

REGISTRATION REPORT
Part B
Section 3
Efficacy Data and Information

Concise summary

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 States: Poland

CORE ASSESSMENT
(Authorisation)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: November 2024, update: March 2025

MS Finalisation date: April 2025 (initial Core Assessment)

August 2025 (final Core Assessment)

Version history

When	What
November 2024	Initial dRR - UPL Holdings Coöperatief U.A.
March 2025	Updated dRR (GAP table expanded to detail individual countries on separate lines and include minor uses according to article 51) - UPL Holdings Coöperatief U.A.
April 2025	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and ~~shaded~~ for transparency. 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.
August 2025	Final report (Core Assessment updated following the commenting period) 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.

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3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

Transformation of the dRR (applicant version) into the RR (zRMS version)

Comments of zRMS:

Conclusions from the assessment were prepared using grey commenting boxes placed at the end of each chapter. Textual changes were done using grey highlights in the text. The parts of the text amended or added by the zRMS evaluator are highlighted in grey, whereas the parts struck off are ~~visibly marked with the grey font~~.

3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract by zRMS

This application has been submitted for authorization of the new fungicide FGE03 containing 350 g/kg boscalid (SDHI fungicide; FRAC group 7) and 200 g/kg prothioconazole (DMI fungicide; FRAC group 3). FGE03 is a water-dispersible granule formulation, intended to be authorized for the control of *Sclerotinia sclerotiorum* in oilseed rape (winter and spring form) in Czech Republic (Maritime EPPO zone), Hungary (South-East EPPO zone) and in winter oilseed rape in Poland (North-East EPPO zone) based on the grounds of article 33 of regulation 1107/2009. For Poland, the use spring oilseed rape: *Sclerotinia sclerotiorum* and additonall uses: gold of pleasure, winter turnip rape, mustard, sunflower, poppy, linseed, flax, hemp, borage: *Sclerotinia sclerotiorum* are intended to be registered on the grounds of article 51 of regulation 1107/2009. FGE03 is recommended to be applied at dose rate of 0.7 kg/ha 1 time per gowing season within the growth stage of the crop ranging from 61 to 69 in Maritime (Czech Republic) and South-East (Hungary) EPPO climatic zone, or 2 times per growing season within the growth stage of the crop ranging from 61 to 73 in Maritime (Czech Republic), North-East (Poland) and South-East (Hungary) EPPO climatic zones.

Preliminary trials

The advantage of co-formulation of prothioconazole and boscalid and their proper ratio in the FGE03 (140 g/245 g per ha) have been considered as demonstrated and justified effectively.

Minimum effective dose

The target dose rate of 0.7 kg/ha has been effectively demonstrated and justified, as the minimum effective dose (MED) in the control of *Sclerotinia sclerotiorum* in oilseed rape in 3 EPPO climatic zones: Maritime, North-East and South-East both for the variant of application 1 time per growing season and for the variant of application 2 times per growing season.

Efficacy

The submission contains 38 valid efficacy trials carried out between 2022 and 2024 in 3 EPPO zones: Maritime (Austria, Czech Republic, Denmark, Northern France, the United Kingdom), North-East (Lithuania, Poland) and South-East (Bulgaria, Hungary, Romania).

Based on the submitted efficacy trial results, it can be concluded, that the fungicide FGE03, applied once or twice per growing season, at the recommended dose rate of 0.7 kg/ha is effective in the control of target pathogen *Sclerotinia sclerotiorum* on winter oilseed rape and the authorization may be granted for this claimed use in Maritime (Czech Republic), North-East (Poland) and South-East (Hungary) EPPO zone. Based on efficacy data from Maritime and South-East EPPO zone, it is recommended to include in the national product labels for CZ and HU remark about moderate level of efficacy of FGE03 applied once per growing season.

Optionally, due to different ways of presenting information on the level of efficacy in commercial product labels, national labels may include details on the spectrum of control depending on the number of applications, in accordance with the table below:

Sclerotinia sclerotiorum control

EPPO climatic zone	1 application	2 applications
Maritime (CZ)	Moderate control	Good control
North-East (PL)	Not applicable	Good control
South-East (HU)	Moderate control	Good control

For Poland, based on data from valid efficacy trials, the BBCH growth stage of the crop has been narrowed from 61-73 to 61-69.

As no efficacy data has been submitted for spring oilseed rape, the decision on acceptance this claimed use is to be taken at the national level, according to the national requirements. In Maritime EPPO zone the conducted trials did not completely cover the requested BBCH growth stage range 61-73 for the scenario of use with 2 applications of FGE03. Therefore, the application timing is to be confirmed by cMS Czech Republic.

The zRMS is kindly asking the cMSs to not only take their decisions, but also to **share** the underlying information with the zRMS PL, **within the commenting period framework**.

After commenting period, taking into account the decision of the cMS HU regarding the extrapolation of data from BRSNW to BRSNS, the use on BRSNS has been accepted for HU.

Phytotoxicity, yield, propagation material, transformation processes, succeeding crops and adjacent crops

Phytotoxicity and adverse effects on the yield, propagation material, transformation processes, succeeding crops and adjacent crops are not expected after application of FGE03, when used according to GAP recommendations.

Resistance management strategy

- Use FGE03 at full recommended dose rate,
- Do not exceed the maximum recommended number of treatments per growing season,
- Use FGE03 predominantly preventively or at the early stages of disease development,
- Include in the adopted plant protection program fungicides containing active substances from other groups according to the FRAC classification, with different modes of action (use the products alternately or in a tank mixture),
- Non-chemical measures such as resistant crop varieties, plant hygiene, appropriate crop rotation should be taken into consideration to reduce the infection pressure of the target pathogen.

The cMSs are kindly encouraged to adopt or adjust the wording, according to their local circumstances and requirements.

Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. (*)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (*)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	HU	Oilseed rape (winter and spring) BRSNW, BRSNS BRSNN	F	Sclerotinia (<i>Sclerotinia sclerotiorum</i>) SCLESC	Spraying overall	BBCH 61- 69	a) 1 per use b) 1 per crop / season	-	a) 0.7 kg/ha b) 0.7 kg/ha	a) 245 boscalid 140 Prothioconazole b) 245 boscalid 140 Prothioconazole	100- 400	35	-	A BRSNW BRSNS
	CZ	Oilseed rape (winter and spring) BRSNW, BRSNS BRSNN	F	Sclerotinia (<i>Sclerotinia sclerotiorum</i>) SCLESC	Spraying overall	BBCH 61- 69	a) 1 per use b) 1 per crop /season	-	a) 0.7 kg/ha b) 0.7 kg/ha	a) 245 boscalid 140 Prothioconazole b) 245 boscalid 140 Prothioconazole	100- 400	35	-	A BRSNW C BRSNS
2	PL	Oilseed rape (winter) BRSNW BRSNN	F	Sclerotinia (<i>Sclerotinia sclerotiorum</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 boscalid 140 Prothioconazole b) 490 boscalid 280 Prothioconazole	100- 400	35	-	A
	HU	Oilseed rape (winter and spring) BRSNW, BRSNS BRSNN	F	Sclerotinia (<i>Sclerotinia sclerotiorum</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 boscalid 140 Prothioconazole b) 490 boscalid 280 Prothioconazole	100- 400	35	-	A BRSNW BRSNS
	CZ	Oilseed rape	F	Sclerotinia (<i>Sclerotinia</i>)	Spraying overall	BBCH 61- 73	a) 2 per use	14	a) 0.7 kg/ha b) 1.4 kg/ha	a) 245 boscalid 140 Prothioconazole	100- 400	35	-	A BRSNW

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) (winter and spring) BRSNW, BRSNS BRSNN	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group) <i>sclerotiorum</i>) SCLESC	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (+)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
							b) 2 per crop / season			b) 490 boscalid 280 Prothioconazole				
Minor uses according to Article 51 (zonal uses)														
3	PL	Spring rape, gold of pleasure, winter turnip rape, mustard, sunflower, poppy linseed, flax, hemp, borage	F	Scelrotinia (<i>Sclerotinia sclerotiorum</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 boscalid 140 g/ha prothioconazole b) 490 g/ha boscalid 280 g/ha prothioconazole	100- 400	35	-	n.r.

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 (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (+)	zRMS Conclusion (efficacy)	
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max				
Remarks columns:	1	Numeration necessary to allow references							7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application					
	2	Use official codes/nomenclatures of EU Member States							8	The maximum number of application possible under practical conditions of use must be provided.					
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)							9	Minimum interval (in days) between applications of the same product					
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application							10	For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.					
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.							11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).					
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.							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					

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

Comments of zRMS – to the GAP table:

Please note, that where a particular use is marked blue in the GAP table, it means that taking individual decision on that use by the respective cMS is welcome. It should not be meant as an off-loading, of the decision-taking, by the zRMS onto the cMS. Instead, it aims at allowing the cMSs to take decisions different from that taken by zRMS for their own country, in recognition of the cMSs` different national requirements or preferences. Bearing that in mind, zRMS has discussed, in the commenting boxes, any doubtful issues, highlighting positive efficacy results where relevant, while also sharing with cMSs the reasons for which taking different decisions may be justified in different zones.

In case of the **draft** Registration Report there is still time for any cMS to express their view and argue, in favour or against the authorization in their country. That is why the zRMS is kindly asking the cMSs to not only take their decisions, but also to **share** the underlying information with the zRMS PL, **within the commenting period framework**. Only then will the zRMS be able to complete the GAP table unambiguously, in the **final Registration Report**, for all the EPPO zones and for all the concerned Member States, for which the present dossier has been submitted.

3.2 Efficacy data (KCP 6)

Introduction

This document is the **concise summary** of the Biological Assessment Dossier (BAD) and summarises the information related to the efficacy of the plant protection product FGE03, a water-dispersible granule (WG) formulation containing the active substances boscalid (350 g/kg) and prothioconazole (200 g/kg). The efficacy and selectivity data presented in this concise summary fully support the application for registration of FGE03, a new fungicide product for the control of *Sclerotinia sclerotiorum* in oilseed rape (winter and spring variants).

This dossier aims to support the authorisation of FGE03 in Member States belonging to the Central registration zone in Europe, as defined in Annex I to Regulation (EC) No 1107/2009. zRMS in charge of the evaluation of this preparation is Poland and Member States concerned by the authorization (cMS = concerned Member State) are Czech Republic and Hungary.

Table 3.2-1: Zonal Rapporteur Member State (zRMS) and concerned Member States (cMS)

zRMS	Poland	PL
cMS	Czech Republic	CZ
	Hungary	HU

Data to support the label claims in the targeted Member States of the Central registration zone where registration is sought were generated in the relevant EPPO climatic zones of comparable climates (as defined in EPPO Standard PP1/241(2)): *i.e.* Maritime (with trials carried out in Austria, Belgium, Czech Republic, Germany, Northern France, Denmark, Ireland, the United Kingdom and Sweden), North-East (with trials carried out in Poland and Lithuania), South-East (with trials carried out in Bulgaria, Hungary and Romania)

Description of active substance

Boscalid was included in Annex I of Directive 91/414/EEC, in accordance with Commission Directive 2008/44/EC of 4 April 2008 and 79/117/EEC of 21 October 2009. Boscalid was later deemed to have been approved under Regulation (EC) No 1107/2009 and listed in Part A of the Annex to the Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011. Several Commission Implementing Regulation (EU), with the last one Commission Implementing Regulation (EU) 2023/918 of 4 May 2023, extended the approval period of boscalid to allow the completion of the renewal assessment. The current expiry date of the approval of boscalid is 15 April 2026.

The SANCO report for boscalid (SANCO/3919/2007-rev.5 - 21 January 2008) is considered to provide the relevant review information, or a reference, to where such information can be found.

The Annex (Part A) to Commission Implementing Regulation (EU) No 540/2011 provides specific provisions which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on boscalid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account.

For the purposes of efficacy, there is risk of accumulation of the active substance in soil following use on perennial crops or successive use in succeeding crops.

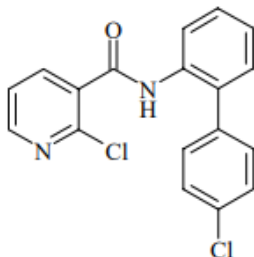
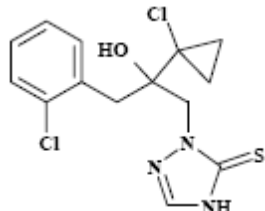
Prothioconazole was included in Annex I of Directive 91/414/EEC, in accordance with Commission Directive 2008/44/EC of 4 April 2008 and 79/117/EEC of 21 October 2009. Prothioconazole was later deemed to have been approved under Regulation (EC) No 1107/2009 and listed in Part A of the Annex to the Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011. Several Commission Implementing Regulation (EU), with the last one Commission Implementing Regulation (EU) 2023/918 of 4 May 2023, extended the approval period of boscalid to allow the completion of the renewal assessment. The current expiry date of the approval of boscalid is 15 August 2025.

The SANCO report for prothioconazole (SANCO/3923/2007 – final, 10 December 2007), updated on 26 January 2021, is considered to provide the relevant review information, or a reference, to where such information can be found.

The Annex (Part A) to Commission Implementing Regulation (EU) No 540/2011 provides specific provisions which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on prothioconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account.

Mode of action

Table 3.2-2: Details of the active substance

Active substance	Boscalid	Prothioconazole
Concentration (Unit: g/kg or g/L...)	350 g/kg	200 g/kg
Chemical name (IUPAC)	2-Chloro-N-(4'-chlorobiphenyl-2-yl)nicotinamide	(RS)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3-thione
CAS No	188425-85-6	178928-70-6
Molecular formula	C ₁₈ H ₁₂ Cl ₂ N ₂ O	C ₁₄ H ₁₅ Cl ₂ N ₃ OS
Molecular mass	343.21 g/mol	344.26 g/mol
Chemical group	Pyridine-carboxamides	Triazolinthiones
FRAC Group	C2 Group 7	G1 Group 3
Mode of action	Target site: Complex II-succinate dehydrogenase SDHI fungicides: Succinate-DeHydrogenase Inhibitors	Target site: C14-demethylase in sterol biosynthesis (erg11/cyp51) DMI fungicides: DeMethylation Inhibitors (SBI class I: Sterol Biosynthesis Inhibitors)
Biological action	Penetration by leaves (or roots) Systemic (acropetal movement) and translaminar activity with preventative and curative action	Penetration by plant tissues Systemic activity (upwards through the xylem) with curative, preventative and eradicated action
Structural formula		

Further information about the physical and chemical properties of FGE03 can be found in the Registration Report Part B Sections 1, 2 and 4.

Boscalid is a fungicide used in agriculture for control of various diseases including powdery mildew (*Erysiphe necator*), grey mould (*Botrytis cinerea*), sclerotinia (*Sclerotinia sclerotiorum*), fruit rot and blossom blight (*Monilia fructigena* and *Monilia laxa*) among others.

Boscalid stands as a systemic pesticide categorized within the SDHI fungicides group, specifically hailing from the carboxamide family. Employed to combat pathogenic fungi, it achieves this by impeding mitochondrial ATP production within their cells. 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.

Boscalid is active against different fungal stages on and in the plant. When applied protectively, boscalid inhibits spore germination and further development of germinated fungal spores. Due to its ability to penetrate into the leaf and its further translocation, it can also control fungal stages that have already become established in deeper tissue layers. Boscalid is effective under preventative and curative conditions.

Boscalid represents a fungicide with broad-spectrum capabilities, classified as a carboxamide (succinate dehydrogenase inhibitor). Its efficacy extends across various stages of fungal development, particularly impacting spore germination and germ tube elongation. Additionally, it hinders other critical stages such as appressoria formation and mycelial growth. Upon leaf absorption, boscalid undergoes translaminar and acropetal transport. Remarkably safe for plants, it provides extensive coverage against a wide array of diseases. This fungicide effectively manages diverse fungal pathogens in both arable and specialty crops, including ornamentals.

Prothioconazole is a very broad-spectrum fungicide with excellent residual activity, being active against seed and soil-borne pathogens in the seed treatment segment and exhibiting systemic activity when applied as a foliar spray. It controls diseases caused by pathogenic fungi from all three classes: Ascomycetes, Deuteromycetes and Basidiomycetes.

Prothioconazole is a member of the DMI (DeMethylation Inhibitors) fungicide group. It is a systemic fungicide that interferes with fungal sterol biosynthesis resulting in the impairment of membrane function and limitation of fungal growth. Ergosterol is a unique component of the membrane of fungi, the inhibition of its biosynthesis makes the cell membrane rigid and leaky, so that the pathogen's hyphae cannot grow and infect the plant. It inhibits growth of fungal mycelia during germ elongation and growth of mycelium in the plant tissue but does not act as germination inhibitor.

DMI fungicides act by inhibiting the Cytochrome P450-dependent C-14 demethylase reaction in fungal sterol biosynthesis. Blockage of the sterol biosynthesis leads to a reduction in the normal sterol pathway end products and an accumulation of other abnormal sterols.

FGE03 is a new co-formulated product containing prothioconazole and boscalid. No co-formulation containing prothioconazole and boscalid is currently registered on oilseed rape across Europe, but a large number of products containing solo formulations of prothioconazole or boscalid are available in all concerned member states. Table 3.2-3 presents some examples by countries (non-exhaustive list).

Table 3.2-3: Products containing solo prothioconazole or boscalid - List of authorizations granted by country - *Sclerotinia sclerotiorum* on oilseed rape (non-exhaustive list)

Country	Example of product of products based on Prothioconazole	Example of product of products based on Boscalid
CZ	<u>JOUST</u> (Prothioconazole 250 g/L, EC by Nufarm ; No. 5989-0) <u>PROLINE 250 EC</u> (Prothioconazole 250 g/L, EC by Bayer-Cropscience ; No. 4523-1) <u>PROTENDO 300 EC</u> (Prothioconazole 300 g/L, EC by Globachem-NV ; No. 5683-0)	<u>BOSET</u> (Boscalid 500 g/kg, WG by Sharda ; No. 5823-3) <u>PROPATAN</u> (Boscalid 500 g/kg, WG by BASF ; No. 4889-1)
PL	<u>JOUST 250 EC</u> (Prothioconazole 250 g/L, EC by Nufarm ; No. R-119/2023) <u>PRAKTIS</u> (Prothioconazole 250 g/L, EC by Sharda ; No. R-222/2019) <u>PROTENDO 300 EC</u> (Prothioconazole 300 g/L, EC by Globachem-NV ; No. R-224/2019)	<u>CANTUS</u> (Boscalid 500 g/kg, WG by BASF ; No. R-111/2018) <u>RASPUT</u> (Boscalid 500 g/kg, WG by Globachem-NV ; No. R-86/2022) <u>ROYALTY</u> (Boscalid 500 g/kg, WG by Sharda ; No. R-188/2019)
HU	<u>JOUST 250 EC</u> (Prothioconazole 250 g/L, EC by Nufarm ; No. 6700/0032591-1/2024) <u>PATEL 300 EC</u> (Prothioconazole 300 g/L, EC by Globachem-NV ; No. 6300/731-2/2021) <u>PROTENDO 300 EC</u> (Prothioconazole 300 g/L, EC by Globachem-NV ; No. 6300/731-1/2021)	<u>CANTUS</u> (Boscalid 500 g/kg, WG by BASF ; No. 47140/2004) <u>RASPUT</u> (Boscalid 500 g/kg, WG by Globachem-NV ; No. 6700/1346-1/2023) <u>ROYALTY</u> (Boscalid 500 g/kg, WG by Sharda ; No. 6300/3300-1/2021)

Description of the target pest

FGE03 is intended for professional use as a fungicide for the control of *Sclerotinia sclerotiorum* on Oilseed rape.

The main target of FGE03 can found in the below.

Table 3.2-4: Glossary of pest mentioned in the dossier

Crop	Pest		
	EPPO code	Scientific name	Common name
Oilseed rape (BRSNN)	SCLESC	<i>Sclerotinia sclerotiorum</i>	Sclerotinia stem rot

Fungal diseases can cause considerable yield and quality losses on crops, which can be reduced using appropriate disease control strategies including the application of fungicides relevant to the particular disease situation. Below is a short description of the targeted disease that FGE03 will control when applied as a foliar spray to the crop mentioned.

Sclerotinia sclerotiorum (SCLESC) is the causative agent responsible for sclerotinia stem rot, impacting a broad spectrum of crops. Yield loss of 30 % is possible in rapeseed.

This soil-borne disease endures in the soil through sclerotia, small black dots ranging from 1 to 10 mm, with the ability to remain dormant for up to a decade. During the spring, under favourable conditions such as soil moisture and temperatures exceeding 10°C, sclerotia can undergo germination. This process leads to the formation of apothecia, and when mature, these apothecia release spores. These spores pose a threat by contaminating the surfaces of plants, particularly adhering to petals. Petal contamination is a crucial factor in the disease propagation, as it adheres to leaf and stem surfaces, providing a conducive environment for spore germination and penetration into the plant.

Initially, the first symptoms manifest as pale brown patches, but the more distinctive signs of the disease become apparent later in the season. These include large white lesions on stems, at times accompanied by visible black sclerotia on the surface and numerous sclerotia inside the stem or root cavity. These lesions contribute to premature pod ripening by disrupting nutrient and water supply. The sclerotia produced during the crop cycle act as a fresh source of contamination for the soil and other crops through harvest contamination.

Conditions conducive to the disease's prevalence include a history of soil contamination, adequate temperature, and showery conditions during flowering, facilitating the adherence of fallen petals during the contamination period. The critical phase for safeguarding crops against sclerotinia is during early to mid-flowering¹.

General information on the crop

The following table shows the crop area of oilseed rape in countries involved in this request.

Table 3.2-5: General information on OSR area (source: Eurostat², average on 2014-2023)

Country	Crop area x 1000 ha
	Oilseed rape
PL	951
CZ	377
HU	259

Major/minor status of intended uses

According to the applicant's actual knowledge and the database of EUMUDA3 the major/minor crop/pest status is given in the Table 3.2-6 below.

¹ Koch, S. *et al.*, 2007. [A crop loss-related forecasting model for Sclerotinia stem rot in winter oilseed rape. Analytical and theoretical plant pathology.](#)

² Eurostat - [Link](#) (accessed in May 2024).

³ EUMUDA European Minor Uses Database - [Link](#) (accessed in December 2023).

In some countries, only the crop status was available, not the pest status. In such a situation, if the crop is considered a major crop, and given the detrimental effect the pests can have on the respective crops, pests relevant for this crop in the context of this dossier were also considered as major. On the contrary, if the crop was given to be a minor crop, pests relevant for this crop in the context of this dossier were considered as minor.

Table 3.2-6: Major / minor status of intended uses (for all cMS and zRMS)

Crop and/or situation	Country	Crop status*		Pests or group of pests controlled	Pest status*	
		Major	Minor		Major	Minor
Oilseed rape (BRSNN)	CZ	X		<i>Sclerotinia sclerotiorum</i> (SCLESC)	X	
	PL	X (BRSNW)	X (BRSNS)		X	
	HU	X			X	

Compliance with the Uniform Principles

The overall assessment was performed according to the Uniform Principles.

All the trials were carried out by officially recognised organisations which follow the EPPO standards and are officially recognised by the competent authorities to perform efficacy testing in accordance with the principles of Good Experimental Practice (GEP).

The testing facilities responsible for the conduct of the efficacy trials are detailed in point 3.7 where a copy of official compliance certificates is presented.

The trials included in this dossier followed the requirements of the general EPPO standards:

- PP 1/239(3) ‘Dose expression for plant protection products’;
- PP 1/152(4) ‘Design and analysis of efficacy evaluation trials’;
- PP 1/181(4 or 5) ‘Conduct and reporting of efficacy evaluation trials including good experimental practice’;
- PP 1/223(2), (4) ‘Introduction to the efficacy evaluation of plant protection products’;
- PP 1/225(2), (4) ‘Minimum effective dose’;
- PP 1/135(4) ‘Phytotoxicity assessment’.

The trials also followed the requirements of the specific efficacy EPPO standard PP 1/78(3 or 4) ‘Root, stem, foliar and pod disease of rape’.

Justification for inclusion of data from other formulations

All data included in this dossier has been generated using the formulation FGE03 to be registered.

Justification for the inclusion of data from different nations

Location of trials

The locations and geographical distribution of all individual trials summarised in this dossier are shown in maps presented in Figure 3.2-1.

Justification for inclusion of data from different nations

According to EPPO PP 1/241(1) zones, the Central registration zone is composed of 3 EPPO climatic zones: Maritime, North-East and South-East zone.

Table 3.2-7: EPPO climatic zones concerning by Member state of Central EU zone concerning by this request

Use (Crop*Target)	Member state requested	EPPO climatic zone ⁽¹⁾	Location of trials to cover EPPO climatic zone
Oilseed rape * <i>Sclerotinia sclerotiorum</i>	Czech Republic	Maritime	Maritime AT, BE, CZ, DE, DK ⁽²⁾ , FR (North) ⁽²⁾ , IE, SE ⁽²⁾ , UK ⁽²⁾
	Poland	North-East	North-East PL, LT ⁽²⁾
	Hungary	South-East	South-East HU, RO, BG ⁽²⁾

⁽¹⁾ EPPO climatic zone according to guidelines presented in EPPO standard PP 1/241(2) '*Guidance on comparable climates*'.

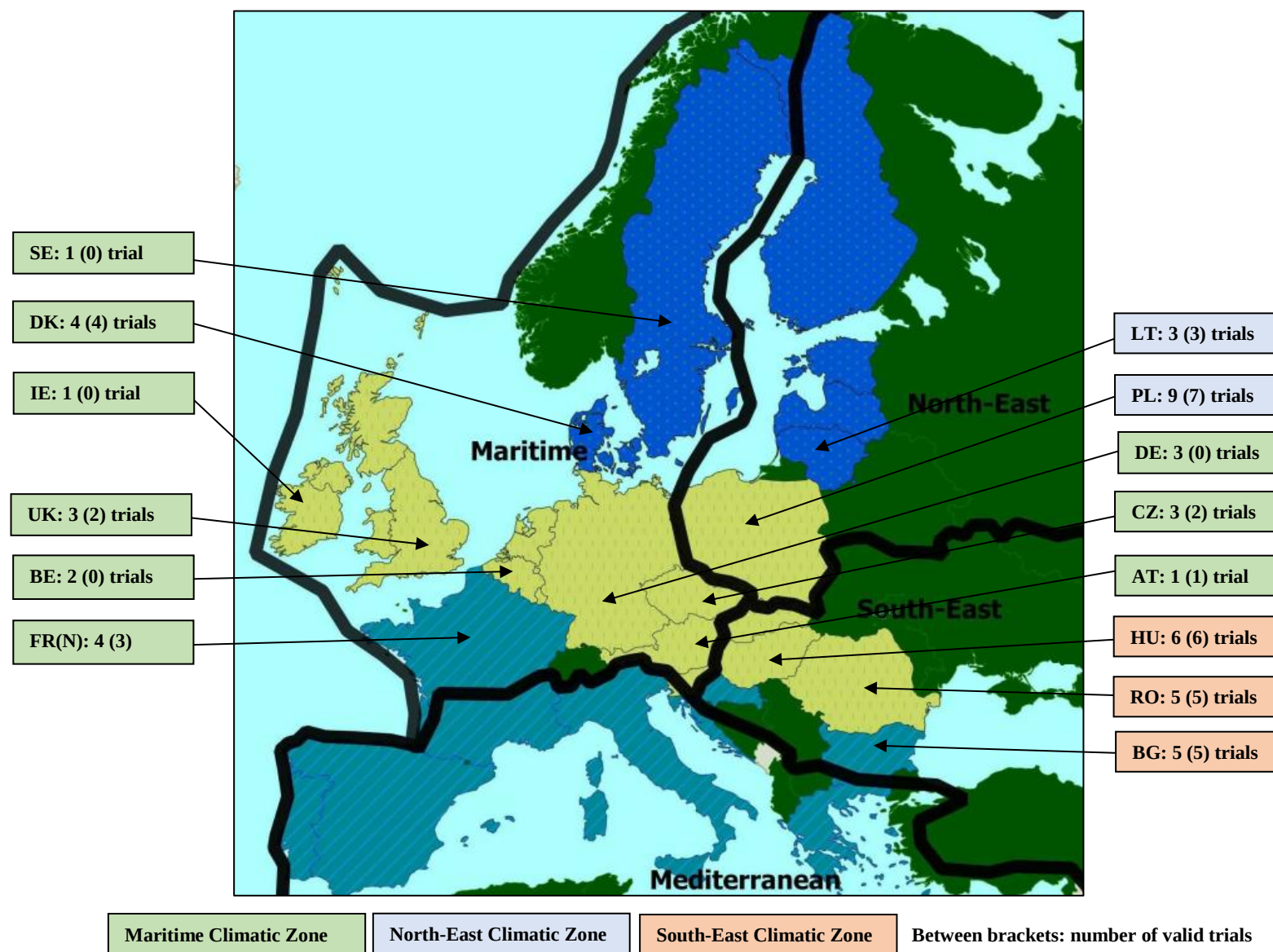
⁽²⁾ Extra-zonal data obtained from trials carried out in countries of the Southern and Northern EU zone belonging to the Maritime, North-East and South-East EPPO climatic zone.

Data from the Southern and Northern registration zones were also used in this dossier to support Czech Republic (Maritime EPPO climatic zone), Poland (North-East climatic EPPO zone) and Hungary (South-East climatic EPPO zone). These trials were performed in Denmark, North of France, Sweden and the United Kingdom belonging to the Maritime EPPO climatic zone; Lithuania belonging to the North-East EPPO climatic zone; and Bulgaria belonging to the South-East EPPO climatic zone, according to EPPO PP 1/241(1) '*Guidance on comparable climates*'.

Similar trial methodologies were used in all countries. All trials are in compliance with GEP and were undertaken by official or officially recognised testing facilities in accordance with the relevant EPPO guideline. Furthermore, identical methods of assessment for efficacy and crop tolerance were employed. Trial sites were selected on the basis of known disease infestations and located within a commercial area in each respective country, grown according to the principles of good agricultural practice (GAP). These areas have been found to be particularly suitable for all crops due to their innate similarity in terms of soil type and climate.

In addition, according to Poland national guidance [Skuteczność działania środków ochrony roślin; updated on 15/09/2023], that data from countries adjacent to PL can be considered supportive. Therefore, data from CZ is also relevant for PL and presented in this dossier.

Figure 3.2-1: Location of the trial sites - Efficacy trials - Oilseed rape



Information on trials submitted (3.2 Efficacy data)

The efficacy of FGE03 (350 g/kg boscalid + 200 g/kg prothioconazole) against *Sclerotinia sclerotiorum* in winter oilseed rape was investigated in a total of 50 trials carried out from 2022 to 2024.

Among these trials, 22 trials were carried out in Maritime EPPO climatic zone (Austria, Belgium, Czech Republic, Germany, Northern France, Denmark, Ireland and the United Kingdom), 12 trials in North-East EPPO climatic zone (with trials carried out in Poland and Lithuania), 16 trials in South-East (with trials carried out in Bulgaria, Hungary and Romania).

All efficacy data are generated on winter oilseed rape (BRSNW), but it is fully supportive of the GAP and label which requests both winter and spring variants. Indeed, it is known that the fungicide activity on plants depends more on susceptibility properties of oilseed rape varieties to fungal diseases than on winter/spring type, it is considered that results obtained on winter oilseed rape can be extrapolated to spring oilseed rape and vice versa. In addition, this is supported by the EPPO Extrapolation Database (use ID 438) which indicates that data can be generated on oilseed rape in general (BRSNN), and does not specify an exact variant.

Both winter and spring oilseed rape have comparable crop phenology and agronomy. Although there is a difference in sowing timing, spring oilseed rape develops quickly; and as application in both crops is at flowering, which generally occurs around the same time in both crop variants, it is considered that both crops are at the same development stage and thus a similar control against *Sclerotinia sclerotiorum* after FGE03 application is expected.

To cover the largest spectrum of climatic, soil conditions, trials were located in the Maritime, North-East and South-East climatic zones in the main crops production areas.

A summary of the submitted efficacy trials is provided in Table 3.2-8 and Table 3.2-9 below. Table 3.2-10 gives an overview of the reference products used in the trials.

Table 3.2-8: Trials repartition: preliminary, minimum effective dose and efficacy trials

Crop	Target	Year	EPPO climatic zone (number of valid trials)														Total
			Maritime									South-East			North-East		
			AT	BE	CZ	DE	DK	FR(N)	UK	IE	SE	BG	HU	RO	LT	PL	
Oilseed rape	SCLESC	2022	-	-	2 (2)	-	2 (2)		1 (0)	-	-	-	3 (3)	-	2 (2)	2 (0)	12 (9)
		2023	-	-	1 (0)	2 (0)	-	2 (2)	1 (1)	1 (0)	-	2 (2)	2 (2)	-	4 (4)	17 (13)	
		2024	1 (1)	2 (0)	-	1 (0)	2 (2)	2 (1)	1 (1)	-	1 (0)	3 (3)	1 (1)	3 (3)	1 (1)	3 (3)	21 (16)
Total		2022-2024	1 (1)	2 (0)	3 (2)	3 (0)	4 (4)	4 (3)	3 (2)	1 (0)	1 (0)	5 (5)	6 (6)	5 (5)	3 (3)	9 (7)	50 (38)

Table 3.2-9: Presentation of preliminary, minimum effective dose and efficacy trials

Crop(s)*	Target(s)*	Country	Years	Type of trials**	Application number of FGE03	Number of trials (number of valid trials****)			GEP, non-GEP, official***
						Maritime zone	North-East zone	South-East zone	
Winter oilseed rape (BRSNW)	<i>Sclerotinia sclerotiorum</i> (SCLESC)	AT	2024	PRE+MED+E	1	1 (1)	-	-	GEP
		BE	2024	PRE+MED+E	1	2 (0)	-	-	GEP
		CZ	2023	E	1	1 (0)	-	-	GEP
		DE	2023	E	1	2 (0)	-	-	GEP
			2024	PRE+MED+E	1	1 (0)	-	-	GEP
		DK	2024	MED+E	1	2 (2)	-	-	GEP
		IE	2023	E	1	1 (0)	-	-	GEP
		UK	2024	PRE+MED+E	1	1 (1)	-	-	GEP
		SE	2024	MED+E	1	1 (0)	-	-	GEP
		FR	2023	E	1	2 (2)	-	-	GEP
			2024	PRE+MED+E	1	2 (1)			GEP
		LT	2024	PRE+MED+E	1	-	1 (1)	-	GEP
		PL	2024	PRE+MED+E	1	-	3 (3)	-	GEP
		BG	2024	PRE+E	1	-	-	1 (1)	GEP
			2024	PRE+MED+E	1	-	-	2 (2)	GEP
		HU	2023	E	1	-	-	2 (2)	GEP
			2024	PRE+MED+E	1	-	-	1 (1)	GEP
		RO	2023	E	1	-	-	2 (2)	GEP
			2024	PRE+MED+E	1	-	-	2 (2)	GEP
			2024	PRE+E	1	-	-	1 (1)	GEP
		Total of trials - 1 application				16 (7)	4 (4)	11 (11)	31 (22)
		CZ	2022	MED+E	2	2 (2)	-	-	GEP
		DK	2022	MED+E	2	2 (2)	-	-	GEP
		UK	2022	MED+E	2	1 (0)	-	-	GEP
			2023	MED+E	2	1 (1)	-	-	GEP
		LT	2022	MED+E	2	-	2 (2)	-	GEP

		PL	2022	MED+E	2	-	2 (0)	-	GEP
			2023	MED+E	2	-	4 (4)	-	GEP
		BG	2023	MED+E	2	-	-	2 (2)	GEP
		HU	2022	MED+E	2	-	-	3 (3)	GEP
		Total of trials - 2 applications				6 (5)	8 (6)	5 (5)	17 (16)
		Total of trials					22 (12)	12 (10)	16 (16)

* According to the GAP table.

** PRE = Preliminary / interest of the mixture and ration justification, MED = Minimum Effective Dose, E = Efficacy.

*** GEP: Good Experimental Practices, Official: carried out by a national official organisation.

**** Trials considered valid for the efficacy analysis: sufficient infestation level in the untreated plot and expected behaviour of the reference product.

Table 3.2-10: Presentation of reference standards used in preliminary, minimum effective dose and efficacy trials

Crop(s)* target(s)	Reference standard	Country(ies) where the product is registered ⁽¹⁾	Authorisation number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)*	Remark ⁽⁴⁾
					Type ⁽²⁾	Conc. of a.s.			
Reference products based on prothioconazole solo									
Winter oilseed rape (BRSNW)* <i>Sclerotinia sclerotiorum</i> (SCLESC)	PROLINE	AT	3371-0	prothioconazole	EC	250 g/L	0.7 L/ha	0.7 L/ha	175 g a s/ha
	PROLINE*	BE	9805P/B	prothioconazole	EC	250 g/L	Not registered on winter oilseed rape	0.7 L/ha	175 g a s/ha
	PROLINE	BG	Not registered	prothioconazole	EC	250 g/L	Not registered	0.7 L/ha	175 g a s/ha
	MELVAR	BG	02031- 1/31.01.2023	prothioconazole	EC	250 g/L	0.7 L/ha	0.7 L/ha	175 g a s/ha
	PROLINE 250 EC	CZ	4523-1	prothioconazole	EC	250 g/L	0.7 L/ha	0.7 L/ha	175 g a s/ha
	PROLINE	DE	025287-00	prothioconazole	EC	250 g/L	0.7 L/ha	0.7 L/ha	175 g a s/ha
	PROLINE ~~EC~~ 250*	DK	18-473/72200	prothioconazole	EC	250 g/L	Not registered on winter oilseed rape	0.7 L/ha	175 g a s/ha
	JOAO	FR	2060116	prothioconazole	EC	250 g/L	0.7 L/ha	0.7 L/ha	175 g a s/ha
	PROLINE	UK	12084	prothioconazole	EC	250 g/L	0.7 L/ha	0.7 L/ha	175 g a s/ha
	PROLINE*	HU	6300/1205-1/2020	prothioconazole	EC	250 g/L	Not registered on winter oilseed rape	0.7 L/ha	175 g a s/ha
	PROLINE	IE	03786	prothioconazole	EC	250 g/L	0.7 L/ha	0.7 L/ha	175 g a s/ha
	PROLINE*	LT	AS2-6F(2018)	prothioconazole	EC	250 g/L	Not registered on winter oilseed rape	0.7 L/ha	175 g a s/ha

Crop(s)* target(s)	Reference standard	Country(ies) where the product is registered ⁽¹⁾	Authorisation number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)*	Remark ⁽⁴⁾
					Type ⁽²⁾	Conc. of a.s.			
	PROLINE*	PL	Not registered	prothioconazole	EC	250 g/L	Not registered	0.7 L/ha	175 g a s/ha
	PRAKTIS 250	PL	R-222/2019	prothioconazole	EC	250 g/L	0.7 L/ha	0.7 L/ha	175 g a s/ha
	PROLINE	RO	457PC	prothioconazole	EC	250 g/L	0.7 L/ha	0.7 L/ha	175 g a s/ha
	PROLINE	SE	4688	prothioconazole	EC	250 g/L	0.7 L/ha	0.7 L/ha	175 g a s/ha
	PROLINE 275	UK	14790	prothioconazole	EC	275 g/L	0.63 L/ha	0.63 L/ha	173 g a s/ha
	PROTENDO 300 EC	HU	6300/731-1/2021	prothioconazole	EC	300 g/L	0.3-0.6 L/ha	0.6 0.58 L/ha	180 174 g a s/ha
	PROTENDO 300 EC	LT	AS2-20F(2020)	prothioconazole	EC	300 g/L	0.3-0.6 L/ha	0.6 0.58 L/ha	180 174 g a s/ha
	PROTENDO 300 EC	PL	R-224/2019	prothioconazole	EC	300 g/L	0.3-0.6 L/ha	0.58-0.6 L/ha	174-180 g a s/ha
Reference products based on boscalid solo									
Winter oilseed rape (BRSNW)* <i>Sclerotinia sclerotiorum</i> (SCLESC)	CANTUS	AT	3149-0	Boscalid	WG	500 g/kg	0.5 kg/ha	0.5 kg/ha	250 g as/ha
	CANTUS	BE	9582P/B	Boscalid	WG	500 g/kg	0.5 kg/ha	0.5 kg/ha	250 g as/ha
	CANTUS	BG	09-664/09.12.2004r	Boscalid	WG	500 g/kg	0.5 kg/ha	0.5 kg/ha	250 g as/ha
	CANTUS	DE	025180-00	Boscalid	WG	500 g/kg	0.5 kg/ha	0.5 kg/ha	250 g as/ha
	CANTUS	HU	47140/2004	Boscalid	WG	500 g/kg	0.3-0.5 kg/ha	0.5 kg/ha	250 g as/ha
	CANTUS	LT	AS2-34F(2019)	Boscalid	WG	500 g/kg	0.5 kg/ha	0.5 kg/ha	250 g as/ha
	CANTUS	PL	R-111/2018	Boscalid	WG	500 g/kg	0.2-0.5 kg/ha	0.5 kg/ha	250 g as/ha
	CANTUS	RO	2760	Boscalid	WG	500 g/kg	0.2-0.5 kg/ha	0.5 kg/ha	250 g as/ha
	PICTOR PRO	FR	2050075	Boscalid	WG	500 g/kg	0.5 kg/ha	0.5 kg/ha	250 g as/ha
Reference products based on Prothioconazole + tebuconazole									
Winter oilseed rape (BRSNW)* <i>Sclerotinia</i>	TILMOR	CZ	4775-2	Prothioconazole + tebuconazole	EC	80 g/L + 160 g/L	1.0 L/ha	1.0 L/ha	80 g as/ha +160 g as/ha
	TILMOR	HU	04.2/7910/1/2011	Prothioconazole + tebuconazole	EC	80 g/L + 160 g/L	1.2 L/ha	1.2 L/ha	96 g as/ha +192 g as/ha

Crop(s)* target(s)	Reference standard	Country(ies) where the product is registered ⁽¹⁾	Authorisation number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)*	Remark ⁽⁴⁾
					Type ⁽²⁾	Conc. of a.s.			
<i>sclerotiorum</i> (SCLESC)	TILMOR	RO	2831	Prothioconazole + tebuconazole	EC	80 g/L + 160 g/L	1.0 L/ha	1.0 L/ha	80 g as/ha +160 g as/ha
	PROSARO EC 250	DK	18-667/72516	Prothioconazole + tebuconazole	EC	125 g/L + 125 g/L	0.54-1.5 L/ha	1.0 L/ha	125 g as/ha +125 g as/ha

*In Belgium, Denmark, Hungary and Lithuania, PROLINE is not registered on winter oilseed rape against *Sclerotinia sclerotiorum* but on cereals only. In Poland and Bulgaria, PROLINE is not registered at all.

However, similar products (active substance, concentration and formulation type) are registered in each country on oilseed rape against *Sclerotinia sclerotiorum*. (e.g. JOUST in Belgium (No. 32908P/B); PRAKTIS 250 in Poland (No. R-222/2019), INNOX in Lithuania (No. AS2-38F(2023), MELVAR in Bulgaria (No. 02031-1/31.01.2023), JOUST 250 EC in Hungary (No. 6700/0032591-1/2024). In Denmark no product based on prothioconazole solo are available but the efficacy of prothioconazole is well known and many products are approved in neighbouring countries.

In the concerned trials, although PROLINE is not a registered reference product, the product was included as a transversal zonal reference product to allow comparison to other trials where the product is registered for the proposed use. Other additional locally registered products registered for the proposed use was also included to act as valid reference products.

3.2.1 Preliminary tests (KCP 6.1)

FGE03 is a product containing 2 active substances, boscalid (350 g/kg) and prothioconazole (200 g/kg). According to FRAC (FRAC recommendations for fungicide mixtures, 2010⁴), the interest of a mixture is to extend the spectrum of activity compared to each of the mixture components applied alone, to secure the disease control when resistance is present and to ensure a good management of resistance (presented in point 3.3).

In this part, to confirm the interest of each active substance in this mixture, 14 efficacy field trials were conducted in oilseed rape in 2024. FGE03 was compared to prothioconazole straight and boscalid straight.

Among these 14 trials, 13 trials were to study the ratio between both active substances contained in FGE03.

The following Table 3.2-11 presents an overview of trials used in this preliminary part.

Table 3.2-11: Overview of preliminary tests - Oilseed rape - *Sclerotinia sclerotiorum*

Number of trials	Crop	Pest	Year	Country	EPPO climate zone	Comment
1 trial	BRSNN	SCLESC	2024	FR	Maritime	-
1 trial	BRSNN	SCLESC	2024	AT	Maritime	-
1 trial	BRSNN	SCLESC	2024	UK	Maritime	-
3 trials	BRSNN	SCLESC	2024	PL	Northeast	-
1 trial	BRSNN	SCLESC	2024	LT	Northeast	-
3 trials	BRSNN	SCLESC	2024	BG	Southeast	-
1 trial	BRSNN	SCLESC	2024	HU	Southeast	-
3 trials	BRSNN	SCLESC	2024	RO	Southeast	-

3.2.1.1 Material and methods

The justification of the association boscalid and prothioconazole containing in FGE03 product was supported by the data from 14 valid efficacy trials carried out in 2024 in oilseed rape. These trials are also used to justify the minimum effective dose and the efficacy of FGE03. Therefore, Material and Methods used in these efficacy trials are given within Section 3.2.3.1 “Efficacy tests (KCP 6.2)”.

Table 3.2-12 presents the characteristics of protocols used in the preliminary trials.

Table 3.2-12: Main characteristics of protocols used preliminary trials

Number of trials	FGE03 at 0.7 kg/ha	Interest of each active substance in this mixture		Study the ratio between the 2 active substances	
	Boscalid + Prothio 245 + 140 g a.s./ha [1N+1N]	Boscalid 250 g a.s./ha [equivalent to 1N]	Prothio 140 g a.s./ha [equivalent to 1N]	Boscalid + Prothio 250 + 70 g a.s./ha [1N+0.5N]	Boscalid + Prothio 125 + 140 g a.s./ha [0.5+1N]
13 trials	X	X	X	X	X
1 trial	X	X	-	-	-

3.2.1.1.1 Benefit of the mixture of boscalid and prothioconazole in FGE03 to control *Sclerotinia sclerotiorum* in oilseed rape

A total of 14 valid efficacy trials are available to study the benefit of the association of boscalid and prothioconazole in FGE03 product for the control of *Sclerotinia sclerotiorum* in oilseed rape. These trials were carried out in 2024.

⁴ FRAC; FRAC recommendations for fungicide mixtures designed to delay resistance evolution; 2010; [link](#) (consulted in July 2024).

A. Benefit of the mixture of boscalid and prothioconazole on oilseed rape (BRSNN) - *Sclerotinia sclerotiorum* (SCLESC) - 1 application - Maritime EPPO climatic zone

Against *Sclerotinia sclerotiorum*, a total of 3 valid efficacy trials were carried out to confirm the interest of this association boscalid + prothioconazole in the product FGE03. These trials were carried out in 2024 in the Maritime EPPO climatic zone in Austria (1 trial), North of France (1 trial) and the United Kingdom (1 trial).

Table 3.2-13 presents a summary of the results.

Table 3.2-13: Summary results: Comparison of efficacy between prothioconazole applied alone (140 g a.i./ha), boscalid applied alone (250 g a.i./ha) and FGE03: prothioconazole and boscalid mixed (140 g a.i./ha + 245 g a.i./ha) - Oilseed rape - SCLESC on stems - Maritime EPPO climatic zone - 1 application

Parameters	Assessment timing	Parts	EPPO climatic zone	No. of trials	Days after application	Untreated (% of infestation)			% Control												No. of trials where Prothio + Boscalid ha is statistically ⁽¹⁾ > ; = ; < compared to	
									FGE03 Prothioconazole + Boscalid 140 + 245 g a.i./ha Application : A				Prothioconazole 140 g a.i./ha Application : A				Boscalid 250 g a.i./ha Application : A					
						Mean	Min	Max	Mean	Min	Max	SD	Mean	Min	Max	SD	Mean	Min	Max	SD	Prothio 140 g a.i./ha	Boscalid 250 g a.i./ha
Severity (%)	BBCH 82-87	STEM	Maritime	3	[54-74 DA-A]	19.1	6.4	37.9	79.2	70.5	88.2	8.8	68.0	50.5	80.8	15.7	54.0	25.5	72.3	25.0	0>;3=;0<	1>;2=;0<
Incidence (%)	BBCH 82-87	STEM	Maritime	3	[54-74 DA-A]	50.0	31.0	61.0	46.5	36.6	61.2	13.0	37.3	18.0	59.0	20.6	18.2	9.0	30.0	10.8	0>;3=;0<	2>;1=;0<

⁽¹⁾ Comparison based on statistics carried out in each trial report.

In these trials, at the assessment (BBCH 82⁷⁵-87), in the untreated control, the average infestation was good (19% disease severity and 50% disease incidence on stems on average across 3 trials), varying from 6% to 38% disease severity, and from 31% to 61% disease incidence in individual trials.

On disease severity, the benefit of the mixture was clearly shown with a synergy between the two active substances. Indeed, the mixture (FGE03) gave 79.2% mean control, 11.2 points higher than Prothioconazole applied alone (68.0% mean control) and 25.2 points higher than Boscalid applied alone (54.0% mean control). In addition, a statistical effect was highlighted in 1 out of 3 trials between the mixture (FGE03) vs. Boscalid applied alone. Moreover, the mixture was characterised by a better homogeneity of control than both active substances applied alone.

Regarding disease incidence, the synergy is confirmed.

To conclude, the synergy between both active substances Prothioconazole and Boscalid for the control of *Sclerotinia sclerotiorum* in oilseed rape was clearly demonstrated in a set of 3 trials in the Maritime EPPO climatic zone.

B. Benefit of the mixture of boscalid and prothioconazole on oilseed rape (BRSNN) - *Sclerotinia sclerotiorum* (SCLESC) - 1 application - North-East EPPO climatic zone

Against *Sclerotinia sclerotiorum*, a total of 4 valid efficacy trials were carried out to confirm the interest of this association Boscalid + prothioconazole in the product FGE03. These trials were carried out in 2024 in the North-East EPPO climatic zone in Lithuania (1 trial) and Poland (3 trials).

Table 3.2-14 presents a summary of the results.

Table 3.2-14: Summary results: Comparison of efficacy between prothioconazole applied alone (140 g a.i./ha), boscalid applied alone (250 g a.i./ha) and FGE03: prothioconazole and boscalid mixed (140 g a.i./ha + 245 g a.i./ha) - Oilseed rape - SCLESC on stems - North-East EPPO climatic zone - 1 application

Parameters	Assessment timing	Parts	EPPO climatic zone	No. of trials	Days after application	Untreated (% of infestation)			% Control												No. of trials where Prothio + Boscalid ha is statistically ⁽¹⁾ > ; = ; < compared to	
									FGE03 Prothioconazole + Boscalid 140 + 245 g a.i./ha Application : A				Prothioconazole 140 g a.i./ha Application : A				Boscalid 250 g a.i./ha Application : A					
						Mean	Min	Max	Mean	Min	Max	SD	Mean	Min	Max	SD	Mean	Min	Max	SD	Prothio 140 g a.i./ha	Boscalid 250 g a.i./ha
Severity (%)	BBCH 85-87	STEM	North-East	3	[46-47 DA-A]	18.5	17.6	19.4	96.7	96.5	96.9	0.2	93.7	93.3	94.3	0.6	97.4	97.3	97.5	0.1	2>;1=;0<	0>;3=;0<
	BBCH 85-87	STEM	North-East	4	[46-53 DA-A]	21.3	17.6	29.6	93.9	85.6	96.9	5.5	-	-	-	-	89.3	65.1	97.5	16.1	-	1>;3=;0<
Incidence (%)	BBCH 85-87	STEM	North-East	3	[46-47 DA-A]	37.7	37.0	39.0	90.2	89.2	91.7	1.3	82.3	78.3	86.4	4.1	90.2	89.2	91.7	1.3	1>;2=;0<	0>;3=;0<
	BBCH 85-87	STEM	North-East	4	[46-53 DA-A]	44.0	37.0	63.0	84.9	68.8	91.7	10.7	-	-	-	-	78.4	42.8	91.7	23.7	-	1>;3=;0<

In these trials, at the assessment (BBCH 85-87), in the untreated control, the average infestation was good (21% disease severity and 44% disease incidence on stems on average across 4 trials), varying from 18% to 30% disease severity and from 37% to 63% disease incidence in individual trials.

On disease severity, compared to Prothioconazole applied alone, the benefit of the mixture was slightly showed in 3 trials. Indeed, the mixture (FGE03) gave 96.7% mean control, 3.0 points higher than Prothioconazole applied alone (93.7% mean control). In addition, a statistical effect was highlighted in 2 out of 3 trials between the mixture (FGE03) vs. Prothioconazole applied alone.

Compared to Boscalid applied alone, the benefit of the mixture was slightly showed considering the average efficacy from 4 trials. Indeed, the mixture (FGE03) gave 93.9% mean control, 4.6 points higher than Boscalid applied alone (89.3% mean control). In addition, a statistical effect was highlighted in 1 out of 4 trials between the mixture (FGE03) vs. Boscalid applied alone.

Regarding disease incidence, the interest of the mixture compared to both active substances applied alone is confirmed.

The results on the synergy between Prothioconazole and Boscalid in the mixture (FGE03) is more pronounced in the Maritime (see paragraph A) and the South-East zone (see paragraph C). Indeed, the Central registration zone is composed of 3 EPPO climatic zones where oilseed rape is a major crop, and has similar agricultural practices in these 3 areas. However, *Sclerotinia sclerotiorum* development is overall similar but can represent a greater challenge in Maritime and South-East EPPO zones.

To conclude, the interest of Prothioconazole and Boscalid for the control of *Sclerotinia sclerotiorum* in oilseed rape was clearly demonstrated in a set of 4 trials in the North-East EPPO climatic zone.

C. Benefit of the mixture of boscalid and prothioconazole on oilseed rape (BRSNN) - *Sclerotinia sclerotiorum* (SCLESC) - 1 application - South-East EPPO climatic zone

Against *Sclerotinia sclerotiorum*, a total of 7 valid efficacy trials were carried out to confirm the interest of this association boscalid + prothioconazole in the FGE03 product. These trials were carried out in 2024 in the South-East EPPO climatic zone in Bulgaria (3 trials), Hungary (1 trial) and Romania (3 trials).

Table 3.2-15 presents a summary of the result.

Table 3.2-15: Summary results: Comparison of efficacy between prothioconazole applied alone (140 g a.i./ha), boscalid applied alone (250 g a.i./ha) and FGE03: prothioconazole and boscalid mixed (140 g a.i./ha + 250 g a.i./ha) - Oilseed rape - SCLESC on stems - South-East EPPO climatic zone - 1 application

Prothioconazole and Boscalid mixed (140 g a.i./ha + 250 g a.i./ha) - Shadedrape - SELESC systems - South-East EPPO climatic zone - Fungicide																						
Parameters	Assessment timing	Parts	EPPO climatic zone	No. of trials	Days after application	Untreated (% of infestation)			% Control												No. of trials where Prothio + Boscalid ha is statistically ⁽¹⁾ > ; = ; < compared to	
									FGE03 Prothioconazole + Boscalid 140 + 245 g a.i./ha Application : A				Prothioconazole 140 g a.i./ha Application : A				Boscalid 250 g a.i./ha Application : A					
						Mean	Min	Max	Mean	Min	Max	SD	Mean	Min	Max	SD	Mean	Min	Max	SD	Prothio 140 g a.i./ha	Boscalid 250 g a.i./ha
Severity (%)	BBCH 77-87	STEM	South-East	7	[42-60 DA-A]	9.8	5.2	21.6	79.8	59.0	94.4	13.7	61.1	48.5	83.5	12.8	69.0	49.3	86.4	15.0	5>;2=;0<	2>;5=;0<
Incidence (%)	BBCH 83-87	STEM	South-East	6	[42-60 DA-A]	51.5	16.0	74.0	64.8	37.1	87.7	20.1	38.9	0.0	58.5	22.6	51.2	24.6	79.7	19.4	4>;2=;0<	2>;4=;0<

⁽¹⁾ Comparison based on statistics carried out in each trial report.

In these trials, at the assessment (BBCH 77~~75~~-87), in the untreated control, the average infestation was moderate (10% disease severity and 52% disease incidence on stems on average across 7 trials), varying from 5% to 22% disease severity and from 16% to 74% disease incidence in individual trials.

On disease severity, the benefit of the mixture was clearly shown with a synergy between the two active substances. Indeed, the mixture (FGE03) gave 79.8% mean control, 18.7 points higher than Prothioconazole applied alone (61.1% mean control) and 10.8 points higher than Boscalid applied alone (69.0% mean control). In addition, a statistical effect was highlighted in 5 out of 7 trials between the mixture (FGE03) vs. Prothioconazole applied alone, and in 2 out of 7 trials between the mixture (FGE03) vs. Boscalid applied alone.

Regarding disease incidence, the synergy is confirmed.

To conclude, the synergy between both active substances Prothioconazole and Boscalid for the control of *Sclerotinia sclerotiorum* in oilseed rape was clearly demonstrated in a set of 7 trials in South-East EPPO climatic zone .

D. Conclusion: Benefit of the mixture of boscalid and prothioconazole on oilseed rape (BRSNN) - *Sclerotinia sclerotiorum* (SCLESC) - 1 application - All EPPO climatic zone

Against *Sclerotinia sclerotiorum*, a total of 14 valid efficacy trials were carried out to confirm the interest of this association Boscalid + prothioconazole in the product FGE03. These trials were carried out in 2024 in the Maritime (3 trials), North-East (4 trials) and South-East EPPO (7 trials) climatic zones.

Table 3.2-16 presents a summary of the results to confirm the interest of this association and Figure 3.2-2 (disease severity) and Figure 3.2-3 (disease incidence) represent the benefit of the mixture of boscalid and prothioconazole in box plot graphics against *Sclerotinia sclerotiorum*.

Table 3.2-16: Summary results: Comparison of efficacy between prothioconazole applied alone (140 g a.i./ha), boscalid applied alone (250 g a.i./ha) and FGE03: prothioconazole and boscalid mixed (140 g a.i./ha + 245 g a.i./ha) - (% control based on disease severity and incidence on stems at BBCH 77-87) in oilseed rape to control *Sclerotinia sclerotiorum* - 1 application

Crop code	Pest code	Regulatory zone	EPPO climatic zone	Parameters	No. of trials	Untreated (% of infestation)	% Control			No. of trials where Prothio + Boscalid ha is statistically ⁽¹⁾ > ; = ; < compared to	
							FGE03 Prothioconazole + Boscalid	Prothioconazole	Boscalid	Prothio 140 g a.i./ha	Boscalid 250 g a.i./ha
							140 + 245 g a.i./ha Application : A	140 g a.i./ha Application : A	250 g a.i./ha Application : A		
BRSNN	SCLESC	-	Maritime	Severity (%)	3	19.1	79.2	68.0	54.0	0>;3=;0<	1>;2=;0<
				Incidence (%)	3	50.0	46.5	37.3	18.2	0>;3=;0<	2>;1=;0<
			North-East	Severity (%)	3	18.5	96.7	93.7	97.4	2>;1=;0<	0>;3=;0<
					4	21.3	93.9	-	89.3	-	1>;3=;0<
				Incidence (%)	3	37.7	90.2	82.3	90.2	1>;2=;0<	0>;3=;0<
					4	44.0	84.9	-	78.4	-	1>;3=;0<
			South-East	Severity (%)	7	9.8	79.8	61.1	69.0	5>;2=;0<	2>;5=;0<
				Incidence (%)	6	51.5	64.8	38.9	51.2	4>;2=;0<	2>;4=;0<
		Central zone	Maritime + NE + SE	Severity (%)	13	14.0	83.6	70.2	72.1	7>;6=;0<	3>;10=;0<
					14	15.1	83.7	-	71.6	-	4>;10=;0<
				Incidence (%)	12	47.7	66.6	49.3	52.7	5>;7=;0<	4>;8=;0<
					13	48.8	66.8	-	52.0	-	5>;8=;0<

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Figure 3.2-2: Benefit of the mixture of boscalid and prothioconazole - Oilseed rape - SCLESC - Disease severity on stems at BBCH 77-87 - All EPP0 climatic zones - Box plot graphics - Means of 13 trials - 1 application

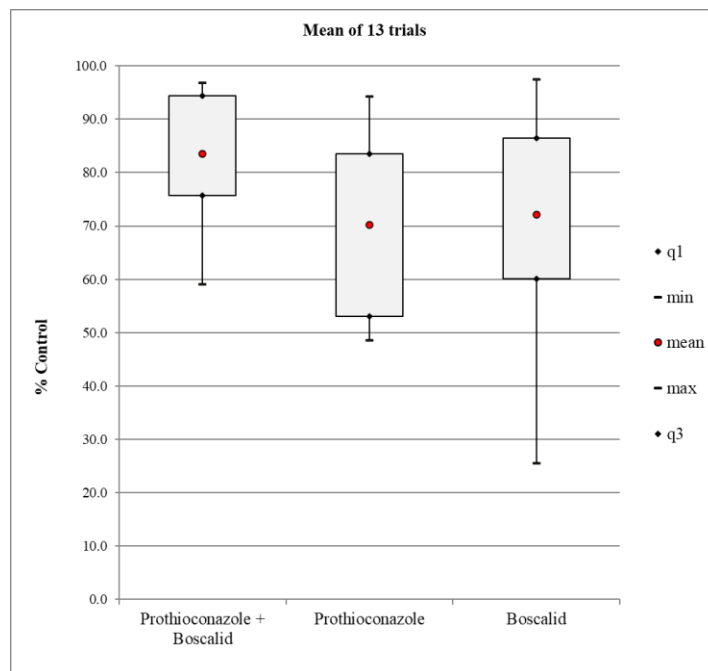
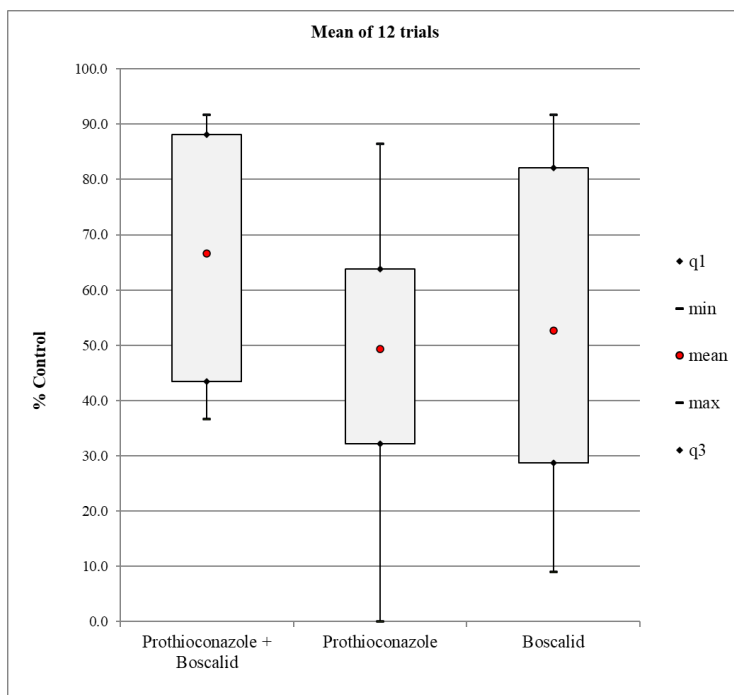


Figure 3.2-3: Benefit of the mixture of boscalid and prothioconazole - Oilseed rape - SCLESC - Disease incidence on stems at BBCH 77-87 - All EPP0 climatic zones - Box plot graphics - Means of 12 trials - 1 application



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).

The results on the synergy between Prothioconazole and Boscalid in the mixture (FGE03) is more pronounced in the Maritime and the South-East zones. Indeed, the Central registration zone is composed of 3 EPPO climatic zones where oilseed rape is a major crop and has similar agricultural practices in these 3 areas. However, *Sclerotinia sclerotiorum* development is overall similar but can represent a greater challenge in Maritime and South-East EPPO zones.

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.

3.2.1.1.2 Study of the mixture ratio of boscalid and prothioconazole in FGE03 for *Sclerotinia sclerotiorum* control in oilseed rape

A total of 13 valid efficacy trials are available to study the best ratio of boscalid and prothioconazole in FGE03 for the control of *Sclerotinia sclerotiorum* in oilseed rape. These trials were carried out in 2024. In this preliminary part, Maritime, North-East and South-East EPPO zones are presented. Indeed, although these 3 zones belong to different climatic and/or administration zones, these data were presented together in the BAD and dRR B3. Oilseed rape is a major crop and has similar agricultural practices in these 3 areas. *Sclerotinia sclerotiorum* development is overall similar but can represent a greater challenge in Maritime and South-East EPPO zones. Thus, each country can take into account the data from their relevant EPPO zone(s) for its evaluation. In addition protocols were identical in all trials. Table 3.2-17 presents a summary of the results.

Table 3.2-17: Summary results: Study of the mixture ratio of boscalid and prothioconazole - Oilseed rape - SCLESC on stems - All EPPO climatic zone - 1 application

Application																							
Parameters	EPPO climatic zone	Assessment timing	Parts	No. of trials	Days after application	Untreated (% of infestation)			% Control												No. of trials where Prothio + Boscalid ha is statistically ⁽¹⁾ > ; = ; < compared to		
									FGE03 Prothioconazole + Boscalid 140 + 245 g a.i./ha Application : A				Prothioconazole + Boscalid 70 + 245 g a.i./ha Application : A				Prothioconazole + Boscalid 140 + 125 g a.i./ha Application : A						
						Mean	Min	Max	Mean	Min	Max	SD	Mean	Min	Max	SD	Mean	Min	Max	SD	Prothio 70 + 245 g a.i./ha	Boscalid 140 + 125 g a.i./ha	
Severity (%)	Maritime	BBCH 82 75-87	STEM	3	[54-74]	19.1	6.4	37.9	79.2	70.5	88.2	8.8	78.2	73.8	86.8	7.4	78.9	70.7	88.5	9.0	0>;3=;0<	0>;3=;0<	
	North-East	BBCH 85 75-87	STEM	3	[46-47]	18.5	17.6	19.4	96.7	96.5	96.9	0.2	99.0	98.7	99.4	0.4	98.2	97.8	98.5	0.3	0>;3=;0<	0>;3=;0<	
	South-East	BBCH 77 75-87	STEM	7	[42-60]	9.8	5.2	21.6	79.8	59.0	94.4	13.7	76.5	57.7	91.9	11.2	74.4	55.2	87.8	12.0	1>;6=;0<	1>;6=;0<	
	All zones	BBCH 77 75-87	STEM	13	[42-74]	14.0	5.2	37.9	83.6	59.0	96.9	12.7	82.1	57.7	99.4	12.9	80.9	55.2	98.5	13.6	1>;12=;0<	1>;12=;0<	
Incidence (%)	Maritime	BBCH 82 75-87	STEM	3	[54-74]	50.0	31.0	61.0	46.5	36.6	61.2	13.0	41.2	31.1	56.1	13.1	50.4	39.3	62.8	11.8	0>;3=;0<	0>;3=;0<	
	North-East	BBCH 85 75-87	STEM	3	[46-47]	37.7	37.0	39.0	90.2	89.2	91.7	1.3	95.5	94.4	97.5	1.7	91.9	91.7	92.2	0.3	0>;3=;0<	0>;3=;0<	
	South-East	BBCH 83 75-87	STEM	6	[42-60]	51.5	16.0	74.0	64.8	37.1	87.7	20.1	56.7	30.8	85.3	18.8	52.1	23.4	73.3	21.6	1>;5=;0<	1>;5=;0<	
	All zones	BBCH 77 75-87	STEM	12	[42-74]	47.7	16.0	74.0	66.6	36.6	91.7	21.9	62.5	30.8	97.5	25.2	61.6	23.4	92.2	23.9	1>;11=;0<	1>;11=;0<	

⁽¹⁾ Comparison based on statistics carried out in each trial report.

In these trials, at the assessment (BBCH 77-87), in the untreated control, the average infestation was moderate (14% disease severity and 48% disease incidence on stems on average across 13 trials), varying from 5% to 38% disease severity and from 16% to 74% disease incidence in individual trials.

In the Maritime EPPO climatic, in 3 trials, the mixture ratio of boscalid and prothioconazole in FGE03 (140 g Prothioconazole/ha + 245 g Boscalid/ha) showed a slight trend to be show a better control than lower ratio of both active substances (**70** g Prothioconazole/ha + 245 g Boscalid/ha and 140 g Prothioconazole/ha + **125** g Boscalid/ha). Indeed, 140 g Prothioconazole/ha + 245 g Boscalid/ha (FGE03) gave 79.2% mean control, 1.0 point higher than with **70** g Prothioconazole/ha + 245 g Boscalid/ha (78.2% mean control) and 0.3 points higher than 140 g Prothioconazole/ha + **125** g Boscalid/ha (78.9% mean control).

On disease incidence, the mixture ratio of boscalid and prothioconazole in FGE03 (140 g Prothioconazole/ha + 245 g Boscalid/ha) showed a trend to be show a better control than lower ratio of **70** g Prothioconazole/ha + 245 g Boscalid/ha. Indeed, 140 g Prothioconazole/ha + 245 g Boscalid/ha (FGE03) gave 46.5% mean control, 5.3 points higher than with **70** g Prothioconazole/ha + 245 g Boscalid/ha (41.2% mean control).

In the North-East EPPO climatic, no effect of the ratio of the control was showed.

In the South-East EPPO climatic, in 7 trials, the mixture ratio of boscalid and prothioconazole in FGE03 (140 g Prothioconazole/ha + 245 g Boscalid/ha) showed a trend to be show a better control than lower ratio of both active substances (**70** g Prothioconazole/ha + 245 g Boscalid/ha and 140 g Prothioconazole/ha + **125** g Boscalid/ha). Indeed, 140 g Prothioconazole/ha + 245 g Boscalid/ha (FGE03) gave 79.8% mean control, 3.3 points higher than with **70** g Prothioconazole/ha + 245 g Boscalid/ha (76.5% mean control) and 5.4 points higher than 140 g Prothioconazole/ha + **125** g Boscalid/ha (74.4% mean control). In addition, a statistical effect was highlighted in 1 out of 7 trials.

On disease incidence, in 6 trials, the mixture ratio of boscalid and prothioconazole in FGE03 (140 g Prothioconazole/ha + 245 g Boscalid/ha) showed a trend to be show a better control than lower ratio of **70** g Prothioconazole/ha + 245 g Boscalid/ha. Indeed, 140 g Prothioconazole/ha + 245 g Boscalid/ha (FGE03) gave 64.8% mean control, 8.1 points higher than with **70** g Prothioconazole/ha + 245 g Boscalid/ha (56.7% mean control) and **12.7** ~~3.2~~ points higher than 140 g Prothioconazole/ha + **125** g Boscalid/ha (52.1% mean control). In addition, a statistical effect was highlighted in 1 out of 6 trials.

Considering the average efficacy from all zones ~~Data generated across~~ (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 ~~clearly~~ demonstrated that, the best ratio of each active substance in FGE03 ~~in this mixture~~ is 140 g/ha prothioconazole and 245 g/ha boscalid. ~~350 g/kg boscalid and 200 g/kg prothioconazole.~~

**Comments of zRMS on:
Preliminary tests (3.2.1)**

Ratio and Co-formulation justification

FGE03 is a new co-formulated fungicide containing 350 g/kg boscalid and 200 g/kg prothioconazole. Results from fourteen preliminary efficacy trials carried out in 2024 have been presented to show the benefits of co-formulation mixture of boscalid with prothioconazole (FGE03), applied once in the control of *Sclerotinia sclerotiorum* in winter oilseed rape as compared with products containing single active substances applied at the same dose rates of active substance per hectare. 13 out of 14 trials presents also data to justify the most effective ratio of boscalid and prothioconazole in the co-formulation, where 140 + 245 g a.i./ha (prothioconazole 1N + boscalid 1N) was compared with 70 + 245 g a.i./ha (prothioconazole 0.5 N + boscalid 1N) and with 140 + 125 g a.i./ha (prothioconazole 1 N + boscalid 0.5 N).

Preliminary tests were carried out in Maritime EPPO zone (Austria, France and United Kingdom), North-East EPPO zone (Latvia and Poland) and in South-East EPPO zone (Bulgaria, Hungary and Romania).

Conclusions from the trials for individual EPPO climatic zones are presented below.

Co-formulation mixture justification

Maritime EPPO zone (3 trials)

Considering disease severity, a co-formulation mixture of boscalid with prothioconazole (FGE03) was visibly more effective as compared with solo prothioconazole and solo boscalid product, with statistically significantly higher efficacy in favour of FGE03 vs. solo boscalid product demonstrated in 1 out of 3 trials. Regarding disease incidence FGE03 was visibly more effective than solo prothioconazole and solo boscalid product, with statistically significantly higher efficacy in favour of FGE03 vs. solo boscalid product demonstrated in 2 out of 3 trials. No statistically significant, but only differences in numerical values were observed between FGE03 and solo prothioconazole product for disease severity and disease incidence.

North-East EPPO zone (4 trials)

Considering disease severity, a co-formulation mixture of boscalid with prothioconazole was slightly more effective as compared with solo prothioconazole and solo boscalid product, with statistically significantly higher efficacy in favour of co-formulation demonstrated in 2 out of 3 trials and in 1 out of 4 trials respectively. Regarding disease incidence, FGE03 was more effective than solo prothioconazole and solo boscalid product with statistically significantly higher efficacy in favour of co-formulation demonstrated in 1 out of 3 trials and in 1 out of 4 trials respectively.

South-East EPPO zone (7 trials)

Considering disease severity, FGE03 was visibly more effective as compared with solo prothioconazole and solo boscalid product, with statistically significantly higher efficacy in favour of FGE03 demonstrated in 5 out of 7 trials and in 2 out of 7 trials respectively. Regarding disease incidence, FGE03 was visibly more effective than solo prothioconazole and solo boscalid product with statistically significantly higher efficacy in favour of co-formulation demonstrated in 4 out of 6 trials and in 2 out of 6 trials respectively.

Ratio justification

Maritime EPPO zone (3 trials)

Considering disease severity, the ratio of boscalid and prothioconazole in FGE03 (140 g prothioconazole/ha, 1N + 245 g boscalid/ha, 1N) was slightly more effective as compared with the ratio of boscalid and prothioconazole (70 g prothioconazole/ha, 0.5 N + 245 g boscalid/ha, 1N) and with the ratio of boscalid and prothioconazole (140 g prothioconazole/ha, 1 N + 125 g boscalid/ha, 0.5 N). No statistically significant differences in efficacy between the ratio of tested product FGE03 (140 g Prothioconazole/ha + 245 g Boscalid/ha, 1N) and the ratio of boscalid and prothioconazole (70 g prothioconazole/ha, 0.5 N + 245 g boscalid/ha, 1N) and the ratio of boscalid and prothioconazole (140 g prothioconazole/ha, 1 N + 125 g boscalid/ha, 0.5 N) were observed. Regarding disease incidence, the ratio of boscalid and prothioconazole in FGE03 (140 g prothioconazole/ha, 1N + 245 g boscalid/ha, 1N) was more effective as compared with the ratio of boscalid and prothioconazole (70 g prothioconazole/ha, 0.5 N + 245 g boscalid/ha, 1N), while the ratio of boscalid and prothioconazole (140 g prothioconazole/ha, 1 N + 125 g boscalid/ha, 0.5 N) was visibly more effective, than the ratio of boscalid and

prothioconazole in FGE03 (140 g prothioconazole/ha, 1N + 245 g boscalid/ha, 1N). Statistically, all 3 trials were similar and there were no significant differences between the tested ratios.

North-East EPPO zone (3 trials)

The effect of the ratio was not demonstrated in North-East EPPO zone. All combinations of the ratios for prothioconazole and boscalid gave high average efficacy. No statistically significant differences have been noted between individual combinations in the presented trials.

South-East EPPO zone (7 trials)

Considering disease severity and disease incidence, the ratio of boscalid and prothioconazole in FGE03 (140 g prothioconazole/ha, 1N + 245 g boscalid/ha, 1N) was more effective as compared with the ratio of boscalid and prothioconazole (70 g prothioconazole/ha, 0.5 N + 245 g boscalid/ha, 1N) and with the ratio of boscalid and prothioconazole (140 g prothioconazole/ha, 1 N + 125 g boscalid/ha, 0.5 N). Statistically significantly higher efficacy in favour of the ratio of boscalid and prothioconazole in FGE03 was demonstrated in 1 out of 7 trials for disease severity and in 1 out of 6 trials for disease incidence.

General conclusions on preliminary tests

Based on the submitted preliminary efficacy trial results it can be concluded, that the benefits of the use of co-formulation of boscalid and prothioconazole has been justified. The proper ratio of active substances in FGE03 (140 g prothioconazole/ha + 245 g boscalid/ha) has been demonstrated and effectively justified. Additionally it can be noted, that the new mixture of two active substances with different mode of action [prothioconazole, belonging to the triazolinthiones chemical group (DMI fungicide; SBI: Class I; FRAC group 3) and boscalid, from the pyridine-carboxamides chemical group (SDHI fungicide; FRAC group 7)] would be a valuable tool in resistance management strategy.

3.2.2 Minimum effective dose tests (KCP 6.2)

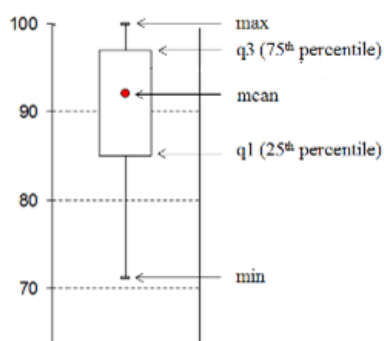
3.2.2.1 Minimum effective dose tests - Material and methods

The full materials and methods are already described in detail within Section 3.2.3.1 (Material and methods) and is not repeated here.

Interpretation of data

In order to illustrate the data distribution between the different rates of FGE03, box plot graphs are presented in this part. Only assessments with data included in at least 5 trials (number of relevant data to create a suitable box plot) are presented. The Figure 3.2-4 presents box plot parameters.

Figure 3.2-4: Explanation of box plot parameters



3.2.2.2 Minimum effective dose tests - Results

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”.

3.2.2.2.1 Minimum effective dose tests - Results - 1 application

The label claim for this use is summarised in Table 3.2-18.

Table 3.2-18: Label claim for oilseed rape against *Sclerotinia sclerotiorum*

Crops	Target	Country	Application timing	No. of applications	Application volume	Dose rate
Oilseed rape (BRSNN)	<i>Sclerotinia sclerotiorum</i> (SCLESC)	PL, HU, CZ	BBCH 61-69	1	100-400 L/ha	0.7 kg/ha

A total of 14 valid efficacy trials were carried out in 2024 to evaluate the minimum effective dose of FGE03 after 1 application (5 trials in the Maritime EPPO climatic zone, 4 trials in the North-East EPPO climatic zone and 5 trials in the South-East EPPO climatic zone). FGE03 was tested at 0.35 kg/ha (0.5 N), 0.5 kg/ha (0.7N) and 0.7 kg/ha (N) for the control of *Sclerotinia sclerotiorum* on oilseed rape.

A summary of all trials generating data on oilseed rape against *Sclerotinia sclerotiorum* is presented in Table 3.2-19.

Table 3.2-19: Overview of all efficacy trials generating data on minimum effective dose - Oilseed rape - *Sclerotinia sclerotiorum* - 1 application

Number of trials	Crop	Target	Year	Country	EPPO climatic zone	Tested rates in trials
1 trial	BRSNN	SCLESC	2024	FR	Maritime	0.35, 0.5 and 0.75 kg/ha*
1 trial	BRSNN	SCLESC	2024	AT	Maritime	0.35, 0.5 and 0.7 kg/ha
1 trial	BRSNN	SCLESC	2024	UK	Maritime	0.35, 0.5 and 0.7 kg/ha
2 trials	BRSNN	SCLESC	2024	DK	Maritime	0.35, 0.5 and 0.7 kg/ha
3 trials	BRSNN	SCLESC	2024	PL	Northeast	0.35, 0.5 and 0.7 kg/ha
1 trial	BRSNN	SCLESC	2024	LT	Northeast	0.35, 0.5 and 0.7 kg/ha
2 trials	BRSNN	SCLESC	2024	BG	Southeast	0.35, 0.5 and 0.7 kg/ha
1 trial	BRSNN	SCLESC	2024	HU	Southeast	0.35, 0.5 and 0.7 kg/ha
2 trials	BRSNN	SCLESC	2024	RO	Southeast	0.35, 0.5 and 0.7 kg/ha

*FGE03 was applied at the rate of at 0.75 kg/ha (150 + 263 g a.i./ha; less than 10% deviation of N rate requested).

A. Results of Minimum effective dose on oilseed rape (BRSNN) - *Sclerotinia sclerotiorum* (SCLESC) - 1 application - Maritime EPPO climatic zone

Against *Sclerotinia sclerotiorum*, a total of 5 valid efficacy trials were carried out to confirm the requested dose of FGE03. These trials were carried out in 2024 in the Maritime EPPO climatic zone in Austria (1 trial), North of France (1 trial), Denmark (2 trials) and the United Kingdom (1 trial).

Table 3.2-20 presents a summary of the results of minimum effective dose. Figure 3.2-5 (disease severity) and Figure 3.2-6 (disease incidence) represent the minimum effective dose in box plot graphics against *Sclerotinia sclerotiorum*.

Table 3.2-20: Summary results: minimum effective dose of FGE03 - Oilseed rape - SCLESC on stems - Maritime EPPO climatic zone - 1 application

Parameters	Assessment timing	Parts	EPPO climatic zone	No. of trials	Days after application	Untreated (% of infestation)			% Control												No. of trials where FGE03 at 0.70 kg/ha is statistically ⁽¹⁾ > ; = ; < compared to	
									FGE03 0.35 kg/ha Application : A				FGE03 0.50 kg/ha Application : A				FGE03 0.70 kg/ha Application : A					
						Mean	Min	Max	Mean	Min	Max	SD	Mean	Min	Max	SD	Mean	Min	Max	SD	0.35 kg/ha	0.50 kg/ha
Severity (%)	BBCH 75-85 87	STEM	Maritime	5	27-74 DA-A	22.9	6.4	37.9	55.0	46.5	70.3	9.1	66.8	62.8	75.3	5.5	75.0	62.3	88.2	9.6	1>;4=;0<	0>;5=;0<
Incidence (%)	BBCH 75-85 87	STEM	Maritime	5	27-74 DA-A	57.1	31.0	69.7	26.5	3.3	40.9	14.5	36.2	15.0	51.8	14.9	46.6	36.6	61.2	9.5	1>;4=;0<	1>;4=;0<

⁽¹⁾ Comparison based on statistics carried out in each trial report.3.03

Figure 3.2-5: Minimum effective dose of FGE03 - Oilseed rape - SCLESC - Disease severity on stems at BBCH 75-8587 - Maritime EPPO climatic zone - Box plot graphics - Means of 5 trials - 1 application

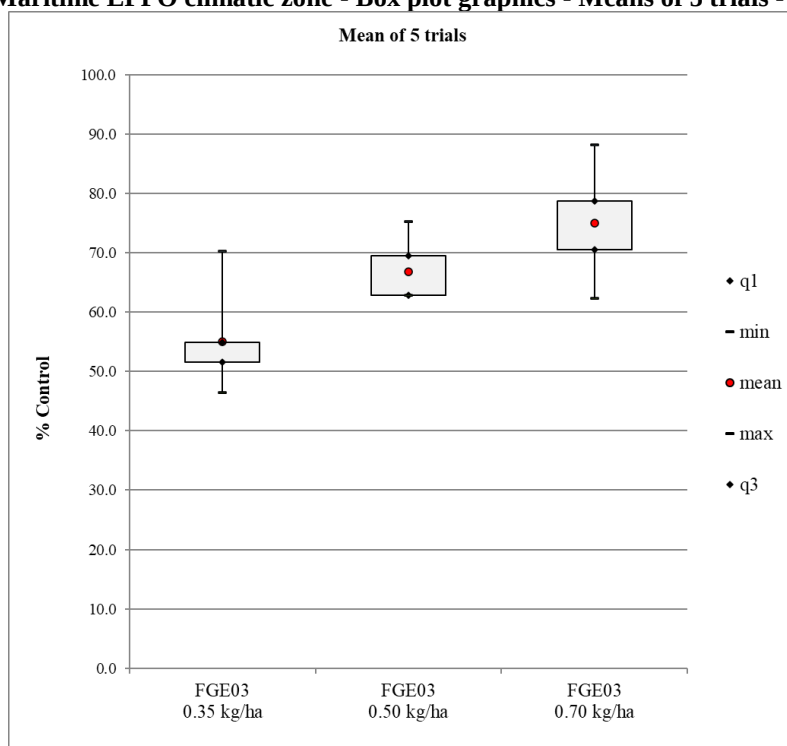
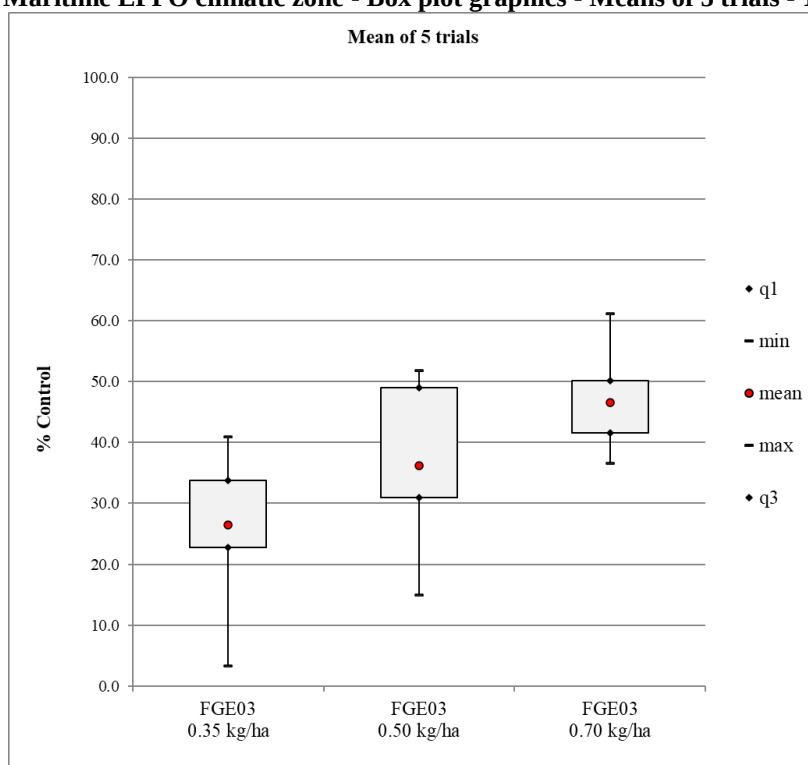


Figure 3.2-6: Minimum effective dose of FGE03 - Oilseed rape - SCLESC - Disease incidence on stems at BBCH 75-8587 - Maritime EPPO climatic zone - Box plot graphics - Means of 5 trials - 1 application



In these trials, at the assessment (BBCH 75-8587), in the untreated control, the average infestation was good (23% disease severity and 57% disease incidence on stems on average across 5 trials), varying from 6% to 38% disease severity and from 31% to 70% disease incidence in individual trials.

On disease severity, FGE03 showed a clear dose response between the 3 rates in 5 trials. Indeed, FGE03 applied at 0.7 kg/ha gave 75.0% mean control, 20.0 points higher than at 0.35 kg/ha (55.0% mean control) and 8.2 points higher than at 0.5 kg/ha (66.8% mean control). In addition, a statistical effect was highlighted in 1 out of 5 trials between FGE03 at 0.7 kg/ha vs. 0.35 kg/ha. Regarding disease incidence, the dose response is confirmed.

According to box plot graphs, the highest dose of FGE03 showed the highest level of control and overall the lowest dispersion and variation between means (see Figure 3.2-5 and Figure 3.2-6).

In summary, in the Maritime EPPO climatic zone, when considering data from 5 trials investigating FGE03 minimum effective dose for the control of *Sclerotinia sclerotiorum* in oilseed rape at the last assessment timing (BBCH 75-85~~87~~), in conditions of good disease pressure, FGE03 applied once demonstrated a clear dose response, with the best effectiveness obtained from the intended rate of 0.7 kg/ha.

B. Results of Minimum effective dose on oilseed rape (BRSNN) - *Sclerotinia sclerotiorum* (SCLESC) - 1 application - North-East EPPO climatic zone

Against *Sclerotinia sclerotiorum*, a total of 4 valid efficacy trials were carried out to confirm the requested dose of FGE03. These trials were carried out in 2024 in the North-East EPPO climatic zone in Lithuania (1 trial) and Poland (3 trials).

Table 3.2-21 presents a summary of the results of minimum effective dose.

Table 3.2-21: Summary results: minimum effective dose of FGE03 - Oilseed rape - SCLESC on stems - North-East EPPO climatic zone - 1 application

Parameters	Assessment timing	Parts	EPPO climatic zone	No. of trials	Days after application	Untreated (% of infestation)			% Control												No. of trials where FGE03 at 0.70 kg/ha is statistically ⁽¹⁾ > ; = ; < compared to	
									FGE03 0.35 kg/ha Application : A				FGE03 0.50 kg/ha Application : A				FGE03 0.70 kg/ha Application : A					
						Mean	Min	Max	Mean	Min	Max	SD	Mean	Min	Max	SD	Mean	Min	Max	SD	0.35 kg/ha	0.50 kg/ha
Severity (%)	BBCH 85-87	STEM	North-East	4	46-53 DA-A	21.3	17.6	29.6	87.8	86.9	88.8	0.8	89.2	81.1	92.3	5.4	93.9	85.6	96.9	5.5	3>;1=;0<	3>;1=;0<
Incidence (%)	BBCH 85-87	STEM	North-East	4	46-53 DA-A	44.0	37.0	63.0	71.5	67.5	81.1	6.5	76.9	60.8	86.4	11.3	84.9	68.8	91.7	10.7	2>;2=;0<	1>;3=;0<

⁽¹⁾ Comparison based on statistics carried out in each trial report.

In these trials, at the assessment (BBCH 85⁷⁵-87), in the untreated control, the average infestation was good (21% disease severity and 44% disease incidence on stems on average across 4 trials), varying from 18% to 30% disease severity and from 37% to 63% disease incidence in individual trials.

On disease severity, FGE03 showed a clear dose response between the 3 rates in 4 trials. Indeed, FGE03 applied at 0.7 kg/ha gave 93.9% mean control, 6.1 points higher than at 0.35 kg/ha (87.8% mean control) and 4.7^{8.2} points higher than at 0.5 kg/ha (89.2% mean control). In addition, a statistical effect was highlighted in 3 out of 4 trials between FGE03 at 0.7 kg/ha vs. 0.35 kg/ha and between FGE03 at 0.7 kg/ha vs. 0.5 kg/ha.

Regarding disease incidence, the dose response is confirmed.

In summary, in the North-East EPPO climatic zone, when considering data from 4 trials investigating FGE03 minimum effective dose for the control of *Sclerotinia sclerotiorum* in oilseed rape at the last assessment timing (BBCH 85⁷⁵-87), in conditions of good disease pressure, FGE03 applied once demonstrated a clear dose response, with the best effectiveness obtained from the intended rate of 0.7 kg/ha.

C. Results of Minimum effective dose on oilseed rape (BRSNN) - *Sclerotinia sclerotiorum* (SCLESC) - 1 application - South-East EPPO climatic zone

Against *Sclerotinia sclerotiorum*, a total of 5 valid efficacy trials were carried out to confirm the requested dose of FGE03. These trials were carried out in 2024 in the South-East EPPO climatic zone in Bulgaria (2 trials), Hungary (1 trial) and Romania (2 trials).

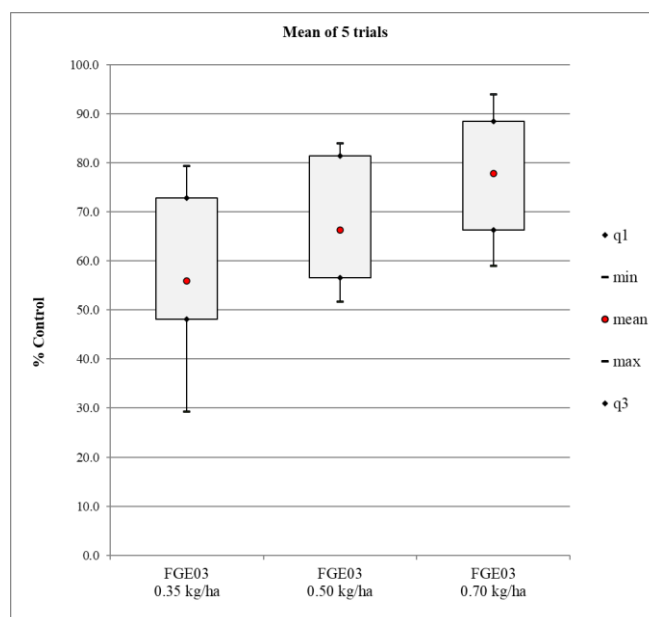
Table 3.2-22 presents a summary of the results of minimum effective dose. Figure 3.2-7 (disease severity) represents the minimum effective dose in box plot graphics against *Sclerotinia sclerotiorum*.

Table 3.2-22: Summary results: minimum effective dose of FGE03 - Oilseed rape - SCLESC on stems - South-East EPPO climatic zone - 1 application

Parameters	Assessment timing	Parts	EPPO climatic zone	No. of trials	Days after application	Untreated (% of infestation)			% Control																No. of trials where FGE03 at 0.70 kg/ha is statistically ⁽¹⁾ > ; = ; < compared to	
									FGE03 0.35 kg/ha Application : A				FGE03 0.50 kg/ha Application : A				FGE03 0.70 kg/ha Application : A									
						Mean	Min	Max	Mean	Min	Max	SD	Mean	Min	Max	SD	Mean	Min	Max	SD	Mean	Min	Max	SD	0.35 kg/ha	0.50 kg/ha
Severity (%)	BBCH 77-87	STEM	South-East	5	42-60 DA-A	10.6	5.2	21.6	55.9	29.3	79.3	20.2	66.4	51.7	84.0	15.1	77.8	59.0	94.0	14.8	3>;2=;0<	1>;4=;0<				
Incidence (%)	BBCH 83-87	STEM	South-East	4	42-60 DA-A	46.5	16.0	65.0	35.5	11.3	58.9	20.3	42.4	19.9	64.3	19.0	58.4	37.1	79.8	21.0	3>;1=;0<	2>;2=;0<				

⁽¹⁾ Comparison based on statistics carried out in each trial report

Figure 3.2-7: Minimum effective dose of FGE03 - Oilseed rape - SCLESC - Disease severity on stems at BBCH 77-87 - South-East EPPO climatic zone - Box plot graphics - Means of 5 trials - 1 application



In these trials, at the assessment (BBCH 77-87), in the untreated control, the average infestation was moderate (11% disease severity and 47% disease incidence on stems on average across 5 trials), varying from 5% to 22% disease severity and from 16% to 65% disease incidence in individual trials.

On disease severity, FGE03 showed a clear dose response between the 3 rates in 5 trials. Indeed, FGE03 applied at 0.7 kg/ha gave 77.8% mean control, 21.9 points higher than at 0.35 kg/ha (55.9% mean control) and 11.4 points higher than at 0.5 kg/ha (66.4% mean control). In addition, a statistical effect was highlighted in 3 out of 5 trials between FGE03 at 0.7 kg/ha vs. 0.35 kg/ha and in 1 out of 5 trials between FGE03 at 0.7 kg/ha vs. 0.5 kg/ha.

Regarding disease incidence, the dose response is confirmed.

According to box plot graphs, the highest dose of FGE03 showed the highest level of control and overall the lowest dispersion and variation between means (see Figure 3.2-7).

In summary, in the South-East EPPO climatic zone, when considering data from 5 trials investigating FGE03 minimum effective dose for the control of *Sclerotinia sclerotiorum* in oilseed rape at the last assessment timing (BBCH 77-87), in conditions of good disease pressure, FGE03 applied once demonstrated a clear dose response, with the best effectiveness obtained from the intended rate of 0.7 kg/ha.

D. Conclusion: results of Minimum effective dose on oilseed rape (BRSNN) - *Sclerotinia sclerotiorum* (SCLESC) - 1 application - All EPPO climatic zones

Against *Sclerotinia sclerotiorum*, a total of 14 valid efficacy trials were carried out to confirm the requested dose of FGE03 applied once. These trials were carried out in 2024 in the Maritime (5 trials), North-East (4 trials) and South-East EPPO (5 trials) climatic zones.

Table 3.2-23 presents a summary of the results of minimum effective dose and Figure 3.2-8 (disease severity) and Figure 3.2-9 (disease incidence) represent the minimum effective dose in box plot graphics against *Sclerotinia sclerotiorum*.

Table 3.2-23: Summary results: minimum effective dose of FGE03 (% control based on disease severity and incidence on stems at BBCH 75-87) in oilseed rape to control *Sclerotinia sclerotiorum* - 1 application

Crop code	Pest code	Regulatory zone	EPPO climatic zone	Parameters	No. of trials	Untreated (% of infestation)	Mean control (%) on disease on stem			No. of trials where FGE03 at 0.70 kg/ha is statistically ⁽¹⁾ > ; = ; < compared to	
							FGE03 0.35 kg/ha Application : A	FGE03 0.50 kg/ha Application : A	FGE03 0.70 kg/ha Application : A		
BRSNN	SCLESC	-	Maritime	Severity (%)	5	22.9	55.0	66.8	75.0	1>;4=;0<	0>;5=;0<
				Incidence (%)	5	57.1	26.5	36.2	46.6	1>;4=;0<	1>;4=;0<
			North-East	Severity (%)	4	21.3	87.8	89.2	93.9	3>;1=;0<	3>;1=;0<
				Incidence (%)	4	44.0	71.5	76.9	84.9	2>;2=;0<	1>;3=;0<
			South-East	Severity (%)	5	10.6	55.9	66.4	77.8	3>;2=;0<	1>;4=;0<
				Incidence (%)	4	46.5	35.5	42.4	58.4	3>;1=;0<	2>;2=;0<
		Central zone	Maritime + NE + SE	Severity (%)	14	18.0	64.7	73.0	81.4	7>;7=;0<	4>;10=;0<
				Incidence (%)	13	49.8	43.1	50.6	62.0	6>;7=;0<	4>;9=;0<

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Figure 3.2-8: Minimum effective dose of FGE03 - Oilseed rape - SCLESC - Disease severity on stems at BBCH 75-87 - All EPPO climatic zones - Box plot graphics - Means of 14 trials - 1 application

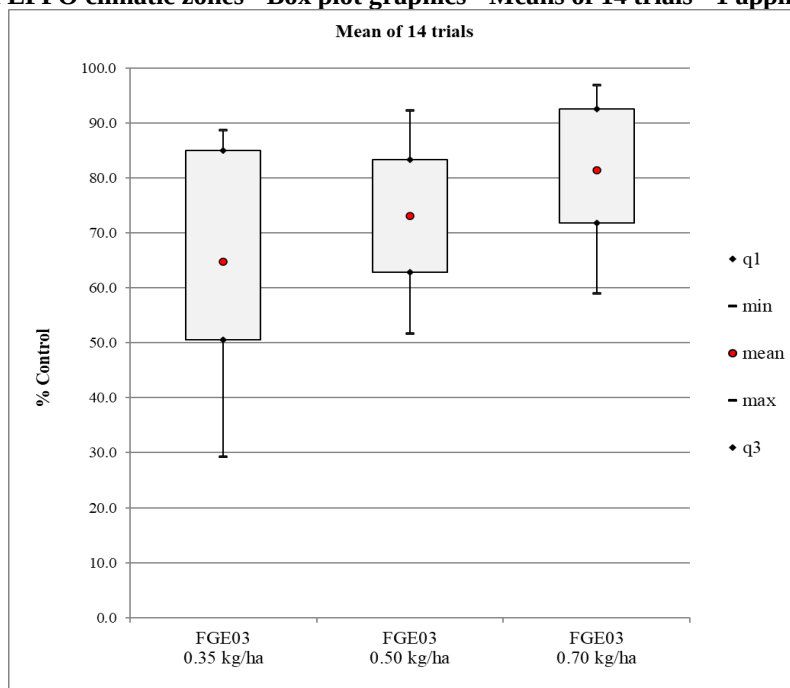
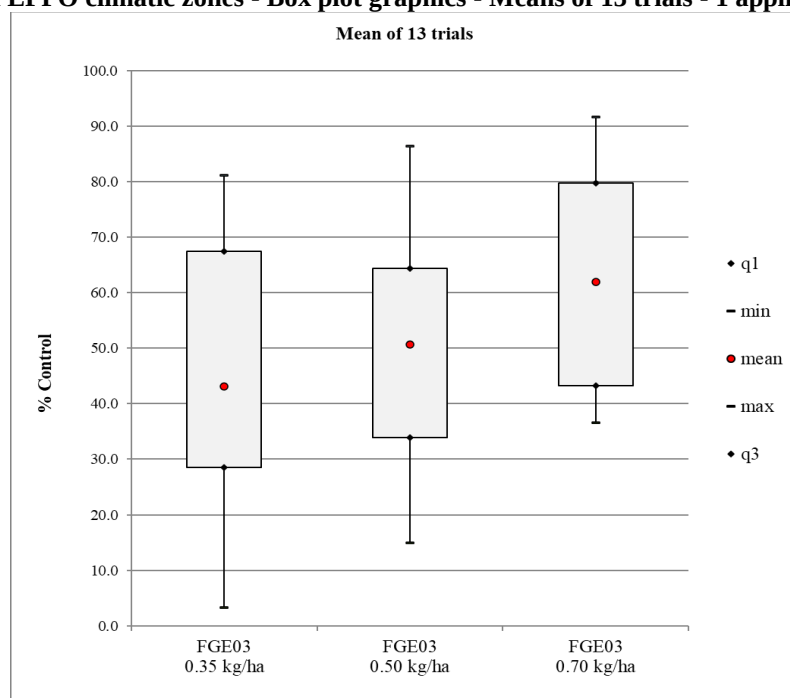


Figure 3.2-9: Minimum effective dose of FGE03 - Oilseed rape - SCLESC - Disease incidence on stems at BBCH 75-87 - All EPPO climatic zones - Box plot graphics - Means of 13 trials - 1 application



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.

It is therefore reasonable to conclude that the proposed label rate of 0.7 kg/ha of FGE03 applied once is fully justified as the minimum effective dose in the Central registration zone.

Comments of zRMS on:

Minimum effective dose tests – Results – 1 application (3.2.2.2.1)

Results from 14 efficacy trials have been presented to determine the Minimum effective dose (MED) of FGE03 applied once in the control of *Sclerotinia sclerotiorum* on winter oilseed rape. The trials were carried out in 3 EPPO zones: Maritime (North of France - 1 trial, Austria - 1 trial, the United Kingdom - 1 trial, Denmark - 2 trials). North-East (Lithuania - 1 trial, Poland - 3 trials) and South-East (Bulgaria - 2 trials, Hungary - 1 trial, Romania - 2 trials) in 2024.

The recommended dose rate of 0.7 kg/ha was compared with lower dose rates: 0.35 kg/ha and 0.5 kg/ha corresponding to 50% and 71% of the target dose rate respectively.

Conclusions from the MED trials for individual EPPO climatic zones are presented below.

Maritime EPPO zone (5 trials)

Based on the submitted results regarding disease severity, a clear dose response was seen for FGE03 between dose rates 0.35 kg/ha, 0.5 kg/ha and 0.7 kg/ha. The highest tested dose rate of 0.7 kg/ha provided the best efficacy results. Statistically significant differences were demonstrated in 1 out of 5 trials between dose rates of 0.35 kg/ha and 0.7 kg/ha in favour of the recommended dose rate of 0.7 kg/ha. There were no statistically differences between dose rates 0.5 kg/ha and 0.7 kg/ha. Only differences in numerical values were noted. Considering disease incidence, a visible dose response was also seen comparing the efficacy of FGE03 applied at 0.7 kg/ha with the efficacy results achieved for lower dose rates: 0.35 kg/ha and 0.5 kg/ha. Statistically significant differences were demonstrated in 1 out of 5 trials comparing dose rates 0.35 kg/ha and 0.7 kg/ha and 0.5 kg/ha and 0.7 kg/ha, in favour of the recommended dose rate of 0.7 kg/ha.

North-East EPPO zone (4 trials)

Considering disease severity, a clear dose response was noted comparing the efficacy of FGE03 applied at 0.7 kg/ha with the efficacy results achieved for lower dose rates: 0.35 kg/ha and 0.5 kg/ha. Statistically significant differences were demonstrated in 3 out of 4 trials in favour of the recommended dose rate of 0.7 kg/ha. For disease incidence, FGE03 achieved the best efficacy results at the highest tested dose rate of 0.7 kg/ha, and a visible dose response was also observed comparing 3 tested dose rates. Statistically significant differences were demonstrated in 2 out of 4 trials, comparing dose rates 0.35 kg/ha and 0.7 kg/ha and in 1 out of 4 trials comparing effects for 0.5 kg/ha and 0.7 kg/ha application rates, in favour of the recommended dose rate of 0.7 kg/ha.

South-East EPPO zone (5 trials)

For disease severity, FGE03 achieved the best efficacy results at the highest tested dose rate of 0.7 kg/ha, and a clear dose response was observed comparing 3 tested dose rates: 0.35 kg/ha, 0.5 kg/ha and 0.7 kg/ha. Statistically significant differences were demonstrated in 3 out of 5 trials, comparing dose rates 0.35 kg/ha and 0.7 kg/ha and in 1 out of 5 trials comparing effects for 0.5 kg/ha and 0.7 kg/ha application rates, in favour of the recommended dose rate of 0.7 kg/ha. For disease incidence, a visible dose response was also seen comparing the efficacy of FGE03 applied at 0.7 kg/ha with the efficacy results achieved for lower dose rates: 0.35 kg/ha and 0.5 kg/ha. Statistically significant differences were demonstrated in 3 out of 4 trials, comparing dose rates 0.35 kg/ha and 0.7 kg/ha and in 2 out of 4 trials comparing effects for 0.5 kg/ha and 0.7 kg/ha application rates, in favour of the recommended dose rate of 0.7 kg/ha.

3.2.2.2.2 Minimum effective dose tests - Results - 2 applications

The label claim for this use is summarised in Table 3.2-24.

Table 3.2-24: Label claim for oilseed rape against *Sclerotinia sclerotiorum*

Crops	Target	Country	Application timing	No. of applications	Application volume	Dose rate
Oilseed rape (BRSNN)	<i>Sclerotinia sclerotiorum</i> (SCLESC)	PL, HU, CZ	BBCH 61-73	2	100-400 L/ha	0.7 kg/ha

A total of 16 valid efficacy trials were carried in 2022 and 2023 out to evaluate the minimum effective dose of FGE03 after 2 applications (5 trials in the Maritime EPPO climatic zone, 6 trials in the North-

East EPPO climatic zone and 5 trials in the South-East EPPO climatic zone). FGE03 was tested at 0.35 kg/ha (0.5 N), 0.5 kg/ha (0.7N) and 0.7 kg/ha (N) for the control of *Sclerotinia sclerotiorum* on oilseed rape.

A summary of all trials generating data on oilseed rape against *Sclerotinia sclerotiorum* is presented in Table 3.2-25.

Table 3.2-25: Overview of efficacy trials generating data on minimum effective dose - Oilseed rape - *Sclerotinia sclerotiorum* - 2 applications

Number of trials	Crop	Target	Year	Country	EPPO climatic zone	Tested rates in trials
2 trials	Oilseed rape	SCLESC	2022	DK	Maritime	0.35, 0.5 and 0.7 kg/ha
2 trials	Oilseed rape	SCLESC	2022	CZ	Maritime	0.35, 0.5 and 0.7 kg/ha
1 trial	Oilseed rape	SCLESC	2023	UK	Maritime	0.35 and 0.7 kg/ha
2 trials	Oilseed rape	SCLESC	2022	LT	Northeast	0.35, 0.5 and 0.7 kg/ha
4 trials	Oilseed rape	SCLESC	2023	PL	Northeast	0.35 and 0.7 kg/ha
2 trials	Oilseed rape	SCLESC	2023	BG	Southeast	0.35 and 0.7 kg/ha
3 trials	Oilseed rape	SCLESC	2022	HU	Southeast	0.35, 0.5 and 0.7 kg/ha

A. Results of Minimum effective dose on oilseed rape (BRSNN) - *Sclerotinia sclerotiorum* (SCLESC) - 2 applications - Maritime EPPO climatic zone

Against *Sclerotinia sclerotiorum*, a total of 5 valid efficacy trials were carried out to confirm the requested dose of FGE03. These trials were carried out in 2022 and 2023 in the Maritime EPPO climatic zone in Czech Republic (2 trials), Denmark (2 trials) and the United Kingdom (1 trial).

Table 3.2-26 presents a summary of the results of minimum effective dose and Figure 3.2-10 (disease severity) and Figure 3.2-11 (disease incidence) represent the minimum effective dose in box plot graphics against *Sclerotinia sclerotiorum*.

Table 3.2-26: Summary results: minimum effective dose of FGE03 - Oilseed rape - SCLESC on stems - Maritime EPPO climatic zone - 2 applications

Parameters	Assessment timing	Parts	EPPO climatic zone	No. of trials	Days after application	Untreated (% of infestation)			% Control												No. of trials where FGE03 at 0.70 kg/ha is statistically ⁽¹⁾ > ; = ; < compared to	
									FGE03 0.35 kg/ha Application : A + B				FGE03 0.50 kg/ha Application : A + B				FGE03 0.70 kg/ha Application : A + B					
						Mean	Min	Max	Mean	Min	Max	SD	Mean	Min	Max	SD	Mean	Min	Max	SD		
Severity (%)	BBCH 81-85 75-87	STEM	Maritime	5	[42-62 DA-B]	23.0	10.8	32.8	65.3	41.7	90.6	21.1	-	-	-	-	89.3	80.9	98.3	7.7	1>;4=;0<	-
	BBCH 82-85 75-87	STEM	Maritime	4	[42-56 DA-B]	26.0	17.6	32.8	60.5	41.7	90.6	21.0	73.3	61.3	94.4	15.2	87.0	80.9	94.4	6.7	-	0>;4=;0<
Incidence (%)	BBCH 81-85 75-87	STEM	Maritime	5	[42-62 DA-B]	36.8	21.0	58.0	58.2	32.8	82.9	24.3	-	-	-	-	83.2	76.2	93.3	7.1	2>;3=;0<	-
	BBCH 82-85 75-87	STEM	Maritime	4	[42-56 DA-B]	38.5	21.0	58.0	52.7	32.8	82.9	24.3	66.1	55.2	90.2	16.3	80.7	76.2	87.8	5.0	-	1>;3=;0<

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Figure 3.2-10: Minimum effective dose of FGE03 - Oilseed rape - SCLESC - Disease severity on stems at BBCH 81-85 75-87 - Maritime EPPO climatic zone - Box plot graphics - Means of 5 trials - 2 applications

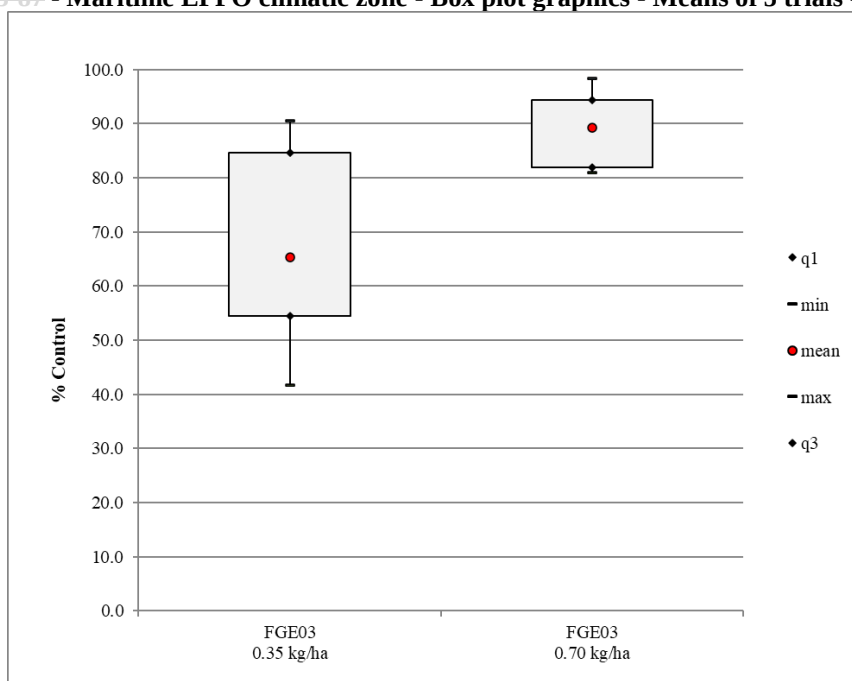
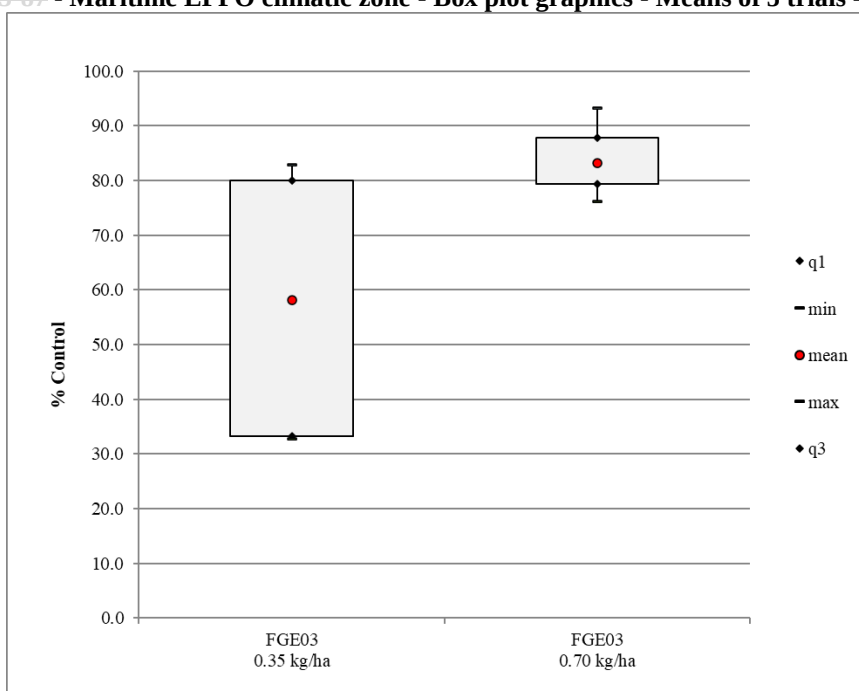


Figure 3.2-11: Minimum effective dose of FGE03 - Oilseed rape - SCLESC - Disease incidence on stems at BBCH 81-85 75-87 - Maritime EPPO climatic zone - Box plot graphics - Means of 5 trials - 2 applications



In these trials, at the assessment (BBCH 81-85 75-87), in the untreated control, the average infestation was good (23% disease severity and 37% disease incidence on stems on average across 5 trials), varying from 11% to 33% disease severity and from 21 to 58% disease incidence in individual trials.

On disease severity, FGE03 showed a clear dose response between 0.35 kg/ha and 0.7 kg/ha in 5 trials. Indeed, FGE03 applied at 0.7 kg/ha gave 89.3% mean control, 24.0 points higher than at 0.35 kg/ha (65.3% mean control). In addition, a statistical effect was highlighted in 1 out of 5 trials between FGE03 at 0.7 kg/ha vs. 0.35 kg/ha.

In 4 trials, FGE03 showed a clear dose response between the 3 rates. Indeed, FGE03 applied at 0.7 kg/ha gave 87.0% mean control, 26.5 points higher than at 0.35 kg/ha (60.5% mean control) and 13.7 points higher than at 0.5 kg/ha (73.3% mean control).

Regarding disease incidence, the dose response is confirmed.

Moreover, the difference between the dose rates was characterised by a better homogeneity of control for the highest rate of 0.7 kg/ha. Indeed, according to box plot graphs, the highest dose of FGE03 showed the highest level of control and the lowest dispersion and variation between means (see Figure 3.2-10 and Figure 3.2-11).

In summary, in the Maritime EPPO climatic zone, when considering data from 5 trials investigating FGE03 minimum effective dose for the control of *Sclerotinia sclerotiorum* in oilseed rape at the last assessment timing (BBCH 81-85 75-87), in conditions of good disease pressure, FGE03 applied twice demonstrated a clear dose response, with the best effectiveness obtained from the intended rate of 0.7 kg/ha.

B. Results of Minimum effective dose on oilseed rape (BRSNN) - *Sclerotinia sclerotiorum* (SCLESC) - 2 applications - North-East EPPO climatic zone

Against *Sclerotinia sclerotiorum*, a total of 6 valid efficacy trials were carried out to confirm the requested dose of FGE03. These trials were carried out in 2022 and 2023 in the North-East EPPO climatic zone in Lithuania (2 trials) and Poland (4 trials).

In addition, according to Poland national guidance [Skuteczność działania środków ochrony roślin; updated on 15/09/2023], that data from countries adjacent to PL can be considered supportive. Therefore, data from CZ is also relevant for PL and presented in the following tables (North-East zone + CZ*).

Table 3.2-27 presents a summary of the results of minimum effective dose and Figure 3.2-12 (disease severity) and Figure 3.2-13 (disease incidence) represent the minimum effective dose in box plot graphics against *Sclerotinia sclerotiorum*.

Table 3.2-27: Summary results: minimum effective dose of FGE03 - Oilseed rape - SCLESC on stems - North-East EPPO climatic zone - 2 applications

Parameters	Assessment timing	Parts	EPPO climatic zone	No. of trials	Days after application	Untreated (% of infestation)			% Control												No. of trials where FGE03 at 0.70 kg/ha is statistically ⁽¹⁾ > ; = ; < compared to	
									FGE03 0.35 kg/ha Application : A + B				FGE03 0.50 kg/ha Application : A + B				FGE03 0.70 kg/ha Application : A + B					
						Mean	Min	Max	Mean	Min	Max	SD	Mean	Min	Max	SD	Mean	Min	Max	SD	Mean	Min
North-East EPPO climatic zone																						
Severity (%)	BBCH 80-85 75-87	STEM	North-East	6	[40-52 DA-B]	15.1	9.6	19.7	77.5	42.3	88.8	18.3	-	-	-	-	84.1	46.5	95.9	19.1	0>;6=;0<	-
	BBCH 80 75-87	STEM	North-East	2	[40-50 DA-B]	14.6	9.6	19.7	57.6	42.3	72.9	21.6	54.7	32.2	77.2	31.9	64.6	46.5	82.6	25.5	-	0>;2=;0<
Incidence (%)	BBCH 80-85 75-87	STEM	North-East	6	[40-52 DA-B]	38.8	25.0	68.0	68.8	36.4	81.3	16.6	-	-	-	-	78.7	44.2	92.0	17.9	0>;6=;0<	-
	BBCH 80 75-87	STEM	North-East	2	[40-50 DA-B]	53.3	38.5	68.0	52.3	36.4	68.3	22.5	51.3	29.9	72.8	30.4	60.7	44.2	77.2	23.4	-	0>;2=;0<
North-East EPPO climatic zone + CZ*																						
Severity (%)	BBCH 80-85 75-87	STEM	NE+CZ*	8	[40-56 DA-B]	18.7	9.6	32.8	74.7	41.7	90.6	20.9	-	-	-	-	85.1	46.5	95.9	16.6	1>;7=;0<	-
	BBCH 80-85 75-87	STEM	NE+CZ*	4	[40-56 DA-B]	22.1	9.6	32.8	61.9	41.7	90.6	24.1	66.7	32.2	94.4	26.4	76.4	46.5	94.4	20.7	-	0>;4=;0<
Incidence (%)	BBCH 80-85 75-87	STEM	NE+CZ*	8	[40-56 DA-B]	41.4	25.0	68.0	66.1	32.8	82.9	20.0	-	-	-	-	80.0	44.2	92.0	15.5	1>;7=;0<	-
	BBCH 80-85 75-87	STEM	NE+CZ*	4	[40-56 DA-B]	51.4	38.5	68.0	55.1	32.8	82.9	24.5	62.0	29.9	90.2	25.8	72.1	44.2	87.8	19.2	-	1>;3=;0<

⁽¹⁾ Comparison based on statistics carried out in each trial report.

* This additional line includes North-East EPPO climatic zone data + Czech Republic data. Indeed, Poland is a country bordering Czech Republic, which belongs to the Maritime EPPO zone and thus, the climate conditions and the disease development are quite similar, even though they belong to different climatic zones (according to Poland national guidance “Skuteczność działania środków ochrony roślin”; updated on 15/09/2023).

Figure 3.2-12: Minimum effective dose of FGE03 - Oilseed rape - SCLESC - Disease severity on stems at BBCH 80-85 75-87 - North-East EPPO climatic zone - Box plot graphics - Means of 6 trials - 2 applications

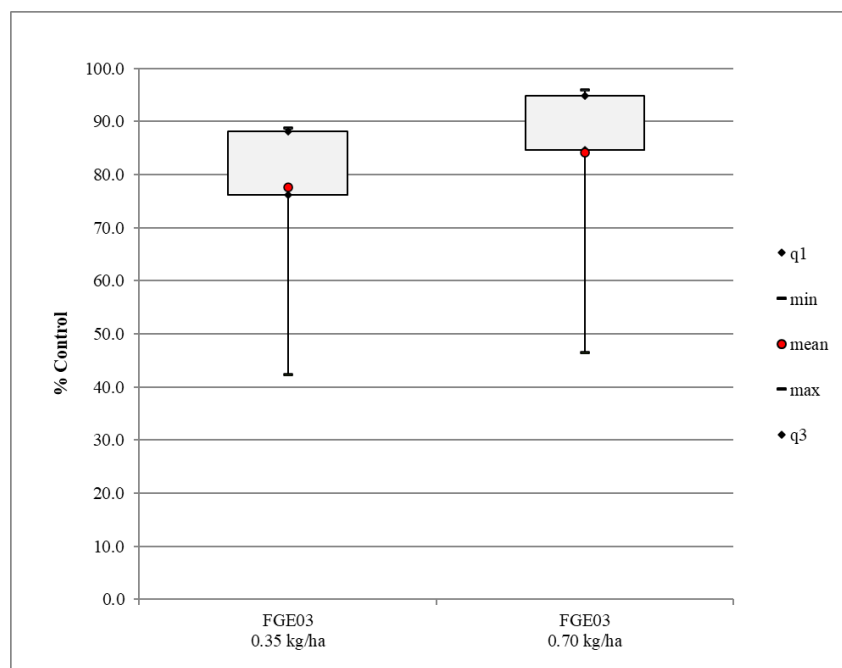
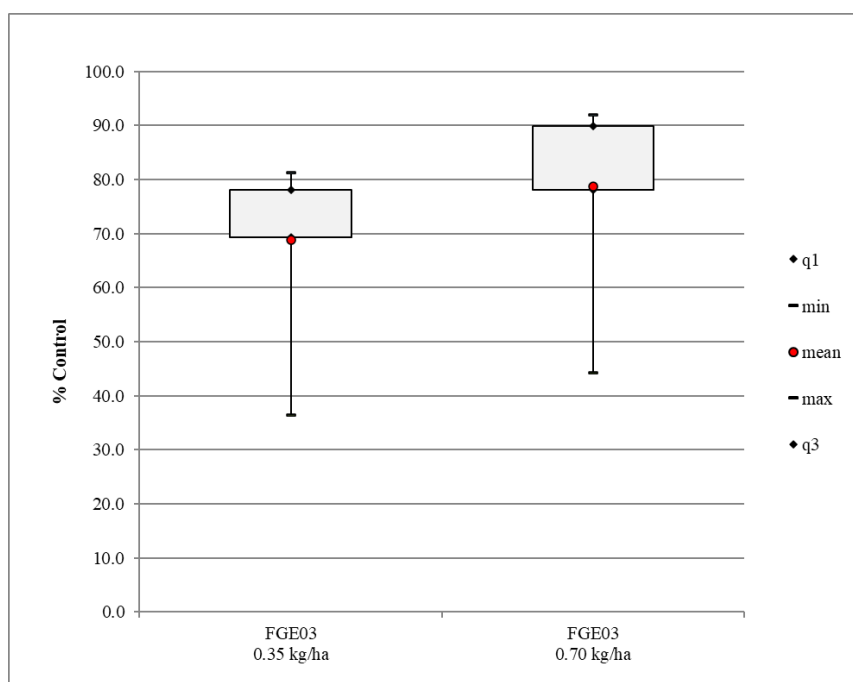


Figure 3.2-13: Minimum effective dose of FGE03 - Oilseed rape - SCLESC - Disease incidence on stems at BBCH 80-85 75-87 - North-East EPPO climatic zone - Box plot graphics - Means of 6 trials - 2 applications



In these trials, at the assessment (BBCH 80-85 ⁷⁵⁻⁸⁷), in the untreated control, the average infestation was good (15% disease severity and 39% disease incidence on stems on average across 6 trials), varying from 10% to 20% disease severity and from 25% to 68% disease incidence in individual trials.

On disease severity, FGE03 showed a dose response between 0.35 kg/ha and 0.7 kg/ha in 6 trials. Indeed, FGE03 applied at 0.7 kg/ha gave 84.1% mean control, 6.6 points higher than at 0.35 kg/ha (77.5% mean control).

In 2 trials, FGE03 showed a dose response between 0.7 kg/ha and both lowest rates (0.35 kg/ha and 0.5 kg/ha). Indeed, FGE03 applied at 0.7 kg/ha gave 64.6% mean control, 7.0 points higher than at 0.35 kg/ha (57.6% mean control) and 9.9 points higher than at 0.5 kg/ha (54.7% mean control). Although the dose effect was not highlighted by the statistical analysis, there is a clear numerical trend.

On disease incidence, the dose response is confirmed in all trials presented.

For information, these results were confirmed for Poland (North-East EPPO climatic zone data + Czech Republic data). Indeed, on disease severity, FGE03 showed a clear dose response between 0.35 kg/ha and 0.7 kg/ha in 8 trials. Indeed, FGE03 applied at 0.7 kg/ha gave 85.1% mean control, 10.4 points higher than at 0.35 kg/ha (74.7% mean control). The dose effect was highlighted by the statistical significance in 1 out of 8 trials.

In 4 trials, FGE03 showed a dose response between 0.7 kg/ha and both lowest rates (0.35 kg/ha and 0.5 kg/ha). Indeed, FGE03 applied at 0.7 kg/ha gave 76.4% mean control, 14.5 points higher than at 0.35 kg/ha (61.9% mean control) and 9.7 points higher than at 0.5 kg/ha (66.7% mean control).

On disease incidence, the dose response is confirmed in all trials presented.

Moreover, the difference between the dose rates was characterised by a better homogeneity of control for the highest rate of 0.7 kg/ha. Indeed, according to box plot graphs, the highest dose of FGE03 showed the highest level of control (see Figure 3.2-12 and Figure 3.2-13).

In summary, in the North-East EPPO climatic zone, when considering data from 6 trials investigating FGE03 minimum effective dose for the control of *Sclerotinia sclerotiorum* in oilseed rape at the last assessment timing (BBCH 80-85 ⁷⁵⁻⁸⁷), in conditions of good disease pressure, FGE03 applied twice demonstrated a clear dose response, with the best effectiveness obtained from the intended rate of 0.7 kg/ha.

C. Results of Minimum effective dose on oilseed rape (BRSNN) - *Sclerotinia sclerotiorum* (SCLESC) - 2 applications - South-East EPPO climatic zone

Against *Sclerotinia sclerotiorum*, a total of 5 valid efficacy trials were carried out to confirm the requested dose of FGE03. These trials were carried out in 2022 and 2023 in the South-East EPPO climatic zone in Bulgaria (2 trials) and Hungary (3 trials).

Table 3.2-28 presents a summary of the results of minimum effective dose and Figure 3.2-14 (disease severity) and Figure 3.2-15 (disease incidence) represent the minimum effective dose in box plot graphics against *Sclerotinia sclerotiorum*.

Table 3.2-28: Summary results: minimum effective dose of FGE03 - Oilseed rape - SCLESC on stems - South-East EPPO climatic zone - 2 applications

Parameters	Assessment timing	Parts	EPPO climatic zone	No. of trials	Days after application	Untreated (% of infestation)			% Control												No. of trials where FGE03 at 0.70 kg/ha is statistically ⁽¹⁾ > ; = ; < compared to	
									FGE03 0.35 kg/ha Application : A + B				FGE03 0.50 kg/ha Application : A + B				FGE03 0.70 kg/ha Application : A + B					
						Mean	Min	Max	Mean	Min	Max	SD	Mean	Min	Max	SD	Mean	Min	Max	SD	0.35 kg/ha	0.50 kg/ha
Severity (%)	BBCH 77-85 75-87	STEM	South-East	5	[21-41 DA-B]	14.2	5.0	24.8	62.2	41.5	70.0	11.8	-	-	-	-	84.2	77.1	94.5	6.7	4>;1=;0<	-
	BBCH 81-85 75-87	STEM	South-East	3	[21-41 DA-B]	17.7	13.8	24.8	59.2	41.5	68.9	15.4	80.2	66.7	92.8	13.0	86.0	77.1	94.5	8.7	-	1>;2=;0<
Incidence (%)	BBCH 77-85 75-87	STEM	South-East	5	[21-41 DA-B]	45.8	21.0	73.0	49.4	33.3	61.1	12.8	-	-	-	-	74.9	65.7	80.6	6.0	4>;1=;0<	-
	BBCH 81-85 75-87	STEM	South-East	3	[21-41 DA-B]	28.7	21.0	36.0	44.1	33.3	61.1	14.9	67.9	61.9	72.4	5.4	78.7	76.2	80.6	2.2	-	0>;3=;0<

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Figure 3.2-14: Minimum effective dose of FGE03 - Oilseed rape - SCLESC - Disease severity on stems at BBCH 77-85 75-87 - South-East EPPO climatic zone - Box plot graphics - Means of 5 trials - 2 applications

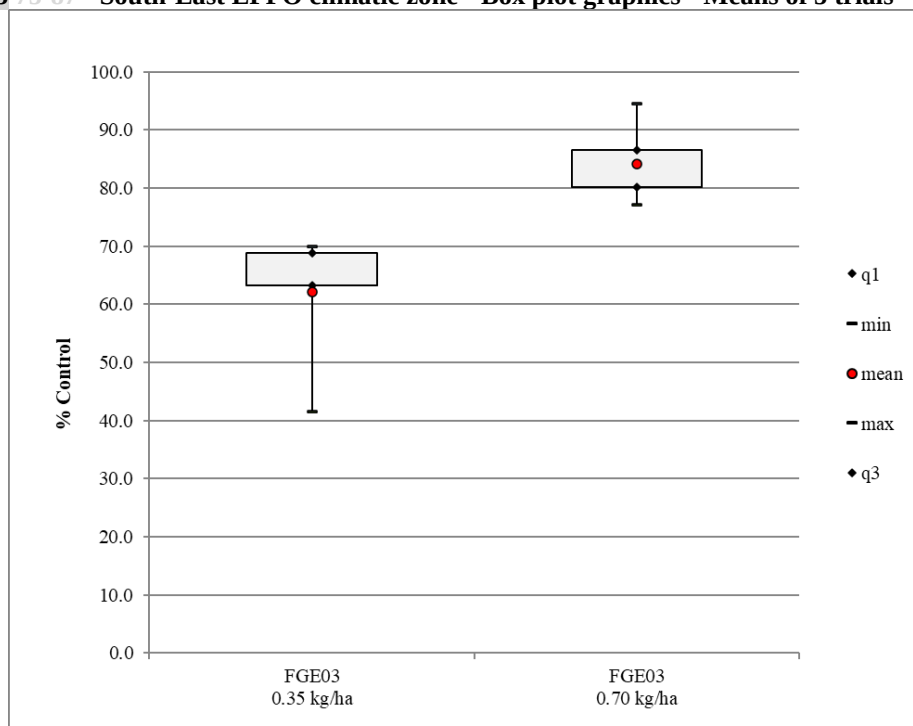
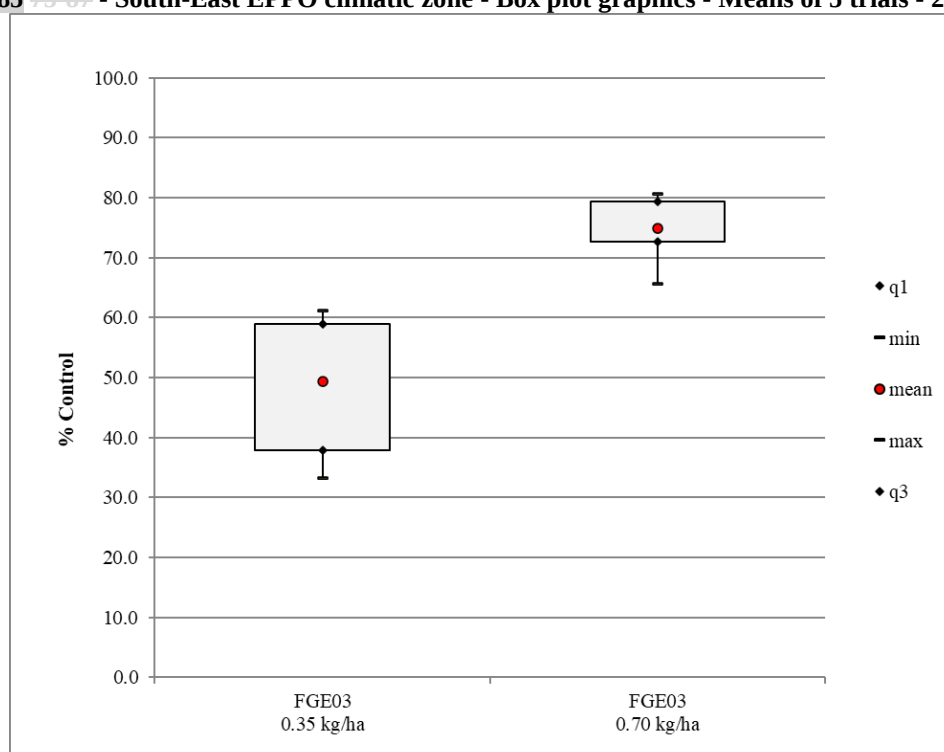


Figure 3.2-15: Minimum effective dose of FGE03 - Oilseed rape - SCLESC - Disease incidence on stems at BBCH 77-85 75-87 - South-East EPPO climatic zone - Box plot graphics - Means of 5 trials - 2 applications



In these trials, at the assessment (BBCH 77-85 75-87), in the untreated control, the average infestation was good (14% disease severity and 46% disease incidence on stems on average across 5 trials), varying from 5% to 25% disease severity and from 21% to 73% disease incidence in individual trials.

On disease severity, FGE03 showed a clear dose response between 0.35 kg/ha and 0.7 kg/ha in 5 trials. Indeed, FGE03 applied at 0.7 kg/ha gave 84.2% mean control, 22.0 points higher than at 0.35 kg/ha

(62.2% mean control). In addition, a statistical effect was highlighted in 4 out of 5 trials between FGE03 at 0.7 kg/ha vs. at 0.35 kg/ha.

In 3 trials, FGE03 showed a clear dose response between the 3 rates. Indeed, FGE03 applied at 0.7 kg/ha gave 86.0% mean control, 26.8 ~~23.8~~ points higher than at 0.35 kg/ha (59.2% mean control) and 5.8 points higher than at 0.5 kg/ha (80.2% mean control). In addition, a statistical effect was highlighted in 1 out of 3 trials between FGE03 at 0.7 kg/ha vs. 0.5 kg/ha.

On disease incidence, the dose response is confirmed in all trials presented.

Moreover, the difference between the dose rates was characterised by a better homogeneity of control for the highest rate of 0.7 kg/ha. Indeed, according to box plot graphs, the highest dose of FGE03 showed the highest level of control and the lowest dispersion and variation between means (see Figure 3.2-14 and Figure 3.2-15)

In summary, in the South-East EPPO climatic zone, when considering data from 5 trials investigating FGE03 minimum effective dose for the control of *Sclerotinia sclerotiorum* in oilseed rape at the last assessment timing (BBCH 77-85 ~~75-87~~), in conditions of good disease pressure, FGE03 applied twice demonstrated a clear dose response, with the best effectiveness obtained from the intended rate of 0.7 kg/ha.

D. Conclusion: results of Minimum effective dose on oilseed rape (BRSNN) - *Sclerotinia sclerotiorum* (SCLESC) - 2 applications - All EPPO climatic zones

Against *Sclerotinia sclerotiorum*, a total of 16 valid efficacy trials were carried out to confirm the requested dose of FGE03 applied twice. These trials were carried out in 2022 and 2023 in the Maritime (5 trials), North-East (6 trials) and South-East EPPO (5 trials) climatic zones.

In addition, according to Poland national guidance [Skuteczność działania środków ochrony roślin; updated on 15/09/2023], that data from countries adjacent to PL can be considered supportive. Therefore, data from CZ is also relevant for PL and presented in the following tables (North-East zone + CZ).

Table 3.2-29 presents a summary of the results of minimum effective dose and Figure 3.2-16 (disease severity) and

Figure 3.2-17 (disease incidence) represent the minimum effective dose in box plot graphics against *Sclerotinia sclerotiorum*.

Table 3.2-29: Minimum effective dose of FGE03 (% control based on disease severity and incidence on stems at BBCH 77-85 ~~75-87~~) in oilseed rape to control *Sclerotinia sclerotiorum* - 2 applications

Regulatory zone	EPPO climatic zone	Parameters	# Trials	Untreated (% infestation)	Mean control (%) on disease on stem			No. of trials where FGE03 at 0.70 kg/ha is statistically ⁽¹⁾ > ; = ; < compared to	
					FGE03 0.35 kg/ha 123+70 g a.s./ha 0.5N Application : A + B	FGE03 0.5 kg/ha 175+100 g a.s./ha 0.71N Application : A + B	FGE03 0.7 kg/ha 245+140 g a.s./ha N Application : A + B	FGE03 0.35 kg/ha	FGE03 0.50 kg/ha
-	Maritime	Severity (%)	5	23.0	65.3	-	89.3	1>;4=;0<	-
			4	26.0	60.5	73.3	87.0	-	0>;4=;0<
		Incidence (%)	5	36.8	58.2	-	83.2	2>;3=;0<	-
			4	38.5	52.7	66.1	80.7	-	1>;3=;0<
	North-East	Severity (%)	6	15.1	77.5	-	84.1	0>;6=;0<	-
			2	14.6	57.6	54.7	64.6	-	0>;2=;0<
		Incidence (%)	6	38.8	68.8	-	78.7	0>;6=;0<	-
			2	53.3	52.3	51.3	60.7	-	0>;2=;0<
	South-East	Severity (%)	5	14.2	62.2	-	84.2	4>;1=;0<	-
			3	17.7	59.2	80.2	86.0	-	1>;2=;0<
		Incidence (%)	5	45.8	49.4	-	74.9	4>;1=;0<	-
			3	28.7	44.1	67.9	78.7	-	0>;3=;0<
Central zone	Maritime + NE + SE	Severity (%)	16	17.3	68.9	-	85.8	5>;11=;0<	
			9	20.7	59.4	71.5	81.7		1>;8=;0<
		Incidence (%)	16	40.4	59.4	-	78.9	6>;10=;0<	
			9	38.5	49.7	63.4	75.6		1>;8=;0<
Poland*	North-East + CZ trials	Severity (%)	8	18.7	74.7	-	85.1	1>;7=;0<	
			4	22.1	61.9	66.7	76.4		0>;4=;0<
		Incidence (%)	8	41.4	66.1		80.0	1>;7=;0<	
			4	51.4	55.1	62.0	72.1		1>;3=;0<

⁽¹⁾ Comparison based on statistics carried out in each trial report.

* This additional line includes North-East EPPO climatic zone data + Czech Republic data. Indeed, Poland is a country bordering Czech Republic, which belongs to the Maritime EPPO zone and thus, the climate conditions and the disease development are quite similar, even though they belong to different climatic zones (according to Poland national guidance “Skuteczność działania środków ochrony roślin”; updated on 15/09/2023).

Figure 3.2-16: Minimum effective dose of FGE03 - Oilseed rape - SCLESC - Disease severity on stems at BBCH 77-85 75-87- All EPPO climatic zones - Box plot graphics - 2 applications

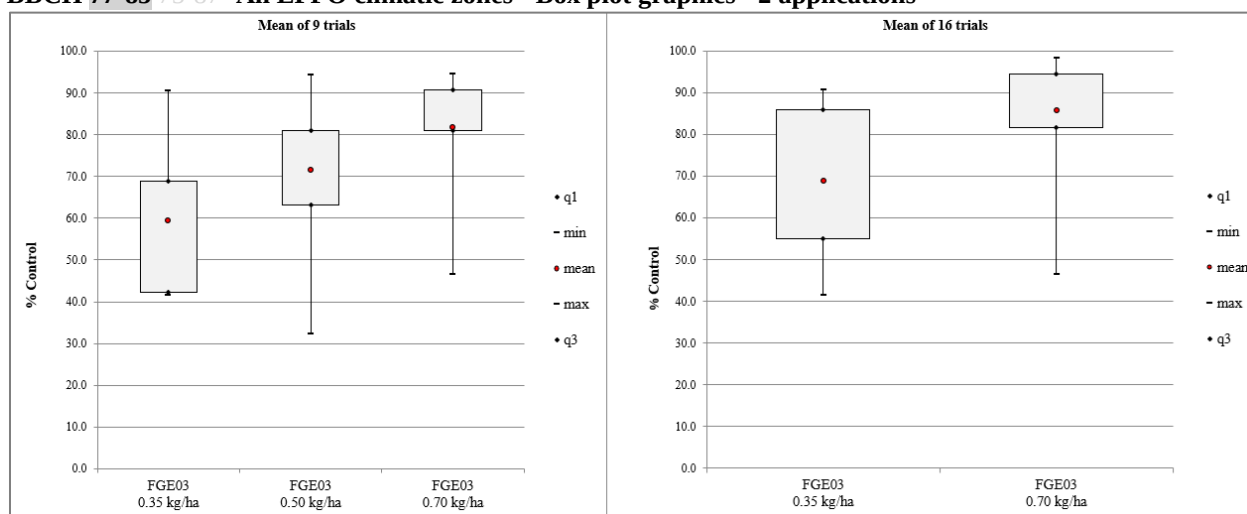
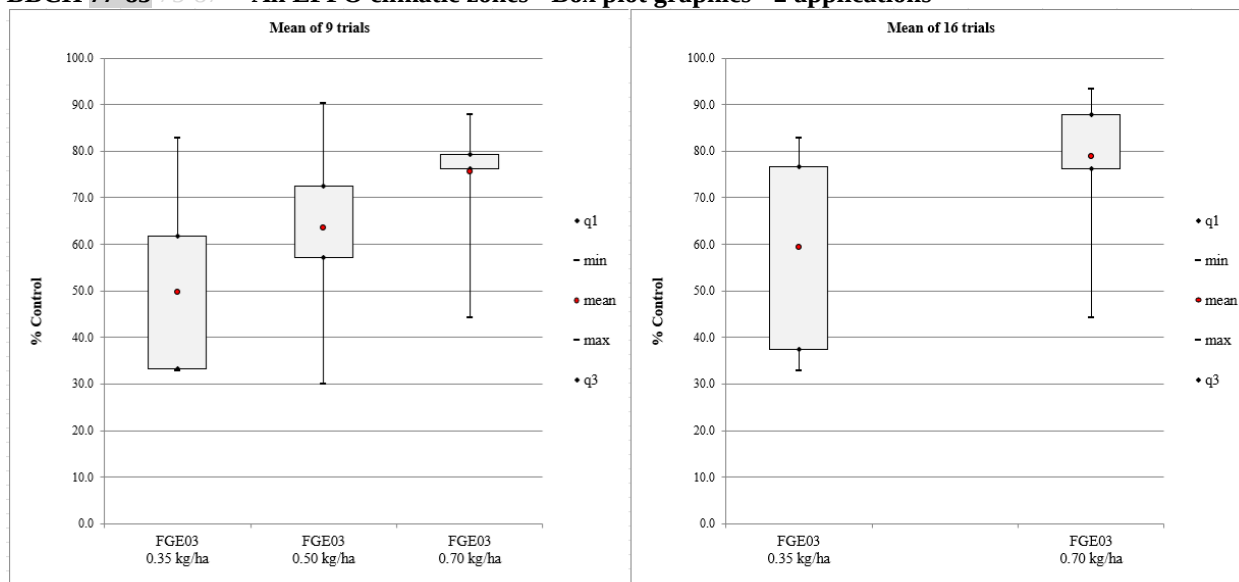


Figure 3.2-17: Minimum effective dose of FGE03 - Oilseed rape - SCLESC - Disease incidence on stems at BBCH 77-85 75-87- All EPPO climatic zones - Box plot graphics - 2 applications



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.

It is therefore reasonable to conclude that the proposed label rate of 0.7 kg/ha of FGE03 applied twice is fully justified as the minimum effective dose in the Central registration zone.

Comments of zRMS on:
Minimum effective dose tests – Results – 2 applications (3.2.2.2.2)

Results from 16 efficacy trials have been presented to determine the Minimum effective dose (MED) of FGE03 applied twice in the control of *Sclerotinia sclerotiorum* on winter oilseed rape. The trials were carried out in 3 EPPO zones: Maritime (Denmark - 2 trials, Czech Republic - 2 trials, the United Kingdom -1 trial), North-East (Lithuania - 2 trials, Poland - 4 trials) and South-East (Bulgaria - 2 trials, Hungary - 3 trials) in the years 2022-2023.

The recommended dose rate of 0.7 kg/ha of FGE03 was compared with lower dose rates: 0.5 kg/ha and/ or 0.35 kg/ha corresponding to 71% and 50% of the target dose rate respectively.

Conclusions from the MED trials for individual EPPO climatic zones are presented below.

Maritime EPPO zone (5 trials)

For disease severity and disease incidence, FGE03 achieved the best efficacy results at the highest tested dose rate of 0.7 kg/ha. A clear dose response was observed comparing 3 tested dose rates: 0.35 kg/ha, 0.5 kg/ha and 0.7 kg/ha in 4 trials and between dose rates: 0.35 kg/ha and 0.7 kg/ha in 5 trials. Comparing dose rates 0.35 kg/ha and 0.7 kg/ha statistically significant differences were observed in 1 out of 5 trials, in favour of the recommended dose rate of 0.7 kg/ha for disease severity and in 2 out of 5 trials in favour of the recommended dose rate of 0.7 kg/ha. Comparing dose rates 0.5 kg/ha and 0.7 kg/ha, there were no statistically significant differences for disease severity. Only differences in numerical values were noted. For disease incidence, statistically significant differences were observed in 1 out of 4 trials in favour of the recommended dose rate of 0.7 kg/ha.

North-East EPPO zone (6 trials)

Regarding disease severity and disease incidence, a clear dose response was noted comparing the efficacy of FGE03 applied at 0.7 kg/ha with the efficacy results achieved for lower dose rate 0.35 kg/ha in 6 trials. Only differences in numerical values were noted. No statistically significant differences between tested dose rates were demonstrated in these trials. A visible dose response was demonstrated comparing the recommended dose rate 0.7 kg/ha with lower application rates 0.5 kg/ha in 2 trials. Only differences in numerical values were noted. No statistically significant differences between tested dose rates were demonstrated in these trials.

North-East EPPO zone + Maritime EPPO zone - CZ (8 trials)

For disease severity and disease incidence, a clear dose response was noted comparing the efficacy of FGE03 applied at 0.7 kg/ha with the efficacy results achieved for lower dose rate 0.35 kg/ha in 8 trials. Statistically significant differences were demonstrated in 1 out of 8 trials in favour of the recommended dose rate of 0.7 kg/ha.

Considering results from 4 trials, and comparing dose rate 0.5 kg/ha with 0.7 kg/ha, a clear dose response was demonstrated for disease severity and disease incidence. No statistically differences between dose rates were observed for disease severity. Only differences in numerical values were noted. For disease incidence, statistically significant differences were demonstrated in 1 out of 4 trials in favour of the recommended dose rate of 0.7 kg/ha.

South-East EPPO zone (5 trials)

For disease severity and disease incidence, FGE03 achieved the best efficacy results at the highest tested dose rate of 0.7 kg/ha, and a clear dose response was observed comparing 3 tested dose rates: 0.35 kg/ha, 0.5 kg/ha and 0.7 kg/ha in 3 trials and between dose rates: 0.35 kg/ha and 0.7 kg/ha in 5 trials. Comparing dose rates 0.35 kg/ha and 0.7 kg/ha statistically significant differences were observed in 4 out of 5 trials in favour of the recommended dose rate of 0.7 kg/ha for disease severity and disease incidence. Comparing dose rates 0.5 kg/ha and 0.7 kg/ha statistically significant differences were observed in 1 out of 3 trials in favour of the recommended dose rate of 0.7 kg/ha for disease severity. For disease incidence no statistically differences between dose rates were observed in these 3 trials. Only differences in numerical values were noted.

General conclusion of zRMS on:

Minimum effective dose tests (3.2.2)

Based on the submitted trial results it can be concluded, that minimum effective dose rate of 0.7 kg/ha has been justified for the control of *Sclerotinia sclerotiorum* on winter oilseed rape in Maritime, North-East and South-East EPPO climatic zones both for the variant of application 1 time per growing season and for the variant of application 2 times per growing season.

3.2.3 Efficacy tests (KCP 6.2)

All the trials were carried out by officially recognised organisations in accordance with the Principles of Good Experimental Practice (GEP). These trials were performed following EPPO guidelines or trial

method recommendations published by the CEB (“Commission des Essais Biologiques”). The “CEB” methods are in accordance with EPPO guidelines.

For information, since it is known that the fungicide activity on plants depends more on susceptibility properties of oilseed rape varieties to fungal diseases than on winter/spring type, it is considered that results obtained on winter oilseed rape can be extrapolated to spring oilseed rape and vice versa.

All the efficacy trials were carried out in areas representative of the crop growing conditions of the relevant countries.

3.2.3.1 Material and methods

Site description

A total of 50 trials were established in the Maritime EPPO zone (22 trials), in North-East EPPO zone (12 trials) and in the South-East EPPO zone (16 trials) in order to investigate the performance of FGE03 on *Sclerotinia sclerotiorum* in oilseed rape.

Maritime EPPO climatic zone

- 1 application

Results from 7 valid field trials are presented to study the efficacy of FGE03 applied once for the control of *Sclerotinia sclerotiorum* in oilseed rape. These trials were carried out in 2023 and 2024 in Austria (1 trial), Northern France (3 trials), Denmark (2 trials) and the United Kingdom (1 trial). In addition, 9 other trials were carried out in 2023 and 2024 but not valid. These efficacy trials are taken into account only for selectivity data in this dossier.

Main characteristics are summarised in Table 3.2-30 (valid efficacy trials) and Table 3.2-31 (not valid efficacy trials) and detailed data per trial (trial location, crop cultivar, experimental design, number of replicates, plot size and applications) are presented in Biological Assessment Dossier.

Table 3.2-30: Details on trial methodology - Valid efficacy trials (with disease) - Maritime EPPO zone - 1 application

Guidelines	General guidelines	PP1/135(4): “Phytotoxicity assessment”. PP1/152(4): “Design and analysis of efficacy evaluation trials”. PP1/181(4/5): “Conduct and reporting of efficacy evaluation trials, including good experimental practice”. PP1/223(2): “Introduction to the efficacy evaluation of plant protection products”. PP 1/225(2): “Minimum effective dose”.
	Specific guidelines	PP1/78(4): “Root, stem, foliar and pod diseases of rape”
Experimental design	Plot design	Randomized Complete Block (RCB)
	Plot size	24-45 m²
	Number of replications	4
Crop	Trials per crop	7 valid efficacy trials
	Varieties per crop	Creed (1), DK Expension (1), Kadji (1), LG Aviron (1), LG Scorpion (1), Ramses (1), Umberto (1).
	Sowing period	August 2022 August 2023
Application	Crop stage (BBCH) at application	FGE03: application between BBCH 65-69 (April-May)
	Number of applications	FGE03: 1 application in all trials (7 trials) Reference products: - 1 application in trials carried in 2024 (5 trials) - 2 applications in trials carried out in 2023 (2 trials)
	Spray volumes	Foliar spraying: 150-400 L/ha.
Assessment	Assessment types	Disease incidence and disease severity on stem. Harvest (5 trials). Phytotoxicity assessments.
	Assessment dates	Key assessment selected: at last assessment BBCH 75-85 ~~87~~ (between 27-74 DA-A)
Other relevant information	e.g. Natural / artificial inoculation...	Natural infection: 0 trial Artificial inoculation: 7 trials
	e.g. Field / Greenhouse...	Field

Table 3.2-31: Details on trial methodology - Not valid efficacy trials (without or with too low disease pressure) - Maritime EPPO zone - 1 application

Guidelines	General guidelines	PP1/135(4): “Phytotoxicity assessment”. PP1/152(4): “Design and analysis of efficacy evaluation trials”. PP1/181(4/5): “Conduct and reporting of efficacy evaluation trials, including good experimental practice”. PP1/223(2): “Introduction to the efficacy evaluation of plant protection products”. PP 1/225(2): “Minimum effective dose”.
	Specific guidelines	PP1/78(3/4): “Root, stem, foliar and pod diseases of rape”
Experimental design	Plot design	Randomized Complete Block (RCB)
	Plot size	24-40 m ²
	Number of replications	4
Crop	Trials per crop	9 not valid efficacy trials - Valid only for selectivity data
	Varieties per crop	Arianos (1), Avatar (1), DK Expectation (1), Hermann (1), KWS Allessandro (1), LG Ambassador (1), PX211 (1), RGT Ozzone (1), Traithlon (1).
	Sowing period	August 2022 August - September 2023
Application	Crop stage (BBCH) at application	FGE03: application between BBCH 61-67 (April-May)
	Number of applications	FGE03: 1 application in all trials (9 trials) Reference products: - 1 application in trials carried in 2024 (5 trials) - 2 applications in trials carried out in 2023 (4 trials)
	Spray volumes	Foliar spraying: 200-400 L/ha.
Assessment	Assessment types	Phytotoxicity assessments
	Assessment dates	-
Other relevant information	e.g. Natural / artificial inoculation...	-
	e.g. Field / Greenhouse...	Field

- 2 applications

Results from 5 valid field trials are presented to study the efficacy of FGE03 applied twice for the control of *Sclerotinia sclerotiorum* in oilseed rape. These trials were carried out in 2022 and 2023 in Czech Republic (2 trials), Denmark (2 trials) and the United Kingdom (1 trial). In addition, another trial was carried out in the United Kingdom in 2022, but due to a too low level of disease, this efficacy trial is taken into account only for selectivity data in this dossier.

Main characteristics are summarised in Table 3.2-32 and Table 3.2-33 and detailed data per trial (trial location, crop cultivar, experimental design, number of replicates, plot size and applications) are presented in Biological Assessment Dossier.

Table 3.2-32: Details on trial methodology - Valid efficacy trials (with disease) - Maritime EPPO zone - 2 applications

Guidelines	General guidelines	PP1/135(4): “Phytotoxicity assessment”. PP1/152(4): “Design and analysis of efficacy evaluation trials”. PP1/181(4): “Conduct and reporting of efficacy evaluation trials, including good experimental practice”. PP1/223(2): “Introduction to the efficacy evaluation of plant protection products”. PP 1/225(2): “Minimum effective dose”.
	Specific guidelines	PP1/78(3/4): “Root, stem, foliar and pod diseases of rape”
Experimental design	Plot design	Randomized Complete Block (RCB)
	Plot size	25-36 m ²
	Number of replications	4
Crop	Trials per crop	5 valid efficacy trials
	Varieties per crop	Aurelia (1), Crome (1), DK Exception (1), LG Anarion (1), Plastic (1)
	Sowing period	August 2021 September 2022
Application	Crop stage (BBCH) at application	First application: BBCH 60-65 (April) Second application: BBCH 65-69 ~~70~~ (May)
	Number of applications	2
	Spray volumes	Foliar spraying: 150-300 L/ha.
Assessment	Assessment types	Disease incidence and disease severity on stem. Harvest (5 trials) Phytotoxicity assessments.
	Assessment dates	Key assessment selected: at last assessment BBCH ~~77-85~~ ~~75-87~~ (between 21-62 DA-B)
Other relevant information	e.g. Natural / artificial inoculation...	Natural infection: 3 trials Artificial inoculation: 2 trials
	e.g. Field / Greenhouse...	Field

Table 3.2-33: Details on trial methodology - Not valid efficacy trials (without or with too low disease pressure) - Maritime EPPO zone - 2 applications

Guidelines	General guidelines	PP1/135(4): “Phytotoxicity assessment”. PP1/152(4): “Design and analysis of efficacy evaluation trials”. PP1/181(4): “Conduct and reporting of efficacy evaluation trials, including good experimental practice”. PP1/223(2): “Introduction to the efficacy evaluation of plant protection products”. PP 1/225(2): “Minimum effective dose”.
	Specific guidelines	PP1/78(3): “Root, stem, foliar and pod diseases of rape”
Experimental design	Plot design	Randomized Complete Block (RCB)
	Plot size	36 m ²
	Number of replications	4
Crop	Trials per crop	1 not valid efficacy trial - Valid only for selectivity data
	Varieties per crop	<i>Ramses (1)</i>
	Sowing period	August 2021
Application	Crop stage (BBCH) at application	First application: BBCH 65 (May) Second application: BBCH 69 (May)
	Number of applications	2
	Spray volumes	Foliar spraying: 300 L/ha.
Assessment	Assessment types	Phytotoxicity assessments
	Assessment dates	-
Other relevant information	e.g. Natural / artificial inoculation...	
	e.g. Field / Greenhouse...	Field

North-East EPPO climatic zone

- 1 application

Results from 4 valid field trials are presented to study the efficacy of FGE03 applied once for the control of *Sclerotinia sclerotiorum* in oilseed rape. These trials were carried out in 2024 in Lithuania (1 trial) and Poland (3 trials).

Main characteristics are summarised in Table 3.2-34 (valid efficacy trials) and detailed data per trial (trial location, crop cultivar, experimental design, number of replicates, plot size and applications) are presented in Biological Assessment Dossier.

Table 3.2-34: Details on trial methodology - Valid efficacy trials (with disease) - North-East EPPO zone - 1 application

Guidelines	General guidelines	PP1/135(4): “Phytotoxicity assessment”. PP1/152(4): “Design and analysis of efficacy evaluation trials”. PP1/181(4/5): “Conduct and reporting of efficacy evaluation trials, including good experimental practice”. PP1/223(2): “Introduction to the efficacy evaluation of plant protection products”. PP 1/225(2): “Minimum effective dose”.
	Specific guidelines	PP1/78(3/4): “Root, stem, foliar and pod diseases of rape”
Experimental design	Plot design	Randomized Complete Block (RCB)
	Plot size	21-42 m ²
	Number of replications	4
Crop	Trials per crop	4 valid efficacy trials
	Varieties per crop	Architect (1), Duplo (1), Gemini (1), Umberto (1).
	Sowing period	August-September 2024
Application	Crop stage (BBCH) at application	FGE03: application between BBCH 63-69 (April-May)
	Number of applications	FGE03: 1 application in all trials (4 trials)
	Spray volumes	Foliar spraying: 200-300 L/ha.
Assessment	Assessment types	Disease incidence and disease severity on stem. Harvest (4 trials). Phytotoxicity assessments.
	Assessment dates	Key assessment selected: at last assessment BBCH ~~85~~ 75-87 (between ~~46-53~~ 27-74 DA-A)
Other relevant information	e.g. Natural / artificial inoculation...	Natural infection: 3 trials Artificial inoculation: 1 trial
	e.g. Field / Greenhouse...	Field

- 2 applications

Results from 6 valid field trials are presented to study the efficacy of FGE03 applied twice for the control of *Sclerotinia sclerotiorum* in oilseed rape. These trials were carried out in 2022 and 2023 in Lithuania (2 trials) and Poland (4 trials). In addition, 2 other trials were carried out in Poland in 2022, but due to no presence of disease, these efficacy trials are taken into account only for selectivity data in this dossier.

Main characteristics are summarised in Table 3.2-35 (valid efficacy trials) and Table 3.2-36 (not valid efficacy trials) and detailed data per trial (trial location, crop cultivar, experimental design, number of replicates, plot size and applications) are presented in Biological Assessment Dossier.

Table 3.2-35: Details on trial methodology - Valid efficacy trials (with disease) - North-East EPPO zone - 2 applications

Guidelines	General guidelines	PP1/135(4): “Phytotoxicity assessment”. PP1/152(4): “Design and analysis of efficacy evaluation trials”. PP1/181(4): “Conduct and reporting of efficacy evaluation trials, including good experimental practice”. PP1/223(2): “Introduction to the efficacy evaluation of plant protection products”. PP 1/225(2): “Minimum effective dose”.
	Specific guidelines	PP1/78(3/4): “Root, stem, foliar and pod diseases of rape”
Experimental design	Plot design	Randomized Complete Block (RCB)
	Plot size	21-27 m ²
	Number of replications	4
Crop	Trials per crop	6 valid efficacy trials
	Varieties per crop	Bono (1), Dariot (1), Kepler (1), KWS Factor (1), LG Artemis (1), Oriolus (1)
	Sowing period	August 2021 & 2022 September 2022
Application	Crop stage (BBCH) at application	First application: BBCH 60-65 (April-May) Second application: BBCH 65-69 (May-June)
	Number of applications	2
	Spray volumes	Foliar spraying: 300 L/ha.
Assessment	Assessment types	Disease incidence and disease severity on stem. Harvest (2 trials) Phytotoxicity assessments
	Assessment dates	Key assessment selected: at last assessment BBCH 80-85 ~~75-87~~ (between 40-52 ~~21-62~~ DA-B)
Other relevant information	e.g. Natural / artificial inoculation...	Natural infection: 6 trials
	e.g. Field / Greenhouse...	Field

Table 3.2-36: Details on trial methodology - Not valid efficacy trials (without or with too low disease pressure) - North-East EPPO zone - 2 applications

Guidelines	General guidelines	PP1/135(4): “Phytotoxicity assessment”. PP1/152(4): “Design and analysis of efficacy evaluation trials”. PP1/181(4): “Conduct and reporting of efficacy evaluation trials, including good experimental practice”. PP1/223(2): “Introduction to the efficacy evaluation of plant protection products”. PP 1/225(2): “Minimum effective dose”.
	Specific guidelines	PP1/78(3): “Root, stem, foliar and pod diseases of rape”
Experimental design	Plot design	Randomized Complete Block (RCB)
	Plot size	30 m ²
	Number of replications	4
Crop	Trials per crop	2 not valid efficacy trials - Valid only for selectivity data
	Varieties per crop	<i>Aganos (1), Atora (1)</i>
	Sowing period	August
Application	Crop stage (BBCH) at application	First application: BBCH 65 (May) Second application: BBCH 71 (May)
	Number of applications	2
	Spray volumes	Foliar spraying: 200-250 L/ha.
Assessment	Assessment types	Phytotoxicity assessments
	Assessment dates	-
Other relevant information	e.g. Natural / artificial inoculation...	-
	e.g. Field / Greenhouse...	Field

South-East EPPO climatic zone

- 1 application

Results from 11 valid field trials are presented to study the efficacy of FGE03 applied once for the control of *Sclerotinia sclerotiorum* in oilseed rape. These trials were carried out in 2023 and 2024 in Bulgaria (3 trials), Hungary (3 trials) and Romania (5 trials).

Main characteristics are summarised in Table 3.2-37 (valid efficacy trials) and detailed data per trial (trial location, crop cultivar, experimental design, number of replicates, plot size and applications) are presented in Biological Assessment Dossier.

Table 3.2-37: Details on trial methodology - Valid efficacy trials (with disease) - South -East EPPO zone - 1 application

Guidelines	General guidelines	PP1/135(4): “Phytotoxicity assessment”. PP1/152(4): “Design and analysis of efficacy evaluation trials”. PP1/181(4/5): “Conduct and reporting of efficacy evaluation trials, including good experimental practice”. PP1/223(2): “Introduction to the efficacy evaluation of plant protection products”. PP 1/225(2): “Minimum effective dose”.
	Specific guidelines	PP1/78(3/4): “Root, stem, foliar and pod diseases of rape”
Experimental design	Plot design	Randomized Complete Block (RCB)
	Plot size	24-45 m ²
	Number of replications	4
Crop	Trials per crop	11 valid efficacy trials
	Varieties per crop	Duke (1), ES Capello (1), Invigor (1), Konstruktor (1), LG Absolut (1), PT298 (1), PT279CL (1), PT303 (1), PT314 (1), Umberto (2).
	Sowing period	August-September 2022 September-October 2023
Application	Crop stage (BBCH) at application	FGE03: application between BBCH 60-69 (April-May)
	Number of applications	FGE03: 1 application in all trials (11 trials) Reference products: - 1 application in trials carried in 2024 (7 trials) - 2 applications in trials carried out in 2023 (4 trials)
	Spray volumes	Foliar spraying: 200-400 L/ha.
Assessment	Assessment types	Disease incidence and disease severity on stem. Harvest (7 trials). Phytotoxicity assessments.
	Assessment dates	Key assessment selected: at last assessment BBCH ~~77~~ 75-87 (between ~~35-65~~ 27-74 DA-A)
Other relevant information	e.g. Natural / artificial inoculation...	Natural infection: 7 trials Artificial inoculation: 4 trials
	e.g. Field / Greenhouse...	Field

- 2 applications

Results from 5 valid field trials are presented to study the efficacy of FGE03 applied twice for the control of *Sclerotinia sclerotiorum* in oilseed rape. These trials were carried out in 2022 and 2023 in Bulgaria (2 trials) and Hungary (3 trials).

Main characteristics are summarised in Table 3.2-38 and details per trial (trial location, crop cultivar, experimental design, number of replicates, plot size and applications) are presented in Biological Assessment Dossier.

Table 3.2-38: Details on trial methodology - Valid efficacy trials (with disease) - South-East EPPO zone - 2 applications

Guidelines	General guidelines	PP1/135(4): “Phytotoxicity assessment”. PP1/152(4): “Design and analysis of efficacy evaluation trials”. PP1/181(4): “Conduct and reporting of efficacy evaluation trials, including good experimental practice”. PP1/223(2): “Introduction to the efficacy evaluation of plant protection products”. PP 1/225(2): “Minimum effective dose”.
	Specific guidelines	PP1/78(3/4): “Root, stem, foliar and pod diseases of rape”
Experimental design	Plot design	Randomized Complete Block (RCB)
	Plot size	21-30 m ²
	Number of replications	4
Crop	Trials per crop	5 valid efficacy trials
	Varieties per crop	Constructor (1), Dalton (1), Dariot (1), Jeremy (1), PT302 (1)
	Sowing period	August-September 2021 September 2022
Application	Crop stage (BBCH) at application	First application: BBCH 60-67 61-65 (April-May) Second application: BBCH 65-71 67-69 (May)
	Number of applications	2
	Spray volumes	Foliar spraying: 250-400 L/ha.
Assessment	Assessment types	Disease incidence and disease severity on stem. Harvest (3 trials) Phytotoxicity assessments
	Assessment dates	Key assessment selected: at last assessment BBCH 77-85 75-87 (between 21-41 62 DA-B)
Other relevant information	e.g. Natural / artificial inoculation...	Natural infection: 5 trials
	e.g. Field / Greenhouse...	Field

Treatments and reference products

FGE03 was tested at several dose rates and was compared to several reference products. Taking into account the variability of protocols between all trials, only the most relevant treatments for this dossier are presented in this part. All other treatments not presented in this dossier are in Biological Assessment Dossier or individual trial reports in Document K.

► Tested product

For pest management on crops, FGE03 applied once or twice was tested at 0.35, 0.5 and 0.7 kg/ha. These dose rates reflect 50%, 71% and 100% of the full rate of 0.7 kg/ha, in accordance with the EPPO guideline PP 1/225(2) “Minimum effective dose”.

The Minimum effective dose results are presented in point 3.2.2 and showed that the intended rate of 0.7 kg/ha secured a better level of control. Hence in the Efficacy part, only the intended rate of 0.7 kg/ha is presented.

In 1 trial due to an error in the protocol, FGE03 was applied at the rate of at 0.75 kg/ha (263 g boscalid/ha + 150 g prothioconazole/ha) instead of the target rate of 0.70 kg/ha (245 g boscalid/ha + 140 g prothioconazole/ha). The difference being less than 10% deviation of N rate requested, the results obtained with the rate 0.75 kg/ha were merged with the results of the target rate of 0.7 kg/ha.

Trials with 1 application of FGE03:

Treatments were applied at timings between April and May, at crop growth stages ranging between BBCH 60-69, therefore, except in 1 trial, all were within the application window of the proposed label range of BBCH 61-69. In the last trial, the first application was conducted from BBCH 60 slightly earlier to the application window but still regarded as valid to the proposed label range of BBCH 61-69.

Trials with 2 applications of FGE03:

First treatment was applied at timings between April and May, at crop growth stages ranging between BBCH 60-65 and second treatment was applied at timings between May and early June, at crop growth stages ranging between BBCH 65-71. Overall, all treatments are within the application window of the proposed label range of BBCH 61-73, except in 1 trial. In the last trial, the first application was conducted from BBCH 60 slightly earlier to the application window but still regarded as valid to the proposed label range of BBCH 61-73.

► Reference products

For this dossier, a comparison of FGE03 at its intended rate 0.7 kg/ha with 1, 2 or 3 of the most relevant reference products is presented.

In order to compare the efficacy of FGE03, the cross-reference (transversal reference) in this dossier is a product based on **prothioconazole solo** (EC formulation). This reference was chosen because its efficacy is known throughout Europe. Depending on the country the product name may be different (see Table 3.2-10), but are similar regarding to the efficacy and results are grouped in the mean tables for this dossier (Prothioconazole 175 g as/ha [174-180 g as/ha]). If this product was not registered in the country or not applied according to its registered use, a second reference product applied according to its registered use was included to validate the trial. The information with all reference products detailed used in trials are available in Biological Assessment Dossier and individual trial reports in Document K.

Regarding boscalid reference product, in France for marketing positioning and segmentation reasons, the 500 g/kg boscalid formulation registered by BASF France SAS has the tradename CANTUS for use on grapevine, and for other crops it is sold using the name PICTOR PRO. Thus, for reasons of product availability, in French trials the reference product applied in the trials was CANTUS or PICTOR PRO without distinction. Both products were strictly similar, (see table below) thus, we grouped both products by the same name of CANTUS in this dossier (most represented commercial name in the countries targeted by this dossier). However, the information with the real reference products used in French trials are available in Biological Assessment Dossier and individual trial reports in Document K.

Product name	CANTUS	PICTOR PRO
Formulation	BOSCALID 500 g/kg WG	BOSCALID 500 g/kg WG
No. AMM	2050076	2050075
Date of first registration	14/06/2005	14/06/2005
Company	BASF FRANCE SAS	BASF FRANCE SAS
Classification	TCC2; H411	TCC2; H411
Crop	Grapevine	Flax, oilseed rape, beans and peas
MSDS	Identical to PICTOR PRO (link)	Identical to CANTUS (link)

Regarding to **the trials with 1 application of FGE03**, we have 2 types of protocols compared to the number of applications of the reference products:

- ***Trials carried out in 2023 (10 trials)***: the reference products were applied twice.
The first application (A) was carried out at the same time that the single application FGE03 (between BBCH 60-65) and the second application (B) was carried out between 14 and 17 days after the first application (between BBCH 65-73).
- ***Trials carried out in 2024 (21 trials)***: the reference products were applied once (A) at the same time that FGE03 between BBCH 61-69 (April-May).

Regarding to **the trials with 2 applications of FGE03**, we have 1 type of protocols with also 2 applications of the reference products at the same timing.

Each application timing is indicated for each treatment in the result tables.

Table 3.2-39 (trials with 1 application of FGE03) and Table 3.2-40 (trials with 2 applications of FGE03) below present the reference products and the dose rates used in this dossier in each trial.

Table 3.2-39: Plant protection products used in efficacy trials - 1 application of FGE03

Number of trials	Year	Country	EPPO climatic zone	Number of applications of the reference product	PROLINE 250 Prothioconazole 175 gai/ha 0.7 L/ha	JOAO Prothioconazole 175 gai/ha 0.7 L/ha	PROTENDO 300 EC Prothioconazole 174 gai/ha 0.58 L/ha	TILMOR Prothioconazole + tebuconazole 240 g ai/ha 1.0 L/ha	TILMOR Prothioconazole + tebuconazole 288 g ai/ha 1.2 L/ha	PICTOR PRO Boscalid 250 gai/ha 0.5 kg/ha	CANTUS Boscalid 250 gai/ha 0.5 kg/ha
1 trial	2024	AT	Maritime	1	X						X
2 trials *	2024	BE	Maritime	1	X						X
1 trial *	2023	CZ	Maritime	2	X						
2 trials *	2023	DE	Maritime	2	X						
1 trial *	2024	DE	Maritime	1	X						X
2 trials	2024	DK	Maritime	1	X						
2 trials	2023	FR	Maritime	2		X					
1 trial *	2024	FR	Maritime	1		X				X	
1 trial	2024	FR	Maritime	1		X				X	
1 trial	2024	UK	Maritime	1	X					X	
1 trial *	2023	IE	Maritime	2	X						
1 trial *	2024	SE	Maritime	1	X						
1 trial	2024	LT	North-East	1	X						X
3 trials	2024	PL	North-East	1			X				X
2 trials	2024	BG	South-East	1	X						X
1 trial	2024	BG	South-East	1	X						X
2 trials	2023	HU	South-East	2	X				X		
1 trial	2024	HU	South-East	1	X						X
1 trial	2023	RO	South-East	2	X						
1 trial	2023	RO	South-East	2	X			X			
2 trials	2024	RO	South-East	1	X						X
1 trial	2024	RO	South-East	1	X						X

* Not valid trial for efficacy part

Table 3.2-40: Plant protection products used in efficacy trials - 2 applications of FGE03

Number of trials	Year	Country	EPPO climatic zone	Number of reference product applications	PROLINE 250 Prothioconazole 175 gai/ha 0.7 L/ha	PROLINE 275 Prothioconazole 173 gai/ha 0.63 L/ha	MELVAR Prothioconazole 175 gai/ha 0.7 L/ha	PRAKTIS 250 Prothioconazole 175 gai/ha 0.7 L/ha	PROTENDO 300 EC Prothioconazole 180 gai/ha 0.60 L/ha	TILMOR Prothioconazole + tebuconazole 240 g ai/ha 1.0 L/ha	PROSARO EC 250 Prothioconazole + tebuconazole 250 g ai/ha 1.0 L/ha
1 trial	2022	CZ	Maritime	2						X	
1 trial	2022	CZ	Maritime	2	X						
2 trials	2022	DK	Maritime	2							X
1 trial *	2022	UK	Maritime	2		X					
1 trial	2023	UK	Maritime	2	X						
2 trials	2022	LT	North-East	2					X		
2 trials *	2022	PL	North-East	2				X			
4 trials	2023	PL	North-East	2	X				X		
2 trials	2023	BG	South-East	2	X		X				
3 trials	2022	HU	South-East	2					X		

* Not valid trial for efficacy part

Table 3.2-41 and Table 3.2-42 below presents the plant protection products and the rates used in this part.

Table 3.2-41: Plant protection products used in efficacy trials - Oilseed rape - 1 application

Product name	Active substance(s)	Formulation		Application dose in trials (per treatment)	Country	Rate of active substance per ha	Remark
		Type ^[1]	Concentration of a.s.				
FGE03	Boscalid+ prothioconazole	WG	350 g/kg + 200 g/kg	0.70 kg/ha	-	245+140 g a.s./ha	-
Maritime EPPO climatic zone							
PROLINE	Prothioconazole	EC	250 g/L	0.7 L/ha	AT, BE, CZ, DE, DK, UK, IE, SE	175 g a.s./ha	-
JOAO	Prothioconazole	EC	250 g/L	0.7 L/ha	FR	175 g a.s./ha	-
North-East EPPO climatic zone							
PROLINE	Prothioconazole	EC	250 g/L	0.7 L/ha	LT	175 g a.s./ha	-
PROTENDO 300 EC	Prothioconazole	EC	300 g/L	0.58 L/ha	PL	174 g a.s./ha	-
South-East EPPO climatic zone							
PROLINE	Prothioconazole	EC	250 g/L	0.7 L/ha	BG, HU, RO	175 g a.s./ha	-
TILMOR	Prothioconazole + tebuconazole	EC	80 g/L + 160 g/L	1.0 L/ha	RO	80+160 g a.s./ha	-
TILMOR	Prothioconazole + tebuconazole	EC	80 g/L + 160 g/L	1.2 L/ha	HU	96+192 g a.s./ha	-

^[1] EC: Emulsifiable Concentrate; WG: Water-dispersible Granules.

Table 3.2-42: Plant protection products used in efficacy trials - Oilseed rape - 2 applications

Product name	Active substance(s)	Formulation		Application dose in trials (per treatment)	Country	Rate of active substance per ha	Remark
		Type ^[1]	Concentration of a.s.				
FGE03	Boscalid+ prothioconazole	WG	350 g/kg + 200 g/kg	0.70 kg/ha	-	245+140 g a.s./ha	-
Maritime EPPO climatic zone							
PROLINE	Prothioconazole	EC	250 g/L	0.7 L/ha	CZ, UK	175 g a.s./ha	-
PROLINE 275	Prothioconazole	EC	275 g/L	0.63 L/ha	UK	173 g a.s./ha	-
TILMOR	Prothioconazole + tebuconazole	EC	80 g/L + 160 g/L	1.0 L/ha	CZ	80+160 g a.s./ha	-
PROSARO EC 250	Prothioconazole + tebuconazole	EC	125 g/L + 125 g/L	1.0 L/ha	DK	125+125 g a.s./ha	-
North-East EPPO climatic zone							
PROLINE	Prothioconazole	EC	250 g/L	0.7 L/ha	PL	175 g a.s./ha	-
PRAKTIS 250	Prothioconazole	EC	250 g/L	0.7 L/ha	PL	175 g a.s./ha	-
PROTENDO 300 EC	Prothioconazole	EC	300 g/L	0.6 L/ha	LT PL	180 g a.s./ha	-
South-East EPPO climatic zone							
PROLINE	Prothioconazole	EC	250 g/L	0.7 L/ha	BG	175 g a.s./ha	-
PROTENDO 300 EC	Prothioconazole	EC	300 g/L	0.6 L/ha	HU	180 g a.s./ha	-
MELVAR	Prothioconazole	EC	250 g/L	0.7 L/ha	BG	175 g a.s./ha	-

^[1] EC: Emulsifiable Concentrate WG: Water-dispersible Granules.

Assessment methods

In all trials, efficacy was assessed according to EPPO guidelines 1/78(3/4). Assessments of efficacy were made on different plant parts (25 stems per plot) or in the whole plant (25 plants per plot) or leaves and stems of 25 plants per plot.

Data was recorded from 25 randomly plants or plant parts as either percentage of visual infection of disease (disease severity) or as percentage of incidence or occurrence (disease incidence).

Disease severity: (PESSEV)

0% = no disease infestation,
 100% = total disease infestation.

Disease incidence: (PESINC)

0% = no disease present in plot,
 100% = all specified plant parts infected in plot.

Efficacy was calculated according to the formula of Abbott. The efficacy calculation was present in the trial reports, otherwise, the calculation was done with the formula:

$$Efficacy (\%) = \left(1 - \frac{X \text{ treated plot}}{Y \text{ control}}\right) \times 100$$

X treated plot = % of incidence or severity in the treated plot

Y control = % of incidence or severity in the untreated control plot

% control on disease severity = CONSEV and % control on disease incidence = CONINC.

Only results on assessment on stems were presented in this dossier. Indeed, *Sclerotinia sclerotiorum* (called stem rot) grows mainly on stem and it is on the stem that it causes the most damages. In addition, the assessments on whole plants or on leaves are available only in few trials.

Data selection

Regarding efficacy, only data considered valid are presented in the trial groupings. The validity criteria are as follows:

- Infection level: only the trials and assessments with a sufficient infection level in the untreated control are considered in the calculation of means. Thus, only assessments with the pest severity (PESSEV) and pest incidence (PESINC) in the untreated reached at least 5% were considered.

- Normal behaviour of the reference products at their tested rate (usually their registered rate) or FGE03 at the intended rate of 0.7 kg/ha:

* The assessments with no statistical difference between the untreated control and all reference products or between the untreated control and FGE03 applied at 0.7 kg/ha were not taken into account in the data groupings.

* Also, if all reference products at their tested rate (usually their registered rate) and FGE03 applied at 0.7 kg/ha showed a level of control lower than expected (<30% control), this assessment was not taken into account in the data groupings.

Harvest data

The potential effects on yield and on quality were analysed in a selection of efficacy trials.

Where determined, crop yield was evaluated at normal commercial harvest date. Moisture content of the grain was also determined, and yield calculated in t/hectare (corrected to the relevant % humidity of each country).

In the summaries of this dossier, data were expressed in t/ha for the untreated check and in percentage relative compared to the untreated check (% rel.) for the treatments, using this formula:

$\% \text{ relative/UTC} = (\text{Treated value} \times 100) / \text{Untreated value}$
--

Where this calculation was not available in the trial reports, this value was calculated for the dossier following the same formula, so as to make homogeneous trial groupings.

The yield results are considered as part of the summary when the disease was observed in the trial.

In 1 trial, due to a protocol error, Moisture content was not assessed and thus the corrected yield could not be calculated. However, on quality parameters, results were available.

In addition, different quality parameters were measured in trials:

- Oil Content
- Protein content
- Thousand Grain Weight (TGW)
- Specific weight (HLW)

Results layout

All treatments of each trial are not systematically presented in this dossier, only relevant treatments are summarised. All data are available in individual trial reports in Document K and are present in Biological Assessment Dossier.

Only 1 key assessment on stems was selected and summarised in this part, according to the EPPO guideline PP1/78 “Root, stem, foliar and pod diseases of oilseed rape”. This selected assessment is the most representative according to the disease and oilseed rape development and was done between BBCH 75 and BBCH 87 and corresponding at the last valid assessments in the trials. The assessment was performed on stems.

Description of disease severity in UTC and test product behaviour

The infection level in the untreated check is described in the comments of the dossier according to the following scale:

Disease severity in UTC (%)	Description
< 15%	moderate
≥ 15% and < 30%	good
≥ 30% and < 50%	high
≥ 50%	very high

The effectiveness of FGE03 applied at 0.7 kg/ha is described in the comments of the dossier according to the following scale:

% control	Description
< 50%	weak
≥ 50% and < 65%	medium
≥ 65% and < 80%	moderate/adequate
≥ 80% and < 90%	good
≥ 90%	very good

Statistical analyses

Data were analysed using an analysis of variance (ANOVA) on untransformed data. The probability of no significant difference occurring between treatment means was calculated at the F probability value $p(F)=0.05$ (95% confidence limit).

A Newman and Keuls’ test was then applied to assess any treatment differences identified on the basis of the ANOVA test. Results obtained are indicated by a letter. Treatment means with no letter in common are significantly different.

Statistical analyses for individual trial data were performed using the ARMst software.

For clarity, where the term “significant” is used, this means statistically significant according to the calculations.

Phytotoxicity assessments

Phytotoxicity was assessed on an overall plot basis following a 0-100% scale, where 0% means no damages and 100% mean that the crop is completely destroyed.

3.2.3.2 Efficacy of FGE03 after 1 application

The label claim for this use is summarised in Table 3.2-43.

Table 3.2-43: Label claim for oilseed rape against *Sclerotinia sclerotiorum*

Crops	Target	Country	Application timing	No. of applications	Application volume	Dose rate
Oilseed rape (BRSNN)	<i>Sclerotinia sclerotiorum</i> (SCLESC)	PL, HU, CZ	BBCH 61-69	1	100-400 L/ha	0.7 kg/ha

Results from 22 valid field trials are presented to investigate the efficacy of FGE03 at 0.7 kg/ha applied once (245 g boscalid/ha +140 g prothioconazole/ha) against *Sclerotinia sclerotiorum* in oilseed rape. They were carried out in 2023 and 2024. Among these trials, 7 trials were conducted in the Maritime EPPO climatic zone, 4 trials in the North-East EPPO climatic zone and 11 trials in the South-East EPPO climatic zone.

A summary of all trials generating data on oilseed rape against *Sclerotinia sclerotiorum* is presented in Table 3.2-44.

Table 3.2-44: Overview of valid efficacy trials with 1 application - Oilseed rape - *Sclerotinia sclerotiorum*

Number of trials	Crop	Target	Year	Country	EPPO climatic zone	Comment
2 trials	BRSNN	SCLESC	2023	FR	Maritime	Harvest results
1 trial	BRSNN	SCLESC	2024	FR	Maritime	Harvest results
1 trial	BRSNN	SCLESC	2024	AT	Maritime	Harvest results
1 trial	BRSNN	SCLESC	2024	UK	Maritime	-
1 trial	BRSNN	SCLESC	2024	DK	Maritime	-
1 trial	BRSNN	SCLESC	2024	DK	Maritime	Harvest results
3 trials	BRSNN	SCLESC	2024	PL	Northeast	Harvest results
1 trial	BRSNN	SCLESC	2024	LT	Northeast	Harvest results
1 trial *	BRSNN	SCLESC	2023	HU	Southeast	Harvest results
1 trial	BRSNN	SCLESC	2023	HU	Southeast	-
1 trial	BRSNN	SCLESC	2024	HU	Southeast	Harvest results
1 trial	BRSNN	SCLESC	2023	RO	Southeast	Harvest results
1 trial	BRSNN	SCLESC	2023	RO	Southeast	-
3 trials	BRSNN	SCLESC	2024	RO	Southeast	Harvest results
1 trial	BRSNN	SCLESC	2024	BG	Southeast	Harvest results
2 trials	BRSNN	SCLESC	2024	BG	Southeast	-

* Due to a protocol error, the corrected yield could not be calculated but quality results were available.

3.2.3.2.1 Efficacy of FGE03 after 1 application - Maritime EPPO zone

A. Efficacy results of FGE03 after 1 application - Maritime EPPO zone

A total of 7 valid efficacy trials (1 trial in Austria, 3 trials in North of France, 2 trials in Denmark and 1 trial in the United Kingdom) were carried out in the Maritime EPPO zone in 2023 and 2024 to evaluate the efficacy of FGE03 applied once at 0.7 kg/ha (245 g boscalid/ha +140 g prothioconazole/ha) for the control of *Sclerotinia sclerotiorum* in oilseed rape. FGE03 was compared to the reference products Prothioconazole at 175 g a.s./ha (=Proline or Joao) applied once (5 trials carried out in 2024) and twice (2 trials carried out in 2023).

The summary results of the effect of FGE03 applied at 0.7 kg/ha compared to reference products are shown in Table 3.2-45.

Table 3.2-45: Summary results: efficacy of FGE03 - Oilseed rape - SCLESC - Maritime EPPO climatic zone - 1 application

Parameters	Assessment timing	Parts	EPPO climatic zone	No. of trials	Days after application	Untreated (% of infestation)			% Control									No. of trials where FGE03 at 0.70 kg/ha applied once (A) is statistically* > ; = ; < compared to	
									FGE03 ⁽¹⁾ 0.70 kg/ha			Joao/Proline 250 ⁽²⁾ Prothio. 175 g as/ha 0.70 L/ha			Joao/Proline 250 ⁽²⁾ Prothio. 175 g as/ha 0.70 L/ha				
						Application : A			Application : A + B			Application : A			Joao/Proline A + B	Joao/Proline A			
						Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max		
Severity (%)	BBCH 75-85 ₈₇	STEM	Maritime	7	27-74 DA-A	24.9	6.4	37.9	76.8	62.3	88.2							-	-
	BBCH 77-85 ₇₅₋₈₇	STEM	Maritime	2	47-49 DA-A 33-35 DA-B	29.8	24.6	35.0	81.2	74.6	87.9	77.9	67.1	88.6				0>;2=;0<	-
	BBCH 75-85 ₈₇	STEM	Maritime	5	27-74 DA-A	22.9	6.4	37.9	75.0	62.3	88.2				67.7	57.1	92.4	-	0>;5=;0<
Incidence (%)	BBCH 75-85 ₈₇	STEM	Maritime	7 6	27-74 DA-A	60.5 60.0	31.0	74.0	47.6 45.2	36.6	62.2 61.2							-	-
	BBCH 77-85 ₇₅₋₈₇	STEM	Maritime	2 1	47-49 DA-A 33-35 DA-B 49 DA-A / 35 DA-B	68.8 74.0	63.5 74.0	74.0	50.4 38.5	38.5	62.2 38.5	47.2 24.3	24.3	70.1 24.3				0>;2 1=;0<	-
	BBCH 75-85 ₈₇	STEM	Maritime	5	27-74 DA-A	57.1	31.0	69.7	46.6	36.6	61.2				42.3	32.8	50.7	-	0>;5=;0<

⁽¹⁾ FGE03 = Boscalid + Prothioconazole (350+200 g/kg; WG) at 245+140 g as/ha.

⁽²⁾ Joao/Proline = Prothioconazole (250 g/L; EC) applied at 175 g as/ha.

* Comparison based on statistics carried out in each trial report.

In the Maritime EPPO climatic zone, at the last assessment (BBCH 75-85⁸⁷), in the untreated control, the average infestation was good (25% disease severity and 60% disease incidence on stems on average across 7 trials), varying from 6% to 38% disease severity and from 31% to 74% disease incidence in individual trials.

FGE03 applied once at the intended rate of 0.7 kg/ha (245+140 g a.s./ha) demonstrated a moderate level of intrinsic effectiveness on disease severity with 76.8% mean efficacy in 7 trials.

FGE03 applied once at 0.7 kg/ha showed a level of control slightly better than the reference products prothioconazole at 175 g as/ha applied once (75.0% vs. 67.7% mean efficacy in 5 trials) and similar to that of the reference product prothioconazole at 175 g as/ha applied twice (81.2% vs. 77.9% mean efficacy in 2 trials). No statistical differences were found in all individual trials between FGE03 and the reference products prothioconazole at 175 g as/ha applied once or twice.

On the disease incidence, the mean control of FGE03 applied once at 0.7 kg/ha was slightly better than the reference product prothioconazole at 175 g as/ha twice (50.4 38.5% vs. 47.2 24.3% efficacy in 2 ± trials) and similar to that of the reference product prothioconazole at 175 g as/ha applied once (46.6% vs. 42.3% mean efficacy in 5 trials). No statistical differences were found in all individual trials between FGE03 and the reference product prothioconazole at 175 g as/ha applied once or twice.

In summary, in the Maritime EPPO zone, when considering severity data from 7 trials investigating FGE03 effectiveness for the control of *Sclerotinia sclerotiorum* in oilseed rape after once application, in conditions of good *Sclerotinia sclerotiorum* pressure, FGE03 applied at 0.7 kg/ha demonstrated an adequate effectiveness, and performed at a level better or close to that of the reference products prothioconazole at 175 g as/ha applied once or twice.

B. Yield results of FGE03 after 1 application - Maritime EPPO zone

A total of 5 valid efficacy trials (3 trials in France, 1 trial in Austria and 1 trial Denmark) were harvested in the Maritime EPPO zone in 2023 and 2024. The objective was to confirm the yield response of FGE03 in the presence of *Sclerotinia sclerotiorum* in oilseed rape crop.

FGE03 applied once was compared to the reference products Prothioconazole at 175 g a.s./ha (=Proline or Joao) applied once (3 trials carried out in 2024) and twice (2 trials carried out in 2023).

Table 3.2-46 shows a summary of effect on the yield of FGE03 applied at 0.7 kg/ha compared to the reference product.

Table 3.2-46: Summary results: Positive effect on the yield of FGE03 at 0.7 kg/ha compared to the reference products - Oilseed rape - SCLESC - Maritime EPPO climatic zone - 1 application

Parameters	EPPO climatic zone	No. of trials	Days after application	Untreated (T/ha)			% of untreated check (%UTC)									No. of trials where FGE03 at 0.70 kg/ha applied once (A) is statistically* > ; = ; < compared to Prothioconazole 175 g as/ha	
							FGE03 ⁽¹⁾ 0.70 kg/ha			Joao/Proline ⁽²⁾ Prothioconazole 175 g as/ha 0.70 L/ha			Joao/Proline ⁽²⁾ Prothioconazole 175 g as/ha 0.70 L/ha				
										Application : A			Application : A + B				
				Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max		
				Yield	Maritime	5	63-106 DA-A	3.7	2.7	5.9	116.6	102.0	128.9	-	-	-	-
Maritime	2	105-106 DA-A /91-92 DA-B	3.4		3.3	3.4	122.6	121.6	123.6	126.5	117.9	135.0	-	-	-	0>;1=;1<	-
Maritime	3	63-99 DA-A	3.9		2.7	5.9	112.5	102.0	128.9	-	-	-	105.0	98.0	113.9	-	1>;2=;0<

⁽¹⁾ FGE03 = Boscalid + Prothioconazole (350+200 g/kg; WG) at 245+140 g as/ha.

⁽²⁾ Proline/Jao = Prothioconazole (250 g/L; EC) at 175 g as/ha.

* Comparison based on statistics carried out in each trial report.

In this trial series, on average across 5 trials, the yield in the untreated check was of 3.7 t/ha, ranging from 2.7 to 5.9 t/ha in individual trials.

FGE03 applied once at 0.7 kg/ha had a positive effect on the yield of oilseed rape in presence of disease and generated a good gain in yield (+16.6%) compared to the untreated check. This was statistically highlighted in 4 out of the 5 trials according to individual trial results.

FGE03 applied once at 0.7 kg/ha provided a similar gain in yield to reference product prothioconazole at 175 g as/ha applied twice (123 vs. 127% mean in 2 trials) and a slightly higher gain in yield than reference product prothioconazole at 175 g as/ha applied once (113% vs. 105% mean in 3 trials).

In summary, the results of 5 trials conducted in oilseed rape in the Maritime EPPO zone in 2023 and 2024 confirmed that FGE03 applied once at 0.7 kg/ha (245+140 g a.s./ha) had a positive effect on crop yield compared to the untreated check in the presence of good disease pressure and performs at a level equivalent or slightly higher than the reference products.

C. Quality results (in the presence of challenging pest populations) of FGE03 after 1 application - Maritime EPPO zone

Different quality parameters (thousand grain weight, oil content, specific weight and protein content) were measured in 2 efficacy trials (1 trial in Austria and 1 trial in Denmark) in the Maritime EPPO zone 2024 in the presence of *Sclerotinia sclerotiorum* in oilseed rape crop.

FGE03 was compared to the reference product prothioconazole at 175 g a.s./ha (=Proline).

Table 3.2-47 shows a summary of effect on the quality parameters of FGE03 applied at 0.7 kg/ha compared to the reference product.

Table 3.2-47: Summary results: Quality parameters of FGE03 at 0.7 kg/ha compared to the reference products - Oilseed rape - SCLESC - Maritime EPPO climatic zone - 1 application

Zone 1 Application													
Parameters	EPPO climatic zone	No. of trials	Days after application	Untreated			% of untreated check (%UTC)						No. of trials where FGE03 at 0.7 kg/ha applied once (A) is statistically* > ; = ; < compared to
							FGE03 ⁽¹⁾			Proline ⁽²⁾ Prothioconazole 175 g as/ha 0.7 L/ha			
							0.70 kg/ha			0.7 L/ha			
				Application : A			Application : A						
				Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Prothioconazole 175 g as/ha
Thousand grain weight (g)	Maritime	2	72-82 DA-A	4.7	4.4	5.1	101.6	96.3	106.8	99.3	93.8	104.7	0>;2=;0<
Oil content (%)	Maritime	2	72-98 DA-A	46.5	43.1	49.9	100.2	99.7	100.7	100.3	99.7	100.9	0>;2=;0<
Specific weight (kg/hL)	Maritime	1	63 DA-A	63.4	63.4	63.4	99.0	99.0	99.0	99.5	99.5	99.5	0>;1=;0<
Protein content (%)	Maritime	1	72 DA-A	19.3	19.3	19.3	96.7	96.7	96.7	97.2 99.5	97.2 99.5	97.2 99.5	0>;1=;0<

⁽¹⁾ FGE03 = Boscalid + Prothioconazole (350+200 g/kg; WG) at 245+140 g as/ha.

⁽²⁾ Proline = Prothioconazole (250 g/L; EC) at 175 g as/ha.

* Comparison based on statistics carried out in each trial report.

In this trial series, on average across 2 trials, the TGW (thousand grain weight) in the untreated check was 4.7 g for 1000 grains (mean in 2 trials), the oil content was 46.5% (mean in 2 trials), the specific weight was 63.4 kg/hL (1 trial) and the protein content was 19.3% (1 trial).

FGE03 applied once at 0.7 kg/ha had a slight positive effect on TGW in presence of disease (+1.6%) compared to the untreated check. This was statistically highlighted in 1 out of the 2 trials according to individual trial results.

FGE03 applied once at 0.7 kg/ha provided a gain in TGW equivalent to reference product prothioconazole at 175 g a.s./ha applied once. Furthermore, there was no significant difference between FGE03 at 0.7 kg/ha and the reference product in both trials.

FGE03 applied once at 0.7 kg/ha had no effect on oil content, specific weight and protein content in presence of disease compared to the untreated check and to the reference product. In this case, it can be concluded that FGE03 at 0.7 kg/ha has no negative effect on oil content, specific weight and protein content.

3.2.3.2.2 Efficacy of FGE03 after 1 application - North-East EPPO zone

A. Efficacy results of FGE03 after 1 application - North-East EPPO zone

A total of 4 valid efficacy trials (1 trial in Lithuania and 3 trials in Poland) were carried out in the North-East in 2024 to evaluate the efficacy of FGE03 applied once at 0.7 kg/ha (245 g boscalid/ha +140 g prothioconazole/ha) for the control of *Sclerotinia sclerotiorum* in oilseed rape. FGE03 was compared to the reference product Prothioconazole at 175 g a.s./ha (=Proline 250 or Protendo 300 SC) applied once.

The summary results of the effect of FGE03 applied at 0.7 kg/ha compared to reference products are shown in Table 3.2-48.

Table 3.2-48: Summary results: efficacy of FGE03 - Oilseed rape - SCLESC - North-East EPPO climatic zone - 1 application

Parameters	Assessment timing	Parts	EPPO climatic zone	No. of trials	Days after application	% Control									No. of trials where FGE03 at 0.70 kg/ha applied once (A) is statistically* > ; = ; < compared to Prothioconazole 175 g as/ha A
						Untreated (% of infestation)			FGE03 ⁽¹⁾ 0.70 kg/ha Application : A			Protendo 300 SC/Proline ⁽²⁾ 175 g as/ha prothioconazole Application : A			
						Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	
Severity (%)	BBCH 85-87	STEM	North-East	4	[46-53 DA-A]	21.3	17.6	29.6	93.9	85.6	96.9	86.9	62.8	95.4	2>;2=;0<
Incidence (%)	BBCH 85-87	STEM	North-East	4	[46-53 DA-A]	44.0	37.0	63.0	84.9	68.8	91.7	74.7	43.9	89.2	2>;2=;0<

⁽¹⁾ FGE03 = Boscalid + Prothioconazole (350+200 g/kg; WG) at 245+140 g as/ha.

⁽²⁾ Protendo 300 SC = Prothioconazole (300 g/L SC; SC) at 174 g as/ha (0.58 L/ha) /Proline = Prothioconazole (250 g/L; EC) at 175 g as/ha (0.7 L/ha).

* Comparison based on statistics carried out in each trial report.

In the North-East EPPO climatic zone, at the last assessment (BBCH 85-87), in the untreated control, the average infestation was good (21% disease severity and 44% disease incidence on stems on average across 4 trials), varying from 18% to 30% disease severity and from 37% to 63% disease incidence in individual trials.

FGE03 applied once at the intended rate of 0.7 kg/ha (245+140 g a.s./ha) demonstrated a good level of intrinsic effectiveness on disease severity with 93.9% mean efficacy in 4 trials.

FGE03 applied once at 0.7 kg/ha showed a level of control slightly better than the reference product prothioconazole at 175 g as/ha applied once (93.9% vs. 86.9% mean efficacy in 4 trials). This difference was significant higher in 2 trials out of 4 compared to prothioconazole at 175 g as/ha.

These results were confirmed on the disease incidence, where the mean control of FGE03 applied once at 0.7 kg/ha was slightly better than the reference product prothioconazole at 175 g as/ha applied once (84.9% vs. 74.7% mean efficacy in 4 trials). This difference was significant higher in 2 trials out of 4 compared to prothioconazole at 175 g as/ha.

In summary, in North-East EPPO zone, when considering severity data from 4 trials investigating FGE03 effectiveness for the control of *Sclerotinia sclerotiorum* in oilseed rape after once application, in conditions of good *Sclerotinia sclerotiorum* pressure, FGE03 applied at 0.7 kg/ha demonstrated a good effectiveness, and performed at a level slightly better than the reference product prothioconazole at 175 g as/ha applied once.

B. Yield results of FGE03 after 1 application - North-East EPPO zone

A total of 4 valid efficacy trials (1 trial in Lithuania and 3 trials in Poland) were harvested in the - North-East EPPO zone in 2024. The objective was to confirm the yield response of FGE03 in the presence of *Sclerotinia sclerotiorum* in oilseed rape crop.

FGE03 applied once was compared to the reference products Prothioconazole 175 g a.s./ha (=Proline 250 or Protendo 300 SC) applied once.

Table 3.2-49 shows a summary of effect on the yield of FGE03 applied at 0.7 kg/ha compared to the reference product.

Table 3.2-49: Summary results: Positive effect on the yield of FGE03 at 0.7 kg/ha compared to the reference products - Oilseed rape - SCLESC - North-East EPPO climatic zone - 1 application

Climatic zone : 1 Application													
Parameters	EPPO climatic zone	No. of trials	Days after application	Untreated (T/ha)			% of untreated check (%UTC)						No. of trials where FGE03 at 0.70 kg/ha applied once (A) is statistically* > ; = ; < compared to
							FGE03 ⁽¹⁾ 0.70 kg/ha			Protendo 300 SC/Proline ⁽²⁾ Prothioconazole 175 g as/ha 175 g as/ha			
				Application : A			Application : A						
				Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Prothioconazole 175 g as/ha
Yield	North-East	4	60-72 DA-A	2.5	2.0	3.0	113.9	101.8	120.4	105.4	79.2	117.6	1>;3=;0<

⁽¹⁾ FGE03 = Boscalid + Prothioconazole (350+200 g/kg; WG) at 245+140 g as/ha.

⁽²⁾ Protendo 300 SC = Prothioconazole (300 g/L SC; SC) at 174 g as/ha (0.58 L/ha) / Proline = Prothioconazole (250 g/L; EC) at 175 g as/ha (0.7 L/ha).

* Comparison based on statistics carried out in each trial report.

In this trial series, on average across 4 trials, the yield in the untreated check was of 2.5 t/ha, ranging from 2.0 to 3.0 t/ha in individual trials.

FGE03 applied once at 0.7 kg/ha had a positive effect on the yield of oilseed rape in presence of disease and generated a good gain in yield (+13.9%) compared to the untreated check. This was statistically highlighted in 3 out of the 4 trials according to individual trial results.

FGE03 applied once at 0.7 kg/ha provided a better gain in yield than reference product prothioconazole at 175 g a.s./ha applied once (114% vs. 105% mean in 4 trials). This was statistically highlighted in 1 out of the 4 trials according to individual trial results

In summary, the results of 4 trials conducted in oilseed rape in the North-East EPPO zone in 2024 confirmed that FGE03 applied once at 0.7 kg/ha (245+140 g a.s./ha) had a positive effect on crop yield compared to the untreated check in the presence of good disease pressure and performs at a level equivalent to the reference products.

C. Quality results (in the presence of challenging pest populations) of FGE03 after 1 application - North-East EPPO zone

Different quality parameters (thousand grain weight and oil content) were measured in 3 efficacy trials (3 trials in Poland) in the North-East EPPO zone in 2024 in the presence of *Sclerotinia sclerotiorum* in oilseed rape crop.

FGE03 was compared to the reference product prothioconazole at 175 g a.s./ha (=Protendo 300 SC).

Table 3.2-50 shows a summary of effect on the quality parameters of FGE03 applied at 0.7 kg/ha compared to the reference products.

Table 3.2-50: Summary results: Quality parameters of FGE03 at 0.7 kg/ha compared to the reference products - Oilseed rape - SCLESC - North-East EPPO climatic zone - 1 application

Parameters	EPPO climatic zone	No. of trials	Days after application	Untreated			% of untreated check (%UTC)						No. of trials where FGE03 at 0.70 kg/ha applied once (A) is statistically* > ; = ; < compared to Protendo 300 SC Application : A
							FGE03 ⁽¹⁾ 0.70 kg/ha			Protendo 300 SC ⁽²⁾ 0.58 L/ha			
							Application : A			Application : A			
				Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	
Thousand grain weight (g)	North-East	3	72 DA-A	4.8	4.4	5.5	106.2	104.0	107.4	104.7	103.7	105.6	0>;3=;0<
Oil content (%)	North-East	3	72 DA-A	42.4	42.3	42.5	101.1	100.5	101.4	101.0	100.4	101.5	0>;3=;0<

⁽¹⁾ FGE03 = Boscalid + Prothioconazole (350+200 g/kg; WG) at 245+140 g as/ha.

⁽²⁾ Protendo 300 SC = Prothioconazole (300 g/L SC; SC) at 174 g as/ha (0.58 L/ha)

* Comparison based on statistics carried out in each trial report.

In this trial series, on average across 3 trials, the TGW (thousand grain weight) in the untreated check was of 4.8 g for 1000 grains and the oil content was 42.4% (mean in 2 trials).

FGE03 applied once at 0.7 kg/ha had a slight positive effect on TGW in presence of disease (+6.2%) compared to the untreated check. This was statistically highlighted in 2 out of the 3 trials according to individual trial results.

FGE03 applied once at 0.7 kg/ha provided a gain in TGW equivalent to reference product prothioconazole at 175 g a.s./ha applied once. Furthermore, there was no significant difference between FGE03 at 0.7 kg/ha and the reference product in all trials.

FGE03 applied once at 0.7 kg/ha had no effect on oil content in presence of disease compared to the untreated check and to the reference product. In this case, it can be concluded that FGE03 at 0.7 kg/ha has no negative effect on oil content.

3.2.3.2.3 Efficacy of FGE03 after 1 application - South-East EPPO zone

A. Efficacy results of FGE03 after 1 application - South-East EPPO zone

A total of 11 valid efficacy trials (3 trials in Bulgaria, 3 trials in Hungary and 5 trials in Romania) were carried out in the South-East EPPO zone in 2023 and 2024 to evaluate the efficacy of FGE03 applied once at 0.7 kg/ha (245 g boscalid/ha +140 g prothioconazole/ha) for the control of *Sclerotinia sclerotiorum* in oilseed rape. FGE03 was compared to the reference products Prothioconazole at 175 g a.s./ha (=Proline 250) applied once (7 trials carried out in 2024) and twice (4 trials carried out in 2023). In addition, in the 3 out of 4 trials carried out in 2023, FGE03 was also compared to the reference product prothioconazole+tebuconazole at 80+160 g a.s./ha (=Tilmor).

The summary results of the effect of FGE03 applied at 0.7 kg/ha compared to reference products are shown in Table 3.2-51.

Table 3.2-51: Summary results: efficacy of FGE03 - Oilseed rape - SCLESC - South-East EPPO climatic zone - 1 application

Parameters	Assessment timing	Parts	EPPO climatic zone	No. of trials	Days after application	Untreated (% of infestation)			% Control												No. of trials where FGE03 at 0.70 kg/ha applied once (A) is statistically* > ; = ; < compared to		
									FGE03 ⁽¹⁾ 0.70 kg/ha			Proline ⁽²⁾ 0.70 L/ha			Tilmor ⁽³⁾ 1.0-1.2 L/ha			Proline ⁽²⁾ 0.70 L/ha					
						Application : A			Application: A+B			Application: A+B			Application : A			Proline A+B	Tilmor A+B	Proline A			
						Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max				Mean	Min	Max
Severity (%)	BBCH 77-87	STEM	South-East	11	35-65 DA-A	12.3	5.2	32.9	78.0	48.5	94.4										-	-	-
	BBCH 77-85	STEM	South-East	4	35-65 DA-A 21-51 DA-B	16.7	8.3	32.9	74.9	48.5	87.1	78.4	64.8	93.4						0>;2=;2<	-	-	
	BBCH 79-85	STEM	South-East	3	35-65 DA-A 21-51 DA-B	18.2	8.3	32.9	73.5	48.5	87.1				83.1	64.0	95.8			-	0>;2=;1<	-	
	BBCH 77-87	STEM	South-East	7	42-60 DA-A	9.8	5.2	21.6	79.8	59.0	94.4							72.3	54.4	95.1	-	-	3>;4=;0<
Incidence (%)	BBCH 77-87	STEM	South-East	10	35-65 DA-A	53.3	16.0	85.0	61.1	37.1	87.7										-	-	-
	BBCH 77-85	STEM	South-East	4	35-65 DA-A 21-51 DA-B	56.0	16.0	85.0	55.6	43.2	68.8	60.4	53.2	72.9						0>;3=;1<	-	-	
	BBCH 79-85	STEM	South-East	3	35-65 DA-A 21-51 DA-B	48.3	16.0	85.0	53.0	43.2	68.8				70.9	56.8	81.2				0>;2=;1<	-	
	BBCH 83-87	STEM	South-East	6	42-60 DA-A	51.5	16.0	74.0	64.8	37.1	87.7							51.9	6.8	78.4	-	-	3>;3=;0<

⁽¹⁾ FGE03 = Boscalid + Prothioconazole (350+200 g/kg; WG) at 245+140 g as/ha.

⁽²⁾ Proline = Prothioconazole (250 g/L; EC) at 175 g as/ha.

⁽³⁾ Tilmor = Prothioconazole + Tebuconazole (80+160 g/L; EC) at 80+160 g as/ha.

* Comparison based on statistics carried out in each trial report.

In the South-East EPPO climatic zone, at the last assessment (BBCH 77 75-87), in the untreated control, the average infestation was moderate (12% disease severity and 53% disease incidence on stems on average across 11 trials), varying from 5% to 33% disease severity and from 16% to 85% disease incidence in individual trials.

FGE03 applied once at the intended rate of 0.7 kg/ha (245+140 g a.s./ha) demonstrated a moderate level of intrinsic effectiveness on disease severity with 78.0% mean efficacy in 11 trials.

FGE03 applied once at 0.7 kg/ha showed a level of control quite close to that of the reference products prothioconazole at 175 g as/ha applied twice (74.9% vs. 78.4% mean efficacy in 4 trials), Tilmor applied twice (73.5% vs. 83.1% mean efficacy in 3 trials) and prothioconazole at 175 g as/ha applied once (79.8% vs. 72.3% mean efficacy in 7 trials).

These differences were significant higher in 3 trials out of 7 compared to prothioconazole at 175 g as/ha applied once and significant lower in 2 trials out of 4 compared to prothioconazole at 175 g as/ha applied twice and in 1 trial out of 3 compared to Tilmor applied twice.

On the disease incidence, the mean control of FGE03 applied once at 0.7 kg/ha was better than the reference product prothioconazole at 175 g as/ha once (64.8% vs. 51.9% mean efficacy in 6 trials), similar to that of the reference product prothioconazole at 175 g as/ha applied twice (55.6% vs. 60.4% mean efficacy in 4 trials) and lower than the reference product Tilmor applied twice (53% vs. 70.9% mean efficacy in 3 trials). These differences were significant higher in 3 trials out of 6 compared to prothioconazole at 175 g as/ha applied once and significant lower in 1 trial out of 4 compared to prothioconazole at 175 g as/ha applied twice and in 1 trial out of 3 compared to Tilmor applied twice.

In summary, in the South-East EPPO zone, when considering severity data from 11 trials investigating FGE03 effectiveness for the control of *Sclerotinia sclerotiorum* in oilseed rape after once application, in conditions of moderate *Sclerotinia sclerotiorum* pressure, FGE03 applied at 0.7 kg/ha demonstrated an adequate effectiveness, and performed at a level better than that of the reference product prothioconazole at 175 g as/ha applied once and close to or lower than that of the reference products prothioconazole at 175 g as/ha and Tilmor applied twice.

B. Yield results of FGE03 after 1 application - South-East EPPO zone

A total of 6 valid efficacy trials (1 trial in Bulgaria, 1 trial in Hungary and 4 trials in Romania) were harvested in the South-East EPPO zone in 2023 and 2024. The objective was to confirm the yield response of FGE03 in the presence of *Sclerotinia sclerotiorum* in oilseed rape crop.

FGE03 was compared to the reference products Prothioconazole at 175 g a.s./ha (=Proline 250) applied once (5 trials carried out in 2024) and twice (1 trial carried out in 2023).

Table 3.2-52 shows a summary of effect on the yield of FGE03 applied at 0.7 kg/ha compared to the reference product.

Table 3.2-52: Summary results: Positive effect on the yield of FGE03 at 0.7 kg/ha compared to the reference products - Oilseed rape - SCLESC - South-East EPPO climatic zone - 1 application

Climatic zone : T Application																	
Parameters	EPPO climatic zone	No. of trials	Days after application	Untreated (T/ha)			% of untreated check (%UTC)									No. of trials where FGE03 at 0.70 kg/ha applied once (A) is statistically > ; = ; < compared to	
							FGE03 ⁽¹⁾ 0.70 kg/ha			Proline ⁽²⁾ Prothio. 175 g as/ha 0.70 L/ha			Proline ⁽²⁾ Prothio. 175 g as/ha 0.70 L/ha				
							Application : A			Application : A + B			Application : A				
				Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Prothioconazole 175 g as/ha A + B	A
Yield	South-East	6	64-87 DA-A	2.6	1.7	3.5	110.8	96.0	123.0	-	-	-	-	-	-	-	-
	South-East	1	83 DA-A / 68 DA-B	3.5	3.5	3.5	122.9	122.9	122.9	128.6	128.6	128.6	-	-	-	0>;1=;0<	-
	South-East	5	64-87 DA-A	2.4	1.7	3.3	108.4	96.0	123.0	-	-	-	106.8	97.0	120.0	-	1>;4=;0<

⁽¹⁾ FGE03 = Boscalid + Prothioconazole (350+200 g/kg; WG) at 245+140 g as/ha.

⁽²⁾ Proline = Prothioconazole (250 g/L; EC) at 175 g as/ha.

* Comparison based on statistics carried out in each trial report.

In this trial series, on average across 6 trials, the yield in the untreated check was of 2.6 t/ha, ranging from 1.7 to 3.5 t/ha in individual trials.

FGE03 applied once at 0.7 kg/ha had a positive effect on the yield of oilseed rape in presence of disease and generated a good gain in yield (+10.8%) compared to the untreated check. This was statistically highlighted in 2 out of the 6 trials according to individual trial results.

FGE03 applied once at 0.7 kg/ha provided a similar gain in yield to reference product Prothioconazole at 175 g a.s./ha applied twice (123% vs. 129% in 1 trial).

FGE03 applied once at 0.7 kg/ha provided a similar gain in yield to reference product Prothioconazole at 175 g a.s./ha applied once (108% vs. 107% mean in 5 trials).

In summary, the results of 6 trials conducted in oilseed rape in the South-East EPPO zone in 2023 and 2024 confirmed that FGE03 applied once at 0.7 kg/ha (245+140 g a.s./ha) had a positive effect on crop yield compared to the untreated check in the presence of good disease pressure and performs at a level equivalent to the reference products.

C. Quality results (in the presence of challenging pest populations) of FGE03 after 1 application - South-East EPPO zone

Different quality parameters (thousand grain weight, oil content and specific weight) were measured in 7 efficacy trials (1 trial in Bulgaria, 2 trials in Hungary and 4 trials in Romania) in the South-East EPPO zone in 2024 in the presence of *Sclerotinia sclerotiorum* in oilseed rape crop.

FGE03 applied once (A) was compared to the reference products Prothioconazole at 175 g a.s./ha (=Proline) applied once (5 trials carried out in 2024) and twice (2 trials carried out in 2023). In addition, in the 1 out of 2 trials carried out in 2023, FGE03 was also compared to the reference product prothioconazole+tebuconazole at 96+192 g a.s./ha (=Tilmor).

Table 3.2-53 shows a summary of effect on the quality parameters of FGE03 applied at 0.7 kg/ha compared to the reference products.

Table 3.2-53: Summary results: Quality parameters of FGE03 at 0.7 kg/ha compared to the reference products - Oilseed rape - SCLESC - South EPPO climatic zone - 1 application

Parameters	EPPO climatic zone	No. of trials	Days after application	Untreated			% of untreated check (%UTC)												No. of trials where FGE03 at 0.70 kg/ha applied once (A) is statistically* > ; = ; < compared to		
							FGE03 ⁽¹⁾ 0.70 kg/ha			Proline ⁽²⁾ Prothio 175 g as/ha 0.7 L/ha			Tilmor ⁽³⁾ 1.0 L/ha			Proline ⁽²⁾ Prothio 175 g as/ha 0.7 L/ha					
							Application : A			Application: A+B			Application: A+B			Application : A					
				Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Prothio. A+B	Tilmor A+B	Prothio. A
Thousand grain weight (g)	South-East	7	73-120 DA-A	4.6	3.4	5.5	105.5	96.4	111.2	-	-	-	-	-	-	-	-	-	-	-	-
	South-East	2	83-120 DA-A 68-105 DA-B	5.0	4.7	5.4	106.2	102.1	110.2	107.6	102.8	112.3	-	-	-	-	-	-	0>;2=;0<	-	-
	South-East	1	120 DA-A 105 DA-B	4.7	4.7	4.7	102.1	102.1	102.1	-	-	-	101.7	101.7	101.7	-	-	-	-	0>;1=;0<	-
	South-East	5	73-106 DA-A	4.5	3.4	5.5	105.3	96.4	111.2	-	-	-	-	-	-	103.7	98.1	112.1	-	-	1>;4=;0<
Oil content (%)	South-East	6	73-129 DA-A	47.9	42.8	62.2	101.3	99.0	103.5	-	-	-									
	South-East	1	120 DA-A 105 DA-B	43.2	43.2	43.2	100.0	100.0	100.0	99.4	99.4	99.4	98.8	98.8	98.8				0>;1=;0<	0>;1=;0<	-
	South-East	5	73-129 DA-A	48.9	42.8	62.2	101.5	99.0	103.5	-	-	-	-	-	-	100.7	99.0	102.9	-	-	1>;4=;0<
Specific weight (kg/hL)	South-East	3	64-83 DA-A	65.2	64.2	66.2	101.8	100.7	103.0							101.2	101.1	101.2			0>;3=;0<

⁽¹⁾ FGE03 = Boscalid + Prothioconazole (350+200 g/kg; WG) at 245+140 g as/ha.

⁽²⁾ Proline = Prothioconazole (250 g/L; EC) at 175 g as/ha.

⁽³⁾ Tilmor = Prothioconazole + Tebuconazole (80+160 g/L; EC) at 80+160 g as/ha.

* Comparison based on statistics carried out in each trial report.

In this trial series, on average across 7 trials, the TGW (thousand grain weight) in the untreated check was of 4.6 g for 1000 grains (mean in 7 trials), the oil content was 47.9% (mean in 6 trials) and the specific weight was 65.2 kg/hL (mean in 3 trials).

FGE03 applied once at 0.7 kg/ha had a slight positive effect on TGW in presence of disease (+5.5%) compared to the untreated check. This was statistically highlighted in 2 out of the 7 trials according to individual trial results.

FGE03 applied once at 0.7 kg/ha provided a gain in TGW equivalent to reference products prothioconazole at 175 g as/ha applied twice (106.2% vs. 107.6% mean in 2 trials), Tilmor applied twice (102.1% vs. 101.7% in 1 trial) and prothioconazole at 175 g as/ha applied once (105.3% vs. 103.7% mean in 5 trials). Furthermore, except in 1 trial there was no significant difference between FGE03 at 0.7 kg/ha and the reference products in all trials. In the last trial, FGE03 applied once at 0.7 kg/ha was statistically higher than reference product prothioconazole at 175 g as/ha applied once at 0.7 L/ha.

FGE03 applied once at 0.7 kg/ha had no effect on oil content and specific weight in presence of disease compared to the untreated check and to the reference products. In this case, it can be concluded that FGE03 at 0.7 kg/ha has no negative effect on oil content and specific weight.

3.2.3.2.4 Conclusion - Efficacy results of FGE03 after 1 application - All EPPO zones

Against *Sclerotinia sclerotiorum*, a total of 22 valid efficacy trials were carried out to evaluate the efficacy of FGE03 applied once at 0.7 kg/ha (245 g boscalid/ha +140 g prothioconazole/ha) for the control of *Sclerotinia sclerotiorum* in oilseed rape. These trials were carried out in 2023 and 2024 in the Maritime (7 trials), North-East (4 trials) and South-East EPPO (11 trials) climatic zones.

Summarised results on oilseed rape for the control of *Sclerotinia sclerotiorum* are detailed in Table 3.2-54.

Table 3.2-54: Efficacy of FGE03 (% control based on disease severity and incidence on stems at BBCH 75-87) in oilseed rape to control *Sclerotinia sclerotiorum* - 1 application

Regulatory zone	EPPO climatic zone	Parameters	# Trials	Untreated (% of infestation)	Mean control (%) on disease on stem			No. of trials where FGE03 at 0.70 kg/ha is statistically ⁽¹⁾ > ; = ; < compared to	
					FGE03 0.7 kg/ha 245 g as/ha boscalid + 140 g as/ha prothioconazole Application : A	Ref prothioconazole: 175 g as/ha prothioconazole Application : A + B	Ref prothioconazole: 175 g as/ha prothioconazole Application : A	Ref prothio Appli : A + B	Ref prothio Appli : A
-	Maritime	Severity (%)	7	24.9	76.8	-	-	-	-
			2	29.8	81.2	77.9	-	0>;2=;0<	-
			5	22.9	75.0	-	67.7	-	0>;5=;0<
		Incidence (%)	7	60.5	47.6	-	-	-	-
			2	68.8	50.4	47.2	-	0>;2=;0<	-
			5	57.1	46.6	-	42.3	-	0>;5=;0<
	North-East	Severity (%)	4	21.3	93.9	-	86.9	-	2>;2=;0<
		Incidence (%)	4	44.0	84.9	-	74.7	-	2>;2=;0<
	South-East	Severity (%)	11	12.3	78.0	-	-	-	-
			4	16.7	74.9	78.4	-	0>;2=;2<	-
			7	9.8	79.8	-	72.3	-	3>;4=;0<
		Incidence (%)	10	53.3	61.1	-	-	-	-
			4	56.0	55.6	60.4	-	0>;3=;1<	-
			6	51.5	64.8	-	51.9	-	3>;3=;0<
Central zone	Maritime + NE + SE	Severity (%)	22	18.0	80.5	-	-	-	-
			6	21.1	77.0	78.2	-	0>;4=;2<	-
			16	16.8	81.9	-	74.5	-	5>;11=;0<
		Incidence (%)	21	53.9	61.2	-	-	-	-
			6	60.3	53.9	56.0	-	0>;5=;1<	-
			15	51.4	64.1	-	54.8	-	5>;10=;0<

Severity data from 22 trials investigating the efficacy of FGE03 applied in the Maritime, North-East and South-East EPPO zones for the control of *Sclerotinia sclerotiorum* in oilseed rape showed that FGE03 applied once at the intended rate of 0.7 kg/ha has a good effectiveness (80.5% mean efficacy on disease severity in 22 trials). FGE03 applied once 0.7 kg/ha was similar to the reference product based prothioconazole at 175 g a.s./ha applied twice (77.0% vs. 78.2% mean efficacy on disease severity in 6 trials) and equivalent or better than the reference product based prothioconazole at 175 g a.s./ha applied once (81.9% vs. 74.5% mean efficacy on disease severity in 16 trials).

Data generated across 22 trials carried out in the Maritime, North-East and South-East 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.

Comments of zRMS on:

Efficacy of FGE03 after 1 application (3.2.3.2)

22 valid efficacy trials present data to assess the efficacy of FGE03 applied once per growing season in the control of *Sclerotinia sclerotiorum* on winter oilseed rape. The trials were carried out in 3 EPPO zones: Maritime (North of France - 3 trials, Austria - 1 trial, the United Kingdom - 1 trial, Denmark - 2 trials), North-East (Lithuania – 1 trial, Poland – 3 trials) and South-East (Bulgaria – 3 trials, Hungary – 3 trials, Romania – 5 trials) in the years 2023-2024.

Conclusions for individual EPPO climatic zones are presented below.

Maritime EPPO zone (7 trials carried out in 2023-2024)

FGE03 was applied once at target dose rate of 0.7 kg/ha, at BBCH crop growth stage 65-69 and with water volume 150-400 L/ha. Moderate efficacy of FGE03 at target dose rate was demonstrated for disease severity (76.8%). For disease incidence, FGE03 achieved lower level of efficacy (47.6%). No statistically significant differences were noted between FGE03 applied once and standard Proline/Joao applied once (on 5 trials) and twice (in 2 trials).

North-East EPPO zone (4 trials carried out in 2024)

In the presented trials, the test item FGE03 at recommended dose rate of 0.7 kg/ha was applied once at BBCH growth stage of the crop 63-69, and with water volume 200-300 L/ha. High efficacy of FGE03 at target rate was demonstrated for disease severity (94% efficacy) and for disease incidence as well (85% efficacy). The efficacy of tested product was statistically comparable (in 2 trials) or statistically higher (in 2 trials), than efficacy of Protendo 300 EC/ Proline standard products.

South-East EPPO zone (11 trials carried out in 2023-2024)

FGE03 at target dose rate of 0.7 kg/ha was applied once at BBCH growth stage of the crop 60-69 and with water volume 200-400 L/ha. Moderate efficacy of FGE03 at target dose rate was demonstrated for disease severity (78% efficacy) and for disease incidence as well (61% efficacy). The efficacy of tested product was statistically comparable (in 2 trials for disease severity and in 3 trials for disease incidence) or statistically lower (in 2 trials for disease severity and in 1 trial for disease incidence), than efficacy of standard Proline applied twice. No statistically significant differences were noted between FGE03 applied once and standard Tilmor applied twice in 2 trials. FGE03 applied once achieved statistically lower efficacy as compared with standard Tilmor applied twice in 1 trial. The efficacy of tested product applied once was statistically comparable (in 4 trials for disease severity and in 3 trials for disease incidence) or statistically higher (in 3 trials for disease severity and for disease incidence) than efficacy of standard Proline applied once.

Yield from efficacy trials

Maritime EPPO zone

Positive effect of FGE03 on the yield with about 17% increase as compared with untreated control was noted in 5 trials. No statistically significant differences in yield were observed comparing results for FGE03 with results achieved for prothioconazole standard products applied once or twice in 3 trials. Statistically higher yield for

FGE03 was demonstrated in 1 trial comparing with results achieved for prothioconazole reference product applied once. Statistically lower yield for FGE03 was demonstrated in 1 trial comparing with results achieved for prothioconazole reference product applied twice.

Slight positive effect on TGW with 1.6% increase as compared with untreated control was noted in 2 trials. No statistically significant differences in TGW, oil content, specific weight (HLW) and protein content between FGE03 and standard Joao/Proline were noted in 2 trials (TGW, Oil content) and 1 trial (HLW, Protein content).

North-East EPPO zone

Positive effect of FGE03 on the yield with about 14% increase as compared with untreated control was noted in 4 trials. No statistically significant differences in yield were observed comparing results for FGE03 with results achieved for prothioconazole standard product in 3 trials. Statistically higher yield for FGE03 was demonstrated in 1 out of 4 trials comparing with results achieved for reference product.

About 6% increase of TGW was demonstrated for FGE03 as compared with untreated control. No statistically significant differences in TGW and oil content between FGE03 and standard Protendo 300 SC were noted in 3 trials.

South-East EPPO zone

Positive effect of FGE03 on the yield with about 11% increase as compared with untreated control was noted in 6 trials. No statistically significant differences in yield were observed comparing results for FGE03 with results achieved for prothioconazole standard products applied once or twice in 5 trials. Statistically higher yield for FGE03 was demonstrated in 1 trial comparing with results achieved for prothioconazole reference product applied once.

Positive effect of FGE03 on TGW with about 6% increase as compared with untreated control was noted in the presented 7 trials. No statistically significant differences in TGW, oil content and HLW were observed comparing results for FGE03 with results achieved for Proline standard applied once or twice and/or Tilmor standard applied twice in most of the trials. Statistically higher TGW and oil content for FGE03 was demonstrated in 1 trial comparing with results achieved for Proline standard applied once.

3.2.3.3 Efficacy of FGE03 after 2 applications

The label claim for this use is summarised in Table 3.2-55.

Table 3.2-55: Label claim for oilseed rape against *Sclerotinia sclerotiorum*

Crops	Target	Country	Application timing	No. of applications	Application volume	Dose rate
Oilseed rape (BRSNN)	<i>Sclerotinia sclerotiorum</i> (SCLESC)	PL, HU, CZ	BBCH 61-73	2	100-400 L/ha	0.7 kg/ha

Results from 16 valid field trials are presented to investigate the efficacy of FGE03 at 0.7 kg/ha applied twice (245 g boscalid/ha +140 g prothioconazole/ha) against *Sclerotinia sclerotiorum* in oilseed rape. They were carried out in 2022 and 2023. Among these trials, 5 trials were conducted in the Maritime EPPO climatic zone, 6 trials in the North-East EPPO climatic zone and 5 trials in the South-East EPPO climatic zone.

A summary of all trials generating data on oilseed rape against *Sclerotinia sclerotiorum* is presented in Table 3.2-56.

Table 3.2-56: Overview of valid efficacy trials with 2 applications - Oilseed rape - *Sclerotinia sclerotiorum* - 2 applications

Number of trials	Crop	Target	Year	Country	EPPO climatic zone	Comment
2 trials	Oilseed rape	SCLESC	2022	DK	Maritime	Harvest results
2 trials	Oilseed rape	SCLESC	2022	CZ	Maritime	Harvest results
1 trial	Oilseed rape	SCLESC	2023	UK	Maritime	Harvest results
2 trials	Oilseed rape	SCLESC	2022	LT	Northeast	Harvest results
4 trials	Oilseed rape	SCLESC	2023	PL	Northeast	-
3 trials	Oilseed rape	SCLESC	2022	HU	Southeast	Harvest results
2 trials	Oilseed rape	SCLESC	2023	BG	Southeast	-

3.2.3.3.1 Efficacy of FGE03 after 2 applications - Maritime EPPO zone

A. Efficacy results of FGE03 after 2 applications - Maritime EPPO zone

A total of 5 valid efficacy trials (2 trials in Czech Republic, 2 trials in Denmark and 1 trial in the United Kingdom) were carried out in the Maritime EPPO zone in 2022 and 2023 to evaluate the efficacy of FGE03 applied twice at 0.7 kg/ha (245 g boscalid/ha +140 g prothioconazole/ha) for the control of *Sclerotinia sclerotiorum* in oilseed rape. FGE03 was compared to the reference products prothioconazole at 175 g a.s./ha (=Proline 250), prothioconazole+tebuconazole at 125+125 g a.s./ha (Prosaro 250 EC) and prothioconazole+tebuconazole at 80+160 g a.s./ha (=Tilmor).

The summary results of the effect of FGE03 applied at 0.7 kg/ha compared to reference products are shown in Table 3.2-57.

Table 3.2-57: Summary results: efficacy of FGE03 - Oilseed rape - SCLESC - Maritime EPPO climatic zone - 2 applications

Parameters	Assessment timing	Parts	EPPO climatic zone	No. of trials	Days after application	Untreated (% of infestation)			% Control												No. of trials where FGE03 at 0.70 kg/ha is statistically* > ; = ; < compared to					
									FGE03 ⁽¹⁾			Proline ⁽²⁾ prothio 175 g as/ha			Prosaro 250 EC ⁽³⁾			Tilmor ⁽⁴⁾								
									0.70 kg/ha			0.70 L/ha			1.0 L/ha			1.0 L/ha								
									Application : A + B			Application : A + B			Application : A + B			Application : A + B								
						Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Prothio	Prosaro	Tilmor
Severity (%)	BBCH 75-87	STEM	Maritime	5	[42-62 DA-B]	23.0	10.8	32.8	89.3	80.9	98.3	-	-	-	-	-	-	-	-	-	-	-				
	BBCH 75-87	STEM	Maritime	2	[56-62 DA-B]	21.8	10.8	32.8	90.1	81.9	98.3	68.2	36.4	100.0	-	-	-	-	-	-	1>;1=;0<	-	-			
	BBCH 75-87	STEM	Maritime	2	42 DA-B	22.5	17.6	27.4	85.8	80.9	90.8	-	-	-	-	-	-	-	-	-	0>;2=;0<	-	-			
	BBCH 75-87	STEM	Maritime	1	49 DA-B	26.3	-	-	94.4	-	-	-	-	-	-	-	-	-	74.9	-	-	-	-	0>;1=;0<		
Incidence (%)	BBCH 75-87	STEM	Maritime	5	[42-62 DA-B]	36.8	21.0	58.0	83.2	76.2	93.3	-	-	-	-	-	-	-	-	-	-	-	-			
	BBCH 75-87	STEM	Maritime	2	[56-62 DA-B]	44.0	30.0	58.0	86.3	79.3	93.3	65.5	31.0	100.0	-	-	-	-	-	-	-	1>;1=;0<	-	-		
	BBCH 75-87	STEM	Maritime	2	42 DA-B	27.5	21.0	34.0	77.8	76.2	79.4	-	-	-	-	-	-	-	69.2	61.9	76.5	-	-	-	0>;2=;0<	-
	BBCH 75-87	STEM	Maritime	1	49 DA-B	41.0	-	-	87.8	-	-	-	-	-	-	-	-	-	-	75.6	-	-	-	-	-	0>;1=;0<

⁽¹⁾ FGE03 = Boscalid + Prothioconazole (350+200 g/kg; WG) at 245+140 g as/ha.

⁽²⁾ Proline = Prothioconazole (250 g/L; EC) at 175 g as/ha.

⁽³⁾ Prosaro 250 EC = Prothioconazole + Tebuconazole (125+125 g/L; EC) at 125+125 g as/ha.

⁽⁴⁾ Tilmor = Prothioconazole + Tebuconazole (80+160 g/L; EC) at 80+160 g as/ha.

* Comparison based on statistics carried out in each trial report.

In the Maritime EPPO climatic zone, at the last assessment (BBCH 75-85), in the untreated control, the average infestation was good (23% disease severity and 37% disease incidence on stems on average across 5 trials), varying from 11% to 33% disease severity and from 21 to 58% disease incidence in individual trials.

FGE03 applied twice at the intended rate of 0.7 kg/ha (245+140 g a.s./ha) demonstrated a good level of intrinsic effectiveness on disease severity with 89.3% mean efficacy in 5 trials.

FGE03 applied twice at 0.7 kg/ha showed a level of control better than the reference products prothioconazole at 175 g as/ha (90.1% vs. 68.2% mean efficacy in 2 trials) and Tilmor (94.4% vs. 74.9% efficacy in 1 trial) and quite close to that of the reference product Prosaro 250 EC (85.8% vs. 77.0% mean efficacy in 2 trials). These differences were not statistically significant compared to Tilmor and Prosaro and were significant higher in 1 trial out of 2 compared to prothioconazole at 175 g as/ha.

These results were confirmed on the disease incidence, where the mean control of FGE03 applied at 0.7 kg/ha was better than the reference products prothioconazole at 175 g as/ha (86.3% vs. 65.5% mean efficacy in 2 trials) and Tilmor (87.8% vs. 75.6% efficacy in 1 trial) and quite close to that of the reference product Prosaro 250 EC (77.8% vs. 69.2% mean efficacy in 2 trials). These differences were not statistically significant compared to Tilmor and Prosaro and were significant higher in 1 trial out of 2 compared to prothioconazole at 175 g as/ha.

In summary, in the Maritime EPPO zone, when considering severity data from 5 trials investigating FGE03 effectiveness for the control of *Sclerotinia sclerotiorum* in oilseed rape after two applications, in conditions of good *Sclerotinia sclerotiorum* pressure, FGE03 applied at 0.7 kg/ha demonstrated a good effectiveness, and performed at a level better or close to that of the reference products.

B. Yield results (in the presence of challenging pest populations) of FGE03 after 2 applications - Maritime EPPO zone

A total of 5 valid efficacy trials (2 trials in Czech Republic, 2 trials in Denmark and 1 trial in the United Kingdom) were harvested in the Maritime EPPO zone in 2022 and 2023. The objective was to confirm the yield response of FGE03 in the presence of *Sclerotinia sclerotiorum* in oilseed rape crop.

FGE03 was compared to the reference products prothioconazole at 175 g a.s./ha (=Proline 250), prothioconazole+tebuconazole at 125+125 g a.s./ha (Prosaro 250 EC) and prothioconazole+tebuconazole at 80+160 g a.s./ha (=Tilmor).

Table 3.2-58 shows a summary of effect on the yield of FGE03 applied at 0.7 kg/ha compared to the reference products.

Table 3.2-58: Summary results: Positive effect on the yield of FGE03 at 0.7 kg/ha compared to the reference products - Oilseed rape - SCLESC - Maritime EPPO climatic zone - 2 applications

Parameters	EPPO climatic zone	No. of trials	Days after application	Untreated (T/ha)			% of untreated check (%UTC)												No. of trials where FGE03 at 0.70 kg/ha is statistically* > ; = ; < compared to		
							FGE03 ⁽¹⁾			Proline ⁽²⁾ Prothio 175 g ai/ha			Prosaro 250 EC ⁽³⁾			Tilmor ⁽⁴⁾					
							0.70 kg/ha			0.70 L/ha			1.0 L/ha			1.0 L/ha					
							Application : A + B			Application : A + B			Application : A + B			Application : A + B					
							Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max			
Yield	Maritime	5	[62-86 DA-B]	5.0	3.5	5.7	109.4	104.4	113.3	-	-	-	-	-	-	-	-	-	-	-	
	Maritime	2	[66-86 DA-B]	5.6	5.6	5.7	109.2	108.3	110.1	104.1	101.7	106.6	-	-	-	-	-	-	0>;2=;0<	-	
	Maritime	2	70 DA-B	5.2	4.7	5.7	107.6	104.4	110.8	-	-	-	106.7	103.8	109.5	-	-	-	-	0>;2=;0<	
	Maritime	1	62 DA-B	3.5	-	-	113.3	-	-	-	-	-	-	-	-	112.9	-	-	-	0>;1=;0<	

⁽¹⁾ FGE03 = Boscalid + Prothioconazole (350+200 g/kg; WG) at 245+140 g as/ha.

⁽²⁾ Proline = Prothioconazole (250 g/L; EC) at 175 g as/ha.

⁽³⁾ Prosaro 250 EC = Prothioconazole + Tebuconazole (125+125 g/L; EC) at 125+125 g as/ha.

⁽⁴⁾ Tilmor = Prothioconazole + Tebuconazole (80+160 g/L; EC) at 80+160 g as/ha.

* Comparison based on statistics carried out in each trial report.

In this trial series, on average across 5 trials, the yield in the untreated check was of 5.0 t/ha, ranging from 3.5 to 5.7 t/ha in individual trials.

FGE03 at 0.7 kg/ha had a positive effect on the yield of oilseed rape in presence of disease and generated a good gain in yield (+9.4%) compared to the untreated check. This was statistically highlighted in 1 out of the 5 trials according to individual trial results.

FGE03 at 0.7 kg/ha provided a gain in yield equivalent to reference products. Furthermore, there was no significant difference between FGE03 at 0.7 kg/ha and the reference products in all trials.

In summary, the results of 5 trials conducted in oilseed rape in the Maritime EPPO zone in 2022 and 2023 confirmed that FGE03 at 0.7 kg/ha (245+140 g a.s./ha) had a positive effect on crop yield compared to the untreated check in the presence of good disease pressure and performs at a level equivalent to the reference products.

C. Quality results (in the presence of challenging pest populations) of FGE03 after 2 applications - Maritime EPPO zone

Different quality parameters (thousand grain weight and oil content) were measured in 5 efficacy trials (2 trials in Czech Republic, 2 trials in Denmark and 1 trial in the United Kingdom) in the Maritime EPPO zone in 2022 and 2023 in the presence of *Sclerotinia sclerotiorum* in oilseed rape crop.

FGE03 was compared to the reference products prothioconazole at 175 g a.s./ha (=Proline 250), prothioconazole+tebuconazole at 125+125 g a.s./ha (Prosaro 250 EC) and prothioconazole+tebuconazole at 80+160 g a.s./ha (=Tilmor).

Table 3.2-59 shows a summary of effect on the quality parameters of FGE03 applied at 0.7 kg/ha compared to the reference products.

Table 3.2-59: Summary results: Quality parameters of FGE03 at 0.7 kg/ha compared to the reference products - Oilseed rape - SCLESC - Maritime EPPO climatic zone - 2 applications

Zone 2 applications																					
Parameters	EPPO climatic zone	No. of trials	Days after application	Untreated			% of untreated check (%UTC)												No. of trials where FGE03 at 0.70 kg/ha is statistically* > ; = ; < compared to		
							FGE03 ⁽¹⁾ 0.70 kg/ha			Proline ⁽²⁾ 0.70 L/ha			Prosaro 250 EC ⁽³⁾ 1.0 L/ha			Tilmor ⁽⁴⁾ 1.0 L/ha					
							Application : A + B			Application : A + B			Application : A + B			Application : A + B					
				Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Proline	Prosaro	Tilmor
Thousand grain weight (g)	Maritime	5	[62-90 DA-B]	4.0	2.1	5.2	103.9	99.9	107.6	-	-	-	-	-	-	-	-	-	-	-	
	Maritime	2	[66-90 DA-B]	4.7	4.2	5.2	104.1	100.5	107.6	102.4	100.8	103.9	-	-	-	-	-	-	0>;2=;0<	-	
	Maritime	2	70 DA-B	4.2	3.9	4.4	105.7	104.5	106.8	-	-	-	101.0	100.4	101.6	-	-	-	-	1>;1=;0<	
	Maritime	1	62 DA-B	2.1	-	-	99.9	-	-	-	-	-	-	-	-	99.6	-	-	-	0>;1=;0<	
Oil content (%)	Maritime	5	[62-90 DA-B]	45.8	38.9	50.8	100.1	98.8	101.4	-	-	-	-	-	-	-	-	-	-	-	
	Maritime	2	[66-90 DA-B]	39.7	38.9	40.4	100.4	99.4	101.4	100.7	100.1	101.2	-	-	-	-	-	-	0>;2=;0<	-	
	Maritime	2	70 DA-B	50.7	50.6	50.8	100.5	100.3	100.7	-	-	-	100.5	100.3	100.7	-	-	-	-	0>;2=;0<	
	Maritime	1	62 DA-B	48.3	-	-	98.8	-	-	-	-	-	-	-	-	96.9	-	-	-	1>;0=;0<	

⁽²⁾ Proline = Prothioconazole (250 g/L; EC) at 175 g as/ha.

⁽³⁾ Prosaro 250 EC = Prothioconazole + Tebuconazole (125+125 g/L; EC) at 125+125 g as/ha.

⁽⁴⁾ Tilmor = Prothioconazole + Tebuconazole (80+160 g/L; EC) at 80+160 g as/ha.

* Comparison based on statistics carried out in each trial report.

In this trial series, on average across 5 trials, the TGW (thousand grain weight) in the untreated check was of 4 g for 1000 grains and the oil content was 45.8%.

FGE03 at 0.7 kg/ha had a slight positive effect on TGW in presence of disease (+3.9%) compared to the untreated check. This was statistically highlighted in 1 out of the 5 trials according to individual trial results.

FGE03 at 0.7 kg/ha provided a gain in TGW equivalent to reference products. Furthermore, except in 1 trial there was no significant difference between FGE03 at 0.7 kg/ha and the reference products in all trials. In the last trial, FGE03 at 0.7 kg/ha was statistically higher than reference product Prosaro 250 EC.

FGE03 at 0.7 kg/ha had no effect on oil content in presence of disease compared to the untreated check and to the reference products. In this case, it can be concluded that FGE03 at 0.7 kg/ha has no negative effect on oil content.

In summary, the results of 5 trials conducted in oilseed rape in the Maritime EPPO zone in 2022 and 2023 confirmed that FGE03 at 0.7 kg/ha (245+140 g a.s./ha) had a slight positive effect on TGW and no impact on oil content compared to the untreated check and performs at a level equivalent to the reference products in the presence of good disease pressure.

3.2.3.3.2 Efficacy of FGE03 after 2 applications - North-East EPPO zone

A. Efficacy results of FGE03 after 2 applications - North-East EPPO zone

A total of 6 valid efficacy trials (2 trials in Lithuania and 4 trials in Poland) were carried out in the North-East EPPO zone in 2022 and 2023 to evaluate the efficacy of FGE03 applied twice at 0.7 kg/ha (245 g boscalid/ha +140 g prothioconazole/ha) for the control of *Sclerotinia sclerotiorum* in oilseed rape. FGE03 was compared to the reference product Prothioconazole at 180 g a.s./ha (=Protendo 300 EC).

In addition, according to Poland national guidance [Skuteczność działania środków ochrony roślin; updated on 15/09/2023], that data from countries adjacent to PL can be considered supportive. Therefore, data from CZ is also relevant for PL and presented in the following tables (North-East zone + CZ*).

The summary results of the effect of FGE03 applied at 0.7 kg/ha compared to reference product are shown in Table 3.2-60.

Table 3.2-60: Summary results: efficacy of FGE03 - Oilseed rape - SCLESC - North-East EPPO climatic zone - 2 applications

Parameters	Assessment timing	Parts	EPPO climatic zone	No. of trials	Days after application	Untreated (% of infestation)			% Control									No. of trials where FGE03 at 0.70 kg/ha is statistically ⁽⁵⁾ > ; = ; < compared to	
									FGE03 ⁽¹⁾ 0.70 kg/ha Application : A + B			Protendo 300 EC ⁽²⁾ 180 g as/ha prothioconazole 0.60 L/ha Application : A + B			Tilmor ⁽⁴⁾ 1.0 L/ha Application : A + B				
						Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Prothio	Tilmor
North-East EPPO climatic zone																			
Severity (%)	BBCH 80-85 75-87	STEM	North-East	6	[40-52 DA-B]	15.1	9.6	19.7	84.1	46.5	95.9	87.6	64.5	96.8				0>;6=;0<	
Incidence (%)	BBCH 80-85 75-87	STEM	North-East	6	[40-52 DA-B]	38.8	25.0	68.0	78.7	44.2	92.0	83.3	55.8	96.9				0>;6=;0<	
North-East EPPO climatic zone + CZ*																			
Severity (%)	BBCH 80-85 75-87	STEM	N-E + CZ*	8	[40-56 DA-B]	18.7	9.6	32.8	85.1	46.5	95.9								
	BBCH 80-85 75-87	STEM	N-E + CZ*	7	[40-56 DA-B]	17.6	9.6	32.8	83.8	46.5	95.9	80.3 ⁽³⁾	36.4 ⁽³⁾	96.8 ⁽³⁾				1>;6=;0<	
	BBCH 85 75-87	STEM	N-E + CZ*	1	[52 DA-B]	26.3	26.3	26.3	94.4	94.4	94.4				74.9	74.9	74.9	0>;1=;0<	
Incidence (%)	BBCH 80-85 75-87	STEM	N-E + CZ*	8	[40-56 DA-B]	41.4	25.0	68.0	80.0	44.2	92.0								
	BBCH 80-85 75-87	STEM	N-E + CZ*	7	[40-56 DA-B]	41.5	25.0	68.0	78.8	44.2	92.0	75.8 ⁽³⁾	31.0 ⁽³⁾	96.9 ⁽³⁾				1>;6=;0<	
	BBCH 85 75-87	STEM	N-E + CZ*	1	[52 DA-B]	41.0	41.0	41.0	87.8	87.8	87.8				75.6	75.6	75.6	0>;1=;0<	

* This additional line includes North-East EPPO climatic zone data + Czech Republic data. Indeed, Poland is a country bordering Czech Republic, which belongs to the Maritime EPPO zone and thus, the climate conditions and the disease development are quite similar, even though they belong to different climatic zones (according to Poland national guidance “Skuteczność działania środków ochrony roślin”; updated on 15/09/2023).

⁽¹⁾ FGE03 = Boscalid + Prothioconazole (350+200 g/kg; WG) at 245+140 g as/ha.

⁽²⁾ Protendo 300 EC = Prothioconazole (300 g/L; EC) at 180 g as/ha.

⁽³⁾ Protendo 300 EC = Prothioconazole (300 g/L; EC) at 180 g as/ha (North-East trials) and Proline = Prothioconazole (250 g/L; EC) at 175 g as/ha (CZ trial).

⁽⁴⁾ Tilmor = Prothioconazole + Tebuconazole (80+160 g/L; EC) at 80+160 g as/ha.

⁽⁵⁾ Comparison based on statistics carried out in each trial report.

In the North-East EPPO climatic zone, at the last assessment (BBCH 80-85 ~~75-87~~), in the untreated control, the average infestation was good (15% disease severity and 39% disease incidence on stems on average across 6 trials), varying from 10% to 20% disease severity and from 25% to 68% disease incidence in individual trials.

FGE03 applied twice at the intended rate of 0.7 kg/ha (245+140 g a.s./ha) demonstrated a good level of intrinsic effectiveness on disease severity with 84.1% mean efficacy in 6 trials.

FGE03 applied at 0.7 kg/ha showed a level of control similar to the reference product prothioconazole at 180 g as/ha (84.1% vs. 87.6% mean efficacy in 6 trials). No statistical differences were found in all individual trials.

These results were confirmed on the disease incidence, where the mean control of FGE03 applied at 0.7 kg/ha was similar to the reference product prothioconazole at 180 g as/ha (78.7% vs. 83.3% mean efficacy in 6 trials).

For information, these results were confirmed for Poland (North-East EPPO climatic zone data + Czech Republic data). Indeed, FGE03 applied twice at the intended rate of 0.7 kg/ha (245+140 g a.s./ha) demonstrated a good level of intrinsic effectiveness on disease severity with 85.1% mean efficacy in 8 trials. FGE03 applied at 0.7 kg/ha showed a level of control similar to the reference products prothioconazole at 175-180 g as/ha (83.8% vs. 80.3% mean efficacy in 7 trials). These results were confirmed on the disease incidence, where the mean control of FGE03 applied at 0.7 kg/ha was similar to the reference product prothioconazole at 175-180 g as/ha (78.8% vs. 75.8% mean efficacy in 7 trials). FGE03 was significantly higher in 1 trial out of 7 compared to prothioconazole.

In summary, in the North-East EPPO zone, when considering severity data from 6 trials investigating FGE03 effectiveness for the control of *Sclerotinia sclerotiorum* in oilseed rape after two applications, in conditions of good *Sclerotinia sclerotiorum* pressure, FGE03 applied at 0.7 kg/ha demonstrated a good effectiveness, and performed at a level equivalent to the reference product.

B. Yield results (in the presence of challenging pest populations) of FGE03 after 2 applications - North-East EPPO zone

A total of 2 valid efficacy trials (2 trials in Lithuania) were harvested in the North-East EPPO zone in 2022. The objective was to confirm the yield response of FGE03 in the presence of *Sclerotinia sclerotiorum* in oilseed rape crop.

FGE03 was compared to the reference product prothioconazole at 180 g a.s./ha (=Protendo 300 EC).

Table 3.2-61 shows a summary of effect on the yield of FGE03 applied at 0.7 kg/ha compared to the reference product.

Table 3.2-61: Summary results: Positive effect on the yield of FGE03 at 0.7 kg/ha compared to the reference products - Oilseed rape - SCLESC - North-East EPPO climatic zone - 2 applications

Parameters	EPPO climatic zone	No. of trials	Days after application	Untreated (T/ha)			% of untreated check (%UTC)						No. of trials where FGE03 at 0.70 kg/ha is statistically* > ; = ; < compared to
							FGE03 ⁽¹⁾ 0.70 kg/ha			Protendo 300 EC ⁽²⁾ 180 g as/ha prothioconazole 0.60 L/ha			
							Application : A + B			Application : A + B			
				Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	180 g as/ha prothioconazole
Yield	North-East	2	[63-66 DA-B]	3.1	2.6	3.6	110.2	105.8	114.6	107.0	106.9	107.2	0>;2=;0<

⁽¹⁾ FGE03 = Boscalid + Prothioconazole (350+200 g/kg; WG) at 245+140 g as/ha.

⁽²⁾ Protendo 300 EC = Prothioconazole (300 g/L; EC) at 180 g as/ha.

* Comparison based on statistics carried out in each trial report.

In this trial series, on average across 2 trials, the yield in the untreated check was of 3.1 t/ha, ranging from 2.6 to 3.6 t/ha in individual trials.

FGE03 at 0.7 kg/ha had a positive effect on the yield of oilseed rape in presence of disease and generated a good gain in yield (+10.2%) compared to the untreated check. This was statistically highlighted in 1 out of the 2 trials according to individual trial results.

FGE03 at 0.7 kg/ha provided a gain in yield equivalent to reference product prothioconazole at 180 g as/ha. Furthermore, there was no significant difference between FGE03 at 0.7 kg/ha and the reference product in both trials.

In summary, the results of 2 trials conducted in oilseed rape in the North-East EPPO zone in 2022 confirmed that FGE03 at 0.7 kg/ha (245+140 g a.s./ha) had a positive effect on crop yield compared to the untreated check in the presence of good disease pressure and performs at a level equivalent to the reference product.

C. Quality results (in the presence of challenging pest populations) of FGE03 after 2 applications - North-East EPPO zone

Different quality parameters (thousand grain weight and oil content) were measured in 2 efficacy trials (2 trials in Lithuania) in the North-East EPPO zone in 2022 in the presence of *Sclerotinia sclerotiorum* in oilseed rape crop.

FGE03 was compared to the reference product prothioconazole at 180 g a.s./ha (=Protendo 300 EC).

Table 3.2-62 shows a summary of effect on the quality parameters of FGE03 applied at 0.7 kg/ha compared to the reference product.

Table 3.2-62: Summary results: Quality parameters of FGE03 at 0.7 kg/ha compared to the reference products - Oilseed rape - SCLESC - North-East EPPO climatic zone - 2 applications

Parameters	EPPO climatic zone	No. of trials	Days after application	Untreated			% of untreated check (%UTC)						No. of trials where FGE03 at 0.7 kg/ha is statistically* > ; = ; < compared to
							FGE03 ⁽¹⁾			Protendo 300 EC ⁽²⁾ 180 g as/ha prothioconazole 0.60 L/ha			
							0.70 kg/ha			0.60 L/ha			
				Application : A + B			Application : A + B						
				Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	180 g as/ha prothioconazole
Thousand grain weight (g)	North-East	2	[105-108] DA-B	4.8	4.7	5.0	100.2	100.1	100.3	100.9	100.4	101.3	0>;2=;0<
Oil content (%)	North-East	2	[105-108] DA-B	44.7	44.0	45.3	100.7	100.2	101.2	99.8	99.7	99.9	0>;2=;0<

⁽¹⁾ FGE03 = Boscalid + Prothioconazole (350+200 g/kg; WG) at 245+140 g as/ha.

⁽²⁾ Protendo 300 EC = Prothioconazole (300 g/L; EC) at 180 g as/ha.

* Comparison based on statistics carried out in each trial report.

In this trial series, on average across 2 trials, the TGW (thousand grain weight) in the untreated check was of 4.8 g for 1000 grains and the oil content was 44.7%.

In summary, the results of 2 trials conducted in oilseed rape in the North-East EPPO zone in 2022, showed FGE03 applied at 0.7 kg/ha had no effect TGW and on oil content in presence of disease compared to the untreated check and the reference product. In this case, it can be concluded that FGE03 at 0.7 kg/ha has no negative effect on TGW and oil content.

3.2.3.3.3 Efficacy of FGE03 after 2 applications - South-East EPPO zone

A. Efficacy results of FGE03 after 2 applications - South-East EPPO zone

A total of 5 valid efficacy trials (3 trials in Hungary and 2 trials in Bulgaria) were carried out in the South-East EPPO zone in 2022 and 2023 to evaluate the efficacy of FGE03 applied twice at 0.7 kg/ha (245 g boscalid/ha +140 g prothioconazole/ha) for the control of *Sclerotinia sclerotiorum* in oilseed rape. FGE03 was compared to the reference products prothioconazole at 180 g a.s./ha (=Protendo 300 EC) and prothioconazole at 175 g a.s./ha (=Melvar).

The summary results of the effect of FGE03 applied at 0.7 kg/ha compared to reference products are shown in Table 3.2-63.

Table 3.2-63: Summary results: efficacy of FGE03 - Oilseed rape - SCLESC - South-East EPPO climatic zone - 2 applications

Parameters	Assessment timing	Parts	EPPO climatic zone	No. of trials	Days after application	Untreated (% of infestation)			% Control												No. of trials where FGE03 at 0.70 kg/ha is statistically* > ; = ; < compared to		
									FGE03 ⁽¹⁾			Protendo 300 EC ⁽²⁾ Prothio.180 g as/ha			Melvar ⁽³⁾ Prothio.175 g as/ha			Prothioconazole ⁽⁴⁾ 175-180 g as/ha					
						0.70 kg/ha			0.60 L/ha			0.7 L/ha			1.0 L/ha								
						Application : A + B			Application : A+B			Application : A+B			Application : A + B								
Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Prothio. 180 g as/ha	Prothio. 175 g as/ha	Prothio. 175-180 g as/ha			
Severity (%)	BBCH 77-85 75-87	STEM	South-East	5	[21-41 DA-B]	14.2	5.0	24.8	84.2	77.1	94.5	-	-	-	-	-	-	76.6	61.9	91.6	-	-	2>;3=;0<
	BBCH 81-85 75-87	STEM	South-East	3	[21-41 DA-B]	17.7	13.8	24.8	86.0	77.1	94.5	83.8	74.8	91.6	-	-	-	-	-	-	0>;3=;0<	-	-
	BBCH 77-85 75-87	STEM	South-East	2	[38-40 DA-B]	8.9	5.0	12.8	81.5	80.1	82.8	-	-	-	65.7	61.9	69.5	-	-	-	-	2>;0=;0<	-
Incidence (%)	BBCH 77-85 75-87	STEM	South-East	5	[21-41 DA-B]	45.8	21.0	73.0	74.9	65.7	80.6	-	-	-	-	-	-	66.8	47.9	81.0	-	-	1>;4=;0<
	BBCH 81-85 75-87	STEM	South-East	3	[21-41 DA-B]	28.7	21.0	36.0	78.7	76.2	80.6	78.2	75.9	81.0	-	-	-	-	-	-	0>;3=;0<	-	-
	BBCH 77-85 75-87	STEM	South-East	2	[38-40 DA-B]	71.5	70.0	73.0	69.2	65.7	72.6	-	-	-	49.7	47.9	51.4	-	-	-	-	1>;1=;0<	-

⁽¹⁾ FGE03 = Boscalid + Prothioconazole (350+200 g/kg; WG) at 245+140 g as/ha.

⁽²⁾ Protendo 300 EC = Prothioconazole (300 g/L; EC) at 180 g as/ha.

⁽³⁾ Melvar = Prothioconazole (250 g/L; EC) at 175 g as/ha.

⁽⁴⁾ Protendo 300 EC = Prothioconazole (300 g/L; EC) at 180 g as/ha or Melvar = Prothioconazole (250 g/L; EC) at 175 g as/ha.

* Comparison based on statistics carried out in each trial report.

In the South-East EPPO climatic zone, at the last assessment (BBCH 77-85 ~~75-87~~), in the untreated control, the average infestation was good (14% disease severity and 46% disease incidence on stems on average across 5 trials), varying from 5% to 25% disease severity and from 21% to 73% disease incidence in individual trials.

FGE03 applied twice at the intended rate of 0.7 kg/ha (245+140 g a.s./ha) demonstrated a good level of intrinsic effectiveness on disease severity with 84.2% mean efficacy in 5 trials.

FGE03 applied twice at 0.7 kg/ha showed a level of control better than the reference product Melvar (81.5% vs. 65.7 mean efficacy in 2 trials) and similar to that of the reference product Protendo 300 EC (86.0% vs. 83.8% mean efficacy in 3 trials). FGE03 was significantly higher in 2 trials out of 2 compared to Melvar.

These results were confirmed on the disease incidence, where the mean control of FGE03 applied at 0.7 kg/ha was better than the reference product Melvar (69.2% vs. 49.7% mean efficacy in 2 trials) and similar to that of the reference product Protendo 300 EC (78.7% vs. 78.2% mean efficacy in 3 trials). FGE03 was significantly higher in 1 trial out of 2 compared to Melvar.

In summary, in the South-East EPPO zone, when considering severity data from 5 trials investigating FGE03 effectiveness for the control of *Sclerotinia sclerotiorum* in oilseed rape after two applications, in conditions of good *Sclerotinia sclerotiorum* pressure, FGE03 applied at 0.7 kg/ha demonstrated a good effectiveness, and performed at a level better or equivalent to that of the reference products.

B. Yield results (in the presence of challenging pest populations) of FGE03 after 2 applications - South-East EPPO zone

A total of 3 valid efficacy trials (3 trials in Hungary) were harvested in the South-East EPPO zone in 2022. The objective was to confirm the yield response of FGE03 in the presence of *Sclerotinia sclerotiorum* in oilseed rape crop.

FGE03 was compared to the reference product prothioconazole at 180 g a.s./ha (=Protendo 300 EC).

Table 3.2-64 shows a summary of effect on the yield of FGE03 applied at 0.7 kg/ha compared to the reference product.

Table 3.2-64: Summary results: Positive effect on the yield of FGE03 at 0.7 kg/ha compared to the reference products - Oilseed rape - SCLESC - South-East EPPO climatic zone - 2 applications

Parameters	EPPO climatic zone	No. of trials	Days after application	Untreated (T/ha)			% of untreated check (%UTC)						No. of trials where FGE03 at 0.70 kg/ha is statistically* > ; = ; < compared to
							FGE03 ⁽¹⁾ 0.70 kg/ha			Protendo 300 EC ⁽²⁾ 180 g as/ha prothioconazole 0.60 L/ha			
				Application : A + B			Application : A + B						
				Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	180 g as/ha prothioconazole
Yield	South-East	3	[38-59 DA-B]	2.2	1.9	2.6	105.8	102.7	107.8	104.3	102.7	105.2	0>;3=;0<

⁽¹⁾ FGE03 = Boscalid + Prothioconazole (350+200 g/kg; WG) at 245+140 g as/ha.

⁽²⁾ Protendo 300 EC = Prothioconazole (300 g/L; EC) at 180 g as/ha.

* Comparison based on statistics carried out in each trial report.

In this trial series, on average across 3 trials, the yield in the untreated check was of 2.2 t/ha, ranging from 1.9 to 2.6 t/ha in individual trials.

FGE03 at 0.7 kg/ha had a positive effect on the yield of oilseed rape in presence of disease and generated a good gain in yield (+5.8%) compared to the untreated check.

FGE03 at 0.7 kg/ha provided a gain in yield equivalent to reference product prothioconazole 180 g as/ha (Protendo 300 EC at 0.6 L/ha). Furthermore, there was no significant difference between FGE03 at 0.7 kg/ha and the reference product in all trials.

In summary, the results of 3 trials conducted in oilseed rape in the South-East EPPO zone in 2022 confirmed that FGE03 at 0.7 kg/ha (245+140 g a.s./ha) had a positive effect on crop yield compared to the untreated check in the presence of good disease pressure and performs at a level equivalent to the reference product.

C. Quality results (in the presence of challenging pest populations) of FGE03 after 2 applications - South-East EPPO zone

Different quality parameters (thousand grain weight and oil content) were measured in 3 efficacy trials (3 trials in Hungary) in the South-East EPPO zone in 2022 in the presence of *Sclerotinia sclerotiorum* in oilseed rape crop.

FGE03 was compared to the reference product prothioconazole at 180 g a.s./ha (=Protendo 300 EC).

Table 3.2-65 shows a summary of effect on the quality parameters of FGE03 applied at 0.7 kg/ha compared to the reference product.

Table 3.2-65: Summary results: Quality parameters of FGE03 at 0.7 kg/ha compared to the reference products - Oilseed rape - SCLESC - South-East EPPO climatic zone - 2 applications

Parameters	EPPO climatic zone	No. of trials	Days after application	Untreated			% of untreated check (%UTC)						No. of trials where FGE03 at 0.70 kg/ha is statistically* > ; = ; < compared to
							FGE03 ⁽¹⁾ 0.70 kg/ha			Protendo 300 EC ⁽²⁾ 180 g as/ha prothioconazole 0.60 L/ha			
							Application : A + B			Application : A + B			
				Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	180 g as/ha prothioconazole
Thousand grain weight (g)	Southeast	3	[43-77] DAB	4.1	3.8	4.6	103.2	100.0	105.7	102.2	99.8	103.4	0>;3=;0<
Oil content (%)	Southeast	2	[50-77] DAB	39.4	36.4	42.4	101.4	101.4	101.4	100.6	100.2	100.9	0>;2=;0<

⁽¹⁾ FGE03 = Boscalid + Prothioconazole (350+200 g/kg; WG) at 245+140 g as/ha.

⁽²⁾ Protendo 300 EC = Prothioconazole (300 g/L; EC) at 180 g as/ha.

* Comparison based on statistics carried out in each trial report.

In this trial series, on average, the TGW (thousand grain weight) in the untreated check was of 4.1 g for 1000 grains (mean in 3 trials) and the oil content was 39.4% (mean in 2 trials).

FGE03 at 0.7 kg/ha had a slight positive effect on TGW in presence of disease (+3.2%) compared to the untreated check. FGE03 at 0.7 kg/ha provided a gain in TGW equivalent to reference product prothioconazole 180 g as/ha (Protendo 300 EC).

FGE03 at 0.7 kg/ha had no effect on oil content in presence of disease compared to the untreated check and to the reference product. In this case, it can be concluded that FGE03 at 0.7 kg/ha has no negative effect on oil content.

In summary, the results of 3 trials conducted in oilseed rape in the South-East EPPO zone in 2022 confirmed that FGE03 at 0.7 kg/ha (245+140 g a.s./ha) had a slight positive effect on TGW and no impact on oil content compared to the untreated check and performs at a level equivalent to the reference product in the presence of good disease pressure.

3.2.3.3.4 Conclusion - Efficacy results of FGE03 after 2 applications - All EPPO zones

Against *Sclerotinia sclerotiorum*, a total of 16 valid efficacy trials were carried out to evaluate the efficacy of FGE03 applied twice at 0.7 kg/ha (245 g boscalid/ha +140 g prothioconazole/ha) for the control of *Sclerotinia sclerotiorum* in oilseed rape. These trials were carried out in 2022 and 2023 in the Maritime (5 trials), North-East (6 trials) and South-East EPPO (5 trials) climatic zones.

In addition, according to Poland national guidance [Skuteczność działania środków ochrony roślin; updated on 15/09/2023], that data from countries adjacent to PL can be considered supportive. Therefore, data from CZ is also relevant for PL and presented in the following tables (North-East zone + CZ).

Summarised results on oilseed rape for the control of *Sclerotinia sclerotiorum* are detailed in Table 3.2-66.

Table 3.2-66: Efficacy of FGE03 (% control based on disease severity and incidence on stems at BBCH 75-87) in oilseed rape to control *Sclerotinia sclerotiorum* - 2 applications

Regulatory zone	EPPO climatic zone	Parameters	# Trials	Untreated (% of infestation)	Mean control (%) on disease on stem			No. of trials where FGE03 at 0.70 kg/ha is statistically ⁽¹⁾ > ; = ; < compared to	
					FGE03 0.7 kg/ha 245 g as/ha boscalid + 140 g as/ha prothioconazole	Ref prothio: 175-180 g as/ha prothioconazole	Ref prothio+Tebuco: 80-125 g as/ha prothioconazole + 125-160 g as/ha tebuconazole	Ref prothio	Ref prothio+Tebuco
					Application : A + B	Application : A + B	Application : A + B		
-	Maritime	Severity (%)	5	23.0	89.3	-	-	-	-
			2	21.8	90.1	68.2	-	1>;1=;0<	-
			3	23.8	88.7	-	76.3	-	0>;3=;0<
		Incidence (%)	5	36.8	83.2	-	-	-	-
			2	44.0	86.3	65.5	-	1>;1=;0<	-
			3	32.0	81.1	-	71.3	-	0>;3=;0<
	North-East	Severity (%)	6	15.1	84.1	87.6	-	0>;6=;0<	-
		Incidence (%)	6	38.8	78.7	83.3	-	0>;6=;0<	-
	South-East	Severity (%)	5	14.2	84.2	76.6	-	2>;3=;0<	-
		Incidence (%)	5	45.8	74.9	66.8	-	1>;4=;0<	-
Central zone	Maritime + NE + SE	Severity (%)	16	17.3	85.8	-	-	-	-
			13	15.8	85.1	80.4	-	3>;10=;0<	-
			3	23.8	88.7	-	76.3	-	0>;3=;0<
		Incidence (%)	16	40.3	78.9	-	-	-	-
			13	42.3	78.4	74.2	-	2>;11=;0<	-
			3	32.0	81.1	-	71.3	-	0>;3=;0<
Poland*	North-East + CZ trials	Severity (%)	8	18.7	85.1	-	-	-	-
			7	17.6	83.8	80.3	-	1>;6=;0<	-
			1	26.3	94.4	-	74.9	-	0>;1=;0<
		Incidence (%)	8	41.4	80.0	-	-	-	-
			7	41.5	78.8	75.8	-	1>;6=;0<	-
			1	41.0	87.8	-	75.6	-	0>;1=;0<

⁽¹⁾ Comparison based on statistics carried out in each trial report.

* This additional line includes North-East EPPO climatic zone data + Czech Republic data. Indeed, Poland is a country bordering Czech Republic, which belongs to the Maritime EPPO zone and thus, the climate conditions and the disease development are quite similar, even though they belong to different climatic zones (according to Poland national guidance “Skuteczność działania środków ochrony roślin”; updated on 15/09/2023).

Severity data from 16 trials investigating the efficacy of FGE03 applied in the Maritime, North-East and South-East EPPO zone for the control of *Sclerotinia sclerotiorum* in oilseed rape showed that FGE03 applied twice at the intended rate of 0.7 kg/ha has a good effectiveness (85.8% mean efficacy on disease severity in 16 trials). FGE03 applied twice 0.7 kg/ha was similar or better than the reference products based prothioconazole applied twice (85.1% vs. 80.4% mean efficacy on disease severity in 13 trials) and than the reference products based prothioconazole+tebuconazole applied twice (81.1% vs. 71.3% mean efficacy on disease severity in 3 trials).

Data generated across 16 trials carried out in the Maritime, North-East and South-East 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.

Comments of zRMS on:

Efficacy of FGE03 after 2 applications (3.2.3.3)

16 valid efficacy trials present data to assess the efficacy of FGE03 applied twice per growing season in the control of *Sclerotinia sclerotiorum* on winter oilseed rape. The trials were carried out in 3 EPPO zones: Maritime (Czech Republic – 2 trials, Denmark - 2 trials, the United Kingdom – 1 trial), North-East (Lithuania - 2 trials, Poland - 4 trials) and South-East (Bulgaria - 2 trials, Hungary - 3 trials) in the years 2022-2023. Conclusions for individual EPPO climatic zones are presented below.

Maritime EPPO zone (5 trials carried out in 2022-2023)

FGE03 at target dose rate of 0.7 kg/ha was applied twice at BBCH growth stage of the crop 60-69 and with water volume 150-300 L/ha. High efficacy of FGE03 at target dose rate was demonstrated for disease severity (89.3% efficacy) and for diseases incidence as well (83.2% efficacy) in 5 trials.

FGE03 applied twice achieved statistically higher efficacy as compared with standard Proline applied twice (in 1 trial) for disease severity and disease incidence. The efficacy of tested product was statistically comparable with the efficacy of standards: Prosaro (in 2 trials) and Tilmor (in 1 trial) for disease severity and disease incidence.

North-East EPPO zone (6 trials carried out in 2022-2023) + 2 supportive trials from Maritime EPPO zone (Czech Republic trials carried out in 2022)

In 6 trials conducted in North-East EPPO zone, FGE03 at recommended dose rate of 0.7 kg/ha was applied twice at BBCH growth stage of the crop 60-69, and with water volume 300 L/ha. In 2 supportive trials, FGE03 at recommended dose rate of 0.7 kg/ha was applied twice at BBCH growth stage of the crop 60-67, and with water volume 150-200 L/ha.

High efficacy of FGE03 at target rate was demonstrated for disease severity (84% efficacy) and moderate efficacy was noted for disease incidence (79% efficacy) in the 6 trials conducted in North-East EPPO zone. The efficacy of tested product was statistically comparable with the efficacy of Protendo 300 EC standard in all 6 trials.

Including supportive efficacy results from the trials carried out in Czech Republic, FGE03 was highly effective regarding disease severity (85% efficacy) and disease incidence (80% efficacy) as well. The efficacy of tested product was statistically comparable (in 6 trials for disease severity and disease incidence) or statistically higher (in 1 trial for disease severity and for disease incidence), than efficacy of standard Proline. No statistically significant differences in efficacy were observed between FGE03 and standard Tilmor for disease severity and disease incidence in 1 trial.

South-East EPPO zone (5 trials carried out in 2022-2023)

FGE03 at target dose rate of 0.7 kg/ha was applied twice at BBCH growth stage of the crop 60-71 and with water volume 250-400 L/ha. High efficacy of FGE03 at target dose rate was demonstrated for disease severity (84% efficacy) and moderate efficacy was noted for diseases incidence (75% efficacy). The efficacy of tested product was statistically comparable or statistically higher than efficacy of prothioconazole standard products.

Yield from efficacy trials

Maritime EPPO zone

Positive effect of FGE03 on the yield with about 9% increase as compared with untreated control was noted in 5 trials. No statistically significant differences in yield were observed comparing results for FGE03 with results achieved for standard products in these trials.

Slight positive effect of FGE03 on TGW with about 4% increase as compared with untreated control was observed in 5 trials. Statistically higher TGW was noted for FGE03 in 1 out of 2 trials comparing with results achieved for Prosaro standard. There were no statistically significant differences in TGW between FGE03 and standards: Proline and Tilmor (in 2 trials and 1 trial, respectively). Statistically higher oil content was noted for FGE03 comparing with results achieved for Tilmor in 1 trial, while there was no significant difference between FGE03 and standards: Proline in 2 trials and Prosaro in 2 trials.

North-East EPPO zone

Positive effect of FGE03 on the yield with about 10% increase as compared with untreated control was noted in 2 trials. No statistically significant differences in yield were observed comparing results for FGE03 with results achieved for prothioconazole standard product in these trials.

No statistically significant differences in TGW and oil content between FGE03 and standard Protendo 300 SC were noted in 2 trials.

South-East EPPO zone

Positive effect of FGE03 on the yield with about 6% increase as compared with untreated control was noted in 3 trials. No statistically significant differences in yield were observed comparing results for FGE03 with results achieved for prothioconazole standard product in these trials.

Positive effect of FGE03 on TGW with about 3% increase as compared with untreated control was noted in 3 trials. No statistically significant differences in TGW and oil content were observed comparing results for FGE03 with results achieved for prothioconazole standard in 3 and 2 trials respectively.

General conclusion of zRMS on:

Efficacy tests (3.2.3)

Results from 38 valid efficacy trials carried out between 2022 and 2024 have been presented to support the evaluation of the fungicide FGE03. The trials were carried out in Maritime EPPO zone (Austria, Czech Republic, Denmark, Northern France, the United Kingdom), North-East EPPO zone (Lithuania, Poland) and South-East EPPO zone (Bulgaria, Hungary, Romania). All the efficacy trials were carried out by the officially GEP-recognized testing units.

FGE03 is intended to be authorized for the control of *Sclerotinia sclerotiorum* in oilseed rape (winter and spring form) in Czech Republic (Maritime EPPO zone), Hungary (South-East EPPO zone) and in winter oilseed rape in Poland (North-East EPPO zone) based on the grounds of article 33 of regulation 1107/2009 - these uses are subject to evaluation. For Poland, the use spring oilseed rape: *Sclerotinia sclerotiorum* and additional uses: gold of pleasure, winter turnip rape, mustard, sunflower, poppy, linseed, flax, hemp, borage: *Sclerotinia sclerotiorum* are intended to be registered on the grounds of article 51 of regulation 1107/2009- off-label uses not subject to evaluation.

Detailed conclusions from the evaluation are contained in zRMS commenting boxes under the chapters 3.2.3.2 and 3.2.3.3.

General Conclusions on efficacy

Maritime EPPO climatic zone

Winter and spring oilseed rape/ *Sclerotinia Sclerotiorum*

GAP claims:

Application rate: 0.7 kg/ha

Water volume: 150-400 L/ha

FGE03 is intended to be used once per growing season within the crop growth stage ranging from 60 to 69 or twice per growing season within the crop growth stage range BBCH 61-73.

Based on the efficacy data package from Maritime EPPO zone, the use of FGE03 in the control of *Sclerotinia*

sclerotium on winter oilseed rape under conditions of use consistent with GAP may be granted. It is recommended to include in the product label remark about moderate level of efficacy of FGE03 applied once per growing season. The conducted trials did not completely cover the requested BBCH growth stage range 61-73 for the scenario of use with 2 applications of FGE03. Therefore the application timing is to be confirmed by cMS Czech Republic.

As no efficacy data has been submitted for spring oilseed rape the decision on acceptance this claimed use is to be taken at the national level, according to the national requirements. The zRMS is kindly asking the cMS to not only take their decisions, but also to share the underlying information with the zRMS PL, within the commenting period framework.

North-East EPPO climatic zone

Winter oilseed rape/ *Sclerotinia Sclerotium*

GAP claims:

Application rate: 0.7 kg/ha

Water volume: 100-400 L/ha

FGE03 is intended to be used twice per growing season within the crop stage range BBCH 61-73

Based on the efficacy data package from North-East EPPO zone and regarding supportive efficacy data from Czech Republic trials, the use of FGE03 in the control of *Sclerotinia sclerotium* on winter oilseed rape under conditions of use consistent with GAP may be granted in Poland.

Based on data from valid efficacy trials, the BBCH growth stage of the crop has been narrowed from 61-73 to 61-69.

South-East EPPO climatic zone

Winter and spring oilseed rape/ *Sclerotinia Sclerotium*

GAP claims:

Application rate: 0.7 kg/ha

Water volume: 100-400 L/ha

FGE03 is intended to be used once per growing season within the crop growth stage range BBCH 61-69 or twice per growing season within the crop growth stage range BBCH 61-73

Based on the efficacy data package from South-East EPPO zone, the use of FGE03 in the control of *Sclerotinia sclerotium* on winter oilseed rape under conditions of use consistent with GAP may be granted. It is recommended to include in the product label remark about moderate level of efficacy of FGE03 applied once per growing season.

As no efficacy data has been submitted for spring oilseed rape the decision on acceptance this claimed use is to be taken at the national level, according to the national requirements. The zRMS is kindly asking the cMS to not only take their decisions, but also to share the underlying information with the zRMS PL, within the commenting period framework.

After commenting period, taking into account the decision of the cMS HU regarding the extrapolation of data from BRSNW to BRSNS, the use on BRSNS has been accepted for HU.

General conclusion on yield for all EPPO climatic zones

Adverse effects on the yield and its quality parameters are not expected after 1 and 2 applications of FGE03 at recommended dose rate of 0.7 kg/ha.

3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

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 sclerotium* on oilseed rape (winter and spring) by foliar application method. Please refer to the GAP table in Table 3.1-1.

Prothioconazole is a broad-spectrum synthetic fungicide of the triazolinthione family of compounds with curative, preventative and eradication 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, DMI's belong to different classes.

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 possibility of development of resistance or cross-resistance to the active substances contained in FGE03 is discussed thereafter based on the requirements detailed in EPPO standard PP1/213(4) 'Resistance risk analysis'.

3.3.1 Mode of action

The biological mode of action of **prothioconazole** has been shown to be based on inhibition of the sterol biosynthesis pathway in fungi. Ergosterol is a unique component of the membrane of fungi, the inhibition of its biosynthesis makes the cell membrane rigid and leaky, so that the pathogen's hyphae cannot grow and infect the plant. At the target site level prothioconazole inhibits C-14 demethylase of ergosterol precursors, which then accumulate at the expense of ergosterol and belongs to the group of compounds collectively termed as De-Methylation Inhibitors (DMIs). The molecule is classified by FRAC in group 3 (G1, C-14 demethylase in sterol biosynthesis (erg11/cyp51)).

Boscalid is a member of the fungicide group succinate dehydrogenase inhibitors (SDHI) and the mode of action at the molecular level is the inhibition of the enzyme succinate dehydrogenase (SDH), also known as complex II in the mitochondrial electron transport chain. Such as other complexes of the respiratory chain, this enzyme is a component of the inner mitochondrial membrane. It consists of four nucleus-encoded subunits (SDH A, B, C, D). Two of these polypeptides (SDH C, D) anchor the complex in the membrane whilst the others project into the mitochondrial matrix where they catalyze the oxidation of succinate to fumarate as part of the tricarboxylic acid (TCA) cycle. The electrons so released are channelled into the electron transport chain via the co-substrate ubiquinol. Through its inhibition of complex II, boscalid disrupts fungal growth by preventing energy production and by eliminating the availability of the chemical building blocks for the synthesis of other essential cellular components. The molecule is classified by FRAC in group 7 (C2, Complex II-succinate dehydrogenase in respiration chain).

3.3.2 Mechanism of Resistance

Prothioconazole and other DMI fungicides are considered to have a **medium risk** of resistance development⁵.

The primary mechanism of resistance is the accumulation of several independent mutations in the target site. Each individual mutation typically causes only a small reduction in sensitivity, and it is not observed to impact efficacy under field conditions until multiple mutations accumulate in an isolate that are large enough to cause a reduction in sensitivity. Hence, resistance to DMI's is mostly characterised by a slow, stepwise erosion of efficacy over several years of intensive use rather than by a rapid loss of control. Thus, the resistance type characteristics for DMIs is often described as “multigenic”, “continuous”, “quantitative” or “shifting”.

In addition to mutations at the target site, reductions in sensitivity of individual isolates can also be attributed to overexpression of the cyp51 gene and transport of the fungicide away from the target site by ABC transporters. It is not clear how important these mechanisms of resistance are under field conditions as they often co-exist with mutations at the target site.

Boscalid and other SDHI fungicides are considered to have a **medium to high risk**⁷ of resistance development. Studies on earlier SDHIs showed that single site mutations in the SDH genes were responsible for the loss of fungicide efficacy (Keon *et al.* 1991, Skinner *et al.* 1998, Matsson *et al.* 1998,

⁵ FRAC Code List 2024: Fungal control agents sorted by cross-resistance pattern and mode of action, Fungicide Resistance Action Committee, Online, [Link](#)

2001, Ito *et al.* 2004). With investigations of SDHI resistance moving forward after the introduction of broad spectrum SDHIs such as boscalid, a complex picture is forming. Several mutations in the target protein at different positions in three SDH subunits B, C and D were detected in field isolates of some plant pathogens such as *Botrytis cinerea* (Stammler *et al.* 2007, Veloukas *et al.* 2011), *Corynespora cassiicola* (Miyamoto *et al.* 2009, 2010a), *Alternaria alternata* (Avenot and Michaelidis 2007), *Alternaria solani* (Miles *et al.* 2014), *Didymella bryoniae* (Avenot *et al.* 2012, Fernandez-Ortuno *et al.* 2012), *Podosphaera xanthii* (Miyamoto *et al.* 2010b), *Pyrenophora teres* (Stammler *et al.* 2014) and *Sclerotinia sclerotiorum* (Glaetli *et al.* 2009), and in laboratory mutants of *Zymoseptoria tritici* (= *Mycosphaerella graminicola*) (Skinner *et al.* 1998, Stammler *et al.* 2010, Fraaije *et al.* 2012, Scalliet *et al.* 2012). Different mutations were found at one gene location, and at different gene locations in different subunits. Table 3.3-1 provides an overview of mutations so far detected in field and laboratory isolates. The numbering of mutations needs some explanation. Several of these amino acids, which have been found to be exchanged in different species, are homologous, but have different numbers, since the number of amino acids ahead in the protein may vary in different species. Homologous mutations found in several species but with different numbering are described in Table 3.3-2. This diversity of mutations complicates the interpretation of sensitivity findings in an unprecedented manner. There are mutations with amino acid exchanges leading to more or less complete resistance to all SDHIs, but some exchanges have also been detected which affect sensitivity to different SDHIs differently. Mutations at homologous sites may even have different effects in different fungal species.

Table 3.3-1: List of cases of SDHI-resistant fungal plant pathogen species, their origin, and mutations found conferring SDHI resistance

Letter codes given for species are used in Table 3.3-2. Table reflects the list published on the FRAC webpage (Status July 2014) with some updates based on BASF, unpublished data

Species name		Reported from host	Origin	Resistance mechanism (Subunit-mutation)
<i>Ustilago maydis</i>	a	(Laboratory)	Lab	B-H257L
<i>Aspergillus oryzae</i>	b	(Laboratory)	Lab	B-H249Y/L/N, C-T90I, D-D124E
<i>Zymoseptoria tritici</i>	c	(Laboratory)	Lab	B-N225I, B-H267Y/R/L, B-I269V, C-A84V, C-H152R, C-T79I, C-N86K, C-G90R, D-H129E and several others
<i>Zymoseptoria tritici</i>	d	Wheat	Field	B-N225T, C-T79N, C-W80S, C-N86S
<i>Pyrenophora teres</i>	e	Barley	Field	B-H277Y, C-N75S, C-G79R, C-H134R, C-S135R, D-D124N/E, D-H134R, D-D145G
<i>Botrytis cinerea</i>	f	various	Field	B-P225L/T/F, B-H272Y/R/L/V, B-N230I, D-H132R, C-A85V
<i>Botrytis elliptica</i>	g	Lillies	Field	B-H272Y/R
<i>Alternaria alternata</i>	h	Pistachio	Field	B-H277Y/R, C-H134R, D-D123E, D-H133R
<i>Alternaria solani</i>	i	Potatoes	Field	B-H277Y/R, D-H133R
<i>Corynespora cassiicola</i>	j	Cucurbits	Field	B-H278Y/R, C-S73P, D-S89P, D-G109V
<i>Didymella bryoniae</i>	k	Cucurbits	Field	B-H277R/Y
<i>Podosphaera xanthii</i>	l	Cucurbits	Field	B-H->Y (homologous to H272 in <i>B. cinerea</i>)
<i>Sclerotinia sclerotiorum</i>	m	Oilseed rape	Field	B-H273Y, C-H146R, D-H132R
<i>Stemphylium vesicarium</i>	n	Asparagus	Field	B-P225L, H272Y/R
<i>Venturia inaequalis</i>	o	Apple	Field	C-H151R

Table 3.3-2: Amino acids in the different SDH subunits, which were found to be exchanged and to influence SDHI sensitivity (first column). Homologous position (number) in different species (Letter codes see Table 3.3-1) is given in the second column

Amino acid	Homologous positions
B-Proline	220c, 225f,n
B-Histidine	257a, 249b, 267c, 277e,h,i,k, 272f,g,n, 278j, 273m
B-Asparagine	225c,d, 230f
C-Alanine	84c, 85f , also homologous position to S73 in <i>C. cassiicola</i>
C-Asparagine	86c,d, 75e
C-Glycine	90c, 79e
C-Histidine	145c, 134e,h, 146m
C-Histidine	152c, 151o

Amino acid	Homologous positions
D-Asparagine acid	124e, 123h
D-Histidine	118c, 132f,m, 134e, 133h

3.3.3 Evidence of Resistance

The risk of fungal phytopathogens developing resistance to prothioconazole is **medium**. The EPPO and FRAC databases (EPPO, 2024⁶ and FRAC, 2020⁷) report various entries for cases of resistance to DMI fungicides. In practice, there has been reported no case observed on *Sclerotinia sclerotiorum* in oilseed rape. Other cases of resistance (non exhaustive list) relate to fungal pathogens not relevant to the GAP for FGE03 (Table 3.3-3).

Table 3.3-3: Pathogens resistant to DMI Fungicides (prothioconazole)

MOA Code	FRAC Group Code	Pathogen	Crop	Reference	Remarks
G1	3	<i>Aspergillus nidulans</i>	-	De Waard & van Nistelrooy 1979	Genetic study
		<i>Blumeriella jaapii</i>	Cherry	Proffer <i>et al.</i> 2006	Field
		<i>Botryosphaeria dothidea</i>	-	Fan Kun <i>et al.</i> 2013	Laboratory
		<i>Botrytis cinerea</i>	Vegetable Various	Elad 1992 Stehmann & De Waard 1996	Field laboratory Investigation of lack of intrinsic activity
		<i>Calonectria pauciramosa</i>	Nurseries	Guarnaccia <i>et al.</i> 2014	Field
		<i>Calonectria polizzii</i>	Nurseries	Guarnaccia <i>et al.</i> 2014	Field
		<i>Cerospora beticola</i>	Sugar beet	Henry & Trivellas 1989 Karaoglanidis <i>et al.</i> 2000 Budakov <i>et al.</i> 2014	Laboratory mutants Field isolates Field
		<i>Cladosporium caryigenum</i>	Pecan	Reynolds <i>et al.</i> 1997	Cross resistance, laboratory
		<i>Colletotrichum gloeosporoides</i>	Mango	Gutierrez-Alonso <i>et al.</i> 2003	Postharvest / laboratory
		<i>Erysiphe graminis</i> f.sp. <i>hordei</i>	Barley	Fletcher & Wolfe 1981	Field
		<i>Erysiphe graminis</i> f.sp. <i>tritici</i>	Wheat	De Waard <i>et al.</i> 1986	Field
		<i>Fusarium asiaticum</i>	Wheat	Yin <i>et al.</i> 2009	Lab study on isolates from China
		<i>Fusarium graminearum</i>	Wheat	Spolti <i>et al.</i> 2014	Field
		<i>Fusarium fujikuroi</i>	-	Zhao Zhi-hua <i>et al.</i> 2007	Laboratory mutation (prochloraz)
		<i>Fusarium moniliforme</i>	Rice	Yanh HongFu <i>et al.</i> 2013	Field
		<i>Fusarium solani</i> . See <i>Nectria haematococca</i> var. <i>cucurbitae</i>	Foot rot	Kalamarakis <i>et al.</i> 1991	Genetic study
		<i>Fusarium verticillioides</i>	Corn	Fan <i>et al.</i> 2014	Laboratory
		<i>Microdochium (Fusarium) nivale</i>	-	Cristani & Gambogi 1993	Laboratory
		<i>Monilinia fructicola</i>	Stone fruit	Nuninger-Ney <i>et al.</i> 1989 Elmer <i>et al.</i> 1992 Chen <i>et al.</i> 2013	Laboratory Field Field
		<i>Mycosphaerella fijiensis</i>	Banana	Anonymous 1992	-
		<i>Mycosphaerella graminicola</i> = <i>Zymoseptoria tritici</i>	Wheat	Metcalf <i>et al.</i> 2000 Mavroedi & Shaw 2005 HGCA 2005 Cools <i>et al.</i> 2005	Field experiments Field experiments Field Laboratory
		<i>Mycovellosiella natrassii</i>	Eggplant	Yamaguchi <i>et al.</i> 2000	Field
		<i>Nectria haematococca</i> var. <i>cucurbitae</i>	Cucurbits	Kalamarakis <i>et al.</i> 1991	Laboratory genetics
		<i>Penicillium digitatum</i>	Citrus	Eckert 1987 Wang Jinlong <i>et al.</i> 2014	Laboratory selection Storage
		<i>Penicillium italicum</i>	-	De Waard <i>et al.</i> 1982	Laboratory

⁶ List of Resistance Cases, EPPO Database on Resistance Cases, EPPO, Online, [Link](#) Accessed July 2024.

⁷ List of first confirmed cases of plant pathogenic organisms resistant to disease control agents, Revised May 2020, FRAC, Online, [Link](#)

MOA Code	FRAC Group Code	Pathogen	Crop	Reference	Remarks
		<i>Phakopsara pachyrhize</i>	Soybeans	Schmitz <i>et al.</i> 2014	Field
		<i>Pseudocercospora herpotrichoides</i> Lente or R type	Wheat	Leroux & Marchegay 1991	Field
		<i>Puccinia horiana</i>	Chrysanthemum	Cevat 1992 Cook 2001	Field Field
		<i>Puccinia striiformis</i>	Wheat	Bayles <i>et al.</i> 2000 Napier <i>et al.</i> 2000	Sensitivity shift laboratory
		<i>Pyrenopeziza brassicae</i>	Oilseed rape	Carter <i>et al.</i> 2014	Field
		<i>Pyrenophora teres</i>	Barley	Sheridan <i>et al.</i> 1985	Field
		<i>Pyrenophora tritici-repentis</i>	Wheat	Reimann & Deising 2005	Field
		<i>Ramularia collo-cygni</i>	Barley	FRAC 2016	Field
		<i>Rhizoctonia solani</i>	Rice	Manish Agrawal <i>et al.</i> 2013	Field
		<i>Rhynchosporium secalis</i>	Barley	Hunter <i>et al.</i> 1986 Kendall & Hollomon 1990 Kendall <i>et al.</i> 1993 Cooke <i>et al.</i> 2004	Glasshouse Field Field isolates Field
		<i>Sclerotinia homoeocarpa</i>	- Turfgrass	Vargas <i>et al.</i> 1992 Ma & Tredway 2013	Laboratory Field
		<i>Sphaerotheca fuliginea</i>	Cucumber	Schepers 1983, 1985a, 1985b	Field
		<i>Sphaerotheca mors-uvae</i>	Black currant	Goszczyński <i>et al.</i> 1988	Field
		<i>Sphaerotheca pannosa</i>	Nectarine	Reuveni 2001	Field
		<i>Trichoderma koningii</i>	-	Figueras-Roca <i>et al.</i> 1996	Laboratory
		<i>Uncinula necator</i>	Grapevine	Steva <i>et al.</i> 1990 Reidi & Steinkellner 1996 Miller & Gubler 2003	Field Field Field
		<i>Ustilago avenae</i>	Oats	Hippe & Koller 1986	Laboratory
		<i>Ustilago maydis</i>	Maize	Walsh & Sisler 1981	Laboratory
		<i>Venturia inaequalis</i>	Apple	Stanis & Jones 1985 Köller <i>et al.</i> 1991	Field Laboratory
		<i>Venturia nashicola</i>	Pear	Tomita & Ishii 1998	Field

The risk of fungal phytopathogens developing resistance to boscalid is **medium to high**. Resistance development (non exhaustive list) towards SDHI fungicides was observed for several pathogens including *Sclerotinia sclerotiorum* in oilseed rape, which is the claimed target in this dossier (Table 3.3-4).

Table 3.3-4: Pathogens resistant to SDHI Fungicides (boscalid)

MOA Code	FRAC Group Code	Pathogen	Crop	Reference	Remarks
C2	7	<i>Alternaria alternata</i>	Pistachio Tomato	Avenot & Michallides 2007 Avenot <i>et al.</i> 2008 FRAC 2012	Field Resistance mechanism Field
		<i>Alternaria solani</i>	Potato	Mallik <i>et al.</i> 2014 Miles <i>et al.</i> 2014	Laboratory Field
		<i>Aspergillus oryzae</i>	Rice	(FRAC:) Shima, Y. <i>et al.</i> 2009	Laboratory
		<i>Aspergillus nidulans</i>	-	White & Georgopoulos 1986	Mutant study
		<i>Blumeriella jaapii</i>	Cherry	Outwater <i>et al.</i> 2013	Field
		<i>Botryotinia fuckeliana</i> (<i>Botrytis cinerea</i>)	-	Angelini <i>et al.</i> 2010	Laboratory genetic analysis
		<i>Botrytis cinerea</i>	Grapevine Strawberry Kiwi fruit Apple	FRAC 2007 FRAC 2007 Bardas <i>et al.</i> 2010 Yin <i>et al.</i> 2011	Field Field Multiple resistance Field
		<i>Botrytis elliptica</i>	Lilly	FRAC 2007	Field
		<i>Coprinus cinereus</i>	-	Ito <i>et al.</i> 2004	Mutation study and genetic analysis

MOA Code	FRAC Group Code	Pathogen	Crop	Reference	Remarks
		<i>Corynespora cassiicola</i>	Cucumber	Miyamoto <i>et al.</i> 2007 Ishii <i>et al.</i> 2007 Miyamoto <i>et al.</i> 2009 Miyamoto <i>et al.</i> 2010b	Field (greenhouses) Molecular mechanism Full field report Field
		<i>Didymella bryoniae</i>	Cucurbits	FRAC 2007 Stevenson <i>et al.</i> 2008	Field Field
		<i>Erysiphe necator</i>	Grapevine	FRAC 2016	Field
		<i>Helminthosporium solani</i>	Potato	FRAC 2014	Field
		<i>Monilinia fructicola</i>	Peach	Chen <i>et al.</i> 2013	Field
		<i>Mycosphaerella graminicola</i> = <i>Zymoseptoria tritici</i>	Wheat	Skinner <i>et al.</i> 1998	Laboratory mutation study
		<i>Phakopsara pachyrhize</i>	Soybean	FRAC 2017	Field
		<i>Podosphaera xanthii</i>	Melon Cucumber	FRAC 2007 Miyamoto <i>et al.</i> 2010a	Field Field (Japan, glasshouses)
		<i>Puccinia hordei</i>	Barley	FRAC 2019	Field
		<i>Pyrenophora teres</i>	Barley	Stammler G. 2014	Field
		<i>Ramularia collo-cygni</i>	Barley	FRAC 2017	Field
		<i>Sclerotinia sclerotiorum</i>	OSR	FRAC 2014	Field
		<i>Stemphylium vesicarium</i>	Asparagus Pear	FRAC 2014 FRAC 2018	Field Field
		<i>Ustilago maydis</i>	Maize	Keon <i>et al.</i> 1991	Laboratory mutation study
		<i>Ustilago nuda</i>	Barley	Leroux & Berthier 1988	Field
		<i>Venturia inaequalis</i>	Apple	FRAC 2014	Field

*Lines highlighted in grey corresponds to targets present in this dossier.

According to FRAC⁸, *Sclerotinia sclerotiorum* is considered to have **low** risk of development of resistance to fungicides. Details of resistance of the target pathogen for this submission, as reported by FRAC, are given in Table 3.3-5.

Table 3.3-5: Resistance of the target pathogen against different classes of fungicides, reported by FRAC

Fungicide group	MOA Code	FRAC Group code	Pathogen	Crop	Reference	Remarks
MBC fungicides (Methyl Benzimidazole Carbamates), β -tubulin assembly in mitosis	B1	1	<i>Sclerotinia sclerotiorum</i>	Oilseed rape	-	-
SDHI fungicides (Succinate dehydrogenase inhibitors) : Complex II succinate-dehydrogenase	C2	7	<i>Sclerotinia sclerotiorum</i>	Oilseed rape	FRAC 2014	Field
PP fungicides (Phenylpyrroles). MAP / Histidine-kinase in osmotic signal transduction (os-2, HOG1)	E2	12	<i>Sclerotinia sclerotiorum</i>	Rapeseed	Duan YaBing <i>et al.</i> 2014	Methodology/Mutation studies
Dicarboximides. MAP / Histidine-kinase in osmotic signal transduction (os-1, Daf1)	E3	2	<i>Sclerotinia sclerotiorum</i>	Oilseed rape & soybeans	Zhou Feng <i>et al.</i> 2014	Field (low frequency)

3.3.4 Cross-resistance

All DMI fungicides inhibit pathogens by interacting with the same target site (C14-demethylase) and are therefore considered to be cross-resistant with each other. Generally, compounds within each

⁸ <https://www.frac.info/docs/default-source/publications/pathogen-risk/frac-pathogen-list-2019.pdf>

subgroup of SBI's (G1=DMI's, G2=amines, G3=KRI's) are cross-resistant with other members within the same group, but there is no cross-resistance between members of different groups. Furthermore, DMI's show no cross-resistance to any of the other important fungicide groups such as QoI or SDHI fungicides. It is therefore wise to accept this finding as the basis of an anti-resistance strategy.

A general cross-resistance can be postulated for SDHIs, even if the effects may be somewhat different in some cases. However, there are exceptions, where no cross-resistance seems to be present. In addition, uses of specific SDHIs also influence which mutation will occur in various fungal species, and variability in the frequency of mutations is therefore not only a result of the fungal species but also of the use of various SDHIs. However, monitoring studies were made for many target pathogens of boscalid without any finding of any isolate with a sensitivity outside the baseline.

3.3.5 Sensitivity data

No baseline or sensitivity data is provided as both active substances have been used commercially in Europe for many years.

Monitoring data derived from several industry plant protection product manufacturers are published on the FRAC webpage. The following information on the resistance status of the target pathogen *Sclerotinia sclerotiorum* for which control is claimed on the FGE03 label is available in oilseed rape, sunflower, beans and lettuce from the Sterol Biosynthesis Inhibitor (SBI) Working Group (2024 meeting), FRAC⁹.

Regarding *Sclerotinia sclerotiorum* in oilseed rape, monitoring was carried out between 2016 and 2022 in Austria, Bulgaria, Czech Republic, Denmark, Estonia, France, Germany, Hungary, Latvia, Lithuania, Netherlands, Poland, Romania, Slovakia, Sweden, Ukraine, and United Kingdom. In 2023, monitoring was carried out in Austria, Bulgaria, Czech Republic, Denmark, Estonia, France, Germany, Hungary, Latvia, Lithuania, Poland, Romania, Sweden, and United Kingdom. All monitoring data from 2016 to 2023 showed a stable and narrow sensitivity range with no geographical differences.

Regarding *Sclerotinia sclerotiorum* in sunflower, initial monitoring was carried in 2019 in Bulgaria, Romania, and Slovakia. Data showed a narrow sensitivity range with EC₅₀ values comparable to *S. sclerotiorum* in oilseed rape. Then, monitoring was carried out in 2022 in Romania and France. Data showed a narrow sensitivity range with EC₅₀ values comparable to *S. sclerotiorum* in oilseed rape and cabbage.

Regarding *Sclerotinia sclerotiorum* in beans and green beans, the first-time monitoring was carried out in 2020 in France, and in 2021, samples from France and Belgium were analysed. All isolates collected showed a narrow sensitivity range and high sensitivity (low EC₅₀ values). Then, monitoring was carried out in 2022 in Belgium, France and the Netherlands. Data showed a narrow sensitivity range with EC₅₀ values comparable to *S. sclerotiorum* in oilseed rape and cabbage.

Regarding *Sclerotinia sclerotiorum* in lettuce, the first-time sensitivity monitoring was carried out in 2020 in Spain. In 2021, samples from France, Italy, and Spain were analysed. All isolates collected showed a narrow sensitivity range and high sensitivity (low EC₅₀ values).

There is an annual meeting of the FRAC SDHI Working Group (2024 meeting)¹⁰, where current monitoring data are discussed and decision is made whether changes to the next year's use recommendations are required. According to the intended pathogen for which activity of FGE03 is claimed, monitoring data for *Sclerotinia sclerotiorum* in oilseed rape, peas, beans and lettuce are presented.

Concerning *Sclerotinia sclerotiorum* in oilseed rape, extensive monitoring programs were carried out from 2006 to 2022 derived from many countries across Europe. In 2014 and 2015, single resistant isolates were detected in France. No resistant isolates were detected in 2014 in Czech Republic, Germany, the United Kingdom and Poland. In 2015, no resistance was detected in the Netherlands, Belgium, France, Poland, Czech Republic, Croatia and Germany. In the season 2016, samples were tested from Germany, France, the United Kingdom, Czech Republic, Lithuania, Denmark and Poland.

⁹ Sterol Biosynthesis Inhibitor (SBI) Working Group Minutes from WG meeting on January 19th, 2024 [Link](#)

¹⁰ Succinate Dehydrogenase Inhibitor (SDHI) Working Group Minutes from WG meeting on January 16-17th and 22nd March, 2024 [Link](#)

No to low frequency of resistance was detected in France and Germany. Disease pressure in 2017 was low to moderate. In the season 2017, samples were tested from Germany, France, the United Kingdom, Czech Republic, Latvia, Sweden, Romania, Denmark and Poland. Full sensitivity was observed in Czech Republic, Romania and Poland. Low frequency of resistance was detected in Germany, France, the United Kingdom, Latvia, Sweden and Denmark. In the season 2018, samples were tested from France, Germany, Hungary, Romania, Poland and the United Kingdom. A low frequency of adapted isolates was detected in France. In the season 2019, samples were tested from Czech Republic, Germany, Hungary, Romania, Slovakia, Poland, Ukraine and the United Kingdom. All samples showed full sensitivity. A low frequency of adapted isolates was detected in France. In 2020, monitoring was carried out in Bulgaria, Czech Republic, Denmark, France, Germany, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Ukraine and the United Kingdom. Stable and low frequency was observed in France in 2019 and 2020. Decreased sensitivity was observed in Germany and Lithuania in single locations at a very low frequency. In 2021, results from monitoring programs in Bulgaria, Czech Republic, France, Germany, Hungary, the Netherlands, Poland, Romania and Ukraine show high sensitivity. Stable and low frequency of sensitivity adaptation was observed in France as in the previous seasons. Decreased sensitivity was observed in Germany in a single location at a very low frequency. In 2022, samples were investigated coming from Bulgaria, Czech Republic, Denmark, Estonia, Germany, France, Hungary, Latvia, Lithuania, Poland, Romania and Sweden. Full sensitivity was observed in Bulgaria, Czech Republic, Denmark, Estonia, Hungary, Latvia, Poland and Romania. A stable situation was observed in France as in the previous seasons with a low frequency of sensitivity adaptation. Decreased sensitivity was observed in samples from Germany, Lithuania Poland and Sweden from single locations at a very low frequency. Then, samples were investigated in 2023 coming from France and Poland. Full sensitivity was observed Poland. A stable situation was observed in France as in the previous seasons with a low frequency of sensitivity adaptation.

Regarding *Sclerotinia sclerotiorum* in peas, beans and lettuce, data from 2015 to 2021 is derived from several countries, i.e. France, Spain, Belgium, Germany, the Netherlands and Poland. Overall, full sensitivity is detected from all the samples collected since 2015. Only one single isolate originating from lettuce on a trial site in Spain showed decreased sensitivity in 2020.

3.3.6 Use pattern

FGE03 is a new fungicide formulated as a water-dispersible granule (WG) preparation containing 350 g/kg boscalid and 200 g/kg prothioconazole.

FGE03 is proposed for the control of *Sclerotinia sclerotiorum* in oilseed rape (winter and spring).

FGE03 is intended to be applied via foliar spray. The dose rate of 0.7 kg product/ha (245 g boscalid/ha + 140 g prothioconazole/ha) is recommended. One application between BBCH 61-69 (from 10% of flowers on main raceme open, main raceme elongating, to the end of flowering), or two applications between BBCH 61-73 (from 10% of flowers on main raceme open, main raceme elongating, to 30% of pods have reached final size), with 14 days interval between applications, are recommended per season. FGE03 is intended to be sprayed with a water volume ranging from 100 to 400 L/ha, depending on the typical local practice. The pre-harvest interval (PHI) is recommended at 35 days.

In the most intensive growing regions of Europe and especially in seasons with high disease pressure, up to 2 foliar sprays per crop are done. Selection pressure resulting from unrestricted use pattern would increase the risk of quick resistance development compared to a usage according to a management strategy.

3.3.7 Resistance risk assessment of unrestricted use pattern

The development of resistance depends on three parts: the fungicide risk, the pathogen risk and the agronomic risk.

Inherent active substance associated risk

The active substances of the fungicide FGE03, prothioconazole and boscalid, have been used in crop protection for many years and are well established in the market.

The DMI fungicides like prothioconazole are classified as having an inherent **medium** risk of resistance development (FRAC, 2022).

The SDHI fungicide boscalid is classified as having an inherent **medium to high** risk of resistance development (FRAC, 2022).

Inherent pathogen associated risk

The resistance risk of a pathogen to a fungicide is classified in three different situations - low, medium, and high.

In a low-risk situation, restrictions in the use pattern are not required. In a moderate-risk situation, restrictions in the use pattern should be recommended. In a high-risk situation, specific resistance management strategies are always required (including specific label warnings).

Generally, the risk increases when a pathogen undergoes many and short disease cycles per season, the dispersal through spores over time and space is high, sexual recombination is mandatory in the disease cycle, and the competitive ability of a resistant individual is at least as high as that of the wild type (in the absence of selection pressure). Furthermore, the risk is considered as high when resistance has evolved already after only a few years of fungicide product use.

As no scientific criteria are available to accurately determine the risk of pathogen to develop resistance, the FRAC classification is based on the reported resistance claims over the last 50 years.

Therefore, FRAC considers the pathogen risk as medium to high only if resistance was reported in commercial situations for more than one fungicide class (FRAC, 2013). In conclusion, the resistance risk of the diseases for which registration is requested can be summarised as follows:

Table 3.3-6: Pathogen risk summary

Pathogen	Crop	Risk	Risk class
<i>Sclerotinia sclerotiorum</i>	Various	Low	1

Inherent combined risk

When the pathogen risk is reported in a table with the inherent resistance risk of the DMIs group and SDHIs group, the combined resistance risk for each fungicide/pathogen combination can be estimated as follow (FRAC, 2019)¹¹.

Table 3.3-7: Combined Inherent risk for each active substance contained in FGE03

Molecule Risk ↓	Combined Risk		
High = 3 <i>boscalid</i>	3	6	9
Medium = 2 <i>boscalid, prothioconazole</i>	2	4	6
Low=1	1	2	3
Pathogen risk →	Low =1 <i>Sclerotinia sclerotiorum</i>	Medium = 2	High = 3

Combined Risk: 1 = low, 2 to 6 = medium, 9 = high (FRAC, 2019)

When considering the combined risk of resistance based upon the inherent risk of prothioconazole and boscalid, and the inherent risk of the target pathogen, according to the combined risk schematic developed by Brent and Hollomon and amended by FRAC¹² (Table 3.3-7), the combined inherent risk for prothioconazole and boscalid is **medium** for the proposed use against *Sclerotinia sclerotiorum* on oilseed rape. However, this table does not consider the agronomic risk.

The actual risk of resistance depends not only on the inherent risk of a particular fungicide - pathogen combination, as indicated in the previous table, but also on the conditions of fungicide use. In fact, there are important parameters of resistance risk in practice that must be included in an integral part of resistance risk assessment.

¹¹ <https://www.frac.info/docs/default-source/publications/pathogen-risk/frac-pathogen-list-2019.pdf>

¹² Brent, K and Hollomon, D, 2007, Fungicide Resistance in Crop Pathogens: How Can it Be Managed 2nd edition, [Link](#)

Different agronomic practices (rotation of crops, cultural techniques, irrigation, cultivars, use of alternate chemicals with different modes of action, and/or timing of application) help to reduce the selection pressure and the risk of resistance development. The agronomic risk interacts in a complex way, whereas the fungicide and pathogen risks are inherent. The agronomic risk varies depending on different factors (*e.g.* climatic conditions, agricultural practice).

The use of mitigation measures can reduce the agronomic risk, thus allowing reducing the combined risk to low levels.

For the target disease- *Sclerotinia sclerotiorum*, fungicides are not systematically applied. Application is performed according to the disease contamination level and is based on the assessment carried out by the plant protection technical department of various partners. Those assessments are completed by modelling systems which refine the date of application. All the results are communicated to farmers through various supports. This process avoids excessive number of applications on pathogens.

According to the Good Agricultural Practices, FGE03 is applied one or twice in oilseed rape, in consequence the agronomic risk on the disease is **medium** and equal to 0.5.

Table 3.3-8 reports the combined risk for FGE03 considering the agronomic risk.

Table 3.3-8: Possible combined risk for FGE03 in relation with the agronomic risk level

Molecule Risk ↓	Combined risk			Agronomic Risk
High=6 <i>boscalid</i>	6 3 1.5	12 6 3	18 9 4.5	High =1 Medium = 0.5 Low = 0.25
Medium=4 <i>boscalid</i> , <i>prothioconazole</i>	4 2 1	8 4 2	12 6 3	High =1 Medium = 0.5 Low = 0.25
Low=1	1 0.5 0.25	2 1 0.5	3 1.5 0.75	High =1 Medium = 0.5 Low = 0.25
Pathogen risk →	Low =1 <i>Sclerotinia sclerotiorum</i>	Medium = 2	High = 3	

Highest possible value = 18 (high molecule risk high pathogen risk and high agronomy risk).

Considering the agronomic risk, the combined risk adapted to the use of FGE03 is the following one:

Table 3.3-9: Summary of the combined risk for FGE03

Pathogen	Crop	Prothioconazole Combined Risk	Boscalid Combined Risk
<i>Sclerotinia sclerotiorum</i>	Oilseed rape	2	3

When considering the impact of agronomic risk on the combined risk of resistance, according to the schematic modified according to Kuck, 2005¹³ (where risk is rated from 0.25-18), the overall combined risk in combination with all levels of agronomic risk (0.25-1) gives an overall risk of less than 4. A score of less than 4 represents **low** overall risk, even in situations with the highest pathogen risk.

The different target site activity each active substance in FGE03 makes the development and proliferation of resistant pathogenic fungus strains unlikely, especially when the compounds are incorporated in annual spray programs, *e.g.* in combination with or in alternation with single-site acting fungicides that normally give a higher risk of development of resistant strains of the target pathogen as a response to repeated and unbalanced use of single-site acting fungicides.

Therefore, the risk of resistance is considered acceptable when FGE03 is used according to Good Agricultural Practices and label recommendations.

¹³ <https://www.frac.info/docs/default-source/publications/pathogen-risk/frac-pathogen-list-2019.pdf>

3.3.8 Management strategy

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 (benodanil, benzovindiflupyr, bixafen, boscalid, carboxin, cyclobutrifluram, fenfuram, fluindapyr, fluopyram, flutolanil, fluxapyroxad, furametpyr, inpyrfluxam, isofetamid, isoflucypram, isopyrazam, mepronil, oxycarboxin, penflufen, penthiopyrad, pydiflumetofen, sedaxane, thifluzamide) 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.

3.3.9 Implementation of the management strategy

Resistance management strategies are communicated in two forms: product label recommendations and practical use guidelines tailored to particular situations or regions. Label recommendations form the basis of the resistance management strategy, providing instruction relevant to all product usages, and all appropriate resistance management statements and restrictions for the relevant country.

Additionally, the FRAC guidelines for minimizing the risk of resistance developing to crop fungicides are available (eg. www.frac.info) and are communicated actively by FRAC to plant protection advisors in European countries.

3.3.10 Monitoring, reporting and reaction to changes in performance

UPL continuously monitors efficacy of its plant protection products in commercial situation at the farm level. Additionally, national official services recommending and monitoring good agricultural practices and IPM strategies also monitor the efficacy and screen any efficacy failure event suspected to be in response to a resistance problem. In case of an efficacy shift or possibility of resistance, they are investigated and if confirmed they are reported to the registration authority and appropriate action is taken.

Comments of zRMS on:

Information on the occurrence or possible occurrence of the development of resistance (3.3)

FGE03 is a new fungicide containing a mixture of two known active substances: prothioconazole (chemical group: triazolinthiones, group name: DMI-fungicides, SBI: Class I; FRAC group code: 3) and boscalid (chemical group: pyridine-carboxamides, group name: SDHI-fungicides, FRAC group code: 7).

The resistance risk for DMI-fungicides and for SDHI-fungicides has been defined by FRAC as medium and medium to high respectively. A mixture of two active substances with different modes of action is an effective tool in resistance management strategy.

According to the FRAC Pathogen Risk List (revised in September 2019), *Sclerotinia sclerotiorum* is defined as low risk of resistance pathogen. FRAC List of first confirmed cases of plant pathogenic organisms resistant to disease control agents (revised in May 2020) includes one case of resistance of *Sclerotinia sclerotiorum* on

oilseed rape to SDHI-fungicides (case from 2024 year). EPPO database on resistance cases includes 4 cases of resistance of *Sclerotinia sclerotiorum* on oilseed rape to SDHI-fungicides from France (2008), Germany (2010), Sweden (2017), United Kingdom (2017). No cases of resistance of the target pathogen to DMI-fungicides have been described in FRAC and EPPO database.

The combined inherent risk for prothioconazole and boscalid has been defined as medium for the claimed use *Sclerotinia sclerotiorum* on oilseed rape, while the overall risk of resistance regarding additionally agronomic risk has been defined as low.

According to results from monitoring studies reported by FRAC Sterol Biosynthesis Inhibitor (SBI) Working Group (Minutes from WG meeting on January 19st and March 21st, 2024): For Oilseed rape/ *Sclerotinia sclerotiorum*: All monitoring data from 2016 to 2023 showed a stable and narrow sensitivity range with no geographical differences. In 2023 monitoring was carried out in Austria, Bulgaria, Czech Republic, Denmark, Estonia, France, Germany, Hungary, Latvia, Lithuania, Poland, Romania, Sweden and United Kingdom.

According to results from monitoring studies reported by FRAC Succinate Dehydrogenase Inhibitor (SDHI) Working Group (Minutes from virtual meeting on January 16-17 and march 22, 2024): For Oilseed rape/ *Sclerotinia sclerotiorum*: In 2023, samples were investigated coming from France, and Poland. Full sensitivity was observed Poland. A stable situation was observed in France as in the previous seasons with a low frequency of sensitivity adaptation. Samples originating from Canada were collected in 2021 and 2022 and showed full sensitivity.

Based on the submitted data, to avoid the possible development of resistance, the following resistance management strategy is recommended to be included in the label of FGE03:

- Use FGE03 at full recommended dose rate,
- Do not exceed the maximum recommended number of treatments per growing season,
- Use FGE03 predominantly preventively or at the early stages of disease development,
- Include in the adopted plant protection program fungicides containing active substances from other groups according to the FRAC classification, with different modes of action (use the products alternately or in a tank mixture),
- Non-chemical measures such as resistant crop varieties, plant hygiene, appropriate crop rotation should be taken into consideration to reduce the infection pressure of the target pathogen.

The cMSs are kindly encouraged to adopt or adjust the wording, according to their local circumstances and requirements.

3.4 Adverse effects on treated crops (KCP 6.4)

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

FGE03 being a fungicide, no specific selectivity trials are provided in this dossier (in accordance with EPPO standard PP1/135(4) “Phytotoxicity assessment”). However, the crop sensitivity was assessed in 50 efficacy trials and their distribution across EPPO climatic zones is presented in Table 3.4-1. This includes trials with sufficient disease pressure for use in Section 3.2, and trials with insufficient disease pressure to be considered valid for use in Section 3.2.

For information, since it is known that the fungicide activity on plants depends more on susceptibility properties of oilseed rape varieties to fungal diseases than on winter/spring type, it is considered that results obtained on winter oilseed rape can be extrapolated to spring oilseed rape. Both winter and spring oilseed rape have comparable crop phenology and agronomy. Although there is a difference in sowing timing, spring oilseed rape develops quickly; and as application in both crops is at flowering, which generally occurs around the same time in both crop variants, it is considered that both crops are at the same development stage and susceptibility to any potential effects from FGE03 application.

Table 3.4-1: Efficacy trials distribution with crop sensitivity assessment

Crop	EPPO climatic zone			
	Maritime	North-East	South-East	Total
Oilseed rape	22	12	16	50

3.4.1.1 Material and methods

These efficacy trials were performed from 2022 to 2024. All the trials were carried out by Good

Experimental Practice (GEP) accredited testing facilities. For details on the materials and methods of the trials, please refer to Point 3.2.3.1.

3.4.1.2 Phytotoxicity to host crop - Results

3.4.1.2.1 Phytotoxicity in oilseed rape - Efficacy trials - 1 application

Phytotoxicity in efficacy trials - 1 application - Maritime EPPO zone

The potential phytotoxic effects of FGE03 applied once were investigated in a total of 16 efficacy trials carried out in winter oilseed rape in 2023 and 2024, in which FGE03 applied once at the intended rate of at 0.7 kg/ha (245 g boscalid/ha + 140 g prothioconazole/ha) was compared to the untreated check and to reference products. In 1 trial due to an error in the protocol, FGE03 was applied at the rate of at 0.75 kg/ha (263 g boscalid/ha + 150 g prothioconazole/ha) instead of the target rate of 0.70 kg/ha (245 g boscalid/ha +140 g prothioconazole/ha). The difference being less than 10% deviation of N rate requested, the results obtained with the rate 0.75 kg/ha were merged with the results of the target rate of 0.7 kg/ha.

The potential impact of variety on the occurrence of phytotoxicity was tested in 15 different varieties of oilseed rape (Table 3.4-2).

Table 3.4-2: Phytotoxicity assessments of FGE03 - Varieties of oilseed rape tested in efficacy trials – Maritime EPPO climatic zone - 1 application

Crop	No of trials	No of varieties	Variety names (No of trials)
Oilseed rape	16	15	<i>Arianos (1), Avatar (1), Creed (1), DK Expectation (2), Hermann (1), Kadji (1), KWS Alessandro (1), LG Airon (1), LG Ambassador (1), LG Scorpion (1), PX211 (1), Ramses (1), RGT Ozone (1), Traithlon (1), Umberto (1).</i>

Results on phytotoxicity assessments carried out in the efficacy trials are provided in Biological Assessment Dossier. A summary is presented in Table 3.4-3.

Table 3.4-3: Phytotoxicity of FGE03 in efficacy trials - Maritime EPPO climatic zone - 1 application

Number of trials with...		FGE03 0.70-0.75 kg/ha A	Reference products at their authorised rates*
Maximum of phytotoxicity recorded during the trials	0%	16	16
	>0% to 5%	-	-
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
Level of symptoms at the last assessments	0%	16	16
	>0% to 5%	-	-
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-

*Proline (Prothioconazole; 250 g/L EC) at 0.7 L/ha in AT, BE, CZ, DE, DK, IE, UK and SE.

*Joao (Prothioconazole; 250 g/L EC) at 0.7 L/ha in FR.

No phytotoxicity symptoms after 1 application of FGE03 at 0.7 or 0.75 kg/ha in oilseed rape were observed in any of the 16 trials. Indeed, FGE03 applied once at the N dose (0.7 kg/ha i.e. 245+140 g a.s./ha) demonstrated a perfect crop safety when applied over a wide range of crop growth stages and across a wide range of agronomic and climatic conditions.

One application of FGE03 at the intended rate (0.7 kg/ha i.e. 245 g boscalid/ha + 140 g prothioconazole/ha) were perfectly safe to oilseed rape, whatever the crop growth stage, agronomic and climatic conditions. It can thus be concluded that FGE03 applied according to the proposed GAP and label recommendations is safe to oilseed rape crop.

Phytotoxicity in efficacy trials - 1 application - North-East EPPO zone

The potential phytotoxic effects of FGE03 applied once were investigated in a total of 4 efficacy trials

carried out in winter oilseed rape in 2024, in which FGE03 applied once at the intended rate of at 0.7 kg/ha (245 g boscalid/ha + 140 g prothioconazole/ha) was compared to the untreated check and to reference products.

The potential impact of variety on the occurrence of phytotoxicity was tested in 4 different varieties of oilseed rape (Table 3.4-4).

Table 3.4-4: Phytotoxicity assessments of FGE03 - Varieties of oilseed rape tested in efficacy trials - North-East EPPO climatic zone - 1 application

Crop	No of trials	No of varieties	Variety names (No of trials)
Oilseed rape	4	4	<i>Architect (1), Duplo (1), Gemini (1), Umberto (1)</i>

Results on phytotoxicity assessments carried out in the efficacy trials are provided in Biological Assessment Dossier. A summary is presented in Table 3.4-5

Table 3.4-5: Phytotoxicity of FGE03 in efficacy trials - North-East EPPO climatic zone - 1 application

Number of trials with...		FGE03 0.7 kg/ha A	Reference products at their authorised rates*
Maximum of phytotoxicity recorded during the trials	0%	4	4
	>0% to 5%	-	-
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
Level of symptoms at the last assessments	0%	4	4
	>0% to 5%	-	-
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-

*Proline (Prothioconazole; 250 g/L EC) at 0.7 L/ha in LT.

Protendo 300 EC (Prothioconazole; 300 g/L EC) at 0.6 L/ha in PL.

No phytotoxicity symptoms after 1 application of FGE03 at 0.7 kg/ha in oilseed rape were observed in any of the 4 trials. Indeed, FGE03 applied once at the N dose (0.7 kg/ha i.e. 245+140 g a.s./ha) demonstrated a perfect crop safety when applied over a wide range of crop growth stages and across a wide range of agronomic and climatic conditions.

One application of FGE03 at the intended rate (0.7 kg/ha i.e. 245 g boscalid/ha + 140 g prothioconazole/ha) were perfectly safe to oilseed rape, whatever the crop growth stage, agronomic and climatic conditions. It can thus be concluded that FGE03 applied according to the proposed GAP and label recommendations is safe to oilseed rape crop.

Phytotoxicity in efficacy trials - 1 application - South-East EPPO zone

The potential phytotoxic effects of FGE03 applied once were investigated in a total of 11 efficacy trials carried out in winter oilseed rape in 2023 and 2024, in which FGE03 applied once at the intended rate of at 0.7 kg/ha (245 g boscalid/ha + 140 g prothioconazole/ha) was compared to the untreated check and to reference products.

The potential impact of variety on the occurrence of phytotoxicity was tested in 10 different varieties of oilseed rape (Table 3.4-6).

Table 3.4-6: Phytotoxicity assessments of FGE03 - Varieties of oilseed rape tested in efficacy trials - South-East EPPO climatic zone - 1 application

Crop	No of trials	No of varieties	Variety names (No of trials)
Oilseed rape	11	10	<i>Duke (1), ES Capello (1), Invigor (1), Konstruktor (1), LG Absolut (1), PT298 (1), PT279CL (1), PT303 (1), PT314 (1), Umberto (2).</i>

Results on phytotoxicity assessments carried out in the efficacy trials are provided in Biological Assessment Dossier. A summary is presented in Table 3.4-7.

Table 3.4-7: Phytotoxicity of FGE03 in efficacy trials - South-East EPPO climatic zone - 1 application

Number of trials with...		FGE03 0.7 kg/ha A	Reference products at their authorised rates*
Maximum of phytotoxicity recorded during the trials	0%	11	11
	>0% to 5%	-	-
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
Level of symptoms at the last assessments	0%	11	11
	>0% to 5%	-	-
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-

*Proline (Prothioconazole; 250 g/L EC) at 0.7 L/ha in BG, HU, RO.

Tilmor (Prothioconazole + tebuconazole; 80+160 g/L EC) at 1.0 or 1.2 L/ha in HU, RO.

No phytotoxicity symptoms after 1 application of FGE03 at 0.7 kg/ha in oilseed rape were observed in any of the 11 trials. Indeed, FGE03 applied once at the N dose (0.7 kg/ha *i.e.* 245+140 g a.s./ha) demonstrated a perfect crop safety when applied over a wide range of crop growth stages and across a wide range of agronomic and climatic conditions.

One application of FGE03 at the intended rate (0.7 kg/ha *i.e.* 245 g boscalid/ha + 140 g prothioconazole/ha) were perfectly safe to oilseed rape, whatever the crop growth stage, agronomic and climatic conditions. It can thus be concluded that FGE03 applied according to the proposed GAP and label recommendations is safe to oilseed rape crop.

3.4.1.2.2 Phytotoxicity in oilseed rape - Efficacy trials - 2 applications

Phytotoxicity in efficacy trials - 2 applications - Maritime EPPO zone

The potential phytotoxic effects of FGE03 were investigated in a total of 6 efficacy trials carried out in winter oilseed rape in 2022 and 2023, in which FGE03 applied twice at the intended rate of at 0.7 kg/ha (245 g boscalid/ha + 140 g prothioconazole/ha) was compared to the untreated check and to reference products.

The potential impact of variety on the occurrence of phytotoxicity was tested in 5 different varieties of oilseed rape (Table 3.4-8).

Table 3.4-8: Phytotoxicity assessments of FGE03 - Varieties of oilseed rape tested in efficacy trials - Maritime EPPO climatic zone - 2 applications

Crop	No trials	No varieties	Variety names (No of trials)
Oilseed rape	6	6	<i>Aurelia (1), Crome (1), DK Exception (1), LG Anarion (1), Plastic (1), Ramses (1)</i>

Results on phytotoxicity assessments carried out in the efficacy trials are provided in Biological Assessment Dossier. A summary is presented in Table 3.4-9

Table 3.4-9: Phytotoxicity of FGE03 in efficacy trials - Maritime EPPO climatic zone - 2 applications

Number of trials with...		FGE03 0.7 kg/ha AB	Reference products at their authorised rates*
Maximum of phytotoxicity recorded during the trials	0%	6	6
	>0% to 5%	-	-
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
Level of symptoms at the last assessments	0%	6	6
	>0% to 5%	-	-
	>5% to 10%	-	-

Number of trials with...		FGE03 0.7 kg/ha AB	Reference products at their authorised rates*
	>10% to 15%	-	-
	>15 %	-	-

*Proline (Prothioconazole; 250 g/L EC) at 0.7 L/ha in CZ and UK.

Proline 275 (Prothioconazole; 275 g/L EC) at 0.63 L/ha in IE.

Prosaro EC 250 (Prothioconazole + tebuconazole; 125+125 g/L EC) at 1.0 L/ha in DK.

Tilmor (Prothioconazole + tebuconazole; 80+160 g/L EC) at 1.0 L/ha CZ.

No phytotoxicity symptoms after 2 applications of FGE03 at 0.7 kg/ha in oilseed rape were observed in any of the 6 trials. Indeed, FGE03 applied twice (GAP is at maximum 2 applications per crop) at the N dose (0.7 kg/ha *i.e.* 245+140 g a.s./ha) demonstrated a perfect crop safety when applied over a wide range of crop growth stages and across a wide range of agronomic and climatic conditions.

Two applications of FGE03 at the intended rate (0.7 kg/ha *i.e.* 245 g boscalid/ha + 140 g prothioconazole/ha) were perfectly safe to oilseed rape, whatever the crop growth stage, agronomic and climatic conditions. It can thus be concluded that FGE03 applied according to the proposed GAP and label recommendations is safe to oilseed rape crop.

Phytotoxicity in efficacy trials - 2 applications - North-East EPPO zone

The potential phytotoxic effects of FGE03 were investigated in a total of 8 efficacy trials carried out in winter oilseed rape in 2022 and 2023, in which FGE03 applied twice at the intended rate of at 0.7 kg/ha (245 g boscalid/ha + 140 g prothioconazole/ha) was compared to the untreated check and to reference products.

The potential impact of variety on the occurrence of phytotoxicity was tested in 8 different varieties of oilseed rape (Table 3.4-10).

Table 3.4-10: Phytotoxicity assessments of FGE03 - Varieties of oilseed rape tested in efficacy trials - Maritime EPPO climatic zone - 2 applications

Crop	No trials	No of varieties	Variety names (No of trials)
Oilseed rape	8	8	<i>Aganos (1), Atora (1), Bono (1), Dariot (1), Kepler (1), KWS Factor (1), LG Artemis (1), Oriolus (1)</i>

Results on phytotoxicity assessments carried out in the efficacy trials are provided in Biological Assessment Dossier. A summary is presented in Table 3.4-11.

Table 3.4-11: Phytotoxicity of FGE03 in efficacy trials - North-East EPPO climatic zone - 2 applications

Number of trials with...		FGE03 0.7 kg/ha AB	Reference products at their authorised rates*
Maximum of phytotoxicity recorded during the trials	0%	8	8
	>0% to 5%	-	-
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
Level of symptoms at the last assessments	0%	8	8
	>0% to 5%	-	-
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-

*Proline (Prothioconazole; 250 g/L EC) at 0.7 L/ha in PL.

Protendo 300 EC (Prothioconazole; 300 g/L EC) at 0.6 L/ha in LT and PL.

Praktis (Prothioconazole; 250 g/L EC) at 0.7 L/ha in PL.

No phytotoxicity symptoms after 2 applications of FGE03 at 0.7 kg/ha in oilseed rape were observed in any of the 8 trials. Indeed, FGE03 applied twice (GAP is at maximum 2 applications per crop) at the N dose (0.7 kg/ha *i.e.* 245+140 g a.s./ha) demonstrated a perfect crop safety when applied over a wide range of crop growth stages and across a wide range of agronomic and climatic conditions.

Two applications of FGE03 at the intended rate (0.7 kg/ha i.e. 245 g boscalid/ha + 140 g prothioconazole/ha) were perfectly safe to oilseed rape, whatever the crop growth stage, agronomic and climatic conditions. It can thus be concluded that FGE03 applied according to the proposed GAP and label recommendations is safe to oilseed rape crop.

Phytotoxicity in efficacy trials - 2 applications - South-East EPPO zone

The potential phytotoxic effects of FGE03 were investigated in a total of 5 efficacy trials carried out in winter oilseed rape in 2022 and 2023, in which FGE03 applied twice at the intended rate of at 0.7 kg/ha (245 g boscalid/ha + 140 g prothioconazole/ha) was compared to the untreated check and to reference products.

The potential impact of variety on the occurrence of phytotoxicity was tested in 5 different varieties of oilseed rape (Table 3.4-12).

Table 3.4-12: Phytotoxicity assessments of FGE03 - Varieties of oilseed rape tested in efficacy trials - South-East EPPO climatic zone - 2 applications

Crop	No of trials	No of varieties	Variety names (No of trials)
Oilseed rape	5	5	Constructor (1), Dalton (1), Dariot (1), Jeremy (1), PT302 (1)

Results on phytotoxicity assessments carried out in the efficacy trials are provided in Biological Assessment Dossier. A summary is presented in Table 3.4-13.

Table 3.4-13: Phytotoxicity of FGE03 in efficacy trials - South-East EPPO climatic zone - 2 applications

Number of trials with...		FGE03 0.7 kg/ha AB	Reference products at their authorised rates*
Maximum of phytotoxicity recorded during the trials	0%	5	5
	>0% to 5%	-	-
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
Level of symptoms at the last assessments	0%	5	5
	>0% to 5%	-	-
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-

*Proline (Prothioconazole; 250 g/L EC) at 0.7 L/ha in BG.

Protendo 300 EC (Prothioconazole; 300 g/L EC) at 0.6 L/ha in HU.

Melvar (Prothioconazole; 250 g/L EC) at 0.7 L/ha in BG.

No phytotoxicity symptoms after 2 applications of FGE03 at 0.7 kg/ha in oilseed rape were observed in any of the 5 trials. Indeed, FGE03 applied twice (GAP is at maximum 2 applications per crop) at the N dose (0.7 kg/ha i.e. 245+140 g a.s./ha) demonstrated a perfect crop safety when applied over a wide range of crop growth stages and across a wide range of agronomic and climatic conditions.

Two applications of FGE03 at the intended rate (0.7 kg/ha i.e. 245 g boscalid/ha + 140 g prothioconazole/ha) were perfectly safe to oilseed rape, whatever the crop growth stage, agronomic and climatic conditions. It can thus be concluded that FGE03 applied according to the proposed GAP and label recommendations is safe to oilseed rape crop.

Comments of zRMS on: Phytotoxicity to host crop (3.4.1)

As no phytotoxicity symptoms were observed in any of 50 trials carried out in winter oilseed rape, it can be concluded, that FGE03 applied in accordance with GAP, can be safely used on this target crop.

3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

FGE03 being a fungicide, no specific selectivity trials are provided in this dossier (in accordance with EPPO standard PP1/135(4) “Phytotoxicity assessment”). However, the potential effect on the yield of treated plants or plant products was analysed in efficacy trials carried out on oilseed rape, in presence of challenging disease infection. For more details, please refer to section 3.2.3. In all efficacy trials, FGE03 at 0.7 kg/ha (245+140 g a.s./ha) showed no negative effect on the yield of oilseed rape in any of the efficacy trials conducted in a significant presence of disease. On the contrary, FGE03 at 0.7 kg/ha had a positive effect on yield compared to the untreated check on oilseed rape, across all EPPO climatic zones. In addition, FGE03 crop safety has been proved through phytotoxicity assessments conducted in efficacy trials.

Thus, FGE03 is considered to have no negative effect on the yield of treated plants or plant product when applied following the label recommendations.

Comments of zRMS on:
Effects on yield of treated plants or plant products (3.4.2)

Yield results achieved from efficacy trials are presented and commented by zRMS in section 3.2.3 (Efficacy data).

3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

FGE03 being a fungicide, no specific selectivity trials are provided in this dossier (in accordance with EPPO standard PP1/135(4) “Phytotoxicity assessment”). However, the potential effect on the quality of plants or plant products was analysed in efficacy trials carried out on oilseed rape, in presence of challenging disease infection. For more details, please refer to section 3.2.3. In all efficacy trials, FGE03 at 0.7 kg/ha (245+140 g a.s./ha) showed no negative effect on the quality parameters (thousand grain weight, protein content, specific weight and oil content) of oilseed rape in any of the efficacy trials conducted in a significant presence of disease. On the contrary, FGE03 at 0.7 kg/ha had a positive effect on the quality compared to the untreated check on oilseed rape, across all EPPO climatic zones. In addition, FGE03 crop safety has been proved through phytotoxicity assessments conducted in efficacy trials.

Thus, FGE03 is assumed to have no negative effect on quality of plants or plant products when applied following the label recommendations.

Comments of zRMS on:
Effects on quality of plants and plant products (3.4.3)

Results on yield quality achieved from efficacy trials are presented and commented by zRMS in section 3.2.3 (Efficacy data).

3.4.4 Effects on transformation processes (KCP 6.4.4)

The use of FGE03 is intended on oilseed rape and no biological process to rapeseed grain is expected through usual process. Therefore, and because oilseed rape is generally only submitted to physical or chemical processes, it is assumed that FGE03 to have no negative impact on its processing.

**Comments of zRMS on:
Effects on transformation processes (3.4.4)**

Accepted.

3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

FGE03 is a fungicide and has no herbicidal activity. As no phytotoxicity symptoms occurred in any of efficacy trials, no selectivity trials have been conducted for FGE03 and propagation material taken from these trials has not been assessed. ~~Therefore, there is no requirement for the evaluation of secondary effect on plants for propagating purposes.~~

~~In addition,~~ Many products containing boscalid and prothioconazole have been approved and widely used in many countries of Europe for the control of several diseases on oilseed rape and proven to have no impact on treated plants or plant products to be used for propagation.

Therefore, no impact on treated plants or plant products to be used for propagation is expected if FGE03 is used in accordance with good agricultural practices, including label instructions.

**Comments of zRMS on:
Impact on treated plants or plant products to be used for propagation (3.4.5)**

Accepted. The impact of FGE03 on treated plants or plants products to be used for propagation is not expected.

3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

Fungicides usually do not exhibit herbicidal activity. No symptoms of phytotoxicity of FGE03 were observed in any of the efficacy trials in all crops. For more details on phytotoxicity results, please refer to Section 3.4.1.

In addition, any potential impact of FGE03 on succeeding crops would principally be related to the active substance. Boscalid and Prothioconazole have been used in Europe for many years and no effect on succeeding crops is known in Europe.

Nevertheless, a more detailed analysis is presented below.

Seedling emergence data have been generated in a laboratory study carried out in 2023 in Germany. Although no ER₁₀ values were calculated in this study, NOER values were determined, and these are considered to represent a worst-case scenario. These values are used here to evaluate the risk to succeeding or replacement crops. The study was carried out on a range of six different sensitive indicator plant species with FGE03 according to the following guidelines:

- OECD 208 (July 2006), Terrestrial Plant Test: Seedling Emergence and Growth Test
- SANTE/2020/12830 Rev. 2, Guidance document on pesticide analytical methods for risk assessment and post-approval control and monitoring purposes, February 14th, 2023.

Table 3.5.1-1: Study generating seedling emergence data for FGE03

Number of studies	Year	Crop	Country	Official recognition: Y/N
1 study	2023	Wild cabbage (BRSOX), Carrot (DAUCA), Soybean (GLXMA), Lettuce (LACSA), Onion (ALLCE), Oat (AVESA)	Germany, Indoor pot trial	Y - GLP

The indoor pot trial was conducted across six different commonly grown crop types with 4 replicates per dose level and control tested in a randomised block design for carrot, onion and oats, 7 replicates per dose level and control tested in a randomised block design for cabbage and lettuce, and 10 replicates per dose level and control tested in a randomised block design for soybean. The number of seeds per test container varied from 2 to 5.

A stock solution of FGE03 was prepared in deionised water, diluted to a concentration of 1.9 kg product/ha (669.2 g Boscalid/ha + 386.3 g Prothioconazole/ha) it was applied to the surface of the soil, and the seeds were sown as noted above. Control groups were also sown with the test medium treated with deionised water only.

Although EPPO guidance indicates that the test product should be mixed into the soil, the determination of NOER values instead of EC₁₀ values is considered to compensate.

The test was conducted in a climatic chamber with conditions suitable for normal growth and reflecting typical environmental conditions for the species and varieties tested. The course of temperature and relative humidity depicted the day and night interval. The study was conducted over 34 days, with a definitive exposure phase of 14 or 21 days after 50% emergence in the control. At the end of the study, the number of emerged seedlings was counted and the fresh weight of the shoots was determined. The percentage inhibition of biomass growth (shoot fresh weight) for each plant species was calculated in relation to the control. NOER-values were calculated via regression analysis. Calculation of the confidence intervals for NOER-values was carried out using standard procedures.

The study is considered valid as the validity criteria according to the guidelines were fulfilled:

- the mean seedling growth exhibited no visible phytotoxic effects and the plants exhibited only normal variations in growth and morphology.
- environmental conditions and growing media were identical for each plant species.
- a minimum of 70 % emergence in the control*.
- the survival of the control plants was at least 90% at the end of the test.

* For *Lactuca sativa* the emergence rate of the control seeds was 67%. However, this deviation was not considered significant by the laboratory. During the emergence phase *Lactuca sativa* is very sensitive to drying out of the soil surface. One emerged seed more in the control group and the criterion of 70% would have been met and then emergence of the seeds

in the control and the treatment group would also not be statistically significant. The deviation is therefore considered negligible.

The NOER (No Observed Effect Rate) for all species was found to be 1.9 kg product/ha. No effects were observed with regard to emergence and fresh weight. Summary effects for all species tested are given in Table 6.5.1-2.

Table 3.5.1-2: Summary of effect rates based on fresh weight of plants

Species	NOER (kg/ha)
Wild cabbage	1.90
Carrot	1.90
Soybean	1.90
Lettuce	1.90
Onion	1.90
Oat	1.90

For further details, please refer to the individual study reports and also to Part B Section 9 (“Ecotoxicological Studies”) of the Registration Report.

Risk assessment - TER values for succeeding / replacement crops

The maximum proposed dose rate per application for FGE03 is 0.7 kg/ha, corresponding to 245 g boscalid/ha + 140 g prothioconazole/ha. The NOER value 1.9 kg/ha is 2.7 x higher than the maximum dose rate, therefore it is considered that there is no risk to the relevant crop species tested. Additionally, as boscalid and prothioconazole have been used in Europe for many years and no effect on succeeding crops is known in Europe, it is considered that there is no risk to all succeeding or replacement crops.

Comments of zRMS on: Impact on succeeding crops (3.5.1)

Results from Seedling emergence and growth test of six different indicator plant species: wild cabbage, carrot, soybean, lettuce, onion and oat have shown the NOER value 1.9 kg/ha which is 2.7 x higher than the maximum dose rate of FGE03: 0.7 kg/ha, therefore it is considered that there is no risk to tested plant species.

Based on the submitted data and regarding, that both active substances boscalid and prothioconazole are well known and used in Europe for many years, **it can be concluded, that adverse effect of FGE03 applied at recommended dose rate range 0.7 kg/ha on succeeding crops is not expected.**

3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

FGE03 is a fungicide and is not expected to have any significant herbicidal activity.

In addition, many products containing Boscalid and Prothioconazole have been approved and widely used in many countries of Europe for the control of several diseases and proven to have no effects on adjacent crops.

Nevertheless, a more detailed analysis is presented below.

Seedling emergence data have been generated for 6 different commonly rotated crops in a laboratory study carried out in Germany in 2023, as described in Section 3.5.1.

In addition, a study of vegetative vigour conducted in Germany in 2023 has generated data on the effects of FGE03 on the growth and vigour of 6 indicator plant species, and these data used here to evaluate the risk to non-target crops. The study was carried out with the FGE03 according to the OECD Guideline for the Testing of Chemicals No. 227 “Terrestrial Plant Test: Vegetative Vigour Test” following the principles of Good Laboratory Practice (GLP).

Table 3.5.2-1: Study generating vegetative vigour data for GPF716

Number of studies	Year	Crop	Country	Official recognition: Y/N
1 study	2023	Wild cabbage (BRSOX), Carrot (DAUCA), Soybean (GLXMA), Lettuce (LACSA), Onion (ALLCE), Oat (AVESA)	Germany, Indoor pot trial	Y - GLP

Six different plant species were grown from the seeds, in pots containing standard soil type 2.3 (LUF A Speyer - Germany), until the 2 to 4 true leaf stage was reached. Then, the test item was sprayed on the plant and leaf surfaces. After application of the test item, the plants were evaluated for effects on vegetative vigour and growth up to 21 days after treatment and compared to the untreated control groups.

A stock solution of FGE03 was prepared in deionised water, diluted to a concentration of 1.9 kg product/ha (669.2 g Boscalid/ha + 386.3 g Prothioconazole/ha). Control groups were also sown with the test medium treated with deionised water only. Application was made at crop growth stages 2 to 4 true leaves (BBCH 12-14).

The test was conducted in a climatic chamber with conditions suitable for normal growth and reflecting typical environmental conditions for the species and varieties tested. The course of temperature and relative humidity depicted the day and night interval. The study was conducted over 21 days, with a definitive exposure phase of 21 days.

Effects on plants as mortality and visual phytotoxicity (deformations, modifications in colour, necrosis) were recorded at 7, 14 and 21 days after the treatment (DAT). At the end of the test, the biomass (fresh shoot weight) was measured. The percentage inhibition of biomass growth (shoot fresh weight) for each plant species was calculated in relation to the control. NOER-values were calculated via regression analysis. Calculation of the confidence intervals for NOER-values was carried out using standard procedures.

The study is considered valid as the validity criteria according to the guidelines were fulfilled:

- the plant growth exhibited no visible phytotoxic effects and the plants exhibited only normal variations in growth and morphology.
- environmental conditions and growing media were identical for each plant species.
- a minimum of 70 % emergence in the control.
- the survival of the control plants was at least 90% at the end of the test.

The NOER (No Observed Effect Rate) for all species was found to be 1.9 kg product/ha. No effects were observed with regard to fresh weight.

Table 3.5.2-4: Effects of FGE03 on vegetative vigour of treated plants.

Species	NOER (kg/ha)
Wild cabbage	1.90
Carrot	1.90
Soybean	1.90
Lettuce	1.90
Onion	1.90
Oat	1.90

For further details, please refer to the individual study reports and also to Part B Section 9 (“Ecotoxicological Studies”) of the Registration Report.

Risk assessment - TER values for non-target plants, including adjacent crops

The maximum proposed dose rate per application for FGE03 is 0.7 kg/ha, corresponding to 245 g boscalid/ha +140 g prothioconazole/ha. The NOER value 1.9 kg/ha (669.2 g Boscalid/ha + 386.3 g Prothioconazole/ha) is 2.7x higher than the maximum dose rate, therefore it is considered that there is no risk to all crop species tested.

Additionally, as boscalid and prothioconazole have been used in Europe for many years and no effect on adjacent crops is known in Europe, it is considered that there is no risk to all adjacent crops.

Tank cleaning

As a fungicidal product with no known herbicidal activity against a wide range of monocotyledonous and dicotyledonous plants, it is not considered necessary to assess the risk to subsequently treated crops caused by FGE03 tank residues. Nevertheless, a detailed analysis follows.

Estimate of FGE03 residues in pesticide application equipment (PAE)

The amount of FGE03 residues remaining in PAE (Pesticide Application Equipment) following a normal commercial application is estimated according to the guidelines presented in EPPO standard PP 1/292(1).

Calculations for FGE03 are based on the assumption that 2.6% of the spray solution remains in the PAE after an application at the maximum proposed rate per application of 0.7 kg product/ha, applied in a minimum water volume of 100 L/ha, which is a worst-case scenario.

Calculation:

Risk assessment for impact on non-target plants

Seedling emergence and vegetative vigour data have been generated in laboratory studies carried out with FGE03 in 2023 in Germany.

Table 3.5.2-6: Seedling emergence and vegetative vigour data for FGE03

Species	Seedling emergence	Vegetative vigour
	NOER (kg product/ha)	NOER (kg test item/ha)
Wild cabbage	1.90	1.90
Carrot	1.90	1.90
Soybean	1.90	1.90
Lettuce	1.90	1.90
Onion	1.90	1.90
Oat	1.90	1.90

The NOER (No Observed Effect Rate) for all species was found to be 1.9 kg/ha (669.2 g Boscalid/ha + 386.3 g Prothioconazole/ha).

The estimated amount of FGE03 residues applied in a subsequent commercial spray operation is 182 g product/ha with no tank washing, and 4.73 g product/ha or 0.12 g product/ha after 1 or 2 rinses, respectively. Therefore, following no tank washing the estimated amount of FGE03 in a subsequent treatment is 182 g product/ha, which is approximately 10.4 times less than that needed to have No Observable Effect on all test species.

Based on a worst-case estimate of residual FGE03 in PAE, and worst-case NOER values for FGE03 from studies on a range of indicator field crop plant species, it has been possible to demonstrate that no tank washing, or a standard tank washing procedure is more than sufficiently effective in removing harmful levels of FGE03. Additionally, as boscalid and prothioconazole have been used in Europe for many years and no effect on non-target crops is known in Europe, it is considered that there is no risk to crops treated after the target crop.

Comments of zRMS on:

Impact on other plants including adjacent crops (3.5.2)

Results from Vegetative vigour test of six different indicator plant species: wild cabbage, carrot, soybean, lettuce, onion and oat have shown the NOER value 1.9 kg/ha which is 2.7 x higher than the maximum dose rate of FGE03: 0.7 kg/ha, therefore it is considered that there is no risk to tested plant species.

Based on the submitted data and regarding, that both active substances boscalid and prothioconazole are well known and used in Europe for many years, **it can be concluded, that adverse effect of FGE03 applied at recommended dose rate range 0.7 kg/ha on adjacent crops is not expected.**

According to the rules of Good Agricultural Practice, to avoid any risk of adverse effects on adjacent crops, it is recommended to include, in the product label, the following remark: *When using FGE03 do not allow spray drift to the neighbouring crop plantations.*

Tank cleaning

It is recommended to follow the principles of Good Plant Protection Practice, when tank cleaning.

3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Part B, Section 9 (Ecotoxicology). Special tests to investigate this purpose are not required. In addition, there were no adverse effects on beneficial or other non-target organisms observed in a part of any of the 50 efficacy trials conducted (see in Biological Assessment Dossier).

Comments of zRMS on: Effects on beneficial and other non-target organisms (3.5.3)

Adverse effects on non-target organisms were not observed in a part of efficacy trials. In other trials no observations on beneficial or non-target organisms have been reported. Detailed studies are contained in Part B, Section 9 (Ecotoxicology).

3.6 Other/special studies

No other studies relevant for the aim of this dossier have been conducted.

3.7 List of test facilities including the corresponding certificates

The corresponding certificates, confirming that all the test facilities mentioned have been officially recognized as organizations for efficacy testing of plant protection products according to the Directive 93/71/EC, are available in the GEP certibase (www.gepcertibase.eu).

Table 3.7-1: List of test facilities

Organisation	Town Country	Year of trials	GEP certification	
			GEP Statutes	Link of GEP Certibase
AGRECO Sp. z o.o.	Al. Lipowa 21 Iok. 1 53-124 Wrocław Poland	2023, 2024	GEP	Link
CPR Europe Kft.	Szombathely, Török Ignác u. 30, 9700 Hungary	2022	GEP	Link
Crop Research Limited	Mountdoyle, Moynalvey, Summerhill, County Meath Ireland	2023	GEP	-
Field Research Support	Max-Planck-Str. 5 D-31515 Wunstorf Germany	2023	GEP	Link
Agricultural Research Institute Kromeriz (Zemědělský výzkumný ústav Kroměříž)	Havlíčková 2787/121 76701 - Kromeriz Czech Republic	2022	GEP	-
Lithuania Institute of Agriculture	Instituto al.1, Akademijs LT 58344 - Kedainiai Lithuania	2022	GEP	Link
VKST Field Trials	Kongstedvej 4 B 4100 - Ringsted Denmark	2022, 2024	GEP	Link
Zemědělska zkusební stanice Kujavy, s.r.o	Kujavy 48 742 44 - Kujavy Czech Republic	2022	GEP	-
Ephydia	1 rue de Courcellette	2023, 2024	GEP	Link

Organisation	Town Country	Year of trials	GEP certification	
			GEP Statues	Link of GEP Certibase
	62450 Martinpuich France			
Eurofins Agrosience Services BG / EAS Bulgaria	Letnitsa Zar Kalojan Str 5 5570 - Letnitsa	2023, 2024	GEP	Link
Eurofins Agrosience Services PL / EAS Poland	Kazmierz Parkowa street 6 64-530 - Kazmierz Poland	2022	GEP	Link
Eurofins Agrosience Services UK / EAS UK, North West	Hoscar Hall Farm Hoscar Moss Road Lathom Lancashire L40 4BG United Kingdom	2022	GEP	Link
Eurofins Agrosience Services UK / EAS UK, North West	Slade Lane Wilson Melbourne Derbyshire DE73 8AG UK	2023	GEP	Link
Eurofins Agrosience Services UK / EAS UK, North West	Slade Lane Wilson Melbourne Derbyshire DE73 8AG United Kingdom	2023	GEP	Link
Agrartest GmbH, Groß-Lobke Eurofins Agrosience Services	Groß-Lobke Andreasplatz 2 31191 - Groß-Lobke Germany	2024	GEP	Link
Eurofins Agrosience Services France Bourgogne	Z.A. de l'Aubepin 71700 - Uchizy France	2024	GEP	Link
Eurofins Agrosience Services Romania, Timisoara	Muntele mic Street no.20 307210 – Giarmata Timis Romania	2024	GEP	Link
Staphyt Austria GmbH.	Am Futterplatz., 2471 Rohrau, Austria	2024	GEP	Link
Staphyt - Belgium	Rue de la Grosse Borne 2, 1360 Perwez, Belgium	2024	GEP	Link
Staphyt - Bulgaria	Station Plovdiv 25 April str. 4110 Parvenets Bulgaria	2024	GEP	Link
Staphyt s.r.o. - Czech Republic	Měnin 569 Měnin, 664 57 Czech Republic	2023	GEP	Link
Staphyt - France	23 Rue de Moeuvres, 62860 Inchy-en-Artois France	2024	GEP	Link
Staphyt - Hungary	5000 Szolnok, Piroskai út 2, Hungary	2023,2024	GEP	Link
Staphyt - Romania	18, Petrolistor str, Urziceni 925300 Romania	2023, 2024	GEP	Link
SynTech Research Romania	Str. Ioan Brezoianu, Nr. 1 Arad, Jud. ARAD, 310370 Romania	2023	GEP	Link
SyntechResearch GmbH Germany	Loofter Str.9 25593 Christinenthal Germany	2023	GEP	Link

Organisation	Town Country	Year of trials	GEP certification	
			GEP Statues	Link of GEP Certibase
UAB Agrolab Baltic - Lithuania	UAB Agrolab Baltic Bugėnių km. LT-89452 Mažeikių raj. Lithuania	2024	GEP	Link
UAB Agrolab Baltic - Sweden	Agrolab Sverige AB Backgården 24193 Eslöv Sweden	2024	GEP	-

→ **Crop Research Limited (Ireland)**

TFTP No. 009 (2022)



An Roinn Talmhaíochta,
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Test Facility Trial Permit (TFTP)

In accordance with the European Communities (Plant Protection Products) Regulations, 2012 (S.I. No. 159 of 2012 as amended), the Minister for Agriculture, Food and the Marine, grants a Test Facility Trial Permit to:

- **Crop Research Ltd., Mountdoyle, Moynalvey, Summerhill, Co. Meath, IRELAND**

for the conducting of:

- **Efficacy effectiveness & crop safety trials/experiments on;**
Grassland (forage & amenity), amenity, cereals, maize, oilseeds and potatoes.

All such trials are subject to the terms and conditions specified in Annex I to this Permit.

Test Facility Trial Permit expiry date:

31st December 2022

On behalf of the Department of Agriculture Food and the Marine (Competent Authority)

David Billorey

Sinead Phelan

Date issued: 24th March 2022

Official Stamp:



→ **Crop Research Limited (Ireland)**

TFTP No. 009 (2022)

Annex I

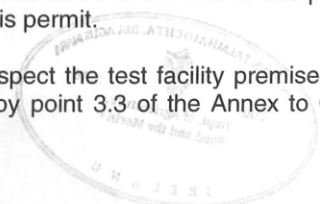
In accordance with European Communities (Plant Protection Products) Regulations, 2012 (S.I. No. 159 of 2012 as amended).

The following terms and conditions apply:

1. The TFTP holder must forward details of all tested plant protection products and location(s) to the DAFM by the date of first application of the test product(s) to each trial (as per 3.2 of the Annex to Commission Regulation (EU) No. 284/2013). Delaying forwarding this information until a number of trials of a crop type or at a trial site have started does not meet this condition when such trials have a range of commencement dates.
2. All trials/experiments must be carried out in compliance with the requirements specified in the Principles of Good Experimental Practice [GEP].
3. This Test Facility Trial Permit is valid only for trials/experiments conducted under the direct supervision of the following professionally qualified personnel:

Name	Address
Dr Tom McCabe	Mountdoyle, Moynalvey, Summerhill, Co. Meath and UCD Lyons Research Farm, Newcastle, Co. Dublin
Dr John Tobin	UCD Lyons Research Farm, Newcastle, Co. Dublin
Dr Cathal McCabe	

4. Only Plant Protection Products (PPPs) authorised for such use, or PPPs that have APPPT approval for such use may be used in trials/experiments by the TFTP holder. Any APPPT applications received directly by an TFTP holder should be forwarded immediately to the DAFM.
5. Any amendments to the information or details provided must be notified immediately to the DAFM by the TFTP holder.
6. An annual report (using the appropriate headings) must be submitted to the DAFM by the TFTP holder containing all information to demonstrate that they can satisfy the requirements provided for in point 3.2 of the Annex to Commission Regulation (EU) No. 284/2013. The report should be submitted at the end of this permit period and prior to an application for renewal of this permit.
7. An authorised officer of the DAFM may inspect the test facility premises or sites at any time during the year (as is required by point 3.3 of the Annex to Commission Regulation (EU) No. 284/2013).



→ **Crop Research Limited (Ireland)**

TFTP No. 009 (2022)

Annex I (continued)

8. For trial crop produce that needs to be excluded from the feed or food chain, TFTP personnel are directly responsible for ensuring safe disposal of same. Trials/experiments conducted by the TFTP holder, using plant protection products must be such that:
 - a) there are no harmful effects on human or animal health and no unacceptable impacts on the environment. Produce from treated crops may need to be disposed of by appropriate means to preclude consumption by humans or animals. The use of PPP(s) may be restricted to crops other than food or feed crops, or the nature of the use is such that residues at harvest are precluded.
 - b) any conditions or restrictions relating to a specific plant protection product must be adhered to.
9. The crop safety and/or effectiveness trials/experiments facilitated by this TFTP are only valid for the crop types listed and the locations recorded on the original (or amended) trial notifications to the DAFM. These are identified in Appendix 1 to this TFTP Permit.
10. A clear pathway must be established between adjacent plots in field trials prior to first application of test product(s) and must be maintained on all trial plots.
11. Officially recognised testing facilities (TFTP holders) must meet the requirements in Commission Regulation (EU) No. 284/2013 and S.I. 159 of 2012 (as amended) in order that trial data obtained can be officially recognised by the DAFM.

→ **Agricultural Research Institute Kromeriz / Zemědělský výzkumný ústav Kroměříž**

ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

Odbor přípravků na ochranu rostlin

Zemědělská 1a, Brno, PSČ 613 00

Příloha rozhodnutí č.j.: UKZUZ 118418/2021 ze dne 15. 7. 2021

OSVĚDČENÍ

GEP/KRO/2021

o způsobilosti k provádění zkoušek
v souladu se zásadami správné pokusnické praxe

Official Recognition Certificate / GEP - Certificate

právní osoba: **Zemědělský výzkumný ústav Kroměříž, s.r.o.**

sídlo právnické osoby: Havlíčkova 2787/121, 767 01 Kroměříž

IČ právnické osoby: 46904841

je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe podle § 45 odst. 1 zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, v platném znění, v návaznosti na Směrnici 91/414/EHS.

oblasti zkoušení / categories of official recognition:

- polní plodiny a zelenina / field crops and vegetables
- trvalé kultury / high crops
- moření osiva / seed treatment
- laboratorní testy a analýzy / laboratory tests and analyses

Ústřední kontrolní a zkušební ústav zemědělský
Sekce zemědělských vstupů
Odbor přípravků na ochranu rostlin
613 00 Brno, Zemědělská 1a
- 2 -



Ing. Pavel Minář, Ph.D.
ředitel odboru

→ **Zemědělská zkušební stanice Kujavy, s.r.o**



ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

Zemědělská zkušební stanice KUJAVY, s.r.o.
Kujavy 48
742 45 Kujavy

Úřvar: Odbor přípravků na ochranu rostlin
Adresa: Zemědělská 1a, 613 00 Brno

Sp.zn: SZ UKZUZ 023591/2021/04867 Č.j.: UKZUZ 057358/2021 Datum: 6. 4. 2021
Vyřizuje: Ing. Dana Valešová, Ph.D. Tel.: 545 110 482 E-mail: dana.valesova@ukzuz.cz

ROZHODNUTÍ

Ústřední kontrolní a zkušební ústav zemědělský (dále jen „ÚKZÚZ“), Hroznová 2, 656 06 Brno, jako věcně příslušný správní orgán podle § 72 odst. 1 písm. c) zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, ve znění pozdějších předpisů (dále jen „zákon“) a v návaznosti na čl. 54 odst. 4 Nařízení Evropského parlamentu a Rady (ES) č. 1107/2009, o uvádění přípravků na ochranu rostlin na trh a o zrušení směrnic Rady 79/117/EHS a 91/414/EHS, v platném znění, v provedení § 45 odst. 1 zákona, v řízení o způsobilosti k provádění pokusů a zkoušek s přípravky nebo dalšími prostředky na základě žádosti společnosti Zemědělská zkušební stanice KUJAVY, s.r.o., Kujavy 48, 742 45 Kujavy, IČ 25816349 dále jen „společnost Zemědělská zkušební stanice KUJAVY, s.r.o.“ a to:

žádosti o prodloužení platnosti a změnu rozhodnutí o způsobilosti k provádění zkoušek podle § 45 odst. 1 zákona ze dne 4. 2. 2021, doručené ÚKZÚZ dne 8. 2. 2021, č.j. UKZUZ 023591/2021

rozhodl takto:

společnost Zemědělská zkušební stanice KUJAVY, s.r.o. je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe.

právnícká osoba: Zemědělská zkušební stanice KUJAVY, s.r.o.

sídlo právnické osoby: Kujavy 48, 742 45 Kujavy

IČ právnické osoby: 25816349

GEP kód: GEP/KUJ/2021

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656 06 BRNO	E-mail: podatelna@ukzuz.cz		

→ **Zemědělská zkušební stanice Kujavy, s.r.o**

oblasti zkoušení: **polní plodiny a zelenina**
trvalé kultury
skleníky a jiné kryté prostory
moření osiva
laboratorní testy a analýzy

dobu platnosti rozhodnutí: 5 let ode dne nabytí účinnosti tohoto rozhodnutí

Tímto rozhodnutím se k datu nabytí jeho účinnosti zrušuje rozhodnutí č.j. UKZUZ 038222/2016 ze dne 11. 4. 2016.

Odůvodnění:

Řízení ve věci uznání osoby za způsobilou provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe bylo zahájeno na základě žádosti ze dne 4. 2. 2021, doručené UKZUZ dne 8. 2. 2021.

Rozhodnutí o způsobilosti k provádění pokusů a zkoušek v souladu s požadavky správné pokusnické praxe bylo vydáno na základě auditu ÚKZÚZ konaného v únoru a březnu 2021, zaevidovaného pod č.j. UKZUZ 057357/2021, kterým bylo prokázáno, že žadatel splnil požadavky stanovené v § 45 odst. 11 a 13 zákona v návaznosti na § 4 odst. 2 vyhlášky č. 32/2012 Sb., o přípravcích a dalších prostředcích na ochranu rostlin, ve znění pozdějších předpisů.

Vzhledem k výše uvedeným skutečnostem bylo rozhodnuto tak, jak je stanoveno ve výrokové části tohoto rozhodnutí.

Správní poplatek podle zákona č. 634/2004 Sb., o správních poplatcích, ve znění pozdějších předpisů, podle Sazebníku, Položky 86 písm. b) „Přijetí žádosti o vydání osvědčení o způsobilosti k provádění zkoušek pro účely povolení“ ve výši 100,- Kč, k žádosti doručené ÚKZÚZ dne 8. 2. 2021, č.j. UKZUZ 023591/2021, byl uhrazen dne 8. 2. 2021 formou kolkové známky.

Poučení:

Proti tomuto rozhodnutí lze podat odvolání do 15 dnů ode dne jeho doručení, nejpozději však do 15 dnů po uplynutí desátého dne ode dne, kdy bylo nedoručené a uložené rozhodnutí připraveno k vyzvednutí, a to k Ministerstvu zemědělství České republiky, odbor rostlinných komodit, prostřednictvím Ústředního kontrolního a zkušebního ústavu zemědělského, sekce zemědělských vstupů, odboru přípravků na ochranu rostlin, Zemědělská 1a, 613 00 Brno.

Ing. Pavel Minář, Ph.D.
ředitel odboru

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DIČ: CZ00020332

Dokument je podepsán elektronicky/podpisem:
Podpisující: Ing. Pavel Minář, Ph.D.
Organizace, GI: 00059
Seriové č. cert.: 22274918
Vydávací inst.: FintSignum Qualified CA 4
Datum a čas: 06.04.2021 11:17:06
Divod:
Mata:

UAB Agrolab Baltic - Sweden

ACKREDITERINGSCERTIFIKAT/ACCREDITATION CERTIFICATE



Ackred. nr 8074

Provning

ISO/IEC 17025

Agrolab Sverige AB

Eslöv

Organisationsnummer 556824-2878

är ackrediterat som provningslaboratorium för uppgifter enligt bilaga 1 i beslut daterat 2020-09-17/is
accredited as a testing laboratory for the scope specified in appendix 1 to decision dated 2020-09-17.

Laboratoriet är ackrediterat enligt den internationella standarden ISO/IEC 17025:2017. Ackrediteringen innebär
att det ackrediterade laboratoriet har bedömts ha erforderlig kompetens och att opartiskt och konsekvent
utföra ackrediterade tjänster inom de områden som definieras i bilaga 1 enligt ovan. Det ackrediterade
laboratoriet ansvarar för resultat av utförd provning./This laboratory is accredited to the International Standard
ISO/IEC 17025:2017. The accreditation is a recognition of the competence for and consistent performance and
impartiality in the provision of the services defined in appendix 1. The accredited laboratory is responsible for
the outcome of performed testing.

Ackrediteringen gäller tills vidare. Styrelsen för ackreditering och teknisk kontroll (Swedac) genomför
regelbundet tillsyn, och vart fjärde år en förnyad bedömning, för att bekräfta att gällande krav för
ackrediteringen kontinuerligt uppfylls./The accreditation is valid until further notice. The Swedish Board for
Accreditation and Conformity Assessment (Swedac) regularly carries out surveillance, and a full reassessment
every fourth year, in order to verify that the applicable requirements for accreditation are continually fulfilled.

Detta ackrediteringscertifikat utfärdades 2020-09-17/This accreditation certificate was issued 2020-09-17
Helen Nyman,

Enhetschef enheten för miljö och hälsa/Division Manager of the Health and Environment Division

Beslutet om ackreditering utfärdades med stöd av artikel 5.1 i Europaparlamentets och rådets förordning (EG) nr 765/2008 om krav för ackreditering och
marknadskontroll m.m. och lagen (2011:791) om ackreditering och teknisk kontroll. Swedac är nationellt ackrediteringsorgan ansvarigt för bedömning av
certifieringsorgan, kontrollorgan, laboratorier, miljökontrollanter, verifierings-/valideringsorgan och arrangörer av program för kompetensprövning som
ansöker om ackreditering. Den här ackrediteringen har utfärdats under EAs MIA-avtal och kan därmed betraktas som likvärdig andra ackrediteringar under
EAs MIA-avtal med samma ackrediteringsomfattning. /Accreditation was granted in accordance with Article 5 (1) of Regulation (EC) No 765/2008 regarding
accreditation and market surveillance etc. and the Act (SFS 2011:791) concerning Accreditation and Conformity Assessment. Swedac is the Swedish national
accreditation body responsible for the assessment of certification bodies, inspection bodies, laboratories, environmental verifiers, validation and verification
bodies and bodies for providing programme for proficiency testing applying for accreditation. This accreditation has been issued under the EA MIA and is
therefore recognised as equivalent to other accreditations with the same scope of accreditation issued under the EA MIA./Accreditation was granted in
accordance with Article 5 (1) of Regulation (EC) No 765/2008 regarding accreditation and market surveillance etc. and the Act (SFS 2011:791) concerning
Accreditation and Conformity Assessment. Swedac is the Swedish national accreditation body responsible for the assessment of certification bodies, inspection
bodies, laboratories, environmental verifiers, validation and verification bodies and bodies for providing programme for proficiency testing applying for
accreditation. This accreditation has been issued under the EA MIA and is therefore recognised as equivalent to other accreditations with the same scope of
accreditation issued under the EA MIA.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Owner
-	UPL Holdings Coöperatief	2024	Biological Assessment Dossier (BAD): KCP Section 6: Efficacy Data and Information, Detailed Summary. Product code: FGE03 Product name: Patton Boost, Nebbia boost Central Registration zone (zRMS Poland) Core Assessment (Authorisation) UPL Holdings Coöperatief. n/a n/a Unpublished	N	Y	UPL Europe Ltd.
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	UPL Europe Ltd.
~~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	UPL Europe Ltd.
~~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-006 Staphyt GEP Unpublished	N	Y	UPL Europe Ltd.

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	Owner
~~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	UPL Europe Ltd.
~~3.2.3~~ 3.4.1	S. GAYOT	~~2023~~ 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	UPL Europe Ltd.
~~3.2.3~~ 3.4.1	S. GAYOT	~~2023~~ 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	UPL Europe Ltd.
~~3.2.1~~ ~~3.2.2~~ ~~3.2.3~~ 3.4.1	N. BIRKINSHAW	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	UPL Europe Ltd.
3.2.2 ~~3.2.3~~ 3.4.1	N. BIRKINSHAW	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	UPL Europe Ltd.

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	Owner
3.2.2 3.2.3 3.4.1	N. BIRKINSHAW	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-002 Eurofins Agrosience Services GEP Unpublished	N	Y	UPL Europe Ltd.
3.2.3 3.4.1	R. VERCRUYSSSE	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	UPL Europe Ltd.
3.2.3 3.4.1	R. VERCRUYSSSE	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	UPL Europe Ltd.
~~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	UPL Europe Ltd.
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	UPL Europe Ltd.

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	Owner
3.2.1 3.2.2 3.2.3 3.4.1	N. BIRKINSHAW	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	UPL Europe Ltd.
~~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 Report No. F23EU-032-AMA-004 Crop Research Limited/Field Research Support GEP Unpublished	N	Y	UPL Europe Ltd.
~~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	UPL Europe Ltd.
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	UPL Europe Ltd.
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	UPL Europe Ltd.

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	Owner
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	UPL Europe Ltd.
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	UPL Europe Ltd.
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, BULGARIA, 2024 Report No. F24EU-010-MOA-009 Staphyt GEP Unpublished	N	Y	UPL Europe Ltd.
3.2.1 3.2.2 3.2.3 3.4.1	N. BIRKINSHAW	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	UPL Europe Ltd.
3.2.1 3.2.3 3.4.1	N. BIRKINSHAW	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	UPL Europe Ltd.

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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	UPL Europe Ltd.
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	UPL Europe Ltd.
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	UPL Europe Ltd.
3.2.3 3.4.1	B. FERENCZ	~~2023~~ 2024	The efficacy of FGE03 and FGR06 applied in OSR for the control of Sclerotinia sclerotiorum (SCLESC) in Europe. EPPO South-East ROMANIA Report No. F23EU-033-AMA-008 Syntech Research GEP Unpublished	N	Y	UPL Europe Ltd.
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	UPL Europe Ltd.

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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	UPL Europe Ltd.
3.2.1 3.2.2 3.2.3 3.4.1	N. BIRKINSHAW	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	UPL Europe Ltd.
3.2.1 3.2.3 3.4.1	N. BIRKINSHAW	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	UPL Europe Ltd.
3.2.2 3.2.3 3.4.1	J. PACKWOOD	~~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	UPL Europe Ltd.
3.2.2 3.2.3 3.4.1	J. PACKWOOD	~~2022~~ 2023	The efficacy of FGE03 applied in OSR for the control of Sclerotinia sclerotiorum (SCLESC) in Europe. Report No. F22EU-023-AMA-008 EAS / ZZS Kujavy, s.r.o. GEP Unpublished	N	Y	UPL Europe Ltd.

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3.2.2 3.2.3 3.4.1	J. PACKWOOD	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	UPL Europe Ltd.
3.2.2 3.2.3 3.4.1	J. PACKWOOD	~~2022~~ 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	UPL Europe Ltd.
~~3.2.2~~ ~~3.2.3~~ 3.4.1	J. PACKWOOD	~~2022~~ 2023	The efficacy of FGE03 applied in OSR for the control of Sclerotinia sclerotiorum (SCLESC) in Europe Report No. F22EU-023-AMA-004 Eurofins Agrosience Services UK GEP Unpublished	N	Y	UPL Europe Ltd.
3.2.2 3.2.3 3.4.1	J. PACKWOOD	~~2023~~ 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 Agrosience Services UK GEP Unpublished	N	Y	UPL Europe Ltd.
3.2.2 3.2.3 3.4.1	J. PACKWOOD	~~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	UPL Europe Ltd.

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~~3.2.2~~ ~~3.2.3~~ 3.4.1	J. PACKWOOD	~~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	UPL Europe Ltd.
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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	UPL Europe Ltd.
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	UPL Europe Ltd.

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	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-004 Agreco sp. z o.o. GEP Unpublished	N	Y	UPL Europe Ltd.
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	UPL Europe Ltd.
3.2.2 3.2.3 3.4.1	J. PACKWOOD	2023 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	UPL Europe Ltd.
3.2.2 3.2.3 3.4.1	J. PACKWOOD	2023 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	UPL Europe Ltd.
3.2.2 3.2.3 3.4.1	I MAKO	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	UPL Europe Ltd.

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	Owner
3.2.2 3.2.3 3.4.1	S. NÉMETH	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	UPL Europe Ltd.
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	UPL Europe Ltd.
3.5.1	S. STURTZ & C HORSTMANN	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	UPL Europe Ltd.
3.5.2	S. STURTZ & C HORSTMANN	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	UPL Europe Ltd.