

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: FGG01

Product names: Lozzare Pro

Chemical active substance:

Boscalid, 500 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland

(Article 33 application for a new product registration)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: 08/05/2024; 01/10/2024, 12/03/2025

MS Finalisation date: 12/2024; 03/2025

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.
01/10/2024	Second applicant version. Addition of efficacy trials for which the results were available in September 2024 Change highlighted in blue (however due to changes made by ZRMs are not visible in dossier)
December 2024	ZRMs evaluated dRR submitted by Applicant.
March 2025	ZRMs made changes in line to the commenting period.
March 2025	Minor updates in Reference list on request of zRMS

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted on behalf of UPL Holdings Coöperatief U.A. for a first registration of the product LOZZARE PRO (FGG01) in Poland according to Regulation (EC) No 1107/2009.

This application is for a first registration in member states Austria, Belgium, Czech Republic, Hungary, Netherlands, Poland, Romania, Slovakia and Slovenia. A similar application is submitted concurrently to the southern zone member states Bulgaria, Croatia, France, Greece (zRMS), Italy, Portugal and Spain, with additional uses in flax, pome fruit and stone fruit and post-harvest use in kiwi.

The product is a water dispersible granule (WG) formulated fungicide containing 500 g/kg of the active substance boscalid.

The risk assessment conclusions are based on the information, data and assessments provided in the Registration Report, Part B Sections 0-10 and Part C. The information, data and assessments provided in the Registration Report, Part B includes assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to FGG01 where that data has not been considered in the EU peer review of boscalid. Otherwise, assessments for the safe use of FGG01 have been made using endpoints agreed in the EU review of boscalid.

This document describes the specific conditions of use and labelling required for Poland for the registration of FGG01.

Appendix 1 of this document is a copy of the national decision on product authorisation.

Appendix 2 of this document is a copy of the draft product label as proposed by the applicant.

Appendix 3 of this document is a copy of the letter(s) of access, where relevant.

1.2 Letters of Access

Access to active substance data is via unprotected data. Any new data provided with this application is owned.

1.3 Justification for submission of tests and studies

To obtain approval, the product FGG01 must meet the conditions of Commission Implementing Regulation (EU) No 540/2011 and be supported by dossiers satisfying the requirements according to Commission Regulation (EU) No 284/2013, with an assessment to Uniform Principles, using agreed endpoints.

This application was submitted in order to allow the first registration of this product in accordance with the above.

The reference lists included in Part A Appendix 4 define the list of studies and reports, submitted by the applicant and relied on as well as a list of studies submitted by the applicant but not relied on for the

authorisation.

Furthermore, Appendix 4 lists submitted or referred to studies relied on but already evaluated at EU peer review and also studies necessary but not submitted.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4 to this document.

2 Details of the authorization decision

2.1 Product identity

Product code	FGG01
Product name in MS	Lozzare Pro
Authorization number	Not applicable, this application is for a first registration of the product
Function	Fungicide
Applicant	UPL Holdings Coöperatief U.A.
Active substance (incl. content)	Boscalid, 500 g/kg
Formulation type	Water dispersible granule (WG)
Packaging	120 g HDPE bottle 300 g, 600 g, 1000 g HDPE jar 2500 g and 5000 g HDPE Carboy 25000 g HDPE drum 120 g, 300 g, 600 g, 1000 g, 2500 g, 5000 g and 25000 g Trilaminat pouch Professional use
Coformulants of concern for national authorizations	None
Restrictions related to identity	None
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for Lozzare Pro resulted in the decision to grant the authorization.

Physical-chemical section: Data gap – 2-years study

Efficacy section: In Poland, FGG01 can be granted on winter oilseed rape against SCLESC and LEPTMA and grapevines against Powdery mildew. All minor uses claimed in GAP table for authorisation in line to Article 51 are accepted. Use on peas and beans against BOTRSP and spring oilseed rape against SCLESC and LEPTMA is not accepted (only authorisation in line to Article 51 is possible).

Mammalian toxicology section:

LOZZARE PRO is unclassified.. No risk for the operator and worker using FGG01 / LOZZARE PRO is anticipated for all intended uses should be use work wear (arms, body and legs covered) M/L and risk for residents and bystanders with buffer zone 2-3m except for viticulture where the buffer zone is 5m.

Metabolism and residues section:

Acceptance of use No2 left to decisions at Member State level. In Poland this use was accepted.

Legumes: accepted fresh with pods **only and without pods**.

Evaluators verified whether the co-formulants contained in plant protection product FGG01 are listed in Annex III to Regulation (EC) No 1107/2009 and/or could be considered unacceptable based on the criteria indicated in the Annex to the Commission Implementing Regulation (EU) 2023/574 of 13 March 2023.

Based on the currently available MSDSs and other information provided by applicant or manufacturer of co-formulant, the product FGG01 does not contain any unacceptable co-formulant/ingredient listed in the Commission Regulation (EU) 2021/383 amending Annex III to Regulation (EC) No 1107/2009.

According to the current knowledge and available information none of the co-formulants in the plant protection product FGG01 meets the Annex to Regulation (EU) 2023/574 criteria for identification of co-formulants that are unacceptable for inclusion in a plant protection products. Taking this into account, none of the co-formulants/ingredients in this product is considered to be a candidate for inclusion in Annex III of Regulation (EU) 1107/2009.

Detailed assessment of co-formulants according to Article 3 of Regulation (EU) 2023/574 can be found in the dRR Part C and in the Annex to Part C (confidential).

2.3 Substances of concern for national monitoring

None.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Hazardous to the aquatic environment – Chronic, category 2
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	GHS09
Signal word:	None
Hazard statement(s):	H411 Toxic to aquatic life with long lasting effects
Precautionary statement(s):	P273 - Avoid release to the environment P391 - Collect spillage P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation
Additional labelling phrases:	None

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
-	None

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
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2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
-	None
Worker protection:	
-	None
Integrated pest management (IPM)/sustainable use:	
-	None
Environmental protection	
-	None.
Other specific restrictions	
-	None.

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
-	None

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
-	None	-
Environmental protection:		Relevant for use no.
-	None	-

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code): LOZZARE PRO / FGG01
Active substance 1: Boscalid
Safener: None
Synergist: None
Applicant: UPL Holdings Coöperatief U.A.
Zone(s): Central
Verified by MS: yes

GAP rev. 1, date: 2024-May-08
Formulation type: Water dispersible granule (WG)
Conc. of as 1: 500 g/kg
Conc. of safener: -
Conc. of synergist: -
Professional use: ☒
Non professional use: ☐

Field of use: Fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ⁽ⁱ⁾
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
2	PL	Grapevine, wine & table 0151010 0151020	F	<i>Uncinula necator</i> , Powdery mildew (UNCINE)	Spraying overall	BBCH 15-81	a) 3 per use b) 3 per crop / season	10-14	a) 0.2 kg/ha b) 1.0 kg/ha	a) 100 g/ha b) 300 g/ha	100- 1000	21	0.14 kg product / 10000 m ² LWA 0.02 kg/100 L (optional) Metabolism and residues: Acceptance of use No2 left to decisions at Member State level. In Poland this use was accepted.
3	PL	Oilseed rape (winter and spring)	F	<i>Sclerotinia sclerotiorum</i> (SCLESC)	Spraying overall	BBCH 57-69	a) 1 per use	-	a) 0.5 kg/ha	a) 250 g/ha	100- 300	35	Eff. section: only use on winter oilseed rape

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ⁽ⁱ⁾
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
		0401060					b) 1 per crop / season		b) 0.5 kg/ha	b) 250 g/ha			is accepted.
5	PL	Oilseed rape (winter and spring) 0401060	F	<i>Leptosperia maculans</i> (LEPTMA)	Spraying overall	BBCH 13-57	a) 1 per use b) 1 per crop / season	-	a) 0.5 kg/ha b) 0.5 kg/ha	a) 250 g/ha b) 250 g/ha	100- 300	35	Eff. section: only use on winter oilseed rape is accepted.
6	PL	Beans and peas (fresh) with pods 0260010 0260030 and without pods 026020 026040	F	<i>Botrytis</i> (BOTRSP)	Spraying overall	BBCH 60-69	a) 2 per use b) 2 per crop/ season	7	a) 1.0 kg/ha b) 2.0 kg/ha	a) 500 g/ha b) 1000 g/ha	150- 600	7	Eff. section: use not accepted in line to Art. 33. Metabolism and residues :accepted fresh with pods only and without pods (legumes)
Minor uses according to Article 51 (zonal uses)													
8	PL	Spring rape (0401060) gold of pleasure (0401130), winter turnip rape (0401060), Mustard (0401080), Sunflower (0401050), Poppy (0401030), Linseed (0401010), Flax (0401010), Hemp (0401140), Borage (0401120)	F	<i>Alternaria</i> species (ALTESP) <i>Sclerotinia sclerotiorum</i> (SCLESC)	Spraying overall	BBCH 57-69	a) 1 per use b) 1 per crop / season	-	a) 0.5 kg/ha b) 0.5 kg/ha	a) 250 g/ha b) 250 g/ha	100- 300	35	-

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ⁽ⁱ⁾
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
9	PL	Spring rape gold of pleasure, winter turnip rape, mustard, poppy linseed, flax, hemp, borage	F	<i>Leptosperia maculans</i> (LEPTMA)	Spraying overall	BBCH 13-57	a) 1 per use b) 1 per crop / season	-	a) 0.5 kg/ha b) 0.5 kg/ha	a) 250 g/ha b) 250 g/ha	100- 300	35	-
10	PL	Grapevine, wine & table 0151010 0151020	F	<i>Botrytis cinerea</i> (BOTRI)	Spraying overall	BBCH 60-85	a) 1 per use b) 1 per crop / season	-	a) 1.0 kg/ha b) 1.0 kg/ha	a) 500 g/ha b) 500 g/ha	100- 1000	21	0.72 kg product / 10000 m ² LWA (optional)
11	PL	Beans for fresh seeds (fresh beans without pods - 026020), Broad bean French beans (0260010), Peas for fresh seeds (fresh peas without pods - 026040), edible podded peas (0260030) Accepted all group of legumes	F	<i>Sclerotinia</i> (SCLESP) <i>Botrytis cinerea</i> (BOTRI)	Spraying overall	BBCH 60-69	a) 2 per use b) 2 per crop / season	7	a) 1.0 kg/ha b) 2.0 kg/ha	a) 500 g/ha b) 1000 g/ha	150- 600	7	Metabolism and residues :accepted fresh with pods only and without pods (legumes)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ⁽ⁱ⁾
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Remarks columns:	1	Numeration necessary to allow references					7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application					
	2	Use official codes/nomenclatures of EU Member States					8	The maximum number of application possible under practical conditions of use must be provided.					
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)					9	Minimum interval (in days) between applications of the same product					
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application					10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.					
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.					11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).					
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench					12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.					
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.					13	PHI - minimum pre-harvest interval					
							14	Remarks may include: Extent of use/economic importance/restrictions					

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

LOZZARE PRO (FGG01) is a brown granules appearance product with characteristic odour, water dispersible granules formulation, containing 500 g/kg boscalid. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. 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 together with other products.

Implications for labelling:

None.

Compliance with FAO specifications:

The product FH-047 complies with FAO specifications of the respective formulation type.

Nature and characteristics of the packaging:

Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

3.2 Efficacy (Part B, Section 3)

3.3 Efficacy data

This document summarises the information related to the efficacy of the plant protection product FGG01 containing boscalid; proposed trade name is LOZZARE PRO®.

FGG01 is a Water dispersible Granules (WG) preparation containing 500 g/kg boscalid addressed to control fungal diseases on various crops. In fact, the draft Registration Report (dRR) supports submission for authorisation of the new product FGG01 as a WG (Water dispersible Granules) formulation for use as a fungicide in the Central registration zone in Austria, Belgium, Czech Republic, Hungary, the Netherlands, Romania, Slovakia and Slovenia as concerned Member States (cMS) and Poland as zRMS.

Several boscalid-based products are currently registered in Europe. The present dossier is based on a combination of studies owned by the applicant and unprotected data of the product CANTUS in Austria, Belgium, Czech Republic, Hungary, Romania, Slovakia, Slovenia and Poland and the product also named PROPATAN in Czech Republic. Both products are identical with each other and with the intended product. Indeed, they are all the same boscalid 500 g/kg WG formulation, manufactured by BASF, except in Czech Republic with the name of PROPATAN, all of them share the same tradename.

Therefore, according to the countries and uses, two strategies are presented:

- Bridging strategy (reduced dataset) with the objective to demonstrate the equivalence at the same dose rates of the product FGG01 to the boscalid reference product CANTUS, for which the claimed uses are not protected,
- Full efficacy data package strategy (complete dataset) with the objective to demonstrate the efficacy of the product FGG01 (when the reference product CANTUS is not registered or when CANTUS data are still under data protection). The size of such datasets may vary according to the major or minor classification of the respective uses.

This document summarises the information related to the efficacy data of FGG01 against a wide range of diseases in different crops:

- Oilseed rape against *Sclerotinia sclerotiorum* (SCLESC), *Alternaria* sp. (ALTESP) and *Plenodomus lingam* (LEPTMA),
- Grapevine against *Erysiphe necator* (UNCINE) and *Botrytis cinerea* (BOTRCI),
- Fresh beans and peas against *Botrytis* sp. (BOTRSP) and *Sclerotinia* sp. (SCLESP).

In Poland, the following minor uses are also claimed (registration in line to Article 51): on grapevine against *Botrytis cinerea* (BOTRCI), beans for fresh seeds, broad beans, French beans, peas for fresh seeds and edible podded peas against *Sclerotinia* sp. (SCLESP), *Botrytis cinerea* (BOTRCI) and *Erysiphe pisi* (ERYSPI), on sunflower, spring oilseed rape, flax or linseed, gold of pleasure, white mustard, winter turnip rape, poppy, hemp and borage against *Sclerotinia sclerotiorum* (SCLESC), *Alternaria* sp. (ALTESP) and *Plenodomus lingam* (LEPTMA). No trials for those uses are required.

Minimum effective dose of FGG01

The minimum effective dose of boscalid fungicide can vary depending on factors such as the specific crop, fungal pathogen and local agricultural guidelines. Typical application rates range for grapevines from 200 to 400 grams of boscalid per hectare. For winter oilseed rape recommended rates are also range from around 250 to 500 grams per hectare. For peas and beans usually from 500 to 1000 grams of boscalid per hectare. It is crucial to follow the specific product label instructions and regulations.

The Applicant proposed doses of Lozzare Pro, Miller Pro, Palator Pro (product code: FGG01) that reflect those of currently authorized boscalid products across the EU. To provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least two lower dose(s) than recommended dose. In the appropriate research of efficacy were tested differ doses and to register was chosen the lowest effective, which is in line to EPPO 1/225(2).

Applicant did not present any separate MED trials. Minimum effective dose was studied during efficacy trials. Applicant in total presented 50 efficacy trials carried out in Maritime EPPO zone (28 trials), N-E EPPO zone (16 trials) and S-E EPPO zone (6 trials) in different growing seasons (2021-2024). Additionally, 21 efficacy trials from MED EPPO zone are presented in this dossier as a supportive trials. Also, still 8 trials (Maritime – 4 trials and MED -4 trials) are ongoing and are not available for this submission of dossier.

Winter oilseed rape was studied in 29 efficacy trials carried out in Maritime EPPO zone (7 trials: BE-2, DK-1, FR-3, UK-1), N-E EPPO zone (16 trials: PL) and S-E EPPO zone (6 trials: HU). Grapevines were studied in 13 efficacy trials carried out in Maritime EPPO zone (13 trials : AT-7 and DE-6) and 13 supportive trials from MED EPPO zone (13 trials: FR-3, IT-5, PT-2, ES-3). Green beans were studied in 5 efficacy trials in Maritime EPPO zone (BE-2, FR-3) and 7 supportive trials from MED (ES-7). Broad beans were studied in one trial from Maritime EPPO zone (DE) and one supportive trial from MED EPPO zone (ES). Peas were studied in 2 trials carried out in Maritime EPPO zone(CZ, UK).

Due to the different registration approach strategies in this dossier (bridging or full data package) the justification of the Minimum Effective Dose is not required for all uses claimed for FGG01. Indeed, when a bridging strategy is targeted (use unprotected data of registered product in the country where the use is requested) in this case, this dossier is intended to demonstrate the comparability between the reference product CANTUS and FGG01 and in this context, no Minimum Effective Dose trials are needed. Conversely, in the countries where CANTUS is not authorized or when CANTUS data is still under data pro-

tection for a use, a study of the dose is necessary with a complete data package; the size of this data package may vary according to the major or minor classification of the respective use. Submission strategies are presented in the dossier in Table 3.2-1 by Applicant.

✓ **winter oilseed rape:**

During trials carried out on winter oilseed rape following doses were studied against SCLESC, ALTEBA and LEPTMA: 0.25 kg/ha; 0.375 kg/ha and 0.5 kg/ha (N recommended). Applicant presented MED results for winter oilseed rape against SCLESC carried out in N-E EPPO zone. Efficacy was assessed on the basis on incidence and severity on stem. The best efficacy was noted for dose 0.5 kg/ha (89.0% eff. – severity and 76.5% eff – incidence). In Austria, Czech Republic, Hungary, Romania and Slovakia the ref. product (CANTUS, known in CZ as a PROPATAN) has been authorized for use as a fungicide in oilseed rape against SCLESC for more than 10 years (use not protected). In the NL, CANTUS is not authorized for this use, but for a minor use is not necessary in the opinion of Applicant.

Applicant studied different doses against ALTEBA. However, no results were presented in this dossier from trials as in Austria, Belgium, Czech Republic, Hungary, Romania and Slovakia the ref. product (CANTUS, in CZ known as a PROPATAN) is authorized for use in oilseed rape against ALTEBA for more than 10 years (use not protected). In the NL, CANTUS is not authorized for this use, but for a minor use is not necessary in the opinion of Applicant.

Applicant submitted 9 trials against LEPTMA carried out in NE and 3 trials from SE. Severity and incidence on plant in SE and incidence and severity on leaf and stem in NE was studied. The most effective was dose 0.5 kg/ha. In Austria, Czech Republic, Hungary, Romania and Slovakia, the ref. product (CANTUS, known as a PROPATAN in CZ) has been authorized for use as a fungicide on oilseed rape against LEPTMA for more than 10 years (data not protected).

✓ **grapevines:**

During trials carried out on grapevines following doses were studied against BOTRCI – 0.36 kg/ 10000 m² LWA 0.54 kg/ 10000 m² LWA and 0.72 kg/ 10000m² LWA (N recommended) in Maritime EPPO trials. During supportive trials from MED trials following doses were studied: 0.5 kg/ha; 0.75 kg/ha and 1.0 kg/ha.

During trials carried out on grapevines following doses were studied against UNCINE – 0.01 kg/ 100 L; 0.015 kg/100 L; 0.02 kg/100 L; 0.2 kg/ha; 0.2 kg/ha; 0.07 kg/ 10000m² LWA; 0.10 kg/ 10000m² LWA; 0.13 kg/ 10000m² LWA and 0.14 kg/ 10000m² LWA (N recommended) in Maritime EPPO trials. During supportive trials from MED trials following doses were studied: 0.01 kg/100 L; 0.015 kg/100 L; 0.02 kg/ 100 L; 0.2 kg/ha and 0.2 kg/ 10000m² LWA.

The dose rate of 0.72 kg/10000 m² LWA has been determined based upon conversion of the proposed ground-based dose rate of 1.0 kg/ha and a typical leaf wall area of grapevine in many Member States in the Central zone. In the trials, a conversion factor of 1.4 was used between the dose expressions in ground area and the LWA concept. CANTUS has been authorized in Austria, Belgium, Czech Republic and Slovenia for use as a fungicide on grapevine against BOTRCI for more than 10 years (data not protected). So, lack of MED trials presented by Applicant against BOTRCI on grapevines should be acceptable.

The ref. product CANTUS is not authorization on grapevine against UNCINE in AT, BE, CZ, SL and PL, so results were presented by Applicant. According to the efficacy trials results, the minimum effective dose rate of FGG01 for the control of *Erysiphe necator* (UNCINE) in grapevine is confirmed at 0.14 kg/10000 m² LWA in the Maritime EPPO climatic zone (on the basis on 6 trials carried out in DE-3 trials and AT-3 trials) and dose 0.02 kg/100 L on the basis on 4 trials (AT-2 trials, DE-2 trials). This dose was the most effective against UNCINE on grapevines.

✓ **peas and beans:**

During trials carried out on beans and peas following doses were studied: 0.5 kg/ha; 0.75 kg/ha and 1.0 kg/ha (N recommended) against BOTRSP and SCLESP. In supportive trials from MED EPPO zone the same doses were studied.

In Austria, Belgium and the Czech Republic, the ref. product (CANTUS, known as a PROPATAN in CZ) has been authorized for use as a fungicide on fresh beans and peas against BOTRCI for more than 10 years (not protected data). In the NL and PL, CANTUS is not authorized for this use. Due to fact that it is a minor use, such data are not necessary in the opinion of Applicant. For PL, those data are necessary. Poland can use data from neighboring countries from Maritime EPPO zone (CZ and DE) as valid. In trial from Germany, the broad bean against BOTRFA was studied. In trial from CZ - *Pisum sativum* (pea) against BOTRCI was studied. Unfortunately, only one trial for pea and bean cannot be accepted for PL. Only registration in line to Article 51 can be consider by Poland. NL can also use trial from UK carried out on *Pisum sativum* against BOTRCI, *Phaseolus vulgaris* against BOTRCI from BE and *Phaseolus vulgaris* against BOTRSP from North France. The most effective was dose 1.0 kg/ha.

In Austria, Belgium and the Czech Republic the ref. product (CANTUS, known in CZ as a PROPATAN) has been authorized for use against SCLESC on fresh beans and peas over 10 years (data not protected). So, no results for minimum effective dose were presented by Applicant.

On the basis of tables presented by Applicant in this dossier for the summary for minimum effective dose and/or data from st. ref. products used in trials (CANTUS, known as a PROPATAN in Czech Republic), it can be concluded that the most effective dose for winter oilseed rape against SCLESC, ALTEBA and LEPTMA is 0.5 kg/ha applied once a season; for beans and peas against BOTRSP and SCLESP is dose 1,0 kg/ha applied twice a season and for grapevine against BOTRCI is dose 0.72 kg/ 10000m² LWA applied once a season and against UNCINE is dose 0.14 kg/ 10000m² LWA applied max. three times per season.

Efficacy of FGG01 for claimed uses in GAP table for Poland

On the basis on literature data, boscalid is effective against several key fungal diseases affecting winter oilseed rape, grapevine and beans and peas. It is recommended to use it as a part of an integrated diseases management program, including rotating fungicides with different modes of action and applying fungicides based on disease risk. Trials were conducted according to EPPO guidelines. The GEP certificates of the official testing organizations were provided. EPPO standard PP 1/226 provides guidance on the number of trials in target crops needed to demonstrate the efficacy of a plant protection product at the recommended dose. Where authorization is sought across a range of diverse conditions, such as across an authorization zone (PP 1/278), then the number of trials conducted may need to increase. These trials should be done across the range of climatic and environmental conditions likely to be encountered and over at least 2 years.

Applicant submitted in total 50 efficacy trials: 29 efficacy trials carried out on winter oilseed rape in Maritime EPPO zone (7 trials: BE-2, DK-1, FR-3, UK-1), N-E EPPO zone (16 trials: PL) and S-E EPPO zone (6 trials: HU) in 2021-2024; 13 efficacy trials performed on grapevines in Maritime EPPO zone (AT-7 and DE-6) in 2021 and 2023; 5 efficacy trials on green beans in Maritime (BE-2, FR-3) in 2023; 1 trial on broad bean in Maritime EPPO zone (DE) in 2022 and 2 trials on peas in Maritime EPPO zone (CZ-1, UK-1) in 2023. Number of trials should be consider in the approach of full data package for FGG01, bridging approach (FGG01 and CANTUS) or extrapolating results in the light of existing authorizations of st. ref. product with the same formulation and active content of boscalid (CANTUS, known in Czech Republic as a PROPATAN) by a cMS. Number of studied fungal diseases is also important. Major diseases should be represented by at least 6 valid efficacy trials, and minor – by at least 3 trials. For AT - a reduced data set of at least 3 trials on spring oilseed rape for the authorization of spring oilseed rape in line with Article 33 would be necessary or registration in line to Article 51. can be considered (added information from commenting period).

Assessment of **use no 1 against BOTRCI on grapevines in AT, BE, CZ and SL** as no claimed in GAP for Poland is presented in B3 only.

Use no 2 against UNCINE on grapevines in AT, BE, CZ, SL and PL

In the countries claimed for authorization on grapevine against *Erysiphe necator*, the reference product CANTUS is not authorized for this use and therefore, a full data package is necessary on grape-vine against *Erysiphe necator*. Except in Poland (minor use), as this is a major use in all of these countries, a full data package is required and was generated. Applicant submitted in total 10 trials carried out in Mari-

time EPPO zone (AT-5, DE-5) in 2022 and 2023. For Poland we can use trials from DE as a neighboring country. Number of trials (5) is sufficient for a minor crop.

FGG01 applied at 0.13-0.14 kg/10000 m² LWA, at 0.2 kg/ha and at 0.02 kg/100 L for the control of *Erysiphe necator* on grapevine in comparison to the reference standard CANTUS at 0.2 kg/ha or to different local references in the Maritime EPPO climatic zone (Austria and Germany). Results were comparable to st. ref. product (CANTUS at 0.2 kg/ha). On the obtained results it can be concluded that FGG01 moderately effectively control UNCINE on leaf and branches of grapevines at dose 0.13-0.14 kg/10000m² LWA and moderately control UNCINE at dose 0.2 kg/ha and 0.02 kg/100L.

Application was done at BBCH 14-89 in Maritime EPPO zone. Application window proposed by Applicant (BBCH 15-81) should be accepted as consistent with submitted trials, plant protection programs for boscalid fungicides and with st. ref. product.

Following water volume was studied: 100-800 L/ha in Maritime EPPO zone. Proposed by Applicant water volume 100-1000 L/ha can be accepted as consistent with plant protection programs for boscalid fungicide and with st. ref. product.

Use no 3 against SCLESC on oilseed rape in AT, BE, CZ, HU, NL, PL, RO and SK

Applicant submitted in total 15 efficacy trials carried out in Maritime EPPO zone – 5 trials (DK-1, FR-3, UK-1), N-E EPPO zone – 7 trials (PL) and S-E EPPO zone – 3 trials (HU) in three growing seasons (2021, 2023 and 2024). In Austria, Belgium, Czech Republic, Hungary, Romania and Slovakia, the reference product CANTUS (also known under the name of PROPATAN in Czech Republic; AMM: 4889-1) has been authorized for use as a fungicide on oilseed rape against *Sclerotinia sclerotiorum* for more than 10 years and the use is not protected. In this bridging context, according to guideline EPPO 1/307(2) a reduced data package is required to demonstrate the comparability between CANTUS and FGG01. Concerning the Netherlands, CANTUS is not authorized for this use. However, due to the fact that it is a minor use, a reduced data package is required in the opinion of Applicant. cMS from NL should decide if this approach can be accepted. In Poland, CANTUS, is authorized for this use but data is still protected, therefore, a full data package was necessary for this major use.

For Poland, Applicant submitted enough number of trials (7) characterized by acceptable level of infestation. Results for FGG01 at recommended dose (0.5 kg/ha) were comparable to st. ref. product (CANTUS at 0.5 kg/ha). On the basis on obtained results it can be stated that FGG01 effectively control SCLESC on winter oilseed rape (lack of trials for spring oilseed rape). The average eff. from incidence on stem (76.5%) and severity on stem (89.0%) was 82.75%. Eff. on leaves and pods were not studied. Spring oilseed rape cannot be accepted in line to Article 33 without any trial (at least 1-2 eff. trials should be submitted by Applicant), only its registration in line to Article 51 can be consider.

For bridging approach for cMS, limited number of trials from Maritime (5 trials) and S-E EPPO zone (3 trials) should be acceptable. Results of FGG01 at recommended dose (0.5 kg/ha) and st. reference product (CANTUS at 0.5 kg/ha) were comparable.

Severity and incidence was studied during trials. It can be concluded that FGG01 limited the occurrence of SCLESC on stem (66.8% eff. severity; 47.9% incidence, so average eff. is 57.35%) and effectively control SCLESC on pod (97.1% severity, 86.4% incidence). So, it can be concluded that FGG01 moderately effectively control SCLESC on winter oilseed rape in the Maritime EPPO zone. Eff. on leaves were not studied.

It can be concluded that FGG01 effectively control SCESC on stem of winter oilseed rape (89.5% eff. severity). Eff. on pods and leaves were not studied.

Lack of trials for spring oilseed rape. Extrapolating results from winter oilseed rape should be consider by cMS.

Application was done at BBCH 61-65 in N-E EPPO zone, at BBCH 65-67 in S-E EPPO zone and BBCH 61-65 in Maritime EPPO zone. Application window proposed by Applicant (BBCH 57-69) should be accepted as consistent with submitted trials, plant protection programs for boscalid fungicides and with st. ref. product.

Following water volume was studied: 300 L/ha in N-E EPPO zone, 200-300 L/ha in Maritime and 300 L/ha in S-E EPPO zone. Proposed by Applicant water volume 100-300 L/ha can be accepted as consistent with plant protection programs for boscalid fungicide and with st. ref. product.

Assessment of use no 4 against ALTESP on oilseed rape in AT, BE, CZ, NL, SK, HU and RO as no claimed in GAP for Poland is presented in B3 only.

Use no 5 against LEPTMA on oilseed rape in HU, PL, RO, SK, AT and CZ

Applicant submitted in total 12 efficacy trials carried out in N-E EPPO zone (9 trials: PL) and S-E EPPO zone (3 trials: HU) in 2021, 2022 and 2024. In Austria, Czech Republic, Hungary, Romania and Slovakia, the reference product CANTUS (also known under the name of PROPATAN in Czech Republic; AMM: 4889-1) has been authorised for use as a fungicide on oilseed rape against *Plenodomus lingam* for more than 10 years and the use is not protected. In this bridging context, according to guideline EPPO 1/307(2) a reduced data package is required to demonstrate the comparability between CANTUS and FGG01. In Poland, CANTUS is authorised for this use but data is still protected and therefore a full data package would be required in this context. Nevertheless, due to the fact that it is a minor use, a reduced full data package is necessary. In the opinion of ZRMs, number of trials (9) for Poland is sufficient. AT and CZ should consider extrapolating results and HU, RO and SK a bridging approach with limited number of trials. According to the commenting period, LEPTMA a reduced data set for AT would be necessary, but extrapolation may be possible in line to the bridging approach.

Results for FGG01 at recommended dose (0.5 kg/ha) were comparable to st. ref. product (CANTUS at 0.5 kg/ha or PICTOR 0.5 L/ha) in N-E EPPO zone. On the basis on obtained results, it can be concluded that FGG01 moderately efficiency control LEPTMA on leaf and stem of winter oilseed rape in N-E EPPO trials. Average of incidence on leaf was 67.16 % and on stem 66.58%. Average of severity on leaf was 87.48% and on stem – 80.75%. On the basis on obtained results it can be concluded that FGG01 moderately effectively control LEPTMA on leaf and stem of winter oilseed rape in N-E EPPO zone (average eff: 75.49%). Lack of trials for spring oilseed rape. Without ant trial carried out on spring oilseed rape, extrapolating results in Poland is not possible.

Results for FGG01 at recommended dose (0.5 kg/ha) were comparable to st. ref. product (CANTUS at 0.5 kg/ha) in S-E EPPO zone. On the basis on obtained results, it can be concluded that FGG01 moderately efficiency control LEPTMA on plant of winter oilseed rape in S-E EPPO trials. Average of incidence on plant was 62.7 %. Average of severity on plant was 82.6%. On the basis on obtained results it can be concluded that FGG01 moderately effectively control LEPTMA on plant of winter oilseed rape in S-E EPPO zone (average eff.: 72.65%). Lack of trials for spring oilseed rape. cMS should decide if extrapolating results from winter oilseed rape is possible.

Application was done at BBCH 14-18 in S-E EPPO zone and at BBCH 14-51 in N-E EPPO zone. Application window proposed by Applicant (BBCH 13-57) should be accepted as consistent with submitted trials, plant protection programs for boscalid fungicides and with st. ref. product.

Following water volume was studied: 300 L/ha in S-E and 250-300 L/ha in N-E EPPO zone. Proposed by Applicant water volume 100-300 L/ha can be accepted as consistent with plant protection programs for boscalid fungicide and with st. ref. product.

Use no 6 against BOTRSP on beans and peas (fresh) in AT, BE, CZ, NL and PL

In Austria, Belgium and the Czech Republic, the reference product CANTUS has been authorised for use as a fungicide on fresh beans and peas against *Botrytis sp.* for more than 10 years and the use is not protected. In this bridging context, according to guideline EPPO 1/307(2) a reduced data package is required to demonstrate the comparability between CANTUS and FGG01. However, in the Netherlands, CANTUS is not authorised and in Poland, CANTUS is authorised for this use but data are still protected. However, for both countries, due to the fact that *Botrytis sp.* on fresh beans and peas is a minor use, a reduced data package is required and was generated.

Applicant submitted in total 5 trials carried out in Maritime EPPO zone (BE-1, CZ-1, DE-1, FR-1, UK-1). On the obtained results it can be concluded that results were comparable to st. ref. product (CANTUS at 1.0 kg/ha). FGG01 moderately effectively control BOTRSP on peas and beans in Maritime EPPO zone.

Considering PHSVX - it is considered as high growing crop in AT and therefore the application rate in tLWA or at least the application rate in connection with the plant height (e.g. due to the trial data) may be provided for AT, as it is authorised for the bridging partner CANTUS.

Poland is required a full package data for minor use, so at least 2 trials carried out on peas and 2 trials on beans against BOTRCI should be presented by Applicant. Those trials should be performed in N-E EPPO

zone or neighbouring countries to Poland from other zones. In trial from Germany, the broad bean against BOTRFA was studied. In trial from CZ - *Pisum sativum* (pea) against BOTRCI was studied. Unfortunately, only one trial for pea and bean cannot be accepted by PL. Only registration in line to Article 51 can be considered by Poland. For pea or bean at least 2-3 efficacy trials carried out in N-E EPPO zone are required against BOTRCI and 1-2 eff. trials carried out on bean or pea for the extrapolating possibilities according to Polish harmonisation agreements.

NL can also use trial from UK carried out on *Pisum sativum* against BOTRCI, *Phaseolus vulgaris* against BOTRCI from BE and *Phaseolus vulgaris* against BOTRSP from North France. CMS from AT, BE, CZ and SK should decide if bridging approach with limited number of trials can be acceptable.

Application was done at BBCH 61-70 in Maritime EPPO zone. Application window proposed by Applicant (BBCH 60-69) should be accepted as consistent with submitted trials, plant protection programs for boscalid fungicides and with st. ref. product.

Following water volume was studied: 200-500 L/ha in Maritime EPPO zone. Proposed by Applicant water volume 150-600 L/ha can be accepted as consistent with plant protection programs for boscalid fungicide and with st. ref. product.

Assessment of *use no 7 against SCLESP on beans and peas (fresh) in AT, BE and CZ* as no claimed in GAP for Poland is presented in B3 only.

Minor uses in line to Article 51 claimed for PL:

All minor uses claimed in GAP table and Polish label project can be accepted in line to Article 51. No trials are required.

Applicant also presented supportive trials from MED EPPO zone carried out on grapevines and bean and peas. Each CMS should consider possibility of using them. In Poland trials from MED EPPO zone cannot be used for authorization FGG01. Those trials were presented by Applicant in the chapter about efficacy.

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

The applicant addresses all points of the EPPO Standard PP 1/213 to evaluate the possible actual resistance risk of FGG01.

The emergence of resistance to boscalid in fungal populations is a significant concern, as it is for any fungicide. Boscalid is a succinate dehydrogenase inhibitor (SDHI), and resistance to SDHI fungicides has been observed in several pathogen species affecting various crops. Fungicide resistance presents a major challenge to effective disease management in agriculture, and assessing the fungicide sensitivity of field isolates is a critical step in evaluating the risk of resistance development. Recent reports indicate that the sensitivity of many pathogens to SDHI fungicides is gradually shifting, suggesting that quantitative resistance is beginning to develop. According to the Fungicide Resistance Action Committee (FRAC), the risk of resistance to SDHI fungicides is currently considered moderate to high due to the compound's strong intrinsic activity, high specificity for their target enzymes and their widespread and continuous use in recent years.

Boscalid inhibits mitochondrial respiration, specifically targeting complex II, which is essential for energy production in fungi. Pathogens may develop mutations in the target site, reducing the fungicide's effectiveness. Frequent use of boscalid, especially without rotation with fungicides of different classes, increases selection pressure on fungal populations, promoting resistance development. Fungal populations can vary significantly, and some species may have inherent resistance or can acquire resistance through genetic variation. Conditions such as humidity and temperature can influence the effectiveness of boscalid and the rate of resistance development.

Winter oilseed rape:

Pathogens like *Alternaria brassicae* and *Sclerotinia sclerotinum* are controlled by boscalid in winter oilseed rape but have the potential to develop resistance. Although specific resistance cases in oilseed rape may be less documented than in cereals, ongoing vigilance is crucial.

Some SCLESC strains may develop mutations in their target sites, rendering boscalid less effective. The expression of efflux pumps can increase the removal of boscalid from fungal cells, leading to decreased sensitivity. The ability of SCLESC to produce sclerotia allows it to withstand unfavorable conditions, increasing the chance of resistance establishment.

ALTEBA may develop pathways to metabolize boscalid, leading to reduced effectiveness. Resistance to other fungicides can lead to cross-resistance against boscalid due to similar modes of action.

Genetic changes in LEPTMA may occur, affecting the target sites for boscalid and resulting in reduced susceptibility. Different isolates of LEPTMA may show varying levels of sensitivity to boscalid due to population diversity.

Peas and beans:

Some strains of BOTRCI may exhibit mutations in the target genes affected by boscalid, reducing the fungicide's efficacy. Efflux pumps can increase the removal of boscalid from fungal cells, decreasing its concentration and effectiveness. The pathogen may adapt through metabolic pathways that enable the breakdown or alteration of boscalid, resulting in reduced sensitivity.

Resistance may arise due to genetic changes in the fungal cell's target sites for boscalid, making the fungicide less effective. SCLESP can exhibit varying sensitivity based on environmental conditions or genetic variation within its populations. The ability of SCLESC to produce sclerotia allows it to survive adverse conditions, complicating management and increasing the likelihood of resistance development.

Grapevine

Some strains of *Botrytis cinerea* have developed mutations in the target site for boscalid, leading to reduced sensitivity. Increased expression of efflux pump genes can facilitate the expulsion of boscalid from fungal cells, decreasing its effective concentration. Enhanced metabolism of boscalid through enzymatic modifications can contribute to resistance.

Similar to BOTRCI, pathogens can undergo genetic mutations affecting sites that boscalid targets, leading to diminished efficacy. Resistance in *Uncinula necator* may be influenced by the genetic diversity within fungal populations, including the presence of naturally resistant strains.

Mitigation strategies :

- ✓ *fungicide rotation and mixtures*: rotate boscalid with fungicides that have different modes of action, and consider combining it with other fungicides to reduce the potential for resistance.
- ✓ *Integrated Pest Management (IPM)*: integrate non-chemical control measures and apply fungicides strategically, avoiding overuse.
- ✓ *follow guidelines*: adhere to recommended application rates and frequency as specified on product labels to prevent misuse.
- ✓ *resistance monitoring*: participate in local or regional resistance monitoring programs to stay updated on resistance levels and best practices for fungicide use.

By implementing these strategies, the risk of resistance development can be minimized, helping to maintain boscalid's effectiveness in managing fungal diseases.

Effective resistance management for boscalid (SDHI fungicides) :

A comprehensive approach is necessary to reduce the risk of resistance to boscalid in fungal populations.

- ✓ *rotate fungicide modes of action*: incorporate boscalid into a fungicide rotation program. Avoid consecutive applications of boscalid or other SDHIs. Instead, alternate with fungicides that act through different mechanisms, such as DMI or QoI fungicides.
- ✓ *formulate mixtures*: combine boscalid with another fungicide that has a different mode of action to reduce selection pressure on pathogen populations by exposing them to multiple modes of attack.
- ✓ *Integrated Pest Management*: use crop rotation and diversification to disrupt the pathogen lifecycle. When available, plant resistant crop varieties to reduce disease pressure. Ensure proper crop sanitation by removing plant debris that may harbour pathogens. Regularly scout fields to detect early disease symptoms and evaluate fungicide efficacy.

- ✓ *optimized application practices*: always follow label instructions for application rates, timing and treatment frequency. Both underuse and overuse can contribute to resistant development.
- ✓ *resistance monitoring*: keep detailed records of fungicide performance and any instances of reduced efficacy, which will assist in future decision making.

Taking into account that the inherent risk of boscalid is medium to high, the inherent risk of the target pathogens are low to high and the agronomic risk is low to medium, it can be considered that a management strategy is necessary to reduce the risk of resistance development. Therefore, the risk of resistance development against FGG01 is considered to be medium to high if the product is used in adherence with the proposed management strategy. Based on submitted information it can be concluded to accept the data provided by the applicant. The management strategy presented by the applicant should be implemented in cMS based on the latest FRAC recommendations and consideration in that cMS conditions. Considering VITVI and UNCINE as well as BOTRCI – from a theoretical point of view, it should be kept in mind that the low application rate against UNCINE with max 0.2 kg/ha BBCH 15-81 compared to BOTRCI application rate of max 1 kg/ha at BBCH 60-85 could contribute to a possible development of resistance of an undetected BOTRCI infection (e.g. latent infection during flowering) or/and may result in a failed BOTRCI control.

3.3.2 Adverse effects on treated crops

Phytotoxicity assessment:

Boscalid is generally effective and safe when used according to guidelines. However, when applied at higher than recommended doses, boscalid can cause phytotoxicity, which may manifest as stunted growth, chlorosis or necrosis. Repeated and excessive use of boscalid can lead to the development of resistance in fungal populations, reducing its effectiveness over time. This can necessitate the use of higher doses or additional fungicides, potentially increasing the risk of adverse effects.

Both, EU Directive 91/414 (EU, 1991 and EPPO PP 1/226(3) – requires testing phytotoxicity at normal (N) and double (2N) recommended dose. However, EPPO 1/135 (3) states: «*EPPO Standards on fungicides, insecticides and plant growth regulators, on the other hand, include only a relatively simple special section on phytotoxicity assessment, because for these types of plant protection products, phytotoxic effects will be less frequent. Selectivity trials were not required, which is in accordance with EPPO 1/135(3)*» Boscalid is used for many years in agriculture practice and there is lack of information about any adverse effects than already known. So, no special studies are required in the opinion of ZRMs.

The crop safety of applying FGG01 at recommended doses was evaluated during efficacy trials carried out in N-E EPPO zone (16 trials), Maritime EPPO zone (28 trials) and S-E EPPO zone (6 trials). Also, Applicant presented supportive trials carried out in grapevine (13 trials) and fresh peas and beans (8 trials) in MED EPPO zone. In total, 71 trials in which phytotoxicity effect at N dose were presented by Applicant. Winter oilseed rape was studied in 29 trials carried out in Maritime EPPO zone (7 trials), N-E EPPO zone (16 trials) and S-E EPPO zone (6 trials). Grapevine was studied in 13 trials carried out in Maritime EPPO zone and 13 trials from MED EPPO zone (supportive trials). Fresh peas and beans were studied in 8 trials carried out in Maritime EPPO zone and 8 trials from MED EPPO zone (supportive trials). Lack of trials for spring oilseed rape – cMS should decide if it can be acceptable. For PL – at least 1-2 eff. trials in which phytotoxic effect will be assessed are required (without them, extrapolating results is not possible).

No adverse effects on treated crops (winter oilseed rape, grapevine and fresh beans and peas) by FGG01 with boscalid (500 g/kg) were observed in any of submitted efficacy trials. No phytotoxic effect was observed. In conclusion, **no negative impact of the product FGG01 is to be expected when at the intended rate and used according to the label recommendations.**

Impact on the yield:

Boscalid controls fungal diseases. Improved disease control generally leads to healthier plants and increased yields. Weather conditions where fungal diseases are more prevalent, the yield benefits from

boscalid treatments can be more pronounced. In conclusion, the use of boscalid fungicide has the potential to positively impact the yield of winter oilseed rape, grapevines and fresh beans and peas through effective disease management, provided it's used judiciously and in combination with other agronomic practices. However, the specific yield responses can vary depending on disease pressure, environmental conditions and how well the fungicide application is managed.

In conclusion, no negative impact of the product FGG01 on the yield of winter oilseed rape and fresh beans and peas is to be expected when at the intended rate and used according to label recommendations. Detailed results were presented in point 3.2.3. Yield was assessed in 6 trials carried out on winter oilseed rape (1 trial from N-E EPPO zone: PL) and 5 trials performed on peas and beans (3 trials from Maritime EPPO zone: BE, DE, CZ and 2 trials from MED EPPO zone: ES). Those results show that FGG01 will have no adverse effect on yield and in the presence of disease are likely to result in a significant increase. Results were comparable to st. ref. product. Lack of yield for grapevine. However, EPPO 1/17 states that *grapes harvested from different plots can be weighed. However, extrapolation of the data is only valid when the vineyard is homogeneous*. So, yield data for grapevines are not required.

In line to EPPO 1/80 - *Record-keeping is essential. For facilitate harvesting, divide the rows, when the first seeds are half brown. The yield should be recorded in kg per ha and according to the moisture content (according to national standards) national standards* and EPPO 1/78 - *Recording yields can be useful. For facilitate harvesting and reduce losses, it is necessary to divide the rows before development stage 71-78 on the BBCH. The yield should be calculated in kg ha⁻¹ according to the determined humidity level (according to national or international standards), and in relation to in relation to a control plot or preparation comparison plot. Useful information can also be by measuring the weight of 1,000 grains (g) and measuring the oil content*. Given the number of fungicides with boscalid on the market and that it has been a known substance for a long time, only one trial for winter oilseed rape was accepted by ZRMs.

In line to EPPO 1/54 - *the quantity harvested (and its quality, if necessary) should be recorded, so that additional information can be obtained information on phytotoxicity and controlling the spread of the disease*. Applicant submitted 3 trials from Maritime and 2 supportive trials for MED. This documentation for yield was assessed as sufficient by ZRMs.

Impact on the quality of yield:

Effectively diseases control generally leads to improved plant health, which can translate into higher yields. Quality of yield was assessed in one efficacy trial carried out on winter oilseed rape in N-E EPPO zone (PL) and beans and peas – 2 trials carried out in Maritime EPPO zone (DE, CZ). During those trials parameters such as a moisture and oil content in in winter oilseed rape and HLW, moicon and TKW in beans and peas were studied. Those results show that FGG01 will have no adverse effect on the quality of yield and in the presence of disease are likely to result in a significant increase. Those results were comparable to st. ref. product. Lack of trials for grapevines. Given the number of fungicides with boscalid on the market and that it has been a known substance for a long time, only one trial for winter oilseed rape was accepted by ZRMs.

3.3.3 Observations on other undesirable or unintended side-effects

Impact on the succeeding crops:

Boscalid has a relatively long soil half-life, which means it can remain active in the soil for several months following application. This residual presence may impact subsequent crops, especially those that are more sensitive to fungicides. Sensitivity to residual boscalid can vary among different crops. While boscalid is an effective solution for controlling a range of fungal diseases, its extended persistence in soil requires careful consideration when planning for future crops. To reduce any potential negative effects on subsequent plantings, farmers can test soil residue levels, select appropriate crop rotations and manage field conditions to promote the breakdown of the fungicide, thereby preserving both crop health and soil quality.

Applicant presented information's from seedling emergence data have been generated in a laboratory study carried out in Germany in 2022. The maximum proposed dose rate per application for FGG01 is 1.0 kg/ha, corresponding to 500 g a.s./ha. As this amount is 50% lower than the NOER, then it is considered that there is no risk to all crop species tested. As boscalid has been used in Europe for many years and no effect on succeeding crops is known in Europe, it is considered that there is no risk to al succeeding or replacement crops.

Impact on the adjacent crops:

Boscalid is generally targeted at controlling fungal pathogens on specific crops, but its application can indirectly impact adjacent crops.

When boscalid is applied, there is a risk of chemical drift to adjacent crops, depending on wind conditions and application methods. This can cause unintentional residue on non-target crops. In areas with significant rainfall or irrigation, boscalid can leach into soil and groundwater, potentially affecting neighboring plants. Adjacent crops not labeled for boscalid use might experience phytotoxic effects or stress depending on their sensitivity. Boscalid can alter soil health, affecting nutrient levels and microbial activity, which might indirectly influence the growth conditions of nearby plants. To minimize these impacts, strategies such as buffer zones, precise application techniques, and adherence to weather guidelines during spraying can be effective. Monitoring the health of adjacent crops post-application can also help in identifying and mitigating any adverse effects at early level.

A study of vegetative vigour conducted in Germany in 2022 has generated data on the effects of FGG01 on the growth and vigour of 6 indicator plant species. The NOER (No Observed Effect Rate) for all species was found to be 1000 g as./ha (2 kg product /ha). No effects were observed with regard to fresh weight. The maximum proposed dose rate per application for FGG01 is 1.0 kg/ha, corresponding to 500 g a.s./ha. As this amount is 50% lower than the NOER, then it is considered that there is no risk to all crop species tested. As boscalid has been used in Europe for many years and no effect on adjacent crops is known in Europe, it is considered that there is no risk to all adjacent crops.

It is not expected that appropriate applications of FGG01 will lead to adverse effects on adjacent crops. No negative effects of applications of boscalid containing products on adjacent crops are known, neither from field trials nor from long term agricultural use when the products were applied according to the use instructions.

Impact on the transformation processes:

The impact of boscalid fungicides on transformation processes in treated winter oilseed rape, grapevines, peas and beans can significantly influence oil production, wine quality and other important agricultural outputs.

Winter oilseed rape: effective disease management can lead to healthier plants, ultimately increasing seed yield and oil content. Boscalid may influence the biochemical composition of seeds, potentially enhancing oil quality and yield. Impact on the oil content was assessed in one trial which noted that FGG01 have positive impact on this parameter.

Grapevine: controlling diseases like powdery mildew helps maintain grape quality, resulting in better fermentation and higher wine quality. Boscalid could impact the synthesis of phenolic compounds which are critical for color, flavor and stability of wines. Improvements in the health of grapevines might enhance flavor development in grapes, critical for premium wines.

Possible effects on the production and quality of red grape cultivars treated with FGG01 at the rate of 1.0 kg/ha (maximum rate requested) were examined in 2 trials carried out in France and Germany. A further two trials are in progress (from South France and Germany). The parameters assessed were the following ripening of grapes at harvest or just after harvest, the analytical composition of the musts, fermentation process and malolactic fermentation, the analytical composition of the wines, organoleptic characteristics of the wines. No adverse effects on must, wine quality parameters is expected when FGG01 is applied at the maximum rate of 1.0 kg/ha which maximum of 1 application per season on red grapevine varieties

(PHI21).

Peas and beans: effective control of fungal pathogens allows for better plant health, leading to increased pod and seed development. Boscalid applications may affect the nutrient composition of seeds, such as protein content and essential amino acids, which are crucial for marketability.

Optimal use of boscalid can lead to improved product quality and increased profitability for farmers. In the opinion of ZRMs, no undesirable effects are expected on transformation processes.

Impact on the propagating purposes:

Residues of pesticides on seeds could potentially affect their ability to germinate. Although boscalid is formulated to minimize phytotoxicity, high residue levels may still have an adverse impact on seed germination. Seeds exposed to excessive fungicide residues may experience reduced germination rates. Therefore, it is essential to ensure that boscalid residues remain within safe levels to support successful seed germination. In conclusion, while boscalid is an important tool for disease management in crops like winter oilseed rape and cereals, careful consideration is required when using it on seeds intended for propagation. Monitoring residue levels, adhering to regulatory guidelines, and understanding potential effects on soil ecosystem are key factors for ensuring the safe and effective use of treated seeds for future planting.

Field trials have shown no signs of phytotoxicity, suggesting that when applied according to label instructions, boscalid does not negatively impact the plant parts used for propagation. Furthermore, boscalid containing fungicides have been in use for several years without evidence of significant negative effects on propagation processes or the treated plants and plant products.

Based on knowledge about boscalid and submitted documentation by Applicant, it can be concluded that no adverse effects on treated plants such as phytotoxicity symptoms, negative impact on yield quality and transformation processes were observed in efficacy trials of FGG01.

Impact on beneficial and non-target organisms:

Boscalid is a fungicide commonly used in agricultural settings to control a wide range of fungal pathogens. While it is effective for its intended use, there are concerns about its impact on non-target and beneficial organisms.

Boscalid can be detrimental to aquatic organisms if it makes its way into water bodies. It may affect fish and invertebrates like *Daphnia*. The presence of boscalid in soil may affect microbial communities. It can potentially alter the structure and function of microbial populations which are crucial for soil health.

Boscalid is considered relatively safer for pollinators compared to other pesticides, there is still a risk of exposure. Sub-lethal effects might include changes in behaviour or physiology. Boscalid is known for its relatively long persistence in the environment. This can increase the risk of exposure to non-target organisms over time, as residues can remain active for several weeks or months.

Including boscalid in an IPM strategy requires careful consideration of its broader ecological effects. Monitoring and managing dosages, as well as timing applications to minimize exposure to beneficial species, are critical practices.

To mitigate the risks associated with boscalid, it is essential for application to follow guidelines and regulations related to its usage and to consider alternative pest control options when feasible. Enhanced awareness and research into its sub-lethal and long term impact are also crucial for better understanding and minimizing its unintended consequences.

3.4 Methods of analysis (Part B, Section 5)

Sufficiently sensitive and selective analytical methods are available for the active substance and relevant impurities in the plant protection product.

Noticed data gaps are: None

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

3.4.1 Analytical method for the formulation

Analytical methodology for the determination of active substance in the formulation is available and validated.

As the active substance boscalid does not contain any relevant impurity, no pertinent analytical method is required.

3.4.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report (DAR), and in this dossier and validated for the determination of residues of boscalid in plants (high water content, high acid content, high oil content and high protein/high starch content matrices), foodstuffs of animal origin, soil, water (surface and drinking) and air.

The active substance is neither toxic nor very toxic, hence no analytical method was required for the determination of residues in biological fluids and tissues. However, an analytical method is provided to be in accordance with requirements of Regulation (EU) No 283/2013.

An analytical method and ILV are provided for the determination of boscalid in honey and a new ILV is provided for the determination of boscalid in drinking water to be in accordance with requirements of Regulation (EU) No 283/2013 and guidance document SANTE/2020/12380 rev.2.

Data gap: primary and ILV methods with LOQ of 0.01 mg/kg for muscle. This gap can be filled after registration (within two years).

3.5 Mammalian toxicology (Part B, Section 6)

3.5.1 Acute toxicity

FGG01 / LOZZARE PRO containing 500 g/kg boscalid, has a low acute oral and dermal toxicity with predicted LD₅₀ values exceeding 2000°mg/kg bw. FGG01 / LOZZARE PRO is not harmful by inhalation. Based on the rules laid down in Regulation (EC) No 1272/2008, FGG01 / LOZZARE PRO is not irritating to skin and eyes, and not a skin sensitizer.

Predictions are supported by studies performed for other regions than Europe and that will not be submitted as part of this application:

3.5.2 Operator exposure

Using the AOEM model, operator exposure is predicted to be in a range of 0.003 mg/kg bw/d to 0.01 mg/kg bw/d equal to approximately 3% and 13% of the AOEL for boscalid for tractor-mounted spraying

to low and high crops incl. viticulture and high vegetables, respectively, if normal work wear is worn by the operator. Similarly, for hand-held spraying using a knapsack sprayer, exposure is estimated to range from 0.003 to 0.007 mg/kg bw/d for low and high crops, equal to ca. 3.2 to 7.3% of the AOEL.

Please note, use of hand-held spraying equipment is considered to be safe as well, as results are within the range of results (risk envelope) presented. Thus, no risk for the operator using FGG01 / LOZZARE PRO is anticipated for all intended uses even without personal protective equipment. This has no labelling implications.

No risk for the operator using FGG01 / LOZZARE PRO is anticipated for all intended uses even without personal protective equipment(PPE) but should be use work wear (arms, body and legs covered) M/L and A.

3.5.3 Worker exposure

Potential worker exposure is estimated to range from 0.01 to 0.07 mg/kg bw/d equal to approximately 11 to 73% of the AOEL for re-entry activities in field crops and low vegetables such as inspection/irrigation, searching and reaching/picking. For hand harvesting of grapevines, worker exposure is estimated to be 0.07 mg/kg bw/d equal to ca. 69% of the AOEL if normal workwear is worn. Thus, no risk for workers upon re-entry is anticipated for all intended outdoor uses of FGG01 / LOZZARE PRO even without personal protective equipment. This has no labelling implications. However, as a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

No risk for workers upon re-entry is anticipated for all intended outdoor uses of FGG01 / LOZZARE PRO if use work wear (arms, body and legs covered)

3.5.4 Bystander and resident exposure

Resident exposure for children is estimated to range from 0.003 to 0.02 mg/kg bw/d equal to approximately 3 to 18% of the AOEL for boscalid. Resident exposure of adults is predicted to range from 0.001 to 0.01 mg/kg bw/d equal to approximately 1 - 10% of the AOEL. Thus, no risk for residents and bystanders is anticipated for all intended uses of FGG01/LOZZARE PRO. This has no labelling implications.

No risk for residents and bystanders is anticipated for all intended uses of FGG01/LOZZARE PRO and buffer zone 2-3m except for viticulture where the buffer zone is 5m.

3.6 Residues and consumer exposure (Part B, Section 7)

3.6.1 Residues

Storage stability

In the framework of the peer review, storage stability of boscalid was demonstrated for a period of 16 months in commodities with high acid content (grape) and 24 months in commodities with high water content (cabbage, peach, pea), high oil content (rape seed), dry commodities (wheat grain) and cereal straw.

Boscalid and M510F01 in milk, muscle, fat, liver, kidney and egg for up to 5 months was demonstrated, when stored deep frozen.

Additionally, the applicant provided new storage stability study for honey for up to 5 months.

The storage period submitted in the original monograph and the additional study are sufficient to cover the storage period of the intended GAP table for this application.

Metabolism in plants and animals

Plant residue definition for monitoring Boscalid (Regulation n°2022/1324)

Plant residue definition for risk assessment Boscalid (EFSA 2014)

Magnitude of residues in plants

Grapevine, wine & table

Proposed GAP:

1 application; BBCH 60-85; 0.50 kg as/ha; PHI: 21 days (use No 1 and 10)

3 applications (interval 10-14 days); BBCH 15-81; 0.10 kg as/ha (application rate); PHI: 21 days (use No 2)

Applicant refers to the unprotected data from the DAR:

Trials GAP: 1 x 0.6 kg as/ha, BBCH 60-81, PHI 21d, outdoor

Residues (NEU): 0.24, 0.28, 0.39, 0.50, 2x 0.78, 0.88, 1.03 mg/kg

Number of trials is sufficient.

Uses No 1 and 10:

The trials are overdosed but the difference is within $\pm 25\%$ (acceptable deviation according to the SANTE/2019/12752 Rev01) and can support the proposed uses.

The data submitted show that no exceedance of the EU MRLs for grape will occur. Uses are accepted.

Use No 2:

The GAP of the proposed application differs in 2 parameters from the GAP of the field trials (number of treatments per season and dose). According to the current requirements (SANTE/2019/12752 Rev01), the allowable differences are 1 parameter.

However, the applicant submitted his position paper justifying the acceptance of field studies to support the proposed use (presented below).

Based on SANTE/2019/12752

On pg 11, pt 3.1 it says:

“However, based on an expert judgment, minor deviations on more than one parameter may be accepted in exceptional and specific cases, especially if the deviation is not expected to have a major influence on the residue level in the harvested products (e.g. trial conducted with applications at 1100 g/ha and a 16 day PHI may be considered in compliance with a GAP defined as 1000 g/ha with a 14 day PHI)”

Moreover on pg 13:

“3.6. Deviations of residue trials regarding number of applications

In order to encompass the least favourable trial conditions, the trials must be carried out with the maximum number of applications defined in the cGAP. Where a PPP is applied in several applications, generally, the last application prior to harvest is the one that has the highest impact on the final residue in the harvested crop. The applications in fruits and fruiting vegetables prior to flowering are most of the time of less importance.

Generally, a deviation of the number of applications compared to the GAP is also acceptable under the following conditions:

II. If the number of applications in the residue trials is lower than the number of applications defined in the GAP by more than 25% and if it can be demonstrated that additional applications (e.g. at an early growth stage, rapid decline of residues after treatment) are unlikely to contribute significantly to the final residues."

In our case we have 3 x 0.1 kg a.s/ha, BBCH 15-81, PHI 21

cGAP used in residue studies: 1 x 0.6 kg a.s/ha, BBCH 79-81, PHI 21

Therefore, we can argue that according to SANTE/12752 minor deviations on more than one parameter may be accepted in exceptional and specific cases especially if the deviation is not expected to have a major influence on the residue level in the harvested product which is the case here. Intended application is to be used with twice lower dose rate from the one used in residue studies. Moreover, intended application is to be used with 3 number of applications with last application at BBCH81 the latest, which is comparable with application done in residue trials (BBCH 79-81). Following SANTE/12752 deviation of the number of applications compared to the GAP is acceptable if the number of applications in the residue trials is lower than the number of applications defined in the GAP by more than 25% and if it can be demonstrated that additional applications (e.g. at an early growth stage) are unlikely to contribute significantly to the final residues which is the case here (intended application is between BBCH 15-81).

To conclude, SANTE/12752 states, Where a PPP is applied in several applications, generally, the last application prior to harvest is the one that has the highest impact on the final residue in the harvested crops. The application in fruits and fruiting vegetables prior flowering are most of the time of less importance. In our case, last application prior to harvest which has the highest impact on the final residue in the harvested crops presented in residue studies is done with dose rate twice higher from intended one and it shows acceptable results.

Taking the above into account, the evaluator considers that the recognition of the applicant's arguments may be considered at the level of the Member States.

Poland agreed with the applicant's position. The available trials can support the use No 2. Use is accepted.

Field studies from the southern zone were not used in the assessment.

Oilseed rape (winter and spring),

gold of pleasure, winter turnip rape, mustard, sunflower, poppy, linseed, flax, hemp, borage

Proposed GAP:

1 application; BBCH 57-69 and BBCH 13-57; 250 g as/ha, PHI: 35

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

Trials are overdosed (two application instead 1).

Trials GAP (oilseed rape): 2 x 0.25 kg as/ha, BBCH 57-81, PHI 35d, outdoor

Results (NEU): <LOQ, 0.016, 0.041, 0.074, 0.081, 0.12, 0.16, 0.22 mg/kg

Trials can be accepted as worst case scenario.

Sufficient trials are available to support the proposed use on oilseed rape.

The data submitted show that no exceedance of the EU MRLs for oilseed rape will occur.

According to the SANTE/2019/12752 Rev01 extrapolation from oilseed rape to gold of pleasure, winter turnip rape, mustard, sunflower, poppy, linseed, flax, hemp and borage is accepted.

Uses are accepted. Field studies from the southern zone were not used in the assessment.

401000	Oilseeds	MRL
401010	Linseeds	1

401020	Peanuts/groundnuts	1
401030	Poppy seeds	1
401040	Sesame seeds	1
401050	Sunflower seeds	1
401060	Rapeseeds/canola seeds	1
401070	Soyabeans	3
401080	Mustard seeds	1
401090	Cotton seeds	1
401100	Pumpkin seeds	1
401110	Safflower seeds	1
401120	Borage seeds	1
401130	Gold of pleasure seeds	1
401140	Hemp seeds	1
401150	Castor beans	1
401990	Others (2)	0,06

Beans and peas (fresh),

broad bean, french beans, peas and beans for fresh seeds, edible podded peas

Proposed GAP:

2 applications (interval: 7 days); BBCH 60-69; 500 g as/ha (application rate), PHI: 7

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

Trials GAP (beans (fresh with pods)): 2 x 0.5 kg as/ha, BBCH 65-87, PHI 7d, outdoor

Residues (NEU, beans with pods): 0.19, 0.25, 0.26, 0.28, 0.36, 0.61, 0.76, 2.0 mg/kg

According to the SANTE/2019/12752 Rev01 extrapolation from beans (fresh with pods) to fresh peas with pods, french beans, edible podded peas is accepted. Number of trials is sufficient. The data submitted show that no exceedance of the EU MRLs for beans and peas with pods **and without pods** will occur. Uses are accepted.

Extrapolation from beans with pod to peas and beans for seeds is not possible. Uses on broad bean and peas and beans for fresh seeds are not accepted.

Legumes: accepted fresh with pods only.

Field studies from the southern zone were not used in the assessment.

Crops in the GAP table were not presented clearly. The applicant is obliged use code numbers according to Annex I of Regulation (EU) No 396/2005.

The lack of a precisely defined plant causes misunderstanding.

According to the SANTE/2019/12752 Rev01 extrapolation from beans and peas with pods to all group of legumes (application is made before the forming of the edible part of the plant) is acceptable.

zRMS agrees to use of the PPP in the protection of legumes with and without pods.

Magnitude of residues in livestock

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

STMR and HR from the new residue trials are less than used in dietary burden calculation for art.12 review (EFSA Journal 2014;12(7):3799). Additional data are not required.

Processing studies

Studies investigating the magnitude of residues in processed commodities of different crops were reported in the framework of the peer review (DAR, 2002). Data are considered acceptable to derive robust processing factors for different crops.

New studies have been submitted by the applicant in the framework of this application. The objective of the study was to determine the residue level of boscalid in processing fractions of oilseed rape. The same levels of boscalid residue in processed commodities was found in the raw agricultural commodity, generating a processing factor of 1.0 for raw and crude oil.

Further processing studies are not required, as they are not expected to affect the outcome of the risk assessment.

Magnitude of residues in representative succeeding crops

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

Occurrence of Boscalid residues in rotational crops was already investigated during the peer review. It is concluded that metabolic patterns in primary and succeeding crops are similar and that a potential for accumulation of Boscalid residues in crops grown in rotation is expected. EFSA is aware that instead of defining risk mitigating measures, risk managers may have the interest to establish MRLs accommodating for the uptake of residues from previously treated soils, EFSA therefore recalculated the MRL proposals to take into account such residues.

Waiting periods before planting following succeeding crops: not required.

Additional data are not required.

Other / special studies

New studies have been submitted by the applicant in the framework of this application.

Trials were performed in protected oilseed rape located in representative areas of honey production. Protected oilseed rape was treated with two foliar applications with Boscalid 500 g/Kg WG formulation (code FGG01) at a dose rate of 500 g boscalid/ha (equivalent to 1 kg product/ha) and nominal 300 L/ha water spray volume. The applications targeted a 7±1 day retreatment interval with the second application performed during the flowering period (BBCH 60-69). Residues of boscalid found in honey ranged from < 0.01 to 0.0455 mg/kg. The new data was input into the MRL calculator and the calculated EU MRL was 0.1 mg/kg, indicating that no exceedance of the MRL on honey (0.15 mg/kg – Reg (EU) no. 2021/590) will occur after the application of the plant protection product FGG01.

The results are acceptable. No risk for consumers is expected.

3.6.2 Consumer exposure

A first-tier chronic consumer risk assessment was assessed using the EFSA PRIMo model rev 3.1. The median residue level for raw agricultural commodity derived from the submitted trials and the median residues derived by EFSA in previous assessments (EFSA, 2014, 2015, 2019, 2020) were the values used in the calculation. With the current EFSA model the chronic risk assessment ranges from 4 to 71% of ADI. The diet with the highest TMDI is “NL toddler” with 71% of ADI. For this diet, the highest contributor are apples with 11% of ADI. The diet with the second highest TMDI is “DE child” with 50% of ADI, in which apples still the major contributor with 13% of ADI.

The acute risk assessment resulted in no exceedance of the toxicological reference values for any unprocessed and processed commodities (intended crops). The data available are considered sufficient for

risk assessment. The proposed uses of boscalid in the formulation FGG01 do not represent unacceptable acute and chronic risks for the consumer.

Noticed data gaps are:

- Residue trials supporting uses on fresh legumes without pods.

3.7 Environmental fate and behaviour (Part B, Section 8)

This document reviews the environmental fate studies and modelling for the first authorisation of the product LOZZARE PRO (FGG01).

The review report for boscalid (SANCO/3919/2007 – rev. 5, dated 21 January 2008) is considered to provide the relevant review information or a reference to where such information can be found. Furthermore, the information, data and assessments provided in Registration Report, Part B includes assessment of further data or information as required at national registration by the EU review.

Metabolite M510F64 occurred at amounts >5% in 2 sequential measurements in the higher-tier outdoor water/sediment study presented for the original approval of boscalid. Metabolite M510F64 reached maximum 9.4% TAR after 30 days in the water phase. Additionally, this compound is of no toxicological and ecotoxicological relevance. Following the approaches taken for the currently authorised products containing boscalid, no exposure assessment was presented for metabolite M510F64.

No other metabolites potentially relevant for exposure assessment have been observed.

Further details about the route and rate of degradation of boscalid in soil, in water and in air, are described in Part B, Section 8.

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

The PEC_{soil} of boscalid has been assessed with the FOCUS guidelines (FOCUS, 1997¹), FOCUS groundwater interception values (EFSA, 2014²) and the EU agreed DT₅₀ value.

PEC_{accumulation} was also assessed as the soil dissipation DT₉₀ values for boscalid were above 1 year.

The maximum PEC_{soil} value is 0.397 mg/kg, calculated based upon two applications of 500 g a.s./ha on beans and peas. With regard to single application the maximum PEC_{soil} value is 0.267 mg/kg, calculated based upon a single application of 500 g a.s./ha on grapevine (vine and fresh).

The maximum PEC_{accumulation} is 0.509 mg/kg (FOCUS Approach).

This assessment covers all uses proposed for the authorisation of the product LOZZARE PRO (FGG01).

Results were used for the ecotoxicological risk assessment.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

The PEC of boscalid in groundwater has been conducted in accordance with the FOCUS GW report

¹ FOCUS (1997) Soil persistence models and EU Registration - The Final Report of the Soil Modelling Workgroup of FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use) – 29 February 1997.

² EFSA 2014 European Food Safety Authority. Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662, 38 pp., doi:10.2903/j.efsa.2014.3662

(FOCUS, 2014³) and the FOCUS Generic Guidance (FOCUS, 2023⁴) and assessed with standard FOCUS scenarios to obtain outputs from the leaching models FOCUS PEARL 5.5.5 and FOCUS PELMO 6.6.4. Calculation of PEC_{GW} with FOCUS MACRO 5.5.4 was not considered required as PEC_{GW} concentrations with FOCUS PEARL and FOCUS PELMO were < 0.001 µg/L for all scenarios.

Simulations were conducted considering various use patterns on vines, winter and spring oilseed rape, beans and peas.

Boscalid is not predicted to leach into ground water above the critical 0.1 µg/L threshold following a 26-year period of application to vines, winter and spring oilseed rape, beans and peas.

The results indicate that any contamination of groundwater at concentrations relevant for the environment and for consumer exposure by the active substance boscalid must not be expected following the GAP proposed uses of LOZZARE PRO (FGG01).

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

A PEC_{sw} calculation was performed for the product LOZZARE PRO (FGG01) according to the FOCUS SW report (2001)⁵ and the FOCUS Generic Guidance (2015)⁶.

PEC_{sw} and PEC_{sed} values for boscalid as well as major metabolites for FOCUS evaluation steps 1 and 2 were calculated using the modelling software STEPS 1-2 (version 3.2). Within the scope of evaluation steps 3 with active substance boscalid, for every main entry route, different software was used as recommended, i.e. FOCUS SWASH 5.3, Drift calculator 1.1 (spray drift), MACRO 5.5.4 (drainage) and PRZM 4.3.1 (runoff). Based on the different pesticide inputs calculated, TOXSWA 5.5 was used to simulate the fate of pesticide entries in typical surface water bodies and finally to calculate maximum as well as actual and time weighted average concentrations in water layer and sediment for different dates or periods.

Results were used for the ecotoxicological risk assessment.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

Based on vapour pressure, information on volatilisation from plants and soil, and DT₅₀ calculation, no significant contamination of the air compartment is expected for the intended uses.

3.8 Ecotoxicology (Part B, Section 9)

For all intended uses, no risk mitigation measures are required.

³ FOCUS GW report (2014): European Commission (2014) “Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU” Report of the FOCUS Ground Water Work Group, EC Document Reference SANCO/13144/2010 version 3, 613 pp.

⁴ FOCUS Generic Guidance (2023): Generic Guidance for Tier 1 FOCUS Ground Water Assessments, version 2.4, March 2023

⁵ FOCUS (2001) “FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC”, Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2, 245 pp, May 2003

⁶ FOCUS (2015): Generic guidance for FOCUS surface water scenarios, version 1.4, May 2015

3.8.1 Effects on terrestrial vertebrates

Birds

Acute and long-term/reproductive TER values at the screening step and/or Tier 1 exceed the relevant trigger values; thus, risk for birds can be excluded for all intended uses. Therefore, a higher-Tier risk assessment is not required.

The risk for birds due to uptake of contaminated drinking water from puddles is acceptable for all intended uses of FGG01.

The log P_{ow} of Boscalid does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

Terrestrial vertebrates other than birds

Acute and long-term/reproductive TER values at the screening step and/or Tier 1 exceed the relevant trigger values; thus, risk for mammals can be excluded for all intended uses. Therefore, a higher-Tier risk assessment is not required.

The risk for mammals due to uptake of contaminated drinking water from puddles is acceptable for all intended uses of FGG01.

The log P_{ow} of Boscalid does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

Reptiles and amphibians

Appropriate test guidelines and guidance documents are currently not available to address the risk to reptiles and amphibians. However, due to the acceptable risk of Boscalid to terrestrial vertebrates and fish, adverse effects following the intended uses are considered unlikely.

3.8.2 Effects on aquatic species

For the intended uses in oilseed rape (use 3 to 5), calculated PEC/RAC ratios for Boscalid at Tier 1 indicate acceptable risk for all groups of aquatic organisms in all FOCUS step 1 and/or 2 scenarios.

For the intended uses in vines (uses 1 & 2) and beans and peas (uses 6 & 7), calculated PEC/RAC ratios for Boscalid at Tier 1 indicate acceptable risk for all groups of aquatic organisms up to FOCUS step 3.

Therefore, further PEC/RAC ratios based on FOCUS Step 4 PEC_{sw} are not required.

For all intended uses, no risk is indicated for sediment-dwelling organism at FOCUS step 1.

3.8.3 Effects on bees

Based on the acute Tier-1 risk assessment (honeybees and bumble bees) according to SANCO/10329/2002 rev.2 (final), October 17, 2002, and the chronic Tier-1 risk assessment (honeybees) according to the modified EPPO (2010)/ECPA (2017) scheme, respectively, acceptable risk to bees following the intended uses of FGG01 is indicated.

Based on the screening risk assessment according to EFSA/2013/3295, acceptable acute contact and oral risk to honeybees and bumble bees and acceptable chronic larvae risk for honeybees is indicated following all intended uses. Acceptable risk is further indicated based on chronic adult ETR values for honeybees following the intended uses in grapevine at 100 g a.s./ha.

Based on the Tier 1 risk assessment according to EFSA/2013/3295, the chronic adult ETR values for all scenarios are below the relevant trigger values for all uses at 250 g a.s./ha indicating acceptable risk to bees following the intended uses of FGG01 in oilseed rape. The chronic adult ETR values for the treated crop scenario slightly exceed the relevant trigger values for all uses at 500 g a.s./ha in grapevine, beans and peas. However, considering that the short cut values (SV) used at lower tiers are based on default

RUD values, this risk assessment is a very conservative approach. Considering that the trigger values are only slightly exceeded under worst-case assumptions, risk for bees for the treated crop scenario following the uses in grapevine, beans and peas is deemed acceptable.

The risk assessment for honeybees (acute and chronic) and bumble bees (acute) indicates no risk to other pollinators with certain margin of safety.

3.8.4 Effects on other arthropod species other than bees

For all intended uses, Tier-1 in-field and off-field HQ values are below the relevant trigger value for both indicator species. Thus, higher-Tier risk assessment and/or risk mitigation measures are not required.

3.8.5 Effects on soil organisms

Non-target soil meso- and macrofauna

All Tier-1 TER values for earthworms and other non-target soil organisms (meso- and macrofauna) exceed the relevant trigger values indicating no risk for all intended uses. Therefore, higher-Tier risk assessment is not required.

Effects on soil microbial activity

The maximum concentration of Boscalid with effects on micro-organisms $\leq 25\%$ exceed the respective maximum PEC_{soil} value indicating no risk for all intended uses.

3.8.6 Effects on non-target terrestrial plants

Risk is considered acceptable since data on seedling emergence and vegetative vigour from six species do not indicate phytotoxic effects $> 50\%$ at the maximum intended application rate. Therefore, a Tier-2 risk assessment based on dose-response data is not required.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Not available and not required.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Product FGG01 contains active substance boscalid which is not approved as a candidate for substitution. Therefore, a comparative assessment is not required.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Metabolism and residues:

Acceptance of use No2 left to decisions at Member State level. In Poland this use was accepted.

Legumes: accepted fresh with pods only.

Noticed data gaps are:

- ~~Residue trials supporting uses on fresh legumes without pods.~~

Analytical methods

Data gap: primary and ILV methods with LOQ of 0.01 mg/kg for muscle. This gap can be filled after registration (within two years).

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

Appendix 2 Copy of the product label

Sekcja skuteczność: Zastosowanie przeciwko szarej pleśni na fasoli zwykłej, fasoli szparagowej, fasoli wielokwiatowej, grochu zielonym cukrowym, grochu zielonym łuskowym i bobie zostało wykreślone z głównej części etykiety. Dodano zapis iż środek charakteryzuje się średnią skutecznością przeciwko suchej zgniliźnie na rzepaku ozimym oraz mączniakowi prawdziwemu na winorośli. Pozostałych zapisów etykiety nie zmieniano.

Sekcja pozostałości: wykreślono rośliny zielarskie (nie były przedmiotem oceny). Brak jest zgody na zastosowania roślin strączkowych przeznaczonych na suche nasiona.

Posiadacz zezwolenia:

UPL Holdings Coöperatief U.A., Claudius Prinsenlaan 144a, Block A, 4818CP Breda, Królestwo Niderlandów, tel.: +31 85 071 23 00, e-mail: uplholdingscoop@upl-ltd.com

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:

UPL Polska Sp. z o.o., ul. Stawki 40, 01-040 Warszawa, tel.: +48 22 434 00 90, e-mail: sekretariat@upl-ltd.com

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:

(...)

Podmiot odpowiedzialny za końcowe etykietowanie środka ochrony roślin:

(...)


Lozzare Pro

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Substancja czynna:

boskalid (związek z grupy anilidów)- 500 g/kg (51,02 %)

Zezwolenie MRiRW nr R - xx/2025 z dnia xx.xx.2025 r.

	
H411	Działa toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P273	Unikać uwolnienia do środowiska.
P391	Zebrać wyciek
P501	Puste opakowanie przekazać do punktów odbioru odpadów niebezpiecznych lub do sklepów ogrodnich bądź hurtowni.

OPIS DZIAŁANIA

FUNGICYD w postaci granul do sporządzania zawiesiny wodnej (WG) o działaniu układowym do stosowania zapobiegawczego i interwencyjnego w ochronie roślin przed chorobami powodowanymi przez grzyby.

Zgodnie z klasyfikacją FRAC substancja czynna boskalid zaliczana jest do grupy 7.

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych.

Rzepak ozimy

Zgnilizna twardzikowa

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,5 kg/ha.

Termin stosowania: Środek stosować od fazy gdy widoczne są pojedyncze nadal zamknięte pąki kwiatowe (kwiatostany boczne) do fazy wykształcenia się pierwszych łuszczyn (BBCH 57-69).

Liczba zabiegów: 1.

Zalecana ilość wody: 100 - 300 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Sucha zgnilizna kapustnych

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,5 kg/ha.

Termin stosowania: Środek stosować od fazy 3 liści rzepaku do momentu, gdy widoczne są pojedyncze nadal zamknięte pąki kwiatowe (kwiatostany boczne) (BBCH 13-57).

Liczba zabiegów: 1.

Zalecana ilość wody: 100 - 300 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Fasola zwyczajna uprawiana na świeże nasiona, fasola szparagowa fasola wielokwiatowa uprawiana na jadalne strąki, groch zielony cukrowy uprawiany na jadalne strąki, groch zielony łuskowy uprawiany na zielone nasiona, bób uprawiany na świeże nasiona

Świeża plama

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,0 kg/ha.

Termin stosowania: Środek stosować od końca fazy rozwoju kwiatostanu (widoczne otwarcie pierwszych kwiatów) do końca fazy kwitnienia (BBCH 60-69).

Liczba zabiegów: 2

Odstęp między zabiegami: co najmniej 7 dni.

Zalecana ilość wody: 150 – 600 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Winorośl

Mączniak prawdziwy winorośli

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,2 kg/ha (0,14 kg/ha ściany liści).

Termin stosowania: Środek stosować od końca fazy rozwoju liści do początku dojrzewania jagód (BBCH 15-81).

Liczba zabiegów: 3.

Odstęp między zabiegami: 10 do 14 dni.

Zalecana ilość wody: 100 - 1000 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 3

STOSOWANIE ŚRODKA OCHRONY ROŚLIN W UPRAWACH I ZASTOSOWANIACH MAŁOOBSZAROWYCH

Odpowiedzialność za skuteczność działania i fitotoksyczność środka ochrony roślin stosowanego w uprawach małoobszarowych ponosi wyłącznie jego użytkownik.

Gorczyca biała, gorczyca czarna, gorczyca sarepska, rzepak jary, rzepik ozimy, lnianka siewna

Zgnilizna twardzikowa, czerń krzyżowych

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,5 kg/ha.

Termin stosowania: Środek stosować od fazy gdy widoczne są pojedyncze nadal zamknięte pąki kwiatowe (kwiatostany boczne) do fazy wykształcenia się pierwszych łuszczyń (BBCH 57-69).

Liczba zabiegów: 1.

Zalecana ilość wody: 100 - 300 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Sucha zgnilizna kapustnych

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,5 kg/ha.

Termin stosowania: Środek stosować od fazy 3 liści rzepaku do momentu, gdy widoczne są pojedyncze nadal zamknięte pąki kwiatowe (kwiatostany boczne) (BBCH 13-57).

Liczba zabiegów: 1.

Zalecana ilość wody: 100 - 300 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Mak lekarski, len zwyczajny, słonecznik zwyczajny, konopie siewne, rośliny zielarskie: ogórecznik lekarski

Zgnilizna twardzikowa, alternarioza

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,5 kg/ha.

Termin stosowania: Środek stosować zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów choroby z zachowaniem okresu karencji.

Liczba zabiegów: 1.

Zalecana ilość wody: 100 - 300 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Mak lekarski, len zwyczajny, konopie siewne, rośliny zielarskie: ogórecznik lekarski

Sucha zgnilizna

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,5 kg/ha.

Termin stosowania: Środek stosować zapobiegawczo lub natychmiast po zaobserwowaniu pierwszych objawów choroby z zachowaniem okresu karencji.

Liczba zabiegów: 1.

Zalecana ilość wody: 100 - 300 l/ha.
Zalecane opryskiwanie: drobnokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Fasola zwykła uprawiana na świeże nasiona, groch zwyczajny uprawiany na świeże nasiona, fasola wielokwiatowa uprawiana na świeże nasiona, fasola wielokwiatowa uprawiana na jadalne strąki, fasola szparagowa, groch zielony cukrowy uprawiany na jadalne strąki, groch zielony łuskowy uprawiany na zielone nasiona, groch zwyczajny siewny, groch zwyczajny polny, bób uprawiany na świeże nasiona.

Zgnilizna twardzikowa, szara pleśń

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,0 kg/ha.
Termin stosowania: Środek stosować od końca fazy rozwoju kwiatostanu (widoczne otwarte pierwsze kwiaty) do końca fazy kwitnienia (BBCH 60-69).
Liczba zabiegów: 2.
Odstęp między zabiegami: co najmniej 7 dni.
Zalecana ilość wody: 150 - 600 l/ha.
Zalecane opryskiwanie: drobnokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

Winorośl

Szara pleśń

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1 kg/ha (0,72 kg/ha ściany liści).
Termin stosowania: Środek stosować od początku fazy kwitnienia do mięknięcia jagód (BBCH 60-85).
Liczba zabiegów: 1.
Zalecana ilość wody: 100-1000 l/ha.
Zalecane opryskiwanie: drobnokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

Fasola szparagowa, fasola zwykła, fasola wielokwiatowa, groch zielony cukrowy, groch zielony łuskowy, groch zwyczajny siewny, groch zwyczajny polny, bób – 7 dni

Winorośl – 21 dni

Rzepak ozimy, rzepak jary, gorczyca biała, gorczyca czarna, gorczyca sarepska, rzepik ozimy, lnianka siewna, mak lekarski, len zwyczajny, słonecznik zwyczajny, konopie siewne, rośliny zielarskie: ogórecznik lekarski – 35 dni

Środek zawiera substancję czynną boskalid z grupy anilidów (karboksamidów) (fungicydy inhibitory dehydrogenazy bursztynianowej - SDHI - grupa FRAC 7).

W ramach strategii zarządzania odpornością zaleca się:

- stosowanie środka przede wszystkim do zabiegów zapobiegawczych,
- stosowanie środka wyłącznie w zalecanych dawkach i terminach,
- w przypadku łącznego stosowania drugi środek powinien zawierać substancję czynną z innej grupy, o innym mechanizmie działania i wykazywać wysoką skuteczność w zwalczaniu chorób, które mają być celem zabiegu,
- w przypadku konieczności wykonania kolejnych zabiegów użycie środków grzybobójczych, zawierających substancje czynne o innych mechanizmach działania (stosowanie przemienne).

Środek charakteryzuje się średnią skutecznością przeciwko suchej zgniliźnie na rzepa-ku ozimym oraz mączniakowi prawdziwemu na winorośli

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlewniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać. W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy:

- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć oraz przepłukać co najmniej trzykrotnie wodą.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

Stosować rękawice ochronne i odzież roboczą w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Unikać wdychania rozpylonej cieczy.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):

nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

Dla winorośli strefa buforowa 5 m

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 1 m od zbiorników i cieków wodnych.

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0 °C-30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

Not applicable.

Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
Section B124, phys-chem							
KCP 1.4.2/01	Anonymous	2024	Boscalid Safety Data Sheet Version: 2.2 GLP: no Published	N	N	-	UPL Europe
KCP 2.1 KCP 2.2.2 KCP 2.3.2 KCP 2.3.3 KCP 2.4.2 KCP 2.6.2 KCP 2.8.1 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.1 KCP 2.8.5.1.2 KCP 2.8.5.2.1 KCP 2.8.5.3 KCP 2.8.7.1	Chaudhari, M.N.	2022a	Physico-chemical properties of Boscalid 500 g/Kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 270-2-11-31452) UPL EUROPE LTD (UPL/2022/0952) GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 2.2.1 <i>Included in</i>	García Carril, A.M.	2024	Scientific statement: Boscalid 500 WG/FGG01 (LOZZARE PRO), Statement on explosive properties	N	Y	Study report never submitted before to support a product	UPL Europe

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
<i>Part C</i>			Report Number: 213 2 230 – CP 2.2.1-01 GLP: no Unpublished <i>Included in Part C</i>			authorisation in this EU member state nor used for a product authorisation in any EU Member State	
KCP 2.7.1	Chaudhari, M.N.	2022b	Accelerated storage stability and corrosion characteristics of Boscalid 500 g/Kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 270-2- 11-31452) UPL EUROPE LTD (UPL/2022/0952) GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 2.8.5.1.3 KCP 2.7.5 KCP 4.4/01	Patel, D.	2024	Two Years Storage Stability and Corrosion Characteristics study of Boscalid 500 g/kg WG (Interim Report-I) JAI RESEARCH FOUNDATION (JRF Study Number: 237-2- 11-31229) UPL EUROPE LTD (UPL/2022/2092) GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 4.2/01	Prajapati, P.N.	2024	Effectiveness of Cleaning Procedures of Boscalid 500 g/Kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 284-2- 11-36679) UPL EUROPE LTD (UPL/2024/0502) GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 4.3/01 KCP 4.5/01	Anonymous	2024	FGG01 / GPF 516 Safety Data Sheet Version: 3.0 GLP: no Published	N	N	-	UPL Europe
Section B3, efficacy							
KCP 3.2 KCP 3.4	UPL Holdings Coöperatief	2023	<u>Biological Assessment Dossier (BAD):</u> KCP Section 6: Efficacy Data and Information, Detailed Summary. Product code: FGG01	N	N	-	UPL Europe

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Product name: Lozzare Pro, Miller Pro, Palator Pro Central Registration zone (zRMS Poland) Core Assessment UPL Holdings Coöperatief. n/a n/a Unpublished				
KCP 3.2.2 KCP 3.2.3 KCP 3.4.1	Maluga, P.	2021	The efficacy of FGG01 applied in OSR for the control of <i>Sclerotinia sclerotiorum</i> (SCLESC) in Europe, 2021. SynTech Research Poland Sp. z o.o., Bydgoszcz, Poland, Report No. SRPL21-329-129FE Report No. F21EU-024-011-004 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.2 KCP 3.2.3 KCP 3.4.1	Potocka, K.	2021	The efficacy of FGG01 applied in OSR for the control of <i>Sclerotinia sclerotiorum</i> (SCLESC) in Europe, 2021. SynTech Research Poland Sp. z o.o., Bydgoszcz, Poland, Report No. SRPL21-330-129FE Report No. F21EU-024-011-005 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.2 KCP 3.2.3 KCP 3.4.1	Ćwiek, M.	2021	The efficacy of FGG01 applied in OSR for the control of <i>Sclerotinia sclerotiorum</i> (SCLESC) in Europe, 2021. SynTech Research Poland Sp. z o.o., Bydgoszcz, Poland, Report No. SRPL21-331-129FE Report No. F21EU-024-011-006 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.2 KCP 3.2.3 KCP 3.4.1	Furman-Frątczak, K.	2023	The efficacy of FGG01 and FGG04 applied for the control of <i>Sclerotinia sclerotiorum</i> on winter oilseed rape in Poland, 202KCP 3. AGRECO Sp. z o.o., Wrocław, Poland, Report No. 23UPL01294-1 Report No. F23EU-045-AMA-007 UPL	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP Unpublished				
KCP 3.2.2 KCP 3.2.3 KCP 3.4.1 KCP 3.4.2	Furman-Frątczak, K.	2023	The efficacy of FGG01 and FGG04 applied for the control of <i>Sclerotinia sclerotiorum</i> on winter oilseed rape in Poland, 2023AGRECO Sp. z o.o., Wrocław, Poland, Report No. 23UPL01294-2 Report No. F23EU-045-AMA-008 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.2 KCP 3.2.3 KCP 3.4.1	Furman-Frątczak, K.	2023	The efficacy of FGG01 and FGG04 applied for the control of <i>Sclerotinia sclerotiorum</i> on winter oilseed rape in Poland, 202KCP 3. AGRECO Sp. z o.o., Wrocław, Poland, Report No. 23UPL01294-3 Report No. F23EU-045-AMA-009 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.2 KCP 3.2.3 KCP 3.4.1	Furman-Frątczak, K.	2023	The efficacy of FGG01 and FGG04 applied for the control of <i>Sclerotinia sclerotiorum</i> on winter oilseed rape in Poland, 202KCP 3. AGRECO Sp. z o.o., Wrocław, Poland, Report No. 23UPL01294-4 Report No. F23EU-045-AMA-010 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.2 KCP 3.2.3 KCP 3.4.1	Maciej, K.	2021	The efficacy of FGG01 applied in OSR for the control of <i>Plenodomus lingam</i> (LEPTMA) in Europe, 2021 SynTech Research Poland Sp. z o.o., Bydgoszcz, Poland, Report No. SRPL21-332-129FE Report No. F21EU-025-011-004 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.2 KCP 3.2.3	Potocka, K.	2021	The efficacy of FGG01 applied in OSR for the control of <i>Plenodomus lingam</i> (LEPTMA) in Europe, 2021	N	Y	Study report never submitted before to support a product	UPL Europe

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 3.4.1			SynTech Research Poland Sp. z o.o., Bydgoszcz, Poland, Report No. SRPL21-333-129FE Report No. F21EU-025-011-005 UPL GEP Unpublished			authorisation in this EU member state nor used for a product authorisation in any EU Member State	
KCP 3.2.2 KCP 3.2.3 KCP 3.4.1	Świtkowski, M.	2021	The efficacy of FGG01 applied in OSR for the control of <i>Plenodomus lingam</i> (LEPTMA) in Europe, 2021 SynTech Research Poland Sp. z o.o., Bydgoszcz, Poland, Report No. SRPL21-334-129FE Report No. F21EU-025-011-006 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.2 KCP 3.2.3 KCP 3.4.1	Dimon, C.	2022	The efficacy of FGG01 applied in OSR for the control of <i>Plenodomus lingam</i> (LEPTMA) in Europe. Eurofins Agrosience Services Sp. z o.o, Kazmierz, Poland, Report No. S22-01827-01 Report No. F22EU-002-AMA-001 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.2 KCP 3.2.3 KCP 3.4.1	Dimon, C.	2022	The efficacy of FGG01 applied in OSR for the control of <i>Plenodomus lingam</i> (LEPTMA) in Europe. Eurofins Agrosience Services Sp. z o.o, Kazmierz, Poland, Report No. S22-01827-02 Report No. F22EU-002-AMA-002 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.2 KCP 3.2.3 KCP 3.4.1	Fejes, A.	2021	The efficacy of FGG01 applied in OSR for the control of <i>Plenodomus lingam</i> (LEPTMA) in Hungary. SynTech Research Hungary Kft., Csömör, Hungary, Report No. GEP 21/153 Report No. F21EU-025-011-001 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 3.2.2 KCP 3.2.3 KCP 3.4.1	Ettig, B.	2021	The efficacy of FGG01 applied in OSR for the control of <i>Plenodomus lingam</i> (LEPTMA) in Hungary. SynTech Research Hungary Kft., Csömör, Hungary, Report No. GEP 21/154 Report No. F21EU-025-011-002 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.2 KCP 3.2.3 KCP 3.4.1	Ettig, B.	2021	The efficacy of FGG01 applied in OSR for the control of <i>Plenodomus lingam</i> (LEPTMA) in Hungary. SynTech Research Hungary Kft., Csömör, Hungary, Report No. GEP 21/155 Report No. F21EU-025-011-003 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.2 KCP 3.2.3 KCP 3.4.1	Heinzmann, S.	2022	The efficacy of FGG01 applied preventive against powdery mildew (<i>Erysiphe necator</i>) in grapevine in Europe. Eurofins Agrosience Services Germany, Stade Germany, Report No. S22-01830-02 Report No. F22EU-004-AMA-002 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.2 KCP 3.2.3 KCP 3.4.1	Schönhofen-Müller, M.	2022	The efficacy of FGG01 applied preventive against powdery mildew (<i>Erysiphe necator</i>) in grapevine in Europe. Eurofins Agrosience Services Germany, Stade, Germany, Report No. S22-01830-03 Report No. F22EU-004-AMA-003 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.2 KCP 3.2.3 KCP 3.4.1	Beber, M.	2022	The efficacy of FGG01 applied preventive against powdery mildew (<i>Erysiphe necator</i>) in grapevine in Europe. Eurofins Agrosience Services Austria, Graz, Austria, Report No. S22-01830-04 Report No. F22EU-004-AMA-004 UPL	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP Unpublished				
KCP 3.2.2 KCP 3.2.3 KCP 3.4.1	Beber, M.	2022	The efficacy of FGG01 applied preventive against powdery mildew (<i>Erysiphe necator</i>) in grapevine in Europe. Eurofins Agrosience Services Austria, Graz, Austria, Report No. S22-01830-05 Report No. F22EU-004-AMA-005 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.2 KCP 3.2.3 KCP 3.4.1	Gröss-Ahr, K.	2023	GEP efficacy trial of FGG01 and FGG04 applied preventive against powdery mildew (<i>Erysiphe necator</i>) in grapevine in Europe, GERMANY 202KCP 3. Staphyt, Blaufelden-Herrentierbach, Germany, Report No. MKH-23-105476-01-DE02 Report No. F23EU-044-AMA-001 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.2 KCP 3.2.3 KCP 3.4.1	Notterpek , J.	2023	GEP efficacy trial of FGG01 and FGG04 applied preventive against powdery mildew (<i>Erysiphe necator</i>) in grapevine in Europe, AUSTRIA 202KCP 3. Staphyt, Rohrau, Austria, Report No. MKH-23-105476-01-AT03 Report No. F23EU-044-AMA-002 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.2 KCP 3.2.3 KCP 3.4.1	Hiebler, A.	2023	The efficacy of FGG01 and FGG04 applied preventive against powdery mildew (<i>Erysiphe necator</i>) in grapevine in Europe Hiebler Agricultural Engineering , Markt Hartmannsdorf, Austria, Report No. FRS121/23-V3-AT Report No. F23EU-044-AMA-005 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.2 KCP 3.2.3	Hiebler, A.	2023	The efficacy of FGG01 and FGG04 applied preventive against powdery mildew (<i>Erysiphe necator</i>) in grapevine in Europe	N	Y	Study report never submitted before to support a product	UPL Europe

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 3.4.1			Hiebler Agricultural Engineering , Markt Hartmannsdorf, Austria, Report No. FRS121/23-V4-AT Report No. F23EU-044-AMA-006 UPL GEP Unpublished			authorisation in this EU member state nor used for a product authorisation in any EU Member State	
KCP 3.2.2 KCP 3.2.3 KCP 3.4.1	Štrbac, S.	2023	The efficacy of FGG01 and FGG04 applied preventive against powdery mildew (<i>Erysiphe necator</i>) in grapevine in Europe 202KCP 3. SynTech Research Germany GmbH, Löptin, Germany, Report No. EU-23-0691-01 Report No. F23EU-044-AMA-007 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.2 KCP 3.2.3 KCP 3.4.1	Štrbac, S.	2023	The efficacy of FGG01 and FGG04 applied preventive against powdery mildew (<i>Erysiphe necator</i>) in grapevine in Europe 202KCP 3. SynTech Research Germany GmbH, Löptin, Germany, Report No. EU-23-0691-02 Report No. F23EU-044-AMA-008 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Eigaard, T.	2023	The efficacy of FGG01 and FGG04 applied in OSR for the control of <i>Sclerotinia sclerotiorum</i> (SCLESC) in Europe. Agrolab, Middelfart, Denmark, Report No. FRS122/23-V2-DK Report No. F23EU-045-AMA-002 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Torturu, F.	2023	The efficacy of FGG01 and FGG04 applied in OSR for the control of <i>Sclerotinia sclerotiorum</i> (SCLESC) in Europe. Oxford Agricultural Trials Ltd., Bicester, United Kingdom, Report No. FRS122/23-V3-UK Report No. F23EU-045-AMA-005 UPL GEP	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 3.2.3 KCP 3.4.1	Laplace, B.	2023	The efficacy of FGG01 and FGG04 applied in OSR for the control of <i>Botrytis cinerea</i> . SynTech Research France, La Chapelle-de-Guinchay, France, Report No. EU-23-0693-01 Report No. F23EU-048-AMA-001 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Biró, A.	2021	The efficacy of FGG01 applied in OSR for the control of <i>Sclerotinia sclerotiorum</i> (SCLESC) in Hungary 2021. BioteK Agriculture Hungary Kft., Pomaz, Hungary, Report No. GEP 21/150 Report No. F21EU-024-011-001 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Biró, A.	2021	The efficacy of FGG01 applied in OSR for the control of <i>Sclerotinia sclerotiorum</i> (SCLESC) in Hungary 2021. BioteK Agriculture Hungary Kft., Pomaz, Hungary, Report No. GEP 21/151 Report No. F21EU-024-011-002 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Ettig, B.	2021	The efficacy of FGG01 applied in OSR for the control of <i>Sclerotinia sclerotiorum</i> (SCLESC) in Hungary 2021. BioteK Agriculture Hungary Kft., Pomaz, Hungary, Report No. GEP 21/152 Report No. F21EU-024-011-003 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Siebold, M.	2023	The efficacy of FGG01 and FGG04 applied in OSR for the control of <i>Alternaria brassicae</i> (ALTEBA) in Europe. Verify, Zwaagdijk-Oost, Netherlands, Report No. FRS123/23-V1-BE Report No. F23EU-047-AMA-001	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member	UPL Europe

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			UPL GEP Unpublished			State	
KCP 3.2.3 KCP 3.4.1	Siebold, M.	2023	The efficacy of FGG01 and FGG04 applied in OSR for the control of <i>Alternaria brassicae</i> (ALTEBA) in Europe. Vertify, Zwaagdijk-Oost, Netherlands, Report No. FRS123/23-V2-BE Report No. F23EU-047-AMA-002 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Hiebler, A.	2023	The efficacy of FGG01 and FGG04 applied preventive against <i>Botrytis cinerea</i> in grapevine in Europe. Hiebler Agricultural Engineering , Markt Hartmannsdorf, Austria, Report No. FRS120/23-V3-AT Report No. F23EU-042-AMA-003 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Hiebler, A.	2023	The efficacy of FGG01 and FGG04 applied preventive against <i>Botrytis cinerea</i> in grapevine in Europe. Hiebler Agricultural Engineering , Markt Hartmannsdorf, Austria, Report No. FRS120/23-V4-AT Report No. F23EU-042-AMA-004 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	GRÖß-Ahr, K.	2023	GEP efficacy trial of FGG01 and FGG04 applied preventive against <i>Botrytis cinerea</i> in grapevine, Europe GERMANY 2023 Staphyt, Blaufelden-Herrentierbach, Germany, Report No. MKH-23-105475-01-DE02 Report No. F23EU-042-AMA-006 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Martínez, L.	2021	The efficacy and selectivity of FGG01 applied preventive against <i>Botrytis cinerea</i> in grapevine in Portugal - EPOMED -	N	Y	Study report never submitted before to support a product	UPL Europe

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			2021 SynTech Research Portugal, Caldas da Rainha, Portugal, Report No. SRPT21-070-038FE Report No. F21EU-022-011-001 UPL GEP Unpublished			authorisation in this EU member state nor used for a product authorisation in any EU Member State	
KCP 3.2.3 KCP 3.4.1	Martínez, L.	2021	The efficacy and selectivity of FGG01 applied preventive against <i>Botrytis cinerea</i> in grapevine in Portugal - EPOMED - 2021 SynTech Research Portugal, Caldas da Rainha, Portugal, Report No. SRPT21-079-038FE Report No. F21EU-022-011-002 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Boyer, C.	2023	The efficacy of FGG01 and FGG04 applied preventive against <i>Botrytis cinerea</i> in grapevine in Europe. Agrolis Consulting, Villeneuve-Lez-Avignon, France, Report No. AGL23FR224 Report No. F23EU-041-AMA-001 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Tessari, F.	2023	The efficacy of FGG01 and FGG04 applied preventive against <i>Botrytis cinerea</i> in grapevine in Europe. Agrolis Consulting, Ronco all'Adige (VR), Italy, Report No. AGL23IT024 Report No. F23EU-041-AMA-003 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Valori, R.	2023	GEP efficacy trial of FGG01 and FGG04 applied preventive against <i>Botrytis cinerea</i> in grapevine in Europe, ITALY, 2023 Staphyt, Milano, Italy, Report No. MKH-23-105475-01-IT01 Report No. F23EU-041-AMA-004 UPL	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP Unpublished				
KCP 3.2.3 KCP 3.4.1	Japón, P.P.	2023	Field study to evaluate the efficacy and selectivity of FGG01 and FGG04 for the control of <i>Botrytis cinerea</i> in grapevines in Spain during 202KCP 3. Phytest Hispania S.L., Coria del Rio, Spain, Report No. F23EU-041-AMA Report No. F23EU-041-AMA-005 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Farinetti, P.	2022	The efficacy of FGG01 applied preventive against powdery mildew (<i>Erysiphe necator</i>) in grapevine in Europe. SAGEA Centro di Saggio s.r.l., Castagnito d'Alba (CN), Italy, Report No. 306.F.SAG22/e Report No. F22EU-004-AMA-007 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Rauscher, C.	2023	The efficacy of FGG01 and FGG04 applied preventive against powdery mildew (<i>Erysiphe necator</i>) in grapevine in Europe Agrolis consulting, L'Isle - sur - la - Sorgue, France, Report No. AGL23FR225 Report No. F23EU-043-AMA-001 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Ruel, F.	2023	The GEP efficacy of FGG01 and FGG04 applied preventive against powdery mildew (<i>Erysiphe necator</i>) in grapevine in Europe, FRANCE 2023 Staphyt, Inchy-en-Artois, France, Report No. MKH-23-105476-01-FR01 Report No. F23EU-043-AMA-002 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3	Tessari, F.	2023	The efficacy of FGG01 and FGG04 applied preventive against	N	Y	Study report never submitted	UPL Europe

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 3.4.1			powdery mildew (<i>Erysiphe necator</i>) in grapevine in Europe Agrolis consulting, Ronco all'Adige (VR), Italy, Report No. AGL23IT025 Report No. F23EU-043-AMA-003 UPL GEP Unpublished			before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	
KCP 3.2.3 KCP 3.4.1	Stefani, F.	2023	The efficacy of FGG01 and FGG04 applied preventive against powdery mildew (<i>Erysiphe necator</i>) in grapevine in Europe SynTech Research Italy, Imola , Italy Report No. EU-23-0690-03 Report No. F23EU-043-AMA-004 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Japón, P.P.	2023	Field study to evaluate the efficacy and selectivity of FGG01 and FGG04 for the control of powdery mildew (<i>Erysiphe necator</i>) in grapevines in Spain during 202KCP 3. Phytest Hispania S.L.,Coria del Rio, Spain, Report No. Report No. F23EU-043-AMA-005 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Sánchez, M.	2023	The efficacy of FGG01 and FGG04 applied preventive against powdery mildew (<i>Erysiphe necator</i>) in grapevine in Europe SynTech Research Spain, Picanya, Spain, Report No. EU-23-0690-02 Report No. F23EU-043-AMA-006 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1 KCP 3.4.2	Jarlaud, A.	2022	The efficacy of FGG01 applied in peas and beans for the control of Botrytis (BOTRSP) in Europe. Eurofins Agrosiences Services, Stade, Germany, Report No. S22-01824-02 Report No. F22EU-006-AMA-002 UPL GEP	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 3.2.2 KCP 3.2.3 KCP 3.4.1	Charton, A.	2023	GEP efficacy trial of FGG01 and FGG04 applied in peas and beans for the control of Botrytis (BOTRSP) in Europe STAPHYT, Inchy en Artois, France , Report No. MKH-23-105482-01-FR02 Report No. F23EU-049-AMA-007 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1 KCP 3.4.2	Dada, K.	2023	Evaluate the efficacy of FGG01 and FGG04 applied in peas and beans for the control of Botrytis (BOTRSP) in Europe.2023 SynTech Research Czech S.R.O, Semcice, Czech Republic, Report No. EU-23-0694-04 Report No. F23EU-049-AMA-008 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Sumner, K.	2023	The efficacy of FGG01 and FGG04 applied in peas and beans for the control of Botrytis (BOTRSP) in Europe. SynTech Research UK, Hopton, United Kingdom, Report No. EU-23-0694-05 Report No. F23EU-049-AMA-009 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Venneman, S.	2023	The efficacy of FGG01 and FGG04 applied in peas and beans for the control of Botrytis (BOTRSP) in Europe. Proefstation voor de Groenteteelt, Sint-Katelijne-Waver, Belgium, Report No. FRS125/23-BE Report No. F23EU-049-AMA-010 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Japón, P.P.	2023	Field study to evaluate the efficacy and selectivity of FGG01 and FGG04 for the control of <i>Botrytis cinerea</i> in beans in Spain during 202KCP 3. Phytest Hispania S.L., Coria del Rio, Spain.	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product	UPL Europe

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report No. F23EU-049-AMA-001 UPL GEP Unpublished			authorisation in any EU Member State	
KCP 3.2.3 KCP 3.4.1	Japón, P.P.	2023	Field study to evaluate the efficacy and selectivity of FGG01 and FGG04 for the control of <i>Botrytis cinerea</i> in beans in Spain during 202KCP 3. Phytest Hispania S.L., Coria del Rio, Spain. Report No. F23EU-049-AMA-002 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Rial, F.J.	2023	Evaluate the efficacy of FGG01 and FGG04 applied in peas and beans for the control of Botrytis (BOTRSP) in Europe.2023 SynTech Research Spain, Pincayia, Spain, Report No. EU-23-0694-01 Report No. F23EU-049-AMA-003 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Brohard, C.	2023	GEP efficacy trail of FGG01 and FGG04 applied in peas and beans for the control of Botrytis (BOTRSP) in Europe, FRANCE 2023 STAPHYT, Inchy-en-Artois, France, Report No. MKH-23-105482-01-FR01 Report No. F23EU-049-AMA-006 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Charton, A.	2023	GEP efficacy trial of FGG01 and FGG04 applied in peas and beans for the control of Sclerotinia (SCLESP) in Europe FRANCE, 2023 STAPHYT, Inchy-en-Artois, France, Report No. MKH-23-105484-01-FR03 Report No. F23EU-050-AMA-007 UPL GEP	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 3.2.3 KCP 3.4.1	Venneman, S.	2023	The efficacy of FGG01 and FGG04 applied in peas and beans for the control of Sclerotinia (SCLESP) in Europe. Proefstation voor de Groenteteelt, Sint-Katelijne-Waver, Belgium, Report No. FRS127/23-BE Report No. F23EU-050-AMA-011 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Marin, C.	2022	The efficacy of FGG01 applied in peas and beans for the control of Sclerotinia (SCLESP) in Europe. Eurofins Agrosiences Services, Sevilla, Spain, Report No. S22-01825-06 Report No. F22EU-007-AMA-006 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Japón, P.P.	2023	Field study to evaluate the efficacy and selectivity of FGG01 and FGG04 for the control of <i>Sclerotinia sp.</i> in beans in Spain during 202KCP 3. Phytest Hispania S.L., Coria del Rio. Report No. F23EU-050-AMA-001 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Japón, P.P.	2023	Field study to evaluate the efficacy and selectivity of FGG01 and FGG04 for the control of <i>Sclerotinia sp.</i> in beans in Spain during 202KCP 3. Phytest Hispania S.L., Coria del Rio. Report No. F23EU-050-AMA-002 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.2.3 KCP 3.4.1	Rial, F.J.	2023	Evaluate the efficacy of FGG01 and FGG04 applied in peas and beans for the control of Sclerotinia (SCLESP) in Europe.2023 SynTech Research Spain, Picanya, Spain, Report No. EU-23-0695-01	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member	UPL Europe

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report No. F23EU-050-AMA-003 UPL GEP Unpublished			State	
KCP 3.2.3 KCP 3.4.1	Rial, X.	2023	The efficacy of FGG01 and FGG04 applied in peas and beans for the control of Sclerotinia (SCLESP) in Europe. SynTech Research Spain, Picanya, Spain, Report No. EU-23-0695-07 Report No. F23EU-050-AMA-005 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.4.1 KCP 3.4.3	Heinzmann, S.	2022	Evaluation of unintentional effects of FGG01 on fermentation processes and characteristics of wine,1 Site in Germany 2022-2024 Eurofins Agrosiences Services, Stade, Germany, Report No. S22-01828-01 Report No. F22EU-005-AMA-001 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.4.1 KCP 3.4.3	Farinetti, P.	2022	Unintentional effects of FGG01 on wine making process SAGEA Centro di Saggio s.r.l., Castagnito d'Alba (CN), Italy, Report No. 308.V.SAG22/e Report No. F22EU-005-AMA-002 UPL GEP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.5.1	S. Stürtz & C. Horstmann	2022	Boscalid 500 WG: Effects on Terrestrial (Non-Target) Plants: Seedling Emergence and Seedling Growth Test Ibacon GmbH, Rossdorf, Germany, Report No. 165091086 Report No. UPL/2022/0597 UPL GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 3.5.2	S. Stürtz & C. Horstmann	2022	Boscalid 500 WG: Effects on Terrestrial (Non-Target) Plants: Vegetative Vigour Test Ibacon GmbH, Rossdorf, Germany, Report No. 165091087	N	Y	Study report never submitted before to support a product authorisation in this EU member	UPL Europe

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report No. UPL/2022/0598 UPL GLP Unpublished			state nor used for a product authorisation in any EU Member State	
Section B5, analytical methods							
KCP 5.1.1/01	Chaudhari M.N	2022	Validation of analytical method for determination of active ingredient content of Boscalid 500 g/kg WG UPL/2022/0950 Jai Research Foundation 228-2-12-31215 GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 5.1.2/01	Rastogi T.	2022	Validation of the Analytical Method for Determination of Boscalid in Different Matrices of Plant Origin. Study UPL/2022/2099 Eurofins Agrosience Services, EAG Laboratories GmbH S22-06799 GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 5.1.2/02	Rastogi T.	2023	Cross-Validation - Comparing Amounts of Boscalid extracted from Samples of Plant Origin with incurred Residues using three different Solvent Systems. UPL/2023/1062 Eurofins Agrosience Services, EAG Laboratories GmbH S22-00983 GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 5.1.2/03	Pandey P.K.	2023	Validation of Analytical Method for Determination of Active Ingredient Concentration and Stability of Boscalid in Matrix, following the Application of Boscalid 500 g/kg WG UPL/2022/2648 Jai Research Foundation 228-2-13-31234	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Unpublished				
KCP 5.1.2/04	Knautz T. Kowalczyk F.	2022a	Boscalid 500 WG: Acute Contact and Oral Toxicity to Bumblebees (<i>Bombus terrestris</i> L.) in the Laboratory UPL/2022/2874 ibacon GmbH 165091105 GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 5.1.2/05	Knautz T. Kowalczyk F.	2022b	Boscalid 500 WG: Chronic Oral Toxicity Test on the Honey Bee (<i>Apis mellifera</i> L.) in the Laboratory UPL/2022/2873 ibacon GmbH 165091136, GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 5.1.2/06	Colli M.	2022	Effects of BOSCALID 500 WG (FGG01) on honeybees (<i>Apis mellifera</i> L.) 22-day larval toxicity test with repeated exposure. UPL/2022/2796 BioTecnologie BT S.r.l. BT115/22 GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 5.1.2/07	Stürtz S., Horstmann C.,	2022 a	Boscalid 500 WG: Effects on Terrestrial (Non-Target) Plants: Seedling Emergence and Seedling Growth Test UPL/2022/0597 ibacon GmbH 165091086 GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 5.1.2/08	Stürtz S., Horstmann C.	2022 b	Boscalid 500 WG: Effects on Terrestrial (Non-Target) Plants: Vegetative Vigour Test UPL/2022/0598	N	Y	Study report never submitted before to support a product authorisation in this EU member	UPL Europe

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			ibacon GmbH 165091087 GLP Unpublished			state nor used for a product authorisation in any EU Member State	
KCP 5.2/01	Sahvorost N.	2022	Validation of the Analytical Method for the Determination of Residues of Boscalid in Honey, Report Amendment 1, UPL/2022/0354 Eurofins Agroscience Services EcoChem GmbH S22-00776 GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 5.2/02	Rastogi T.	2022	Independent Laboratory Validation of the Analytical method for Determination of Residues of Boscalid in Honey UPL/2022/0845 Eurofins Agroscience Services EcoChem GmbH S22-00783 GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 5.2/03	Kaiser M.	2023	Independent Laboratory Validation of an Analytical Method for Determination of Boscalid and its Metabolites M510F47, M510F49 and M510F64 in Ground and Drinking Water, UPL/2022/21136, Eurofins Agroscience Services EcoChem GmbH S22-01028 GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 5.2/04	Rastogi T.	2022	Development and Validation of an Multi-Residue Method QuEChERS for the Determination of Boscalid and its Metabolite M510F01 in Body Fluids UPL/2022/2054 Eurofins Agroscience Services, EAG Laboratories GmbH S22-00982	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Unpublished				
Section B6, toxicology							
KCP 7.3/01		2023	Boscalid 500 g/kg WG: In vitro dermal absorption of Boscalid using human split-thickness skin in a flow through diffusion system Report No: 617-1-06-33435 (study no. UPL/2023/0583) Jai Research Foundation, Valvada - 396105, Dist. Valsad, Gujarat, India GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
Section B7, metabolism and residues							
KCA 6.1	Flore, S.	2022	Storage Stability of Boscalid in Honey under Deep Frozen Conditions Report no. S22-01684 – UPL/2022/0340 Eurofins Agroscience Services EcoChem GmbH, Germany GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCA 6.3, KCA 6.10	Davolos, C.	2024	OECD calculator for oilseed rape, beans with pod and honey for the active substance boscalid based on the use of the FGG01 formulation. File name: OECD Calculator_FGG01_intended uses non GLP Unpublished	N	N	-	UPL Europe
KCA 6.3.2/01 and 6.5.2	North, L.	2023	Determination of residues of Boscalid after two applications of Boscalid 500 WG in Oilseed rape and its processed fractions at 4 sites in Northern Europe and 4 sites in Southern Europe 2022 Report no. S22-01575 – UPL/2022/0442 Eurofins Agroscience Services Ltd., United Kingdom GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCA 6.3.2/02	North, L.	2024	Determination of residues of Boscalid after two applications of Boscalid 500 WG in Oilseed rape at 4 sites in Northern Europe and 4 sites in Southern Europe 2023 Report no. S23-00040 - UPL/2023/0503 Eurofins Agroscience Services Ltd., United Kingdom GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.3/01	North, L.	2023	Determination of residues of Boscalid after two applications of Boscalid 500 WG in Beans with pods at 3 sites in Northern Europe and 4 sites in Southern Europe 2022 Report no. S22-01575 – UPL/2022/0403 Eurofins Agroscience Services Ltd., United Kingdom GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCA 6.3.3/02	North, L.	2024	Determination of residues of Boscalid after two applications of Boscalid 500 WG in Beans with pods at 5 sites in Northern Europe and 4 sites in Southern Europe 2023 Report no. S23-00041 – UPL/2023/0507 Eurofins Agroscience Services Ltd., United Kingdom GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCA 6.4	Davolos, C.	2024	Animal burden calculation of boscalid based on the use of the FGG01 formulation. File name: boscalid_mrl_guidelines_animal_model_2017 non GLP Unpublished	N	N	-	UPL Europe
KCA 6.9	Davolos, C.	2024	Dietary Risk Assessment of boscalid based on the use of the FGG01 formulation. File name: Chronic_EFSA_PRIMo_rev3.1_boscalid non GLP Unpublished	N	N	-	UPL Europe
KCA 6.10	Knoll, M.	2022	Boscalid 500 WG: Determination of Residues of Boscalid in Honey after two Applications in Winter Oilseed Rape at Four Sites in Northern and Southern Europe in 2022 Report no. S22-00761 – UPL/2022/0377 Eurofins Agroscience Services EcoChem GmbH, Germany GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
Section B8, environmental fate							
KCP 9.2.4.1/01	Šulc, A.	2024a	Report on calculation of Predicted Environmental Concentrations of boscalid in groundwater (PECgw) – Boscalid 50 WG (FGG01) - GW-213-220810-01 Vali Consulting GmbH, Weinheim, Germany non GLP	N	N	-	UPL Europe

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			Unpublished				
KCP 9.2.5/01	Šulc, A.	2024b	Report on Predicted Environmental Concentrations of boscalid in Surface Water and Sediment (PEC _{sw} and PEC _{sed}) - Boscalid 50 WG (FGG01) - SW-213-220810-01 Vali Consulting GmbH, Weinheim, Germany non GLP Unpublished	N	N	-	UPL Europe
Section B9, ecotoxicology							
KCP 10.2.1/01	Rana, J.R.	2023a	Acute Immobilisation Study of Boscalid 500 g/Kg WG to <i>Daphnia magna</i> Report No. 502-3-07-31231, UPL/2022/21324 Jai Research Foundation, Valvada, Gujarat, India GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 10.2.1/02	Rana, J.R.	2023b	Alga (<i>Pseudokirchneriella subcapitata</i>), Growth Inhibition Test with Boscalid 500 g/Kg WG Report No. 501-3-07-31230, UPL/2022/21323 Jai Research Foundation, Valvada, Gujarat, India GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 10.3.1.1.1/01 & KCP 10.3.1.1.2/01	Knautz, T.	2022	Boscalid 500 WG: Effects (Acute Contact and Oral) on Honey Bees (<i>Apis mellifera</i> L.) in the Laboratory Report No. UPL/2022/0605, UPL/2022/0605 ibacon GmbH, Rossdorf, Germany GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 10.3.1.1.1/02 & KCP 10.3.1.1.2/02	Knautz, T. & Kowalczyk, F.	2022a	Boscalid 500 WG: Acute Contact and Oral Toxicity to Bumblebees (<i>Bombus terrestris</i> L.) in the Laboratory Report No. 165091105, UPL/2022/2874 ibacon GmbH, Rossdorf, Germany GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 10.3.1.2/01	Knautz, T. & Kowalczyk, F.	2022b	Boscalid 500 WG: Chronic Oral Toxicity Test on the Honey Bee (<i>Apis mellifera</i> L.) in the Laboratory Report No. 165091136, UPL/2022/2873 ibacon GmbH, Rossdorf, Germany GLP	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member	UPL Europe

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished			State	
KCP 10.3.1.3/01	Colli, M.	2022	Effects of BOSCALID 500 WG (FGG01) on honeybees (<i>Apis mellifera</i> L.) 22-day larval toxicity test with repeated exposure Report No. BT115/22, UPL/2022/2796 BioTecnologie BT S.r.l., Todi (PG), Italy GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 10.3.2.1/01	Leopold, J.	2023a	Boscalid 500 WG: Effects on the Parasitoid <i>Aphidius rhopalosiphi</i> (Hymenoptera: Braconidae) in the Laboratory. A Dose Response Test on Glass Plates Report No. 165091001, UPL/2022/0591 ibacon GmbH, Rossdorf, Germany GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 10.3.2.1/02	Leopold, J.	2023b	Boscalid 500 WG: Effects on the Predatory Mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae) in the Laboratory. A Dose Response Test on Glass Plates Report No. 165091063, UPL/2022/0590 ibacon GmbH, Rossdorf, Germany GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 10.4.1.1/01	Rana, J.R.	2023c	Reproduction toxicity test of Boscalid 500 g/kg WG to earthworm, <i>Eisenia fetida</i> Report No. 522-3-08-31232, UPL/2022/21325 Jai Research Foundation, Valvada, Gujarat, India GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 10.4.2.1/01	Hübner, S.	2022a	Boscalid 500 WG: Effects on Reproduction of Collembola (<i>Folsomia candida</i>) in Artificial Soil Report No. 165091016, UPL/2022/0609 ibacon GmbH, Rossdorf, Germany GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 10.4.2.1/02	Hübner, S.	2022b	Boscalid 500 WG: Effects on Reproduction of the Predatory Mite <i>Hypoaspis aculeifer</i> in Artificial Soil Report No. 165091089, UPL/2022/0610 ibacon GmbH, Rossdorf, Germany GLP	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member	UPL Europe

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished			State	
KCP 10.5/01	Raithatha, A.	2023	Effect of Boscalid 500 WG on Soil Microorganisms: Nitrogen Transformation Test Report No. 608-3-15-31233, UPL/2022/0863 Jai Research Foundation, Valvada, Gujarat, India GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 10.6.2/01	Stürtz, S.	2022a	Effects on Terrestrial (Non-Target) Plants: Vegetative Vigour Test Report No. 165091087, UPL/2022/0598 ibacon GmbH, Rossdorf, Germany GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe
KCP 10.6.2/02	Stürtz, S.	2022b	Effects on Terrestrial (Non-Target) Plants: Seedling Emergence and Seedling Growth Report No. 165091086, UPL/2022/0597 ibacon GmbH, Rossdorf, Germany GLP Unpublished	N	Y	Study report never submitted before to support a product authorisation in this EU member state nor used for a product authorisation in any EU Member State	UPL Europe

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 Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
Section B5, analytical methods							
CP 5.1.2	Weeren, R.D., Pelz, S.	1999	Validation of DFG method S19 for the determination of BAS 510 F in various plant materials Az. M8020/99 1999/11461 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
CP 5.1.2	Reichert, N.	2001	Independent laboratory validation of a method of analysis for the determination of BAS 510 F in white cabbage, rape (seed), hop,	N	N	Study already included in original DAR and hence no longer protected	BAS

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			and lettuce IF-100/35725-00 2000/1014886 GLP Unpublished				
CP 5.1.2	Class, T.	2001	Assessment and validation of the adapted multi-residue method DFG S19 for the determination of BAS 510 F and its metabolite M510F01 in animal matrices Report no. P/B 453 G. 2000/1017227 GLP, Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
CP 5.1.2	Funk, H., Mackenroth, Ch.	2001	Validation of BASF method no. 445/0: determination of BAS 510 F in plant matrices; study code 41840. 2000/1012404 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
CP 5.1.2	Fabian, E.	2001	The validation of BASF method 476/0: the determination of BAS 510 F residues (as M510F53) in liver and milk by microwave treatment Study code 96997. 2000/1017224 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
CP 5.1.2	Keller, W.	1998b	Validation of analytical method no. 411, determination of BAS 510 F ai residues in water; study no. 41877. 1998/10922 GLP, Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
CP 5.1.2	Grote, C	2003b	Report Amendment No.1 to Validation of analytical method No. 411. Determination of BAS 510 F ai residues in water; BASF Doc ID 2003/1000976 unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
CP 5.1.2	Grote, Ch.	2001	Validation of analytical method no. 411/0, GC/MS determination of BAS 510 F ai residues in surface water;	N	N	Study already included in original DAR and hence no longer protected	BAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			study code 110241. 2001/1008955 GLP, unpublished				
CP 5.1.2	Grote, C	2003	Report Amendment No.1 to Validation of analytical method No. 411/0. GC/MS determination of BAS 510 F ai residues in surface water BASF Doc ID 2003/1000975 unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
CP 5.1.2	Keller, W.	1998	Validation of analytical method no. 408/1, GC MS determination of BAS 510 F active ingredient residues in soil and sediment after methanol extraction; study code 48541. 1998/11314 GLP, Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
CP 5.1.2	Grote, C.	2003	Report Amendment No.1 to Validation of analytical method No. 408/1. GC-MS determination of BAS 510 F active ingredient residues in soil and sediment after methanol extraction; BASF Doc ID 2003/1000977 Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
CP 5.1.2	Zangmeister, W.	2000	Validation of analytical method 460, determination of BAS 510 F (Reg.no. 300355) in air by GC-MS; study code 41886. BASF Doc ID 2000/1014992 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
CP 5.1.2	Kampke-Thiel, K.	2001	Independent laboratory validation of the adapted multi-residue method DFG S19 for the determination of BAS 510 F and its metabolite M510F01 in animal matrices PTRL Europe Study No. P453G. 2000/1017226 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
CP 5.1.2	Grosshans, F.	2001	The validation of BASF method 471/0: The determination of BAS 510F and the metabolite M510F01 in animal matrices Study code 42392. 2000/1017223	N	N	Study already included in original DAR and hence no longer protected	BAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Unpublished				
CP 5.1.2	Bross, M.	2001	Investigations on the extractability of 14C-BAS 510 F residues from plant matrices; study code 73479. 2001/1001739 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
Section B7, metabolism and residues							
KCA 6.1	Funk H., Mackenroth, C.	2001	Investigation of the Stability of Residues of BAS 510 F in Plant Matrices under Storage Conditions. Report No. 2001/1015028; RIP2002-192 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.2.1	Rabe U., Schlueter H.	2001	Metabolism of 14C-BAS 510 F in grapevine BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. Report No. 2000/1014860 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.2.1	Hamm R.T.	1999	BAS 510 F in lettuce Report No. 1999/11240 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.2.1	Veit P.	2001	Metabolism of 14C-BAS 510 F in beans Report No. 2000/1014861 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.2.2	Confidential	2000	The Metabolism of 14C-BAS 510F in Lactating Goat. Report No. 000/1012353; RIP2001-331 GLP Unpublished	Y	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.2.2	Confidential	2000	14C-BAS 510 F- Absorption, Distribution and Excretion after Repeated Oral Administration in Lactating Goats. Report No. BASF DocID: 2000/1017221; RIP2001-330GLP Unpublished	Y	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.2.2	Confidential	2001	Nature of Residues of 14C-BAS 510 F in Laying Hens.	Y	N	Study already included in original	BAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report No. 2000/5154; RIP2001-332 GLP Unpublished			DAR and hence no longer protected	
KCA 6.3.1	Beck, J.	2003	Study on the residue behavior of Boscalid (BAS 510 F) in grapes (wine) after application of BAS 510 01 F under field conditions in Germany, France, Italy and Spain, 2002 Report no. 2003/1001357 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.3.1	Moreno, S.	2003	Study on the residue behavior of Boscalid (BAS 510 F) in grapes (wine) after application of BAS 510 01 F under field conditions in Spain, 2002 Report no. 2003/1001279 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.3.1	Schulz, H.	2004	Study on the residue behavior of BAS 510 F in vines after application of BAS 510 01 F under field conditions in France (N & S), Spain, Italy and Germany, 2003 Report no. 2004/1015915 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.3.2	Raunft, E.	2001	Study on the residue behavior of BAS 510 F in winter rape after treatment with BAS 510 01 F under field conditions in Germany, Sweden and Great Britain, 2000. Report no. BASF DocID 2000/1014851 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.3.2	Peny, A.	2001	Residue study in oil seed rape following treatment with the preparation BAS 510 01 F under field conditions in France in 2000. Report no. BASF DocID 2000/1014877 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.3.2	Schulz, H.	2005	Study on the residue behavior of BAS 510 F in spring rape after treatment with BAS 510 01 F under field conditions in Germany, England and Sweden, 2004 Report no. BASF DocID 2005/1004971 GLP	N	N	Study already included in original DAR and hence no longer protected	BAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCA 6.3.2	Oxspring S.,	2007	Study on the residue behaviour of BAS 510 F in spring oilseed rape after treatment with BAS 510 01 F under field conditions in Southern Europe during 2006 Report no. BASF DocID 2007/1007952 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.3.2	Schaeufele, M.	2009	Residue study (decline) with BAS 664 AS F, BAS 510 01 F and BAS 555 00 F applied to oilseed rape in Germany and Northern France in 2008 Report no. BASF DocID 2008/1074165 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.3.3	Heck, W.	2000	Study on the residue behavior of BAS 510 F in peas after treatment with BAS 510 01 F under field conditions in Germany, Denmark and Sweden, 1999 Report no. BASF DocID 2000/1014848 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.3.3	Schulz, H.	2000	Determination of the residue of BAS 510 F in peas following treatment with BAS 510 01 F under field conditions in France 1999 Report no. BASF DocID 2000/1014879 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.3.3	Heck W., Mackenroth C.	2001	Study on the residue behavior of BAS 510 F in peas after treatment with BAS 510 01 F under field conditions in Germany, Denmark, France and Sweden, 2000 Report no. BASF DocID 2000/1014852 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.3.3	Perny, A.	2001	Residue study in green peas following treatment with the preparation BAS 510 01 F under field conditions in France in 2000 Report no. BASF DocID 2000/1014878 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.3.3	Klaas, P.	2008	Study on the residue behavior of BAS 510 F in green beans after	N	N	Study already included in original	BAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			treatment with BAS 510 01 F under field conditions in Germany, the Netherlands, United Kingdom and Northern France, 2007. Report no. BASF DocID 2008/1028266 GLP Unpublished			DAR and hence no longer protected	
KCA 6.3.3	Schulz, H.	2011	Study on the residue behavior of Boscalid in green beans after treatment with BAS 510 01 F under field conditions in Germany, the Netherlands, Northern France, Belgium, Southern France, Greece, Italy and Spain, 2009 Report no. BASF DocID 2010/1165744 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.3.3	Meyer M.	2011	Study on the residue behaviour of Boscalid in green beans after treatment with BAS 510 01 F under field conditions in Southern Europe (Southern France, Greece, Italy and Spain) and Northern Europe (Belgium), 2010 Report no. BASF DocID 2011/1251203 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.4.1	Confidential	2002	A meat and egg magnitude of the residue study with BAS 510 F in laying hens. Report no. 2002/5002466 GLP Unpublished	Y	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.4.2	Confidential	2001	Residues in milk and edible tissues following oral administration of BAS 510 F to lactating dairy cattle. Report no. 2000/1017228 GLP Unpublished	Y	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.4.2	Confidential	2008	A meat and milk magnitude of the residue study with BAS 510 F in lactating dairy cows Report no. 2008/7015330 GLP Unpublished	Y	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.5.1	Scharf J.	1998	Hydrolysis of BAS 510 F at 90°C, 100°C, and 120°C Report no. 1998/10878 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS

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KCA 6.5.3	Meumann H. et al.	2000	Study on the residue behaviour of BAS 510 F in grape process fractions after treatment with BAS 510 01 F under field conditions in Germany, 1999 Report no. 2000/1012412 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.5.3	Scharm M.	2001	Determination of the residue of Reg. no. 300 355 in peas and processed products following treatment with BAS 510 01 F under field conditions in Germany 2000 Report no. 2000/1014885 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.5.3	Versoi P.L., Abdel-Baky S.	2001	The magnitude of BAS 510 F residues in canola seed processed fractions. Report no. 2001/5001064 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.6.1	Hamm R.T., Veit P.	2001	Confined rotational crop study with 14C-BAS 510 F Report no. 2000/1014862 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.6.2	Funk H., Mackenroth C.	2001	Determination of the residues of BAS 510 F in wheat obtained from the trial year 2000 Report no. 2000/1014853 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.6.2	Funk H., Mackenroth C.	2001	Report amendment no. 1 to final report: Determination of the residues of BAS 510 F in wheat obtained from the trial year 2000. Report no. 2001/1000989, RIP2001-375 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.6.2	Jeannine M. J.	2002	Cereal Grains and Soybean Field Rotational Study for BAS 510 F, Report no. 2002/5001341 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.6.2	Jeannine M. J.	2002	Field Rotational Study for BAS 510 F on Grasses, Alfalfa and	N	N	Study already included in original	BAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Clover as Livestock Feed Crops Report no. 2002/5002063 GLP Unpublished			DAR and hence no longer protected	
KCA 6.6.2	David W. Haughey, Samy Abdel-Baky	2001	Limited Rotational Crop Study for the Use of BAS 510 F Report no. 2001/5000966 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.6.2	Versoi, P., Abdel-Baby, S.	2001	Magnitude of the Residue of BAS 510 F in Peas and Beans Planted as Rotational Crops and of BAS 500 F in Peas and Beans When Applied as a Foliar Spray Report no. 2001/5003311 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.6.2	Raymond C. L.	2002	Sugar Beet, Garden Beet and Turnip Field Rotational Crop Study for BAS 510 02 F Residues. Report no. 2002/5004273 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.6.2	Beck, J., Lehmann, A. Grote, C., Mackenroth, C.	2003	Study on the residue behaviour of Boscalid (BAS 510 F) on succeeding crops after application of BAS 510 01 F on bare soil and cultivation of potatoes under field conditions in Denmark, France, Germany and Great Britain, 2002 Report no. 2003/1001358 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.6.2	Schroth E., Martin, T.	2008	Study on the residue behaviour of BAS 510 F on the rotational crop: Carrots, after the application to the soil of BAS 510 01 F under field conditions in France (South), Germany, Netherlands and Spain, 2007 Report no. 2008/1036949 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS
KCA 6.6	Hamm, T.R.; Veit, P.	2001	Confined Rotational Crop Study with 14CBAS 510 F. BASF DocID.: 2000/1014862 - RIP2001-373 GLP Unpublished	N	N	Study already included in original DAR and hence no longer protected	BAS

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 Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	Owner

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	Owner