

# 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: FGG01

Product name: Lozzare Pro, Miller Pro, Palator Pro

Chemical active substance:

Boscalid, 500 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

## CORE ASSESSMENT

(Article 33 application for a new product registration)

Applicant: UPL Holdings Coöperatief U.A

Submission date: 08/05/2024

MS Finalisation date: 11/2024, 02/2025

## Version history

| When        | What  |
|-------------|---|
| 08 May 2024 | V0 – Version from applicant for submission to z-RMS Poland in the frame of the PPP Authorization according to Article 33 of Regulation (EC) No 1107/2009. |
| 11.2024     | zRMS first evaluation   |
| 02.2025     | zRMS post-commentary fRR  |
|             |   |

## 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) .....  | 4         |
| 1.2.3             | Statement of purity (and detailed information on impurities) of the active substance(s) .....                       | 4         |
| 1.2.3.1           | Boscalid.....   | 4         |
| 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).....   | 5         |
| 1.4.3             | Information on safeners, synergists and co-formulants (KCP 1.4.3).....  | 6         |
| 1.5               | Type and code of the plant protection product (KCP 1.5).....  | 6         |
| 1.6               | Function (KCP 1.6) .....  | 6         |
| <b>2</b>          | <b>Section 2: Physical, chemical and technical properties of the plant protection product .....</b>                 | <b>7</b>  |
| <b>3</b>          | <b>Section 3 is presented as a separate document .....</b>  | <b>18</b> |
| <b>4</b>          | <b>Section 4: Further information on the plant protection product .....</b>   | <b>19</b> |
| 4.1               | Safety intervals and other precautions to protect humans, animals and the environment (KCP 4.1) .....               | 19        |
| 4.2               | Recommended methods and precautions (KCP 4.2) .....   | 19        |
| 4.3               | Emergency measures in the case of an accident (KCP 4.3).....  | 21        |
| 4.4               | Packaging and Compatibility with the Preparation (KCP 4.4) .....  | 22        |
| 4.5               | Procedures for the destruction or decontamination of the plant protection product and its packaging (KCP 4.5) ..... | 25        |
| <b>Appendix 1</b> | <b>Lists of data considered in support of the evaluation .....</b>  | <b>27</b> |
| <b>Appendix 2</b> | <b>Additional data on the physical, chemical and technical properties of the active substance.....</b>              | <b>31</b> |
| A 2.1             | Boscalid.....   | 31        |

**zRMS comment:**

Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance.  
Noticed data gaps are – 2 years study

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

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

Name: UPL Holdings Coöperatief U.A  
Address: Claudius Prinsenlaan 144a, Blok A, 4818CP Breda,  
The Netherlands

Contact person: [REDACTED]  
[REDACTED]  
[REDACTED]

### **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 Boscalid**

Boscalid

min 960 g/kg (Directive 2008/44/EC)  
min 980 g/Kg (UPL source)

Boscalid does not contain impurities of toxicological, ecotoxicological or environmental concern.

Further information/justification is provided in Part C.

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

Trade name: LOZZARE PRO. Please refer also to Registration Report Part A for more details

Company code number: FGG01

### 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**

| Active substance | Declared content of the pure active substance / variant (g/L or g/kg) | FAO Limits (min – max) | Technical content* (g/kg) | Technical content** (% w/w) |
|------------------|---|------------------------|---------------------------|-----------------------------|
| Boscalid         | 500 g/kg  | 475-525 g/kg           | 510.2 g/kg                | 51.02%                      |

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

The preparation is not the representative formulation evaluated for the inclusion of the active substance Boscalid. Therefore, physico chemical properties were provided for this preparation.

No safener or synergist is used in the formulation.

FGG01 is a WG formulation containing 500 g/kg of Boscalid.

There are no relevant impurities in the formulation.

Further information on the active substance and on the certified limits of formulants is considered confidential and is provided separately (Part C).

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

**Table 1.4-2: Information on Boscalid**

| Type            | Name/Code Number |
|-----------------|------------------|
| ISO common name | Boscalid         |
| CAS No.         | 188425-85-6      |
| EC No.          | 606-143-0        |
| CIPAC No.       | 673              |

Please refer also to the Safety Data Sheet of the active ~~smn-vexz~~ substance (KCP 1.4.2/01)

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

The formulation does not contain any safeners or synergists.

CONFIDENTIAL information is provided separately (Part C).

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

Type: Water dispersible granules

[Code: WG]

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

Fungicide.

## 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 brown granules having a characteristic odour. It is not explosive and has no oxidising properties. The product is not flammable. It has a self-ignition temperature of greater than 139°C. In aqueous solution, it has a pH value around 4.75 at 20°C. There is no effect of high temperature on the stability of the formulation, since after 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 Trilaminated Aluminium Pouch packaging material (same composition as the commercial container). Results are available after 1 year storage (237-2-11-31229 (Interim Report-I) and the 2 years shelf-life final report will be provided as soon as possible. Its technical characteristics are acceptable for a WG formulation.

The intended concentration of use is 0.02% to 1% w/v.

The product is not intended to be mixed in the tank.

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

| Classification according to | DPD<br>(Directive 67/845/EEC) | CLP<br>(Regulation (EC) No 1272/2008) |
|-----------------------------|-------------------------------|---------------------------------------|
|                             | Hazard symbol(s)              | Pictograms                            |
|                             | Not required to be provided   | None                                  |
|                             | Indications of danger         | Signal word                           |
|                             | Not required to be provided   | None                                  |
|                             |                               | Hazard class and hazard category      |
|                             |                               | None                                  |

No implication for labelling

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

| With respect to physical/chemical data | Risk phrases:               | Hazard statements:       |
|--|-----------------------------|--------------------------|
|  | Not required to be provided | Not classified           |
|  | Safety phrases:             | Precautionary statements |
|  | Not required to be provided | None                     |

### Compliance with FAO specifications:

The product FGG01 complies with FAO specifications of the respective formulation type.

### Formulation used for tests

All tests have been conducted with the preparation FGG01.

**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<br>OPPTS 830.6303<br>OPPTS 830.6304 | FGG01<br>Boscalid 500 g/Kg WG<br>Lot No. ARD/BD364/50/WG/0422/59<br>Content: 513.34 ± 0.40 g/kg | Brown granules having characteristic odour   | Y       | Chaudhari, M.N. 2022a (UPL/2022/0952)   | Accepted   |
| Explosive properties (KCP 2.2.1)    | Theoretical justification                          | FGG01<br>Boscalid 500 g/Kg WG   | Based on theoretical evaluation of the product Boscalid 500 WG/FGG01, it can be concluded that the formulation has no explosive properties. No testing of the explosive properties according to UN RTDG or Regulation (EC) No. 440/2008 is required, and the formulation does not need to be classified as “explosive” according to the CLP Regulation.  | N       | García Carril, A.M. 2024<br>Confidential information, please refer to Part C for the reference. | Accepted<br><br>Based on the justification and the composition of the preparation, explosive properties are not expected |
| Oxidizing properties (KCP 2.2.2)    | EC A.17  | FGG01<br>Boscalid 500 g/Kg WG<br>Lot No. ARD/BD364/50/WG/0422/59<br>Content: 513.34 ± 0.40 g/kg | Preliminary test:<br><br>The burning time of mixtures of the test item with cellulose (2:1) is higher than the burning time of the reference mixture of barium bromate with cellulose (6:4), therefore the test item is <b>Non-Oxidising in Nature</b> , and no further testing was required to be carried out.<br>Since the product does not need to be classified as oxidizing, no UN test method is required. | Y       | Chaudhari, M.N. 2022a (UPL/2022/0952)   | Accepted<br><br>Oxidizing properties are not expected  |
| Flash point (KCP 2.3.1)             | -  | -   | Not required for WG formulation  | -       | -   | -  |
| Flammability                        | EC A.10  | FGG01   | Preliminary screening test: the test item FGG01  | Y       | Chaudhari, M.N.   | Accepted   |



| Annex point   | Method used / deviations | Test material  | Findings  | GLP Y/N | Reference                             | Acceptability / comments   |
|---|--------------------------|--|---|---------|---------------------------------------|--|
| (KCP 2.3.2)   |                          | Boscalid 500 g/Kg WG<br>Lot No. ARD/BD364/50/WG/0422/59<br>Content: 513.34 ± 0.40 g/kg | could not be ignited applying a flame as ignition source for at least 2 minutes.<br>Therefore, in view of the above preliminary screening test, FGG01 was considered as ' <b>Not-Highly Flammable (Non-Flammable)</b> ', and no further testing (burning rate test) was needed to be carried out.<br>Since no positive result as a flammable mixture was obtained with EC method, no additional UN test method is required. |         | 2022a (UPL/2022/0952)                 | Considered non-flammable   |
| Self-heating (KCP 2.3.3)  | EC A.16                  | Boscalid 500 g/Kg WG<br>Lot No. ARD/BD364/50/WG/0422/59<br>Content: 513.34 ± 0.40 g/kg | DSC screening:<br>The relative self-ignition temperature of the test item was concluded to be greater than 139°C and the test material does not relatively self-ignite below its melting temperature.<br>Since no positive result was obtained as a shelf-heating mixture with the EC method, no additional UN test method is required.   | Y       | Chaudhari, M.N. 2022a (UPL/2022/0952) | Accepted<br><br>The formulation should not be classified as auto-flammable solid |
| Acidity or alkalinity and pH (KCP 2.4.1)                        | -                        | -  | Please refer to point 2.4.2   | -       | -                                     | As pH is > 4, the acidity test was not performed                                 |
| pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2) | CIPAC MT 75.3            | Boscalid 500 g/Kg WG<br>Lot No. ARD/BD364/50/WG/0422/59<br>Content: 513.34 ± 0.40 g/kg | After 1 Minute: 4.76 at 20.0°C<br>After 2 Minutes: 4.74 at 20.0°C   | Y       | Chaudhari, M.N. 2022a (UPL/2022/0952) | Accepted   |
| Viscosity (KCP 2.5.1)   | -                        | -  | Not applicable for WG formulations.   | -       | -                                     | -  |
| Surface tension (KCP 2.5.2)                                     | -                        | -  | Not applicable for WG formulations.   | -       | -                                     | -  |

| Annex point   | Method used / deviations   | Test material  | Findings  | GLP Y/N | Reference                                  | Acceptability / comments  |
|---|--|--|---|---------|--|---|
| Relative density (KCP 2.6.1)  | -  | -  | Not applicable for WG formulations.   | -       | -  | -   |
| Bulk density (KCP 2.6.2)  | CIPAC MT 186   | Boscalid 500 g/Kg WG<br>Lot No. ARD/BD364/50/WG/0422/59<br>Content: 513.34 ± 0.40 g/kg | Pour Density: 0.5786 ± 0.0029 g/mL<br>Tap Density: 0.5999 ± 0.0032 g/mL   | Y       | Chaudhari, M.N. 2022a (UPL/2022/0952)      | Accepted  |
| Storage Stability after 14 days at 54°C (KCP 2.7.1)                       | CIPAC MT 46.4<br><br>Analytical method validated in Part B5 (JRF Study Number: 228-2-12-31215) | Boscalid 500 g/Kg WG<br>Lot No. ARD/BD364/50/WG/0422/59<br>Content: 513.34 ± 0.40 g/kg | Accelerated storage stability of the test substance was tested by storing the test substance Boscalid 500 g/Kg WG in a tri-laminated Aluminium pouch (provided by Sponsor) containing 1000 g test item at 54 ± 2°C for 14 days. On completion of storage the test substance was tested for appearance (colour, physical state, and odour), pH, active ingredient content, wet sieve test, suspensibility, wettability, dispersibility, dust content, attrition resistance, and particle size distribution with the same methods used as before storage. The test item was also found to be non-corrosive to the tri-laminated aluminium pouch while in storage, with respect to the parameters tested.<br><br>See Table 2-2 for a summary of before and after parameter measurements. | Y       | Chaudhari, M.N. 2022b (UPL/2022/0952 0951) | Accepted<br><br>Commercial packaging used (tri-laminated pouch)<br><br>A.s. decrease after storage: 0.23%. The preparation and the packaging remained stable and were not adversely affected by the accelerated temperature.<br><br>For details, see Table 2-2 below. |
| Stability after storage for other periods and/or temperatures (KCP 2.7.2) | -  | -  | Please refer to point 2.7.1   | -       | -  | See KCP 2.7.1   |
| Minimum content after   | -  | -  | Please refer to point 2.7.1   | -       | -  | See KCP 2.7.1   |

| Annex point   | Method used / deviations   | Test material  | Findings  | GLP Y/N | Reference                      | Acceptability / comments   |
|---|--|--|---|---------|--------------------------------|--|
| heat stability testing (KCP 2.7.3)                  |  |  |   |         |                                |  |
| Effect of low temperatures on stability (KCP 2.7.4) | -  | -  | Not applicable for WG formulation   | -       | -                              | -  |
| Ambient temperature shelf life (KCP 2.7.5)          | CLI Technical Monograph 1, 3 <sup>rd</sup> edition<br>OCSPP 830.6320<br>OCSPP 830.6317 | Boscalid 500 g/Kg WG<br>Lot No. ARD/BD364/50/WG/0422/59<br>Content: 513.34 ± 0.40 g/kg | On going study.<br>See Table 2-3 for a summary of before and after 1 year storage parameter measurements. | Y       | Patel, D. 2024 (UPL/2022/2092) | 1 year study – accepted<br><br>Commercial packaging used (tri-laminated pouch)<br><br>A.s. increase after storage: 0.14%. The preparation and the packaging remained stable and were not adversely affected by the accelerated temperature.<br><br>For details, see Table 2-3 below.<br><br>2-years study – data gap. The study is expected to be completed by mid-2025. A provisional authorisation for 2 years is possible and proposed. |
| Shelf life in months (if less than 2 years)         | -  | -  | Please refer to point 2.7.5   | -       | -                              | See KCP 2.7.5  |

| Annex point                        | Method used / deviations | Test material  | Findings  | GLP Y/N | Reference                             | Acceptability / comments |
|------------------------------------|--------------------------|--|---|---------|---------------------------------------|--------------------------|
| (KCP 2.7.6)                        |                          |  |   |         |                                       |                          |
| Wettability (KCP 2.8.1)            | CIPAC MT 53.3.1          | Boscalid 500 g/Kg WG<br>Lot No. ARD/BD364/50/WG/0422/59<br>Content: 513.34 ± 0.40 g/kg | 33s (without swirling in CIPAC water D)   | Y       | Chaudhari, M.N. 2022a (UPL/2022/0952) | Accepted                 |
| Persistence of foaming (KCP 2.8.2) | CIPAC MT 47.3            | Boscalid 500 g/Kg WG<br>Lot No. ARD/BD364/50/WG/0422/59<br>Content: 513.34 ± 0.40 g/kg | Minimum dose (0.02% w/v, CIPAC water D):<br>- Initial Volume: 7.1 mL<br>- 1 Minutes ± 10 Seconds: 0.0 mL<br>- 12 Minutes ± 10 Seconds: 0.0 mL<br><br>Maximum Dose (1% w/v, CIPAC water D):<br>- Initial Volume: 56.8 mL<br>- 1 Minutes ± 10 Seconds: 11.8 mL<br>- 12 Minutes ± 10 Seconds: 0.0 mL   | Y       | Chaudhari, M.N. 2022a (UPL/2022/0952) | Accepted                 |
| Suspensibility (KCP 2.8.3.1)       | CIPAC MT 184.1           | Boscalid 500 g/Kg WG<br>Lot No. ARD/BD364/50/WG/0422/59<br>Content: 513.34 ± 0.40 g/kg | 0.1% of total volume*:<br>92.47%<br><br>Maximum Dose (1% w/v, CIPAC water D)::<br>94.66%<br><br>Performed at 30°C<br><br>*Note: As the minimum recommended dose quantity is very low [0.05 g (calculated from the minimum recommended dose of 0.2 kg of product in 1000 L water/ha)], as per CIPAC MT 184.1 (Note 1), experiment should be performed at 0.1% of total volume (if suspended matter is less than 0.1%). | Y       | Chaudhari, M.N. 2022a (UPL/2022/0952) | Accepted                 |

| Annex point   | Method used / deviations     | Test material  | Findings  |                |       | GLP Y/N | Reference                             | Acceptability / comments |
|---|------------------------------|--|---|----------------|-------|---------|---------------------------------------|--------------------------|
| Spontaneity of dispersion (KCP 2.8.3.2)                                     | CIPAC MT 174                 | Boscalid 500 g/Kg WG<br>Lot No. ARD/BD364/50/WG/0422/59<br>Content: 513.34 ± 0.40 g/kg | The active substance spontaneity of dispersion was 99.34% (for 1% w/v)                      |                |       | Y       | Chaudhari, M.N. 2022a (UPL/2022/0952) | Accepted                 |
| Dispersion stability (KCP 2.8.3.3)  | -                            | -  | Not applicable for WG formulations  |                |       | -       | -                                     | -                        |
| Degree of dissolution and dilution stability (KCP 2.8.4)                    | -                            | -  | Not applicable for WG formulations  |                |       | -       | -                                     | -                        |
| Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1) | CIPAC MT 187<br>CIPAC MT 166 | Boscalid 500 g/Kg WG<br>Lot No. ARD/BD364/50/WG/0422/59<br>Content: 513.34 ± 0.40 g/kg | Particle size (µm):<br>0.59 µm d(0.1) [10%], 5.17 µm d(0.5) [50%] and 12.33 µm d(0.9) [90%] |                |       | Y       | Chaudhari, M.N. 2022a (UPL/2022/0952) | Accepted                 |
| Wet sieve test (KCP 2.8.5.1.2)  | CIPAC MT 185                 | Boscalid 500 g/Kg WG<br>Lot No. ARD/BD364/50/WG/0422/59<br>Content: 513.34 ± 0.40 g/kg | Residue on 75 µm sieve: 0.05%   |                |       | Y       | Chaudhari, M.N. 2022a (UPL/2022/0952) | Accepted                 |
| Dry sieve test (KCP 2.8.5.1.3)  | CIPAC MT 170                 | Boscalid 500 g/Kg WG   | Rx1 ≥ 90%   | R1: For 125 µm | 98.93 | Y       | Patel, D. 2024 (UPL/2022/2092)        | Accepted                 |

| Annex point                              | Method used / deviations | Test material  | Findings   |                   |       | GLP Y/N | Reference                                   | Acceptability / comments                          |
|--|--------------------------|--|--|-------------------|-------|---------|---|---|
|  |                          | Lot No.<br>ARD/BD364/<br>50/WG/0422/59<br>Content:<br>513.34 ± 0.40<br>g/kg                            |  | R2: For<br>125 µm | 98.73 |         |   |   |
|  |                          |  | Rx2 ≤<br>10%)  | R1: for 355<br>µm | 9.41  |         |   |   |
|  |                          |  |  | R2: for 355<br>µm | 9.32  |         |   |   |
| Dust content<br>(KCP 2.8.5.2.1)          | CIPAC MT 171.1           | Boscalid 500<br>g/Kg WG<br>Lot No.<br>ARD/BD364/<br>50/WG/0422/59<br>Content:<br>513.34 ± 0.40<br>g/kg | Dust content (mg):<br>1.75 mg (Nearly dust-free)   |                   |       | Y       | Chaudhari, M.N.<br>2022a<br>(UPL/2022/0952) | Accepted  |
| Particle size of dust<br>(KCP 2.8.5.2.2) | -                        | -  | Not applicable as the product is considered as<br>“nearly dusty free”. Please refer to point 2.8.5.2.1 |                   |       | -       | -   | Not required, see<br>KCP 2.8.5.2.1 and<br>2.8.5.3 |
| Attrition<br>(KCP 2.8.5.3)               | CIPAC MT 178.2           | Boscalid 500<br>g/Kg WG<br>Lot No.<br>ARD/BD364/<br>50/WG/0422/59<br>Content:<br>513.34 ± 0.40<br>g/kg | The product showed good resistance to attrition:<br>99.84%   |                   |       | Y       | Chaudhari, M.N.<br>2022a<br>(UPL/2022/0952) | Accepted  |
| Hardness and integrity<br>(KCP 2.8.5.4)  | -                        | -  | Not applicable for WG formulations.  |                   |       | -       | -   | -   |
| Emulsifiability<br>(KCP 2.8.6.1)         | -                        | -  | Not applicable for WG formulations.  |                   |       | -       | -   | -   |

| Annex point   | Method used / deviations | Test material  | Findings   | GLP Y/N | Reference                             | Acceptability / comments |
|---|--------------------------|--|--|---------|---------------------------------------|--------------------------|
| Emulsion stability (KCP 2.8.6.2)                        | -                        | -  | Not applicable for WG formulations.  | -       | -                                     | -                        |
| Re-emulsifiability (KCP 2.8.6.3)                        | -                        | -  | Not applicable for WG formulations.  | -       | -                                     | -                        |
| Flowability (KCP 2.8.7.1)                               | CIPAC MT 172.2           | Boscalid 500 g/Kg WG<br>Lot No. ARD/BD364/50/WG/0422/59<br>Content: 513.34 ± 0.40 g/kg | The test item dropped through a 4.75 mm sieve spontaneously and 100% of material passed through the sieve and no material was retained on the sieve.   | Y       | Chaudhari, M.N. 2022a (UPL/2022/0952) | Accepted                 |
| Pourability (KCP 2.8.7.2)                               | -                        | -  | Not applicable for WG formulations   | -       | -                                     | -                        |
| Dustability following accelerated storage (KCP 2.8.7.3) | -                        | -  | Not applicable for WG formulations   | -       | -                                     | -                        |
| Physical compatibility of tank mixes (KCP 2.9.1)        | -                        | -  | It is not intended to apply FGG01 with other plant protection protects, therefore, no physical compatibility studies with other products are required. | -       | -                                     | -                        |
| Chemical compatibility of tank mixes (KCP 2.9.2)        | -                        | -  | It is not intended to apply FGG01 with other plant protection protects, therefore, no physical compatibility studies with other products are required. | -       | -                                     | -                        |
| Adhesion to seeds (KCP 2.10.1)                          | -                        | -  | Not applicable for WG formulations   | -       | -                                     | -                        |
| Distribution to seed (KCP 2.10.2)                       | -                        | -  | Not applicable for WG formulations   | -       | -                                     | -                        |
| Other/special studies (KCP 2.11)                        | -                        | -  | None   | -       | -                                     | -                        |

**Table 2-2: Summary of FGG01 properties before and after accelerated temperature storage (14 days at 54°C) period (Study No.: 234-2-11-31227, UPL/2022/09520951, Chaudhari, M.N. 2022b)**

| Test/method   | Measurement/parameter   |                         | Results  |   |
|---|---|-------------------------|--|---|
|   |   |                         | Before Storage   | After Storage at 54 ± 2°C for 14 Days                               |
| Visual observation  | Corrosion characteristics   | Perforation             | No   | No  |
|   |   | Distortion              | No   | No  |
|   |   | Discoloration           | No   | No  |
|   |   | Splitting at the seam   | No   | No  |
| Visual observation  | Appearance of the Commercial Container (visual) [Tri-laminated aluminium Pouch] | Shape                   | Rectangular  | Rectangular   |
|   |   | Colour                  | Silver   | Silver  |
|   |   | Crack                   | No   | No  |
| OPPTS 830.6302, 830.6303 and 830.6304                                   | Appearance  |                         | Brown coloured, Solid (Granules) with Characteristic Odour   | Brown coloured, Solid (Granules) with Characteristic Odour          |
| CIPAC MT 75.3   | pH (1% w/v Aqueous Dispersion)  | 1 Minute                | 4.82 at 20.0°C   | 4.91 at 20.1°C  |
|   |   | 2 Minute                | 4.81 at 20.0°C   | 4.91 at 20.1°C  |
| In house method validated in part B5 [JRF Study Number: 228-2-12-31215] | Active Ingredient Content   |                         | 51.32% w/w or 513.23 g/kg  | 51.20% w/w or 512.03 g/kg   |
|   |   |                         | The % loss of active ingredient after storage at a temperature of 54 ± 2°C for a period of 14 days, was 0.23%. |   |
| CIPAC MT 185  | Wet Sieve Test [Material Retained on the Sieve (%)]                             |                         | 0.04   | 0.05  |
| CIPAC MT 184.1  | Suspensibility (%)  | At 0.1% of total volume | 92.76  | 94.67   |
|   |   | Maximum                 | 94.94  | 96.07   |
| CIPAC MT 53.3.1 Without Swirling  | Wettability   |                         | 33 seconds   | 24 seconds  |
| CIPAC MT 174  | Dispersibility (%)  |                         | 99.20  | 99.38   |
| CIPAC MT 171.1 Sampling (CIPAC MT 166)                                  | Dustiness(mg)   |                         | 1.78 (Nearly dust-free)  | 1.66 (Nearly dust-free)   |
| CIPAC MT 178.2  | Attrition Resistance (%)  |                         | 100  | 99.88   |
| CIPAC MT 187 Sampling (CIPAC MT 166)                                    | Particle Size Distribution  |                         | 0.59 µm d[0.1(10%)]; 5.01 µm d[0.5(50%)]; and 12.01 µm d[0.9(90%)];  | 0.58 µm d[0.1(10%)]; 5.01 µm d[0.5(50%)]; and 12.16 µm d[0.9(90%)]; |



**Table 2-3: Summary of FGG01 properties before and after long term storage in commercial packaging (ongoing study, Study No.: 237-2-11-31229 (Interim Report-I), UPL/2022/2092, Patel D. 2024)**

| Test/method   | Measurement/parameter   |                         | Results   |   |
|---|---|-------------------------|---|---|
|   |   |                         | Before Storage  | After Storage (12 months)                                 |
| Visual observation  | Corrosion characteristics   | Perforation             | No  | No  |
|   |   | Distortion              | No  | No  |
|   |   | Discoloration           | No  | No  |
| Visual observation  | Appearance of the Commercial Container (visual) [Tri-laminated aluminium Pouch] | Splitting at the seam   | No  | No  |
|   |   | Shape                   | Rectangular   | Rectangular   |
|   |   | Colour                  | Silver  | Silver  |
|   |   | Crack                   | No  | No  |
| OPPTS 830.6302, 830.6303 and 830.6304                                   | Appearance  |                         | Brown colour solid (granules) with a characteristic odour | Brown colour solid (granules) with a characteristic odour |
| CIPAC MT 75.3   | pH (1% w/v Aqueous Dispersion)  | 1 Minute                | 4.78 at 20.1 °C   | 4.91 at 19.6 °C   |
|   |   | 2 Minute                | 4.78 at 20.2 °C   | 4.91 at 19.6 °C   |
| In house method validated in part B5 [JRF Study Number: 228-2-12-31215] | Active Ingredient Content   |                         | 48.78% w/w or 487.78 g/kg                                 | 48.85% w/w or 488.48 g/kg                                 |
| CIPAC MT 185  | Wet Sieve Test [Material Retained on the Sieve (%)]                             |                         |   |   |
| CIPAC MT 184.1  | Suspensibility (%)  | At 0.1% of total volume | 92.69   | 95.12   |
|   |   | Maximum                 | 94.64   | 94.65   |
| CIPAC MT 53.3.1 Without Swirling  | Wetting Time (Wettability)  |                         | 30  | 26  |
| CIPAC MT 174  | Dispersibility (%)  |                         | 99.46   | 100.37  |
| CIPAC MT 171.1 Sampling (CIPAC MT 166)                                  | Dustiness(mg)   |                         | 9.41 mg (Nearly dust-free)                                | 6.20 mg (Nearly dust-free)                                |
| CIPAC MT 178.2  | Attrition Resistance (%)  |                         | 99.85   | 100.00  |
| CIPAC MT 187 Sampling (CIPAC MT 166)                                    | Particle Size Distribution  | d (0.1) [10%]           | 0.58  | 0.60  |
|   |   | d (0.5) [50%]           | 5.21  | 5.23  |
|   |   | d (0.9) [90%]           | 12.67   | 12.63   |
| CIPAC MT 170 Sampling (CIPAC MT 166)                                    | Dry Sieve Test  | Rx1 ≥ 90%               | R1: For 125 µm  | 98.20   |
|   |   |                         | R2: For 125 µm  | 97.99   |
|   |   | Rx2 ≤                   | R1: for 355 µm  | 7.46  |

|  |  |      |                |      |      |
|--|--|------|----------------|------|------|
|  |  | 10%) | R2: for 355 µm | 9.32 | 8.98 |
|--|--|------|----------------|------|------|

### **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 Safety intervals and other precautions to protect humans, animals and the environment (KCP 4.1)

#### Waiting period (in days) between last application and sowing or planting succeeding crops

The recommendation from the renewal process of the active substance boscalid (Slovakia, 2018-AIR 3, RAR Volume 3CP BAS 510 01 F) is applicable to the intended formulation FGG01.

*“Boscalid has been applied since many years with several different formulations across a wide range of crops without any reports of phytotoxic effects on succeeding crops. Due to the broad range of crops, in which the product has been used, most rotational crop possibilities have been appeared in practice. Hence no negative impact on succeeding crops is expected.*

*Consequently, there is no necessity for restrictions (related an eventual phytotoxicity) in the choice of following crops, even in the event of crop failure on a field, which has been treated with BAS 510 01 F.”*

### 4.2 Recommended methods and precautions (KCP 4.2)

|                   |   |
|-------------------|---|
| Comments of zRMS: | No implications for labelling with respect to physical and chemical properties. Precautions for safe handling below are acceptable. |
|-------------------|---|

Precautions for safe handling: Ensure good ventilation of the work station. Avoid contact with skin and eyes. Avoid breathing dust. Wear personal protective equipment.

Hygiene measures: Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product.

Always wash hands after handling the product.

A study on the effectiveness of the cleaning procedures for the test substance at the recommended concentration is summarized below.

|                   |   |
|-------------------|---|
| Comments of zRMS: | Acceptable. Cleaning procedure tested is considered effective |
|-------------------|---|

|                |   |
|----------------|---|
| Reference:     | KCP 4.2/01  |
| Report         | Effectiveness of Cleaning Procedures of Boscalid 500 g/Kg WG.<br>Prajapati, P.N., 2024<br><br>JRF Study Number: 284-2-11-36679, UPL EUROPE LTD<br>(UPL/2024/0502) |
| Guideline(s):  | Pesticide Safety Directorate, 2004: Pesticide Safety Directorate (PSD) Efficacy Guideline 305 “Cleaning Application Equipment – Small scale jar test protocol”.   |
| Deviations:    | No  |
| GLP:           | No, not subject to GLP regulations  |
| Acceptability: | Yes   |

This study was performed to determine the effectiveness of cleaning procedures of Boscalid 500 g/Kg

WG. The study was conducted in compliance with the OECD Principles of GLP (1998).

#### Tank mix preparation:

A volume of 300 mL of CIPAC water D was placed into a 500 mL beaker and stirred and the appropriate amount of the product was added ( $3.6 \pm 0.1$  g test item, calculated from the maximum recommended dose of 1.2 kg product in 100 L water/ha). After 2 min of stirring, 100 mL aliquots are poured into three polyethylene bottles (about 45 mm in diameter and 90 mm high). The bottles were capped and allowed to stand for 24 hours at room temperature.

#### Tank cleaning procedure:

After 24 hours, the bottles stored above were inverted twice and shaken to re-suspend any sealed material and the tank mix were discarded.

Three procedures were performed:

- Bottle 1-Single Rinse Procedure: A volume of 10 mL tap water was added, and the bottle was inverted twice. The rinse was discarded.
- Bottle 2-Double Rinse Procedure: The rinse procedure as described for bottle-1 was performed twice for double rinse.
- Bottle 3-Triple Rinse Procedure: The rinse procedure as described for bottle-1 was performed thrice for triple rinse.

After discarding the rinse, a volume of 10 mL diluent (Acetonitrile (70): Milli-Q water (30), %v/v) was added to each of the bottles and the bottles were shaken to coat all surfaces to extract residual pesticide from the bottle surfaces and the sample were filtered through 0.45 µm nylon syringe filter and analysed by HPLC for determination of the active ingredient (a.i.) content.

The experiment was carried out in triplicate and the mean value along with standard deviation was reported.

#### Analysis

The content of the active ingredient was determined by HPLC. The analytical method was validated according to guidance SANCO/3030/99 rev.5 (22/03/2019).

Table 4.2-1: results of analytical method validation

| Parameters                                 |   |        |        | Results   |       |                      |
|--|---|--------|--------|---|-------|----------------------|
| Specificity                                | (Non-analyte Interference)                |        |        | No interference                                     |       |                      |
| LOD (mg/L) (based on S/N ratio)            |   |        |        | 0.05  |       |                      |
| LOQ (%w/w) (in sample based on % recovery) |   |        |        | 0.0199  |       |                      |
| Linearity                                  | Concentration Range (mg/L)                |        |        | For Effectiveness Cleaning Procedure and % Recovery |       |                      |
|  | Intercept (a)                             |        |        | 0.07 to 20.11                                       |       |                      |
|  | Slope (b)                                 |        |        | -125.34   |       |                      |
|  | Correlation Coefficient (r)               |        |        | 22852.83  |       |                      |
|  |   |        |        | 0.999   |       |                      |
| Recovery (Accuracy)                        | Level / Mean Recovery (%)                 | I      | II     | Overall Mean Recovery (%)                           | % RSD | Acceptable Limit (%) |
|  |   | 100.30 | 106.28 |   |       |                      |
|  | % RSD (%w/w)                              | 1.5    | 0.22   |   |       |                      |
|  | Acceptable % RSD (Extended Horwitz)       | 4.83   | 2.02   |   |       |                      |
|  | Horrat Value (H <sub>r</sub> )            | 0.3106 | 0.1089 |   |       |                      |
|  | Acceptable Horrat Value (H <sub>r</sub> ) | ≤ 1    | ≤ 1    |   |       |                      |

#### Evaluation

The “% Removed from the bottle by cleaning” was calculated as follows:

$$\% \text{ removed} = \{1 - (\text{mg pesticide AI recovered}) / (\text{mg pesticide AI charged (added)})\} \times 100$$

**Table 4.2-2: Effectiveness of Cleaning Procedures (at 1.2 kg product in 100 L water) [Rinsing / % Active Substance Removed from Bottle]**

| <b>Rinsing</b> | <b>% Active Substance Removed from Bottle</b> |
|----------------|---|
| Single         | 99.95   |
| Double         | 99.99   |
| Triple         | 99.99   |

### **4.3 Emergency measures in the case of an accident (KCP 4.3)**

Reference: KCP 4.3/01  
Report FGG01 / GPF 516  
Safety Data Sheet

Guideline(s): REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Deviations: No

GLP: No, not subject to GLP regulations

Acceptability: Yes

The safety data sheet contains advice for emergency measures in case of an accident with FH FGG01, based on scientific tests.

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

As per CCC study the material is compatible in HDPE Container & Trilaminated Pouches. Details of the packaging are included in the tables below.

**Table 4.4-1 Detailed packaging description for HDPE bottle and jar, 120 g, 300 g, 600 g and 1000 g**

| S. No. | Parameters             | Pack Size                    |                           |                           |                           |
|--------|------------------------|------------------------------|---------------------------|---------------------------|---------------------------|
|        |                        | 120 g                        | 300g                      | 600g                      | 1000g                     |
| 1      | Material:              | HDPE Bottle                  | HDPE Jar                  | HDPE JAR                  | HDPE JAR                  |
| 2      | Shape/size:            | Round                        | Round                     | Round                     | Round                     |
| 3      | Opening:               | 40 mm                        | 79 mm                     | 79 mm                     | 79 mm                     |
| 4      | Closure:               | HDPE Screw Cap               | HDPE Screw Cap            | HDPE Screw Cap            | HDPE Screw Cap            |
| 5      | Seal:                  | Induction sealing            | Induction sealing         | Induction sealing         | Induction sealing         |
| 6      | Manner of construction | Extrusion Blow Molded Bottle | Extrusion Blow Molded Jar | Extrusion Blow Molded Jar | Extrusion Blow Molded Jar |
| 7      | UN/ADR                 | Complies                     | Complies                  | Complies                  | Complies                  |

**Table 4.4-2 Detailed packaging description for HDPE bottle and jar, 2500 g, 5000 g and 25000 g rectangular container**

| S. No. | Parameters             | Pack Size                    |                              |   |
|--------|------------------------|------------------------------|------------------------------|---|
|        |                        | 2500g                        | 5000g                        | 25000g                                  |
| 1      | Material:              | HDPE Carboy                  | HDPE Carboy                  | HDPE ( Full open Type                   |
| 2      | Shape/size:            | Rectangular                  | Rectangular                  | Round                                   |
| 3      | Opening:               | 52 mm                        | 52 mm                        | 322mm                                   |
| 4      | Closure:               | HDPE Screw Cap               | HDPE Screw Cap               | Press fit type Cap fitted with a gasket |
| 5      | Seal:                  | Induction sealing            | Induction sealing            | Lever type Galvanized lock ring         |
| 6      | Manner of construction | Extrusion Blow Molded Carboy | Extrusion Blow Molded Carboy | Extrusion Blow Molded Drum              |
| 7      | UN/ADR                 | Complies                     | Complies                     | Complies                                |

**Table 4.4-3 Detailed packaging description for 120 g, 300 g, 600 g and 1000 g Trilaminate pouch**

| S. No. | Parameters             | Pack Size                        |                                   |                                   |                                   |
|--------|------------------------|----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|
|        |                        | 120 g                            | 300g                              | 600g                              | 1000g                             |
| 1      | Material:              | Trilaminate pouch                | Trilaminate pouch                 | Trilaminate pouch                 | Trilaminate pouch                 |
| 2      | Shape/size:            | Pillow Type                      | Pillow Type                       | Pillow Type                       | Pillow Type                       |
| 3      | Opening:               | Full open mouth                  | Full open mouth                   | Full open mouth                   | Full open mouth                   |
| 4      | Closure:               | NA                               | NA                                | NA                                | NA                                |
| 5      | Seal:                  | Heat sealing                     | Heat sealing                      | Heat sealing                      | Heat sealing                      |
| 6      | Manner of construction | 12 Mic/PET/9 Mic - Al/75Mic LDPE | 12 Mic/PET/9 Mic -Al/100 Mic LDPE | 12 Mic/PET/9 Mic - Al/100Mic LDPE | 12 Mic/PET/9 Mic - Al/100Mic LDPE |
| 7      | UN/ADR                 | Complies                         | Complies                          | Complies                          | Complies                          |

**Table 4.4-4 Detailed packaging description for 2500 g, 5000 g and 25000 g Trilaminare pouch**

| S. No. | Parameters             | Pack Size                        |                                  |                                  |
|--------|------------------------|----------------------------------|----------------------------------|----------------------------------|
|        |                        | 2500g                            | 5000g                            | 25000g                           |
| 1      | Material:              | Trilaminare pouch                | Trilaminare pouch                | Trilaminare pouch                |
| 2      | Shape/size:            | Pillow Type                      | Pillow Type                      | Pillow Type                      |
| 3      | Opening:               | Full open mouth                  | Full open mouth                  | Full open mouth                  |
| 4      | Closure:               | NA                               | NA                               | NA                               |
| 5      | Seal:                  | Heat sealing                     | Heat sealing                     | Heat sealing                     |
| 6      | Manner of construction | 12 Mic/PET/9 Mic -Al/120Mic LDPE | 12 Mic/PET/9 Mic -Al/140Mic LDPE | 12 Mic/PET/9 Mic -Al/180Mic LDPE |
| 7      | UN/ADR                 | Complies                         | Complies                         | Complies                         |

|                   |  |
|-------------------|--|
| Comments of zRMS: | <p>The accelerated stability study and shelf life study (12 mths) were conducted in a commercial packaging – Trilaminare pouch, the formulation and the packaging remained stable. Barrier material – LDPE. Extrapolation to the other requested packaging type – HDPE container is acceptable.</p> <p><u>All proposed commercial packaging is acceptable.</u></p> |
|-------------------|--|



Reference: KCP 4.4/01  
Report Two Years Storage Stability and Corrosion Characteristics study of Boscalid 500 g/kg WG (Interim Report-I), Patel, D., 2024  
JRF Study Number: 237-2-11-31229, UPL EUROPE LTD (UPL/2022/2092)  
Guideline(s): OCSPP 830.6317, 830.6320, CRD 3.9.2  
Deviations: No  
GLP: Yes  
Acceptability: Yes

#### Summary:

Stability of packaging along with the corrosion characteristics was determined according to Test Guideline OCSPP 830.6317, 830.6320, CRD 3.9.2 by observing the appearance of the container and weighting them before and after storage under specified conditions. Seven bags (Trilaminated Aluminium Pouch) of the same composition as the commercial container with test item (1000 g) were stored at ambient temperature for 2 years. One bag (Trilaminated Aluminium Pouch) of the test item was drawn initially (0 day) and after 3, 6, 9, and 12 months of storage and the test item was evaluated for corrosion characteristics (perforation, distortion, discoloration, splitting at the seam), appearance of the container (Trilaminated Aluminium Pouch) (by visual: shape, colour and crack if any), appearance of the test item (colour, physical state and odour), pH, and active ingredient content of Boscalid 500 g/kg WG. The packaging material of test substance remained stable without any damage and no significant weight change was observed during the 1 year storage period.

#### 4.5 Procedures for the destruction or decontamination of the plant protection product and its packaging (KCP 4.5)

|                   |                                      |
|-------------------|--------------------------------------|
| Comments of zRMS: | Recommendations below are acceptable |
|-------------------|--------------------------------------|

Reference: KCP 4.5/01  
Report FGG01 / GPF 516  
Safety Data Sheet  
Guideline(s): REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878  
Deviations: No  
GLP: No, not subject to GLP regulations  
Acceptability: Yes

The safety data sheet contains advice for the destruction or decontamination of the plant protection product and its packaging.

Product/Packaging disposal recommendations: Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Ecology - waste materials: Avoid release to the environment.

## 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 1.4.2/01  | Anonymous           | 2024  | Boscalid Safety Data Sheet<br>Version: 2.2<br>GLP: no<br>Published  | N                       | UPL<br>EUROPE<br>LTD. |
| KCP 2.1<br>KCP 2.2.2<br>KCP 2.3.2<br>KCP 2.3.3<br>KCP 2.4.2<br>KCP 2.6.2<br>KCP 2.8.1<br>KCP 2.8.2<br>KCP 2.8.3.1<br>KCP 2.8.3.2<br>KCP 2.8.5.1.1<br>KCP 2.8.5.1.2<br>KCP 2.8.5.2.1<br>KCP 2.8.5.3<br>KCP 2.8.7.1 | Chaudhari, M.N.     | 2022a | Physico-chemical properties of Boscalid 500 g/Kg WG<br>JAI RESEARCH FOUNDATION (JRF Study Number: 270-2-11-31452)<br>UPL EUROPE LTD (UPL/2022/0952)<br>GLP<br>Unpublished                     | N                       | UPL<br>EUROPE<br>LTD. |
| KCP 2.2.1<br><i>Included in Part C</i>  | García Carril, A.M. | 2024  | Scientific statement: Boscalid 500 WG/FGG01 (LOZZARE PRO), Statement on explosive properties<br>Report Number: 213 2 230 – CP 2.2.1-01<br>GLP: no<br>Unpublished<br><i>Included in Part C</i> | N                       | UPL<br>EUROPE<br>LTD. |
| KCP 2.7.1   | Chaudhari, M.N.     | 2022b | Accelerated storage stability and corrosion characteristics of Boscalid 500 g/Kg WG   | N                       | UPL                   |

| 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           |
|--|-----------------|------|--|-------------------------|-----------------|
|  |                 |      | JAI RESEARCH FOUNDATION (JRF Study Number: 270-2-11-31452)<br>UPL EUROPE LTD (2022/0951)<br>GLP<br>Unpublished   |                         | EUROPE LTD.     |
| KCP 2.7.5<br>KCP 2.8.5.1.3<br>KCP 4.4/01 | Patel, D.       | 2024 | Two Years Storage Stability and Corrosion Characteristics study of Boscalid 500 g/kg WG (Interim Report-I)<br>JAI RESEARCH FOUNDATION (JRF Study Number: 237-2-11-31229)<br>UPL EUROPE LTD (UPL/2022/2092)<br>GLP<br>Unpublished | N                       | UPL EUROPE LTD. |
| KCP 4.2/01                               | Prajapati, P.N. | 2024 | Effectiveness of Cleaning Procedures of Boscalid 500 g/Kg WG<br>JAI RESEARCH FOUNDATION (JRF Study Number: 284-2-11-36679)<br>UPL EUROPE LTD (UPL/2024/0502)<br>GLP<br>Unpublished   | N                       | UPL EUROPE LTD. |
| KCP 4.3/01<br>KCP 4.5/01                 | Anonymous       | 2024 | FGG01 / GPF 516 Safety Data Sheet<br>Version: 3.0<br>GLP: no<br>Published  | N                       | UPL EUROPE LTD. |

**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 |
|------------|-----------|------|---|-------------------------|-------|
| KCP XX     | Author    | YYYY | Title   | Y/N                     | Owner |

| 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 |
|------------|-----------|------|---|----------------------------|-------|
|            |           |      | Company Report No<br>Source<br>GLP/non GLP/GEP/non GEP<br>Published/Unpublished                               |                            |       |
|            |           |      |   |                            |       |
|            |           |      |   |                            |       |

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

| Data point | Author(s) | Year | Title<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 |
|------------|-----------|------|---|----------------------------|-------|
| KCP XX     | Author    | YYYY | Title<br>Company Report No<br>Source<br>GLP/non GLP/GEP/non GEP<br>Published/Unpublished                      | Y/N                        | Owner |
|            |           |      |   |                            |       |

**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</b><br><b>Company Report No.</b><br><b>Source (where different from company)</b><br><b>GLP or GEP status</b><br><b>Published or not</b> | <b>Vertebrate<br/>study<br/>Y/N</b> | <b>Owner</b> |
|-------------------|------------------|-------------|--|-------------------------------------|--------------|
| KCP XX            | Author           | YYYY        | Title<br>Company Report No<br>Source<br>GLP/non GLP/GEP/non GEP<br>Published/Unpublished   | Y/N                                 | Owner        |
|                   |                  |             |  |                                     |              |

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

### **A 2.1            Boscalid**

Not applicable.