

# 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: Acetamipryd 200 SL

Product name(s): -

Chemical active substance:

acetamiprid, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

## CORE ASSESSMENT

(authorization)

Applicant: Pestila Sp. z o.o. / ProAgri International Sp. z o.o.

Submission date: March 2024, update December 2024

MS Finalisation date: 02.2025; 08.2025

## Version history

| When    | What  |
|---------|---|
| 12.2024 | Supplement - storage stability after 2 years              |
| 02.2025 | zRMS assessment of dRR                                    |
| 08.2025 | The final Registration Report after the reporting period. |
|         |   |
|         |   |

## Table of Contents

|                   |   |           |
|-------------------|---|-----------|
| <b>1</b>          | <b>Section 1: Identity of the plant protection product.....</b>   | <b>4</b>  |
| 1.1               | Applicant (KCP 1.1) .....   | 4         |
| 1.2               | Producer of the plant protection product and of the active substances (KCP 1.2) .....                   | 4         |
| 1.2.1             | Producer(s) of the preparation .....  | 4         |
| 1.2.2             | Producer(s) of the active substance(s) .....  | 5         |
| 1.2.3             | Statement of purity (and detailed information on impurities) of the active substance(s) .....           | 5         |
| 1.2.3.1           | Acetamiprid.....  | 5         |
| 1.3               | Trade names and producer's development code numbers for the preparation (KCP 1.3) .....                 | 5         |
| 1.4               | Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4) ..... | 5         |
| 1.4.1             | Composition of the plant protection product (KCP 1.4.1).....  | 5         |
| 1.4.2             | Information on the active substance(s) (KCP 1.4.2).....   | 6         |
| 1.4.3             | Information on safeners, synergists and co-formulants (KCP 1.4.3).....                                  | 6         |
| 1.5               | Type and code of the plant protection product (KCP 1.5).....  | 6         |
| 1.6               | Function (KCP 1.6) .....  | 6         |
| <b>2</b>          | <b>Section 2: Physical, chemical and technical properties of the plant protection product .....</b>     | <b>7</b>  |
| <b>3</b>          | <b>Section 3 is presented as a separate document .....</b>  | <b>16</b> |
| <b>4</b>          | <b>Section 4: Further information on the plant protection product .....</b>                             | <b>17</b> |
| 4.1               | Packaging and Compatibility with the Preparation (KCP 4.4) .....  | 17        |
| <b>Appendix 1</b> | <b>Lists of data considered in support of the evaluation .....</b>                                      | <b>21</b> |
| <b>Appendix 2</b> | <b>Additional data on the physical, chemical and technical properties of the active substance.....</b>  | <b>24</b> |
| A 2.1             | Acetamiprid.....  | 24        |

Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance(s).

Noticed data gaps:

- none

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

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

Name: Pestila Spółka z ograniczoną odpowiedzialnością  
Address: Studzianki 24a  
97-320 Wolbórz  
Poland

Contact: [REDACTED]  
Telephone number: [REDACTED]  
e-mail: [REDACTED]

and

Name: ProAgri International Spółka z ograniczoną odpowiedzialnością  
Address: ul. Józefa Piusa Dziekońskiego 1  
00-728 Warszawa  
Poland

Contact: [REDACTED]  
Telephone number: [REDACTED]  
e-mail: [REDACTED]

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

Name: Pestila Spółka z ograniczoną odpowiedzialnością  
Address: Studzianki 24a  
97-320 Wolbórz  
Poland

Contact: [REDACTED]  
Telephone number: [REDACTED]  
e-mail: [REDACTED]

and

Name: ProAgri International Spółka z ograniczoną odpowiedzialnością  
Address: ul. Józefa Piusa Dziekońskiego 1  
00-728 Warszawa  
Poland

Contact: [REDACTED]  
Telephone number: [REDACTED]  
e-mail: [REDACTED]

#### **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 Acetamiprid

Acetamiprid min. 990 g/kg

| Relevant impurity | Maximum content (g/L or g/kg)  |
|-------------------|--|
| None              | According to the Renewal Report (SANTE/10502/2017 Rev 4 13 December 2017 and Rev 8 24 September 20242) |

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

Trade name: Please refer to application form

Company code number: Acetamipryd 200 SL

## 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) |
|----------------------------|---|------------------------|----------------------------------|----------------------------|
| Acetamiprid                | 200 g/L   | 188 – 412 212 g/L      | 202.0 g/L                        | 17.7%                      |

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

\*\* Based on the density of the formulation = 1.144 g/mL

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

| Safener / synergist | Declared content of the safener / synergist (g/L or g/kg) | FAO Limits (min – max) | Technical content* (g/L or g/kg) | Technical content** (%w/w) |
|---------------------|---|------------------------|----------------------------------|----------------------------|
| Not applicable      | Not applicable  | Not applicable         | Not applicable                   | Not applicable             |

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

\*\* Based on the density of the formulation

**Table 1.4-3: Relevant impurities**

| Relevant impurity | Maximum content (g/L or g/kg) |
|-------------------|-------------------------------|
| Not applicable    | Not applicable                |

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

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

| Type            | Name/Code Number |
|-----------------|------------------|
| ISO common name | Acetamiprid      |
| CAS No.         | 135410-20-7      |
| EC No.          | 603-921-1        |
| CIPAC No.       | 649              |

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

Not relevant. Product does not contain safeners and synergists.

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

Type: Soluble liquid

[Code: SL]

**1.6 Function (KCP 1.6)**

Insecticide.

## 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 clear homogenous light yellow liquid of characteristic odour. It is not explosive, has no oxidizing properties. The product is not flammable. It has a self-ignition temperature of 275°C. In aqueous solution, it has a pH value around 6.57 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. 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 SL formulation.

The intended concentration of use is 0.008% to 0.125%.

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

| Study                                    | Result                                      | Classification acc. to Reg. 1272/2008 | Labelling acc. to Reg. 1272/2008 |
|--|---|---------------------------------------|----------------------------------|
| Explosive properties (A.14)              | Product does not have explosive properties. | Not classified.                       | None.                            |
| Oxidizing properties (A.21)              | Product does not have oxidizing properties. | Not classified.                       | None.                            |
| Flammability – not relevant for liquids. | Product is not flammable.                   | Not classified.                       | None.                            |
| Flash point (A.9)                        | 96°C  | Not classified.                       | None.                            |

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

Not relevant.

### Compliance with FAO specifications:

~~The product Acetamipryd 200 SL complies with FAO specifications. At the time of the evaluation, no FAO specification was available for acetamipryd.~~

### Formulation used for tests

Product used in the test has the same composition as the one cited in Part C.

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

| Annex point                         | Method used / deviations | Test material                              | Findings  | GLP Y/N | Reference             | Acceptability / comments   |
|-------------------------------------|--------------------------|--|---|---------|-----------------------|--|
| Colour and physical state (KCP 2.1) | OPPTS 830.6302-04        | Acetamipryd 200 SL<br>Batch no. 1/ACE/2022 | Acetamipryd 200 SL is a clear homogenous light yellow liquid of characteristic odour. | Y       | Kupiec J. BF-23/22    | Accepted.  |
| Explosive properties (KCP 2.2.1)    | A.14                     | Acetamipryd 200 SL<br>Batch no. 1/ACE/2022 | Acetamipryd 200 SL does not have explosive properties.                                | Y       | Ołowski G. BW – 14/22 | In the impact sensitivity test (BAM Fallhammer apparatus) no explosion occurred.<br>In the thermal sensitivity test (Koenen apparatus) no explosion occurred.<br>Accepted.   |
| Oxidizing properties (KCP 2.2.2)    | A.21                     | Acetamipryd 200 SL<br>Batch no. 1/ACE/2022 | Acetamipryd 200 SL does not have the oxidizing properties.                            | Y       | Flasińska P. BC-46/22 | During the test no spontaneous ignition was noted; the mean pressure rise time (pressure did not reach the critical value of 690 kPa) was higher than the reference substance (65% aqueous nitric(V) acid and cellulose) (4957±224 ms).<br>Accepted. |
| Flash point (KCP 2.3.1)             | A.9                      | Acetamipryd 200 SL<br>Batch no. 1/ACE/2022 | Acetamipryd 200 SL does not have has got the flash point 96°C.                        | Y       | Flasińska P. BC-46/22 | The test was performed with the Pensky-Martens closed-cup apparatus (PN-EN ISO 2719:2016). The formulation is not flammable.<br>Accepted.  |

| Annex point   | Method used / deviations | Test material                              | Findings  | GLP Y/N | Reference             | Acceptability / comments   |
|---|--------------------------|--|---|---------|-----------------------|--|
| Flammability (KCP 2.3.2)  | -                        | -  | Not relevant. Acetamipryd 200 SL is liquid form.  | -       | -                     |  |
| Self-heating (KCP 2.3.3)  | A.15                     | Acetamipryd 200 SL<br>Batch no. 1/ACE/2022 | Acetamipryd 200 SL has got the auto-ignition temperature: 275°C.  | Y       | Flasińska P. BC–46/22 | The test was performed according to DIN 51794:2003-05. Accepted.   |
| Acidity or alkalinity and pH (KCP 2.4.1)                        | CIPAC MT 75.3            | Acetamipryd 200 SL<br>Batch no. 1/ACE/2022 | <u>Before storage:</u> pH = 7.80<br><u>After accelerated storage:</u> pH = 7.73                                 | Y       | Kupiec J. BF–23/22    | Accepted.  |
| pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2) | CIPAC MT 75.3            | Acetamipryd 200 SL<br>Batch no. 1/ACE/2022 | <u>Before storage:</u> pH = 6.57<br><u>After accelerated storage:</u> pH = 6.61                                 | Y       | Kupiec J. BF–23/22    | Accepted.  |
| Viscosity (KCP 2.5.1)   | CIPAC MT 192             | Acetamipryd 200 SL<br>Batch no. 1/ACE/2022 |   | Y       | Kupiec J. BF–23/22    | The dynamic viscosity was determined with Brookfield rotational viscometer. The formulation is a Newtonian liquid. The formulation does not pose an aspiration hazard (it does not contain substances classified as a Category 1 aspiration hazard). Accepted. |
|   |                          |  |   |         |                       |  |
|   |                          |  |   |         |                       |  |
|   |                          |  |   |         |                       |  |
|   |                          |  |   |         |                       |  |
| Surface tension (KCP 2.5.2)                                     | A.5                      | Acetamipryd 200 SL<br>Batch no.            | <u>Concentrate (neat):</u> 38.82 mN/m<br><u>Highest concentration of usable liquid (0.125% v/v):</u> 43.21 mN/m | Y       | Kupiec J. BF–23/22    | The surface tension of the formulation was tested using the ring method.   |

| Annex point  | Method used / deviations  | Test material                              | Findings   | GLP Y/N     | Reference          | Acceptability / comments  |   |  |  |
|--|---|--|--|-------------|--------------------|---|---|--|--|
|  |   | 1/ACE/2022                                 |  |             |                    | Surface tension was determined at the highest in-use spray concentration and for the neat formulation.<br>The preparation is classified as surface-active.<br>Accepted. |   |  |  |
| Relative density (KCP 2.6.1)                         | A.3   | Acetamipryd 200 SL<br>Batch no. 1/ACE/2022 | Density: 1.144 g/ml<br>Relative density: 1.144   | Y           | Kupiec J. BF-23/22 | Accepted.   |   |  |  |
| Bulk density (KCP 2.6.2)                             | -   | -  | Not relevant. Acetamipryd 200 SL is liquid form. | -           | -                  |   |   |  |  |
| Storage Stability after 14 days at 54° C (KCP 2.7.1) | CIPAC MT 46.4<br>OPPTS 830.6302-04<br>CIPAC MT 75.3<br>CIPAC MT 47.3<br>CIPAC MT 41.1<br>CropLife International Technical Monograph No. 17<br>MT/BA-50/22 | Acetamipryd 200 SL<br>Batch no. 1/ACE/2022 | Storage stability after 14 days at 54°C.         |             | Y                  | Kupiec J. BF-23/22  | The formulation was stored in original package (1L HDPE bottle).<br>The temperature varied between 53.3°C and 54.2°C.<br>The change in a.s. content during storage was 0.2%.<br>The content of the a.s. was determined with the method validated according to SANCO/3030/99 rev.5 (see Part B5 of the dRR).<br>No significant changes in the formulation's physical, chemical, and technical properties were observed |  |  |
|  |   |  | Test type  |             |                    |   |   | Initial preparation  | After accelerated storage                                    |
|  |   |  | Appearance                                       |             |                    |   |   | clear homogenous light yellow liquid of characteristic odour | clear homogenous light yellow liquid of characteristic odour |
|  |   |  | pH   | undiluted   |                    |   |   | 7.80   | 7.73   |
|  |   |  |  | 1% solution |                    |   |   | 6.57   | 6.61   |
|  |   |  | Persistent foam                                  | 0.008%      |                    |   |   | 13 ml after 1 min<br>9 ml after 12 min                       | 9 ml after 1 min<br>6 ml after 12 min                        |
|  |   |  |  | 0.125%      |                    |   |   | 25 ml after 1 min<br>15 ml after 12 min                      | 23 ml after 1 min<br>7 ml after 12 min                       |
|  |   |  | Dilution   | 0.008%      |                    |   |   | After 30 min:<br>clear homogenous                            | After 30 min:<br>clear homogenous                            |
|  |   |  |  | 0.125%      |                    |   |   |  |  |

| Annex point   | Method used / deviations  | Test material                              | Findings   |             |  |  | GLP Y/N | Reference          | Acceptability / comments  |
|---|---|--|--|-------------|--|--|---------|--------------------|---|
|   |   |  | stability  | 1%          | After 24 h:  | After 24 h:  |         |                    | following storage in HDPE-based commercial packaging. The original HDPE bottle's shape or colour did not change after storage, and its weight changed negligibly. Accepted.   |
|   |   |  | Package stability  |             | White, cylindrical 1 litre HDPE package                      | The shape and colour of the 1 litre HDPE package were stable, negligible mass change |         |                    |   |
|   |   |  | Acetamiprid content  |             | 17.40 % (199.11 g/L)   | 17.37% (198.71 g/L)  |         |                    |   |
| Stability after storage for other periods and/or temperatures (KCP 2.7.2) | -   | -  | Not relevant. Acetamipryd 200 SL was stable after 14 days at 54°C. |             |  |  | -       | -                  |   |
| Minimum content after heat stability testing (KCP 2.7.3)                  | MT/BA-48/22   | Acetamipryd 200 SL<br>Batch no. 1/ACE/2022 | 17.31 % (198.03 g/L)   |             |  |  | Y       | Kupiec J. BF-23/22 | Accepted.   |
| Effect of low temperatures on stability (KCP 2.7.4)                       | CIPAC MT 39.3<br>OPPTS 830.6302-04<br>CIPAC MT 75.3<br>CIPAC MT 47.3<br>CIPAC MT 41.1<br>CropLife | Acetamipryd 200 SL<br>Batch no. 1/ACE/2022 | Storage stability after 7 days at 0°C.                             |             |  |  | Y       | Kupiec J. BF-23/22 | During storage, the temperature varied between 0.8°C and 0.6°C. Needle-shaped crystals were present in the preparation immediately after storage at low temperatures in a volume of 50 ml. The preparation after 24 hours at room temperature (22.5 – |
|   |   |  | Test type  |             | Initial preparation  | After low temperature storage  |         |                    |   |
|   |   |  | Appearance   |             | clear homogenous light yellow liquid of characteristic odour | clear homogenous light yellow liquid of characteristic odour                         |         |                    |   |
|   |   |  | pH   | undiluted   | 7.80   | 7.26   |         |                    |   |
|   |   |  |  | 1% solution | 6.57   | 6.62   |         |                    |   |

| Annex point   | Method used / deviations  | Test material  | Findings  |  |  |  | GLP Y/N   | Reference | Acceptability / comments               |   |           |   |   |                           |            |  |  |  |    |                     |      |                      |                     |      |      |  |        |  |  |        |   |   |                    |        |  |  |        |    |                   |  |   |   |   |                        |   |
|---|---|--|---|--|--|--|---|-----------|--|---|-----------|---|---|---------------------------|------------|--|--|--|----|---------------------|------|----------------------|---------------------|------|------|--|--------|--|--|--------|---|---|--------------------|--------|--|--|--------|----|-------------------|--|---|---|---|------------------------|---|
|   | International Technical Monograph No. 17 MT/BA-50/22  |  | <table><tr><td rowspan="2">Persistent foam</td><td>0.008%</td><td>13 ml after 1 min<br/>9 ml after 12 min</td><td>17 ml after 1 min<br/>11 ml after 12 min</td></tr><tr><td>0.125%</td><td>25 ml after 1 min<br/>15 ml after 12 min</td><td>25 ml after 1 min<br/>22 ml after 12 min</td></tr><tr><td rowspan="3">Dilution stability</td><td>0.008%</td><td rowspan="3">After 30 min:<br/>clear homogenous<br/>After 24 h:<br/>clear homogenous</td><td rowspan="3">After 30 min:<br/>clear homogenous<br/>After 24 h:<br/>clear homogenous</td></tr><tr><td>0.125%</td></tr><tr><td>1%</td></tr><tr><td colspan="2">Acetamiprid content</td><td>17.40 % (199.11 g/L)</td><td>17.44% (199.47 g/L)</td></tr></table>   |  |  |  | Persistent foam   | 0.008%    | 13 ml after 1 min<br>9 ml after 12 min | 17 ml after 1 min<br>11 ml after 12 min | 0.125%    | 25 ml after 1 min<br>15 ml after 12 min | 25 ml after 1 min<br>22 ml after 12 min | Dilution stability        | 0.008%     | After 30 min:<br>clear homogenous<br>After 24 h:<br>clear homogenous | After 30 min:<br>clear homogenous<br>After 24 h:<br>clear homogenous | 0.125%   | 1% | Acetamiprid content |      | 17.40 % (199.11 g/L) | 17.44% (199.47 g/L) |      |      | 23.8°C) was clear homogenous liquid. The change in a.s. content during storage was 0.2%. Accepted. |        |  |  |        |   |   |                    |        |  |  |        |    |                   |  |   |   |   |                        |   |
| Persistent foam   | 0.008%  | 13 ml after 1 min<br>9 ml after 12 min                               | 17 ml after 1 min<br>11 ml after 12 min   |  |  |  |   |           |  |   |           |   |   |                           |            |  |  |  |    |                     |      |                      |                     |      |      |  |        |  |  |        |   |   |                    |        |  |  |        |    |                   |  |   |   |   |                        |   |
|   | 0.125%  | 25 ml after 1 min<br>15 ml after 12 min                              | 25 ml after 1 min<br>22 ml after 12 min   |  |  |  |   |           |  |   |           |   |   |                           |            |  |  |  |    |                     |      |                      |                     |      |      |  |        |  |  |        |   |   |                    |        |  |  |        |    |                   |  |   |   |   |                        |   |
| Dilution stability  | 0.008%  | After 30 min:<br>clear homogenous<br>After 24 h:<br>clear homogenous | After 30 min:<br>clear homogenous<br>After 24 h:<br>clear homogenous  |  |  |  |   |           |  |   |           |   |   |                           |            |  |  |  |    |                     |      |                      |                     |      |      |  |        |  |  |        |   |   |                    |        |  |  |        |    |                   |  |   |   |   |                        |   |
|   | 0.125%  |  |   |  |  |  |   |           |  |   |           |   |   |                           |            |  |  |  |    |                     |      |                      |                     |      |      |  |        |  |  |        |   |   |                    |        |  |  |        |    |                   |  |   |   |   |                        |   |
|   | 1%  |  |   |  |  |  |   |           |  |   |           |   |   |                           |            |  |  |  |    |                     |      |                      |                     |      |      |  |        |  |  |        |   |   |                    |        |  |  |        |    |                   |  |   |   |   |                        |   |
| Acetamiprid content   |   | 17.40 % (199.11 g/L)   | 17.44% (199.47 g/L)   |  |  |  |   |           |  |   |           |   |   |                           |            |  |  |  |    |                     |      |                      |                     |      |      |  |        |  |  |        |   |   |                    |        |  |  |        |    |                   |  |   |   |   |                        |   |
| Ambient temperature shelf life (KCP 2.7.5)                          | CropLife International Technical Monograph No. 17 OPPTS 830.6302-04 CIPAC MT 75.3 CIPAC MT 47.3 CIPAC MT 41.1 MT/BA-50/22 | Acetamipryd 200 SL Batch no. 1/ACE/2022                              | <table><tr><td colspan="2">Storage stability after 2<sup>nd</sup> year at ambiet temperature.</td><td></td><td></td></tr><tr><td colspan="2">Test type</td><td>Initial preparation</td><td>After accelerated storage</td></tr><tr><td colspan="2">Appearance</td><td>clear homogenous light yellow liquid of characteristic odour</td><td>clear homogenous light yellow liquid of characteristic odour</td></tr><tr><td rowspan="2">pH</td><td>undiluted</td><td>7.80</td><td>7.52</td></tr><tr><td>1% solution</td><td>6.57</td><td>5.14</td></tr><tr><td rowspan="2">Persistent foam</td><td>0.008%</td><td>13 ml after 1 min<br/>9 ml after 12 min</td><td>12 ml after 1 min<br/>9 ml after 12 min</td></tr><tr><td>0.125%</td><td>25 ml after 1 min<br/>15 ml after 12 min</td><td>19 ml after 1 min<br/>11 ml after 12 min</td></tr><tr><td rowspan="3">Dilution stability</td><td>0.008%</td><td rowspan="3">After 30 min:<br/>clear homogenous<br/>After 24 h:<br/>clear homogenous</td><td rowspan="3">After 30 min: clear homogenous<br/>After 24 h: clear homogenous</td></tr><tr><td>0.125%</td></tr><tr><td>1%</td></tr><tr><td colspan="2">Package stability</td><td>White, cylindrical 1 litre HDPE package</td><td>The shape and colour of the 1 litre HDPE package were stable, negligible mass</td></tr></table> |  |  |  | Storage stability after 2 <sup>nd</sup> year at ambiet temperature. |           |  |   | Test type |   | Initial preparation                     | After accelerated storage | Appearance |  | clear homogenous light yellow liquid of characteristic odour         | clear homogenous light yellow liquid of characteristic odour | pH | undiluted           | 7.80 | 7.52                 | 1% solution         | 6.57 | 5.14 | Persistent foam  | 0.008% | 13 ml after 1 min<br>9 ml after 12 min | 12 ml after 1 min<br>9 ml after 12 min | 0.125% | 25 ml after 1 min<br>15 ml after 12 min | 19 ml after 1 min<br>11 ml after 12 min | Dilution stability | 0.008% | After 30 min:<br>clear homogenous<br>After 24 h:<br>clear homogenous | After 30 min: clear homogenous<br>After 24 h: clear homogenous | 0.125% | 1% | Package stability |  | White, cylindrical 1 litre HDPE package | The shape and colour of the 1 litre HDPE package were stable, negligible mass | Y | Rymarzak O. BF – 23/22 | The formulation was stored in original package (1L HDPE bottle). The temperature varied between 19.1°C and 24.8°C. The change in a.s. content during storage was 1%. The content of the a.s. was determined with the method validated according to SANCO/3030/99 rev.5 (see Part B5 of the dRR). No significant changes in the formulation's physical chemical, and technical properties were observed following storage in HDPE-based commercial packaging. The original HDPE bottle's shape or colour did |
| Storage stability after 2 <sup>nd</sup> year at ambiet temperature. |   |  |   |  |  |  |   |           |  |   |           |   |   |                           |            |  |  |  |    |                     |      |                      |                     |      |      |  |        |  |  |        |   |   |                    |        |  |  |        |    |                   |  |   |   |   |                        |   |
| Test type   |   | Initial preparation  | After accelerated storage   |  |  |  |   |           |  |   |           |   |   |                           |            |  |  |  |    |                     |      |                      |                     |      |      |  |        |  |  |        |   |   |                    |        |  |  |        |    |                   |  |   |   |   |                        |   |
| Appearance  |   | clear homogenous light yellow liquid of characteristic odour         | clear homogenous light yellow liquid of characteristic odour  |  |  |  |   |           |  |   |           |   |   |                           |            |  |  |  |    |                     |      |                      |                     |      |      |  |        |  |  |        |   |   |                    |        |  |  |        |    |                   |  |   |   |   |                        |   |
| pH  | undiluted   | 7.80   | 7.52  |  |  |  |   |           |  |   |           |   |   |                           |            |  |  |  |    |                     |      |                      |                     |      |      |  |        |  |  |        |   |   |                    |        |  |  |        |    |                   |  |   |   |   |                        |   |
|   | 1% solution   | 6.57   | 5.14  |  |  |  |   |           |  |   |           |   |   |                           |            |  |  |  |    |                     |      |                      |                     |      |      |  |        |  |  |        |   |   |                    |        |  |  |        |    |                   |  |   |   |   |                        |   |
| Persistent foam   | 0.008%  | 13 ml after 1 min<br>9 ml after 12 min                               | 12 ml after 1 min<br>9 ml after 12 min  |  |  |  |   |           |  |   |           |   |   |                           |            |  |  |  |    |                     |      |                      |                     |      |      |  |        |  |  |        |   |   |                    |        |  |  |        |    |                   |  |   |   |   |                        |   |
|   | 0.125%  | 25 ml after 1 min<br>15 ml after 12 min                              | 19 ml after 1 min<br>11 ml after 12 min   |  |  |  |   |           |  |   |           |   |   |                           |            |  |  |  |    |                     |      |                      |                     |      |      |  |        |  |  |        |   |   |                    |        |  |  |        |    |                   |  |   |   |   |                        |   |
| Dilution stability  | 0.008%  | After 30 min:<br>clear homogenous<br>After 24 h:<br>clear homogenous | After 30 min: clear homogenous<br>After 24 h: clear homogenous  |  |  |  |   |           |  |   |           |   |   |                           |            |  |  |  |    |                     |      |                      |                     |      |      |  |        |  |  |        |   |   |                    |        |  |  |        |    |                   |  |   |   |   |                        |   |
|   | 0.125%  |  |   |  |  |  |   |           |  |   |           |   |   |                           |            |  |  |  |    |                     |      |                      |                     |      |      |  |        |  |  |        |   |   |                    |        |  |  |        |    |                   |  |   |   |   |                        |   |
|   | 1%  |  |   |  |  |  |   |           |  |   |           |   |   |                           |            |  |  |  |    |                     |      |                      |                     |      |      |  |        |  |  |        |   |   |                    |        |  |  |        |    |                   |  |   |   |   |                        |   |
| Package stability   |   | White, cylindrical 1 litre HDPE package                              | The shape and colour of the 1 litre HDPE package were stable, negligible mass   |  |  |  |   |           |  |   |           |   |   |                           |            |  |  |  |    |                     |      |                      |                     |      |      |  |        |  |  |        |   |   |                    |        |  |  |        |    |                   |  |   |   |   |                        |   |

| Annex point   | Method used / deviations  | Test material                           | Findings   |                         |  | GLP Y/N | Reference                       | Acceptability / comments  |  |
|---|---|---|--|-------------------------|--|---------|---------------------------------|---|--|
|   |   |   | Acetamiprid content  | 17.40 %<br>(199.11 g/L) | 17.24%<br>(197.17 g/L)   |         |                                 | not change after storage, and its weight changed negligibly. Accepted.  |  |
| Shelf life in months (if less than 2 years) (KCP 2.7.6) | CropLife International Technical Monograph No. 17 OPPTS 830.6302-04 CIPAC MT 75.3 CIPAC MT 47.3 CIPAC MT 41.1 MT/BA-50/22 | Acetamipryd 200 SL Batch no. 1/ACE/2022 | Storage stability after 1 year at ambient temperature.                   |                         |  | Y       | Rymarzak O. BF – 23/22 Stage II | The formulation was stored in original package (1L HDPE bottle). The temperature varied between 19.1°C and 20.9°C. The change in a.s. content during storage was 1%. The content of the a.s. was determined with the method validated according to SANCO/3030/99 rev.5 (see Part B5 of the dRR). No significant changes in the formulation's physical, chemical, and technical properties were observed following storage in HDPE-based commercial packaging. The original HDPE bottle's shape or colour did not change after storage, and its weight changed negligibly. Accepted. |  |
|   |   |   | Test type  |                         | Initial preparation  |         |                                 |   | After accelerated storage  |
|   |   |   | Appearance   |                         | clear homogenous light yellow liquid of characteristic odour         |         |                                 |   | clear homogenous light yellow liquid of characteristic odour         |
|   |   |   | pH   | undiluted               | 7.80   |         |                                 |   | 6.64   |
|   |   |   |  | 1% solution             | 6.57   |         |                                 |   | 4.89   |
|   |   |   | Persistent foam  | 0.008%                  | 13 ml after 1 min<br>9 ml after 12 min                               |         |                                 |   | 29 ml after 1 min<br>12 ml after 12 min                              |
|   |   |   |  | 0.125%                  | 25 ml after 1 min<br>15 ml after 12 min                              |         |                                 |   | 33 ml after 1 min<br>13 ml after 12 min                              |
|   |   |   | Dilution stability   | 0.008%                  | After 30 min:<br>clear homogenous<br>After 24 h:<br>clear homogenous |         |                                 |   | After 30 min:<br>clear homogenous<br>After 24 h:<br>clear homogenous |
|   |   |   |  | 0.125%                  |  |         |                                 |   |  |
|   |   |   |  | 1%                      |  |         |                                 |   |  |
| Package stability                                       |   | White, cylindrical 1 litre HDPE package | The shape and colour of the 1 litre HDPE package were stable, negligible |                         |  |         |                                 |   |  |
| Acetamiprid content                                     |   | 17.40 %<br>(199.11 g/L)                 | 17.23%<br>(197.10 g/L)   |                         |  |         |                                 |   |  |
| Wettability (KCP 2.8.1)                                 | -   | -                                       | Not relevant. Acetamipryd 200 SL is liquid form.                         |                         |  | -       | -                               |   |  |

| Annex point   | Method used / deviations | Test material                              | Findings   |        |  | GLP Y/N                 | Reference          | Acceptability / comments |                                   |  |
|---|--------------------------|--|--|--------|--|-------------------------|--------------------|--------------------------|-----------------------------------|--|
| Persistence of foaming (KCP 2.8.2)  | CIPAC MT 47.3            | Acetamipryd 200 SL<br>Batch no. 1/ACE/2022 | <u>At concentration 0.008%:</u> after 1 min. – 13 mL, after 12 min – 9 mL<br><u>At concentration 0.125%:</u> after 1 min – 25 mL, after 12 min – 15 mL |        |  | Y                       | Kupiec J. BF–23/22 | Accepted.                |                                   |  |
| Suspensibility (KCP 2.8.3.1)  | -                        | -  | Not required for SL formulation.   |        |  | -                       | -                  |                          |                                   |  |
| Spontaneity of dispersion (KCP 2.8.3.2)                                     | -                        | -  | Not required for SL formulation.   |        |  | -                       | -                  |                          |                                   |  |
| Dispersion stability (KCP 2.8.3.3)  | -                        | -  | Not required for SL formulation.   |        |  | -                       | -                  |                          |                                   |  |
| Degree of dissolution and dilution stability (KCP 2.8.4)                    | CIPAC MT 41.1            | Acetamipryd 200 SL<br>Batch no. 1/ACE/2022 | Test type  |        | Initial preparation  | After accelerated stor- | Y                  | Kupiec J. BF–23/22       | CIPAC water D was used. Accepted. |  |
|   |                          |  | Dilution stability   | 0.008% | After 30 min:<br>clear homogenous<br>After 24 h:<br>clear homogenous |                         |                    |                          |                                   | After 30 min:<br>clear homogenous<br>After 24 h:<br>clear homogenous |
|   |                          |  |  | 0.125% |  |                         |                    |                          |                                   |  |
|   |                          |  |  | 1%     |  |                         |                    |                          |                                   |  |
| Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1) | -                        | -  | Not required for SL formulation.   |        |  | -                       | -                  |                          |                                   |  |
| Wet sieve test (KCP 2.8.5.1.2)  | -                        | -  | Not required for SL formulation.   |        |  | -                       | -                  |                          |                                   |  |

| Annex point   | Method used / deviations | Test material | Findings  | GLP Y/N | Reference | Acceptability / comments |
|---|--------------------------|---------------|---|---------|-----------|--------------------------|
| Dust content (KCP 2.8.5.2.1)                            | -                        | -             | Not required for SL formulation.  | -       | -         |                          |
| Particle size of dust (KCP 2.8.5.2.2)                   | -                        | -             | Not relevant. Acetamipryd 200 SL is liquid form.                          | -       | -         |                          |
| Attrition (KCP 2.8.5.3)                                 | -                        | -             | Not relevant. Acetamipryd 200 SL is liquid form.                          | -       | -         |                          |
| Hardness and integrity (KCP 2.8.5.4)                    | -                        | -             | Not relevant. Acetamipryd 200 SL is liquid form.                          | -       | -         |                          |
| Emulsifiability (KCP 2.8.6.1)                           | -                        | -             | Not required for SL formulation.  | -       | -         |                          |
| Emulsion stability (KCP 2.8.6.2)                        | -                        | -             | Not relevant. Acetamipryd 200 SL is a soluble concentrate.                | -       | -         |                          |
| Re-emulsifiability (KCP 2.8.6.3)                        | -                        | -             | Not relevant. Acetamipryd 200 SL is a soluble concentrate.                | -       | -         |                          |
| Flowability (KCP 2.8.7.1)                               | -                        | -             | Not relevant. Acetamipryd 200 SL is a soluble concentrate.                | -       | -         |                          |
| Pourability (KCP 2.8.7.2)                               | -                        | -             | Not required for SL formulation.  | -       | -         |                          |
| Dustability following accelerated storage (KCP 2.8.7.3) | -                        | -             | Not relevant. Acetamipryd 200 SL is liquid form.                          | -       | -         |                          |
| Physical compatibility of                               | -                        | -             | Not relevant. Acetamipryd 200 SL is not recommended for tank-mixes usage. | -       | -         |                          |

| Annex point                                      | Method used / deviations | Test material                              | Findings  | GLP Y/N | Reference          | Acceptability / comments   |
|--|--------------------------|--|---|---------|--------------------|--|
| tank mixes (KCP 2.9.1)                           |                          |  |   |         |                    |  |
| Chemical compatibility of tank mixes (KCP 2.9.2) | -                        | -  | Not relevant. Acetamipryd 200 SL is not recommended for tank-mixes usage. | -       | -                  |  |
| Adhesion to seeds (KCP 2.10.1)                   | -                        | -  | Not relevant. Acetamipryd 200 SL is not a seedtreatment.                  | -       | -                  |  |
| Distribution to seed (KCP 2.10.2)                | -                        | -  | Not relevant. Acetamipryd 200 SL is not a seedtreatment.                  | -       | -                  |  |
| Other/special studies (KCP 2.11)                 | EPPO PP 1/292(1)         | Acetamipryd 200 SL<br>Batch no. 1/ACE/2022 | Application equipment cleaning effectiveness: 100 %                       | Y       | Kupiec J. BF–23/22 | The procedure of cleaning used in the test was triple rinse with water. Tests were performed in triplicate and the results averaged. Accepted. |

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

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

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

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

|               |  |
|---------------|--|
| zRMS comments | In the accelerated storage and 2-year shelf-life stability study, the formulation was stored in commercial packaging (1 L bottles made of HDPE) and the packaging remained stable during the storage. According to SANCO/10473/2003 – rev.5, the HDPE packaging would be a worst case commercial packaging and would be representative of the other commercial packaging types. Therefore, extrapolation from HDPE to HDPE/PA (COEX) and f-HDPE is acceptable. Therefore, the proposed commercial packs are considered acceptable. |
|---------------|--|

Taking into account extrapolation rules of *Polish guideline on the general principles for approval of packaging of plant protection products* (actualization 18.10.2021), we are applying for additional packaging made of HDPE/PA (COEX) and f-HDPE (fluorinated HDPE) for professional users. According to this guideline extrapolation from HDPE to HDPE/PA (COEX) and f-HDPE (fluorinated HDPE) is possible for SL formulations.

**Table 4.1-1: Packaging information for 250 ml bottle**

| Type                          | Description            |                          |                        |
|-------------------------------|------------------------|--------------------------|------------------------|
| <b>Material:</b>              | HDPE                   | HDPE/PA (COEX)           | f-HDPE                 |
| <b>Shape/size:</b>            | 126mm x Ø63.5mm        | 126mm x Ø63.5mm          | 126mm x Ø63.5mm        |
| <b>Opening:</b>               | 50mmTE                 | 50mmBE                   | 50mmTE                 |
| <b>Closure:</b>               | 50mmTE                 | 50mmBE                   | 50mmTE                 |
| <b>Seal:</b>                  | HIS or PE              | IHS                      | IHS or PET/ALU         |
| <b>Manner of construction</b> | Blow moulded extrusion | Blow moulded coextrusion | Blow moulded extrusion |
| <b>UN/ADR</b>                 | Y 1,5/120              | Y 1,9/120                | Y 1,5/120              |

**Table 4.1-2: Packaging information for 0.5 L bottle**

| Type                          | Description                                       |   |   |
|-------------------------------|---|---|---|
| <b>Material:</b>              | HDPE  | HDPE/PA (COEX)                                    | f-HDPE  |
| <b>Shape/size:</b>            | cylindrical / approx. 77.6 mm diameter x 160.6 mm | cylindrical / approx. 77.6 mm diameter x 160.6 mm | cylindrical / approx. 69 mm diameter x 186.2 mm |
| <b>Opening:</b>               | 31,3 mm diameter                                  | 31,3 mm diameter                                  | 45 mm inner diameter                            |
| <b>Closure:</b>               | high-density polyethylene cap (screw-on type)     | high-density polyethylene cap (screw-on type)     | 31,3 mm inner diameter                          |
| <b>Seal:</b>                  | HF-seal   | HF-seal   | HF-seal   |
| <b>Manner of construction</b> | blowing extrusion                                 | blowing extrusion                                 | blowing extrusion                               |
| <b>UN/ADR</b>                 | not relevant                                      | not relevant                                      | UN certified                                    |

**Table 4.1-3: Packaging information for 1L bottle**

| Type             | Description |                |       |
|------------------|-------------|----------------|-------|
| <b>Material:</b> | HDPE        | HDPE/PA (COEX) | fHDPE |

| Type                          | Description                                     |   |   |
|-------------------------------|---|---|---|
| <b>Shape/size:</b>            | cylindrical / approx. 84 mm diameter x 230.1 mm | cylindrical / approx. 88 mm diameter x 236.5 mm | cylindrical / approx. 88.5 mm diameter x 233.2 mm |
| <b>Opening:</b>               | 31,3 mm diameter                                | 48 mm inner diameter                            | 45 mm inner diameter                              |
| <b>Closure:</b>               | high-density polyethylene cap (screw-on type)   | high-density polyethylene cap (screw-on type)   | high-density polyethylene cap (screw-on type)     |
| <b>Seal:</b>                  | HF-seal   | HF-seal   | HF-seal   |
| <b>Manner of construction</b> | blowing extrusion                               | blowing extrusion                               | blowing extrusion                                 |
| <b>UN/ADR</b>                 | not relevant                                    | not relevant                                    | UN certified                                      |

**Table 4.1-4: Packaging information for 5L canister**

| Type                          | Description   |   |   |
|-------------------------------|---|---|---|
| <b>Material:</b>              | HDPE  | HDPE/PA (COEX)  | fHDPE   |
| <b>Shape/size:</b>            | cuboid / approx. 186 x 140 mm, H <sub>max</sub> =300 mm | cuboid / approx. 187 x 135 mm, H <sub>max</sub> =305 mm | cuboid / approx. 193 x 142 mm, H <sub>max</sub> =305 mm |
| <b>Opening:</b>               | 54 mm diameter  | 53 mm inner diameter                                    | 54 mm inner diameter                                    |
| <b>Closure:</b>               | high-density polyethylene cap (screw-on type)           | high-density polyethylene cap (screw-on type)           | high-density polyethylene cap (screw-on type)           |
| <b>Seal:</b>                  | HF-seal   | HF-seal   | HF-seal   |
| <b>Manner of construction</b> | blowing extrusion                                       | blowing extrusion                                       | blowing extrusion                                       |
| <b>UN/ADR</b>                 | not relevant  | not relevant  | UN certified  |

**Table 4.1-5: Packaging information for 10L canister**

| Type                          | Description   |   |   |
|-------------------------------|---|---|---|
| <b>Material:</b>              | HDPE  | HDPE/PA (COEX)  | fHDPE   |
| <b>Shape/size:</b>            | cuboid / approx. 228 x 192 mm, H <sub>max</sub> =306.6 mm | cuboid / approx. 230 x 166 mm, H <sub>max</sub> =375 mm | cuboid / approx. 240 x 179 mm, H <sub>max</sub> =377.5 mm |
| <b>Opening:</b>               | 46,8 mm diameter  | 53 mm inner diameter                                    | 54 mm inner diameter                                      |
| <b>Closure:</b>               | high-density polyethylene cap (screw-on type)             | high-density polyethylene cap (screw-on type)           | high-density polyethylene cap (screw-on type)             |
| <b>Seal:</b>                  | HF-seal   | HF-seal   | HF-seal   |
| <b>Manner of construction</b> | blowing extrusion   | blowing extrusion                                       | blowing extrusion   |
| <b>UN/ADR</b>                 | compliant   | compliant   | UN certified  |

**Table 4.1-6: Packaging information for 20L canister**

| Type               | Description   |   |   |
|--------------------|---|---|---|
| <b>Material:</b>   | HDPE  | HDPE/PA (COEX)  | fHDPE   |
| <b>Shape/size:</b> | cuboid / approx. 259 x 237 mm, H <sub>max</sub> =415±3 mm | cuboid / approx. 292 x 256 mm, H <sub>max</sub> =345,4 mm | cuboid / approx. 294 x 245 mm, H <sub>max</sub> =400 mm |
| <b>Opening:</b>    | 63,4 mm diameter  | 46,8 mm diameter  | 53 mm diameter  |
| <b>Closure:</b>    | high-density polyethylene cap (screw-on type)             | high-density polyethylene cap (screw-on type)             | high-density polyethylene cap (screw-on type)           |
| <b>Seal:</b>       | HF-seal   | HF-seal   | HF-seal   |

| Type                   | Description       |                   |                   |
|------------------------|-------------------|-------------------|-------------------|
| Manner of construction | blowing extrusion | blowing extrusion | blowing extrusion |
| UN/ADR                 | compliant         | compliant         | compliant         |

**Table 4.1-7: Packaging information for 220L barrel**

| Type                          | Description  |  |
|-------------------------------|--|--|
| <b>Material:</b>              | HDPE   | HDPE   |
| <b>Shape/size:</b>            | 935 (± 5) mm x Ø581 (± 5) mm   | 973mm x Ø590mm   |
| <b>Opening:</b>               | Ø581 (±5)  | Ø590mm   |
| <b>Closure:</b>               | Cap types:<br>2 layer high-density polyethylene - HBCS<br>70x6 (Ø80 ± 0,5mm, height 23 ±1 mm)<br>or<br>2 caps high-density polyethylene - BCS<br>56x4 (Ø71,8 ±0,3 mm, height 21,4 ±1 mm) | Lid injection moulded out of HDPE with lever action clamping ring, made from galvanised steel. |
| <b>Seal:</b>                  | EPDM foam rubber or PE   | PUR foamed or EPDM foam rubber   |
| <b>Manner of construction</b> | Blow moulded in one operation together with top and bottom out and integrated L - ring in top.   | Blow moulded out of high molecular HDPE in a one-step process.                                 |
| <b>UN/ADR</b>                 | UN 1H1   | UN 1H2   |

**Table 4.1-8: Packaging information for 1000 L container**

| Type                          | Description  |   |   |
|-------------------------------|--|---|---|
| <b>Material:</b>              | HDPE container in steel cage on plastic pallet   | HDPE container in steel cage on wooden pallet   | HDPE container in steel cage on hybrid pallet   |
| <b>Shape/size:</b>            | 1000mm x 1200mm x 1180mm   | 1000mm x 1200mm x 1174 mm   | 1000 mm x 1200mm x 1151mm (± 5mm)   |
| <b>Opening:</b>               | NW150  | NW150   | NW150   |
| <b>Closure:</b>               | DN 50  | DN 50   | DN 50   |
| <b>Seal:</b>                  | ETFE/PE  | EPDM  | ETFE/PE   |
| <b>Manner of construction</b> | Blow-molded from high-density UV-stabilized PE, galvanized steel cage, plastic pallet. | Blow-molded from high-density UV-stabilized PE, galvanized steel cage, wooden pallet. | Blow-molded from high-density UV-stabilized PE, galvanized steel cage, palette made of steel corners are filled with plastic. |
| <b>UN/ADR</b>                 | UN 31HA1   | UN 31HA1  | UN 31HA1  |

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

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

### List of data submitted by the applicant and relied on

| Data point  | Author(s)    | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not   | Vertebrate study<br>Y/N | Owner                |
|---|--------------|------|---|-------------------------|----------------------|
| KCP 2.1<br>KCP 2.4.1<br>KCP 2.4.2<br>KCP 2.5.1<br>KCP 2.5.2<br>KCP 2.6.1<br>KCP 2.7.1<br>KCP 2.7.3<br>KCP 2.7.4<br>KCP 2.8.2<br>KCP 2.8.4<br>KCP 2.11 | Kupiec J.    | 2022 | ACETAMIPRYD 200 SL: Stage I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage and low temperature storage<br>Report No: BF – 23/22<br>Łukasiewicz Research Network – Institute of Industrial Organic Chemistry<br>GLP<br>Unpublished | N                       | Pestila*<br>ProAgri* |
| KCP 2.2.1   | Ołowski G.   | 2022 | ACETAMIPRYD 200 SL. Determination of explosive properties.<br>Report No: BW-14/22<br>Łukasiewicz Research Network – Institute of Industrial Organic Chemistry<br>GLP<br>Unpublished   | N                       | Pestila*<br>ProAgri* |
| KCP 2.2.2<br>KCP 2.3.1<br>KCP 2.3.3   | Flasińska P. | 2022 | Acetamipryd 200 SL Determination of flash point, auto-ignition temperature and oxidizing properties.<br>Report No: BW-46/22<br>Łukasiewicz Research Network – Institute of Industrial Organic Chemistry<br>GLP<br>Unpublished   | N                       | Pestila*<br>ProAgri* |

| Data point | Author(s)   | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not  | Vertebrate study<br>Y/N | Owner                |
|------------|-------------|------|--|-------------------------|----------------------|
| KCP 2.7.5  | Rymarzak O. | 2024 | Final report, Acetamipryd 200 SL, Determination of physicochemical properties<br>Report No: BF – 23/22<br>Łukasiewicz Research Network – Institute of Industrial Organic Chemistry<br>GLP<br>Unpublished                             | N                       | Pestila*<br>ProAgri* |
| KCP 2.7.6  | Rymarzak O. | 2023 | Acetamipryd 200 SL: Stage II: Determination of physicochemical properties after the first year of storage<br>Report No: BF – 23/22<br>Łukasiewicz Research Network – Institute of Industrial Organic Chemistry<br>GLP<br>Unpublished | N                       | Pestila*<br>ProAgri* |

\*Pestila Spółka z ograniczoną odpowiedzialnością (short name: Pestila Sp. z o.o.)

\*\*ProAgri Spółka z ograniczoną odpowiedzialnością or ProAgri International Spółka z ograniczoną odpowiedzialnością (short name: ProAgri Sp. z o.o. or ProAgri International Sp. z o.o.)

#### List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

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

The following tables are to be completed by MS.

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

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

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

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

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

### **A 2.1            Acetamiprid**

No further data available.