

# 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: ADM.00150.I.2.A

Product name(s): LEAXO

Chemical active substance:

Acetamiprid, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

### CORE ASSESSMENT/

(Authorisation acc. to Art. 33)

Sponsor: ADAMA Makhteshim Ltd.

Applicant: Country organisation / representative of ADAMA,  
as given in Part A

Submission date: August 2023

MS Finalisation date: January 2024 (initial Core Assessment)

November 2024 (final Core Assessment)

### Version history

| When          | What   |
|---------------|--|
| August 2023   | Applicant version v 1.0  |
| January 2024  | <p>Initial zRMS assessment</p> <p>The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and <b>highlighted in grey</b>. Not agreed or not relevant information are <del>struck through</del> and <del>shaded</del> for transparency.</p> |
| November 2024 | <p>Final report (Core Assessment updated following the commenting period)</p> <p>Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are <b>highlighted in yellow</b>. Not agreed or not relevant information are <del>struck through</del> and <del>shaded</del> for transparency.</p>  |

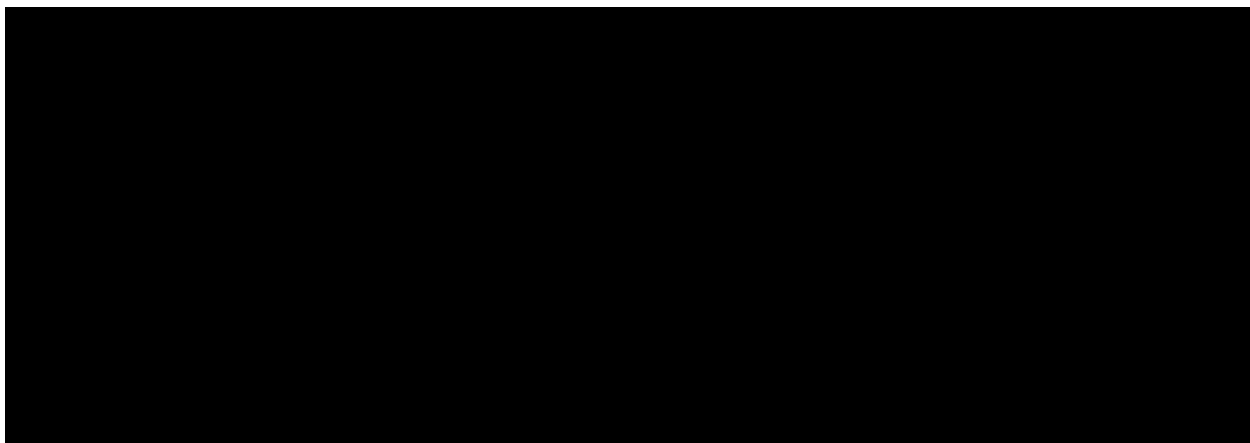
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Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance.

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

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



### **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 Acetamiprid**

Acetamiprid min. 990 g/kg

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

### **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

Company code number: ADM.00150.I.2.A

### **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)**

ADM.00150.I.2.A (or formerly MCW-2222) was not the representative formulation in the previous active

substance renewal<sup>1</sup>.

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

| Active substance / variant | Declared content of the pure active substance / variant (g/L) | FAO Limits (min – max)   | Technical content* (g/L) | Technical content** (%w/w) |
|----------------------------|---|--------------------------|--------------------------|----------------------------|
| Acetamiprid                | 200 g/L   | 188 – 212 g/L<br>[± 6 %] | 202.0                    | 17.78                      |

\* Based on the minimum purity of acetamiprid as declared by EFSA (2016)<sup>1</sup> i.e. 990 g/kg

\*\* Based on the density of the formulation = 1.1361 g/cm<sup>3</sup>, provided under KCP 2.6.1/01

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

**Table 1.4-2: 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)

CONFIDENTIAL information is provided separately (Part C).

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

Type: Soluble concentrate

[Code: SL]

## 1.6 Function (KCP 1.6)

The product is an insecticide.

<sup>1</sup> EFSA Journal 2016;14(11):4610

## 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 a clear, yellow-orange liquid, with a characteristic odour. It is not explosive, has no oxidising properties. The product has a flash point of >55 °C, thus it is not classified as a flammable liquid. It has a self-ignition temperature of 285 °C. In aqueous solution at a 1% w/v dilution, it has a pH value around 6 to 7 at 20 °C. There is no effect of high temperature on the stability of the formulation, since after 8 weeks at 40 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 3 years at ambient temperature when stored in HDPE containers. The product is sensitive to low temperatures. Its technical characteristics are acceptable for a soluble concentrate (SL) formulation.

The intended concentration of use is ~~0.009%~~ **0.013%** to 0.3%.

The product can be mixed in the tank together with each of the following products CORAGEN (Chlorantraniliprole 200 g/L SC), POLISOLFURO DI CALCIO POLISENIO (Polisolfuro di calcio 380 g/L AL) and SWITCH (Cyprodinil 37,5 g + Fludioxonil 25 g WG). Studies regarding the combination with CORAGEN, POLISOLFURO DI CALCIO POLISENIO and SWITCH were submitted and the application as tank mixture is acceptable.

The SDS is provided under KCP 1.4.3/01.

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

Other hazards: Keep from freezing.

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

Other hazards: Keep from freezing.

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

The product ADM.00150.I.2.A complies with FAO specifications.

### **Formulation used for tests**

The product ADM.00150.I.2.A was tested in the tank mix compatibility study. All other studies were conducted on the product MCW-2222. ADM.00150.I.2.A is the product cited in dRR Part C. MCW-2222 has the same composition as ADM.00150.I.2.A.

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

| Annex point                         | Method used / deviations   | Test material  | Findings  | GLP Y/N | Reference  | Acceptability / comments  |
|-------------------------------------|--|--|---|---------|--|---|
| Colour and physical state (KCP 2.1) | Visual and olfactorial inspection  | MCW-2222, Acetamiprid 200 g/L SL<br>Batch no.: 611-280413-01<br>Content of a.s.: 201 g/L | <u>Before storage and after storage for 8 weeks at 40 ± 2°C:</u><br>MCW-2222 was a clear, yellow-orange liquid. It had a characteristic odour.  | Y       | KCP 2.1/01<br>Walter, D., 2014a<br>Report No S13-03100<br>Sponsor's study No R-33406   | Accepted.   |
|                                     | Visual and olfactorial inspection  | MCW-2222, Acetamiprid 200 g/L SL<br>Batch no.: 611-280413-01<br>Content of a.s.: 201 g/L | <u>Before storage and after storage for 6, 12, 24 and 36 months at 20 ± 2°C:</u><br>MCW-2222 was a clear, yellow-orange liquid. It had a characteristic odour.  | Y       | KCP 2.1/02<br>Walter, D., 2015<br>Report No S13-03102<br>Sponsor's study No R-33408<br><br>KCP 2.1/03<br>Walter, D., 2016<br>Report No S15-05766<br>Sponsor's study No R-36824 | Accepted.   |
| Explosive properties (KCP 2.2.1)    | OECD 113<br>EEC A.14<br><br>Differential Scanning Calometry (DSC)<br><br>Mechanical Sensitivity (shock)<br><br>Thermal sensitivity | MCW-2222, Acetamiprid 200 SL<br>Batch no.: 611-280413-01<br>Content of a.s.: 201 g/L     | <u>DSC:</u><br>Exothermal effect in the temperature range of 275 – 360 °C with an energy of 1095 J/g and 1178 J/g, respectively. The energy release was >500 J/g.<br><br><u>Mechanical Sensitivity (shock):</u><br>No explosion within 6 tests using a mass of 10 kg falling from a height of 0.4 m was observed.<br><br><u>Thermal sensitivity:</u><br>Triplicates at 2 mm and 6 mm nozzle width.<br>Time to any reaction, e.g. whistle or flame: 50 s.<br>Time to main reaction, e.g. rupture or tube flashing: >300 s.<br><br>The test item has no explosive properties in the sense of the European Commission Regulation (EC) No. 440/2008, Method A.14. | Y       | KCP 2.2.1/01<br>Krack, M., 2013a<br>Report No 20130274.01<br>Sponsor's study No R-33398  | Accepted.<br>ADM.00150.I.2.A is not explosive.<br><br>The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual. |
| Oxidizing properties                | Expert statement   | MCW-2222,  | None of the components involved in MCW-2222 were  | N       | KCP 2.2.2/01   | Accepted.   |

| Annex point                              | Method used / deviations  | Test material   | Findings  | GLP Y/N | Reference   | Acceptability / comments   |
|--|---|---|---|---------|---|--|
| (KCP 2.2.2)                              |   | Acetamidrid 200 SL<br>Batch no.: 611-280413-01<br>Content of a.s.: 201 g/L              | classified as oxidizing substance. Therefore the formulation should be considered as a substance without oxidizing properties.  |         | Walter, D., 2014b<br>Report No S13-03094<br>Sponsor's study No R-33400                  | The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.                  |
| Flash point (KCP 2.3.1)                  | EEC A.9<br><br>Pensky-Martens Semi Automatic Tester (DIN 51758) | MCW-2222,<br>Acetamidrid 200 SL<br>Batch no.: 611-280413-01<br>Content of a.s.: 201 g/L | 99 °C at 1013 hPa (mean of two replicates).<br><br>Since the flash point is >55 °C, the test item should be classified as a non-flammable liquid.   | Y       | KCP 2.3.1/01<br>Walter, D., 2014c<br>Report No S13-03095<br>Sponsor's study No R-33401  | Accepted.<br><br>The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual. |
| Flammability (KCP 2.3.2)                 | -   | -   | Not applicable, since the test substance is a liquid formulation.   | -       | -   | -  |
| Self-heating (KCP 2.3.3)                 | EEC A.15  | MCW-2222,<br>Acetamidrid 200 SL<br>Batch no.: 611-280413-01<br>Content of a.s.: 201 g/L | Auto-ignition temperature: 285 °C.<br><br>The lowest auto-ignition temperature of the test item was determined to be 288 °C in one the three main test (2 °C steps) at 1006 – 1012.9 hPa barometric pressure. Due to safety reasions and according to the guidelines, the temperature was rounded down to the next lower number divisible by 5. | Y       | KCP 2.3.3/01<br>Krack, M., 2013b<br>Report No 20130274.02<br>Sponsor's study No R-33399 | Accepted.<br><br>The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual. |
| Acidity or alkalinity and pH (KCP 2.4.1) | -   | -   | Acidity or alkalinity is not relevant since the pH in a 1% w/v aqueous dilution is between 4-10.  | -       | -   | -  |
|  | -   | -   | For the pH of the neat formulation, please see statement in confidential Part C.  | -       | -   | -  |



| Annex point   | Method used / deviations | Test material  | Findings  | GLP Y/N    | Reference  | Acceptability / comments |                |      |   |                  |      |      |           |  |           |           |      |      |   |   |           |
|---|--------------------------|--|---|------------|--|--------------------------|----------------|------|---|------------------|------|------|-----------|--|-----------|-----------|------|------|---|---|-----------|
| pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2) | CIPAC MT 75.3            | MCW-2222, Acetamiprid 200 g/L SL<br>Batch no.: 611-280413-01<br>Content of a.s.: 201 g/L | 1% w/v aqueous dilution of the product before and after storage for 8 weeks at 40 °C ± 2 °C, mean of two replicates: <table><tr><td>Time point</td><td>pH</td><td>Mean temperature [°C]</td></tr><tr><td>Before storage</td><td>6.35</td><td>21.5</td></tr><tr><td>8 weeks at 40 °C</td><td>7.36</td><td>20.0</td></tr></table>   | Time point | pH   | Mean temperature [°C]    | Before storage | 6.35 | 21.5  | 8 weeks at 40 °C | 7.36 | 20.0 | Y         | KCP 2.4.2/01<br>Walter, D., 2014a<br>Report No S13-03100<br>Sponsor's study No R-33406<br><br>Filed under KCP 2.1/01<br><br>KCP 2.4.2/02<br>Hemm, C., 2022 | Accepted. |           |      |      |   |   |           |
|   | Time point               | pH   | Mean temperature [°C]   |            |  |                          |                |      |   |                  |      |      |           |  |           |           |      |      |   |   |           |
| Before storage  | 6.35                     | 21.5   |   |            |  |                          |                |      |   |                  |      |      |           |  |           |           |      |      |   |   |           |
| 8 weeks at 40 °C  | 7.36                     | 20.0   |   |            |  |                          |                |      |   |                  |      |      |           |  |           |           |      |      |   |   |           |
|   | CIPAC MT 75.3            | MCW-2222, Acetamiprid 200 g/L SL<br>Batch no.: 611-280413-01<br>Content of a.s.: 201 g/L | 1% w/v aqueous dilution of the product before and after storage for 6, 12 and 24 months at 20 °C ± 2 °C, mean of two replicates: <table><tr><td>Time point</td><td>pH</td><td>Mean temperature [°C]</td></tr><tr><td>Before storage</td><td>6.35</td><td>21.4</td></tr><tr><td>6 months</td><td>6.31</td><td>20.0</td></tr><tr><td>12 months</td><td>6.59</td><td>20.6</td></tr><tr><td>24 months</td><td>6.37</td><td>21.1</td></tr></table> | Time point | pH   | Mean temperature [°C]    | Before storage | 6.35 | 21.4  | 6 months         | 6.31 | 20.0 | 12 months | 6.59   | 20.6      | 24 months | 6.37 | 21.1 | Y | KCP 2.4.2/03<br>Walter, D., 2015<br>Report No S13-03102<br>Sponsor's study No R-33408<br><br>Filed under KCP 2.1/02<br><br>KCP 2.4.2/04<br>Koch, A., 2017 | Accepted. |
| Time point  | pH                       | Mean temperature [°C]  |   |            |  |                          |                |      |   |                  |      |      |           |  |           |           |      |      |   |   |           |
| Before storage  | 6.35                     | 21.4   |   |            |  |                          |                |      |   |                  |      |      |           |  |           |           |      |      |   |   |           |
| 6 months  | 6.31                     | 20.0   |   |            |  |                          |                |      |   |                  |      |      |           |  |           |           |      |      |   |   |           |
| 12 months   | 6.59                     | 20.6   |   |            |  |                          |                |      |   |                  |      |      |           |  |           |           |      |      |   |   |           |
| 24 months   | 6.37                     | 21.1   |   |            |  |                          |                |      |   |                  |      |      |           |  |           |           |      |      |   |   |           |
|   | CIPAC MT 75.3            | MCW-2222, Acetamiprid 200 g/L SL<br>Batch no.: 611-280413-01<br>Content of a.s.: 201 g/L | 1% w/v aqueous dilution of the product after storage for 36 months at 20 °C ± 2 °C, mean of two replicates, assessed at ambient temperature: <table><tr><td>Time point</td><td>pH</td></tr><tr><td>36 months</td><td>6.13</td></tr></table>   | Time point | pH   | 36 months                | 6.13           | Y    | KCP 2.4.2/05<br>Walter, D., 2016<br>Report No S15-05766<br>Sponsor's study No R-36824<br><br>Filed under KCP 2.1/03 | Accepted.        |      |      |           |  |           |           |      |      |   |   |           |
| Time point  | pH                       |  |   |            |  |                          |                |      |   |                  |      |      |           |  |           |           |      |      |   |   |           |
| 36 months   | 6.13                     |  |   |            |  |                          |                |      |   |                  |      |      |           |  |           |           |      |      |   |   |           |
| Viscosity (KCP 2.5.1)   | OECD 114<br>CIPAC MT 192 | MCW-2222, Acetamiprid 200 g/L SL<br>Batch no.: 611-280413-01<br>Content of a.s.: 201 g/L | Test performed in duplicate.<br><br>Dynamic viscosity:<br>12.5 mPa·s (20 °C, shear rates 5 s <sup>-1</sup> to 100 s <sup>-1</sup> )<br>7.0 mPa·s (40 °C, shear rates 5 s <sup>-1</sup> to 100 s <sup>-1</sup> )<br><br>The test item is a Newtonian liquid because the viscosity was constant with the shear rate.  | Y          | KCP 2.5.1/01<br>Walter, D., 2014d<br>Report No S13-03096<br>Sponsor's study No R-33402 | Accepted.                |                |      |   |                  |      |      |           |  |           |           |      |      |   |   |           |

| Annex point  | Method used / deviations                            | Test material   | Findings   | GLP Y/N | Reference  | Acceptability / comments   |
|--|---|---|--|---------|--|--|
|  |   |   | Kinematic viscosity:<br>20 °C, shear rates 5 s <sup>-1</sup> to 100 s <sup>-1</sup> : 11.00 mm/s<br>40 °C, shear rates 5 s <sup>-1</sup> to 100 s <sup>-1</sup> : 6.16 mm/s  |         |  |  |
| Surface tension (KCP 2.5.2)                          | EEC A.5<br>OECD 115<br><br>Ring tensiometer         | MCW-2222,<br>Acetamiprid 200 g/L SL<br>Batch no.: 611-280413-01<br>Content of a.s.: 201 g/L | At 1.00 g/L (0.1% w/v) in demineralized water at 20.3 °C ± 0.5 °C (mean of 11 determinations over the course of 50 min):<br><br>41.7 mN/m<br><br>The test item is regarded as surface active as the results show a surface tension <60 mN/m. | Y       | KCP 2.5.2/01<br>Walter, D., 2014e<br>Report No S13-03097<br>Sponsor's study No R-33403 | Accepted.<br>Product is surface active.<br><br>The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual. |
| Relative density (KCP 2.6.1)                         | OECD 109<br>EEC A.3<br><br>Oscillating densitometer | MCW-2222,<br>Acetamiprid 200 g/L SL<br>Batch no.: 611-280413-01<br>Content of a.s.: 201 g/L | <u>Mean of two replicates:</u><br><br><u>Relative density:</u><br>1.1361 (20 °C ± 0.1 °C)<br><br><u>Absolute density:</u><br>1.1361 g/cm <sup>3</sup> (20 °C ± 0.1 °C)   | Y       | KCP 2.6.2/01<br>Walter, D., 2014f<br>Report No S13-03098<br>Sponsor's study No R-33404 | Accepted.  |
| Bulk density (KCP 2.6.2)                             | -   | -   | Not applicable for liquid preparations.  | -       | -  | -  |
| Storage Stability after 14 days at 54° C (KCP 2.7.1) | -   | -   | Study was not conducted but an alternative time/temperature regime of 8 weeks at 40 °C chosen, s. KCP 2.7.2/01.  | -       | -  | -  |

| Stability after storage for other periods and/or temperatures (KCP 2.7.2) | CIPAC MT 46.3     | MCW-2222, Acetamiprid 200 g/L SL<br>Batch no.: 611-280413-01<br>Content of a.s.: 201 g/L | <p>MCW-2222 was stored for 8 weeks at 40 °C ± 2 °C (as alternative time/temperature regime to 14 days at 54 °C) in original 1 L HDPE containers.</p> <p><u>Active ingredient and relevant impurity concentration:</u><br/>Acetamiprid content was quantified before and after storage (each replicate mean of two determinations):</p> <table><tr><th>Time point</th><th>Replicates</th><th>Mean content of Acetamiprid [% w/w]</th></tr><tr><td>Before storage</td><td>5</td><td>18.0</td></tr><tr><td>8 weeks at 40 °C</td><td>3</td><td>17.5</td></tr></table> <p>For details on the analytical method used (S13-03099), s. section B5.</p> <p>The change in acetamiprid content was below 5%.</p> <p><u>Packaging weight change:</u></p> <table><tr><th>Time point</th><th>Weight change [%]</th></tr><tr><td>Before storage</td><td>-</td></tr><tr><td>8 weeks at 40 °C</td><td>-0.02</td></tr></table> <p>No significant change in weight was found after storage.</p> <p><u>Packaging Appearance:</u><br/>Before and after storage for 8 weeks at 40 °C ± 2 °C:<br/>The container (screw capped HDPE bottle) shut tightly. No damage to the container shape or size was observed after storage.</p> <p>For the remaining physical and chemical properties tested before and after accelerated storage, please refer to the corresponding data points (CP 2.1/01, CP 2.4.2/01, CP 2.8.2/02, CP 2.8.4/01) for summaries.</p> <p>MCW-2222 product is compatible with the storage conditions and the original 1 L HDPE containers with screw caps.</p> <p>The preparation is stable for 8 weeks at 40 °C, as physical</p> | Time point | Replicates | Mean content of Acetamiprid [% w/w] | Before storage | 5 | 18.0 | 8 weeks at 40 °C | 3 | 17.5 | Time point | Weight change [%] | Before storage | - | 8 weeks at 40 °C | -0.02 | Y | KCP 2.7.2/01<br>Walter, D., 2014a<br>Report No S13-03100<br>Sponsor’s study No R-33406<br><br>Filed under KCP 2.1/01 | <p>The product showed no significant physical changes after accelerated storage.</p> <p>No significant changes were observed in the packaging and therefore it can be concluded that the test item was not corrosive to the container material.</p> <p>No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage.</p> <p>The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging (HDPE).</p> |
|---|-------------------|--|--|------------|------------|-------------------------------------|----------------|---|------|------------------|---|------|------------|-------------------|----------------|---|------------------|-------|---|--|--|
| Time point  | Replicates        | Mean content of Acetamiprid [% w/w]  |  |            |            |                                     |                |   |      |                  |   |      |            |                   |                |   |                  |       |   |  |  |
| Before storage  | 5                 | 18.0   |  |            |            |                                     |                |   |      |                  |   |      |            |                   |                |   |                  |       |   |  |  |
| 8 weeks at 40 °C  | 3                 | 17.5   |  |            |            |                                     |                |   |      |                  |   |      |            |                   |                |   |                  |       |   |  |  |
| Time point  | Weight change [%] |  |  |            |            |                                     |                |   |      |                  |   |      |            |                   |                |   |                  |       |   |  |  |
| Before storage  | -                 |  |  |            |            |                                     |                |   |      |                  |   |      |            |                   |                |   |                  |       |   |  |  |
| 8 weeks at 40 °C  | -0.02             |  |  |            |            |                                     |                |   |      |                  |   |      |            |                   |                |   |                  |       |   |  |  |

| Annex point  | Method used / deviations | Test material  | Findings   | GLP Y/N | Reference  | Acceptability / comments  |
|--|--------------------------|--|--|---------|--|---|
|  |                          |  | state, pH, technical characteristics and packaging checked after storage are comparable to initial characteristics.  |         |  |   |
| Minimum content after heat stability testing (KCP 2.7.3) | -                        | -  | Within the accelerated storage stability test at 40°C over 8 weeks the product MCW-2222 SC did not show a variation of the a.s. content. Therefore no additional study has to be conducted.  | -       | -  | -   |
| Effect of low temperatures on stability (KCP 2.7.4)      | CIPAC MT 39.3            | MCW-2222,<br>Acetamidiprid 200 g/L SL<br>Batch no.: 2331-250214-01<br>Content of a.s.: 203 g/L | Before and after storage the test item was a homogeneous orange-brown liquid. Some crystals were adhering to the surface of the glass tube at the end of the storage period. 0.5 to 1 mL separated crystals were observed after standing 24 h at 23 °C and were not solved after inversion.<br><br>The product is not stable at temperatures below 0 °C. | Y       | KCP 2.7.4/01<br>Deierling, T. & Herrmann, S., 2014<br>Report No 91841204<br>Sponsor's study No R-34771 | Accepted.<br>The product is sensitive to low temperatures.<br>Keep from freezing. |

| Ambient temperature shelf life (KCP 2.7.5) | CropLife International, Technical Monograph No. 17, 2 <sup>nd</sup> edition | MCW-2222, Acetamiprid 200 g/L SL<br>Batch no.: 611-280413-01<br>Content of a.s.: 201 g/L | <p>MCW-2222 was stored for up to 36 months at 20 °C ± 2 °C in original 1 L HDPE containers.</p> <p><u>Active ingredient and relevant impurity concentration:</u><br/>Acetamiprid content was quantified before and after storage (each replicate mean of two determinations):</p> <table><tr><th>Time point</th><th>Replicates</th><th>Mean content of Acetamiprid [% w/w]</th></tr><tr><td>Before storage</td><td>5</td><td>18.0</td></tr><tr><td>6 months</td><td>4</td><td>17.4</td></tr><tr><td>12 months</td><td>4</td><td>17.4</td></tr><tr><td>24 months</td><td>4</td><td>17.6</td></tr><tr><td>36 months</td><td>4</td><td>17.3</td></tr></table> <p>For details on the analytical method used (S13-03099), s. section B5.</p> <p>The change in acetamiprid content was below 5%.</p> <p><u>Packaging weight change:</u></p> <table><tr><th>Time point</th><th>Weight change (mean of all remaining containers) [%]</th></tr><tr><td>Before storage</td><td>-</td></tr><tr><td>6 months</td><td>-0.02</td></tr><tr><td>12 months</td><td>-0.01</td></tr><tr><td>24 months</td><td>-0.02</td></tr><tr><td>36 months</td><td>-0.06</td></tr></table> <p>No significant change in weight was found after storage.</p> <p><u>Packaging Appearance:</u><br/>Before storage and after storage for 6, 12, 24 and 36 months at 20 °C ± 2 °C:<br/>The container (screw capped HDPE bottle) shut tightly. No damage to the container shape or size was observed after storage.</p> <p>For the remaining physical and chemical properties tested before and after accelerated storage, please refer to the corresponding data points (CP 2.1/02+03, CP 2.4.2/02+03,</p> | Time point | Replicates | Mean content of Acetamiprid [% w/w] | Before storage | 5 | 18.0 | 6 months | 4 | 17.4 | 12 months | 4 | 17.4 | 24 months | 4 | 17.6 | 36 months | 4 | 17.3 | Time point | Weight change (mean of all remaining containers) [%] | Before storage | - | 6 months | -0.02 | 12 months | -0.01 | 24 months | -0.02 | 36 months | -0.06 | <p>KCP 2.7.5/01<br/>Walther, D., 2015<br/>Report No S13-03102<br/>Sponsor’s study No R-33408</p> <p>Filed under KCP 2.1/01</p> <p>KCP 2.7.5/02<br/>Walther, D., 2016<br/>Report No S15-05766<br/>Sponsor’s study No R-36824</p> <p>Filed under KCP 2.1/02</p> | <p>Accepted.<br/>The product showed no significant physical changes after storage.</p> <p>No significant changes were observed in the packaging and therefore it can be concluded that the test item was not corrosive to the container material.</p> <p>No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage.</p> <p>The stability data indicate a shelf life of 3 years at ambient temperature when stored in commercial packaging (HDPE).</p> |
|--|---|--|---|------------|------------|-------------------------------------|----------------|---|------|----------|---|------|-----------|---|------|-----------|---|------|-----------|---|------|------------|--|----------------|---|----------|-------|-----------|-------|-----------|-------|-----------|-------|---|---|
| Time point                                 | Replicates  | Mean content of Acetamiprid [% w/w]  |   |            |            |                                     |                |   |      |          |   |      |           |   |      |           |   |      |           |   |      |            |  |                |   |          |       |           |       |           |       |           |       |   |   |
| Before storage                             | 5   | 18.0   |   |            |            |                                     |                |   |      |          |   |      |           |   |      |           |   |      |           |   |      |            |  |                |   |          |       |           |       |           |       |           |       |   |   |
| 6 months                                   | 4   | 17.4   |   |            |            |                                     |                |   |      |          |   |      |           |   |      |           |   |      |           |   |      |            |  |                |   |          |       |           |       |           |       |           |       |   |   |
| 12 months                                  | 4   | 17.4   |   |            |            |                                     |                |   |      |          |   |      |           |   |      |           |   |      |           |   |      |            |  |                |   |          |       |           |       |           |       |           |       |   |   |
| 24 months                                  | 4   | 17.6   |   |            |            |                                     |                |   |      |          |   |      |           |   |      |           |   |      |           |   |      |            |  |                |   |          |       |           |       |           |       |           |       |   |   |
| 36 months                                  | 4   | 17.3   |   |            |            |                                     |                |   |      |          |   |      |           |   |      |           |   |      |           |   |      |            |  |                |   |          |       |           |       |           |       |           |       |   |   |
| Time point                                 | Weight change (mean of all remaining containers) [%]                        |  |   |            |            |                                     |                |   |      |          |   |      |           |   |      |           |   |      |           |   |      |            |  |                |   |          |       |           |       |           |       |           |       |   |   |
| Before storage                             | -   |  |   |            |            |                                     |                |   |      |          |   |      |           |   |      |           |   |      |           |   |      |            |  |                |   |          |       |           |       |           |       |           |       |   |   |
| 6 months                                   | -0.02   |  |   |            |            |                                     |                |   |      |          |   |      |           |   |      |           |   |      |           |   |      |            |  |                |   |          |       |           |       |           |       |           |       |   |   |
| 12 months                                  | -0.01   |  |   |            |            |                                     |                |   |      |          |   |      |           |   |      |           |   |      |           |   |      |            |  |                |   |          |       |           |       |           |       |           |       |   |   |
| 24 months                                  | -0.02   |  |   |            |            |                                     |                |   |      |          |   |      |           |   |      |           |   |      |           |   |      |            |  |                |   |          |       |           |       |           |       |           |       |   |   |
| 36 months                                  | -0.06   |  |   |            |            |                                     |                |   |      |          |   |      |           |   |      |           |   |      |           |   |      |            |  |                |   |          |       |           |       |           |       |           |       |   |   |

| Annex point   | Method used / deviations | Test material  | Findings  | GLP Y/N          | Reference        | Acceptability / comments |    |   |    |    |    |                  |                  |   |    |   |    |    |    |   |   |           |
|---|--------------------------|--|---|------------------|------------------|--------------------------|----|---|----|----|----|------------------|------------------|---|----|---|----|----|----|---|---|-----------|
|   |                          |  | CP 2.8.2/03+04, CP 2.8.4/02+03) for summaries.<br><br>MCW-2222 product is compatible with the storage conditions and the original 1 L HDPE containers with screw caps.<br><br>The preparation is stable after 36 months at 20 °C, as physical state, pH, technical characteristics and packaging checked after storage are comparable to initial characteristics.   |                  |                  |                          |    |   |    |    |    |                  |                  |   |    |   |    |    |    |   |   |           |
| Shelf life in months (if less than 2 years) (KCP 2.7.6) | -                        | -  | A shelf life of at least 3 years is proposed on the basis of the two studies presented under KCP 2.7.5.   | -                | -                | -                        |    |   |    |    |    |                  |                  |   |    |   |    |    |    |   |   |           |
| Wettability (KCP 2.8.1)                                 | -                        | -  | Only required for solids. The product MCW-2222 SL is a liquid.  | -                | -                | -                        |    |   |    |    |    |                  |                  |   |    |   |    |    |    |   |   |           |
| Persistence of foaming (KCP 2.8.2)                      | CIPAC MT 47.3            | Acetamiprid 200 SL; MCW-2222<br>Batch no.: 906-091016-02<br>Content of a.s.: 198.1 g/L | 0.0125% v/v of product in CIPAC water D: <table><tr><th>Time point [min]</th><th>Foam volume [mL]</th></tr><tr><td>0</td><td>34</td></tr><tr><td>1</td><td>31</td></tr><tr><td>12</td><td>29</td></tr></table><br>0.5% v/v of product in CIPAC water D: <table><tr><th>Time point [min]</th><th>Foam volume [mL]</th></tr><tr><td>0</td><td>45</td></tr><tr><td>1</td><td>41</td></tr><tr><td>12</td><td>36</td></tr></table><br>The volume of foam after 1 min was below 60 mL for both dilutions of 0.0125% v/v and 0.5% v/v of product in CIPAC water D. | Time point [min] | Foam volume [mL] | 0                        | 34 | 1 | 31 | 12 | 29 | Time point [min] | Foam volume [mL] | 0 | 45 | 1 | 41 | 12 | 36 | Y | KCP 2.8.2/01<br>Tsesin, N., 2018<br>Report No 40400.029FL<br>Sponsor's study No R-40400 | Accepted. |
| Time point [min]  | Foam volume [mL]         |  |   |                  |                  |                          |    |   |    |    |    |                  |                  |   |    |   |    |    |    |   |   |           |
| 0   | 34                       |  |   |                  |                  |                          |    |   |    |    |    |                  |                  |   |    |   |    |    |    |   |   |           |
| 1   | 31                       |  |   |                  |                  |                          |    |   |    |    |    |                  |                  |   |    |   |    |    |    |   |   |           |
| 12  | 29                       |  |   |                  |                  |                          |    |   |    |    |    |                  |                  |   |    |   |    |    |    |   |   |           |
| Time point [min]  | Foam volume [mL]         |  |   |                  |                  |                          |    |   |    |    |    |                  |                  |   |    |   |    |    |    |   |   |           |
| 0   | 45                       |  |   |                  |                  |                          |    |   |    |    |    |                  |                  |   |    |   |    |    |    |   |   |           |
| 1   | 41                       |  |   |                  |                  |                          |    |   |    |    |    |                  |                  |   |    |   |    |    |    |   |   |           |
| 12  | 36                       |  |   |                  |                  |                          |    |   |    |    |    |                  |                  |   |    |   |    |    |    |   |   |           |

| Annex point | Method used / deviations | Test material   | Findings  | GLP Y/N    | Reference        | Acceptability / comments |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
|-------------|--------------------------|---|---|------------|------------------|--------------------------|----|-------|----|-------|----|--------|----|------------|------------------|------|----|-------|----|-------|----|--------|----|---|--|-----------|
|             | CIPAC MT 47.2            | MCW-2222,<br>Acetamiprid 200 g/L SL<br>Batch no.: 611-280413-01<br>Content of a.s.: 201 g/L | <p>In CIPAC water D.</p> <p>Before storage, mean weight: 1.139 g / 200 mL water:</p> <table><tr><td>Time point</td><td>Foam volume [mL]</td></tr><tr><td>10 s</td><td>27</td></tr><tr><td>1 min</td><td>21</td></tr><tr><td>3 min</td><td>21</td></tr><tr><td>12 min</td><td>20</td></tr></table> <p>After storage for 8 weeks at 40 °C ± 2 °C, mean weight: 1.138 g / 200 mL water:</p> <table><tr><td>Time point</td><td>Foam volume [mL]</td></tr><tr><td>10 s</td><td>28</td></tr><tr><td>1 min</td><td>27</td></tr><tr><td>3 min</td><td>25</td></tr><tr><td>12 min</td><td>23</td></tr></table> <p>Persistent foam at 1.138 – 1.139 mg / 200 mL in water prior and after storage for 8 weeks at 40 °C in HDPE-containers is below 60 mL after 1 minute.</p> | Time point | Foam volume [mL] | 10 s                     | 27 | 1 min | 21 | 3 min | 21 | 12 min | 20 | Time point | Foam volume [mL] | 10 s | 28 | 1 min | 27 | 3 min | 25 | 12 min | 23 | Y | KCP 2.8.2/02<br>Walter, D., 2014a<br>Report No S13-03100<br>Sponsor’s study No R-33406<br><br>Filed under KCP 2.1/01 | Accepted. |
| Time point  | Foam volume [mL]         |   |   |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| 10 s        | 27                       |   |   |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| 1 min       | 21                       |   |   |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| 3 min       | 21                       |   |   |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| 12 min      | 20                       |   |   |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| Time point  | Foam volume [mL]         |   |   |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| 10 s        | 28                       |   |   |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| 1 min       | 27                       |   |   |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| 3 min       | 25                       |   |   |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| 12 min      | 23                       |   |   |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |

| Annex point | Method used / deviations | Test material   | Findings   | GLP Y/N    | Reference        | Acceptability / comments |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
|-------------|--------------------------|---|--|------------|------------------|--------------------------|----|-------|----|-------|----|--------|----|------------|------------------|------|----|-------|----|-------|----|--------|----|------------|------------------|------|----|-------|----|-------|----|--------|----|------------|------------------|------|----|-------|----|-------|----|--------|----|---|--|-----------|
|             | CIPAC MT 47.2            | MCW-2222,<br>Acetamiprid 200 g/L SL<br>Batch no.: 611-280413-01<br>Content of a.s.: 201 g/L | <p>In CIPAC water D.</p> <p>Before storage, mean weight: 1.139 g / 200 mL water:</p> <table><tr><td>Time point</td><td>Foam volume [mL]</td></tr><tr><td>10 s</td><td>27</td></tr><tr><td>1 min</td><td>21</td></tr><tr><td>3 min</td><td>21</td></tr><tr><td>12 min</td><td>20</td></tr></table> <p>After storage for 6 months at 20 °C ± 2 °C, mean weight: 1.141 g / 200 mL water:</p> <table><tr><td>Time point</td><td>Foam volume [mL]</td></tr><tr><td>10 s</td><td>30</td></tr><tr><td>1 min</td><td>28</td></tr><tr><td>3 min</td><td>26</td></tr><tr><td>12 min</td><td>23</td></tr></table> <p>After storage for 12 months at 20 °C ± 2 °C, mean weight: 1.136 g / 200 mL water:</p> <table><tr><td>Time point</td><td>Foam volume [mL]</td></tr><tr><td>10 s</td><td>29</td></tr><tr><td>1 min</td><td>26</td></tr><tr><td>3 min</td><td>23</td></tr><tr><td>12 min</td><td>21</td></tr></table> <p>After storage for 24 months at 20 °C ± 2 °C, mean weight: 1.136 g / 200 mL water:</p> <table><tr><td>Time point</td><td>Foam volume [mL]</td></tr><tr><td>10 s</td><td>26</td></tr><tr><td>1 min</td><td>24</td></tr><tr><td>3 min</td><td>22</td></tr><tr><td>12 min</td><td>20</td></tr></table> <p>Persistent foam at 1.136 – 1.141 mg / 200 mL in water prior and after storage for 6, 12 and 24 months at 20 °C in HDPE-containers is below 60 mL after 1 minute.</p> | Time point | Foam volume [mL] | 10 s                     | 27 | 1 min | 21 | 3 min | 21 | 12 min | 20 | Time point | Foam volume [mL] | 10 s | 30 | 1 min | 28 | 3 min | 26 | 12 min | 23 | Time point | Foam volume [mL] | 10 s | 29 | 1 min | 26 | 3 min | 23 | 12 min | 21 | Time point | Foam volume [mL] | 10 s | 26 | 1 min | 24 | 3 min | 22 | 12 min | 20 | Y | KCP 2.8.2/03<br>Walther, D., 2015<br>Report No S13-03102<br>Sponsor’s study No R-33408<br><br>Filed under KCP 2.1/02 | Accepted. |
| Time point  | Foam volume [mL]         |   |  |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| 10 s        | 27                       |   |  |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| 1 min       | 21                       |   |  |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| 3 min       | 21                       |   |  |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| 12 min      | 20                       |   |  |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| Time point  | Foam volume [mL]         |   |  |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| 10 s        | 30                       |   |  |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| 1 min       | 28                       |   |  |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| 3 min       | 26                       |   |  |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| 12 min      | 23                       |   |  |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| Time point  | Foam volume [mL]         |   |  |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| 10 s        | 29                       |   |  |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| 1 min       | 26                       |   |  |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| 3 min       | 23                       |   |  |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| 12 min      | 21                       |   |  |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| Time point  | Foam volume [mL]         |   |  |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| 10 s        | 26                       |   |  |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| 1 min       | 24                       |   |  |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| 3 min       | 22                       |   |  |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |
| 12 min      | 20                       |   |  |            |                  |                          |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |            |                  |      |    |       |    |       |    |        |    |   |  |           |



| Annex point  | Method used / deviations | Test material   | Findings  | GLP Y/N    | Reference  | Acceptability / comments |    |       |    |       |    |        |    |   |  |           |
|--|--------------------------|---|---|------------|--|--------------------------|----|-------|----|-------|----|--------|----|---|--|-----------|
|  | CIPAC MT 47.3            | MCW-2222,<br>Acetamidrid 200 g/L SL<br>Batch no.: 611-280413-01<br>Content of a.s.: 201 g/L | After storage for 36 months at 20 °C ± 2 °C, mean weight: 1.139 g / 200 mL water at 28 °C: <table><tr><th>Time point</th><th>Foam volume [mL]</th></tr><tr><td>10 s</td><td>20</td></tr><tr><td>1 min</td><td>19</td></tr><tr><td>3 min</td><td>18</td></tr><tr><td>12 min</td><td>17</td></tr></table><br><br>Persistent foam at 1.136 – 1.141 mg / 200 mL in water prior and after storage for 36 months at 20 °C in HDPE-containers is below 60 mL after 1 minute.         | Time point | Foam volume [mL]   | 10 s                     | 20 | 1 min | 19 | 3 min | 18 | 12 min | 17 | Y | KCP 2.8.2/04<br>Walther, D., 2016<br>Report No S15-05766<br>Sponsor's study No R-36824<br><br>Filed under KCP 2.1/03 | Accepted. |
| Time point   | Foam volume [mL]         |   |   |            |  |                          |    |       |    |       |    |        |    |   |  |           |
| 10 s   | 20                       |   |   |            |  |                          |    |       |    |       |    |        |    |   |  |           |
| 1 min  | 19                       |   |   |            |  |                          |    |       |    |       |    |        |    |   |  |           |
| 3 min  | 18                       |   |   |            |  |                          |    |       |    |       |    |        |    |   |  |           |
| 12 min   | 17                       |   |   |            |  |                          |    |       |    |       |    |        |    |   |  |           |
| Suspensibility (KCP 2.8.3.1)                             | -                        | -   | Not required, since MCW-2222 SL is not a water dispersible product.   | -          | -  | -                        |    |       |    |       |    |        |    |   |  |           |
| Spontaneity of dispersion (KCP 2.8.3.2)                  | -                        | -   | Not required, since MCW-2222 SL is not a water dispersible product.   | -          | -  | -                        |    |       |    |       |    |        |    |   |  |           |
| Dispersion stability (KCP 2.8.3.3)                       | -                        | -   | Not required, since MCW-2222 SL is not a water dispersible product.   | -          | -  | -                        |    |       |    |       |    |        |    |   |  |           |
| Degree of dissolution and dilution stability (KCP 2.8.4) | CIPAC MT 41              | MCW-2222,<br>Acetamidrid 200 g/L SL<br>Batch no.: 611-280413-01<br>Content of a.s.: 201 g/L | Dilution in CIPAC water D at two concentrations: approximately 0.011% w/v and 0.568% w/v.<br>After 30 min of standing and 18 hours at 30 °C, the material was observed for any separated material. The standing dilution was then poured out on a 45 µm sieve and the sieve rinsed with 50 mL water.<br>Test performed in duplicates.<br><br><u>Before storage and after storage for 8 weeks at 40 °C ± 2 °C:</u><br>No phase separation, no separated material was observed. | Y          | KCP 2.8.4/01<br>Walter, D., 2014a<br>Report No S13-03100<br>Sponsor's study No R-33406<br><br>Filed under KCP 2.1/01 | Accepted.                |    |       |    |       |    |        |    |   |  |           |

| Annex point   | Method used / deviations | Test material   | Findings  | GLP Y/N | Reference  | Acceptability / comments |
|---|--------------------------|---|---|---------|--|--------------------------|
|   | CIPAC MT 41              | MCW-2222,<br>Acetamiprid 200 g/L SL<br>Batch no.: 611-280413-01<br>Content of a.s.: 201 g/L | Dilution in CIPAC water D at two concentrations: approximately 0.011% w/v and 0.568% w/v.<br>After 30 min of standing and 18 hours at 30 °C, the material was observed for any separated material. The standing dilution was then poured out on a 45 µm sieve and the sieve rinsed with 50 mL water.<br>Test performed in duplicates.<br><br><u>Before storage and after storage for 6, 12, 24 and 36 months at 20 °C ± 2 °C:</u><br>No phase separation, no separated material was observed. |         | KCP 2.8.4/02<br>Walter, D., 2015<br>Report No S13-03102<br>Sponsor's study No R-33408<br><br>Filed under KCP 2.1/02<br><br>KCP 2.8.4/03<br>Walter, D., 2016<br>Report No S15-05766<br>Sponsor's study No R-36824<br><br>Filed under KCP 2.1/03 | Accepted.                |
| Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1) | -                        | -   | Only required for powders and solids. MCW-2222 SL is a liquid preparation.  | -       | -  | -                        |
| Wet sieve test (KCP 2.8.5.1.2)  | -                        | -   | Not required, since MCW-2222 SL is not a water dispersible product, but a liquid preparation.   | -       | -  | -                        |
| Dust content (KCP 2.8.5.2.1)  | -                        | -   | Not required, since MCW-2222 SL is not a water dispersible product, but a liquid preparation.   | -       | -  | -                        |
| Particle size of dust (KCP 2.8.5.2.2)                                       | -                        | -   | Not required, since MCW-2222 SL is not a water dispersible product, but a liquid preparation.   | -       | -  | -                        |
| Attrition (KCP 2.8.5.3)   | -                        | -   | Not required, since MCW-2222 SL is a liquid preparation.  | -       | -  | -                        |
| Hardness and integrity (KCP 2.8.5.4)  | -                        | -   | Not required, since MCW-2222 SL is a liquid preparation.  | -       | -  | -                        |
| Emulsifiability (KCP 2.8.6.1)   | -                        | -   | Not required, since MCW-2222 SL is a soluble concentrate and does not form an emulsion.   | -       | -  | -                        |
| Emulsion stability (KCP 2.8.6.2)  | -                        | -   | Not required, since MCW-2222 SL is a soluble concentrate and does not form an emulsion.   | -       | -  | -                        |
| Re-emulsifiability (KCP 2.8.6.3)  | -                        | -   | Not required, since MCW-2222 SL is a soluble concentrate and does not form an emulsion.   | -       | -  | -                        |

| <b>Annex point</b>   | <b>Method used / deviations</b>            | <b>Test material</b>  | <b>Findings</b>   | <b>GLP Y/N</b> | <b>Reference</b>   | <b>Acceptability / comments</b>   |
|--|--|---|---|----------------|--|---|
| Flowability<br>(KCP 2.8.7.1)                               | -  | -   | Not required, since MCW-2222 SL is not a granular product.  | -              | -  | -   |
| Pourability<br>(KCP 2.8.7.2)                               | -  | -   | Not required, since MCW-2222 SL is not a suspension.  | -              | -  | -   |
| Dustability following accelerated storage<br>(KCP 2.8.7.3) | -  | -   | Not required, since MCW-2222 SL is not a powder preparation.  | -              | -  | -   |
| Physical compatibility of tank mixes<br>(KCP 2.9.1)        | ASTM E1518-05<br><br>Dynamic Shaker Method | ADM.00150.I.2.A,<br>Acetamiprid 200 g/L SL<br>Batch no 41190054<br>Content of a.s.: 198 g/L | <u>Physical compatibility:</u><br>ADM.00150.I.2.A at a concentration equivalent to an application rate of 0.35 L/ha was mixed with the following formulations at 22 °C:<br><br>CORAGEN (Chlorantraniliprole 200 g/L SC):<br>0.27 L/ha, 800 L water/ha.<br>pH was 6.07.<br>The two products are compatible.<br><br>POLISOLFURO DI CALCIO POLISENIO (Polisolfuro di calcio 380 g/L AL):<br>5.0 L/ha, 400 L water/ha.<br>pH was 9.64.<br>The two products are compatible.<br><br>SWITCH (Cyprodinil 37,5 g + Fludioxonil 25 g WG):<br>1.0 L/ha, 1000 L water/ha.<br>pH was 7.96.<br>The two products are compatible.<br><br>All mixtures gave well-dispersed mixtures in water. No separation, flocculation, coagulation, gel or curd were noticed. There were no residues on the wall of the flasks and no residues remaining on a 0.3 mm sieve.<br><br>Under the parameters of this study, the results define whether the pesticide mixture is or is not compatible in the laboratory. Compatibility or incompatibility should be confirmed under field spray conditions.<br>In any case the spraying mixtures should be used shortly after preparation. | Y              | KCP 2.9.1/01<br>Thomas, H., 2022<br>Report No 22 35 CRX 0007<br>Sponsor's study No 000110777   | Accepted.<br>Compatibility has been confirmed.<br>The product ADM.00150.I.2.A can be used in tank mixture with:<br>- CORAGEN (Chlorantraniliprole 200 g/L SC);<br>- POLISOLFURO DI CALCIO POLISENIO (Polisolfuro di calcio 380 g/L AL);<br>- SWITCH (Cyprodinil 37,5 g + Fludioxonil 25 g WG) |
| Chemical compatibility of tank mixes<br>(KCP 2.9.2)        |  |   |   |                | KCP 2.9.1/02<br>CoA for Batch no. 41190054<br><br>KCP 2.9.2/01<br>Thomas, H., 2022<br>Report No 22 35 CRX 0007<br>Sponsor's study No 000110777<br><br>Filed under KCP 2.9.1/01<br><br>KCP 2.9.2/02<br>CoA for Batch no. 41190054<br><br>Filed under KCP 2.9.1/02 |   |

| Annex point                       | Method used / deviations | Test material | Findings   | GLP Y/N | Reference | Acceptability / comments |
|-----------------------------------|--------------------------|---------------|--|---------|-----------|--------------------------|
|                                   |                          |               | <p><u>Chemical compatibility:</u><br/> No chemical reactions were observed in the tested mixtures.</p> <p>From the chemical data of the active substances, the following conclusions can be drawn:</p> <p>Acetamiprid, the active substance of ADM.00150.I.2.A (Acetamiprid 200 g/L SL), is stable at all pH ranges at ambient temperature<br/> The pH of the mixing partners is not significantly changed by mixing with ADM.00150.I.2.A.<br/> No cationic and anionic actives are combined in the mixes</p> <p>Based on the individual chemistries of the active substances, tank mixing of ADM.00150.I.2.A (Acetamiprid 200 g/L SL) with all products should be possible.</p> |         |           |                          |
| Adhesion to seeds (KCP 2.10.1)    | -                        | -             | Not required since MCW-2222 SL is not intended for use in seed treatment.  | -       | -         | -                        |
| Distribution to seed (KCP 2.10.2) | -                        | -             | Not required since MCW-2222 SL is not intended for use in seed treatment.  | -       | -         | -                        |
| Other/special studies (KCP 2.11)  | -                        | -             | -  | -       | -         | -                        |

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

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

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

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

|                   |   |
|-------------------|---|
| Comments of zRMS: | The accelerated and ambient stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging (HDPE). |
|-------------------|---|

A three-year storage stability study was carried out in commercial containers (1 L HDPE bottles) at 20 °C. No changes were observed in the product formulation and no evidence of corrosion of the packaging material was observed during the course of the study (see KCP 2.7.5/01 and KCP 2.7.5/02) indicating good compatibility of the product with its packaging.

In addition, an 8-week accelerated storage stability study was carried out in commercial containers (1 L HDPE bottles) at 40 °C. No changes were observed in the product formulation and no evidence of corrosion of the packaging material was observed during the course of the study (see KCP 2.7.2/01) indicating good compatibility of the product with its packaging.

**Table 4.1-1: Packaging information for 1 L Mobilak generic Bottle (KCP 4.4/01)**

| Type                   | Description   |
|------------------------|---|
| Material:              | HDPE  |
| Shape/size:            | Cylindrical, Ø approx. 90 mm, 240 mm high.<br>Brimful capacity: 1.2 L<br>Minimum wall thickness: 0.9 mm |
| Opening:               | 38 mm inner diameter  |
| Closure:               | HDPE screw cap  |
| Seal:                  | PET+EPE+PET   |
| Manner of construction | Blow-moulded  |
| UN/ADR                 | Compliant (1H1/Y1.4/150/xx/IL/ML/2015232)   |

**Table 4.1-2: Packaging information for 1 L Mobilak branded Bottle (KCP 4.4/02)**

| Type                   | Description  |
|------------------------|--|
| Material:              | HDPE   |
| Shape/size:            | Rectangular bottle, approx. 94.3 mm x 77.3 mm, 207.5 mm high.<br>Brimful capacity: 1.140 L<br>Minimum wall thickness: 0.9 mm |
| Opening:               | 53 mm inner diameter   |
| Closure:               | HDPE screw cap   |
| Seal:                  | PET+EPE+PET  |
| Manner of construction | Blow-moulded   |
| UN/ADR                 | Compliant (3H1/Y1.4/150/XX/IL/ML/2021032)  |

**Table 4.1-3: Packaging information for 1 L Pachmas generic Bottle (KCP 4.4/03)**

| Type        | Description   |
|-------------|---|
| Material:   | HDPE  |
| Shape/size: | Cylindrical, approx. 90 mm, 240 mm high.<br>Brimful capacity: 1.180 L<br>Minimum wall thickness: 0.9 mm |
| Opening:    | 38 mm inner diameter  |
| Closure:    | HDPE screw cap  |
| Seal:       | PET+EPE+PET   |

| Type                   | Description                             |
|------------------------|---|
| Manner of construction | Blow-moulded                            |
| UN/ADR                 | Compliant (3H1/Y1.5/150/xx/IL/PMI 0933) |

**Table 4.1-4: Packaging information for 1 L Pachmas branded Bottle (KCP 4.4/04)**

| Type                   | Description  |
|------------------------|--|
| Material:              | HDPE   |
| Shape/size:            | Rectangular bottle, approx. 94.3 mm x 77.3 mm, 207.5 mm high.<br>Brimful capacity: 1.140 L<br>Minimum wall thickness: 0.9 mm |
| Opening:               | 52.5 mm inner diameter   |
| Closure:               | HDPE screw cap   |
| Seal:                  | PET+EPE+PET  |
| Manner of construction | Blow-moulded   |
| UN/ADR                 | Compliant (3H1/Y1.6/150/xx/IL/PMI2021044)  |

**Table 4.1-5: Packaging information for 1 L Reyde Bottle (KCP 4.4/05)**

| Type                   | Description   |
|------------------------|---|
| Material:              | HDPE  |
| Shape/size:            | Square bottle, approx. 94.3 mm x 77.3 mm, 207.5 mm high.<br>Brimful capacity: 1.140 L<br>Minimum wall thickness: 1 mm |
| Opening:               | 52.5 mm inner diameter  |
| Closure:               | HDPE screw cap  |
| Seal:                  | PET+EPE+PET   |
| Manner of construction | Blow-moulded  |
| UN/ADR                 | Compliant   |

**Table 4.1-6: Packaging information for 5 L Reyde Jerrycan (KCP 4.4/06)**

| Type                   | Description   |
|------------------------|---|
| Material:              | HDPE  |
| Shape/size:            | Jerrycan, approx. 190 mm x 140 mm, 303 mm high.(neck height)<br>Brimful capacity: 5.7 L<br>Minimum wall thickness: 0.7 mm |
| Opening:               | 52.5 mm inner diameter  |
| Closure:               | HDPE screw cap  |
| Seal:                  | PET+EPE+PET   |
| Manner of construction | Blow-moulded  |
| UN/ADR                 | Compliant (3H1/Y1,5/150/XX/E/J-3034/AA3)  |

**Table 4.1-7: Packaging information for 5 L Pachmas Jerrycan (KCP 4.4/07)**

| Type                   | Description   |
|------------------------|---|
| Material:              | HDPE  |
| Shape/size:            | Jerrycan, approx. 190 mm x 140 mm, 305 mm high. (medium height, neck is 303 handle is 307)<br>Brimful capacity: 5.7 L<br>Minimum wall thickness: 0.7 mm |
| Opening:               | 57.8 mm outer diameter  |
| Closure:               | HDPE screw cap  |
| Seal:                  | PET+EPE+PET   |
| Manner of construction | -   |
| UN/ADR                 | Compliant (3H1/Y1.5/150/XX/IL/PMI2017441)   |

**Table 4.1-8: Packaging information for 5 L Mobilak Jerrycan (KCP 4.4/08)**

| Type                   | Description  |
|------------------------|--|
| Material:              | HDPE   |
| Shape/size:            | Jerrycan, approx. 190 mm x 140 mm, 305 mm high. (medium height, neck is 303 handle is 307)<br>Brimful capacity: 5.75 L<br>Minimum wall thickness: 0.6 mm |
| Opening:               | 53.3 mm inner diameter   |
| Closure:               | HDPE screw cap   |
| Seal:                  | PET+EPE+PET  |
| Manner of construction | -  |
| UN/ADR                 | Compliant (3H1/Y1.5/150/XX/IL/ML/2018579)  |

**Table 4.1-9: Packaging information for 10 L Reyde Jerrycan (KCP 4.4/09)**

| Type                   | Description   |
|------------------------|---|
| Material:              | HDPE  |
| Shape/size:            | Jerrycan, approx. 227 mm x 157 mm, 400.8 mm high.<br>Brimful capacity: 11.300 L<br>Minimum wall thickness: 0.7 mm |
| Opening:               | 52.5 mm inner diameter  |
| Closure:               | HDPE screw cap  |
| Seal:                  | PET+EPE+PET   |
| Manner of construction | Blow-moulded  |
| UN/ADR                 | Compliant   |

**Table 4.1-10: Packaging information for 10 L Pachmas Jerrycan (KCP 4.4/10)**

| Type                   | Description   |
|------------------------|---|
| Material:              | HDPE  |
| Shape/size:            | Jerrycan, approx. 227 mm x 157 mm, 402 mm high.<br>Brimful capacity: 11.300 L<br>Minimum wall thickness: 0.6 mm |
| Opening:               | 58 mm outer diameter  |
| Closure:               | PE screw cap  |
| Seal:                  | PET+EPE+PET   |
| Manner of construction | Blow-moulded  |

| Type   | Description                                |
|--------|--|
| UN/ADR | Compliant (3H1/Y1.6/160/XX/IL/PMI 2020002) |

**Table 4.1-11: Packaging information for 10 L Mobilak Jerrycan (KCP 4.4/11)**

| Type                   | Description   |
|------------------------|---|
| Material:              | HDPE  |
| Shape/size:            | Jerrycan, approx. 227 mm x 157 mm, 401 mm high.<br>Brimful capacity: 11.300 L<br>Minimum wall thickness: 0.6 mm |
| Opening:               | 58 mm outer diameter  |
| Closure:               | PE screw cap  |
| Seal:                  | PET+EPE+PET   |
| Manner of construction | Blow-moulded  |
| UN/ADR                 | Compliant)<br>(3H1/Y1.6/150/XX/IL/ML 2020056)   |

All containers are neither refillable nor returnable.



## **Reference list**

EFSA, 2016: EFSA Journal 2016;14(11):4610, 1-77, Peer review of the pesticide risk assessment of the active substance acetamiprid.

## 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 company)<br>GLP or GEP status<br>Published or not  | Vertebrate study<br>Y/N | Owner                             |
|--------------|------------|-------|--|-------------------------|-----------------------------------|
| KCP 1.4.3/01 | Anonymous  | 2020  | Safety Data Sheet – Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH) Annex II<br>Acetamiprid 200 SL<br>ADAMA Makhteshim Ltd<br>Beer Sheva, Israel<br>Non-GLP<br>Published  | N                       | ADAMA Makhteshim Ltd.             |
| KCP 2.1/01   | Walter, D. | 2014a | Physical and chemical properties of MCW-2222 before and after accelerated storage at 40° C for 8 weeks<br>Report No S13-03100<br>Sponsor's study No R-33406<br>Eurofins Agrosience Services, EcoChem GmbH,<br>Niefern-Öschelbronn, Germany<br>GLP<br>Unpublished       | N                       | ADM*                              |
| KCP 2.1/02   | Walter, D. | 2015  | Physical and chemical properties of MCW-2222 over 2 years at 20°C<br>Report No S13-03102<br>Sponsor's study No R-33408<br>Eurofins Agrosience Services, EcoChem GmbH / Eurofins Agrosience Services Ecotox GmbH,<br>Niedern-Öschelbronn, Germany<br>GLP<br>Unpublished | Y                       | ADM*                              |
| KCP 2.1/03   | Walter, D. | 2016  | Physico-chemical properties of MCW-2222 over 3 years at 20 °C<br>Report No S15-05766<br>Sponsor's study No R-36824<br>Eurofins Agrosience Services, EcoChem GmbH / Eurofins Agrosience Services Ecotox GmbH,<br>Niefern-Öschelbronn, Germany<br>GLP<br>Unpublished     | N                       | ADAMA Agricultural Solutions Ltd. |
| KCP 2.2.1/01 | Krack, M.  | 2013a | MCW-2222, Explosive Properties A.14.<br>Report No 20130274.01<br>Sponsor's study No R-33398<br>SIEMENS, Prozess-Sicherheit,<br>Frankfurt am Main, Germany  | N                       | ADM*                              |

| <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> |
|--|------------------|-------------|--|-------------------------------------|--------------|
|  |                  |             | GLP<br>Unpublished   |                                     |              |
| KCP<br>2.2.2/01<br>filed under<br>Part C | Walter, D.       | 2014b       | Statement about Oxidizing Properties of MCW-2222<br>Report No S13-03094<br>Sponsor's study No R-33400<br>Eurofins Agrosience Services, EcoChem GmbH,<br>Niefern-Öschelbronn, Germany<br>Non GLP<br>Unpublished | N                                   | ADM*         |
| KCP<br>2.3.1/01                          | Walter, D.       | 2014c       | Flash Point of MCW-2222<br>Report No S13-03095<br>Sponsor's study No R-33401<br>Eurofins Agrosience Services, EcoChem GmbH,<br>Niefern-Öschelbronn, Germany<br>GLP<br>Unpublished                              | N                                   | ADM*         |
| KCP<br>2.3.3/01                          | Krack, M.        | 2013b       | MCW-2222, Auto-Ignition Temperature (Liquids and Gases) A.15.<br>Report No 20130274.02<br>Sponsor's study No R-33399<br>SIEMENS, Prozess-Sicherheit,<br>Frankfurt am Main, Germany<br>GLP<br>Unpublished       | N                                   | ADM*         |
| KCP<br>2.4.2/01                          | Walter, D.       | 2014a       | Sponsor's study No R-33406<br>Filed under KCP 2.1/01   | N                                   | ADM*         |
| KCP<br>2.4.2/02                          | Hemm, C.         | 2022        | Statement on S13-03100<br>Eurofins Agrosience Services, EcoChem GmbH,<br>Niefern-Öschelbronn, Germany<br>GLP<br>Unpublished  | N                                   | ADM*         |
| KCP<br>2.4.2/03                          | Walter, D.       | 2015        | Sponsor's study No R-33408<br>Filed under KCP 2.1/02   | N                                   | ADM*         |

| <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>                            |
|-------------------|---------------------------------|-------------|---|-------------------------------------|---|
| KCP<br>2.4.2/04   | Koch, A.                        | 2017        | Statement on S13-03102<br>Eurofins Agroscience Services, EcoChem GmbH,<br>Niefern-Öschelbronn, Germany<br>GLP<br>Unpublished  | N                                   | ADM*                                    |
| KCP<br>2.4.2/05   | Walter, D.                      | 2016        | Sponsor's study No R-36824<br>Filed under KCP 2.1/03  | N                                   | ADAMA<br>Agricultural<br>Solutions Ltd. |
| KCP<br>2.5.1/01   | Walter, D.                      | 2014d       | Viscosity of MCW-2222<br>Report No S13-03096<br>Sponsor's study No R-33402<br>Eurofins Agroscience Services, EcoChem GmbH,<br>Niefern-Öschelbronn, Germany<br>GLP<br>Unpublished        | N                                   | ADM*                                    |
| KCP<br>2.5.2/01   | Walter, D.                      | 2014e       | Surface tension of MCW-2222<br>Report No. S13-03097<br>Sponsor's study No R-33403<br>Eurofins Agroscience Services, EcoChem GmbH,<br>Niefern-Öschelbronn, Germany<br>GLP<br>Unpublished | N                                   | ADM*                                    |
| KCP<br>2.6.2/01   | Walter, D.                      | 2014f       | Relative Density of MCW-2222<br>Report No S13-03098<br>Sponsor's study No R-33404<br>Eurofins Agroscience Services, EcoChem GmbH,<br>Niefern-Öschelbronn, Germany<br>GLP<br>Unpublished | N                                   | ADM*                                    |
| KCP<br>2.7.2/01   | Walter, D.,                     | 2014a       | Sponsor's study No R-33406<br>Filed under KCP 2.1/01  | N                                   | ADM*                                    |
| KCP<br>2.7.4/01   | Deierling, T. &<br>Herrmann, S. | 2014        | Determination of the Low Temperature Stability of MCW-2222<br>Report No 91841204<br>Sponsor's study No R-34771<br>IBACON GmbH,  | N                                   | ADM*                                    |

| <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>                            |
|-------------------|------------------|-------------|--|-------------------------------------|---|
|                   |                  |             | Rossdorf, Germany<br>GLP<br>Unpublished  |                                     |   |
| KCP<br>2.7.5/01   | Walter, D.       | 2015        | Sponsor's study No R-33408<br>Filed under KCP 2.1/02   | N                                   | ADM*                                    |
| KCP<br>2.7.5/02   | Walter, D.       | 2016        | Sponsor's study No R-36824<br>Filed under KCP 2.1/03   | N                                   | ADAMA<br>Agricultural<br>Solutions Ltd. |
| KCP<br>2.8.2/01   | Tsesin, N.       | 2018        | Persistent foam test of formulation product Acetamiprid 200 SL (MCW-2222)<br>Report No 40400.029FL<br>Sponsor's study No R-40400<br>Registration Laboratory, Research and Development Division, Adama Makhteshim Ltd.,<br>Beer-Sheva, Isreal<br>GLP<br>Unpublished | N                                   | ADAMA<br>Makhteshim<br>Ltd.             |
| KCP<br>2.8.2/02   | Walter, D.       | 2014a       | Sponsor's study No R-33406<br>Filed under KCP 2.1/01   | N                                   | ADM*                                    |
| KCP<br>2.8.2/03   | Walter, D.       | 2015        | Sponsor's study No R-33408<br>Filed under KCP 2.1/02   | N                                   | ADM*                                    |
| KCP<br>2.8.2/04   | Walter, D.       | 2016        | Sponsor's study No R-36824<br>Filed under KCP 2.1/03   | N                                   | ADAMA<br>Agricultural<br>Solutions Ltd. |
| KCP<br>2.8.4/01   | Walter, D.       | 2014a       | Sponsor's study No R-33406<br>Filed under KCP 2.1/01   | N                                   | ADM*                                    |
| KCP<br>2.8.4/02   | Walter, D.       | 2015        | Sponsor's study No R-33408<br>Filed under KCP 2.1/02   | N                                   | ADM*                                    |
| KCP<br>2.8.4/03   | Walter, D.       | 2016        | Sponsor's study No R-36824<br>Filed under KCP 2.1/03   | N                                   | ADAMA<br>Agricultural                   |

| <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>              |
|-------------------|------------------|-------------|--|-------------------------------------|---------------------------|
|                   |                  |             |  |                                     | Solutions Ltd.            |
| KCP<br>2.9.1/01   | Thomas, H.       | 2022        | Evaluation of the Physical and Chemical Compatibility of Tank Mixtures of ADM.00150.I.2.A<br>Report No 22 35 CRX 0007<br>Sponsor's study No 000110777<br>BioChem agrar, Labor für biologische und chemische Analytik GmbH<br>Machern OT Gerichshain, Germany<br>GLP<br>Unpublished | N                                   | ADM*                      |
| KCP<br>2.9.1/02   | Abohezira, L.    | 2022        | CoA for Batch no. 41190054<br>ADAMA Makhteshim Ltd.<br>Be'er Sheva, Israel<br>Non-GLP<br>Unpublished   | N                                   | ADM*                      |
| KCP<br>2.9.2/01   | Thomas, H.       | 2022        | Sponsor's study No 000110777<br>Filed under KCP 2.9.1/01   | N                                   | ADM*                      |
| KCP<br>2.9.2/02   | Abohezira, L.    | 2022        | CoA for Batch no. 41190054<br>Filed under KCP 2.9.1/02   | N                                   | ADM*                      |
| KCP 4.4/01        | Anonymous        | 2015        | Packaging specification 1 L Mobilak no brand bottle  | N                                   | Mobilak                   |
| KCP 4.4/02        | Anonymous        | 2021        | Packaging specification 1 L Mobilak branded bottle   | N                                   | Mobilak                   |
| KCP 4.4/03        | Anonymous        | 2019        | Packaging specification 1 L Pachmas no brand bottle  | N                                   | Pachmas<br>packaging Ltd. |
| KCP 4.4/04        | Anonymous        | 2022        | Packaging specification 1 L Pachmas branded bottle   | N                                   | Pachmas<br>packaging Ltd. |
| KCP 4.4/05        | Anonymous        | 2020        | Packaging specification 1 L Reyde Bottle   | N                                   | Reyde S.A.                |
| KCP 4.4/06        | Anonymous        | 2019        | Packaging specification 5 L Reyde Jerrycan   | N                                   | Reyde S.A.                |
| KCP 4.4/07        | Anonymous        | 2017        | Packaging specification 5 L Pachmas Jerrycan   | N                                   | Pachmas<br>packaging Ltd. |
| KCP 4.4/08        | Anonymous        | 2018        | Packaging specification 5 L Mobilak Jerrycan   | N                                   | Mobilak                   |
| KCP 4.4/09        | Anonymous        | 2019        | Packaging specification 10 L Reyde Jerrycan  | N                                   | Reyde S.A.                |
| KCP 4.4/10        | Anonymous        | 2023        | Packaging specification 10 L Pachmas Jerrycan  | N                                   | Pachmas                   |

| 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<br>study<br>Y/N | Owner          |
|------------|-----------|------|---|----------------------------|----------------|
|            |           |      |   |                            | packaging Ltd. |
| KCP 4.4/11 | Anonymous | 2020 | Packaging specification 10 L Mobilak Jerrycan   | N                          | Mobilak        |

\* ADM Makhteshim Ltd. member of ADAMA Agricultural Solutions

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

Not applicable.

**List of data submitted by the applicant and not 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<br>study<br>Y/N | Owner |
|------------|-----------|------|---|----------------------------|-------|
| -          | -         | -    | -   | -                          | -     |

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

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

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

**A 2.1            Acetamiprid**

Not applicable.