

REGISTRATION REPORT

Part A

Risk Management

Product code: GPF515/ FGE03

Product name(s): Boscalid/ Prothioconazole 350/ 200 WG/
Patton Boost

Chemical active substance:

350 g/kg boscalid + 200 g/kg prothioconazole

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland
(Authorisation)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: November 2024, update March 2025

MS Finalisation date: June 2025, update October 2025 (initial
National Assessment)

November 2025, update April 2026 (final National Assessment)

Version history

When	What
November 2024	V01 – 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 - UPL Holdings Coöperatief U.A.
March 2025	Updated dRR (Clarification of the oilseed rape form in GAP table) - UPL Holdings Coöperatief U.A.
June 2025	Initial zRMS assessment In order to facilitate tracking of changes of the intended uses of the product due to the performed evaluation, amendments of the GAP table and in the product label (Appendix 2) and Lists of data considered for national authorization (Appendix 4) are highlighted in grey, while not agreed use pattern ~~is struck through~~ and shaded. Following the evaluation and before sending the document for commenting, all coloured highlighting was removed, from the parts updated by the Applicant, for better legibility.
October 2025	National Assessment updated following the commenting period and adding an assessment of new studies Additional information/assessments included by the zRMS in the report in response to comments received from the CMS and the Applicant are highlighted in yellow. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.
November 2025	Final report (National Assessment updated following the commenting period) No additional information or assessments after the commenting period.
April 2026	Update of the Final Report (National Assessment) Update of Point 2.2 to include conclusions regarding co-formulants. The changes are highlighted in yellow.
April 2026	Updated final report prepared following the comments submitted by the Ministry of Agriculture. All additional information and revisions have been highlighted in green.

Table of Contents

1	Details of the application.....	5
1.1	Application background	5
1.2	Letters of Access	5
1.3	Justification for submission of tests and studies.....	5
1.4	Data protection claims	5
2	Details of the authorization decision.....	6
2.1	Product identity	6
2.2	Conclusion.....	6
2.3	Substances of concern for national monitoring	6
2.4	Classification and labelling	6
2.4.1	Classification and labelling under Regulation (EC) No 1272/2008	6
2.4.2	Standard phrases under Regulation (EU) No 547/2011	7
2.4.3	Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009).....	7
2.5	Risk management	7
2.5.1	Restrictions linked to the PPP	7
2.5.2	Specific restrictions linked to the intended uses.....	8
2.6	Intended uses (only NATIONAL GAP).....	9
3	Background of authorization decision and risk management.....	12
3.1	Physical and chemical properties (Part B, Section 2).....	12
3.2	Efficacy (Part B, Section 3).....	12
3.3	Efficacy data	12
3.3.1	Information on the occurrence or possible occurrence of the development of resistance	14
3.3.2	Adverse effects on treated crops.....	15
3.3.3	Observations on other undesirable or unintended side-effects	16
3.4	Methods of analysis (Part B, Section 5)	16
3.4.1	Analytical method for the formulation	16
3.4.2	Analytical methods for residues	16
3.5	Mammalian toxicology (Part B, Section 6)	19
3.5.1	Acute toxicity	19
3.5.2	Operator exposure	19
3.5.3	Worker exposure	20
3.5.4	Bystander and resident exposure	22
3.5.5	Combined exposure	23
3.6	Residues and consumer exposure (Part B, Section 7)	26
3.6.1	Residues.....	26
3.6.2	Consumer exposure	28
3.7	Environmental fate and behaviour (Part B, Section 8).....	29
3.7.1	Predicted environmental concentrations in soil (PEC _{soil})	29
3.7.2	Predicted environmental concentrations in groundwater (PEC _{gw})	29
3.7.3	Predicted environmental concentrations in surface water (PEC _{sw})	29
3.7.4	Predicted environmental concentrations in air (PEC _{air}).....	30
3.8	Ecotoxicology (Part B, Section 9)	30
3.8.1	Effects on terrestrial vertebrates	30
3.8.2	Effects on aquatic species.....	31
3.8.3	Effects on bees.....	32
3.8.4	Effects on other arthropod species other than bees	32
3.8.5	Effects on soil organisms.....	32
3.8.6	Effects on non-target terrestrial plants.....	32
3.8.7	Effects on other terrestrial organisms (Flora and Fauna)	33
3.9	Relevance of metabolites (Part B, Section 10)	33

4	Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009).....	33
5	Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization.....	33
Appendix 1	Copy of the product authorization.....	34
Appendix 2	Copy of the product label.....	35
Appendix 3	Letter of Access.....	41
Appendix 4	Lists of data considered for national authorization.....	50

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 Boscalid / Prothioconazole 350 / 200 WG (GPF515 / FGE03) in Poland according to Regulation (EC) No 1107/2009.

This application is for a first registration in member states Poland (zRMS), Czech Republic and Hungary. A similar application is submitted concurrently to the southern zone member states France (zRMS) and Bulgaria, and to the northern zone member states Sweden (zRMS), Denmark, Estonia, Finland, Latvia and Lithuania.

The product is a water dispersible granule (WG) formulated fungicide containing 350 g/kg of the active substance boscalid and 200 g/kg active substance prothioconazole. It is intended to be used as fungicide to control Sclerotinia in oilseed rape.

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. Part B includes assessment of data or information relating to GPF515 / FGE03 where that data has not been considered in the EU peer review. Otherwise, assessments for the safe use of GPF515 / FGE03 have been made using endpoints agreed in the EU review of boscalid and prothioconazole. Part B also includes assessment of further data or information as required at national registration by the EU review.

This document describes the specific conditions of use and labelling required for Poland for the registration of GPF515/FGE03.

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

Not needed.

1.3 Justification for submission of tests and studies

To obtain approval, the product GPF515 / FGE03 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	GPF515 / FGE03
Product name in MS	Patton Boost
Authorization number	Not applicable, this application is for a first registration of the product
Function	Fungicide
Applicant	UPL Holdings Coöperatief U.A.
Active substance(s) (incl. content)	Boscalid, 350 g/kg Prothioconazole: 200 g/kg
Formulation type	Water dispersible granule (WG)
Packaging	2.5 kg and 10 kg HDPE Jerry Can 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 authorisation of GPF515 / FGE03 for the uses specified in 2.6 of this document can be granted.

Based on the currently available MSDSs and other information provided by applicant or manufacturer of co-formulant, the product **Patton Boost** 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 **Patton Boost** 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 annex to Part C of this submission.

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 – Acute, cat.1 Hazardous to the aquatic environment – Chronic, cat. 2 ~~Skin Irrit Cat 2~~ ~~Eye damage Cat 1~~
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The following labelling information is derived from the classification and to be mentioned in the safe-

ty data sheet. The information which is determined for the **label is formatted bold:**

Hazard pictograms:	  GHS05 GHS09
Signal word:	~~Danger~~ Warning
Hazard statement(s):	~~H315 – Causes skin irritation~~ ~~H318 – Causes serious eye damage~~ H410 - Very toxic to aquatic life with long lasting effects
Precautionary statement(s):	~~P280 – Wear protective gloves/eye protection/face protection.~~ ~~P264 Wash ... thoroughly after handling.~~ ~~P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.~~ ~~P310 Immediately call a POISON CENTER/ doctor/...~~ ~~P302 + P352 IF ON SKIN: Wash with plenty of water/...~~ ~~P332 + P313 If skin irritation occurs: Get medical advice/attention.~~ ~~P362 + P364 Take off contaminated clothing and wash it before reuse.~~ 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:	-

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

See Part C for justifications of the classification and labelling proposals.

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).
SPe3 .	Oilseed rape winter and spring, gold of pleasure, winter turnip rape, mustard, sunflower, poppy linseed, flax, hemp, borage To protect aquatic organisms, respect a vegetated buffer zone of 10 m to surface water bodies To protect aquatic organisms, respect a vegetated buffer zone of 10 m to surface water bodies

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.
Bystander & Resident	
10 m buffer strip and 50% drift reduction are required with respect to resident and bystander safety	
Integrated pest management (IPM)/sustainable use:	
respective code if available	None.
Environmental protection	
SPe3 .	Oilseed rape winter and spring, gold of pleasure, winter turnip rape, mustard, sunflower, poppy linseed, flax, hemp, borage To protect aquatic organisms, respect a vegetated buffer zone of 10 m to surface water bodies
Other specific restrictions	
-	None.

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

Integrated pest management (IPM)/sustainable use:	
respective code if available	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.
SPe3 .	To protect aquatic organisms, respect a vegetated buffer zone of 10 m to surface water bodies	Uses no 2 (oilseed rape winter) Uses no 3 : (Spring oilseed rape, gold of pleasure, winter turnip rape, mustard, sunflower, poppy linseed, flax, hemp, borage)

PPP (product name/code):	Patton Boost (GPF5015/FGE03)
Active substance 1:	Boscalid
Active substance 2:	Prothioconazole
Safener:	-
Synergist:	-
Applicant:	UPL Holdings Coöperatief U.A.
Zone(s):	Central ^(d)
Verified by MS:	Yes
Field of use:	Fungicide

Formulation type:	Water dispersible granules (WG)
Conc. of as 1:	350 g/kg
Conc. of as 2:	200 g/ka
Conc. of safener:	-
Conc. of synergist:	-
Professional use:	☒
Non professional use:	☐

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15									
Use-No. (¹⁶)	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 (day s)	Re- marks: e.g. g safener/ synergist per ha (¹⁷)	zRMS Conclusion									
					Method /Kind	Tim- ing /growt h stage of crop & season	Max. number a) per use b) per crop/seas on	Min. interval between applica- tions (days)	kg prod- uct / ha a) max. rate per appl. b) max. total rate per crop/seas on	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min /max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy		
Zonal uses (field or outdoor uses, certain types of protected crops)																							
2	PL	Oilseed rape (winter) (<i>Brassica napus</i>): BRSNW BRSNN	F	Scelrotinia (<i>Sclero- tinia scleroti- orum</i>) SCLESC	Spraying overall	BBCH 61-69 73	a) 2 per use b) 2 per crop/ season	14	a) 0.7 kg/ha b) 1.4 kg/ha	a) 245 g/ha bos- calid 140 g/ha prothio- conazole b) 490 g/ha bos- calid 280 g/ha prothio- conazole	100- 400	35	-	A	R *** see below	A	A R ± see below	A	R Aquatics (R1 scenario)	A	A		
																				A	Remain- ing organism		
Minor uses according to Article 51 (zonal uses)																							

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15							
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 (addition- ally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (day s)	Re- marks: e.g. g safener/ synergist per ha (+)	zRMS Conclusion							
					Method /Kind	Tim- ing /growt h stage of crop & season	Max. number a) per use b) per crop/seas on	Min. interval between applica- tions (days)	kg prod- uct / ha a) max. rate per appl. b) max. total rate per crop/seas on	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min /max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
3	PL	Spring rape, gold of pleasure, winter turnip rape, mus- tard, sunflower, poppy, linseed, flax, hemp, borage	F	Scelrotinia (<i>Sclero- tinia scleroti- orum</i>) SCLESC	Spraying overall	BBCH 61-73	a) 2 per use b) 2 per crop/ season	14	a) 0.7 kg/ha b) 1.4 kg/ha	a) 245 g/ha bos- calid 140 g/ha prothio- conazole b) 490 g/ha bos- calid 280 g/ha prothio- conazole	100- 400	35	-	A	R *** see below	A	N for gold of pleasur e, hemp, borage R ≠ A for winter turnip rape, mustar d, sunflo wer, poppy, linseed **sunfl ower BBCH 61-65 (see below)	A	R Aquatics (R1 scenario) A Remain- ing organism	A	n.r.

- Remarks columns:**
- 1 Numeration necessary to allow references
 - 2 Use official codes/nomenclatures of EU Member States
 - 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)
 - 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
 - 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.
 - 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
 - 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
 - 8 The maximum number of application possible under practical conditions of use must be provided.
 - 9 Minimum interval (in days) between applications of the same product
 - 10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
 - 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
 - 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
 - 13 PHI - minimum pre-harvest interval
 - 14 Remarks may include: Extent of use/economic importance/restrictions
 - 15 Overall conclusions - explanation for the column 15 is below

Explanation for column 15 “zRMS Conclusion”

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by CMS
N	Not acceptable/evaluation not possible
n.r.	Not relevant for section 3

Remark (Metabolism and Residues):

* The interval from sampling until extraction for 1,2,4 T and TA in the Bousquet's study (647-2023; 2023) was longer than the storage stability period for 1,2,4 T and TA in oilseed rape from S. Baxter, B. Phipps study (QG/21/002). Therefore additional data on storage stability for 1,2,4 T and TA in oilseed rape, winter turnip rape (0401060-002), mustard (0401080), sunflower (0401050), poppy (0401030), linseed (0401010) are required (data gap).

*** The use on sunflower (0401050) is accepted before forming of the edible part, before BBCH 65 (BBCH 61-65).

*** The lack of an analytical method for monitoring purposes for determination of boscalid in hops, spices and herbal infusions has been identified during review of the Maximum Residue Levels (EFSA Journal 2014;12(7):3799). This is post-registration requirement. This data gap should be addressed during the renewal of boscalid.

3 Background of authorization decision and risk management

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

Boscalid / Prothioconazole 350 / 200 WG (GPF515 / FGE03) is a beige solid appearance granule having characteristic odour. 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 > 400°C. In aqueous solution, it has a pH value around 7.2 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 ingredients content and associated impurities nor the technical properties were changed. The stability data indicate a shelf life of at least 2 3 years at ambient temperature when stored in commercial container tri laminated aluminium pouch. Results are available after 1 year storage (237-2-11-33020 (Interim Report-I) and the 3 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 0.175% w/v to 0.7 % w/v.

The product is not intended to be mixed in the tank together with other products. It is not intended to apply GPF515 / FGE03 with other plant protection products, therefore, no physical and/or chemical compatibility studies with other products are required.

Implications for labelling:

None.

Compliance with FAO specifications:

The product GPF515 / FGE03 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 FGE03 containing boscalid and prothioconazole; proposed tradenames are PATTON BOOST® and NEBBIA BOOST®.

FGE03 is a Water dispersible Granules (WG) preparation containing 350 g/kg boscalid + 200 g/kg prothioconazole addressed to control fungal diseases on oilseed rape crop. In fact, the draft Registration Report (dRR) supports submission for authorisation of the new product FGE03 as a WG (Water dispersible Granules) formulation for use as a fungicide in the Central registration zone in Czech Republic and Hungary as concerned Member States (cMS) and Poland as zRMS.

This document summarises the information related to the efficacy data of FGE03 against *Sclerotinia sclerotiorum* (SCLESC) in oilseed rape applied once or twice.

Preliminary trials

The new fungicide FGE03 is a water dispersible granule (WG) formulation boscalid and prothioconazole (350 g/kg + 200 g/kg).

a) Benefit of the mixture of boscalid and prothioconazole

Data generated across 14 trials carried out in Maritime zone (3 trials), North-East (4 trials) and South-East (7 trials) giving results on *Sclerotinia sclerotiorum* control in oilseed rape clearly demonstrated the interest of each active substance in FGE03 for the synergy between both active substances in this mixture (prothioconazole and boscalid).

In addition, the mixture of 2 modes of action (DMI for prothioconazole and SDHI for boscalid) has an interest for resistance management, and the results presented demonstrate that the key requirement mentioned by FRAC ([FRAC recommendations for fungicide mixtures](#), 2010) “the dose rates of each component used in the mixture should provide sufficient control of sensitive isolates when used alone” is met for FGE03.

b) Study of the mixture ratio of boscalid and prothioconazole

Considering the average efficacy from all zones (13 trials carried out in Maritime zone (3 trials), North-East (3 trials) and South-East (7 trials)) giving results on *Sclerotinia sclerotiorum* control in oilseed rape it was demonstrated that, the best ratio of each active substance in FGE03 is 140 g/ha prothioconazole and 245 g/ha boscalid.

Minimum effective dose of FGE03

In order to justify the choice of the dose rate of FGE03 for the control of *Sclerotinia sclerotiorum* (SCLESC) on oilseed rape, different dose rates were studied. FGE03 was tested at 0.35, 0.50 and 0.70 kg/ha in a total of 30 efficacy trials (14 trials with 1 application and 16 trials with 2 applications of FGE03). These rates reflect 50%, 71% and 100% of the target dose rate (0.7 kg/ha, the full recommended dose of FGE03) in accordance with the EPPO guideline PP 1/225(2) “Minimum effective dose”.

a) FGE03 applied once

Data generated across 14 trials carried out in the Maritime (5 trials), North-East (4 trials) and South-East (5 trials) EPPO climatic zones demonstrated similar results and clearly showed that the efficacy of FGE03 applied once at 0.7 kg/ha (245+140 g a.s./ha) against *Sclerotinia sclerotiorum* in oilseed rape is better than the lower rates 0.35 kg/ha and 0.5 kg/ha.

b) FGE03 applied twice

Data generated across 16 trials carried out in the Maritime (5 trials), North-East (6 trials) and South-East (5 trials) EPPO climatic zones demonstrated similar results and clearly showed that the efficacy of FGE03 applied twice at 0.7 kg/ha (245+140 g a.s./ha) against *Sclerotinia sclerotiorum* in oilseed rape is better than the lower rates 0.35 kg/ha and 0.5 kg/ha.

Efficacy of FGE03

a) FGE03 applied once

Data generated across 22 trials carried out in the Maritime (7 trials), North-East (4 trials) and South-East (11 trials) EPPO climatic zones show that FGE03 applied once at 0.7 kg/ha has a good effectiveness against *Sclerotinia sclerotiorum* in winter and spring oilseed rape.

It is therefore concluded that the data presented fully support the label claim for the use of FGE03 applied once at 0.7 kg/ha to *Sclerotinia sclerotiorum* in winter and spring oilseed rape in the Central registration zone.

Additionally, a total of 16 trials (5 trials in the Maritime, 4 trials in North-East and 7 trials in South-East EPPO zones) were harvested in the presence of *Sclerotinia sclerotiorum*. FGE03 improved the yield in the harvested trials. In addition, FGE03 did not show a negative impact on the quality parameters or FGE03 improved these parameters in the harvested trials. Therefore, FGE03 applied once at the proposed label rate has a positive effect on the harvest parameters.

b) FGE03 applied twice

Data generated across 16 trials carried out in the Maritime (5 trials), North-East (6 trials) and South-East (5 trials) EPPO climatic zones show that FGE03 applied twice at 0.7 kg/ha has a good effectiveness against *Sclerotinia sclerotiorum* in winter and spring oilseed rape.

It is therefore concluded that the data presented fully support the label claim for the use of FGE03 applied twice at 0.7 kg/ha to *Sclerotinia sclerotiorum* in winter and spring oilseed rape in the Central registration zone.

Additionally, a total of 10 trials (5 trials in the Maritime, 2 trials in North-East and 3 trials in South-East EPPO zones) were harvested in the presence of *Sclerotinia sclerotiorum*. FGE03 improved the yield in the harvested trials. In addition, FGE03 did not show a negative impact on the quality parameters or FGE03 improved these parameters in the harvested trials. Therefore, FGE03 applied twice at

the proposed label rate has a positive effect on the harvest parameters.

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

FGE03 is a water-dispersible granule (WG) formulation containing the active substances boscalid (350 g/kg) and prothioconazole (200 g/kg). This co-formulated fungicide is intended for the control of *Sclerotinia sclerotiorum* on oilseed rape (winter and spring) by foliar application method.

Prothioconazole is a broad-spectrum synthetic fungicide of the triazolinthione family of compounds with curative, preventative and eradicated action. It belongs to the Sterol Biosynthesis Inhibitors (SBI fungicides), SBI class I, group name: DMI (De-Methylation Inhibitors), SBI Class I. SBI fungicides inhibit the C14 demethylation step within fungal sterol biosynthesis. Chemically, DMIs belong to different classes. The molecule is classified by FRAC in group 3 (G1, C-14 demethylase in sterol biosynthesis (erg11/cyp51)).

Boscalid effectively manages diverse fungal pathogens in both arable and specialty crops, including ornamentals. It is effective under preventative and curative conditions. It is as a systemic fungicide categorized within the SDHI fungicides group, specifically hailing from the carboxamide family. SDHI (succinate dehydrogenase inhibitors) fungicides are extensively utilized in agriculture with the primary objective of disrupting the activity of the enzyme succinate dehydrogenase, a pivotal player in cellular respiration. The molecule is classified by FRAC in group 7 (C2, Complex II-succinate dehydrogenase in respiration chain).

The risk evaluation concludes that the combined risk is **low**, thus, the resistance risk is therefore acceptable when used according to the proposed label recommendations.

Although the risk evaluation is acceptable, additional recommendations can be proposed:

Utilisation of fungicide resistance management strategies in practice is one of the most important tools to slow down the evolution of fungicide resistant plant pathogens. FRAC gives some general recommendations for resistance management for all the crops.

The SBI fungicides represent one of the most potent classes of fungicides available to the grower for the control of many economically important pathogens. It is in the best interest of all those involved in recommending and using these fungicides that they are utilised in such a way that their effectiveness is maintained. The working group concentrates its resources on the major crop/pathogen targets from the point of view of resistance risk. Inevitably many, still important pathogens are omitted. To help in making recommendations for crops and pathogens not directly covered, the following general recommendations can be made:

- Repeated application of SBI fungicides alone should not be used on the same crop in one season against a high-risk pathogen in areas of high disease pressure for that particular pathogen.
- For crop/pathogen situations where repeated spray applications (e.g., orchard crops/powdery mildew) are made during the season, alternation (block sprays or in sequence) or mixtures with an effective non-cross-resistant fungicide are recommended.
- Where alternation or the use of mixtures is not feasible because of a lack of effective or compatible non-cross-resistant partner fungicides, then input of SBI's should be reserved for critical parts of the season or crop growth stage.
- If the performance of SBIs should decline and sensitivity testing has confirmed the presence of less sensitive isolates, SBIs should only be used in mixture or alternation with effective non-cross-resistant partner fungicides.
- The introduction of new classes of chemistry offers opportunities for more effective resistance management. The use of different modes of action should be maximized for the most effective resistance management strategies.
- Users must adhere to the manufacturers' recommendations. In many cases, reports of "resistance" have, on investigation, been attributed to cutting recommended use rates, or to poorly timed applications.

- Fungicide input is only one aspect of crop management. Fungicide use does not replace the need for resistant crop varieties, good agronomic practice, plant hygiene/sanitation, etc.
- Exclusive frequency measurements of single cyp51 mutations are not sufficient to describe the sensitivity situation towards DMIs but can help to better understand the background of sensitivity shifts.

Strategies for the management of SDHI fungicide resistance, in all crops, are based on the statements listed below. These statements serve as a fundamental guide for the development of local resistance management programs. Resistance management strategies have been designed in order to be proactive and to prevent or delay the development of resistance to SDHI fungicides.

- A fundamental principle that must be adhered to when applying resistance management strategies for SDHI fungicides is that:

The SDHI fungicides are in the same cross-resistance group.

- Fungicide programs must deliver effective disease management. Apply SDHI fungicide-based products at effective rates and intervals according to manufacturers' recommendations.
- Effective disease management is a critical component to delay the build-up of resistant pathogen populations.
- The number of applications of SDHI fungicide-based products within a total disease management program must be limited.
- When mixtures are used for SDHI fungicide resistance management, applied as tank mix or as a co-formulated mixture, the mixture partner:
 - should provide satisfactory disease control when used alone on the target disease.
 - must have a different mode of action.
- Mixtures of two or more SDHI fungicides can be applied to provide good biological efficacy; however, they do not provide an anti-resistance strategy and must be treated as a solo SDHI for resistance management. Each application of such a mixture when used in a spray program counts as one SDHI application.
- SDHI fungicides should be used preventively or at the early stages of disease development.
- Species can carry different mutations which affect SDHIs. A few mutations can lead to different sensitivities depending on the chemical structure of the active ingredient.
- As SDHIs are cross-resistant, resistance management must be the same for all SDHIs.
- All monitoring and guideline related statements refer to the entire group of SDHIs.

Concerning the specific recommendations for oilseed rape, based upon guidance from the FRAC SDHI Working Group, extensive monitoring programs have been carried out and reduced sensitivity has been detected in *S. sclerotiorum*. Further monitoring programs will continue and clarify the necessity for a specific crop guideline. The general guidelines for the use of SDHIs are currently considered to be sufficient because current data shows sporadic detection, no consistent increase and spread of resistant mutations. In addition, the life cycle of the pathogen, its distribution and rotation with non-host crops confirm that Sclerotinia in oilseed rape justify the classification as a low-risk pathogen.

Additionally, major points of risk reduction are the agronomic measures. In many crops, cultivation and other non-chemical methods according to Good Agricultural Practice are necessary to hold the resistance risk at a low level. This includes crop rotation, alternation of fungicides and reduced number of applications.

3.3.2 Adverse effects on treated crops

No phytotoxicity symptoms caused by FGE03 applied once or twice at the proposed maximum dose rates on oilseed rape were recorded in a total of 50 efficacy trials carried out in all crops presented previously.

No specific selectivity trials are provided.

No negative effects on yield and quality of plants or plant products are observed in all efficacy harvested trials.

The results confirmed that FGE03 at the rates tested is safe to oilseed rape

In addition, many products containing boscalid or prothioconazole have been approved and widely used in many countries of Europe for the control of several diseases and proven to have no adverse effects on oilseed rape.

3.3.3 Observations on other undesirable or unintended side-effects

No impact is expected on succeeding and adjacent crops if FGE03 is used according to the Good Agricultural Practices and label recommendations.

Concerning the effects on beneficial and other non - target organisms, no effect is expected on beneficial or other non - target organisms if FGE03 is used according to the Good Agricultural Practices and label recommendations.

In addition, many products containing boscalid or prothioconazole have been approved and widely used in many countries of Europe for the control of several diseases and proven to have no adverse effects upon succeeding and adjacent crops.

3.4 Methods of analysis (Part B, Section 5)

Sufficiently sensitive and selective analytical methods are available for the active substances 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 methodologies for the determination of active substances boscalid and prothioconazole in the formulation are available and validated.

Validated analytical methods are available for the determination of relevant impurities Toluene and prothioconazole-desthio in the formulation GPF515 / FGE03 with LOQ of 0.00059% and 0.00078% respectively, covering the maximum acceptable content of impurities in the formulation.

Toluene maximum content in formulation: 0.1% w/w

Prothioconazole-Desthio maximum content in formulation: 0.01% w/w

3.4.2 Analytical methods for residues

The Applicant submitted a number of methods for analysis of residues of boscalid and prothioconazole for the generation of pre-authorization data. The analytical were successfully validated and accepted. The details of the evaluation of new and additional studies are referred in Appendix 2 of Part B5.

Prothioconazole

Sufficiently sensitive analytical methods are available and validated for all components included in the prothioconazole residue definition, for soil, water, air, food of plant origin, food of animal origin and in body fluids.

The Applicant submitted a number of methods for analysis of residues of prothioconazole for the generation of pre-authorization data and methods for post-authorization control and monitoring purposes. The details of the evaluation of new and additional studies are referred in Appendix 2 of Part B5.

Since many MRLs have been lowered to 0.01 mg/kg, the validated LOQ of the EU agreed methods by Weeren and Pelz (2000) and Class (2001) are not sufficient to monitor these lowered MRLs for food

of plant origin. To cover the current residue definition and MRL limits, the applicant provided the analytical method of Pearson (2022, Report No. QG/20/011) and its ILV (Boubakri, 2023, Report No. S21-08354) for the determination of prothioconazole-desthio residues in/on matrices of plant origin (high water content, high acid, high oil content and high protein/high starch content) with LOQ of 0.005 mg/kg. The ILV is acceptable. The analytical method of Pearson (2022, Report No. QG/20/011) was successfully independently validated. The details of the evaluation of new study is referred in Appendix 2 of Part B5.

The Applicant provided new method (D. Kleinhenz, 2023, Report No. S21-08355) validated for the determination of prothioconazole-desthio (as sum of isomers) in five different matrices of food of animal origin (milk, egg, fat, liver and meat) with the LOQ of 0.004 mg/kg for milk and 0.01 mg/kg for remaining matrices and its ILV (T. Rastogi, 2023, Report No. S21-08868) for the determination of prothioconazole-desthio residues in milk and fat with LOQ of 0.004 mg/kg and 0.01 mg/kg, respectively.

Additionally, analytical method and its ILV for determination of prothioconazole-desthio in honey is available.

The Applicant provided new method (N. Boubakri, 2023, Report No. S21-08361) validated for the determination of prothioconazole-desthio in urine with the LOQ of 0.01 mg/L.

No additional data are required.

Applicant submitted the LC-MS/MS analytical method (D. Kaiser, 2022, Report No. S21-08359) with its ILV (S. Jooß, 2023, Report No. S21-08869) for the determination of prothioconazole and prothioconazole-desthio in drinking water with LOQ of 0.05 µg/L.

Additionally the Applicant provided analytical method for determination of prothioconazole with LOQ of 0.006 mg/kg and prothioconazole-desthio with 0.002 mg/kg in soil (M. Kaiser, 2022, Report No. S21-08358).

No additional data are required.

Boscalid

According to the EFSA Journal 2014;12(7):3799:

Methods for enforcement of residues in food of plant origin

“During the peer review under Directive 91/414/EEC, an analytical method using GC-MS and its ILV was evaluated and validated for the determination of boscalid in plant matrices with an LOQ of 0.01 mg/kg in high water content (tomato), 0.02 mg/kg in high fat content (oilseed rape), and 0.01 mg/kg in acidic (lemon) and dry commodities (wheat grain) (Germany, 2002). The method is however not highly specific according to SANCO/825/00 rev 8.1 (EC, 2010b).

In addition, an analytical method using HPLC-MS/MS was evaluated and validated for the determination of boscalid in plant matrices with an LOQ of 0.05 mg/kg in high water (apple, sour cherry, strawberry, carrot, onion, tomato, broccoli, white cabbage, leek, dwarf bean), high acid (grape) and high fat content (oilseed rape) commodities (Germany, 2002; FAO, 2006).

The multi-residue QuEChERS method in combination with HPLC-MS/MS, as described by CEN (2008), is also reported for analysis of parent boscalid with an LOQ of 0.01 mg/kg in dry commodities, high water content, high fat content and acidic commodities.

Hence it is concluded that boscalid can be enforced in food of plant origin with an LOQ of 0.01 mg/kg in high water content, high fat content, dry and acidic commodities.

No analytical method is available for hops, spices and herbal infusions. Considering that analytical methods are validated in four matrix groups and that dilutions of extracts before analysis should reduce the analysis difficulties inherent to those commodities, it is likely that validated methods presented above can be used to enforce the high residue levels observed in hops, spices and herbal infusions. Nevertheless, full validation data is in principle still required.”

It should be noted that the ILV method of Reichert N. (2001 BASF DocID 2000/1014886) was

validated in white cabbage (high water content commodity), rape seed (high oil content commodities), hops (no group) and lettuce (high water content commodity). According to the SANTE/2020/12830, Rev.2, 14. February 2023 *If the primary method is identical for all matrix groups, it is sufficient to perform the ILV for commodities of two of these groups, one of them with high water content.*

The new multi-residue method QuEChERS and its ILV for determination of residues of boscalid was fully validated on in/on five different matrices of plant origin i.e. wheat grains, wheat straw, lettuce, whole orange and oilseed rape seeds according to SANTE/2020/12830, rev.1 with LOQ of 0.01 mg/kg (Rastogi, T., 2022b, Study Number: S22-00980; ILV: Gustloff, C., 2022, Study Number: S22-05632).

The lack of an analytical method for hops, spices and herbal infusions has been identified during review of the Maximum Residue Levels (EFSA Journal 2014;12(7):3799) **(data gap)**. **This data gap should be addressed during the renewal of boscalid.**

During the peer review under Directive 91/414/EEC, an analytical method using GC-ECD, confirmed by GC-MS, and its ILV were evaluated and validated for the determination of boscalid and its metabolite M510F01 (free and conjugated) in food of animal origin with an LOQ of 0.01 mg/kg for each compound in milk and 0.025 mg/kg for each compound in meat, fat, liver, kidney and eggs (Germany, 2002). The method should be able to analyse the conjugates of the metabolite but the hydrolysis step has not been validated. Moreover, the method is not highly specific according to SANCO/825/00 rev 8.1 (EC, 2010b).

Nevertheless, an analytical method using HPLC-MS/MS was also evaluated and validated for the determination of boscalid and its metabolite M510F01 (free and conjugated) in animal matrices with an LOQ of 0.01 mg/kg for each compound in milk, cream and eggs, and 0.025 mg/kg for each compound in muscle, fat, kidney and liver. The method is able to analyse the conjugates of the metabolite and the hydrolysis step is considered as validated.

Hence it is concluded that boscalid can be enforced in food of animal origin with an LOQ of 0.01 mg/kg in milk and eggs, and an LOQ of 0.025 mg/kg in muscle and fat. Boscalid and its metabolite M510F01 (free and conjugated) can be enforced in liver and kidney with an LOQ of 0.025 mg/kg for each compound. Further validation of the hydrolytic step dissociating the conjugates of metabolite M510F01 should be required for GC-ECD method. However, considering the hydrolysis step was validated for another analytical method, this information is considered as desirable only (minor deficiency)."

Three new analytical methods and ILV for determination of residues of boscalid, M510F01, M510F52 and M510F53 were fully validated on in/on matrices of animal origin such as bovine meat (as muscle), bovine fat, milk, poultry's eggs, bovine liver and bovine kidney according to SANTE/2020/12830, rev.1 with LOQ of 0.01 mg/kg in each matrices (Rastogi, T. 2023, Study No. S22-00981, ILV: Spielvogel Ch., Timmann, A., 2023; Study No. S22-05633 (EAG-2202V)).

Additionally, analytical method and its ILV for determination of boscalid in honey with LOQ of 0.01 mg/kg is available. The method is accepted. More details please see in Appendix 2 of Part B5.

The GC-MS BASF-method 408/1 is available for determination of boscalid with LOQ of 0.01 mg/kg in soil.

The GC-MS method is available for determination of boscalid with LOQ of 1.5 µg/m³ in air.

The Applicant provided additional analytical method for the determination of boscalid and metabolites M510F47, M510F49 and M510F64 in groundwater and surface water.

The analytical method of Rastogi, T. (2022) has been successfully validated and fulfils the requirements with regard to specificity, linearity, limit of quantification, recoveries and repeatability for the analysis of BAS 510 F (boscalid) and boscalid metabolites M510F47, M510F49 and M510F64

in groundwater and surface water with LOQ of 0.1 µg/kg using LC-MS/MS. The method is independently validated (Kaiser, M., 2023).

The Applicant provided additional analytical method for the determination of boscalid and its metabolite M510F01 in/on body fluids (blood and urine).

The analytical method of Rastogi, T. (2022) has been successfully validated and fulfils the requirements with regard to specificity, linearity, limit of quantification, recoveries and repeatability for the analysis of boscalid and its metabolite M510F01 in/on body fluids (blood and urine) with LOQ of 0.01 mg/L for both analytes in both investigated matrices using LC-MS/MS.

3.5 Mammalian toxicology (Part B, Section 6)

Risk assessment has been performed using the following endpoints:

Active substance 1 (incl. content)	Boscalid (350 g/kg)
AOEL systemic	0.1 mg/kg bw/d (Review Report SANCO/3919 /2007-rev. 5, 21 January 2008)
Dermal absorption	Concentrate: 0.11% Dilution: 3.1% (Nagane, 203)
Active substance 2 (incl. content)	Prothioconazole (200 g/kg)
AOEL systemic	0.2 mg/kg bw/d (EFSA Scientific Report (2007) 106, 1-98)
Dermal absorption	Concentrate: 0.77% Dilution: 14% (Desai, 2024)
Degradation product (incl. content)	Prothioconazole-desthio (A conversion of 100% is assumed. Based on a molecular weight of 344.254 g/mol for Prothioconazole and 312.194 g/mol for prothioconazole-desthio a factor of 0.907 was applied)
AOEL systemic	0.01 mg/kg bw/d (refer to Prothioconazole)
Dermal absorption	Concentrate: N/A Dilution: 27% (Desai, 2023)

No risk to operators, workers or bystanders and residents is predicted following the intended GAP uses of GPF515/FGE03. Risk mitigation measures, i.e. personal protective equipment, are not required for operator or worker safety (except mandatory labelling). However, regarding CLP classification it is strongly recommended to use by the operators protective glasses and protective wear and gloves also considering formation of prothioconazole-desthio under worst case assumptions. a For B&R 10 m buffer strip and 50% drift reduction are required with respect to resident and bystander safety.

3.5.1 Acute toxicity

No studies to assess the acute toxicological profile of GPF515/FGE03 have been performed. As reliable and sufficient toxicological data on the active substances and all co-formulants are available, it is reasonable to assess the toxicological properties of the formulation according to the rules laid down in Regulation (EC) No 1272/2008.

Applying the calculation method accordingly using Acute Toxicity Estimates (ATE) and Specific or Generic Concentration Limits (SCL/GCL), the product does not warrant classification for acute oral, dermal or inhalation toxicity nor being a skin and eye irritant or skin sensitiser. Based on content (SCL/GCL) of co-formulants product is considered as irritating to skin (H315) and eyes (H318).

3.5.2 Operator exposure

Using the AOEM model (EFSA Online Calculator, version 1.0.2), potential operator exposure is predicted to be in a range of 0.003 mg/kg bw/d and 0.006 mg/kg bw/d equal to approximately 2.9% and 3.1% of the AOEL for Boscalid and Prothioconazole for tractor-mounted spraying to field crops.

Potential operator exposure for the degradation product Prothioconazole-desthio, formed during application, is predicted at 0.003 mg/kg bw/d, equal to ca. 30% of the AOEL, considering 50% drift reduction. Thus, no risk for the operator using GPF515/ FGE03 is anticipated for all intended uses even without personal protective equipment. Regarding CLP classification it is strongly recommended to use by the operators protective goggles and protective gloves.

Table 3.5-1: Estimated operator exposure (longer term exposure)

Table 3.3.1: Estimated operator exposure (longer term exposure)					
		Boscalid		Prothioconazole	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to field crops					
Application rate		0.245 kg a.s./ha		0.140 kg a.s./ha	
Spray application outdoor (AOEM; 95 th percentile) Body weight: 60 kg	Potential exposure (no work wear, no PPE)	0.003	2.9	0.006	3.1
	Work wear (arms, body and legs covered) M/L and A	0.002	2.3	0.004	2.1

Table 3.5-2: Estimated operator exposure (longer term exposure) - desthio

Table 3.3-1: Estimated operator exposure (longer term exposure) outdoors					
		Boscalid		Prothioconazole-desthio*	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to field crops, 50% drift reduction					
Application rate		0.245 kg a.s./ha		0.127 kg a.s./ha**	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential exposure (no work wear, no PPE)	0.002	1.9	0.003	30.3
	Work wear (arms, body and legs covered) M/L and A	0.002	1.7	0.003	26.8

* Exposure only relevant for in-use dilution during application

** (A conversion of 100% is assumed. Based on a molecular weight of 344.254 g/mol for prothioconazole and 312.194 g/mol for prothioconazole-desthio a factor of 0.907 was applied.

3.5.3 Worker exposure

Potential worker exposure is estimated at 0.02 mg/kg bw/d equal to approximately 16% of the AOEL for Boscalid and 0.04 mg/kg bw/d equal to approximately 21% of the AOEL for Prothioconazole for inspection/irrigation re-entry activities in field crops.

As Prothioconazole-desthio is formed during application, normal work wear should be worn with exposure estimated at 0.008 mg/kg bw equal to 82% of the AOEL.

Thus, overall, no risk for workers upon re-entry is anticipated if normal work wear is worn.

Table 3.5-3: Estimated worker exposure (longer term exposure)

Table S.13.5: Estimated worker exposure (longer term exposure)					
		Boscalid		Prothioconazole	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Inspection, irrigation Outdoor Work rate: 2 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 14 days					

Number of applications and application rate		2 × 0.245 kg a.s./ha		2 × 0.140 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0.02	16.3	0.04	21.1
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.002	1.8	0.005	2.4
	Work wear (arms, body and legs covered) and gloves TC: 1250 cm ² /person/h	0.002	1.6	0.004	2.1

Table 3.5-4: Estimated worker exposure (longer term exposure) - desthio

		Boscalid		Prothioconazole-desthio*	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Inspection, irrigation Outdoor Work rate: 2 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 14 days					
Number of applications and application rate		2 × 0.245 kg a.s./ha		2 × 0.127 kg a.s./ha**	
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0.02	16.3	0.07	735
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.002	1.8	0.008	82.4
	Work wear (arms, body and legs covered) and gloves TC: 1250 cm ² /person/h	0.002	1.6	0.007	73.5

* Exposure only relevant for in-use dilution during application

** A conversion of 100% is assumed. Based on a molecular weight of 344.254 g/mol for prothioconazole and 312.194 g/mol for prothioconazole-desthio a factor of 0.907 was applied.

3.5.4 Bystander and resident exposure

No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.

Resident exposure for children is estimated at 0.003 and 0.008 mg/kg bw/d equal to approximately 3 and 4% of the AOEL for Boscalid and Prothioconazole, respectively.

Total mean exposure towards Prothioconazole-desthio is predicted to be 0.009 mg/kg bw/d for children and 0.005 mg/kg bw/d for an adult, equal approximately 95% or 47% of the AOEL, respectively. Thus, no risk for residents and bystanders is anticipated for use of GPF515/ FGE03.

Table 3.5-5: Estimated resident exposure (longer term exposure)

Table 5.13.5: Estimated Resident Exposure (longer term exposure)					
		Boscalid		Prothioconazole	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to field crops Buffer zone: 2-3 m Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 14 days					
Number of applications and application rate		2 × 0.245 kg a.s./ha		2 × 0.140 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.002	2.1	0.005	2.7
	Vapour (75 th perc.)	8 × 10 ⁻⁵	0.08	8 × 10 ⁻⁸	4 × 10 ⁻⁵
	Deposits (75 th perc.)	0.0003	0.3	0.0007	0.3
	Re-entry (75 th perc.)	0.002	2.2	0.006	2.8

	Sum (mean)	0.003	3.2	0.008	4
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0005	0.5	0.001	0.6
	Vapour (75 th perc.)	3×10^{-5}	0.03	3×10^{-8}	1×10^{-5}
	Deposits (75 th perc.)	9×10^{-5}	0.09	0.0002	0.1
	Re-entry (75 th perc.)	0.001	1.2	0.003	1.6
	Sum (mean)	0.001	1.3	0.003	1.6

Table 3.5-6: Estimated resident exposure (longer term exposure) - desthio

Table 3.3-6: Estimated resident exposure (longer term exposure) – desthio					
		Boscalid		Prothioconazole-desthio	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to field crops Buffer zone: 10 m Drift reduction technology: yes (50%) DT ₅₀ : 30days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 14 days					
Number of applications and application rate		2 × 0.245 kg a.s./ha		2 × 0.127 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0006	0.6	0.003	25.3
	Vapour (75 th perc.)	8 × 10 ⁻⁵	0.08	1 × 10 ⁻⁸	0.0001
	Deposits (75 th perc.)	4 × 10 ⁻⁵	0.04	0.0001	1.2
	Re-entry (75 th perc.)	0.002	2.2	0.01	99.3
	Sum (mean)	0.002	2.2	0.009	94.2
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0001	0.1	0.0005	4.7
	Vapour (75 th perc.)	3 × 10 ⁻⁵	0.03	3 × 10 ⁻⁹	3 × 10 ⁻⁵
	Deposits (75 th perc.)	1 × 10 ⁻⁵	0.01	5 × 10 ⁻⁵	0.5
	Re-entry (75 th perc.)	0.001	1.2	0.006	55.2
	Sum (mean)	0.001	1.1	0.005	46.9

* Exposure only relevant for in-use dilution during application

** A conversion of 100% is assumed. Based on a molecular weight of 344.254 g/mol for prothioconazole and 312.194 g/mol for prothioconazole-desthio a factor of 0.907 was applied.

3.5.5 Combined exposure

The product is a mixture of two active substances. Based on commonality in the toxicological profiles of the two active substances, combined exposure was calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity.

According to the calculations, it can be concluded that combined exposure to all active substances in GPF515/ FGE03 is not expected to present a risk for operators, workers, residents and bystanders.

Table 3.5-7: Risk assessment from combined exposure (longer term exposure)

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Operators – tractor mounted, (potential exposure)	Boscalid	0.029
	Prothioconazole	0.031
	Cumulative risk operators (HI)	0.06
Workers – inspection/irrigation (potential exposure)	Boscalid	0.17
	Prothioconazole	0.22

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Cumulative risk workers (HI)	0.4
Resident – child (2-3 m, no drift reduction)	Boscalid	
	Drift	0.021
	Vapour	0.0008
	Deposits	0.003
	Re-entry	0.022
	Sum of all pathways	0.032
	Prothioconazole	
	Drift	0.027
	Vapour	4×10^{-7}
	Deposits	0.003
	Re-entry	0.028
	Sum of all pathways	0.04
	Cumulative risk resident – child (HI)	
	Drift	0.05
	Vapour	0.0008
	Deposits	0.007
	Re-entry	0.05
	Sum of all pathways	0.07
Resident – adult (2-3 m, no drift reduction)	Boscalid	
	Drift	0.005
	Vapour	0.0003
	Deposits	0.0009
	Re-entry	0.012
	Sum of all pathways	0.013
	Prothioconazole	
	Drift	0.006
	Vapour	1×10^{-7}
	Deposits	0.001
	Re-entry	0.016
	Sum of all pathways	0.016
	Cumulative risk resident – adult (HI)	
	Drift	0.01
	Vapour	0.0003
	Deposits	0.002
	Re-entry	0.03
	Sum of all pathways	0.03

The Hazard Index is < 1. Thus, combined exposure to all active substances in GPF515/ FGE03 is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

However, for Prothioconazole-containing products, its degradation product prothioconazole-desthio

has also to be evaluated as regards combined exposure.

Table 3.5-8: Risk assessment from combined exposure (longer term exposure) - desthio

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Operators – tractor mounted, (potential exposure)	Boscalid	0.019
	Prothioconazole-desthio	0.303
	Cumulative risk operators (HI)	0.322
Workers – inspection/irrigation (workwear and gloves)	Boscalid	0.018
	Prothioconazole-desthio	0.824
	Cumulative risk workers (HI)	0.8
Resident – child (10 m, 50% drift reduction)	Boscalid	
	Drift	0.006
	Vapour	0.0008
	Deposits	0.0004
	Re-entry	0.022
	Sum of all pathways	0.022
	Prothioconazole-desthio	
	Drift	0.0253
	Vapour	0.0001
	Deposits	0.012
	Re-entry	0.993
	Sum of all pathways	0.942
	Cumulative risk resident – child (HI)	
	Drift	0.3
	Vapour	0.0008
	Deposits	0.01
	Re-entry	1
	Sum of all pathways	1
Resident – adult (10 m, 50% drift reduction)	Boscalid	
	Drift	0.001
	Vapour	0.0003
	Deposits	0.0001
	Re-entry	0.012
	Sum of all pathways	0.011
	Prothioconazole-desthio	
	Drift	0.047
	Vapour	3×10^{-5}
	Deposits	0.005
	Re-entry	0.552
	Sum of all pathways	0.469
	Cumulative risk resident – adult (HI)	
	Drift	0.05

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
	Vapour	0.0003
	Deposits	0.005
	Re-entry	0.6
	Sum of all pathways	0.5

The Hazard Index for combined resident exposure towards Boscalid and Prothioconazole-desthio is not exceeding 1.

As displayed by the EFSA online calculator, yellow colour-coding indicates a “Safe use with drift reduction and/or increased buffer strip”. Thus, further refinement of the assessment is not required..

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

3.6.1 Residues

The formulation FGE03 is a plant protection product containing the active substances boscalid at 350 g/kg and prothioconazole at 200 g/Kg intended to be used on oilseed rape and minor oilseeds. Oilseed rape is the major crop in northern Europe (SANTE/2019/12752). A minimum of eight trials are required.

Prothioconazole

Five new magnitude of residue studies were submitted in the framework of this application.

Sufficient trials on oilseed rape were conducted in accordance with the following GAP: 2 x 175 g a.s. /ha, application interval - 14 days, 2nd application at BBCH 80 (outdoor) to determine of the residues of prothioconazole metabolites: PTZ-dethio, PTZ-alpha-OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio, PTZ-5-OH-desthio, PTZ-6-OH-desthio, triazole derived metabolites (TDM's) in oilseed rape specimens: seed and plant (rest of plant or immature plant).

Available results show that the in force MRL of prothioconazole on oilseed rape of 0.15 mg/kg (Reg. (EU) 2024/1318) will not be exceeded. The current EU MRL for prothioconazole is sufficient to support the proposed use.

The trials are supported by valid storage stability data and validated analytical methods.

Remark:

The Bousquet's study (647-2023; 2023) on the magnitude of residues of the PTZ-OH-desthio metabolites is valid with regard to storage stability. The interval from sampling until extraction for 1,2,4-T and TA in this study was longer than the storage stability period for 1,2,4-T and TA in oilseed rape from S. Baxter, B. Phipps study (QG/21/002). **Therefore additional data on storage stability for 1,2,4-T and TA in oilseed rape are required (data gap).**

Commenting period, 10.2025:

The Applicant provided new storage stability study (Jooß, 2025; Study Code S23-105428). The Bousquet's study (647-2023; 2023) on the magnitude of residues of 1,2,4-T and TA is supported by new valid storage stability data.

The proposed use on oilseed rape is considered acceptable.

Minor uses: gold of pleasure (0401130), winter turnip rape (0401060-002), mustard (0401080), sunflower (0401050), poppy (0401030), linseed (0401010), flax, hemp (0401140), borage (0401120)

Based on the Technical Guidelines SANTE/2019/12752, rev.01:

- 8 residue trials on oilseed rape (0401060) can be used for extrapolation to linseeds (0401010), poppy seeds (0401030), mustard seeds (0401080) and gold of pleasure seeds (0401130) after forming of the edible part.

- 8 residue trials on oilseed rape (0401060) can be used for extrapolation to Whole group Oilseeds (0401000), except peanuts/groundnuts (0401020) before forming of the edible part (for oilseeds, a significant part of the edible part is present from full blossom (BBCH 65) onwards).

Available results show that the in force MRLs of prothioconazole (Reg. (EU) 2024/1318) on oilseed rape (0401060), winter turnip rape (0401060-002), mustard (0401080), sunflower (0401050), poppy (0401030), linseed (0401010) will not be exceeded.

An exceedance of the current MRLs for prothioconazole as laid down in Reg. (EU) 2024/1318 is expected for gold of pleasure (0401130), hemp (0401140) and borage (0401120). These uses are not accepted.

Taking into account the possibility of extrapolation (SANTE/2019/12752, rev.01) the proposed uses on minor crops: winter turnip rape (0401060-002), linseeds (0401010), poppy seeds (0401030), mustard seeds (0401080) after forming of the edible part is considered acceptable. Minor use on sunflower (0401050) is accepted before forming of the edible part, before BBCH 65.

The effects of processing on the nature of prothioconazole residues have been investigated. As residues of prothioconazole do not exceed the trigger values defined in Reg (EU) No 283/2013 (except Triazole Derivative Metabolites - TDMs), there is no need to investigate the effect of industrial and/or household processing on prothioconazole residues except for TDMs.

Regarding TDMs, studies show that they remained stable under the standard hydrolysis conditions. Studies on magnitude of residues in processed commodities in wheat after treatment with prothioconazole were presented in the Triazole Derivate Metabolites Addendum - Confirmatory data (B.7.5.2, UK, 2018).

Residues of prothioconazole residues (except TDMs) in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues exceeding residues in primary crops will be present in succeeding crops. Regarding TDMs, in the framework of the confirmatory data, several field rotational crop trials have been conducted to investigate the magnitude of TDM residues in rotational crops after the use of triazole active substances. Residues of TA, TLA and TAA were found above 0.01 mg/kg in succeeding crops. These results were considered in the consumer risk assessment performed in the framework of the review of TDMs confirmatory data.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Regarding TDM arising from prothioconazole uses, as concluded by the UK, “further consideration is not required due to the fact that none of the TDMs were identified” in the available livestock metabolism studies conducted with prothioconazole.

Boscalid

Oilseed rape

Two new magnitude of residue studies were submitted in the framework of this application.

Eight N-EU trials were conducted in accordance with the following GAP: 2 x 250 g a.s. /ha, application interval - 14 days, 2nd application at BBCH 67-81 (outdoor) to determine of the residues of boscalid in oilseed rape specimens: seed and whole plant.

Available results show that the in force MRL of boscalid on oilseed rape of 1 mg/kg (Reg. (EU) 2022/1324) will not be exceeded. The current EU MRL for boscalid is sufficient to support the proposed use.

The trials are supported by valid storage stability data and validated analytical methods.

The proposed uses on oilseed rape is considered acceptable.

Minor uses: gold of pleasure (0401130), winter turnip rape (0401060-002), mustard (0401080), sunflower (0401050), poppy (0401030), linseed (0401010), flax, hemp (0401140), borage (0401120)

Available results show that the in force MRL of boscalid on oilseed rape (0401060), gold of pleasure (0401130), winter turnip rape (0401060-002), mustard (0401080), sunflower (0401050), poppy (0401030), linseed (0401010), hemp (0401140) and borage (0401120) of 1 mg/kg (Reg. (EU) 2022/1324) will not be exceeded. The current EU MRL for boscalid is sufficient to support the proposed uses.

Taking into account the possibility of extrapolation (SANTE/2019/12752, rev.01) the proposed uses on minor uses: winter turnip rape (0401060-002), linseeds (0401010), poppy seeds (0401030), mustard seeds (0401080) and gold of pleasure seeds (0401130) after forming of the edible part is considered acceptable.

Following minor uses: sunflower (0401050), hemp (0401140) and borage (0401120) are accepted before forming of the edible part, before BBCH 65.

The effects of processing on the nature of boscalid residues have been investigated.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

3.6.2 Consumer exposure

Prothioconazole

The calculation of the TMDI using EFSA model (version 3.1) and MRLs values according to the Regulation (EU) 2024/1318 and appropriate conversion factors for enforcement to risk assessment led to a utilisation of the ADI of 42% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is wheat with 8% of the ADI. The intended uses will not result in a consumer chronic exposure exceeding the ADI for prothioconazole-destho.

An acute consumer risk assessment was performed only for the crops under consideration. IESTI: for children – 18.56% (Bovine: Liver), for adults – 16.45% (Swine: Other products).

TDMs

The dietary risk assessment was calculated using PRIMo rev 3.1 for each TDM. Toxicological reference values and input values from EFSA conclusion on confirmatory data on TDMs (EFSA, 2018) were taken into account.

Boscalid

The calculation of the TMDI using EFSA model (version 3.1) and all MRLs according to current Reg. (EU) No 2022/1324 led to a utilisation of the ADI of 400% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is spinach with 90% of the ADI.

The refined assessment of chronic risk is required as TMDI calculations exceeded 100% of the ADI. IEDI calculation has been performed with the STMRs values taken from the corresponding EFSA reasoned opinions, instead of the MRLs, are included in the assessment, considering the combined assessment of primary uses and uptake of residues from previously treated soil. The input values are presented in Table 7.3-16, corrected by zRMS.

The total chronic intake calculated accounted for 72% of the ADI (NL toddler) with apples (11%) as highest contributing commodity. Therefore the intended uses will not result in a consumer chronic exposure exceeding the ADI.

Since the setting of an ARfD was not deemed necessary for boscalid, no acute consumer risk assessment was performed.

The data available are considered sufficient for risk assessment. The chronic and the short-term intakes of prothioconazole, boscalid residues and TDMs are unlikely to present a public health concern. The intended uses of FGE03/Patton Boost are accepted.

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

Predicted environmental concentrations (PEC) were calculated for both active substances boscalid and prothioconazole and its metabolites for the environmental exposure risk assessment. The assessments undertaken for the soil, groundwater and surface water compartments are described in the following sections.

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

Soil exposure for boscalid and prothioconazole and its metabolites were calculated using approach described in respective FOCUS guidance for the intended uses of FGE03. For all compounds, EU agreed data were taken into account. Soil exposure for the formulated product was also calculated. The results for PEC_{soil} for boscalid and prothioconazole and its metabolites were used for the ecotoxicological risk assessment.

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

The groundwater exposure assessment was conducted according to FOCUS guidance using models PEARL v5.5.5 and PELMO v6.6.4. 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 use patterns as presented in the GAP table.

The active substance prothioconazole was assessed along with its major soil metabolites, prothioconazole S-methyl (M01) and prothioconazole-desthio (M04). All endpoints were taken from the peer review conclusion for prothioconazole (EFSA, 2007). The maximum 80th percentile PEC_{gw} values for the prothioconazole and its metabolites were far below the threshold concentration of 0.1 µg/L in all crops and scenarios, indicating that no unacceptable leaching of this substance is expected after application of FGE03 according to the intended use pattern.

Predicted concentrations of boscalid in groundwater were far below the threshold concentration of 0.1 µg/L in all crops and scenarios indicating that no unacceptable leaching of this substance is expected after application of FGE03 according to the intended use pattern.

The results indicate that any contamination of groundwater at concentrations relevant for the environment and for consumer exposure by the active substances boscalid, prothioconazole and prothioconazole metabolites must not be expected following the GAP proposed uses of FGE03.

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

A PEC_{SW} calculation was performed for the product FGE03 according to the FOCUS SW report (2001)¹ and the FOCUS Generic Guidance (2015)² using most up-to-date versions of the models. Obtained PEC_{SW/SED} values for boscalid and prothioconazole and its relevant metabolites were used in the risk assessment for aquatic organisms.

The surface water exposure to the formulated product was calculated using Spray Drift Calculator. Obtained PEC_{sw} values were used in the risk assessment for aquatic organisms.

¹ 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

² FOCUS (2015): Generic guidance for FOCUS surface water scenarios, version 1.4, May 2015

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

Air is not a relevant exposure pathway for boscalid and prothioconazole due to low vapour pressure ($<10^{-5}$ Pa) and DT₅₀ in the atmosphere <2 days.

3.8 Ecotoxicology (Part B, Section 9)

It should be noted the the risk assessment for main crop such as oilseed rape (spring and winter) and sunflower covers the risk assessment for minor crops relevant for Poland and including in the GAP Table such as: gold of pleasure, winter turnip rape, mustard, poppy, linseed, flax ,hemp, borage. For more details please see in the Core Assessment.

3.8.1 Effects on terrestrial vertebrates

Birds

Acute and long-term/reproductive TER values for the two active substances and the relevant metabolite Prothioconazole-desthio (M04) as well as combi-TER calculations exceed the relevant trigger values at the screening step and/or Tier 1 following the intended use in oilseed rape at 2×0.7 kg product/ha covering all intended uses; 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 FGE03.

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. However, the log P_{ow} of Prothioconazole and metabolites M01 and M04 exceed the trigger value of 3. The risk assessment indicates no risk due to secondary poisoning for all intended uses.

Terrestrial vertebrates other than birds

Acute and long-term/reproductive TER values for the two active substances and the relevant metabolite Prothioconazole-desthio (M04) as well as combi-TER calculations considering Prothioconazole TER values exceed the relevant trigger values at the screening step and/or Tier 1 following the intended use in oilseed rape at 2×0.7 kg product/ha covering all intended uses.

However, when the long-term/reproductive TER values for the metabolite Prothioconazole-desthio are used for combi-TER calculations, combi-TER_{it} for the generic focal species vole at BBCH ≥ 40 is slightly below the relevant trigger value. It should be noted that the assumption of full conversion of the parent to the metabolite is worst case. Nevertheless, in a conservative approach, a higher-Tier risk assessment based on a refined deposition factor is presented.

Higher Tier TER value for vole exceeds the relevant trigger value of 5. Therefore, further assessment is not required.

No risk is indicated for the intended single application already at Tier 1.

The risk for mammals due to uptake of contaminated drinking water from puddles is acceptable for all intended uses of FGE03.

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. However, the log Pow of Prothioconazole and metabolites M01 and M04 exceed the trigger value of 3. The risk assessment indicates no risk due to secondary poisoning for all intended uses.

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 and Prothioconazole 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 and sunflower, calculated PEC/RAC ratios at Tier 1 for the individual active substances Boscalid and Prothioconazole as well as the relevant metabolites Prothioconazole-S-methyl (M01) and 1,2,4-Triazole (M13) indicate acceptable risk for all groups of aquatic organisms up to FOCUS Step 3.

However, for the relevant metabolite Prothioconazole-desthio (M04), calculated PEC/RAC ratios at Tier 1 based on the RAC of 0.334 µg/L for the most sensitive organism group fish prolonged exceed the trigger of 1 for the following scenarios indicating that risk cannot be excluded.

- R1 (stream) scenario – two applications in winter oilseed rape
- R1 (stream) scenario – two applications in spring oilseed rape
- R1 (stream) scenario – two applications in sunflower

Therefore, STEP 4 calculations have been provided and acceptable risk for these scenarios can be concluded when 10-meter vegetated buffer zone to surface water bodies is applied.

Mixture toxicity assessment for scenarios relevant for Poland

For the assessment of the combined toxicity of Boscalid, Prothioconazole and metabolites, the step-wise approach according to the aquatic guidance document as well as the decision tree for metabolites according to document FAQ Aquatic MixTox Tool_v2 is considered. The assessment is performed separately for each organism group.

In summary, mixture toxicity assessment should be based on the combined toxicity of the two parents as well as on the combined toxicity of Boscalid and metabolite Prothioconazole-desthio (M04). Combined toxicity from Boscalid and Prothioconazole is relevant for all organism groups (for fish long-term and invertebrates long-term only for certain scenarios). Combined toxicity from Boscalid and metabolite M04 is relevant fish long-term and invertebrates long-term (remaining scenarios).

Regarding the combined toxicity of the two parents, a simplified approach according to the aquatic guidance document was chosen for all organism groups and scenarios where the decision tree indicates that the mixture tox assessment should be based on the two actives, since no synergistic effects are indicated and all ETR values of the individual active substances contained in the formulation are below the relevant trigger value (corresponding to a PEC/RAC ratio < 1) up to FOCUS Step 3 calculations. The simplified approach indicates no risk from the combined toxicity of Boscalid and Prothioconazole.

Regarding the combined toxicity of Boscalid and metabolite Prothioconazole-desthio (M04), a mixture toxicity risk assessment for the intended uses of FGE03 in oilseed rape according to step 8 of the AGD based on ETR_{mix-CA} calculations for Boscalid and metabolite Prothioconazole-desthio (M04) was presented. The assessment was performed for fish chronic only. This is deemed appropriate since PEC/RAC ratios for both Boscalid and metabolite M04 are clearly worst case for this organism group covering all other organism groups.

Risk from combined exposure to Boscalid and metabolite Prothioconazole-desthio (M04) for the most sensitive organism group fish prolonged and relevant scenarios for Poland (D3, D4 and R1) is acceptable when the following risk mitigation measures for the relevant scenarios are considered:

- two applications of 0.7 kg FGE03/ha in winter oilseed rape – 10 m vegetated buffer (scenario R1 stream)
- two applications of 0.7 kg FGE03/ha in spring oilseed rape - 10 m vegetated buffer (scenario R1)
- two applications of 0.7 kg FGE03/ha in sunflower - 10 m vegetated buffer (scenario R1 stream,)
- No risk mitigation measures are required for single application in winter/spring oilseed rape and sunflower.

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.

The chronic larval Tier-1 ETR values for honeybees are also below the relevant trigger value for the use in oilseed rape for most scenarios. However, for “treated crop” scenario (BBCH 61-69), chronic larval Tier-1 ETR exceeds the trigger when the very conservative lower limit of the ED₁₀ is used for risk assessment. It should be noted that risk is acceptable already at the screening step if the 3-fold higher median ED₁₀ or NOED, respectively, from the larval study are used.

In the same time, it should be noted that for Poland the chronic risk assessment for bees according EFSA GD 2013 is not required yet.

There is currently no validated methodology for the assessment of toxicity to bumble bees (chronic) and solitary bees (both acute and chronic). Consequently, such studies are not considered necessary for the time being. Further risk assessment is not considered necessary here.

3.8.4 Effects on other arthropod species other than bees

For all intended uses, Tier-1 in-field HQ values are below the relevant trigger value for the indicator species *Aphidius rhopalosiphi*. For *Typhlodromus pyri*, Tier-1 in-field HQ values based on the ER₅₀ are below the relevant trigger value. However, extended lab studies with *Typhlodromus pyri* and *Poecilus cupreus* indicate no in-field risk; thus, additional testing and/or risk mitigation measures are not required to exclude risk to the in-field.

For all intended uses, Tier-1 and higher-Tier 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 to protect non-target arthropods in the off-field.

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 except for the Boscalid endpoint from the Annex-I inclusion for the intended multiple application when the additional approach for PEC calculation is considered (no risk for single application and/or considering FOCUS approach). However, endpoints from Annex I inclusion for the two actives and corresponding risk assessments are only presented for sake of completeness since studies were performed on the respective representative formulations and are not considered relevant for the assessment of FGE03. The risk assessment with the FGE03 study endpoint supersedes the assessment for the Boscalid endpoint. Risk is also acceptable when the two additional Boscalid endpoints (a.s. endpoint from the RAR and endpoint from study with FGG01, respectively) are used. These endpoints are potentially more appropriate for the risk assessment for earthworms from exposure to FGE03 according to the intended GAP. Therefore, higher-Tier risk assessment is not required.

Effects on soil microbial activity

The maximum concentrations with effects on micro-organisms $\leq 25\%$ exceed the respective maximum PEC_{soil} values 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.

3.9 Relevance of metabolites (Part B, Section 10)

No assessment of the relevance of metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is required.

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

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

Analytical methods:

Noticed data gaps are:

- The lack of an analytical method for monitoring purposes for determination of boscalid in hops, spices and herbal infusions has been identified during review of the Maximum Residue Levels (EFSA Journal 2014;12(7):3799)

~~— This is post-registration requirement.~~

This data gap should be addressed during the renewal of boscalid.

Metabolism and Residues:

Noticed data gaps are: **none.**

~~Storage stability study for oilseeds for 1,2,4-T and TA~~

~~This data gap should be filled in as post-registration requirement.~~

Additional remark: The use on sunflower (0401050) is accepted before forming of the edible part, before BBCH 65 (BBCH 61-65).

Appendix 1 Copy of the product authorization

Appendix 2 Copy of the product label

Komentarz oceniających:

Etykieta została sprawdzona w zakresie fizykochemii, metod analitycznych, pozostałości, toksykologii i istotności toksykologicznej metabolitów, losu i zachowania, ekotoksykologii oraz skuteczności. Zmiany wynikające z oceny wprowadzono do poniższej etykiety w widoczny sposób, poprzez zaznaczenie ich szarym kolorem, fragmenty usunięte zostały przekreślone i zaznaczone szarą czcionką.

Sekcja właściwości fizykochemiczne:

1. Środek nie wykazuje właściwości wybuchowych i utleniających, znakowanie środka wynikające z wyżej wymienionych właściwości fizykochemicznych zgodne z zapisami Rozporządzenia Parlamentu Europejskiego i Rady (WE) NR 1272/2008 z dnia 16 grudnia 2008 r. nie jest wymagane.
2. Okres ważności: 3-letnie badania stabilności są rozpoczęte. Dostępne są wyniki badania przyspieszonego starzenia (14 dni w temperaturze 54°C) jak również wyniki po pierwszym roku przechowywania w temperaturze pokojowej środka ochrony roślin przechowywanego w aluminiowych torebkach. Na podstawie dostępnych danych można uznać warunkowo 2-letni okres przechowywania.
Na podstawie zapisów wytycznej Ministerstwa Rolnictwa i Rozwoju Wsi w sprawie zasad zatwierdzania opakowań środków ochrony roślin z dnia 05/09/2023 dla środków ochrony roślin w postaci stałej (formulacja WG) możliwa jest ekstrapolacja pomiędzy każdym typem opakowań. W związku z powyższym wszystkie opakowania wymienione w punkcie 4.3 Sekcji 1,2,4 oraz w punkcie 2.1 dokumentu A można uznać za odpowiednie do celów transportu i magazynowania środka ochrony roślin.
3. Brak uwag do zaproponowanych w etykiecie zapisów dotyczących warunków przechowywania i bezpiecznego usuwania środka ochrony roślin.
4. Brak uwag do nazw grup chemicznych, do których przyporządkowano substancje czynne.
5. Zgodnie z informacjami zawartymi w tabeli 2-1, w punkcie 2.9.1 i 2.9.2 Sekcji 1 Raportu Rejestracyjnego środek nie jest dedykowany do łącznego stosowania.

Sekcja skuteczność:

1. W części STOSOWANIE ŚRODKA: na podstawie ważnych badań skuteczności, zawężono zakres BBCH.
2. W części ŚRODKI OSTROŻNOŚCI ORAZ SZCZEGÓLNE WARUNKI STOSOWANIA: uzupełniono zalecenia dla strategii zarządzania odpornością.
3. W części: POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY: doprecyzowano zapis dotyczący mycia aparatury.

Sekcja metody analityczne:

1. Brak uwag.

Sekcja toksykologia i istotność toksykologiczna metabolitów:

1. ~~W projekcie etykiety, części dotyczącej klasyfikacji (CLP) zagrożeń wprowadzono odpowiednie klasy zagrożeń razem z odpowiednimi zwrotami H3**, oraz odpowiadające im zwroty wskazujące środki ostrożności – zapobieganie i reagowanie, zgodnie z zaproponowaną przez zRMS klasyfikacją środka Patton Boost, patrz dRR B6 tabela 6.1 2, 6.3 1 oraz Part C pkt 1.3.2 tabela 1.3 1.~~
2. W części dotyczącej środków ostrożności dla osób stosujących środek, pracowników oraz osób postronnych odpowiedni zapis został dostosowany do wymogów klasyfikacji zagrożeń CLP (ustalenia harmonizacyjne Min Rol. Toksykologia aktualizacja 11/12/2024). **Dodatkowo wprowadzono wymogi dotyczące stosowania strefy ochronnej od zabudowań mieszkalnych/siedlisk oraz osób postronnych oraz stosowania techniki zmniejszające znoszenie preparatu (ustalenia harmonizacyjne Min Rol. Toksykologia aktualizacja 29/12/2025).**
3. **W części klasyfikacji zagrożeń CLP odpowiednie zwroty i znaki zostały zmienione i dostosowane do zaakceptowanej klasyfikacji CLP po drugim etapie komentowania raportu rejestracyjnego wnioskowanego środka ochrony roślin.**

Sekcja pozostałości:

1. ~~W przypadku rzepaku i oleistych upraw małoobszarowych dla metabolitów triazolowych 1,2,4-T oraz TA brakuje badań stabilności próbek. Zgodnie z ustaleniami harmonizacyjnymi z dnia 14 maja 2025 możliwe jest dopuszczenie warunkowe zezwolenia, pod warunkiem uzupełnienia danych przez Wnioskodawcę.~~
2. Brak zgody dla zastosowania środka w ochronie lnicznika siewnego (lnianki siewnej), konopi siewnych oraz ogórecznika lekarskiego ze względu na możliwość przekroczeń wartości NDP dla prothioconazolu (Reg. (EU) 2024/1318) po zastosowaniu środka. Zastosowania te zostały wykreślone z etykiety.

3. Zastosowanie środka w ochronie słonecznika możliwe jest tylko przed wytworzeniem części jadalnych, tzn. w fazie BBCH 61-65. Należy to uwzględnić w etykiecie.
4. W zakresie zapisów dotyczących roślin następczych nie ma potrzeby wpisywania restrykcji. Opcjonalnie można do etykiety dodać następujący zapis:
„Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie: nie ma ograniczeń co do okresu od ostatniego zastosowania środka do dnia, w którym można siać lub sadzić rośliny uprawiane następnie.”

Sekcja los i zachowanie w środowisku:

1. Brak uwag.

Sekcja ekotoksykologia:

1. Dodano zwrot P391.
2. Dodano zwrot P501.
3. Zmieniono zarządzanie ryzykiem dla organizmów wodnych. Wprowadzono 10 metrową zadarnioną strefę ochronną od zbiorników i cieków wodnych.

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:

.....

Patton Boost

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Substancje czynne:

boskalid (związek z grupy anilidów) - 350 g/kg (35,0%)

protiokonazol (związek z grupy triazoli) – 200 g/kg (20,0 %)

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

	
Uwaga Niebezpieczeństwo Uwaga	
H315 H318 H410	Działa drażniąco na skórę Powoduje poważne uszkodzenie oczu Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.

P280	Stosować rękawice ochronne/ochronę oczu/ochronę twarzy
P264	Dokładnie umyć (ręce) po użyciu.
P305+ P351+ P338	W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
P310	Natychmiast skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem/...
P302 + P352	W PRZYPADKU KONTAKTU ZE SKÓRĄ: umyć dużą ilością wody/...
P332 + P313	W przypadku wystąpienia podrażnienia skóry: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P391	Zebrać rozsypany produkt.
P501	Zawartość/pojemnik usuwać do odpowiedniego miejsca utylizacji zgodnie z lokalnymi i krajowymi przepisami

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, a substancja czynna protiokonazol zaliczana jest do grupy 3.

STOSOWANIE ŚRODKA

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

Rzepak ozimy

Zgnilizna twardzikowa

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,7 kg/ha.

Termin stosowania środka:

Środek stosować od początku do końca fazy początku kwitnienia gdy otwartych jest 10% kwiatów na głównym kwiatostanie, do fazy gdy 30% łuszczyń osiągnęło typową wielkość (BBCH 61-69 73).

Liczba zabiegów: 2.

Odstęp między zabiegami: co najmniej 14 dni.

Zalecana ilość wody: 100 - 400 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

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, rzepak ozimy, ~~lnianka siewna~~ *Zgnilizna twardzikowa*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,7 kg/ha.

Termin stosowania środka:

Środek stosować od fazy początku kwitnienia gdy otwartych jest 10% kwiatów na głównym kwiatostanie, do fazy gdy 30% łuszczyń osiągnęło typową wielkość (BBCH 61-73).

Liczba zabiegów: 2.

Odstęp między zabiegami: co najmniej 14 dni.

Zalecana ilość wody: 100 - 400 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

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,7 kg/ha.

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

Liczba zabiegów: 2.

Odstęp między zabiegami: co najmniej 14 dni.

Zalecana ilość wody: 100 - 400 l/ha.

Zalecane opryskiwanie: drobnokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2

ŚRODKI OSTROŻNOŚCI I SZCZEGÓLNE WARUNKI STOSOWANIA

Środek zawiera substancję czynną boskalid z grupy anilidów (karboksamidów) (fungicydy inhibitory dehydrogenazy bursztynianowej - SDHI - grupa FRAC 7) i substancję czynną protiokonazol – związek triazolowy, z grupy inhibitorów biosyntezy steroli – inhibitorów demetylacji (SBI-DMI) (grupa FRAC 3).

W ramach strategii zarządzania odpornością zaleca się:

- stosować środek wyłącznie w pełnej zalecanej dawce, ~~zalecanych dawkach,~~
- nie przekraczać maksymalnej zalecanej w sezonie wegetacyjnym liczby zabiegów,
- stosować środek głównie zapobiegawczo lub w początkowym okresie infekcji,
- ~~stosować środek przemiennie ze środkami grzybobójczymi zawierającymi substancje czynne z innych grup chemicznych, o odmiennym mechanizmie działania.~~
- włączenie do przyjętego programu ochrony środków grzybobójczych, zawierających substancje czynne z innych grup wg klasyfikacji FRAC, o odmiennych mechanizmach działania (stosowanie środków przemiennie lub w mieszaninie zbiornikowej),
- włączenie do przyjętego programu ochrony przed chorobami innych niż chemiczne metod zwalczania, zgodnych z zasadami integrowanej ochrony np. uprawa odmian odpornych, dbanie o higienę roślin, właściwe zmianowanie.

Podczas stosowania środka nie dopuścić do:

- znoszenia cieczy użytkowej na sąsiednie rośliny uprawne.
- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

OKRESY KARENCJI

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

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

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 mieszałem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po dodaniu 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

Po pracy aparaturę dokładnie wymyć, postępując zgodnie z zasadami dobrej praktyki ochrony roślin.

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.~~

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 (kombinezon) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.~~

~~Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież roboczą (kombinezon), w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu~~

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

Strefy ochronne:

W czasie oprysku należy zastosować co najmniej 10 m strefę ochronną od zabudowań mieszkalnych/siedlisk oraz osób postronnych.

W czasie oprysku należy zastosować techniki zmniejszające znoszenie preparatu (dysze antyznoszeniowe 50%).

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.

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 10 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



To Whom It May Concern

SUPPLY CERTIFICATE - BOSCALID TECHNICAL

In support of Boscalid / Prothioconazole 350 / 200 g/kg WG – FGE03

Dear Sir/Madam,

We, the undersigned, **Hebei Lansheng Biotech Co., Ltd.** a company having its principal offices registered at Mayu Village, Jinzhou City, Shijiazhuang City, Hebei Province, P.R. China (The manufacturing site address is Mayu Village, Jinzhou City, Shijiazhuang City, Hebei Province, P.R. China), wishes to inform the competent registration authorities in your country that it has granted **UPL Holdings Coöperatief U.A.**, located at Claudius Prinsenlaan 144 A, Blok A, 4818CP Breda, The Netherlands, access to all data and the report on equivalence assessment with regard to the active substance Boscalid with Minimum purity 980 g/kg, owned by **Hebei Lansheng Biotech Co., Ltd.** Data for equivalence assessment was submitted to ANSES in France, under Dossier N° 2020-3813 and the report on equivalence assessment was uploaded on CIRCABC website.

UPL Holdings Coöperatief U.A. of Claudius Prinsenlaan 144 A, Blok A, 4818CP Breda, The Netherlands, is hereby authorized to refer to the said data and report in the registration process of its own product based on **Boscalid / Prothioconazole 350 / 200 g/kg WG (FGE03)**, containing Boscalid which will be supplied by **Hebei Lansheng Biotech Co., Ltd.** as manufacturer of Boscalid technical.

For and on behalf of **Hebei Lansheng Biotech Co., Ltd.**

Name: Wang Ciming
Title: registration Manager
Date: Jun.06, 2024
(Stamp)





Operating as Arysta LifeScience Benelux SPRL
26/1 rue de Renory
4102 Ougrée
Belgium

w: upl-ltd.com
e: frontdeskougree@upl-ltd.com
t: +32 4 385 97 11

Ougrée, 5 November 2024

TO WHOM IT MAY CONCERN

**Letter of Supply / Letter of Access for Arysta LifeScience Benelux SPRL equivalence
to support the registration of UPL product code FGE03**

Dear Sir/Madam,

We, **Arysta LifeScience Benelux SPRL**, with address at 26/1 Rue de Renory, 4102 Ougrée, Belgium, authorize **UPL Europe Ltd.** with address at the Engine Rooms, Birchwood Park, Warrington, Cheshire, WA3 6YN, UK, to include **Arysta LifeScience Benelux SPRL** as an approved source of **Prothioconazole Technical**, in applications for registration of the UPL product **FGE03** by **UPL Europe Ltd.** and affiliates (including **UPL Holdings Coöperatief U.A.** with address Claudius Prinsenlaan 144A, Block A, 4818 CP Breda, the Netherlands).

Product Code	Formulation Type	Content of active substances
FGE03	WG	350 g/kg Boscalid; 200 g/kg Prothioconazole

Therefore, on behalf of **Arysta LifeScience Benelux SPRL**, we hereby authorize the relevant authorities to access all relevant confidential data on the following active substance:

Common name (ISO): **Prothioconazole**
Chemical name (IUPAC): **(RS)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3-thione**
Chemical name (CA): **2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione**
CIPAC No: **745**
CAS No: **178928-70-6**
Minimum purity: **980 g/kg**

Manufacturing site/plant: Anhui Jiuyi Agriculture Co., Ltd., Hefei Circulate Economy Zone, Hefei City, Anhui Province, P.R. China

In addition, **Arysta LifeScience Benelux SPRL** will be supplying to UPL Europe Ltd. and its affiliates the technical material Prothioconazole for use in their prothioconazole-based products.

Registered Office: 26/1 rue de Renory 4102 Ougrée, Belgium. T +32 4 385 97 11
BCE 0877 444 281



For and on behalf of **Arysta LifeScience Benelux SPRL**

Yours Sincerely,

A handwritten signature in blue ink, consisting of a large, stylized 'B' followed by a horizontal line and a small loop at the end.

Bart Vanhoof
Regional Regulatory Lead – Fungicides

DocuSign Envelope ID: 83BABB4C-4250-4059-9E6D-CC87EB937F8F

TDMG

Triazole Derivative Metabolite Group

Fourth Amendment to the Access Agreement

This Fourth Amendment to the Access Agreement is made by and between the following parties:

BAYER AG – Crop Science Division, a corporation organized and existing under the laws of Germany and having its office at Alfred-Nobel-Strasse 50, 40789 Monheim, Germany (hereinafter referred to as “BAYER”);

BASF SE, a German corporation with its principal offices at Carl-Bosch-Strasse 38, D-67056 Ludwigshafen, Germany (hereinafter referred to as “BASF”);

Corteva Agriscience LLC, a limited liability company with its principal offices at Indianapolis, IN, the United States of America (hereinafter referred to as “Corteva”), successor to Dow AgroSciences, LLC, a limited liability company;

Gowan Crop Protection Limited, an English corporation with its principal offices at Highlands House, Basingstoke Road, Spencers Wood, Reading, Berkshire, England RG7 1NT (hereinafter referred to as “GCP”), successor to Isagro S.p.A., an Italian corporation;

Syngenta Crop Protection AG, a Swiss corporation with its principal offices at CH-4002 Basel, Switzerland (hereinafter referred to as “Syngenta”); and

UPL Europe Limited, an English corporation with its principal offices at The Engine Rooms, 1st Floor, Birchwood Park, Warrington, Cheshire WA3 6YN, UK (hereinafter referred to as “Licensee”), successor to Arysta LifeScience Corporation, a Japanese corporation.

WITNESSETH THAT:

Whereas BAYER, BASF, Corteva, GCP and Syngenta, the sole members of the Triazole Derivative Metabolite Group (collectively the “TDMG” or the “Licensor”), entered into that certain Access Agreement (the “Access Agreement”) effective as of August 2006 with Arysta LifeScience Corporation, subsequently amended by the First Amendment to the Access Agreement as of February 2015 (also with Arysta LifeScience Corporation); the Second Amendment as of January, 2023 (with UPL Europe Limited) and the Third Amendment as of May 2023 (with UPL Europe Limited);

Whereas the Licensee has notified the TDMG that Licensee wants to access four additional studies; and

Whereas the TDMG and the Licensee are willing to further amend the Access Agreement to reflect the foregoing.

DocuSign Envelope ID: 83BABB4C-4250-4059-9E6D-CC87EB937F8F

Now therefore, for good and valuable consideration, the sufficiency and receipt of which is expressly recognized, it is mutually agreed that the Access Agreement as amended shall be further amended as follows:

(Studies)

1. Appendix A to the Access Agreement is amended by adding thereto the following four (4) studies:

Ref. No.	Author(s), Title; Report Number; Performing Company and Report Date
A123	Jooß S. and Tussetschläger S.; Method Development and Validation of BASF analytical method L0263/02 for the determination of 1,2,4 T, TA, TAA and TLA in animal matrices. BASF Study ID 869352. EAG Laboratories GmbH Eiselaue Weg 4, Geb./Bldg. 5 89081 Ulm, Germany. Report No. 8693523, Document No. VV-903139, issued June 18, 2020
B51	Jooß S. and Tussetschläger S.; Storage Stability of Triazole Alanine (TA), Triazole Acetic Acid (TAA) and Triazole Lactic Acid (TLA) in Animal Matrices under Deep Frozen Conditions. EAG Laboratories GmbH Eiselaue Weg 4, Geb./Bldg. 5 89081 Ulm, Germany. BASF Study ID: 869333. EAG Lab ID: P 5069 G., issued October 27, 2020
D07	Carle, F. and Andre, M. Determination of the Triazole Derived Metabolites in Eggs and Tissues of Laying Hens following Multiple Oral Administration of Triazole Lactic Acid, Report No. IF19-05004879, SGS Institute Fresenius GmbH, Germany. Syngenta Doc. No. VV-902666 issued February 22, 2021
D08	Andre, M. Determination of the Triazole Derived Metabolites in Milk and Tissues of Dairy Cows following Multiple Oral Administration of Triazole Lactic Acid. SGS Institut Fresenius GmbH Report No. IF19-05004884. Syngenta Doc. No. VV-902663, issued February 25, 2021

(Consideration)

2. The total amount of 127,266.65€ is due from Licensee to the Licensor in consideration for access to the above-listed studies, payable as follows:

Each of the five members of the Licensor shall invoice the Licensee 25,453.33€ (for a total of 127,266.65€) and the Licensee shall pay each such invoice within sixty (60) days of Licensee receiving the invoice from the respective member of the Licensor. Licensee shall pay each of the five invoices by electronic transfer in accordance with the instructions specified in each invoice.

(Other Provisions)

3. All other provisions of the Access Agreement as amended are re-affirmed and remain unchanged.

(Effective Date)

4. This Fourth Amendment to the Access Agreement shall become effective as of the date of the signature of the party last to sign this Amendment. This Amendment may be executed in one or more counterparts, each of which shall be deemed an original, but all of which

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taken together shall constitute one and the same instrument. Confirmation of execution by electronic transmission of a facsimile signature page shall be binding on a party so confirming.

IN WITNESS WHEREOF, the Parties have caused their duly authorized representatives to execute this Fourth Amendment to the Access Agreement on the dates written below.

Licensor:

Licensor:

BASF SE:

BASF SE:

By:  DocuSigned by:
AT61823897A0426...
Name: Jan Rether
Title: Head of Global Registration Crop Protection
Date: 21-Feb-2024

By:  DocuSigned by:
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Name: Matt Sauer
Title: Global Regulatory Manager Fungicides
Date: 21-Feb-2024

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Licensor:

Syngenta Crop Protection AG:

Syngenta Crop Protection AG

By:  DocuSigned by:
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Name: Eric Lawton
Title: Global Regulatory Manager
Date: 13 March 2024

By:  DocuSigned by:
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Name: Sonia Goetz
Title: Global Regulatory Lead Fungicides
Date: 12 March 2024

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Licensor:

Gowan Crop Protection Limited

By: DocuSigned by:
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Name: Tammy Dominowski

Title: Strategic Outsourcing Leader

Date: 12-March 2024

By: DocuSigned by:
Mario Visentin
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Name: Mario Visentin

Title: Regulatory Product Scientist

Date: 15 March 2024

Licensor:

Bayer AG – Crop Science Division:

Licensor:

Bayer AG – Crop Science Division:

By: DocuSigned by:
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Name: Angela Hendrickson Culler

Title: Head of Regulatory Affairs Crop
Protection

Date: 21Feb2024

By: DocuSigned by:
Karsten Stroeck
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Name: Karsten Stroeck

Title: Global Regulatory Manager

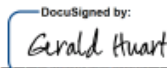
Date: 19-Feb-2024

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Licensee:

UPL Europe Limited

By:  795A891B0395466...

Name: Gerald Huart

Title: EU Regulatory Affairs Head

Date: 12/03/2024

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Signature: Email: tammy.dominowski@corteva.com

Signature: Email: gerald.huart@upl-ltd.com

Appendix 4 Lists of data considered for national authorization

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 technical Safety Data Sheet Version: 2.2 GLP: no Published	N	Y	Study report never submitted before to PL	UPL Europe
KCP 1.4.2/02	Anonymous	2024	Prothioconazole technical Safety Data Sheet Version: 1.3 GLP: no Published	N	Y	Study report never submitted before to PL	UPL Europe
KCP 2.1	Desai, H.	2023a	Appearance (colour, physical state and odour) of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 201-2-11-33001) UPL EUROPE LTD (UPL/2022/21111) GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 2.2.1	Desai, H.	2023b	Explodability of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 238-2-11-33006) UPL EUROPE LTD (UPL/2023/0027) GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 2.2.2	Desai, H.	2023c	Oxidising properties of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 230-2-11-33005) UPL EUROPE LTD (UPL/2022/21116) GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 2.3.2	Desai, H.	2023d	Flammability of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 213-2-11-33003) UPL EUROPE LTD (UPL/2022/21113) GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 2.3.3	Desai, H.	2023e	Relative self-ignition temperature of Boscalid 350 g/kg + prothioconazole 200 g/Kg WG Shelf heating of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 229-2-11-33004)	N	Y	Study report never submitted before to PL	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 EUROPE LTD (UPL/2023/0051) GLP Unpublished				
KCP 2.4.2	Desai, H.	2023f	pH of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 210-2-11-33002) UPL EUROPE LTD (UPL/2022/21112) GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 2.6.2	Desai, H.	2023g	Bulk density of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 264-2-11-33015) UPL EUROPE LTD (UPL/2023/0054) GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 2.7.1/01	Desai, H.	2023h	Accelerated storage stability and corrosion characteristics of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 234-2-11-33019) UPL EUROPE LTD (UPL/2023/0417) GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 2.7.1/02	Desai, H.	2024a	Accelerated storage stability of boscalid 350 g/kg + prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 234-2-11-37859) UPL EUROPE LTD (UPL/2024/1237) GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 2.7.5	Desai, H.	2024b	Three years storage stability and corrosion characteristics study of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG Interim Report-I JAI RESEARCH FOUNDATION (JRF Study Number: 237-2-11-33020) UPL EUROPE LTD (UPL/2023/1452) GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 2.8.1	Desai, H.	2023i	Wettability of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 246-2-11-33010) UPL EUROPE LTD (UPL/2023/0052) GLP Unpublished	N	Y	Study report never submitted before to PL	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
KCP 2.8.2	Desai, H.	2023j	Persistent foaming of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 248-2-11-33011) UPL EUROPE LTD (UPL/2023/0256) GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 2.8.3.1	Desai, H.	2023k	Suspensibility of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 251-2-11-33013) UPL EUROPE LTD (UPL/2023/0392) GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 2.8.3.2	Desai, H.	2023l	Dispersibility of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 247-2-11-33017) UPL EUROPE LTD (UPL/2023/0253) GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 2.8.5.1.1	Desai, H.	2023m	Particle size distribution of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 250-2-11-33018) UPL EUROPE LTD (UPL/2023/0254) GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 2.8.5.1.2	Desai, H.	2023n	Wet sieve test of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 245-2-11-33009) UPL EUROPE LTD (UPL/2022/21114) GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 2.8.5.1.3	Desai, H.	2024b	Three years storage stability and corrosion characteristics study of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG Interim Report-I JAI RESEARCH FOUNDATION (JRF Study Number: 237-2-11-33020) UPL EUROPE LTD (UPL/2023/1452) GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 2.8.5.2.1	Desai, H.	2023o	Dust content of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 243-2-11-33007) UPL EUROPE LTD (UPL/2023/0250) GLP	N	Y	Study report never submitted before to PL	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 2.8.5.3	Desai, H.	2023p	Attrition resistance of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 249-2-11-33012) UPL EUROPE LTD (UPL/2023/0053) GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 2.8.7.1	Desai, H.	2023q	Flowability of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 244-2-11-33008) UPL EUROPE LTD (UPL/2023/0391) GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 4.2/01	Prajapati, P.N.	2024	Effectiveness of Cleaning Procedures of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG JAI RESEARCH FOUNDATION (JRF Study Number: 284-2-11-36678) UPL EUROPE LTD (UPL/2024/0501) GLP: no Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 4.3/01 KCP 4.5/01	Anonymous	2024	Boscalid/Prothioconazole(350+200) WDG Safety Data Sheet Version: 2.0 GLP: no Published	N	Y	Study report never submitted before to PL	UPL Europe
Section B3, efficacy							
3.2.1 3.2.2 3.2.3 3.4.1	O. GOEBEL	2024	The efficacy of FGE03 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2024. GEP Trial, AUSTRIA, 2024 Report No. F24EU-010-MOA-004 Staphyt GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
~~3.2.1~~ ~~3.2.2~~ ~~3.2.3~~ ~~3.4.1~~	~~O. GOEBEL~~	~~2024~~	~~The efficacy of FGE03 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2024. GEP Trial, BELGIUM, 2024 Report No. F24EU-010-MOA-005 Staphyt GEP Unpublished~~	~~N~~	~~Y~~	~~Study report never submitted before to PL~~	~~UPL Europe~~
~~3.2.1~~ ~~3.2.2~~ ~~3.2.3~~	~~O. GOEBEL~~	~~2024~~	~~The efficacy of FGE03 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2024. GEP Trial, BELGIUM, 2024 Report No. F24EU-010-MOA-006~~	~~N~~	~~Y~~	~~Study report never submitted before to PL~~	~~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
3.4.1			Staphyt GEP Unpublished				
3.2.3 3.4.1	A. SEDANO	2023	Efficacy of FGE03 and FGR06 applied in oilseed rape for the control of Sclerotinia sclerotiorum (SCLESC) in Europe GEP Trial, CZECH REPUBLIC, 2023 Report No. F23EU-033-AMA-001 Staphyt GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.3 3.4.1	S. GAYOT	2024	The efficacy of FGE03, FGR06 and FGR07 applied in OSR for the control of sclerotinia sclerotiorum (SCLESC) in Europe. Spring 2023 EPPO Maritime – Germany Report No. F23EU-032-AMA-005 Syntech Research Germany GmbH GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.3 3.4.1	S. GAYOT	2024	The efficacy of FGE03, FGR06 and FGR07 applied in OSR for the control of sclerotinia sclerotiorum (SCLESC) in Europe. Spring 2023 EPPO Maritime – Germany Report No. F23EU-032-AMA-006 SyntechResearch GmbH Germany GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.1 3.2.2 3.2.3 3.4.1	N. BIRKIN-SHAW	2024	The efficacy of FGE03 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2024 Report No. F24EU-010-MOA-007 Eurofins Agrosience Services GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.2 3.2.3 3.4.1	N. BIRKIN-SHAW	2024	The efficacy of FGE03 applied for the control of sclerotinia sclerotiorum on oil seed rape in northern Europe, 2024. Report No. F24EU-014-MOA-001 Eurofins Agrosience Services GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.2	N. BIRKIN-	2024	The efficacy of FGE03 applied for the control of sclerotinia sclerotiorum	N	Y	Study report	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
3.2.3 3.4.1	SHAW		on oil seed rape in northern Europe, 2024. Report No. F24EU-014-MOA-002 Eurofins Agrosience Services GEP Unpublished			never submitted before to PL	
3.2.3 3.4.1	R. VER- CRUYSSSE	2023	The efficacy of FGE03, FGR06 and FGR07 applied in OSR for the control of Sclerotinia sclerotiorum SCLESC in Europe Report No. F23EU-032-AMA-001 Ephydia GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.3 3.4.1	R. VER- CRUYSSSE	2023	The efficacy of FGE03, FGR06 and FGR07 applied in OSR for the control of Sclerotinia sclerotiorum (SCLESC) in Europe. Report No. F23EU-032-AMA-002 Ephydia GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.1 3.2.2 3.2.3 3.4.1	O. GOEBEL	2024	The efficacy of FGE03 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2024. GEP Trial, FRANCE, 2024 Report No. F24EU-010-MOA-002 Staphyt GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.1 3.2.2 3.2.3 3.4.1	G. WALLART	2024	The efficacy of FGE03 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2024 Report No. F24EU-010-MOA-003 Ephydia GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.1 3.2.2 3.2.3 3.4.1	N. BIRKIN- SHAW	2024	The efficacy of FGE03 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2024. Report No. F24EU-010-MOA-008 Eurofins Agrosience Services GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.3 3.4.1	M. SIEBOLD	2023	The efficacy of FGE03, FGR06 and FGR07 applied in OSR for the control of Sclerotinia sclerotiorum (SCLESC) in Europe	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	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report No. F23EU-032-AMA-004 Crop Research Limited/Field Research Support GEP Unpublished			before to PL	
~~3.2.2~~ ~~3.2.3~~ ~~3.4.1~~	~~E. LELEŠIUS & P. PERSSON~~	~~2024~~	~~The efficacy of FGE03 applied for the control of sclerotinia sclerotiorum on oil seed rape in northern Europe, 2024~~ Report No. F24EU-014-MOA-003 UAB Agrolab Baltic GEP Unpublished	~~N~~	~~Y~~	~~Study report never submitted before to PL~~	~~UPL Europe~~
3.2.1 3.2.2 3.2.3 3.4.1	E. LELEŠIUS & R. ŽITKUTE	2024	The efficacy of FGE03 applied for the control of sclerotinia sclerotiorum on oil seed rape in northern Europe, 2024 Report No. F24EU-014-MOA-004 UAB Agrolab Baltic GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.1 3.2.2 3.2.3 3.4.1	K. FURMAN	2024	The efficacy of FGE03 applied for the control of Sclerotinia sclerotiorum on oilseed rape in Europe, 2024 Report No. F24EU-011-MOA-001 AGRECO Sp. z o.o. GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.1 3.2.2 3.2.3 3.4.1	K. FURMAN	2024	The efficacy of FGE03 applied for the control of Sclerotinia sclerotiorum on oilseed rape in Europe, 2024 Report No. F24EU-011-MOA-002 AGRECO Sp. z o.o. GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.1 3.2.2 3.2.3 3.4.1	K. FURMAN	2024	The efficacy of FGE03 applied for the control of Sclerotinia sclerotiorum on oilseed rape in Europe, 2024 Report No. F24EU-011-MOA-003 AGRECO Sp. z o.o. GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.1 3.2.2 3.2.3	O. GOEBEL	2024	The efficacy of FGE03 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2024. GEP Trial, BULGARIA, 2024 Report No. F24EU-010-MOA-009	N	Y	Study report never submitted before to PL	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
3.4.1			Staphyt GEP Unpublished				
3.2.1 3.2.2 3.2.3 3.4.1	N. BIRKIN-SHAW	2024	The efficacy of FGE03 applied for the control of Sclerotinia sclerotiorum (SCLESC) on oilseed rape in Europe, 2024 Report No. F24EU-010-MOA-012 Eurofins Agrosience Services GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.1 3.2.3 3.4.1	N. BIRKIN-SHAW	2024	The efficacy of FGE03 applied for the control of Sclerotinia sclerotiorum (SCLESC) on oilseed rape in Europe, 2024 Report No. F24EU-012-MOA-002 Eurofins Agrosience Services GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.3 3.4.1	A. SEDANO	2023	Efficacy of FGE03 and FGR06 applied in oilseed rape for the control of Sclerotinia sclerotiorum (SCLESC) in Europe GEP Trial, HUNGARY, 2023 Report No. F23EU-033-AMA-006 Staphyt GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.3 3.4.1	A. SEDANO	2023	Efficacy of FGE03 and FGR06 applied in oilseed rape for the control of Sclerotinia sclerotiorum (SCLESC) in Europe GEP Trial, HUNGARY, 2023 Report No. F23EU-033-AMA-007 Staphyt GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.1 3.2.2 3.2.3 3.4.1	O. GOEBEL	2024	The efficacy of FGE03 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2024. GEP Trial, HUNGARY, 2024 Report No. F24EU-010-MOA-010 Staphyt GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.3 3.4.1	B. FERENCZ	2024	The efficacy of FGE03 and FGR06 applied in OSR for the control of Sclerotinia sclerotiorum (SCLESC) in Europe. EPPO South East	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
			ROMANIA Report No. F23EU-033-AMA-008 Syntech Research GEP Unpublished			before to PL	
3.2.3 3.4.1	A. SEDANO	2023	Efficacy of FGE03 and FGR06 applied in oilseed rape for the control of Sclerotinia sclerotiorum (SCLESC) in Europe GEP Trial, ROMANIA, 2023 Report No. F23EU-033-AMA-009 Staphyt GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.1 3.2.2 3.2.3 3.4.1	O. GOEBEL	2024	The efficacy of FGE03 applied for the control of sclerotinia sclerotiorum on oil seed rape in Europe, 2024. GEP Trial, ROMANIA, 2024 Report No. F24EU-010-MOA-011 Staphyt GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.1 3.2.2 3.2.3 3.4.1	N. BIRKIN-SHAW	2024	The efficacy of FGE03 applied for the control of Sclerotinia sclerotiorum (SCLESC) on oilseed rape in Europe, 2024 Report No. F24EU-010-MOA-013 Eurofins Agrosience Services GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.1 3.2.3 3.4.1	N. BIRKIN-SHAW	2024	The efficacy of FGE03 applied for the control of Sclerotinia sclerotiorum (SCLESC) on oilseed rape in Europe, 2024 Report No. F24EU-012-MOA-003 Eurofins Agrosience Services GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.2 3.2.3 3.4.1	J. PACK-WOOD	~~2022~~ 2023	The efficacy of FGE03 applied in OSR for the control of Sclerotinia sclerotiorum (SCLESC) in Europe. Report No. F22EU-023-AMA-007 EAS / Agricultural Research Institute Kromeriz, Ltd. GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.2	J. PACK-	2022	The efficacy of FGE03 applied in OSR for the control of Sclerotinia	N	Y	Study report	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
3.2.3 3.4.1	WOOD	~~2023~~	sclerotiorum (SCLESC) in Europe. Report No. F22EU-023-AMA-008 EAS / ZZS Kujavy, s.r.o. GEP Unpublished			never submitted before to PL	
~~3.2.2 3.2.3 3.4.1~~	~~J. PACK- WOOD~~	~~2022~~	~~The efficacy of FGE03 applied in OSR for the control of Sclerotinia sclerotiorum (SCLESC) in Europe. Report No. F22EU-023-AMA-005 EAS / VKST Field Trials GEP Unpublished~~	~~N~~	~~Y~~	~~Study report never submitted before to PL~~	~~UPL Europe~~
~~3.2.2 3.2.3 3.4.1~~	~~J. PACK- WOOD~~	~~2023~~	~~The efficacy of FGE03 applied in OSR for the control of Sclerotinia sclerotiorum (SCLESC) in Europe. Report No. F22EU-023-AMA-006 EAS / VKST Field Trials GEP Unpublished~~	~~N~~	~~Y~~	~~Study report never submitted before to PL~~	~~UPL Europe~~
~~3.2.2 3.2.3 3.4.1~~	~~J. PACK- WOOD~~	~~2023~~	~~The efficacy of FGE03 applied in OSR for the control of Sclerotinia sclerotiorum (SCLESC) in Europe Report No. F22EU-023-AMA-004 Eurofins Agroscience Services UK GEP Unpublished~~	~~N~~	~~Y~~	~~Study report never submitted before to PL~~	~~UPL Europe~~
~~3.2.2 3.2.3 3.4.1~~	~~J. PACK- WOOD~~	~~2024~~	~~The efficacy of FGE03, FGR06 and FGR07 applied in OSR for the control of Sclerotinia sclerotiorum (SCLESC) in Europe Report No. F23EU-032-AMA-003 Eurofins Agroscience Services UK GEP Unpublished~~	~~N~~	~~Y~~	~~Study report never submitted before to PL~~	~~UPL Europe~~
3.2.2 3.2.3 3.4.1	J. PACK- WOOD	~~2022~~ ~~2023~~	The efficacy of FGE03 applied in OSR for the control of Sclerotinia sclerotiorum (SCLESC) in Europe. Report No. F22EU-023-AMA-009 EAS / Lithuania Institute of Agriculture GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.2 3.2.3	J. PACK- WOOD	~~2022~~ ~~2023~~	The efficacy of FGE03 applied in OSR for the control of Sclerotinia sclerotiorum (SCLESC) in Europe.	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	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
3.4.1			Report No. F22EU-023-AMA-010 EAS / Lithuania Institute of Agriculture GEP Unpublished			before to PL	
~~3.2.2~~ ~~3.2.3~~ 3.4.1	J. PACK- WOOD	~~2022~~ ~~2023~~	The efficacy of FGE03 applied in OSR for the control of Sclerotinia sclerotiorum (SCLESC) in Europe Report No. F22EU-023-AMA-011 Eurofins PL GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
~~3.2.2~~ ~~3.2.3~~ 3.4.1	J. PACK- WOOD	~~2022~~ ~~2023~~	The efficacy of FGE03 applied in OSR for the control of Sclerotinia sclerotiorum (SCLESC) in Europe. Report No. F22EU-023-AMA-012 Eurofins PL GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.2 3.2.3 3.4.1	K. FURMAN- FRĄTCZAK	~~2023~~ ~~2024~~	The efficacy of FGE03 and FGR06 applied for the control of Sclerotinia sclerotiorum on oilseed rape in Europe Report No. F23EU-033-AMA-002 Agreco sp. z o.o. GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.2 3.2.3 3.4.1	K. FURMAN- FRĄTCZAK	~~2023~~ ~~2024~~	The efficacy of FGE03 and FGR06 applied for the control of Sclerotinia sclerotiorum on oilseed rape in Europe Report No. F23EU-033-AMA-003 Agreco sp. z o.o. GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.2 3.2.3 3.4.1	K. FURMAN- FRĄTCZAK	~~2023~~ ~~2024~~	The efficacy of FGE03 and FGR06 applied for the control of Sclerotinia sclerotiorum on oilseed rape in Europe Report No. F23EU-033-AMA-004 Agreco sp. z o.o. GEP Unpublished	N	Y	Study report never submitted before to PL	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
3.2.2 3.2.3 3.4.1	K. FURMAN-FRĄTCZAK	~~2023~~ 2024	The efficacy of FGE03 and FGR06 applied for the control of Sclerotinia sclerotiorum on oilseed rape in Europe Report No. F23EU-033-AMA-005 Agreco sp. z o.o. GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.2 3.2.3 3.4.1	J. PACK-WOOD	2024	The efficacy of FGE03 and FGR06 applied in OSR for the control of Sclerotinia sclerotiorum (SCLESC) in Europe Report No. F23EU-033-AMA-010 EAS Bulgaria GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.2 3.2.3 3.4.1	J. PACK-WOOD	2024	The efficacy of FGE03 and FGR06 applied in OSR for the control of Sclerotinia sclerotiorum (SCLESC) in Europe Report No. F23EU-033-AMA-011 EAS Bulgaria GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.2 3.2.3 3.4.1	I. MAKÓ	2022	The efficacy of FGE03 applied in OSR for the control of sclerotinia sclerotiorum (sclesc) in europe Report No. F22EU-023-AMA-001 CPR Europe Kft. GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.2 3.2.3 3.4.1	S. NEMETH	2022	The efficacy of FGE03 applied in OSR for the control of Sclerotinia sclerotiorum (SCLESC) in Europe. Report No. F22EU-023-AMA-002 CPR Europe Kft. GEP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.2.2 3.2.3 3.4.1	Z. ENESSEY	2022	The efficacy of FGE03 applied in OSR for the control of Sclerotinia sclerotiorum (SCLESC) in Europe. Report No. F22EU-023-AMA-003 CPR Europe Kft. GEP Unpublished	N	Y	Study report never submitted before to PL	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
3.5.1	S. STURTZ & C HORST-MANN	2023	Boscalid + Prothioconazole (350 + 200 g/kg - WG): Effects on Terrestrial (Non-Target) Plants: Seedling Emergence and Seedling Growth Test Report No. UPL/2023/0742 (176531086) Ibacon GmbH GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
3.5.2	S. STURTZ & C HORST-MANN	2023	Boscalid + Prothioconazole (350 + 200 g/kg - WG): Effects on Terrestrial (Non-Target) Plants: Vegetative Vigour Test Report No. UPL/2023/0743 (176531087) Ibacon GmbH GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
Section B5, analytical methods							
KCP 5.1.1/01	Desai H.	2023	Validation of analytical method for determination of active ingredient content of boscalid 350 g/kg + prothioconazole 200 g/kg WG UPL/2023/0300 Jai Research Foundation 228-2-12-33016 GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 5.1.1/02	Desai H.	2024	Validation of Analytical Method for Determination of Associated Impurities of Boscalid 350 g/Kg + Prothioconazole 200 g/Kg WG UPL/2024/1238 Jai Research Foundation 228-2-12-37860 GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 5.1.2/01	Rastogi T.	2022a	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 PL	UPL Europe
KCP 5.1.2/02	Rastogi T.	2023a	Cross-Validation - Comparing Amounts of Boscalid extracted from Samples of Plant Origin with incurred Residues using three different	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	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Solvent Systems. UPL/2023/1062 Eurofins Agrosience Services, EAG Laboratories GmbH S22-00983 GLP Unpublished			before to PL	
KCP 5.1.2/03 KCP 5.2/0+5	Sahvorost N.	2022	Validation of the Analytical Method for the Determination of Residues of Boscalid in Honey, Report Amendment 1, UPL/2022/0354 Eurofins Agrosience Services EcoChem GmbH S22-00776 GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 5.1.2/04	Mahera N.	2023	Validation of Analytical Method for Determination of Active Ingredient Concentration and Stability of Boscalid and Prothioconazole in Matrix, following the Application of Boscalid 350 g/kg and Prothioconazole 200 g/kg WG UPL/2022/21191 Jai Research Foundation 228-2-13-33021 Used in studies: 502-3-07-33000 – Daphnia and 501-3-07-32999 - algae	N	Y	Study report never submitted before to PL	UPL Europe
KCP 5.1.2/05 (filled under KCP 10.3.1.3/01)	Venturi, S.	2024	Effects of Boscalid + Prothioconazole (350 + 200 g/kg – WG) on honeybees (Apis mellifera L.) 22-day larval toxicity test with repeated exposure UPL/2023/1235 BioTecnologie BT S.r.l. BT073_23 (Analytical phase, KCP 10.3.1.3/01)	N	Y	Study report never submitted before to PL	UPL Europe
KCP 5.1.2/06 (filled under KCP 10.3.1.2/01)	Knautz, T., Horstmann, C.	2023	Boscalid + Prothioconazole (350 + 200 g/kg – WG): Chronic Oral Toxicity Test on the Honey Bee (Apis mellifera L.) in the Laboratory UPL/2023/1209 ibacon GmbH 176531136 (Analytical phase, KCP 10.3.1.2/01)	N	Y	Study report never submitted before to PL	UPL Europe
KCP 5.1.2/07 (filled under KCP	Chwiesko, D., Horstmann, C.,	2023	Boscalid + Prothioconazole (350 + 200 g/kg – WG): Acute Contact and Oral Toxicity to Bumblebees (Bombus terrestris L.) in the Laboratory UPL/2023/1279	N	Y	Study report never submitted before to PL	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
10.3.1.1.1/02)			176531105 ibacon GmbH (Analytical phase, KCP 10.3.1.1.1/02)				
KCP 5.1.2/08 (filled under KCP 10.6.2/01)	Stürtz, S., Horstmann, C.,	2023a	Boscalid + Prothioconazole (350 + 200 g/kg - WG): Effects on Terrestrial (Non-Target) Plants: Vegetative Vigour Test, UPL/2023/0743 176531087 ibacon GmbH (Analytical phase, KCP 10.6.2/01)	N	Y	Study report never submitted before to PL	UPL Europe
KCP 5.1.2/09 (filled under KCP 10.6.2/02)	Stürtz, D., Horstmann, C.	2023b	Boscalid + Prothioconazole (350 + 200 g/kg - WG): Effects on Terrestrial (Non-Target) Plants: Seedling Emergence and Seedling Growth Test UPL/2023/0742 ibacon GmbH 176531086 (Analytical phase, KCP 10.6.2/02)	N	Y	Study report never submitted before to PL	UPL Europe
KCP 5.2/01	Rastogi T.	2022b	Development and Validation of Multi-Residue Method QuEChERS for Determination of Boscalid in Different Matrices of Plant Origin Study UPL/2022/0592 Eurofins Agrosience Services, EAG Laboratories GmbH S22-000980 GLP Unpublished	N			UPL
KCP 5.2/02	Gustloff C.	2022	Independent Laboratory Validation of Multi-Residue Method QuEChERS for Determination of Boscalid in Different Matrices of Plant Origin Study UPL/2022/0875 Eurofins Agrosience Services, EAG Laboratories GmbH S22-05632 GLP Unpublished	N			UPL
KCP 5.2/03	Rastogi T.	2023	Development and Validation of Analytical Methods for Determination of Boscalid and its Metabolite M510F01 and Bound Residues in Different Matrices of Animal Origin Study UPL/2022/2043 Eurofins Agrosience Services, EAG Laboratories GmbH S22-00981 GLP Unpublished	N			UPL

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 5.2/04	Spielvogel Ch., Timmann A.	2023	Amendment No. 1 to Final Report Independent Laboratory Validation of Analytical Methods for Determination of Boscalid and its Metabolite M510F01 and Bound Residues of the Metabolites M510F52 and M510F53 in Different Matrices of Animal Origin – Amended 09 April 2025 Study UPL/2023/0500 Eurofins Agrosience Services, EAG Laboratories GmbH S22-05633 (EAG-2202V) GLP Unpublished	N			UPL
KCP 5.2/06	Rastogi T.	2022	Independent Laboratory Validation of the Analytical method for Determination of Residues of Boscalid in Honey UPL/2022/0845 Eurofins Agrosience Services EcoChem GmbH S22-00783 GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 5.2/07	Rastogi T.	2022	Validation of Analytical Method for Determination of Boscalid and its Metabolites M510F47, M510F49 and M510F64 in Ground Water and Surface Water UPL/2022/2227 Eurofins Agrosience Services EAG Laboratories GmbH S22-00979 GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 5.2/08	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 Agrosience Services EcoChem GmbH S22-01028 GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 5.2/09	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 Agrosience Services, EAG Laboratories GmbH	N	Y	Study report never submitted before to PL	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
			S22-00982 GLP Unpublished				
KCP 5.1.2/10 KCP 5.2/06 10	Pearson J.	2022	Prothioconazole-desthio: Method Validation in Crops Company Report No. QG/20/011 Battelle UK GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 5.1.2/11	Giancola D.	2023	Hydroxy Metabolites of prothioconazole-desthio: Method Validation in Crops Report No. QG/22/001 Battelle UK GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 5.1.2/12	Phipps B.	2024	Triazole Derived Metabolites (TDM's) (1,2,4-Triazole, triazole acetic acid, triazole alanine and triazole lactic acid): Method Validation in Crops Report No. QG/20/012 Battelle UK GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 5.1.2/13 (Filled in KCA 6.10/03 (CP 7.3.7))	Lebrun F.	2024	Magnitude of the residue of triazole derivative metabolites in phacelia honey in Northern and Southern Europe – 2023 Report No. 644-2023 Analytical phase code. S23-101384-L1 (TES-2307) TESTAPI GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Albaugh Sipcam Barclay
KCP 5.2/09 11	Boubakri N.	2023	Independent Laboratory Validation of Multi Residue Method for Determination of Prothioconazole-desthio in Different Matrices of Plant Origin Report No. S21-08354 Eurofins Agrosience Services GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 5.2/06 12	Kleinhenz D.	2023	Development and Validation of an Analytical Method for Determination of Prothioconazole-desthio in Food of Animal Origin Report No. S21-08355 Eurofins Agrosience Services	N	Y	Study report never submitted before to PL	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
			GLP Unpublished				
KCP 5.2/09 13	Rastogi T.	2023	Independent Laboratory Validation of Prothioconazole-desthio in Different Matrices of Animal Origin Report No. S21-08868 GLP Eurofins Agroscience Services Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 5.2/14 14	Hitchens J.	2023	Prothioconazole-desthio and hydroxy metabolites: Method Validation in Honey Report No. QG/21/009 Battelle UK GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 5.2/15 15	Wanger J.	2023	Independent Laboratory Validation of an Analytical Method for the Determination of Prothioconazole-desthio in Honey Report No. S21-08357 Eurofins Agroscience Services GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 5.2/16 16	Kaiser M.	2022	Development and Validation of an Analytical Method for Determination of Prothioconazole and Prothioconazole-desthio in Soil Eurofins Agroscience Services Report No. S21-08358 GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 5.2/17 17	Kaiser D.	2022	Development and Validation of an Analytical Method for Determination of Prothioconazole and Prothioconazole-desthio in Water Eurofins Agroscience Services Report No. S21-08359 GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 5.2/18 18	Jooß S.	2023	Independent Laboratory Validation of an Analytical Method for the Determination of Prothioconazole-desthio in Water Report No. S21-08869 Eurofins Agroscience Services GLP	N	Y	Study report never submitted before to PL	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 5.2/45 19	Boubakri N.	2023	Development and Validation of an Analytical Method for Determination of Prothioconazole-desthio in Urine Report No, S21-08361 Eurofins Agrosience Services GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
Section B6, toxicology							
KCP 7.3/01	Nagane, R.M.	2023	Boscalid 350 g/kg + Prothioconazole 200 g/kg: In vitro dermal absorption of Boscalid using human split-thickness skin in a flow through diffusion system. Report No. 617-1-06-33517 (study no. UPL/2023/0324) Jai Research Foundation, Valvada - 396105, Dist. Valsad, Gujarat, India GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 7.3/02	Desai, K.R.	2024	Boscalid 350 g/kg + Prothioconazole 200 g/kg: In vitro dermal absorption of Prothioconazole using human split-thickness skin in a flow through diffusion system. Report No. 617-1-06-34204 (study no. UPL/2023/0584) Jai Research Foundation, Valvada - 396105, Dist. Valsad, Gujarat, India GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 7.3/02	Desai, K.R.	2023	Boscalid 350 g/kg + Prothioconazole 200 g/kg: In vitro dermal absorption of Prothioconazole-desthio using human split-thickness skin in a flow through diffusion system. Report No. 617-1-06-34201 study no. UPL/2023/0585) Jai Research Foundation, Valvada - 396105, Dist. Valsad, Gujarat, India GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
Section B7, metabolism and residues							
KCA 6.1/01 (CP 7.2.1)	Flore, S.	2022	Storage Stability of Boscalid in Honey under Deep Frozen Conditions Report no. S22-01684 – UPL/2022/0340 Eurofins Agrosience Services EcoChem GmbH, Germany GLP Unpublished	N	Y	Study report never submitted before to PL	UPL
KCA 6.3/01 (CP 7.3.3)	Davolos, CC.	2024	OECD calculator for oilseed rape and honey for the active substance boscalid and prothioconazole based on the use of the FGE03 formulation.	N	Y	Study report never submitted	UPL

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
			File name: OECD Calculator_FGG03_prothioconazole_intended uses Unpublished			before to PL	
KCA 6.3.1/01; KCA 6.5.2/01 (CP 7.2.3 and (CP 7.2.5)	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. S22-01574 – UPL/2022/0442 Eurofins Agrosience Services Ltd., United Kingdom GLP Unpublished	N	Y	Study report never submitted before to PL	UPL
KCA 6.3.1/02 (CP 7.2.3)	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 Agrosience Services Ltd., United Kingdom GLP Unpublished	N	Y	Study report never submitted before to PL	UPL
KCA 6.4/01 (CP 7.2.4)	Davolos, CC.	2024b	Animal burden calculation of boscalid based on the use of the FGE03 formulation. File name: boscalid_mrl_guidelines_animal_model_2017 Unpublished	N	Y	Study report never submitted before to PL	UPL
KCA 6.9/01 (CP 7.2.8)	Davolos, CC.	2024b	Dietary Risk Assessment of boscalid based on the use of the FGE03 formulation. File name: Chronic_EFSA_PRIMO_rev3.1_boscalid Unpublished	N	Y	Study report never submitted before to PL	UPL
KCA 6.10/01 (CP 7.2.7)	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 Agrosience Services EcoChem GmbH, Germany GLP Unpublished	N	Y	Study report never submitted before to PL	UPL
KCA 6.1/02 (CP 7.3.1)	Giancola, D.	2024b	Prothioconazole-desthio and 5 hydroxy metabolites: Frozen Storage Stability in Crops – Interim Report Report No.: QG/21/001 Battelle UK, Essex, UK GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe Limited Sipcam Oxon S.p.A Barclays Chemicals (R&D) Limited

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
							Albaugh Europe Sàrl
KCA 6.1/0403	Baxter, B. Phipps	2025	Triazole Derived Metabolites: Frozen Storage Stability in Crops for 12 Months; Study No.: QG/21/002 Battelle UK, Essex, UK GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe Limited
KCA 6.1/04 (CP 7.3.1)	Jooß, S.	2025	Storage Stability of the Triazole Derivative Metabolites (TDMs) in Plant Matrices under Deep Frozen Conditions. Study No.: S23-105428 Eurofins Agrosience Services EAG Laboratories GmbH GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe Limited
KCA 6.1/0405 (CP 7.3.1)	Giancola, D.	2023	Prothioconazole-desthio and 5 hydroxy metabolites: Frozen Storage Stability in Honey Study No.: QG/21/007 Battelle UK, Essex, UK GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe Limited Sipcam Oxon S.p.A Barclays Chemicals (R&D) Limited Albaugh Europe Sàrl
KCA 6.1/0406 (CP 7.3.1)	Mealing, H.	2024	Triazole Derivative Metabolites: Frozen Storage Stability in Honey for 6 months Study No.: QG/21/006 Battelle UK, Essex, UK GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe Limited Sipcam Oxon S.p.A Barclays Chemicals (R&D) Limited Albaugh Europe Sàrl
KCA 6.1/0407 (CP 7.3.1)		2020	Storage Stability of Triazole Alanine (TA), Triazole Acetic Acid (TAA) and Triazole Lactic Acid (TLA) in Animal Matrices under Deep Frozen Conditions. Report No. 869333 GLP Unpublished	Y	Y	Study report never submitted before to PL	TDMG (LoA to UPL)
KCA 6.1/06	Baxter, B. Phipps	2025	Triazole Derived Metabolites: Frozen Storage Stability in Crops for 12 Months; Study No.: QG/21/002 Battelle UK, Essex, UK	N	Y	Study report never submitted before to PL	UPL Europe Limited

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				
KCA 6.5.1/01 (CP 7.3.2.3)	Bloß, K.	2022	[¹⁴ C] Prothioconazole-desthio Hydrolysis under Typical Conditions (pH, Temperature and Time) of Processing. Report No.: S21-04814 Eurofins Agrosience Services EcoChem GmbH GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe Limited
~~KCA 6.3.1/03 (CP 7.3.3)~~	~~Hardy, J.; Coleman, H.~~	~~2024~~	~~Magnitude of Residues of Prothioconazole-desthio, Hydroxy-prothioconazole-desthio-metabolites, Triazole Lactic Acid and Triazole Acetic Acid Following Two Applications of a 250 g/L EC Formulation to Oilseed Rape in Southern Europe, 2020 Report No.: QG20008 GLP Unpublished~~	~~N~~	~~Y~~	~~Study report never submitted before to PL~~	~~UPL Europe Limited Barclays Chemicals (R&D) Limited Albaugh Europe Sàrl~~
KCA 6.3.1/04 (CP 7.3.3)	Toscano-Saes, R.; Coleman, H.	2023	Magnitude of Residues of Prothioconazole-desthio and Hydroxyprothioconazole-desthio Metabolites Following Two Applications of a Prothioconazole 250 g/L DC Formulation to Oilseed Rape in Northern and Southern Europe, 2021 Report No.: NZ/21/002 GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe Limited Barclays Chemicals (R&D) Limited Albaugh Europe Sàrl
~~KCA 6.3.1/05 (CP 7.3.3)~~	~~Toscano-Saes, R.; Coleman, H.~~	~~2023~~	~~Magnitude of Residues of Prothioconazole-desthio and Hydroxyprothioconazole-desthio-metabolites Following Two Applications of Prothioconazole 250 g/L DC (FGR06) to Oilseed rape in southern Europe, 2022 Report No.: QG22006 GLP Unpublished~~	~~N~~	~~Y~~	~~Study report never submitted before to PL~~	~~UPL Europe Limited Sipcam Oxon S.p.A Barclays Chemicals (R&D) Limited Albaugh Europe Sàrl~~
KCA 6.3.1/06 (CP 7.3.3)	Toscano-Saes, R.; Coleman, H.	2023	Magnitude of Residues of Prothioconazole-desthio and Hydroxyprothioconazole-desthio metabolites Following Two Applications of Prothioconazole 250 g/L DC (FGR06) to Oilseed rape in northern Europe, 2022 Report No.: QG22007 GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe Limited Sipcam Oxon S.p.A Barclays Chemicals (R&D) Limited Albaugh Europe Sàrl
KCA 6.3.1/07 (CP 7.3.3)	Bousquet, C.	2024	Magnitude of the residue of prothioconazole metabolites in oilseed rape in Northern and Southern Europe – 2023 Report No.: 647-2023	N	Y	Study report never submitted before to PL	UPL Europe Limited Barclays Chemicals

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				(R&D) Limited Albaugh Europe Sàrl
KCA 6.3.1/08 (CP 7.3.3)	Gibson, G.; Toscano-Saes, R.	2022	Magnitude of Residues of Triazole Derived Metabolites (TDM's) (triazole acetic acid and triazole lactic acid) Following Two Applications of Prothioconazole 250 g/L DC (FGR06) to Oilseed Rape in Northern and Southern Europe, 2021 Report No.: NZ/21/003 GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe Limited Barclays Chemicals (R&D) Limited Albaugh Europe Sàrl
KCA 6.3.1/09 (CP 7.3.3)	Toscano-Saes, R.	2023	Magnitude of Residues of Triazole Derived Metabolites (TDM's) (triazole acetic acid and triazole lactic acid) Following Two Applications of Prothioconazole 250 g/L DC (FGR06) to Oilseed Rape in Southern Europe, 2022 Report No.: EE/23/006 GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe Limited Barclays Chemicals (R&D) Limited Albaugh Europe Sàrl
KCA 6.3.1/10 (CP 7.3.3)	Phipps, B.	2023	Magnitude of Residues of Triazole Derived Metabolites (TDM's) (triazole acetic acid and triazole lactic acid) in Oilseed Rape Following Two Applications of Prothioconazole 250 g/L DC (FGR06) in Northern Europe, 2022 Report No.: EE/23/007 GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe Limited Barclays Chemicals (R&D) Limited Albaugh Europe Sàrl
KCA 6.4/02 (CP 7.3.4)	Davolos, CC.	2024	Animal burden calculation of prothioconazole based on the use of the FGE03 formulation. File name: prothioconazole_mrl_guidelines_animal_model_2017 Unpublished	N	Y	Study report never submitted before to PL	UPL
KCA 6.4.2/01 (CP 7.3.4)	██████	2021	Determination of the Triazole Derived Metabolites in Eggs and Tissues of Laying Hens following Multiple Oral Administration of Triazole Lactic Acid Report No. IF19-05004879 ██████ GLP Unpublished	Y	Y	Study report never submitted before to PL	TDMG (LoA to UPL)
KCA 6.4.2/02 (CP 7.3.4)	██████	2021	Determination of the Triazole Derived Metabolites in Milk and Tissues of Dairy Cows Multiple Oral Administration of Triazole Lactic Acid Report No. IF19-05004884 ██████ GLP	Y	Y	Study report never submitted before to PL	TDMG (LoA to UPL)

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 6.6.2/01 (CP 7.3.6)	Semrau, J.	2022	Determination of residues of prothioconazole metabolites and triazole derivative metabolites in rotational crops (turnip, leaf lettuce, wheat) after one application of Prothioconazole 250g/L EC on bare soil at 2 sites in Northern Europe and 2 sites in Southern Europe 2022-2024. Report No.: S22-02433 (Study Plan) Eurofins Agrosience Services EcoChem GmbH GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe Limited
~~KCA 6.9/02 (CP 7.3.8)~~	~~Davolos, CC.~~	~~2024~~	~~Dietary Risk Assessment of prothioconazole based on the use of the FGE03 formulation. File name: Chronic_EFSA_PRIMo_rev3.1_prothioconazole Unpublished~~	~~N~~	~~Y~~	~~Study report never submitted before to PL~~	~~UPL~~
KCA 6.10/02 (CP 7.3.7)	Andrews, G. Coleman, H.	2023	Magnitude of Residues of Prothioconazole-desthio and Hydroxy prothioconazole-desthio Metabolites in Honey Following Two Tunnel Applications of a Prothioconazole 250 g/L EC Formulation (FF-065) to Phacelia in Northern and Southern Europe, 2021 Study No.: QG/21/003 Battelle UK, Essex, UK GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe Limited Sipcam Oxon S.p.A Barclays Chemicals (R&D) Limited Albaugh Europe Sàrl
KCA 6.10/03 (CP 7.3.7)	Lebrun, F.	2024	Magnitude of the residue of triazole derivative metabolites in phacelia honey in Northern and Southern Europe – 2023 Study No.: 644-2023 Battelle UK, Essex, UK GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe Limited Albaugh Europe Sàrl
Section B8, environmental fate							
KCP 9.2.4.1/01	Šulc, A.	2024a	Report on calculation of Predicted Environmental Concentrations of boscalid, prothioconazole and their metabolites in groundwater (PECgw) - FGE03 (GPF515) / Central Zone - GW-213-220810CZ-01 Vali Consulting GmbH, Rossdorf, Germany non GLP Unpublished	N	N	-	UPL Europe
KCP 9.2.5/01	Šulc, A.	2024b	Report on Predicted Environmental Concentrations of boscalid, prothioconazole and their metabolites in Surface Water and Sediment	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	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			(PECsw and PECsed) - FGE03 (GPF515) / Central Zone - SW-213-220810CZ-01 Vali Consulting GmbH, Rossdorf, Germany non GLP Unpublished				
Section B9, ecotoxicology							
KCP 10.2.1/01		2024	Study plan: Acute toxicity study of boscalid 350 g/kg + prothioconazole 200 g/kg wg (equivalent to boscalid 35.0% + prothioconazole 20.0% w/w wg) to rainbow trout, <i>oncorhynchus mykiss</i> .	Y	Y	Study report never submitted before to PL	UPL Europe Limited
KCP 10.2.1/01	Kamle, M.K.	2023a	Acute Immobilisation Study of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG to <i>Daphnia magna</i> Report No. 502-3-07-33000, UPL/2022/2968 Jai Research Foundation, Valvada, Gujarat, India GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 10.2.1/02	Kamle, M.K.	2023b	Alga (<i>Pseudokirchneriella subcapitata</i>), Growth Inhibition Test with Boscalid 350 g/kg + Prothioconazole 200 g/kg WG Report No. 501-3-07-32999, UPL/2022/2965 Jai Research Foundation, Valvada, Gujarat, India GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 10.3.1.1.1/01 & KCP 10.3.1.1.2/01	Knautz, T.	2023	Boscalid 500 g/kg + Prothioconazole 200 g/kg WG: Effects (Acute Contact and Oral) on Honey Bees (<i>Apis mellifera</i> L.) in the Laboratory Report No. 176531035, UPL/2023/1236 ibacon GmbH, Rossdorf, Germany GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 10.3.1.1.1/02 & KCP 10.3.1.1.2/02	Chwiesko, D. & Horstmann, C.	2023	Boscalid + Prothioconazole (350 g/kg + 200 g/kg WG): Acute Contact and Oral Toxicity to Bumblebees (<i>Bombus terrestris</i> L.) in the Laboratory Report No. 176531105, UPL/2023/1279 ibacon GmbH, Rossdorf, Germany GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 10.3.1.2/01	Knautz, T. & Horstmann, C.	2023	Boscalid + Prothioconazole (350 g/kg + 200 g/kg WG): Chronic Oral Toxicity Test on the Honey Bee (<i>Apis mellifera</i> L.) in the Laboratory Report No. 176531136, UPL/2023/1209	N	Y	Study report never submitted before to PL	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
			ibacon GmbH, Rossdorf, Germany GLP Unpublished				
KCP 10.3.1.3/01	Venturi, S.	2022	Effects of Boscalid + Prothioconazole (350 g/kg + 200 g/kg WG) on honeybees (<i>Apis mellifera</i> L.) 22-day larval toxicity test with repeated exposure Report No. BT073/23, UPL/2023/1235 BioTecnologie BT S.r.l., Todi (PG), Italy GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 10.3.2.1/01	Leopold, J.	2023a	Boscalid + Prothioconazole (350 g/kg + 200 g/kg WG): Effects on the Parasitoid <i>Aphidius rhopalosiphi</i> (Hymenoptera: Braconidae) in the Laboratory. A Dose Response Test on Glass Plates Report No. 176531001, UPL/2023/1053 ibacon GmbH, Rossdorf, Germany GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 10.3.2.1/02	Leopold, J.	2023b	Boscalid + Prothioconazole (350 g/kg + 200 g/kg WG): Effects on the Predatory Mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae) in the Laboratory. A Dose Response Test on Glass Plates Report No. 176531063, UPL/2023/1054 ibacon GmbH, Rossdorf, Germany GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 10.3.2.2/01	Leopold, J.	2024	Boscalid + Prothioconazole (350 g/kg + 200 g/kg WG): Effects on the Predatory Mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae), Extended laboratory study - Dose Response Test Report No. 176531062, UPL/2024/0298 ibacon GmbH, Rossdorf, Germany GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 10.3.2.2/02	Knautz, T.	2024	Boscalid + Prothioconazole (350 g/kg + 200 g/kg WG): Effects on the Carabid Beetle <i>Poecilus cupreus</i> L. - Extended laboratory study - Dose Response Study Report No. 176531007, UPL/2024/0337 ibacon GmbH, Rossdorf, Germany GLP	N	Y	Study report never submitted before to PL	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				
KCP 10.4.1.1/01	Hübner, S.	2023a	Boscalid + Prothioconazole (350 g/kg + 200 g/kg WG): Effects on Reproduction and Growth of the Earthworm (<i>Eisenia fetida</i>) in Artificial Soil Report No. 176531022, UPL/2023/2769 ibacon GmbH, Rossdorf, Germany GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 10.4.2.1/01	Hübner, S.	2023b	Boscalid + Prothioconazole (350 g/kg + 200 g/kg WG): Effects on Reproduction of Collembola (<i>Folsomia candida</i>) in Artificial Soil Report No. 176531016, UPL/2023/2772 ibacon GmbH, Rossdorf, Germany GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 10.4.2.1/02	Hübner, S.	2023c	Boscalid + Prothioconazole (350 g/kg + 200 g/kg WG): Effects on Reproduction of the Predatory Mite <i>Hypoaspis aculeifer</i> in Artificial Soil Report No. 176531089, UPL/2023/1436 ibacon GmbH, Rossdorf, Germany GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 10.5/01	Raithatha, A.	2023	Effect of Boscalid 350 g/kg + Prothioconazole 200 g/kg WG (GPF515) on Soil Microorganisms: Nitrogen Transformation Test Report No. 608-3-15-33022, UPL/2022/21328 Jai Research Foundation, Valvada, Gujarat, India GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 10.6.2/01	Stürtz, S.	2023a	Boscalid + Prothioconazole (350 + 200 g/kg – WG): Effects on Terrestrial (Non-Target) Plants: Vegetative Vigour Test Report No. 176531087, UPL/2023/0743 ibacon GmbH, Rossdorf, Germany GLP Unpublished	N	Y	Study report never submitted before to PL	UPL Europe
KCP 10.6.2/02	Stürtz, S.	2023b	Boscalid + Prothioconazole (350 + 200 g/kg – WG): Effects on Terrestrial (Non-Target) Plants: Seedling Emergence and Seedling Growth Report No. 176531086, UPL/2023/0742 ibacon GmbH, Rossdorf, Germany GLP Unpublished	N	Y	Study report never submitted before to PL	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	-	BASF
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, and lettuce IF-100/35725-00 2000/1014886 GLP Unpublished	N	N	-	BASF
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	-	BASF
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	-	BASF
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	-	BASF
CP 5.1.2	Keller, W.	1998b	Validation of analytical method no. 411, determination of BAS 510 F ai residues in water;	N	N	-	BASF

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 no. 41877. 1998/10922 GLP, Unpublished				
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	-	BASF
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; study code 110241. 2001/1008955 GLP, unpublished	N	N	-	BASF
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	-	BASF
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	-	BASF
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	-	BASF
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	-	BASF
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	N	N	-	BASF

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
			in animal matrices PTRL Europe Study No. P453G. 2000/1017226 GLP Unpublished				
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 GLP Unpublished	N	N	-	BASF
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	-	BASF
CP 5.1.2	Heinemann , O.	2000a	Analytical determination of residues of JAU 6476 and dethio-JAU 6476 in/on cereals by HPLC/MS/MS Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 00598, Edition Number: M 028457-01-1 Method Report No.: MR 401/99 EPA MRID No.: 46477702 Date: 2000-03 20 GLP/GEP: yes, unpublished	N	N	-	BASF
CP 5.1.2	Heinemann , O.	2000b	Analytical determination of residues of JAU6476 and JAU6476 desthio in/on cereals and canola by HPLC-MS/MS (method modification 00598/M001) Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 00598/M001, Edition Number: M 047681-01-1 Method Report No.: MR 689/99 EPA MRID No.: 46477703 Date: 2000-08 28 GLP/GEP: yes, unpublished	N	N	-	BASF

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
CP 5.1.2 CP 5.2	Weeren, R. D.; Pelz, S.	2000	Modification M033 of method 00086: Validation of DFG method S 19 (extended revision) for the determination of residues of JAU 6476 desthio in materials of plant and animal origin Dr. Specht & Partner, Chemische Laboratorien GmbH, Hamburg, Germany Bayer CropScience, Report No.: 00086/M033, Edition Number: M 027637-01-1 Date: 2000-11 20 GLP/GEP: yes, unpublished	N	N	-	BASF
CP 5.1.2 CP 5.2	Class, T.	2001	Independent laboratory validation of DFG method S19 (extended revision) for the determination of residues of JAU 6476 desthio (Bayer method 00086/M033) in plant materials PTRL Europe GmbH, Ulm, Germany Bayer CropScience, Report No.: P/B 484 G, Edition Number: M 033019-01-1 Method Report No.: P/B 484 G Date: 2001-05 15 GLP/GEP: yes, unpublished	N	N	-	BASF
CP 5.1.2 CP 5.2	Heinemann, O.	2001a	Analytical determination of residues of JAU6476-3 hydroxy desthio, JAU6476-4 hydroxy desthio, and JAU6476 desthio in/on matrices of animal origin by HPLC MS/MS Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 00655, Edition Number: M 037709-01-1 Method Report No.: MR 537/00 EPA MRID No.: 46477704 Date: 2001-02 27 GLP/GEP: yes, unpublished	N	N	-	BASF
CP 5.1.2 CP 5.2	Heinemann, O.	2001c	Analytical determination of residues of JAU6476-3 hydroxy-desthio, JAU6476-4 hydroxy desthio, and JAU6476 desthio in milk by HPLC MS/MS (00655/M001) Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 00655/M001, Edition Number: M 021546-01-1 Method Report No.: MR 170/01 Date: 2001-05 04 GLP/GEP: yes, unpublished	N	N	-	BASF

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
CP 5.1.2 CP 5.2	Dubey, L.	2001	Independent laboratory validation of Bayer methods 00655 and 00655/M001 for the determination of residues of JAU6476-3 hydroxy desthio, JAU6476-4 hydroxy desthio, and JAU6476 desthio in/on matreces of animal origin by HPLC MS/MS Battelle Geneva Research Centres, Geneva, Switzerland Bayer CropScience, Report No.: A 14-01-01, Edition Number: M 081595-01-1 Method Report No.: A-14-01 01 Date: 2001-10 16 GLP/GEP: yes, unpublished	N	N	-	BASF
CP 5.1.2	Schramel, O.	2000	Residue analytical method 00610 (MR-643/99) for the determination of JAU 6476 and the metabolites JAU6476 desthio and JAU6476-S methyl in soil by HPLC MS/MS Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: MR-643/99, Edition Number: M 041798-01-1 Method Report No.: MR 643/99 EPA MRID No.: 46246543 Date: 2000-07- 13 GLP/GEP: yes, unpublished	N	N	-	BASF
CP 5.1.2	Steinhauer, S.	2001	Enforcement method 00086/M038 for the determination of the residues of JAU 6476 desthio in soil - validation of DFG method S 19 (extended revision) – Dr. Specht & Partner, Chemische Laboratorien GmbH, Hamburg, Germany Bayer CropScience, Report No.: 00086/M038, Edition Number: M 067970-01-1 Method Report No.: BAY 0107V Date: 2001-07 25 GLP/GEP: yes, unpublished	N	N	-	BASF
CP 5.1.2	Sommer, H.	1999	Method for the determination of JAU 6476 and SXX 0665 in test water from aquatic toxicity tests by HPLC [Tox/Ecotox method] Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 00586, Edition Number: M 012801-01-1 Method Report No.: MR 291/99	N	N	-	BASF

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
			Date: 1999-05 18 GLP/GEP: no, unpublished				
CP 5.1.2	Sommer, H.	2001a	Method for determination of JAU6476-S methyl in test water from aquatic toxicity tests by HPLC UV [Tox/Ecotox method] Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 00699, Edition Number: M 052730-01-1 Method Report No.: MR 250/01 Date: 2001-06 21 GLP/GEP: no, unpublished	N	N	-	BASF
CP 5.1.2 CP 5.2	Sommer, H.	2001b	Enforcement method 00684 for determination of JAU 6476 and JAU 6476 desthio in drinking and surface water by HPLC MS/MS Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 00684, EditionNumber: M 079449-01-1 Method Report No.: MR 105/01 Date: 2001-10 23 GLP/GEP: yes, unpublished	N	N	-	BASF
CP 5.1.2 CP 5.2	Maasfeld, W.	2002a	Method for the determination of JAU 6476 in air by HPLC MS/MS Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 00724, Edition Number: M 032554-01-1 Method Report No.: MR 601/01 Date: 2002-01 22 GLP/GEP: yes, unpublished	N	N	-	BASF
CP 5.1.2 CP 5.2	Maasfeld, W.	2002b	Method for the determination of JAU 6476 desthio (SXX 0665) in air by HPLC-MS/MS Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 00731, Edition Number: M 036729-01-1 Method Report No.: MR 003/02 Date: 2002-02 13 GLP/GEP: yes,	N	N	-	BASF

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				
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	-	BASF
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	-	BASF
KCA 6.2.1	Hamm R.T.	1999	BAS 510 F in lettuce Report No. 1999/11240 GLP Unpublished	N	N	-	BASF
KCA 6.2.1	Veit P.	2001	Metabolism of 14C-BAS 510 F in beans Report No. 2000/1014861 GLP Unpublished	N	N	-	BASF
KCA 6.2.2	■■■■	2000	The Metabolism of 14C-BAS 510F in Lactating Goat. Report No. 000/1012353; RIP2001-331 GLP Unpublished	Y	N	-	BASF
KCA 6.2.2	■■■■	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	-	BASF
KCA 6.2.2	■■■■	2001	Nature of Residues of 14C-BAS 510 F in Laying Hens. Report No. 2000/5154; RIP2001-332 GLP Unpublished	Y	N	-	BASF
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	N	N	-	BASF

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				
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	-	BASF
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	-	BASF
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	-	BASF
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	-	BASF
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 Unpublished	N	N	-	BASF
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	-	BASF
KCA 6.3.2	Schaeufele, M.	2009	Residue study (decline) with BAS 664 AS F, BAS 510 01 F and BAS 555	N	N	-	BASF

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			00 F applied to oilseed rape in Germany and Northern France in 2008 Report no. BASF DocID 2008/1074165 GLP Unpublished				
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	-	BASF
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	-	BASF
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	-	BASF
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	-	BASF
KCA 6.3.3	Klaas, P.	2008	Study on the residue behavior of BAS 510 F in green beans after 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	N	N	-	BASF
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	N	N	-	BASF

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			Unpublished				
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	-	BASF
KCA 6.4.1	██████	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	-	BASF
KCA 6.4.2	██████	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	-	BASF
KCA 6.4.2	██████	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	-	BASF
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	-	BASF
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	-	BASF
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	N	N	-	BASF

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			Unpublished				
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	-	BASF
KCA 6.6.1	Hamm R.T., Veit P.	2001	Confined rotational crop study with ¹⁴ C-BAS 510 F Report no. 2000/1014862 GLP Unpublished	N	N	-	BASF
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, RIP2001-374 GLP Unpublished	N	N	-	BASF
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	-	BASF
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	-	BASF
KCA 6.6.2	Jeannine M. J,	2002	Field Rotational Study for BAS 510 F on Grasses, Alfalfa and Clover as Livestock Feed Crops Report no. 2002/5002063 GLP Unpublished	N	N	-	BASF
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	-	BASF
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	N	N	-	BASF

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			Unpublished				
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	-	BASF
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	-	BASF
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	-	BASF
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	-	BASF
KCA 6.1	Heinemann, O.	2001	18 months storage stability of residues of JAU 6476 and JAU 6476-desthio during frozen storage in/on wheat matrices Report no. MR-282/00 GLP Unpublished	N	N	-	BCS
KCA 6.2	Hass M.; Bor- natsch W.	2000	Metabolism of JAU 6476 in sugar beets Report no. 200466 GLP Unpublished	N	N	-	BCS
KCA 6.2	Vogeler K.; Sakamoto H.; Brauner A.	1993	Metabolism of SXX 0665 in summer wheat Report no. PF3906 GLP Unpublished	N	N	-	BCS
KCA 6.2	Haas M.	2001	Metabolism of JAU 6476 in spring wheat after seed dressing	N	N	-	BCS

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			Report no. MR-467/99 GLP Unpublished				
KCA 6.2	Haas M.	2001	Extraction efficient testing of the residue method (00647) for the determination of JAU 6476 residues in spring wheat using aged radioactive residues. Report no. MR-467/99 GLP Unpublished	N	N	-	BCS
KCA 6.2	██████	2002	[Phenyl-UL-14C]JAU 6476 Absorption, distribution, excretion and metabolism in the lactating goat Report no. MR-092/01 GLP Unpublished	Y	N	-	BCS
KCA 6.2	██████	2002	[Phenyl-UL-14C] JAU 6476-desthio Absorption, distribution, excretion, and metabolism in the lactating goat Report no. MR-091/01 GLP Unpublished	Y	N	-	BCS
KCA 6.2	██████	2001	[Phenyl-UL-14C]JAU 6476 Absorption, distribution, excretion and metabolism in laying hens Report no. MR-309/01 GLP Unpublished	Y	N	-	BCS
KCA 6.4	██████	2001	JAU 6476-desthio – Dairy cattle feeding study Report No.: MR-535/00 GLP Unpublished	Y	N	-	BCS
KCA 6.5	Gilges M.	2001	Hydrolysis of JAU 6476 under conditions of processing Report No.: MR-166/00 GLP Unpublished	N	N	-	BCS
KCA 6.6	Haas M.	2001	Confined rotational crop study with JAU 6476 Report no. MR-159/00 GLP Unpublished	N		-	BCS

TDMs - for the relevant studies please refer to the EU peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (UK, 2018b, EFSA, 2018b, amendment 1)

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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
-	-	-	-	-	-	-	-

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
-	-	-	-	-	-	-	-