

# FINAL REGISTRATION REPORT

## Part B

### Section 3

#### **Efficacy Data and Information**

Concise summary

Product code: FGG01

Product name(s): Lozzare Pro

Chemical active substance(s):

Boscalid

500 g/kg

Central registration zone

Zonal Rapporteur Member State: Poland

#### CORE ASSESSMENT

(Authorisation)

Applicant: UPL Holdings Coöperatief

Submission date: 01/10/2024

MS Finalisation date: 11/2024 03/2025

## Version history

When	What
08/05/2024	First applicant version.
01/10/2024	Second applicant version. Addition of oilseed rape trials for which the results were available in September 2024 Change highlighted in blue.
November 2024	ZRMs evaluated dRR submitted by Applicant.
03/2025	ZRMs made changes in line to the commenting period.

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

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

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

The process chosen by the zRMS to transform the dRR into a RR should be explained. Options are to rewrite the document (with track change or not) or to use commenting boxes as the following:

<b>Comments of zRMS</b>	Comments of ZRMs are presented in commenting boxes at the end of each chapter. The text of dRR was generally not changed or rewritten (small changes in the document are marked by grey colour). <b>Changes made during the commenting period are marked in green.</b>
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##### Summary and conclusion of zRMS on Section 3: Efficacy (KCP 6)

##### Abstract

**Comments of zRMS:** Overall summaries are not necessary here. It was provided at the end of each chapter of this dossier. However, in briefly summary, decision about possibility of authorisation of FGG01 was left to cMS (on the basis on submitted and assessed data and bridging approach from st. ref. product – CANTUS). In Poland, FGG01 can be granted on winter oilseed rape against SCLESC and LEPTMA and grapevines against Powdery mildew. All minor uses claimed in GAP table for authorisation in line to Article 51 are accepted. Use on peas and beans against BOTRSP and spring oilseed rape against SCLESC and LEPTMA is not accepted (only authorisation in line to Article 51 is possible)

**SI is not accepted use against *Botrytis cinarea* and *Uncinula necator* on grapevines. SK – accepted use on winter oilseed rape against ALTEBA, SCLESC and LEPTMA on oilseed rape. AT-accepted information in GAP is to be confirmed by cMS**

**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
Use- No. <sup>(e)</sup>	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 (f)
					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	AT, BE, CZ, <b>SL</b>	Grapevine, wine & table	F	<i>Botrytis cinerea</i> (BOTRCI)	Spraying overall	BBCH 60-85	a) 1 per use  b) 1 per crop / season	-	a) 1.0 kg/ha  b) 1.0 kg/ha	a) 500 g/ha  b) 500 g/ha	100- 1000	21	0.72 kg product / 10000 m² LWA <b>Eff. section:</b> to be confirmed by cMS <b>SL</b> <b>not accepted</b>
2	AT, BE, CZ, <b>SL</b> , PL	Grapevine, wine & table	F	<i>Uncinula necator</i> , Powdery mildew (UNCINE)	Spraying overall	BBCH 15-81	a) 3 per use  b) 3 per crop / season	10-14	a) 0.2 kg/ha  b) 0.6 kg/ha	a) 100 g/ha  b) 300 g/ha	100- 1000	21	0.14 kg product / 10000 m² LWA 0.02 kg/100 L <b>Eff. section:</b> to be confirmed by cMS. Use accepted in PL <b>SL</b> <b>not accepted</b>
3	AT, BE, CZ, HU, NL, PL, RO, SK	Oilseed rape (winter and spring)	F	<i>Sclerotinia sclerotiorum</i> (SCLESC)	Spraying overall	BBCH 57-69	a) 1 per use  b) 1 per crop / season	-	a) 0.5 kg/ha  b) 0.5 kg/ha	a) 250 g/ha  b) 250 g/ha	100- 300	35	<b>Eff. section:</b> to be confirmed by cMS, <b>SK-accepted</b> . Use accepted in PL on winter oilseed rape.
4	AT, BE, CZ, NL, SK, HU, RO	Oilseed rape (winter and spring)	F	<i>Alternaria</i> species (ALTESP)	Spraying overall	BBCH 57-69	a) 1 per use  b) 1 per crop / season	-	a) 0.5 kg/ha  b) 0.5 kg/ha	a) 250 g/ha  b) 250 g/ha	100- 300	35	<b>Eff. section:</b> to be confirmed by cMS. <b>SK-accepted</b> .
5	HU, PL, RO, SK, AT, CZ	Oilseed rape (winter and spring)	F	<i>Leptosperia maculans</i> (LEPTMA)	Spraying overall	BBCH 13-57	a) 1 per use  b) 1 per crop / season	-	a) 0.5 kg/ha  b) 0.5 kg/ha	a) 250 g/ha  b) 250 g/ha	100- 300	35	<b>Eff. section:</b> to be confirmed by cMS. <b>SK-accepted</b> . Use accepted in PL on winter oilseed rape.

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	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 ( <sup>o</sup> )
					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		
6	AT, BE, CZ, NL, PL	Beans and peas (fresh)	F	<i>Botrytis</i> (BOTRSP)	Spraying overall	BBCH 60-69	a) 2 per use  b) 2 per crop / season	7	a) 1.0 kg/ha  b) 2.0 kg/ha	a) 500 g/ha  b) 1000 g/ha	150- 600	7	<b>Eff. section:</b> to be confirmed by cMS. Not accepted in PL in line to Art. 33
7	AT, BE, CZ	Beans and peas (fresh)	F	<i>Sclerotinia</i> (SCLESP)	Spraying overall	BBCH 60-69	a) 2 per use  b) 2 per crop / season	7	a) 1.0 kg/ha  b) 2.0 kg/ha	a) 500 g/ha  b) 1000 g/ha	150- 600	7	<b>Eff. section:</b> to be confirmed by cMS.
Minor crops – Art.51													
8	PL	spring rape gold of pleasure, winter turnip rape, mustard, sunflower, poppy linseed, flax, hemp, borage	F	<i>Alternaria</i> species (ALTESP) <i>Sclerotinia sclerotiorum</i> (SCLESC)	Spraying overall	BBCH 57-69	a) 1 per use  b) 1 per crop / season	-	a) 0.5 kg/ha  b) 0.5 kg/ha	a) 250 g/ha  b) 250 g/ha	100- 300	35	<b>Eff. section:</b> use accepted.
9	PL	spring rape gold of pleasure, winter turnip rape, mustard, sunflower, poppy linseed, flax, hemp, borage	F	<i>Leptosperia maculans</i> (LEPTMA)	Spraying overall	BBCH 13-57	a) 1 per use  b) 1 per crop / season	-	a) 0.5 kg/ha  b) 0.5 kg/ha	a) 250 g/ha  b) 250 g/ha	100- 300	35	<b>Eff. section:</b> use accepted.

Remarks columns:	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m <sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants	13	PHI - minimum pre-harvest interval
		- type of equipment used must be indicated.	14	Remarks may include: Extent of use/economic importance/restrictions

## 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 FGG01 containing boscalid (500 g/kg) which was included in Annex I of Directive 91/414 (inclusion directive 79/117/EEC and 91/414/EEC, dated 21/10/2009). The SANCO report for boscalid (SANCO/3919 /2007-rev.5 -21/01/2008) 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 13 March 2009 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.

In fact, this dossier supports submission for authorisation of the new product FGG01 as a WG (Water dispersible Granules; trade names: LOZZARE PRO<sup>®</sup>, MILLER PRO<sup>®</sup>, PALATOR PRO<sup>®</sup>) formulation for the control of diseases in various crops in the Central registration zone. FGG01 is a formulation with boscalid 500 g/kg. Several boscalid based products are currently registered in Europe, notably, Austria, Belgium, Czech Republic, Hungary, the Netherlands, Romania, Slovakia, Slovenia or Poland, to control fungal pathogens in various crops. In this BAD, according to the countries and uses, 2 strategies are presented:

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

The present dossier is based on a combination of studies owned by the applicant and unprotected data of the following products:

Member state	Product name	Registration number
Austria	CANTUS	3149-0
Belgium	CANTUS	9582P/B
Czech Republic	CANTUS	4889-0
	PROPATAN	4889-1
The Netherlands	CANTUS	Not registered
Hungary	CANTUS	47140/2004
Romania	CANTUS	2760
Slovakia	CANTUS	06-02-0783
Slovenia	CANTUS	U34330-1/23/11
Poland	CANTUS	R-111/2018

All products mentioned in the table above are identical with each other and with the intended product. Indeed, they are all the same boscalid 500 g/kg WG formulation, manufactured by BASF and except in Czech Republic, all of them share the same tradename.



In Czech Republic for marketing positioning and segmentation reasons, the 500 g/kg boscalid formulation registered by BASF SE has the tradename CANTUS (registered on grapevine, peas and beans but not on oilseed rape) and also the name PROPATAN (registered on grapevine, peas and beans and oilseed rape). Both products are strictly similar (see table below), thus, they have been grouped by the same name of CANTUS in this dossier (most represented commercial name in the countries targeted by this dossier).

<b>Product name</b>	<b>CANTUS</b>	<b>PROPATAN</b>
Formulation	BOSCALID 500 g/kg WG	BOSCALID 500 g/kg WG
No. AMM	4889- <b>0</b>	4889- <b>1</b>
Date of first registration	20/06/2023	20/06/2023
Company	BASF SE	BASF SE
Classification	SP1, SPe3	SP1, SPe3
Crop	Grapevine, beans and peas	Grapevine, beans and peas, <b>oilseed rape</b>
MSDS	Identical to PROPATAN	Identical to CANTUS

Table 3.2-1 summarises the strategies presented in this dossier for each use submitted.

**Table 3.2-1: Submission strategies presented in the dossier**

Country EPPO zones Admin zone		Number of trials and location EPPO climatic zone				Austria Maritime Central	Belgium Maritime Central	Czech Republic Maritime Central	Netherlands Maritime Central	Hungary South-East Central	Romania South-East Central	Slovakia South-East Central	Slovenia South-East Central	Poland North-East Central
		Maritime	NE	SE	Medi <sup>[1]</sup>									
Oilseed rape	SCLESC	5	7	3	-	Bridging	Bridging	Bridging	Full package (Minor use)	Bridging	Bridging	Bridging	-	Full package (Major use)
	ALTEBA	2	-	-	-	Bridging	Bridging	Bridging	Full package (Minor use)	Bridging (Extrapolation)	Bridging (Extrapolation)	Bridging (Extrapolation)	-	-
	LEPTMA	-	9	3	-	Bridging (Extrapolation)	-	Bridging (Extrapolation)	-	Bridging	Bridging	Bridging	-	Full package (Major use)
Grapevine	BOTRCI	3	-	-	6	Bridging	Bridging	Bridging	-	-	-	-	Bridging	-
	UNCINE	10	-	-	7	Full package (Major use)	Full package (Major use)	Full package (Major use)	-	-	-	-	Full package (Major use)	Full package (Minor use)
Fresh beans and peas	BOTRSP	5	-	-	3 + (4*)	Bridging	Bridging	Bridging	Full package (Minor use)	-	-	-	-	Full package (Minor use)
	SCLESC	3 + (4*)	-	-	5	Bridging	Bridging	Bridging	-	-	-	-	-	-

<sup>[1]</sup> Supportive data (extra-zonal data obtained from trials carried out in the other climatic zone).

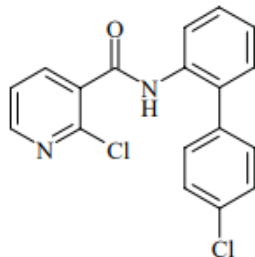
\* Additional trials currently ongoing this year (no results are currently available for these trials; results will be available in November 2024).

zRMS in charge of the evaluation of this preparation is Poland and Member States concerned by the authorization (cMS = concerned Member State) are Austria, Belgium, Czech Republic, Hungary, The Netherlands, Romania, Slovakia and Slovenia.

### Description of active substance

Active substance properties are summarised in Table 3.2-2.

**Table 3.2-2: Details of the active substance**

Active substance	Boscalid
Concentration (Unit: g/kg or g/L...)	500 g/kg
Chemical name (IUPAC)	2-Chloro-N-(4'-chlorobiphenyl-2-yl)nicotinamide
CAS No	188425-85-6
Molecular formula	C <sub>18</sub> H <sub>12</sub> Cl <sub>2</sub> N <sub>2</sub> O
Molecular mass	343.21 g/mol
Chemical group	Pyridine-carboxamides
FRAC Group	C2 Group 7
Mode of action	Complex II: inhibitor of succinate-dehydrogenase (SDHI) Group C2: SDHI fungicides
Biological action	Systemic and translaminar activity with preventative and curative action.
Structural formula	

### Mode of action

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

### **Description of the plant protection product**

FGG01 is a Water dispersible Granules (WG) preparation containing boscalid (500 g/kg) addressed to control a range of diseases of many crops by foliar application method.

In all requested countries of the Central regulatory zone, several preparations containing boscalid (straight or mixed) are currently registered and sold under many trade names in Europe for the control of diseases in arable and speciality crops, e.g.: CANTUS, COLLIS, PICTOR ACTIVE, PICTOR PRO, BELLIS, etc.

Table 3.2-3 summarises the whole of products containing boscalid (as a solo formulation, or co-formulated with other active substances) registered in all requested countries of the Central regulatory zone for the requested uses.

**Table 3.2-3: Products containing boscalid registered in the Central registration zone against a range of diseases - List of authorizations granted**

Country	Registration No.	Product name	Owner	Active substance	Rate of active substance	Formul.	Crop	Pest	Registered dose rate	Rate (g a.s./ha or g a.s./100 L)
Austria	4443-0	BONA FIDE	Sharda Cropchem Espana S.L.	Boscalid	500 g/kg	WG	Winter oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria brassicae</i>	0.5 kg/ha	250 g a.s./ha
							Dwarf French bean (PHSVN),	<i>Botrytis cinerea</i> <i>Sclerotinia sclerotiorum</i>	1.0 kg/ha	500 g a.s./ha
							Broad bean (VICFX), Pea (PIBSX)	<i>Botrytis sp.</i> <i>Sclerotinia sclerotiorum</i>	1.0 kg/ha	500 g a.s./ha
							Grapevine	<i>Botrytis cinerea</i>	1.2 kg/ha	600 g a.s./ha
	3149-0	CANTUS	BASF Österreich GmbH.	Boscalid	500 g/kg	WG	Winter oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria brassicae</i>	0.5 kg/ha	250 g a.s./ha
							Dwarf French bean (PHSVN), broad bean (VICFX), Pea (PIBSX)	<i>Botrytis sp.</i> <i>Sclerotinia sclerotiorum</i>	1.0 kg/ha	500 g a.s./ha
							Grapevine	<i>Botrytis cinerea</i>	1.2 kg/ha	600 g a.s./ha
	4445-0	CANTUS REVY	BASF Österreich GmbH.	Boscalid Mefentrifluconazole	200 g/L 100 g/L	SC	Spring and winter oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria brassicae</i>	1.0 L/ha	200 g a.s./ha
	3299-0	COLLIS	BASF Österreich GmbH.	Boscalid Kresoxim-methyl	200 g/L 100 g/L	SC	Grapevine	<i>Erysiphe necator</i>	0.64 L/ha	128 g a.s./ha 64 g a.s./ha
	4260-0	PICTOR ACTIVE	BASF Österreich GmbH.	Boscalid Pyraclostrobin	150 g/L 250 g/L	SC	Winter oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria sp.</i>	0.8 L/ha	120 g a.s./ha 200 g a.s./ha
Belgium	4197-0	ROYALTY	Sharda Cropchem Espana S.L.	Boscalid	500 g/kg	WG	Winter oilseed rape	<i>Sclerotinia sclerotiorum</i>	0.5 kg/ha	250 g a.s./ha
	4418-0	WEDDELL	UPL Holdings Coöperatief U.A.	Boscalid	500 g/kg	WG	Winter oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria brassicae</i>	0.5 kg/ha	250 g a.s./ha
							Dwarf French bean (PHSVN),	<i>Botrytis cinerea</i> <i>Sclerotinia sclerotiorum</i>	1.0 kg/ha	500 g a.s./ha
							Broad bean (VICFX), Pea (PIBSX)	<i>Botrytis sp.</i> <i>Sclerotinia sclerotiorum</i>	1.0 kg/ha	500 g a.s./ha
	28525P/B	BOSCAVI	Sharda Cropchem Espana S.L.	Boscalid	500 g/kg	WG	Grapevine	<i>Botrytis cinerea</i>	0.7 kg/ha hedge	350 g a.s./ha hedge
	9582P/B	CANTUS	BASF Belgium Coordination Center	Boscalid	500 g/kg	WG	Winter and spring oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria brassicae</i>	0.5 kg/ha	250 g a.s./ha
							Dwarf French bean (PHSVX)	<i>Sclerotinia sclerotiorum</i> <i>Botrytis fabae</i>	1.0 kg/ha	500 g a.s./ha
							Broad bean (VICFX), Pea (PIBSX)	<i>Sclerotinia sclerotiorum</i> <i>Botrytis cinerea</i>	1.0 kg/ha	500 g a.s./ha
							Grapevine	<i>Botrytis cinerea</i>	0.7 kg/ha hedge	350 g a.s./ha hedge
	10468P/B	CANTUS GOLD	BASF Belgium Coordination Center	Boscalid Dimoxystrobin	200 g/L 200 g/L	SC	Winter and spring oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria brassicae</i>	0.5 L/ha	250 g a.s./ha

Country	Registration No.	Product name	Owner	Active substance	Rate of active substance	Formul.	Crop	Pest	Registered dose rate	Rate (g a.s./ha or g a.s./100 L)
Belgium	30849P/B	LOZZARE	UPL Holdings Coöperatief U.A.	Boscalid	500 g/kg	WG	Winter and spring oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria brassicae</i>	0.5 kg/ha	250 g a.s./ha
							Dwarf French bean	<i>Sclerotinia sclerotiorum</i> <i>Botrytis fabae</i>	1.0 kg/ha	500 g a.s./ha
							Broad bean (VICFX), Peas (PIBSX)	<i>Sclerotinia sclerotiorum</i> <i>Botrytis cinerea</i>	1.0 kg/ha	500 g a.s./ha
							Grapevine	<i>Botrytis cinerea</i>	0.7 kg/ha hedge	350 g a.s./ha hedge
	11110P/B	PICTOR ACTIVE	BASF Belgium Coordination Center	Boscalid Pyaclostrobin	150 g/L 250 g/L	SC	Winter and spring oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria brassicae</i>	0.8 L/ha	120 g a.s./ha 200 g a.s./ha
Czech Republic	31291P/B	REVDAS	BASF Belgium Coordination Center	Boscalid Mefentrifluconazole	200 g/L 100 g/L	SC	Winter and spring oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria brassicae</i>	1.0 L/ha	200 g a.s./ha 100 g a.s./ha
	11093P/B	ROYALTY	Sharda Cropchem Espana S.L.	Boscalid	500 g/kg	WG	Winter oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria brassicae</i>	0.5 kg/ha	250 g a.s./ha
	5823-3	BOSET	Sharda Cropchem Limited	Boscalid	500 g/kg	WG	Winter and spring oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria sp.</i>	0.5 kg/ha	250 g a.s./ha
	5823-4	BOSGUARD	Sharda Cropchem Limited	Boscalid	500 g/kg	WG	Winter and spring oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria sp.</i>	0.5 kg/ha	250 g a.s./ha
	5823-1	BOSS	Sharda Cropchem Limited	Boscalid	500 g/kg	WG	Winter and spring oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria sp.</i>	0.5 kg/ha	250 g a.s./ha
	4889-0	CANTUS	BASF SE	Boscalid	500 g/kg	WG	Beans for pods	<i>Sclerotinia sclerotiorum</i> <i>Botrytis cinerea</i>	1-2 kg/ha according to plant height	500-1000 g a.s./ha
							Green beans, broad beans, Peas	<i>Sclerotinia sclerotiorum</i> <i>Botrytis cinerea</i>	1.0 kg/ha	500 g a.s./ha
							Grapevine	<i>Botrytis cinerea</i>	1.2 kg/ha	600 g a.s./ha
	4606-0V	CANTUS GOLD	PZ - Lesinka s.r.o.	Boscalid Dimoxystrobin	200 g/L 200 g/L	SC	Winter and spring oilseed rape	<i>Sclerotinia sclerotiorum</i>	0.5 L/ha	100 g a.s./ha 100 g a.s./ha
	4896-0	COLLIS	BASF SE	Boscalid Kresoxim-methyl	200 g/L 100 g/L	SC	Grapevine	<i>Erysiphe necator</i>	0.3 L/ha	60 g a.s./ha 30 g a.s./ha
	5093-0	EFILOR	BASF SE	Boscalid Metconazole	133 g/L 60 g/L	SC	Winter and spring oilseed rape	<i>Sclerotinia sclerotiorum</i>	1.0 L/ha	133 g a.s./ha 60 g a.s./ha
	5481-1	KAPITAN	BASF SE	Boscalid Pyraclostrobin	150 g/L 250 g/L	SC	Winter and spring oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria sp.</i>	0.6-1.0 L/ha	90-150 g a.s./ha 150-250 g a.s./ha
	4606-0V	PICTOR 400 SC	FARMA ORYX spol. s r. o.	Boscalid Dimoxystrobin	200 g/L 200 g/L	SC	Grapevine	<i>Sclerotinia sclerotiorum</i>	0.5 L/ha	100 g a.s./ha 100 g a.s./ha
	5481-0	PICTOR ACTIVE	BASF SE	Boscalid Pyraclostrobin	150 g/L 250 g/L	SC	Winter and spring oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria sp.</i>	0.6-1.0 L/ha	90-150 g a.s./ha 150-250 g a.s./ha
	5930-0	PICTOR REVY	BASF SE	Boscalid Mefentrifluconazole	200 g/L 100 g/L	SC	Winter and spring oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria sp.</i>	0.6-1.0 L/ha	120-200 g a.s./ha 60-100 g a.s./ha

Country	Registration No.	Product name	Owner	Active substance	Rate of active substance	Formul.	Crop	Pest	Registered dose rate	Rate (g a.s./ha or g a.s./100 L)
Czech Republic	4889-1	PROPATAN	BASF SE	Boscalid	500 g/kg	WG	Winter oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria sp.</i>	0.5 kg/ha	250 g a.s./ha
							Broad beans, peas, green beans	<i>Sclerotinia sclerotiorum</i> <i>Botrytis cinerea</i>	1.0 kg/ha	500 g a.s./ha
							Beans for pods	<i>Sclerotinia sclerotiorum</i> <i>Botrytis cinerea</i>	1.0-2.0 kg/ha according to the height of the plants	500-1000 g a.s./ha
							Grapevine	<i>Botrytis cinerea</i>	1.2 kg/ha	600 g a.s./ha
	6029-0	RASPUT (BONTOC, MARMOT)	GLOBACHEM nv.	Boscalid	500 g/kg	WG	Winter oilseed rape	<i>Sclerotinia sclerotiorum</i>	0.5 kg/ha	250 g a.s./ha
Hungary	5823-0	ROYALTY	Sharda Crop-chem Limited	Boscalid	500 g/kg	WG	Winter and spring oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria sp.</i>	0.5 kg/ha	250 g a.s./ha
	47140/2004	CANTUS	BASF Hungária Kft	Boscalid	500 g/kg	WG	Winter and spring oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria brassicae</i> <i>Plenodomus lingam</i>	0.5 kg/ha	250 g a.s./ha
							Grapevine	<i>Botrytis cinerea</i> <i>Erysiphe necator</i>	1.0-1.4 kg/ha	500-700 g a.s./ha
	02.5/1334/2/2007	COLLIS SC	Basf SE Crop Protection Division	Boscalid Kresoxim-methyl	200 g/L 100 g/L	SC	Grapevine	<i>Botrytis cinerea</i> <i>Erysiphe necator</i>	0.3-0.4 L/ha	60-80 g a.s./ha 30-40 g a.s./ha
	04.2/1429-1/2012	EFILOR	BASF S.E.	Boscalid Metconazole	133 g/L 60 g/L	SC	Winter and spring oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria brassicae</i> <i>Plenodomus lingam</i>	1.0 L/ha	133 g a.s./ha 60 g a.s./ha
	6300/940-1/2020	PICTOR ACTIVE (PICASSO ACTIVE)	BASF SE	Boscalid Pyraclostrobin	150 g/L 250 g/L	SC	Winter and spring oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria brassicae</i> <i>Plenodomus lingam</i>	0.6-1.0 L/ha	90-150 g a.s./ha 150-250 g a.s./ha
	6700/1346-1/2023	RASPUT	Globachem NV	Boscalid	500 g/kg	WG	Winter and spring oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria brassicae</i> <i>Plenodomus lingam</i>	0.3-0.5 kg/ha	150-250 g a.s./ha
	6700/1553-1/2023	REVDAS	BASF Hungária Kft	Boscalid Mefentrifluconazole	200 g/L 100 g/L	SC	Winter and spring oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria brassicae</i>	0.6-1.0 L/ha	120-200 g a.s./ha 60-100 g a.s./ha
Netherlands	6300/3300-1/2021	ROYALTY	Sharda Hungary Kft.	Boscalid	500 g/kg	WG	Winter and spring oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria brassicae</i>	0.3-0.5 kg/ha	150-250 g a.s./ha
	12504 N	COLLIS	BASF Nederland B.V.	Boscalid Kresoxim-methyl	200 g/L 100 g/L	SC	Grapevine (wine and table grapes)	<i>Erysiphe necator</i>	0.64 L/ha	128 g a.s./ha 64 g a.s./ha
	12630 N	SIGNUM	BASF Nederland B.V.	Boscalid Pyraclostrobin	267 g/kg 67 g/kg	WG	Beans with pods, peas with pods	<i>Sclerotinia sclerotiorum</i>	1.8 kg/ha	480.6 g a.s./ha 120.6 g a.s./ha
							Broad beans	<i>Botrytis fabae</i>	1.0 kg/ha	267 g a.s./ha 67 g a.s./ha
Netherlands	12630 N	SIGNUM	BASF Nederland B.V.	Boscalid Pyraclostrobin	267 g/kg 67 g/kg	WG	Winter and spring oilseed rape	<i>Alternaria brassicae</i> <i>Alternaria brassicicola</i>	1.0 kg/ha	267 g a.s./ha 67 g a.s./ha

Country	Registration No.	Product name	Owner	Active substance	Rate of active substance	Formul.	Crop	Pest	Registered dose rate	Rate (g a.s./ha or g a.s./100 L)
Poland	R-104/2022	BRELYCO	BASF Agro B.V.	Boscalid Mefentrifluconazole	200 g/L 100 g/L	SC	Winter and spring oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria sp.</i>	1.0 L/ha	200 g a.s./ha 100 g a.s./ha
							Sunflower	<i>Sclerotinia sclerotiorum</i> <i>Alternaria sp.</i>	1.0 L/ha	200 g a.s./ha 100 g a.s./ha
	R-111/2018	CANTUS (BIS-METIC)	BASF SE	Boscalid	500 g/kg	WG	Winter oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria sp.</i> <i>Plenodomus lingam</i>	0.5 kg/ha	250 g a.s./ha
	R-101/2013	EFILOR 193 SC	BASF SE	Boscalid Metconazole	133 g/L 60 g/L	SC	Winter oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria sp.</i>	0.67-1.0 L/ha	89.1-133 g a.s./ha 40.2-60 g a.s./ha
	R-158/2015	EMOT	BASF SE	Boscalid Metconazole	133 g/L 60 g/L	SC	Winter oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria sp.</i>	0.67-1.0 L/ha	89.1-133 g a.s./ha 40.2-60 g a.s./ha
	R-117/2020	PICTOR ACTIVE (ANISTRO 400 SC, CAPARTIS SHEPHERD, PRESCOT ACTIVE)	BASF SE	Boscalid Pyraclostrobin	150 g/L 250 g/L	SC	Winter and spring oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria sp.</i> <i>Plenodomus lingam</i>	0.6-1.0 L/ha	90-150 g a.s./ha 150-250 g a.s./ha
							Winter and spring turnip rape White mustard Gold of pleasure	<i>Sclerotinia sclerotiorum</i> <i>Alternaria sp.</i> <i>Plenodomus lingam</i>	0.6-1.0 L/ha	90-150 g a.s./ha 150-250 g a.s./ha
							Flax	<i>Sclerotinia sclerotiorum</i> <i>Alternaria sp.</i>	0.6-1.0 L/ha	90-150 g a.s./ha 150-250 g a.s./ha
							Poppy	<i>Alternaria sp.</i>	1.0 L/ha	150 g a.s./ha 250 g a.s./ha
	R-86/2022	RASPUT (PROCERES)	Globachem N.V.	Boscalid	500 g/kg	WG	Winter oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Plenodomus lingam</i>	0.2-0.5 kg/ha	100-250 g a.s./ha
							Spring oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria sp.</i> <i>Plenodomus lingam</i>	0.2-0.5 kg/ha	100-250 g a.s./ha
	R-106/2022	REVDAS (PICTOR REVY)	BASF Agro B.V.	Boscalid Mefentrifluconazole	200 g/L 100 g/L	SC	Winter and spring oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria sp.</i>	1.0 L/ha	200 g a.s./ha 100 g a.s./ha
							Sunflower	<i>Alternaria sp.</i>		
	R-188/2019	ROYALTY (OLIVIER)	Sharda Crop-Chem Ltd.	Boscalid	500 g/kg	WG	Winter oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria sp.</i>	0.5 kg/ha	250 g a.s./ha





Country	Registration No.	Product name	Owner	Active substance	Rate of active substance	Formul.	Crop	Pest	Registered dose rate	Rate (g a.s./ha or g a.s./100 L)
	23-01592-AU	RASPUT	Globachem N.V.	Boscalid	500 g/kg	WG	Winter and spring oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria sp.</i> <i>Plenodomus lingam</i>	0.3-0.5 kg/ha	150-250 g a.s./ha
	20-00856-AU	ROYALTY	Sharda Cropchem España S.L.	Boscalid	500 g/kg	WG	Winter and spring oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Alternaria sp.</i>	0.5 kg/ha	250 g a.s./ha
	23-01649-AU	VINITUS	Globachem N.V.	Boscalid	500 g/kg	WG	Grapevine	<i>Botrytis cinerea</i>	1.2 kg/ha	600 g a.s./ha
Slovenia	327-02-352/02/25 3433-522/09/4 U34330-61/14/3 U34330-158/14/2 U34330-48/19/2 U34330-1/21/5 U34330-1/23/11	CANTUS	BASF SE	Boscalid	500 g/kg	WG	Grapevine	<i>Botrytis cinerea</i>	1.2 kg/ha	600 g a.s./ha
	U34330-1/14/7 U34330-1/14/12 U34330-48/19/2 U34330-1/21/5 U34330-1/14/17 U34330-137/13/25 U34330-1/23/11	COLLIS	BASF SE	Boscalid Kresoxim-methyl	200 g/L 100 g/L	SC	Grapevine	<i>Erysiphe necator</i>	0.4 L/ha	80 g a.s./ha 40 g a.s./ha

\*In italic: second trade names of product.

## Requested uses

The simplified recommendations proposed for FGG01 are presented in Table 3.2-4. Further details are in the table “All intended uses” in Part B - Section 0 and Table 3.1-1.

**Table 3.2-4: Simplified table of requested uses for FGG01**

Crop	Target	Member state	Requested registration			Comments / other relevant details on GAPs
			Requested dose per application	Application number	Application crop stage	
Oilseed rape (winter and spring) (BRSNW, BRSNS)	Sclerotinia stem rot - SCLESC ( <i>Sclerotinia sclerotiorum</i> )	AT, BE, CZ, HU, NL, PL, RO, SK	0.5 kg/ha	1	BBCH 57-69	100-300 L/ha
	Alternaria - ALTESP ( <i>Alternaria</i> sp.)	AT, BE, CZ, NL, RO, SK, HU				
	Dry rot of crucifers - LEPTMA ( <i>Plenodomus lingam</i> )	AT, CZ, HU, PL, RO, SK			BBCH 13-57	
Grapevine (wine and table grapes) (VITVI)	Grey mould - BOTRCI ( <i>Botrytis cinerea</i> )	AT, BE, CZ, SL	1.0 kg/ha 0.72 kg/10000 m² LWA	1	BBCH 60-85	100-1000 L/ha
	Powdery mildew - UNCINE <i>Erysiphe necator</i>	AT, BE, CZ, SL, PL	0.2 kg/ha 0.14 kg/10000 m² LWA 0.02 kg/100 L	3	BBCH 15-81	100-1000 L/ha
Fresh beans and peas with and without pods (PHSVX, PIBSS, VICFX)	Grey mould - BOTRSP ( <i>Botrytis</i> sp.)	AT, BE, CZ, NL, PL	1.0 kg/ha	2	BBCH 60-69	150-600 L/ha
	Sclerotinia stem rot - SCLESP ( <i>Sclerotinia</i> sp.)	AT, BE, CZ				
Additional minor uses for Poland only						
Beans for fresh seeds, Broad beans, French beans, Peas for fresh seeds, edible podded peas	Sclerotinia stem rot - SCLESC ( <i>Sclerotinia sclerotiorum</i> ) Grey mould - BOTRSP ( <i>Botrytis</i> sp.) Powdery mildew of black medick - ERYSPI ( <i>Erysiphe pisi</i> )	PL	1.0 kg/ha	2	BBCH 60-69	150-600 L/ha
Spring rape, gold of pleasure, winter turnip rape, mustard, sunflower, poppy, linseed, flax, hemp, borage	Sclerotinia stem rot - SCLESC ( <i>Sclerotinia sclerotiorum</i> ) Alternaria - ALTESP ( <i>Alternaria</i> sp.)	PL	0.5 kg/ha	1	BBCH 57-69	100-300 L/ha
Spring rape, gold of pleasure, winter turnip rape, mustard, sunflower, poppy, linseed, flax, hemp, borage	Dry rot of crucifers - LEPTMA ( <i>Plenodomus lingam</i> )	PL	0.5 kg/ha	1	BBCH 13-57	100-300 L/ha
Grapevine	Grey mould - BOTRCI ( <i>Botrytis cinerea</i> )	PL	1.0 kg/ha	1	BBCH 60-85	100-1000 L/ha

## Description of the target pest

The diseases concerned by this dossier are summarised in the following Table 3.2-5.

**Table 3.2-5: Glossary of pests mentioned in the trials**

EPPO code	Scientific name	Common name
ALTEAL	<i>Alternaria alternata</i>	Core rot of apple
ALTEBA	<i>Alternaria brassicae</i>	Black spot of rape
ALTESP	<i>Alternaria sp.</i>	Alternaria
BOTRCI	<i>Botrytis cinerea</i>	Grey mould
BOTRFA	<i>Botrytis fabae</i>	Grey mould of broad bean
BOTRSP	<i>Botrytis sp.</i>	Grey mould
LEPTMA	<i>Plenodomus lingam</i> / syn.: <i>Leptosphaeria maculans</i>	Black leg of crucifers
SCLESC	<i>Sclerotinia sclerotiorum</i>	Sclerotinia stem rot
SCLESP	<i>Sclerotinia sp.</i>	Sclerotinia
UNCINE	<i>Erysiphe necator</i>	Powdery mildew

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. The product FGG01 provides a broad spectrum of activity for use on oilseed rape (BRSNN), grapevine (VITVI) and fresh beans and peas (PHSVX, PIBSX, VICFX). Below is a short description of each of the diseases that FGG01 will control when applied as a foliar spray to the crops mentioned.

**a) Oilseed rape**

Sclerotinia stem rot (*Sclerotinia sclerotiorum*):

*Sclerotinia sclerotiorum* (SCLESC) is the causative agent responsible for sclerotinia stem rot, impacting a broad spectrum of crops. 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-flowering<sup>1</sup>.

*Alternaria sp.*

*Alternaria* diseases, commonly affecting oilseed crops such as canola or rapeseed, present distinctive symptoms that can significantly impact plant health and yield. These diseases are primarily caused by various species within the *Alternaria* genus, and their manifestations are characterized by dark lesions on leaves, stems, and pods.

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

The symptoms manifest as follows:

- On the leaves, there are small, rounded black spots (ranging from 0.5 to 3 mm) encircled by a light yellow halo. These spots evolve into circular shapes, reaching diameters of up to 15 mm, often displaying alternating light and dark concentric rings.
- On stems and stalks, small, elongated black spots, a few millimetres in size, emerge.
- On the siliques, the spots are deeply black, round, and well-defined, sometimes developing a lighter central depression as they mature.

The negative consequences extend beyond foliage damage. *Alternaria* diseases can significantly reduce crop yield by impeding the plant's growth, leading to premature senescence. If the infection reaches the pods, there is a risk of diminished seed quality and overall yield, impacting the economic viability of the crop.

*Alternaria* sp. employ spores as a means of dissemination, spreading through air, water, or physical contact. This mechanism contributes to the rapid transmission of the disease within and between crops.

In the spring and summer disease development becomes more active. There will often be reinfection and transfer to uninfected plants via airborne spores released from 'target-spots'. Optimum conditions for infection are 17 to 25°C and spores can infect within four hours of landing on a wet leaf at 22°C.

The warm and humid conditions are conducive to the proliferation of *Alternaria* diseases, creating an environment where the fungi thrive and infect susceptible plants<sup>2</sup>.

#### Dry rot of crucifers - (*Plenodomus lingam*)

Symptoms primarily manifest on the leaves and at the base. Mild and humid autumn conditions, with temperatures around 15°C accompanied by rain or dew, create favourable circumstances for the disease to thrive.

From emergence to the rosette stage, seedling damping-off and leaf spots are the main symptoms. Gray-ashy macules or spots, rounded and speckled with black dots (pycnidia), appear on cotyledons and leaves in autumn. They may also appear later on stems. Upon winter emergence, grey to black cavernous necrosis may appear at the base. Plant death through base sectioning can occur from early winter to the end of flowering.

The fungus remains alive and active in contaminated crop residues for at least 3-4 years. Rapeseed is particularly susceptible to infection by ascospores during the early months of its growth before establishing mechanical resistance at the base, providing protection against phoma penetration.

In autumn, triggered by rainfall and mild temperatures, it forms fruiting bodies (perithecia) that release ascospores. Dispersed by rain and wind, ascospores contaminate seedlings as early as the cotyledon stage. They germinate on leaves as mycelial filaments, leading to the appearance of initial symptoms (macules) after around fifteen days of incubation. The mycelium then progresses towards the base, inducing necrosis through plant tissue reaction.

New spores are produced from the macules, capable of secondary contaminations or infecting older plants through their naturally cracked base or any other mechanical injury. These spores invade the main root without forming a characteristic necrosis<sup>3</sup>.

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<sup>2</sup>[www.syngenta.fr/traitements/alternariose-du-colza](http://www.syngenta.fr/traitements/alternariose-du-colza)

<sup>3</sup><https://www.syngenta.fr/traitements/phoma-du-colza>

## **b) Grapevine**

### Powdery mildew of grapevine (*Erysiphe necator*):

*Erysiphe necator* is one of the principal pathogenic fungi of grapevines, and is responsible for significant viticulture losses in France and the rest of Europe. This fungus is visible under naked eye as a white-greyish downy growth that may cover the leaves, young shoots and bunches.

#### *Description:*

In the shoots, brown spots with a white-greyish powder originating from deformations in the younger ones, and yellow brownish spots with fibrous-looking edges in the mature ones. In the leaves, light brown spots in the veins of the leaf (lower surface) originating from deformations with wavy and crinkly aspect; greyish-white dusty outer covering, on the leaf surfaces.

In the clusters, death and fall of flowers and young berries and splitting of the developing ones occurs (the susceptibility ceases when the sugar contents reaches 12-15%); the clusters show a powdery appearance similar to the leaves.

#### *Biology:*

The fungus employs a robust survival strategy, particularly during adverse conditions, ensuring its persistence through the winter. This resilience is achieved through the formation of sexual fructifications known as cleistothecia. These structures, harboring the potential for sexual reproduction, play a crucial role in the fungus's life cycle.

Simultaneously, the fungus adopts a dormant state as mycelia, strategically sheltered beneath the protective bud scales. This serves as the primary mechanism for the fungus to sustain itself during less favourable periods. Both sexual fructifications and dormant mycelia contribute to the fungus's ability to endure and thrive in challenging environmental conditions.

The onset of infections comes from multiple sources, originating both from the aforementioned mycelium and sexual spores, specifically ascospores. The superficial mycelia, a network of fungal threads, adeptly infiltrates the epidermal cells of the host, facilitated by specialized structures known as haustoria. This invasion establishes a connection with the host plant, allowing the fungus to extract nutrients and facilitate its life cycle.

Externally, the fungus develops conidiophores, structures responsible for the production of chains of asexual spores called conidia. These conidia, released into the surrounding environment, serve as agents for the initiation of secondary infections, contributing to the spread and propagation of the fungus.

As autumn approaches, a significant developmental shift occurs as delicate mycelia covering leaves and immature shoot tips transform into cleistothecia. These structures represent a key phase in the fungus's life cycle, contributing to the production of sexual spores and the potential for genetic variation.

Notably, the fungus exhibits a unique characteristic, it cannot be cultivated in artificial media. This underscores its obligate parasitic nature, emphasizing its dependence on a living host for sustenance and reproduction. This aspect adds a layer of complexity to the study and management of the fungus, as its cultivation in controlled environments remains unattainable.

#### *Epidemiology:*

The conditions favourable to the attack of this parasite are: temperatures of 25-28 °C (optimal), after the bursting of the shoots, and absence of water; the attack starts from the dormant mycelia of the buds and from the ascospores (primary infections) or from conidia (secondary infections); the ascospores have a low range of dissemination (limited to places where the disease occurred in the previous year); the conidia are carried out by the wind and, both germinate on the green surfaces in the absence of water (rain or condensation).

### Grey mould of grapevine (*Botrytis cinerea*)

*Botrytis cinerea* is the causative agent responsible for grey mould, a significant disease that poses a substantial threat to grapevines (*Vitis vinifera* L.), resulting in considerable global losses in both yield and quality. This versatile fungus operates as a saprophyte, necrotroph, or parasite, targeting various grape organs, including leaves, green shoots, rachides, flowers, and bunch trash (encompassing calyptras, deceased stamens, aborted flowers and berries, as well as tendrils) during different stages of development. From flowering to fruit set and following ripening, *B. cinerea* engages in multiple infection pathways, showcasing its adaptability and capacity to exploit diverse points of vulnerability in the grapevine's life cycle<sup>4</sup>.

*Botrytis cinerea*, the culprit behind grey mould, exhibits a comprehensive assault on various segments of the vine, with a particular affinity for leaves and young shoots, especially preceding flowering. Notably, on leaves, the presence of large reddish-brown spots along the leaf blade periphery may be observed. It's worth noting that these symptoms, while visually striking, do not inflict direct damage to the plant.

The fungus, however, takes a more insidious approach when it comes to grape bunches. The vulnerability arises as soon as the flower caps fall off, providing an entry point for *Botrytis cinerea* through wounds incurred during cap removal. Additionally, the fungus can exploit the presence of flower caps adhering to young, developing berries, facilitating its penetration into nascent bunches. Once inside, *B. cinerea* may assume a quiescent state within the berry until ripening, when the berries transition into a receptive state. At this pivotal stage, contamination spreads from one berry to another, and the bunches succumb to the fungal invasion, a process facilitated either by conidia or mycelium under favourable conditions. This intricate interaction underscores the dynamic and opportunistic nature of *Botrytis cinerea*, weaving through the vine's lifecycle with precision and strategic persistence.

Over the winter period, *Botrytis cinerea* adopts a survival strategy, existing in the form of sclerotia on twigs and in mycelial form beneath the bark's epidermis. Additionally, conidia can endure in bark crevices. When spring arrives, both sclerotia and mycelium become active, generating conidia. The dissemination of these conidia occurs through the collaborative efforts of rain and wind, reaching herbaceous organs either directly or through existing wounds. It marks a significant transition for the fungus, shifting from a saprophytic state to a parasitic one.

Once activated, *Botrytis cinerea* infiltrates various parts of the vine, initiating necrosis along its path. Notably, the fungus exhibits differential progress rates—below 13°C, its advancement is nearly stagnant, while around 25°C, it undergoes a rapid escalation. This nuanced response to temperature underscores the dynamic nature of *Botrytis cinerea*, adapting its activity levels based on the prevailing environmental conditions<sup>5</sup>.

### **c) Legume vegetables**

#### Grey mould on peas (*Botrytis cinerea*)

*Botrytis cinerea* develops on wilted petals that remain attached to the tips of the pods or fall onto leaves and stems.

It appears from pea flowering onwards in wet, warm years. Without fungicide protection at this stage of the cycle, it can cause yield losses of up to 20 q/ha.

A dense, greyish mat develops on various parts of the plant (leaves, vines, stems, flowers and pods), developing into a soft, moist rot. *B. cinerea* can cause affected flowers to drop, young pods to abort, and pods to rot and drop, resulting in significant yield loss. Attacks can even lead to plant death.

<sup>4</sup> : Altieri, V.; Rossi, V.; Fedele, G. Biocontrol of *Botrytis cinerea* as Influenced by Grapevine Growth Stages and Environmental Conditions. *Plants* 2023, 12, 3430. <https://doi.org/10.3390/plants12193430>

<sup>5</sup> [www.syngenta.fr](http://www.syngenta.fr)

The disease is favoured by high humidity and high temperatures (15-20°C), but also by dense, poorly aerated or sloping crops. In wet conditions, the disease can spread very quickly throughout the plant and then the field<sup>6</sup>.

The fungus is found in the soil in the form of :

- Mycelium,
- sclerotia in plant debris,
- mycelium inside and outside the seed.

Abundant sporulation of conidia ensures widespread spread.

Infestation often occurs in two stages: first, the fungus establishes itself as a primary parasite on dead or senescent plant parts (wounds, senescent or dried leaves, etc.) and then spreads to healthy plant tissue. Once fertilised, the wilting flowers provide an excellent nutrient base for *B. cinerea*. Flowering marks the start of the maximum risk period, especially if weather conditions are favourable<sup>7</sup>.

#### Grey mould on Green beans (*Botrytis cinerea*)

The disease manifests as tender, grey, circular blemishes found on stems, blossoms, pods, and foliage. Typically, it initiates at the extremity of pre-existing pods and then extends to encompass the entire plant. On the leaves, botrytis causes large, zoned spots in the centre of which the withered petal can still be seen. Under conducive conditions, the outbreak has the potential to rapidly propagate throughout the entire cultivation area.

It is an "opportunistic" fungus that colonises weakened tissue more easily. It is a soil-dwelling fungus that takes different forms (conidia, mycelium and sclerotia) on plant debris, in the soil and on various alternative hosts, be they crops or weeds. Sclerotia are long-lived and can persist for several years.

Infection is initiated from desiccated petals, which serve as a 'nutrient base' for the fungus before it penetrates the bean tissue. The germ tube of the conidia or the mycelium of the sclerotia infiltrates the tissue, often taking advantage of wounds caused by other pests. The fungus spreads rapidly throughout the tissue, causing decay within a few days.

The abundant conidia produced on decaying tissue facilitate wind dispersal and, to a lesser extent, dispersal by rain and splashing water.

High humidity is required for plant contamination to occur, with mild temperatures (optimum of 20°C): a situation encountered during summer thunderstorms.

Crops that are heavily fertilised, dense, poorly aerated or with a slope are ideal breeding grounds for the disease.<sup>8</sup>

#### *Sclerotinia* sp. on peas

This illness stems from a fungus known as *Sclerotinia sclerotiorum*. *Sclerotinia* is a versatile fungus capable of infecting a wide range of host crops. The fungus can persist in the soil for several years in the form of sclerotia. These sclerotia give rise to two modes of contamination: either through the soil, where a mycelium develops and attacks the plant root system, or through the air by emitting spores from apothecia.

Typically, symptoms manifest at maturity, although young plants can also fall victim to the disease. Moist necroses appear on leaves, stems, and pods, followed by premature drying of the affected organs. In the presence of moisture, such as when the plant lies on the ground, a white cottony mycelium covers the plant, leading to the formation of sclerotia on stems and pods. These sclerotia, ranging from beige to black with a white interior, can exceed 1 cm in diameter.

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<sup>6</sup> [www.agro.basf.fr](http://www.agro.basf.fr)

<sup>7</sup> [www.syngenta.fr/traitements/pourriture-grise-du-pois-proteagineux](http://www.syngenta.fr/traitements/pourriture-grise-du-pois-proteagineux)

<sup>8</sup> [www.syngenta.fr/traitements/pourriture-grise-du-haricot](http://www.syngenta.fr/traitements/pourriture-grise-du-haricot)



A dark green-brown rot develops on the stem, displaying downy white mycelium and black sclerotia. Subsequently, the plants wilt and dry out. The disease, while rare and generally not highly damaging to peas, is most commonly observed in a few isolated plants or small foci within a plot. Conditions favouring the disease include temperatures between 15 and 20°C and high humidity (>92%)<sup>9</sup>.

#### *Sclerotinia* sp. on Green beans

Bean sclerotinia is caused by the fungus *Sclerotinia sclerotiorum*. Soft rot develops on the stems, petioles and pods, typically showing a characteristic whitish, cotton-like felting. Within the stems and pods the presence of white and later black sclerotia is evident. If the sclerotia come into direct contact with the roots, this fungus has the potential to cause soft rot at the node, collar or base of the stem. The rapid spread of the mycelium can lead to the death of the entire plant or specific parts of it.

*Sclerotinia sclerotiorum* thrives on a diverse array of crops, having been documented on over 400 different plants, encompassing both cultivated species and weeds. Its highly versatile nature facilitates easy multiplication and widespread dissemination. The fungus infects a broad spectrum of vegetable crops cultivated in rotation with beans, including carrots, celery, beans, cabbage, and various legumes and crucifers. Notably, only monocotyledonous plants remain unaffected.

Persisting in the soil in the form of sclerotia, the fungus can endure for 8 to 10 years, firmly establishing its presence in the plot. Dissemination occurs during cultivation through sclerotia or ascospores transported by air currents. Ascospores are generated by the apothecia formed on the sclerotia during the sediment phase. The fungus efficiently penetrates senescent or deceased tissue, progressing into healthy tissue. Under favourable humidity conditions, *Sclerotinia sclerotiorum* produces a white mycelium and sclerotia on compromised tissue during the asexual phase. These sclerotia exhibit a size akin to a flageolet grain, ranging from 2 to 20 mm in length, with the potential to yield over 50 sclerotia per infected plan.

Crops characterized by lush vegetation and/or excessive growth, as well as crop rotations that involve susceptible plants such as oilseed and protein crops, clover, alfalfa, and vegetable crops, face a heightened risk of infection. The disease thrives under temperature conditions ranging from 15 to 25°C and requires elevated humidity levels for its development<sup>10</sup>.

### **Description of the crops**

Table 3.2-6 presents the details of the production area used in cMS.

**Table 3.2-6: Production area (1000 ha) used for all crops in the Central regulatory zone in 2022<sup>(11)</sup>**

Crop	Country								
	Austria	Belgium	Czech Republic	Hungary	Netherlands	Poland	Romania	Slovakia	Slovenia
Oilseeds	191.72	9.05	437.08	964.13	3.00	1158.16	1701.33	293.13	9.72
Grapes	42.84	0.68	16.42	58.01	0.21	1.10	159.74	7.79	14.42
Fresh beans	1.05	7.63	0.00 <sup>(n)</sup>	1.00	4.02	7.10	3.03	0.00 <sup>(n)</sup>	0.37
Fresh peas	1.92	10.20	1.44	17.64	4.25	8.00	0.67	1.14	0.09
Field peas	5.88	0.71	40.63	10.85	0.00 <sup>(n)</sup>	27.56	68.06	12.25	0.32

<sup>(n)</sup>not significant

### **Major / minor status of intended uses**

According to the applicant's actual knowledge and the database of EUMUDA the status of each crop and each use in the concerned Member States is given in the Table 3.2-7.

<sup>9</sup> [www.syngenta.fr/traitements/sclerotinia-du-pois-proteagineux](http://www.syngenta.fr/traitements/sclerotinia-du-pois-proteagineux)

<sup>10</sup> [www.syngenta.fr/traitements/sclerotiniose-du-haricot](http://www.syngenta.fr/traitements/sclerotiniose-du-haricot)

<sup>11</sup> Source: <http://ec.europa.eu/eurostat/data/database>

**Table 3.2-7: Major / minor status of intended uses (for all cMS and zRMS).**

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	Minor		Major	Minor
<b>Oilseed rape</b> (BRSNN)	AT, BE, CZ, HU, PL, RO, SK	NL	Sclerotinia stem rot - SCLESC ( <i>Sclerotinia sclerotiorum</i> )	AT, BE, CZ, HU, PL, RO, SK	NL
			Alternaria - ALTESP ( <i>Alternaria sp.</i> )	AT, BE, CZ, SK, HU	NL, RO
			Dry rot of crucifers - LEPTMA ( <i>Plenodomus lingam</i> )	AT, CZ, HU, PL, RO, SK	-
<b>Grapevine</b> (VITVI)	AT, CZ, SL	BE, PL	Grey mould - BOTRCI ( <i>Botrytis cinerea</i> )	CZ, SL	BE, AT
			Powdery mildew - UNCINE ( <i>Erysiphe necator</i> )	CZ, SL, PL	BE, AT, <del>PL</del>
<b>Fresh beans</b> (PHSVX, VICFX)	-	AT, BE, CZ, NL, PL	Grey mould - BOTRCI ( <i>Botrytis cinerea</i> )	<del>PL</del>	AT, CZ, NL, BE, <del>PL</del>
			Sclerotinia stem rot - SCLESC ( <i>Sclerotinia sclerotiorum</i> )	-	AT, CZ, BE
<b>Fresh peas</b> (PIBSX)	CZ	AT, BE, NL, PL	Grey mould - BOTRCI ( <i>Botrytis cinerea</i> )	CZ, <del>PL</del>	AT, NL, BE, <del>PL</del>
			Sclerotinia stem rot - SCLESC ( <i>Sclerotinia sclerotiorum</i> )	CZ	AT, BE

### Compliance with the Uniform Principles

The overall assessment was performed according to the uniform principles.

The GEP efficacy trials were carried out by officially recognised organisations which follow the EPPO standards. The organisations 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 these trials and a link to their official compliance certificates are presented in Section 3.7 “List of test facilities including the corresponding certificates”.

The efficacy GEP trials 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), (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’.

### Justification for the use of data from different countries

EPPO 1/307(2) describes the development of a new product which is to be based on the principle of comparing with, and ‘bridging’ to, an existing formulation. The existing authorized formulation should have a full underlying supporting data package. The location of trials should reflect challenging conditions based on crop/pest and environment. Moreover, testing in different zones may be more likely where the diversity of uses or crops is such that they are insufficiently represented in any one EPPO climate region, or where disease pressure may represent more challenging conditions.

According to this standard EPPO 1/307(2), data from other registration zones were used in this dossier. Moreover, 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.

Data from the Southern registration zone were also used in this dossier to support the Maritime EPPO zone in this Central registration dossier. These trials were performed in northern France belonging to the Maritime EPPO climatic zone, according to EPPO PP 1/241(1) 'Guidance on comparable climates'. Additionally, data from another EPPO climatic zone not within the Central Registration zone are presented as supportive data on grapevine against *Botrytis cinerea* and *Erysiphe necator*, and on fresh beans and peas against *Sclerotinia sp.* and *Botrytis sp.* These trials were carried out in the Mediterranean EPPO climatic zone (South of France, Italy, Portugal or Spain). Although these data are from a different EPPO climatic zone, they are considered as supportive since the disease development is similar, as well as the agricultural practices. Furthermore, in these countries, grapevine and fresh beans and peas are also major crops and these target diseases can be a key problem and so, this presents a worst-case situation on grapevine and fresh beans and peas (Table 3.2-8).

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.

For the case of oilseed rape against *Plenodomus lingam*, only data from North-East and South-East EPPO climatic zones are presented. East of Europe is mainly the region where this disease is developed, and no data from the Maritime EPPO zone have been generated. Nevertheless, this could be extrapolated from the North-East and South-East EPPO data, as Austria and Czech Republic, are border countries of Hungary and Poland respectively, where the data have been generated, and thus it can be considered that the climatic conditions and the disease development are similar. In addition, the strategy approach used for this use in Austria and Czech Republic is a bridging approach with the CANTUS product and, data were generated on oilseed rape against SCLESC and ALTEBA in this Maritime EPPO zone.

Regarding grapevine, no data in the South-East EPPO zone is presented to support the registration in Slovenia against BOTRCI and UNCINE, neither in the North-East EPPO zone to support the registration in Poland against UNCINE. Grapevine is a crop much more extended in other countries belonging to neighbouring countries like Austria, Germany or Italy, where data have been generated, and thus, it can be considered that the climatic conditions and the disease development are similar or more challenging. Therefore, data could also be easily extrapolated from the Maritime and Mediterranean EPPO zones data.

**Table 3.2-8: EPPO climatic zones concerning by Member state of EU Central zone concerning by this request**

Use (Crop*Target)	Number of trials and location EPPO climatic zone				Member state requested	EPPO climatic zone <sup>(1)</sup>	Remark	Location of trials to cover EPPO climatic zone
	Mar.	NE	SE	Medi*				
Oilseed rape (BRSNN) / SCLESC	5	7	3		AT, BE, CZ, HU, NL, PL, RO, SK	AT, BE, CZ, NL: Maritime PL: North-East HU, RO, SK: South-East	-	<b>Maritime:</b> FR <sup>(2)</sup> , DK, UK <b>North-East:</b> PL <b>South-East:</b> HU
Oilseed rape (BRSNN) / ALTEBA	2				AT, BE, CZ, NL, SK, HU, RO	AT, BE, CZ, NL: Maritime HU, RO, SK: South-East	No data in South-East EPPO zone are presented, because of bridging label approach, data were generated on SCLESC and LEPTMA uses in this zone.	<b>Maritime:</b> BE
Oilseed rape (BRSNN) / LEPTMA		9	3		AT, CZ, HU, PL, RO, SK	AT, CZ: Maritime PL: North-East HU, RO, SK: South-East	<i>Plenodomus lingam</i> is mainly developed in the East of Europe. No data in Maritime EPPO zone are presented, because of bridging label approach, data were generated on SCLESC and ALTEBA uses in this zone.	<b>North-East:</b> PL <b>South-East:</b> HU
Grapevine (VITVI) / (BOTRCI)	3			6	AT, BE, CZ, SL	AT, BE, CZ: Maritime SL: South-East	No data from Slovenia or other countries from South-East EPPO zone are presented, as grapevine is a crop much more extended in other countries belonging to neighbouring countries like Austria or Italy.	<b>Maritime:</b> AT, DE <b>Medi. (supportive):</b> ES <sup>(3)</sup> , FR <sup>(3)</sup> , IT <sup>(3)</sup> , PT <sup>(3)</sup>
Grapevine (VITVI) / UNCINE)	10			7	AT, BE, CZ, PL, SL	AT, BE, CZ: Maritime PL: North-East SL: South-East	No data from Slovenia or other countries from South-East EPPO zone are presented, as grapevine is a crop much more extended in other countries belonging to neighbouring countries like Austria or Italy. No data from Poland or other countries from North-East EPPO zone are presented, however Poland accepts data from neighbouring countries like Germany.	<b>Maritime:</b> AT, DE <b>Medi. (supportive):</b> ES <sup>(3)</sup> , FR <sup>(3)</sup> , IT <sup>(3)</sup>
Fresh beans and peas (PHSVX, VICFX, PIBSX) / (SCLESP)	3 (+4*)			5	AT, BE, CZ	AT, BE, CZ: Maritime	-	<b>Maritime:</b> BE, FR <sup>(2)</sup> <b>Medi. (supportive):</b> ES <sup>(3)</sup>
Fresh beans and peas (PHSVX, VICFX, PIBSX) / BOTRSP	5			3 (+4*)	AT, BE, CZ, NL, PL	AT, BE, CZ, NL: Maritime PL: North-East	No data from Poland or other country from North-East EPPO zone are presented, however Poland accepts data from neighbouring countries like Germany or Czech Republic.	<b>Maritime:</b> BE, CZ, DE, FR <sup>(2)</sup> , UK <sup>(2)</sup> <b>Medi. (supportive):</b> ES <sup>(3)</sup>

<sup>(1)</sup> EPPO climatic zone according to guidelines presented in EPPO standard PP 1/241(2); Guidance on comparable climates.

<sup>(2)</sup> Extra-zonal data obtained from trials carried out in countries of the Southern EU zone belonging to the Maritime EPPO climatic zone.

<sup>(3)</sup> Extra-zonal data obtained from trials carried out in countries of the Southern EU zone belonging to the Mediterranean EPPO climatic zone.

\* Additional trials currently ongoing this year (no results are currently available for these trials: results will be available in November 2024).

### Information on trials submitted (3.1 Efficacy data)

Data to confirm the efficacy claims for the applications of FGG01 in oilseed rape, grapevine and fresh beans and peas crops against fungal diseases were taken from a set of 50 efficacy trials carried out in the Maritime (28 trials), North-East (16 trials) and South-East (6 trials) EPPO climatic zones from 2021 to 2024. Additionally, 21 efficacy trials from the Mediterranean EPPO climatic zone are also presented as supportive data. Moreover, 8 efficacy trials are ongoing in 2024 carried out in the Maritime (4 trials) and the supportive Mediterranean (4 trials) EPPO climatic zones; the results will be available after the submission of this dossier (November 2024).

To cover the largest spectrum of climatic, soil conditions and crop varieties, trials were located in the main growing areas of each requested crop of the Maritime, North-East and South-East EPPO climatic zones and also as supportive data in the Mediterranean EPPO climatic zone. Table 3.2-9 presents the efficacy trials repartition for all crops and Table 3.2-10,

Table 3.2-11 and Table 3.2-12 present the trials distribution for each disease on oilseed rape, grapevine and fresh beans and peas respectively.

**Table 3.2-9: Trials repartition per crop - Efficacy trials**

Crop	Year	EPPO climatic zone										Supportive trials	Mediterranean*				Total
		Maritime							North-East	South-East	France (South)		Italy	Portugal	Spain		
		Austria	Belgium	Czech Republic	Denmark	France (North)	Germany	United Kingdom	Poland	Hungry							
Oilseed rape BRNSW	2021-2024	-	2	-	1	3		1	16	6		-	-	-	-	29	
Total Oilseed rape		-	2	-	1	3	-	1	16	6		-	-	-	-	29	
Grapevine VITVI	2021-2023	7	-	-	-	-	6	-				3	5	2	3	13+13*	
Total Grapevine		7	-	-	-	-	6	-	-	-		3	5	2	3	13+13*	
Green beans PHSVX	2023	-	2	-	-	3	-	-	-	-		-	-	-	7	5-7*	
Broad beans VICFX	2022	-	-	-	-	-	1	-	-	-		-	-	-	1	1+1*	
Peas PIBSX	2023	-	-	1	-	-	-	1	-	-		-	-	-	-	2	
Total Fresh beans and Peas		-	2	1	-	3	1	1	-	-		-	-	-	8	8+8*	
TOTAL (ALL CROPS)		7	4	1	1	6	7	2	16	6		3	5	2	11	50+21*	

\* Supportive data (extra-zonal data obtained from trials carried out in the other climatic zone).

**Table 3.2-10: Efficacy trials distribution on Oilseed rape**

Crop	Target	Year	EPPO climatic zone						Total
			Maritime				North-East	South-East	
			BE	DK	N-FR	UK	PL	HU	
Oilseed rape	SCLESC	2021	-	-	-	-	3	3	6
		2023	-	1	1	1	4	-	7
		2024			2				2
Total oilseed rape SCLESC		2021-2024		1	3	1	7	3	15
Oilseed rape	ALTEBA	2023	2	-	-	-	-	-	2
Total oilseed rape ALTEBA		2023	2	-	-	-	-	-	2
Oilseed rape	LEPTMA	2021	-	-	-	-	3	3	6
		2022	-	-	-	-	2	-	2
		2023	-	-	-	-	4	-	4
Total oilseed rape LEPTMA		2021-2023	-	-	-	-	9	3	12

**Table 3.2-11: Efficacy trials distribution on Grapevine**

Crop	Target	Year	EPPO climatic zone						Total
			Maritime		Mediterranean*				
			AT	DE	ES	S-FR	IT	PT	
Grapevine	BOTRCI	2021	-	-	-	-	-	2*	2*
		2023	2	1	1*	1*	2*	-	3+4*
Total grapevine BOTRCI		2021-2023	2	1	1*	1*	2*	2*	3+6*
Grapevine	UNCINE	2022	2	2	-	2*	1*	-	4+3*
		2023	3	3	2*	-	2*	-	6+4*
Total grapevine UNCINE		2022-2023	5	5	2*	2*	3*	-	10+7*

\* Supportive data (extra-zonal data obtained from trials carried out in the other climatic zone).

**Table 3.2-12: Efficacy trials distribution on Fresh beans and peas**

Crop	Target	Year	EPPO climatic zone						Total
			Maritime					Mediterranean*	
			BE	CZ	DE	N-FR	UK	ES	
Fresh beans and peas	BOTRSP	2021	-	-	1	-	-	-	1
		2023	1	1	-	1	1	3*	4+3*
Total grapevine BOTRCI		2021-2023	1	1	1	1	1	3*	5+3*
Fresh beans and peas	SCLESP	2022	-	-	-	-	-	1*	1*
		2023	1	-	-	2	-	4*	3+4*
Total grapevine UNCINE		2022-2023	1	-	-	2	-	5*	3+5*

\* Supportive data (extra-zonal data obtained from trials carried out in the other climatic zone).

In addition, for the use Fresh beans and peas\_BOTRSP, Mediterranean EPPO climatic zone (4 trials in Italy) are currently on going in 2024 but no results are currently available for these 4 later trials.

In addition, for the use Fresh beans and peas\_SCLESP, Maritime EPPO climatic zone (4 trials in North of France) are currently on going on 2024 but no results are currently available for these 4 later trials.

An overview of available trials is provided in:

- Table 3.2-13 for **Oilseed rape**. Figure 3.2-1 presents the efficacy trials repartition for oilseed rape trials;
- Table 3.2-14 for **Grapevine**. Figure 3.2-2 presents the efficacy trials repartition for grapevine trials;
- Table 3.2-15 for **Fresh beans and peas**. Figure 3.2-3 presents the efficacy trials repartition for fresh beans and peas trials.



**Table 3.2-13: Presentation of efficacy trials - Oilseed rape**

Crop(s) <sup>(1)</sup>	Target(s) <sup>(1)</sup>	EPPO climatic zone <sup>(2)</sup>	Country	Year	Nb. of trials	Type of trial <sup>(3)</sup>	GEP, non-GEP, official <sup>(4)</sup>	Comments (any other relevant information)
Winter oilseed rape	ALTEBA	Maritime	Belgium	2023	2	E + S	GEP	-
	SCLESC	Maritime	Denmark	2023	1	E + S	GEP	-
			United Kingdom	2023	1			
			France (North)	2023-2024	3			
		North-East	Poland	2021-2023	6	MED + E + S	GEP	-
				2023	1	MED + E + S + Y + Q	GEP	-
		South-East	Hungary	2021	3	E + S	GEP	-
	LEPTMA	South-East	Hungary	2021	3	MED + E + S	GEP	-
		North-East	Poland	2021-2023	9			

<sup>(1)</sup> According to the GAP table. <sup>(2)</sup> According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".

<sup>(3)</sup> E = efficacy trial - MED = Minimum effective dose trial - S= Trial with phytotoxicity assessment - Y= Yield - Q= Quality

<sup>(4)</sup> GEP: Good Experimental Practices. Official: carried out by a national official organisation.

**Table 3.2-14: Presentation of efficacy trials - Grapevine**

Crop(s) <sup>(1)</sup>	Target(s) <sup>(1)</sup>	EPPO climatic zone <sup>(2)</sup>	Country	Year	Nb. of trials	Type of trial <sup>(2)</sup>	GEP, non-GEP, official <sup>(4)</sup>	Comments (any other relevant information)
Grapevine	BOTRCI	Maritime	Austria	2023	2	E + S	GEP	-
			Germany	2023	1			
	UNCINE	Maritime	Austria	2022-2023	5	MED + E + S		
			Germany	2022-2023	5			
Supportive data from other climatic EPPO zones								
Grapevine	BOTRCI	Mediterranean	France (South)	2023	1	E + S	GEP	-
			Italy	2023	2			
			Portugal	2021	2			
			Spain	2023	1			
	UNCINE	Mediterranean	France (South)	2023	2	E + S	GEP	-
			Italy	2023	3			
			Spain	2023	2			

<sup>(1)</sup> According to the GAP table. <sup>(2)</sup> According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".

<sup>(3)</sup> E = efficacy trial - MED = Minimum effective dose trial - S= Trial with phytotoxicity assessment.

<sup>(4)</sup> GEP: Good Experimental Practices. Official: carried out by a national official organisation.

**Table 3.2-15: Presentation of efficacy trials - Fresh beans and peas**

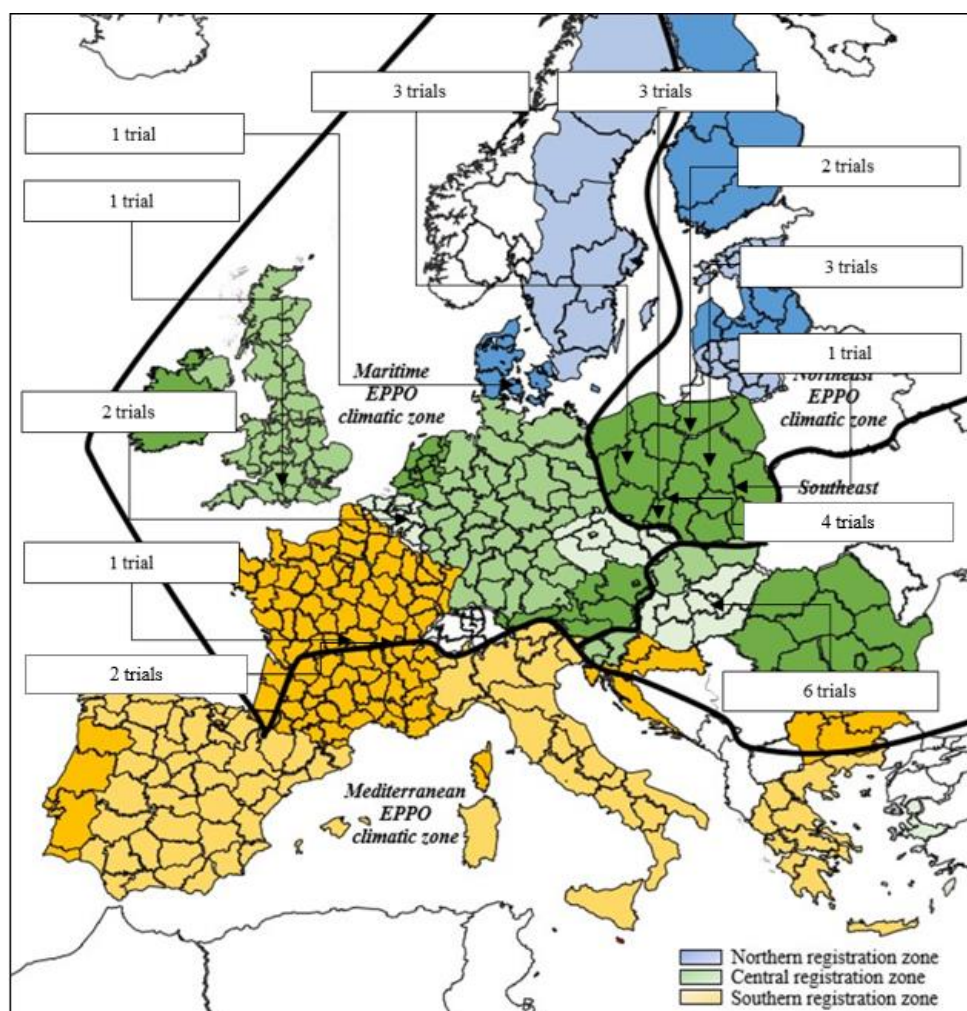
Crop(s) <sup>(1)</sup>	Target(s) <sup>(1)</sup>	EPPO climatic zone <sup>(2)</sup>	Country	Year	Nb. of trials	Type of trial <sup>(3)</sup>	GEP, non-GEP, official <sup>(4)</sup>	Comments (any other relevant information)
Fresh beans and peas	BOTRSP	Maritime	France	2023	1	E + S	GEP	-
			United Kingdom	2023	1			
		Maritime	Belgium	2023	1	E + S + Y	GEP	-
			Maritime	Germany	2022	1	E + S + Y + Q	GEP
		Czech Republic		2023	1			
		SCLESP	Maritime	France (North)	2023	2	E + S	GEP
	Maritime		Belgium	2023	1	E + S + Y		
	Supportive data from other climatic EPPO zones							
Fresh beans and peas	BOTRCI	Mediterranean	Spain	2023	1	E + S	GEP	-
			Spain	2023	2	E + S + Y		
	SCLESP	Mediterranean	Spain	2022-2023	3	E + S	GEP	-
			Spain	2023	2	E + S + Y		

<sup>(1)</sup> According to the GAP table. <sup>(2)</sup> According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".

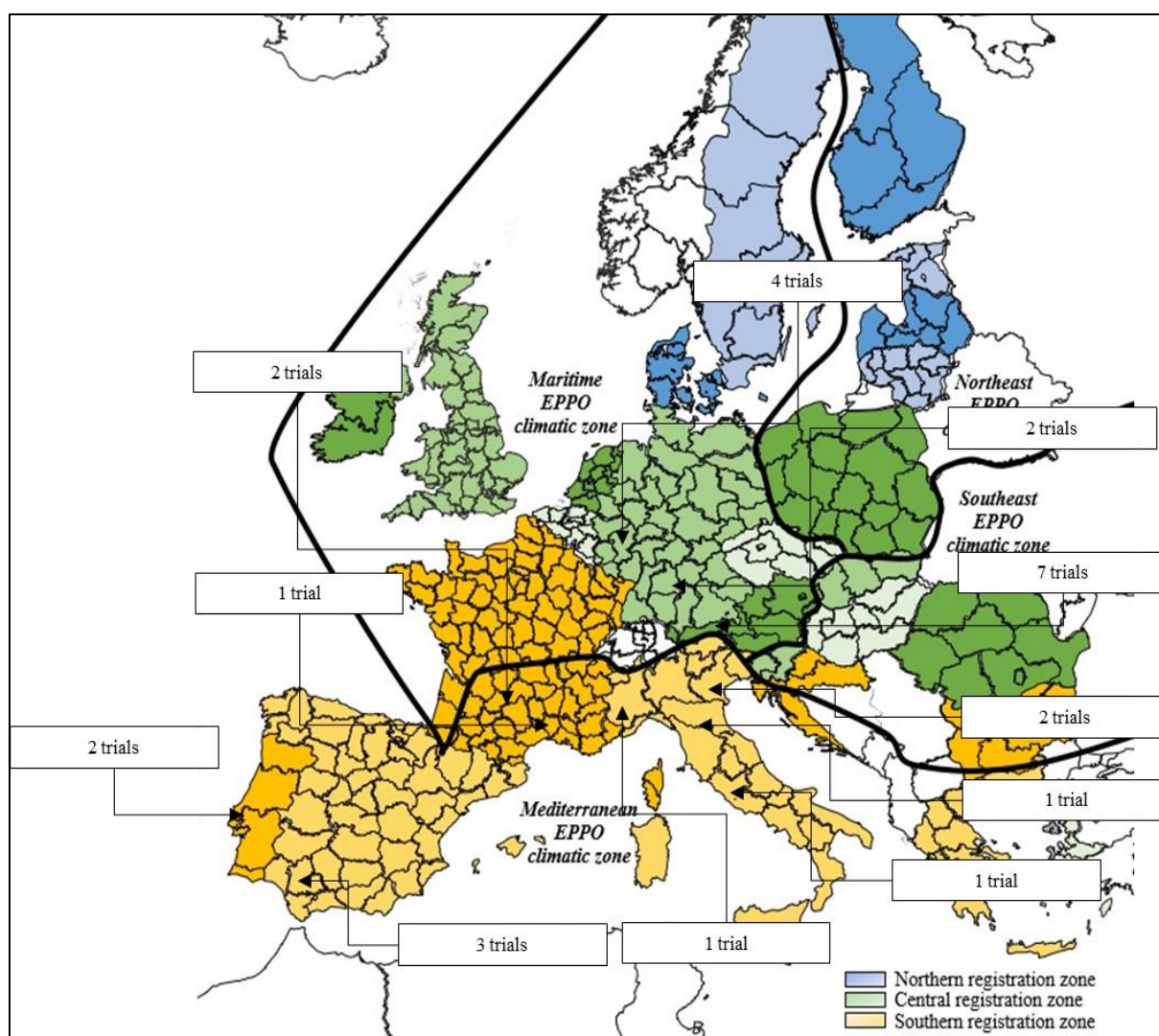
<sup>(3)</sup> E = Efficacy trial - S= Trial with phytotoxicity assessment - Y = Yield - Q = Quality.

<sup>(4)</sup> GEP: Good Experimental Practices. Official: carried out by a national official organisation.

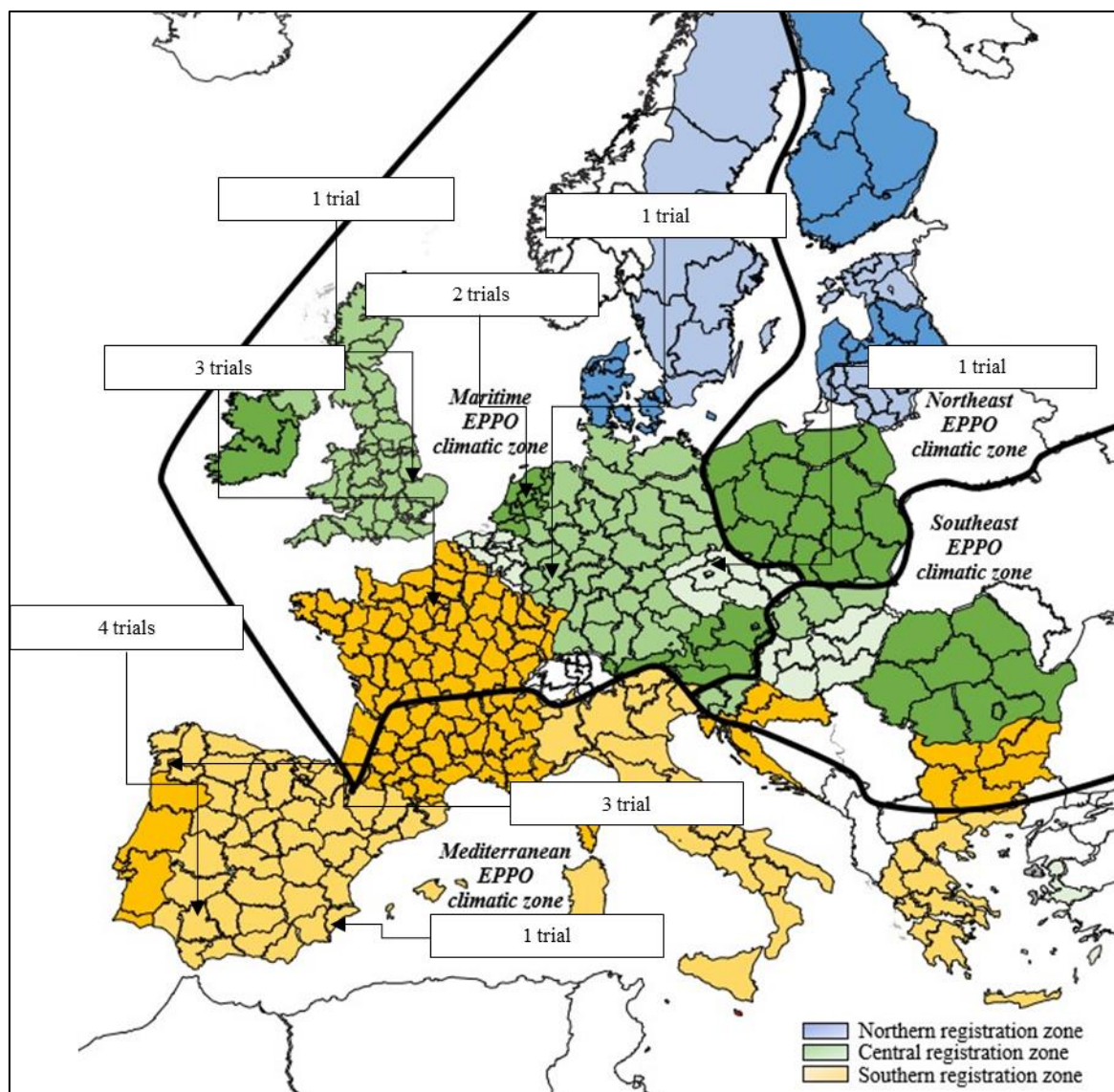
**Figure 3.2-1** **Location of the trial sites - Efficacy trials - Oilseed rape**



**Figure 3.2-2 Location of the trial sites - Efficacy trials - Grapevine**



**Figure 3.2-3 Location of the trial sites - Efficacy trials - Fresh beans and peas**





**Table 3.2-16: Presentation of reference standards used in efficacy trials - All crops**

Product name	Active substance(s)	Formulation		Country(ies) where the product was registered <sup>(1)</sup>	Registration number	Crop(s)	Target	Registered application dose <sup>(3)</sup>	Dose rate in trials (per treatment)	Rate of active substance per ha	Remark
		Type <sup>(2)</sup>	Concentration of a.s.								
CANTUS (PICTOR PRO, FILAN)	Boscalid	WG	500 g/kg	AT	025180-00	Grapevine	<i>Botrytis cinerea</i>	1.2 kg/ha	1.0 kg/ha	500 g a.s./ha	-
					Not registered	Grapevine	<i>Erysiphe necator</i>	-	0.2 kg/ha	100 g a.s./ha	-
				BE	9582P/B	Oilseed rape	<i>Alternaria brassicae</i>	0.5 kg/ ha	0.5 kg/ ha	250 g a.s./ha	-
						Green beans	<i>Botrytis cinerea</i> <i>Sclerotinia sclerotiorum</i>	1.0 kg/ha	1.0 kg/ha	500 g a.s./ha	-
				CZ	4889-0	Peas	<i>Botrytis cinerea</i>	1.0 kg/ha	1.0 kg/ha	500 g a.s./ha	-
				DE	3149-0	Grapevine	<i>Botrytis cinerea</i>	0.3 kg/ha (400 L/ha water) 0.6 kg/ha (800 L/ha water) 0.9 kg/ha (1200 L/ha water) 1.2 kg/ha (1600 L/ha water)-	1.0 kg /ha	500 g a.s./ha	-
					Not registered	Grapevine	<i>Erysiphe necator</i>	-	0.2 kg/ha	100 g a.s./ha	-
					3149-0	Fresh Beans	<i>Botrytis sp.</i>	1.0 kg /ha (300-600 L/ha)	1.0 kg /ha	500 g a.s./ha	-
				DK	19-161	Oilseed rape	<i>Sclerotinia sclerotiorum</i>	0.5 kg/ ha	0.5 kg/ha	250 g a.s./ha	-
				ES	23750	Beans	<i>Botrytis cinerea</i> <i>Sclerotinia sclerotiorum</i>	1.0 kg /ha	1.0 kg/ha	500 g a.s./ha	-
					Not registered	Grapevine	<i>Botrytis cinerea</i>	-	1.0 kg/ha	500 g a.s./ha	-
					23750	Grapevine	<i>Erysiphe necator</i>	0.2 kg/ha	0.2 kg/ha	100 g a.s./ha	-
				FR	2050075 (Pictor pro)	Oilseed rape	<i>Sclerotinia sclerotiorum</i>	0.5 kg/ha	0.5 kg/ha	250 g a.s./ha	-
					2050076	Grapevine	<i>Botrytis cinerea</i>	1.2 kg/ha	1.0 kg/ha	500 g a.s./ha	-
					Not registered	Grapevine	<i>Erysiphe necator</i>	-	0.2 kg/ha	100 g a.s./ha	-
					2050075 (Pictor pro)	Green beans	<i>Botrytis sp.</i> <i>Sclerotinia sclerotiorum</i>	1.0 kg/ha	1.0 kg/ha	500 g a.s./ha	-
				HU	47140/2004	Oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Plenodomus lingam</i>	0.5 kg/ ha	0.5 kg/ ha	250 g a.s./ha	-
				IT	012862	Grapevine	<i>Botrytis cinerea</i> <i>Erysiphe necator</i>	1.0-1.2 kg/ha	1.0 kg/ha 0.2 kg/ha	500 g a.s./ha 100 g a.s./ha	-
						Kiwi (post-harvest)	<i>Botrytis cinerea</i>	75 g/100 L	75 g/100 L	37.5 g a.s./100 L	-
				PL	R-111/2018	Oilseed rape	<i>Sclerotinia sclerotiorum</i> <i>Plenodomus lingam</i>	0.3-0.5 kg/ha	0.5 kg/ha	250 g a.s./ha	-
				PT	0153	Grapevine	<i>Botrytis cinerea</i>	1.0-1.2 kg/ha	1.0 kg/ha	500 g a.s./ha	-
				UK	11449 (FILAN)	Oilseed rape	<i>Sclerotinia sclerotiorum</i>	0.5 kg/ha	0.5 kg/ha	250 g a.s./ha	-
					Not registered	Peas	<i>Botrytis cinerea</i>	-	1.0 kg/ha	500 g a.s./ha	-

Product name	Active substance(s)	Formulation		Country(ies) where the product was registered <sup>(1)</sup>	Registration number	Crop(s)	Target	Registered application dose <sup>(3)</sup>	Dose rate in trials (per treatment)	Rate of active substance per ha	Remark
		Type <sup>(2)</sup>	Concentration of a.s.								
COLLIS	Boscalid Kresoxim-methy	SC	200 g/L 100 g/L	AT	035203-00	Grapevine	<i>Erysiphe necator</i>	0.64 L/ha	0.64 L/ha	128 g a.s./ha 64 g a.s./ha	
				DE	3299-0	Grapevine	<i>Erysiphe necator</i>	0.16 L/ha (400 L/ha water) 0.32 L/ha (800 L/ha water) 0.48 L/ha (1200 L/ha water) 0.64 L/ha (1600 L/ha water)	0.64 L/ha	128 g a.s./ha 64 g a.s./ha	-
GEOXE 50 WG	Fludioxonil	WG	50%	ES	25920	Grapevine	<i>Botrytis cinerea</i>	0.1 kg/100 L (1.0 kg/ha)	1.0 kg/ha	500 g a.s./ha	-
KUMULUS WG	Sulphur	WG	800 g/kg	AT	052273-00	Grapevine	<i>Erysiphe necator</i>	8 kg/ha	5-8 kg/ha	4-6.4 kg a.s./ha	Named also KUMULUS in this BAD
PROSPER TEC	Spiroxamine	SC	300 g/L	AT	4025-0	Grapevine	<i>Erysiphe necator</i>	1.0 L/ha	0.66 L/ha	198 g/ha	Named also PROSPER in this BAD
				DE	008814-00	Grapevine	<i>Erysiphe necator</i>	0.33 L/ha (400 L/ha water) 0.66 L/ha (800 L/ha water) 0.99 L/ha (1200 L/ha water)	0.66 L/ha	198 g/ha	
SIGNUM	Boscalid Pyraclostrobin	WG	267 g/kg 67 g/kg	UK	11450	Peas	<i>Botrytis cinerea</i>	1.0 kg/ha	1.0 kg/ha	276 g a.s./ha 67 g a.s./ha	-
TOPAS	Penconazole	EC	100g /L	DE	3275-0	Grapevine	<i>Erysiphe necator</i>	0.08 L/ha (400 L/ha water) 0.16 L/ha (800 L/ha water) 0.24 L/ha (1200 L/ha water) 0.32 L/ha (1600 L/ha water)	0.08 L/ha	8 g a.s./ha	-

<sup>(1)</sup> Only on use(s) applied for (with the test product) - <sup>(2)</sup> EC: Emulsionate concentrate. SC: Suspension Concentrate. WG: Water dispersible Granules. <sup>(3)</sup> Dose(s) / dose range authorized on that use in the country - <sup>(4)</sup> Other relevant information.

CANTUS, PICTOR PRO and FILAN were strictly similar, thus, we grouped all products by the same name of CANTUS in this dossier (most represented commercial name in the countries targeted by this dossier).

For the purposes of supporting a bridging approach and direct comparison between FGG01 and solo boscalid formulations (e.g. CANTUS, or equivalent), some solo boscalid reference products have been used which were not registered for some uses in selected countries. Nevertheless, all relevant trials contained a secondary registered reference product which was used as registered.

For some grapevine trials, a maximum rate of 1.0 kg/ha was tested for bridging purposes as this is the most commonly registered rate in Europe, and allows direct orthogonal comparison across all trials as part of a bridging approach.

**ZRMs comments:** Boscalid is a fungicide commonly applied to crops like winter oilseed rape, grapevines, beans, and peas, which often require fungicidal treatment to protect against yield and quality loss due to fungal diseases. Farmers must adhere to recommended usage guidelines to maximize efficacy and maintain environmental safety.

Boscalid provides broad protection against various fungal pathogens, making it a versatile option for crops prone to issues like powdery mildew, gray mold, and other fungal diseases. This fungicide offers systemic action, meaning it can move upward within plant tissues, shielding new growth along with treated areas. With a long-lasting residual effect, boscalid reduces the need for frequent applications by offering extended protection. Often, it is used alongside other fungicides as part of resistance management to avoid the buildup of resistant fungal strains due to its distinctive mode of action. When applied as directed, boscalid is generally safe for use on multiple crops, demonstrating low phytotoxicity and protecting plants without causing harm. Effective fungal control with boscalid supports better plant health, contributing to increased yields and improved crop quality. Additionally, its flexible application timing accommodates different crop stages, adapting to varying disease pressures and environmental conditions.

Despite its effectiveness, boscalid has some limitations. Prolonged use may encourage the development of resistant fungal strains, necessitating rotation or combination with other fungicides to mitigate this risk. While it is relatively safe, improper or excessive use could affect non-target organisms and ecosystems, highlighting the importance of responsible management. By taking these drawbacks into account, farmers and growers can optimize their fungicide strategies to reduce potential risks.

This document summarizes the information related to the efficacy of the plant protection product – Lozzare Pro, Miller Pro, Palator Pro (product code: FGG01). Lozzare Pro, Miller Pro, Palator Pro is a water dispersible granules (WG) preparation containing boscalid (500 g/kg) addressed to control a range of diseases of many crops by foliar application method.

For now, this mentioned active substance (boscalid) is on the list of approved active substances. All necessary information's about tested plant protection product, active substance, studied fungal diseases, reference products, etc. are correctly presented in this dossier by Applicant. In Poland, 45 plant protection products containing boscalid as an active compound are already registered (on the basis of Ministry Register dated 31.10.2024).

The product – Lozzare Pro, Miller Pro, Palator Pro (product code : FGG01) containing boscalid (500 g/kg) by UPL Holdings Coöperatief U.A. was evaluated by Poland as a ZRMs. Austria, Belgium, Czech Republic, Hungary, Netherlands, Romania, Slovakia, Slovenia are the cMS from Central zone.

ZRMs kindly asked cMS for checking major/minor status of crop and pest from table 3.2.7.

### 3.2.1 Preliminary tests (KCP 6.1)

No preliminary tests were implemented by the applicant, the test product FGG01 is composed of only a single active substance. Moreover, the active ingredient of FGG01 (500 g/kg of boscalid) has been approved for the control of a range of diseases since 2008. The fungicidal activity of this compound has therefore been widely researched and proven in commercial use in several countries across Europe. Based on this, the chemistry and biology of the active ingredient is well understood. Therefore, no specific preliminary/screening tests have been undertaken with FGG01.

**ZRMs comments:** Since its introduction in the early 2000s, boscalid has been utilized as a fungicide. BASF first registered it in 2002, and it quickly gained widespread use in agriculture for its broad-spectrum efficacy against fungal diseases across various crops. Boscalid inhibits fungal respiration, helping to safeguard crops such as fruits, vegetables, and cereals from harmful pathogens. It has thus



been in agricultural use for nearly two decades. In Poland, boscalid received its initial registration in 2005.

Large scale efficacy trials are available to evaluate the effectiveness of products containing boscalid. So, preliminary tests were not necessary in the opinion of ZRMs. For, example in Poland 45 PPPs with boscalid are registered and commonly use as a fungicide.

### **3.2.2 Minimum effective dose tests (KCP 6.2)**

According to uses and countries, the present dossier is submitted in view to support the application for registration label of FGG01 (500 g/kg of boscalid, WG) by using a bridging approach with the reference product CANTUS (500 g/kg of boscalid, WG; also known under the name of PROPATAN in Czech Republic; AMM: 4889-1) or by using a full data package approach (when the reference product CANTUS is not registered or when CANTUS data is still under data protection).

FGG01 contains 500 g/kg of boscalid which has been approved for the control of a range of diseases since 2008. Similar fungicides with same formulation and same quantity of active ingredient (boscalid, 500 g/kg; WG) have been developed and approved for use in agriculture for many years. Therefore, overall, the minimum effective dose of FGG01 is already known (cf. Table 3.2-3).

Due to the different registration approach strategies in this dossier (bridging or full data package) the justification of the Minimum Effective Dose is not required for all uses claimed for FGG01. Indeed, when a bridging strategy is targeted (use unprotected data of registered product in the country where the use is requested) in this case, this dossier is intended to demonstrate the comparability between the reference product CANTUS and FGG01 and in this context, no Minimum Effective Dose trials are needed. Conversely, in the countries where CANTUS is not authorized or when CANTUS data is still under data protection for a use, a study of the dose is necessary with a complete data package; the size of this data package may vary according to the major or minor classification of the respective use.

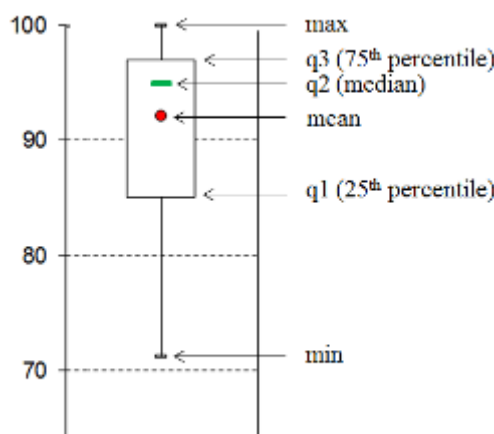
#### **3.2.2.1 Material and methods**

Material and Methods used in these efficacy trials are given within Section 3.2.3, Efficacy tests (KCP 6.2) and is not repeated here.

#### **Interpretation of data**

In order to illustrate the data distribution between the different dose rates of FGG01, box plot graphics 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 Results of minimum effective dose on oilseed rape (BRSNN)

In oilseed rape, fungicides with boscalid in solo ready mixes have been developed and approved for the control of foliar diseases.

In order to justify the choice of the dose rate of FGG01 for the control of *Sclerotinia sclerotiorum* (SCLESC) and *Plenodomus lingam* (LEPTMA) on oilseed rape, different dose rates were studied. FGG01 was tested at 0.25, 0.375 and 0.5 kg/ha in the efficacy trials. These rates reflect 50%, 75% and 100% of the target dose rate (0.5 kg/ha, the recommended dose of FGG01) in accordance with the EPPO guideline PP 1/225(2) “Minimum effective dose”.

#### 3.2.2.2.1 Results of Minimum effective dose on oilseed rape (BRSNN) - *Sclerotinia sclerotiorum* (SCLESC)

The label claim for this use is summarised in Table 3.2-17.

**Table 3.2-17: Label claim for oilseed rape against *Sclerotinia sclerotiorum***

Crops	Target	Country	Dossier strategy	Application timing	No. of applications	Application volume L/ha	Dose rate kg product/ha
Oilseed rape (BRSNN)	<i>Sclerotinia sclerotiorum</i> (SCLESC)	AT, BE, CZ, HU, RO, SK	Bridging	BBCH 57-69	1	100-300	0.5
Oilseed rape (BRSNN)	<i>Sclerotinia sclerotiorum</i> (SCLESC)	NL	Full package (minor use)	BBCH 57-69	1	100-300	0.5
Oilseed rape (BRSNN)	<i>Sclerotinia sclerotiorum</i> (SCLESC)	PL	Full package (major use)	BBCH 57-69	1	100-300	0.5

In Austria, Belgium, Czech Republic, Hungary, Romania and Slovakia, the reference product CANTUS (also known under the name of PROPATAN in Czech Republic; AMM: 4889-1) has been authorised for use as a fungicide on oilseed rape against *Sclerotinia sclerotiorum* for more than 10 years and the use is not protected. In a context to demonstrate the comparability between CANTUS and FGG01, no minimum effective dose trials are needed.

However, in the Netherlands CANTUS is not authorised for this use (but as minor use), and in Poland, it is authorised for this use but data is still protected and therefore, a study of the dose to support the

registration in Poland is necessary. Concerning the Netherlands, due to the fact that it is a minor use, a study of the dose is not necessary. Therefore, only in Poland when this use is a major use, a full data package is required in this context.

A total of 7 valid efficacy trials were carried out to evaluate the minimum effective dose of FGG01, in the North-East EPPO climatic zone (Poland) in 2021 and 2023 at 0.25, 0.375 and 0.5 kg/ha for the control of *Sclerotinia sclerotiorum* on oilseed rape.

A summary of all trials generating data for minimum effective dose on oilseed rape against *Sclerotinia sclerotiorum* is presented in Table 3.2-18.

**Table 3.2-18: Overview of efficacy trials generating data on minimum effective dose - Oilseed rape - *Sclerotinia sclerotiorum***

Nb. of trials	Crop	Target	Year	Country	EPPO climatic zone	Tested rates in trials
3 trials	Winter oilseed rape	SCLESC	2021	Poland	North-East	0.25, 0.375 and <b>0.5 kg/ha</b>
4 trials	Winter oilseed rape	SCLESC	2023	Poland	North-East	0.25, 0.375 and <b>0.5 kg/ha</b>

#### **A. Results of Minimum effective dose on oilseed rape (BRSNN) - *Sclerotinia sclerotiorum* (SCLESC) - North-East EPPO zone**

Against *Sclerotinia sclerotiorum*, a total of 7 valid efficacy trials were carried out to confirm the requested dose of FGG01. These trials were carried out in 2021 and 2023 in the North-East EPPO climatic zone in Poland (7 trials).

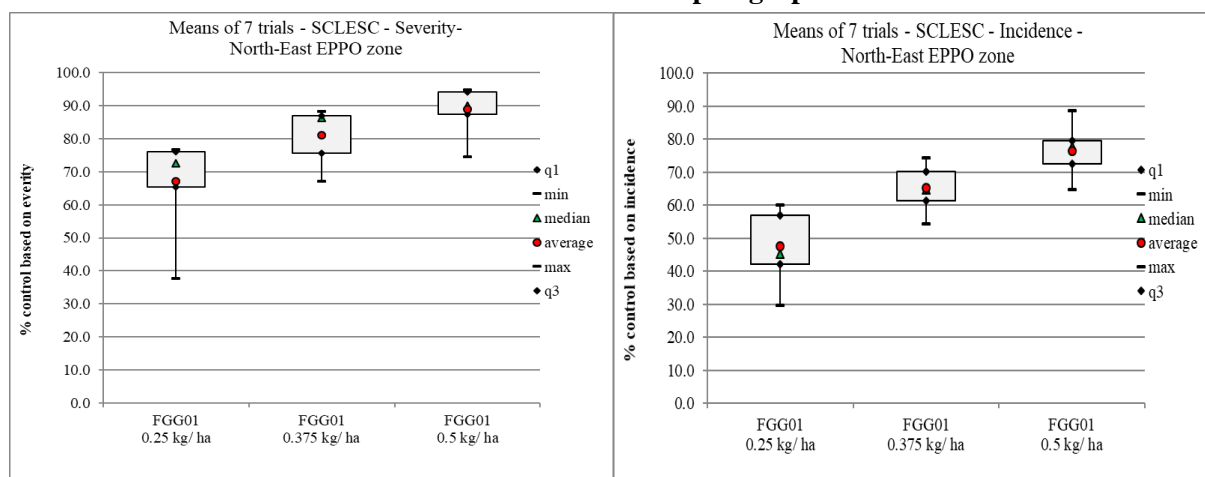
Table 3.2-19 presents a summary of the results of minimum effective dose and Figure 3.2-5 represents the minimum effective dose in box plot graphics against *Sclerotinia sclerotiorum*.

**Table 3.2-19: Summary results: minimum effective dose of FGG01 - Oilseed rape - SCLESC - North-East EPPO zone - Assessment at BBCH 79-85**

Parts	Parameters	EPPO climatic zone	No. of trials	Days after application	Untreated control			FGG01 0.25 kg/ha				FGG01 0.375 kg/ha				FGG01 0.50 kg/ha				No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at 0.5 kg/ha vs.	
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	FGG01 at 0.25 kg/ha	FGG01 at 0.375 kg/ha
STEM	Severity (%)	North-East	7	[42-67 DA-A]	<b>31.6</b>	14.8	66.9	<b>67.1</b>	37.7	76.7	12.8	<b>81.0</b>	67.2	88.2	7.6	<b>89.0</b>	74.5	94.9	6.7	6> ; 1= ; 0<	5> ; 2= ; 0<
	Incidence (%)	North-East	7	[42-67 DA-A]	<b>51.4</b>	31.0	89.0	<b>47.5</b>	29.6	60.0	<b>10.2</b>	<b>65.2</b>	54.3	74.3	6.7	<b>76.5</b>	64.6	88.6	7.0	6> ; 1= ; 0<	6> ; 1= ; 0<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

**Figure 3.2-5 Minimum effective dose of FGG01 - Oilseed rape - SCLESC - Disease severity and incidence on stems - North-East EPPO zone - Box plot graphics**



In the North-East EPPO climatic zone, on severity on stem at BBCH 79-85, in 7 valid efficacy trials, the infestation in untreated plot reached up to 32%, ranging from 15% to 67% of severity. FGG01 demonstrated a clear dose response between the rate of 0.5 kg/ha and both lower dose rates (0.25 kg/ha and 0.375 kg/ha). The mean efficacy increased depending on the dose rate of FGG01. Indeed, on disease severity, FGG01 applied at 0.5 kg/ha showed better level of control compared to the lower tested doses 0.25 kg/ha and 0.375 kg/ha (respectively 89% vs. 67% and 81% mean control) for the control of SCLESC. In addition, this difference was statistically significant in 6 out of 7 trials between FGG01 applied at 0.5 kg/ha and FGG01 applied at 0.25 kg/ha and also statistically significant between FGG01 at 0.5 kg/ha and FGG01 at 0.375 kg/ha in 5 out of 7 trials.

On disease incidence on stem at BBCH 79-85, in 7 valid efficacy trials, the infestation in untreated plot reached up to 51%, ranging from 31% to 89% of incidence. FGG01 demonstrated a clear dose response between the rate of 0.5 kg/ha and both lower dose rates (0.25 kg/ha and 0.375 kg/ha). The mean efficacy increased depending on the dose rate of FGG01. Indeed, on disease incidence, FGG01 applied at 0.5 kg/ha showed better level of control compared to the lower tested doses 0.25 kg/ha and 0.375 kg/ha (respectively 77% vs. 65% and 48% mean control) for the control of SCLESC. In addition, this difference was statistically significant in 6 out of 7 trials between FGG01 applied at 0.5 kg/ha and FGG01 applied at 0.25 kg/ha and 0.375 kg/ha.

Moreover, according to Standard Deviation data and box plot graphics, the difference between the dose rates was characterised by a better homogeneity of control for the highest rate of 0.5 kg/ha compared to the lower rates.

**Therefore, according to the efficacy trials results, the minimum effective dose rate of FGG01 for the control of *Sclerotinia sclerotiorum* (SCLESC) in oilseed rape crop is confirmed at 0.5 kg/ha in the North-East EPPO climatic zone.**

### 3.2.2.2 Results of Minimum effective dose on oilseed rape (BRSNN) - *Alternaria brassicae* (ALTEBA) - Maritime EPPO zone

The label claim for this use is summarised in Table 3.2-20.

**Table 3.2-20: Label claim for oilseed rape against *Alternaria sp.***

Crops	Target	Country	Dossier strategy	Application timing	No. of applications	Application volume L/ha	Dose rate kg product/ha
Oilseed rape (BRSNN)	<i>Alternaria sp.</i> (ALTESP)	AT, BE, CZ	Bridging	BBCH 57-69	1	100-300	0.5
Oilseed rape (BRSNN)	<i>Alternaria sp.</i> (ALTESP)	NL	Full package (minor use)	BBCH 57-69	1	100-300	0.5
Oilseed rape (BRSNN)	<i>Alternaria sp.</i> (ALTESP)	SK, HU, RO	Bridging/ Extrapolation	BBCH 57-69	1	100-300	0.5

In Austria, Belgium and Czech Republic, Hungary, Romania and Slovakia the reference product CANTUS (also known under the name of PROPATAN in Czech Republic; AMM: 4889-1) has been authorised for use as a fungicide on oilseed rape against *Alternaria sp.* for more than 10 years and the use is not protected. In a context to demonstrate the comparability between CANTUS and FGG01, no minimum effective dose trials are needed.

However, in the Netherlands CANTUS is not authorised for this use, but it is a minor use and therefore a study of the dose is not necessary.

### 3.2.2.2.3 Results of Minimum effective dose on oilseed rape (BRSNN) - *Plenodomus lingam* (LEPTMA)

The label claim for this use is summarised in Table 3.2-21.

**Table 3.2-21: Label claim for oilseed rape against *Plenodomus lingam***

Crops	Target	Country	Dossier strategy	Application timing	No. of applications	Application volume L/ha	Dose rate kg product/ha
Oilseed rape (BRSNN)	<i>Plenodomus lingam</i> (LEPTMA)	HU, RO, SK	Bridging	BBCH 13-57	1	100-300	0.5
Oilseed rape (BRSNN)	<i>Plenodomus lingam</i> (LEPTMA)	PL	Full package (major use)	BBCH 13-57	1	100-300	0.5
Oilseed rape (BRSNN)	<i>Plenodomus lingam</i> (LEPTMA)	AT, CZ	Bridging/ Extrapolation	BBCH 13-57	1	100-300	0.5

In Austria, Czech Republic, Hungary, Romania and Slovakia, the reference product CANTUS (also known under the name of PROPATAN in Czech Republic; AMM: 4889-1) has been authorised for use as a fungicide on oilseed rape against *Plenodomus lingam* for more than 10 years and the use is not protected. In a context to demonstrate the comparability between CANTUS and FGG01, no minimum effective dose trials are needed.

However, in Poland, CANTUS is authorised for this use but data is still protected and therefore, a study of the dose is necessary, so a full data package is required in this context.

A total of 12 valid efficacy trials were carried out to evaluate the minimum effective dose of FGG01, 9 trials in the North-East (Poland) and 3 trials in the South-East (use in this case as supportive data) EPPO climatic zones between 2021 and 2023 at 0.25, 0.375 and 0.5 kg/ha for the control of *Plenodomus lingam* on oilseed rape.

A summary of all trials generating data on oilseed rape against *Plenodomus lingam* is presented in Table 3.2-22.

**Table 3.2-22: Overview of efficacy trials generating data on minimum effective dose - Oilseed rape - *Plenodomus lingam***

Nb. of trials	Crop	Target	Year	Country	EPPO climatic zone	Tested rates in trials
3 trials	Oilseed rape	LEPTMA	2021	PL	North-East	0.25, 0.375 and <b>0.5 kg/ha</b>
2 trials	Oilseed rape	LEPTMA	2022	PL	North-East	0.25, 0.375 and <b>0.5 kg/ha</b>
4 trials	Oilseed rape	LEPTMA	2023	PL	North-East	0.25, 0.375 and <b>0.5 kg/ha</b>
3 trials	Oilseed rape	LEPTMA	2021	HU	South-East	0.25, 0.375 and <b>0.5 kg/ha</b>

**A. Results of Minimum effective dose on oilseed rape (BRSNN) - *Plenodomus lingam* (LEPTMA) - North-East EPPO zone**

Against *Plenodomus lingam*, a total of 9 valid efficacy trials were carried out to confirm the requested dose of FGG01. These trials were carried out between 2021 and 2023 in the North-East EPPO climatic zone in Poland (9 trials).

Table 3.2-23 presents a summary of the results of minimum effective dose against *Plenodomus lingam*.

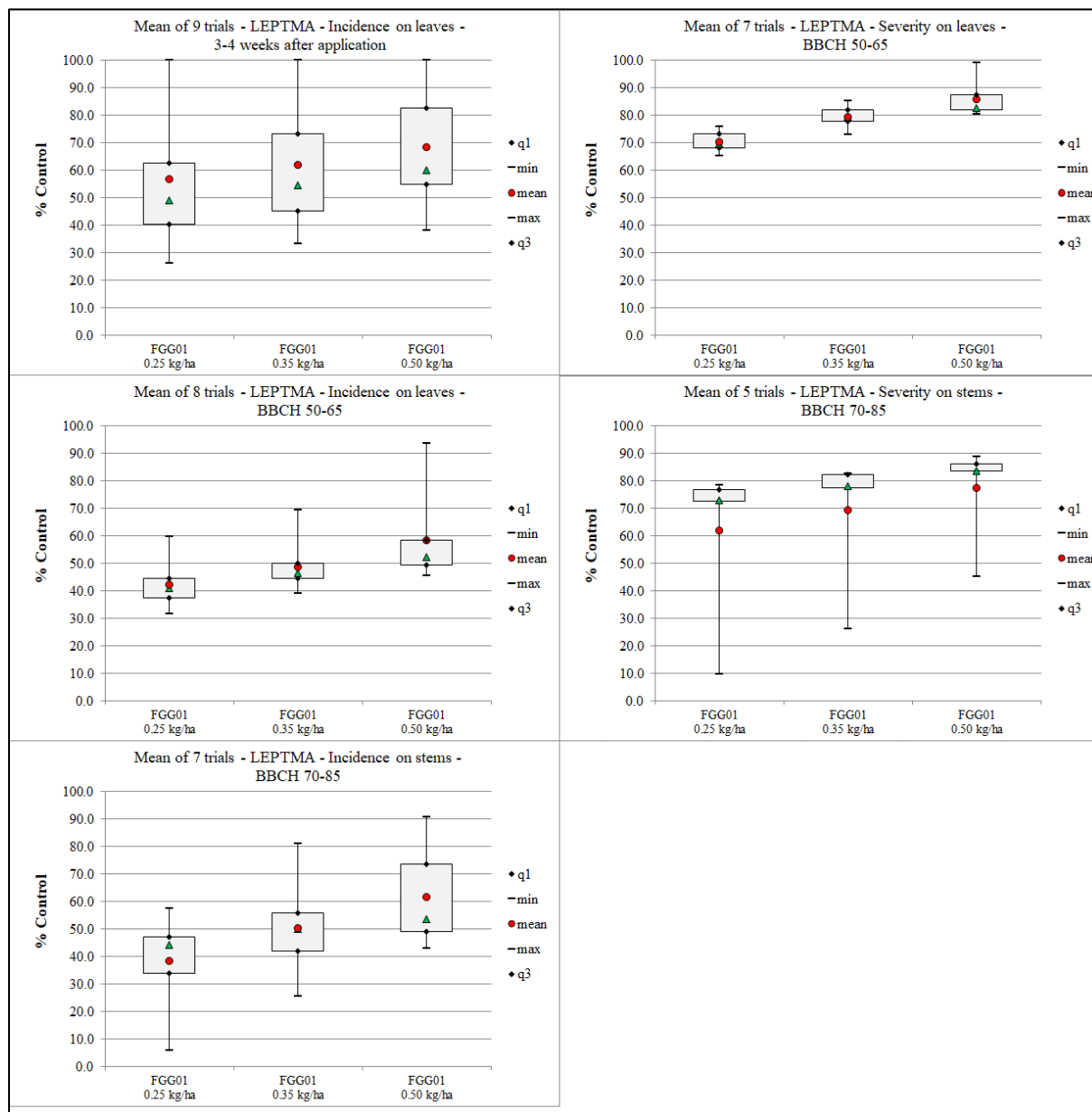
**Table 3.2-23: Summary results: minimum effective dose of FGG01 - Oilseed rape - LEPTMA - North-East EPPO zone**

Assessment	No. of applications	Parts	Parameters	EPPO climatic zone	No. of trials	Days after application	Untreated control			FGG01 0.25 kg/ha				FGG01 0.375 kg/ha				FGG01 0.5 kg/ha				No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at 0.5 kg/ha vs.	
							Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	FGG01 at 0.25 kg/ha	FGG01 at 0.375 kg/ha
3-4 weeks after application	1 application	LEAF	Incidence (%)	North-East	9	[20-28 DA-A]	42.1	5.0	75.0	56.8	26.2	100.0	25.0	62.1	33.3	100.0	23.6	68.5	38.1	100.0	21.2	3> ; 6= ; 0<	2> ; 7= ; 0<
Assessment at BBCH 50-65	1 application	LEAF	Severity (%)	North-East	7	[166-209 DA-A]	7.4	4.9	8.5	70.4	65.2	75.7	3.7	79.5	73.0	85.1	3.7	85.8	80.2	99.1	6.1	7> ; 0= ; 0<	2> ; 5= ; 0<
		LEAF	Incidence (%)	North-East	8	[166-209 DA-A]	75.3	62.0	94.0	42.3	31.6	59.7	8.1	48.8	39.2	69.4	8.6	58.3	45.6	93.6	15.2	5> ; 3= ; 0<	2> ; 6= ; 0<
	2 applications	LEAF	Severity (%)	North-East	1	28 DA-B	7.8	-	-	48.0	-	-	-	83.3	-	-	-	88.4	-	-	-	1> ; 0= ; 0<	1> ; 0= ; 0<
		LEAF	Incidence (%)	North-East	1	29 DA-B	91.0	-	-	13.2	-	-	-	49.5	-	-	-	58.2	-	-	-	1> ; 0= ; 0<	1> ; 0= ; 0<
Assessment at BBCH 70-85	1 application	STEM	Severity (%)	North-East	5	[256-269 DA-A]	10.7	7.4	13.8	62.1	9.6	78.3	26.3	69.3	26.1	82.6	21.7	77.5	45.2	88.7	16.2	3> ; 2= ; 0<	0> ; 5= ; 0<
		STEM	Incidence (%)	North-East	7	[245-269 DA-A]	26.7	13.0	51.0	38.5	5.9	57.5	15.6	50.3	25.5	81.1	16.2	61.8	43.1	90.6	16.5	4> ; 3= ; 0<	1> ; 6= ; 0<
	2 applications	STEM	Severity (%)	North-East	2	[69-73 DA-B]	11.3	11.2	11.3	62.4	61.6	63.3	0.9	73.6	70.5	76.7	3.1	84.0	79.7	88.2	4.3	2> ; 0= ; 0<	1> ; 1= ; 0<
		STEM	Incidence (%)	North-East	2	[69-73 DA-B]	59.5	59.0	60.0	44.5	39.0	50.0	5.5	55.5	55.0	55.9	0.5	66.4	66.1	66.7	0.3	1> ; 1= ; 0<	0> ; 2= ; 0<
		LEAF	Severity (%)	North-East	1	73 DA-B	21.2	-	-	66.4	-	-	-	80.0	-	-	-	86.5	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<
		LEAF	Incidence (%)	North-East	1	73 DA-B	97.0	-	-	45.4	-	-	-	64.9	-	-	-	68.0	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.



**Figure 3.2 - 6 Minimum effective dose of FGG01 - Oilseed rape - LEPTMA - Disease severity and incidence on leaves and stems - North-East EPPO zone - Box plot graphics**



### **Assessment at 3-4 weeks after application**

In the North-East EPPO climatic zone, on disease incidence on leaves, in 9 valid efficacy trials with one application, the infestation in untreated plot reached up to 42%, ranging from 5% to 75% of incidence. FGG01 demonstrated a clear dose response between the rate of 0.5 kg/ha and both lower dose rates (0.25 kg/ha and 0.375 kg/ha). The mean efficacy increased depending on the dose rate of FGG01. Indeed, FGG01 applied at 0.5 kg/ha showed better level of control compared to the lower tested doses 0.25 kg/ha and 0.375 kg/ha (respectively 69% vs. 57% and 62% mean control) for the control of LEPTMA. In addition, this difference was statistically significant in 3 out of 9 trials between FGG01 applied at 0.5 kg/ha and FGG01 applied at 0.25 kg/ha and also statistically significant between FGG01 at 0.5 kg/ha and FGG01 at 0.375 kg/ha in 2 out of 9 trials.

### **Assessment at BBCH 50-65**

On disease severity on leaves, in 7 valid efficacy trials with one application, the infestation in untreated plot reached up to 7%, ranging from 5% to 9% of severity. FGG01 demonstrated a clear dose response between the rate of 0.5 kg/ha and both lower dose rates (0.25 kg/ha and 0.375 kg/ha). The mean efficacy increased depending on the dose rate of FGG01. Indeed, FGG01 applied at 0.5 kg/ha showed better level of control compared to the lower tested doses 0.25 kg/ha and 0.375 kg/ha (respectively 86% vs. 70% and 80% mean control) for the control of LEPTMA. In addition, this difference was statistically significant in 7 out of 7 trials between FGG01 applied at 0.5 kg/ha and FGG01 applied at 0.25 kg/ha and also statistically significant between FGG01 at 0.5 kg/ha and FGG01 at 0.375 kg/ha in 2 out of 7 trials.

On disease incidence on leaves, in 8 valid efficacy trials with one application, the infestation in untreated plot reached up to 75%, ranging from 62% to 94% of incidence. FGG01 demonstrated a clear dose response between the rate of 0.5 kg/ha and both lower dose rates (0.25 kg/ha and 0.375 kg/ha). The mean efficacy increased depending on the dose rate of FGG01. Indeed, FGG01 applied at 0.5 kg/ha showed better level of control compared to the lower tested doses 0.25 kg/ha and 0.375 kg/ha (respectively 58% vs. 42% and 49% mean control) for the control of LEPTMA. In addition, this difference was statistically significant in 5 out of 8 trials between FGG01 applied at 0.5 kg/ha and FGG01 applied at 0.25 kg/ha and also statistically significant between FGG01 at 0.5 kg/ha and FGG01 at 0.375 kg/ha in 2 out of 8 trials.

On disease severity on leaves, in 1 single trial with 2 applications, the infestation in untreated plot reached up to 8% of severity. FGG01 demonstrated a clear dose response between the rate of 0.5 kg/ha and both lower dose rates (0.25 kg/ha and 0.375 kg/ha). The efficacy increased depending on the dose rate of FGG01. Indeed, FGG01 applied at 0.5 kg/ha showed better level of control compared to the lower tested doses 0.25 kg/ha and 0.375 kg/ha (respectively 88% vs. 48% and 83% control) for the control of LEPTMA. In addition, this difference was statistically significant between FGG01 applied at 0.5 kg/ha and FGG01 applied at 0.25 kg/ha and at 0.375 kg/ha.

The same trend was observed on disease incidence on leaves, where the infestation in untreated plot reached up to 91% of incidence. FGG01 demonstrated a clear dose response between the rate of 0.5 kg/ha and both lower dose rates (0.25 kg/ha and 0.375 kg/ha). The efficacy increased depending on the dose rate of FGG01. Indeed, FGG01 applied at 0.5 kg/ha showed better level of control compared to the lower tested doses 0.25 kg/ha and 0.375 kg/ha (respectively 58% vs. 13% and 50% control) for the control of LEPTMA. In addition, this difference was statistically significant between FGG01 applied at 0.5 kg/ha and FGG01 applied at 0.25 kg/ha and at 0.375 kg/ha.

### **Assessment at BBCH 70-85**

On disease severity on stems, on trials with a single application, in 5 valid efficacy trials, the infestation in untreated plot reached up to 11%, ranging from 7% to 14% of severity. FGG01 demonstrated a clear dose response between the rate of 0.5 kg/ha and both lower dose rates (0.25 kg/ha and 0.375 kg/ha). The efficacy increased depending on the dose rate of FGG01. Indeed, FGG01 applied at 0.5 kg/ha showed better level of control compared to the lower tested doses 0.25 kg/ha and 0.375 kg/ha (respectively 78% vs. 69% and 62% control) for the control of LEPTMA. In addition, this difference was statistically significant in 3 out of 5 trials between FGG01 applied at 0.5 kg/ha and FGG01 applied at 0.25 kg/ha.

On disease incidence on stems, on trials with a single application, in 7 valid efficacy trials, the infestation in untreated plot reached up to 27%, ranging from 13% to 51% of incidence. FGG01 demonstrated a clear dose response between 0.5 kg/ha and both lower dose rates (0.25 kg/ha and 0.375 kg/ha). The mean efficacy increased depending on the dose rate of FGG01. Indeed, FGG01 applied at 0.5 kg/ha showed better level of control compared to the lower tested doses 0.25 kg/ha and 0.375 kg/ha (respectively 62% vs. 39% and 50% mean control) for the control of LEPTMA. In addition, this difference was statistically significant in 4 out of 7 trials between FGG01 applied at 0.5 kg/ha and FGG01 applied at 0.25 kg/ha and also statistically significant between FGG01 at 0.5 kg/ha and FGG01 at 0.375 kg/ha in 1 out of 7 trials.

On diseases severity on stems, on trials with 2 applications, in 2 valid efficacy trials, the infestation in untreated plot reached up to 11% of severity. FGG01 demonstrated a clear dose response between 0.5 kg/ha and both lower dose rates (0.25 kg/ha and 0.375 kg/ha). The mean efficacy increased depending on the dose rate of FGG01. Indeed, FGG01 applied at 0.5 kg/ha showed better level of control compared to the lower tested doses 0.25 kg/ha and 0.375 kg/ha (respectively 84% vs. 62% and 74% control) for the control of LEPTMA. In addition, this difference was statistically significant in 2 out of 2 trials between FGG01 applied at 0.5 kg/ha and FGG01 at 0.25 kg/ha and also statistically significant between FGG01 at 0.5 kg/ha and FGG01 at 0.375 kg/ha in 1 out of 2 trials.

On disease incidence on stems, in 2 valid efficacy trials with 2 applications, the infestation in untreated plot reached up to 60%, ranging from 59% to 60% of incidence. FGG01 demonstrated a clear dose response between 0.5 kg/ha and both lower dose rates (0.25 kg/ha and 0.375 kg/ha). The mean efficacy increased depending on the dose rate of FGG01. Indeed, FGG01 applied at 0.5 kg/ha showed better level of control compared to the lower tested doses 0.25 kg/ha and 0.375 kg/ha (respectively 66% vs. 45% and 56% mean control) for the control of LEPTMA. In addition, this difference was significant in 1 out of 2 trials between FGG01 applied at 0.5 kg/ha and FGG01 applied at 0.25 kg/ha.

On disease severity and incidence on leaves, these results are confirmed in 1 efficacy trial with 2 applications, where the same trend of dose response was observed.

Moreover, according to Standard Deviation data and box plot graphics, the difference between the dose rates was characterised by a better homogeneity of control for the highest rate of 0.5 kg/ha compared to the lower rates.

**Therefore, according to the efficacy trials results, the minimum effective dose rate of FGG01 for the control of *Plenodomus lingam* (LEPTMA) in oilseed rape is confirmed at 0.5 kg/ha in the North-East EPPO zone.**

## **B. Results of Minimum effective dose on oilseed rape (BRSNN) - *Plenodomus lingam* (LEPTMA) - South-East EPPO zone - Supportive data**

Against *Plenodomus lingam*, a total of 3 valid efficacy trials were carried out to confirm the requested dose of FGG01. These trials were carried out in 2021 in the South-East EPPO climatic zone in Hungary (3 trials).

Table 3.2-24 presents a summary of the results of minimum effective dose against *Plenodomus lingam*.

**Table 3.2-24: Summary results: minimum effective dose of FGG01 - Oilseed rape - LEPTMA - South-East EPPO zone**

Assessment	Parts	Parameters	EPPO climatic zone	No. of trials	Days after application	Untreated control			FGG01 0.25 kg/ha				FGG01 0.375 kg/ha				FGG01 0.5 kg/ha				No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at 0.5 kg/ha vs.	
						Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	FGG01 at 0.25 kg/ha	FGG01 at 0.375 kg/ha
3-4 weeks after application	PLANT	Severity (%)	South-East	3	[27-36 DA-A]	15.1	6.1	29.3	37.7	24.8	58.6	14.9	56.9	47.6	69.5	9.2	75.5	61.0	8.2	10.4	3> ; 0= ; 0<	2> ; 1= ; 0<
		Incidence (%)	South-East	3	[27-36 DA-A]	70.0	69.0	71.0	18.7	7.1	36.2	12.6	31.1	21.1	47.8	11.9	50.1	35.2	63.8	11.7	2> ; 1= ; 0<	2> ; 1= ; 0<
Assessment at BBCH 50-65	PLANT	Severity (%)	South-East	2	[177-191 DA-A]	43.6	38.8	48.4	29.9	18.3	41.5	11.6	60.9	51.8	70.0	9.1	82.3	79.4	85.2	2.9	2> ; 0= ; 0<	2> ; 0= ; 0<
		Incidence (%)	South-East	3	[177-200 DA-A]	63.3	31.0	86.0	29.6	4.1	58.1	22.1	53.9	24.7	87.1	25.7	64.0	37.0	96.8	24.8	2> ; 1= ; 0<	0> ; 3= ; 0<
Assessment at BBCH 70-85	PLANT	Severity (%)	South-East	1	250 DA-A	6.1	-	-	58.0	-	-	-	78.5	-	-	-	89.9	-	-	-	1> ; 0= ; 0<	1> ; 0= ; 0<
		Incidence (%)	South-East	3	[240-250 DA-A]	61.7	31.0	87.0	46.9	39.1	61.3	10.2	51.4	16.1	90.3	30.4	74.0	53.7	93.5	16.3	1> ; 2= ; 0<	1> ; 2= ; 0<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

### **Assessment at 3-4weeks after application**

In the South-East EPPO climatic zone, on disease severity on plants, in 3 valid efficacy trials, the infestation in untreated plot reached up to 15%, ranging from 6% to 29% of severity. FGG01 demonstrated a clear dose response between the rate of 0.5 kg/ha and both lower dose rates (0.25 kg/ha and 0.375 kg/ha). The mean efficacy increased depending on the dose rate of FGG01. Indeed, FGG01 applied at 0.5 kg/ha showed better level of control compared to the lower tested doses 0.25 kg/ha and 0.375 kg/ha (respectively 76% vs. 38% and 57% mean control) for the control of LEPTMA. In addition, this difference was statistically significant in all trials between FGG01 applied at 0.5 kg/ha and FGG01 applied at 0.25 kg/ha and in 2 out of 3 trials between FGG01 applied at 0.5 kg/ha and FGG01 applied at 0.375 kg/ha.

On disease incidence on plants, in 3 valid efficacy trials, the infestation in untreated plot reached up to 70%, ranging from 69% to 71% of incidence. FGG01 demonstrated a clear dose response between the rate of 0.5 kg/ha and both lower dose rates (0.25 kg/ha and 0.375 kg/ha). The mean efficacy increased depending on the dose rate of FGG01. Indeed, FGG01 applied at 0.5 kg/ha showed better level of control compared to the lower tested doses 0.25 kg/ha and 0.375 kg/ha (respectively 50% vs. 19% and 31% mean control) for the control of LEPTMA. In addition, this difference was statistically significant in 2 out of 3 trials between FGG01 applied at 0.5 kg/ha and FGG01 applied at 0.25 kg/ha and 0.375 kg/ha in 2 out of 3 trials.

### **Assessment at BBCH 50-65**

On disease severity on plants, in 2 valid efficacy trials, the infestation in untreated plot reached up to 44%, ranging from 39% to 48% of severity. FGG01 demonstrated a clear dose response between the rate of 0.5 kg/ha and both lower dose rates (0.25 kg/ha and 0.375 kg/ha). The mean efficacy increased depending on the dose rate of FGG01. Indeed, FGG01 applied at 0.5 kg/ha showed better level of control compared to the lower tested doses 0.25 kg/ha and 0.375 kg/ha (respectively 82% vs. 30% and 61% mean control) for the control of LEPTMA. In addition, this difference was statistically significant in all trials between FGG01 applied at 0.5 kg/ha and FGG01 applied at 0.25 kg/ha and at 0.375 kg/ha.

On disease incidence on plants, in 3 valid efficacy trials, the infestation in untreated plot reached up to 63%, ranging from 31% to 86% of incidence. FGG01 demonstrated a clear dose response between the rate of 0.5 kg/ha and both lower dose rates (0.25 kg/ha and 0.375 kg/ha). The mean efficacy increased depending on the dose rate of FGG01. Indeed, FGG01 applied at 0.5 kg/ha showed better level of control compared to the lower tested doses 0.25 kg/ha and 0.375 kg/ha (respectively 64% vs. 30% and 54% mean control) for the control of LEPTMA. In addition, this difference was statistically significant in 2 out of 3 trials between FGG01 applied at 0.5 kg/ha and FGG01 applied at 0.25 kg/ha.

### **Assessment at BBCH 70-85**

On disease severity on plants, in 1 single valid trial, the infestation in untreated plot reached up to 6% of severity. FGG01 demonstrated a clear dose response between the rate of 0.5 kg/ha and both lower dose rates (0.25 kg/ha and 0.375 kg/ha). The efficacy increased depending on the dose rate of FGG01. Indeed, FGG01 applied at 0.5 kg/ha showed better level of control compared to the lower tested doses 0.25 kg/ha and 0.375 kg/ha (respectively 90% vs. 58% and 79% control) for the control of LEPTMA. In addition, this difference was statistically significant between FGG01 applied at 0.5 kg/ha and FGG01 applied at 0.25 kg/ha and at 0.375 kg/ha.

On disease incidence on plants, in 3 valid efficacy trials, the infestation in untreated plot reached up to 62%, ranging from 31% to 87% of incidence. FGG01 demonstrated a clear dose response between the rate of 0.5 kg/ha and both lower dose rates (0.25 kg/ha and 0.375 kg/ha). The mean efficacy increased depending on the dose rate of FGG01. Indeed, FGG01 applied at 0.5 kg/ha showed better level of control compared to the lower tested doses 0.25 kg/ha and 0.375 kg/ha (respectively 74% vs. 47% and 51%

mean control) for the control of LEPTMA. In addition, this difference was statistically significant in 1 out of 3 trials between FGG01 applied at 0.5 kg/ha and FGG01 applied at 0.25 kg/ha and 0.375 kg/ha.

Moreover, according to Standard Deviation data, in general, the difference between the dose rates was characterised by a better homogeneity of control for the highest rate of 0.5 kg/ha compared to the lower rates.

**Therefore, according to the efficacy trials results, the minimum effective dose rate of FGG01 for the control of *Plenodomus lingam* (LEPTMA) in oilseed rape is confirmed at 0.5 kg/ha in the South-East EPPO zone.**

### 3.2.2.3 Results of Minimum effective dose on grapevine (VITVI)

In grapevine, fungicides with boscalid in solo ready mixes have been developed and approved for the control of *Botrytis cinerea* (BOTRCI) and *Erysiphe necator* (UNCINE) on grapevine.

#### 3.2.2.3.1 Results of Minimum effective dose on grapevine - *Botrytis cinerea* (BOTRCI)

The label claim for this use is summarised in Table 3.2-25.

**Table 3.2-25: Label claim for grapevine against *Botrytis cinerea***

Crops	Target	Country	Dossier strategy	Application timing	No. of applications	Application volume L/ha	Dose rate kg product/ha
Grapevine (wine and table) (VITVI)	<i>Botrytis cinerea</i> (BOTRCI)	AT, BE, CZ, SL	Bridging	BBCH 60-85	1	100-1000	1.0 kg/ha 0.72 kg/1000 m <sup>2</sup> LWA

The dose rate of 0.72 kg/10000 m<sup>2</sup> LWA has been determined based upon conversion of the proposed ground-based dose rate of 1.0 kg/ha and a typical leaf wall area of grapevine in many Member States in the Central zone. In the trials, a conversion factor of 1.4 was used between the dose expressions in ground area and the LWA concept. Although it is accepted that there can be a variation in leaf wall area between cropping systems, regions, and countries, it is considered that a leaf wall area of 10000 m<sup>2</sup> is a typical overall theoretical value for the conversion.

For further details on the dose expression in the trials, please refer to the efficacy part in point 3.2.3.2.

For this use, this dossier is intended to demonstrate the comparability between the reference product CANTUS and FGG01. CANTUS has been authorised in Austria, Belgium, Czech Republic and Slovenia for use as a fungicide on grapevine against *Botrytis cinerea* for more than 10 years. In this context, no minimum effective dose trials are needed.

#### 3.2.2.3.2 Results of Minimum effective dose on grapevine - *Erysiphe necator* (UNCINE)

The label claim for this use is summarised in Table 3.2-26.

**Table 3.2-26: Label claim for grapevine against *Erysiphe necator***

Crops	Target	Country	Dossier strategy	Application timing	No. of applications	Application volume L/ha	Dose rate kg product/ha
Grapevine (wine and table) (VITVI)	<i>Erysiphe necator</i> (UNCINE)	AT, BE, CZ, SL	Full data package (major use)	BBCH 15-81	3	100-1000	0.2 kg/ha
		PL	Full data package (minor use)				0.02 kg/100 L 0.14 kg/10000 m <sup>2</sup> LWA

The dose rate of 0.14 kg/10000 m<sup>2</sup> LWA has been determined based upon conversion of the proposed ground-based dose rate of 0.2 kg/ha and a typical leaf wall area of grapevine in many Member States in the Central zone. In the trials, a conversion factor of 1.4 was used between the dose expressions in ground area and the LWA concept. Although it is accepted that there can be a variation in leaf wall area between cropping systems, regions, and countries, it is considered that a leaf wall area of 10000 m<sup>2</sup> is a typical overall theoretical value for the conversion.

The dose rate of 0.02 kg/100 L has been determined based upon conversion of the proposed ground-based dose rate of 0.2 kg/ha with a spray volume of 1000 L/ha as a standard in many Member States in the Central zone. Although it is accepted that there can be adjustment in spray volume according to the crop stage, increasing with the seasonal development, and depending on the spraying equipment, it is considered that a spray volume of 1000 L/ha is a typical overall theoretical value for the conversion.

For further details on the dose expression in the trials, please refer to the efficacy part in point 3.2.3.2.

In the countries claimed for authorization on grapevine against *Erysiphe necator*, the reference product CANTUS is not authorised for this use and therefore, a study of the dose is necessary on grapevine against *Erysiphe necator*. Except in Poland, as this is a major use in all of these countries, a full data package is required and was generated. No data are available on the North-East and South-East EPPO climatic zones, which are concerned by Poland (minor use) and Slovenia respectively. Nevertheless, the use in both countries can be supported with the available data package in the Maritime EPPO zone, as these are countries bordering Germany and Austria, 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.

In order to justify the choice of the dose rate of FGG01 for the control of *Erysiphe necator* of grapevine, different dose rates were studied. FGG01 was tested at 0.010, 0.015 and 0.020 kg/100 L and was also tested at 0.07, 0.10 and 0.14 kg/10000 m<sup>2</sup> LWA in the efficacy trials. These rates reflect 50%, 75% and 100% of the target dose rates (0.02 kg/100 L and 0.14 kg/10000 m<sup>2</sup> LWA, the full recommended doses of FGG01) in accordance with the EPPO guideline PP 1/225(2) “Minimum effective dose”.

A total of 10 valid efficacy trials were carried out to evaluate the minimum effective dose of FGG01 in the Maritime (Austria and Germany) EPPO climatic zone in 2022 and 2023. 4 trials were carried out at the dose rates of 0.01, 0.015 and 0.02 kg/100 L and 6 trials at the dose rates of 0.07, 0.10 and 0.14 kg/10000 m<sup>2</sup> LWA for the control of *Erysiphe necator* on grapevine.

A summary of all trials generating data on grapevine against *Erysiphe necator* is presented in Table 3.2-27.



**Table 3.2-27: Overview of efficacy trials generating data on minimum effective dose - Grapevine - *Erysiphe necator*.**

Nb. of trials	Crop	Target	Year	Country	EPPO climatic zone	Tested rates in trials
2 trials	Grapevine	UNCINE	2022	DE	Maritime	0.01, 0.015 and <b>0.02 kg/100 L</b>
2 trials	Grapevine	UNCINE	2022	AT	Maritime	0.01, 0.015 and <b>0.02 kg/100 L</b>
3 trials	Grapevine	UNCINE	2023	DE	Maritime	0.07, 0.10, <b>0.14 kg/10000 m<sup>2</sup> LWA</b>
3 trials	Grapevine	UNCINE	2023	AT	Maritime	0.07, 0.10, <b>0.14 kg/10000 m<sup>2</sup> LWA</b>

**A. Results of Minimum effective dose on grapevine - *Erysiphe necator* (UNCINE) - Maritime EPPO zone**

Against grapevine powdery mildew (*Erysiphe necator*) on bunches and leaves, a total of 10 valid efficacy trials were carried out to confirm the requested dose of FGG01 at the doses expressed in kg/100 L and in kg/10000 m<sup>2</sup> LWA. These trials were carried out in 2022 and 2023 in the Maritime EPPO climatic zone in Austria (5 trials) and in Germany (5 trials).

**Results of Minimum effective dose in kg/100 L**

4 valid efficacy trials and at the doses of 0.01, 0.015 and 0.020 kg/100 L were carried out in 2022 in the Maritime EPPO climatic zone in Austria (2 trials) and in Germany (2 trials).

Table 3.2-28 presents a summary of the results of minimum effective dose against UNCINE.

**Table 3.2-28: Summary results: minimum effective dose of FGG01 - Grapevine - UNCINE - Maritime EPPO zone**

Assessment timing	Parts	Parameters	EPPO climatic zone	No. of trials	Untreated control			FGG01 0.01 kg/100 L				FGG01 0.015 kg/100 L				FGG01 0.02 kg/100 L				No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at 0.02 kg/100 L vs.	
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	FGG01 at 0.01 kg/100 L	FGG01 at 0.015 kg/100 L
BBCH 77-89	LEAF	Severity (%)	Maritime	4	29.9	8.3	62.5	67.5	52.6	74.6	8.8	69.2	59.9	74.4	5.8	74.9	62.4	84.2	8.6	0> ; 4= ; 0<	0> ; 4= ; 0<
BBCH 71-79	BUNCH	Severity (%)	Maritime	4	21.1	6.7	44.1	70.1	59.2	80.8	8.9	67.2	54.7	84.5	11.3	79.7	61.5	86.9	10.6	0> ; 4= ; 0<	0> ; 4= ; 0<
BBCH 81-89	BUNCH	Severity (%)	Maritime	4	47.7	21.4	64.8	62.5	43.3	77.5	13.5	58.1	44.0	67.9	8.9	70.3	53.5	76.2	9.7	0> ; 4= ; 0<	0> ; 4= ; 0<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

On disease severity of leaves at BBCH 77-89 assessment timing, in 4 valid efficacy trials, the infestation in untreated plot reached up to 30%, ranging from 8% to 63% of severity. FGG01 demonstrated a clear dose response between 0.02 kg/100 L and both lower dose rates (0.015 kg/100 L and 0.01 kg/100 L). The mean efficacy increased depending on the dose rate of FGG01. Indeed, FGG01 applied at 0.02 kg/100 L showed a better level of control than the lower tested doses 0.01 kg/100 L and 0.015 kg/100 L (respectively 75% vs. 68% and 69% mean control) for the control of UNCINE. Although the dose effect was not highlighted by the statistical analysis, there is a clear numerical trend.

Overall, on disease severity of bunches at BBCH 71-79 assessment timing, in 4 valid efficacy trials, the infestation in untreated plot reached up to 21%, ranging from 7% to 44% of severity. FGG01 demonstrated a clear dose response between 0.02 kg/100 L and both lower dose rates (0.015 kg/100 L and 0.01 kg/100 L). FGG01 applied at 0.02 kg/100 L showed a better level of control than both lower rates (0.01 kg/100 L and 0.015 kg/100 L). Indeed, FGG01 at 0.02 kg/100 L gave 80% mean control, 10 points higher than at 0.01 kg/100 L (70% mean control) and 13 points higher than at 0.015 kg/100 L (67% mean control). Although the dose effect was not highlighted by the statistical analysis, there is a clear numerical trend.

On disease severity of bunches at BBCH 81-89 assessment timing, in 4 valid efficacy trials, the infestation in untreated plot reached up to 48%, ranging from 21% to 65% of severity. FGG01 demonstrated a clear dose response between 0.02 kg/100 L and both lower dose rates (0.015 kg/100 L and 0.01 kg/100 L). FGG01 applied at 0.02 kg/100 L showed a better level of control than both lower rates (0.01 kg/100 L and 0.015 kg/100 L). Indeed, FGG01 at 0.02 kg/100 L gave 70% mean control, 8 points higher than at 0.01 kg/100 L (63% mean control) and 12 points higher than at 0.015 kg/100 L (58% mean control). Although the dose effect was not highlighted by the statistical analysis, there is a clear numerical trend.

**Therefore, according to the efficacy trials results, the minimum effective dose rate of FGG01 for the control of *Erysiphe necator* (UNCINE) in grapevine is confirmed at 0.02 kg/100 L in the Maritime EPPO climatic zone.**

#### **Results of Minimum effective dose in kg/10000 m<sup>2</sup> LWA**

6 valid efficacy trials and at the doses of 0.07, 0.10 and 0.14 kg/10000 m<sup>2</sup> LWA were carried out in 2023 in the Maritime EPPO climatic zone in Austria (3 trials) and in Germany (3 trials).

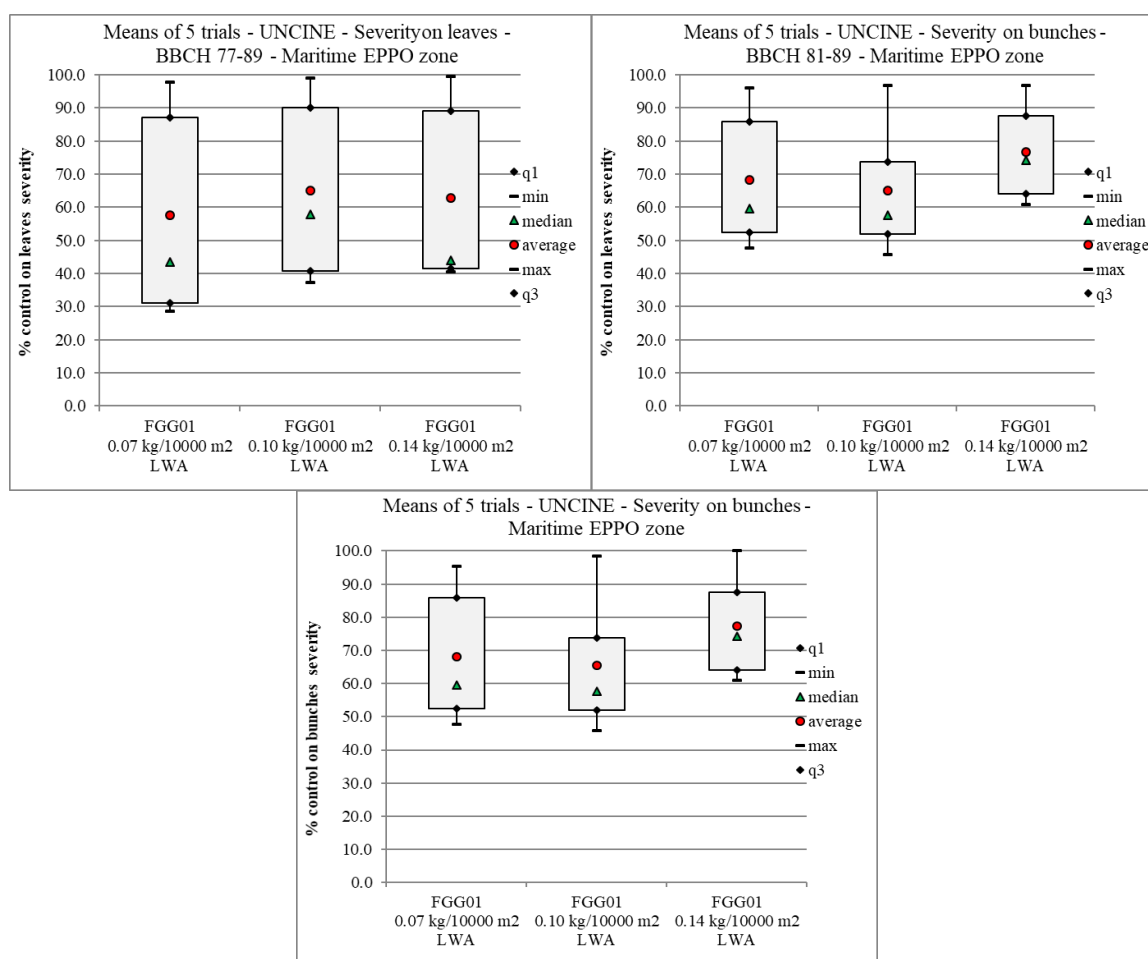
Table 3.2-29 presents a summary of the results of minimum effective dose against UNCINE and Figure 3.2 - 7 represents the minimum effective dose in box plot graphics for severity on leaves at BBCH 77-89 and on bunches at BBCH 81-89.

**Table 3.2-29: Summary results: minimum effective dose of FGG01 - Grapevine - UNCINE - Maritime EPPO zone**

Assessment timing	Parts	Parameters	EPPO climatic zone	No. of trials	Untreated control			FGG01 0.07 kg/10000 m <sup>2</sup> LWA				FGG01 0.10 kg/10000 m <sup>2</sup> LWA				FGG01 0.14 kg/10000 m <sup>2</sup> LWA				No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at 0.14 kg/10000 m <sup>2</sup> LWA vs.	
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	FGG01 at 0.07 kg/10000 m <sup>2</sup> LWA	FGG01 at 0.10 kg/10000 m <sup>2</sup> LWA
BBCH 77-89	LEAF	Severity (%)	Maritime	5	26.7	10.5	57.6	57.5	28.5	97.7	29.1	65.0	37.4	98.9	25.2	62.9	40.4	99.6	25.9	0> ; 5= ; 0<	0> ; 5= ; 0<
BBCH 71-79	BUNCH	Severity (%)	Maritime	2	12.7	10.4	15.0	61.8	38.5	85.0	23.3	65.3	55.5	75.0	9.8	74.9	65.8	84.0	9.1	0> ; 2= ; 0<	0> ; 2= ; 0<
BBCH 81-89	BUNCH	Severity (%)	Maritime	5	24.0	6.4	51.7	68.2	47.8	95.3	18.9	65.5	45.8	98.4	18.9	77.4	60.9	100.0	14.7	0> ; 5= ; 0<	0> ; 5= ; 0<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

**Figure 3.2 - 7 Minimum effective dose of FGG01 - Grapevine - UNCINE - Disease severity on leaves (BBCH 77-89) and on bunches (BBCH 81-89) - Maritime EPPO zone - Box plot graphics**



On disease severity of leaves at BBCH 77-89 assessment timing, in 5 valid efficacy trials, the infestation in untreated plot reached up to 27%, ranging from 11% to 58% of severity. FGG01 demonstrated a dose response between 0.14 kg/10000 m² LWA and the lowest dose of 0.07 kg/10000 m² LWA. Indeed, FGG01 applied at 0.14 kg/10000 m² LWA showed a better level of control than the lower tested dose of 0.07 kg/10000 m² LWA and similar control to the dose of 0.10 kg/10000 m² LWA (respectively 63% vs. 58% and 65% mean control) for the control of UNCINE.

On disease severity of bunches at BBCH 71-79 assessment timing, in 2 valid efficacy trials, the infestation in untreated plot reached up to 13%, ranging from 10% to 15% of severity. FGG01 showed a clear dose response between 0.14 kg/10000 m² LWA and both lower dose rates (0.07 and 0.10 kg/10000 m² LWA). FGG01 applied at 0.14 kg/10000 m² LWA showed a better level of control than both lower rates (0.07 kg/10000 m² LWA and 0.10 kg/10000 m² LWA). Indeed, FGG01 at 0.14 kg/10000 m² LWA gave 75% mean control, 13 points higher than at 0.07 kg/10000 m² LWA (62% mean control) and 10 points higher than at 0.10 kg/10000 m² LWA (65% mean control). Although the dose effect was not highlighted by the statistical analysis, there is a clear numerical trend.

On disease severity of bunches at BBCH 81-89 assessment timing, in 5 valid efficacy trials, the infestation in untreated plot reached up to 24%, ranging from 6% to 52% of severity. FGG01 showed a clear dose response between 0.14 kg/10000 m² LWA and both lower dose rates (0.07 and 0.10 kg/10000 m² LWA). FGG01 applied at 0.14 kg/10000 m² LWA showed a better level of control than both lower rates (0.07 kg/10000 m² LWA and 0.10 kg/10000 m² LWA). Indeed, FGG01 at 0.14 kg/10000 m² LWA gave 77% mean control, 9 points higher than at 0.07 kg/10000 m² LWA (68% mean control) and 11

points higher than at 0.10 kg/10000 m<sup>2</sup> LWA (66% mean control). Although the dose effect was not highlighted by the statistical analysis, there is a clear numerical trend.

Moreover, according to Standard Deviation data and the box plot graphics on severity on bunches, the difference between the dose rates was characterised by a better homogeneity of control for the highest rate of 0.14 kg/10000 m<sup>2</sup> LWA compared to the lower rates.

**Therefore, according to the efficacy trials results, the minimum effective dose rate of FGG01 for the control of *Erysiphe necator* (UNCINE) in grapevine is confirmed at 0.14 kg/10000 m<sup>2</sup> LWA in the Maritime EPPO climatic zone.**

### 3.2.2.4 Results of Minimum effective dose on fresh beans and peas (PHSVX, PIBSX, VICFX)

In order to justify the choice of the dose rate of FGG01 for the control of *Botrytis cinerea* (BOTRCI) and *Sclerotinia sclerotiorum* (SCLESC) of fresh beans and peas, different dose rates were studied. FGG01 was tested at 0.5, 0.75 and 1.0 kg/ha in the efficacy trials. These rates reflect 50%, 75% and 100% of the target dose rate (1.0 kg/ha, the full recommended dose of FGG01) in accordance with the EPPO guideline PP 1/225(2) “Minimum effective dose”.

#### 3.2.2.4.1 Results of Minimum effective dose on fresh beans and peas (PHSVX, PIBSX, VICFX) - *Botrytis spp.* (BOTRCI, BOTRFA, BOTRSP)

The label claim for this use is summarised in Table 3.2-30.

**Table 3.2-30: Label claim for fresh beans and peas against *Botrytis sp.***

Crops	Target	Country	Dossier strategy	Application timing	No. of applications	Application volume L/ha	Dose rate kg product/ha
Fresh beans and peas (PHSVX, PIBSX, VICFX)	<i>Botrytis sp.</i> (BOTRSP)	AT, BE, CZ	Bridging	BBCH 60-69	2	150-600	1
		NL, PL	Full pack (minor use)				

In Austria, Belgium and the Czech Republic, the reference product CANTUS (also known under the name of PROPATAN in Czech Republic; AMM: 4889-1) has been authorised for use as a fungicide on fresh beans and peas against *Botrytis sp.* for more than 10 years. In a context to demonstrate the comparability between CANTUS and FGG01, no minimum effective dose trials are needed. However, in the Netherlands and Poland, CANTUS is not authorised for this use but due to the fact that it is a minor use, a study of the dose is not necessary.

#### 3.2.2.4.2 Results of Minimum effective dose on fresh beans and peas (PHSVX, VICFX) - *Sclerotinia spp.* (SCLESC, SCLESP)

The label claim for this use is summarised in Table 3.2-31.

**Table 3.2-31: Label claim for fresh beans and peas against *Sclerotinia sp.***

Crops	Target	Country	Dossier strategy	Application timing	No. of applications	Application volume L/ha	Dose rate kg product/ha
Fresh beans and peas (PHSVX, PIBSX, VICFX)	<i>Sclerotinia sp.</i> (SCLESP)	AT, BE, CZ	Bridging	BBCH 60-69	2	150-600	1.0

In Austria, Belgium and the Czech Republic, the reference product CANTUS (also known under the name of PROPATAN in Czech Republic; AMM: 4889-1) has been authorised for use as a fungicide on fresh beans and peas against *Sclerotinia sp.* for more than 10 years. In a context to demonstrate the comparability between CANTUS and FGG01, no minimum effective dose trials are needed.

#### ZRMs comments:

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

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

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

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

Due to the different registration approach strategies in this dossier (bridging or full data package) the justification of the Minimum Effective Dose is not required for all uses claimed for FGG01. Indeed, when a bridging strategy is targeted (use unprotected data of registered product in the country where the use is requested) in this case, this dossier is intended to demonstrate the comparability between the reference product CANTUS and FGG01 and in this context, no Minimum Effective Dose trials are needed. Conversely, in the countries where CANTUS is not authorized or when CANTUS data is still under data protection for a use, a study of the dose is necessary with a complete data package; the size of this data package may vary according to the major or minor classification of the respective use. Submission strategies are presented in the dossier in Table 3.2-1 by Applicant.

✓ **winter oilseed rape:**

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

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

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

✓ **grapevines:**



During trials carried out on grapevines following doses were studied against BOTRCI – 0.36 kg/ 10000 m<sup>2</sup> LWA 0.54 kg/ 10000 m<sup>2</sup> LWA and 0.72 kg/ 10000m<sup>2</sup> LWA (N recommended) in Maritime EPPO trials. During supportive trials from MED trials following doses were studied: 0.5 kg/ha; 0.75 kg/ha and 1.0 kg/ha.

During trials carried out on grapevines following doses were studied against UNCINE – 0.01 kg/ 100 L; 0.015 kg/100 L; 0.02 kg/100 L; 0.2 kg/ha; 0.2 kg/ha; 0.07 kg/ 10000m<sup>2</sup> LWA; 0.10 kg/ 10000m<sup>2</sup> LWA; 0.13 kg/ 10000m<sup>2</sup> LWA and 0.14 kg/ 10000m<sup>2</sup> LWA (N recommended) in Maritime EPPO trials. During supportive trials from MED trials following doses were studied: 0.01 kg/100 L; 0.015 kg/100 L; 0.02 kg/ 100 L; 0.2 kg/ha and 0.2 kg/ 10000m<sup>2</sup> LWA.

The dose rate of 0.72 kg/10000 m<sup>2</sup> LWA has been determined based upon conversion of the proposed ground-based dose rate of 1.0 kg/ha and a typical leaf wall area of grapevine in many Member States in the Central zone. In the trials, a conversion factor of 1.4 was used between the dose expressions in ground area and the LWA concept. CANTUS has been authorized in Austria, Belgium, Czech Republic and Slovenia for use as a fungicide on grapevine against BOTRCI for more than 10 years (data not protected). So, lack of MED trials presented by Applicant against BOTRCI on grapevines should be acceptable.

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

✓ **peas and beans:**

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

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

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

**On the basis of tables presented by Applicant in this dossier for the summary for minimum effective dose and/or data from st. ref. products used in trials (CANTUS, known as a PROPATAN in Czech Republic), it can be concluded that the most effective dose for winter oilseed rape against SCLESC, ALTEBA and LEPTMA is 0.5 kg/ha applied once a season; for beans and peas against BOTRSP and SCLESP is dose 1,0 kg/ha applied twice a season and for grapevine against BOTRCI is dose 0.72 kg/ 10000m<sup>2</sup> LWA applied once a season and against UNCINE is dose 0.14 kg/ 10000m<sup>2</sup> LWA applied max. three times per season.**

### 3.2.3 Efficacy tests (KCP 6.2)

#### 3.2.3.1 Efficacy trials in oilseed rape (BRSNN)

A total of 29 efficacy trials were carried out from 2021 to 2024 to justify the interest of FGG01 (500 g/kg of boscalid, WG) applied at 0.5 kg/ha for the control of *Sclerotinia sclerotiorum* (SCLESC), *Alternaria brassicae* (ALTEBA) and *Plenodomus lingam* (LEPTMA) in oilseed rape. All trials were carried out in the Maritime, North-East EPPO and South-East EPPO climatic zones.

Although all the trials were carried out on winter oilseed rape (BRSNW), the extrapolation can be done to spring oilseed rape (BRSNS), belonging both forms to the same crop oilseed rape (BRSNN). Furthermore, winter and spring oilseed rape have similar development and both are hosted plants for the fungal pathogens targeted: *Sclerotinia sclerotiorum*, *Alternaria sp.* and *Plenodomus lingam*.

##### 3.2.3.1.1 Material and Methods

#### Experimental details

All the trials presented in Table 3.2-13 were carried out by officially recognised organisations in accordance with the Principles of Good Experimental Practice (GEP). These trials were performed following EPPO guidelines.

Main characteristics are summarised in Table 3.2-32 (Maritime), Table 3.2-33 (South-East) and Table 3.2-34 (North-East) for trials against SCLESC, in Table 3.2-35 (Maritime) for trials against ALTEBA and in Table 3.2-36 (South-East) and Table 3.2-37 (North-East) for trials against LEPTMA. Details per trial (trial location, crop cultivar, experimental design, number of blocks, plot size and application(s)) are presented in Biological Assessment Dossier and in individual trial reports in Document K.

**Table 3.2-32: Details on trial methodology - Efficacy trials - Oilseed rape - SCLESC - Maritime EPPO zone**

<b>Guidelines</b>	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), (4): “Minimum effective dose”.
	Specific guidelines	PP1/78(3): “Root, stem, foliar and pod diseases of rape”
<b>Experimental design</b>	Plot design	Randomized Complete Block (RCB)
	Plot size	24-30 m <sup>2</sup>
	Number of replications	4 replications.
<b>Crop</b>	Number of trials	5 valid efficacy trials
	Varieties	Amarone (1), DK Placis (1), ES Mambo (1), Hostine (1), LG Aviron (1).
<b>Application</b>	Application timing	1 application between BBCH 61-65
	Spray volumes	Foliar spraying: 200-300 L/ha.
<b>Assessment</b>	Assessment dates	At around 3-4 weeks, at 5-6 weeks after the application and at BBCH 70-85.
	Assessment types	Disease incidence and disease severity on stem, pod and whole plant. Phytotoxicity assessments
<b>Results &amp; Analysis</b>	Statistical analysis	ANOVA - Newman - Keuls test (5%).

**Table 3.2-33: Details on trial methodology - Efficacy trials - Oilseed rape - SCLESC - South-East**

<b>Guidelines</b>	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), (4) “Minimum effective dose”.
	Specific guidelines	PP1/78(3): “Root, stem, foliar and pod diseases of rape”
<b>Experimental design</b>	Plot design	Randomized Complete Block (RCB)
	Plot size	20-24 m²
	Number of replications	4 replications.
<b>Crop</b>	Number of trials	3 valid efficacy trials
	Varieties	<i>Shrek (2), Trezor (1)</i> .
<b>Application</b>	Application timing	1 application between BBCH 65-67
	Spray volumes	Foliar spraying: 300 L/ha.
<b>Assessment</b>	Assessment dates	At around 1-2 weeks, at 4-5 weeks after the application and at BBCH 70-85.
	Assessment types	Disease incidence and disease severity on stem or whole plant. Phytotoxicity assessments
<b>Results &amp; Analysis</b>	Statistical analysis	ANOVA - Newman - Keuls test (5%).

**Table 3.2-34: Details on trial methodology - Efficacy trials - Oilseed rape - SCLESC - North-East**

<b>Guidelines</b>	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), (4) “Minimum effective dose”.
	Specific guidelines	PP1/78(3): “Root, stem, foliar and pod diseases of rape”
<b>Experimental design</b>	Plot design	Randomized Complete Block (RCB)
	Plot size	20-30 m²
	Number of replications	4 replications.
<b>Crop</b>	Number of trials	7 valid efficacy trials
	Varieties	<i>Digger (1), Elevation (1), Kepler (1), Kuga (1), KWS Factor (1), KWS Feliciano (1), LG Artemis (1)</i> .
<b>Application</b>	Application timing	1 application between BBCH 61-65
	Spray volumes	Foliar spraying: 300 L/ha.
<b>Assessment</b>	Assessment dates	At around 3-4 weeks, at 5-6 weeks after the application and at BBCH 70-85.
	Assessment types	Disease incidence and disease severity on stem and whole plant. Phytotoxicity assessments
<b>Results &amp; Analysis</b>	Statistical analysis	ANOVA - Newman - Keuls test (5%).

**Table 3.2-35: Details on trial methodology - Efficacy trials - Oilseed rape - ALTEBA - Maritime EPPO zone**

<b>Guidelines</b>	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), (4): “Minimum effective dose”.
	Specific guidelines	PP1/78(3): “Root, stem, foliar and pod diseases of rape”
<b>Experimental design</b>	Plot design	Randomized Complete Block (RCB)
	Plot size	24 m²
	Number of replications	4 replications.
<b>Crop</b>	Number of trials	2 valid efficacy trials
	Varieties	Avatar (1), Exlibres (1).
<b>Application</b>	Application timing	1 application between BBCH 62-65
	Spray volumes	Foliar spraying: 300 L/ha.
<b>Assessment</b>	Assessment dates	At around 3 and 6 weeks after the application.
	Assessment types	Disease incidence and disease severity on stem and whole plant. Phytotoxicity assessments
<b>Results &amp; Analysis</b>	Statistical analysis	ANOVA - Newman - Keuls test (5%).

**Table 3.2-36: Details on trial methodology - Efficacy trials - Oilseed rape - LEPTMA - South-East**

<b>Guidelines</b>	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), (4): “Minimum effective dose”.
	Specific guidelines	PP1/78(3): “Root, stem, foliar and pod diseases of rape”
<b>Experimental design</b>	Plot design	Randomized Complete Block (RCB)
	Plot size	20 m²
	Number of replications	4 replications.
<b>Crop</b>	Number of trials	3 valid efficacy trials
	Varieties	Hybrirock (1), Nizza CL(1), Shrek (1).
<b>Application</b>	Application timing	1 application between BBCH 14-18.
	Spray volumes	Foliar spraying: 300 L/ha.
<b>Assessment</b>	Assessment dates	At around 3-4 weeks, at 5-6 weeks after the application and at BBCH 70-85.
	Assessment types	Disease incidence and disease severity on stem, leaves and whole plant. Phytotoxicity assessments
<b>Results &amp; Analysis</b>	Statistical analysis	ANOVA - Newman - Keuls test (5%).

**Table 3.2-37: Details on trial methodology - Efficacy trials - Oilseed rape - LEPTMA - North-East**

<b>Guidelines</b>	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), (4) “Minimum effective dose”.
	Specific guidelines	PP1/78(3): “Root, stem, foliar and pod diseases of rape”
<b>Experimental design</b>	Plot design	Randomized Complete Block (RCB)
	Plot size	15-25 m²
	Number of replications	4 replications.
<b>Crop</b>	Number of trials	9 valid efficacy trials
	Varieties	Architect (1), Bachus (1), Derrick (1), DK extorm (1), LG Apollonia (1), LG architect (1), Shield (1), SY Ilona (1), Sy rokas (1).
<b>Application</b>	Application timing	1 application between BBCH 14-17 (3 trials). 2 applications for trials: 2 trials (BBCH 14-17 for first application and BBCH 32-51 for second application).
	Spray volumes	Foliar spraying: 250-300 L/ha.
<b>Assessment</b>	Assessment dates	At around 3-4 weeks, at 5-6 weeks after the application (BBCH 50-65) and at BBCH 70-85.
	Assessment types	Disease incidence and disease severity on stem, leaves and whole plant. Phytotoxicity assessments
<b>Results &amp; Analysis</b>	Statistical analysis	ANOVA - Newman - Keuls test (5%).

### Treatments and reference standards

In all efficacy trials, the efficacy of FGG01 applied once at 0.25, 0.375 and 0.5 kg/ha was compared to the reference standards CANTUS (Boscalid 500 g/kg) applied at 0.5 kg/ha or PICTOR (Boscalid + Dimoxystrobine, 200 +200 g/L) applied at 0.5 L/ha (Table 3.2-16). The rate of CANTUS is equivalent to the dose of FGG01 requested (0.5 kg/ha).

Table 3.2-38 below presents the plant protection products and the rates used in this part.

**Table 3.2-38: Plant protection products used in efficacy trials - Oilseed rape**

Product name	Active substance(s)	Formulation		Application dose in trials (per treatment)	Country	Rate of active substance per ha	Remark
		Type <sup>[1]</sup>	Concentration of a.s.				
FGG01	Boscalid	WG	500 g/kg	0.5 kg/ha	-	250 g a.s./ha	-
CANTUS	Boscalid	WG	500 g/kg	0.5 kg/ha	BE, DK, FR, UK HU, PL	250 g a.s./ha	-
PICTOR PRO	Boscalid	WG	500 g/kg	0.5 kg/ha	FR	250 g a.s./ha	-
PICTOR	Boscalid + Dimoxystrobine	SC	200 g/L + 200 g/L	0.5 L/ha	PL	100 g a.s./ha 100 g a.s./ha	-

<sup>[1]</sup> SC: Suspension Concentrate WG: Water-dispersible granules

### Assessment methods

In all trials, efficacy was assessed according to EPPO guidelines (1/78(3)). 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 15 or 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:

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

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

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

### **Phytotoxicity assessments**

In efficacy trials, phytotoxicity was also assessed. Phytotoxicity assessments were carried out in accordance with EPPO guideline PP1/135 (“Phytotoxicity assessment”). Assessments were carried out at various intervals post application by recording visual percentage injury (0% = no injury, 100% = complete expression of injury symptom). Crop safety results are presented in Section 0.

### **Statistical analyses**

Observed or calculated variables are subjected to an analysis of variance (ANOVA) after or not a transformation depending on the variability of the raw data (only the numerical values from the raw data are considered).

When the result of the analysis is significant, a multiple comparison of treatments is performed. The averages are classified using the Newman and Keuls tests and divided into homogeneous groups (a, b, c, ...). Treatment means with no letter in common are significantly different in accordance with the test conducted at a 95% confidence level.

### **Results layout**

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

Against *Sclerotinia sclerotiorum*, the last valid assessments where the pest severity (PESSEV) and incidence (PESINC) in the untreated reached at least 5% was considered.

Only 1 key assessment on stems was selected and summarised in this part, according to the EPPO guideline PP1/78(4) “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 79 and BBCH 85. However, in 1 trial, due to a late attack of *Sclerotinia sclerotiorum*, the only available assessment on stems was carried out after harvest at BBCH 99. This later assessment does not impact the efficacy results as the trial showed the same behaviour as the others and is presented separately in the result tables.

Against *Alternaria brassicae*, only 1 valid assessment where the pest severity (PESSEV) and incidence (PESINC) in the untreated reached at least 5% of plant was considered and summarised in this part carried out at 20 DA-A as the key assessment. Nevertheless, another assessment at 43 DA-A (last assessment) is also presented in this dossier for information.

Against *Plenodomus lingam*, the last valid assessments where the pest severity (PESSEV) and incidence (PESINC) in the untreated reached at least 5% was considered.

3 valid assessments on stems, leaves or the whole plant were selected and summarised in this part. These selected assessments are the most representative according to the disease and oilseed rape development and was done as the key assessments:

- at 3-4 weeks after the first application; except for 1 trial which was assessed later due to a late development of the disease (5 weeks; 36 DA-A; but with no impact in the results) than others since the disease developed a bit later; [21-36 DA-A],
- at BBCH 50-65; [166-209 DA-A for trials with 1 application and 28 DA-B for trials with 2 applications],
- at BBCH 70-85; [240-269 DA-A for trials with 1 application and 69 DA-B for trials with 2 applications].

Although a single application of FGG01 is requested for this use, in two trials, 2 applications were carried out. Thus, the assessments carried out after the second application are presented in the separate tables of the trials with a single application and are presented as supportive data.

### 3.2.3.1.2 Results on oilseed rape (BRSNN) - *Sclerotinia sclerotiorum* (SCLESC)

A total of 15 valid efficacy trials were carried out in 2021 and 2024 to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) applied at 0.5 kg/ha for the control of *Sclerotinia sclerotiorum* on oilseed rape in comparison to the reference standard CANTUS (500 g/kg of boscalid, WG) at 0.5 kg/ha in the Maritime EPPO climatic zone in the Central registration zone (Denmark and United Kingdom) and also from Southern registration zone belonging also to the Maritime EPPO climatic zone (North of France) and in the North-East (Poland) and South-East (Hungary) EPPO climatic zones.

The label claim for this use is summarised in Table 3.2-39.

**Table 3.2-39: Label claim for oilseed rape against *Sclerotinia sclerotiorum***

Crops	Target	Country	Dossier strategy	Application timing	No. of applications	Application volume L/ha	Dose rate kg product/ha
Oilseed rape (BRSNN)	<i>Sclerotinia sclerotiorum</i> (SCLESC)	AT, BE, CZ, HU, RO, SK	Bridging	BBCH 57-69	1	100-300	0.5
Oilseed rape (BRSNN)	<i>Sclerotinia sclerotiorum</i> (SCLESC)	NL	Full package (minor use)	BBCH 57-69	1	100-300	0.5
Oilseed rape (BRSNN)	<i>Sclerotinia sclerotiorum</i> (SCLESC)	PL	Full package (major use)	BBCH 57-69	1	100-300	0.5

In Austria, Belgium, Czech Republic, Hungary, Romania and Slovakia, the reference product CANTUS (also known under the name of PROPATAN in Czech Republic; AMM: 4889-1) has been authorised for use as a fungicide on oilseed rape against *Sclerotinia sclerotiorum* for more than 10 years and the use is not protected. In this bridging context, according to guideline EPPO 1/307(2) a reduced data package is required to demonstrate the comparability between CANTUS and FGG01.

In Poland, CANTUS, is authorised for this use but data is still protected, therefore, a full data package is necessary for this major use.

Concerning the Netherlands, CANTUS is not authorised for this use. However, due to the fact that it is a minor use, a reduced data package is required.

Of these trials, 5 were conducted within the Maritime (3 trials in France (north), 1 trial in Denmark and 1 trial in United Kingdom), 3 within the South-East (3 trials in Hungary) and 7 within the North-East (7 trials in Poland) EPPO climatic zones.

A summary of all trials generating data on oilseed rape against *Sclerotinia sclerotiorum* is presented in Table 3.2-40.

**Table 3.2-40: Overview of efficacy trials - Oilseed rape - *Sclerotinia sclerotiorum***

Nb. of trials	Crop	Target	Year	Country	EPPO climatic zone	Comment
1 trial	OSR	SCLESC	2023	DK	Maritime	-
1 trial	OSR	SCLESC	2023	UK	Maritime	-
1 trial	OSR	SCLESC	2023	FR-N	Maritime	-
2 trials	OSR	SCLESC	2024	FR-N	Maritime	-
3 trials	OSR	SCLESC	2021	HU	South-East	-
3 trials	OSR	SCLESC	2021	PL	North-East	-
4 trials	OSR	SCLESC	2023	PL	North-East	-

#### **A. Results on oilseed rape (BRSNN) - *Sclerotinia sclerotiorum* (SCLESC) - Maritime EPPO zone**

A total of 5 valid efficacy trials were carried out in 2023 and 2024 to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) applied at 0.5 kg/ha applied once for the control of *Sclerotinia sclerotiorum* on oilseed rape in comparison to the reference standard CANTUS (500 g/kg of boscalid, WG) at 0.5 kg/ha in the Maritime EPPO climatic zone. An overview of these trials is presented in Table 3.2-13.

The summary results of the effect of FGG01 applied at 0.5 kg/ha compared to reference standard are shown in Table 3.2-41.



**Table 3.2-41: Summary results: efficacy of FGG01 against *Sclerotinia sclerotiorum* on oilseed rape - Maritime EPPO zone**

Parameters	Assessment timing	Parts	EPPO climatic zone	No. of trials	Days after application	Untreated control (% infestation)			FGG01 0.5 kg/ha			CANTUS 0.5 kg/ha			No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at 0.5 kg/ha vs. CANTUS at 0.5 kg/ha
						Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	
Severity (%)	BBCH 79-85	STEM	Maritime	4	[55-77 DA-A]	17.4	11.0	26.8	74.6	46.6	90.8	68.1	39.8	90.8	0> ; 4= ; 0<
	BBCH 99	STEM	Maritime	1	[117 DA-A]	44.7	-	-	59.0	-	-	51.9	-	-	0> ; 1= ; 0<
	BBCH 79-85	POD	Maritime	2	[77 DA-A]	5.4	5.2	5.6	97.1	95.8	98.5	96.6	95.4	97.8	0> ; 2= ; 0<
Incidence (%)	BBCH 79-85	STEM	Maritime	4	[55-77 DA-A]	56.8	44.0	65.0	49.3	31.8	65.8	49.9	22.7	64.4	0> ; 4= ; 0<
	BBCH 99	STEM	Maritime	1	[117 DA-A]	69.0	-	-	46.4	-	-	40.6	-	-	0> ; 1= ; 0<
	BBCH 79-85	POD	Maritime	2	[77 DA-A]	73.5	68.0	79.0	87.6	87.2	88.0	86.4	82.1	90.6	0> ; 2= ; 0<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

In the Maritime EPPO climatic zone, at BBCH 79-85 assessment, on disease severity on stems, the infestation in untreated plot reached up to 17% (ranging from 11% to 27%) in 4 trials. FGG01 applied at 0.5 kg/ha showed a control quite close to the reference standard CANTUS applied at 0.5 kg/ha (respectively 75% vs. 68% mean control). No statistical differences were found in the 4 trials.

On disease incidence on stems, at BBCH 79-85 assessment, the infestation in untreated plot reached up to 57% (ranging from 44 % to 65%) in 4 trials. FGG01 applied at 0.5 kg/ha showed similar control to the reference standard CANTUS applied at 0.5 kg/ha (respectively 49% vs. 50% mean control). No statistical differences were found in the 4 trials.

On disease severity on pods, at BBCH 79-85 assessment, the infestation in untreated plot reached up to 5% (ranging from 5% to 6%) in 2 trials. FGG01 applied at 0.5 kg/ha showed similar control to the reference standard CANTUS applied at 0.5 kg/ha (respectively 97% vs. 97% mean control). No statistical differences were found in the 2 trials.

On disease incidence on pods, at BBCH 79-85 assessment, the infestation in untreated plot reached up to 74% (ranging from 68% to 79%) in 2 trials. FGG01 applied at 0.5 kg/ha showed similar control to the reference standard CANTUS applied at 0.5 kg/ha (respectively 88% vs. 86% mean control). No statistical differences were found in the 2 trials

For information, at BBCH 99 on disease severity, the infestation in untreated plot reached up to 45% in 1 trial. FGG01 applied at 0.5 kg/ha showed a control quite close to that of the reference standard CANTUS applied at 0.5 kg/ha (respectively 59% vs. 52% control). These results were confirmed on the disease incidence, where the infestation in untreated plot reached up to with 69%, the mean control of FGG01 applied at 0.5 kg/ha was similar to the reference standard CANTUS applied at 0.5 kg/ha (respectively 46% vs. 41% control). No statistical differences were found in the trial.

**Therefore, by and large, data from 5 trials, with a moderate level of infestation, FGG01 applied once at 0.5 kg/ha showed an adequate to very good effectiveness, at an equivalent level of control to the reference CANTUS applied at 0.5 kg/ha against *Sclerotinia sclerotiorum* (SCLESC) on oilseed rape in the Maritime EPPO climatic zone. Therefore, one application at the rate of 0.5 kg/ha will be recommended on the product label for the control of SCLESC in the Maritime EPPO climatic zone.**

## **B. Results on oilseed rape (BRSNN) - *Sclerotinia sclerotiorum* (SCLESC) - North-East EPPO zone**

A total of 7 valid efficacy trials were carried out in 2021 and 2023 to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) applied at 0.5 kg/ha applied once for the control of *Sclerotinia sclerotiorum* on oilseed rape in comparison to the reference standard CANTUS (500 g/kg of boscalid, WG) at 0.5 kg/ha in the North-East EPPO climatic zone. An overview of these trials is presented in Table 3.2-13.

The summary results of the effect of FGG01 applied at 0.5 kg/ha compared to reference standard are shown in Table 3.2-42.

**Table 3.2-42: Summary results: efficacy of FGG01 against *Sclerotinia sclerotiorum* on oilseed rape - North-East EPPO zone**

Parameters	Assessment timing	Parts	EPPO climatic zone	No. of trials	Days after application	Untreated control (% infestation)			FGG01 0.5 kg/ha			CANTUS 0.5 kg/ha			No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at 0.5 kg/ha vs. CANTUS at 0.5 kg/ha
						Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	
Severity (%)	BBCH 79-85	STEM	North-East	7	[42-67 DA-A]	31.6	14.8	66.9	89.0	74.5	94.9	90.1	74.9	97.0	0> ; 6= ; 1<
Incidence (%)	BBCH 79-85	STEM	North-East	7	[42-67 DA-A]	51.4	31.0	89.0	76.5	64.6	88.6	79.3	70.7	88.6	0> ; 7= ; 0<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

In the North-East EPPO climatic zone, at BBCH 79-85 on disease severity on stems, the infestation in untreated plot reached up to 32% (ranging from 15% to 67%) in 7 trials. FGG01 applied at 0.5 kg/ha showed a similar control to the reference standard CANTUS applied at 0.5 kg/ha (respectively 89% vs. 90% mean control). No statistical differences were found in the 6 out of 7 trials.

On incidence at BBCH 79-85, the infestation in untreated plot reached up to 51% (ranging from 31% to 89%) in 7 trials. FGG01 applied at 0.5 kg/ha showed similar control to the reference standard CANTUS applied at 0.5 kg/ha (respectively 77% vs. 79% mean control). No statistical differences were found in the 7 trials.

**Therefore, by and large, data from 7 trials, with a moderate level of infestation, FGG01 applied once at 0.5 kg/ha showed a good effectiveness, at an equivalent level of control to the reference CANTUS applied at 0.5 kg/ha against *Sclerotinia sclerotiorum* (SCLESC) on oilseed rape in the North-East EPPO climatic zone. These results confirm that one application at the rate of 0.5 kg/ha can be recommended on the product label for the control of SCLESC in Poland.**

### **C. Results on oilseed rape (BRSNN) - *Sclerotinia sclerotiorum* (SCLESC) - South-East EPPO zone**

A total of 3 valid efficacy trials were carried out in 2021 to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) applied at 0.5 kg/ha applied once for the control of *Sclerotinia sclerotiorum* on oilseed rape in comparison to the reference standard CANTUS (500 g/kg of boscalid, WG) at 0.5 kg/ha in the South-East EPPO climatic zone. An overview of these trials is presented in Table 3.2-13.

The summary results of the effect of FGG01 applied at 0.5 kg/ha compared to reference standard are shown in Table 3.2-43.

**Table 3.2-43: Summary results: efficacy of FGG01 against *Sclerotinia sclerotiorum* on oilseed rape - South-East EPPO zone**

Parameters	Assessment timing	Parts	EPPO climatic zone	No. of trials	Days after application	Untreated control			FGG01 0.5 kg/ha			CANTUS 0.5 kg/ha			No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at 0.5 kg/ha vs. CANTUS at 0.5 kg/ha
						Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	
Severity (%)	BBCH 79-85	STEM	South-East	3	[43-49 DA-A]	21.6	10.3	43.1	89.5	82.2	94.8	93.5	83.9	99.3	0> ; 3= ; 0<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

In the South-East EPPO climatic zone, at BBCH 79-85 on disease severity on stems, the infestation in untreated plot reached up to 22% (ranging from 10% to 43%) in 3 trials. FGG01 applied at 0.5 kg/ha showed a similar control to the reference standard CANTUS applied at 0.5 kg/ha (respectively 90% vs. 94% mean control). No statistical differences were found in the 3 trials.

**Therefore, by and large, data from 3 trials, with a moderate level of infestation, FGG01 applied once at 0.5 kg/ha showed a good effectiveness, at an equivalent level of control to the reference CANTUS applied at 0.5 kg/ha against *Sclerotinia sclerotiorum* (SCLESC) on oilseed rape in the South-East EPPO climatic zone. These results confirm that, one application at the rate of 0.5 kg/ha can be recommended on the product label for the control of SCLESC in South-East EPPO climatic zone.**

#### D. Results on oilseed rape (BRSNN) - *Sclerotinia sclerotiorum* (SCLESC) - All EPPO zones

A total of 15 valid efficacy trials were carried out to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) in the All EPPO climatic zones from 2021 to 2024 applied once at 0.5 kg/ha for the control of *Sclerotinia sclerotiorum* on oilseed rape in comparison to the reference standard CANTUS (500 g/kg of boscalid, WG) at 0.5 kg/ha. An overview of these trials is presented in Table 3.2-13.

The summary results of the effect of FGG01 applied at 0.5 kg/ha compared to references standard are shown in Table 3.2-44.

**Table 3.2-44: Summary results: efficacy of FGG01 against *Sclerotinia sclerotiorum* on oilseed rape - All EPPO zones**

Parameters	Parts	EPPO climatic zone	No. of trials	Days after application	Untreated control Infestation (%)			Efficacy (%)						No. of assessments significantly <sup>(1)</sup> >, =, < FGG01 at 0.5 kg/ha vs. CANTUS at 0.5 kg/ha
								FGG01 0.5 kg/ha			CANTUS 0.5 kg/ha			
					Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	
Severity (%)	STEM	All zones	15	[42-117 DA-A]	26.7	10.3	66.9	83.3	46.6	94.9	82.4	39.8	99.3	0> ; 14= ; 1<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

In all EPPO climatic zones, on disease severity on stems, the infestation in untreated plot reached up to 27% (ranging from 10% to 67%) in 13 trials. FGG01 applied at 0.5 kg/ha showed a similar control to the reference standard CANTUS applied at 0.5 kg/ha (respectively 83% vs. 82% mean control). No statistical differences were found in 14 out of 15 trials.

**Therefore, by and large, data from 15 trials, with a moderate level of infestation, FGG01 applied at 0.5 kg/ha showed a good effectiveness, at an equivalent level of control to the reference CANTUS applied at 0.5 kg/ha against *Sclerotinia sclerotiorum* (SCLESC) on oilseed rape across all EPPO climatic zones. Therefore, one application at the rate of 0.5 kg/ha will be recommended on the product label for the control of SCLESC in the Central registration zone on oilseed rape.**

#### E. Conclusion on oilseed rape - *Sclerotinia sclerotiorum* (SCLESC)

A total of 15 valid efficacy trials conducted in the Maritime (5 trials), North-East (7 trials) and South-East (3 trials) EPPO climatic zones, evaluated the efficacy of FGG01 applied once at 0.5 kg/ha against *Sclerotinia sclerotiorum* in oilseed rape.

In summary, the set of data submitted on oilseed rape against *Sclerotinia sclerotiorum*, demonstrated that the efficacy provided by FGG01 (500 g/kg of boscalid, WG) at 0.5 kg/ha was equivalent to the efficacy provided by the reference product CANTUS (500 g/kg of boscalid, WG) applied at the same rate.

Table 3.2-45 below summarises the results from the efficacy trials.

**Table 3.2-45: Overall summary of efficacy of FGG01 on oilseed rape against *Sclerotinia sclerotiorum* in Central registration zone**

Crop code	Pest code	EPPO climatic zone	Parameter	Nb of trials	Untreated	Efficacy (%)		No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 vs. CANTUS
					Infestation (%)	FGG01 0.5 kg/ha	CANTUS 0.5 kg/ha	
BRSNN	SCLESC	Maritime	Disease severity on stem at BBCH 99	1	44.7	59.0	51.9	0> ; 1= ; 0<
			Disease incidence on stem at BBCH 99	1	69.0	46.4	40.6	0> ; 1= ; 0<
			Disease severity on stem at BBCH 79-85	4	17.4	74.6	68.1	0> ; 4= 0<
			Disease incidence on stem at BBCH 79-85	4	56.8	49.3	49.9	0> ; 4= ; 0<
			Disease severity on pods at BBCH 79-85	2	5.4	97.1	96.6	0> ; 2= ; 0<
			Disease incidence on pods at BBCH 79-85	2	73.5	87.6	86.4	0> ; 2= ; 0<
		North-East	Disease severity on stem at BBCH 79-85	7	31.6	89.0	90.1	0> ; 6= ; 1<
			Disease incidence on stem at BBCH 79-85	7	51.4	76.5	79.3	0> ; 7= ; 0<
		South-East	Disease severity on stem at BBCH 79-85	3	21.6	89.5	93.5	0> ; 3= ; 0<
		All zones	Disease severity on stem at BBCH 79-85	15	26.7	83.3	82.4	0> ; 14= ; 1<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

In a total of 15 trials, FGG01 applied at 0.5 kg/ha showed a good effectiveness, at an equivalent level of control to the reference product CANTUS at 0.5 kg/ha against *Sclerotinia sclerotiorum* (SCLESC) and both products were statistically equivalent in 14 out of 15 trials. Therefore, one application at the rate of 0.5 kg/ha will be recommended on the product label for the control of SCLESC on oilseed rape in the Central registration zone.

### 3.2.3.1.3 Results on oilseed rape (BRSNN) - *Alternaria brassicae* (ALTEBA)

A total of 2 valid efficacy trials were carried out in 2023 to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) applied at 0.5 kg/ha for the control of *Alternaria brassicae* on oilseed rape in comparison to the reference standard CANTUS (500 g/kg of boscalid, WG) at 0.5 kg/ha in the Maritime EPPO climatic zone (Belgium).

The label claim for this use is summarised in Table 3.2-46.

**Table 3.2-46: Label claim for oilseed rape against *Alternaria sp.***

Crops	Target	Country	Dossier strategy	Application timing	No. of applications	Application volume L/ha	Dose rate kg product/ha
Oilseed rape (BRSNN)	<i>Alternaria sp.</i> (ALTESP)	AT, BE, CZ	Bridging	BBCH 57-69	1	100-300	0.5
Oilseed rape (BRSNN)	<i>Alternaria sp.</i> (ALTESP)	NL	Full package (minor use)	BBCH 57-69	1	100-300	0.5
Oilseed rape (BRSNN)	<i>Alternaria sp.</i> (ALTESP)	SK, HU, RO	Bridging/ Extrapolation	BBCH 57-69	1	100-300	0.5

In Austria, Belgium, Czech Republic, Hungary, Romania and Slovakia, the reference product CANTUS (also known under the name of PROPATAN in Czech Republic; AMM: 4889-1) has been authorised

for use as a fungicide on oilseed rape against *Alternaria sp.* for more than 10 years and the use is not protected. In this bridging context, according to guideline EPPO 1/307(2) a reduced data package is required.

Concerning the Netherlands, CANTUS is not authorised for this use. However, due to the fact that it is a minor use, a reduced data package is required.

Trials have only been conducted in the Maritime EPPO climatic zone even if Hungary, Romania and Slovakia are included in the South-East EPPO climatic zone. In this bridging context, no data package was generated for this use. Indeed, according to guideline EPPO 1/307(2) when comparability is demonstrated between the products, it is not necessary to cover all uses: “A demonstration of comparability (whether by a relevant reasoned case or an appropriate data package) allows, in effect, extrapolation to the complete associated claims/uses for the authorized product and the underlying supporting data”.

The comparability between FGG01 applied at 0.5 kg/ha and the reference product CANTUS applied at 0.5 kg/ha in the same conditions has been proven on oilseed rape:

- Against *Sclerotinia sclerotiorum* in 3 trials carried out in South-East EPPO climatic zone (+12 trials carried out in Maritime and North-East EPPO climatic zones),
- Against *Plenodomus lingam* in 3 trials carried out in South-East EPPO climatic zone (+9 trials carried out in North-East EPPO climatic zone),
- Against *Alternaria sp.* in 2 trials carried out in Maritime EPPO climatic zone. Although, these data are from a different EPPO climatic zone, they are considered as supportive since the disease development is similar, as well as the agricultural practices. Furthermore, this area is representative of *Alternaria sp.* occurrence in Europe and is the most challenging for this disease. This is justified by EPPO standard PP 1/307 (2) "Efficacy on considerations and data generation when making changes to the chemical composition or formulation type of plant protection products" (also applicable to for “a new product based on a ‘bridging’ approach to an existing authorized formulation”) which states that “For existing products authorized on a zonal basis, effectiveness and crop safety across all relevant EPPO climatic regions will have been originally established. Therefore, when proposing changes in chemical composition it is not necessary to generate comparability data across all regions. As indicated, the location of trials should reflect challenging conditions based on crop/pest and environment.”.

In addition, in this dossier, the comparability between FGG01 and the reference product CANTUS has been also proven on many major crops for many uses (grapevine against BOTRCI and peas and beans against BOTRSP and SCLESP).

In this context, the comparability between FGG01 and the reference product CANTUS can be extrapolated to *Alternaria sp.* in oilseed rape in Hungary, Romania and Slovakia.

A summary of all trials generating data on oilseed rape against *Alternaria sp.* is presented in Table 3.2-47.

**Table 3.2-47: Overview of efficacy trials - Oilseed rape - *Alternaria sp.***

Nb. of trials	Crop	Target	Year	Country	EPPO climatic zone	Comment
2 trials	OSR	ALTEBA	2023	BE	Maritime	-

#### **A. Results on oilseed rape (BRSNN) - *Alternaria brassicae* (ALTEBA) - Maritime EPPO zone**

A total of 2 valid efficacy trials were carried out in 2023 to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) applied once at 0.5 kg/ha for the control of *Alternaria brassicae* on oilseed rape in comparison to the reference standard CANTUS (500 g/kg of boscalid, WG) at 0.5 kg/ha in the Maritime (Belgium) EPPO climatic zone. An overview of these trials is presented in Table 3.2-13.

The summary results of the effect of FGG01 applied at 0.5 kg/ha compared to reference standard are shown in Table 3.2-48.



**Table 3.2-48: Summary results: efficacy of FGG01 against *Alternaria brassicae* on oilseed rape - Maritime EPPO zone**

Parameters	Parts	EPPO climatic zone	No. of trials	Days after application	Untreated control			FGG01 0.5 kg/ha			CANTUS 0.5 kg/ha			No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at 0.5 kg/ha vs. CANTUS at 0.5 kg/ha
					Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	
Severity (%)	PLANT	Maritime	2	[20-20 DA-A]	<b>9.2</b>	6.7	11.6	<b>89.8</b>	88.4	91.2	<b>91.6</b>	90.3	92.9	0> ; 2= ; 0<
		Maritime	2	[43-43 DA-A]	<b>8.1</b>	7.6	8.5	<b>62.0</b>	61.1	62.8	<b>42.4</b>	32.9	51.9	0> ; 2= ; 0<
Incidence (%)	PLANT	Maritime	1	20 DA-A	<b>91.0</b>	-	-	<b>68.1</b>	-	-	<b>63.7</b>	-	-	0> ; 1= ; 0<
		Maritime	1	43 DA-A	<b>85.0</b>	-	-	<b>41.2</b>	-	-	<b>42.4</b>	-	-	0> ; 1= ; 0<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

In the Maritime EPPO climatic zone, on disease severity at 20 DA-A, the infestation in untreated plot reached up to 9% (ranging from 7 % to 12%) in 2 trials. FGG01 applied at 0.5 kg/ha showed a similar control to the reference standard CANTUS applied at 0.5 kg/ha (respectively 90% vs. 92% mean control). No statistically significant differences were found in the two trials.

These results were confirmed on the disease incidence, where the infestation in untreated plot at 20 DA-A reached up to 91% in 1 trial. FGG01 applied at 0.5 kg/ha showed a similar control to the reference standard CANTUS applied at 0.5 kg/ha (respectively 68% vs. 64% control). No statistically significant difference was found.

For information, on disease severity at 43 DA-A, the infestation in untreated plot reached up to 8% (ranging from 8% to 9%) in 2 trials. In 1 trial, FGG01 applied at 0.5 kg/ha showed a similar control to the reference standard CANTUS applied at 0.5 kg/ha and a better control in the other trial. However, no statistically significant differences were found in both trials. Regarding incidence data, the infestation in untreated plot reached up 85% of incidence in 1 trial. FGG01 applied at 0.5 kg/ha showed a similar control to the reference standard CANTUS applied at 0.5 kg/ha (respectively 41% vs. 42% control). No statistically significant difference was found.

**Therefore, by and large, data from 2 trials, with a moderate level of infestation, FGG01 applied once at 0.5 kg/ha showed an adequate to good effectiveness, at an equivalent level of control to the reference CANTUS applied at 0.5 kg/ha against *Alternaria brassicae* (ALTEBA) on oilseed rape in the Maritime EPPO climatic zone. Therefore, one application at rate of 0.5 kg/ha will be recommended on the product label for the control of *Alternaria sp.* in the Maritime EPPO climatic zone.**

## B. Conclusion on oilseed rape - *Alternaria brassicae* - (ALTEBA)

A total of 2 valid efficacy trials conducted in the Maritime EPPO climatic zone (Belgium) evaluated the efficacy of FGG01 applied once at 0.5 kg/ha against *Alternaria brassicae* in oilseed rape.

In summary, the set of data submitted on oilseed rape against *Alternaria brassicae*, demonstrated that the efficacy provided by FGG01 (500 g/kg of boscalid, WG) at 0.5 kg/ha was equivalent to the efficacy provided by the reference product CANTUS (500 g/kg of boscalid, WG) applied at the same rate.

Table 3.2-49 below summarises the results from the efficacy trials.

**Table 3.2-49: Overall summary of efficacy of FGG01 on oilseed rape against *Alternaria brassicae* in Central registration zone**

Crop code	Pest code	EPPO climatic zone	Parameter	Nb of trials	Untreated	Efficacy (%)		No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 vs. CANTUS
					Infestation (%)	FGG01 0.5 kg/ha	CANTUS 0.5 kg/ha	
BRSNN	ALTEBA	Maritime	Disease severity on plant (20 DA-A)	2	9.2	89.8	91.6	0> ; 2= ; 0<
			Disease incidence on plant (20 DA-A)	1	91.0	68.1	63.7	0> ; 1= ; 0<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

In a total of 2 trials, FGG01 applied at 0.5 kg/ha showed an equivalent level of control to the reference product CANTUS at 0.5 kg/ha against *Alternaria brassicae* (ALTEBA) no statistical differences were detected between both products in all trials. Therefore, one application at the rate of 0.5 kg/ha will be recommended on the product label for the control of ALTEBA in the Maritime EPPO climatic zone on oilseed rape.

Trials have only been conducted in the Maritime EPPO climatic zone even if Hungary, Romania and Slovakia (claimed countries) are included in the South-East EPPO climatic zone. Indeed, this area is representative of *Alternaria brassicae* occurrence in Europe and is the most challenging for this disease.

Therefore, according to EPPO standard PP 1/307 (2), the data generated in the Maritime EPPO climatic zone can be extrapolated in Hungary, Romania and Slovakia.

In addition, in this dossier, the comparability between FGG01 and the reference product CANTUS has been also proven on many major crops for many uses on oilseed rape and also on grapevine, on peas and beans. In this context, the comparability between FGG01 and the reference product CANTUS can be extrapolated to *Alternaria sp.* in oilseed rape in Hungary, Romania and Slovakia.

Therefore, one application at the rate of 0.5 kg/ha will be recommended on the product label for the control of ALTESP in oilseed rape in the Central registration zone.

### 3.2.3.1.4 Results on oilseed rape (BRSNN) - *Plenodomus lingam* (LEPTMA)

A total of 8 valid efficacy trials were carried out in 2021 and 2022 to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) applied at 0.5 kg/ha for the control of *Plenodomus lingam* on oilseed rape in comparison to the reference standards CANTUS (Boscalid 500 g/kg; WG) at 0.5 kg/ha and PICTOR (200 g/L Boscalid + 200 g/L Dimoxystrobin; SC) at 0.5 L/ha in the South-East and North-East EPPO climatic zones in the Central registration zone (Poland and Hungary).

The label claim for this use is summarised in Table 3.2-50.

**Table 3.2-50: Label claim for oilseed against *Plenodomus lingam***

Crops	Target	Country	Dossier strategy	Application timing	No. of applications	Application volume L/ha	Dose rate kg product/ha
Oilseed rape (BRSNN)	<i>Plenodomus lingam</i> (LEPTMA)	HU, RO, SK	Bridging	BBCH 13-57	1	100-300	0.5
Oilseed rape (BRSNN)	<i>Plenodomus lingam</i> (LEPTMA)	PL	Full package (major use)	BBCH 13-57	1	100-300	0.5
Oilseed rape (BRSNN)	<i>Plenodomus lingam</i> (LEPTMA)	AT, CZ	Bridging /Extrapolation	BBCH 13-57	1	100-300	0.5

In Austria, Czech Republic, Hungary, Romania and Slovakia, the reference product CANTUS (also known under the name of PROPATAN in Czech Republic; AMM: 4889-1) has been authorised for use as a fungicide on oilseed rape against *Plenodomus lingam* for more than 10 years and the use is not protected. In this bridging context, according to guideline EPPO 1/307(2) a reduced data package is required to demonstrate the comparability between CANTUS and FGG01.

However, in Poland, CANTUS is authorised for this use but data is still protected and therefore a full data package would be required in this context.

Trials have only been conducted in the South-East and North-East EPPO climatic zones even if Austria and Czech Republic are included in the Maritime EPPO climatic zone. In this bridging context, no data package was generated for this use. Indeed, according to guideline EPPO 1/307(2) when comparability is demonstrated between the products, it is not necessary to cover all uses: “A demonstration of comparability (whether by a relevant reasoned case or an appropriate data package) allows, in effect, extrapolation to the complete associated claims/uses for the authorized product and the underlying supporting data”.

The comparability between FGG01 applied at 0.5 kg/ha and the reference product CANTUS applied at 0.5 kg/ha in the same conditions has been proven on oilseed rape:

- Against *Sclerotinia sclerotiorum* in 5 trials carried out in Maritime EPPO climatic zone (+10 trials carried out in South-East and North-East EPPO climatic zones),
- Against *Alternaria sp.* in 2 trials carried out in Maritime EPPO climatic zone,
- Against *Plenodomus lingam* in 3 trials carried out in South-East EPPO climatic zone and 9 trials carried out in North-East zone. Although, these data are from different EPPO climatic zones, they are considered as supportive since the disease development is similar, as well as the

agricultural practices. Furthermore, this area is representative of *Plenodomus lingam* occurrence in Europe and is the most challenging for this disease. This is justified by EPPO standard PP 1/307 (2) "Efficacy on considerations and data generation when making changes to the chemical composition or formulation type of plant protection products" (also applicable to for "a new product based on a 'bridging' approach to an existing authorized formulation") which states that *"For existing products authorized on a zonal basis, effectiveness and crop safety across all relevant EPPO climatic regions will have been originally established. Therefore, when proposing changes in chemical composition it is not necessary to generate comparability data across all regions. As indicated, the location of trials should reflect challenging conditions based on crop/pest and environment."*

In addition, in this dossier, the comparability between FGG01 and the reference product CANTUS has been also proven on many major crops for many uses (grapevine, on peas and beans). In this context, the comparability between FGG01 and the reference product CANTUS can be extrapolated to *Plenodomus lingam* in oilseed rape in Austria and Czech Republic.

A summary of all trials generating data on pear against *Plenodomus lingam* is presented in Table 3.2-51.

**Table 3.2-51: Overview of efficacy trials - Oilseed rape - *Plenodomus lingam***

Nb. of trials	Crop	Target	Year	Country	EPPO climatic zone	Comment
3 trials	OSR	LEPTMA	2021	HU	South-East	-
3 trials	OSR	LEPTMA	2021	PL	North-East	-
2 trials	OSR	LEPTMA	2022	PL	North-East	-
4 trials	OSR	LEPTMA	2023	PL	North-East	-

#### **A. Results on oilseed rape (BRSNN) - *Plenodomus lingam* (LEPTMA) - North-East EPPO zone**

A total of 9 valid efficacy trials were carried out between 2021 and 2023 to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) applied at 0.5 kg/ha for the control of *Plenodomus lingam* on oilseed rape in comparison to the reference standards CANTUS (Boscalid 500 g/kg; WG) at 0.5 kg/ha and PICTOR (200 g/L Boscalid + 200 g/L Dimoxystrobine; SC) at 0.5 L/ha in the North-East EPPO climatic zone (Poland). An overview of these trials is presented in Table 3.2-13.

The summary results of the effect of FGG01 applied at 0.5 kg/ha compared to references standard are shown in Table 3.2-52.

**Table 3.2-52: Summary results: efficacy of FGG01 against *Plenodomus lingam* on oilseed rape - North-East EPPO zone**

Assessment	No. of applications	Parts	Parameters	EPPO climatic zone	No. of trials	Days after application	Untreated control (% infestation)			FGG01 0.5 kg/ha			CANTUS 0.5 kg/ha			PICTOR 0.5 L/ha			No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at 0.5 kg/ha vs.	
							Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	CANTUS (0.5 kg/ha)	PICTOR (0.5 L/ha)
3-4 weeks after application	1 application	LEAF	Incidence (%)	North-East	9	[20-28 DA-A]	42.1	5.0	75.0	68.5	38.1	100.0	-	-	-	-	-	-	-	-
					7	[20-28 DA-A]	52.3	36.0	75.0	59.5	38.1	82.7	65.8	49.2	84.0	-	-	-	0> ; 6= ; 1<	-
					2	[25-25 DA-A]	6.5	5.0	8.0	100.0	100.0	100.0	-	-	-	100.0	100.0	100.0	-	0> ; 2= ; 0<
Assessment at BBCH 50-65	1 application	LEAF	Severity (%)	North-East	7	[166-209 DA-A]	7.4	4.9	8.5	85.8	80.2	99.1	-	-	-	-	-	-	-	-
					5	[166-182 DA-A]	7.0	4.9	8.2	82.5	80.2	85.6	82.2	81.5	83.2	-	-	-	0> ; 5= ; 0<	-
					2	[199-209 DA-A]	8.4	8.2	8.5	94.2	89.3	99.1	-	-	-	93.2	90.3	96.0	-	0> ; 2= ; 0<
		LEAF	Incidence (%)	North-East	8	[166-209 DA-A]	75.3	62.0	94.0	58.3	45.6	93.6	-	-	-	-	-	-	-	-
					6	[166-207 DA-A]	74.0	62.0	83.0	53.8	45.6	71.0	53.4	47.1	69.4	-	-	-	0> ; 6= ; 0<	-
	2 applications	LEAF	Incidence (%)	North-East	2	[199-209 DA-A]	79.0	64.0	94.0	71.8	50.0	93.6	-	-	-	64.9	53.1	76.6	-	1> ; 1= ; 0<
					1	28 DA-B	7.8	-	-	88.4	-	-	79.3	-	-	-	-	-	1> ; 0= ; 0<	-
Assessment at BBCH 70-85	1 application	STEM	Severity (%)	North-East	5	[256-269 DA-A]	10.7	7.4	13.8	77.5	45.2	88.7	76.3	37.6	88.0	-	-	-	0> ; 5= ; 0<	-
					7	[245-269 DA-A]	26.7	13.0	51.0	61.8	43.1	90.6	-	-	-	-	-	-	-	-
		STEM	Incidence (%)	North-East	5	[245-269 DA-A]	30.6	23.0	51.0	53.0	43.1	70.4	59.9	45.1	70.4	-	-	-	0> ; 5= ; 0<	-
					2	[245-252 DA-A]	17.1	13.0	21.2	83.7	76.9	90.6	-	-	-	87.6	84.6	90.6	-	0> ; 2= ; 0<
	2 applications	STEM	Severity (%)	North-East	2	[69-73 DA-B]	11.3	11.2	11.3	84.0	79.7	88.2	76.7	75.4	78.0	-	-	-	1> ; 1= ; 0<	-
		STEM	Incidence (%)	North-East	2	[69-73 DA-B]	59.5	59.0	60.0	66.4	66.1	66.7	56.3	52.5	60.0	-	-	-	1> ; 1= ; 0<	-
		LEAF	Severity (%)	North-East	1	73 DA-B	21.2	-	-	86.5	-	-	88.3	-	-	-	-	-	0> ; 1= ; 0<	-
		LEAF	Incidence (%)	North-East	1	73 DA-B	97.0	-	-	68.0	-	-	64.9	-	-	-	-	-	0> ; 1= ; 0<	-

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

### **Assessment at 3-4 weeks**

In the North-East EPPO climatic zone, on disease incidence on leaves, the infestation in untreated plot reached up to 42% (ranging from 5% to 75%) in 9 trials. FGG01 applied at 0.5 kg/ha showed 69% mean control in 9 trials.

When comparing with the reference standards, in 7 trials, FGG01 applied at 0.5 kg/ha showed a similar control to the reference standard CANTUS applied at 0.5 kg/ha (respectively 60% vs. 66% mean control). No statistical differences were found in 6 out of 7 trials. In 2 trials, FGG01 applied at 0.5 kg/ha showed a similar control to the reference standard PICTOR applied at 0.5 L/ha (respectively 100% vs. 100% mean control). No statistical differences were found in the 2 trials.

### **Assessment at BBCH 50-65:**

On disease severity on leaves in trials with 1 application, the infestation in untreated plot reached up to 7% (ranging from 5% to 9%) in 7 trials. FGG01 applied at 0.5 kg/ha showed 86% mean control in 7 trials.

When comparing with the reference standards, similar values of efficacy were observed. In 5 trials, FGG01 applied at 0.5 kg/ha showed a similar control to the reference standard CANTUS applied at 0.5 kg/ha (respectively 83% vs. 82% mean control). No statistical differences were found. In 2 trials, FGG01 applied at 0.5 kg/ha showed a similar control to the reference standard PICTOR applied at 0.5 L/ha (respectively 94% vs. 93% mean control). No statistical differences were found in the 2 trials.

On disease incidence on leaves with 1 application, the infestation in untreated plot reached up to 75% (ranging from 62% to 94%) in 8 trials. FGG01 applied at 0.5 kg/ha showed 58% mean control in 8 trials.

When comparing with the reference standards, in 6 trials, FGG01 applied at 0.5 kg/ha showed a similar control to reference standard CANTUS applied at 0.5 kg/ha (respectively 54% vs. 53% mean control). No statistical differences were found in the 6 trials.

In 2 trials, FGG01 applied at 0.5 kg/ha showed a control quite close to that of the reference standard PICTOR applied at 0.5 L/ha (respectively 72% vs. 65% mean control). Furthermore, FGG01 applied at 0.5 kg/ha was statistically similar to PICTOR at 0.5 L/ha in 1 out of 2 trials and superior in the last trial.

On disease severity on leaves with 2 applications, for information, in 1 single trial, the infestation in untreated plot reached up to 8%. FGG01 applied at 0.5 kg/ha showed a control quite close to that of the reference standard CANTUS applied at 0.5 kg/ha (respectively 88% vs. 79% control). However, FGG01 applied at 0.5 kg/ha was statistically superior to CANTUS at 0.5 kg/ha.

On disease incidence on leaves with 2 applications, for information, in 1 single trial, the infestation in untreated plot reached up to 91%. FGG01 applied at 0.5 kg/ha showed a superior control to the reference standard CANTUS applied at 0.5 kg/ha (respectively 58% vs. 42% control). Furthermore, FGG01 applied at 0.5 kg/ha was statistically superior to CANTUS at 0.5 kg/ha. These results should nevertheless be considered carefully owing to the reduced data set.

### **Assessment at BBCH 70-85:**

On disease severity on stems with 1 application, in 5 valid efficacy trials, the infestation in untreated plot reached up to 11% (ranging from 7% to 14%). FGG01 applied at 0.5 kg/ha showed 78% mean control in 5 trials. FGG01 applied at 0.5 kg/ha showed a control quite close to that of the reference standard CANTUS applied at 0.5 kg/ha (respectively 78% vs. 76% mean control). No statistical differences were found in the 5 trials.

On disease incidence on stems with 1 application, the infestation in untreated plot reached up to 27% (ranging from 13% to 51%) in 7 trials. FGG01 applied at 0.5 kg/ha showed 62% mean control in 7 trials.

When comparing with the reference standards, **in 5 valid efficacy trials**, FGG01 applied at 0.5 kg/ha **showed a control quite close** to the reference standard CANTUS applied at 0.5 kg/ha (respectively **53% vs. 60% mean** control). Furthermore, no statistical differences were found.

In 2 trials, FGG01 applied at 0.5 kg/ha showed a similar control to the reference standard PICTOR applied at 0.5 L/ha (respectively 84% vs. 88% mean control). Furthermore, no statistical differences were found in the 2 trials.

On disease severity on stems with 2 applications, the infestation in untreated plot reached up to 11% in 2 trials. FGG01 applied at 0.5 kg/ha showed a control quite close to that of the reference standard CANTUS applied at 0.5 kg/ha (respectively 84% vs. 77% mean control). FGG01 applied at 0.5 kg/ha was statistically similar to CANTUS at 0.5 kg/ha in 1 out of 2 trials and superior in the last trial.

On disease incidence on stems with 2 applications, the infestation in untreated plot reached up to 60% (ranging from 59% to 60%) in 2 trials. FGG01 applied at 0.5 kg/ha showed a control quite close to that of the reference standard CANTUS applied at 0.5 kg/ha (respectively 66% vs. 56% mean control). FGG01 applied at 0.5 kg/ha was statistically similar to CANTUS at 0.5 kg/ha in 1 out of 2 trials and superior in the last trial.

On disease severity on leaves, in 1 single valid efficacy trial with 2 applications, the untreated plot reached up to 21%. FGG01 applied at 0.5 kg/ha showed a similar control to the reference standard CANTUS applied at 0.5 kg/ha (respectively 87% vs. 88% control). No statistical differences were found. In the same trial, the disease incidence on leaves in untreated plot reached up to 97%. FGG01 applied at 0.5 kg/ha showed a similar control to the reference standard CANTUS applied at 0.5 kg/ha (respectively 68% vs. 65% control). No statistical differences were found.

**Therefore, by and large, data from 9 trials, with a moderate level of infestation, FGG01 applied at 0.5 kg/ha showed an adequate to good effectiveness, at an equivalent level of control to the references CANTUS applied at 0.5 kg/ha and PICTOR applied at 0.5 L/ha against *Plenodomus lingam* (LEPTMA) on oilseed rape in the North-East EPPO zone. Therefore, one application at the rate of 0.5 kg/ha will be recommended on the product label for the control of LEPTMA in the in the North-East EPPO climatic zone on oilseed rape.**

## **B. Results on oilseed rape (BRSNN) - *Plenodomus lingam* (LEPTMA) - South-East EPPO zone**

A total of 3 valid efficacy trials were carried out in 2021 to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) applied once at 0.5 kg/ha for the control of *Plenodomus lingam* on oilseed rape in comparison to the reference standard CANTUS (500 g/kg of boscalid, WG) at 0.5 kg/ha in the South-East (Hungary) EPPO climatic zone. An overview of these trials is presented in Table 3.2-13.

The summary results of the effect of FGG01 applied at 0.5 kg/ha compared to references standard are shown in Table 3.2-53.

**Table 3.2-53: Summary results: efficacy of FGG01 against *Plenodomus lingam* on oilseed rape - South-East EPPO zone**

Assessment	Parts	Parameters	EPPO climatic zone	No. of trials	Days after application	Untreated control Infestation (%)			FGG01 0.5 kg/ha			CANTUS 0.5 kg/ha			No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at 0.5 kg/ha vs. CANTUS at 0.5 kg/ha
						Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	
3-5 weeks after application	PLANT	Severity (%)	South-East	3	[27-36 DA-A]	15.1	6.1	29.3	75.5	61.0	84.2	83.6	73.4	89.1	0> ; 3= ; 0<
	PLANT	Incidence (%)	South-East	3	[27-36 DA-A]	70.0	69.0	71.0	50.1	35.2	63.8	59.1	52.9	69.6	0> ; 3= ; 0<
Assessment at BBCH 50-65	PLANT	Severity (%)	South-East	2	[177-191 DA-A]	43.6	38.8	48.4	82.3	79.4	85.2	88.0	86.2	89.7	0> ; 2= ; 0<
	PLANT	Incidence (%)	South-East	3	[177-200 DA-A]	63.3	31.0	86.0	64.0	37.0	96.8	66.8	47.9	100.0	0> ; 3= ; 0<
Assessment at BBCH 70-85	PLANT	Severity (%)	South-East	1	250 DA-A	6.1	-	-	89.9	-	-	88.3	-	-	0> ; 1= ; 0<
	PLANT	Incidence (%)	South-East	3	[240-250 DA-A]	61.7	31.0	87.0	74.0	53.7	93.5	61.6	38.8	100.0	1> ; 2= ; 0<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.



### **Assessment at around 3-5 weeks:**

In the South-East EPPO climatic zone, on disease severity on plants, the infestation in untreated plot reached up to 15% (ranging from 6% to 29%) in 3 trials. FGG01 applied at 0.5 kg/ha showed a control quite close to that of the reference standard CANTUS applied at 0.5 kg/ha (respectively 76% vs. 84% mean control). Furthermore, no statistical differences were found in the 3 trials.

On disease incidence on plants, the infestation in untreated plot reached up to 70% (ranging from 69% to 71%) in 3 trials. FGG01 applied at 0.5 kg/ha showed a control quite close to that of the reference standard CANTUS applied at 0.5 kg/ha (respectively 50% vs. 59% mean control). Furthermore, no statistical differences were found in the 3 trials.

### **Assessment at BBCH 50-65:**

On disease severity on plants, the infestation in untreated plot reached up to 44% (ranging from 39% to 48%) in 2 trials. FGG01 applied at 0.5 kg/ha showed a control quite close to that of the reference standard CANTUS applied at 0.5 kg/ha (respectively 82% vs. 88% mean control). Furthermore, no statistical differences were found in the 2 trials.

On disease incidence on plants, the infestation in untreated plot reached up to 63% (ranging from 31% to 86%) in 3 trials. FGG01 applied at 0.5 kg/ha showed a similar control to the reference standard CANTUS applied at 0.5 kg/ha (respectively 64% vs. 67% mean control). No statistical differences were found in the 3 trials.

### **Assessment at around BBCH 70-85:**

On disease severity on plants, in 1 single valid efficacy trial, the infestation in untreated plot reached up to 6%. FGG01 applied at 0.5 kg/ha showed a similar control to the reference standard CANTUS applied at 0.5 kg/ha (respectively 90% vs. 88% control). No statistical differences were found.

On disease incidence on plants, the infestation in untreated plot reached up to 62% (ranging from 31% to 87%) in 3 trials. FGG01 applied at 0.5 kg/ha showed a slightly superior control to the reference standard CANTUS applied at 0.5 kg/ha (respectively 74% vs. 62% mean control). FGG01 applied at 0.5 kg/ha was statistically similar to CANTUS at 0.5 kg/ha in 2 out of 3 trials and superior in the last trial.

**Therefore, by and large, data from 3 trials, with a moderate level of infestation, FGG01 applied at 0.5 kg/ha showed an adequate to good effectiveness, at an equivalent level of control to the reference CANTUS applied at 0.5 kg/ha against *Plenodomus lingam* (LEPTMA) on oilseed rape in the South-East EPPO zone. Therefore, one application at the rate of 0.5 kg/ha will be recommended on the product label for the control of LEPTMA in the South-East EPPO climatic zone on oilseed rape.**

## **C. Results on oilseed rape (BRSNN) - *Plenodomus lingam* (LEPTMA) - All EPPO zones**

A total of 12 valid efficacy trials were carried out in 2021, 2022 and 2023 to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) applied at 0.5 kg/ha for the control of *Plenodomus lingam* on oilseed rape in comparison to the reference standards CANTUS (Boscalid 500 g/kg; WG) at 0.5 kg/ha and PICTOR (200 g/L Boscalid + 200 g/L Dimoxystrobin; SC) at 0.5 L/ha across all EPPO climatic zones. An overview of these trials is presented in Table 3.2-13.

The summary results of the effect of FGG01 applied at 0.5 kg/ha compared to reference standards are shown in Table 3.2-54.

**Table 3.2-54: Summary results: efficacy of FGG01 against *Plenodomus lingam* on oilseed rape - All EPPO zones**

Assessment	Nb. applications	Parts	Parameters	EPPO climatic zone	No. of trials	Days after application	Untreated control			FGG01 0.5 kg/ha			CANTUS 0.5 kg/ha			PICTOR 0.5 L/ha			No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at 0.5 kg/ha vs.	
							Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	CANTUS (0.5 kg/ha)	PICTOR (0.5 L/ha)
3-4 weeks after application	1 application	LEAF	Incidence (%)	North-East	9	[20-28 DA-A]	42.1	5.0	75.0	68.5	38.1	100.0	-	-	-	-	-	-	-	-
					7	[20-28 DA-A]	52.3	36.0	75.0	59.5	38.1	82.7	65.8	49.2	84.0	-	-	-	0> ; 6= ; 1<	-
					2	[25-25 DA-A]	6.5	5.0	8.0	100.0	100.0	100.0	-	-	-	100.0	100.0	100.0	-	0> ; 2= ; 0<
		PLANT	Severity (%)	South-East	3	[27-36 DA-A]	15.1	6.1	29.3	75.5	61.0	84.2	83.6	73.4	89.1	-	-	-	0> ; 3= ; 0<	-
					3	[27-36 DA-A]	70.0	69.0	71.0	50.1	35.2	63.8	59.1	52.9	69.6	-	-	-	0> ; 3= ; 0<	-
					12	[20-36 DA-A]	49.1	5.0	75.0	63.9	35.2	100.0	-	-	-	-	-	-	-	-
Assessment at BBCH 50-65	1 application	LEAF	Severity (%)	North-East	7	[166-209 DA-A]	7.4	4.9	8.5	85.8	80.2	99.1	-	-	-	-	-	-	-	-
					5	[166-182 DA-A]	7.0	4.9	8.2	82.5	80.2	85.6	82.2	81.5	83.2	-	-	-	0> ; 5= ; 0<	-
					2	[199-209 DA-A]	8.4	8.2	8.5	94.2	89.3	99.1	-	-	-	93.2	90.3	96.0	-	0> ; 2= ; 0<
		LEAF	Incidence (%)	North-East	8	[166-209 DA-A]	75.3	62.0	94.0	58.3	45.6	93.6	-	-	-	-	-	-	-	-
					6	[166-207 DA-A]	74.0	62.0	83.0	53.8	45.6	71.0	53.4	47.1	69.4	-	-	-	0> ; 6= ; 0<	-
					2	[199-209 DA-A]	79.0	64.0	94.0	71.8	50.0	93.6	-	-	-	64.9	53.1	76.6	-	1> ; 1= ; 0<
		PLANT	Severity (%)	South-East	2	[177-191 DA-A]	43.6	38.8	48.4	82.3	79.4	85.2	88.0	86.2	89.7	-	-	-	0> ; 2= ; 0<	-
					3	[177-200 DA-A]	63.3	31.0	86.0	64.0	37.0	96.8	66.8	47.9	100.0	-	-	-	0> ; 3= ; 0<	-
					9	[166-209 DA-A]	15.4	4.9	48.4	85.0	79.4	99.1	-	-	-	-	-	-	-	-
		LEAF / PLANT	Severity (%)	All zones	7	[166-191 DA-A]	17.5	4.9	48.4	82.4	79.4	85.6	83.9	81.5	89.7	-	-	-	0> ; 7= ; 0<	-
					11	[166-209 DA-A]	72.0	31.0	94.0	59.9	37.0	96.8	-	-	-	-	-	-	-	-
					9	[166-207 DA-A]	70.4	31.0	86.0	57.2	37.0	96.8	57.9	47.1	100.0	-	-	-	0> ; 9= ; 0<	-
Assessment at BBCH 70-85	1 application	STEM	Severity (%)	North-East	5	[256-269 DA-A]	10.7	7.4	13.8	77.5	45.2	88.7	76.3	37.6	88.0	-	-	-	0> ; 5= ; 0<	-
					7	[245-269 DA-A]	26.7	13.0	51.0	61.8	43.1	90.6	-	-	-	-	-	-	-	-
		STEM	Incidence (%)	North-East	5	[245-269 DA-A]	30.6	23.0	51.0	53.0	43.1	70.4	59.9	45.1	70.4	-	-	-	0> ; 5= ; 0<	-
					2	[245-252 DA-A]	17.1	13.0	21.2	83.7	76.9	90.6	-	-	-	87.6	84.6	90.6	-	0> ; 2= ; 0<
		PLANT	Severity (%)	South-East	1	250 DA-A	6.1	-	-	89.9	-	-	88.3	-	-	-	-	-	0> ; 1= ; 0<	-
					3	[240-250 DA-A]	61.7	31.0	87.0	74.0	53.7	93.5	61.6	38.8	100.0	-	-	-	1> ; 2= ; 0<	-
		STEM / PLANT	Severity (%)	All zones	6	[250-269 DA-A]	9.9	6.1	13.8	79.6	45.2	89.9	78.3	37.6	88.3	-	-	-	0> ; 6= ; 0<	-
					10	[240-269 DA-A]	37.2	13.0	87.0	65.5	43.1	93.5	-	-	-	-	-	-	-	-
		STEM / PLANT	Incidence (%)	All zones	8	[240-269 DA-A]	42.3	23.0	87.0	60.9	43.1	93.5	60.5	38.8	100.0	-	-	-	1> ; 7= ; 0<	-

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

### **Assessment at around 3-5 weeks:**

In the All EPPO climatic zones, on disease incidence on leaves/plants, the infestation in untreated plot reached up to 49% (ranging from 5% to 75%) in 12 trials. FGG01 applied at 0.5 kg/ha reached 64% mean control.

In comparison with the reference standard, in 10 trials, FGG01 applied at 0.5 kg/ha showed a control quite close to that of the reference standard CANTUS applied at 0.5 kg/ha (respectively 57% vs. 64% mean control). No statistical differences were found in 9 out of 10 trials.

### **Assessment at BBCH 50-65:**

On disease severity on leave/plants, the infestation in untreated plot reached up to 15% (ranging from 5% to 48%) in 9 trials. FGG01 applied at 0.5 kg/ha reached 85% mean control.

In comparison with the reference standard, in 7 trials, FGG01 applied at 0.5 kg/ha showed a similar control to the reference standard CANTUS applied at 0.5 kg/ha (respectively 82% vs. 84% mean control). No statistical differences were found in the 7 trials.

On disease incidence on leaves/plants, the infestation in untreated plot reached up to 72% (ranging from 31% to 94%) in 11 trials. FGG01 applied at 0.5 kg/ha reached 60% mean control.

In comparison with the reference standard, in 9 trials, FGG01 applied at 0.5 kg/ha showed a similar control to the reference standard CANTUS applied at 0.5 kg/ha (respectively 57% vs. 58% mean control). No statistical differences were found in the 9 trials.

### **Assessment at BBCH 70-85:**

On disease severity on stems/plants, the infestation in untreated plot reached up to 10% (ranging from 6% to 14%) in 6 trials. FGG01 applied at 0.5 kg/ha reached 80% mean control.

FGG01 applied at 0.5 kg/ha showed a similar control to the reference standard CANTUS applied at 0.5 kg/ha (respectively 80% vs. 78% mean control). No statistical differences were found in the 6 trials.

On disease incidence on stems/plants, the infestation in untreated plot reached up to 37% (ranging from 13% to 87%) in 10 trials. FGG01 applied at 0.5 kg/ha reached 66% control.

In comparison with the reference standard, in 8 trials, FGG01 applied at 0.5 kg/ha showed a similar control to the reference standard CANTUS applied at 0.5 kg/ha (respectively 61% vs. 61% mean control). FGG01 applied at 0.5 kg/ha was statistically similar to CANTUS at 0.5 kg/ha in 7 out of 8 trials and superior in the last trial.

**Therefore, by and large, data from 12 trials, with a moderate level of infestation, FGG01 applied at 0.5 kg/ha showed an adequate to good effectiveness, at an equivalent level of control to the reference CANTUS applied at 0.5 kg/ha against *Plenodomus lingam* (LEPTMA) on oilseed rape in all EPPO climatic zones. Therefore, one application at the rate of 0.5 kg/ha will be recommended on the product label for the control of LEPTMA in the Central registration zone on oilseed rape.**

## **D. Conclusion on oilseed rape - *Plenodomus lingam* (LEPTMA)**

A total of 12 valid efficacy trials were carried out in 2021, 2022 and 2023 to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) applied at 0.5 kg/ha for the control of *Plenodomus lingam* on oilseed rape in comparison to the reference standard CANTUS (Boscalid 500 g/kg; WG) at 0.5 kg/ha and PICTOR (200 g/L Boscalid + 200 g/L Dimoxystrobine; SC) at 0.5 L/ha in the North-East (Poland) and South-East (Hungary) EPPO climatic zones.

The summary results of the effect of FGG01 applied at 0.5 kg/ha compared to the reference standards in the North-East, South-East and all EPPO climatic zones are shown in Table 3.2-55.

**Table 3.2-55: Overall summary of efficacy of FGG01 on oilseed rape against *Plenodomus lingam* in the Central registration zone**

Crop code	Pest code	EPPO climatic zone	Part assessed	Nb of trials	Untreated control	Efficacy (%) of			No. of assessments significantly <sup>(1)</sup> >, =, < FGG01 at 0.5 kg/ha vs.	
					(% infestation)	FGG01 0.5 kg/ha	CANTUS 0.5 kg/ha	PICTOR 0.5 L/ha	CANTUS 0.5 kg/ha	PICTOR 0.5 L/ha
BRSNN	LEPTMA	North-East	Disease incidence on leaves - 3-4 weeks after the first application	9	42.1	68.5	-	-	-	-
				7	52.3	59.5	65.8	-	0> ; 6= ; 1<	-
				2	6.5	100.0	-	100.0	-	0> ; 2= ; 0<
			Disease severity on leaves - BBCH 50-65 - 1 application	7	7.4	85.8	-	-	-	-
				5	7.0	82.5	82.2	-	0> ; 5= ; 0<	-
				2	8.4	94.2	-	93.2	-	0> ; 2= ; 0<
			Disease incidence on leaves - BBCH 50-65 - 1 application	8	75.3	58.3	-	-	-	-
				6	74.0	53.8	53.4	-	0> ; 6= ; 0<	-
				2	79.0	71.8	-	64.9	-	1> ; 1= ; 0<
			Disease severity on leaves - BBCH 50-65 - 2 applications	1	7.8	88.4	79.3	-	1> ; 0= ; 0<	-
				1	91.0	58.2	41.8	-	1> ; 0= ; 0<	-
				5	10.7	77.5	76.3	-	0> ; 5= ; 0<	-
		South-East	Disease incidence on stems - BBCH 70-85 - 1 application	3	28.4	70.2	-	-	-	-
				1	51.0	43.1	45.1	-	0> ; 1= ; 0<	-
				2	17.1	83.7	-	87.6	-	0> ; 2= ; 0<
			Disease severity on stems - BBCH 70-85 - 2 applications	7	26.7	61.8	-	-	-	-
				5	30.6	53.0	59.9	-	0> ; 5= ; 0<	-
				1	21.2	86.5	88.3	-	0> ; 1= ; 0<	-
			Disease incidence on leaves - BBCH 70-85 - 2 applications	1	97.0	68.0	64.9	-	0> ; 1= ; 0<	-
				3	15.1	75.5	83.6	-	0> ; 3= ; 0<	-
				3	70.0	50.1	59.1	-	0> ; 3= ; 0<	-
			Disease severity on plants - BBCH 50-65 - 1 application	2	43.6	82.3	88.0	-	0> ; 2= ; 0<	-
				3	63.3	64.0	66.8	-	0> ; 3= ; 0<	-
				1	6.1	89.9	88.3	-	0> ; 1= ; 0<	-
		All zones	Disease incidence on plants - BBCH 70-85 - 1 application	3	61.7	74.0	61.6	-	1> ; 2= ; 0<	-
				12	49.1	63.9	-	-	-	-
				10	57.6	56.7	63.8	-	0> ; 9= ; 1<	-
			Disease severity on leaves/plants - BBCH 50-65 - 1 application	9	15.4	85.0	-	-	-	-
				7	17.5	82.4	83.9	-	0> ; 7= ; 0<	-
				11	72.0	59.9	-	-	-	-
			Disease incidence on leaves/plants - BBCH 50-65 - 1 application	9	70.4	57.2	57.9	-	0> ; 9= ; 0<	-
				6	9.9	79.6	78.3	-	0> ; 6= ; 0<	-
				10	37.2	65.5	-	-	-	-
			Disease incidence on stems/plants - BBCH 70-85 - 1 application	8	42.3	60.9	60.5	-	1> ; 7= ; 0<	-

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

In 12 trials, FGG01 applied at 0.5 kg/ha showed an equivalent level of control to the reference product CANTUS at 0.5 kg/ha *Plenodomus lingam* (LEPTMA) and overall, no statistical differences were detected between both products in all trials. Therefore, one application at the rate of 0.5 kg/ha will be recommended on the product label for the control of LEPTMA in the North-East and South-East EPPO climatic zones.

Trials have only been conducted in the North-East and South-East EPPO climatic zones even if Austria and Czech Republic (claimed countries) are included in the Maritime EPPO climatic zone. Indeed, this area is representative of *Plenodomus lingam* occurrence in Europe and is the most challenging for this

disease. Therefore, according to EPPO standard PP 1/307 (2), the data generated in the North-East and South-East EPPO climatic zones can be extrapolated in Austria and Czech Republic.

In addition, in this dossier, the comparability between FGG01 and the reference product CANTUS has been also proven on many major crops for many uses on oilseed rape and also on grapevine, on peas and beans. In this context, the comparability between FGG01 and the reference product CANTUS can be extrapolated to *Plenodomus lingam* in oilseed rape in Austria and Czech Republic.

### **3.2.3.1.5 Effect on the yield in presence of oilseed rape diseases**

#### **A. Effect on the yield of oilseed rape in presence of *Sclerotinia sclerotiorum* (SCLESC)**

A total of 1 efficacy trial was harvested in 2023 in the North-East (Poland) EPPO climatic zone. The objective was to confirm the yield response of FGG01 (500 g/kg of boscalid, WG) in the presence of *Sclerotinia sclerotiorum* in oilseed rape crop.

Table 3.2-56 shows a summary of positive effect on the yield of FGG01 (500 g/kg of boscalid, WG) applied at 0.5 kg/ha compared to the reference standard CANTUS (500 g/kg of boscalid, WG) at 0.5 kg/ha.

**Table 3.2-56: Summary results: Positive effect on the yield of FGG01 at 0.5 kg/ha compared to the reference standard CANTUS - Oilseed rape - SCLESC**

Parameters	Disease present	Crop	Parts	EPPO climatic zone	No. of trials	Days after application	Untreated control (t/ha)			FGG01 0.5 kg/ha (% of untreated check)			CANTUS 0.5 kg/ha (% of untreated check)			No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at 0.5 kg/ha vs. CANTUS (0.5 kg/ha)
							Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	
YIELD	SCLESC	BRSNW	GRAIN	North-East	1	75 DA-A	2.87	-	-	102.7	-	-	101.9	-	-	0> ; 1= ; 0<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

### **In the North-East EPPO climatic zone**

FGG01 at 0.5 kg/ha had no negative impact on the yield of oilseed rape in the presence of *Sclerotinia sclerotiorum*. In fact, in 1 trial there was similar yield compared to the untreated (increased by only 3%). Furthermore, there was no statistically significant difference between FGG01 at 0.5 kg/ha and the reference standard CANTUS at 0.5 kg/ha.

## **B. Conclusion on the effect on the yield of oilseed rape in presence of diseases**

In 1 harvested trial in the North-East EPPO climatic zone oilseed rape in the presence of *Sclerotinia sclerotiorum*, it was observed a similar yield between FGG01 at the proposed label rate of 0.5 kg/ha and the untreated plot. Furthermore, no statistically significant differences were found between FGG01 applied at 0.5 kg/ha compared to the reference CANTUS applied at the same dose rate of 0.5 kg/ha.

**Therefore, overall FGG01 at the proposed label rate of 0.5 kg/ha is expected to have a positive effect on the yield of crops treated on the presence of disease.**

### **3.2.3.2 Efficacy trials in grapevine (VITVI)**

A total of 26 efficacy trials, including supportive data (13 trials), were carried out to justify the interest of FGG01 (500 g/kg of boscalid, WG) applied at different target dose rates according to the disease, in comparison to different reference standards for the control of *Botrytis cinerea* and *Erysiphe necator* in grapevine. The trials were carried out in the Maritime EPPO climatic zone and additionally, supportive data from Mediterranean EPPO climatic zone are also presented to complete the data package, as already justified in the page 26 of this document under the part 'Justification for the use of data from different countries'.

#### **3.2.3.2.1 Material and Methods**

##### **Experimental details**

All the trials presented in Table 3.2-14 were carried out by officially recognised organisations in accordance with the Principles of Good Experimental Practice (GEP). These trials were performed following EPPO guidelines.

Main characteristics are summarised in Table 3.2-57 (Maritime) for trials against *Botrytis cinerea* and in Table 3.2-58 (Mediterranean) for the supportive trials against this disease. Table 3.2-59 (Maritime) summarises the main characteristics of trials against *Erysiphe necator* and in Table 3.2-60 (Mediterranean) the supportive trials against this disease. Details per trial (trial location, crop cultivar, experimental design, number of blocks, plot size and application(s)) are presented in Biological Assessment Dossier and in individual trial reports in Document K.

**Table 3.2-57: Details on trial methodology - Efficacy trials - Grapevine - BOTRCI - Maritime EPPO climatic zone**

<b>Guidelines</b>	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”. PP 1/239(3): “Dose expression for plant protection products”
	Specific guidelines	PP1/17(3): “Botrytis cinerea on grapevine”
<b>Experimental design</b>	Plot design	Randomized Complete Block (RCB)
	Plot size	24-30 m²
	Number of replications	4 replications.
<b>Crop</b>	Number of trials	3 valid efficacy trials
	Varieties	<i>Bacchus (1), Weissburgunder (2).</i>
<b>Application</b>	Application timing	Between BBCH 67-85
	Number of applications	4 applications.
	Spray volumes	Foliar spraying: 450-800 L/ha.
<b>Assessment</b>	Assessment dates	On bunches from appearance of the first symptoms in the untreated, an intermediate assessment and at harvest.
	Assessment types	Disease incidence and disease severity on bunches. Phytotoxicity assessments.
<b>Results &amp; Analysis</b>	Statistical analysis	ANOVA - Newman - Keuls test (5%).

**Table 3.2-58: Details on trial methodology - Efficacy trials - Grapevine - BOTRCI - Supporting trials - Mediterranean EPPO climatic zone**

<b>Guidelines</b>	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”. PP 1/239(3): “Dose expression for plant protection products”
	Specific guidelines	PP1/17(3): “Botrytis cinerea on grapevine”
<b>Experimental design</b>	Plot design	Randomized Complete Block (RCB)
	Plot size	20-36 m²
	Number of replications	4 replications.
<b>Crop</b>	Number of trials	6 valid efficacy trials
	Varieties	<i>Bellone (1), Negrette (1), Pinot Gris (1), Tinta Roriz (2) and Zalema (1).</i>
<b>Application</b>	Application timing	Between BBCH 65-85
	Number of applications	4 applications.
	Spray volumes	Foliar spraying: 200-1000 L/ha.
<b>Assessment</b>	Assessment dates	On bunches from appearance of the first symptoms in the untreated, an intermediate assessment and at harvest.
	Assessment types	Disease incidence and disease severity on bunches. Phytotoxicity assessments.
<b>Results &amp; Analysis</b>	Statistical analysis	ANOVA - Newman - Keuls test (5%).



**Table 3.2-59: Details on trial methodology - Efficacy trials - Grapevine - UNCINE - Maritime EPPO climatic zone**

<b>Guidelines</b>	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”. PP 1/239(3): “Dose expression for plant protection products”
	Specific guidelines	PP1/4(4): “Efficacy evaluation of fungicides - <i>Uncinula necator</i> ” PP1/17(3): “ <i>Botrytis cinerea</i> on grapevine”
<b>Experimental design</b>	Plot design	Randomized Complete Block (RCB)
	Plot size	20-25 m <sup>2</sup>
	Number of replications	4 replications.
<b>Crop</b>	Number of trials	10 valid efficacy trials
	Varieties	Acolon (1), Blauburgunder (1), Chardonnay (1), Morillon (2), Müller-Thurgau (1), Riesling (1), Sämling 88 (1), Trolinger (1), Weissburgunder (1).
<b>Application</b>	Application timing	Between BBCH 14-81 (7 trials). Between BBCH 14-89 (3 trials): last application a bit late but without impact in the efficacy results.
	Number of applications	8 applications: 9 trials 9 applications: 1 trial
	Spray volumes	Foliar spraying: 100-800 L/ha.
<b>Assessment</b>	Assessment dates	On leaves (at least 3 assessments): from appearance of the first symptoms in the untreated, before each application and at bunches assessments. On bunches (at least 2 assessments): at BBCH 71 and at BBCH 81. More assessments if relevant.
	Assessment types	Disease incidence and disease severity on leaves and bunches. Phytotoxicity assessments.
<b>Results &amp; Analysis</b>	Statistical analysis	ANOVA - Newman - Keuls test (5%).

**Table 3.2-60: Details on trial methodology - Efficacy trials - Grapevine - UNCINE - Supporting trials - Mediterranean EPPO climatic zone**

<b>Guidelines</b>	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”. PP 1/239(3): “Dose expression for plant protection products”
	Specific guidelines	PP1/4(4): “Efficacy evaluation of fungicides - <i>Uncinula necator</i> ” PP1/17(3): “ <i>Botrytis cinerea</i> on grapevine”
<b>Experimental design</b>	Plot design	Randomized Complete Block (RCB)
	Plot size	17-44 m <sup>2</sup>
	Number of replications	4 replications.
<b>Crop</b>	Number of trials	7 valid efficacy trials
	Varieties	Carignan (2), Chardonnay (2), Freisa (1), Palomino (1), Zalema (1).
<b>Application</b>	Application timing	Between BBCH 14-81
	Number of applications	From 5 to 8 applications.
	Spray volumes	Foliar spraying: 200-1000 L/ha.
<b>Assessment</b>	Assessment dates	On leaves (at least 3 assessments): from appearance of the first symptoms in the untreated, before each application and at bunches assessments. On bunches (at least 2): at BBCH71 and at BBCH81. More assessments if relevant.
	Assessment types	Disease incidence and disease severity on leaves and bunches. Phytotoxicity assessments.
<b>Results &amp; Analysis</b>	Statistical analysis	ANOVA - Newman - Keuls test (5%).

## Dose expression in trials

According to the protocols, the products were applied according to 2 different doses expression in efficacy trials:

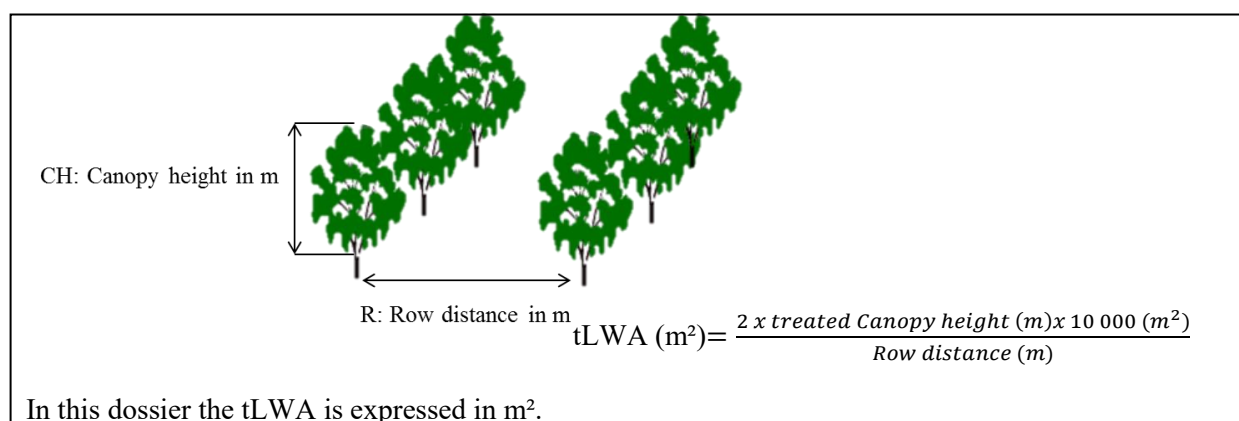
- Ground area (kg/ha)
- Leaf wall area (kg/10 000 m<sup>2</sup> LWA = kg/ha LWA)

In this dossier, the rate expression chosen is the ground area (kg/ha) for all countries. However, the LWA is a rate expression requested by some countries to reach a harmonisation of dose expression between European countries.

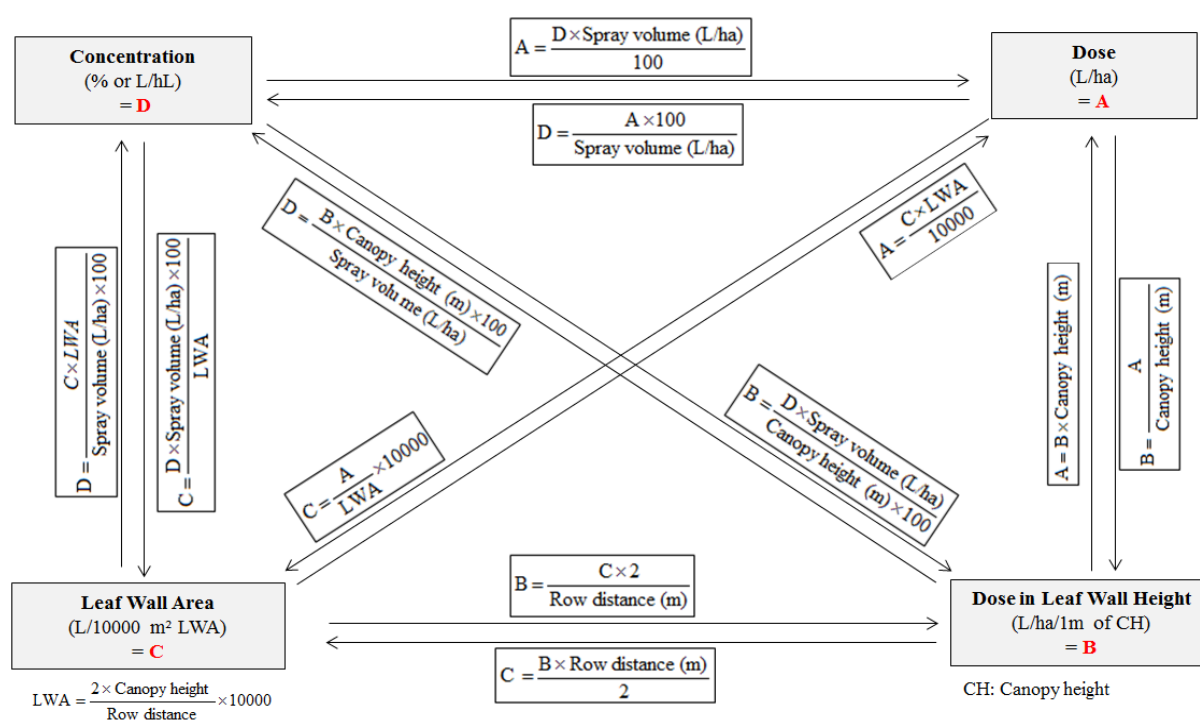
Regarding the dose rate expression in the GAP table (in Table 3.1-1), 3 expressions are available: kg/ha, kg/100 L and kg/10000 m<sup>2</sup> LWA. In the trials, the rate in kg/ha is available in all zones and the rates in kg/100 L and kg/10000 m<sup>2</sup> LWA are available in some trials. Indeed, the ground-based rate (kg/ha) is present in all the trials because it's the most common dose rate expression.

The following Figure 3.2-8 and Figure 3.2-9 present the calculation formulas of the treated Leaf Wall Area (tLWA) and conversion between the different expression rates.

**Figure 3.2-8**      **Formula of the tLWA (treated Leaf Wall Area)**



**Figure 3.2-9 Conversion formulas between the different expression rates of application**



## Treatments and reference standards

### Efficacy trials against *Botrytis cinerea*

In all maritime efficacy trials against *Botrytis cinerea*, the efficacy of FGG01 applied at 0.72 kg/10000 m² LWA and at 1.0 kg/ha, while in the supportive Mediterranean trials, the target dose was 1.0 kg/ha. In all the trials FGG01 was compared to the reference standard CANTUS applied at 1.0 kg/ha (Table 3.2-16). This rate is equivalent to the maximum dose of FGG01 requested (1.0 kg/ha).

The following Table 3.2-61 presents the main characteristics of protocols used in each trial.

Table 3.2-62 below presents the plant protection products and the rates applied in the efficacy trials against *Botrytis cinerea*.

**Table 3.2-61: Main characteristics of protocols - Grapevine - BOTRCI**

EPPO climatic zone	Nb. of trials	Country	Year	FGG01		Transversal reference products	Local reference product for trial validation
				1.0 kg/ha	0.72 kg/10000 m <sup>2</sup> LWA	CANTUS 1.0 kg/ha	
Maritime	2 trials	AT	2023	X	X	X	CANTUS at 1.0 kg/ha
	1 trial	DE	2023	X	X	X	CANTUS at 1.0 kg/ha
Mediterranean	2 trials	PT	2021	X		X	CANTUS at 1.0 kg/ha
	1 trial	FR	2023	X		X	CANTUS at 1.0 kg/ha
	2 trials	IT	2023	X		X	CANTUS at 1.0 kg/ha
	1 trial	ES	2023	X		X	GEOXE 50 WG at 1.0 kg/ha

**Table 3.2-62: Plant protection products used in efficacy trials - Grapevine - BOTRCI**

Product name	Active substance(s)	Formulation		Application dose in trials (per treatment)			Country	Rate of active substance	Remark
		Type <sup>[1]</sup>	Concentration of a.s.	kg/ha	kg/100 L	kg/10000 m <sup>2</sup> LWA			
FGG01	Boscalid	WG	500 g/kg	1.0 kg/ha	-	0.72 kg/10000 m <sup>2</sup> LWA	-	500 g a.s./ha 360 g a.s./10000 m <sup>2</sup> LWA	-
CANTUS	Boscalid	WG	500 g/kg	1.0 kg/ha	-	-	AT, DE, FR, IT, PT, ES	500 g a.s./ha	-
GEOXE 50 WG	Fludioxonil	WG	50%	1.0 kg/ha		-	ES	500 g a.s./ha	-

<sup>[1]</sup> WG: Water-dispersible granules

In countries like Austria and Germany, lower doses of the registered reference CANTUS can also be applied according to the BBCH crop stage with a maximum of 1.2 kg/ha. In countries like France, where a dose range is not indicated for the registered rate of CANTUS, only 1.2 kg/ha on grapevine against *Botrytis cinerea* is indicated. However, in the neighbouring countries where the trials were carried out like Italy, Portugal and Spain, the registered rate is indicated as a range of doses 1.0-1.2 kg/ha. Indeed, in practice, on grapevine against *Botrytis cinerea*, CANTUS is usually used at 1.0 kg/ha. Therefore, the dose of 1.0 kg/ha of CANTUS is the transversal dose selected for the trials and it can be considered as a reliable reference for the trials validation.

#### Efficacy trials against *Erysiphe necator*

In the Maritime efficacy trials against *Erysiphe necator*, FGG01 was applied at 0.20 kg/ha, at 0.01, 0.015 0.02 kg/100 L and/or at 0.07, 0.1, 0.13 or 0.14 kg/10000 m<sup>2</sup> LWA, these last two doses have been summarised together (0.13-0.14 kg/10000 m<sup>2</sup> LWA) as there is less than 10% difference between them, the deviation is not considered significant. On the other hand, in the supportive Mediterranean trials, FGG01 was tested at 0.2 kg/ha.

The following Table 3.2-63 presents the main characteristics of protocols used in each trial. Table 3.2-64 below presents the plant protection products and the rates applied in the efficacy trials against *Erysiphe necator*.

**Table 3.2-63: Main characteristics of protocols - Grapevine - UNCINE**

EPPO climatic zone	Nb. of trials	Country	Year	FGG01							Transversal reference products		Local reference product for trial validation*	
				0.01 kg/100 L	0.015 kg/100 L	0.02 kg/100 L	0.07 kg/10000 m <sup>2</sup> LWA	0.1 kg/10000 m <sup>2</sup> LWA	0.13 kg/10000 m <sup>2</sup> LWA	0.14 kg/10000 m <sup>2</sup> LWA	0.2 kg/ha	CANTUS 0.2 kg/ha		COLLIS 0.64 L/ha
Maritime	2 trials	DE	2022	X	X	X			X		X		X	COLLIS at 0.64 L/ha
	2 trials	AT	2022	X	X	X			X		X		X	COLLIS at 0.64 L/ha
	1 trial	DE	2023				X	X		X	X	X		PROSPER TEC at 0.66 L/ha
	1 trial	AT	2023				X	X		X	X	X		PROSPER TEC at 0.66 L/ha
	2 trials	AT	2023				X	X		X	X	X		KUMULUS DF at 5-8 kg/ha
	2 trials	DE	2023				X	X		X	X	X		TOPAS at 0.8 L/ha
Mediterranean	1 trial	IT	2022								X			CANTUS at 0.1 kg/100 L
	1 trial	FR	2023								X	X		COLLIS at 0.64 L/ha
	1 trial	FR	2023								X	X		CANTUS at 0.2 kg/ha
	2 trials	IT	2023								X	X		CANTUS at 0.2 kg/ha
	2 trials	ES	2023								X	X		CANTUS at 0.2 kg/ha

\* Reference products not presented in the efficacy part but included in the Appendix 3 of the Biological Assessment Dossier .

**Table 3.2-64: Plant protection products used in efficacy trials - Grapevine - UNCINE**

Product name	Active substance(s)	Formulation		Application dose in trials (per treatment)			Country	Rate of active substance	Remark
		Type <sup>[1]</sup>	Concentration of a.s.	kg/ha	kg/100 L	kg/10000 m <sup>2</sup> LWA			
FGG01	Boscalid	WG	500 g/kg	0.2 kg/ha	0.01, 0.015, 0.02 kg/100 L	0.07, 0.10, 0.13, 0.14 kg/10000 m <sup>2</sup> LWA	-	100 g a.s./ha 5-10 g a.s./100 L 35-70 g a.s./ 10000 m <sup>2</sup> LWA	In supportive trials more doses were tested of FGG01 but not shown in this BAD
CANTUS	Boscalid	WG	500 g/kg	0.2 kg/ha	0.1 kg/100 L	-	IT	50 g a.s./100 L	-
					-	-	AT, DE, ES, FR, IT	100 g a.s./ha	-
COLLIS	Boscalid Kresoxim-methyl	SC	200 g/L 100 g/L	0.4 L/ha	-	-	FR	80 g a.s./ha 40 g a.s./ha	-
				0.64 L/ha	-	-	AT, DE	128 g a.s./ha 64 g a.s./ha	-
GEOXE 50 WG	Fludioxonil	WG	50%	1.0 kg/ha	-	-	ES	500 g s.a./ha	-
KUMULUS DF	Sulphur	WG	800 g/kg	A, B: 5 kg/ha C-F: 8 kg/ha	-	-	AT	4-6.4 kg a.s./ha	Also named KUMULUS in this BAD
PICTOR PRO	Boscalid	WG	500 g/kg	0.2 kg/ha	-	-	FR	100 g a.s./ha	Also named CANTUS in this BAD
PROSPER TEC	Spiroxamine	SC	300 g/L	0.66 L/ha	-	-	AT, DE	198 g a.s./ha	Also named PROSPER in this BAD
TOPAS	Penconazole	EC	100g /L	0.08 L/ha	-	-	DE	8 g a.s./ha	-

<sup>[1]</sup> EC: Emulsifiable concentrate - SC: Suspension concentrate - WG: Water-dispersible granules

In all trials FGG01 was compared to the reference standard CANTUS at 0.2 kg/ha. If this transversal reference product was not registered in the country or not applied according to its registered use, a second local reference product (COLLIS, KUMULUS DF, PROSPER TEC, TOPAS) was added in the trial and applied according to its registered use to validate the trial.

In Italy and France, the reference standard CANTUS was applied at a lower dose rate compared to the registered rate (1.0-1.2 kg/ha) without a second local reference product. Nevertheless, the transversal dose of CANTUS at 0.2 kg/ha can be considered as a reliable reference for the trials validation. Indeed, in several neighbouring countries (e.g. Spain or Italy), CANTUS is registered at 0.2 kg/ha against *Erysiphe necator*. In addition, in all efficacy trials, the reference standard CANTUS applied at 0.2 kg/ha showed a control of *Erysiphe necator* as expected.

In 1 trial, CANTUS was applied at the rate of 0.1 kg/100 L by mistake (i.e. between 0.3 and 0.7 kg/ha) instead of 0.2 kg/ha. However, according to the efficacy results in this trial, the control of *Erysiphe necator* was as expected. Therefore, CANTUS at 0.1 kg/100 L can be considered as a reliable local reference for this trial validation. Like all local reference products, this reference is not presented in the efficacy part but the results are included in the Biological Assessment Dossier.

### Assessment methods

In all trials, efficacy was assessed according to EPPO guidelines. Assessments of efficacy were made on different plant parts: leaves and bunches.

Data was recorded on 50-100 bunches and 100 leaves per plot as either percentage of visual infection of disease (disease severity) on specified plant parts 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. This efficacy calculation was present in the trial reports, otherwise, the calculation was done with the Abbott formula:

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

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

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

### Phytotoxicity assessments

In efficacy trials, phytotoxicity was also assessed. Phytotoxicity assessments were carried out in accordance with EPPO guideline PP1/135 (“Phytotoxicity assessment”). Assessments were carried out at various intervals post application by recording visual percentage injury (0% = no injury, 100% = complete expression of injury symptom). Crop safety results are presented in Section 3.4.1.

### Statistical analyses

Observed or calculated variables are subjected to in this context analysis of variance (ANOVA) after or not a transformation depending on the variability of the raw data (only the numerical values from the raw data are considered).

When the result of the analysis is significant, a multiple comparison of treatments is performed. The averages are classified using the Newman and Keuls tests and divided into homogeneous groups (a, b,

c, ...). Treatment means with no letter in common are significantly different in accordance with the test conducted at a 95% confidence level.

## Results layout

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

### - Results on *Botrytis cinerea*

Only the last valid assessment is summarised before harvest on severity and incidence of bunches. It is the most representative assessment and it was carried out between BBCH 87-89, 21-35 days after the forth application.

Only assessments where area infected (PESSEV) in the untreated reached at least 5% on bunches and where the frequency of the attack (PESINC) was superior to 10%, were considered as valid. Also, only assessments where reference standard reached a normal efficacy (>50% control) were considered as valid.

Particularly, in the 1 trial the last assessment was considered as not valid, due to the abnormal drop in of efficacy data for the product FGG01 (showing an inverse dose response) and furthermore, it was the previous assessment selected by the CRO and commented in the trial report.

### - Results on *Erysiphe necator*

One last valid assessment is presented on leaves and 2 assessments are presented on bunches: first valid assessment between BBCH 71-79 and the first valid assessment between BBCH 81-89.

Only assessments where area infected (PESSEV) in the untreated reached at least 5% of leaves or bunches for the first assessment were considered as valid. On bunches for the second assessment, the minimum area infected (PESSEV) in the untreated to consider the assessment as valid was 10%, when the disease should already be well developed. Regarding the frequency of the attack (PESINC), the minimum incidence in the untreated to consider the assessment as valid was 10%. Additionally, only assessments where at least one of the reference standards tested reached a normal efficacy (>50% control on leaves and >40% control on bunches) were considered as valid.

One exception is presented in 1 trial, where the last assessment was not selected as there was a high decrease (34 points) of the efficacy compared to the previous one, so it was not considered as valid. In this case, the previous assessment was selected.

## 3.2.3.2.2 Results on grapevine (VITVI) - *Botrytis cinerea* (BOTRCI)

A total of 9 valid efficacy trials were carried out in 2021 and 2023, to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) applied at 1.0 kg/ha and 0.72 kg/10000 m<sup>2</sup> LWA for the control of *Botrytis cinerea* on grapevine in comparison to the reference standard CANTUS (500 g/kg of boscalid, WG) at 1.0 kg/ha, 3 trials in the Maritime (Austria and Germany) and 6 trials in the Mediterranean (South of France, Italy, Portugal and Spain; used as supportive data) EPPO climatic zones.

The label claim for this use is summarised in Table 3.2-65.

**Table 3.2-65: Label claim for grapevine against *Botrytis cinerea***

Crops	Target	Country	Dossier strategy	Application timing	No. of applications	Application volume L/ha	Dose rate kg product/ha
Grapevine (wine and table) (VITVI)	<i>Botrytis cinerea</i> (BOTRCI)	AT, BE, CZ, SL	Bridging	BBCH 60-85	1	100-1000	1.0 kg/ha 0.72 kg/10000 m <sup>2</sup> LWA



In order to be able to convert the rate kg/ha in kg/10000 m<sup>2</sup> LWA a coefficient of 1.4 was used (ground-based rate converted using theoretical calculations and typical LWA for grapevine. Moreover, this factor was confirmed from UPL database from trials carried out across Central zone on different type of vineyards.

In addition, according to the 10 trial results the bridging between both expression rates was proven (see Table 3.2-67).

For this use, this dossier is intended to demonstrate the comparability between the reference product CANTUS and FGG01. CANTUS has been authorised in Austria, Belgium, Czech Republic and Slovenia for use as a fungicide on grapevine against *Botrytis cinerea* for more than 10 years and the use is not protected. In this bridging context, according to guideline EPPO 1/307(2) a reduced data package is required to demonstrate the comparability between CANTUS and FGG01.

No data are available on the South-East EPPO climatic zone, which is concerned by Slovenia. Nevertheless, the use in this country can be supported with the available data package in the Maritime EPPO climatic zone and with the supportive data presented in the Mediterranean EPPO climatic zone, as this is a country bordering Austria, which belongs to the Maritime EPPO climatic zone and Italy, which belongs to the Mediterranean EPPO climatic zone and thus, the climate conditions and the disease development are quite similar even though they belong to different climatic zones. Furthermore, these areas are representative of *Botrytis cinerea* occurrence in Europe and are the most challenging for this disease. This is justified by EPPO standard PP 1/307 (2) "*Efficacy on considerations and data generation when making changes to the chemical composition or formulation type of plant protection products*" (also applicable to for "a new product based on a 'bridging' approach to an existing authorized formulation") which states that "*For existing products authorized on a zonal basis, effectiveness and crop safety across all relevant EPPO climatic regions will have been originally established. Therefore, in the bridging context, it is not necessary to generate comparability data across all regions. As indicated, the location of trials should reflect challenging conditions based on crop/pest and environment.*".

The reference product CANTUS is registered across Europe in grapevine against *Botrytis* between 1.0 and 1.2 kg/ha depending on the country. Exceptionally, in Hungary it is registered with the range of doses at 1.0-1.4 kg/ha and in Belgium where the rate is expressed differently at 0.7 kg/ha hedge. In central Europe, in countries like Austria, Czech Republic and Slovenia, the registered rate is 1.2 kg/ha, while in other countries from the central Europe like Germany it differs depending on the water volume from 0.3 kg/ha till 1.2 kg/ha. In the South of Europe, in many countries like Croatia, Italy, Portugal, and Spain, the registered rate of CANTUS is indicated as a range of doses 1.0-1.2 kg/ha. In countries like France, where a dose range is not indicated for the registered rate of CANTUS, only 1.2 kg/ha on grapevine against *Botrytis cinerea* is indicated. In Bulgaria, the registered rate of CANTUS is 1.0 kg/ha.

However, in practice, on grapevine against *Botrytis cinerea*, CANTUS is usually applied at 1.0 kg/ha by farmers. Therefore, to have a transversal and homogenous rate of FGG01 across all countries in Europe, the rate of 1.0 kg/ha is claimed for this use. In addition, the lower rate of 1.0 kg/ha was selected due to the potential expectation of the rate reduction (any possible new endpoints).

A summary of all trials generating data on grapevine against *Botrytis cinerea* is presented in Table 3.2-66.

**Table 3.2-66: Overview of efficacy trials - Grapevine - *Botrytis cinerea***

Nb. of trials	Crop	Target	Year	Country	EPPO climatic zone	Comment
2 trials	Grapevine	BOTRCI	2023	AT	Maritime	-
1 trial	Grapevine	BOTRCI	2023	DE	Maritime	-
2 trials	Grapevine	BOTRCI	2021	PT	Mediterranean	Supportive data
1 trial	Grapevine	BOTRCI	2023	FR	Mediterranean	Supportive data
2 trials	Grapevine	BOTRCI	2023	IT	Mediterranean	Supportive data
1 trial	Grapevine	BOTRCI	2023	ES	Mediterranean	Supportive data

A total of 3 valid efficacy trials were carried out to evaluate the efficacy of FGG01 in the Maritime EPPO climatic zone (Austria and Germany) in 2023 at 1.0 kg/ha and 0.72 kg/10000 m<sup>2</sup> LWA for the control of *Botrytis cinerea* on grapevine in comparison to the reference standard CANTUS at 1.0 kg/ha or a local reference. Additionally, a set of 6 supportive trials carried out in the Mediterranean EPPO climatic zone (South of France, Italy, Portugal and Spain) in 2022 and 2023 are also here presented to support the dose of FGG01 at 1.0 kg/ha.

#### **A. Results on grapevine (VITVI) - *Botrytis cinerea* (BOTRCI) - Maritime EPPO zone**

A total of 3 valid efficacy trials were carried out in 2023 to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) applied at 0.72 kg/10000 m<sup>2</sup> LWA and at 1.0 kg/ha for the control of *Botrytis cinerea* on grapevine in comparison to the reference standard CANTUS (500 g/kg of boscalid, WG) at 1.0 kg/ha in the Maritime EPPO climatic zone in Austria (2 trials) and in Germany (1 trial). An overview of these trials is presented in Table 3.2-14.

The summary results of the effect of FGG01 applied at 0.72 kg/10000 m<sup>2</sup> LWA and at 1.0 kg/ha compared to reference standard are shown in Table 3.2-67.

**Table 3.2-67: Summary results: efficacy of FGG01 against *Botrytis cinerea*. on grapevine - Maritime EPPO zone**

Parts	Parameters	EPPO climatic zone	No. of trials	Days after application	Untreated control Infestation (%)			FGG01 0.72 kg/10000 m <sup>2</sup> LWA			FGG01 1.0 kg/ha			CANTUS 1.0 kg/ha			No. of assessments significantly <sup>(1)</sup> > , = , <		
					Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	FGG01 at 0.72 kg/10000 m <sup>2</sup> LWA vs. CANTUS at 1.0 kg/ha	FGG01 at 1.0 kg/ha vs. CANTUS at 1.0 kg/ha	FGG01 at 0.72 kg/10000 m <sup>2</sup> LWA vs. FGG01 at 1.0 kg/ha
BUNCH	Severity (%)	Maritime	3	[21-22 DA-D]	17.8	6.3	34.0	67.9	62.8	73.9	74.7	69.2	83.6	75.6	68.0	83.1	0> ; 3= ; 0<	0> ; 3= ; 0<	0> ; 3= ; 0<
	Incidence (%)	Maritime	3	[21-22 DA-D]	53.3	38.5	78.0	51.6	49.4	55.3	63.2	59.0	70.8	64.4	55.8	71.8	0> ; 3= ; 0<	0> ; 3= ; 0<	0> ; 3= ; 0<

.<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

In the Maritime EPPO climatic zone, at BBCH 87-89 on disease severity on bunches, the infestation in untreated plot reached up to 18% (ranging from 6 % to 34%) in 3 trials. FGG01 applied at 0.72 kg/10000 m<sup>2</sup> LWA showed under these conditions, a control quite close to that of the reference standard CANTUS at 1.0 kg/ha (respectively 68% vs. 76% mean control). Furthermore, FGG01 at 0.72 kg/10000 m<sup>2</sup> LWA was statistically equivalent to the reference CANTUS applied at 1.0 kg/ha in the 3 trials. FGG01 applied at 1.0 kg/ha showed under these conditions, a similar control to the reference standard CANTUS at 1.0 kg/ha (respectively 75% vs. 76% mean control). In addition, FGG01 at 1.0 kg/ha was statistically equivalent to the reference CANTUS applied at 1.0 kg/ha in the 3 trials.

**Therefore, by and large, data from 3 trials, with a moderate level of infestation in the Maritime EPPO climatic zone, FGG01 applied at 0.72 kg/10000 m<sup>2</sup> LWA and at 1.0 kg/ha showed an adequate effectiveness, at an equivalent level of control to the reference CANTUS applied at 1.0 kg/ha against *Botrytis cinerea* (BOTRCI). Therefore, one application at the rate of 1.0 kg/ha or 0.72 kg/10000 m<sup>2</sup> LWA will be recommended on the product label for the control of BOTRCI in the Maritime EPPO climatic zone.**

## **B. Results on grapevine (VITVI) - *Botrytis cinerea* (BOTRCI) - Mediterranean EPPO zone - Supportive data**

A total of 6 valid efficacy trials were carried out in 2021 and 2023 to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) applied at 1.0 kg/ha for the control of *Botrytis cinerea* on grapevine in comparison to the reference standard CANTUS (500 g/kg of boscalid, WG) at 1.0 kg/ha in the Mediterranean EPPO climatic zone in France (South of France, 1 trial), Italy (2 trials), Portugal (2 trials) and Spain (1 trial). Data generated in trials carried out within the Mediterranean climatic zone are fully supportive towards demonstrating proposed label claims for the efficacy and crop safety of FGG01 in Central EU zone. Indeed, extra-zonal data obtained from trials carried out in countries of the Southern EU zone belonging to the Mediterranean EPPO climatic zone are also presented in this dossier to further support the label claims. Indeed, area is fully representative of *Botrytis cinerea* occurrence in Europe and is the most challenging for this disease.

An overview of these trials is presented in Table 3.2-14.

The summary results of the effect of FGG01 applied at 1.0 kg/ha compared to reference standard are shown in Table 3.2-68.

**Table 3.2-68: Summary results: efficacy of FGG01 against *Botrytis cinerea*. On grapevine - Mediterranean EPPO zone**

Parts	Parameters	EPPO climatic zone	No. of trials	Days after application	Untreated control			FGG01 1.0 kg/ha			CANTUS 1.0 kg/ha			No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at 1.0 kg/ha vs. CANTUS at 1.0 kg/ha
					Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	
BUNCH	Severity (%)	Mediterranean	6	[21-35 DA-D]	13.1	6.0	18.8	75.7	59.6	95.9	76.7	62.0	96.4	0> ; 6= ; 0<
	Incidence (%)	Mediterranean	6	[21-35 DA-D]	53.5	16.3	72.5	58.3	42.1	83.9	58.1	46.0	87.1	0> ; 6= ; 0<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

In the Mediterranean EPPO climatic zone, at BBCH 89 on disease severity on bunches, the infestation in untreated plot reached up to 13% (ranging from 6 % to 19%) in 6 trials. FGG01 applied at 1.0 kg/ha showed a similar control to the reference standard CANTUS at the same dose of 1.0 kg/ha (respectively 76% vs. 77% mean control). Furthermore, no statistical differences were found in the 6 trials.

These results were confirmed on the disease incidence, where the infestation in untreated plot at BBCH 89 reached up to 54% (ranging from 16% to 73%) in 6 trials. FGG01 applied at 1.0 kg/ha showed a similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 58% vs. 58% mean control). Furthermore, no statistical differences were found in the 6 trials.

**Therefore, by and large, data from 6 trials, with a moderate level of infestation in the Mediterranean EPPO climatic zone, FGG01 at 1.0 kg/ha showed an adequate to a good effectiveness, at an equivalent level of control to the reference product CANTUS at 1.0 kg/ha against *Botrytis cinerea* (BOTRCI). These supportive data (from Mediterranean EPPO climatic zone) confirm that one application of FGG01 at the rate of 1.0 kg/ha or 0.72 kg/10000 m<sup>2</sup> LWA will be recommended on the product label for the control of BOTRCI in the Central registration zone.**

### C. Conclusion on grapevine - *Botrytis cinerea* (BOTRCI)

A total of 9 valid efficacy trials were carried out in 2021 and 2023 to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) applied at 1.0 kg/ha and 0.72 kg/10000 m<sup>2</sup> LWA for the control of *Botrytis cinerea* on grapevine in comparison to the reference standard CANTUS (500 g/kg of boscalid, WG) at 1.0 kg/ha in the Maritime and Mediterranean EPPO climatic zones.

The summary results of the effect of FGG01 applied at 1.0 kg/ha and 0.72 kg/10000 m<sup>2</sup> LWA compared to the reference standard in the Maritime and Mediterranean EPPO climatic zones are shown in Table 3.2-69.

**Table 3.2-69: Overall summary of efficacy of FGG01 on grapevine against *Botrytis cinerea* in the Central registration zone**

Crop code	Pest code	EPPO climatic zone	Part assessed	Nb of trials	Untreated (infestation in %)	Efficacy (%)			No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at	
						FGG01 0.72 kg/10000 m <sup>2</sup> LWA	FGG01 1.0 kg/ha	CANTUS 1.0 kg/ha	0.72 kg/10000 m <sup>2</sup> LWA vs. CANTUS	1.0 kg/ha vs. CANTUS
VITVI	BOTRCI	Maritime	Disease severity on bunches	3	17.8	67.9	74.7	75.6	0> ; 3= ; 0<	0> ; 3= ; 0<
			Disease incidence on bunches	3	53.3	51.6	63.2	64.4	0> ; 3= ; 0<	0> ; 3= ; 0<
		Supportive data								
		Medit.	Disease severity on bunches	6	13.1	-	75.7	76.7	-	0> ; 6= ; 0<
				4	13.5	-	70.8	72.5	-	0> ; 4= ; 0<
			Disease incidence on bunches	6	53.5	-	58.3	58.1	-	0> ; 6= ; 0<
				4	62.2	-	56.9	59.4	-	0> ; 4= ; 0<
		All climatic zones								
		All zones	Disease severity on bunches	9	14.7	-	75.4	76.3	-	0> ; 9= ; 0<
			Disease incidence on bunches	9	53.4	-	60.0	60.2	-	0> ; 9= ; 0<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

In 9 trials, FGG01 applied at 1.0 kg/ha showed an equivalent level of control to the reference product CANTUS at 1.0 kg/ha against *Botrytis cinerea* (BOTRCI) on grapevine. In the same way, in 3 trials, FGG01 applied at 0.72 kg/10000 m<sup>2</sup> LWA showed a control quite close to that of the reference product CANTUS at 1.0 kg/ha. In all efficacy trials FGG01 at 0.72 kg/10000 m<sup>2</sup> LWA and at 1.0 kg/ha were statistically equivalent to CANTUS at 1.0 kg/ha. Therefore, one application at the rate of 1.0 kg/ha, or 0.72 kg/10000 m<sup>2</sup> LWA will be recommended on the product label for the control of *Botrytis cinerea* (BOTRCI) on grapevine in the Central registration zone.

### 3.2.3.2.3 Results on grapevine (VITVI) - *Erysiphe necator* (UNCINE)

The label claim for this use is summarised in Table 3.2-70.

**Table 3.2-70: Label claim for grapevine against *Erysiphe necator***

Crops	Target	Country	Dossier strategy	Application timing	No. of applications	Application volume L/ha	Dose rate kg product/ha
Grapevine (wine and table) (VITVI)	<i>Erysiphe necator</i> (UNCINE)	AT, BE, CZ, SL,	Full data package (major use)	BBCH 15-81	3	100-1000	0.2 kg/ha
		PL	Full data package (minor use)				0.02 kg/100 L 0.14 kg/10000 m <sup>2</sup> LWA

In the countries claimed for authorization on grapevine against *Erysiphe necator*, the reference product CANTUS is not authorised for this use and therefore, a full data package is necessary on grapevine against *Erysiphe necator*. Except in Poland (minor use), as this is a major use in all of these countries, a full data package is required and was generated.

In order to be able to convert the rate kg/ha in kg/10000 m<sup>2</sup> LWA a coefficient of 1.4 was used (ground-based rate converted using theoretical calculations and typical LWA for grapevine. Moreover, this factor was confirmed from UPL database from trials carried out across Central zone on different type of vineyards.

In addition, according to the 10 trial results the bridging between both expression rates was proven (see Table 3.2-72).

In order to be able to convert the rate kg/ha in kg/100 L a coefficient of 0.1 was used (ground-based rate converted using theoretical calculations and typical grapevine; based on maximum water volume of 1000 L/ha). This conversion is done basically in country level when adding kg/hL in their labels. Indeed, this coefficient of 0.1 is the same that used for CANTUS in the labels in of many countries. Therefore, as the equivalence between FGG01 and CANTUS applied at 0.2 kg/ha it has been proven in trials thus the bridge at ground-based (kg/ha), can be extrapolate to kg/hL (0.02 kg/100 L). In addition, according to the 10 trial results the bridging between both expression rates was proven (see Table 3.2-72).

A summary of all trials generating data on grapevine against *Erysiphe necator* is presented in Table 3.2-71.

**Table 3.2-71: Overview of efficacy trials - Grapevine - *Erysiphe necator***

Nb. of trials	Crop	Target	Year	Country	EPPO climatic zone	Comment
2 trials	Grapevine	UNCINE	2022	DE	Maritime	-
2 trials	Grapevine	UNCINE	2022	AT	Maritime	-
3 trials	Grapevine	UNCINE	2023	DE	Maritime	-
3 trials	Grapevine	UNCINE	2023	AT	Maritime	-
1 trial	Grapevine	UNCINE	2022	IT	Mediterranean	Supportive data
2 trials	Grapevine	UNCINE	2023	FR	Mediterranean	Supportive data
2 trials	Grapevine	UNCINE	2023	IT	Mediterranean	Supportive data
2 trials	Grapevine	UNCINE	2023	ES	Mediterranean	Supportive data

No data are available on the South-East EPPO climatic zone, which is concerned by Slovenia. Nevertheless, the use in this country can be supported with the available data package in the Maritime EPPO climatic zone and with the supportive data presented in the Mediterranean EPPO climatic zone, as this is a country bordering Austria, which belongs to the Maritime EPPO climatic zone and Italy,



which belongs to the Mediterranean EPPO climatic zone and thus, the climate conditions and the disease development are quite similar, even though they belong to different climatic zones.

No data are available on the North-East EPPO climatic zone, which is concerned by Poland. Nevertheless, the use in this country can be supported with the available data package in the Maritime EPPO climatic zone and with the supportive data presented in the Mediterranean EPPO climatic zone, as this is a country bordering Germany, which belong to the Maritime EPPO climatic zone and thus, the climate conditions and the disease development are quite similar, even though they belong to different climatic zones. In addition this use is minor in Poland.

Furthermore, Maritime and Mediterranean climatic zones are representative of *Erysiphe necator* occurrence in Europe and are the most challenging for this disease.

A total of 10 valid efficacy trials were carried out in 2022 and 2023 to evaluate the efficacy of FGG01 applied at 0.13-0.14 kg/10000 m<sup>2</sup> LWA, at 0.2 kg/ha and at 0.02 kg/100 L for the control of *Erysiphe necator* on grapevine in comparison to the reference standard CANTUS at 0.2 kg/ha or to different local references in the Maritime EPPO climatic zone (Austria and Germany). Additionally, a set of 7 supportive trials carried out in 2022 and 2023 in the Mediterranean EPPO climatic zone (South of France, Italy, Portugal and Spain) are also here presented as support of FGG01 applied at 0.2 kg/ha.

#### **A. Results on grapevine (VITVI) - *Erysiphe necator* (UNCINE) - Maritime EPPO zone**

A total of 10 valid efficacy trials were carried out in 2022 and 2023 to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) applied at 0.13-0.14 kg/10000 m<sup>2</sup> LWA, at 0.2 kg/ha and at 0.02 kg/100 L for the control of *Erysiphe necator* on grapevine in comparison to the reference standard CANTUS (500 g/kg of boscalid, WG) at 0.2 kg/ha or to a local reference in the Maritime EPPO climatic zone. An overview of these trials is presented in Table 3.2-14.

The summary results of the effect of FGG01 applied at 0.13-0.14 kg/10000 m<sup>2</sup> LWA, at 0.2 kg/ha and at 0.02 kg/100 L compared to reference standards are shown in Table 3.2-72.

**Table 3.2-72: Summary results: efficacy of FGG01 against *Erysiphe necator* on grapevine - Maritime EPPO zone**

No. of trials	Untreated control			FGG01 0.13-0.14 kg/10000 m <sup>2</sup> LWA			FGG01 0.2 kg/ha			FGG01 0.02 kg/100 L			CANTUS 0.2 kg/ha			LOCAL REFERENCE				No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at							
	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Name Ref.	0.13-0.14 kg/1000 m <sup>2</sup> LWA vs.		0.2 kg/ha vs.				0.02 kg/100 L vs.	
																				CANTUS	Local Ref.	CANTUS	Local Ref.	0.13-0.14 kg/1000 m <sup>2</sup> LWA	0.02 kg/100 L	Local Ref.	
LEAF - Last valid assessment (BBCH 77-79) - Severity (%)																											
9	28.1	8.3	62.5	67.7	40.4	99.6	75.4	51.3	98.8	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0> ; 9= ; 0<	-	-	
4	29.9	8.3	62.5	73.8	65.8	84.8	79.3	68.7	87.0	74.9	62.4	84.2	-	-	-	72.3	55.0	89.0	(1)*	-	0> ; 4= ; 0<	-	0> ; 4= ; 0<	-	0> ; 4= ; 0<	0> ; 4= ; 0<	
5	26.7	10.5	57.6	62.9	40.4	99.6	72.2	51.3	98.8	-	-	-	69.3	49.6	98.6	-	-	-	-	0> ; 5= ; 0<	-	0> ; 5= ; 0<	-	-	-	-	
2	35.2	12.7	57.6	94.3	89.0	99.6	97.4	96.0	98.8	-	-	-	-	-	-	98.9	98.7	99.0	(2)*	-	0> ; 2= ; 0<	-	0> ; 2= ; 0<	-	-	-	
2	26.3	14.8	37.8	42.2	40.4	44.0	57.6	56.6	58.5	-	-	-	-	-	-	99.8	99.6	100.0	(3)*	-	0> ; 0= ; 2<	-	0> ; 0= ; 2<	-	-	-	
1	10.5	-	-	41.4	-	-	51.3	-	-	-	-	-	-	-	-	55.2	-	-	(4)*	-	0> ; 1= ; 0<	-	0> ; 1= ; 0<	-	-	-	
BUNCH - BBCH 71-79 - Severity (%)																											
6	18.3	6.7	44.1	66.9	51.6	87.2	65.2	31.0	91.2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0> ; 6= ; 0<	-	-	
4	21.1	6.7	44.1	62.9	51.6	87.2	71.6	53.7	91.2	79.7	61.5	86.9	-	-	-	81.2	54.3	95.4	(1)*	-	0> ; 4= ; 0<	-	0> ; 4= ; 0<	-	0> ; 4= ; 0<	0> ; 4= ; 0<	
2	12.7	10.4	15.0	74.9	65.8	84.0	52.6	31.0	74.2	-	-	-	72.2	65.3	79.0	-	-	-	-	0> ; 2= ; 0<	-	0> ; 2= ; 0<	-	-	-	-	
1	10.4	-	-	84.0	-	-	31.0	-	-	-	-	-	-	-	-	96.0	-	-	(2)*	-	0> ; 1= ; 0<	-	0> ; 1= ; 0<	-	-	-	
1	15.0	-	-	65.8	-	-	74.2	-	-	-	-	-	-	-	-	94.7	-	-	(3)*	-	0> ; 1= ; 0<	-	0> ; 1= ; 0<	-	-	-	
BUNCH - BBCH 71-79 - Incidence (%)																											
7	44.7	11.5	78.0	60.7	37.5	91.3	69.7	42.0	100.0	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0> ; 7= ; 0<	-	-	
3	67.8	54.5	78.0	61.4	42.9	77.1	70.7	49.3	82.1	71.3	67.9	78.2	-	-	-	82.0	78.2	86.2	(1)*	-	0> ; 3= ; 0<	-	0> ; 3= ; 0<	-	0> ; 3= ; 0<	0> ; 3= ; 0<	
4	27.4	11.5	49.0	60.2	37.5	91.3	69.0	42.0	100.0	-	-	-	79.0	58.0	100.0	-	-	-	-	0> ; 4= ; 0<	-	0> ; 4= ; 0<	-	-	-	-	
1	37.0	-	-	57.0	-	-	42.0	-	-	-	-	-	-	-	-	82.0	-	-	(2)*	-	0> ; 1= ; 0<	-	0> ; 1= ; 0<	-	-	-	
2	30.5	12.0	49.0	46.3	37.5	55.1	67.0	66.7	67.3	-	-	-	-	-	-	90.7	87.5	93.9	(3)*	-	0> ; 2= ; 0<	-	0> ; 2= ; 0<	-	-	-	
BUNCH - BBCH 81-89 - Severity (%)																											
9	35.5	10.7	64.8	69.8	46.3	96.7	67.6	38.6	96.7	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0> ; 9= ; 0<	-	-	
4	47.7	21.4	64.8	61.2	46.3	80.2	67.3	46.6	82.5	70.3	53.5	76.2	-	-	-	64.6	46.9	80.6	(1)*	-	0> 4 = ; 0<	-	0> ; 4= ; 0<	-	0> ; 4= ; 0<	0> ; 4= ; 0<	
5	25.7	10.7	51.7	76.7	60.9	96.7	67.8	38.6	96.7	-	-	-	77.5	69.3	96.7	-	-	-	-	0> ; 5= ; 0<	-	0> ; 5= ; 0<	-	-	-	-	
2	12.9	10.7	15.1	92.2	87.6	96.7	67.6	38.6	96.7	-	-	-	-	-	-	96.9	94.4	99.3	(2)*	-	0> ; 2= ; 0<	-	0> ; 2= ; 0<	-	-	-	
2	44.3	36.9	51.7	67.6	60.9	74.3	72.5	62.1	82.8	-	-	-	-	-	-	97.9	97.3	98.5	(3)*	-	0> ; 1= ; 1<	-	0> ; 1= ; 1<	-	-	-	
1	14.3	-	-	64.1	-	-	58.9	-	-	-	-	-	-	-	-	59.1	-	-	(4)*	-	0> ; 1= ; 0<	-	0> ; 1= ; 0<	-	-	-	
BUNCH - BBCH 81-89 - Incidence (%)																											
6	67.7	38.0	90.5	54.6	16.9	98.2	56.4	31.6	100.0	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0> ; 6= ; 0<	-	-	
2	82.5	82.0	83.0	27.6	16.9	98.2	41.2	32.9	49.4	57.3	49.4	65.2	-	-	-	40.6	39.6	41.6	(1)*	-	0> ; 2= ; 0<	-	0> ; 2= ; 0<	-	0> ; 2= ; 0<	0> ; 2= ; 0<	
4	60.3	38.0	90.5	68.0	49.6	98.2	63.9	31.6	100.0	-	-	-	67.0	48.1	100.0	-	-	-	-	0> 4 = ; 0<	-	0> 4 = ; 0<	-	-	-	-	
2	41.7	38.0	45.3	82.7	67.1	98.2	65.8	31.6	100.0	-	-	-	-	-	-	86.9	73.7	100.0	(2)*	-	0> ; 2= ; 0<	-	0> ; 2= ; 0<	-	-	-	
2	79.0	67.5	90.5	53.3	49.6	57.0	62.1	53.0	71.1	-	-	-	-	-	-	92.4	90.6	94.1	(3)*	-	0> ; 0= ; 2<	-	0> ; 0= ; 2<	-	-	-	

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

\*(1)= COLLIS at 0.64 L/ha, (2)= PROSPER at 0.66 L/ha, (3)= KUMULUS at 5-8 kg/ha (4)=TOPAS at 0.08 L/ha

## **Efficacy of FGG01 at 0.13-0.14 kg/10000 m<sup>2</sup> LWA**

### **Assessments on leaves at last valid assessment**

In the Maritime EPPO climatic zone at BBCH 77-89, on disease severity on leaves, the infestation in untreated plot reached up to 28% (ranging from 8% to 63%) in 9 trials. FGG01 applied at 0.13-0.14 kg/10000 m<sup>2</sup> LWA showed 68% mean control in 9 trials.

In 4 trials, FGG01 applied at 0.13-0.14 kg/10000 m<sup>2</sup> LWA showed similar control to the reference standard COLLIS applied at 0.64 L/ha (respectively 74% vs. 72% mean control). FGG01 was statistically equivalent to the reference COLLIS in the 4 trials.

In 5 trials, FGG01 applied at 0.13-0.14 kg/10000 m<sup>2</sup> LWA showed similar control to the reference standard CANTUS applied at 0.2 kg/ha (respectively 63% vs. 69% mean control). No statistical difference was found in the 5 trials.

In 2 trials, FGG01 applied at 0.13-0.14 kg/10000 m<sup>2</sup> LWA showed similar control to the reference standard PROSPER applied at 0.66 L/ha (respectively 94% vs. 99% mean control). No statistical difference was found in the 2 trials.

In 2 trials, FGG01 applied at 0.13-0.14 kg/10000 m<sup>2</sup> LWA showed lower control than the reference standard KUMULUS applied at 5-8 kg/ha (respectively 42% vs. 100% mean control). FGG01 at 0.13-0.14 kg/10000 m<sup>2</sup> LWA was statistically inferior to the standard KUMULUS at 5-8 kg/ha in the 2 trials.

### **Assessments on bunches at BBCH 71-79**

In the Maritime EPPO climatic zone at BBCH 71-79, on disease severity on bunches, the infestation in untreated plot reached up to 18% (ranging from 7% to 44%) in 6 trials. FGG01 applied at 0.13-0.14 kg/10000 m<sup>2</sup> LWA showed 67% mean control in 6 trials.

In 4 trials, FGG01 applied at 0.13-0.14 kg/10000 m<sup>2</sup> LWA showed numerically lower control to the reference standard COLLIS applied at 0.64 L/ha (respectively 63% vs. 81% mean control). However, FGG01 was statistically equivalent to the reference COLLIS in the 4 trials.

In 2 trials, FGG01 applied at 0.13-0.14 kg/10000 m<sup>2</sup> LWA showed similar control to the reference standard CANTUS applied at 0.2 kg/ha (respectively 75% vs. 72% mean control). No statistical difference was found.

On disease incidence on bunches, the infestation in untreated plot reached up to 45% (ranging from 12% to 78%) in 7 trials. FGG01 applied at 0.13-0.14 kg/10000 m<sup>2</sup> LWA showed 61% mean control in 7 trials.

In 3 trials, FGG01 applied at 0.13-0.14 kg/10000 m<sup>2</sup> LWA showed numerically lower control to the reference standard COLLIS applied at 0.64 L/ha (respectively 61% vs. 82% mean control). However, FGG01 was statistically equivalent to the reference COLLIS in the 3 trials.

In 4 trials, FGG01 applied at 0.13-0.14 kg/10000 m<sup>2</sup> LWA showed numerically lower control to the reference standard CANTUS applied at 0.2 kg/ha (respectively 60% vs. 79% mean control). However, FGG01 was statistically equivalent to the reference CANTUS in the 4 trials.

In 2 trials, FGG01 applied at 0.13-0.14 kg/10000 m<sup>2</sup> LWA showed numerically lower control to the reference standard KUMULUS applied at 5-8 kg/ha (respectively 46% vs. 91% mean control). However, FGG01 was statistically equivalent to the reference KUMULUS in the 2 trials.

### **Assessments on bunches at BBCH 81-89**

In the Maritime EPPO climatic zone at BBCH 81-89 on disease severity on bunches, the infestation in untreated plot reached up to 36% (ranging from 11% to 65%) in 9 trials. FGG01 applied at 0.13-0.14 kg/10000 m<sup>2</sup> LWA showed 70% mean control in 9 trials.

When comparing with the reference standards, in 4 trials, FGG01 applied at 0.13-0.14 kg/10000 m<sup>2</sup> LWA showed a similar control to the reference standard COLLIS applied at 0.64 L/ha (respectively 61% vs. 65% mean control). No statistical differences were found in the 4 trials.

In 5 trials, FGG01 applied at 0.13-0.14 kg/10000 m<sup>2</sup> LWA showed similar control to the reference standard CANTUS applied at 0.2 kg/ha (respectively 77% vs. 78% mean control). No statistical differences were found in the 5 trials.

In 2 trials, FGG01 applied at 0.13-0.14 kg/10000 m<sup>2</sup> LWA showed similar control to the reference standard PROSPER applied at 0.66 L/ha (respectively 92% vs. 97% mean control). No statistical differences were found in the 2 trials.

In 2 trials, FGG01 applied at 0.13-0.14 kg/10000 m<sup>2</sup> LWA showed numerically lower control to the reference standard KUMULUS applied at 5-8 kg/ha (respectively 68% vs. 98% mean control). However, they were statistically equivalent in 1 out of 2 trials.

### **Efficacy of FGG01 at 0.2 kg/ha**

#### **Assessments on leaves at BBCH 77-89**

In the Maritime EPPO climatic zone, at BBCH 77-89 on disease severity on leaves, the infestation in untreated plot reached up to 28% (ranging from 8% to 63%) in 9 trials. FGG01 applied at 0.2 kg/ha showed 75% mean control in 9 trials.

Comparing with the reference standards, in 4 trials, FGG01 applied at 0.2 kg/ha showed a slightly higher control than the reference standard COLLIS applied at 0.64 L/ha (respectively 79% vs. 72% mean control). No statistical differences were found in the 4 trials.

In 5 trials, FGG01 applied at 0.2 kg/ha showed a similar control to the reference standard CANTUS applied at 0.2 kg/ha (respectively 72% vs. 69% mean control). No statistical differences were found in the 5 trials.

In 2 trials, FGG01 applied at 0.2 kg/ha showed a similar control to the local reference standard PROSPER applied at 0.66 L/ha (respectively 97% vs. 99% mean control). No statistical differences were found in the 2 trials.

In 2 trials, FGG01 applied at 0.2 kg/ha, under these conditions, showed numerically lower control than the local reference standard KUMULUS applied at 5-8 kg/ha (respectively 58% vs. 100% mean control). FGG01 at 0.2 kg/ha was statistically inferior to the standard KUMULUS at 5-8 kg/ha in the 2 trials.

#### **Assessments on bunches at BBCH 71-79**

In the Maritime EPPO climatic zone at BBCH 71-79, on disease severity on bunches, the infestation in untreated plot reached up to 18% (ranging from 7% to 44%) in 6 trials. FGG01 applied at 0.2 kg/ha showed 65% mean control in 6 trials.

In 4 trials, FGG01 applied at 0.2 kg/ha showed a slightly lower control than the reference standard COLLIS at 0.64 L/ha (respectively 72% vs. 81% mean control). However, it was statistically equivalent to the reference COLLIS.

In 2 trials, FGG01 applied at 0.2 kg/ha showed numerically lower control than the reference standard CANTUS applied at 0.2 kg/ha (respectively 53% vs. 72% mean control). However, they were statistically equivalent in the 2 trials.

On disease incidence on bunches, the infestation in untreated plot reached up to 45% (ranging from 12% to 78%) in 7 trials. FGG01 applied at 0.2 kg/ha showed 70% mean control in 7 trials.

In 3 trials, FGG01 applied at 0.2 kg/ha showed a inferior slightly control to the reference standard COLLIS at 0.64 L/ha (respectively 71% vs. 82% mean control). However, they were statistically equivalent in the 3 trials.

In 4 trials, FGG01 applied at 0.2 kg/ha showed numerically slightly lower control than the reference standard CANTUS applied at 0.2 kg/ha (respectively 69% vs. 79% mean control). However, they were statistically equivalent in the 4 trials.

In 2 trials, FGG01 applied at 0.2 kg/ha showed numerically lower control than the reference standard KUMULUS applied at 5-8 kg/ha (respectively 67% vs. 91% mean control). However, they were statistically equivalent the 2 trials.

#### **Assessments on bunches at BBCH 81-89**

In the Maritime EPPO climatic zone at BBCH 81-89 on disease severity on bunches, the infestation in untreated plot reached up to 36% (ranging from 11% to 65%) in 9 trials. FGG01 applied at 0.2 kg/ha showed 68% mean control in 9 trials.

Comparing with the reference standards, in 4 trials, FGG01 applied at 0.2 kg/ha showed similar control to the reference standard COLLIS applied at 0.64 L/ha (respectively 67% vs. 65% mean control). No statistical differences were found in the 4 trials.

In 5 trials, FGG01 applied at 0.2 kg/ha showed numerically slightly lower control than the reference standard CANTUS applied at 0.2 kg/ha (respectively 68% vs. 78% mean control). However, they were statistically equivalent in the 5 trials.

In 2 trials, FGG01 applied at 0.2 kg/ha showed numerically lower control than the reference standard PROSPER applied at 0.66 L/ha (respectively 68% vs. 97% mean control). However, they were statistically equivalent in the 2 trials.

In 2 trials, FGG01 applied at 0.2 kg/ha showed numerically lower control than the reference standard KUMULUS applied at 5-8 kg/ha (respectively 73% vs. 98% mean control). However, they were statistically equivalent in 1 out of 2 trials.

#### **Efficacy of FGG01 at 0.02 kg/100 L**

##### **Assessments on leaves at BBCH 77-89**

In the Maritime EPPO climatic zone, at BBCH 77-89 on disease severity on leaves, the infestation in untreated plot reached up to 30% (ranging from 8% to 63%) in 4 trials. FGG01 applied at 0.02 kg/100 L showed similar control to the reference standard COLLIS applied at 0.64 L/ha (respectively 75% vs. 72% mean control). No statistical differences were found in the 4 trials.

##### **Assessments on bunches at BBCH 71-79**

In the Maritime EPPO climatic zone at BBCH 71-79 on disease severity on bunches, the infestation in untreated plot reached up to 21% (ranging from 7% to 44%) in 4 trials. FGG01 applied at 0.02 kg/100 L showed a similar control to the reference standard COLLIS applied at 0.64 L/ha (respectively 80% vs. 81% mean control). No statistical differences were found in the 4 trials.

On disease incidence on bunches, the infestation in untreated plot reached up to 68% (ranging from 55% to 78%) in 3 trials. FGG01 applied at 0.02 kg/100 L showed numerically lower control than the reference standard COLLIS applied at 0.64 L/ha (respectively 71% vs. 82% mean control). However, they were statistically equivalent in the 3 trials.

##### **Assessments on bunches at BBCH 81-89**

In the Maritime EPPO climatic zone at BBCH 81-89 on disease severity on bunches, the infestation in untreated plot reached up to 48% (ranging from 21% to 65%) in 4 trials. FGG01 applied at 0.02 kg/100 L showed slightly higher control than the reference standard COLLIS applied at 0.64 L/ha (respectively 70% vs. 65% mean control). No statistical differences were found in the 4 trials.

**Therefore, by and large, data from 10 trials, with a moderate level of infestation, FGG01 applied at 0.2 kg/ha, 0.02 kg/100 L and 0.13-0.14 kg/10000 m<sup>2</sup> LWA showed an adequate effectiveness, at an equivalent level of control or numerically slightly lower than the product references tested against *Erysiphe necator* (UNCINE). However, overall, FGG01 was statistically equivalent to the standard references in all trials. Therefore, a maximum of three applications at the rate of 0.2 kg/ha, 0.02 kg/100 L or 0.14 kg/10000 m<sup>2</sup> LWA will be recommended on the product label for the control of UNCINE in the Maritime EPPO climatic zone.**

### **B. Results on grapevine (VITVI) - *Erysiphe necator* (UNCINE) - Mediterranean EPPO zone - Supportive data**

A total of 7 valid efficacy trials were carried out in 2022 and 2023 to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) applied at 0.2 kg/ha for the control of *Erysiphe necator* on grapevine in comparison to the reference standard CANTUS (500 g/kg of boscalid, WG) at 0.2 kg/ha in the Mediterranean EPPO climatic zone (South of France, Italy and Spain). An overview of these trials is presented in Table 3.2-14.

Data generated in trials carried out within the Mediterranean climatic zone are fully supportive towards demonstrating proposed label claims for the efficacy and crop safety of FGG01 in Central EU zone. Indeed, extra-zonal data obtained from trials carried out in countries of the Southern EU zone belonging to the Mediterranean EPPO climatic zone are also presented in this dossier to further support the label claims. Indeed, this area is fully representative of *Erysiphe necator* occurrence in Europe and is the most challenging for this disease.

The summary results of the effect of FGG01 applied at 0.2 kg/ha compared to reference standard are shown in Table 3.2-73.

**Table 3.2-73: Summary results: efficacy of FGG01 against *Erysiphe necator* on grapevine - Mediterranean EPPO zone**

Parts	Assessment Timing	Parameters	EPPO climatic zone	No. of trials	Untreated control			FGG01 0.2 kg/ha			CANTUS 0.2 kg/ha			CANTUS 0.1 kg/100 L			No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at 0.2 kg/ha vs.	
					Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	CANTUS at 0.2 kg/ha	CANTUS at 0.1 kg/100 L
LEAF	BBCH 77-79	Severity (%)	Mediterranean	3	32.0	7.8	58.0	75.7	43.2	94.2	74.4	50.9	89.8	-	-	-	0> ; 3= ; 0<	-
BUNCH	BBCH 71-79	Severity (%)	Mediterranean	4	51.7	14.7	96.4	78.9	26.7	99.9	83.1	46.0	99.2	-	-	-	0> ; 4= ; 0<	-
		Incidence (%)	Mediterranean	6	41.8	9.5	81.8	87.2	78.0	100.0	-	-	-	-	-	-	-	-
			Mediterranean	1	9.5	-	-	100.0	-	-	-	-	-	100.0	-	-	-	0> ; 1= ; 0<
			Mediterranean	5	48.3	18.5	81.8	84.7	78.0	99.5	84.3	72.7	96.6	-	-	-	0> ; 5= ; 0<	-
	BBCH 81-89	Severity (%)	Mediterranean	4	21.7	12.0	47.3	85.0	76.4	91.1	-	-	-	-	-	-	-	-
			Mediterranean	1	12.0	-	-	77.6	-	-	-	-	-	76.4	-	-	-	0> ; 1= ; 0<
			Mediterranean	3	24.9	12.6	47.3	87.8	81.6	91.1	84.0	82.5	86.4	-	-	-	0> ; 3= ; 0<	-
		Incidence (%)	Mediterranean	4	48.5	18.0	96.5	67.9	41.4	78.5	-	-	-	-	-	-	-	-
			Mediterranean	3	58.7	37.0	96.5	76.8	74.1	78.5	75.1	71.0	80.3	-	-	-	0> ; 3= ; 0<	-
			Mediterranean	1	18.0	-	-	41.4	-	-	-	-	-	47.2	-	-	-	0> ; 1= ; 0<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

### **Assessments on leaves:**

In the Mediterranean EPPO climatic zone, at the last valid assessment (BBCH 77-79), on disease severity on leaves, the infestation in untreated plot reached up to 32% (ranging from 8% to 58%) in 3 trials. FGG01 applied at 0.2 kg/ha showed a similar control to the reference standard CANTUS applied at 0.2 kg/ha (respectively 76% vs. 74% mean control). No statistical differences were found in the 3 trials.

### **Assessments on bunches at BBCH 71-79:**

In the Mediterranean EPPO climatic zone at BBCH 71-79, on disease severity on bunches, the infestation in untreated plot reached up to 52% (ranging from 15 % to 96%) in 4 trials. FGG01 applied at 0.2 kg/ha showed a good control, similar to the reference standard CANTUS applied at 0.2 kg/ha (respectively 79% vs. 83% mean control). No statistical differences were found in the 4 trials.

On disease incidence on bunches, in 6 trials the infestation in untreated plot reached up to 42% (ranging from 10% to 82%). FGG01 applied at 0.2 kg/ha showed a good control with 87% mean control.

In 5 trials FGG01 applied at 0.2 kg/ha showed a similar control to the reference standard CANTUS applied at 0.2 kg/ha (respectively 85% vs. 84% mean control). No statistical differences were found in the 5 trials.

### **Assessments on bunches at BBCH 81-89:**

At BBCH 81-89 on disease severity on bunches, in 4 trials the infestation in untreated plot reached up to 22% (ranging from 12% to 47%). FGG01 applied at 0.2 kg/ha showed a good control with 85% mean control.

In 3 trials, FGG01 applied at 0.2 kg/ha showed a similar control to the reference standard CANTUS applied at 0.2 kg/ha (respectively 88% vs. 84% mean control). No statistical differences were found in the 3 trials.

On disease incidence on bunches, in 4 trials the infestation in untreated plot reached up to 49% (ranging from 18% to 97%). FGG01 applied at 0.2 kg/ha showed an adequate control with 68% mean control.

In 3 trials FGG01 applied at 0.2 kg/ha showed a similar control to the reference standard CANTUS applied at 0.2 kg/ha (respectively 77% vs. 75% mean control). No statistical differences were found in the 3 trials.

**Therefore, by and large, data from 7 trials, with a moderate level of infestation, FGG01 applied at 0.2 kg/ha showed a good effectiveness, at an equivalent level of control to the reference product CANTUS at 0.2 kg/ha or at 0.1 kg/100 L against *Erysiphe necator* (UNCINE) in the Mediterranean EPPO climatic zone (supportive data). These results confirm that a maximum of three applications at the rate of 0.2 kg/ha (also 0.14 kg/10000 m<sup>2</sup> LWA and 0.02 kg/100 L) will be recommended on the product label for the control of UNCINE in the Central registration zone.**

## **C. Conclusion on grapevine (VITVI) - *Erysiphe necator* (UNCINE)**

A total of 10 valid efficacy trials were carried out in 2022 and 2023 to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) applied at 0.13-0.14 kg/10000 m<sup>2</sup> LWA, 0.2 kg/ha and 0.02 kg/100 L for the control of *Erysiphe necator* on grapevine in comparison to different reference standards in the Maritime EPPO climatic zone. Additionally, 7 supportive efficacy trials carried out in the Mediterranean EPPO zone are also here presented to support the dose expressed in kg/ha (0.2 kg/ha).

The summary results of the effect of FGG01 applied at 0.13-0.14 kg/10000 m<sup>2</sup> LWA, 0.2 kg/ha and 0.02 kg/100 L, compared to different reference standards in the Maritime and in the Mediterranean EPPO climatic zones are shown in Table 3.2-74.



**Table 3.2-74: Overall summary of efficacy of FGG01 on grapevine against *Erysiphe necator* in the Central registration zone**

Crop code	Pest code	EPPO climatic zone	No. of trials	Untreated	Efficacy (%) of					No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at...						
				(infestation %)	FGG01 0.13-0.14 kg/ha LWA	FGG01 0.2 kg/ha	FGG01 0.02 kg/100 L	CANTUS 0.2 kg/ha	LOCAL REFERENCE		0.13-0.14 kg/1000 m <sup>2</sup> LWA vs.		0.2 kg/ha vs.		0.02 kg/100 L vs.	
									-	Name Ref	CANTUS	Local Ref.	CANTUS	Local Ref.	CANTUS	Local Ref.
VITVI	UNCINE	Maritime	Disease Severity on leaves at Last assessment (BBCH 77-89)													
			9	28.1	67.7	75.4	-	-	-	-	-	-	-	-	-	-
			4	29.9	73.8	79.3	74.9	-	72.3	(1)*	-	0> ; 4= ; 0<	-	0> ; 4= ; 0<	-	0> ; 4= ; 0<
			5	26.7	62.9	72.2	-	69.3	-	-	0> ; 5= ; 0<	-	0> ; 5= ; 0<	-	-	-
			2	35.2	94.3	97.4	-	-	98.9	(2)*	-	0> ; 2= ; 0<	-	0> ; 2= ; 0<	-	-
			2	26.3	42.2	57.6	-	-	99.8	(3)*	-	0> ; 0= ; 2<	-	0> ; 0= ; 2<	-	-
			1	10.5	41.4	51.3	-	-	55.2	(4)*	-	0> ; 1= ; 0<	-	0> ; 1= ; 0<	-	-
			Disease Severity on bunches at BBCH 71-79													
			6	18.3	66.9	65.2	-	-	-	-	-	-	-	-	-	-
			4	21.1	62.9	71.6	79.7	-	81.2	(1)*	-	0> ; 4= ; 0<	-	0> ; 4= ; 0<	-	0> ; 4= ; 0<
			2	12.7	74.9	52.6	-	72.2	-	-	0> ; 2= ; 0<	-	0> ; 2= ; 0<	-	-	-
			1	10.4	84.0	31.0	-	-	96.0	(2)*	-	0> ; 1= ; 0<	-	0> ; 1= ; 0<	-	-
			1	15.0	65.8	74.2	-	-	94.7	(3)*	-	0> ; 1= ; 0<	-	0> ; 1= ; 0<	-	-
			Disease Incidence on bunches at BBCH 71-79													
			7	44.7	60.7	69.7	-	-	-	-	-	-	-	-	-	-
			3	67.8	61.4	70.7	71.3	-	82.0	(1)*	-	0> ; 3= ; 0<	-	0> ; 3= ; 0<	-	0> ; 3= ; 0<
			4	27.4	60.2	69.0	-	79.0	-	-	0> ; 4= ; 0<	-	0> ; 4= ; 0<	-	-	-
			1	37.0	57.0	42.0	-	-	82.0	(2)*	-	0> ; 1= ; 0<	-	0> ; 1= ; 0<	-	-
			2	30.5	46.3	67.0	-	-	90.7	(3)*	-	0> ; 2= ; 0<	-	0> ; 2= ; 0<	-	-
			Disease Severity on bunches at BBCH 81-89													
			9	35.5	69.8	67.6	-	-	-	-	-	-	-	-	-	-
			4	47.7	61.2	67.3	70.3	-	64.6	(1)*	-	0> 4 = ; 0<	-	0> ; 4= ; 0<	-	0> ; 4= ; 0<
			5	25.7	76.7	67.8	-	77.5	-	-	0> ; 5= ; 0<	-	0> ; 5= ; 0<	-	-	-
			2	12.9	92.2	67.6	-	-	96.9	(2)*	-	0> ; 2= ; 0<	-	0> ; 2= ; 0<	-	-
			2	44.3	67.6	72.5	-	-	97.9	(3)*	-	0> ; 1= ; 1<	-	0> ; 1= ; 1<	-	-
			1	14.3	64.1	58.9	-	-	59.1	(4)*	-	0> ; 1= ; 0<	-	0> ; 1= ; 0<	-	-
			Disease Incidence on bunches at BBCH 81-89													
			6	67.7	54.6	56.4	-	-	-	-	-	-	-	-	-	-
			2	82.5	27.6	41.2	57.3	-	40.6	(1)*	-	0> ; 2= ; 0<	-	0> ; 2= ; 0<	-	0> ; 2= ; 0<
			4	60.3	68.0	63.9	-	67.0	-	-	0> 4 = ; 0<	-	0> 4 = ; 0<	-	-	-
			2	41.7	82.7	65.8	-	-	86.9	(2)*	-	0> ; 2= ; 0<	-	0> ; 2= ; 0<	-	-
			2	79.0	53.3	62.1	-	-	92.4	(3)*	-	0> ; 0= ; 2<	-	0> ; 0= ; 2<	-	-

Crop code	Pest code	EPPO climatic zone	No. of trials	Untreated	Efficacy (%) of					No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at...						
				(infestation %)	FGG01 0.13-0.14 kg/ha LWA	FGG01 0.2 kg/ha	FGG01 0.02 kg/100 L	CANTUS 0.2 kg/ha	LOCAL REFERENCE		0.13-0.14 kg/1000 m² LWA vs.		0.2 kg/ha vs.		0.02 kg/100 L vs.	
									-	Name Ref	CANTUS	Local Ref.	CANTUS	Local Ref.	CANTUS	Local Ref.
VITVI	UNCINE	Medit.	Supportive data from other climatic EPPO zones													
			Disease Severity on leaves at Last assessment (BBCH 77-89)													
			3	32.0	-	75.7	-	74.4	-	-	-	-	0> ; 3= ; 0<	-	-	-
			Disease Severity on bunches at BBCH 71-79													
			4	51.7	-	78.9	-	83.1	-	-	-	-	0> ; 4= ; 0<	-	-	-
			Disease Incidence on bunches at BBCH 71-79													
			6	41.8	-	87.2	-	-	-	-	-	-	-	-	-	-
			5	48.3	-	84.7	-	84.3	-	-	-	-	0> ; 5= ; 0<	-	-	-
			Disease Severity on bunches at BBCH 81-89													
			4	21.7	-	85.0	-	-	-	-	-	-	-	-	-	-
			1	12.0	-	77.6	-	76.4**	-	-	-	-	0> ; 1= ; 0<	-	-	-
			3	24.9	-	87.8	-	84.0	-	-	-	-	0> ; 3= ; 0<	-	-	-
			Disease Incidence on bunches at BBCH 81-89													
			4	48.5	-	67.9	-	-	-	-	-	-	-	-	-	-
			3	58.7	-	76.8	-	75.1	-	-	-	-	0> ; 3= ; 0<	-	-	-
			1	18.0	-	41.4	-	47.2**	-	-	-	-	0> ; 1= ; 0<	-	-	-
		All zones	Disease Severity on leaves at Last valid assessment (BBCH 77-89)													
			12	29.1	-	75.5	-	-	-	-	-	-	-	-	-	-
			8	28.7	-	73.5	-	71.3	-	-	-	-	0> ; 8= ; 0<	-	-	-
			Disease Severity on bunches at BBCH 71-79													
			10	31.7	-	70.7	-	-	-	-	-	-	-	-	-	-
			6	38.7	-	70.2	-	79.5	-	-	-	-	0> ; 6= ; 0<	-	-	-
			Disease Incidence on bunches at BBCH 71-79													
			13	43.4	-	77.8	-	-	-	-	-	-	-	-	-	-
			9	39.0	-	77.7	-	82.0	-	-	-	-	0> ; 9= ; 0<	-	-	-
			Disease Severity on bunches at BBCH 81-89													
			13	31.3	-	72.9	-	-	-	-	-	-	-	-	-	-
			8	25.4	-	79.9	-	79.9	-	-	-	-	0> ; 8= ; 0<	-	-	-
			Disease Incidence on bunches at BBCH 81-89													
			10	61.3	-	62.5	-	-	-	-	-	-	-	-	-	-
			7	59.6	-	69.4	-	70.5	-	-	-	-	0> ; 7= ; 0<	-	-	-

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

\*(1)= COLLIS at 0.64 L/ha, (2)= PROSPER at 0.66 L/ha, (3)= KUMULUS at 5-8 kg/ha (4)=TOPAS at 0.08 L/ha

\*\*CANTUS applied at 0.1 kg/100 L

Overall all, in the 17 trials, FGG01 applied at 0.13-0.14 kg/10000 m<sup>2</sup> LWA, 0.2 kg/ha and at 0.02 kg/100 L showed an equivalent level of control to the reference products tested against *Erysiphe necator* (UNCINE) and were statistically equivalent in most of the trials. Therefore, 3 applications at the rate of 0.14 kg/10000 m<sup>2</sup> LWA, 0.2 kg/ha or 0.02 kg/100 L will be recommended on the product label for the control of *Erysiphe necator* (UNCINE) on grapevine in the Central registration zone.

### **3.2.3.3 Efficacy trials in fresh beans and peas (PHSVX, PIBSX, VICFX)**

A total of 16 valid efficacy trials, including supportive data (8 trials), were carried out in 2022 and 2023 to justify the interest of FGG01 (500 g/kg of boscalid, WG) applied at 1.0 kg/ha for the control of *Botrytis* sp. (BOTRSP) and *Sclerotinia* sp. (SCLESP) in fresh beans and peas with two applications at BBCH 60-69. The trials were carried out in the Maritime EPPO climatic zone and additionally, supportive data from the Mediterranean EPPO zone are also presented to complete the data package, as already justified in the page 26 of this document under the part 'Justification for the use of data from different countries'.

For these uses, data on green beans, broad beans and peas crops can be summarised together as they belong to the same extrapolation group fresh beans and peas. All of these crops are regarded as proper host plants for these fungal pathogens. Moreover, this extrapolation is in agreement with the extrapolation published by EPPO (Table No. 1/257, "Extrapolation table for effectiveness of fungicides, Diseases on legume vegetables"). Therefore, based upon extrapolation table, efficacy data of FGG01 on fresh peas (PIBSX) could be extrapolated to fresh beans (PHSVX, VICFX), it is expected that comparable efficacy level will be achieved on beans and vice-versa.

#### **3.2.3.3.1 Material and methods**

##### **Experimental details**

All the trials presented in Table 3.2-15 were carried out by officially recognised organisations in accordance with the Principles of Good Experimental Practice (GEP). These trials were performed following EPPO guidelines.

Main characteristics are summarised in Table 3.2-75 (Maritime) for *Botrytis* sp. trials and in Table 3.2-76 (Maritime) for *Sclerotinia* sp. trials carried out in Maritime EPPO climatic zone, while Table 3.2-77 (Mediterranean) and Table 3.2-78 (Mediterranean) summarise the main characteristics for supporting trials against *Botrytis* sp. and *Sclerotinia* sp. respectively, carried out in the Mediterranean EPPO climatic zone. Details per trial (trial location, crop cultivar, experimental design, number of blocks, plot size and application(s)) are presented in Biological Assessment Dossier and in individual trial reports in Document K.

**Table 3.2-75: Details on trial methodology - Efficacy trials - Fresh beans and peas - *Botrytis* sp. (BOTRSP) - Maritime EPPO climatic zone**

<b>Guidelines</b>	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	PP1/54(3): “ <i>Botrytis cinerea</i> on vegetables” PP1/172(2): “ <i>Leaf and pod spots of pea</i> ”
<b>Experimental design</b>	Plot design	Randomized Complete Block (RCB)
	Plot size	10-25 m <sup>2</sup>
	Number of replications	4 replications.
<b>Crop</b>	Number of trials	5 valid efficacy trials (2 trials on peas, 1 trial on broad beans and 2 trials on green beans)
	Varieties	<u>Peas</u> : <i>Eso</i> (1), <i>Sakura</i> (1). <u>Broad beans</u> : <i>Augusta</i> (1). <u>Green beans</u> : <i>Ampere</i> (1), <i>Cadillac</i> (1).
<b>Application</b>	Application timing	Between BBCH 61-70 except in 1 trial where the first application was carried out at BBCH 51 but with no impact in the results.
	Number of applications	2 applications with an interval between application of 7-14 days.
	Spray volumes	Foliar spraying: 200-500 L/ha.
<b>Assessment</b>	Assessment dates	At application, at around 21 DA-B and shortly before harvest.
	Assessment types	Disease incidence and disease severity on plant, pods, leaves and stems. Phytotoxicity assessments.
<b>Results &amp; Analysis</b>	Statistical analysis	ANOVA - Newman - Keuls test (5%).

**Table 3.2-76: Details on trial methodology - Efficacy trials - Fresh beans and peas - *Sclerotinia* sp. (SCLESP) - Maritime EPPO climatic zone**

<b>Guidelines</b>	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	PP1/54(3): “ <i>Botrytis cinerea</i> on vegetables” PP1/172(2): “ <i>Leaf and pod spots of pea</i> ”
<b>Experimental design</b>	Plot design	Randomized Complete Block (RCB)
	Plot size	14-20 m <sup>2</sup>
	Number of replications	4 replications.
<b>Crop</b>	Number of trials	3 valid efficacy trials (3 trials on green beans).
	Varieties	<u>Green beans</u> : <i>Ampere</i> (1), <i>Cadillac</i> (1), <i>Persepolis</i> (1).
<b>Application</b>	Application timing	Between BBCH 60-69 except in one trial where the first application was done at BBCH 51 but with no impact in the results.
	Number of applications	2 applications with an interval between application of 7-15days.
	Spray volumes	Foliar spraying: 200-500 L/ha.
<b>Assessment</b>	Assessment dates	At application, at around 21 DA-B and shortly before harvest.
	Assessment types	Disease incidence and disease severity on plant, pods, leaves and stem. Phytotoxicity assessments
<b>Results &amp; Analysis</b>	Statistical analysis	ANOVA - Newman - Keuls test (5%).

**Table 3.2-77: Details on trial methodology - Efficacy trials - Fresh beans and peas - *Botrytis* sp. (BOTRSP) - Mediterranean EPPO climatic zone - Supporting trials**

<b>Guidelines</b>	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	PP1/54(3): “ <i>Botrytis cinerea</i> on vegetables” PP1/172(2): “ <i>Leaf and pod spots of pea</i> ”
<b>Experimental design</b>	Plot design	Randomized Complete Block (RCB).
	Plot size	6-32 m².
	Number of replications	4 replications.
<b>Crop</b>	Number of trials	3 valid efficacy trials (3 trials on green beans)
	Varieties	<u>Green beans</u> : <i>Contender</i> (2), <i>Oriola</i> (1).
<b>Application</b>	Application timing	Between BBCH 61-69.
	Number of applications	2 applications with an interval between application of 9-13 days.
	Spray volumes	Foliar spraying: 400-600 L/ha.
<b>Assessment</b>	Assessment dates	At application, at around 21 DA-B and shortly before harvest.
	Assessment types	Disease incidence and disease severity on plant, pods, leaves and stems. Phytotoxicity assessments.
<b>Results &amp; Analysis</b>	Statistical analysis	ANOVA - Newman - Keuls test (5%).

**Table 3.2-78: Details on trial methodology - Efficacy trials - Fresh beans and peas - *Sclerotinia* sp. (SCLESP) - Mediterranean EPPO climatic zone - Supporting trials**

<b>Guidelines</b>	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	PP1/54(3): “ <i>Botrytis cinerea</i> on vegetables” PP1/172(2): “ <i>Leaf and pod spots of pea</i> ”
<b>Experimental design</b>	Plot design	Randomized Complete Block (RCB)
	Plot size	6-36 m²
	Number of replications	4 replications.
<b>Crop</b>	Number of trials	5 valid efficacy trials (1 trial on broad beans and 4 trials on green beans)
	Varieties	<u>Broad beans</u> : <i>Fabiola</i> (1). <u>Green beans</u> : <i>Fabiola</i> (1), <i>Luz de otoño</i> (1), <i>Parker</i> (1), <i>Perolar</i> (1).
<b>Application</b>	Application timing	Between BBCH 60-69.
	Number of applications	2 applications with an interval between application of 8-13 days.
	Spray volumes	Foliar spraying: 400-800 L/ha.
<b>Assessment</b>	Assessment dates	At application, at around 21 DA-B and shortly before harvest.
	Assessment types	Disease incidence and disease severity on plant, pods, leaves and stem. Phytotoxicity assessments
<b>Results &amp; Analysis</b>	Statistical analysis	ANOVA - Newman - Keuls test (5%).

### Treatments and reference standards

In all efficacy trials, the efficacy of FGG01 against BOTRSP and SCLESP applied twice at 0.5, 0.75 and 1.0 kg/ha was compared to the reference standard CANTUS applied at 1.0 kg/ha and also SIGNUM applied at 1.0 kg/ha in 1 trial (Table 3.2-16). This rate is equivalent to the dose rate of FGG01 requested (1.0 kg/ha).

Table 3.2-79 below presents the plant protection products and the rates used in this part.

**Table 3.2-79: Plant protection products used in efficacy trials - Fresh beans and peas**

Product name	Active substance(s)	Formulation		Application dose in trials (per treatment)	Country	Rate of active substance per ha	Remark
		Type <sup>[1]</sup>	Concentration of a.s.				
FGG01	Boscalid	WG	500 g/kg	0.5 kg/ha 0.75 kg/ha 1.0 kg/ha	-	250-500 g a.s./ha	-
CANTUS	Boscalid	WG	500 g/kg	1.0 kg/ha	BE, CZ, DE, ES FR	500 g a.s./ha	-
FILAN	Boscalid	WG	500 g/kg	1.0 kg/ha	UK	500 g a.s./ha	Also named CANTUS in this BAD <sup>[2]</sup>
SIGNUM	Boscalid + Pyraclostrobin	WG	267 g/kg + 67 g/kg	1.0 kg/ha	UK	267 g a.s./ha + 67 g a.s./ha	Local reference product for trial validation <sup>[3]</sup>
PICTOR PRO	Boscalid	WG	500 g/kg	1.0 kg/ha	FR	500 g a.s./ha	Also named CANTUS in this BAD <sup>[2]</sup>

<sup>[1]</sup> WG: Water-dispersible granules

<sup>[2]</sup> The 500 g/kg boscalid formulation registered by BASF has the tradename FILAN in United Kingdom and PICTOR PRO in France. CANTUS (MSDS UK: [link](#); MSDS FR: [link](#)), PICTOR PRO (MSDS FR: [link](#)) and FILAN (MSDS UK: [link](#)) were strictly similar, thus, we grouped all products by the same name of CANTUS in this dossier (most represented commercial name in the countries targeted by this dossier).

<sup>[3]</sup> Reference products not presented in the efficacy part but included in the Appendix 3 of the Biological Assessment Dossier.

### Assessment methods

In all trials, efficacy was assessed according to EPPO guidelines. Assessments of efficacy were made on different plant parts. Plant parts assessed were one or some of the following: whole plant, stem, pod and leaves.

Assessments were done at each application event since first disease symptoms were seen until harvest.

Data was recorded on 25 or 50 plants, except in 2 trials, where data were recorded based on only 10 plants; 25 or 50 stems, 100 pods or 100 leaves per plot as either percentage of visual infection of disease (disease severity) on specified plant parts 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. This efficacy calculation was present in the trial reports, otherwise, the calculation was done with the Abbott formula:

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

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

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

## Phytotoxicity assessments

In efficacy trials, phytotoxicity was also assessed. Phytotoxicity assessments were carried out in accordance with EPPO guideline PP1/135 (“Phytotoxicity assessment”). Assessments were carried out at various intervals post application by recording visual percentage injury (0% = no injury, 100% = complaint expression of injury symptom). Crop safety results are presented in Section 3.4.1.

## Statistical analyses

Observed or calculated variables are subjected to an analysis of variance (ANOVA) after or not a transformation depending on the variability of the raw data (only the numerical values from the raw data are considered).

When the result of the analysis is significant, a multiple comparison of treatments is performed. The averages are classified using the Newman and Keuls tests and divided into homogeneous groups (a, b, c, ...). Treatment means with no letter in common are significantly different in accordance with the test conducted at a 95% confidence level.

## Results layout

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

On both diseases, only assessments where area infected (PESSEV) in the untreated reached at least 5% of the part rated and frequency of attack (PESINC) in the untreated reached at least 10% were considered as valid. Also, only assessments where reference standard reached a normal efficacy (>50% control compared to untreated) were considered as valid.

For the 2 target diseases *Sclerotinia sp.* and *Botrytis sp.*, 2 valid assessment timings on plants, pods, stems and/or leaves were selected and summarised in this part. These 2 selected assessments are the most representative according to the disease and fresh beans and peas development:

- First valid assessment at 2-3 weeks after last application: [16-23] DA-B,
- Last valid assessment shortly before harvest: [28-72] DA-B.

For information, in 1 trial, the last valid assessment was at 28 DA-B (quite early compared to other trials) since the crop was already at BBCH 89. This early assessment does not impact the efficacy results.

### 3.2.3.3.2 Results on fresh beans and peas (PHSVX, PIBSX, VICFX) - *Botrytis* spp. (BOTRCI, BOTRFA, BOTRSP)

The label claim for this use is summarised in Table 3.2-80.

**Table 3.2-80: Label claim for fresh beans and peas against *Botrytis* sp.**

Crops	Target	Country	Dossier strategy	Application timing	No. of applications	Application volume L/ha	Dose rate kg product/ha
Fresh beans and peas (PHSVX, PIBSX, VICFX)	<i>Botrytis</i> sp. (BOTRSP)	AT, BE, CZ	Bridging	BBCH 60-69	2	150-600	1
		NL, PL	Full pack (minor use)				

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

A total of 5 valid efficacy trials were carried out in 2022 and 2023 to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) applied at 1.0 kg/ha for the control of *Botrytis* sp. on fresh beans and peas in comparison to the reference standard CANTUS (500 g/kg of boscalid, WG) at 1.0 kg/ha in the Maritime (Belgium, Czech Republic, North of France, Germany and United Kingdom) EPPO climatic zone. Additionally, a set of 3 efficacy trials carried out in the Mediterranean (Spain) EPPO climatic zone in 2023 are also here presented as supportive data to complete the data package. In addition, 4 other trials in Mediterranean EPPO climatic zone (4 trials in Italy) are currently on going and are listed below, although no results are currently available (results will be available in November 2024).

A summary of all trials generating data on fresh beans and peas against *Botrytis* sp. is presented in Table 3.2-81.

**Table 3.2-81: Overview of efficacy trials - Fresh beans and peas - *Botrytis* sp.**

Nb. of trials	Crop	Target	Year	Country	EPPO climatic zone	Comment
1 trial	Faba/Broad bean	BOTRFA	2022	DE	Maritime	-
1 trial	Garden/Green bean	BOTRSP	2023	FR-N	Maritime	-
1 trial	Garden pea	BOTRCI	2023	CZ	Maritime	-
1 trial	Garden pea	BOTRCI	2023	UK	Maritime	-
1 trial	Garden bean	BOTRCI	2023	BE	Maritime	-
3 trials	Garden/Green bean	BOTRCI	2023	ES	Mediterranean	Supportive data
4 trials*		BOTRCI	2024	IT	Mediterranean	On going

\* Additional trials currently ongoing this year (no results are currently available for these trials; results will be available in November 2024).

No data are available on the North-East EPPO climatic zone, which is concerned by Poland. Nevertheless, the use in this country can be supported with the available data package in the Maritime EPPO zone and with the supportive data presented in the Mediterranean EPPO climatic zone. In addition, 2 efficacy trials were carried out in Czech Republic and Germany. Poland is a country bordering Czech Republic and Germany, 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. In addition, this use is minor in Poland.

Furthermore, Maritime and Mediterranean EPPO climatic zones are representative of *Botrytis* sp. occurrence in Europe and are the most challenging for this disease.



### **A. Results on fresh beans and peas (PHSVX, PIBSX, VICFX) - *Botrytis* sp. (BOTRCI, BOTRFA, BOTRSP) - Maritime EPPO zone**

A total of 5 valid efficacy trials were carried out in 2022 and 2023 to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) applied at 1.0 kg/ha applied twice for the control of *Botrytis* sp. on fresh beans and peas in comparison to the reference standard CANTUS (500 g/kg of boscalid, WG) at 1.0 kg/ha in the Maritime EPPO climatic zone in Belgium (1 trial), Czech Republic (1 trial), North of France (1 trial), Germany (1 trial) and United Kingdom (1 trial). An overview of these trials is presented in Table 3.2-15. The summary results of the effect of FGG01 applied at 1.0 kg/ha compared to reference standard are shown in Table 3.2-82.

**Table 3.2-82: Summary results: efficacy of FGG01 against *Botrytis* sp. on fresh beans and peas - Maritime EPPO zone**

Assessment timing	Parts	Parameters	EPPO climatic zone	No. of trials	Days after application	Untreated control			FGG01 1.0 kg/ha			CANTUS 1.0 kg/ha			No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at 1 kg/ha vs. CANTUS (1.0 kg/ha)
						Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	
2-3 weeks after last application	PLANT	Incidence (%)	Maritime	1	[16 DA-B]	27.0	-	-	74.1	-	-	89.2	-	-	0> ; 1= ; 0<
		Severity (%)	Maritime	2	[16-23 DA-B]	15.0	7.5	22.5	71.7	63.7	79.6	62.2	57.4	66.9	0> ; 2= ; 0<
	POD	Incidence (%)	Maritime	3	[16-21 DA-B]	38.2	8.5	88.0	70.3	43.9	86.1	66.4	50.6	97.4	1> ; 2= ; 0<
		Severity (%)	Maritime	3	[16-22 DA-B]	13.6	6.9	17.8	77.6	53.9	93.2	72.4	57.6	88.3	1> ; 2= ; 0<
Last assessment	PLANT	Severity (%)	Maritime	1	72 DA-B	27.9	-	-	63.8	-	-	62.0	-	-	0> ; 1= ; 0<
	POD	Incidence (%)	Maritime	2	[28-72 DA-B]	21.8	18.0	25.6	75.0	49.9	100.0	78.1	56.1	100.0	0> ; 2= ; 0<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

### **Assessment 2-3 weeks after last application:**

In the Maritime EPPO climatic zone, on disease incidence on the whole plants, for information, in a single valid efficacy trial on green beans, the infestation in untreated plot reached up to 27%. FGG01 applied at 1.0 kg/ha showed a slightly lower control than the reference standard CANTUS applied at 1.0 kg/ha (respectively 74% vs. 89% control). However, no statistical differences were found. These results should nevertheless be considered carefully owing to the reduced data set.

On disease severity on the whole plants, the infestation in untreated plot reached up to 15% (ranging from 8% to 23%) in 2 trials on fresh beans. FGG01 applied at 1.0 kg/ha showed a control quite close to that of the reference standard CANTUS applied at 1.0 kg/ha (respectively 72% vs. 62% mean control). No statistical differences were found.

On disease incidence on pods, the infestation in untreated plot reached up to 38% (ranging from 9% to 88%) in 3 trials on green beans and peas. FGG01 applied at 1.0 kg/ha showed a similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 70% vs. 66% mean control). FGG01 applied at 1.0 kg/ha was statistically similar to CANTUS at 1.0 kg/ha in 2 out of 3 trials and superior in the last trial.

On disease severity on pods, the infestation in untreated plot reached up to 14% (ranging from 7% to 18%) in 3 trials on green beans and peas. FGG01 applied at 1.0 kg/ha showed a control quite close to that of the reference standard CANTUS applied at 1.0 kg/ha (respectively 78% vs. 72% mean control). FGG01 applied at 1.0 kg/ha was statistically similar to CANTUS at 1.0 kg/ha in 2 out of 3 trials and superior in the last trial.

### **Last assessment:**

On disease severity on the whole plants, for information, in a single valid efficacy trial on broad beans, the infestation in untreated plot reached up to 28%. FGG01 applied at 1.0 kg/ha showed a similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 64% vs. 62% control). No statistical differences were found.

On disease incidence on pods, the infestation in untreated plot reached up to 22% (ranging from 18% to 26%) in 2 trials on fresh beans. FGG01 applied at 1.0 kg/ha showed similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 75% vs. 78% mean control). No statistical differences were found in the 2 trials.

**Therefore, by and large, data from 5 trials, with a moderate level of infestation, FGG01 applied twice at 1.0 kg/ha showed an adequate to a good effectiveness, at an equivalent level of control to the reference CANTUS applied at 1.0 kg/ha against *Botrytis sp.* (BOTRSP) on fresh beans and peas in the Maritime EPPO zone. Therefore, two applications at the rate of 1.0 kg/ha will be recommended on the product label for the control of BOTRSP in the Maritime EPPO climatic zone.**

## **B. Results on fresh beans and peas (PHSVX, PIBSX, VICFX) - *Botrytis cinerea* (BOTRCI) - Mediterranean EPPO zone - Supportive data**

A total of 3 valid efficacy trials were carried out in 2023 to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) applied at 1.0 kg/ha applied twice for the control of *Botrytis cinerea* on green beans in comparison to the reference standard CANTUS (500 g/kg of boscalid, WG) at 1.0 kg/ha in the Mediterranean EPPO climatic zone in Spain. A further 4 trials are in progress. An overview of these trials is presented in Table 3.2-15.

Data generated in trials carried out within the Mediterranean EPPO climatic zone are fully supportive towards demonstrating proposed label claims for the efficacy and crop safety of FGG01 in Central EU zone. Indeed, extra-zonal data obtained from trials carried out in countries of the Southern EU zone belonging to the Mediterranean EPPO climatic zone are also presented in this dossier to further support the label claims. Indeed, this area is fully representative of *Botrytis cinerea* occurrence in Europe.

The summary results of the effect of FGG01 applied at 1.0 kg/ha compared to reference standard are shown in Table 3.2-83.

**Table 3.2-83: Summary results: efficacy of FGG01 against *Botrytis cinerea* on fresh beans and peas - Mediterranean EPPO zone**

Assessment timing	Parts	Parameters	EPPO climatic zone	No. of trials	Days after application	Untreated control			FGG01 1.0 kg/ha			CANTUS 1.0 kg/ha			No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at 1.0 kg/ha vs. CANTUS at 1.0 kg/ha
						Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	
2-3 weeks after last application	PLANT	Severity (%)	Mediterranean	1	23 DA-B	25.1	-	-	71.1	-	-	69.5	-	-	0> ; 1= ; 0<
	POD	Incidence (%)	Mediterranean	2	[21-22 DA-B]	23.4	7.8	39.0	77.1	60.6	93.7	80.9	64.6	97.2	0> ; 2= ; 0<
		Severity (%)	Mediterranean	1	22 DA-B	18.5	-	-	70.3	-	-	73.0	-	-	0> ; 1= ; 0<
	STEM	Incidence (%)	Mediterranean	2	[21-22 DA-B]	31.5	13.0	50.0	74.7	55.6	93.8	73.0	54.3	91.7	0> ; 2= ; 0<
		Severity (%)	Mediterranean	1	22 DA-B	19.1	-	-	67.5	-	-	69.0	-	-	0> ; 1= ; 0<
Last assessment	POD	Incidence (%)	Mediterranean	2	[48-50 DA-B]	30.4	13.0	47.8	73.1	55.6	90.5	76.1	59.1	93.1	0> ; 2= ; 0<
		Severity (%)	Mediterranean	2	[48-50 DA-B]	14.6	7.1	22.0	80.3	65.6	95.0	80.9	63.9	97.8	0> ; 2= ; 0<
	STEM	Incidence (%)	Mediterranean	2	[48-50 DA-B]	42.0	24.0	60.0	69.3	48.3	90.2	70.0	50.7	89.3	0> ; 2= ; 0<
		Severity (%)	Mediterranean	2	[48-50 DA-B]	19.1	11.1	27.1	79.3	64.0	94.6	80.4	65.7	95.1	0> ; 2= ; 0<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

### **Assessment at around 2-3 weeks after last application:**

In the Mediterranean EPPO climatic zone, on disease severity on the whole plants, for information, in a single valid efficacy trial on green beans, the infestation in untreated plot reached up to 25%. FGG01 applied at 1.0 kg/ha showed a similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 71% vs. 70% control). No statistical differences were found.

On disease incidence on pods, the infestation in untreated plot reached up to 23% (ranging from 8% to 39%) in 2 trials on green beans. FGG01 applied at 1.0 kg/ha showed a similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 77% vs. 81% mean control). No statistical differences were found in the 2 trials.

On disease severity on pods, for information, in a single valid efficacy trial on green beans, the infestation in untreated plot reached up to 19%. FGG01 applied at 1.0 kg/ha showed a similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 70% vs. 73% control). No statistical differences were found.

On disease incidence on stems, the infestation in untreated plot reached up to 32% (ranging from 13% to 50%) in 2 trials on green beans. FGG01 applied at 1.0 kg/ha showed a similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 75% vs. 73% mean control). No statistical differences were found in the 2 trials.

On disease severity on stems, for information, in a single valid efficacy trial on green beans, the infestation in untreated plot reached up to 19%. FGG01 applied at 1.0 kg/ha showed a similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 68% vs. 69% control). No statistical differences were found.

### **Last assessment:**

On disease incidence on pods, the infestation in untreated plot reached up to 30% (ranging from 13% to 48%) in 2 trials on green beans. FGG01 applied at 1.0 kg/ha showed similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 73% vs. 76% mean control). No statistical differences were found in the 2 trials.

On disease severity on pods, the infestation in untreated plot reached up to 15% (ranging from 7% to 22%) in 2 trials on green beans. FGG01 applied at 1.0 kg/ha showed similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 80% vs. 81% mean control). No statistical differences were found in the 2 trials.

On disease incidence on stems, the infestation in untreated plot reached up to 42% (ranging from 24 % to 60%) in 2 trials on green beans. FGG01 applied at 1.0 kg/ha showed similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 69% vs. 70% mean control). No statistical differences were found in the 2 trials.

On disease severity on stems, the infestation in untreated plot reached up to 19% (ranging from 11 % to 27%) in 2 trials on green beans. FGG01 applied at 1.0 kg/ha showed similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 79% vs. 80% mean control). No statistical differences were found in the 2 trials.

**Therefore, by and large, data from 3 trials, with a moderate level of infestation, FGG01 applied twice at 1.0 kg/ha showed an adequate to a good effectiveness, at an equivalent level of control to the reference CANTUS applied at 1.0 kg/ha against *Botrytis cinerea* (BOTRCI) on green beans in the Mediterranean EPPO climatic zone. These supportive data confirm that two applications at the rate of 1.0 kg/ha will be recommended on the product label for the control of BOTRSP in the Central registration zone on green beans and peas.**

### C. Conclusion on fresh beans and peas - *Botrytis* sp. (BOTRSP)

A total of 5 valid efficacy trials were carried out in 2022 and 2023 to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) applied twice at 1.0 kg/ha for the control of *Botrytis* sp. on fresh beans and peas in comparison to the reference standard CANTUS (500 g/kg of boscalid, WG) at 1.0 kg/ha. in the Maritime EPPO climatic zone. Additionally, a set of 3 efficacy trials carried out in the Mediterranean (Spain) EPPO climatic zone in 2023 are also here presented to complete the data package.

The summary results of the effect of FGG01 applied at 1.0 kg/ha compared to the reference standard in the Maritime and Mediterranean EPPO climatic zones are shown in Table 3.2-84.

**Table 3.2-84: Overall summary of efficacy of FGG01 on fresh beans and peas against *Botrytis* sp. in the Central registration zone**

Crop code	Pest code	EPPO climatic zone	Part assessed	Nb of trials	Untreated	Efficacy (%)		No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at 1.0 kg/ha vs. CANTUS 1.0 kg/ha
					Infestation (%)	FGG01 1.0 kg/ha	CANTUS 1.0 kg/ha	
PHSVX PIBSX VICFX	BOTRSP	Maritime	Disease incidence on plants - 2-3 WA-B	1	27.0	74.1	89.2	0> ; 1= ; 0<
			Disease severity on plants - 2-3 WA-B	2	15.0	71.7	62.2	0> ; 2= ; 0<
			Disease incidence on pods - 2-3 WA-B	3	38.2	70.3	66.4	1> ; 2= ; 0<
			Disease severity on pods - 2-3 WA-B	3	13.6	77.6	72.4	1> ; 2= ; 0<
			Disease severity on plants - last assessment	1	27.9	63.8	62.0	0> ; 1= ; 0<
			Disease incidence on pods - last assessment	2	21.8	75.0	78.1	0> ; 2= ; 0<
			Supportive data from other EPPO climatic zone					
		Medit.	Disease severity on plants - 2-3 WA-B	1	25.1	71.1	69.5	0> ; 1= ; 0<
			Disease incidence on pods - 2-3 WA-B	2	23.4	77.1	80.9	0> ; 2= ; 0<
			Disease severity on pods - 2-3 WA-B	1	18.5	70.3	73.0	0> ; 1= ; 0<
			Disease incidence on stems - 2-3 WA-B	2	31.5	74.7	73.0	0> ; 2= ; 0<
			Disease severity on stems - 2-3 WA-B	1	19.1	67.5	69.0	0> ; 1= ; 0<
			Disease incidence on pods - last assessment	2	30.4	73.1	76.1	0> ; 2= ; 0<
			Disease severity on pods - last assessment	2	14.6	80.3	80.9	0> ; 2= ; 0<
			Disease incidence on stems - last assessment	2	42.0	69.3	70.0	0> ; 2= ; 0<
			Disease severity on stems - last assessment	2	19.1	79.3	80.4	0> ; 2= ; 0<
		All zones	Disease severity on plants - 2-3 WA-B	3	18.4	71.5	64.6	0> ; 3= ; 0<
			Disease incidence on pods - 2-3 WA-B	5	32.3	73.0	72.2	1> ; 4= ; 0<
			Disease severity on pods - 2-3 WA-B	4	14.8	75.8	72.6	1> ; 3= ; 0<
			Disease incidence on pods - last assessment	4	26.1	74.0	77.1	0> ; 4= ; 0<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

WA-B = Weeks After application B

In 8 trials, FGG01 applied at 1.0 kg/ha showed an adequate to a good effectiveness, at an equivalent level of control to the reference product CANTUS at 1.0 kg/ha against *Botrytis* sp. (BOTRSP). Therefore, two applications at the rate of 1.0 kg/ha will be recommended on the product label for the control of BOTRSP in the Central registration zone on green beans and peas.

In addition, according to EPPO Extrapolation tables PP 1/257 FEET 78 (1)<sup>12</sup>, data from the use *Botrytis cinerea* on grapevine can complete and support the use *Botrytis cinerea* on peas and beans.

Diseases		Crop: within Legume vegetables		Crops: outside Legume vegetables	
1 Pathogen species	2 Disease group name	3 Indicator crops	4 Extrapolation to other crops	5 Data from these crops can support the indicator crops (reduced data or no data *)	6 Extrapolation to crops (reduced or no data*)
<i>Botryotinia fuckeliana</i> BOTRCI	Grey mold	Any legume vegetable	All legume vegetables	Strawberry FRASS, Grapes VITVI, any other relevant crop	All relevant crops where this disease appear <sup>1</sup>

Therefore, two applications at the rate of 1.0 kg/ha will be recommended on the product label for the control of BOTRSP in the Central registration zone on green beans and peas.

### 3.2.3.3.3 Results on fresh beans and peas (PHSVX, VICFX) - *Sclerotinia* spp. (SCLESC, SCLESP)

The label claim for this use is summarised in Table 3.2-85.

**Table 3.2-85: Label claim for fresh beans and peas against *Sclerotinia* sp.**

Crops	Target	Country	Dossier strategy	Application timing	No. of applications	Application volume L/ha	Dose rate kg product/ha
Fresh beans and peas (PHSVX, PIBSX, VICFX)	<i>Sclerotinia</i> sp. (SCLESP)	AT, BE, CZ	Bridging	BBCH 60-69	2	150-600	1.0

In Austria, Belgium and the Czech Republic, the reference product CANTUS has been authorised for use as a fungicide on fresh beans and peas against *Sclerotinia* sp. for more than 10 years and the use is not protected. Thus, in this bridging context, according to guideline EPPO 1/307(2) a reduced data package is required to demonstrate the comparability between CANTUS and FGG01.

A total of 3 valid efficacy trials were carried out in 2023 to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) applied at 1.0 kg/ha for the control of *Sclerotinia sclerotiorum* on fresh beans and peas in comparison to the reference standard CANTUS (500 g/kg of boscalid, WG) at 1.0 kg/ha in the Maritime (Belgium and North of France) EPPO climatic zone. Additionally, a set of 5 efficacy trials carried out in the Mediterranean EPPO climatic zone (Spain) in 2022 and 2023 are also here presented to complete the data package on fresh beans and peas against *Sclerotinia* sp.. In addition, 4 other trials in Maritime EPPO climatic zone (4 trials in North of France) are currently on going and are listed below, although no results are currently available (results will be available in November 2024).

A summary of all trials generating data on Fresh beans and peas against *Sclerotinia* sp. is presented in Table 3.2-86.

**Table 3.2-86: Overview of efficacy trials - Fresh beans and peas - *Sclerotinia* sp.**

Nb. of trials	Crop	Target	Year	Country	EPPO climatic zone	Comment
2 trials	Garden/Green bean	SCLESC	2023	FR-N	Maritime	-
1 trial	Garden/Green bean	SCLESC	2023	BE	Maritime	-
4 trials*	-	SCLESP	2024	FR-N	Maritime	On going
1 trial	Faba/Broad bean	SCLESP	2022	ES	Mediterranean	Supportive data
2 trials	Garden/Green bean	SCLESC	2023	ES	Mediterranean	Supportive data
2 trials	Garden/Green bean	SCLESP	2023	ES	Mediterranean	Supportive data

\* Additional trials currently ongoing this year (no results are currently available for these trials; results will be available in November 2024).

<sup>12</sup> European and Mediterranean Plant Protection Organization Organisation Européenne et Méditerranéenne pour la Protection des Plantes ; Extrapolation table for effectiveness of fungicides, diseases on legume vegetables, PP 1/257 FEET 78 (1), First published in 2017 ([link](#)).



## **A. Results on fresh beans (PHSVX, VICFX) - *Sclerotinia sclerotiorum*. (SCLESC) - Maritime EPPO zone**

A total of 3 valid efficacy trials were carried out in 2023 to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) applied at 1.0 kg/ha applied twice for the control of *Sclerotinia sclerotiorum* on green beans in comparison to the reference standard CANTUS (500 g/kg of boscalid, WG) at 1.0 kg/ha in the Maritime EPPO climatic zone in Belgium (1 trial) and North of France (2 trials). An overview of these trials is presented in Table 3.2-15.

The summary results of the effect of FGG01 applied at 1.0 kg/ha compared to reference standard are shown in Table 3.2-87.

**Table 3.2-87: Summary results: efficacy of FGG01 against *Sclerotinia sclerotiorum* on fresh beans and peas - Maritime EPPO zone**

Assessment timing	Parts	Parameters	EPPO climatic zone	No. of trials	Days after application	Untreated control Infestation (%)			% Efficacy						No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at 1.0 kg/ha vs. CANTUS at 1.0 kg/ha
									FGG01 1.0 kg/ha			CANTUS 1.0 kg/ha			
						Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	
2-3 weeks after last application	PLANT	Incidence (%)	Maritime	2	[22-23 DA-B]	76.5	73.0	80.0	84.6	81.6	87.7	85.1	73.3	96.9	0> ; 2= ; 0<
		Severity (%)	Maritime	1	22 DA-B	31.2	-	-	97.2	-	-	99.7	-	-	0> ; 1= ; 0<
	POD	Incidence (%)	Maritime	3	[21-23 DA-B]	59.9	39.8	100.0	88.3	85.5	92.7	88.0	75.5	99.5	0> ; 3= ; 0<
		Severity (%)	Maritime	2	[21-22 DA-B]	27.9	26.9	28.9	91.6	87.7	95.5	94.8	89.7	99.9	0> ; 2= ; 0<
	STEM	Severity (%)	Maritime	1	23 DA-B	37.6	-	-	92.5	-	-	80.3	-	-	0> ; 1= ; 0<
Last assessment	POD	Incidence (%)	Maritime	1	28 DA-B	39.8	-	-	74.1	-	-	74.3	-	-	0> ; 1= ; 0<
		Severity (%)	Maritime	1	28 DA-B	31.2	-	-	81.3	-	-	84.3	-	-	0> ; 1= ; 0<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

### **Assessment at around 3 weeks after last application:**

In the Maritime EPPO climatic zone, on disease incidence on the whole plants, the infestation in untreated plot reached up to 77% (ranging from 73% to 80%) in 2 trials on green beans. FGG01 applied at 1.0 kg/ha showed a similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 85% vs. 85% mean control). No statistical differences were found in the 2 trials.

On disease severity at on the whole plants, for information, in a single valid efficacy trial on green beans, the infestation in untreated plot reached up to 31%. FGG01 applied at 1.0 kg/ha showed a similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 97% vs. 100% control). No statistical differences were found.

On disease incidence on pods, the infestation in untreated plot reached up to 60% (ranging from 40% to 100%) in 3 trials on green beans. FGG01 applied at 1.0 kg/ha showed a similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 88% vs. 88% mean control). No statistical differences were found in the 3 trials.

On disease severity on pods, the infestation in untreated plot reached up to 28% (ranging from 27% to 29%) in 2 trials on green beans. FGG01 applied at 1.0 kg/ha showed similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 92% vs. 95% mean control). No statistical differences were found in the 2 trials.

On disease severity on stems, for information, in a single valid efficacy trial on green beans, the infestation in untreated plot reached up to 38%. FGG01 applied at 1.0 kg/ha showed a slightly better control than the reference standard CANTUS applied at 1.0 kg/ha (respectively 93% vs. 80% control). However, no statistical differences were found. These results should nevertheless be considered carefully owing to the reduced data set.

### **Last assessment:**

On disease incidence on pods, for information, in a single valid efficacy trial on green beans, the infestation in untreated plot reached up to 40%. FGG01 applied at 1.0 kg/ha showed similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 74% vs. 74% control). No statistical differences were found. In the same trial, the disease severity on pods reached up to 31% in untreated plot. FGG01 applied at 1.0 kg/ha showed similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 81% vs. 84% control). No statistical differences were found.

**Therefore, by and large, data from 3 trials, with a moderate level of infestation, FGG01 applied twice at 1.0 kg/ha showed an adequate effectiveness, at an equivalent level of control to the reference CANTUS applied at 1.0 kg/ha against *Sclerotinia sclerotiorum* (SCLESC) on green beans in the Maritime EPPO climatic zone. Therefore, two applications at the rate of 1.0 kg/ha will be recommended on the product label for the control of SCLESP on green beans and peas in the Maritime EPPO climatic zone.**

## **B. Results on fresh beans (PHSVX, VICFX) - *Sclerotinia sp.* (SCLESP) - Mediterranean EPPO zone - Supportive data**

A total of 5 valid efficacy trials were carried out in 2022 and 2023 to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) applied at 1.0 kg/ha applied twice for the control of *Sclerotinia sp.* on fresh beans in comparison to the reference standard CANTUS (500 g/kg of boscalid, WG) at 1.0 kg/ha in the Mediterranean EPPO climatic zone in Spain. An overview of these trials is presented in Table 3.2-15.

Data generated in trials carried out within the Mediterranean climatic zone are fully supportive towards demonstrating proposed label claims for the efficacy and crop safety of FGG01 in Central EU zone. Indeed, extra-zonal data obtained from trials carried out in countries of the Southern EU zone belonging to the Mediterranean EPPO climatic zone are also presented in this dossier to further support the label claims. Indeed, this area is fully representative of *Sclerotinia sp.* occurrence in Europe.

The summary results of the effect of FGG01 applied at 1.0 kg/ha compared to reference standard are shown in Table 3.2-88.

**Table 3.2-88: Summary results: efficacy of FGG01 against *Sclerotinia* sp. on fresh beans and peas - Mediterranean EPPO zone**

Assessment timing	Parts	Parameters	EPPO climatic zone	No. of trials	Days after application	Untreated control (% infestation)			% Efficacy						No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at 1.0 kg/ha vs CANTUS at 1.0 kg/ha
									FGG01 1.0 kg/ha			CANTUS 1.0 kg/ha			
						Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	
2-3 weeks after last application	PLANT	Incidence (%)	Mediterranean	2	[19-21 DA-B]	27.8	10.5	45.0	56.1	38.9	73.2	57.8	50.0	65.5	0> ; 2= ; 0<
		Severity (%)	Mediterranean	1	22 DA-B	13.4	-	-	67.5	-	-	57.5	-	-	0> ; 1= ; 0<
	POD	Incidence (%)	Mediterranean	2	[21-22 DA-B]	20.6	12.0	29.3	81.4	73.0	89.8	83.2	80.8	85.5	0> ; 2= ; 0<
		Severity (%)	Mediterranean	3	[21-22 DA-B]	11.1	5.2	14.9	73.0	46.7	91.9	74.2	48.9	89.3	0> ; 3= ; 0<
	STEM	Incidence (%)	Mediterranean	2	[21-22 DA-B]	34.5	26.0	43.0	68.7	64.7	72.7	70.6	66.9	74.2	0> ; 2= ; 0<
		Severity (%)	Mediterranean	2	[21-22 DA-B]	9.5	5.0	13.9	73.8	73.7	73.9	76.4	72.3	80.5	0> ; 2= ; 0<
Last assessment	PLANT	Incidence (%)	Mediterranean	1	75 DA-B	53.0	-	-	58.2	-	-	70.3	-	-	0> ; 1= ; 0<
		Severity (%)	Mediterranean	1	38 DA-B	11.0	-	-	68.5	-	-	68.2	-	-	0> ; 1= ; 0<
	POD	Incidence (%)	Mediterranean	2	[46-49 DA-B]	27.9	20.3	35.5	77.1	70.5	83.6	77.0	75.4	78.7	0> ; 2= ; 0<
		Severity (%)	Mediterranean	3	[38-49 DA-B]	13.7	9.0	20.2	76.3	64.9	87.2	79.7	73.8	86.0	0> ; 3= ; 0<
	STEM	Incidence (%)	Mediterranean	2	[46-49 DA-B]	49.0	48.0	50.0	62.9	59.9	66.0	66.4	61.9	70.9	0> ; 2= ; 0<
		Severity (%)	Mediterranean	3	[46-75 DA-B]	18.0	14.0	24.5	72.1	67.4	74.7	78.3	69.5	88.2	0> ; 3= ; 0<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

### **Assessments at around 2-3 weeks after last application:**

In the Mediterranean EPPO climatic zone, on disease incidence on the whole plants, the infestation in untreated plot reached up to 28% (ranging from 11% to 45%) in 2 trials on fresh beans. FGG01 applied at 1.0 kg/ha showed a similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 56% vs. 58% mean control). No statistical differences were found in the 2 trials.

On disease severity on plants, for information, in a single valid efficacy trial on green beans, the infestation in untreated plot reached up to 13%. FGG01 applied at 1.0 kg/ha showed a control quite close to that of the reference standard CANTUS applied at 1.0 kg/ha (respectively 68% vs. 58% control). No statistical differences were found in this trial.

On disease incidence on pods, the infestation in untreated plot reached up to 21% (ranging from 12% to 29%) in 2 trials on green beans. FGG01 applied at 1.0 kg/ha showed a similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 81% vs. 83% mean control). No statistical differences were found in the 2 trials.

On disease severity on pods, the infestation in untreated plot reached up to 11% (ranging from 5% to 15%) in 3 trials on green beans. FGG01 applied at 1.0 kg/ha showed similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 73% vs. 74% mean control). No statistical differences were found in the 3 trials.

On disease incidence on stems, the infestation in untreated plot reached up to 35% (ranging from 26% to 43%) in 2 trials on green beans. FGG01 applied at 1.0 kg/ha showed a similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 69% vs. 71% mean control). No statistical differences were found in the 2 trials.

On disease severity on stems, the infestation in untreated plot reached up to 10% (ranging from 5% to 14%) in 2 trials on green beans. FGG01 applied at 1.0 kg/ha showed similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 74% vs. 76% mean control). No statistical differences were found in the 2 trials.

### **Last assessment:**

On disease incidence on plants, for information, in a single valid efficacy trial on broad beans, the infestation in untreated plot reached up to 53% in. FGG01 applied at 1.0 kg/ha showed a slightly lower control than the reference standard CANTUS applied at 1.0 kg/ha (respectively 58% vs. 70% control). However, no statistical differences were found. These results should nevertheless be considered carefully owing to the reduced data set.

On disease severity on plants, for information, in a single valid efficacy trial on green beans, the infestation in untreated plot reached up to 11%. FGG01 applied at 1.0 kg/ha showed similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 69% vs. 68% control). No statistical differences were found.

On disease incidence on pods, the infestation in untreated plot reached up to 28% (ranging from 20% to 36%) in 2 trials on green beans. FGG01 applied at 1.0 kg/ha showed similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 77% vs. 77% mean control). No statistical differences were found in the 2 trials.

On disease severity on pods, the infestation in untreated plot reached up to 14% (ranging from 9% to 20%) in 3 trials on green beans. FGG01 applied at 1.0 kg/ha showed similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 76% vs. 80% mean control). No statistical differences were found in the 3 trials.

On disease incidence on stems, the infestation in untreated plot reached up to 49% (ranging from 48% to 50%) in 2 trials. FGG01 applied at 1.0 kg/ha showed similar control to the reference standard CANTUS applied at 1.0 kg/ha (respectively 63% vs. 66% mean control). No statistical differences were found in the 2 trials.

On disease severity on stems, the infestation in untreated plot reached up to 18% (ranging from 14% to 25%) in 3 trials on fresh beans. FGG01 applied at 1.0 kg/ha showed a control quite close to that of the reference standard CANTUS applied at 1.0 kg/ha (respectively 72% vs. 78% mean control). No statistical differences were found in the 3 trials.

**Therefore, by and large, data from 5 trials, with a moderate level of infestation, FGG01 applied once at 1.0 kg/ha showed an adequate to a good effectiveness, at an equivalent level of control to the reference CANTUS applied at 1.0 kg/ha against *Sclerotinia sp.* (SCLESP) on fresh beans in the Mediterranean EPPO climatic zone. These supportive data confirm that two applications at the rate of 1.0 kg/ha will be recommended on the product label for the control of SCLESP on fresh beans and peas in the Central registration zone.**

### C. Conclusion on fresh beans and peas - *Sclerotinia sp.* (SCLESP)

A total of 3 valid efficacy trials were carried out in 2023 to evaluate the efficacy of FGG01 (500 g/kg of boscalid, WG) applied twice at 1.0 kg/ha for the control of *Sclerotinia sp.* on fresh beans and peas in comparison to the reference standard CANTUS (500 g/kg of boscalid, WG) at 1.0 kg/ha in the Maritime EPPO climatic zone. Additionally, a set of 5 efficacy trials carried out in the Mediterranean (Spain) EPPO climatic zone in 2022 and 2023 are also here presented to complete the data package.

The summary results of the effect of FGG01 applied at 1.0 kg/ha compared to the reference standard in the Maritime and Mediterranean climatic zones are shown in Table 3.2-89.

**Table 3.2-89: Overall summary of efficacy of FGG01 on fresh beans and peas against *Sclerotinia sp.* in the Central registration zone**

Crop code	Pest code	EPPO climatic zone	Part assessed	Nb of trials	Untreated control (infestation %)	Efficacy (%)		No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at 1.0 kg/ha vs. CANTUS 1.0 kg/ha
					Raw data (%)	FGG01 1.0 kg/ha	CANTUS 1.0 kg/ha	
PHSVX PIBSX VICFX	SCLESP	Maritime	Disease incidence on plants - 2-3 WA-B	2	76.5	84.6	85.1	0> ; 2= ; 0<
			Disease severity on plants - 2-3 WA-B	1	31.2	97.2	99.7	0> ; 1= ; 0<
			Disease incidence on pods - 2-3 WA-B	3	59.9	88.3	88.0	0> ; 3= ; 0<
			Disease severity on pods - 2-3 WA-B	2	27.9	91.6	94.8	0> ; 2= ; 0<
			Disease severity on stems - 2-3 WA-B	1	37.6	92.5	80.3	0> ; 1= ; 0<
			Disease incidence on pods - last assessment	1	39.8	74.1	74.3	0> ; 1= ; 0<
			Disease severity on pods - last assessment	1	31.2	81.3	84.3	0> ; 1= ; 0<
		Supportive data from other EPPO climatic zone						
		Medit.	Disease incidence on plants - 2-3 WA-B	2	27.8	56.1	57.8	0> ; 2= ; 0<
			Disease severity on plants - 2-3 WA-B	1	13.4	67.5	57.5	0> ; 1= ; 0<
			Disease incidence on pods - 2-3 WA-B	2	20.6	81.4	83.2	0> ; 2= ; 0<
			Disease severity on pods - 2-3 WA-B	3	11.1	73.0	74.2	0> ; 3= ; 0<
			Disease incidence on stems - 2-3 WA-B	2	34.5	68.7	70.6	0> ; 2= ; 0<
			Disease severity on stems - 2-3 WA-B	2	9.5	73.8	76.4	0> ; 2= ; 0<
			Disease incidence on plants - last assessment	1	53.0	58.2	70.3	0> ; 1= ; 0<
			Disease severity on plants - last assessment	1	11.0	68.5	68.2	0> ; 1= ; 0<
			Disease incidence on pods - last assessment	2	27.9	77.1	77.0	0> ; 2= ; 0<
			Disease severity on pods - last assessment	3	13.7	76.3	79.7	0> ; 3= ; 0<
			Disease incidence on stems - last assessment	2	49.0	62.9	66.4	0> ; 2= ; 0<
			Disease severity on stems - last assessment	3	18.0	72.1	78.3	0> ; 3= ; 0<
		All zones	Disease incidence on plants - 2-3 WA-B	4	52.1	70.4	71.4	0> ; 4= ; 0<
			Disease severity on plants - 2-3 WA-B	2	22.3	82.4	78.6	0> ; 2= ; 0<
			Disease incidence on pods - 2-3 WA-B	5	44.2	85.6	86.1	0> ; 5= ; 0<
			Disease severity on pods - 2-3 WA-B	5	17.8	80.4	82.5	0> ; 5= ; 0<
			Disease severity on stems - 2-3 WA-B	3	18.8	80.0	77.7	0> ; 3= ; 0<
			Disease incidence on pods - last assessment	3	31.9	76.1	76.1	0> ; 3= ; 0<
			Disease severity on pods - last assessment	4	18.1	77.6	80.8	0> ; 4= ; 0<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report. WA-B = Weeks After application B

In 8 trials, FGG01 applied twice at 1.0 kg/ha showed a good effectiveness, at an equivalent level of control to the reference product CANTUS at 1.0 kg/ha against *Sclerotinia sp.* (SCLESP) and were statistically equivalent in all trials. Therefore, both applications at the rate of 1.0 kg/ha will be recommended on the product label for the control of SCLESP on fresh beans and peas in the Central registration zone.

**ZRMs comments about efficacy of product:**

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

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

**Use no 1 against BOTRCI on grapevines in AT, BE, CZ and SL**

CANTUS (used as a st. ref. product during eff. trials) has been authorized in Austria, Belgium, Czech Republic and Slovenia for use as a fungicide on grapevine against *Botrytis cinerea* for more than 10 years and the use is not protected. In this bridging context, according to guideline EPPO 1/307(2) a reduced data package is required to demonstrate the comparability between CANTUS and FGG01. Applicant submitted in total 3 trials carried out in Maritime EPPO zone (AT-2, DE-1) in 2021. FGG01 (500 g/kg of boscalid, WG) applied at 0.72 kg/10000 m<sup>2</sup> LWA and at 1.0 kg/ha for the control of *Botrytis cinerea* on grapevine in comparison to the reference standard CANTUS (500 g/kg of boscalid, WG) at 1.0 kg/ha. Results were comparable to st. ref. product (CANTUS at 1.0 kg/ha). On the obtained results it can be concluded that FGG01 limited the occurrence of BOTRCI on grapevine branches at dose 0.72 kg/10000m<sup>2</sup> LWA and moderately control BOTRCI at dose 1.0 kg/ha.

Application was done at BBCH 67-85 in Maritime EPPO zone. Application window proposed by Applicant (BBCH 60-85) should be accepted as consistent with submitted trials, plant protection programs for boscalid fungicides and with st. ref. product.

Following water volume was studied: 450-800 L/ha in Maritime EPPO zone. Proposed by Applicant water volume 100-1000 L/ha can be accepted as consistent with plant protection programs for boscalid fungicide and with st. ref. product.

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

In the countries claimed for authorization on grapevine against *Erysiphe necator*, the reference product CANTUS is not authorized for this use and therefore, a full data package is necessary on grapevine against *Erysiphe necator*. Except in Poland (minor use), as this is a major use in all of these



countries, a full data package is required and was generated. Applicant submitted in total 10 trials carried out in Maritime EPPO zone (AT-5, DE-5) in 2022 and 2023. For Poland we can use trials from DE as a neighboring country. Number of trials (5) is sufficient for a minor crop.

FGG01 applied at 0.13-0.14 kg/10000 m<sup>2</sup> LWA, at 0.2 kg/ha and at 0.02 kg/100 L for the control of *Erysiphe necator* on grapevine in comparison to the reference standard CANTUS at 0.2 kg/ha or to different local references in the Maritime EPPO climatic zone (Austria and Germany). Results were comparable to st. ref. product (CANTUS at 0.2 kg/ha). On the obtained results it can be concluded that FGG01 moderately effectively control UNCINE on leaf and branches of grapevines at dose 0.13-0.14 kg/10000m<sup>2</sup> LWA and moderately control UNCINE at dose 0.2 kg/ha and 0.02 kg/100L.

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

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

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

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

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

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

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

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

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

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

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

***Use no 4 against ALTESP on oilseed rape in AT, BE, CZ, NL, SK, HU and RO***

Applicant submitted in total 2 trials carried out in Maritime EPPO zone (BE) in 2023. Lack of trials for S-E and N-E EPPO zone. In Austria, Belgium, Czech Republic, Hungary, Romania and Slovakia, the reference product CANTUS (also known under the name of PROPATAN in Czech Republic; AMM: 4889-1) has been authorized for use as a fungicide on oilseed rape against *Alternaria* sp. for more than 10 years and the use is not protected. In this bridging context, according to guideline EPPO 1/307(2) a reduced data package is required. cMS from HU, RO and SK should consider extrapolating results from st. ref. product (CANTUS) and using trials from other EPPO zone (Maritime). For AT, BE, CZ the limited number of trials (2) should be consider by cMS as an acceptable. Also, limited number of trials for NL for a minor use should be sufficient. On the basis on obtained results from 2 Maritime trials, it can be concluded that FGG01 at recommended dose (0.5 kg/ha) moderately effectively control ALTEBA on winter oilseed rape (average from severity: 75.9% and incidence : 54.65% on plant). Average from incidence and severity is 65.28%. Results were comparable to st. ref. product (CANTUS at 0.5 kg/ha). Lack of trials for spring oilseed rape. Extrapolating results from winter oilseed rape should be consider by cMS.

Application was done at BBCH 62-65 in Maritime EPPO zone. Application window proposed by Applicant (BBCH 57-69) should be accepted as consistent with submitted trials, plant protection programs for boscalid fungicides and with st. ref. product.

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

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

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

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

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

oilseed rape in S-E EPPO zone (average eff.: 72.65%). Lack of trials for spring oilseed rape. cMS should decide if extrapolating results from winter oilseed rape is possible.

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

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

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

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

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

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

NL can also use trial from UK carried out on *Pisum sativum* against BOTRCI, *Phaseolus vulgaris* against BOTRCI from BE and *Phaseolus vulgaris* against BOTRSP from North France. cMS from AT, BE, CZ and SK should decide if bridging approach with limited number of trials can be acceptable. Considering PHSVX - it is considered as high growing crop in AT and therefore the application rate in tLWA or at least the application rate in connection with the plant height (e.g. due to the trial data) may be provided for AT, as it is authorised for the bridging partner CANTUS.

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

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

**Use no 7 against SCLESP on beans and peas (fresh) in AT, BE and CZ**

In Austria, Belgium and the Czech Republic, the reference product CANTUS has been authorised for use as a fungicide on fresh beans and peas against *Sclerotinia sp.* for more than 10 years and the use is not protected. Thus, in this bridging context, according to guideline EPPO 1/307(2) a reduced data package is required to demonstrate the comparability between CANTUS and FGG01. Applicant submitted in total 3 efficacy trials carried out in Maritime EPPO zone (BE-1, FR-2) for bridging approach. Results from FGG01 and st. ref. product (CANTUS at 1.0 kg/ha) were comparable. On the basis on obtained results, it can be concluded that FGG01 effectively control SCLESP on pod, stem and plant of fresh beans and peas.

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

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

***Minor uses in line to Article 51 claimed for PL:***

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

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

### **3.2.3.3.4 Effect on the yield in presence of fresh beans and peas diseases**

#### **A. Effect on the yield of fresh beans and peas in presence of *Botrytis sp.* (BOTRSP)**

A total of 5 efficacy trials were harvested in 2022 and 2023 in the Maritime (1 trial in Belgium, 1 trial in Czech Republic and 1 trial in Germany) and in the Mediterranean (2 trials in Spain) EPPO climatic zones. The objective was to confirm the yield response of FGG01 (500 g/kg of boscalid, WG) in the presence of *Botrytis sp.* in fresh beans and peas crops.

Table 3.2-90 shows a summary of effect on the yield of FGG01 applied at 1.0 kg/ha compared to the reference standard CANTUS at 1.0 kg/ha.

**Table 3.2-90: Summary results: Positive effect on the yield of FGG01 at 1.0 kg/ha compared to the reference standard CANTUS - Fresh beans and peas - BOTRSP**

Parameters	Disease present	Crop	Parts	EPPO climatic zone	No. of trials	Days after application	Untreated control (T/ha)			% of untreated check (%UTC)						No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at 1.0 kg/ha vs CANTUS at 1.0 kg/ha
										FGG01 1.0 kg/ha			CANTUS 1.0 kg/ha			
							Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	
YIELD	BOTRSP	PIBSX	GRAIN	Maritime zone	1	34 DA-B	2.51	-	-	118.3	-	-	110.8	-	-	0> ; 1= ; 0<
	BOTRFA	VICFX	PLOT	Maritime zone	1	76 DA-B	3.93	-	-	101.3	-	-	101.8	-	-	0> ; 1= ; 0<
	BOTRCI	PHSVX	POD	Maritime zone	1	29 DA-B	13.70	-	-	129.6	-	-	132.8	-	-	0> ; 1= ; 0<
	Supporting data from other EPPO climatic zone															
	BOTRCI	PHSVX	POD	Mediterranean zone	2	[33-50 DA-B]	1.92	1.07	2.77	102.4	90.9	113.8	104.5	93.5	115.4	0> ; 2= ; 0<
	All EPPO climatic zones															
	BOTRCI	PHSVX	POD	All zones	3	[29-50 DA-B]	5.85	1.07	13.70	111.4	90.9	129.6	113.9	93.5	132.8	0> ; 3= ; 0<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

### **Maritime EPPO climatic zone**

In the Maritime EPPO climatic zone, in 3 trials, FGG01 at 1.0 kg/ha has showed a positive effect on the yield of grain of broad bean, on the grain of peas and on the pods of green beans in the presence of *Botrytis sp.* In fact, there was an increase in yield compared to the untreated for peas and green beans (by 18 % and 30 % respectively) and a similar yield to the untreated for broad beans. Furthermore, there was no statistically significant difference between FGG01 at 1.0 kg/ha and the reference standard CANTUS at 1.0 kg/ha in all fresh beans and peas trials.

### **Mediterranean EPPO climatic zone - Supportive data**

In the Mediterranean EPPO climatic zone, in 2 trials, FGG01 at 1.0 kg/ha has showed no negative effect on the yield of pods of green beans in the presence of *Botrytis cinerea*. In fact, in 2 trials similar yield was obtained compared to the untreated for green beans (increased by only 2%). Furthermore, there was no statistically significant difference between FGG01 at 1.0 kg/ha and the reference standard CANTUS at 1.0 kg/ha in the 2 green beans trials.

### **In all EPPO climatic zones**

FGG01 at 1.0 kg/ha has showed a positive effect on the yield of green beans in the presence of *Botrytis cinerea*. In fact, in 3 trials, there was an 11% increase in yield compared to the untreated. Furthermore, there was no statistically significant difference between FGG01 at 1.0 kg/ha and the reference standard CANTUS at 1.0 kg/ha.

## **B. Effect on the yield of fresh beans and peas in presence of *Sclerotinia sp.* (SCLESP)**

A total of 3 efficacy trials on green beans were harvested in 2023 in the Maritime (1 trial in Belgium) and Mediterranean (as supportive data; 2 trials in Spain) EPPO climatic zones. The objective was to confirm the yield response of FGG01 (500 g/kg of boscalid, WG) in the presence of *Sclerotinia sp.* in green beans crops.

Table 3.2-91 shows a summary of effect on the yield of FGG01 applied at 1.0 kg/ha compared to the reference standard CANTUS at 1.0 kg/ha.

**Table 3.2-91: Summary results: Positive effect on the yield of FGG01 at 1.0 kg/ha compared to the reference standard CANTUS - Fresh beans and peas - SCLESP**

Parameters	Disease present	Crop	Parts	EPPO climatic zone	No. of trials	Days after application	Untreated control (T/ha)			% of untreated check (%UTC)						No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at 1.0 kg/ha vs CANTUS at 1.0 kg/ha
										FGG01 1.0 kg/ha			CANTUS 1.0 kg/ha			
							Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	
YIELD	SCLESP	PHSVX	POD	Maritime zone	1	79 DA-B	12.14	-	-	181.2	-	-	148.3	-	-	0> ; 1= ; 0<
				Supporting data from other EPPO climatic zone												
				Mediterranean zone	2	[33-49 DA-B]	1.91	1.09	2.72	103.6	96.6	110.6	106.2	100.3	112.1	0> ; 2= ; 0<
				All EPPO climatic zones												
				All zones	3	[29-49 DA-B]	5.32	1.09	12.14	129.5	96.6	181.2	120.2	100.3	148.3	0> ; 3= ; 0<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

### **Maritime EPPO climatic zone**

In the Maritime EPPO climatic zone, FGG01 at 1.0 kg/ha has showed a positive effect on the yield of pods of green beans in 1 trial, in the presence of *Sclerotinia sclerotiorum*. In fact, there was an increase in yield compared to the untreated by 81%. Furthermore, there was no statistically significant difference between FGG01 at 1.0 kg/ha and the reference standard CANTUS at 1.0 kg/ha.

### **In the Mediterranean EPPO climatic zone - Supportive data**

In the Mediterranean EPPO climatic zone, FGG01 at 1.0 kg/ha has showed a slightly positive effect on the yield of pods of green beans in the presence of *Sclerotinia sp.*. In fact, in 2 trials similar yield was obtained compared to the untreated for green beans (increased by 4%). Furthermore, there was no statistically significant difference between FGG01 at 1.0 kg/ha and the reference standard CANTUS at 1.0 kg/ha in the 2 trials.

### **In all EPPO climatic zones**

FGG01 at 1.0 kg/ha has showed a positive effect on the yield of green beans in the presence of *Sclerotinia sp.* In fact, in 3 trials, 30% increase in yield was gained compared to the untreated. Furthermore, there was no statistically significant difference between FGG01 at 1.0 kg/ha and the reference standard CANTUS at 1.0 kg/ha in the 3 trials.

## **C. Conclusion on the effect on the yield of fresh beans and peas in presence of diseases**

In a total of 4 harvested trials in the Maritime EPPO climatic zone on green beans and peas in the presence of *Botrytis sp.* (3 trials) and *Sclerotinia sp.* (1 trial), FGG01 applied at 1.0 kg/ha has showed a similar or an increase of the yield compared to the untreated plots. Furthermore, no significant differences were found compared to the reference CANTUS applied at the same dose rate of 1.0 kg/ha. Same results were observed with the 4 supporting trials carried out in the Mediterranean EPPO climatic zone.

**Therefore, overall FGG01 applied twice at the proposed label rate of 1.0 kg/ha is expected to have a positive effect on the yield of crops treated on the presence of disease, and yield is comparable to that of CANTUS.**

### **3.2.3.4 Additional minor uses (request for Poland)**

The simplified recommendations for additional minor uses in Poland proposed for FGG01 are presented in Table 3.2-92. Further details are in the table “All intended uses” in Part B - Section 0 and Table 3.1-1.

**Table 3.2-92: Simplified table of requested minor uses for FGG01**

Crop	Target	Member state	Requested registration			Comments / other relevant details on GAPs
			Requested dose per application	Application number	Application crop stage	
Flax / Linseed (LIUUT)	Sclerotinia stem rot - SCLESC ( <i>Sclerotinia sclerotiorum</i> ) Alternaria - ALTESP ( <i>Alternaria sp.</i> )	PL	0.5 kg/ha	1	BBCH 57-69	100-300 L/ha
	Black leg of crucifers - LEPTMA ( <i>Plenodomus lingam</i> )	PL	0.5 kg/ha	1	BBCH 13-71	100-300 L/ha
Spring rape (BRNS)	Sclerotinia stem rot - SCLESC ( <i>Sclerotinia sclerotiorum</i> ) Alternaria - ALTESP ( <i>Alternaria sp.</i> )	PL	0.5 kg/ha	1	BBCH 57-69	100-300 L/ha
	Black leg of crucifers - LEPTMA ( <i>Plenodomus lingam</i> )	PL	0.5 kg/ha	1	BBCH 13-71	100-300 L/ha



Crop	Target	Member state	Requested registration			Comments / other relevant details on GAPs
			Requested dose per application	Application number	Application crop stage	
Gold-of-pleasure (CMASA)	Sclerotinia stem rot - SCLESC ( <i>Sclerotinia sclerotiorum</i> ) Alternaria - ALTESP ( <i>Alternaria sp.</i> )	PL	0.5 kg/ha	1	BBCH 57-69	100-300 L/ha
	Black leg of crucifers - LEPTMA ( <i>Plenodomus lingam</i> )	PL	0.5 kg/ha	1	BBCH 13-71	100-300 L/ha
Mustard (SINAL)	Sclerotinia stem rot - SCLESC ( <i>Sclerotinia sclerotiorum</i> ) Alternaria - ALTESP ( <i>Alternaria sp.</i> )	PL	0.5 kg/ha	1	BBCH 57-69	100-300 L/ha
	Black leg of crucifers - LEPTMA ( <i>Plenodomus lingam</i> )	PL	0.5 kg/ha	1	BBCH 13-71	100-300 L/ha
Winter turnip rape (BRSRO)	Sclerotinia stem rot - SCLESC ( <i>Sclerotinia sclerotiorum</i> ) Alternaria - ALTESP ( <i>Alternaria sp.</i> )	PL	0.5 kg/ha	1	BBCH 57-69	100-300 L/ha
	Black leg of crucifers - LEPTMA ( <i>Plenodomus lingam</i> )	PL	0.5 kg/ha	1	BBCH 13-71	100-300 L/ha
Sunflower (HELAN)	Sclerotinia stem rot - SCLESC ( <i>Sclerotinia sclerotiorum</i> ) Alternaria - ALTESP ( <i>Alternaria sp.</i> )	PL	0.5 kg/ha	1	BBCH 57-69	100-300 L/ha
	Black leg of crucifers - LEPTMA ( <i>Plenodomus lingam</i> )	PL	0.5 kg/ha	1	BBCH 13-71	100-300 L/ha
Common hemp (CNISA)	Sclerotinia stem rot - SCLESC ( <i>Sclerotinia sclerotiorum</i> ) Alternaria - ALTESP ( <i>Alternaria sp.</i> )	PL	0.5 kg/ha	1	BBCH 57-69	100-300 L/ha
	Black leg of crucifers - LEPTMA ( <i>Plenodomus lingam</i> )	PL	0.5 kg/ha	1	BBCH 13-71	100-300 L/ha
Poppy (PAPSO)	Sclerotinia stem rot - SCLESC ( <i>Sclerotinia sclerotiorum</i> ) Alternaria - ALTESP ( <i>Alternaria sp.</i> )	PL	0.5 kg/ha	1	BBCH 57-69	100-300 L/ha
	Black leg of crucifers - LEPTMA ( <i>Plenodomus lingam</i> )	PL	0.5 kg/ha	1	BBCH 13-71	100-300 L/ha
Talewort/Borage (BOROF)	Sclerotinia stem rot - SCLESC ( <i>Sclerotinia sclerotiorum</i> ) Alternaria - ALTESP ( <i>Alternaria sp.</i> )	PL	0.5 kg/ha	1	BBCH 57-69	100-300 L/ha
	Black leg of crucifers - LEPTMA ( <i>Plenodomus lingam</i> )	PL	0.5 kg/ha	1	BBCH 13-71	100-300 L/ha
Grapevine (VITVI)	Grey mould - BOTRCI ( <i>Botrytis cinerea</i> )	PL	1.0 kg/ha	1	BBCH 60-85	100-1000 L/ha
Beans for fresh seeds, broad bean, french beans, peas for fresh seeds, edible podded peas	Grey mould - BOTRCI ( <i>Botrytis cinerea</i> ) Sclerotinia stem rot - SCLESP ( <i>Sclerotinia sp.</i> ) Powdery mildew of legumes ERYSPI ( <i>Erysiphe pisi</i> )	PL	1.0 kg/ha	2	BBCH 60-69	150-600 L/ha

In Poland, the use on spring oilseed rape against *Sclerotinia sclerotiorum*, *Alternaria sp.* and *Plenodomus lingam*, the use on grapevine against *Botrytis cinerea*, the use on beans for fresh seeds, broad bean, french beans, peas for fresh seeds, edible podded peas against *Sclerotinia sp.* and *Botrytis cinerea*, are considered as minor and have already been supported with the data packages presented in this BAD in the section 3.2.3. For some uses, no data are available on the North-East EPPO climatic zone, which is concerned by Poland. Nevertheless, the uses in this country can be supported with the available data package in the Maritime and South-East EPPO climatic zones and with the supportive data presented in the Mediterranean EPPO climatic zone. In addition, as this is a country bordering Czech Republic and Germany, which belong to the Maritime EPPO climatic zone, the climate conditions and the diseases development are quite similar even though they belong to different climatic zones.

In addition, the use on beans for fresh seeds, broad bean, french beans, peas for fresh seeds, edible podded peas against *Sclerotinia sp.* and *Botrytis cinerea* can be supported with the data presented in the Maritime EPPO zone on fresh beans and peas against *Botrytis sp.* and *Sclerotinia sp.* where some data have been generated in Germany, which is a bordering country of Poland. Also, the use on the same crops against *Erysiphe pisi* can be extrapolated from the same data generated on fresh beans and peas against *Botrytis sp.* and *Sclerotinia sp.*, since the same efficacy is expected against *Erysiphe pisi*.

For the other minor uses also listed in the table above, no efficacy data have been presented. However, some crops like flax or linseed, gold of pleasure, white mustard and winter turnip rape, belong to the family Brassicaceae, the same as for oilseed rape. Thus, an extrapolation from oilseed rape to all of these crops against the same targets (*Sclerotinia sclerotiorum*, *Alternaria sp.* and *Plenodomus lingam*) is justified. Finally, for sunflower, hemp, talewort/borage and poppy, although they do not belong to the same family as for oilseed rape, the targeted diseases are the same (*Sclerotinia sclerotiorum*, *Alternaria sp.* and *Plenodomus lingam*) and the extrapolation is also justified, considering that these diseases develop in a similar way on oilseed rape and other kind of crops.

**ZRMs comments about efficacy of product:**

Detailed assessment of yield will be presented in the next chapters. In briefly summary, after this part it can be concluded that no negative impact of FGG01 is to be expected when at intended rate and used according to label recommendations will be used.

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

FGG01 is a fungicide for the control of different diseases on several crops (oilseed rape, fresh beans and peas and grapevine) at different dose rates according to the requested uses.

The formulation contains 500 g/L boscalid as active substance. A resistance risk analysis has been conducted according to EPPO guideline PP1/213(3) 'Resistance risk analysis'.

#### **3.3.1 Mode of Action**

Boscalid is a fungicide used in agriculture for the control of various diseases *Sclerotinia sclerotiorum*, , *Alternaria spp.* (*A. alternata*, *A. brassicae*) *Botrytis cinerea* and *Erysiphe necator* in a range of crops.

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 (Kulka and von Schmeling 1995). 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. Complex II occupies a key function in fungal metabolism. It delivers high-energy electrons for energy production and, additionally, forms an essential junction where components of the TCA cycle can be diverted to become the building blocks for amino acids and lipids. Through its inhibition of complex II, boscalid disrupts fungal growth by preventing energy production and also by eliminating the availability of the chemical building blocks for the synthesis of other essential cellular components.

Based on the FRAC classification, the SDHI's (FRAC code 7) are considered as a medium to high inherent risk group to fungicide resistance development.

### 3.3.2 Mechanism of resistance

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, 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* (Glaettli *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 (e.g. B-P225L/F/T or B-H272Y/R/L/V in *B. cinerea*), and at different gene locations in different subunits (e.g. B-H277Y, C-N75S, C-G79R, C-H134R, C-S135R, D-D124N/E, D-H143R, D-D145G in *Pyrenophora teres*, Stammler *et al.* 2014). 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 (e.g. mutations at P220 in *Z. tritici* and at the homologous site P225 in *B. cinerea* as described by Scalliet *et al.* 2012).

**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; e.g. P220 in *Z. tritici* is homologous to P225 in *B. cinerea* and P225 in *S. vesicarium*.

Amino acid	Homologous positions
B-Proline	220c, 225 f,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. cassicola</i>
C-Asparagine	86c,d, 75e
C-Glycine	90c, 79e
C-Histidine	145c, 134e,h, 146m
C-Histidine	152c, 151o
D-Asparagine acid	124e, 123h
D-Histidine	118c, 132f,m, 134e, 133h

**Table 3.3-3:** Frequency of *B. cinerea* strains with B-H272Y and B-P225L, without Chemical control and after 4 applications of two different SDHIs, in a strawberry trial with sampling after last application. Analysis of mutations in strains was done by pyrosequencing.

Mutation	Untreated	SDHI 1	SDHI 2
B-P225L	<2%	3%	56%
B-H272Y	<2%	92%	29%

### 3.3.3 Evidence of resistance

Resistance development towards SDHI fungicides was observed for *Botrytis cinerea* in grapevine, strawberry, kiwi and apple and *Sclerotinia sclerotiorum* in oilseed rape, which are amongst others, the claimed targets in this dossier (Table 3.3-1).

According to FRAC<sup>13</sup>, *Botrytis cinerea* is considered to be high risk pathogen. This pathogen has evolved resistance to fungicides in a time span sufficiently short to be a serious threat to the commercial success of more than one fungicide class.

*Alternaria brassicae* and *Erysiphe necator* are considered to be medium risk pathogens regarding development of resistance to fungicides. These pathogens are regarded as posing a much lower risk because resistance is not a major problem or has been slow to develop. In some cases this is due to the pattern of product use. Cases of specific isolates being classed as resistant may be known in some instances, but in commercial practice resistance has not created major disease control problems. The EPPO Guideline does not list these and decisions on baseline production must be made on individual case reviews. All other pathogens are considered to have a low risk of development of resistance to fungicides.

**Table 3.3-4:** Pathogens resistant to SDHI Fungicides, reported by FRAC<sup>14</sup>

MOA Code	FRAC Group Code	Pathogen	Common name	Crop	Reference	Remarks
C2	7	<i>Alternaria alternata</i>	Alternaria blight	Pistachio	Avenot & Michallides 2007 Avenot <i>et al.</i> 2008	field resistance mechanism
		<i>Alternaria solani</i>	Early blight	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 leaf spot	Cherry	Outwater <i>et al.</i> 2013	Field

<sup>13</sup> FRAC List of first confirmed cases of plant pathogenic organisms resistant to disease control agents, revised May 2020

<sup>14</sup> FRAC: Pathogen risk list. September 2019

MOA Code	FRAC Group Code	Pathogen	Common name	Crop	Reference	Remarks
		<i>Botryotinia fuckeliana</i> ( <i>Botrytis cinerea</i> )	Grey mould	-	Angelini <i>et al.</i> 2010	Laboratory genetic analysis
		<i>Botrytis cinerea</i>	Grey mould	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>	Grey mould	Lilly	FRAC 2007	field
		<i>Corynespora cassiicola</i>	Corynespora leaf spot	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>	Gummy stem blight	Cucurbits	FRAC 2007 Stevenson <i>et al.</i> 2008	field
		<i>Monilinia fructicola</i>	Brown rot	Peach	Chen <i>et al.</i> 2013	field
		<i>Mycosphaerella graminicola</i> = <i>Zymoseptoria tritici</i>	Leaf spot	Wheat	Skinner <i>et al.</i> 1998	laboratory mutation study
		<i>Phakopsara pachyrhize</i>	Rust	Soybean	FRAC 2017	field
		<i>Podosphaera xanthii</i>	Powdery mildew	Melon Cucumber	FRAC 2007 Miyamoto <i>et al.</i> 2010a	field field (Japan, glasshouses)
		<i>Pyrenophora teres</i>	Net Blotch	Barley	Stammiller G. 2014	field
		<i>Ramularia collo-cygni</i>	Leaf Spot	Barley	FRAC 2017	field
		<i>Sclerotinia sclerotiorum</i>	White Mould	OSR	FRAC 2014	field
		<i>Stemphylium vesicarium</i>	Leaf Blight	Asparagus	FRAC 2014	field
		<i>Ustilago maydis</i>	Smut	Maize	Keon <i>et al.</i> 1991	laboratory mutation study
		<i>Ustilago nuda</i>	Loose smut	Barley	Leroux & Berthier 1988	field
		<i>Venturia inaequalis</i>	Scab	Apple	FRAC 2014	field

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

Details of resistance of the target pathogens for this submission, as reported by FRAC, are given in Table 3.3-5.

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

Fungicide group	MOA Code	FRAC Group code	Pathogen	Crop	Reference	Remarks
MBC fungicides (Methyl Benzimidazole Carbamates), $\beta$ -tubulin assembly in mitosis	B1	1	<i>Botrytis cinerea</i>	Grapes / Vines	Ehrenhardt <i>et al.</i> 1973 Leroux <i>et al.</i> 1982 Elad <i>et al.</i> 1988	field cross resistance to phenyl-carbamates, Group 10
				cyclamen	Bollen & Scholten 1971	laboratory
				Lisianthus	Elad <i>et al.</i> 2008	field
				Beans	Harrison J G 1984	field
N-phenyl carbamates: $\beta$ -tubulin assembly in mitosis	B2	10	<i>Botrytis cinerea</i>	Grapevine	Elad <i>et al.</i> 1988  Katan <i>et al.</i> 1989 Elad <i>et al.</i> 1992	cross resistance to phenyl-carbamates, Group 10 field field
SDHI fungicides (Succinate dehydrogenase inhibitors) : Complex II succinate-dehydrogenase	C2	7	<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
QoI fungicides (Quinone outside Inhib.): Complex III cytochrome bc1 (ubiquinol oxidase) at Qo site (cyt b gene)	C3	11	<i>Botrytis cinerea</i>	Strawberry Strawberry, citrus Kiwi fruit Grapes, soft fruit	Markoglou <i>et al.</i> 2006 FRAC 2007 Ishii 2008 Bardas <i>et al.</i> 2010 FRAC 2015	mutation study Field, G143A, Germany Field, Japan Multiple resistance
Uncouplers of Oxidative Phosphorylation	C5	29	<i>Botrytis cinerea</i>	Adzuki bean	Tamura 2000	field (fluazinam)
AP fungicides (Anilinopyrimidines) Methionine biosynthesis (proposed) (cgs gene)	D1	9	<i>Botrytis cinerea</i> ( <i>Botryotinia fuckeliana</i> )	Grapevine Strawberries Vegetables	Forster & Staub 1996 Chapeland <i>et al.</i> 1999 Sergeeva <i>et al.</i> 2002	field experiments field field field experiments

Fungicide group	MOA Code	FRAC Group code	Pathogen	Crop	Reference	Remarks
				(tomato, peas, beans)	Baroffio <i>et al.</i> 2003 FRAC 2014 FRAC 2015	
			<i>Botrytis cinerea</i>	Lisianthus	Elad <i>et al.</i> 2008	field
PP fungicides (Phenylpyrroles). MAP / Histidine-kinase in osmotic signal transduction (os-2, HOG1)	E2	12	<i>Botrytis cinerea</i>	Blackberry/Strawberry	Li Xingpeng <i>et al.</i> 2014	Mutation studies?
Dicarboximides. MAP / Histidine-kinase in osmotic signal transduction (os-1, Daf1)	E3	2	<i>Botrytis cinerea</i>	Cucumber	Steekelenburg 1987	field
				Grapevine Strawberries Vegetables (tomato, peas, beans)	Holz 1979 Leroux <i>et al.</i> 1982	field
				Strawberry	Davis & Dennis 1979	field
				Lisianthus	Elad <i>et al.</i> 2008	field
AH fungicides (Aromatic Hydrocarbons, chlorophenyls, nitroanilines; and heteroaromatics). Cell peroxidation (proposed)	F3	14	<i>Botrytis cinerea</i>	Glasshouse vegetables	Esuruoso & Wood 1971 Hartill <i>et al.</i> 1983	laboratory / field cross resistance studies with dicarboximides, Group 2
DMI Fungicides (DeMethylation Inhibitors) SBI Class I. C14-demethylase in sterol biosynthesis (erg11 / cyp 51)	G1	3	<i>Botrytis cinerea</i>	Vegetables Various	Elad 1992 Stehmann & De Waard 1996	field laboratory investigation of lack of intrinsic activity
KRI fungicides (KetoReductase Inhibitors), (SBI class III). 3-keto reductase C4-demethylation (erg27)	G3	17	<i>Botrytis cinerea</i> ( <i>Botryotinia fuckeliana</i> )	Grapevine	Baroffio <i>et al.</i> 2003 Ziogas <i>et al.</i> 2003 Saito <i>et al.</i> 2011	field experiments mutants field (New York)
KRI fungicides (KetoReductase Inhibitors), (SBI class III). 3-keto reductase C4-demethylation (erg27)	G3	17	<i>Botrytis cinerea</i>	Lisianthus Raspberries Strawberries	Elad <i>et al.</i> 2008 FRAC 2014 FRAC 2015	field (low frequency)
Dithiocarbamates and relatives (electrophiles)	M	M03	<i>Botrytis cinerea</i>	Not specified	Barak & Edgington 1984	laboratory study
Phthalimides (electrophiles)	M	M04	<i>Botrytis cinerea</i>	Not specified	Barak & Edgington 1985	laboratory study
				Grapevine	Fourie & Holz 2001	laboratory
				Glasshouse cucumber	Malathrakakis 1989	glasshouse
Chloronitriles (phthalonitriles), unspecified mechanism	M	M05	<i>Botrytis cinerea</i>	Not specified	Barak & Edgington 1984	laboratory study
				Glasshouse cucumber	Malathrakakis 1989	-
Sulphamides, (electrophiles)	M	M06	<i>Botrytis cinerea</i>	Glasshouse cucumber	Malathrakakis 1989	-
MBC fungicides (Methyl Benzimidazole Carbamates), $\beta$ -tubulin assembly in mitosis	B1	1	<i>Erysiphe necator</i>	Grapes / Vines	Naegler <i>et al.</i> 1977; Pearson 1980 Pearson & Taschenberg 1980	Field
QoI fungicides (Quinone outside Inhib.): Complex III cytochrome bc1 (ubiquinol oxidase) at Qo site (cyt b gene)	C3	11	<i>Erysiphe necator</i>	Grapevine	Wilcox <i>et al.</i> 2003	Field
AZN: Aza-naphthalenes. Signal transduction (mechanism unknown)	E1	13	<i>Erysiphe necator</i>	Wheat Grapevine	Genet & Jaworska 2009	Baseline, cross resistance studies
DMI Fungicides (DeMethylation Inhibitors) SBI Class I. C14-demethylase in sterol biosynthesis (erg11 / cyp 51)	G1	3	<i>Erysiphe necator</i>	Grapevine	Steva <i>et al.</i> 1990 Reidi & Steinkellner 1996 Miller & Gubler 2003	Field Field Field
MBC fungicides (Methyl Benzimidazole Carbamates), $\beta$ -tubulin assembly in mitosis	B1	1	<i>Sclerotinia sclerotiorum</i>	Oilseed rape	-	-

Fungicide group	MOA Code	FRAC Group code	Pathogen	Crop	Reference	Remarks
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)

Source: FRAC List of first confirmed cases of plant pathogenic organisms resistant to disease control agents, revised May 2020 (<http://www.frac.info/publications>).

### 3.3.4 Cross-resistance

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 (Ishii *et al.* 2011, Veloukas *et al.* 2013, Semar *et al.* 2014). In addition, uses of specific SDHIs also influence which mutation will occur in various fungal species (Table 3.3-3), 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. These include *Puccinia spp.*, *Erysiphe spp.*, *Puccinia spp.*, *Microdochium spp.*, *Podosphaera spp.*, *Monilinia spp.*, *Leptosphaeria maculans* and *Leptosphaeria biglobosa*.

### 3.3.5 Sensitivity data

There is an annual meeting of the SDHI Working Group of FRAC<sup>15</sup>, where current monitoring data are discussed and decision is made whether changes to the next year's use recommendations are required.

The monitoring data derives from several industry plant protection product manufacturers and the results are published on the FRAC webpage. According to the intended pathogens for which activity of FGG01 is claimed, monitoring data for *Botrytis cinerea* and *Erysiphe necator* in grapevine, *Sclerotinia sclerotiorum* in peas and beans and in oilseed rape, and *Leptosphaeria maculans* (*Plenodomus lingam*) in oilseed rape are presented.

Concerning *Botrytis cinerea* in grapevine, monitoring data from 2003 to 2022 is derived from several countries of the Southern zone (France, Italy, Portugal, Spain, Greece) as well as the Central zone (Austria, Germany and Hungary). Latest results show mostly sensitive strains in Italy and high frequency of mutations in Germany with more severe mutations remaining at a low level.

Concerning *Erysiphe necator* in grapevine, monitoring data from 2003 to 2022 is derived from several countries of the Southern zone (France, Italy, Portugal, Spain, Greece and Turkey) as well as the Central zone (Austria, Czech Republic, Germany, Hungary, Slovakia, Slovenia, Switzerland, and Romania). Last results show low to moderate frequencies were detected in Germany, Greece, Hungary and Turkey.

Regarding *Sclerotinia sclerotiorum* in peas and beans data from 2015 to 2021 is derived from several countries of the Southern zone (Croatia, France and Spain) as well as the Central zone (Belgium, Germany, the Netherlands and Poland). Overall, full sensitivity are detected from all the samples collected since 2015. Only 1 single isolate from 1 trial in Spain showed decreased sensitivity in 2020.

<sup>15</sup> Source : [https://www.frac.info/docs/default-source/working-groups/sdhi-fungicides/sdhi-meeting-minutes/minutes-of-the-2023-sdhi-meeting-with-recommendations-for-2023-from-17-18th-jan-and-20th-april-and-6th-sept-2023.pdf?sfvrsn=a9814e9a\\_2](https://www.frac.info/docs/default-source/working-groups/sdhi-fungicides/sdhi-meeting-minutes/minutes-of-the-2023-sdhi-meeting-with-recommendations-for-2023-from-17-18th-jan-and-20th-april-and-6th-sept-2023.pdf?sfvrsn=a9814e9a_2)

Concerning *Sclerotinia sclerotiorum* in oilseed rape data from 2006 to 2022 is derived from many countries across Europe of the Central zone (Belgium, Czech Republic, Denmark, Germany, Hungary, the Netherlands, Poland, Romania, Slovakia, Ukraine, and United Kingdom), Southern zone (Bulgaria, Croatia and France) and as well as the Northern zone (Estonia, Latvia, Lithuania and Sweden). Stable and low frequency of sensitivity adaptation is observed in France for around the last decade; the situation remains stable in France.

Regarding *Leptosphaeria maculans* (*Plenodomus lingam*) in oilseed rape, monitoring data from 2016 to 2021 is derived from several countries of the Central Zone (Austria, Czech Republic, Denmark, Germany, Hungary, Poland, Romania, and United Kingdom) as well as the North Zone (Latvia and Lithuania) and Southern Zone (Bulgaria and France). No sensitivity problems were found in the collected samples since 2016, only a few suspicious isolates from 2020 with slightly lower sensitivity are currently under investigation.

### 3.3.6 Use pattern

FGG01 is used in a wide range of crops and the maximum number of applications varies from 1 to 3 depending on the crop. The target diseases normally need a large number of applications during the full season, so FGG01 is usually applied as part of multiple, season-long spray program. It will be mainly applied in conjunction or sequences with other fungicides with different modes of action in order to avoid potential resistance development.

### 3.3.7 Resistance risk assessment of unrestricted use pattern

This analysis is conducted according to the EPPO guidance document PP/213 “Resistance risk analysis”. The actual risk for the evolution of resistance towards boscalid depends on three different parameters: mechanism of resistance against the compound (intrinsic fungicide risk), biology of the pathogen (pathogen risk) and on agronomical factors (agronomic risk).

#### Inherent active substance associated risk

According to FRAC, the SDHI fungicide boscalid is classified as substance exerting a **medium to high** risk of resistance development.

#### Inherent pathogen associated risk

Large differences in pathogen risk can be found among certain genera and species of plant pathogens. Factors relating directly to disease epidemiology combined with genetic factors can influence the pathogen risk. The most important factors determining pathogen risk appear to be:

- Life cycle of pathogen; the shorter the generation time, the more frequent the need for exposure to the fungicide and the faster the build-up of resistance;
- Abundance of sporulation; the more spores that are released in the crop the greater the availability of individual genomes for mutation and selection, and the faster the spread of resistant mutants;
- Ability of spores to spread between plants, crops and regions;
- Ability to infect at all crops stages, requiring repeated fungicide treatment;
- Occurrence of a sexual stage in the life cycle; this could either favour or hinder resistance development;
- Ability to mutate or express mutant genes; certain pathogens seem to produce fit mutants more readily than others (FRAC, 2007)



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>Alternaria brassicae</i>	Oilseed rape	Medium	2
<i>Botrytis cinerea</i>	various, especially grapevine	High	3
<i>Erysiphe necator</i> *	Grapevine	Medium	2
<i>Leptosphaeria maculans</i> (= <i>Plenodomus lingam</i> )	oilseed rape	Low	1
<i>Sclerotinia sclerotiorum</i>	Various	Low	1

\*The EPPO Guideline lists these pathogens as high risk pathogens of which baseline sensitivity is normally requested

### Inherent combined risk

When the pathogen risk is reported in a table with the inherent resistance risk of the SDHIs group, the combined resistance risk for each pathogen/fungicide combination can be estimated as follows based upon the resistance risk matrix proposed by Brent and Hollomon, and adapted by Kuck (Brent and Hollomon, 2007)<sup>16</sup>.

**Table 3.3-7: Combined Inherent risk for FGG01**

Fungicide Class	Molecule Risk ↓	Combined Risk		
SDHI (boscalid) Medium to high	High = 3	3	6	9
	Medium = 2	2	4	6
-	Low=1	1	2	3
Pathogen risk →		Low = 1	Medium = 2	High = 3
Pathogen →		<i>Leptosphaeria maculans</i> <i>Sclerotinia sclerotiorum</i>	<i>Alternaria brassicae</i> <i>Erysiphe necator</i>	<i>Botrytis cinerea</i>

Combined Risk: 1 = low, 2 to 6 medium, 9 high (FRAC, 2019)

According to the Table 3.3-7, the combined inherent risk for boscalid is **medium to high** for *Botrytis cinerea*, while for the other target pathogens requested, there is a **medium** risk. However this table does not take into account the agronomy 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.

The most important conditions of use that can affect resistance risk are:

- Number of repeated applications of the fungicide; the more frequent the product is applied to the pathogen, the more rapid the selection of mutants,
- Exclusivity of the product, the more exclusive the products with the same mode of action, the more sustained the selection pressure; alternation or combined application with other types of fungicides with different mechanisms of action can reduce resistance risk,

<sup>16</sup><https://www.syngenta.fr/traitements/alternariose-du-colza> Brent, K.J. and Hollomon, D.W. (2007). *Fungicide resistance: the assessment of risk*. FRAC. ([link](#))

- Amounts of pathogen exposed to the fungicide; if disease incidence is relatively low or irregular from season to season, then occurrence and selection of possible resistant mutants is reduced.

Table 3.3-8 reports the combined risk for FGG01 by taking into account the agronomic risk.

**Table 3.3-8: Possible combined risk for FGG01 in relation with the agronomic risk level**

Fungicide Class	Molecule Risk ↓	Combined Risk			Agronomic Risk
SDHI (boscalid) Medium to high	High = 6	6 <u>3</u> 1.5	12 <u>6</u> 3	18 <u>9</u> 4.5	High = 1 <b>Medium = 0.5</b> Low = 0.25
	Medium = 4	4 <u>2</u> 1	8 <u>4</u> 2	12 <u>6</u> 3	High = 1 <b>Medium = 0.5</b> 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	Medium = 2	High = 3	-
Pathogen →		<i>Leptosphaeria maculans</i> <i>Sclerotinia sclerotiorum</i>	<i>Alternaria brassicae</i> <i>Erysiphe necator</i>	<i>Botrytis cinerea</i>	-

Highest possible value = 18 (high molecule risk high pathogen risk and high agronomy risk).

For all those diseases, 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 like SRAL, Arvalis, etc... Those assessments are completed by modelling systems which refine the date of application. All the results are communicated to farmers through various supports like email, fax, technical bulletin etc... This process avoids an excessive number of applications on pathogens.

According to the Good Agricultural Practices, FGG01 is applied 1 to 3 times per season depending on the different target crops considering in this submission, as a consequence the agronomic risk on those diseases is medium (0.5). By taking into account the agronomic risk, the combined risk adapted to the use of FGG01 is the following one:

**Table 3.3-9: Summary of the combined risk for FGG01**

Pathogen	Crop	Combined Risk
<i>Alternaria spp.</i>	Oilseed rape	4-6
<i>Botrytis cinerea</i>	Grapevine	6-9
	Fresh beans and peas	6-9
<i>Erysiphe necator</i>	Grapevine	4-6
<i>Leptosphaeria maculans</i> (= <i>Plenodomus lingam</i> )	Oilseed rape	2-3
<i>Sclerotinia sclerotiorum</i>	Oilseed rape	2-3
	Fresh beans and peas	2-3

In conclusion the combined risk is **low to medium** depending on the pathogen; *Sclerotinia sclerotiorum* and *Plenodomus lingam* are pathogens with a **low** combined risk; while *Alternaria spp.*, *Botrytis cinerea* and *Erysiphe necator* are pathogens with a **medium** combined risk, considering that 18 was the highest possible value of combined risk.

The resistance risk is therefore acceptable.

### 3.3.8 Management strategy

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

Utilization 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 and also some specific ones for grapevine, pome fruits, stone fruits and vegetables.

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, based upon guidance from the FRAC SDHI Working Group:

### **In grapevine**

- Apply SDHI fungicides according to manufacturers' recommendations.
- Apply a max. of 3 SDHI-containing fungicides per year over all diseases, solo or in mixture with effective mixture partners from different cross-resistance groups but not more than 50% of the total number of applications.
- A maximum of 4 SDHI fungicide applications may be used where 12 or more fungicide applications are made per crop.
- If used solo, apply SDHI fungicides in strict alternation with fungicides from a different cross-resistance group.

- If used in mixture, apply SDHI fungicides in a maximum of 2 consecutive applications.
- Apply SDHI fungicides preventively.

For SDHI fungicide applications specifically targeted against grey mould, *Botrytis cinerea*, refer to the Table 3.3-10 below:

**Table 3.3-10: Number of applications of SDHI fungicides against *Botrytis cinerea***

Total number of <i>Botrytis cinerea</i> spray applications per crop	1	2	3	4	5	6	>6
Maximum recommended Solo SDHI fungicide spray (apply in strict alternation)	1	1	1	2	2	2	3
Max. recommended SDHI fungicide sprays in mixture (apply a max. of 2 consecutive applications)	1	1	2	2	2	3	3

### In other multi-spray crops (vegetables)

The following spray Table 3.3-11 shall be used as a guideline irrespective of the targeted disease in the crops specified above.

**Table 3.3-11: Number of applications of SDHI fungicides in vegetables**

Total number of spray applications per crop	1	2	3	4	5	6	7	8	9	10	11	12	>12
Maximum recommended Solo SDHI fungicide sprays (apply in strict alternation)	1	1	1	1	2	2	2	3	3	3	3	4	*
Max. recommended SDHI fungicide sprays in mixture (apply a max. of 2 consecutive applications)	1	1	1	2	2	3	3	3	3	3	4	4	*

\*When more than 12 fungicide applications are made, observe the following guidelines:

- When using a SDHI fungicide as a solo product, the number of applications should be no more than 1/3 (33%) of the total number of fungicide applications per season.
- For programs in which tank mixes or pre-mixes of SDHI are utilized, the number of SDHI containing applications should be no more than 1/2 (50%) of the total number of fungicide application per season.
- In programs where SDHIs are made with both solo products and mixtures, the number of SDHI containing applications should be no more than 1/2 (50%) of the total number of fungicide applied per season.
- If used solo, apply SDHI fungicides in strict alternation with fungicides from a different cross-resistance group.
- If used in mixture, apply SDHI fungicides in a maximum of 2 consecutive applications.

### 3.3.9 Implementation of 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.

### 3.3.10 Monitoring, reporting and reaction to changes in performance

Continuing observation of field performance may be conducted post-registration by the Applicant if necessary. In case of development of resistant strains, the relevant authorities would be informed in a timely manner and a revised resistance management strategy would be agreed.

#### **ZRMs comments:**

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

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

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

#### **Winter oilseed rape:**

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

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

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

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

#### **Peas and beans:**

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

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

#### **Grapevine**

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

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

**Mitigation strategies :**

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

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

**Effective resistance management for boscalid (SDHI fungicides) :**

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

- ✓ *rotate fungicide modes of action*: incorporate boscalid into a fungicide rotation program. Avoid consecutive applications of boscalid or other SDHIs. Instead, alternate with fungicides that act through different mechanisms, such as DMI or QoI fungicides.
- ✓ *formulate mixtures*: combine boscalid with another fungicide that has a different mode of action to reduce selection pressure on pathogen populations by exposing them to multiple modes of attack.
- ✓ *Integrated Pest Management*: use crop rotation and diversification to disrupt the pathogen lifecycle. When available, plant resistant crop varieties to reduce disease pressure. Ensure proper crop sanitation by removing plant debris that may harbour pathogens. Regularly scout fields to detect early disease symptoms and evaluate fungicide efficacy.
- ✓ *optimized application practices*: always follow label instructions for application rates, timing and treatment frequency. Both underuse and overuse can contribute to resistance development.
- ✓ *resistance monitoring*: keep detailed records of fungicide performance and any instances of reduced efficacy, which will assist in future decision making.

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

### 3.4 Adverse effects on treated crops (KCP 6.4)

FGG01 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 71 efficacy trials and their distribution across EPPO climatic zones and crops is presented in Table 3.4-1.

**Table 3.4-1: Efficacy trials distribution with crop sensitivity assessment**

Crop	EPPO climatic zone				Total
	Maritime	South-East	North-East	Mediterranean*	
Oilseed rape	7	6	16	-	29
Grapevine	13	-	-	13	26
Fresh beans and peas	8	-	-	8	16
<b>Total</b>	<b>28</b>	<b>6</b>	<b>16</b>	<b>21</b>	<b>71</b>

\* Supportive data (extra-zonal data obtained from trials carried out in the other climatic zone).

The crop sensitivity was also assessed in 2 transformation trials on grapevine. In addition, 2 selectivity trials in the Mediterranean EPPO climatic zone (2 trials in Greece; supportive data) are currently on going but no results are currently available.

Possible effects on the production and quality of red and white grape cultivars treated with FGG01 at the rate of 1.0 kg/ha were examined in 2 trials carried out in Germany and in Italy. Additionally, 2 other wine making trials are currently on going in the South of France and Germany and are listed here although the results are not currently available, they will be available later (results will be available in November 2024).

**Table 3.4-2: Overview of trials and testing facilities - Processing trials - Grapevine**

EPPO climatic zone	Year	Country	Testing facilities/ Processing laboratory	Nb. of trials	Variety	Trial status
Maritime	2022	Germany	Eurofins	1 trial	<i>Spätburgunder</i>	GEP
Medi.	2022	Italy	Sagea	1 trial	<i>Merlot</i>	GEP
Maritime	2023	Germany	Staphyt	1 trial (on going)	<i>Spätburgunder</i>	GEP
Medi.	2023	France	Staphyt	1 trial (on going)	<i>Grenache</i>	GEP

\* Additional trials currently ongoing this year (no results are currently available for these trials; results will be available in November 2024).

#### 3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

The crop sensitivity was assessed in 71 efficacy trials and their distribution across EPPO climatic zones and crops between 2021 and 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.

##### 3.4.1.1 Oilseed rape

The crop sensitivity was assessed in 29 efficacy trials on oilseed rape in the Maritime (7 trials), North-East (16 trials) and the South-East (6 trials) EPPO climatic zones. These trials were performed between 2021 and 2024. In all trials, no phytotoxicity symptom was observed after the application of FGG01 at the requested rate. Detailed results of the observations carried out in the efficacy trials are provided in the Biological Assessment Dossier and in individual trial reports in Document K. A summary is presented in Table 3.4-3



**Table 3.4-3: Phytotoxicity assessments of FGG01- Efficacy trials - Oilseed rape**

Number of trials with...		FGG01 0.5 kg/ha	References*
Maximum of phytotoxicity recorded during the trials	0%	29	29
	>0% to 5%	0	0
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0
Level of symptoms at the last assessments	0%	29	29
	>0% to 5%	0	0
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

\*CANTUS (boscalid 500 g/kg, WG) applied at 0.5 kg/ha in BE, DK, FR, UK HU, PL  
PICTOR (boscalid + dimoxystrobin 200 + 200 g/L, SC) applied at 0.5 L/ha in PL

In 29 trials of the oilseed rape crops, no phytotoxicity symptom was observed when FGG01 was applied at 0.5 kg/ha.

The potential impact of variety on the occurrence of phytotoxicity was tested in 26 different varieties of oilseed rape (Table 3.4-4).

**Table 3.4-4: Phytotoxicity assessments of FGG01- Varieties tested in efficacy trials - Oilseed rape**

Crop	No of trials	No of varieties	Variety names (No of trials)
Oilseed rape	29	26	Amarone (1), Architect (2), Avatar (1), <b>Bachus (1)</b> , Digger (1), DK Extorm (1), <b>Derrick (1)</b> , <b>DK Placis (1)</b> , Elevation (1), ES Mambo (1), Exlibres (1), <b>Hostine (1)</b> , Hybrirock (1), Kepler (1), Kuga (1), KWS Factor (1), KWS Feliciano (1), <b>LG Apollonia (1)</b> , LG Artemis (1), LG Aviron (1), Nizza CL (1), Shield (1), Shrek (3), <b>SY Ilona (1)</b> , SY Rokas (1), Trezor (1).

**Therefore, no unacceptable phytotoxicity symptom is expected on oilseed rape if FGG01 is used according to the Good Agricultural Practices and label recommendations.**

### 3.4.1.2 Grapevine

The crop sensitivity was assessed in 26 efficacy trials in the Maritime (13 trials) and in the Mediterranean (13 trials) EPPO climatic zones. These trials were performed from 2021 to 2023. In the 26 trials, no phytotoxicity symptom was observed after repeated applications of FGG01 at the requested rates. Detailed results of the observations carried out in the efficacy trials are provided in the Biological Assessment Dossier and in individual trial reports in Document K. The summary results of the observations in all efficacy trials are provided in Table 3.4-5 and Table 3.4-6 for trials affected by *Botrytis cinerea* (FGG01 applied at 1.0 kg/ha) and *Erysiphe necator* respectively (FGG01 applied at 0.2 kg/ha).



**Table 3.4-5: Phytotoxicity assessments of FGG01- Efficacy trials - Grapevine against BOTRCI**

Number of trials with...		FGG01 1.0 kg/ha (x 4 applications)	FGG01 0.72 kg/10000 m <sup>2</sup> LWA (x 4 applications)	References*
Maximum of phytotoxicity recorded during the trials	0%	9	3	9
	>0% to 5%	0	0	0
	>5% to 10%	0	0	0
	>10% to 15%	0	0	0
	>15 %	0	0	0
Level of symptoms at the last assessments	0%	9	3	9
	>0% to 5%	0	0	0
	>5% to 10%	0	0	0
	>10% to 15%	0	0	0
	>15 %	0	0	0

\*CANTUS (boscalid 500 g/kg, WG) applied at 1.0 kg/ha in AT, DE, FR, IT, PT, ES  
GEOXE 50 WG (fludioxonil 50%, WG) applied at 1.0 kg/ha in ES

**Table 3.4-6: Phytotoxicity assessments of FGG01 - Efficacy trials - Grapevine against UNCINE**

Number of trials with...		FGG01 0.2 kg/ha (x 5-9 applications)	FGG01 0.02 kg/100 L (x 5-9 applications)	FGG01 0.13-0.14 kg/10000 m <sup>2</sup> LWA (x 8 applications)	References*
Maximum of phytotoxicity recorded during the trials	0%	17	4	10	17
	>0% to 5%	0	0	0	0
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0
Level of symptoms at the last assessments	0%	17	4	10	17
	>0% to 5%	0	0	0	0
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0

\*CANTUS/PICTOR PRO (boscalid 500 g/kg, WG) applied at 0.2 kg/ha in AT, DE, FR, IT, ES and at 0.1 kg/100 L in IT  
COLLIS (boscalid + kresoxim-methyl 200 + 100 g/L, SC) applied at 0.4 L/ha in FR and at 0.64 L/ha in AT, DE  
GEOXE 50 WG (fludioxonil 50%, WG) applied at 1.0 kg/ha in ES  
KUMULUS (sulphur 800 g/kg, WG) applied at 5 – 8 kg/ha in AT  
PROSPER (spiroxamine 300 g/L, SC) applied at 0.66 L/ha in AT, DE  
TOPAS (penconazole 100 g/L, EC) applied at 0.08 L/ha in DE

In none of the grapevine crops were any phytotoxicity symptoms observed when FGG01 was applied 4 times at 1.0 kg/ha or at 0.72 kg/10000 m<sup>2</sup> LWA against BOTRCI. Also, when FGG01 was applied from 5 to 9 applications at 0.2 kg/ha or 0.02 kg/100 L, or when applied at 8 applications at 0.13-0.14 kg/10000 m<sup>2</sup> LWA against UNCINE no phytotoxicity symptoms were observed.

The potential impact of variety on the occurrence of phytotoxicity was tested in 18 different varieties of grapevine (Table 3.4-7).

**Table 3.4-7: Phytotoxicity assessments of FGG01 - Varieties tested in efficacy trials - Grapevine**

Crop	No of trials	No of varieties	Variety names (No of trials)
Grapevine	26	18	<i>Acolon (1), Bacchus (1), Bellone (1), Blauburgunder (1), Carignan (2) Chardonnay (3), Freisa (1), Morillon (2), Müller-Thurgau (1), Negrette (1), Palomino (1), Pinot Gris (1), Riesling (1), Sämling (1), Tinta Roriz (2), Trolinger (1), Weissburgunder (3) and Zalema (2).</i>

Additionally, the phytotoxicity was also assessed in the 2 transformation trials of grapevine.

These 2 trials were carried out in Germany and Italy. FGG01 was applied at a single application of 1.0 kg/ha, no phytotoxicity symptom was observed after the single application. Results on phytotoxicity assessments carried out in the transformation trials are provided in the Biological Assessment Dossier and in individual trial reports in Document K. The summary results of the observations in all efficacy trials are provided in Table 3.4-8.

**Table 3.4-8: Phytotoxicity assessments of FGG01 - Transformation trials - Grapevine**

Number of trials with...		FGG01 1.0 kg/ha (x 1 application)	CANTUS 1.2 kg/ha (x 1 application)
Maximum of phytotoxicity recorded during the trials	0%	2	2
	>0% to 5%	0	0
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0
Level of symptoms at the last assessments	0%	2	2
	>0% to 5%	0	0
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

In none of the grapevine transformation trials were any phytotoxicity symptoms observed when FGG01 was applied once at 1.0 kg/ha.

The potential impact of variety on the occurrence of phytotoxicity was tested in 2 different varieties of grapevine (Table 3.4-9).

**Table 3.4-9: Phytotoxicity assessments of FGG01 - Varieties tested in Transformation trials - Grapevine**

Crop	No of trials	No of varieties	Variety names (No of trials)
Grapevine	2	2	<i>Merlot(1), Spätburgunder(1).</i>

**Therefore, no unacceptable phytotoxicity symptom is expected on grapevine if FGG01 is used according to the Good Agricultural Practices and label recommendations.**

### 3.4.1.3 Fresh beans and peas

The crop sensitivity was assessed in 16 efficacy trials in the Maritime (8 trials) and in the Mediterranean (8 trials) EPPO climatic zones. These trials were performed in 2022 and 2023. In the 16 trials, no phytotoxicity symptom was observed after repeated applications of FGG01 at the requested rate. Detailed results of the observations carried out in the efficacy trials are provided in the Biological Assessment Dossier and in individual trial reports in Document K. The summary results of the observations in all efficacy trials are provided in Table 3.4-10.

**Table 3.4-10: Phytotoxicity assessments of FGG01 - Efficacy trials - Fresh beans and peas**

Number of trials with...		FGG01 1.0 kg/ha	References*
Maximum of phytotoxicity recorded during the trials	0%	16	16
	>0% to 5%	0	0
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0
Level of symptoms at the last assessments	0%	16	16
	>0% to 5%	0	0
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

\*CANTUS/PICTOR PRO/FILAN (boscalid 500 g/kg, WG) applied at 1.0 kg/ha in BE, CZ, DE, ES, FR, UK

In none of the fresh beans and peas crops were any phytotoxicity symptoms observed when FGG01 was applied at 1.0 kg/ha.

The potential impact of variety on the occurrence of phytotoxicity was tested in a total of 12 different varieties: *i.e.* 10 of fresh beans and 2 of peas (Table 3.4-11).

**Table 3.4-11: Phytotoxicity assessments of FGG01 - Varieties tested in efficacy trials - Fresh beans and peas**

Crop	No of trials	No of varieties	Variety names (No of trials)
Fresh beans	14	10	<i>Ampere (2), Cadillac (2), Contender (2), Fabiola (2), Luz de otoño (1), Oriola (1), Parker (1), Perolar (1), Persepolis (1), Augusta (1)</i>
Fresh peas	2	2	<i>Eso (1), Sakura (1)</i>
<b>Total</b>	<b>16</b>	<b>12</b>	

**Therefore, no unacceptable phytotoxicity symptom is expected on fresh beans and peas if FGG01 is used according to the Good Agricultural Practices and label recommendations.**

### 3.4.1.4 Conclusion on phytotoxicity

The efficacy trials with selectivity assessments were conducted on oilseed rape, grapevine and fresh beans and peas in Maritime, North-East and South-East EPPO climatic zones within the Central registration zone and additionally in Mediterranean EPPO climatic zone belonging to Southern registration zone (as supportive data).

The results demonstrated that the application of FGG01 at dose rates claimed in the label is safe, since in all of the trials no phytotoxic symptoms and/or vigour reductions were observed as well as any other symptom.

#### **ZRMs comments:**

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

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

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

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

### 3.4.2 Effect on the yield of treated plants or plant products (KCP 6.4.2)

FGG01 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 is analysed in efficacy trials carried out on oilseed rape and fresh beans and peas, in presence of challenging disease infection. For more details, please refer to section 3.2.3.

#### ZRMs comments:

Boscalid controls fungal diseases. Improved disease control generally leads to healthier plants and increased yields. Weather conditions influence disease pressure and fungicide performance. In wet, humid conditions where fungal diseases are more prevalent, the yield benefits from boscalid treatments can be more pronounced. In conclusion, the use of boscalid fungicide has the potential to positively impact the yield of winter oilseed rape, grapevines and fresh beans and peas through effective disease management, provided it's used judiciously and in combination with other agronomic practices. However, the specific yield responses can vary depending on disease pressure, environmental conditions and how well the fungicide application is managed.

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

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

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

### 3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

Many products containing boscalid have been approved and widely used in many countries of Europe for the control of several diseases and proven to have no effect on the quality of plants or plant products of the different crops where it is applied. For these reasons and based on the data provided, we can expect no adverse effect on the quality parameters.

However, to deepen the knowledge on FGG01, several trials were carried out to evaluate the unintentional effects of FGG01 compared to the reference standard CANTUS at the requested dose.

### **3.4.3.1 Effects on the quality of oilseed rape**

Material and Methods used in efficacy trials are given within section 3.2.3.1 and is not repeated here.

The possible impact of FGG01 on the quality was studied in 1 efficacy trial in oilseed rape. The trial was carried out by testing facilities officially recognised according to Good Experimental Practice (GEP).

Different quality parameters (moist content and oil content) were measured in 1 efficacy trial performed in the North-East EPPO climatic zone (Poland) in 2023.

All quality results are summarised in Table 3.4-12 (compared to untreated and the reference CAN-TUS).

Also detailed information is presented in the Biological Assessment Dossier and in individual trial reports in Document K.

**Table 3.4-12: Summary Effect on the quality parameters of FGG01 at 0.5 kg/ha - Comparison with the reference standard - Efficacy trials - Oilseed rape**

Quality parameters	EPPO climatic zone	No. of trials	Untreated control			FGG01 0.5 kg/ha			CANTUS 0.5 kg/ha			No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at 0.5 kg/ha vs CANTUS
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	
Moist content (%)	North-East	1	7.7	-	-	7.7	-	-	7.8	-	-	0> ; 1= ; 0<
Oil content (%)	North-East	1	44.1	-	-	44.5	-	-	44.1	-	-	0> ; 1= ; 0<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.

Because FGG01 is a fungicide, no determination of oil content was necessary, however, this was performed in 1 trial to confirm the assumption that FGG01 would have no impact on quality parameters for oilseed rape. Moreover, no negative effect on moisture content was noted after an application of FGG01 at 0.5 kg/ha. Finally, no significant difference was noted with the reference standard CANTUS at 0.5 kg/ha in the trial on all quality parameters.

**Therefore, no negative effect on quality of oilseed rape is expected if FGG01 is applied at the requested rate of 0.5 kg/ha according to the Good Agricultural Practices and label recommendations.**

### 3.4.3.2 Effects on the quality of fresh beans and peas

Material and Methods used in efficacy trials are given within section 3.2.3.3 and is not repeated here.

The possible impact of FGG01 on the quality was studied in 2 efficacy trials in fresh beans and peas. The trials were carried out by testing facilities officially recognised according to Good Experimental Practice (GEP).

Different quality parameters (hectolitre weight, % moisture content in harvested seeds, and thousand seed weight in g) were measured in 2 efficacy trials performed in the Maritime EPPO climatic zone (1 trial in Germany and 1 trial in Czech Republic) in 2023.

All quality results are summarised in Table 3.4-13 (compared to untreated and the reference CANTUS).

Also detailed information is presented in the Biological Assessment Dossier and in individual trial reports in Document K.

**Table 3.4-13: Summary: Effect on the quality of FGG01 at 1.0 kg/ha - Comparison with the reference standard - Efficacy trials - Fresh beans and peas.**

Parameters	Crop	Unit	Parts	EPPO climatic zone	No. of trials	Days after application	Untreated control			% UTC						No. of assessments significantly <sup>(1)</sup> > , = , < FGG01 at 1.0 kg/ha vs. CANTUS (1.0 kg/ha)
										FGG01 1.0 kg/ha			CANTUS 1.0 kg/ha			
							Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	
HLW	VICFX	g/hL	GRAIN	Maritime zone	1	76 DA-B	79.5	-	-	101.3	-	-	96.9	-	-	0> ; 1= ; 0<
MOICON	VICFX	%	PLOT	Maritime zone	1	76 DA-B	10.6	-	-	99.1	-	-	108.5	-	-	0> ; 1= ; 0<
	PIBSX	%	GRAIN	Maritime zone	1	34 DA-B	11.2	-	-	100.9	-	-	96.4	-	-	0> ; 1= ; 0<
TKW	VICFX	g	GRAIN	Maritime zone	1	92 DA-B	344.9	-	-	100.6	-	-	99.8	-	-	0> ; 1= ; 0<
	PIBSX	g	GRAIN	Maritime zone	1	34 DA-B	249.7	-	-	100.3	-	-	100.4	-	-	0> ; 1= ; 0<

<sup>(1)</sup> Comparison based on statistics carried out in each trial report.



Because FGG01 is a fungicide, no determination of quality parameters is necessary, however, this was performed in 2 trials to confirm the assumption that FGG01 would have no impact on quality parameters for fresh beans and peas. Moreover, no negative effect for weight 100 litres (hL), % of moisture content in harvested seeds and thousand seed weight was noted after two applications of FGG01 at 1.0 kg/ha. Finally, no significant difference was noted with the reference standard CANTUS at 1.0 kg/ha on all trials for all quality parameters.

**Therefore, no negative effect on quality of fresh beans and peas is expected if FGG01 is applied at the requested rate of 1.0 kg/ha according to the Good Agricultural Practices and label recommendations.**

### 3.4.3.3 Conclusion on effects of the quality

The efficacy trials with quality parameters assessments were conducted in North-East (for oilseed rape) and in the Maritime (for fresh beans and peas) EPPO zones.

The results demonstrated that the application of FGG01 at dose rates claimed in the label is safe, since in all of the trials no effect on quality parameters were observed on oilseed rape and fresh beans and peas.

#### **ZRMs comments:**

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

### 3.4.4 Effects on transformation processes (KCP 6.4.4)

Many products containing boscalid have been approved and widely used in many countries of Europe for the control of several diseases and proven to have no effect on the transformation processes of the different crops where it is applied.

However, in order to test the effect of FGG01 on the processing procedure of wines, 2 trials were conducted in 2022 in Germany (Maritime EPPO climatic zone) and in Italy (Mediterranean EPPO climatic zone). Additionally, 2 other trials are currently on going in France and Germany and are listed here although the results are not currently available, they will be available the end of 2024.

These trials were led to highlight the effects of FGG01 on:

- ripening of grapes before harvest,
- the analytical composition of the musts,
- the fermentation process (red wine) and malolactic fermentation (red wine),
- the analytical composition of the wines,
- the organoleptic characteristics of the wines.

#### 3.4.4.1 Material and Methods

##### Testing Facility and list of available trials

Possible effects on the production and quality of red grape cultivars treated with FGG01 at the rate of 1.0 kg/ha were examined in 2 trials carried out in Germany and in Italy. In addition, 2 other trials in Germany and in France are currently on going and are listed below although no results are currently available. An overview of available trials is provided in Table 3.4-14.

**Table 3.4-14: Overview of trials and testing facilities - Processing trials - Grapevine**

EPPO climatic zone	Year	Country	Testing facilities/ Processing laboratory	Nb. of trials	Variety	Trial status
Maritime	2022	Germany	Eurofins	1 trial	<i>Spätburgunder</i>	GEP
Medi.	2022	Italy	Sagea	1 trial	<i>Merlot</i>	GEP
Maritime	2023	Germany	Staphyt	1 trial (on going)	<i>Spätburgunder</i>	GEP
Medi.	2023	France	Staphyt	1 trial (on going)	<i>Grenache</i>	GEP

### Experimental details

All the trials were carried out by officially recognised organisations in accordance with the Principles of Good Experimental Practice (GEP). These trials were performed followed EPPO guidelines or trial method recommendations published by the CEB (“Commission des Essais Biologiques”). The “CEB” methods are in accordance with EPPO directives.

Main characteristics are summarised in Table 3.4-15. The details per trial (trial location, crop cultivar, experimental design, number of blocks, plot size and application(s) are presented in Biological Assessment Dossier and in individual trial reports in Document K.

**Table 3.4-15: Details on trial methodology - Processing trials - Grapevine**

<b>Guidelines</b>	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”. PP1/239(2): “Dose expression for plant protection products”
	Specific guidelines	CEB 143: “Method for studying the unintentional effects of plant protection products on fermentation processes and quality of wines and brandy wines”. PP1/268(1): “Study of unintentional effects of plant protection products on fermentation processes and characteristics of wine”.
<b>Experimental design</b>	Plot design	Randomized Complete Block (RCB)
	Plot size	Plot area: 28-72 m <sup>2</sup>
	Number of replications	3-4 replications
<b>Crop</b>	Number of trials	2 trials finalised. 2 trials on going.
	Varieties	Finalised trials: <i>Merlot (1)</i> and <i>Spätburgunder (1)</i> On going trials: <i>Spätburgunder (1)</i> and <i>Grenache (1)</i> .
<b>Application</b>	Application timing	July- August
	Number of applications	1 application
	Spray volumes	Finalised trials: 600 L/ha On going trials: 300-800 L/ha
<b>Assessment</b>	Assessment types	<u>During the field part - Before harvest:</u> <ul style="list-style-type: none"> <li>- Selectivity in % of phytotoxicity (0 = no damage; 100 = plant dead; these results are presented in section 3.4.1 and vigour</li> <li>- Weight of 200 berries</li> <li>- pH of juice with a sample of 200 berries.</li> <li>- Alcohol content in % with a sample of 200 berries.</li> <li>- Total Acidity in g/L (TA) with a sample of 200 berries.</li> <li>- Sugar content in g/L with a sample of 200 berries.</li> </ul>

		<u>Laboratory analyses:</u> <ul style="list-style-type: none"> <li>- Must qualitative analysis (sugar content, pH, Volatile acidity, Total acidity, Not linked SO<sub>2</sub>, Total SO<sub>2</sub>, PAC, K, Nitrogen available).</li> <li>- Alcoholic fermentation (Latent time, alcoholic fermentation duration, Kinetics with sugar content during alcoholic fermentation process).</li> <li>- Study of the malolactic fermentation (MLF) for red wine (alcohol content in % vol, Volatile acidity in g/L H<sub>2</sub>SO<sub>4</sub>, Total acidity in g/L H<sub>2</sub>SO<sub>4</sub>, Free and Total SO<sub>2</sub> in mg/L, T°C, L-malic Acid in g/L, L-lactic Acid in g/L. Latent time of induced MLF, Duration of induced MLF, Latent time spontaneous MLF, Duration spontaneous MLF).</li> <li>- Qualitative analysis of wine:</li> <li>- Taint test after bottling and around 1 year after (triangular test)</li> </ul>
<b>Results &amp; Analysis</b>	Statistical analysis	ANOVA - Newman-Keuls test (5%)

### **Treatments and reference standards**

#### ► Tested product

FGG01 was tested at 1.0 kg/ha (maximum rate requested).

#### ► Reference standards

All reference standards used in selectivity trials are presented in Table 3.2-16.

In the field and laboratory phase of the 2 trials, FGG01 at 1.0 kg/ha was compared to reference standard based boscalid (CANTUS: 500 g/kg boscalid; WG). The reference standard was applied at 1.2 kg/ha. The composition of FGG01 and this reference standard are identical in active ingredient and type of formulation.

### **Main characteristics of processing analyses**

All field phases were carried out by officially recognised organisations in accordance with the Principles of Good Experimental Practice (GEP).

For each trial Processing methods details are available in individual trial reports in Document K. In each trial, the wine samples FGG01 and reference standard had the same Wine-making steps.

#### *Analyses details*

The following table presents the analyses performed in each trial.

**Table 3.4-16: Analyses performed on must and wine in processing trials - Wine grapes**

	<b>Trial no.1</b>	<b>Trial no.2</b>
Cultivar	<i>Spätburgunder</i> (Red variety)	<i>Merlot</i> (Red variety)
Harvest date for Processing	14/9/2022	12/9/2022
<b>Must qualitative analysis</b>		
Sugar content	X (in g/L)	X (in °Brix)
pH	X	X
Total acidity	X (g/L in H <sub>2</sub> SO <sub>4</sub> )	X (g of tartaric acid/L)
Volatile acidity	X (g/L in H <sub>2</sub> SO <sub>4</sub> )	X (g of tartaric acid/L)
Not linked SO <sub>2</sub> (mg/L)	-	X
Total SO <sub>2</sub> (mg/L)	X	X
PAC (% vol)	X	-
K (g/L)	X	-
Alcoholic fermentation process (date + data measured)	19/09/2022 to 29/09/2022 Sugar content, temperature and density	12/09/2022 to 18/09/2022 Sugar content and temperature
Malolactic fermentation (MLF): data measured	Reducing sugars (g/L), Alcohol content (%vol), Total acidity (g/L in H <sub>2</sub> SO <sub>4</sub> ), Volatile acidity (g/L in H <sub>2</sub> SO <sub>4</sub> ), SO <sub>2</sub> free (mg/L), SO <sub>2</sub> Total (mg/L), L-malic acid (g/L), L-lactic acid (g/L), Latent time of induced MLF, Duration of induced MLF, Latent time spontaneous MLF, Duration spontaneous MLF	Duration of induced MLF
<b>Wine qualitative analysis</b>		
Alcohol Content (%)	X	X
Sugar residue (g/L)	-	X
pH	X	X
Total acidity	X (g/L H <sub>2</sub> SO <sub>4</sub> )	X (g/L tartaric acid)
Volatile acidity (g/L H <sub>2</sub> SO <sub>4</sub> )	X	X
Free SO <sub>2</sub> (mg/L)	X	X
Total SO <sub>2</sub> (mg/L)	X	X
DO 280	X	X
DO 420	-	X
DO 520	X	X
DO 620	X	X
Start wine-making process	15/09/2022	12/09/2022
Bottling date	16/01/2023	12/10/2022
First wine tasting session	Not useful due to contamination	12/12/2022
The second tasting session	-	12/10/2023

#### *Wine tasting methods*

Tasting tests on young wine and wine after one year storage in bottle were carried out in the 2 trials. However, in trial no.1 the CRO stated that an undesirable contamination occurred, (not related to the products), thus the results of the taint test are not exploitable. Taint tests will also be carried out in the 2 trials on going. The following table presents the tasting tests performed.

**Table 3.4-17: Tasting tests carried out in processing trials - Wine grapes**

Trial	Test	Date of taint test	No. of tasters
Trial no.1	Triangular test according to the norm ISO 4120	Taint test after bottling	Not exploitable data
		Taint test one year after bottling	
Trial no.2	Triangular test according to the norm ISO 4120	Taint test after bottling	18
		Taint test one year after bottling	18

### 3.4.4.2 Results

In order to study the effects of FGG01 on the processing procedure of vine, 2 trials were carried out in 2022 in France and Germany and 2 other trials are currently on going, results are not yet available and thus, not here presented. In trial no.1 the results are only partially usable. Indeed according to the CRO statements, an undesirable contamination of the grapes occurred, not related to the product (it may have occurred upstream during transport).

#### 3.4.4.2.1 Field trials results - Ripening of grapevine before harvest or just after harvest

In this part only results on ripening before grapevine harvest or the day of the harvest are presented. The results on phytotoxicity are presented in Section 0.

The possible impacts of FGG01 on ripening before grapevine harvest or day of the harvest are presented in Table 3.4-18.

**Table 3.4-18: Results - Ripening before grapevine harvest - Grapevine**

Trial	Country	Year	EPPO Climatic zone	Cultivars	Assessment date	BBCH Stage	DAA	FGG01 1.0 kg/ha	CANTUS 1.2 kg/ha
<b>pH values (standard values: 2.8-4 ±0.2)</b>									
Trial no.1	Germany	2022	Maritime	<i>Spätburgunder</i>	12/9/2022	89	19 DA-A	2.87 <i>a</i>	2.88 <i>a</i>
Trial no.2	Italy	2022	Mediterranean	<i>Merlot</i>	5/9/2022	89	14 DA-A	4.0 <i>a</i>	3.9 <i>a</i>
<b>Sugar content (g/L)</b>									
Trial no.1	Germany	2022	Maritime	<i>Spätburgunder</i>	12/9/2022	89	19 DA-A	204.7 <i>a</i>	198.8 <i>a</i>
Trial no.2	Italy	2022	Mediterranean	<i>Merlot</i>	5/9/2022	89	14 DA-A	168.3 <i>b</i>	181.3 <i>a</i>
<b>Alcohol content (%)</b>									
Trial no.1	Germany	2022	Maritime	<i>Spätburgunder</i>	12/9/2022	89	19 DA-A	12.1 <i>a</i>	11.7 <i>a</i>
<b>Alcohol content (g/L)</b>									
Trial no.2	Italy	2022	Mediterranean	<i>Merlot</i>	5/9/2022	89	14 DA-A	101.0 <i>b</i>	108.8 <i>a</i>
<b>Acid content (g/L H<sub>2</sub>SO<sub>4</sub>)</b>									
Trial no.1	Germany	2022	Maritime	<i>Spätburgunder</i>	15/9/2022	89	19 DA-A	8.2 <i>a</i>	8.6 <i>a</i>
Trial no.2	Italy	2022	Mediterranean	<i>Merlot</i>	5/9/2022	89	14 DA-A	1.1 <i>a</i>	1.4 <i>a</i>

No significant differences on pH, sugar content, alcohol content and acid content before harvest were noted between FGG01 applied at 1.0 kg/ha and reference standard applied in the same conditions. Only in trial no.2 a statistical difference was noted on sugar content between FGG01 and the reference (168.3 g/L vs. 181.3 g/L) and in alcohol content (101.0 g/L vs. 108.8 g/L). Nevertheless, in the conclusions of the trial report it is stated that no significant difference was noted in this qualitative parameters and weight of 200 berries.

**According to the results of 2 processing trials, FGG01 showed no significant impact on ripening before grapevine harvest or just after harvest (according to pH, alcohol content, total acidity and sugar content parameters). Two further trials are on-going.**

### 3.4.4.2.2 Processing results - Must qualitative analysis

The possible impacts of FGG01 on musts are presented in Table 3.4-19.

**Table 3.4-19: Must qualitative analysis results**

	Standard values	Trial no.1		Trial no.2	
		FGG01 1.0 kg/ha	CANTUS 1.2 kg/ha	FGG01 1.0 kg/ha	CANTUS 1.2 kg/ha
pH	(2.8-4) ±0.2	3.25	3.19	4.4	4.32
Total acidity	(2.8-8) ±0.2 (g/L in H <sub>2</sub> SO <sub>4</sub> )	4.17 (g/L in H <sub>2</sub> SO <sub>4</sub> )	4.28 (g/L in H <sub>2</sub> SO <sub>4</sub> )	3.84 (g tartaric acid/L)	3.82 (g tartaric acid/L)
Volatile acidity	-	<.01 (g/l in H <sub>2</sub> SO <sub>4</sub> )	<.01 (g/l in H <sub>2</sub> SO <sub>4</sub> )	0 (g/L tartaric acid)	0 (g/L tartaric acid)
Not linked SO <sub>2</sub> (mg/L)	-	-	-	0	0
Total SO <sub>2</sub> (mg/L)	-	<10	<10	6.22	5.90
PAC (% vol)	(7.5-14) ±0.3	11.20	10.19	-	-
K <sup>+</sup> (g/L)	-	1.22	1.17	-	-
Sugar content (°Brix)	-	-	-	24.7	23.2
Sugar content (g/L)	-	183.3	165.8	-	-
N-available mg/L	>150	218	226	136.24	172.43

No significant difference on must qualitative analysis was noted between FGG01 applied at 1.0 kg/ha and reference standard applied in the same conditions, excepting in trial no.1, where a difference in alcohol content was detected (11.20% vs.10.19%).

### 3.4.4.2.3 Processing results - Alcoholic fermentation process

The latent period and the duration of fermentation are presented in Table 3.4-20.

**Table 3.4-20: Latent period and the duration of fermentation results**

	Latent period (days)		Fermentation length (days)	
	FGG01 1.0 kg/ha	CANTUS 1.2 kg/ha	FGG01 1.0 kg/ha	CANTUS 1.2 kg/ha
<b>Trial no.1</b>	3	3	10	10
<b>Trial no.2</b>	<2	<2	7	7

No significant differences were highlighted on latent period and alcoholic fermentation length between FGG01 applied at 1.0 kg/ha and reference standard CANTUS applied at 1.2 kg/ha in the same conditions.

The kinetics of fermentation were also studied in these 2 trials. In all trials the sugar content and temperature were measured during alcoholic fermentation process. Additionally, the density was also measured in the trial no.1. The detailed results are available in graphical form in each individual report provided in Document K.

FGG01 and reference standard showed similar kinetic profiles in all trials. Thus, it can be concluded that FGG01 showed no negative effects on fermentation kinetics.

However, in trial no.1, in which contamination took place, the graphic of the fermentation kinetics shows the process starting on a Friday, then, no more information until the next Monday. If the musts had no care during the weekend, it could be an explanation for a difficult starting of the fermentation, which was not very dynamic during the five first days. This situation is very favourable to the development of undesirable microorganisms and can be another cause of the contamination on the wine.

Moreover, the wine making steps between both samples (FGG01 and reference standard CANTUS) were similar and detailed in each individual trial reports. Thus, after the end of the alcoholic fermentation process, both products, FGG01 and reference standard, applied during the field phase did not cause any significant negative effect on grapes metabolic activities and on microbial activities during the fermentation kinetics.

### 3.4.4.2.4 Processing results - Malolactic fermentation analysis

The analysis after the malolactic fermentation is presented in Table 3.4-21.

**Table 3.4-21: Analysis after malolactic fermentation on red wine**

	Standard values	Trial no.1		Trial no.2	
		FGG01 1.0 kg/ha	CANTUS 1.2 kg/ha	FGG01 1.0 kg/ha	CANTUS 1.2 kg/ha
Reducing sugars (g/L)	<2 ±1	<0.2	<0.2	-	-
Ethanol (% volume)	>9 ±0.3	9.73	9.61	-	-
Total acidity (g/L in H <sub>2</sub> SO <sub>4</sub> )	(2.8-8) ±0.2	8.03*	5.61*	-	-
Volatile acidity (g/L in H <sub>2</sub> SO <sub>4</sub> )	(0.1-0.55) ±0.1	>1*	>1*	-	-
Free SO <sub>2</sub> (mg/L)	(15-40) ±10	18	14	-	-
Total SO <sub>2</sub> (mg/L)	<140 ±10	42	40	-	-
L-malic Acid (g/L)	/	<0.1*	<0.1*	-	-
L-lactic Acid (g/L)	/	0.98*	1.32*	-	-

\*Due to a contamination of the samples, acidity data should be ignored.

According to the results of these analyses, there were no significant differences between FGG01 and the reference standard. The slight difference on total acidity in trial no.1 were probably linked to the contamination occurred in this trial stated by the CRO.

The synthesis of the malolactic fermentation is presented in Table 3.4-22.

**Table 3.4-22: Synthesis of the malolactic fermentation**

	Trial no.1		Trial no.2	
	FGG01 1.0 kg/ha	CANTUS 1.2 kg/ha	FGG01 1.0 kg/ha	CANTUS 1.2 kg/ha
Latent time of induced MLF	5	5	-	-
Duration of induced MLF	3	3	16	16
Latent time spontaneous MLF	5	5	-	-
Duration spontaneous MLF	8	8	-	-

There were no differences between the samples treated with FGG01 and the reference standard in trial no.1 for both the induced and spontaneous malolactic fermentations period.

In trial no.2, no difference was noted in the duration of the malolactic fermentation (MLF). The conclusion on both trials states that there is no impact of FGG01 in the malolactic fermentation.



### 3.4.4.2.5 Processing results - Wine qualitative analysis

The possible impacts of FGG01 on wine are presented in Table 3.4-23.

**Table 3.4-23: Wine qualitative analysis results**

	Trial no.1		Trial no.2	
	FGG01 1.0 kg/ha	CANTUS 1.2 kg/ha	FGG01 1.0 kg/ha	CANTUS 1.2 kg/ha
Alcohol Content (%)	9.64	9.54	14.59	14.71
Sugar residue (g/L)			0.23	0.29
pH	3.34	3.38	4.10	4.14
Total acidity (g/L)	7.84* (g/L H <sub>2</sub> SO <sub>4</sub> )	5.46* (g/L H <sub>2</sub> SO <sub>4</sub> )	5.50 (g/L tartaric acid)	6.70 (g/L tartaric acid)
Volatile acidity (g/L H <sub>2</sub> SO <sub>4</sub> )	>1*	>1*	0.37	0.46
SO <sub>2</sub> Free (mg/L)	25	21	11.86	6.56
Total SO <sub>2</sub> (mg/L)	63	66	57.50	65.20
DO 420 (1 nm) (P.O. 10 mm)	-	-	2.50	2.50
DO 520(1 nm) (P.O. 10 mm)	1.145	0.916	3.70	3.61
DO 620(1 nm) (P.O. 10 mm)	0.164	0.126	0.41	0.41
DO280(1 nm) (P.O. 10 mm)	20.9	19.3	13.40	12.70

\*Due to a contamination of the samples, acidity data should be ignored.

Overall, no difference on wine qualitative analysis was noted between FGG01 applied at 0.1 kg/ha and reference standard applied in the same conditions. Only in trial no.1 a higher content of total acidity was noted vs. the reference, which is due to the contamination occurred in this trial. Indeed, the very high level of volatile acidity (>1; out of the range defined in the CEB method 143; and according to the COMMISSION REGULATION (EC) No 606/2009 of 10 July 2009 in which the limit of volatile acidity is fixed at 20 milli equivalents per litre for red wines = 0.98 g/L in H<sub>2</sub>SO<sub>4</sub>) is clearly the symptom of a possible contamination by acetobacter).

### 3.4.4.2.6 Processing results - Organoleptic assessment

#### ► Tasting of young wine

Tasting of young wine was carried out in the 2 trials, although as already mentioned, only the results from trial no.2 are exploitable and will be here presented. A summary of the results of the tasting test is presented in following Table 3.4-24.

**Table 3.4-24: Results of tasting of young wine**

Trial	Wine type	Taint test used	Number of tasters	Results
Trial no.2	Red wine	Triangular test	18	No difference

In the trial no.2 no differences on smell or taste were noticed by the assessors on the wine samples between FGG01 and reference product.

#### ► Tasting of wine after storage

Tasting of wine after storage was carried out in trial no.2. A summary of the results of the tasting tests is presented in Table 3.4-25.

**Table 3.4-25: Results of tasting of wine after storage**

Trial	Wine type	Taint test used	Number of tasters	Results
Trial no.2	Red wine	Triangular test	18	No difference

No significant difference was observed between wines from grapevines treated with FGG01 and wines from grapevines treated with the reference standard.

Thus, FGG01 had no significant negative effect on the organoleptic quality of wines after storage.

Furthermore, in the trial report, it was concluded that no negative effects on organoleptic quality of wines after storage due to FGG01 and reference standard were recorded.

### 3.4.4.2.7 Conclusion

Possible effects on the production and quality of red grape cultivars treated with FGG01 at the rate of 1.0 kg/ha (maximum rate requested) were examined in 2 trials carried out in France and Germany. Trials were carried out according to CEB guideline No.143 and EPPO standard No. PP 1/243. FGG01 was applied at 1.0 kg/ha and the reference CANTUS applied at 1.2 kg/ha was used as the reference standard.

The parameters assessed were the following:

- ripening of grapes at harvest or just after harvest,
- the analytical composition of the musts,
- fermentation process and malolactic fermentation,
- the analytical composition of the wines,
- organoleptic characteristics of the wines.

In these trials, FGG01 did not have any significant effect on grape physiology and qualitative parameters during the ripening period or on microbial activities during the fermentation.

The wines from trial no.2 were consistent with the specific properties and basic qualitative parameters typical for each variety tested. The wines did not reveal any significant deviation with regard to the main organoleptic parameters and during the testing session, no negative impact was identified compared to the reference standard.

No adverse effects on must, wine quality parameters is expected when FGG01 is applied at the maximum rate of 1.0 kg/ha with maximum of 1 application per season on red grapevine varieties (PHI 21).

A further two trials are in progress.

#### ZRMs comments:

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

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

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

Possible effects on the production and quality of red grape cultivars treated with FGG01 at the rate of 1.0 kg/ha (maximum rate requested) were examined in 2 trials carried out in France and Germany. A further two trials are in progress (from South France and Germany). The parameters assessed were the following: ripening of grapes at harvest or just after harvest, the analytical composition of the musts, fermentation process and malolactic fermentation, the analytical composition of the wines, organoleptic characteristics of the wines. No adverse effects on must, wine quality parameters is expected when FGG01 is applied at the maximum rate of 1.0 kg/ha with maximum of 1 application per season on red grapevine varieties (PHI 21).

*Peas and beans:* effective control of fungal pathogens allows for better plant health, leading to increased pod and seed development. Boscalid applications may affect the nutrient composition of seeds, such as protein content and essential amino acids, which are crucial for marketability. Optimal use of boscalid can lead to improved product quality and increased profitability for farmers. In the opinion of ZRMs, no undesirable effects are expected on transformation processes.

### **3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)**

FGG01 is a fungicide and has no herbicidal activity. Therefore, there is no requirement for the evaluation of secondary effect on plants for propagating purposes.

In addition, many products containing boscalid have been approved and widely used in many countries of Europe for the control of several diseases 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 FGG01 is used in accordance with good agricultural practices, including label instructions.**

#### **ZRMs comments:**

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

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

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

## **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 FGG01 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 FGG01 on succeeding crops would principally be related to the active substance. Boscalid has 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 Germany in 2022. Although no ER<sub>10</sub> 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 the boscalid product FGG01 according to the following guidelines:

- Efficacy evaluation of plant protection products - Effects on succeeding crops (EPPO PP 1/207 (2), 2007)
- OECD 208 (July 2006), Terrestrial Plant Test: Seedling Emergence and Growth Test

**Table 3.5.1-1: Study generating seedling emergence data for FGG01**

Year	Crop	Country	Official recognition: Y/N
2022	Wild cabbage (BRSOX), Carrot (DAUCA), Soybean (GLXMA), Lettuce (LACSA), Onion (ALLCE), Oat (AVESA)	Indoor pot trial Germany	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 FGG01 was prepared in deionised water, diluted to a concentration of 1000 g a.s./ha (2 kg product/ha) 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 EC<sub>10</sub> 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 28 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 sigmoidal 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.

The NOER (No Observed Effect Rate) for all species was found to be 1000 g a.s./ha (2 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 (g a.s./ha)
Wild cabbage	1000
Carrot	1000
Soybean	1000

Lettuce	1000
Onion	1000
Oat	1000

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 FGG01 is 1.0 kg/ha, corresponding to 500 g a.s./ha. As this amount is 50% lower than the NOER, then it is considered that there is no risk to all crop species tested. As boscalid has been used in Europe for many years and no effect on succeeding crops is known in Europe, it is considered that there is no risk to all succeeding or replacement crops.

**Therefore, no impact is expected on succeeding crops if FGG01 is used according to the Good Agricultural Practices and label recommendations.**

#### **ZRMs comments:**

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

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

### **3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)**

FGG01 is a fungicide and is not expected to have any significant herbicidal activity.

In addition, many products containing boscalid 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 2022, as described in Section 3.5.1.

In addition, a study of vegetative vigour conducted in Germany in 2022 has generated data on the effects of FGG01 on the growth and vigour of 6 indicator plant species, and these data used here to evaluate the risk to non-target crops. The study was carried out with the boscalid product FGG01 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 FGG01**

Year	Crop	Country	Official recognition Y/N
2022	Wild cabbage (BRSOX), Carrot (DAUCA), Soybean (GLXMA), Lettuce (LACSA), Onion (ALLCE), Oat (AVESA)	Indoor pot trial Germany	Y - GLP

Six different plant species were grown from the seeds, in pots containing standard soil type 2.3 (LUFA 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 FGG01 was prepared in deionised water, diluted to a concentration of 1000 g a.s./ha (2 kg product/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 sigmoidal 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 1000 g a.s./ha (2 kg product/ha). No effects were observed with regard to fresh weight.

**Table 3.5.2-4: Effects of FGG01 on vegetative vigour of treated plants.**

Species	NOER (g a.s./ha)
Wild cabbage	1000
Carrot	1000
Soybean	1000
Lettuce	1000
Onion	1000
Oat	1000

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 FGG01 is 1.0 kg/ha, corresponding to 500 g a.s./ha. As this amount is 50% lower than the NOER, then it is considered that there is no risk to all crop species

tested. As boscalid has been used in Europe for many years and no effect on adjacent crops is known in Europe, it is considered that there is no risk to all adjacent crops.

**Therefore, no impact on adjacent crops is expected if FGG01 is used according to the Good Agricultural Practices and label recommendations.**

**ZRMs comments:**

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

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

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

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

**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 FGG01 tank residues. Nevertheless, a detailed analysis follows.

**Estimate of FGG01 residues in pesticide application equipment (PAE)**

The amount of FGG01 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 FGG01 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 1.0 kg product/ha, applied in a minimum water volume of 100 L/ha, which is a worst-case scenario.

Calculation:

Amount of a.s. in 1000 L sprayer (assuming 100 L/ha water volume)	$1000/100 = 10$ $10 \times 1.0 \text{ L/ha} = 10 \text{ L/ha}$	10 L product
Amount left after spraying (2.6%)	$10/100 \times 2.6 = 0.26 \text{ L}$	0.26 L product
Amount left after 1 wash procedure (2.6%)	$0.26/100 \times 2.6 = 0.00676 \text{ L}$	0.00676 L product
Amount left after 2 wash procedures (2.6%)	$0.00676/100 \times 2.6 = 0.0001757 \text{ L}$	0.00018 L product

Amount after re-filling sprayer (1000 L)	-	With no washing = 0.26 L product After 1 wash = 0.00676L product After 2 washes = 0.00018 L product
Dose applied (at 400 L/ha) to 2.5 ha	0.26/2.5 0.00676/2.5 0.00018/2.5	0.104 L product/ha 0.0027 L product/ha 0.00001 L product/ha

### Risk assessment for impact on non-target plants

Seedling emergence and vegetative vigour data have been generated in laboratory studies carried out with FGG01 in Germany in 2022.

**Table 3.5.2-6: Seedling emergence and vegetative vigour data for FGG01**

Species	Seedling emergence	Vegetative vigour
	NOER (kg product/ha)	NOER (L test item/ha)
Wild cabbage	1.0	1.0
Carrot	1.0	1.0
Soybean	1.0	1.0
Lettuce	1.0	1.0
Onion	1.0	1.0
Oat	1.0	1.0

The NOER (No Observed Effect Rate) for all species was found to be 1000 g a.s./ha (2 kg product/ha).

The estimated amount of FGG01 residues applied in a subsequent commercial spray operation is 0.104 L product/ha with no tank washing, and 0.0027 L product/ha or 0.00001 L product/ha after 1 or 2 rinses, respectively. Therefore, following no tank washing the estimated amount of FGG01 in a subsequent treatment is 0.0027 L product/ha, which is over 9.6 times less than that needed to have No Observable Effect on all test species.

Based on a worst-case estimate of residual FGG01 in PAE, and worst-case NOER values for FGG01 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 FGG01. As boscalid has 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.

#### ZRMs comments:

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

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

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

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



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

### 3.6 Other/special studies

No further information is available.

**ZRMs comments:** Statement accepted.

### 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](http://www.gepcertibase.eu)).

**Table 3.7-1: List of test facilities**

Testing facilities	Address	Years of trials	GEP Statues	Link of GEP Certibase
AGRECO Sp. z o.o.	Al. Lipowa 21 Iok. 1 53-124 Wrocław Poland	2023	GEP	<a href="#">1d6cba36575</a>
AGRI 2000 Net S.r.l.	Via Marabini, 14 I-40013 Castel Maggiore (BO) Italy	2023	GEP	<a href="#">ro32LVB41e</a>
AGRI 2000 Net	5 rue de Lombardie 69800 St Priest France	2024	GEP	<a href="#">Link (07/2022-07/2024)</a> <a href="#">Link (07/2024-07/2027)</a>
Agrolab	Røjleskovvej 18 DK-5500 Middelfart Denmark	2023	GEP	<a href="#">1d6cba364d2</a>
Agrolis Consulting	8 bis rue du Lac - ZA Pechnaugué Nord Lot 9 31340 Villemur sur Tarn France	2023	GEP	<a href="#">10GNJ8Opd3</a>
Agrolis Consulting	ZA La Grande Marine - 185 Avenue André Ampère 84800 L'Isle - sur - la - Sorgue France	2023	GEP	<a href="#">10GNJ8Opd3</a>
Agrolis Consulting	Via Fontanelle, 52 I-37055 Ronco all'Adige (VR) Italy	2023	GEP	<a href="#">ro32Ljw41e</a>
Biotek Agriculture Hungary Kft.	Martirok utja 1-3 2013 Pomaz Hungary	2021	GEP	<a href="#">1d5a52adbdd</a>
Eurofins Agroscience Services Sp. z o.o	Kaźmierz, ul. Parkowa 6 64-503 Kaźmierz Poland	2022	GEP	<a href="#">1d6196273c6</a>
Eurofins Agrosciences Services	Carl-Goerdeler-Weg 5 D-21684 Stade Germany	2022	GEP	<a href="#">GgA4DE3pvO</a>
Eurofins Agrosciences Services	Parque Industrial Parque Plata Camino Empedrado 37-39 E-41900 Camas (Sevilla) Spain	2022	GEP	<a href="#">BL9pqV62GA</a>
Eurofins Agrosciences Services	Rudolfstrabbe 21 8010 Graz Austria	2022	GEP	<a href="#">zRwpbyB4yO</a>
Hiebler Agricultural Engineering	Pöllau 21 8311 Markt Hartmannsdorf Austria	2023	GEP	<a href="#">GgA4D0G4vO</a>
Oxford Agricultural Trials Ltd.	West Farm Barn, Launton Rd, Strtton Audley OX27 Bicester United Kingdom	2023	GEP	<a href="#">1d656d02a4b</a>
Phyttest Hispania S.L.	Calle Aljarafe, 19 41102 Coria del Río (Sevilla) Spain	2023	GEP	<a href="#">walNVIOPr</a>
Proefstation voor de Groenteteelt	Duffelsesteenweg 101 2860 Sint Katelijne Waver Belgium	2023	GEP	<a href="#">7zE2xDm2Rl</a>
SAGEA Centro di Saggio s.r.l.	Via San Sudario, 15 I-12050 Castagnito d'Alba (CN) Italy	2022	GEP	<a href="#">Y8z4Y3w23R</a>
SAGEA Centro di Saggio s.r.l.	Via San Sudario, 15 I-12050 Castagnito d'Alba (CN) Italy	2023	GEP	<a href="#">Y8z4Y3w23R</a>
Staphyt Austria GmbH	Am Futerplatz 1 2471 Rohrau Austria	2023	GEP	<a href="#">L1y2e3W4QJ</a>

Testing facilities	Address	Years of trials	GEP Statues	Link of GEP Certibase
Staphyt	23 Route de Moeuvres 62860 Inchy en Artois France	2023	GEP	<a href="#">Y8z4YLN3Rn</a>
Staphyt	Langenburger Str. 35 D-74572 Blaufelden-Herrentierbach Germany	2023	GEP	<a href="#">lqPpwV34gD</a>
Staphyt	Corso di Porta Nuova, 15 20121 Milano Italy	2023	GEP	<a href="#">Qow2GaZ4RO</a>
SynTech Research Czech S.R.O	Zitná 562/10, Nové Mesto 120 00 Praha Czech Republic	2023	GEP	<a href="#">5Z32o0ONdE</a>
SynTech Research France	613 Route du Bois de Loyse 71570 La Chapelle de Guinchay France	2023	GEP	<a href="#">Y8z4YLN3Rn</a>
SynTech Research Germany GmbH	Loofter Str. 9 25593 Christenthal Germany	2023	GEP	<a href="#">k8DNKDV4mA</a>
SynTech Research Hungary Kft.	Széchenyi u. 132/A H-2141 Csömör Hungary	2021	GEP	<a href="#">x7a4RP82jV</a>
SynTech Research Italy	Via Colombarotto, 38 40026 Imola (BO) Italy	2023	GEP	<a href="#">Ae12X77p95</a>
SynTech Research Poland Sp. z o.o.	ul. Jagiellońska 69/1 85-027 Bydgoszcz Poland	2021	GEP	<a href="#">Waj4vGpPBV</a>
SynTech Research Portugal	Rua António Oliveira, N.º 21-L, Zona Industrial das Caldas da Rainha 2500-916 Caldas da Rainha Portugal	2021	GEP	<a href="#">7XA2n0B4VK</a>
SynTech Research Spain	Camino Horts 46210 Picanya Spain	2023	GEP	<a href="#">jgK2WBZp6v</a>
SynTech Research UK	Pakenham Suffolk United Kingdom	2023	GEP	<a href="#">zKoNamXNLr</a>
Verify	Proeftuin Zwaagdijk Tolweg 13 1681 ND Zwaagdijk-Oost Netherlands	2023	GEP	<a href="#">GEP4Owa4b0</a>

## Appendix 1 Lists of data considered in support of the evaluation

### List of data submitted

Annex point/reference number (OECD-Format)	Author	Year	Title Source (where different from company) Company, Report No. Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
3.2 3.4	UPL Holdings Coöperatief	2023	Biological Assessment Dossier (BAD): KCP Section 6: Efficacy Data and Information, Detailed Summary. Product code: FGG01 Product name: Lozzare Pro, Miller Pro, Palator Pro Central Registration zone (zRMS Poland) Core Assessment UPL Holdings Coöperatief. n/a n/a Unpublished	N	Y	New study	UPL
3.2.2 3.2.3 3.4.1	Maluga, P.	2021	The efficacy of FGG01 applied in OSR for the control of <i>Sclerotinia sclerotiorum</i> (SCLESC) in Europe, 2021. SynTech Research Poland Sp. z o.o., Bydgoszcz, Poland, Report No. SRPL21-329-129FE Report No. <b>F21EU-024-011-004</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.2 3.2.3 3.4.1	Potocka, K.	2021	The efficacy of FGG01 applied in OSR for the control of <i>Sclerotinia sclerotiorum</i> (SCLESC) in Europe, 2021. SynTech Research Poland Sp. z o.o., Bydgoszcz, Poland, Report No. SRPL21-330-129FE Report No. <b>F21EU-024-011-005</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.2 3.2.3 3.4.1	Ćwiek, M.	2021	The efficacy of FGG01 applied in OSR for the control of <i>Sclerotinia sclerotiorum</i> (SCLESC) in Europe, 2021. SynTech Research Poland Sp. z o.o., Bydgoszcz, Poland, Report No. SRPL21-331-129FE Report No. <b>F21EU-024-011-006</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.2 3.2.3 3.4.1	Furman-Frątczak, K.	2023	The efficacy of FGG01 and FGG04 applied for the control of <i>Sclerotinia sclerotiorum</i> on winter oilseed rape in Poland, 2023. AGRECO Sp. z o.o., Wrocław, Poland, Report No. 23UPL01294-1 Report No. <b>F23EU-045-AMA-007</b> UPL GEP Unpublished	N	Y	New study	UPL

Annex point/reference number (OECD-Format)	Author	Year	Title Source (where different from company) Company, Report No. Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
3.2.2 3.2.3 3.4.1 3.4.2	Furman-Frątczak, K.	2023	The efficacy of FGG01 and FGG04 applied for the control of <i>Sclerotinia sclerotiorum</i> on winter oilseed rape in Poland, 2023 AGRECO Sp. z o.o., Wrocław, Poland, Report No. 23UPL01294-2 Report No. <b>F23EU-045-AMA-008</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.2 3.2.3 3.4.1	Furman-Frątczak, K.	2023	The efficacy of FGG01 and FGG04 applied for the control of <i>Sclerotinia sclerotiorum</i> on winter oilseed rape in Poland, 2023. AGRECO Sp. z o.o., Wrocław, Poland, Report No. 23UPL01294-3 Report No. <b>F23EU-045-AMA-009</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.2 3.2.3 3.4.1	Furman-Frątczak, K.	2023	The efficacy of FGG01 and FGG04 applied for the control of <i>Sclerotinia sclerotiorum</i> on winter oilseed rape in Poland, 2023. AGRECO Sp. z o.o., Wrocław, Poland, Report No. 23UPL01294-4 Report No. <b>F23EU-045-AMA-010</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.2 3.2.3 3.4.1	Maciej, K.	2021	The efficacy of FGG01 applied in OSR for the control of <i>Plenodomus lingam</i> (LEPTMA) in Europe, 2021 SynTech Research Poland Sp. z o.o., Bydgoszcz, Poland, Report No. SRPL21-332-129FE Report No. <b>F21EU-025-011-004</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.2 3.2.3 3.4.1	Potocka, K.	2021	The efficacy of FGG01 applied in OSR for the control of <i>Plenodomus lingam</i> (LEPTMA) in Europe, 2021 SynTech Research Poland Sp. z o.o., Bydgoszcz, Poland, Report No. SRPL21-333-129FE Report No. <b>F21EU-025-011-005</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.2 3.2.3 3.4.1	Świtkowski, M.	2021	The efficacy of FGG01 applied in OSR for the control of <i>Plenodomus lingam</i> (LEPTMA) in Europe, 2021 SynTech Research Poland Sp. z o.o., Bydgoszcz, Poland, Report No. SRPL21-334-129FE Report No. <b>F21EU-025-011-006</b> UPL GEP Unpublished	N	Y	New study	UPL

Annex point/reference number (OECD-Format)	Author	Year	Title Source (where different from company) Company, Report No. Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
3.2.2 3.2.3 3.4.1	Dimon, C.	2022	The efficacy of FGG01 applied in OSR for the control of <i>Plenodomus lingam</i> (LEPTMA) in Europe. Eurofins Agroscience Services Sp. z o.o., Kazmierz, Poland, Report No. S22-01827-01 Report No. <b>F22EU-002-AMA-001</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.2 3.2.3 3.4.1	Dimon, C.	2022	The efficacy of FGG01 applied in OSR for the control of <i>Plenodomus lingam</i> (LEPTMA) in Europe. Eurofins Agroscience Services Sp. z o.o., Kazmierz, Poland, Report No. S22-01827-02 Report No. <b>F22EU-002-AMA-002</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.2 3.2.3 3.4.1	Furman-Frątczak, K.	2023	The efficacy of FGG01 and FGG04 applied in winter oilseed rape for the control of <i>Plenodomus lingam</i> (LEPTMA) in Europe. Poland 2023, North-East EPPO Zone. AGRECO Sp. z o.o., Wrocław, Poland, Report No. 24UPL01368-1 Report No. <b>F23EU-046-AMA-003</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.2 3.2.3 3.4.1	Furman-Frątczak, K.	2023	The efficacy of FGG01 and FGG04 applied in winter oilseed rape for the control of <i>Plenodomus lingam</i> (LEPTMA) in Europe. Poland 2023, North-East EPPO Zone. AGRECO Sp. z o.o., Wrocław, Poland, Report No. 24UPL01368-2 Report No. <b>F23EU-046-AMA-004</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.2 3.2.3 3.4.1	Furman-Frątczak, K.	2023	The efficacy of FGG01 and FGG04 applied in winter oilseed rape for the control of <i>Plenodomus lingam</i> (LEPTMA) in Europe. Poland 2023, North-East EPPO Zone. AGRECO Sp. z o.o., Wrocław, Poland, Report No. 24UPL01368-3 Report No. <b>F23EU-046-AMA-005</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.2 3.2.3 3.4.1	Furman-Frątczak, K.	2023	The efficacy of FGG01 and FGG04 applied in winter oilseed rape for the control of <i>Plenodomus lingam</i> (LEPTMA) in Europe. Poland 2023, North-East EPPO Zone. AGRECO Sp. z o.o., Wrocław, Poland, Report No. 24UPL01368-4 Report No. <b>F23EU-046-AMA-006</b> UPL GEP Unpublished	N	Y	New study	UPL

Annex point/reference number (OECD-Format)	Author	Year	Title Source (where different from company) Company, Report No. Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
3.2.2 3.2.3 3.4.1	Fejes, A.	2021	The efficacy of FGG01 applied in OSR for the control of <i>Plenodomus lingam</i> (LEPTMA) in Hungary. SynTech Research Hungary Kft., Csömör, Hungary, Report No. GEP 21/153 Report No. <b>F21EU-025-011-001</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.2 3.2.3 3.4.1	Ettig, B.	2021	The efficacy of FGG01 applied in OSR for the control of <i>Plenodomus lingam</i> (LEPTMA) in Hungary. SynTech Research Hungary Kft., Csömör, Hungary, Report No. GEP 21/154 Report No. <b>F21EU-025-011-002</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.2 3.2.3 3.4.1	Ettig, B.	2021	The efficacy of FGG01 applied in OSR for the control of <i>Plenodomus lingam</i> (LEPTMA) in Hungary. SynTech Research Hungary Kft., Csömör, Hungary, Report No. GEP 21/155 Report No. <b>F21EU-025-011-003</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.2 3.2.3 3.4.1	Heinzmann, S.	2022	The efficacy of FGG01 applied preventive against powdery mildew ( <i>Erysiphe necator</i> ) in grapevine in Europe. Eurofins Agrosience Services Germany, Stade Germany, Report No. S22-01830-02 Report No. <b>F22EU-004-AMA-002</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.2 3.2.3 3.4.1	Schönhofen-Müller, M.	2022	The efficacy of FGG01 applied preventive against powdery mildew ( <i>Erysiphe necator</i> ) in grapevine in Europe. Eurofins Agrosience Services Germany, Stade, Germany, Report No. S22-01830-03 Report No. <b>F22EU-004-AMA-003</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.2 3.2.3 3.4.1	Beber, M.	2022	The efficacy of FGG01 applied preventive against powdery mildew ( <i>Erysiphe necator</i> ) in grapevine in Europe. Eurofins Agrosience Services Austria, Graz, Austria, Report No. S22-01830-04 Report No. <b>F22EU-004-AMA-004</b> UPL GEP Unpublished	N	Y	New study	UPL

Annex point/reference number (OECD-Format)	Author	Year	Title Source (where different from company) Company, Report No. Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
3.2.2 3.2.3 3.4.1	Beber, M.	2022	The efficacy of FGG01 applied preventive against powdery mildew ( <i>Erysiphe necator</i> ) in grapevine in Europe. Eurofins Agrosience Services Austria, Graz, Austria, Report No. S22-01830-05 Report No. <b>F22EU-004-AMA-005</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.2 3.2.3 3.4.1	Gröss-Ahr, K.	2023	GEP efficacy trial of FGG01 and FGG04 applied preventive against powdery mildew ( <i>Erysiphe necator</i> ) in grapevine in Europe, GERMANY 2023. Staphyt, Blaufelden-Herrentierbach, Germany, Report No. MKH-23-105476-01-DE02 Report No. <b>F23EU-044-AMA-001</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.2 3.2.3 3.4.1	Notterpek , J.	2023	GEP efficacy trial of FGG01 and FGG04 applied preventive against powdery mildew ( <i>Erysiphe necator</i> ) in grapevine in Europe, AUSTRIA 2023. Staphyt, Rohrau, Austria, Report No. MKH-23-105476-01-AT03 Report No. <b>F23EU-044-AMA-002</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.2 3.2.3 3.4.1	Hiebler, A.	2023	The efficacy of FGG01 and FGG04 applied preventive against powdery mildew ( <i>Erysiphe necator</i> ) in grapevine in Europe Hiebler Agricultural Engineering , Markt Hartmannsdorf, Austria, Report No. FRS121/23-V3-AT Report No. <b>F23EU-044-AMA-005</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.2 3.2.3 3.4.1	Hiebler, A.	2023	The efficacy of FGG01 and FGG04 applied preventive against powdery mildew ( <i>Erysiphe necator</i> ) in grapevine in Europe Hiebler Agricultural Engineering , Markt Hartmannsdorf, Austria, Report No. FRS121/23-V4-AT Report No. <b>F23EU-044-AMA-006</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.2 3.2.3 3.4.1	Štrbac, S.	2023	The efficacy of FGG01 and FGG04 applied preventive against powdery mildew ( <i>Erysiphe necator</i> ) in grapevine in Europe 2023. SynTech Research Germany GmbH, Lößtin, Germany, Report No. EU-23-0691-01 Report No. <b>F23EU-044-AMA-007</b> UPL GEP Unpublished	N	Y	New study	UPL



Annex point/reference number (OECD-Format)	Author	Year	Title Source (where different from company) Company, Report No. Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
3.2.2 3.2.3 3.4.1	Štrbac, S.	2023	The efficacy of FGG01 and FGG04 applied preventive against powdery mildew ( <i>Erysiphe necator</i> ) in grapevine in Europe 2023. SynTech Research Germany GmbH, Löptin, Germany, Report No. EU-23-0691-02 Report No. <b>F23EU-044-AMA-008</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Eigaard, T.	2023	The efficacy of FGG01 and FGG04 applied in OSR for the control of <i>Sclerotinia sclerotiorum</i> (SCLESC) in Europe. Agrolab, Middelfart, Denmark, Report No. FRS122/23-V2-DK Report No. <b>F23EU-045-AMA-002</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Torturu, F.	2023	The efficacy of FGG01 and FGG04 applied in OSR for the control of <i>Sclerotinia sclerotiorum</i> (SCLESC) in Europe. Oxford Agricultural Trials Ltd., Bicester, United Kingdom, Report No. FRS122/23-V3-UK Report No. <b>F23EU-045-AMA-005</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Laplace, B.	2023	The efficacy of FGG01 and FGG04 applied in OSR for the control of <i>Botrytis cinerea</i> . SynTech Research France, La Chapelle-de-Guinchay, France, Report No. EU-23-0693-01 Report No. <b>F23EU-048-AMA-001</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Zhaojun, L.	2024	Evaluate the efficacy of FGG01 and FGG04 applied in OSR for the control of <i>Sclerotinia sclerotiorum</i> in Europe, 2024. AGRI 2000 France, Saint Priest, France, Report No. AFR24-033-116FE Report No. <b>F24EU-002-MAN-003</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Zhaojun, L.	2024	Evaluate the efficacy of FGG01 and FGG04 applied in OSR for the control of <i>Sclerotinia sclerotiorum</i> in Europe, 2024. AGRI 2000 France, Saint Priest, France, Report No. AFR24-034-116FE Report No. <b>F24EU-002-MAN-004</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Biró, A.	2021	The efficacy of FGG01 applied in OSR for the control of <i>Sclerotinia sclerotiorum</i> (SCLESC) in Hungary 2021.	N	Y	New study	UPL

Annex point/reference number (OECD-Format)	Author	Year	Title Source (where different from company) Company, Report No. Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			BioteK Agriculture Hungary Kft., Pomaz, Hungary, Report No. GEP 21/150 Report No. <b>F21EU-024-011-001</b> UPL GEP Unpublished				
3.2.3 3.4.1	Biró, A.	2021	The efficacy of FGG01 applied in OSR for the control of <i>Sclerotinia sclerotiorum</i> (SCLESC) in Hungary 2021. BioteK Agriculture Hungary Kft., Pomaz, Hungary, Report No. GEP 21/151 Report No. <b>F21EU-024-011-002</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Ettig, B.	2021	The efficacy of FGG01 applied in OSR for the control of <i>Sclerotinia sclerotiorum</i> (SCLESC) in Hungary 2021. BioteK Agriculture Hungary Kft., Pomaz, Hungary, Report No. GEP 21/152 Report No. <b>F21EU-024-011-003</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Siebold, M.	2023	The efficacy of FGG01 and FGG04 applied in OSR for the control of <i>Alternaria brassicae</i> (ALTEBA) in Europe. Verify, Zwaagdijk-Oost, Netherlands, Report No. FRS123/23-V1-BE Report No. <b>F23EU-047-AMA-001</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Siebold, M.	2023	The efficacy of FGG01 and FGG04 applied in OSR for the control of <i>Alternaria brassicae</i> (ALTEBA) in Europe. Verify, Zwaagdijk-Oost, Netherlands, Report No. FRS123/23-V2-BE Report No. <b>F23EU-047-AMA-002</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Hiebler, A.	2023	The efficacy of FGG01 and FGG04 applied preventive against <i>Botrytis cinerea</i> in grapevine in Europe. Hiebler Agricultural Engineering, Markt Hartmannsdorf, Austria, Report No. FRS120/23-V3-AT Report No. <b>F23EU-042-AMA-003</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Hiebler, A.	2023	The efficacy of FGG01 and FGG04 applied preventive against <i>Botrytis cinerea</i> in grapevine in Europe. Hiebler Agricultural Engineering, Markt Hartmannsdorf, Austria, Report No. FRS120/23-	N	Y	New study	UPL

Annex point/reference number (OECD-Format)	Author	Year	Title Source (where different from company) Company, Report No. Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			V4-AT Report No. <b>F23EU-042-AMA-004</b> UPL GEP Unpublished				
3.2.3 3.4.1	GRÖß-Ahr, K.	2023	GEP efficacy trial of FGG01 and FGG04 applied preventive against <i>Botrytis cinerea</i> in grapevine, Europe GERMANY 2023 Staphyt, Blaufelden-Herrentierbach, Germany, Report No. MKH-23-105475-01-DE02 Report No. <b>F23EU-042-AMA-006</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Martínez, L.	2021	The efficacy and selectivity of FGG01 applied preventive against <i>Botrytis cinerea</i> in grapevine in Portugal - EPOMED - 2021 SynTech Research Portugal, Caldas da Rainha, Portugal, Report No. SRPT21-070-038FE Report No. <b>F21EU-022-011-001</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Martínez, L.	2021	The efficacy and selectivity of FGG01 applied preventive against <i>Botrytis cinerea</i> in grapevine in Portugal - EPOMED - 2021 SynTech Research Portugal, Caldas da Rainha, Portugal, Report No. SRPT21-079-038FE Report No. <b>F21EU-022-011-002</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Boyer, C.	2023	The efficacy of FGG01 and FGG04 applied preventive against <i>Botrytis cinerea</i> in grapevine in Europe. Agrolis Consulting, Villeneuve-Lez-Avignon, France, Report No. AGL23FR224 Report No. <b>F23EU-041-AMA-001</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Tessari, F.	2023	The efficacy of FGG01 and FGG04 applied preventive against <i>Botrytis cinerea</i> in grapevine in Europe. Agrolis Consulting, Ronco all'Adige (VR), Italy, Report No. AGL23IT024 Report No. <b>F23EU-041-AMA-003</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Valori, R.	2023	GEP efficacy trial of FGG01 and FGG04 applied preventive against <i>Botrytis cinerea</i> in grapevine in Europe, ITALY, 2023	N	Y	New study	UPL

Annex point/reference number (OECD-Format)	Author	Year	Title Source (where different from company) Company, Report No. Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Staphyt, Milano, Italy, Report No. MKH-23-105475-01-IT01 Report No. <b>F23EU-041-AMA-004</b> UPL GEP Unpublished				
3.2.3 3.4.1	Japón, P.P.	2023	Field study to evaluate the efficacy and selectivity of FGG01 and FGG04 for the control of <i>Botrytis cinerea</i> in grapevines in Spain during 2023. Phyttest Hispania S.L., Coria del Rio, Spain, Report No. F23EU-041-AMA Report No. <b>F23EU-041-AMA-005</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Farinetti, P.	2022	The efficacy of FGG01 applied preventive against powdery mildew ( <i>Erysiphe necator</i> ) in grapevine in Europe. SAGEA Centro di Saggio s.r.l., Castagnito d'Alba (CN), Italy, Report No. 306.F.SAG22/e Report No. <b>F22EU-004-AMA-007</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Rauscher, C.	2023	The efficacy of FGG01 and FGG04 applied preventive against powdery mildew ( <i>Erysiphe necator</i> ) in grapevine in Europe Agrolis consulting, L'Isle - sur - la - Sorgue, France, Report No. AGL23FR225 Report No. <b>F23EU-043-AMA-001</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Ruel, F.	2023	The GEP efficacy of FGG01 and FGG04 applied preventive against powdery mildew ( <i>Erysiphe necator</i> ) in grapevine in Europe, FRANCE 2023 Staphyt, Inchy-en-Artois, France, Report No. MKH-23-105476-01-FR01 Report No. <b>F23EU-043-AMA-002</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Tessari, F.	2023	The efficacy of FGG01 and FGG04 applied preventive against powdery mildew ( <i>Erysiphe necator</i> ) in grapevine in Europe Agrolis consulting, Ronco all'Adige (VR), Italy, Report No. AGL23IT025 Report No. <b>F23EU-043-AMA-003</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Stefani, F.	2023	The efficacy of FGG01 and FGG04 applied preventive against powdery mildew ( <i>Erysiphe necator</i> ) in grapevine in Europe SynTech Research Italy, Imola , Italy Report No. EU-23-0690-03	N	Y	New study	UPL

Annex point/reference number (OECD-Format)	Author	Year	Title Source (where different from company) Company, Report No. Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report No. <b>F23EU-043-AMA-004</b> UPL GEP Unpublished				
3.2.3 3.4.1	Japón, P.P.	2023	Field study to evaluate the efficacy and selectivity of FGG01 and FGG04 for the control of powdery mildew ( <i>Erysiphe necator</i> ) in grapevines in Spain during 2023. Phytest Hispania S.L., Coria del Rio, Spain, Report No. Report No. <b>F23EU-043-AMA-005</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Sánchez, M.	2023	The efficacy of FGG01 and FGG04 applied preventive against powdery mildew ( <i>Erysiphe necator</i> ) in grapevine in Europe SynTech Research Spain, Picanya, Spain, Report No. EU-23-0690-02 Report No. <b>F23EU-043-AMA-006</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1 3.4.2	Jarlaud, A.	2022	The efficacy of FGG01 applied in peas and beans for the control of Botrytis (BOTRSP) in Europe. Eurofins Agroservices, Stade, Germany, Report No. S22-01824-02 Report No. <b>F22EU-006-AMA-002</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.2 3.2.3 3.4.1	Charton, A.	2023	GEP efficacy trial of FGG01 and FGG04 applied in peas and beans for the control of Botrytis (BOTRSP) in Europe STAPHYT, Inchy en Artois, France , Report No. MKH-23-105482-01-FR02 Report No. <b>F23EU-049-AMA-007</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1 3.4.2	Dada, K.	2023	Evaluate the efficacy of FGG01 and FGG04 applied in peas and beans for the control of Botrytis (BOTRSP) in Europe. SynTech Research Czech S.R.O, Semcice, Czech Republic, Report No. EU-23-0694-04 Report No. <b>F23EU-049-AMA-008</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Sumner, K.	2023	The efficacy of FGG01 and FGG04 applied in peas and beans for the control of Botrytis (BOTRSP) in Europe. SynTech Research UK, Hopton, United Kingdom, Report No. EU-23-0694-05 Report No. <b>F23EU-049-AMA-009</b> UPL	N	Y	New study	UPL

Annex point/reference number (OECD-Format)	Author	Year	Title Source (where different from company) Company, Report No. Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP Unpublished				
3.2.3 3.4.1	Venneman, S.	2023	The efficacy of FGG01 and FGG04 applied in peas and beans for the control of Botrytis (BOTRSP) in Europe. Proefstation voor de Groenteteelt, Sint-Katelijne-Waver, Belgium, Report No. FRS125/23-BE Report No. <b>F23EU-049-AMA-010</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Japón, P.P.	2023	Field study to evaluate the efficacy and selectivity of FGG01 and FGG04 for the control of <i>Botrytis cinerea</i> in beans in Spain during 2023. Phytest Hispania S.L., Coria del Rio, Spain. Report No. <b>F23EU-049-AMA-001</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Japón, P.P.	2023	Field study to evaluate the efficacy and selectivity of FGG01 and FGG04 for the control of <i>Botrytis cinerea</i> in beans in Spain during 2023. Phytest Hispania S.L., Coria del Rio, Spain. Report No. <b>F23EU-049-AMA-002</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Rial, F.J.	2023	Evaluate the efficacy of FGG01 and FGG04 applied in peas and beans for the control of Botrytis (BOTRSP) in Europe.2023 SynTech Research Spain, Pincayia, Spain, Report No. EU-23-0694-01 Report No. <b>F23EU-049-AMA-003</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Brohard, C.	2023	GEP efficacy trail of FGG01 and FGG04 applied in peas and beans for the control of Botrytis (BOTRSP) in Europe, FRANCE 2023 STAPHYT, Inchy-en-Artois, France, Report No. MKH-23-105482-01-FR01 Report No. <b>F23EU-049-AMA-006</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Charton, A.	2023	GEP efficacy trial of FGG01 and FGG04 applied in peas and beans for the control of Sclerotinia (SCLESP) in Europe FRANCE, 2023 STAPHYT, Inchy-en-Artois, France, Report No. MKH-23-105484-01-FR03 Report No. <b>F23EU-050-AMA-007</b> UPL	N	Y	New study	UPL

Annex point/reference number (OECD-Format)	Author	Year	Title Source (where different from company) Company, Report No. Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP Unpublished				
3.2.3 3.4.1	Venneman, S.	2023	The efficacy of FGG01 and FGG04 applied in peas and beans for the control of Sclerotinia (SCLESP) in Europe. Proefstation voor de Groenteteelt, Sint-Katelijne-Waver, Belgium, Report No. FRS127/23-BE Report No. <b>F23EU-050-AMA-011</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Marin, C.	2022	The efficacy of FGG01 applied in peas and beans for the control of Sclerotinia (SCLESP) in Europe. Eurofins Agroservices Services, Sevilla, Spain, Report No. S22-01825-06 Report No. <b>F22EU-007-AMA-006</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Japón, P.P.	2023	Field study to evaluate the efficacy and selectivity of FGG01 and FGG04 for the control of <i>Sclerotinia sp.</i> in beans in Spain during 2023. Phytest Hispania S.L., Coria del Rio. Report No. <b>F23EU-050-AMA-001</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Japón, P.P.	2023	Field study to evaluate the efficacy and selectivity of FGG01 and FGG04 for the control of <i>Sclerotinia sp.</i> in beans in Spain during 2023. Phytest Hispania S.L., Coria del Rio. Report No. <b>F23EU-050-AMA-002</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Rial, F.J.	2023	Evaluate the efficacy of FGG01 and FGG04 applied in peas and beans for the control of Sclerotinia (SCLESP) in Europe.2023 SynTech Research Spain, Picanya, Spain, Report No. EU-23-0695-01 Report No. <b>F23EU-050-AMA-003</b> UPL GEP Unpublished	N	Y	New study	UPL
3.2.3 3.4.1	Rial, X.	2023	The efficacy of FGG01 and FGG04 applied in peas and beans for the control of Sclerotinia (SCLESP) in Europe. SynTech Research Spain, Picanya, Spain, Report No. EU-23-0695-07 Report No. <b>F23EU-050-AMA-005</b> UPL	N	Y	New study	UPL

Annex point/reference number (OECD-Format)	Author	Year	Title Source (where different from company) Company, Report No. Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP Unpublished				
3.4.1 3.4.3	Heinzmann, S.	2022	Evaluation of unintentional effects of FGG01 on fermentation processes and characteristics of wine, 1 Site in Germany 2022-2024 Eurofins Agroservices Services, Stade, Germany, Report No. S22-01828-01 Report No. <b>F22EU-005-AMA-001</b> UPL GEP Unpublished	N	Y	New study	UPL
3.4.1 3.4.3	Farinetti, P.	2022	Unintentional effects of FGG01 on wine making process SAGEA Centro di Saggio s.r.l., Castagnito d'Alba (CN), Italy, Report No. 308.V.SAG22/e Report No. <b>F22EU-005-AMA-002</b> UPL GEP Unpublished	N	Y	New study	UPL
3.5.1	S. Stürtz & C. Horstmann	2022	Boscalid 500 WG: Effects on Terrestrial (Non-Target) Plants: Seedling Emergence and Seedling Growth Test Ibacon GmbH, Rossdorf, Germany, Report No. 165091086 Report No. <b>UPL/2022/0597</b> UPL GLP Unpublished	N	Y	New study	UPL
3.5.2	S. Stürtz & C. Horstmann	2022	Boscalid 500 WG: Effects on Terrestrial (Non-Target) Plants: Vegetative Vigour Test Ibacon GmbH, Rossdorf, Germany, Report No. 165091087 Report No. <b>UPL/2022/0598</b> UPL GLP Unpublished	N	Y	New study	UPL



