

**Table 1.4-4: Information on Aclonifen**

| Type            | Name/Code Number |
|-----------------|------------------|
| ISO common name | Aclonifen        |
| CAS No.         | 74070-46-5       |
| EC No.          | 77-704-1         |
| CIPAC No.       | 498              |

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

CONFIDENTIAL information is provided separately (Part C).

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

Type: Suspension concentrate

[Code: SC]

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

Herbicide

## **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 that of yellow coloured, with a delicate, characteristic odour. It is not explosive, has no oxidising properties. It has got the auto-ignition temperature – 507°C – according to criteria of PN-EN-ISO/IEC 0079-20-1:2020. Flash point was not observed. In aqueous solution, it has a pH value around  $8\pm 0.5$  at 19.9 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 8 weeks at  $40\pm 2$  °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in *HDPE*. Its technical characteristics are acceptable for a *SC* formulation.

The intended concentration of use is 0.5% to 1.67%.

The product can be mixed in the tank together with BOA PRO 480 EC. Studies regarding the combination with BOA PRO 480 EC were submitted and the application as tank mixture is acceptable.

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

No classification is necessary

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

Not required

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

The product AKO 600 SC complies with FAO specifications.  
There are no FAO specifications for acetonifene.

### **Formulation used for tests**

CHR/H/AKO 600 SC  
Date of production: 23.03.2023  
Batch NO.: CHR/02/2023

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

| Annex point                         | Method used / deviations              | Test material                                      | Findings                                                                                                  |                                                                                                                  |                                                                                                                          | GL P Y/N | Reference                                                | Acceptability / comments                                                                                                                                                                                                              |
|-------------------------------------|---------------------------------------|----------------------------------------------------|-----------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|----------|----------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Colour and physical state (KCP 2.1) | OPPTS 830.6302, 830.6303 and 830.6304 | CHR/H/AKO 600 SC<br>Date of production: 23.03.2023 | Initial                                                                                                   | After storage (Accelerated storage test (8 weeks at 40±2°C)                                                      | After 12 months shelf-life test                                                                                          | Y        | Górka I<br>Study code: ICB/107/2023                      | Accepted                                                                                                                                                                                                                              |
|                                     |                                       |                                                    | Colour (Munsell's notation) – 5Y 8.5/14 (yellow) Physical state – liquid Odour – delicate, characteristic | Colour (Munsell's notation) – 5Y 8.5/14 (yellow) Physical state – opaque liquid Odour – delicate, characteristic | Colour (Munsell's notation) – 7.5Y 8.5/12 (yellow)<br>Physical state – opaque liquid<br>Odour – delicate, characteristic |          | Study code: ICB/136/2023<br><br>Study code: ICB/108/2023 |                                                                                                                                                                                                                                       |
| Explosive properties (KCP 2.2.1)    | A.14                                  | CHR/H/AKO 600 SC<br>Date of production: 23.03.2023 | CHR/H/AKO 600 SC does not have explosive properties according to the criteria of EC A. 14 method          |                                                                                                                  |                                                                                                                          | Y        | Ołowski G.<br>Study code: BW-09/23                       | Accepted<br><br>Determination of explosive properties of CHR/H/AKO 600 SC was performed in accordance with EC 1.14 method published in Council Regulation (EC) No. 440/2008. During the study determination of impact sensitivity and |

|                                  |                |                                                    |                                                                                                                                                                                                                                                                                                                                                                |   |                                         |                                                                                                                                                                                                                                                                                                                                 |
|----------------------------------|----------------|----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|-----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                  |                |                                                    |                                                                                                                                                                                                                                                                                                                                                                |   |                                         | thermal sensitivity was performed. Based on the results of the study, test item AKO 600 SC does not have explosive properties.                                                                                                                                                                                                  |
| Oxidizing properties (KCP 2.2.2) | A 21 TEST O.2. | CHR/H/AKO 600 SC<br>Date of production: 23.03.2023 | <p>CHR/H/AKO 600 SC</p> <p>Has not got the oxidizing properties according to Test UN O.2.</p> <p>Mean pressure rise for the mixture of CHR/H/AKO/600 and cellulose [ms]: pressure did not reach the critical value 690 kPa and 2070 kPa</p> <p>Mean pressure of the mixture of the reference substance (65% aqueous nitric (V) and cellulose (ms): 551±287</p> | Y | Pachnicki P.<br>Study code no. BC-38/23 | <p><b>Accepted</b></p> <p>Oxidising properties was performed according to Test method UN O.2. According to the data obtained during the test, pressure rise did not reach the critical value for mixture of AKO/600 SC and cellulose. Test item AKO 600 SC does not have the oxidising properties according to Test UN O.2.</p> |

|                                                   |                                                                          |                                                              |                                                                                                                                                                                                 |   |                                             |                                                                                                                                                                                                                   |
|---------------------------------------------------|--------------------------------------------------------------------------|--------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|---------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Flammability<br>(KCP 2.3.2)                       | -                                                                        | -                                                            | According to SANCO/10473/2003 -rev. 5 21.10.2021 test methods describing flammability properties of Aclonifen are defined by flash point and self-ignition points which details are shown below |   |                                             | <b>Accepted</b>                                                                                                                                                                                                   |
| Flash point<br>(KCP 2.3.1)                        | A.9                                                                      | CHR/H/AK<br>O 600 SC<br>Date of<br>production:<br>23.03.2023 | Flash point for the test item was not observed. The test flame was extinguished by vapours of the test item at <b>temperature 43.0°C.</b>                                                       | - | Górka I.<br>Study code:<br>ICB/107/202<br>3 | <b>Accepted</b><br><br>The flash point was conducted according to method EEC A.9.<br>Flash point for test item was not observed. Test item AKO 600 SC is not classified as flammable according to CLP Regulation. |
| Self-ignition<br>(KCP 2.3.3)                      | Standard<br>Operating<br>Procedure<br>No.<br>SPO/BC/06/<br>b (6 edition) | CHR/H/AK<br>O 600 SC<br>Date of<br>production:<br>23.03.2023 | Auto-ignition temperature – 507°C – according to criteria of PN-EN-ISO/IEC 0079-20-1:2020                                                                                                       | - | Pachnicki P.<br>Study code<br>no. BC-38/23  | <b>Accepted</b>                                                                                                                                                                                                   |
| Acidity or<br>alkalinity and<br>pH<br>(KCP 2.4.1) | -                                                                        | -                                                            | -                                                                                                                                                                                               | - |                                             | The acidity or alkalinity should be tested if the preparation has pH < 4 or pH > 10 (for either 1 % dilution or neat formulation).                                                                                |

|                                                                 |               |                                                     |                                                |                                                              |                                                |   |                                                          |                                                                                                                                                             |                             |        |
|-----------------------------------------------------------------|---------------|-----------------------------------------------------|------------------------------------------------|--------------------------------------------------------------|------------------------------------------------|---|----------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--------|
| pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2) | CIPAC MT 75.3 | CHR/H/AK O 600 SC<br>Date of production: 23.03.2023 | Initial                                        | After storage (Accelerated storage test (8 weeks at 40±2°C)) | After 12 months shelf-life test                | Y | Górka I<br>Study code: ICB/107/2023                      | Accepted                                                                                                                                                    |                             |        |
|                                                                 |               |                                                     | 1% (w/v) suspension – 7.70<br>Undiluted – 7.84 | 1% (w/v) suspension – 8.40<br>Undiluted – 8.55               | 1% (w/v) suspension – 8.00<br>Undiluted – 8.07 |   | Study code: ICB/136/2023<br><br>Study code: ICB/108/2023 |                                                                                                                                                             |                             |        |
| Viscosity (KCP 2.5.1)                                           | OECD 114      | CHR/H/AK O 600 SC<br>Date of production: 23.03.2023 |                                                |                                                              |                                                | Y | Rymarzak O.<br>Study number: BF-32/23                    | Accepted<br><br>The dynamic viscosity was determined at different shear rates. The test was conducted at 20°C and 40°C. Test item is non-Newtonian liquids. |                             |        |
|                                                                 |               |                                                     | Shear rate                                     | Dynamic viscosity [mPa · s]                                  |                                                |   |                                                          |                                                                                                                                                             | Kinematic viscosity [mm²/s] |        |
|                                                                 |               |                                                     |                                                | 20°C                                                         | 40°C                                           |   |                                                          |                                                                                                                                                             | 20°C                        | 40°C   |
|                                                                 |               |                                                     | 2.5                                            | 1667.0                                                       | 1379.5                                         |   |                                                          |                                                                                                                                                             | 1375,8                      | 1147,9 |
|                                                                 |               |                                                     | 5.0                                            | 1014.3                                                       | 844.5                                          |   |                                                          |                                                                                                                                                             | 837,1                       | 702,7  |
|                                                                 |               |                                                     | 10.0                                           | 629.2                                                        | 523.8                                          |   |                                                          |                                                                                                                                                             | 519,3                       | 435,8  |
|                                                                 |               |                                                     | 25.0                                           | 348.2                                                        | 287.2                                          |   |                                                          |                                                                                                                                                             | 289,7                       | 239,0  |
| Surface tension (KCP 2.5.2)                                     | A.5           | CHR/H/AK O 600 SC<br>Date of production: 23.03.2023 | 2.67% (w/v) – 42.12 [mN/m]                     |                                                              |                                                | Y | Górka I.<br>Study code: ICB/107/2023                     | Accepted<br><br>The determination of the surface tension was conducted according to method EEC A.5 at 20°C. The surface                                     |                             |        |

|                                         |     |                                                           |                                                       |   |                                         |                                                                                                                                                                                                                                                                                                                                                          |
|-----------------------------------------|-----|-----------------------------------------------------------|-------------------------------------------------------|---|-----------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                         |     |                                                           |                                                       |   |                                         | tension is below 60 mN/m, the product is surface active.                                                                                                                                                                                                                                                                                                 |
| Relative density (KCP 2.6.1)            | A.3 | CHR/H/AK<br>O 600 SC<br>Date of production:<br>23.03.2023 | 1.2118 g/ml                                           | Y | Górka I.<br>Study code:<br>ICB/107/2023 | <b>Accepted</b><br><br>Determination of the relative density was carried out by determination of the absolute density (at 20°C) of the test item using an oscillating densitometer, and the relative density was calculated as the average value of all absolute density measurements of the test item to the value of absolute density of water at 4°C. |
| Bulk density (KCP 2.6.2)                | -   | -                                                         | Not required for this type of formulation             | - | -                                       | <b>Accepted</b>                                                                                                                                                                                                                                                                                                                                          |
| Storage Stability after 14 days at 54°C | -   | -                                                         | No studies were carried on for 2 weeks storage period | - | -                                       |                                                                                                                                                                                                                                                                                                                                                          |

| (KCP 2.7.1)                                                               |                                                                                                          |                                                     |                               |                                       |                                                                                                                 |                                                                                                                   |   |                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|---------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|-----------------------------------------------------|-------------------------------|---------------------------------------|-----------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|---|--------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Stability after storage for other periods and/or temperatures (KCP 2.7.2) | CIPAC MT 46.3<br><br>Accelerated storage test (8 weeks at 40±2°C)<br><br>After 12 months shelf-life test | CHR/H/AK O 600 SC<br>Date of production: 23.03.2023 | Colour, physical state, odour | OPPTS 830.6302, 830.6303 and 830.6304 | Accelerated storage test (8 weeks at 40±2°C)                                                                    | After 12 months shelf-life test                                                                                   | Y | Górka I.<br><br>Study code: ICB/136/2023<br><br>Study code: ICB/108/2023 | <b>Accepted</b><br><br>Based on the result of accelerated storage stability study, PPP was concluded to be stable when stored at the elevated temperature of 40°C for 8 weeks.<br><br>Based on the result of 1 year storage stability study at ambient temperature, PPP was concluded to be stable when stored at ambient temperature for 1 year.<br><br>The PPP stored at elevated temperature 40°C (aged sample) for 8n weeks and at ambient temperature for |
|                                                                           |                                                                                                          |                                                     |                               |                                       | Colour (Munsell’s notation) – 5Y 8.5/14 (yellow) Physical state –opaque liquid Odour – delicate, characteristic | Colour (Munsell’s notation) – 7.5Y 8.5/12 (yellow) Physical state –opaque liquid Odour – delicate, characteristic |   |                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|                                                                           |                                                                                                          |                                                     | pH                            | CIPAC MT 75.3                         | Accelerated storage test (8 weeks at 40±2°C)                                                                    | After 12 months shelf-life test                                                                                   |   |                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|                                                                           |                                                                                                          |                                                     |                               |                                       | 1% (w/v) suspension – 8.40 Undiluted – 8.55                                                                     | 1% (w/v) suspension – 8.00 Undiluted – 8.07                                                                       |   |                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|                                                                           |                                                                                                          |                                                     | Suspensibility                | CIPAC MT 184.1                        | Accelerated storage test (8 weeks at 40±2°C)                                                                    | After 12 months shelf-life test                                                                                   |   |                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|                                                                           |                                                                                                          |                                                     |                               |                                       | 0.072% (w/v) in Standard Water D (25±5°C): - aclonifen 83%                                                      | 0.072% (w/v) in Standard Water D (25±5°C): - aclonifen 91%                                                        |   |                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|                                                                           |                                                                                                          |                                                     |                               |                                       | 0.1% (w/v) in Standard Water D (25±5°C): - aclonifen 83%                                                        | 0.1% (w/v) in Standard Water D (25±5°C): - aclonifen 91%                                                          |   |                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|                                                                           |                                                                                                          |                                                     |                               |                                       | 2.67% (w/v) in Standard Water D (25±5°C): - aclonifen 77%                                                       | 2.67% (w/v) in Standard Water D (25±5°C): - aclonifen 86%                                                         |   |                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|                                                                           |                                                                                                          |                                                     | Spontaneity of dispersion     | CIPAC MT 160                          | Accelerated storage test (8 weeks at 40±2°C)                                                                    | After 12 months shelf-life test                                                                                   |   |                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|                                                                           |                                                                                                          |                                                     |                               |                                       | Standard Water C (30±2°C): - aclonifen 85%                                                                      | Standard Water C (30±2°C): - aclonifen 89%                                                                        |   |                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                |

|  |  |  |                             |                                                        |                                                                                                                                                                                  |                                                                                                                                                                                            |  |  |                                                                                                                                                                                                                                                                                                                                                                                                              |
|--|--|--|-----------------------------|--------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  |  |  | Wet sieve                   | CIPAC MT 185                                           | Accelerated storage test (8 weeks at 40±2°C)                                                                                                                                     | After 12 months shelf-life test                                                                                                                                                            |  |  | 1 year in HDPE package was analysed for ist active ingredient content (aclonifen), concontent of relevant impurity of aclonifen - phenol, appearance, stability, pH, spontaneity of dispersion, suspensibility, wet sieve test, pourability, particle size distribution, and for stability of packaging before storage and at the end of the 8 weeks of storage period and the end of 1 year storage period. |
|  |  |  |                             |                                                        | Residue (sieve 75 µm) – 0%                                                                                                                                                       | Residue (sieve 75 µm) – 0%                                                                                                                                                                 |  |  |                                                                                                                                                                                                                                                                                                                                                                                                              |
|  |  |  | Pourability                 | CIPAC MT 148.1                                         | Accelerated storage test (8 weeks at 40±2°C)                                                                                                                                     | After 12 months shelf-life test                                                                                                                                                            |  |  |                                                                                                                                                                                                                                                                                                                                                                                                              |
|  |  |  |                             |                                                        | Residue – 4.00%                                                                                                                                                                  | Residue – 3.81%                                                                                                                                                                            |  |  |                                                                                                                                                                                                                                                                                                                                                                                                              |
|  |  |  | Content of aclonifen        | Standard Operational Procedure SPB/289                 | Accelerated storage test (8 weeks at 40±2°C)                                                                                                                                     | After 12 months shelf-life test                                                                                                                                                            |  |  |                                                                                                                                                                                                                                                                                                                                                                                                              |
|  |  |  |                             |                                                        | aclonifen – 618.35 g/L                                                                                                                                                           | aclonifen – 620.45 g/L                                                                                                                                                                     |  |  |                                                                                                                                                                                                                                                                                                                                                                                                              |
|  |  |  | Particle size distribution  | CIPAC MT 187 and Standard Operational Procedure SPB/32 | Accelerated storage test (8 weeks at 40±2°C)                                                                                                                                     | After 12 months shelf-life test                                                                                                                                                            |  |  |                                                                                                                                                                                                                                                                                                                                                                                                              |
|  |  |  |                             |                                                        | d10-3.717 [µm]<br>d20-4.752[µm]<br>d30-5.680[µm]<br>d40-6.682 [µm]<br>d50-7.809 [µm]<br>d60-9.147 [µm]<br>d70-10.935 [µm]<br>d80-13.608 [µm]<br>d90-19.073[µm]<br>d99-77.527[µm] | d10- 2.227 [µm]<br>d20- 2.846 [µm]<br>d30- 3.411 [µm]<br>d40- 3.999 [µm]<br>d50- 4.615 [µm]<br>d60- 5.307 [µm]<br>d70- 6.112 [µm]<br>d80- 7.198 [µm]<br>d90- 8.945 [µm]<br>d99-23.076 [µm] |  |  |                                                                                                                                                                                                                                                                                                                                                                                                              |
|  |  |  | Stability of package (HDPE) | Standard Operational Procedure SPB/38                  | Accelerated storage test (8 weeks at 40±2°C)                                                                                                                                     | After 12 months shelf-life test                                                                                                                                                            |  |  | Based on the results of the study, it was concluded that the active ingredient content, color, physical state,                                                                                                                                                                                                                                                                                               |
|  |  |  |                             |                                                        | Packaging 2/3 Change in packaging weight – 0.37 [%] Change in gross weight – 0.1 [%]                                                                                             | Packaging 8/14 Change in packaging weight – 0.13 [%] Change in gross weight – 0.04 [%]                                                                                                     |  |  |                                                                                                                                                                                                                                                                                                                                                                                                              |

|  |  |  |                               |                                        |                                                                                       |                                                                                                                                       |  |  |                                                                                                                                                                                                                                                                                                                                  |
|--|--|--|-------------------------------|----------------------------------------|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|--|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  |  |  |                               |                                        | Packaging 3/3 Change in packaging weight – 0.29 [%] Change in gross weight – 0.07 [%] | Packaging 9/14<br>Change in packaging weight – 0.20 [%]<br>Change in gross weight – 0.03 [%]<br>Packages without any visible changes. |  |  | pH, suspensibility, spontaneity of dispersion, wet sieve, pourability, particle size distribution of the test item for sample stored at elevated temperature of 40°C for 8 weeks and for sample storage at ambient temperature for 1 year were well compared with that of the results obtained for the test item before storage. |
|  |  |  | Content of phenol as impurity | Standard Operational Procedure SPB/291 | Accelerated storage test (8 weeks at 40±2°C)                                          | After 12 months shelf-life test                                                                                                       |  |  | The test item found to be non-corrosive for HDPE commercial containers as there was no significant change in the weight of commercial containers and the package showed no signs                                                                                                                                                 |
|  |  |  |                               |                                        | phenol – 0.01061 g/kg                                                                 | phenol – 0.01149 g/kg                                                                                                                 |  |  |                                                                                                                                                                                                                                                                                                                                  |

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|  |  |  |  |  |  |  |  |  | <p>of any visible changes at storage at elevated temperature of 40°C for 8 weeks and after storage at ambient temperature (20°C) for 12 months.</p> <p>The content of active substance – aclonifen - in PPP was determined by High Performance Liquid Chromatography with diode array detection (HPLC-DAD). The method was developed and validated in GLP laboratory (validated in ICB/106/2023). The loss of active substance after 8 weeks storage of test item at 40°C and after 1 year storage at</p> |
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|  |  |  |  |  |  |  |  |  | <p>ambient temperature was almost negligible. It is recognised that a loss of up to 5 % of the active substance is unlikely to adversely affect the safety or efficacy of the preparation. Active substance content before and after storage meet FAO Limits.</p> <p>The content of Impurity - phenol in PPP was determined by High Performance Liquid Chromatography with diode array detection (HPLC-DAD). The method was developed and validated in GLP laboratory (validated in ICB/106/2023). The content of phenol as</p> |
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|                                               |                                                                 |                                                     |                |                |                                                                                                                                                                                     |   |                                                                                     |                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                           |
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|                                               |                                                                 |                                                     |                |                |                                                                                                                                                                                     |   |                                                                                     |                                                                                                                                                                                                                                                                                                                           | impurity in pre storage and after 8 weeks storage at 40°C and after storage at 1 year at ambient temperature was below the specification Limit for this impurity in the active substance as manufactured. |
| Storage test under low temperature conditions | Standard Operational Procedure SPB/157<br><br>(7 days at 0±2°C) | CHR/H/AK O 600 SC<br>Date of production: 23.03.2023 | Suspensibility | CIPAC MT 184.1 | 0.072% (w/v) in Standard Water D (25±5°C): - aclonifen 83%<br>0.1% (w/v) in Standard Water D (25±5°C): - aclonifen 83%<br>2.67% (w/v) in Standard Water D (25±5°C): - aclonifen 77% | Y | Górka I<br><del>Study code: ICB/107/2023</del><br>3<br><br>Study code: ICB/136/2023 | <b>Accepted</b><br><br>Suspensibility: the content of active substance - aclonifen - in suspension was determined by High Performance Liquid Chromatography with diode array detection (HPLC-DAD). The method was developed and validated in GLP laboratory (validated in study ICB/106/2023). Acceptable limits:the mean |                                                                                                                                                                                                           |

|  |  |  |                                         |                                                         |                                                                                                                                                                                                    |  |                                                      |                                                                                                                                                                                                                                                                                         |
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|  |  |  |                                         |                                                         |                                                                                                                                                                                                    |  |                                                      | <p>measured minimum active spontaneity of dispersion or dispersibility must not be less than 60 % or greater than 105 %.</p> <p>The criteria were met for active substances at minimum test item concentration, medium test item concentration and maximum test item concentration.</p> |
|  |  |  | Effect of low temperatures on stability | CIPAC MT 39.3 and Standard Operational Procedure SPB/31 | After low temperature stability 0°C for 7 days – no phase separation, no sediment. After 24 h in room temperature and one invert – no phase separation, no sediment. Residue (sieve 75 µm) – 0.02% |  | <p>Górka I<br/>Study code:<br/>ICB/107/202<br/>3</p> | <p><b>Accepted</b></p> <p>Based on the results of the low temperature stability test, it is concluded that test item was homogenous liquid without any phase separation when stored at 0±2°C for 7 days.</p> <p>Suspensibility</p>                                                      |

|         |   |   |                                           |              |                            |   |   |                                                                                                                                                                                                                                                                                                                                                                   |
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|         |   |   |                                           |              |                            |   |   | and wet sieve test were determined after storage.                                                                                                                                                                                                                                                                                                                 |
|         |   |   | Wet sieve                                 | CIPAC MT 185 | Residue (sieve 75 µm) – 0% |   |   | <b>Accepted</b><br><br>Wet sieve test is required for water dispersible products. The residue remaining on a sieve is determined after dispersion to ensure no unacceptable residue remains which might cause the blockage of nozzles or filters on application equipment. Acceptable limits:<br>Maximum 2 % retained on a 75 µm sieve.<br>The criteria were met. |
| Minimum | - | - | Not required for this type of formulation |              |                            | - | - |                                                                                                                                                                                                                                                                                                                                                                   |

|                                                     |                                                         |                                                  |                                                                                                                                                                                                    |   |                                      |                                                                                                                                                                                                                                                                                                                                                                                                                     |
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| content after heat stability testing (KCP 2.7.3)    |                                                         |                                                  |                                                                                                                                                                                                    |   |                                      |                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Effect of low temperatures on stability (KCP 2.7.4) | CIPAC MT 39.3 and Standard Operational Procedure SPB/31 | CHR/H/AK O 600 SC Date of production: 23.03.2023 | After low temperature stability 0°C for 7 days – no phase separation, no sediment. After 24 h in room temperature and one invert – no phase separation, no sediment. Residue (sieve 75 µm) – 0.02% | Y | Górka I.<br>Study code: ICB/107/2023 | <b>Accepted</b>                                                                                                                                                                                                                                                                                                                                                                                                     |
| Ambient temperature shelf life (KCP 2.7.5)          | -                                                       | -                                                | Not required for this type of formulation                                                                                                                                                          | - | -                                    | <b>Data gap</b><br><br>The shelf life of at least 2 years at ambient temperature when stored in <i>HDPE</i> package was proposed by applicant based on the 1-year storage stability test at ambient temperature. It is suggested by evaluator to perform 2-years storage stability study at ambient temperature to establish shelf-life for the product. Missing storage stability study at ambient temperature - 2 |

|                                                         |               |                                                    |                                                                                                                                       |   |                                      |                                                                                                                                                                                                                                                                     |
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|                                                         |               |                                                    |                                                                                                                                       |   |                                      | years storage stability study. It is required to set a shelf-life for the PPP and may be evaluated in post-registration at national level.                                                                                                                          |
| Shelf life in months (if less than 2 years) (KCP 2.7.6) | -             | -                                                  | Not required for this type of formulation                                                                                             | - | -                                    |                                                                                                                                                                                                                                                                     |
| Wettability (KCP 2.8.1)                                 | -             | -                                                  | Not required for this type of formulation                                                                                             | - | -                                    | <b>Accepted</b>                                                                                                                                                                                                                                                     |
| Persistence of foaming (KCP 2.8.2)                      | CIPAC MT 47.3 | CHR/H/AKO 600 SC<br>Date of production: 23.03.2023 | 0.072% (w/v): - after 1 minute – 27 mL - after 12 minutes – 17 mL<br>2.67% (w/v): - after 1 minute – 46 mL - after 12 minutes – 19 mL | Y | Górka I.<br>Study code: ICB/107/2023 | <b>Accepted</b><br><br>Persistent foam is determined to measure the amount of foam likely to be present in a spray tank or other application equipment following dilution of the preparation. Acceptable Limits: Max 60 mL foam after 1 minute. The above mentioned |

|                              |                |                                                     |                                                                                                                                                                                                    |                                                                                                                                                                                                    |                                                                                                                                                                                                    |   |                                                                                                             | criteria were met.                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
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|                              |                |                                                     | Initial                                                                                                                                                                                            | After storage (Accelerated storage test (8 weeks at 40±2°C)                                                                                                                                        | After 12 months shelf-life test                                                                                                                                                                    |   |                                                                                                             | <b>Accepted</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Suspensibility (KCP 2.8.3.1) | CIPAC MT 184.1 | CHR/H/AK O 600 SC<br>Date of production: 23.03.2023 | <p>0.072% (w/v) in Standard Water D (25±5°C): - aclonifen 92%</p> <p>0.1% (w/v) in Standard Water D (25±5°C): - aclonifen 92%</p> <p>2.67% (w/v) in Standard Water D (25±5°C): - aclonifen 87%</p> | <p>0.072% (w/v) in Standard Water D (25±5°C): - aclonifen 83%</p> <p>0.1% (w/v) in Standard Water D (25±5°C): - aclonifen 83%</p> <p>2.67% (w/v) in Standard Water D (25±5°C): - aclonifen 77%</p> | <p>0.072% (w/v) in Standard Water D (25±5°C): - aclonifen 91%</p> <p>0.1% (w/v) in Standard Water D (25±5°C): - aclonifen 91%</p> <p>2.67% (w/v) in Standard Water D (25±5°C): - aclonifen 86%</p> | Y | <p>Górka I<br/>Study code: ICB/107/2023</p> <p>Study code: ICB/136/2023</p> <p>Study code: ICB/108/2023</p> | <p>Suspensibility: the content of active substance - aclonifen - in suspension was determined by High Performance Liquid Chromatography with diode array detection (HPLC-DAD). The method was developed and validated in GLP laboratory (validated in study ICB/106/2023). Acceptable limits: the mean measured minimum active spontaneity of dispersion or dispersibility must not be less than 60 % or greater than 105 %.</p> <p>The criteria were met for active</p> |

|                                         |              |                                                    |                                            |                                                             |                                            |   |                                                                                                     |                                                                                                                                                                                                                                                                                                                                               |
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|                                         |              |                                                    |                                            |                                                             |                                            |   |                                                                                                     | substances at minimum test item concentration, medium test item concentration and maximum test item concentration.                                                                                                                                                                                                                            |
| Spontaneity of dispersion (KCP 2.8.3.2) | CIPAC MT 160 | CHR/H/AKO 600 SC<br>Date of production: 23.03.2023 | Initial                                    | After storage (Accelerated storage test (8 weeks at 40±2°C) | After 12 months shelf-life test            | Y | Górka I<br>Study code: ICB/107/2023<br><br>Study code: ICB/136/2023<br><br>Study code: ICB/108/2023 | <b>Accepted</b>                                                                                                                                                                                                                                                                                                                               |
|                                         |              |                                                    | Standard Water C (30±2°C): - aclonifen 90% | Standard Water C (30±2°C): - aclonifen 85%                  | Standard Water C (30±2°C): - aclonifen 89% |   |                                                                                                     | The spontaneity of dispersion is determined to show the preparation is rapidly dispersed when diluted with water.<br><br>The content of active substance – aclonifen - in dispersion was determined by High Performance Liquid Chromatography with diode array detection (HPLC-DAD). The method was developed and validated in GLP laboratory |

|                                                                              |                                                        |                                                     |                                                                                                                                                                 |                                                                                                                                                                |                                                                                                                                                                         |   |                                                          |                                                                                                                                                                                           |
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|                                                                              |                                                        |                                                     |                                                                                                                                                                 |                                                                                                                                                                |                                                                                                                                                                         |   |                                                          | (validated in study ICB/106/2023). Acceptable limits: the mean measured minimum active spontaneity of dispersion must not be less than 60 % or greater than 105 %. The criteria were met. |
| Dispersion stability (KCP 2.8.3.3)                                           | -                                                      | -                                                   | Not required for this type of formulation                                                                                                                       |                                                                                                                                                                |                                                                                                                                                                         | - | -                                                        | Accepted                                                                                                                                                                                  |
| Degree of dissolution and dilution stability (KCP 2.8.4)                     | -                                                      | -                                                   | Not required for this type of formulation                                                                                                                       |                                                                                                                                                                |                                                                                                                                                                         | - | -                                                        | Accepted                                                                                                                                                                                  |
| Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1 ) | CIPAC MT 187 and Standard Operational Procedure SPB/32 | CHR/H/AK O 600 SC<br>Date of production: 23.03.2023 | Initial                                                                                                                                                         | After storage (Accelerated storage test (8 weeks at 40±2°C)                                                                                                    | After 12 months shelf-life test                                                                                                                                         | Y | Górka I<br>Study code: ICB/107/2023                      | Accepted                                                                                                                                                                                  |
|                                                                              |                                                        |                                                     | d10-2.048 [µm]<br>d20-2.669 [µm]<br>d30-3.258 [µm]<br>d40-3.874 [µm]<br>d50-4.531 [µm]<br>d60-5.302 [µm]<br>d70-6.248 [µm]<br>d80-7.549 [µm]<br>d90-10.108 [µm] | d10-3.717 [µm]<br>d20-4.752[µm]<br>d30-5.680[µm]<br>d40-6.682 [µm]<br>d50-7.809 [µm]<br>d60-9.147 [µm]<br>d70-10.935 [µm]<br>d80-13.608 [µm]<br>d90-19.073[µm] | d10- 2.227 [µm]<br>d20- 2.846 [µm]<br>d30- 3.411 [µm]<br>d40- 3.999 [µm]<br>d50- 4.615 [µm]<br>d60- 5.307 [µm]<br>d70- 6.112 [µm]<br>d80- 7.198 [µm]<br>d90- 8.945 [µm] |   | Study code: ICB/136/2023<br><br>Study code: ICB/108/2023 |                                                                                                                                                                                           |

|                                    |                 |                                                              |                                           |                                                                |                                    |   |                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                     |
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|                                    |                 |                                                              | d99-47.605 [µm]                           | d99-77.527[µm]                                                 | d99-23.076 [µm]                    |   |                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                     |
| Wet sieve test<br>(KCP 2.8.5.1.2 ) | CIPAC MT<br>185 | CHR/H/AK<br>O 600 SC<br>Date of<br>production:<br>23.03.2023 | Initial                                   | After storage (Accelerated<br>storage test (8 weeks at 40±2°C) | After 12<br>months shelf-life test | Y | Górka I<br>Study code:<br>ICB/107/202<br>3<br><br>Study code:<br>ICB/136/202<br>3<br><br>Study code:<br>ICB/108/202<br>3 | <b>Accepted</b><br><br>A wet sieve test is required for water dispersible products. The residue remaining on a sieve is determined after dispersion to ensure no unacceptable residue remains which might cause the blockage of nozzles or filters on application equipment. Acceptable limits: Maximum 2 % retained on a 75 µm sieve. The above criteria were met. |
|                                    |                 |                                                              | Residue (sieve 75 µm) – 0%                | Residue (sieve 75 µm) – 0%                                     | Residue (sieve 75 µm) – 0%         |   |                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                     |
| Dust content<br>(KCP 2.8.5.2.1 )   | -               | -                                                            | Not required for this type of formulation |                                                                |                                    | - | -                                                                                                                        | <b>Accepted</b>                                                                                                                                                                                                                                                                                                                                                     |

|                                          |                   |                                                           |                                           |                                                             |                                 |   |                                                                                                              |                                                                                                                                                                                              |
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| Particle size of dust<br>(KCP 2.8.5.2.2) | -                 | -                                                         | Not required for this type of formulation |                                                             |                                 | - | -                                                                                                            | Accepted                                                                                                                                                                                     |
| Attrition<br>(KCP 2.8.5.3)               | -                 | -                                                         | Not required for this type of formulation |                                                             |                                 | - | -                                                                                                            | Accepted                                                                                                                                                                                     |
| Hardness and integrity<br>(KCP 2.8.5.4)  | -                 | -                                                         | Not required for this type of formulation |                                                             |                                 | - | -                                                                                                            | Accepted                                                                                                                                                                                     |
| Emulsifiability<br>(KCP 2.8.6.1)         | -                 | -                                                         | Not required for this type of formulation |                                                             |                                 | - | -                                                                                                            | Accepted                                                                                                                                                                                     |
| Emulsion stability<br>(KCP 2.8.6.2)      | -                 | -                                                         | Not required for this type of formulation |                                                             |                                 | - | -                                                                                                            | Accepted                                                                                                                                                                                     |
| Re-emulsifiability<br>(KCP 2.8.6.3)      | -                 | -                                                         | Not required for this type of formulation |                                                             |                                 | - | -                                                                                                            | Accepted                                                                                                                                                                                     |
| Flowability<br>(KCP 2.8.7.1)             | -                 | -                                                         | Not required for this type of formulation |                                                             |                                 | - | -                                                                                                            | Accepted                                                                                                                                                                                     |
| Pourability<br>(KCP 2.8.7.2)             | CIPAC MT<br>148.1 | CHR/H/AK<br>O 600 SC<br>Date of production:<br>23.03.2023 | Initial                                   | After storage (Accelerated storage test (8 weeks at 40±2°C) | After 12 months shelf-life test | Y | Górka I<br>Study code:<br>ICB/107/2023<br><br>Study code:<br>ICB/136/2023<br><br>Study code:<br>ICB/108/2023 | Accepted<br><br>The data are required to demonstrate that the user can make use of the maximum amount of the preparation and that an excessive amount of the material does not remain in the |
|                                          |                   |                                                           | Residue – 4.04%                           | Residue – 4.00%                                             | Residue – 3.81%                 |   |                                                                                                              |                                                                                                                                                                                              |

|                                                                     |                     |                                                                                                                           |                                                                                                                                                                                                                                       |  |  |   |                                        |                                                                                                                                                                                                                                                                                                                                                                                                |
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|                                                                     |                     |                                                                                                                           |                                                                                                                                                                                                                                       |  |  |   |                                        | container.<br>Acceptable<br>Limits:<br>Maximum 5 %<br>residue.<br>The above<br>mentioned<br>criteria were<br>met.                                                                                                                                                                                                                                                                              |
| Dustability<br>following<br>accelerated<br>storage<br>(KCP 2.8.7.3) | -                   | -                                                                                                                         | Not required for this type of formulation                                                                                                                                                                                             |  |  | - | -                                      | <b>Accepted</b>                                                                                                                                                                                                                                                                                                                                                                                |
| Physical<br>compatibility<br>of tank mixes<br>(KCP 2.9.1)           | ASTM E<br>1518 - 05 | CHR/H/AKO<br>600 SC<br>Date of<br>production:<br>23.03.2023<br><br>BOA PRO<br>480 EC<br>Date of<br>production:<br>07.2023 | <p>Components of Mixture I are compatible:<br/>0.05% (v/v) BOA PRO 480 EC<br/>and 0.2% (v/v) CHR/H/AKO 600 S.C.</p> <p>Components of Mixture II are compatible:<br/>0.1% (v/v) BOA PRO 480 EC<br/>and 1.0% (v/v) CHR/H/AKO 600 SC</p> |  |  | Y | Górka I.<br>Study code:<br>ICB/27/2025 | <p><b>Accepted</b></p> <p>Mixture I<br/>Components of<br/>Mixture I are<br/>compatible - any<br/>type of residue<br/>remained on the<br/>sieve and<br/>in the bottle<br/>were not<br/>observed during<br/>the experiment.</p> <p>Mixture II<br/>Components of<br/>Mixture II are<br/>compatible - any<br/>type of residue<br/>remained on the<br/>sieve and<br/>in the bottle<br/>were not</p> |

|                                                  |         |                                                                                                         |                                                                                                       |                                                |   |                                     |                                                                                                                                                                                                                                                                                                                                                                                   |
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|                                                  |         |                                                                                                         |                                                                                                       |                                                |   | observed during the experiment.     |                                                                                                                                                                                                                                                                                                                                                                                   |
| Chemical compatibility of tank mixes (KCP 2.9.2) | SPB/338 | CHR/H/AKO 600 SC<br>Date of production: 23.03.2023<br><br>BOA PRO 480 EC<br>Date of production: 07.2023 |                                                                                                       |                                                | Y | Górka I.<br>Study code: ICB/26/2025 | Accepted<br><br>Determination of chemical compatibility was conducted according to own validated analytical method SPB/338. The study was carried out for two mixtures of test items in Standard Water C (hardness 500 ppm) at 20±5°C. Content of all active ingredients (clomazone and aclonifen) was determined by liquid chromatography with diode array detection (HPLC-DAD). |
|                                                  |         |                                                                                                         | Determination of active ingredient in 0.05% (v/v) emulsion of test item BOA PRO 480 EC                | clomazone – 0.464 [%]                          |   |                                     |                                                                                                                                                                                                                                                                                                                                                                                   |
|                                                  |         |                                                                                                         | Determination of active ingredient in 0.1% (v/v) emulsion of test item BOA PRO 480 EC                 | clomazone – 0.471[%]                           |   |                                     |                                                                                                                                                                                                                                                                                                                                                                                   |
|                                                  |         |                                                                                                         | Determination of active ingredient in 0.2% (v/v) suspension of test item CHR/H/AKO 600 SC             | aclonifen – 0.480 [%]                          |   |                                     |                                                                                                                                                                                                                                                                                                                                                                                   |
|                                                  |         |                                                                                                         | Determination of active ingredient in 1.0% (v/v) suspension of test item CHR/H/AKO 600 SC             | aclonifen – 0.482 [%]                          |   |                                     |                                                                                                                                                                                                                                                                                                                                                                                   |
|                                                  |         |                                                                                                         | Chemical Compatibility of Mixture I (0.05% (v/v) of BOA PRO 480 EC and 0.2% (v/v) CHR/H/AKO 600 S.C.) | clomazone – 0.465 [%]<br>aclonifen - 0.476 [%] |   |                                     |                                                                                                                                                                                                                                                                                                                                                                                   |
|                                                  |         |                                                                                                         | Chemical Compatibility of Mixture II (0.1% (v/v) of BOA PRO 480 EC and 1.0% (v/v) CHR/H/AKO 600 SC)   | clomazone – 0.474 [%]<br>aclonifen – 0.486 [%] |   |                                     |                                                                                                                                                                                                                                                                                                                                                                                   |
|                                                  |         |                                                                                                         |                                                                                                       |                                                |   |                                     |                                                                                                                                                                                                                                                                                                                                                                                   |
| Adhesion to seeds (KCP 2.10.1)                   | -       | -                                                                                                       | Not required for this type of formulation                                                             |                                                | - | -                                   | Accepted                                                                                                                                                                                                                                                                                                                                                                          |
| Distribution to seed (KCP 2.10.2)                | -       | -                                                                                                       | Not required for this type of formulation                                                             |                                                | - | -                                   | Accepted                                                                                                                                                                                                                                                                                                                                                                          |

|                                  |                                        |                                                    | Content of aclonifen (initial) | Content of aclonifen ( after storage - 8 weeks at 40±2°C)) | After 12 months shelf-life test |   |                                                                                                     | Accepted                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|----------------------------------|----------------------------------------|----------------------------------------------------|--------------------------------|------------------------------------------------------------|---------------------------------|---|-----------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                  |                                        |                                                    |                                |                                                            |                                 |   |                                                                                                     | The content of active substance – aclonifen - in PPP was determined by High Performance Liquid Chromatography with diode array detection (HPLC-DAD). The method was developed and validated in GLP laboratory (validated in ICB/106/2023). The loss of active substance after 8 weeks storage of test item at 40°C and after 1 year storage at ambient temperature was almost negligible. It is recognised that a loss of up to 5 % of the active substance is unlikely to adversely affect the safety or efficacy of the |
| Other/special studies (KCP 2.11) | Standard Operational Procedure SPB/289 | CHR/H/AKO 600 SC<br>Date of production: 23.03.2023 | aclonifen – 618.58 g/L         | aclonifen – 618.35 g/L                                     | aclonifen – 620.45 g/L          | Y | Górka I<br>Study code: ICB/107/2023<br><br>Study code: ICB/136/2023<br><br>Study code: ICB/108/2023 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

|  |                                                 |                                                              |                                                                                                 |                                                                                                 |                                                                                                 |   |                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|--|-------------------------------------------------|--------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|---|--------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  |                                                 |                                                              |                                                                                                 |                                                                                                 |                                                                                                 |   |                                                                                                                          | preparation.<br>Active<br>substance<br>conetnt before<br>and after storage<br>meet FAO<br>Limits.                                                                                                                                                                                                                                                                                                                                                                                                   |
|  |                                                 |                                                              | Content of phenol as impurity<br>(initial)                                                      | Content of phenol as impurity<br>(after storage)                                                | After 12<br>months shelf-life test                                                              |   |                                                                                                                          | <b>Accepted</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|  | Standard<br>Operational<br>Procedure<br>SPB/291 | CHR/H/AK<br>O 600 SC<br>Date of<br>production:<br>23.03.2023 | phenol – 0.01149 g/kg<br>(the concentration is given as<br>gram per kilogram of<br>formulation) | phenol – 0.01061 g/kg<br>(the concentration is given as<br>gram per kilogram of<br>formulation) | phenol – 0.01149 g/kg<br>(the concentration is given<br>as gram per kilogram of<br>formulation) | Y | Górka I<br>Study code:<br>ICB/107/202<br>3<br><br>Study code:<br>ICB/136/202<br>3<br><br>Study code:<br>ICB/108/202<br>3 | The content of<br>Impurity -<br>phenol in PPP<br>was determined<br>by High<br>Performance<br>Liquid<br>Chromatograph<br>y with diode<br>array detection<br>(HPLC-DAD).<br>The method was<br>developed and<br>validated in<br>GLP laboratory<br>(validated in<br>ICB/106/2023).<br>The content of<br>phenol as<br>impurity in pre<br>storage and after<br>8 weeks storage<br>at 40°C and<br>after storage at 1<br>year at ambient<br>temperature was<br>below the<br>specification<br>Limit for this |

|                                                                                                                                                                                                                            |                                                     |                                                                                                                                                                                   |  |                                                                                                                                                                                                                                                     |  |   |                                                                     |                                                                                                                                                                                                                                                                                           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|---|---------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                                            |                                                     |                                                                                                                                                                                   |  |                                                                                                                                                                                                                                                     |  |   |                                                                     | impurity in the active substance as manufactured.                                                                                                                                                                                                                                         |
| Standard Operational Procedure SPB/38                                                                                                                                                                                      | CHR/H/AK O 600 SC<br>Date of production: 23.03.2023 | Stability of package (HDPE)                                                                                                                                                       |  |                                                                                                                                                                                                                                                     |  | Y | Górka I<br>Study code: ICB/136/2023<br><br>Study code: ICB/108/2023 | <b>Accepted</b><br><br>The test item found to be non-corrosive for HDPE commercial containers as there was no significant change in the weight of commercial containers and the package showed no signs of any visible changes after storage at ambient temperature (20°C) for 12 months. |
|                                                                                                                                                                                                                            |                                                     | Content of aclonifen ( after storage - 8 weeks at 40±2°C))                                                                                                                        |  | After 12 months shelf-life test                                                                                                                                                                                                                     |  |   |                                                                     |                                                                                                                                                                                                                                                                                           |
|                                                                                                                                                                                                                            |                                                     | Packaging 2/3 Change in packaging weight – 0.37 [%] Change in gross weight – 0.1 [%]<br><br>Packaging 3/3 Change in packaging weight – 0.29 [%] Change in gross weight – 0.07 [%] |  | Packaging 8/14<br>Change in packaging weight – 0.13 [%]<br>Lost Change in gross weight – 0.04 [%]<br>Packaging 9/14<br><br>Change in packaging weight – 0.20 [%]<br>Lost Change in gross weight – 0.03 [%]<br>Packages without any visible changes. |  |   |                                                                     |                                                                                                                                                                                                                                                                                           |
| Efficacy Guideline 305                                                                                                                                                                                                     | CHR/H/AK O 600 SC<br>Date of production: 23.03.2023 | Effectiveness of cleaning                                                                                                                                                         |  |                                                                                                                                                                                                                                                     |  | Y | Górka I<br>Study code: ICB/107/2023                                 | <b>Accepted</b><br>The study was conducted according to Efficacy Guideline 305. The mixture of test item was prepared at a concentration of                                                                                                                                               |
| Single rinse procedure:<br>99.96 [%] aclonifen removed from the bottle<br>Double rinse procedure:<br>99.98 [%] aclonifen removed from the bottle<br>Triple rinse procedure:<br>99.99 [%] aclonifen removed from the bottle |                                                     |                                                                                                                                                                                   |  |                                                                                                                                                                                                                                                     |  |   |                                                                     |                                                                                                                                                                                                                                                                                           |

|  |  |  |  |  |  |                                                                                                                                                                                                                                                                                                                                                  |
|--|--|--|--|--|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  |  |  |  |  |  | 2.67% (w/v), then was poured into 3 polyethylene bottles and allowed to stand at temperature (18-28°C) to next day, but not longer than 24 h. After that, the bottles was rinsed by the tap water. Then the bottles was rinsed with acetonitrile which was analysed for active ingredient content. Three different rinsing procedures were used. |
|--|--|--|--|--|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### 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)

#### ZRMS comments

The HDPE bottle was used in accelerated storage study (8 weeks at 40°C) and ambient storage study (1 year at 20°C). The HDPE bottle was stable in accelerated storage study and 1 year storage study at ambient temperature.

**Table 4.1-1: Packaging information**

|                        |                           |
|------------------------|---------------------------|
| Type                   | BOTTLE                    |
| Material:              | HDPE                      |
| size:                  | 64 mm± 2 mm/130 mm ± 3 mm |
| Opening:               | 40 mm ± 2 mm              |
| Closure:               | screw cap with seal       |
| Capacity               | 250 ml                    |
| Net Capacity           | 250 ml                    |
| Seal:                  | Induction seal            |
| Manner of construction | extruded                  |
| UN/ADR                 | compliant                 |

**Table 4.1-2: Packaging information**

|                        |                             |
|------------------------|-----------------------------|
| Type                   | BOTTLE                      |
| Material:              | HDPE                        |
| size:                  | 72 mm± 2 mm/111,8 mm ± 3 mm |
| Opening:               | 38 mm ± 2 mm                |
| Closure:               | screw cap with seal         |
| Capacity               | 250 ml                      |
| Net Capacity           | 250 ml                      |
| Seal:                  | Induction seal              |
| Manner of construction | extruded                    |
| UN/ADR                 | compliant                   |

**Table 4.1-3: Packaging information**

|                        |                             |
|------------------------|-----------------------------|
| Type                   | BOTTLE                      |
| Material:              | HDPE                        |
| size:                  | 69 mm± 2 mm/186.5 mm ± 2 mm |
| Opening:               | 45.65± 2 mm                 |
| Closure:               | screw cap with seal         |
| Capacity               | 564 ml                      |
| Net Capacity           | 500 ml                      |
| Seal:                  | Induction seal              |
| Manner of construction | extruded                    |
| UN/ADR                 | compliant                   |

**Table 4.1-4: Packaging information**

|                        |                             |
|------------------------|-----------------------------|
| Type                   | BOTTLE                      |
| Material:              | HDPE                        |
| size:                  | 69 mm± 2 mm/186.5 mm ± 2 mm |
| Opening:               | 45.65± 2 mm                 |
| Closure:               | screw cap with seal         |
| Capacity               | 564 ml                      |
| Net Capacity           | 500 ml                      |
| Seal:                  | Induction seal              |
| Manner of construction | extruded                    |
| UN/ADR                 | compliant                   |

**Table 4.1-5: Packaging information**

|                        |                             |
|------------------------|-----------------------------|
| Type                   | BOTTLE                      |
| Material:              | HDPE                        |
| size:                  | 90,5 mm± 2 mm/151 mm ± 3 mm |
| Opening:               | 40,6 mm ± 2 mm              |
| Closure:               | screw cap with seal         |
| Capacity               | 500 ml                      |
| Net Capacity           | 500 ml                      |
| Seal:                  | Induction seal              |
| Manner of construction | extruded                    |
| UN/ADR                 | compliant                   |

**Table 4.1-6: Packaging information**

|                        |                               |
|------------------------|-------------------------------|
| Type                   | BOTTLE                        |
| Material:              | HDPE                          |
| size:                  | 77,6 mm± 2 mm/160,6 mm ± 3 mm |
| Opening:               | 38 mm ± 2 mm                  |
| Closure:               | screw cap with seal           |
| Capacity               | 500 ml                        |
| Net Capacity           | 500 ml                        |
| Seal:                  | Induction seal                |
| Manner of construction | extruded                      |
| UN/ADR                 | compliant                     |

**Table 4.1-7: Packaging information**

|                                   |                     |
|-----------------------------------|---------------------|
| Type                              | JAR                 |
| Material:                         | HDPE                |
| size: approximate diameter/height | 79/80 mm / 138 mm   |
| Opening:                          | 46 mm minimum       |
| Closure:                          | screw cap with seal |
| Capacity                          | 510 ml              |
| Net Capacity                      | 500 ml              |
| Seal:                             | Induction seal      |

|                        |           |
|------------------------|-----------|
| Manner of construction | extruded  |
| UN/ADR                 | compliant |

**Table 4.1-8: Packaging information**

|                        |                           |
|------------------------|---------------------------|
| Type                   | BOTTLE                    |
| Material:              | HDPE                      |
| size:                  | 145.5mm± 2 mm/78mm ± 2 mm |
| Opening:               | 56mm ± 2 mm               |
| Closure:               | screw cap with seal       |
| Capacity               | 600 ml                    |
| Net Capacity           | 500 ml                    |
| Seal:                  | Induction seal            |
| Manner of construction | extruded                  |
| UN/ADR                 | compliant                 |

**Table 4.1-9: Packaging information**

|                                   |                     |
|-----------------------------------|---------------------|
| Type                              | JAR                 |
| Material:                         | HDPE                |
| size: approximate diameter/height | 79/80 mm / 201 mm   |
| Opening:                          | 46 mm minimum       |
| Closure:                          | screw cap with seal |
| Capacity                          | 800 ml              |
| Net Capacity                      | 800 ml              |
| Seal:                             | Induction seal      |
| Manner of construction            | extruded            |
| UN/ADR                            | compliant           |

**Table 4.1-10: Packaging information**

|                        |                           |
|------------------------|---------------------------|
| Type                   | BOTTLE                    |
| Material:              | HDPE                      |
| size:                  | 80 mm± 2 mm/201 mm ± 2 mm |
| Opening:               | 64 mm                     |
| Closure:               | screw cap with seal       |
| Capacity               | 800 ml                    |
| Net Capacity           | 800 ml                    |
| Seal:                  | Induction seal            |
| Manner of construction | extruded                  |
| UN/ADR                 | compliant                 |

**Table 4.1-11: Packaging information**

|           |                               |
|-----------|-------------------------------|
| Type      | BOTTLE                        |
| Material: | HDPE                          |
| size:     | 88.5 mm± 2 mm/283.5 mm ± 2 mm |
| Opening:  | 45.30 mm ± 2 mm               |
| Closure:  | screw cap with seal           |
| Capacity  | 1000 ml                       |

|                        |                |
|------------------------|----------------|
| Net Capacity           | 1000 ml        |
| Seal:                  | Induction seal |
| Manner of construction | extruded       |
| UN/ADR                 | compliant      |

**Table 4.1-12: Packaging information**

|                        |                               |
|------------------------|-------------------------------|
| Type                   | BOTTLE                        |
| Material:              | HDPE                          |
| size:                  | 88.5 mm± 2 mm/283.5 mm ± 2 mm |
| Opening:               | 45.30 mm ± 2 mm               |
| Closure:               | screw cap with seal           |
| Capacity               | 1000 ml                       |
| Net Capacity           | 1000 ml                       |
| Seal:                  | Induction seal                |
| Manner of construction | extruded                      |
| UN/ADR                 | compliant                     |

**Table 4.1-13: Packaging information**

|                        |                           |
|------------------------|---------------------------|
| Type                   | BOTTLE                    |
| Material:              | HDPE                      |
| size:                  | 88 mm± 4 mm/242 mm ± 6 mm |
| Opening:               | 39mm ± 2 mm               |
| Closure:               | screw cap with seal       |
| Capacity               | 1000 ml                   |
| Net Capacity           | 1000 ml                   |
| Seal:                  | Induction seal            |
| Manner of construction | extruded                  |
| UN/ADR                 | compliant                 |

**Table 4.1-14: Packaging information**

|                        |                          |
|------------------------|--------------------------|
| Type                   | BOTTLE                   |
| Material:              | HDPE                     |
| size:                  | 238 mm± 2 mm/90mm ± 2 mm |
| Opening:               | 39 mm ± 2 mm             |
| Closure:               | screw cap with seal      |
| Capacity               | 1000 ml                  |
| Net Capacity           | 1000 ml                  |
| Seal:                  | Induction seal           |
| Manner of construction | extruded                 |
| UN/ADR                 | compliant                |

**Table 4.1-15: Packaging information**

|           |                            |
|-----------|----------------------------|
| Type      | BOTTLE                     |
| Material: | HDPE                       |
| size:     | 234 mm± 2 mm/88.5mm ± 2 mm |
| Opening:  | 42 mm ± 2 mm               |

|                        |                     |
|------------------------|---------------------|
| Closure:               | screw cap with seal |
| Capacity               | 1000 ml             |
| Net Capacity           | 1000 ml             |
| Seal:                  | Induction seal      |
| Manner of construction | extruded            |
| UN/ADR                 | compliant           |

**Table 4.1-16: Packaging information**

|                        |                             |
|------------------------|-----------------------------|
| Type                   | BOTTLE                      |
| Material:              | HDPE                        |
| size:                  | 84 mm± 2 mm/248.2 mm ± 2 mm |
| Opening:               | 50 mm ± 2 mm                |
| Closure:               | screw cap with seal         |
| Capacity               | 1000 ml                     |
| Net Capacity           | 1000 ml                     |
| Seal:                  | Induction seal              |
| Manner of construction | extruded                    |
| UN/ADR                 | compliant                   |

**Table 4.1-17: Packaging information**

|                        |                            |
|------------------------|----------------------------|
| Type                   | BOTTLE                     |
| Material:              | HDPE                       |
| size:                  | 234 mm± 2 mm/88.5mm ± 2 mm |
| Opening:               | 42 mm ± 2 mm               |
| Closure:               | cap with seal              |
| Capacity               | 1200 ± 50 ml               |
| Net Capacity           | 1000 ml                    |
| Seal:                  | Induction seal             |
| Manner of construction | extruded                   |
| UN/ADR                 | compliant                  |

**Table 4.1-18: Packaging information**

|                        |                          |
|------------------------|--------------------------|
| Type                   | BOTTLE                   |
| Material:              | HDPE                     |
| size:                  | 84 ± 1.5 mm/230.1 ± 3 mm |
| Opening:               | 38 mm                    |
| Closure:               | screw cap with seal      |
| Capacity               | 1000 ml                  |
| Net Capacity           | 1000 ml                  |
| Seal:                  | Induction seal           |
| Manner of construction | extruded                 |
| UN/ADR                 | compliant                |

**Table 4.1-19: Packaging information**

|           |      |
|-----------|------|
| Type      | JAR  |
| Material: | HDPE |

|                                   |                     |
|-----------------------------------|---------------------|
| size: approximate diameter/height | 108/110mm / 266 mm  |
| Opening:                          | 46 mm minimum       |
| Closure:                          | screw cap with seal |
| Capacity                          | 2 000 ml            |
| Net Capacity                      | 2000 ml             |
| Seal:                             | Induction seal      |
| Manner of construction            | extruded            |
| UN/ADR                            | compliant           |

**Table 4.1-20: Packaging information**

|                        |                                                     |
|------------------------|-----------------------------------------------------|
| Type                   | CONTAINER                                           |
| Material:              | HDPE                                                |
| size:                  | 232 mm $\pm$ 2 mm/195mm $\pm$ 2 mm/130mm $\pm$ 2 mm |
| Opening:               | 50 mm $\pm$ 2 mm                                    |
| Closure:               | screw cap with seal                                 |
| Capacity               | 3000 ml                                             |
| Net Capacity           | 3000 ml                                             |
| Seal:                  | Induction seal                                      |
| Manner of construction | extruded                                            |
| UN/ADR                 | compliant                                           |

**Table 4.1-21: Packaging information**

|                        |                                               |
|------------------------|-----------------------------------------------|
| Type                   | BOTTLE                                        |
| Material:              | HDPE                                          |
| size:                  | 94 $\pm$ 1 mm/103 $\pm$ 1 mm/272.5 $\pm$ 3 mm |
| Opening:               | 38 mm                                         |
| Closure:               | screw cap with seal                           |
| Capacity               | 2000 ml                                       |
| Net Capacity           | 2000 ml                                       |
| Seal:                  | Induction seal                                |
| Manner of construction | extruded                                      |
| UN/ADR                 | compliant                                     |

**Table 4.1-22: Packaging information**

|                        |                                                 |
|------------------------|-------------------------------------------------|
| Type                   | CANNISTER                                       |
| Material:              | HDPE                                            |
| size:                  | 96 $\pm$ 3 mm/195 $\pm$ 3.5 mm/297.2 $\pm$ 4 mm |
| Opening:               | 38 mm                                           |
| Closure:               | screw cap with seal                             |
| Capacity               | 4000 ml                                         |
| Net Capacity           | 3000 ml                                         |
| Seal:                  | Induction seal                                  |
| Manner of construction | extruded                                        |
| UN/ADR                 | compliant                                       |

**Table 4.1-23: Packaging information**

|                        |                             |
|------------------------|-----------------------------|
| Type                   | BOTTLE                      |
| Material:              | HDPE                        |
| size:                  | 224,1 mm± 2 mm/122mm ± 2 mm |
| Opening:               | 73 mm ± 2 mm                |
| Closure:               | screw cap with seal         |
| Capacity               | 2000 ml                     |
| Net Capacity           | 2000 ml                     |
| Seal:                  | Induction seal              |
| Manner of construction | extruded                    |
| UN/ADR                 | compliant                   |

**Table 4.1-24: Packaging information**

|                        |                                        |
|------------------------|----------------------------------------|
| Type                   | CONTAINER                              |
| Material:              | HDPE                                   |
| size:                  | 305mm± 5 mm/193 mm± 5 mm/142 mm ± 5 mm |
| Opening:               | 59.20 mm minimum ± 5 mm                |
| Closure:               | screw cap with seal                    |
| Capacity               | 5850 ml±150 ml                         |
| Net Capacity           | 5000 ml                                |
| Seal:                  | Induction seal                         |
| Manner of construction | extruded                               |
| UN/ADR                 | compliant                              |

**Table 4.1-25: Packaging information**

|                        |                                        |
|------------------------|----------------------------------------|
| Type                   | CONTAINER                              |
| Material:              | HDPE                                   |
| size:                  | 305mm± 5 mm/193 mm± 5 mm/142 mm ± 5 mm |
| Opening:               | 59.20 mm minimum ± 5 mm                |
| Closure:               | screw cap with seal                    |
| Capacity               | 5850 ml±150 ml                         |
| Net Capacity           | 5000 ml                                |
| Seal:                  | Induction seal                         |
| Manner of construction | extruded                               |
| UN/ADR                 | compliant                              |

**Table 4.1-26: Packaging information**

|           |                                       |
|-----------|---------------------------------------|
| Type      | CONTAINER                             |
| Material: | HDPE                                  |
| size:     | 336 mm± 5 mm/195mm± 5 mm/130mm ± 5 mm |
| Opening:  | 50 mm ± 5 mm                          |
| Closure:  | screw cap with seal                   |
| Capacity  | 5000 ml                               |

|                        |                |
|------------------------|----------------|
| Net Capacity           | 5000 ml        |
| Seal:                  | Induction seal |
| Manner of construction | extruded       |
| UN/ADR                 | compliant      |

**Table 4.1-27: Packaging information**

|                        |                                           |
|------------------------|-------------------------------------------|
| Type                   | CANNISTER                                 |
| Material:              | HDPE                                      |
| size:                  | 190 mm± 5 mm /140 mm± 5 mm/ 314 mm ± 5 mm |
| Opening:               | 54.5 mm ± 5 mm                            |
| Closure:               | screw cap with seal                       |
| Capacity               | 5000 ml                                   |
| Net Capacity           | 5000 ml                                   |
| Seal:                  | Induction seal                            |
| Manner of construction | extruded                                  |
| UN/ADR                 | compliant                                 |

**Table 4.1-28: Packaging information**

|                        |                                         |
|------------------------|-----------------------------------------|
| Type                   | CONTAINER                               |
| Material:              | HDPE                                    |
| size:                  | 310,5 mm± 5 mm/195mm± 5 mm/130mm ± 5 mm |
| Opening:               | 63 mm ± 5 mm                            |
| Closure:               | screw cap with seal                     |
| Capacity               | 5000 ml                                 |
| Net Capacity           | 5000 ml                                 |
| Seal:                  | Induction seal                          |
| Manner of construction | extruded                                |
| UN/ADR                 | compliant                               |

**Table 4.1-29: Packaging information**

|                        |                            |
|------------------------|----------------------------|
| Type                   | CANNISTER                  |
| Material:              | HDPE                       |
| size:                  | 127±2 mm/192±2 mm/285±5 mm |
| Opening:               | 38 mm                      |
| Closure:               | screw cap with seal        |
| Capacity               | 5000 ml                    |
| Net Capacity           | 5000 ml                    |
| Seal:                  | Induction seal             |
| Manner of construction | extruded                   |
| UN/ADR                 | compliant                  |

**Table 4.1-30: Packaging information**

|                        |                           |
|------------------------|---------------------------|
| Type                   | CANNISTER                 |
| Material:              | HDPE                      |
| size:                  | 145±2 mm/190.8±3/294±4 mm |
| Opening:               | 38 mm                     |
| Closure:               | screw cap with seal       |
| Capacity               | 6000 ml                   |
| Net Capacity           | 5000 ml                   |
| Seal:                  | Induction seal            |
| Manner of construction | extruded                  |
| UN/ADR                 | compliant                 |

**Table 4.1-31: Packaging information**

|                        |                           |
|------------------------|---------------------------|
| Type                   | BOTTLE                    |
| Material:              | HDPE                      |
| size:                  | 231,5mm± 5 mm193mm ± 5 mm |
| Opening:               | 115 mm ± 5 mm             |
| Closure:               | screw cap with seal       |
| Capacity               | 5000 ml                   |
| Net Capacity           | 5000 ml                   |
| Seal:                  | Induction seal            |
| Manner of construction | extruded                  |
| UN/ADR                 | compliant                 |

**Table 4.1-32: Packaging information**

|                        |                                        |
|------------------------|----------------------------------------|
| Type                   | CONTAINER                              |
| Material:              | HDPE                                   |
| size:                  | 375mm± 5 mm/240 mm± 5 mm/179 mm ± 5 mm |
| Opening:               | 63 mm ± 5 mm                           |
| Closure:               | screw cap with seal                    |
| Capacity               | 11220±50 ml                            |
| Net Capacity           | 10000 ml                               |
| Seal:                  | Induction seal                         |
| Manner of construction | extruded                               |
| UN/ADR                 | compliant                              |

**Table 4.1-33: Packaging information**

|           |                                        |
|-----------|----------------------------------------|
| Type      | CONTAINER                              |
| Material: | HDPE                                   |
| size:     | 375mm± 5 mm/240 mm± 5 mm/179 mm ± 5 mm |
| Opening:  | 63 mm ± 5 mm                           |

|                        |                     |
|------------------------|---------------------|
| Closure:               | screw cap with seal |
| Capacity               | 11220±50 ml         |
| Net Capacity           | 10000 ml            |
| Seal:                  | Induction seal      |
| Manner of construction | extruded            |
| UN/ADR                 | compliant           |

**Table 4.1-34: Packaging information**

|                        |                                        |
|------------------------|----------------------------------------|
| Type                   | CONTAINER                              |
| Material:              | HDPE                                   |
| size:                  | 375mm± 5 mm/240 mm± 5 mm/179 mm ± 5 mm |
| Opening:               | 63 mm ± 5 mm                           |
| Closure:               | screw cap with seal                    |
| Capacity               | 11220±50 ml                            |
| Net Capacity           | 10000 ml                               |
| Seal:                  | Induction seal                         |
| Manner of construction | extruded                               |
| UN/ADR                 | compliant                              |

**Table 4.1-35: Packaging information**

|                        |                                      |
|------------------------|--------------------------------------|
| Type                   | CONTAINER                            |
| Material:              | HDPE                                 |
| size:                  | 375 mm± 5 mm/230± 5 mm/165 mm ± 5 mm |
| Opening:               | 54.5 mm ± 5 mm                       |
| Closure:               | screw cap with seal                  |
| Capacity               | 10000 ml                             |
| Net Capacity           | 10000 ml                             |
| Seal:                  | Induction seal                       |
| Manner of construction | extruded                             |
| UN/ADR                 | compliant                            |

**Table 4.1-36: Packaging information**

|                        |                                          |
|------------------------|------------------------------------------|
| Type                   | CONTAINER                                |
| Material:              | HDPE                                     |
| size:                  | 377,7 mm± 5 mm/239,5± 5 mm/178 mm ± 5 mm |
| Opening:               | 54 mm ± 5 mm                             |
| Closure:               | screw cap with seal                      |
| Capacity               | 10000 ml                                 |
| Net Capacity           | 10000 ml                                 |
| Seal:                  | Induction seal                           |
| Manner of construction | extruded                                 |

|        |           |
|--------|-----------|
| UN/ADR | compliant |
|--------|-----------|

**Table 4.1-37: Packaging information**

|                        |                         |
|------------------------|-------------------------|
| Type                   | CANNISTER               |
| Material:              | HDPE                    |
| size:                  | 192±3 mm/228±7/313±7 mm |
| Opening:               | 52 mm ± 2 mm            |
| Closure:               | screw cap with seal     |
| Capacity               | 10000 ml                |
| Net Capacity           | 10000 ml                |
| Seal:                  | Induction seal          |
| Manner of construction | extruded                |
| UN/ADR                 | compliant               |

**Table 4.1-38: Packaging information**

|                        |                         |
|------------------------|-------------------------|
| Type                   | CANNISTER               |
| Material:              | HDPE                    |
| size:                  | 185±2 mm/225±2/312±3 mm |
| Opening:               | 40.8 mm ± 0.3 mm        |
| Closure:               | screw cap with seal     |
| Capacity               | 10000 ml                |
| Net Capacity           | 10000 ml                |
| Seal:                  | Induction seal          |
| Manner of construction | extruded                |
| UN/ADR                 | compliant               |

**Table 4.1-39: Packaging information**

|                        |                                 |
|------------------------|---------------------------------|
| Type                   | CONTAINER                       |
| Material:              | HDPE                            |
| size:                  | 443mm/288mm/230mm               |
| Opening:               | 44mm (internal) 60mm (external) |
| Closure:               | screw cap with seal             |
| Capacity               | 22000ml ± 50 ml                 |
| Net Capacity           | 20000 ml                        |
| Seal:                  | Induction seal                  |
| Manner of construction | extruded                        |
| UN/ADR                 | compliant                       |

**Table 4.1-40: Packaging information**

|           |                   |
|-----------|-------------------|
| Type      | CONTAINER         |
| Material: | HDPE              |
| size:     | 443mm/288mm/230mm |

|                        |                                 |
|------------------------|---------------------------------|
| Opening:               | 44mm (internal) 60mm (external) |
| Closure:               | screw cap with seal             |
| Capacity               | 22000ml $\pm$ 50 ml             |
| Net Capacity           | 20000 ml                        |
| Seal:                  | Induction seal                  |
| Manner of construction | extruded                        |
| UN/ADR                 | compliant                       |

**Table 4.1.-41: Packaging information**

|                        |                                              |
|------------------------|----------------------------------------------|
| Type                   | CONTAINER                                    |
| Material:              | HDPE                                         |
| size:                  | 376.3 $\pm$ 3 mm/295 $\pm$ 3mm/246 $\pm$ 3mm |
| Opening:               | 50 mm $\pm$ 5 mm                             |
| Closure:               | screw cap with seal                          |
| Capacity               | 20000 ml                                     |
| Net Capacity           | 20000 ml                                     |
| Seal:                  | Induction seal                               |
| Manner of construction | extruded                                     |
| UN/ADR                 | compliant                                    |

**Table 4.1-42: Packaging information**

|                        |                                           |
|------------------------|-------------------------------------------|
| Type                   | CONTAINER                                 |
| Material:              | HDPE                                      |
| size:                  | 378 $\pm$ 5 mm/288 $\pm$ 5/258 $\pm$ 5 mm |
| Opening:               | 53.7 $\pm$ 1.5 mm                         |
| Closure:               | screw cap with seal                       |
| Capacity               | 22000 ml                                  |
| Net Capacity           | 20 000 ml                                 |
| Seal:                  | Induction seal                            |
| Manner of construction | extruded                                  |
| UN/ADR                 | compliant                                 |

**Table 4.1-43: Packaging information**

|                        |                                             |
|------------------------|---------------------------------------------|
| Type                   | CONTAINER                                   |
| Material:              | HDPE                                        |
| size:                  | 376 $\pm$ 8 mm/257,5 $\pm$ 5/376 $\pm$ 8 mm |
| Opening:               | 52 mm $\pm$ 3                               |
| Closure:               | screw cap with seal                         |
| Capacity               | 20000 ml                                    |
| Net Capacity           | 20 000 ml                                   |
| Seal:                  | Induction seal                              |
| Manner of construction | extruded                                    |
| UN/ADR                 | compliant                                   |

**Table 4.1-44: Packaging information**

|                        |                                  |
|------------------------|----------------------------------|
| Type                   | CANNISTER                        |
| Material:              | HDPE                             |
| size:                  | 257.5±6 mm/292±8/376±8 mm ± 5 mm |
| Opening:               | 52 mm ± 2 mm                     |
| Closure:               | screw cap with seal              |
| Capacity               | 20000 ml                         |
| Net Capacity           | 20 000 ml                        |
| Seal:                  | Induction seal                   |
| Manner of construction | extruded                         |
| UN/ADR                 | compliant                        |

**Table 4.1-45: Packaging information**

|                        |                    |
|------------------------|--------------------|
| Type                   | Description        |
| Material:              | HDPE               |
| Size:                  | 745 mm x 493 mm    |
| Opening:               | BCS 70x6/ BCS 38x6 |
| Closure:               | Bung               |
| Capacity               | 124 L              |
| Net Capacity           | 124 L              |
| Seal:                  | Induction seal     |
| Manner of construction | extruded           |
| UN/ADR                 | compliant          |

**Table 4.1-46: Packaging information**

|                        |                    |
|------------------------|--------------------|
| Type                   | Description        |
| Material:              | HDPE               |
| Size:                  | 935 mm x 581 mm    |
| Opening:               | BCS 70x6/ BCS 56x4 |
| Closure:               | Bung               |
| Capacity               | 220 L              |
| Net Capacity           | 220 L              |
| Seal:                  | Induction seal     |
| Manner of construction | extruded           |
| UN/ADR                 | compliant          |

**Table 4.1-47: Packaging information**

|                        |                                                                                                 |
|------------------------|-------------------------------------------------------------------------------------------------|
| Type                   | Description                                                                                     |
| Material:              | HDPE                                                                                            |
| Size:                  | 942 mm $\pm$ 10 mm x 582 mm $\pm$ 10 mm                                                         |
| Opening:               | 70x6 / 56 x4                                                                                    |
| Closure:               | Openings on top, 3 high, straight wrapped with cover on top<br>Bungs 70x6 and 56 x 4 lose screw |
| Capacity               | 222 L                                                                                           |
| Net Capacity           | 222 L                                                                                           |
| Seal:                  | Induction seal                                                                                  |
| Manner of construction | extruded                                                                                        |
| UN/ADR                 | compliant                                                                                       |

According to guideline from Ministry of Agriculture and Rural Development storage stability study can be extrapolated to new packaging material HDPE/PA, HDPE/F, HDPE/EvOH from provided and evaluated storage stability studies of packing HDPE. Therefore, no further studies are required for the additional packaging materials.

#### ZRMS comments

The HDPE bottle was used in accelerated storage study (8 weeks at 40°C) and ambient storage study (1 year at 20°C). The HDPE bottle was stable in accelerated storage study and 1 year storage study at ambient temperature so the storage stability data obtained in these studies can be extrapolated for storage in HDPE-EVOH; HDPE-F, HDPE/PA or PET bottles.

(According to SANCO/10473/2003 rev.5 “Guidance Document for the Generation and Evaluation of Data on The Physical, Chemical And Technical Properties of Plant Protection Products Under Regulation (EC) No. 1107/2009” and Technical Monograph N°17 3RD Edition Guidelines for Specifying and Managing Shelf Life and Expiry Date of Crop Protection Products, Crop Life International” the following extrapolations are acceptable: for water-based formulations (e.g. SC, FS, SL) extrapolation between plastic materials is possible and stability data generated for one of the materials can be used in support of any of the others).

**Table 4.1-48: Packaging information**

|                        |                               |
|------------------------|-------------------------------|
| Type                   | BOTTLE                        |
| Material:              | HDPE/PA                       |
| size:                  | 59 $\pm$ 1 mm/143 $\pm$ 1 mm/ |
| Opening:               | 41.7 $\pm$ 0.7 mm             |
| Closure:               | screw cap with seal           |
| Capacity               | 275 ml                        |
| Net Capacity           | 250 ml                        |
| Seal:                  | Induction seal                |
| Manner of construction | extruded                      |
| UN/ADR                 | compliant                     |

**Table 4.1-49: Packaging information**

|           |                               |
|-----------|-------------------------------|
| Type      | BOTTLE                        |
| Material: | HDPE/PA                       |
| size:     | 59 $\pm$ 1 mm/143 $\pm$ 1 mm/ |
| Opening:  | 41.7 $\pm$ 0.7 mm             |
| Closure:  | screw cap with seal           |

|                        |                |
|------------------------|----------------|
| Capacity               | 275 ml         |
| Net Capacity           | 250 ml         |
| Seal:                  | Induction seal |
| Manner of construction | extruded       |
| UN/ADR                 | compliant      |

**Table 4.1-50: Packaging information**

|                        |                      |
|------------------------|----------------------|
| Type                   | BOTTLE               |
| Material:              | HDPE/PA              |
| size:                  | 62.5±1 mm/131.3±1 mm |
| Opening:               | 45.65±3 mm           |
| Closure:               | screw cap with seal  |
| Capacity               | 323 ± 5 ml           |
| Net Capacity           | 250 ml               |
| Seal:                  | Induction seal       |
| Manner of construction | extruded             |
| UN/ADR                 | compliant            |

**Table 4.1-51: Packaging information**

|                        |                              |
|------------------------|------------------------------|
| Type                   | BOTTLE                       |
| Material:              | HDPE/PA                      |
| size:                  | 69 mm ± 2 mm/186.5 mm ± 2 mm |
| Opening:               | 45.65±3 mm                   |
| Closure:               | screw cap with seal          |
| Capacity               | 574 ml                       |
| Net Capacity           | 500 ml                       |
| Seal:                  | Induction seal               |
| Manner of construction | extruded                     |
| UN/ADR                 | compliant                    |

**Table 4.1-52: Packaging information**

|                        |                      |
|------------------------|----------------------|
| Type                   | BOTTLE               |
| Material:              | HDPE/PA              |
| size:                  | 74± 1 mm/177 ± 1 mm/ |
| Opening:               | 41.7±0.7 mm          |
| Closure:               | screw cap with seal  |
| Capacity               | 550 ml               |
| Net Capacity           | 500 ml               |
| Seal:                  | Induction seal       |
| Manner of construction | extruded             |
| UN/ADR                 | compliant            |

**Table 4.1-53: Packaging information**

|      |        |
|------|--------|
| Type | BOTTLE |
|------|--------|

|                        |                      |
|------------------------|----------------------|
| Material:              | HDPE/PA              |
| size:                  | 74± 1 mm/177 ± 1 mm/ |
| Opening:               | 41.7±0.7 mm          |
| Closure:               | screw cap with seal  |
| Capacity               | 550 ml               |
| Net Capacity           | 500 ml               |
| Seal:                  | Induction seal       |
| Manner of construction | extruded             |
| UN/ADR                 | compliant            |

**Table 4.1-54: Packaging information**

|                        |                            |
|------------------------|----------------------------|
| Type                   | BOTTLE                     |
| Material:              | HDPE/PA                    |
| size:                  | 88 mm ± 2 mm/238 mm ± 2 mm |
| Opening:               | 50 mm ± 2 mm               |
| Closure:               | screw cap with cutter      |
| Capacity               | 1000 ml                    |
| Net Capacity           | 1000 ml                    |
| Seal:                  | Induction seal             |
| Manner of construction | extruded                   |
| UN/ADR                 | compliant                  |

**Table 4.1-55: Packaging information**

|                        |                     |
|------------------------|---------------------|
| Type                   | BOTTLE              |
| Material:              | HDPE/PA             |
| size:                  | 248.5±3 mm/84±1.5mm |
| Opening:               | 50 mm ± 2 mm        |
| Closure:               | screw cap with seal |
| Capacity               | 1000 ml             |
| Net Capacity           | 1000 ml             |
| Seal:                  | Induction seal      |
| Manner of construction | extruded            |
| UN/ADR                 | compliant           |

**Table 4.1-56: Packaging information**

|                        |                     |
|------------------------|---------------------|
| Type                   | BOTTLE              |
| Material:              | HDPE/PA             |
| size:                  | 248.5±3 mm/84±1.5mm |
| Opening:               | 50 mm ± 5 mm        |
| Closure:               | screw cap with seal |
| Capacity               | 1000 ml             |
| Net Capacity           | 1000 ml             |
| Seal:                  | Induction seal      |
| Manner of construction | extruded            |

|        |           |
|--------|-----------|
| UN/ADR | compliant |
|--------|-----------|

**Table 4.1-57: Packaging information**

|                        |                            |
|------------------------|----------------------------|
| Type                   | BOTTLE                     |
| Material:              | HDPE/PA                    |
| size:                  | 234 mm± 2 mm/88.5mm ± 2 mm |
| Opening:               | 42 mm ± 2 mm               |
| Closure:               | screw cap with seal        |
| Capacity               | 1000 ml                    |
| Net Capacity           | 1000 ml                    |
| Seal:                  | Induction seal             |
| Manner of construction | extruded                   |
| UN/ADR                 | compliant                  |

**Table 4.1.-58: Packaging information**

|                        |                      |
|------------------------|----------------------|
| Type                   | BOTTLE               |
| Material:              | HDPE/PA              |
| size:                  | 238± 1 mm/88 ± 1 mm/ |
| Opening:               | 41.7±0,7 mm          |
| Closure:               | screw cap with seal  |
| Capacity               | 1100 ml              |
| Net Capacity           | 1000 ml              |
| Seal:                  | Induction seal       |
| Manner of construction | extruded             |
| UN/ADR                 | compliant            |

**Table 4.1-59: Packaging information**

|                        |                         |
|------------------------|-------------------------|
| Type                   | BOTTLE                  |
| Material:              | HDPE/PA                 |
| size:                  | 84± 1.5 mm/248.5 ± 3 mm |
| Opening:               | 50 mm ± 3mm             |
| Closure:               | screw cap with seal     |
| Capacity               | 1000 ml                 |
| Net Capacity           | 1000 ml                 |
| Seal:                  | Induction seal          |
| Manner of construction | extruded                |
| UN/ADR                 | compliant               |

**Table 4.1-60: Packaging information**

|           |                            |
|-----------|----------------------------|
| Type      | BOTTLE                     |
| Material: | HDPE/PA                    |
| size:     | 233.5± 1.5 mm/88.5 ± 1 mm/ |
| Opening:  | 39 mm ± 2 mm               |

|                        |                     |
|------------------------|---------------------|
| Closure:               | screw cap with seal |
| Capacity               | 1100 ml             |
| Net Capacity           | 1000 ml             |
| Seal:                  | Induction seal      |
| Manner of construction | extruded            |
| UN/ADR                 | compliant           |

**Table 4.1-61: Packaging information**

|                        |                         |
|------------------------|-------------------------|
| Type                   | BOTTLE                  |
| Material:              | HDPE/PA                 |
| size:                  | 84± 1.5 mm/248.5 ± 3 mm |
| Opening:               | 50 mm ± 3mm             |
| Closure:               | screw cap with seal     |
| Capacity               | 1000 ml                 |
| Net Capacity           | 1000 ml                 |
| Seal:                  | Induction seal          |
| Manner of construction | extruded                |
| UN/ADR                 | compliant               |

**Table 4.1-62: Packaging information**

|                        |                                       |
|------------------------|---------------------------------------|
| Type                   | CONTAINER                             |
| Material:              | HDPE/PA                               |
| size:                  | 305mm± 5 mm/193 mm± 5 mm/142 mm ±5 mm |
| Opening:               | 63 mm minimum ± 5 mm                  |
| Closure:               | screw cap with seal                   |
| Capacity               | 5850 ml±150 ml                        |
| Net Capacity           | 5000 ml                               |
| Seal:                  | Induction seal                        |
| Manner of construction | extruded                              |
| UN/ADR                 | compliant                             |

**Table 4.1-63: Packaging information**

|                        |                                    |
|------------------------|------------------------------------|
| Type                   | BOTTLE                             |
| Material:              | HDPE/PA                            |
| size:                  | 195 ± 3/ 130 ± 5 mm/310,5 mm± 5 mm |
| Opening:               | 63,3 ± 3mm                         |
| Closure:               | screw cap with seal                |
| Capacity               | 5000 ml                            |
| Net Capacity           | 5000 ml                            |
| Seal:                  | Induction seal                     |
| Manner of construction | extruded                           |
| UN/ADR                 | compliant                          |

**Table 4.1-64: Packaging information**

|                        |                                  |
|------------------------|----------------------------------|
| Type                   | BOTTLE                           |
| Material:              | HDPE/PA                          |
| size:                  | 193 ± 3/ 142 ± 5 mm/320 mm± 5 mm |
| Opening:               | 63,3 ± 3mm                       |
| Closure:               | screw cap with seal              |
| Capacity               | 5500 ml                          |
| Net Capacity           | 5000 ml                          |
| Seal:                  | Induction seal                   |
| Manner of construction | extruded                         |
| UN/ADR                 | compliant                        |

**Table 4.1-65: Packaging information**

|                        |                        |
|------------------------|------------------------|
| Type                   | CANNISTER              |
| Material:              | HDPE/PA                |
| size:                  | 313± 5mm/190±3/140±5mm |
| Opening:               | 50 mm ± 3mm            |
| Closure:               | screw cap with seal    |
| Capacity               | 5000 ml                |
| Net Capacity           | 5000 ml                |
| Seal:                  | Induction seal         |
| Manner of construction | extruded               |
| UN/ADR                 | compliant              |

**Table 4.1-66: Packaging information**

|                        |                            |
|------------------------|----------------------------|
| Type                   | CONTAINER                  |
| Material:              | HDPE/PA                    |
| size:                  | 305mm/193 mm/142 mm ± 5 mm |
| Opening:               | 63 mm minimum ± 5 mm       |
| Closure:               | screw cap with seal        |
| Capacity               | 10000 ml±150 ml            |
| Net Capacity           | 10000 ml                   |
| Seal:                  | Induction seal             |
| Manner of construction | extruded                   |
| UN/ADR                 | compliant                  |

**Table 4.1-67: Packaging information**

|              |                                |
|--------------|--------------------------------|
| Type         | CONTAINER                      |
| Material:    | HDPE/PA                        |
| size:        | 377,7mm/178 mm/239,5 mm ± 5 mm |
| Opening:     | 54 mm min ± 5 mm               |
| Closure:     | screw cap with seal            |
| Capacity     | 10000 ml±150 ml                |
| Net Capacity | 10000 ml                       |

|                        |                |
|------------------------|----------------|
| Seal:                  | Induction seal |
| Manner of construction | extruded       |
| UN/ADR                 | compliant      |

**Table 4.1-68: Packaging information**

|                        |                     |
|------------------------|---------------------|
| Type                   | BOTTLE              |
| Material:              | HDPE/F              |
| size:                  | 63.5±1 mm/126±1 mm  |
| Opening:               | 50 mm               |
| Closure:               | screw cap with seal |
| Capacity               | 318 ± 12.5 ml       |
| Net Capacity           | 250 ml              |
| Seal:                  | Induction seal      |
| Manner of construction | extruded            |
| UN/ADR                 | compliant           |

**Table 4.1-69: Packaging information**

|                        |                     |
|------------------------|---------------------|
| Type                   | BOTTLE              |
| Material:              | HDPE/F              |
| size:                  | 63.5±1 mm/126±1 mm  |
| Opening:               | 50 mm               |
| Closure:               | screw cap with seal |
| Capacity               | 312 ± 12.5 ml       |
| Net Capacity           | 250 ml              |
| Seal:                  | Induction seal      |
| Manner of construction | extruded            |
| UN/ADR                 | compliant           |

**Table 4.1-70: Packaging information**

|                        |                     |
|------------------------|---------------------|
| Type                   | BOTTLE              |
| Material:              | HDPE/F              |
| size:                  | 69±1 mm/186±1.6 mm  |
| Opening:               | 50 mm               |
| Closure:               | screw cap with seal |
| Capacity               | 570 ± 12.5 ml       |
| Net Capacity           | 500 ml              |
| Seal:                  | Induction seal      |
| Manner of construction | extruded            |
| UN/ADR                 | compliant           |

**Table 4.1-71: Packaging information**

|           |        |
|-----------|--------|
| Type      | BOTTLE |
| Material: | HDPE/F |

|                        |                     |
|------------------------|---------------------|
| size:                  | 69±1 mm/186±1.6 mm  |
| Opening:               | 50 mm               |
| Closure:               | screw cap with seal |
| Capacity               | 575 ± 12.5 ml       |
| Net Capacity           | 500 ml              |
| Seal:                  | Induction seal      |
| Manner of construction | extruded            |
| UN/ADR                 | compliant           |

**Table 4.1-72: Packaging information**

|                        |                     |
|------------------------|---------------------|
| Type                   | BOTTLE              |
| Material:              | HDPE/F              |
| size:                  | 69±1 mm/186±1.6 mm  |
| Opening:               | 50 mm               |
| Closure:               | screw cap with seal |
| Capacity               | 580 ± 12.5 ml       |
| Net Capacity           | 500 ml              |
| Seal:                  | Induction seal      |
| Manner of construction | extruded            |
| UN/ADR                 | compliant           |

**Table 4.1-73: Packaging information**

|                        |                     |
|------------------------|---------------------|
| Type                   | BOTTLE              |
| Material:              | HDPE/F              |
| size:                  | 69±1 mm/186±1.6 mm  |
| Opening:               | 50 mm               |
| Closure:               | screw cap with seal |
| Capacity               | 585 ± 12.5 ml       |
| Net Capacity           | 500 ml              |
| Seal:                  | Induction seal      |
| Manner of construction | extruded            |
| UN/ADR                 | compliant           |

**Table 4.1-74: Packaging information**

|              |                        |
|--------------|------------------------|
| Type         | BOTTLE                 |
| Material:    | HDPE/F                 |
| size:        | 88.5±1 mm/233.2±1.6 mm |
| Opening:     | 50 mm                  |
| Closure:     | screw cap with seal    |
| Capacity     | 1150 ± 20 ml           |
| Net Capacity | 1000 ml                |
| Seal:        | Induction seal         |

|                        |           |
|------------------------|-----------|
| Manner of construction | extruded  |
| UN/ADR                 | compliant |

**Table 4.1-75: Packaging information**

|                        |                        |
|------------------------|------------------------|
| Type                   | BOTTLE                 |
| Material:              | HDPE/F                 |
| size:                  | 88.5±1 mm/233.2±1.6 mm |
| Opening:               | 50 mm                  |
| Closure:               | screw cap with seal    |
| Capacity               | 1160 ± 20 ml           |
| Net Capacity           | 1000 ml                |
| Seal:                  | Induction seal         |
| Manner of construction | extruded               |
| UN/ADR                 | compliant              |

**Table 4.1-76: Packaging information**

|                        |                        |
|------------------------|------------------------|
| Type                   | BOTTLE                 |
| Material:              | HDPE/F                 |
| size:                  | 88.5±1 mm/233.2±1.6 mm |
| Opening:               | 50 mm                  |
| Closure:               | screw cap with seal    |
| Capacity               | 1170 ± 20 ml           |
| Net Capacity           | 1000 ml                |
| Seal:                  | Induction seal         |
| Manner of construction | extruded               |
| UN/ADR                 | compliant              |

**Table 4.1-77: Packaging information**

|                        |                        |
|------------------------|------------------------|
| Type                   | BOTTLE                 |
| Material:              | HDPE/F                 |
| size:                  | 88.5±1 mm/233.2±1.6 mm |
| Opening:               | 50 mm                  |
| Closure:               | screw cap with seal    |
| Capacity               | 1185 ± 20 ml           |
| Net Capacity           | 1000 ml                |
| Seal:                  | Induction seal         |
| Manner of construction | extruded               |
| UN/ADR                 | compliant              |

**Table 4.1-78: Packaging information**

|           |        |
|-----------|--------|
| Type      | BOTTLE |
| Material: | HDPE/F |

|                        |                        |
|------------------------|------------------------|
| size:                  | 88.5±1 mm/233.2±1.6 mm |
| Opening:               | 50 mm                  |
| Closure:               | screw cap with seal    |
| Capacity               | 1200 ± 20 ml           |
| Net Capacity           | 1000 ml                |
| Seal:                  | Induction seal         |
| Manner of construction | extruded               |
| UN/ADR                 | compliant              |

**Table 4.1-79: Packaging information**

|                        |                          |
|------------------------|--------------------------|
| Type                   | Cannister                |
| Material:              | HDPE/F                   |
| size:                  | 193±2 mm/142±2mm/305±3mm |
| Opening:               | 50 mm                    |
| Closure:               | screw cap with seal      |
| Capacity               | 5880 ± 100 ml            |
| Net Capacity           | 5000 ml                  |
| Seal:                  | Induction seal           |
| Manner of construction | extruded                 |
| UN/ADR                 | compliant                |

**Table 4.1-80: Packaging information**

|                        |                          |
|------------------------|--------------------------|
| Type                   | Cannister                |
| Material:              | HDPE/F                   |
| size:                  | 193±2 mm/142±2mm/305±3mm |
| Opening:               | 63 mm                    |
| Closure:               | screw cap with seal      |
| Capacity               | 5880 ± 100 ml            |
| Net Capacity           | 5000 ml                  |
| Seal:                  | Induction seal           |
| Manner of construction | extruded                 |
| UN/ADR                 | compliant                |

**Table 4.1-81: Packaging information**

|                        |                              |
|------------------------|------------------------------|
| Type                   | BOTTLE                       |
| Material:              | HDPE/F                       |
| size:                  | 297,3mm/193 mm/142 mm ± 2 mm |
| Opening:               | 54,2 mm ± 1 mm               |
| Closure:               | screw cap with seal          |
| Capacity               | 5950 ml ± 100 ml             |
| Net Capacity           | 5000 ml                      |
| Seal:                  | Induction seal               |
| Manner of construction | extruded                     |

|        |           |
|--------|-----------|
| UN/ADR | compliant |
|--------|-----------|

**Table 4.1-82: Packaging information**

|                        |                                  |
|------------------------|----------------------------------|
| Type                   | BOTTLE                           |
| Material:              | HDPE/F                           |
| size:                  | 297,3mm/193 mm/142 mm $\pm$ 2 mm |
| Opening:               | 63.4 mm min $\pm$ 1 mm           |
| Closure:               | screw cap with seal              |
| Capacity               | 5950 ml $\pm$ 100 ml             |
| Net Capacity           | 5000 ml                          |
| Seal:                  | Induction seal                   |
| Manner of construction | extruded                         |
| UN/ADR                 | compliant                        |

**Table 4.1-83: Packaging information**

|                        |                                  |
|------------------------|----------------------------------|
| Type                   | BOTTLE                           |
| Material:              | HDPE/F                           |
| size:                  | 297,3mm/193 mm/142 mm $\pm$ 2 mm |
| Opening:               | 67,5 mm $\pm$ 1 mm               |
| Closure:               | screw cap with seal              |
| Capacity               | 5950 ml $\pm$ 100 ml             |
| Net Capacity           | 5000 ml                          |
| Seal:                  | Induction seal                   |
| Manner of construction | extruded                         |
| UN/ADR                 | compliant                        |

**Table 4.1-84: Packaging information**

|                        |                                  |
|------------------------|----------------------------------|
| Type                   | CANNISTER                        |
| Material:              | HDPE/F                           |
| size:                  | 297,3mm/193 mm/142 mm $\pm$ 2 mm |
| Opening:               | 54,2 mm min $\pm$ 1 mm           |
| Closure:               | screw cap with seal              |
| Capacity               | 5950 ml $\pm$ 100 ml             |
| Net Capacity           | 5000 ml                          |
| Seal:                  | Induction seal                   |
| Manner of construction | extruded                         |
| UN/ADR                 | compliant                        |

**Table 4.1-85: Packaging information**

|           |           |
|-----------|-----------|
| Type      | CANNISTER |
| Material: | HDPE/F    |

|                        |                                  |
|------------------------|----------------------------------|
| size:                  | 297,3mm/193 mm/142 mm $\pm$ 2 mm |
| Opening:               | 63,4 mm min $\pm$ 1 mm           |
| Closure:               | screw cap with seal              |
| Capacity               | 5950 ml $\pm$ 100 ml             |
| Net Capacity           | 5000 ml                          |
| Seal:                  | Induction seal                   |
| Manner of construction | extruded                         |
| UN/ADR                 | compliant                        |

**Table 4.1-86: Packaging information**

|                        |                                  |
|------------------------|----------------------------------|
| Type                   | CANNISTER                        |
| Material:              | HDPE/F                           |
| size:                  | 297,3mm/193 mm/142 mm $\pm$ 2 mm |
| Opening:               | 67,5 mm min $\pm$ 1 mm           |
| Closure:               | screw cap with seal              |
| Capacity               | 5950 ml $\pm$ 100 ml             |
| Net Capacity           | 5000 ml                          |
| Seal:                  | Induction seal                   |
| Manner of construction | extruded                         |
| UN/ADR                 | compliant                        |

**Table 4.1-87: Packaging information**

|                        |                                            |
|------------------------|--------------------------------------------|
| Type                   | Cannister                                  |
| Material:              | HDPE/F                                     |
| size:                  | 240 $\pm$ 2 mm/179 $\pm$ 2mm/375 $\pm$ 3mm |
| Opening:               | 63 mm                                      |
| Closure:               | screw cap with seal                        |
| Capacity               | 10 000 ml                                  |
| Net Capacity           | 10000 ml                                   |
| Seal:                  | Induction seal                             |
| Manner of construction | extruded                                   |
| UN/ADR                 | compliant                                  |

**Table 4.1-88: Packaging information**

|                               |                                      |
|-------------------------------|--------------------------------------|
| Type                          | BOTTLE                               |
| Material:                     | HDPE/ EVOH                           |
| Body diameter / total height: | 62,50 $\pm$ 0,50 / 126,50 $\pm$ 1,50 |
| External thread diameter:     | 49,65 $\pm$ 0,35                     |
| Closure:                      | screw cap with seal                  |
| Capacity                      | 250 ml                               |
| Net Capacity                  | 250 ml                               |
| Seal:                         | Induction seal                       |

|                        |                                                                                                 |
|------------------------|-------------------------------------------------------------------------------------------------|
| Manner of construction | extruded                                                                                        |
| UN/ADR                 | N/A<br>zRMS comment: Packaging should only be authorised if UN/ADR compliance can be confirmed. |

**Table 4.1-89: Packaging information**

|                               |                                                                                                 |
|-------------------------------|-------------------------------------------------------------------------------------------------|
| Type                          | BOTTLE                                                                                          |
| Material:                     | HDPE/ EVOH                                                                                      |
| Body diameter / total height: | 59 +- 1 mm / 143 +- 1 mm                                                                        |
| External thread diameter:     | 41.7 +- 0,4 mm                                                                                  |
| Closure:                      | screw cap with seal                                                                             |
| Capacity                      | 310 ml                                                                                          |
| Net Capacity                  | 250 ml                                                                                          |
| Seal:                         | Induction seal                                                                                  |
| Manner of construction        | extruded                                                                                        |
| UN/ADR                        | N/A<br>zRMS comment: Packaging should only be authorised if UN/ADR compliance can be confirmed. |

**Table 4.1-90: Packaging information**

|                        |                             |
|------------------------|-----------------------------|
| Type                   | BOTTLE                      |
| Material:              | HDPE/ EvOH                  |
| size:                  | 69 mm± 2 mm/186.5 mm ± 2 mm |
| Opening:               | 42±3 mm                     |
| Closure:               | screw cap with cutter       |
| Capacity               | 500 ml                      |
| Net Capacity           | 500 ml                      |
| Seal:                  | Induction seal              |
| Manner of construction | extruded                    |
| UN/ADR                 | compliant                   |

**Table 4.1-91: Packaging information**

|                        |                       |
|------------------------|-----------------------|
| Type                   | BOTTLE                |
| Material:              | HDPE/ EvOH            |
| size:                  | 65 mm/234.8 mm ± 2 mm |
| Opening:               | 27.4 mm               |
| Closure:               | screw cap with seal   |
| Capacity               | 500 ml                |
| Net Capacity           | 500 ml                |
| Seal:                  | Induction seal        |
| Manner of construction | extruded              |

|        |           |
|--------|-----------|
| UN/ADR | compliant |
|--------|-----------|

**Table 4.1-92: Packaging information**

|                        |                                      |
|------------------------|--------------------------------------|
| Type                   | BOTTLE                               |
| Material:              | HDPE/EvOH                            |
| size:                  | 69 mm $\pm$ 1 mm/190 mm $\pm$ 1.5 mm |
| Opening:               | 49.5 mm $\pm$ 0.3 mm                 |
| Closure:               | screw cap with seal                  |
| Capacity               | 579 ml                               |
| Net Capacity           | 500 ml                               |
| Seal:                  | Induction seal                       |
| Manner of construction | extruded                             |
| UN/ADR                 | compliant                            |

**Table 4.1-93: Packaging information**

|                        |                               |
|------------------------|-------------------------------|
| Type                   | BOTTLE                        |
| Material:              | HDPE/EvOH                     |
| size:                  | 234 $\pm$ 3 mm/88.5 $\pm$ 2mm |
| Opening:               | 42 mm $\pm$ 2 mm              |
| Closure:               | screw cap with cutter         |
| Capacity               | 1000 ml                       |
| Net Capacity           | 1000 ml                       |
| Seal:                  | Induction seal                |
| Manner of construction | extruded                      |
| UN/ADR                 | compliant                     |

**Table 4.1-94: Packaging information**

|                        |                               |
|------------------------|-------------------------------|
| Type                   | BOTTLE                        |
| Material:              | HDPE/EvOH                     |
| size:                  | 234 $\pm$ 3 mm/88.5 $\pm$ 2mm |
| Opening:               | 42 mm $\pm$ 2 mm              |
| Closure:               | screw cap with cutter         |
| Capacity               | 1000 ml                       |
| Net Capacity           | 1000 ml                       |
| Seal:                  | Induction seal                |
| Manner of construction | extruded                      |
| UN/ADR                 | compliant                     |

**Table 4.1-95: Packaging information**

|           |                               |
|-----------|-------------------------------|
| Type      | BOTTLE                        |
| Material: | HDPE/EvOH                     |
| size:     | 234 $\pm$ 3 mm/88.5 $\pm$ 2mm |
| Opening:  | 50 mm $\pm$ 3 mm              |

|                        |                       |
|------------------------|-----------------------|
| Closure:               | screw cap with cutter |
| Capacity               | 1000 ml               |
| Net Capacity           | 1000 ml               |
| Seal:                  | Induction seal        |
| Manner of construction | extruded              |
| UN/ADR                 | compliant             |

**Table 4.1-96: Packaging information**

|                        |                       |
|------------------------|-----------------------|
| Type                   | BOTTLE                |
| Material:              | HDPE/EvOH             |
| size:                  | 242±1.5 mm/88.5±1mm   |
| Opening:               | 49.5 mm ± 0.3 mm      |
| Closure:               | screw cap with cutter |
| Capacity               | 1200± 50 ml           |
| Net Capacity           | 1000 ml               |
| Seal:                  | Induction seal        |
| Manner of construction | extruded              |
| UN/ADR                 | compliant             |

**Table 4.1-97: Packaging information**

|                        |                                         |
|------------------------|-----------------------------------------|
| Type                   | CONTAINER                               |
| Material:              | HDPE/EvOH                               |
| size:                  | 165 mm ± 2 mm/195 mm ± 2 mm/228mm± 2 mm |
| Opening:               | 48 mm ± 2 mm                            |
| Closure:               | screw cap with cutter                   |
| Capacity               | 5000 ml                                 |
| Net Capacity           | 5000 ml                                 |
| Seal:                  | Induction seal                          |
| Manner of construction | extruded                                |
| UN/ADR                 | compliant                               |

**Table 4.1-98: Packaging information**

|                        |                                           |
|------------------------|-------------------------------------------|
| Type                   | CANNISTER                                 |
| Material:              | HDPE/EvOH                                 |
| size:                  | 142 mm ± 1.5 mm/193 mm ± 2 mm/307mm± 3 mm |
| Opening:               | 63.3 mm ± 0.3 mm                          |
| Closure:               | screw cap with cutter                     |
| Capacity               | 5650 ml                                   |
| Net Capacity           | 5000 ml                                   |
| Seal:                  | Induction seal                            |
| Manner of construction | extruded                                  |

|        |           |
|--------|-----------|
| UN/ADR | compliant |
|--------|-----------|

**Table 4.1-99: Packaging information**

|                        |                                                     |
|------------------------|-----------------------------------------------------|
| Type                   | CONTAINER                                           |
| Material:              | HDPE/EvOH                                           |
| size:                  | 195 mm $\pm$ 2 mm/225mm $\pm$ 2 mm/306mm $\pm$ 2 mm |
| Opening:               | 48 mm $\pm$ 2 mm                                    |
| Closure:               | screw cap with cutter                               |
| Capacity               | 10000 ml                                            |
| Net Capacity           | 10000 ml                                            |
| Seal:                  | Induction seal                                      |
| Manner of construction | extruded                                            |
| UN/ADR                 | compliant                                           |

**Table 4.1-100: Packaging information**

|                        |                                                     |
|------------------------|-----------------------------------------------------|
| Type                   | CONTAINER                                           |
| Material:              | HDPE/EvOH                                           |
| size:                  | 375 mm $\pm$ 2 mm/290mm $\pm$ 2 mm/245mm $\pm$ 2 mm |
| Opening:               | 85mm $\pm$ 2 mm                                     |
| Closure:               | screw cap with cutter                               |
| Capacity               | 20000 ml                                            |
| Net Capacity           | 20 000 ml                                           |
| Seal:                  | Induction seal                                      |
| Manner of construction | extruded                                            |
| UN/ADR                 | compliant                                           |

## Appendix 1 Lists of data considered in support of the evaluation

### 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<br>company)<br>GLP or GEP status<br>Published or not                                                                                                                                                          | Vertebrate<br>study<br>Y/N | Owner           |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|-----------------|
| KCP 2.1<br>KCP 2.3.1<br>KCP 2.3.2<br>KCP 2.3.3<br>LCP 2.4.1<br>KCP 2.4.2<br>KCP 2.5.2<br>KCP 2.6.1<br>KCP 2.7.2<br>KCP 2.7.4<br>KCP 2.8.2<br>KCP 2.8.3.1<br>KCP 2.8.3.2<br>KCP 2.8.5.1.1<br>KCP 2.8.5.1.2<br>KCP 2.8.7.2<br>KCP 2.11 | Górka I.        | 2023 | Determination of physicochemical properties of CHR/H/AKO 600 SC<br>ICB Pharma 10 Lema Street 43-600, Jaworzno POLAND<br>Study code: ICB/107/2023<br>GLP<br>Unpublished                                                                                                    | N                          | PUH<br>Chemirol |
| KCP 2.2.1                                                                                                                                                                                                                            | Orłowski<br>G.  | 2023 | CHR/H/AKO/600 SC<br>Determination of explosive properties<br>Łukasiewicz Research Network –<br>Institute of Industrial Organic<br>Chemistry, 6 Annopol St., 03-236<br>Warsaw, Poland<br>Study code: BW-09/23<br>GLP<br>Unpublished                                        | N                          | PUH<br>Chemirol |
| KCP 2.2.2<br>KCP 2.3.3                                                                                                                                                                                                               | Pachnicki<br>P. | 2023 | CHR/H/AKO 600 SC<br>Determination of auto-ignition<br>temperature and oxidizing<br>properties<br>Łukasiewicz Research Network –<br>Institute of Industrial Organic<br>Chemistry, 6 Annopol St., 03-236<br>Warsaw, Poland<br>Study code no. BC-38/23<br>GLP<br>Unpublished | N                          | PUH<br>Chemirol |

|                                                                                                                                           |             |      |                                                                                                                                                                                                                                     |   |                 |
|-------------------------------------------------------------------------------------------------------------------------------------------|-------------|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|-----------------|
| KCP. 2.5.1                                                                                                                                | Rymarzak O. | 2023 | CHR/H/AKO 600 SC<br>Determination of viscosity<br>Łukasiewicz Research Network –<br>Institute of Industrial Organic<br>Chemistry, 6 Annopol St., 03-236<br>Warsaw, Poland<br>Study code no. BF-32/23<br>GLP<br>Unpublished          | N | PUH<br>Chemirol |
| KCP 2.1<br>KCP 2.4.1<br>KCP 2.4.2<br>KCP 2.7.2<br>KCP 2.8.3.1<br>KCP 2.8.3.2<br>KCP 2.8.5.1.1<br>KCP 2.8.5.1.2<br>KCP 2.8.7.2<br>KCP 2.11 | Górka I.    | 2023 | CHR/H/AKO 600 SC<br>Determination of physicochemical<br>properties of CHR/H/AKO 600 SC<br>after accelerated storage test<br>ICB Pharma 10 Lema Street 43-<br>600, Jaworzno POLAND<br>Study code: ICB/136/2023<br>GLP<br>Unpublished | N | PUH<br>Chemirol |
| KCP 2.1<br>KCP 2.4.1<br>KCP 2.4.2<br>KCP 2.7.2<br>KCP 2.8.3.1<br>KCP 2.8.3.2<br>KCP 2.8.5.1.1<br>KCP 2.8.5.1.2<br>KCP 2.8.7.2<br>KCP 2.11 | Górka I.    | 2024 | Determination of physicochemical<br>properties of CHR/H/AKO 600 SC<br>after 12 months shelf-life test<br>ICB Pharma 10 Lema Street 43-<br>600, Jaworzno POLAND<br>Study code: ICB/108/2023<br>GLP<br>Unpublished                    | N | PUH<br>Chemirol |
| KCP 2.9.1                                                                                                                                 | Górka I.    | 2025 | Determination of chemical<br>compatibility of BOA PRO 480 EC<br>with CHR/H/AKO 600 S.C.<br>ICB Pharma 10 Lema Street<br>43-600, Jaworzno POLAND<br>Study code: ICB/26/2025<br>GLP<br>Unpublished                                    | N | PUH<br>Chemirol |
| KCP 2.9.2                                                                                                                                 | Górka I.    | 2025 | Determination of chemical<br>compatibility of BOA PRO 480 EC<br>with CHR/H/AKO 600 S.C.<br>ICB Pharma 10 Lema Street<br>43-600, Jaworzno POLAND<br>Study code: ICB/26/2025<br>GLP<br>Unpublished                                    | N | PUH<br>Chemirol |

**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 study<br/>Y/N</b> | <b>Owner</b> |
|-------------------|------------------|-------------|--------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------|
|                   |                  |             |                                                                                                                          |                                 |              |
|                   |                  |             |                                                                                                                          |                                 |              |

**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 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 study<br/>Y/N</b> | <b>Owner</b> |
|-------------------|------------------|-------------|--------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------|
|                   |                  |             |                                                                                                                          |                                 |              |
|                   |                  |             |                                                                                                                          |                                 |              |

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

**A 2.1 Aclonifen**

Not relevant