

REGISTRATION REPORT
Part B
Section 3
Efficacy Data and Information
Concise summary

Product name(s): **INTUITY PLUS**
(Mandestrobin 40 SC)

Chemical active substance:
Mandestrobin, 400 g/L

Central Zone
Zonal Rapporteur Member State: Poland

CORE ASSESSMENT
(authorisation)

Applicant: XXXX
Submission date: February 2024
Evaluation date: January 2025
Finalisation date: August 2025

Version history

When	What
February 2024	Article 33 submission – Initial Applicant’s version
May 2024	- Update of the cover page with the product trade name ‘Intuity Plus’. Mandestrobin 40 SC is the internal unique name. The internal name Mandestrobin 40 SC is the one used across the dRR content. - Update of Appendix 1: studies owner updated
January 2025	zRMS-PL evaluation
August 2025	Update of the section “3.3 Resistance risk” following cMS comment

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

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

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 such as the following:

Comments of zRMS:	The commenting boxes are filled-in by the zRMS. They are usually placed at the end of each chapter. Commenting boxes should be understandable alone and refer very precisely to the text commented. The main advantage of their use is to distinguish easily between the applicant and the zRMS text.
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3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

Mandestrobin 40SC is proposed for use as a systemic contact fungicide with preventative and curative action, for the control of *Sclerotinia sclerotiorum* on winter and spring oilseed rape. The dossier is based on the bridging between the two formulations, Mandestrobin 40SC (mandestrobin 400 g/L) and Mandestrobin 25SC (250 g/L mandestrobin) for the control of *Sclerotinia sclerotiorum* in oilseed rape. The applicant stated that Mandestrobin 25SC is currently registered for controlling *Sclerotinia sclerotiorum* in oilseed rape in several Member States within the Central and Southern zones, including Austria, the Czech Republic, France, Germany, Hungary, the Netherlands, Poland, Romania, Slovenia, and Slovakia. Mandestrobin 40SC has a proposed maximum individual dose of 0.5 l/ha (to deliver 200 g a.s mandestrobin). This product is applied with a water volume of 100-300 l/ha. Only 1 application may be made per season from BBCH 60 to 69.

The cMS are spread between the Maritime, North-East and South-East EPPO climatic zones. The GAP is identical across all Member States where authorisation is being requested.

Preliminary tests

The comparison of the Mandestrobin 40SC and Mandestrobin 25SC was done at the registered dose rate of 200 g a.s./ha to compare efficacy for differences between the formulations. Both formulations at the same rate of the single application, when considering disease incidence and severity, provided equivalent efficacy in the maritime and north EPPO zones. Therefore, the extrapolation of label claims from Mandestrobin 25SC to Mandestrobin 40SC is acceptable. No data for bridging approach were presented for the South East zone.

Minimum effective dose

The proposed rate of 0.5 L/ha should be considered the minimum effective dose to deliver optimum control *Sclerotinia sclerotiorum* in oilseed rape, specifically under higher disease pressure conditions.

Efficacy tests

North-East zone

There is sufficient evidence of efficacy and crop safety to support the use of Mandestrobin 40SC at 0.5 L/ha on oilseed rape in the North-East zone.

Maritime zone

In the Maritime zone, the data showed that Mandestrobin 40SC, applied at the proposed dose of 0.5 L/ha, offers moderate control of *Sclerotinia sclerotiorum*. However, at this dose, the fungicide had a positive impact on the yield of oilseed rape in the presence of the disease, leading to an average yield increase of 9.0% compared to the untreated control.

The concerned Member States are kindly asked to decide for themselves whether to accept the lower efficacy of the applied product against *Sclerotinia sclerotiorum* in oilseed rape.

As part of the comment period process, **cMS DE** submitted the following comment: Due to the low effectiveness and the open points in the resistance risk assessment and effects on adverse crops Germany cannot support an authorisation in Germany if the missing information is not provided .

South-East EPPO

No trials have been conducted in the South-East EPPO zone to demonstrate the efficacy of Mandestrobin 40SC against the target disease *S. sclerotiorum*, which could be deemed unacceptable. For the South-East zone, the applicant provided efficacy data for Mandestrobin 25SC, which has shown similar effectiveness to Mandestrobin 40SC in the maritime and north-eastern EPPO zones. However, there is no direct evidence supporting the efficacy of Mandestrobin 40SC under various conditions from South-East regions. In this case, the concerned Member States may consider whether or not to extrapolate data from the Maritime or North-Eastern zones.

Resistance

Principles for use of Mandestrobin 40SC given by the applicant are consistent with FRAC guidance. Overall, the risk of resistance development against Mandestrobin 40SC is considered to be moderate if the product is used in adherence with the management strategy and label recommendations.

Yield and Quality parameters

The data summarized confirmed that Mandestrobin 40SC was shown to be an effective product for fungicidal control in oilseed rape. Trials showed that the level of control was equal to or better than the reference standard products tested. In addition, Mandestrobin 40SC at the recommended label rate of 0.5 L/ha showed no adverse but rather positive effects on yield and quality parameters.

Adverse effects on succeeding or adjacent crops

Mandestrobin 40SC was tested on 6 different crops. No effects were observed on germination and vegetative vigour with any of crops tested. Mandestrobin 40SC does not pose a risk to succeeding or adjacent crops and justifies the recommendation of no restrictions on succeeding or adjacent crops when applying Mandestrobin 40SC.

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fn, Fnp G, Gn, Gnp or I **	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber a) per use b) per crop/ sea- son	Min. interval between ap- plications (days)	L 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	Central Zone (AT, HU, RO, DE, NL, PL, CZ, SK, SI)	Winter and Spring Oilseed rape	F	<i>Sclerotinia sclerotiorum</i>	Foliar appli- cation	BBCH 60-69	a) 1 b) 1	n.a.	a) 0.5 b) 0.5	a) 200 b) 200	100-300	n.a.	the PHI is covered by the time re- maining between application and harvest	PL

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.

** F: professional field use, Fn: non-professional field use, Fnp: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gnp: professional and non-professional greenhouse use, I: indoor application

Column 15: zRMS conclusion.

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

3.2 Efficacy data (KCP 6)

Introduction

This document summarises the information related to the efficacy of the plant protection product Mandestrobin 40SC to support its authorization under Article 33 of Regulation (EC) No 1107/2009 in the Central regulatory zone.

Mandestrobin 40SC is a suspension concentrate formulation (SC) containing 400 g/L mandestrobin, intended for use as a fungicide against *Sclerotinia sclerotiorum* on oilseed rape.

Only one core dossier is submitted for this application.

In the Central zone, the zRMS is Poland and the concerned Member States are Austria, Czech Republic, Germany, Hungary, the Netherlands, Poland, Romania, Slovakia and Slovenia.

Data to support the label claims in the Central EU Zone were generated in the relevant EPPO climatic zones, *i.e.* Maritime, North-East and South-East.

Mandestrobin 40SC is a new product, not yet authorised in any Member State in the Central regulatory zone.

However, a comparable formulation, Mandestrobin 25SC, mandestrobin 250 g/L (coded S-2200 25SC in the trial reports), is authorized in several Member States from Central and Southern zones (Austria, Czech Republic, France, Germany, Hungary, The Netherlands, Poland, Romania, Slovenia and Slovakia) for the control of *Sclerotinia sclerotiorum* in oilseed rape.

The dossier is based on the bridging between the 2 formulations, Mandestrobin 40SC (mandestrobin 400 g/L) and Mandestrobin 25SC (250 g/L mandestrobin).

Description of active substance

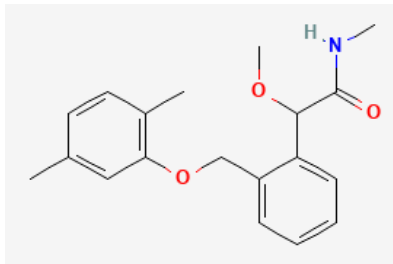
The active substance mandestrobin belongs to the strobilurin group of fungicides. Mandestrobin is a systemic fungicide and has preventive and curative action. Mandestrobin can translocate in plants via trans-laminar movement and systemic transportation.

Mandestrobin acts by inhibiting mitochondrial respiration in fungi. It binds at the Qo-centre on cytochrome b and blocks electron transfer between cytochrome b and cytochrome c1. This disrupts the energy cycle within the fungus by halting the production of adenosine triphosphate (ATP).

Mode of action

Active substance properties are summarised in Table 3.2-1.

Table 3.2-1: Details of the active substance

Active substance (ISO name)	Mandestrobin
Concentration (Unit: g/kg or g/L...)	400 g/L
Chemical name (IUPAC)	(RS)-2-Methoxy-N-methyl-2-[α -(2,5-xylyloxy)-o-tolyl]acetamide
CAS No	173662-97-0
Molecular formula	C ₁₉ H ₂₃ NO ₃
Molecular mass	313.4
Structural formula	
Chemical group or equivalent:	Strobilurin
Mode of action:	Mitochondrial respiratory inhibition
Biological action: Harmful organism, plant growth regulator, growth/developmental stage of pest (e.g. IGRs), etc.	Mandestrobin is a strobilurin fungicide that is effective in the control of foliar fungal diseases caused by a broad spectrum of filamentous fungi.
FRAC Group	Group C3 (QoI: Quinone outside Inhibitor)
Biological action	Spore germination and mycelial growth is inhibited. Existing mycelium or other fungal tissues can also be killed.
Root-uptake, foliar-uptake, systemic etc.	Translaminar and systemic fungicide

Description of the plant protection product

Mandestrobin 40SC is a suspension concentrate (SC) containing 400 g/L mandestrobin for use as a systemic contact fungicide with preventative and curative action, for the control of *Sclerotinia sclerotiorum* on winter and spring oilseed rape.

One foliar application per season is recommended from BBCH growth stage 60 (*i.e.* first flowers open) to 69 (*i.e.* end of flowering) of the crop with a maximum rate per application of 0.5 L/ha of formulated product (*i.e.* 200 g/ha of mandestrobin). Recommended water volume ranges from 100 to 300 L/ha.

Further details are in the table “All intended uses” in Part B - Section 0.

Mandestrobin 40SC is a new product, not yet authorised in any Member State in the Central regulatory zone. However, a comparable formulation, Mandestrobin 25SC (mandestrobin 250 g/L), is authorized in several Member States. Table 3.2-2 presents the uses currently approved in the European Union for Mandestrobin 25SC and Table 3.2-3 presents the uses requested for Mandestrobin 40SC in the frame of this submission.

Table 3.2-2: Simplified table of currently registered uses for Mandestrobin 25SC

Uses		Member State	Currently registered rate	Comments / Other relevant details on GAPs
Crop	Target			
Oilseed rape	<i>Sclerotinia sclerotiorum</i>	AT, CZ, DE, HU, NL, PL, RO, SI, SK	0.8 L/ha	AT : max. 1 application every 2 years on spring oilseed rape, max. 1 application every 3 years on winter oilseed rape

Table 3.2-3: Simplified table of requested uses for Mandestrobin 40SC

Uses		Member State	Requested rate	Comments / Other relevant details on GAPs
Crop	Target			
Oilseed rape	<i>Sclerotinia sclerotiorum</i>	AT, CZ, DE, HU, NL, PL, RO, SI, SK	0.5 L/ha	-

Description of the target pests

The pest mentioned in the efficacy trials are listed in Table 3.2-4.

Table 3.2-4: Glossary of pests mentioned in the dossier.

EPPO code	Scientific name
SCLESC	<i>Sclerotinia sclerotiorum</i>

The importance of *S. sclerotiorum* as a plant pathogen was first described in 1837 (Purdy, 1979 and Bolton et al., 2006).

S. sclerotiorum is a geographically cosmopolitan and nonspecific pathogen. The plants sensitive to this pathogen encompass 64 families including many important crops, particularly flowers and vegetables (Purdy, 1979 and Bolton et al., 2006), including Brassicaceae and in particular oilseed rape.

The life cycle of *S. sclerotiorum* begins as mycelium (white filamentous structures). Mycelium may develop when environmental conditions are favourable (cool and moist conditions) and directly attack the lower parts of plants (e.g. stem, roots).

In addition, a key characteristic of this pathogen is its ability to produce sclerotia (macroscopic and hard black conservation structures). Sclerotia can be viable for multiple years in the soil (Heffer Link and Johnson, 2007). Sclerotia then produce ascospores that infect above-ground portions of host plants with senescent or necrotic tissues generally serving as the nutrient source (Bolton et al., 2006).

In the case of oilseed rape, infections usually develop around petals then spread into branches and stems (Markell et al., 2009). Thus, infection events often coincide with bloom and post-bloom periods, as petals commonly drop and adhere to the plants (Heffer Link and Johnson, 2007).

The first symptoms of infection are water-soaked lesions on plant tissues (Bolton et al., 2006). Secondary symptoms such as wilting, bleaching, and shredding can also be observed on above-ground tissues. Plants may die early or become prone to lodging resulting in a reduction of seed production with up to 50% yield losses (Markell et al., 2009).

Effective fungus control regarding *S. sclerotiorum* is therefore of major agronomic and economic importance. Different cultural practices can be used to manage the disease due to *S. sclerotiorum*: crop rotation, tillage and biological control. Alongside cultural practices, the chemical control with fungicides plays a critical role in the management of this disease.

Major/minor status of intended uses

The crop and pest status indicated in Table 3.2-5 is as indicated in official documents relevant for each country. These documents were consulted from the EUMUDA (European Minor Use Database) website (www.eumuda.eu).

Table 3.2-5: 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
Oilseed rape	AT (BRSNW) CZ DE (BRSNW) HU PL (BRSNW) RO SK (BRSNW) SI	AT (BRSNS) DE (BRSNS) PL (BRSNS) SK (BRSNS) NL	<i>Sclerotinia sclerotiorum</i>	AT (BRSNW) CZ DE (BRSNW) HU PL (BRSNW) RO SK (BRSNW) SI	AT (BRSNS) DE (BRSNS) PL (BRSNS) SK (BRSNS) NL

The cultivated surfaces and annual production of oilseed rape in the zRMS and cMS are indicated in Table 3.2-6 below.

Table 3.2-6: Harvested area and production of oilseed rape (data 2021 source FAO stat¹)

Member State	Area harvested (ha)	Production (tons)
FR	980 130	3 306 520
AT	28 270	86 870
CZ	342 320	1 024 930
DE	1 000 900	3 504 600
HU	257 540	734 020
NL	1 450	4 390
PL	993 410	3 050 910
RO	445 920	1 375 070
SI	2 810	6 910
SK	136 000	424 690

Germany, France and Poland are the three main oilseed rape producing countries in Europe. The trials testing Mandestrobin 40SC against *Sclerotinia sclerotiorum* of oilseed rape have been conducted in these countries.

Compliance with the Uniform Principles

The overall assessment was performed according to the Uniform Principles.

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

¹ <https://www.fao.org/faostat/en/#data/QCL> (accessed on 20/09/2023)

The testing facilities responsible for the conduct of the efficacy trials are detailed in 3.7 List of test facilities, including the corresponding certificates where a copy of official compliance certificates is presented.

The trials included in this dossier followed the requirements of the general EPPO standards:
PP 1/152(4) “Design and analysis of efficacy evaluation trials”;
PP 1/181(3 or 4) “Conduct and reporting of efficacy evaluation trials including good experimental practice”;
PP 1/135(3 or 4) “Phytotoxicity assessment”;
PP 1/223(2) “Introduction to the efficacy evaluation of plant protection products”;
PP 1/225(2) “Minimum effective dose”.

The trials also followed the requirements of specific efficacy EPPO standards, as mentioned in tables of the Material and methods parts.

Information on trials submitted (3.2 Efficacy data)

This document is intended to support the registration of Mandestrobin 40SC (mandestrobin 400 g/L) according to Article 33 of Regulation (EC) No 1107/2009 in the Central zone. The dossier is based on the bridging between 2 formulations: the new product Mandestrobin 40SC (mandestrobin 400 g/L) and Mandestrobin 25SC (250 g/L mandestrobin), already authorised for the control of *Sclerotinia sclerotiorum* in oilseed rape in various countries of the European Union (see Table 3.2-2).

Data to support the label claims for the new fungicide Mandestrobin 40SC and which are summarised in this biological dossier were generated in a total of 79 GEP trials, including 16 trials conducted in 2021 and 2022 with the formulation Mandestrobin 40SC (400 g/L mandestrobin) and supported by 63 trials conducted from 2008 to 2014 with the formulation Mandestrobin 25SC (250 g/L mandestrobin).

Trials conducted from 2008 to 2014 with Mandestrobin 25SC were located across the three different EPPO climatic zones encompassed in the Central EU regulatory zone.

In 2021 and 2022, trials conducted with both Mandestrobin 25SC and Mandestrobin 40SC were located in the Maritime and North-East EPPO climatic zones.

The trials were located as presented in tables below.

Table 3.2-7: Location of the 2008-2014 efficacy trials in the EPPO climatic zones – Central regulatory zone

EPPO Climatic zone	Country	Trials conducted in year:						Total	
		2008	2010	2011	2012	2013	2014		
Maritime	AT	-	-	-	-	-	4	4	43
	DE	7	2	-	-	3	-	12	
	UK	6	4	-	-	2	-	12	
	FR-North	4	6	4	-	1	-	15	
North-East	PL	-	-	-	5	-	6	11	11
South-East	HU	-	-	-	3	-	6	9	9
Total		17	12	4	8	6	16	63	

Table 3.2-8: Presentation of trials - 2021-2022

Crop*	Target*	Country	Year	Type of trial**	Number of trials (number of valid trials) EPPO zone			GEP, non-GEP, of- ficial***
					Maritime	North-East	South-East	
Oilseed rape	2021-2022							
	Sclerotinia sclerotiorum	Germany	2021	P + MED + E	1 (1)	-	-	GEP
		Germany	2021	P + E	3 (3)	-	-	GEP
		France	2021	P + E	3 (2)	-	-	GEP
		France	2021	P + MED + E	2 (2)	-	-	GEP
		Poland	2021-2022	P + MED + E	-	7 (7)	-	GEP
	TOTAL	-	2021-2022	-	9 (8)	7 (7)	-	-

* According to the GAP table.

** P = Preliminary trial, MED = Minimum Effective Dose trial, E = efficacy trial.

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

All the trials were carried out by officially recognised organisations under Good Experimental Practice (GEP) and according to the relevant EPPO Standards. Details of the GEP facilities and copies of their official compliance certificates are presented in point 3.7 List of test facilities including the corresponding certificates.

Table 3.2-9 gives an overview of the reference products used in the efficacy trials conducted in 2021 and 2022 with Mandestrobin 40SC.

Table 3.2-9: Presentation of reference standards used in trials (efficacy trials, preliminary trials...)

Crop	Reference standard	Country where the product is registered (1)	Authorisation number	Active substance(s)	Formulation		Registered application rate(3)	Application rate in trials (per treatment)	Remark(4)
					Type(2)	Concentration of a.s.			
Oilseed rape	Pictor Pro	FR	2050075	boscalid	WG	50% w/w	0.5 kg/ha	0.5 kg/ha	
	Cantus	PL	R-111/2018				0.5 kg/ha		
		DE	025180-00				0.5 kg/ha		

(1) only on use(s) applied for (with the test product).

(2) e.g. WP (wetable powder), EC (emulsifiable concentrate), etc.

(3) dose(s) / dose range authorized on that use in the country.

(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application, etc.).

For the reference products used in the trials conducted between 2008 and 2014, please refer to Part 3.2.3.1.1 below in this document.

3.2.1 Preliminary tests (KCP 6.1)

This document is intended to support the registration of Mandestrobin 40SC (mandestrobin 400 g/L) according to Article 33 of Regulation (EC) No 1107/2009 in the Central zone.

With this objective, the equivalence between two mandestrobin formulations differing by the active substance concentration will be demonstrated in a series of 15 valid trials conducted in 2021 and 2022 in the Maritime (8 trials) and North-East (7 trials) EPPO zones. Mandestrobin 40SC (400 g/L of mandestrobin) and Mandestrobin 25SC (250 g/L of mandestrobin) will be compared at the rate of 200 g a.s./ha in order to justify the presentation of data generated with Mandestrobin 25SC in the minimum effective dose and efficacy sections.

To be noted that the product Mandestrobin 25SC is already registered in several Member States, with an application rate of 0.8 L/ha (200 g a.s./ha, as for the claimed use of Mandestrobin 40SC), see Table 3.2-2.

The list of trials supporting the demonstration of the equivalence between both formulations for the control of *Sclerotinia sclerotiorum* in oilseed rape is presented in Table 3.2-10. For information about material and methods of these trials, refer to Part 3.2.3.2.1.

Table 3.2-10: Preliminary trials distribution

Trial no.	EPPO climatic zone	Country	Year	Crop	Target
8 trials	Maritime	DE	2021	BRSNW	SCLESC
	Maritime	DE	2021	BRSNW	SCLESC
	Maritime	DE	2021	BRSNW	SCLESC
	Maritime	DE	2021	BRSNW	SCLESC
	Maritime	FR Mar	2021	BRSNW	SCLESC
	Maritime	FR Mar	2021	BRSNW	SCLESC
	Maritime	FR Mar	2021	BRSNW	SCLESC
	Maritime	FR Mar	2021	BRSNW	SCLESC
7 trials	North-East	PL	2021	BRSNW	SCLESC
	North-East	PL	2021	BRSNW	SCLESC
	North-East	PL	2021	BRSNW	SCLESC
	North-East	PL	2021	BRSNW	SCLESC
	North-East	PL	2022	BRSNW	SCLESC
	North-East	PL	2022	BRSNW	SCLESC
	North-East	PL	2022	BRSNW	SCLESC

The results obtained are presented here below.

Maritime zone

Disease incidence and severity

Results from 8 valid field trials are presented to investigate the compared efficacy of Mandestrobin 40SC (mandestrobin 400 g/L) at 0.5 L/ha (200 g a.s./ ha) and Mandestrobin 25SC (mandestrobin 250 g/L) at 0.8 L/ha (200 g a.s./ha), against *S. sclerotiorum* on oilseed rape. They were carried out in 2021 in the Maritime EPPO climatic zone, with 4 trials in Germany and 4 trials in France.

For disease incidence, summarised results are presented in **Table 3.2-11**.

For disease severity, summarised results are presented in **Table 3.2-12**.

All individual results are available in Appendix 4 of the BAD.

Table 3.2-11: Summarised results – Efficacy of Mandestrobin 40SC and Mandestrobin 25SC in oilseed rape to control *S. sclerotiorum* – Maritime EPPO climatic zone – Disease incidence

# Trials	<i>Inoculated untreated control (Incidence %)</i>			% control						No. of trials where Mandestrobin 40SC is significantly > ; < ; =, compared to
				Mandestrobin 40SC 0.5 L/ha 200 g a.s./ha			Mandestrobin 25SC 0.8 L/ha 200 g a.s./ha			
	<i>Mean</i>	<i>min</i>	<i>max</i>	Mean	min	max	Mean	min	max	Mandestrobin 25SC
7*	36.7 a	16.5	53.0	53.0 b	24.0	88.0	60.1 b	16.0	97.0	0>;7=;0<

* for 1 trial, disease incidence assessment not taken into account, because no significant efficacy of the reference product.

Table 3.2-12: Summarised results – Efficacy of Mandestrobin 40SC and Mandestrobin 25SC in oilseed rape to control *S. sclerotiorum* – Maritime EPPO climatic zone – Disease severity

# Trials	<i>Inoculated untreated control (Severity %)</i>			% control						No. of trials where Mandestrobin 40SC is significantly > ; < ; =, compared to
				Mandestrobin 40SC 0.5 L/ha 200 g a.s./ha			Mandestrobin 25SC 0.8 L/ha 200 g a.s./ha			
	<i>Mean</i>	<i>min</i>	<i>max</i>	Mean	min	max	Mean	min	max	Mandestrobin 25SC
7*	21.1 a	5.9	40.8	68.2 b	37.7	89.4	68.0 b	20.1	99.2	0>;7=;0<

* for 1 trial, disease severity assessment not taken into account, because infestation level below the 5% threshold.

In these trials, *S. sclerotiorum* incidence on plants was high in the inoculated untreated control, with 36.7% of infected plants on average across 7 trials, varying from 16.5% to 53.0% in individual trials. Mandestrobin 40SC applied at 0.5 L/ha demonstrated a good effectiveness with 53.0% mean control, varying from 24.0% to 88.0% in individual trials. Results obtained were statistically equivalent to those of Mandestrobin 25SC applied at 0.8 L/ha, which demonstrated a similar effectiveness of 60.1% mean control, varying from 16.0% to 97.0%. When considering individual trials, both treatments showed no significant differences with each other.

S. sclerotiorum severity on plants was moderate in the inoculated untreated control, with 21.1% of infected area on stems on average across 7 trials, varying from 5.9% to 40.8% in individual trials. Mandestrobin 40SC applied at 0.5 L/ha demonstrated a good effectiveness with 68.2% mean control, varying from 37.7% to 89.4% in individual trials. Results obtained were statistically equivalent to those of Mandestrobin 25SC applied at 0.8 L/ha, which demonstrated a similar effectiveness with 68.0% mean control, varying from 20.1% to 99.2%. When considering individual trials, both treatments showed no significant differences with each other.

In summary, when considering disease incidence and severity, Mandestrobin 40SC applied at 0.5 L/ha (200 g a.s./ha) and Mandestrobin 25SC applied at 0.8 L/ha (200 g a.s./ha) demonstrated an equivalent efficacy against *S. sclerotiorum* on oilseed rape, in 8 trials conducted in 2021 in the Maritime EPPO climatic zone.

North-East zone

Disease incidence and severity

Results from 7 valid field trials are presented to investigate the compared efficacy of Mandestrobin 40SC (mandestrobin 400 g/L) at 0.5 L/ha (200 g a.s./ha) and Mandestrobin 25SC (mandestrobin 250 g/L) at 0.8 L/ha (200 g a.s./ha), against *S. sclerotiorum* on oilseed rape. They were carried out in 2021 and 2022 in the North-East EPPO climatic zone, all in Poland.

For disease incidence, summarised results are presented in **Table 3.2-13**.

For disease severity, summarised results are presented in **Table 3.2-14**.

All individual results are available in Appendix 4 of the BAD.

Table 3.2-13: Summarised results – Efficacy of Mandestrobin 40SC and Mandestrobin 25SC in oilseed rape to control *S. sclerotiorum* – North-East EPPO climatic zone – Disease incidence

# Trials	<i>Inoculated untreated control (Incidence %)</i>			% control						No. of trials where Mandestrobin 40SC is significantly > ; < ; =, compared to
				Mandestrobin 40SC 0.5 L/ha 200 g a.s./ha			Mandestrobin 25SC 0.8 L/ha 200 g a.s./ha			
	<i>Mean</i>	<i>min</i>	<i>max</i>	Mean	min	max	Mean	min	max	Mandestrobin 25SC
7	59.1 a	25.0	92.0	65.3 b	39.6	84.9	59.0 b	44.0	84.9	2>;5=;0<

Table 3.2-14: Summarised results – Efficacy of Mandestrobin 40SC and Mandestrobin 25SC in oilseed rape to control *S. sclerotiorum* – North-East EPPO climatic zone – Disease severity

# Trials	Inoculated untreated control (Severity %)			% control						No. of trials where Mandestrobin 40SC is significantly > ; < ; =, compared to
				Mandestrobin 40SC 0.5 L/ha 200 g a.s./ha			Mandestrobin 25SC 0.8 L/ha 200 g a.s./ha			
	Mean	min	max	Mean	min	max	Mean	min	max	Mandestrobin 25SC
7	34.9 a	18.3	53.7	83.8 b	62.6	97.8	79.1 b	63.5	98.1	2>;5=;0<

In these trials, *S. sclerotiorum* incidence on plants was very high in the inoculated untreated control, with 59.1% of infected plants on average across 7 trials, varying from 25.0% to 92.0% in individual trials. Mandestrobin 40SC applied at 0.5 L/ha demonstrated a good effectiveness with 65.3% mean control, varying from 39.6% to 84.9% in individual trials. Results obtained were statistically equivalent to those of Mandestrobin 25SC applied at 0.8 L/ha, which demonstrated 59.0% mean control, varying from 44.0% to 84.9%. When considering individual trials, efficacy provided by Mandestrobin 40SC was statistically equivalent to Mandestrobin 25SC in 5 out of the 7 trials.

S. sclerotiorum severity on plants was high in the inoculated untreated control, with 34.9% of infected area on stems on average across 7 trials, varying from 18.3% to 53.7% in individual trials. Mandestrobin 40SC applied at 0.5 L/ha demonstrated a very good effectiveness with a mean 83.8% control, varying from 62.6% to 97.8% in individual trials. Results obtained were statistically equivalent to those of Mandestrobin 25SC applied at 0.8 L/ha, which demonstrated 79.1% control, varying from 63.5% to 98.1%. When considering individual trials, efficacy provided by Mandestrobin 40SC was statistically equivalent to Mandestrobin 25SC in 5 out of the 7 trials.

In summary, when considering disease incidence and severity, Mandestrobin 40SC applied at 0.5 L/ha (200 g a.s./ha) and Mandestrobin 25SC applied at 0.8 L/ha (200 g a.s./ha) demonstrated an equivalent efficacy against *S. sclerotiorum* on oilseed rape, in 7 trials conducted in 2021 and 2022 in the North-East EPPO climatic zone.

Conclusion

The results presented above demonstrated, from 15 valid trials carried out in 2021 and 2022 in the Maritime (8 trials) and North-East (7 trials) EPPO climatic zones, that efficacy provided by Mandestrobin 40SC applied at 0.5 L/ha (200 g a.s./ha) is equivalent to that provided by Mandestrobin 25SC applied at 0.8 L/ha (200 g a.s./ha). This conclusion can be drawn for each EPPO climatic zone.

The EPPO standard PP 1/307 (1) "Efficacy on considerations and data generation when making changes to the chemical composition or formulation type of plant protection products" 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. For example, for a fungicide authorized across Europe: the most appropriate locations to demonstrate comparability under challenging conditions would most likely be in the EPPO Maritime Zone"*,

Thus, it can be concluded that results obtained with Mandestrobin 25SC applied at 0.8 L/ha can be extrapolated to Mandestrobin 40SC applied at 0.5 L/ha and thus can support the demonstration of Mandestrobin 40SC minimum effective dose and efficacy.

Conclusion – Preliminary tests

The efficacy of Mandistrobin 40 SC was compared to the currently registered reference product, Mandistrobin 25 SC, for bridging. The comparison between Mandistrobin 40 SC and Mandistrobin 25 SC was made at the registered dose rate of 200 g a.s./ha to assess any differences in efficacy between the two formulations. Both formulations, when applied once at the same rate, showed equivalent efficacy in terms of disease incidence and severity in the North East zone. In the Maritime Zone, equivalence was observed specifically for disease severity, indicating that it is acceptable to extrapolate label claims from Mandistrobin 25 SC to Mandistrobin 40 SC. No data for bridging approach were presented for the South East zone.

3.2.2 Minimum effective dose tests (KCP 6.2)

This document is intended to support the registration of Mandestrobin 40SC (mandestrobin 400 g/L) according to Article 33 of Regulation (EC) No 1107/2009 in the Central zone.

Minimum effective dose of Mandestrobin 40SC (mandestrobin 400 g/L) will be demonstrated through 2 trials series:

- The first data set consists of a set of 36 trials already evaluated at zonal level and carried out between 2008 and 2014 in the Maritime (16 trials), North-East (11 trials) and South-East EPPO (9 trials) zones and testing the formulation Mandestrobin 25SC (coded S-2200 25SC).
- The second data set consists of a set of 15 trials carried out in 2021-2022 in the Maritime (8 trials) and North-East EPPO zones (7 trials) and testing the formulation Mandestrobin 40SC.

The product Mandestrobin 25SC is already registered in several Member States for the control of *Sclerotinia sclerotiorum* in oilseed rape, with an application rate of 0.8 L/ha (200 g a.s./ha). This application rate has been validated as the minimum effective dose during the zonal evaluation.

The summary tables regarding minimum effective dose tests, as presented in the dossier submitted in 2015 (BAD and dRR B3 Central zone, zRMS AT, December 2015) for authorisations of Mandestrobin 25SC, are presented here below, to support the approval of Mandestrobin 40SC.

Since Mandestrobin 40SC is very similar to Mandestrobin 25SC, and the bridging trials (presented above in 3.2.1) showed that efficacy results obtained with Mandestrobin 25SC can be extrapolated to Mandestrobin 40SC, this application rate of 200 g a.s./ha should be considered also as the minimum effective dose of Mandestrobin 40SC, corresponding to 0.5 L/ha.

Moreover, in the trials conducted in 2021 and 2022, several application rates of Mandestrobin 40SC were tested. In addition to the requested application rate of 0.5 L/ha (200 g a.s./ha, N rate), lower rates of 0.313 L/ha (125 g a.s./ha, 0.625N rate) and 0.375 L/ha (150 g a.s./ha, 0.75N rate) were tested in the Maritime and North-East EPPO climatic zones. Trials conducted in 2021-2022 supporting Mandestrobin 40SC minimum effective dose for the control of *Sclerotinia sclerotiorum* are presented in Table 3.2-15.

Table 3.2-15: Minimum effective dose trials distribution

Trial no.	EPPO climatic zone	Country	Year	Crop	Target
8 trials *,**	Maritime	DE	2021	BRSNW	SCLESC
	Maritime	DE	2021	BRSNW	SCLESC
	Maritime	DE	2021	BRSNW	SCLESC
	Maritime	DE	2021	BRSNW	SCLESC
	Maritime	FR Mar	2021	BRSNW	SCLESC
	Maritime	FR Mar	2021	BRSNW	SCLESC
	Maritime	FR Mar	2021	BRSNW	SCLESC
	Maritime	FR Mar	2021	BRSNW	SCLESC
7 trials	North-East	PL	2021	BRSNW	SCLESC
	North-East	PL	2021	BRSNW	SCLESC
	North-East	PL	2021	BRSNW	SCLESC
	North-East	PL	2021	BRSNW	SCLESC
	North-East	PL	2022	BRSNW	SCLESC
	North-East	PL	2022	BRSNW	SCLESC
	North-East	PL	2022	BRSNW	SCLESC

* for one trial, disease incidence assessment not taken into account, because no significant efficacy of the reference product.

** for another trial, disease severity assessment not taken into account, because infestation level below the 5% threshold.

For material and methods, refer to Part 3.2.3.1.1 for trials with Mandestrobin 25SC and to Part 3.2.3.2.1 for trial with Mandestrobin 40SC. The results obtained are presented here below.

Maritime zone

Mandestrobin 25SC results

Results from 16 valid field trials carried out between 2008 and 2014 in the Maritime EPPO climatic were presented in the dossier submitted in 2015 for authorisation of Mandestrobin 25SC (coded S-2200 25SC). These results are summarized and presented in **Table 3.2-16**.

Table 3.2-16: Dose justification of S-2200 25SC against *S. sclerotiorum* on oilseed rape – Maritime EPPO climatic zone (Northern France, Austria, Germany and the United Kingdom) – 2008 to 2014

EPPO climatic zone	Number of trials	Year	Country	Assessment Type	Days after treatment	Untreated plot	S-2200 25SC		HORIZON /FOLICUR*
							mandestrobin 250 g/L		tebuconazole 250 g/L
							0.6 L/ha 0.75N (150 g as/ha)	0.8 L/ha N (200 g as/ha)	1-2 L/ha (250-500 g as/ha)
Maritime	16 data	2008-2014	AT, FR, DE, UK	Average %PESINC %Efficacy	43-77 DA-A	42.24 a	24.18 b 42.75	21.55 b 48.98	21.6 b 48.86
Maritime	8 data	2008-2014	AT, FR, DE, UK	Average %PESSEV %Efficacy	56-77 DA-A	24.67 a	15.01 b 39.13	13.2 b 46.49	12.98 b 47.37

*Reference products based on tebuconazole 250 g/L EW applied at 1 L/ha (250 g as/ha) in UK and FR, 1.5 L/ha (375 g as/ha) in DE and 2 L/ha (500 g as/ha) in AT.

Mandestrobin 40SC results

Results from 8 valid field trials are presented to investigate the minimum effective dose of Mandestrobin 40SC, against *S. sclerotiorum* on oilseed rape. They were carried out in 2021 in the Maritime EPPO climatic zone, with 4 trials in France and 4 trials in Germany.

Summarised results are presented in **Table 3.2-17**.

All individual results are available in Appendix 4 of the BAD.

Table 3.2-17: Summarised results – Minimum effective dose of Mandestrobin 40SC in oilseed rape to control *S. sclerotiorum* – Maritime EPPO climatic zone – Disease incidence and severity

Comparison	# trials	Inoculated untreated control (Incidence or severity %)			% control									No. of trials where Mande- strobin 40SC at N rate (200 g a.s./ha) is significantly > ; = ; < compared to	
					Mandestrobin 40SC 0.313 L/ha 125 g a.s./ha 0.625N			Mandestrobin 40SC 0.375 L/ha 150 g a.s./ha 0.75N			Mandestrobin 40SC 0.5 L/ha 200 g a.s./ha N				
		Mean	min	max	Mean	min	max	Mean	min	max	Mean	min	max	0.625N 125 g a.s./ha	0.75N 150 g a.s./ha
Incidence - Higher infection level (>50%)	3	51.0 ⁽¹⁾	50.0	53.0	41.1 ⁽¹⁾	16.0	77.0	44.8 ⁽¹⁾	24.5	84.0	48.7 ⁽¹⁾	24.0	88.0	0>;3=;0<	0>;3=;0<
Incidence - All trials	7	36.7 a	16.5	53.0	48.3 b	16.0	77.0	54.7 b	23.8	84.0	53.0 b	24.0	88.0	0>;7=;0<	0>;7=;0<
Severity - All trials	7	21.1 ⁽¹⁾	5.9	40.8	60.4 ⁽¹⁾	29.3	80.5	68.3 ⁽¹⁾	34.3	93.3	68.2 ⁽¹⁾	37.7	89.4	0>;7=;0<	0>;7=;0<

⁽¹⁾ Statistical analysis not available (Violations of ANOVA assumption or trials number <4)

Conclusion – Maritime zone

Incidence data:

In the 16 trials conducted between 2008 and 2014 *S. sclerotiorum* incidence on plants was high in the untreated control, with 42.2% of infected plants on average across 16 trials.

On average across the 16 trials, Mandestrobin 25SC applied at 0.6 L/ha and 0.8 L/ha (0.75N and N rate, 150 and 200 g a.s./ha) provided a mean efficacy of 42.8% and 49.0%, respectively.

Mandestrobin 25SC showed a slight dose response between 0.75N and N application rates. Indeed, application at the N rate provided a gain of +6.2 points of efficacy on disease incidence compared to application at 0.75N rate.

In the whole series of 7 trials conducted in 2021, the incidence was high in the inoculated untreated control, with 36.7% of infected plants. Mandestrobin 40SC showed a dose response with a better level of control at the intended rate of 0.5 L/ha (53.0% mean control) compared to the rate of 0.313 L/ha (48.3% mean control). Mandestrobin 40SC at 0.5 L/ha and 0.375 L/ha showed a similar level of control (53.0% vs. 54.7% mean control), however the rate of 0.5 L/ha demonstrated a higher maximum effectiveness (88.0% vs. 84% mean control) and thus secured a better level of control in various situations.

Regarding the trials conducted in 2021, which showed a challenging disease pressure (>50% incidence), *S. sclerotiorum* incidence on plants was very high in the inoculated untreated control (51.0% of infected plants on average across 3 trials). On average across the 3 trials, Mandestrobin 40SC applied at 0.313 L/ha, 0.375 L/ha and 0.5 L/ha (0.625N, 0.75N and N rate; 125, 150 and 200 g a.s./ha) provided a mean efficacy of 41.1%, 44.8% and 48.7%, respectively. Mandestrobin 40SC showed a slight dose response between 0.625N and N application rates even if this was not statistically highlighted in the individual trials. Indeed, application at the N rate provided a gain of +7.6 points of efficacy on disease incidence compared to application at 0.625N rate and + 3.9 points compared to application at 0.75N rate.

Severity data:

Severity data are presented for information, because disease incidence is considered as the most relevant parameter for the assessment of *Sclerotinia sclerotiorum* symptoms on oilseed rape.

In the 8 trials conducted between 2008 and 2014, *S. sclerotiorum* severity on plants was moderate in the untreated control with 24.7% of plant infected area on average across 8 trials.

On average across the 8 trials, Mandestrobin 25SC applied at 0.6 L/ha and 0.8 L/ha (0.75N and N rate, 150 and 200 g a.s./ha) provided a mean efficacy of 39.1% and 46.5%, respectively.

Mandestrobin 25SC showed a slight dose response between 0.75N and N application rates. Indeed, application at the N rate provided a gain of +7.4 points of efficacy on disease severity compared to application at 0.75N rate.

Regarding the trials conducted in 2021, *S. sclerotiorum* severity on plants was moderate in the untreated control, with 21.1% of plant infected area on average across 7 trials.

On average across the 7 trials, Mandestrobin 40SC applied at 0.313 L/ha, 0.375 L/ha and 0.5 L/ha (0.625N, 0.75N and N rate; 125, 150 and 200 g a.s./ha) provided a mean efficacy of 60.4%, 68.3% and 68.2%, respectively. Mandestrobin 40SC showed a slight dose response between 0.625N and N application rates even if this was not statistically highlighted in the individual trials. Indeed, application at the N rate provided a gain of +7.8 points of efficacy on disease severity compared to application at 0.625N rate.

In summary, when considering incidence of *S. sclerotiorum* on stems, data from 16 trials conducted between 2008 and 2014 in the Maritime EPPO climatic zone showed a dose response of Mandestrobin 25SC, with a better control at 200 g a.s./ha rate compared to 150 g a.s./ha. Similarly, data from 7 trials conducted in 2021 in the Maritime EPPO climatic zone showed a slight dose response of Mandestrobin 40SC, with a better control at 200 g a.s./ha rate compared to 125 and 150 g a.s./ha. This dose effect was more important under high disease pressure conditions.

In addition, data generated from 8 trials conducted between 2008 and 2014 in the Maritime EPPO zone, on disease severity, a parameter considered less relevant for the assessment of *Sclerotinia sclerotiorum* symptoms, confirmed the interest of the rate of 200 g of mandestrobin/ha compared to lower rates. In the context of the 7 trials conducted in 2021, severity data show the benefit of the rate of 200 g of mandestrobin/ha compared to the lower rate of 125 g a.s./ha.

At last, data generated for the formulation Mandestrobin 25SC already authorised at 200 g a.s./ha for the control of *Sclerotinia sclerotiorum* in oilseed rape, support the claim of a minimum effective dose of 200 g a.s./ha for Mandestrobin 40SC.

North-East zone

Mandestrobin 25SC results

Results from 11 valid field trials carried out between 2012 and 2014 in the North-East EPPO climatic were presented in the dossier submitted in 2015 for authorisation of Mandestrobin 25SC (coded S-2200 25SC). These results are summarized are presented in **Table 3.2-18**.

Table 3.2-18: Dose justification of S-2200 25SC against *S. sclerotiorum* on oilseed rape – North-East EPPO climatic zone (Poland) – 2012 and 2014.

Number of trials	Year	Country	Assessment type	Days after treatment	Untreated plot	S-2200 25SC			HORIZON	
						mandestrobin 250 g/L			tebuconazole 250 g/L	
						0.4 L/ha (100 g as/ha)	0.6 L/ha (150 g as/ha)	0.8 L/ha (200 g as/ha)	1.25 L/ha (312 g as/ha)	
6 data	2012-2014	PL	Average %PESINC %Efficacy	44-59 DA-A	26.33 a	9.25 b 64.87	5.92 c 77.53	3.42 d 87.03	3.17 d 87.97	
11 data	2012-2014	PL	Average %PESINC %Efficacy	42-59 DA-A	23.27 a	-	7.73 b 66.8	3.91 c 83.2	5.09 c 78.13	
6 data	2012-2014	PL	Average %PESSEV %Efficacy	44-59 DA-A	9.62 a	2.48 b 74.18	1.53 c 84.06	0.87 d 90.99	0.85 d 91.16	
11 data	2012-2014	PL	Average %PESSEV %Efficacy	42-59 DA-A	7.67 a	-	1.61 b 79.03	0.80 c 89.57	0.92 c 88.03	

Mandestrobin 40SC results

Results from 7 valid field trials are presented to investigate the minimum effective dose of Mandestrobin 40SC, against *S. sclerotiorum* on oilseed rape. They were carried out in 2021 and 2022 in the North-East EPPO climatic zone, all in Poland.

Summarised results are presented in **Table 3.2-19**.

All individual results are available in Appendix 4 of the BAD.

Table 3.2-19: Summarised results – Dose justification of Mandestrobin 40SC in oilseed rape to control *S. sclerotiorum* – North-East EPPO climatic zone – Disease incidence and severity

Comparison	# trials	Inoculated untreated control (Incidence or severity %)			% control									No. of trials where Mande- strobin 40SC at N rate (200 g a.s./ha) is significantly > ; = ; < compared to	
					Mandestrobin 40SC 0.313 L/ha 125 g a.s./ha 0.625N			Mandestrobin 40SC 0.375 L/ha 150 g a.s./ha 0.75N			Mandestrobin 40SC 0.5 L/ha 200 g a.s./ha N				
		Mean	min	max	Mean	min	max	Mean	min	max	Mean	min	max	0.625N 125 g a.s./ha	0.75N 150 g a.s./ha
Incidence	7	59.1 a	25.0	92.0	42.4 b	18.2	68.1	52.3 b	40.3	69.4	65.3 c	39.6	84.9	3>;4=;0<	3>;4=;0<
Severity	7	34.9 ⁽¹⁾	18.3	53.7	65.4 ⁽¹⁾	49.3	80.0	75.3 ⁽¹⁾	66.0	86.9	83.8 ⁽¹⁾	62.6	97.8	3>;4=;0<	3>;4=;0<

⁽¹⁾ Statistical analysis not available (Violations of ANOVA assumption)

Conclusion – North-East zone

Incidence data:

In the 6 trials conducted between 2012 and 2014, where the 0.5N, 0.75N and N application rates (100, 150 and 200 g a.s./ha) were tested, *S. sclerotiorum* incidence on plants was moderate in the untreated control, with 26.3% of infected plants on average.

On average across the 6 trials, Mandestrobin 25SC applied at 0.4 L/ha, 0.6 L/ha and 0.8 L/ha (0.5N, 0.75N and N rates) provided a mean efficacy of 64.9%, 77.5% and 87.0%, respectively.

Mandestrobin 25SC showed a strong and statistical dose response between the 3 application rates. Indeed, application at the N rate provided a gain of +22.1 points of efficacy on disease incidence compared to application at 0.5N rate and +9.5 points compared to application at 0.75N.

When taking into account all the 11 trials conducted between 2012 and 2014, *S. sclerotiorum* incidence on plants was moderate in the untreated control, with 23.3% of infected plants on average.

On average across the 11 trials, Mandestrobin 25SC applied at 0.6 L/ha and 0.8 L/ha (0.75N and N rate) provided a mean efficacy of 66.8% and 83.2%, respectively.

Mandestrobin 25SC showed a strong and statistical dose response between the 2 application rates. Indeed, application at the N rate provided a gain of +16.4 points of efficacy on disease incidence compared to application at 0.75N rate.

In the trials carried out in 2021 and 2022, *S. sclerotiorum* incidence on plants was very high in the inoculated untreated control, with 59.1% of infected plants on average across 7 trials, varying from 25.0% to 92.0% in individual trials.

On average across 7 trials, Mandestrobin 40SC applied at 0.313 L/ha, 0.375 L/ha and 0.5 L/ha (0.625N, 0.75N and N rate; 125, 150 and 200 g a.s./ha) provided a mean efficacy of 42.4%, 52.3% and 65.3%, respectively. Mandestrobin 40SC showed a strong dose response between 0.625N (respectively 0.75N) and N application rates. Indeed, application at the N rate provided a gain of respectively +23 points and +10 points of efficacy on disease incidence compared to application at 0.625N and 0.75N rates. Mandestrobin 40SC at 200 g a.s./ha was statistically better than the lower rates of 125 and 150 g a.s./ha.

When considering individuals trials, these differences were significant in 3 out of 7 cases and corresponded to the trials with the highest disease incidence.

Severity data:

Severity data are presented for information, because disease incidence is considered as the most relevant parameter for the assessment of *Sclerotinia sclerotiorum* symptoms on oilseed rape.

In the 6 trials conducted between 2012 and 2014, where the 0.5N, 0.75N and N application rates (100, 150 and 200 g a.s./ha) were tested, *S. sclerotiorum* severity on plants was low in the untreated control, with 9.6% of plant infected area on average.

On average across the 6 trials, Mandestrobin 25SC applied at 0.4 L/ha, 0.6 L/ha and 0.8 L/ha (0.5N, 0.75N and N rates) provided a mean efficacy of 74.2%, 84.1% and 91.0%, respectively.

Mandestrobin 25SC showed a strong and statistical dose response between the 3 application rates. Indeed, application at the N rate provided a gain of +16.8 points of efficacy on disease severity compared to application at 0.5N rate and +6.9 points compared to application at 0.75N.

When taking into account all the 11 trials conducted between 2012 and 2014, *S. sclerotiorum* severity on plants was low in the untreated control, with 7.7% of plant infected area on average.

On average across the 11 trials, Mandestrobin 25SC applied at 0.6 L/ha and 0.8 L/ha (0.75N and N rate) provided a mean efficacy of 79.0% and 89.6%, respectively.

Mandestrobin 25SC showed a strong and statistical dose response between the 2 application rates. Indeed, application at the N rate provided a gain of +10.6 points of efficacy on disease severity compared to application at 0.75N rate.

In the trials carried out in 2021 and 2022, *S. sclerotiorum* severity on plants was high in the inoculated untreated control, with 34.9% of infected plants on average across 7 trials, varying from 18.3% to 53.7% in individual trials.

On average across 7 trials, Mandestrobin 40SC applied at 0.313 L/ha, 0.375 L/ha and 0.5 L/ha (0.625N, 0.75N and N rate; 125, 150 and 200 g a.s./ha) provided a mean efficacy of 65.4%, 75.3% and 83.8%, respectively. Mandestrobin 40SC showed a strong dose response between 0.625N (respectively 0.75N) and N application rates. Indeed, application at the N rate provided a gain of respectively +18.4 points and + 8.5 points of efficacy on disease severity compared to application at 0.625N and 0.75N rates.

When considering individuals trials, these differences were significant in 3 out of 7 cases and corresponded to the trials with the highest disease incidence.

In summary, when considering disease incidence of *S. sclerotiorum* on stems, data from 11 trials conducted between 2012 and 2014 in the North-East EPPO climatic zone showed a significant dose response of Mandestrobin 25SC, with a significantly better control at 200 g a.s./ha rate compared to 100 and 150 g a.s./ha.

Similarly, data from 7 trials conducted in 2021 and 2022 in the North-East EPPO climatic zone showed a clear dose response of Mandestrobin 40SC (notably in case of high disease pressure), with a significantly better control at 200 g a.s./ha rate compared to 125 and 150 g a.s./ha.

In addition, data generated from 11 trials conducted between 2012 and 2014 and 7 trials conducted in 2021 and 2022 in the North-East EPPO zone on severity, a parameter considered less relevant for the assessment of *Sclerotinia sclerotiorum* symptoms, confirmed the interest of the rate of 200 g of mandestrobin/ha compared to lower rates.

South-East zone

Mandestrobin 25SC results

Results from 9 valid field trials carried out between 2012 and 2014 in the South-East EPPO climatic were presented in the dossier submitted in 2015 for authorisation of Mandestrobin 25SC (coded S-2200 25SC). No 2021 trials are presented for the minimum effective dose justification in the South-East EPPO zone. Indeed, the Maritime EPPO zone has been considered as the most relevant to conduct the bridging according to EPPO standard PP 1/307 (1) "Efficacy on considerations and data generation when making changes to the chemical composition or formulation type of plant protection products" 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. For example, for a fungicide authorized across Europe: the most appropriate locations to demonstrate comparability under challenging conditions would most likely be in the EPPO Maritime Zone*".

These results are summarized in **Table 3.2-20**.

Table 3.2-20: Dose justification of S-2200 25SC against *S. sclerotiorum* on oilseed rape – South-East EPPO climatic zone (Hungary) – 2012 and 2014.

Number of trials	Year	Country	Assessment Type	Days after treatment	Untreated plot	S-2200 25SC			FOLICUR SOLO
						mandestrobin 250 g/L			tebuconazole 250 g/L
						0.4 L/ha (100 g as/ha)	0.6 L/ha (150 g as/ha)	0.8 L/ha (200 g as/ha)	1 L/ha (250 g as/ha)
6 data	2012-2014	HU	Average %PESINC %Efficacy	18-75 DA-A	29.37 a	11.58 b 60.56	8.67 b 70.49	6.08 b 79.28	4.92 b 83.26
9 data	2012-2014	HU	Average %PESINC %Efficacy	18-75 DA-A	24.91 a	-	6.58 b 73.57	4.25 b 82.94	3.28 b 86.84
6 data	2012-2014	HU	Average %PESSEV %Efficacy	18-75 DA-A	12.13 a	6.37 b 47.53	5.20 bc 57.14	4.22 c 65.25	3.70 c 69.51

Conclusion – South-East zone

Incidence data:

In the 6 trials conducted between 2012 and 2014, *S. sclerotiorum* incidence on plants was moderate in the untreated control, with on average 29.4% of infected plants.

On average across the 6 trials, Mandestrobin 25SC applied at 0.4 L/ha, 0.6 L/ha and 0.8 L/ha (0.5N, 0.75N and N rate) provided a mean efficacy of 60.6%, 70.5% and 79.3%, respectively.

Mandestrobin 25SC showed a clear dose response between the 3 application rates. Indeed, application at the N rate provided a gain of +18.7 points of efficacy on disease incidence compared to application at 0.5N rate and + 8.8 points of efficacy compared to application at 0.75N rate.

When taking into account all the 9 trials conducted between 2012 and 2014, *S. sclerotiorum* incidence on plants was moderate in the untreated control, with 24.9% of infected plants on average.

On average across the 9 trials, Mandestrobin 25SC applied at 0.6 L/ha and 0.8 L/ha (0.75N and N rate) provided a mean efficacy of 73.6% and 82.9%, respectively.

Mandestrobin 25SC showed a clear dose response between the 2 application rates. Indeed, application at the N rate provided a gain of +9.3 points of efficacy on disease incidence compared to application at 0.75N rate.

Severity data:

In the 6 trials conducted between 2012 and 2014, *S. sclerotiorum* severity on plants was low in the untreated control, with on average 6.4% of infected plants.

On average across the 6 trials, Mandestrobin 25SC applied at 0.4 L/ha, 0.6 L/ha and 0.8 L/ha (0.5N, 0.75N and N rate) provided a mean efficacy of 47.5%, 57.1% and 65.3%, respectively.

Mandestrobin 25SC showed a clear dose response between the 3 application rates. Indeed, application at the N rate provided a gain of +17.8 points of efficacy on disease severity and was statistically more effective than at 0.5N rate and +8.1 points of efficacy compared to application at 0.75N rate.

In summary, when considering disease incidence, data from 9 trials conducted between 2012 and 2014 in the South-East EPPO climatic zone showed a clear dose response of Mandestrobin 25SC, with a better control at 200 g a.s./ha rate compared to 100 and 150 g a.s./ha.

In addition, data generated from 6 trials conducted between 2021 and 2014 on severity, a parameter considered less relevant for the assessment of *Sclerotinia sclerotiorum* symptoms, confirmed the interest of the rate of 200 g of mandestrobin/ha compared to lower rates.

Data generated for the formulation Mandestrobin 25SC already authorised at 200 g a.s./ha for the control of *Sclerotinia sclerotiorum* in oilseed rape, support the claim of minimum effective dose of 200 g a.s./ha for Mandestrobin 40SC.

This claim is also supported by data generated in the Maritime EPPO zone with the formulation Mandestrobin 40SC.

Conclusion

Summarised results regarding efficacy of Mandestrobin 25SC and Mandestrobin 40SC at different application rates, against *S. sclerotiorum* on oilseed rape, are detailed in **Table 3.2-21** and **Table 3.2-22** for disease incidence and in **Table 3.2-23** and **Table 3.2-24** for disease severity.

Based on the bridging between Mandestrobin 25SC and Mandestrobin 40SC, results obtained with the formulation Mandestrobin 25SC at 0.8 L/ha (200 g a.s./ha) support the claim of Mandestrobin 40SC at 0.5 L/ha (200 g a.s./ha) for the control of *S. sclerotiorum* on oilseed rape.

Table 3.2-21: Weighted mean efficacy of Mandestrobin 25SC at different application rates against *S. sclerotiorum* on oilseed rape - Disease incidence

EPPO climatic zone	# Trials	Inoculated untreated control (%)			Mean control (%) Mandestrobin 25SC 0.6 L/ha 0.75N 150 g a.s./ha			Mean control (%) Mandestrobin 25SC 0.8 L/ha N 200 g a.s./ha		
		Mean	min	max	Mean	min	max	Mean	min	max
		Disease incidence								
Maritime	16	42.2	-	-	42.8	-	-	49.0	-	-
North-East	11	23.3	-	-	66.8	-	-	83.2	-	-
South-East	9	24.9	-	-	73.6	-	-	82.9	-	-
Central zone	36	32.1	-	-	57.8	-	-	67.9	-	-

Table 3.2-22: Weighted mean efficacy of Mandestrobin 40SC at different application rates against *S. sclerotiorum* on oilseed rape - Disease incidence

EPPO climatic zone	# Trials	<i>Inoculated untreated control (%)</i>			Mean control (%) Mandestrobin 40SC 0.313 L/ha 0.625N 125 g a.s./ha			Mean control (%) Mandestrobin 40SC 0.375 L/ha 0.75N 150 g a.s./ha			Mean control (%) Mandestrobin 40SC 0.5 L/ha N 200 g a.s./ha		
		<i>Mean</i>	<i>min</i>	<i>max</i>	Mean	min	max	Mean	min	max	Mean	min	max
		Disease incidence											
Maritime	3*	51.0	50.0	53.0	41.1	16.0	77.0	44.8	24.5	84.0	48.7	24.0	88.0
Maritime	7	36.7	16.5	53.0	48.3	16.0	77.0	54.7	23.8	84.0	53.0	24.0	88.0
North-East	7	59.1	25.0	92.0	42.4	18.2	68.1	52.3	40.3	69.4	65.3	39.6	84.9
Central zone	14	47.9	16.5	92.0	45.4	16.0	77.0	53.5	23.8	84.0	59.2	24.0	88.0

* The series of 3 trials with an infection level higher than 50% incidence in the Maritime EPPO zone is presented for information and is not included in the weighted mean calculation. As a reminder, the minimum effective dose is clearer when considering those 3 highly infected trials.

Table 3.2-23: Weighted mean efficacy of Mandestrobin 25SC at different application rates against *S. sclerotiorum* on oilseed rape - Disease severity

EPPO climatic zone	# Trials	<i>Inoculated untreated control (%)</i>			Mean control (%) Mandestrobin 25SC 0.6 L/ha 0.75N 150 g a.s./ha			Mean control (%) Mandestrobin 25SC 0.8 L/ha N 200 g a.s./ha		
		<i>Mean</i>	<i>min</i>	<i>max</i>	Mean	min	max	Mean	min	max
Disease severity										
Maritime	8	24.7	-	-	39.1	-	-	46.5	-	-
North-East	11	7.7	-	-	79.0	-	-	89.6	-	-
South-East	6	12.1	-	-	57.1	-	-	65.3	-	-
Central zone	25	14.2	-	-	61.0	-	-	70.0	-	-

Table 3.2-24: Weighted mean efficacy of Mandestrobin 40SC at different application rates against *S. sclerotiorum* on oilseed rape - Disease severity

EPPO climatic zone	# Trials	<i>Inoculated untreated control (%)</i>			Mean control (%) Mandestrobin 40SC 0.313 L/ha 0.625N 125 g a.s./ha			Mean control (%) Mandestrobin 40SC 0.375 L/ha 0.75N 150 g a.s./ha			Mean control (%) Mandestrobin 40SC 0.5 L/ha N 200 g a.s./ha		
		<i>Mean</i>	<i>min</i>	<i>max</i>	Mean	min	max	Mean	min	max	Mean	min	max
	Disease severity												
Maritime	7	21.1	5.9	40.8	60.4	29.3	80.5	68.3	34.3	93.3	68.2	37.7	89.4
North-East	7	34.9	18.3	53.7	65.4	49.3	80.0	75.3	66.0	86.9	83.8	62.6	97.8
Central zone	14	28.0	5.9	53.7	62.9	29.3	80.5	71.8	34.3	93.3	76.0	37.7	97.8

Central registration zone

Regarding the parameter “incidence of *S. sclerotiorum* on stems”, considered the most relevant for the assessment of this disease, data generated across 36 valid trials carried out in the Maritime, North-East and South-East EPPO climatic zones show a clear dose response of Mandestrobin 25SC, application at the N rate (200 g a.s./ha) providing a gain of +10.1 points of efficacy on disease incidence compared to application at 0.75N rate. This dose of 200 g a.s./ha is the one already authorised for Mandestrobin 25SC for the control of *S. sclerotiorum* on oilseed rape.

In addition, data generated across 14 valid trials carried out in the Maritime and North-East EPPO climatic zones show a clear dose response of Mandestrobin 40SC, application at the N rate (200 g a.s./ha) providing a gain of +13.8 points of efficacy on disease incidence compared to application at 0.625N rate and +5.7 points of efficacy compared to application at 0.75N rate.

Regarding the parameter “severity of *S. sclerotiorum* on stems”, presented to strengthen incidence data, data generated across 25 valid trials carried out in the Maritime, North-East and South-East EPPO climatic zones show a clear dose response of Mandestrobin 25SC, application at the N rate (200 g a.s./ha) providing a gain of +9.0 points of efficacy on disease severity compared to application at 0.75N rate.

In addition, data generated across 14 valid trials carried out in the Maritime and North-East EPPO climatic zones show a clear dose response of Mandestrobin 40SC, application at the N rate (200 g a.s./ha) providing a gain of +13.1 points of efficacy on disease severity compared to application at 0.625N rate and +4.2 points of efficacy compared to application at 0.75N rate.

It is therefore reasonable to conclude that the proposed label rate of ~~0.8~~ 0.5 L/ha (200 g a.s./ha) of Mandestrobin 40SC is fully justified as the minimum effective dose in the Central registration zone.

Conclusion – Minimum effective dose

The presented data correspond with the requirements of the EPPO Standard PP 1/225.

Maritime zone

Mandestrobin 40SC showed a slight dose-response effect between the 0.625N and N application rates, but this difference was not statistically significant in the individual trials. Application at the N rate led to an increased control of disease incidence and severity compared to application at 0.625N rate and the 0.75N rate. As a result, the proposed rate of 0.5 L/ha (200 g a.s./ha) should be considered the minimum effective dose to deliver optimum control, specifically under higher disease pressure conditions.

North East zone

For *Sclerotinia sclerotiorum*, the proposed dose of 0.5 L/ha Mandestrobin 40SC achieved higher levels of control than the reduced rates of both 125 and 150 g a.s./ha. In many trials the consistency of control was also improved with slightly reduced variability in control levels from the proposed dose. The results showed a better level of consistency in the north-eastern zone in oilseed rape when Mandestrobin 40SC is applied at the proposed dose 0.5L/ha. As a result, the proposed rate of 0.5 L/ha (200 g a.s./ha) should be considered the minimum effective dose to deliver optimum control *Sclerotinia sclerotiorum* in oilseed rape.

South East zone

For the evaluation of the minimum effective dose against *Sclerotinia sclerotiorum*, the applicant presented 9 field trials conducted in 2012 and 2014. In these trials, Mandestrobin 25SC showed a clear dose-response, with better control at 200 g a.s./ha compared to 100 and 150 g a.s./ha. The concerned Member States are invited to decide whether to accept the results of trials conducted a decade ago.

3.2.3 Efficacy tests (KCP 6.2)

This dRR B3 aims at Mandestrobin 40SC authorisation according to Article 33 of Regulation (EC) No 1107/2009 in the Central regulatory zone.

Efficacy of Mandestrobin 40SC (mandestrobin 400 g/L) will be demonstrated through 2 trials series:

- First, efficacy results from trials conducted with a similar formulation, Mandestrobin 25SC (coded S-2200 25SC), are presented (results, tables and comments taken from the dossier submitted in 2015 (BAD and dRR B3 Central zone, zRMS AT, December 2015) for Mandestrobin 25SC authorization).
In the Central zone, a total of 63 efficacy trials including 49 valid trials were carried out in order to confirm the efficacy and interest of the fungicide Mandestrobin 25SC against *Sclerotinia sclerotiorum* on oilseed rape. The trials were conducted from 2008 to 2014 in the Maritime (Austria, France, Germany and the United Kingdom), South-East (Hungary) and North-East (Poland) zones, the three EPPO climatic zones of the Central EU zone.
- Then, efficacy results from trials conducted with Mandestrobin 40SC are presented. The data set consists of a set of 16 trials including 15 valid trials carried out in 2021-2022 in the Maritime (8 valid trials) and North-East EPPO zones (7 trials).

All the trials were conducted with winter oilseed rape. Given that limited acreage of spring oilseed rape is grown, and that spring oilseed rape is less susceptible to *S. sclerotiorum* than winter oilseed rape, it is considered that results generated on winter oilseed rape can be extrapolated to spring oilseed rape.

3.2.3.1 Efficacy tests – Mandestrobin 25SC

All the information and data presented below (in Part 3.2.3.1) have already been submitted (in December 2015) and evaluated for authorisation of Mandestrobin 25SC (code S-2200 25SC) by Austria as zRMS in the Central regulatory zone.

3.2.3.1.1 Material and methods – Efficacy - Mandestrobin 25SC

A total of 63 efficacy trials including 49 valid trials were carried out in order to confirm the efficacy and interest of the fungicide Mandestrobin 25SC (coded S-2200 25SC) against *Sclerotinia sclerotiorum* on oilseed rape.

The trials were conducted from 2008 to 2014 in the Maritime (Austria, France, Germany and the United Kingdom), South-East (Hungary) and North-East (Poland) zones, the three EPPO climatic zones of the Central EU zone.

Trial overview

All the trials were carried out by officially recognised organisations in accordance with the principles of Good Experimental Practice (GEP).

Table 3.2-25: Overview on the efficacy trials carried out from 2008 to 2014 on oilseed rape against *S. sclerotiorum* – Central zone

EPPO Climatic zone	Country	Trials conducted in year:						Total	
		2008	2010	2011	2012	2013	2014		
Maritime	AT	-	-	-	-	-	4	4	43
	DE	7	2	-	-	3	-	12	
	UK	6	4	-	-	2	-	12	
	FR-North	4	6	4	-	1	-	15	
North-East	PL	-	-	-	5	-	6	11	11
South-East	HU	-	-	-	3	-	6	9	9
Total		17	12	4	8	6	16	63	

Trials, Trial Design, Testing Guidelines

The trials were conducted under field conditions, in representative areas of Europe where oilseed rape crops are commercially grown at a large scale.

The experimental sites were selected in homogeneous agronomical areas. In these sites, either *S. sclerotiorum* disease problems were encountered in the previous years (58) or artificial inoculations were performed (5) to ensure the disease occurrence.

No. of trials; trial seasons	63 ; 2008 (17), 2010 (12), 2011 (4), 2012 (8), 2013 (6), 2014 (16)
Trial country and regions	Austria: Lower Austria, Oberösterreich France: Ain, Aisne, Côte d'Or, Essonne, Eure, Indre et Loire, Jura, Loir et Cher, Meuse, Pas de Calais, Saône et Loire Germany: Baden Württemberg, Brandenburg, Mecklenburg-Vorpommern, Niedersachsen, Nordrhein-Westfalen, Schleswig-Holstein and Thüringen United Kingdom: East Yorkshire, Fife, Leicestershire, Lincolnshire, Nottinghamshire, Wiltshire and Yorkshire Hungary: Győr-Ménfőcsanak, Heves, Pest, Vas Poland: Dolnośląskie, Opolskie
Replicates	3 (4) or 4 (59)
Plot size	20 to 45 m ²
Trial design	Randomised complete blocks
Testing guidelines	PP 1/152(3 or 4), PP 1/181(3 or 4), PP 1/135(2 or 3) and PP 1/78(3) or PP 1/80(2) CEB 156 or CEB 220
Soil texture	Clay, clay loam, humic sand, loam, sandy clay, sandy clay loam, sandy loam, sandy silt loam, silt, silt loam, silty clay, silty clay loam

Plant Species, Varieties, Fungicides

The efficacy of S-2200 25SC was compared to the untreated plot and to a number of reference products registered against *Sclerotinia sclerotiorum* on oilseed rape.

Plant species; varieties	<i>Brassica napus</i> (winter); Locally grown commercial varieties: Alpaga, Artoga, Aviator, Bravour, Cabernet, Californium, Camelot, Castille, Catalana, Catalina, Digger, DK Expower, DK Exquisite, DK Exstorm, DK Sequoia, Exocet, Finesse, Flash, Hycolor, KWS Turan, Labrador, Monolit, Neptune, Poznaniak, PR45D03, PR46W20, Rohan, RP45D01, Sesame, Sherlock, SY Alister, Troy, Visby, Vision <i>Brassica napus</i> (spring); Locally grown commercial varieties: Colossus, Seven
Tested product, rates	S-2200 25SC, 0.8 L/ha (corresponding to 200 g as/ha)
Reference products, used rates	FOLICUR, 1- 1.5 - 2 L/ha (corresponding to 250 - 375 - 500 g as/ha) FOLICUR SOLO, 1 L/ha (corresponding to 250 g as/ha) HORIZON, 1 - 1.25 L/ha (corresponding to 250 - 312 g as/ha) PICTOR, 0.5 L/ha (corresponding to 200 g as/ha) PICTOR 400SC, 0.5 L/ha (corresponding to 200 g as/ha) PICTOR PRO, 0.5 kg/ha (corresponding to 250 g as/ha) CANTUS, 0.5 kg/ha (corresponding to 250 g as/ha) FILAN, 0.5 kg/ha (corresponding to 250 g as/ha) PROLINE, 0.7 L/ha (corresponding to 175 g as/ha)

Nine reference products were applied in the trials. The registered rates (hereafter expressed in kg or L/ha formulated product) depend on the individual countries and are provided in the table below with the main information on these reference products.

Table 3.2-26: Reference products included in the efficacy trials carried out from 2008 to 2014 on oilseed rape against *S. sclerotiorum* – Central zone

Product name	Registered rate (Country)	Formulation	Active Substance	AS content
FOLICUR	1 L/ha (UK) 1.5 L/ha (DE) 2 L/ha (AT)	Emulsion, oil in water	tebuconazole	250 g/L
FOLICUR SOLO	1 L/ha (HU)	Emulsion, oil in water	tebuconazole	250 g/L
HORIZON	1 L/ha (FR) 1.25 L/ha (PL)	Emulsion, oil in water	tebuconazole	250 g/L
PICTOR	0.5 L/ha (HU)	Suspension concentrate	boscalid + dimoxystrobin	200 g/L + 200 g/L
PICTOR 400SC	0.5 L/ha (PL)	Suspension concentrate	boscalid + dimoxystrobin	200 g/L + 200 g/L
PICTOR PRO	0.5 kg/ha (FR)	Water dispersible granule	boscalid	500 g/kg
CANTUS	0.5 kg/ha (DE)	Water dispersible granule	boscalid	500 g/kg
FILAN	0.5 kg/ha (UK)	Water dispersible granule	boscalid	500 g/kg
PROLINE	0.7 L/ha (DE/UK)	Emulsifiable concentrate	prothioconazole	250 g/L

FOLICUR, FOLICUR SOLO and HORIZON are all tebuconazole formulations (250 g/L).
CANTUS, FILAN and PICTOR PRO are both boscalid formulations (500 g/kg).

Planting and Application

Sowing; season	According to common practice; <i>Brassica napus</i> (winter): Summer 2009, 2010, 2011, 2012 and 2013 (Aug-Sep) <i>Brassica napus</i> (spring): Spring 2011 (Mar) and Spring 2014 (Apr)
Number of application	1
Application method; season	Overall spray; Spring 2008, 2010, 2011, 2012, 2013 and 2014 (Apr-Jun)
Crop growth stage at application	BBCH 62-69
Spray volume	150-350 L/ha

Assessments

Assessment types	<ul style="list-style-type: none"> - Pest incidence (PESINC) - Yield and quality parameters - Crop safety
Timing of ratings	One week after application to approximately three weeks before the harvest and finally at the harvest

Assessment methods

From one to two assessments were performed in the trials, evaluating the pest incidence.

The percentage of plants infected by *S. sclerotiorum* was used to evaluate the incidence of the disease, *i.e.* PESINC.

Then, an efficacy as percentage of disease reduction versus the untreated plot was calculated according to the Abbott formula:

$$\% \text{Efficacy} = \% \text{Reduction of the disease} = \left(1 - \frac{\text{Treated plot after the application}}{\text{Untreated plot after the application}} \right) \times 100$$

Furthermore, the yield was assessed in decitons per hectare in 44 trials, as well as several quality parameters (thousand grain weight, specific weight, oil content) in some trials. Details of the assessment types and methods, and results are reported in Parts 3.4.2 and 3.4.3.

In all the trials, the potential crop phytotoxicity symptoms and adverse effects were visually assessed. Details of the assessment types and methods, and results are reported in Part 3.4.1.

Statistical analysis:

All data statistical analyses were performed on the pest incidence including the untreated control.

First, data were checked for homogeneity of variances using the Bartlett's test. When this condition was met, an analysis of variance (ANOVA) was performed on the data or transformed data.

Multiple comparison tests were then applied to identify homogeneous groups based on the mean differences that may be detected by the ANOVA. The Student-Newman-Keuls test was used for mean comparisons in all the trials. The results are indicated by a letter. Treatments without any letter in common are significantly different with a 95% confidence level.

3.2.3.1.2 Results – Efficacy - Mandestrobin 25SC

Out of the 63 trials that were carried out, 14 trials did not reach a minimum acceptable level of infestation (<5% incidence of *S. sclerotiorum*, minimum level of disease required by the CRD guidance on efficacy requirements; see Chemicals Regulation Directorate - Data Requirements Handbook, Chapter 8). The results from these trials are excluded from the efficacy analysis; nevertheless, yield and quality results and phytotoxicity observations from these trials are analysed in the respective sections (Parts 3.4.1.1.2, 3.4.2.1 and 3.4.3.1).

Therefore, the results of 49 trials with suitable levels of infestation are presented and analysed below. These trials were conducted in Germany, the United Kingdom, France, Austria, Poland and Hungary from 2008 to 2014.

The recommended minimum effective dose of the fungicide S-2200 25SC at 0.8 L/ha (200 g a.s./ha) was compared to several registered reference products.

The efficacy of S-2200 25SC is studied across the three EPPO climatic zones encompassed in the Central EU regulatory zone, *i.e.* Maritime, North-East and South-East EPPO zones.

Maritime zone

Disease incidence

The disease incidence data from 29 trials carried out in the Maritime EPPO climatic zone (Austria, Germany, United Kingdom and extrazonal data from Northern France) from 2008 to 2014 are presented in **Table 3.2-27** below.

The efficacy of the fungicide S-2200 25SC was analysed and compared to that of the reference products FOLICUR or HORIZON (tebuconazole 250 g/L), CANTUS or FILAN or PICTOR PRO (boscalid 500 g/kg) and PROLINE (prothioconazole 250 g/L).

Table 3.2-27: Summary of the efficacy results obtained with S-2200 25SC – Maritime EPPO climatic zone – 2008 to 2014

Number of trials	Year	Country	Assessment type	Days after treatment	Untreated plot	S-2200 25SC	FOLICUR / HORIZON*	CANTUS / FILAN / PICTOR PRO	PROLINE
						mandestrobin 250 g/L	tebuconazole 250 g/L	boscalid 500 g/kg	prothioconazole 250 g/L
						0.8 L/ha (200 g as/ha)	1-2 L/ha (250-500 g as/ha)	0.5 kg/ha (250 g as/ha)	0.7 L/ha (175 g as/ha)
22 data	2008-2014	AT, DE, UK, FR	Average %PESINC %Efficacy	43-79 DA-A	39.94 a	17.94 b 55.09	18.34 b		
22 data	2008-2014	DE, UK, FR	Average %PESINC %Efficacy	51-84 DA-A	38.57 a	18.02 b 53.29		14.19 b 63.22	
9 data	2008	DE, UK	Average %PESINC %Efficacy	51-79 DA-A	47.48 a	26.44 b 44.30	24.28 b 48.86	21.98 b 53.71	23.98 b 49.50

*Reference products based on tebuconazole 250 g/L EW applied at 1 L/ha (250 g as/ha) in UK and FR, at 1-1.5 L/ha (250-375 g as/ha) in DE and 2 L/ha (500 g as/ha) in AT.

In 22 trials, S-2200 25SC was compared to tebuconazole formulations (FOLICUR or HORIZON). On average, with an infestation level of 39.94% incidence, both treatments offered a statistically significant reduction of the incidence rate: S-2200 25SC applied at 0.8 L/ha reduced the disease incidence by 55.09%. The efficacy of S-2200 25SC appeared equivalent to that of the standard tebuconazole formulations (54.09%) and no statistical difference was noted between the products.

In the 22 trials where S-2200 25SC was compared to boscalid formulations (CANTUS, FILAN or PICTOR PRO), the average incidence level reached 38.57%. The efficacy of the tested formulation (53.29%) was also statistically comparable to that of the standards (63.22%) which showed a tendency to have a slightly better efficacy.

In 9 trials, S-2200 25SC was also compared to a prothioconazole formulation (PROLINE) alongside the two other standard tebuconazole and boscalid formulations. The average incidence level reached 47.48%. The efficacy of S-2200 25SC (44.30%) was statistically comparable to the efficacy of PROLINE (49.50%) and also to that of the two other standards.

Yield from efficacy trials, in the presence of *S. sclerotiorum*

In the Maritime zone, S-2200 25SC was compared to tebuconazole-based specialties in 15 trials and to boscalid-based products in 10 trials.

Table 3.2-28: Summary of the yield results obtained in infected oilseed rape trials with S-2200 25SC in the Maritime zone – 2008 to 2014.

Number of trials	Year	Country	Assessment type	Untreated plot	S-2200 25SC	FOLICUR / HORIZON	CANTUS / FILAN / PICTOR PRO
					mandestrobin 250 g/L	tebuconazole 250 g/L	boscalid 500 g/kg
					0.8 L/ha (200 g as/ha)	1-2 L/ha (250-500 g as/ha)	0.5 kg/ha (250 g as/ha)
15 data	2008-2014	AT, FR, DE, UK	Average Yield (dt/ha)	43.58 b	45.99 a	47.42 a	
10 data	2008-2010	FR, DE, UK	Average Yield (dt/ha)	43.22 b	46.30 a		47.57 a

*Reference products based on tebuconazole 250 g/L EW applied at 1 L/ha (250 g as/ha) in UK and FR, 1.5 L/ha (375 g as/ha) in DE and 2 L/ha (500 g as/ha) in AT.

On average of 15 trials, the yield was 43.58 dt/ha in the untreated plot. The yield obtained after an application of S-2200 25SC at the recommended rate of 0.8 L/ha was significantly higher (45.99 dt/ha) and statistically comparable to that of the plots treated with the reference products based on tebuconazole (47.42 dt/ha).

When S-2200 25SC was compared to boscalid-based products (in 10 trials), similar conclusions were drawn: S-2200 25SC delivered a high level of yield and was statistically as effective as the reference products (46.30 vs. 47.57 dt/ha).

North-East zone

Disease incidence

In the North-Eastern EPPO climatic zone (Poland), 11 efficacy trials were conducted in 2012 and 2014. In all of these trials, the fungicide S-2200 25SC applied at the recommended rate of 0.8 L/ha was compared to the standard HORIZON (tebuconazole 250 g/L). The reference product PICTOR 400SC (boscalid 200 g/L + dimoxystrobin 200 g/L) was also included in 5 trials.

Table 3.2-29: Summary of the efficacy results obtained with S-2200 25SC – North-Eastern EPPO climatic zone – 2012 and 2014.

Number of trials	Year	Country	Assessment type	Days after treatment	Untreated plot	S-2200 25SC	HORIZON	PICTOR 400SC
						mandestrobin 250 g/L	tebuconazole 250 g/L	boscalid 200 g/L + dimoxystrobin 200 g/L
						0.8 L/ha (200 g as/ha)	1.25 L/ha (312 g as/ha)	0.5 L/ha (200 g as/ha)
11 data	2012-2014	PL	Average %PESINC %Efficacy	42-59 DA-A	23.27 <i>a</i>	3.91 <i>b</i> 83.20	5.09 <i>b</i> 78.13	
5 data	2012	PL	Average %PESINC %Efficacy	42-51 DA-A	19.60 <i>a</i>	4.50 <i>b</i> 77.04	7.40 <i>b</i> 62.24	5.70 <i>b</i> 70.92

On average of all 11 trials, the disease incidence was 23.27%. S-2200 25SC allowed statistically reducing this incidence rate, with a level of efficacy of 83.20%, statistically equivalent to HORIZON (78.13%). There was a tendency of S-2200 25SC to deliver a slightly better control than that provided by the standard. On average of the 5 trials where PICTOR 400SC (boscalid 200 g/L + dimoxystrobin 200 g/L) was applied as a second standard, the disease incidence was 19.60% and the efficacy achieved by S-2200 25SC (77.04%) was statistically equivalent to that of PICTOR 400SC (70.92%).

Yield from efficacy trials, in the presence of *S. sclerotiorum*

In the North-Eastern zone, 11 trials compared S-2200 25SC to tebuconazole-based specialties. PICTOR 400SC (boscalid 200 g/L + dimoxystrobin 200 g/L) was also included in 5 of these trials.

Table 3.2-30: Summary of the yield results obtained in infected oilseed rape trials with S-2200 25SC in the North-Eastern zone – Poland – 2012 and 2014.

Num- ber of trials	Year	Coun- try	Assessment type	Untreated plot	S-2200 25SC	HORIZON	PICTOR 400SC
					mandestrobin	tebuconazole	boscalid 200 g/L + dimoxystrobin
					250 g/L	250 g/L	200 g/L
					0.8 L/ha (200 g as/ha)	1.25 L/ha (312 g as/ha)	0.5 L/ha (200 g as/ha)
11 data	2012-2014	PL	Average Yield (dt/ha)	36.22 <i>b</i>	39.97 <i>a</i>	39.70 <i>a</i>	
5 data	2012	PL	Average Yield (dt/ha)	36.70 <i>a</i>	38.42 <i>a</i>		37.94 <i>a</i>

The average yield (11 trials) in the untreated plot was 36.22 dt/ha. S-2200 25SC significantly increased the yield to 39.97 dt/ha, at the same level as the reference product HORIZON.

On average of the 5 trials including PICTOR 400SC, the untreated plot had a yield of 36.70 dt/ha, while the plots treated with S-2200 25SC or PICTOR 400SC reached 38.42 dt/ha and 37.94 dt/ha respectively. No statistically significant difference was detected.

South-East zone

Disease incidence

In the South-East EPPO climatic zone (Hungary), the data from 9 efficacy trials conducted in 2012 and 2014 are analysed and presented in Table 3.2-31 below.

The fungicide S-2200 25SC was compared to the standard FOLICUR SOLO (tebuconazole 250 g/L) in all the trials, and to PICTOR (boscalid 200 g/L + dimoxystrobin 200 g/L) in 3 trials.

Table 3.2-31: Summary of the efficacy results obtained with S-2200 25SC – South-Eastern EPPO climatic zone (Hungary) – 2012 and 2014.

Number of trials	Year	Country	Assessment Type	Days after treatment	Untreated plot	S-2200 25SC	FOLICUR SOLO	PICTOR
						mandestrobin 250 g/L	tebuconazole 250 g/L	boscalid 200 g/L + dimoxystrobin 200 g/L
						0.8 L/ha (200 g as/ha)	1 L/ha (250 g as/ha)	0.5 L/ha (200 g as/ha)
9 data	2012-2014	HU	Average %PESINC %Efficacy	18-75 DA-A	24.91 a	4.25 b 82.94	3.28 b 86.84	
3 data	2012-2014	HU	Average %PESINC %Efficacy	62-64 DA-A	16 a	0.58 b 96.35	0.00 b 100.00	0.00 b 100.00

On average of all 9 trials, the infestation level was 24.91% incidence. Both treatments had a statistically significant effect reducing the disease incidence: the efficacy of S-2200 25SC at 0.8 L/ha was 82.94%. This efficacy was equivalent to that of FOLICUR SOLO (86.84%) with no statistical difference observed. In the 3 trials where PICTOR (boscalid 200 g/L + dimoxystrobin 200 g/L) was also included as a second standard, the average disease incidence was 16.00% and there was no statistical difference between the efficacies of S-2200 25SC (96.38%), FOLICUR SOLO (100%) and PICTOR (100%).

The behaviour of S-2200 25SC and FOLICUR SOLO appeared to be statistically comparable in 8 individual trials out of 9. In only one trial (BR3897), the efficacy of S-2200 25SC was statistically lower than that of the standards (90.91% vs. 100% efficacy respectively).

But, when considering the most infected trials (BR5530 and BR5531) with 35.50% and 35.20% incidence respectively, S-2200 25SC had a level of efficacy statistically comparable to that of the standard (90.14% and 95.74% vs. 95.77% and 98.58% respectively).

It can be noted that these two trials were spring sown with spring oilseed rape varieties, confirming that S-2200 25SC was able to reach a high level of efficacy in this crop too.

Yield from efficacy trials, in the presence of *S. sclerotiorum*

In the South-Eastern zone, S-2200 25SC was compared to FOLICUR SOLO (tebuconazole 250 g/L) in 9 trials, including 2 trials carried out on spring oilseed rape varieties.

Table 3.2-32: Summary of the yield results obtained in infected oilseed rape trials with S-2200 25SC in the South-Eastern zone – 2012 and 2014

Number of trials	Year	Country	Assessment type	Un-treated plot	S-2200 25SC	FOLICUR SOLO	PICTOR
					mandestrobin 250 g/L	tebuconazole 250 g/L	boscalid 200 g/L + dimoxystrobin 200 g/L
					0.8 L/ha (200 g as/ha)	1 L/ha (250 g as/ha)	0.5 L/ha (200 g as/ha)
7 data	2012-2014	HU	Average Winter Oilseed Rape Yield (dt/ha)	28.27 a	30.34 a	31.55 a	
3 data	2012	HU	Average Winter Oilseed Rape Yield (dt/ha)	20.60 b	24.30 a		24.63 a
2 data	2014	HU	Average Spring Oilseed Rape Yield (dt/ha)	9.77 -	9.84 -	9.97 -	

On average, the untreated winter oilseed rape plots yielded 28.27 dt/ha. One application of S-2200 25SC at 0.8 L/ha improved this result with an average of 30.34 dt/ha, equal to a gain of 2 dt/ha. There was no statistical difference between S-2200 25SC and the standard (31.55 dt/ha).

In 3 trials on winter oilseed rape, PICTOR was included as a second standard. On average of these trials, both treatments significantly increased the yield compared to the untreated, but without difference between S-2200 25SC and PICTOR (24.30 dt/ha and 24.63 dt/ha respectively).

In 2 trials (BR5530 and BR5531), spring oilseed rape varieties were sown and harvested. As expected, the yields were lower than the winter-sown varieties (9.77 dt/ha on average in the untreated).

In the individual trial data, no significant differences were detected between any of the treatments and the untreated, showing that S-2200 25SC had no negative impact on yield of spring oilseed rape.

Conclusion Central regulatory zone

63 trials were carried out from 2008 to 2014 in Austria, Northern-France, Germany, the United Kingdom, Poland and Hungary, belonging to the three EPPO climatic zones relevant for registration in the Central EU zone. 49 trials out of the 63 ones had suitable levels of infestation (*i.e.* disease incidence greater than 5%) for the analysis.

The following table shows a comparison between S-2200 25SC and the two main standards categories in the oilseed rape market (tebuconazole and boscalid-based products).

Table 3.2-33: Overall summary of the efficacy results obtained with the fungicide S-2200 25SC – Central EU zone – 2008 to 2014.

EPPO Climatic Zone	Number of trials	Assessment type	Days after treatment	Untreated plot	S-2200 25SC Mandestrobin 250 g/L	Tebuconazole 250 g/L EW	Boscalid 500 g/kg WG	Standard*
					0.8 L/ha (200 g as/ha)	1-2 L/ha (250-500 g as/ha)	0.5 kg/ha (250 g as/ha)	
Maritime	22 data	Average %PESINC %Efficacy	43-79 DA-A	39.94 a	17.94 b 55.09	18.34 b 54.09		
	22 data	Average %PESINC %Efficacy	51-84 DA-A	38.57 a	18.02 b 53.29		14.19 b 63.22	
	29 data	Average %PESINC %Efficacy	43-84 DA-A	37.83 a	17.35 b 54.14			17.15 b 54.66
North-East	11 data	Average %PESINC %Efficacy	42-59 DA-A	23.27 a	3.91 b 83.20	5.09 b 78.13		5.09 b 78.13
South-East	9 data	Average %PESINC %Efficacy	18-75 DA-A	24.91 a	4.25 b 82.94	3.28 b 86.84		3.28 b 86.84
All zones	42 data	Average %PESINC %Efficacy	18-79 DA-A	32.36 a	11.33 b 64.98	11.64 b 64.02		
	22 data	Average %PESINC %Efficacy	51-84 DA-A	38.57 a	18.02 b 53.29		14.19 b 63.22	
	49 data	Average %PESINC %Efficacy	18-84 DA-A	32.19 a	11.93 b 62.95			11.90 b 63.05

*Average of commercial reference products, using primarily tebuconazole formulations where they were available or a boscalid formulation in the other trials.

On average across all zones (49 trials), under an infestation level of 32.19% incidence, the efficacy of the fungicide S-2200 25SC applied at the recommended rate of 0.8 L/ha (200 g a.s./ha) reached 62.95%.

The efficacy of S-2200 25SC was compared to tebuconazole-based specialties in 42 trials. The average results show that the fungicide S-2200 25SC is equivalent to these standards: 64.98% efficacy for S-2200 25SC vs. 64.02% for the standards.

Where S-2200 25SC was compared to boscalid-based formulations (22 data), these reference products tended to be slightly more effective: 53.29% efficacy for S-2200 25SC vs. 63.22% for the standards, but with no statistically significant difference.

The fungicide Mandestrobin 25SC (mandestrobin 250 g/L), coded S-2200 25SC, applied at the recommended minimum effective dose of 0.8 L/ha (200 g a.s./ha) appears to be a relevant alternative to the tested standards for the control of *Sclerotinia sclerotiorum* on oilseed rape, with an efficacy equivalent to tebuconazole- and boscalid-based specialties.

Therefore, the fungicide Mandestrobin 25SC (coded S-2200 25SC) is considered as effective and reliable to control *Sclerotinia sclerotiorum* on winter and spring oilseed rape. It should be applied once at 0.8 L/ha (200 g a.s./ha) during crop flowering, i.e. BBCH 60-69.

The equivalence between both formulations has been demonstrated in point 3.2.1 Preliminary tests (KCP 6.1), thus data generated with Mandestrobin 25SC at 200 g a.s./ha can support the claim of the use of Mandestrobin 40SC at 200 g a.s./ha for the control *Sclerotinia sclerotiorum* on oilseed rape.

3.2.3.2 Efficacy tests – Mandestrobin 40SC

A total of 16 field trials (among them 15 valid) were conducted in Germany, France and Poland in 2021 and 2022 in order to investigate the efficacy of Mandestrobin 40SC at 0.5 L/ha (200 g a.s./ha) to control *S. sclerotiorum* in oilseed rape. 9 trials (8 valid) were carried out in the EPPO Maritime zone (DE and FR) and 7 trials were carried out in the North-East EPPO zone (PL). The trial distribution is detailed in Table 3.2-34.

Table 3.2-34: Efficacy trials distribution

Trial no.	EPPO climatic zone	Country	Year	Crop	Target	Valid for efficacy assessment
9 trials	Maritime	DE	2021	BRSNW	SCLESC	8 trials: Y*, ** 1 trial: N (no efficacy of reference product)
	Maritime	DE	2021	BRSNW	SCLESC	
	Maritime	DE	2021	BRSNW	SCLESC	
	Maritime	DE	2021	BRSNW	SCLESC	
	Maritime	FR Mar	2021	BRSNW	SCLESC	
	Maritime	FR Mar	2021	BRSNW	SCLESC	
	Maritime	FR Mar	2021	BRSNW	SCLESC	
	Maritime	FR Mar	2021	BRSNW	SCLESC	
	Maritime	FR Mar	2021	BRSNW	SCLESC	
7 trials	North-East	PL	2021	BRSNW	SCLESC	Y
	North-East	PL	2021	BRSNW	SCLESC	
	North-East	PL	2021	BRSNW	SCLESC	
	North-East	PL	2021	BRSNW	SCLESC	
	North-East	PL	2022	BRSNW	SCLESC	
	North-East	PL	2022	BRSNW	SCLESC	
	North-East	PL	2022	BRSNW	SCLESC	

* for one trial, disease incidence assessment not taken into account, because no significant efficacy of the reference product.

** for another trial, disease severity assessment not taken into account, because infestation level below the 5% threshold.

3.2.3.2.1 Material and methods – Mandestrobin 40SC

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

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

Site description

Results from 15 valid trials are presented to study the efficacy of Mandestrobin 40SC for the control of *S. sclerotiorum* on oilseed rape.

Main characteristics of methodology are summarised in Table 3.2-35 (Maritime EPPO zone) and Table 3.2-36 (North-East EPPO zone). Details per trial (trial location, crop cultivar, experimental design, number of replicates, plot size and applications) are presented in Appendix 3 of the BAD.

Table 3.2-35: Details on trial methodology – Maritime EPPO zone

Guidelines	General guidelines	PP 1/135(4) PP 1/152(4) PP 1/181(4)
	Specific guidelines	PP 1/78(3)
Experimental design	Plot design	Randomised complete blocks (8 trials)
	Plot size	Plot area: from 24 to 30 m ²
	Number of replications	4 replications (8 trials)
Crop	Trials per crop	Winter oilseed rape (8 trials)
	Varieties per crop	Acropole (1 trial), Cristiano (1 trial), DK Excited (1 trial), DK Exstorm (1 trial), LG Architect (1 trial), RAGT Banquiss (1 trial), Rocca (1 trial), Smaragd (1 trial)
	Sowing period	Late August (19 th -28 th) / 1 st September
Application	Crop stage (BBCH) at application	BBCH 65
	Number of applications	1 application (8 trials)
	Pest stage at application	<i>S. sclerotiorum</i> artificially inoculated before or just after application (8)
	Spray volume	164 - 300 L/ha
Assessment	Assessment types and date	- Pest incidence (PESINC), around 3 weeks before harvest, BBCH 79-85 - Pest severity (PESSEV), around 3 weeks before harvest, BBCH 79-85 - Yield, at harvest - Specific weight (2 trials) - Crop safety
Other relevant information	e.g. Natural / artificial inoculation...	Artificial inoculation (8 trials)
	e.g. Field / Greenhouse...	Field trials

Table 3.2-36: Details on trial methodology – North-East EPPO zone

Guidelines	General guidelines	PP 1/135(4) PP 1/152(4) PP 1/181(4) or (5)
	Specific guidelines	PP 1/78(3)
Experimental design	Plot design	Randomised complete blocks (7 trials)
	Plot size	Plot area: from 21 to 30 m ²
	Number of replications	4 replications (7 trials)
Crop	Trials per crop	Winter oilseed rape (7 trials)
	Varieties per crop	Aspect (2 trials), Dominator (1 trial), Gemini (1 trial), Monolit (1 trial), Orion (1 trial), Sherlock (1 trial)
	Sowing period	Late August (25 th -30 th)
Application	Crop stage (BBCH) at application	BBCH 65
	Number of applications	1 application (7 trials)
	Pest stage at application	<i>S. sclerotiorum</i> artificially inoculated before or just after application (7 trials)
	Spray volume	300 L/ha
Assessment	Assessment types and date	- Pest incidence (PESINC), around 3 weeks before harvest, BBCH 79-85 - Pest severity (PESSEV) , around 3 weeks before harvest, BBCH 79-85 - Specific weight (3 trials) - Yield, at harvest - Crop safety
Other relevant information	e.g. Natural / artificial inoculation...	Artificial inoculation (7 trials)
	e.g. Field / Greenhouse...	Field trials

Treatments and reference standards

Mandestrobin 40SC was tested at the intended rate of 0.5 L/ha (200 g a.s./ha). Other lower applications rates were also tested and are presented in part 3.2.2 above.

Mandestrobin 40SC was compared in all trials to a boscalid-based reference.

These products are described in Table 3.2-37.

Table 3.2-37: Plant protection products applied in efficacy trials

Product name	Active substance(s)	Formulation		Application rate in trials	Rate of active substance
		Type	Concentration		
Mandestrobin 40SC	Mandestrobin	SC	400 g/L	0.5 L/ha	200 g a.s./ha
Cantus / Pictor Pro	Boscalid	WG	500 g/kg	0.5 kg/ha	250 g a.s./ha

Application method

Application details for all efficacy trials are included in individual trial reports and are summarised in Appendix 3 of the BAD.

Products were applied by spraying on the crop.

Artificial inoculation

S. sclerotiorum was artificially inoculated to the soil in all trials.

Several methods were used, and inoculation was done mostly in a few days before or after application of the treatments. In 2 trials, the inoculum was incorporated in the soil some weeks before treatments.

The inoculated untreated control was intended for the comparison with treated modalities, while a non-inoculated untreated control was implemented to check the natural presence of disease in the plot.

Assessment methods

Assessments of disease symptoms on plants

The incidence and severity of *S. sclerotiorum* on plants were assessed once or twice after application. The latest relevant assessment was selected for the summary tables.

The percentage of plants infected by *S. sclerotiorum* was used to evaluate the incidence of the disease, *i.e.* PESINC.

Severity was also assessed in the trials, with PESSEV expressed as a percentage of plant infected area.

Phytotoxicity

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

Efficacy calculation

The efficacy as percentage of disease reduction versus the inoculated untreated plot (% control) was calculated according to the Abbott formula, for incidence and severity, for all the trials:

$$\% \text{ control} = [(\text{Inoculated untreated value} - \text{Treated value}) / \text{Inoculated untreated value}] \times 100$$

The calculation was done for this dossier and are not presented in the trial reports.

The harmfulness of *S. sclerotiorum* on oilseed rape lies in the fact that the rot formed on stems prevent sap circulation and thus plant feeding, leading to lodging and shrivelling. The incidence criteria (percentage of infected stems) is thus considered the most relevant and a particular focus will be put on this parameter in the comments. Severity data (percentage of stem area infected) are presented as additional information.

Assessment of yield

The potential effect on yield was analysed in all the efficacy trials through the harvest of grains on the whole plot. The fresh weight and moisture of harvested grains were recorded, and yield at 9% humidity was calculated.

The percentage relative compared to the inoculated untreated control (%REL) was calculated for the treatments, using this formula:

$$\% \text{ REL} = (\text{Treated value} \times 100) / \text{Inoculated untreated value}$$

The calculation was done for this dossier and are not presented in the trial reports.

The specific weight (HLW) was measured in kg per hectoliter of grain in some trials and is presented in point 3.4.3.2 Effects on the the quality of plants or plant products - Mandestrobin 40SC.

Data selection

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

Infection level

Only the trials with a sufficient infection level in the inoculated untreated check are considered in the calculation of means: a threshold of 10% disease incidence and 5% disease severity was considered acceptable to generate reliable data and was set as a general rule.

The following scale was used to describe the infection level.

Table 3.2-38: Scale for description of *Sclerotinia sclerotiorum* infection level in the untreated inoculated control

Disease incidence / Disease severity	Description
< 10%	low
≥ 10% and < 30%	moderate
≥ 30% and < 50%	high
≥ 50% and < 80%	very high
≥ 80%	extremely high

Normal behaviour of products

If the reference product showed no significant efficacy compared to inoculated untreated control, the trial was not taken into account in the data groupings.

One trial has been considered as invalid for efficacy assessment based on this rule.

Statistical analysis – Individual trial results

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

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

All the trials were available under ARM format and have been processed with ARMst software, selecting Newman-Keuls test as unique mean separation test. For this reason, results of the mean separation test can differ from those presented in the trial report.

Statistical analysis - Grouped data

Statistical analyses were also conducted on grouped data using an analysis of variance (ANOVA) on untransformed or transformed data, for disease incidence, disease severity and yield data, with the untreated check included in the analysis. This statistical analysis was conducted when a minimum of 4 trials was available in a series. Data were analysed with the ARM software. The probability of no significant difference occurring between treatment means was calculated at the F probability value $p(F)=0.05$ (95% confidence limit).

Before running ANOVA tests, ANOVA assumptions were tested as follows:

- Homogeneity of variances was checked using a Bartlett's test.
- Normal distribution was tested using Skewness' and Kurtosis' tests.

If one of the above-mentioned tests failed, data were transformed using log transformation of $X+1$.

If the transformation could not solve the invalidity of the ANOVA assumptions, ANOVA and Newman-Keuls' tests were not included in the result tables.

When assumptions of ANOVA were valid (after data transformation or not), ANOVA and Newman-Keuls' tests were applied on the data set. Newman-Keuls test was applied to highlight any significant treatment differences that might be implied by the ANOVA and statistical classes are indicated by letters in the summary result tables.

These grouped data statistical analysis is provided for the preliminary tests results (Part 3.2.1), for the minimum effective dose tests results (Part 3.2.2) on disease incidence, and for the efficacy tests results (Part 3.2.3.2.2).

Raw data of statistical analyses performed on grouped data are available in Document K.

Description of products behaviour

The effectiveness of Mandestrobin 40SC at 0.5 L/h (200 g a.s./ha) is described in the comments according to the scale detailed in Table 3.2-39. This scale has been defined according to the efficacy levels observed in the trials.

Table 3.2-39: Scale for description of products effectiveness against *Sclerotinia sclerotiorum*

Efficacy (%)	Description
≥ 70%	very good
≥ 50% and < 70%	good
≥ 40% and < 50%	adequate
≥ 20% and < 40%	medium
< 20%	weak

3.2.3.2.2 Results – Mandestrobin 40SC

A total of 15 valid field trials were conducted in Germany, France and Poland in 2021 and 2022 in order to investigate the efficacy of Mandestrobin 40SC at 0.5 L/ha (200 g a.s./ha) to control *S. sclerotiorum* in oilseed rape. 8 trials were carried out in the EPPO Maritime zone (DE and FR) and 7 trials were carried out in the North-East EPPO zone (PL).

Results are presented below.

Maritime zone

Disease incidence and severity

Results from 8 valid field trials are presented to investigate the efficacy of Mandestrobin 40SC against *S. sclerotiorum* on oilseed rape. They were carried out in 2021 in the Maritime EPPO climatic zone, with 4 trials in Germany and 4 trials in France.

For disease incidence, summarised results are presented in **Table 3.2-40**.

For disease severity, summarised results are presented in **Table 3.2-41**.

All individual results are available in Appendix 4 of the BAD.

Table 3.2-40: Summarised results – Efficacy of Mandestrobin 40SC in oilseed rape to control *S. sclerotiorum* – Maritime EPPO climatic zone – Disease incidence

# Trials	Inoculated untreated control (Incidence %)			% control						No. of trials where Mandestrobin 40SC is significantly > ; < ; =, compared to
				Mandestrobin 40SC 0.5 L/ha 200 g a.s./ha			Boscalid 50% WG 0.5 kg/ha 250 g a.s./ha			
	Mean	min	max	Mean	min	max	Mean	min	max	Boscalid 50% WG
7*	36.7 a	16.5	53.0	53.0 b	24.0	88.0	68.3 b	32.0	100.0	0>;6=;1<

* for 1 trial, disease incidence assessment not taken into account, because no significant efficacy of the reference product.

Table 3.2-41: Summarised results – Efficacy of Mandestrobin 40SC in oilseed rape to control *S. sclerotiorum* – Maritime EPPO climatic zone – Disease severity

# Trials	Inoculated untreated control (Severity %)			% control						No. of trials where Mandestrobin 40SC is significantly > ; < ; =, compared to
				Mandestrobin 40SC 0.5 L/ha 200 g a.s./ha			Boscalid 50% WG 0.5 kg/ha 250 g a.s./ha			
	Mean	min	max	Mean	min	max	Mean	min	max	Boscalid 50% WG
7*	21.1 a	5.9	40.8	68.2 b	37.7	89.4	75.1 b	46.6	100.0	0>;7=;0<

* for 1 trial, disease severity assessment not taken into account, because infestation level below the 5% threshold.

In these trials, *S. sclerotiorum* incidence on plants was high in the inoculated untreated control, with 36.7% of infected plants on average across 7 trials, varying from 16.5% to 53.0% in individual trials.

Mandestrobin 40SC applied at 0.5 L/ha demonstrated a good effectiveness with a mean 53.0% control, varying from 24.0% to 88.0% in individual trials.

On average across 7 trials, Mandestrobin 40SC tended to be lower than the reference product Boscalid 50% WG (53.0% vs. 68.3% control), but they were statistically equivalent to each other. This was confirmed by the statistical analyses of individual trials in 6 trials out of 7.

S. sclerotiorum severity on plants was moderate in the inoculated untreated control, with 21.1% of infected area on stems on average across 7 trials, varying from 5.9% to 40.8% in individual trials.

Mandestrobin 40SC applied at 0.5 L/ha demonstrated a good effectiveness with a mean 68.2% control, varying from 37.7% to 89.4% in individual trials.

On average across 7 trials, Mandestrobin 40SC was slightly lower than the reference product Boscalid 50% WG (68.2% vs. 75.1% control), without significant difference between both treatments. Similarly, when considering individuals trials, no significant differences were reported.

In summary, when considering disease incidence and severity, Mandestrobin 40SC applied at 0.5 L/ha (200 g a.s./ha) demonstrated a good efficacy against *S. sclerotiorum* on oilseed rape, in 8 trials conducted in 2021 in the Maritime EPPO climatic zone.

Efficacy provided by Mandestrobin 40SC was equivalent to the efficacy provided by the reference product.

Yield from efficacy trials, in the presence of *S. sclerotiorum*

Yield data were recorded in the 8 trials carried out in the Maritime EPPO zone.

Summarised results are presented in **Table 3.2-42**.

All individual results are available in Appendix 4 of the BAD.

Table 3.2-42: Summarised results – Effect of Mandestrobin 40SC on yield of oilseed rape in presence of *S. sclerotiorum* – Maritime EPPO climatic zone – Yield (t/ha) and percentage relative to inoculated untreated control

# Trials	Inoculated untreated control (Yield t/ha))			Yield %REL						No. of trials where Mandestrobin 40SC is significantly > ; < ; =, compared to	
				Mandestrobin 40SC 0.5 L/ha 200 g a.s./ha			Boscalid 50% WG 0.5 kg/ha 250 g a.s./ha				
	Mean	min	max	Mean	min	max	Mean	min	max	Inoculated un- treated control	Boscalid 50% WG
8	4.1 b	3.0	4.9	109.0 a	99.5	119.9	112.2 a	103.9	126.8	2>;6=;0<	0>;8=;0<

In these trials, at assessment at harvest, in the inoculated untreated control, the yield was of 4.1 t/ha on average across 8 trials with *S. sclerotiorum* infection (varying from 3.0 to 4.9 t/ha in individual trials).

Mandestrobin 40SC applied at 0.5 L/ha demonstrated a positive effect on the yield of oilseed rape in the presence of disease. There was on average +9.0% increase in yield compared to the untreated control, with a significant effect in 2 out of 8 trials.

On average across the 8 trials, this positive effect was similar to that demonstrated by the reference product Boscalid 50% WG (+9.0% vs. +12.2% mean increase). When considering individual trials, no significant difference was highlighted between treatments.

In summary, data from 8 trials investigating the efficacy of Mandestrobin 40SC for the control of *S. sclerotiorum* on oilseed rape in the Maritime EPPO climatic zone, showed that Mandestrobin 40SC applied at the intended rate 0.5 L/ha has a positive effect on yield in the presence of disease. This positive effect was equivalent to that provided by the reference product.

North-East zone

Disease incidence and severity

Results from 7 valid field trials are presented to investigate the efficacy of Mandestrobin 40SC and comparison with Mandestrobin 25SC, against *S. sclerotiorum* on oilseed rape. They were carried out in 2021 and 2022 in the North-East EPPO climatic zone, all in Poland.

For disease incidence, summarised results are presented in **Table 3.2-43**.

For disease severity, summarised results are presented in **Table 3.2-44**.

All individual results are available in Appendix 4 of the BAD.

Table 3.2-43: Summarised results – Efficacy of Mandestrobin 40SC in oilseed rape to control *S. sclerotiorum* – North-East EPPO climatic zone – Disease incidence

# Trials	<i>Inoculated untreated control (Incidence %)</i>			% control						No. of trials where Mandestrobin 40SC is significantly > ; < ; =, compared to
				Mandestrobin 40SC 0.5 L/ha 200 g a.s./ha			Boscalid 50% WG 0.5 kg/ha 250 g a.s./ha			
	<i>Mean</i>	<i>min</i>	<i>max</i>	Mean	min	max	Mean	min	max	Boscalid 50% WG
7	59.1 a	25.0	92.0	65.3 b	39.6	84.9	61.4 b	49.1	82.7	2>;5=;0<

Table 3.2-44: Summarised results – Efficacy of Mandestrobin 40SC in oilseed rape to control *S. sclerotiorum* – North-East EPPO climatic zone – Disease severity

# Trials	Inoculated untreated control (Severity %)			% control						No. of trials where Mandestrobin 40SC is significantly > < ; =, compared to
				Mandestrobin 40SC 0.5 L/ha 200 g a.s./ha			Boscalid 50% WG 0.5 kg/ha 250 g a.s./ha			
	Mean	min	max	Mean	min	max	Mean	min	max	Boscalid 50% WG
7	34.9 a	18.3	53.7	83.8 b	62.6	97.8	80.6 b	60.1	97.4	2>;5=;0<

In these trials, *S. sclerotiorum* incidence on plants was very high in the inoculated untreated control, with 59.1% of infected plants on average across 7 trials, varying from 25.0% to 92.0% in individual trials. Mandestrobin 40SC applied at 0.5 L/ha demonstrated a good effectiveness with 65.3% mean control, varying from 39.6% to 84.9% in individual trials.

On average across 7 trials, Mandestrobin 40SC was similar to the reference product Boscalid 50%WG (65.3% vs. 61.4% control). When considering individuals trials, Mandestrobin 40SC was significantly more effective than the reference product Boscalid 50%WG in 2 out of 7 trials, with very high disease pressure (92.0% and 90.5% disease incidence in the inoculated untreated control). In the other trials, both products were statistically equivalent to each other.

S. sclerotiorum severity on plants was high in the inoculated untreated control, with 34.9% of infected area on stems on average across 7 trials, varying from 18.3% to 53.7% in individual trials.

Mandestrobin 40SC applied at 0.5 L/ha demonstrated a very good effectiveness with a mean 83.8% control, varying from 62.6% to 97.8% in individual trials.

On average across 7 trials, Mandestrobin 40SC was similar to the reference product Boscalid 50%WG (83.8% vs. 80.6% control). When considering individuals trials, Mandestrobin 40SC was significantly more effective than the reference product Boscalid 50%WG in 2 out of 7 trials, with very high disease pressure (53.7% and 51.2% disease severity in the inoculated untreated control). In the other trials, both products were statistically equivalent to each other.

In summary, when considering disease incidence and severity, Mandestrobin 40SC applied at 0.5 L/ha (200 g a.s./ha) demonstrated a good to very good efficacy against *S. sclerotiorum* on oilseed rape, in 7 trials conducted in 2021 and 2022 in the North-East EPPO climatic zone.

Efficacy provided by Mandestrobin 40SC was similar or even slightly better than efficacy provided by the reference product.

Yield from efficacy trials, in the presence of *S. sclerotiorum*

Yield data were recorded in the 7 trials carried out in the North-East EPPO zone.

Summarised results are presented in **Table 3.2-45**.

All individual results are available in Appendix 4 of the BAD.

Table 3.2-45: Summarised results – Effect of Mandestrobin 40SC on yield of oilseed rape in presence of *S. sclerotiorum* – North-East EPPO climatic zone – Yield (t/ha) and percentage relative to inoculated untreated control

# Trials	Inoculated untreated control (Yield t/ha)			Yield %REL						No. of trials where Mandestrobin 40SC is significantly > ; < ; =, com pared to	
				Mandestrobin 40SC 0.5 L/ha 200 g a.s./ha			Boscalid 50% WG 0.5 kg/ha 250 g a.s./ha				
	Mean	min	max	Mean	min	max	Mean	min	max	Inoculated un- treated control	Boscalid 50% WG
7	2.9 b	2.2	3.8	139.4 a	115.3	181.5	131.4 a	108.5	170.3	3>;4=;0<	1>;6=;0<

In these trials, at assessment at harvest, in the inoculated untreated control, the yield was of 2.9 t/ha on average across 7 trials with *S. sclerotiorum* infection (varying from 2.2 to 3.8 t/ha in individual trials).

Mandestrobin 40SC applied at 0.5 L/ha demonstrated a high and significant positive effect on the yield of oilseed rape in the presence of disease. There was on average +39.4% increase in yield compared to the untreated control. When considering individual trials this was significant effect in 3 out of 7 trials.

On average across the 7 trials, this positive effect tended to be better than that of the reference product Boscalid 50% WG (+39.4% vs. +31.4% mean increase) even if they were statistically equivalent to each other. When considering individuals trials, the yield increase was significantly higher with the Mandestrobin 40SC treatment compared to the reference product Boscalid 50% WG in 1 out of 7 trials (where control provided by Mandestrobin 40SC was significantly better than that provided by the reference product).

In summary, data from 7 trials investigating the efficacy of Mandestrobin 40SC for the control of *S. sclerotiorum* on oilseed rape in the North-East EPPO climatic zone, showed that Mandestrobin 40SC applied at the intended rate 0.5 L/ha has a positive effect on yield in the presence of disease. This positive effect tended to be better than that provided by the reference product Boscalid 50% WG.

Conclusion

Summarised results regarding efficacy of Mandestrobin 40SC against *S. sclerotiorum* on oilseed rape, based on disease incidence and severity are detailed in Table 3.2-46. Results regarding yield assessments are summarized in Table 3.2-47.

Table 3.2-46: Weighted mean efficacy of Mandestrobin 40SC against *S. sclerotiorum* on oilseed rape

EPPO climatic zone	# Trials	Inoculated untreated control (%)			Mean control (%) Mandestrobin 40SC 0.5 L/ha			Mean control (%) Boscalid 50WG 0.5 kg/ha		
		Mean	min	max	Mean	min	max	Mean	min	max
Disease incidence										
Maritime	7	36.7 a	16.5	53.0	53.0 b	24.0	88.0	68.3 b	32.0	100.0
North-East	7	59.1 a	25.0	92.0	65.3 b	39.6	84.9	61.4 b	49.1	82.7
Central zone	14	47.9	20.8	72.5	59.2	31.8	86.5	64.9	40.6	91.4
Disease severity										
Maritime	7	21.1 a	5.9	40.8	68.2 b	37.7	89.4	75.1 b	46.6	100.0
North-East	7	34.9 a	18.3	53.7	83.8 b	62.6	97.8	80.6 b	60.1	97.4
Central zone	14	28.0	12.1	47.3	76.0	50.2	93.6	77.9	53.4	98.7

Table 3.2-47: Weighted mean effect of Mandestrobin 40SC on yield of oilseed rape in presence of *S. sclerotiorum*

EPPO climatic zone	# Trials	Inoculated untreated control (Yield t/ha)			Mandestrobin 40SC 0.5 L/ha Yield %REL			Boscalid 50WG 0.5 kg/ha Yield %REL		
		Mean	min	max	Mean	min	max	Mean	min	max
Yield										
Maritime	8	4.1 b	3.0	4.9	109.0 a	99.5	119.9	112.2 a	103.9	126.8
North-East	7	2.9 b	2.2	3.8	139.4 a	115.3	181.5	131.4 a	108.5	170.3
Central zone	15	3.5	2.2	4.9	123.2	99.5	181.5	121.2	103.9	170.3

Central registration zone

Data generated across 15 valid trials carried out in the Maritime and North-East EPPO climatic zones show that Mandestrobin 40SC applied at 0.5 L/ha (200 g a.s./ha) has a good to very good effectiveness (with

59.2% mean efficacy on disease incidence and 76.0% on disease severity), against *S. sclerotiorum* on oilseed rape, in a situation of high disease pressure (47.9% mean disease incidence and 28.0% mean disease severity). Mandestrobin 40SC at 0.5 L/ha was close or equivalent to the reference product.

When considering yield, data from the 15 valid trials showed that Mandestrobin 40SC applied at the intended rate 0.5 L/ha has a positive effect on yield in the presence of disease (123.2% relative yield compared to inoculated untreated control). This positive effect was equivalent to that of the reference product.

Conclusion to “Yield and Quality”

The data presented show that Mandestrobin 40SC, at the proposed rate of 0.5 L/ha, resulted in an average grain yield increase of 23.2% compared to the inoculated untreated control (mean of maritime and north-eastern zones). Mandestrobin 40SC has no adverse effect on yield quality (specific weight) in the presence of the disease.

3.2.3.3 Efficacy – conclusion

The results presented in Part 3.2.3.1 above demonstrated, from 49 valid trials carried out between 2008 and 2014 in different EPPO climatic zones (29 trials in the Maritime zone, 11 in the North-East zone and 9 in the South-East zone), that Mandestrobin 25SC applied at 0.8 L/ha, providing 200 g a.s./ha, is effective against *S. sclerotiorum* on oilseed rape.

The results presented in Part 3.2.3.2 above demonstrated, from 15 valid trials carried out in 2021 and 2022 in the Maritime (8 trials) and North-East zone (7 trials) EPPO climatic zones, that efficacy provided by Mandestrobin 40SC applied at 0.5 L/ha, providing 200 g a.s./ha, is effective against *S. sclerotiorum* on oilseed rape.

Moreover, the results presented in Part 3.2.1 Preliminary trials above demonstrated, from 14 trials carried out in 2021 and 2022 in the Maritime (7 trials) and North-East (7 trials) EPPO climatic zones, that efficacy provided by Mandestrobin 40SC applied at 0.5 L/ha is very similar, and not significantly different, from that provided by Mandestrobin 25SC applied at 0.8 L/ha. Thus, it can be concluded that results obtained with Mandestrobin 25SC applied at 0.8 L/ha can be extrapolated to Mandestrobin 40SC applied at 0.5 L/ha.

A total of 64 trials can thus be considered for demonstration of efficacy of Mandestrobin 40SC applied at 0.5 L/ha, 37 trials in the Maritime EPPO climatic zone, 18 in the North-East EPPO climatic zone and 9 in the South-East EPPO climatic zone. Among the 64 trials, 63 produced valid results for incidence data. The results obtained in these trials on disease incidence on stems are summarised in the Table below.

Table 3.2-48: Weighted mean efficacy of Mandestrobin 40SC and Mandestrobin 25SC at N rate (mandestrobin 200 g a.s./ha) against *S. sclerotiorum* on oilseed rape

EPPO climatic zone Years	# Trials	Inoculated untreated control (Incidence %)			Mean control (%) Mandestrobin 200 g/ha			Mean control (%) Reference product*		
		Mean	min	max	Mean	min	max	Mean	min	max
Disease incidence										
Maritime 2021-2022	7	36.7	16.5	53.0	53.0	24.0	88.0	68.3	32.0	100.0
Maritime 2008-2014	29	37.8	-	-	54.1	-	-	54.7	-	-
North-East 2021-2022	7	59.1	25.0	92.0	65.3	39.6	84.9	61.4	49.1	82.7
North-East 2008-2014	11	23.3	-	-	83.2	-	-	78.1	-	-
South-East 2008-2014	9	24.9	-	-	82.9	-	-	86.8	-	-
Central zone	63	35.7	-	-	64.4	-	-	65.6	-	-

* 2021-2022 trials = Boscalid 250 g a.s./ha

* 2008-2014 trials = average of commercial reference products, using primarily tebuconazole formulations (250 -500 g a.s./ha)

where they were available or a boscalid formulation (250 g a.s./ha) in the other trials

Central registration zone

Data generated across 63 valid trials carried out in relevant EPPO climatic zones show that Mandestrobin applied at 200 g a.s./ha has a good effectiveness with 64.4% mean efficacy on disease incidence against *S. sclerotiorum* on oilseed rape, in a situation of high disease pressure (mean 35.7% disease incidence).

It is therefore concluded that the data presented fully support the label claim for the use of Mandestrobin 40SC at ~~0.8~~ 0.5 L/ha (200 g a.s./ha) in winter and spring oilseed rape in the Central registration zone.

Conclusion to ‘Efficacy tests’

The presented data correspond with the requirements of the EPPO Standards PP 1/135(4) Phytotoxicity assessment, PP 1/152(4) Design and analysis of efficacy evaluation trials, PP 1/181(4) Conduct and reporting of efficacy evaluation trials including GEP, PP 1/78(3) Root, stem, foliar and pod diseases on oilseed rape.

Maritime EPPO zone

For the evaluation of the efficacy against *S. sclerotiorum* 7 valid field trials from maritime EPPO zone were presented by the applicant in the years 2021 to 2022.

The incidence of *S. sclerotiorum* on plants was high in the inoculated untreated control, with an average of 36.7% of plants infected, ranging from 16.5% to 53.0% in individual trials. The severity of *S. sclerotiorum* on plants was moderate in untreated control, with an average of 21.1% of the stem area infected, ranging from 5.9% to 40.8% in individual trials. The mean efficacy in 7 trials was 53% ranging from 24.0% to 88.0% (disease incidence) and 68.2% ranging from 37.7% to 89.4% (disease severity). When considering disease incidence and severity, Mandestrobin 40SC consistently provided a slightly lower level of control compared to the standard product.

Mandestrobin 40SC increased grain yield in the presence of disease by 9.0% compared to the untreated control in oilseed rape. Member States concerned are invited to decide whether to accept the low efficacy of the applied product against *S. sclerotiorum* in oilseed rape. In making this decision, it is important to note that in trials conducted between 2008 and 2014, the reference product Mandestrobin 25 SC, when applied at a rate of 0.8 L/ha, reduced disease incidence by 55.09% across 22 trials. Furthermore, there was no statistically significant difference in efficacy between Mandestrobin 25 SC and the other reference products used in these trials.

North East EPPO zone

For the evaluation of the efficacy against *S. sclerotiorum* 7 field trials from North East EPPO zone were presented by the applicant in the years 2021 to 2022.

S. sclerotiorum incidence on plants was very high in the inoculated untreated control, with 59.1% of infected plants varying from 25.0% to 92.0%. *S. sclerotiorum* severity on plants was high in the inoculated untreated control, with 34.9% of infected area on stems varying from 18.3% to 53.7% in individual trials. The mean efficacy in 7 trials was 65.3% ranging 39.6% to 84.9% (disease incidence) and 83.8% ranging 62.6% to 97.8% (disease severity). Mandestrobin 40SC also increased grain yield in the presence of disease by 39.4% compared to the untreated control in oilseed rape.

It can be concluded that the data provided by the applicant is sufficient to demonstrate effectiveness against *S. sclerotiorum* in oilseed rape.

South-East EPPO

No trials have been conducted in the South-East EPPO zone to demonstrate the efficacy of Mandestrobin 40SC against the target disease *S. sclerotiorum*, which could be deemed unacceptable. For south-eastern zone, the applicant provided efficacy data for Mandestrobin 25SC, which has shown similar effectiveness to Mandestrobin 40SC in the maritime and north-eastern EPPO zones. However, there is no direct evidence supporting the efficacy of Mandestrobin 40SC under various conditions from South-East regions.

In this case, Member States concerned may consider or decide not to extrapolate data from the maritime or north-eastern zones.

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

The possibility of development of resistance or cross-resistance to mandestrobin, the active substance included in Mandestrobin 40SC (400 g/L), is discussed thereafter based on the requirements detailed in the EPPO standard PP1/213(4).

The fungicide Mandestrobin 40SC contains the active substance mandestrobin. It is a QoI fungicide (quinone outside inhibitor).

At the time of writing, no exact mechanism of resistance of the pathogen *S. sclerotiorum* to mandestrobin is documented. Usually, resistances to QoI fungicides are caused by target site mutations in cyt b gene and additional mechanisms. The whole group of QoI fungicides is therefore classified as high risk of resistance if used without any restrictions. *S. sclerotiorum* is classified as low risk of development of resistance to fungicides. Therefore, the combined resistance risk for this use is classified as 3 on a scale of 1 to 9 and can be described as moderate (FRAC 2019).

A baseline sensitivity study was carried out with strains collected from typical field populations over two years (2013 and 2014) across different countries in Europe (France, Germany, United Kingdom, Denmark, Poland, Latvia, Lithuania and Hungary) where oilseed rape is a major crop.

A total of 137 strains (representing 59 different locations across 8 countries) were used in the baseline sensitivity study, with rates of mandestrobin ranging from 0.0016 to 10 ppm.

100% of inhibition is obtained with 10 ppm of mandestrobin TG. For this reason, we consider that 10 ppm is the discriminatory dose which can split population into Resistant category or Sensitive category.

A sensitivity monitoring was then carried out between 2014 and 2022, using the discriminatory dose rate of 10 ppm described previously. A total of 3907 strains were collected from field populations coming from 13 European countries (countries with the most important number of samples being Germany, France and Poland).

Among all the tested strains, no resistance has been detected under the discriminatory dose rate of 10 ppm.

Details from sensitivity monitoring:

Laboratory methods:

A resistance monitoring study was carried out between 2014 and 2022 on a total of 3907 strains, sampled across 13 European countries (countries with the most important number of samples being Germany, France and Poland).

After reception of the samples, sclerotia were disinfected in a 1% hypochlorite solution and rinsed. After drying, sclerotia were cut in two and each part put on a Malt Agar medium and then incubated in the dark at 20°C during 5 days. Then mycelium plugs were cut and deposited on YBA medium amended or not with 10ppm of Mandestrobin, and always with 100ppm of SHAM, an AOX inhibitor. Petri dishes were incubated in the dark at 20°C and after 48h of incubation, the growth of mycelium was assessed by eyes.

Sensitivity results:

A total of 3907 strains were tested in our resistance monitoring studies between 2014 and 2022. The discriminatory dose rate of 10ppm is combined with SHAM 100 ppm.

Further details about the distribution of these samples are given below.

Table 3.3-1: Origin and number of strains sampled for resistance monitoring across Europe between 2014 and 2022 (number of sampled sites is detailed for each number of strains)

	AT	CH	CZ	DE	DK	FR	HU	LT	LV	PL	RO	SK	UK	TOTAL
2014				337 (12)	30 (1)		291 (10)	30 (1)	60 (2)	170 (6)			81 (3)	999
2015	35 (2)	30 (2)			23 (2)	143 (8)		30 (1)	60 (2)	31 (2)				352
2016				175 (6)		370 (13)								545
2017				478 (18)		118 (4)							84 (3)	680
2018						180 (6)				162 (6)				342
2019				39 (2)						218 (8)				257
2020	60 (2)		150 (5)								22 (1)			232
2021				150 (5)		120 (4)						120 (4)		390
2022										110 (4)				110
TOTAL	95	30	150	1179	53	931	291	60	120	691	22	120	165	3907

Sensitivity profile:

Table 3.3-2: number of sensitive and resistant strains characterized per year under the discriminatory dose of 10 ppm of Mandestrobin.

	Sensitive strain	Resistant strains	Total number of strains
2014	999	0	999
2015	352	0	352
2016	545	0	545
2017	680	0	680
2018	342	0	342
2019	257	0	257
2020	232	0	232
2021	390	0	390
2022	110	0	110
TOTAL	3907	0	3907

Among the 3907 strains tested under the discriminant dose rate of 10ppm (and SHAM at 100ppm), none of the strains has shown any resistance to Mandestrobin whatever the year or the origin of the samples. So far, no resistance to Mandestrobin has been detected.

Mandestrobin 40SC is intended to be applied as a foliar spray to oilseed rape to control *S. sclerotiorum*. The number of applications per season is limited to one. The recommendation is to always use the product at its full dose rate or in association with a partner from another mode of action.

Thus, the risk is considered as acceptable when Mandestrobin 40SC is used according to Good Agricultural Practices and label recommendations, with a maximum of only one application per year at the full recommended rate or in mixture with another fungicide.

PROPOSED LABEL STATEMENT: *Use Mandestrobin 40SC as part of an integrated management strategy incorporating other methods of control, including where appropriate other fungicides with a different mode of action.*

Continued observations of field performance are conducted since 2014 in order to study the potential appearance of strains resistant to Mandestrobin. In case of development of resistant strains, the relevant authorities would be informed and a revised resistance management strategy would be agreed.

As a summary, the risk of development of resistant *S. sclerotiorum* strains to mandestrobin is moderate. The situation will be followed carefully by an appropriate monitoring.

Conclusion to Resistance

According to FRAC, mandestrobin is classified under Group 11. This group, which includes all QoI fungicides, is known to have a high risk of resistance development due to its single-site mode of action. *S. sclerotiorum* is classified as an organism at low risk of developing fungicide resistance. The most recent FRAC monitoring (FRAC 2024 minutes) confirms that resistance has not occurred in the target organism *S. sclerotiorum* and usage recommendations have not changed. The 2023 results based on bioassays showed full susceptibility in France, Slovakia, and Poland. Similarly, the 2022 results showed full susceptibility in Bulgaria, the Czech Republic, Denmark, Estonia, France, Germany, Hungary, Latvia, Lithuania, Poland, Romania, and Sweden.

The current resistance management strategies for QoI fungicides is that:

- The QoI fungicides (azoxystrobin, coumoxystrobin, dimoxystrobin, enoxastrobin, famoxadone, fenamidone, fenaminostrobin, fluoxastrobin, flufenoxystrobin, kresoxim-methyl, mandestrobin, metominostrobin, orysastrobin, pyraoxystrobin, picoxystrobin, pyraclostrobin, pyrametastrobin, pyribencarb, triclopyricarb, trifloxystrobin) are in the same cross-resistance group; FRAC Code 11.
- The QoI fungicide in subgroup A (metyltetraprole), Code 11A fungicide, is not cross resistant with Code 11 fungicides in pathogens with G143A mutation.
- Fungicide programmes must deliver effective disease management. Apply QoI 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 QoI fungicide based products within a total disease management program must be limited whether applied solo or in mixtures with other fungicides. This limitation is inclusive to all QoI fungicides. Limitation of QoI fungicides within a spray programme provides time and space when the pathogen population is not influenced by QoI fungicide selection pressure.
- Limitation of the total number of QoI applications is detailed in the specific crop recommendations. In consideration of the cross-resistance profile of subgroups 11 and 11A, the maximum allowed number of QoI-containing sprays is increased by one, where both QoI fungicides (code 11) and QoI fungicides in subgroup A (code 11A) are included in a spray program in a given cropping season. All crop-specific recommendations will be regularly reviewed based on sensitivity monitoring.
- A consequence of limitation of QoI fungicide based products is the need to use it in a spray program with effective fungicides from different cross-resistance groups (refer to the specific crop recommendations).
- QoI products, containing only the solo QoI fungicide, should be used in single or block applications in alternation with fungicides from a different cross-resistance group. Specific recommendation on the number of consecutive treatments (size of blocks) is given for specific crops.
- Mixture partners for QoI fungicides should be chosen carefully to contribute to effective control of the targeted pathogen(s). The mixture partner must have a different mode of action, and in addition it may increase spectrum of activity or provide needed curative activity. Use of mixtures containing only QoI fungicides (including two-way mixtures of code 11 fungicide and code 11A fungicide) must not be considered as an anti-resistance measure.
- An effective partner for a QoI fungicide is one that provides satisfactory disease control when used alone on the target disease.
- QoI fungicides are very effective at preventing spore germination and should therefore be used at the early stages of disease development (preventive treatment).

Principles for use of Mandestrobin 40SC given by the applicant are consistent with FRAC guidance.

The applicant's proposed label text is useful general advice. Overall, the risk of resistance development against Mandestrobin 40SC is considered to be moderate if the product is used in adherence with the management strategy and label recommendations.

3.4 Adverse effects on treated crops (KCP 6.4)

This document is intended to support the registration of Mandestrobin 40SC (mandestrobin 400 g/L) according to Article 33 of Regulation (EC) No 1107/2009 in the Central zone.

Mandestrobin 40SC 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 all efficacy trials.

The absence of unacceptable adverse effects of Mandestrobin 40SC on oilseed rape will be demonstrated through 2 trials series:

- First, results from trials conducted with Mandestrobin 25SC (coded S-2200 25SC), a similar formulation to Mandestrobin 40SC, well-known fungicide already registered on oilseed rape for which no phytotoxicity issues have ever been reported. Those results were already submitted in 2015 for authorisation of Mandestrobin 25SC.

In the Central zone, a total of 63 efficacy trials were carried out from 2008 to 2014 in the Maritime (Austria, France, Germany and the United Kingdom), South-East (Hungary) and North-East (Poland) zones, the three EPPO climatic zones of the Central EU zone.

- Then, results from 16 efficacy trials conducted in 2021 and 2022 with Mandestrobin 40SC, in the Maritime (9 trials) and North-East EPPO zones (7 trials).

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

3.4.1.1 Phytotoxicity in efficacy trials – Mandestrobin 25SC

All the information and data presented below (in Part 3.4.1.1) have already been submitted to (in December 2015) and evaluated for authorisation of Mandestrobin 25SC (code S-2200 25SC) by Austria as zRMS in the Central regulatory zone.

3.4.1.1.1 Material and methods – Phytotoxicity - Mandestrobin 25SC

Crop safety results from 63 efficacy trials carried out in Austria, Northern-France, Germany, the United Kingdom, Poland and Hungary between 2008 and 2014 are summarised in this section.

Potential phytotoxicity symptoms were reported as a percentage.

In addition, the yield results obtained in 7 efficacy trials where the disease incidence was low (less than 5%), were recorded in decitons per hectare. These trials were excluded from the efficacy analysis, and included in this section in order to support the phytotoxicity to host crop analysis.

52 varieties of oilseed rape were tested in the trials and are listed in the table below.

Table 3.4-1: Varieties of oilseed rape tested in the trials carried out in Austria, Germany, France, Hungary, Poland and the United Kingdom – from 2008 to 2014

Crop species	Crop code	Varieties
<i>Brassica napus</i> (winter)	BRSNW	Adriana, Alpaga, Artoga, Astrid, Aurum, Aviator, Banjo, Bravour, Cabernet, Californium, Camelot, Campala, Castille, Catalana, Catalina, Catana, Digger, DK Expower, DK Exquisite, DK Exstorm, DK Sequoia, Excalibur, Exocet, Finesse, Flash, Grizzly, Hycolor, Hydromel, KWS Turán, Labrador, Maestro, Monolit, Nemax, Neptune, Poznaniak, PR45D01, PR45D03, PR46W20, PR46W31, Rohan, Royal, Sesame, Sherlock, SY Alister, Taurus, Titan, Trabant, Troy, Visby, Vision
<i>Brassica napus</i> (spring)	BRSNS	Colossus, Seven

3.4.1.1.2 Results – Phytotoxicity - Mandestrobin 25SC

In all the trials carried out in Austria, Northern-France, Germany, the United Kingdom, Poland and Hungary between 2008 and 2014, no symptom suggesting any kind of phytotoxicity was reported for active substance content from 100 g a.s./ha up to 600 g a.s./ha, including the recommended rate 200 g a.s./ha.

The formulation Mandestrobine 25SC (coded S-2200 25SC) is proved safe to oilseed rape (spring and winter), when it is applied at its proposed rate of 200 g a.s./ha corresponding to 0.8 L/ha and even at higher rates (up to 600 g a.s./ha).

The fungicide Mandestrobine 25SC (coded S-2200 25SC) was as safe as main reference products of the European market based on tebuconazole, boscalid and prothioconazole.

3.4.1.2 Phytotoxicity in efficacy trials – Mandestrobin 40SC

Mandestrobin 40SC crop sensitivity was assessed in 16 efficacy trials on oilseed rape. 9 trials were carried out in the Maritime EPPO climatic zone in 2021, 7 trials were carried out in the North-East zone in 2021 and 2022 (see Table 3.2-34).

3.4.1.2.1 Material and methods – Phytotoxicity - Mandestrobin 40SC

All the trials were carried out by Good Experimental Practice (GEP) accredited testing facilities. For details on the materials and methods of the 15 valid trials, please refer to Part 3.2.3.2.1.

For details on the materials and methods of the additional trial (1 in the Maritime EPPO climatic zone), not used for efficacy assessments, please refer to Table 3.4-2 below.

Table 3.4-2: Details on trial methodology – Maritime EPPO zone

Guidelines	General guidelines	PP 1/135(4) PP 1/152(4) PP 1/181(4)
	Specific guidelines	PP 1/78(3)
Experimental design	Plot design	Randomised complete blocks (1 trial)
	Plot size	Plot area: 30 m ²
	Number of replications	4 replications (1 trial)
Crop	Trials per crop	Winter oilseed rape (1trial)
	Varieties per crop	Blackbuzz (1 trial)
	Sowing period	Early September
Application	Crop stage (BBCH) at application	BBCH 65
	Number of applications	1 application (1 trial)
	Pest stage at application	<i>S. sclerotiorum</i> artificially inoculated before or just after application (1 trials)
	Spray volume	164 L/ha
Assessment	Assessment types and date	Crop safety, 7-8 DA-A
Other relevant information	e.g. Natural / artificial inoculation...	Artificial inoculation (1 trial)
	e.g. Field / Greenhouse...	Field trials

The range of oilseed rape varieties tested in both the valid and not valid efficacy trials is summarised in Table 3.4-3 and Table 3.4-4 below.

Table 3.4-3: Varieties tested in efficacy trials – Maritime EPPO zone

Crop	Varieties (Trial number)
Winter oilseed rape	Acropole (1 trial), Blackbuzz (1 trial), Cristiano (1 trial), DK Excited (1 trial), DK Expansion (1 trial), DK Exstorm (1 trial), LG Architect (1 trial), RAGT Banquiss (1 trial) and Rocca (1 trial).

Table 3.4-4: Varieties tested in efficacy trials – North-East EPPO zone

Crop	Varieties (Trial number)
Winter oilseed rape	Aspect (2 trials), Dominator (1 trial), Gemini (1 trial), Monolit (1 trial), Orion (1 trial) and Sherlock (1 trial).

Potential phytotoxic effects were assessed through visual symptoms on crop on an overall plot basis following a 0-100% scale, where 0% means no damages and 100% means that the crop is completely destroyed.

Assessments were conducted at various timings (from 7 DA-A to 81 DA-A).

3.4.1.2.2 Results – Phytotoxicity - Mandestrobin 40SC (and Mandestrobin 25SC)

Maritime zone

The potential phytotoxic effects of Mandestrobin 40SC (mandestrobin 400 g/L) were investigated in a total of 9 efficacy trials carried out in oilseed rape in 2021 in France and Germany, in which Mandestrobin 40SC applied at the intended rate of 0.5 L/ha (200 g a.s./ha) was compared to the inoculated untreated control and to the reference product Boscalid 50% WG applied at its registered application rate of 0.5 kg/ha.

Results on phytotoxicity assessments carried out in the efficacy trials are provided in Appendix 4 of the BAD. A summary is presented in Table 3.4-5.

Table 3.4-5: Phytotoxicity of Mandestrobin 40SC on winter oilseed rape – Maritime EPPO climatic zone

Number of trials with...		Efficacy trials (9 trials)	
		Mandestrobin 40SC 0.5 L/ha 200 g a.s./ha N	Boscalid 50% WG 0.5 kg/ha 250 g a.s./ha N
Maximum of phytotoxicity recorded during the trials	0%	9	9
	>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%	9	9
	>0% to 5%	0	0
	>5% to 10%	0	0
	>10% to 15%	0	0

Number of trials with...		Efficacy trials (9 trials)	
		Mandestrobin 40SC 0.5 L/ha 200 g a.s./ha N	Boscalid 50% WG 0.5 kg/ha 250 g a.s./ha N
	>15 %	0	0

No phytotoxicity symptoms were observed at any assessment date in any of the 9 trials carried out in the Maritime EPPO climatic zone, after application of Mandestrobin 40SC at 0.5 L/ha or Mandestrobin 25SC at 0.8 L/ha (both providing 200 g a.s./ha).

North-East zone

The potential phytotoxic effects of Mandestrobin 40SC were investigated in a total of 7 efficacy trials carried out in oilseed rape in 2021 and 2022 in Poland, in which Mandestrobin 40SC applied at the intended rate of 0.5 L/ha (200 g a.s./ha) was compared to the inoculated untreated control and to the reference product Boscalid 50% WG applied at its registered application rate of 0.5 kg/ha.

Results on phytotoxicity assessments carried out in the efficacy trials are provided in Appendix 4 of the BAD. A summary is presented in Table 3.4-6.

Table 3.4-6: Phytotoxicity of Mandestrobin 40SC on winter oilseed rape – North-East EPPO climatic zone

Number of trials with...		Efficacy trials (7 trials)	
		Mandestrobin 40SC 0.5 L/ha 200 g a.s./ha N	Boscalid 50% WG 0.5 kg/ha 250 g a.s./ha N
Maximum of phytotoxicity recorded during the trials	0%	7	7
	>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%	7	7
	>0% to 5%	0	0
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

No phytotoxicity symptoms were observed at any assessment date in any of the 7 trials carried out in the North-East EPPO climatic zone, after application of Mandestrobin 40SC at 0.5 L/ha or Mandestrobin 25SC at 0.8 L/ha (both providing 200 g a.s./ha).

In summary, no phytotoxicity symptom caused by Mandestrobin 40SC at the intended dose rate of 0.5 L/ha (200 g a.s./ha) was recorded on winter oilseed rape in any of the 16 trials carried out in 2021 and 2022 in the Maritime and North-East EPPO climatic zones. It can thus be concluded that Mandestrobin 40SC applied according to the proposed GAP and label recommendations is safe to oilseed rape.

Conclusion to “Phytotoxicity to host crop”

The presented data correspond with the requirements of the EPPO Standard PP 1/135 (Phytotoxicity assessment).

No phytotoxicity was observed in the efficacy trials evaluated at the maximum target dose rate of Mandestrobin 40SC in oilseed rape. It can therefore be concluded that the fungicide is safe for oilseed rape when applied according to the proposed GAP and label recommendations.

Based on this data it can be concluded that the data presented by the applicant is acceptable.

3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

Mandestrobin 40SC being a fungicide, no specific selectivity trials generating yield data are provided in this dossier in accordance with EPPO standard PP1/135(4) “Phytotoxicity assessment”.

However, yield results from 7 trials with a low disease incidence were available. They tested the formulation Mandestrobin 25SC at 0.8 L/ha (200 g a.s./ha), already registered on oilseed rape in various countries.

3.4.2.1 Effect on the yield of treated plants or plant products - Mandestrobin 25SC

All the information and data presented below (in Part 3.4.2.1) have already been submitted to (in December 2015) and evaluated for authorisation of Mandestrobin 25SC (code S-2200 25SC) by Austria as zRMS in the Central regulatory zone.

The yield was measured in a total of 44 efficacy trials carried out in Austria, Northern-France, Germany, the United Kingdom, Poland and Hungary belonging to the Maritime, North-Eastern and South-Eastern EPPO climatic zones.

The results observed in 7 trials out of the 44 trials, all in the Maritime EPPO zone, where the disease incidence was low (less than 5%), are described and analysed as potential phytotoxicity symptoms. These trials were excluded from the efficacy analysis. The tested varieties were Alpaga, Neptune, Cabernet, Castille, DK Exstorm, Sherlock and DK Expower.

Table 3.4-7: Summary of the yield results obtained in healthy oilseed rape trials with S-2200 25SC – Austria, France and the United Kingdom – 2010 and 2014.

EPPO Climatic Zone	Trial no.	Assessment type	Untreated plot	S-2200 25SC	FOLICUR / HORIZON*	CANTUS / FILAN / PICTOR PRO
				mandestrobin 250 g/L	tebuconazole 250 g/L	boscalid 500 g/kg
				0.8 L/ha (200 g as/ha)	1-2 L/ha (250-500 g as/ha)	0.5 kg/ha (250 g as/ha)
Maritime	7 data	Average Yield (dt/ha)	37.12 b	38.21 ab	38.97 a	
	4 data	Average Yield (dt/ha)	36.85 a	37.80 a	39.10 a	38.15 a

*Reference products based on tebuconazole 250 g/L EW applied at 1 L/ha (250 g as/ha) in UK and FR and 2 L/ha (500 g as/ha) in AT.

On average of all the 7 trials, the yield in the untreated plots was 37.12 dt/ha. There was a tendency of S-2200 25SC applied at 0.8 L/ha to slightly improve the result (38.21 dt/ha). The yield obtained with S-2200 25SC was also statistically comparable to that of the tebuconazole-based standards (38.97 dt/ha).

In 4 of the trials, S-2200 25SC was also compared to a boscalid-based standard. On average, there was no statistical difference between the yields obtained with both treatments (37.80 dt/ha vs. 38.15 dt/ha).

Thus, even in the absence of a relevant infestation of *S. sclerotiorum*, S-2200 25SC applied according to the recommendations did not show any negative effect towards the harvested yield, and even showed a trend to deliver a slight gain (+ 1 dt/ha).

Given the results obtained in the Maritime EPPO zone after application of Mandestrobin 25SC at 0.8 L/ha (200 g a.s./ha), it can be concluded that the formulation Mandestrobin 40SC applied at at 0.5 L/ha (200 g a.s./ha) will have no negative impact on the yield of oilseed rape.

3.4.2.2 Effect on the yield of treated plants or plant products - Mandestrobin 40SC

Mandestrobin 40SC being a fungicide, no specific selectivity trials generating yield data are provided in this dossier, in accordance with EPPO standard PP 1/135(4) "Phytotoxicity assessment".

However, yield results from 15 efficacy trials with a significant presence of disease are available and presented in Part 3.2.3.2.2 above in this dossier.

Mandestrobin 40SC had no negative effect on the yield of oilseed rape in any of these efficacy trials. On the contrary, Mandestrobin 40SC had a positive effect on yield compared to the inoculated untreated control in all the EPPO climatic zones.

The single efficacy trial not valid for efficacy had a sufficient disease level, thus no trial applied with Mandestrobin 40SC is available for the assessment of the effect on yield in conditions of low disease pressure.

Therefore, no negative impact on the yield of oilseed rape is expected after the application of Mandestrobin 40SC at the intended dose rate of 0.5 L/ha (200 g a.s./ha), as demonstrated with Mandestrobin 25SC and according to the Good Agricultural Practices and label recommendations.

3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

Mandestrobin 40SC being a fungicide, no specific selectivity trials generating yield data are provided in this dossier in accordance with EPPO standard PP1/135(4) "Phytotoxicity assessment".

However, quality parameters results from 12 efficacy trials were available in this dossier. Among them, 7 trials tested the formulation Mandestrobin 25SC at 0.8 L/ha (200 g a.s./ha), already registered on oilseed rape in various countries and 5 efficacy trials tested the formulation Mandestrobin 40SC at 0.5 L/ha (200 g a.s./ha).

3.4.3.1 Effects on the the quality of plants or plant products - Mandestrobin 25SC

All the information and data presented below (in Part 3.4.3.1) have already been submitted (in December 2015) and evaluated for authorisation of Mandestrobin 25SC (code S-2200 25SC) by Austria as zRMS in the Central regulatory zone.

Quality parameters were assessed in 7 trials carried out in Germany (2), belonging to the Maritime EPPO climatic zone and in Poland (5) belonging to the North-Eastern EPPO climatic zone.

All the trials were carried out by officially recognised organisations in accordance with the principles of Good Experimental Practice (GEP).

Table 3.4-8: Summary of the quality results obtained with S-2200 25SC – Germany and Poland – 2012 and 2013

EPPO Climatic Zone	Trial no.	Assessment type	Untreated plot	S-2200 25SC	FOLICUR / HORIZON*	PICTOR 400SC
				mandestrobin 250 g/L	tebuconazole 250 g/L	boscalid 200 g/L + dimoxystrobin 200 g/L
				0.8 L/ha (200 g as/ha)	1.25-1.5 L/ha (312-375 g as/ha)	0.5 L/ha (200 g as/ha)
Maritime	2 data	Average %Oil content	44.96 -	44.85 -	44.72 -	
		Average %Impurity	0.47 -	0.62 -	0.75 -	
North-East	5 data	Average Thousand Grain Weight (g)	4.83 c	5.26 a	5.06 b	5.11 b

*Reference products based on tebuconazole 250 g/L EW applied at 1.25 L/ha (312 g as/ha) in PL and 1.5 L/ha (375 g as/ha) in DE.

First, in two trials carried out in Germany in 2013, the oil content and the percentage of oil impurities were measured and S-2200 25SC applied at 0.8 L/ha was compared to FOLICUR (tebuconazole 250 g/L). The tested products did not have any significant impact on either parameter. In terms of oil content, the untreated plot had 44.96% on average, whereas the plot treated with S-2200 25SC had 44.85%. Regarding the impurities, there was 0.47% in the untreated plot and 0.62% in the plot treated with S-2200 25SC. Therefore, S-2200 25SC did not show any negative effect on the oil-related quality parameters.

Then, in 5 Polish trials, the thousand grain weight (TGW) was assessed, and the standards used were HORIZON and PICTOR 400SC.

On average, the thousand grain weight in the untreated was 4.83 g. All treatments caused a significant increase in this parameter. The thousand grain weight reached in the plot treated with S-2200 25SC (5.26 g on average) was statistically higher compared to the plots treated with HORIZON (5.06 g) or PICTOR 400SC (5.11 g).

When considering the individual trial data, there was no statistically significant difference between any of the treatments or the untreated.

Thus, Mandestrobin 25SC (coded S-2200 25SC) applied according to the GAPs was shown to improve the quality of harvested oilseed rape product in terms of thousand grain weight, and to deliver significantly better results than the tested standards regarding this parameter.

Moreover, no negative effect of Mandestrobin 25SC (coded S-2200 25SC) applied at the recommended dose rate of 0.8 L/ha (200 g a.s./ha) on the oil content or impurity content was observed in the harvested grains.

It can thus be concluded that no negative effects on quality parameters are expected after application of Mandestrobin 40SC at the intended rate of 0.5 L/ha (200 g a.s./ha).

3.4.3.2 Effects on the the quality of plants or plant products - Mandestrobin 40SC

No specific trials evaluating the effect of Mandestrobin 40SC on quality of plants or plant products have been conducted for the use of this product on oilseed rape, for the following reasons:

- Mandestrobin 40SC acts as a fungicide, therefore no negative effect is expected on host crop.
- Mandestrobin 40SC crop safety has been proved through phytotoxicity assessments conducted in efficacy trials.
- Experience has been acquired with a similar formulation, Mandestrobin 25SC, authorised at the same rate of active substance in several countries.

In addition, the risk of taint is considered as low. Since Mandestrobin 40SC is applied at flowering, before the formation of grains, according to EPPO standard PP 1/242 "Taint tests", no tests are required.

Thus, Mandestrobin 40SC is assumed to have no negative effect on quality of plants or plant products when applied following the label recommendations.

The potential effect of Mandestrobin 40SC on specific weight was investigated in a total of 5 efficacy trials carried out in oilseed rape in 2021 in the Maritime EPPO zone (2 trials) and in the North-East EPPO zone (3 trials), in which Mandestrobin 40SC at 0.5 L/ha (200 g a.s./ha) was compared to the inoculated untreated control and to the reference product Boscalid 50% WG applied at its registered application rate of 0.5 kg/ha.

Maritime zone

The specific weight of harvested oilseed rape was measured in 2 efficacy trials carried out in 2021 in the Maritime EPPO climatic zone.

Summarised results are presented in **Table 3.4-9**.

All individual results are available in Appendix 4 of the BAD.

Table 3.4-9: Summarised results – Effect of Mandestrobin 40SC on quality of oilseed rape in presence of *S. sclerotiorum* – Maritime EPPO climatic zone – Specific weight (kg/hL) and percentage relative to inoculated untreated control

# Tri- als	Inoculated untreated control (Specific weight kg/hL)			Specific weight %REL						No. of trials where Mandestrobin 40SC is significantly > ; < ; =, compared to	
				Mandestrobin 40SC 0.5 L/ha 200 g a.s./ha			Boscalid 50% WG 0.5 kg/ha 250 g a.s./ha				
	Mean	min	Mean	Mean	min	max	Mean	min	max	Inoculated untreated control	Boscalid 50% WG
2	60.5	59.3	61.7	99.3	98.9	99.7	98.1	97.4	98.8	0>;2=;0<	0>;2=;0<

In these trials, at assessment at harvest, in the inoculated untreated control, the specific weight of grains was of 60.5 kg/hL on average across 2 trials with *S. sclerotiorum* infection (varying from 59.3 to 61.7 kg/hL in individual trials).

Mandestrobin 40SC applied at 0.5 L/ha demonstrated no adverse effect on the quality of oilseed rape in the presence of disease. The mean specific weight was 99.3% of the inoculated untreated control, equivalent to the of the reference product Boscalid 50% WG (98.1% of the inoculated untreated control).

In summary, data from 2 trials investigating the efficacy of Mandestrobin 40SC for the control of *S. sclerotiorum* on oilseed rape in the Maritime EPPO climatic zone, showed that Mandestrobin 40SC applied at the intended rate 0.5 L/ha has no adverse effect on the quality of yield (specific weight) in the presence of disease.

North-East zone

The specific weight of harvested oilseed rape was measured in 3 efficacy trials carried out in 2021 in the North-East EPPO climatic zone.

Summarised results are presented in **Table 3.4-10**.

All individual results are available in Appendix 4 of the BAD.

Table 3.4-10: Summarised results – Effect of Mandestrobin 40SC on quality of oilseed rape in presence of *S. sclerotiorum* – North-East EPPO climatic zone – Specific weight (kg/hL) and percentage relative to inoculated untreated control

# Tri- als	<i>Inoculated untreated control</i> (<i>Specific weight kg/hL</i>)			Specific weight %REL						No. of trials where Mandestrobin 40SC is significantly > ; < ; =, compared to	
				Mandestrobin 40SC 0.5 L/ha 200 g a.s./ha			Boscalid 50% WG 0.5 kg/ha 250 g a.s./ha				
	<i>Mean</i>	<i>min</i>	<i>Mean</i>	<i>Mean</i>	min	max	<i>Mean</i>	min	max	Inoculated untreated control	Boscalid 50% WG
3	62.0	60.8	63.7	101.2	100.1	101.8	101.4	99.9	102.7	0>;3=;0<	0>;3=;0<

In these trials, at assessment at harvest, in the inoculated untreated control, the specific weight of grains was of 62.0 kg/hL on average across 3 trials with *S. sclerotiorum* infection (varying from 60.8 to 63.7 kg/hL in individual trials).

Mandestrobin 40SC applied at 0.5 L/ha demonstrated no adverse effect on the quality of oilseed rape in the presence of disease. The mean specific weight was 101.2% of the inoculated untreated control, equivalent to the of the reference product Boscalid 50% WG (101.4% of the inoculated untreated control).

In summary, data from 3 trials investigating the efficacy of Mandestrobin 40SC for the control of *S. sclerotiorum* on oilseed rape in the North-East EPPO climatic zone, showed that Mandestrobin 40SC applied at the intended rate 0.5 L/ha has no adverse effect on the quality of yield (specific weight) in the presence of disease.

Conclusion to “Yield and Quality ”

The data presented show that Mandestrobin 40SC, at the proposed rate of 0.5 L/ha, resulted in an average grain yield increase of 23.2% compared to the inoculated untreated control (mean of maritime and north-eastern zones). Mandestrobin 40SC has no adverse effect on yield quality (specific weight) in the presence of the disease.

3.4.4 Effects on transformation processes (KCP 6.4.4)

Mandestrobin 40SC is intended to be used on oilseed rape. Processing of oilseed rape is done by physical processes (extraction of oil...), which do not depend on biological activity and is not affected by the possible presence of the plant protection product (or its residue) on the crop. Thus, according to EPPO standard PP 1/243 (2) "Effects of plant protection products on transformation processes", no studies are deemed necessary to evaluate the effect of Mandestrobin 40SC on transformation processes, and no particular adverse effect is expected after the use of Mandestrobin 40SC following the label recommendations.

Furthermore, experience has been acquired with a similar formulation, Mandestrobin 25SC, authorised at the same rate of active substance in several countries and no adverse effects on transformation processes has been reported so far.

Conclusion to “Effects on transformation processes ”

The case presented by the applicant is acceptable and no further data are required.

3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

Mandestrobin 40SC is applied at flowering of oilseed rape, well before the seed initiation. Moreover, no phytotoxic effects have been seen in the efficacy trials.

Thus, according to EPPO standard PP 1/135 (4) "Phytotoxicity assessment", no data on plant parts to be used for propagation (*i.e.* seeds) are required.

Furthermore, experience has been acquired with a similar formulation, Mandestrobin 25SC, authorised at the same rate of active substance in several countries and no adverse effects on propagation has been reported so far.

Thus, no particular adverse effect is expected on treated plants or plant products to be used for propagation, after use of Mandestrobin 40SC following the label recommendations.

Conclusion to “Impact on treated plants or plant products to be used for propagation ”

The case presented by the applicant is acceptable and no further data are required.

3.4.6 Adverse effects – conclusion

The results presented in Part 3.4.1.1.2 above demonstrated, from 63 trials carried out between 2008 and 2014 in different EPPO climatic zones (43 trials in the Maritime zone, 11 in the North-East zone and 9 in the South-East zone), that Mandestrobin 25SC is proved safe to oilseed rape (spring and winter), when it is applied at its registered rate of 200 g a.s./ha corresponding to 0.8 L/ha and even at higher rates (up to 600 g a.s./ha).

Moreover, as presented in Part 3.4.2.1 and Part 3.4.3.1, Mandestrobin 25SC applied according to the recommendations did not show any negative effect towards the harvested yield nor any negative effect on the oil-related quality parameters: *i.e.* oil content and impurity content.

The results presented in Part 3.4.1.2 above demonstrated, from 16 trials carried out in 2021 and 2022 in the Maritime (9 trials) and North-East (7 trials) EPPO climatic zones, that no phytotoxicity symptoms were caused on winter oilseed rape by Mandestrobin 40SC at the intended dose rate of 0.5 L/ha (200 g a.s./ha). Moreover, Mandestrobin 40SC at the intended dose rate of 0.5 L/ha (200 g a.s./ha) did not show any negative effect on the specific weight quality parameters.

Thus, it can be concluded that for Mandestrobin 40SC applied at 0.5 L/ha, providing 200 g a.s./ha, according to the recommendations, no adverse effect on oilseed rape is expected.

3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

Mandestrobin 40SC has no known herbicidal activity and is therefore not anticipated to have any impact on succeeding crops.

Moreover, Mandestrobin 40SC demonstrated to be crop safe on oilseed rape (see 3.4.1 Phytotoxicity to host crop).

In addition, Mandestrobin 25SC, similar to Mandestrobin 40SC, is a well-known fungicide, already registered on oilseed rape at an equivalent dose rate (200 g a.s./ha) in several Member states, without impact on succeeding crops ever reported.

Mandestrobin 40SC applied according to the label recommendations is therefore expected to have no impact on succeeding crops.

Conclusion to “ Succeeding crops ”

Results from seedling emergence and vegetative vigour test (see annex point ‘Impact on adjacent crops’) were discussed by the applicant. No visible damage was observed on *Triticum aestivum*, *Zea mays*, *Cucumis sativa*, *Glycine max*, *Solanum lycopersicum* and *Lactuca sativa*.

Furthermore, phytotoxicity assessments were conducted in all efficacy trials and no phytotoxicity was observed after application of Mandestrobin 40SC. Overall, it is concluded that using Mandestrobin 40SC at the proposed maximum recommended dose will not cause any adverse effects on succeeding crops or other crops under normal conditions.

3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

Mandestrobin 40SC has no known herbicidal activity and is therefore not anticipated to have any impact on adjacent crops.

Moreover, Mandestrobin 40SC demonstrated to be crop safe on oilseed rape (see 3.4.1 Phytotoxicity to host crop).

In addition, Mandestrobin 25SC, similar to Mandestrobin 40SC, is a well-known fungicide, already registered on oilseed rape at an equivalent dose rate (200 g a.s./ha) in several Member states, without impact on adjacent crops ever reported.

Table 3.5-1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants

Species	Substance	Exposure system	Results	Reference
<i>Triticum aestivum</i> (m) <i>Zea mays</i> (m) <i>Cucumis sativa</i> (d) <i>Glycine max</i> (d) <i>Solanum lycopersicum</i> (d) <i>Lactuca sativa</i> (d)	S-2200 25 SC	21 d Seedling emergence	ER₅₀ > 200 g a.s./ha	EFSA Conclusion (2015)
<i>Triticum aestivum</i> (m) <i>Zea mays</i> (m) <i>Cucumis sativa</i> (d) <i>Glycine max</i> (d) <i>Solanum lycopersicum</i> (d) <i>Lactuca sativa</i> (d)	S-2200 25 SC	21 d Vegetative vigour	ER₅₀ > 200 g a.s./ha	EFSA Conclusion (2015)

m: monocotyledonous; d: dicotyledonous.

Mandestrobin 40SC applied according to the label recommendations is therefore expected to have no impact on adjacent crops.

Conclusion to “ Impact on other plants including adjacent crops ”

Vegetative vigour and seedling emergence limit tests with the formulation S-2200 25 SC indicated no effects greater than 50% at 200 g a.s./ha. As this rate corresponds to the maximum proposed application rate of 200 g a.s./ha, an acceptable risk to non-target terrestrial plants for the proposed use of Mandestrobin 40SC is concluded.

3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Part B Section 9 (Ecotoxicology).

Therefore, no effect is expected on beneficial or other non-target organisms if Mandestrobin 40SC is used according to the Good Agricultural Practices and label recommendations.

From these results it can be concluded that the proposed use pattern of Mandestrobin 40SC will not pose any significant risk to beneficial organisms.

Conclusion to “Effects on beneficial and other non-target organisms ”

The case presented by the applicant is acceptable and no further data are required.

3.6 Other/special studies

No other studies relevant for the aim of this dossier have been conducted.

3.7 List of test facilities including the corresponding certificates

The majority of corresponding certificates, confirming that all the test facilities mentioned have been officially recognised as organisations for efficacy testing of plant protection products, are available in the GEP certibase (www.gepcertibase.eu).

Table 3.7-1: List of test facilities

Test facility	Address	GEP certificate (Yes or No) Link to GEP Certibase	Validity
Maritime EPPO zone			
Biotek agriculture*	Route de Viélaines 10120 Saint Pouange France (FR)	Yes link	17/02/2019 – 16/02/2024
Field Research Support	Max-Planck-Str.5 31515 Wunstorf Germany (DE)	Yes link	16/11/2020 - 15/11/2026
Philagro France	Parc d'Affaires de Crécy 10A, rue de la Voie Lactée 69370 St Didier au Mont d'Or France (FR)	Yes Not available in the GEP certi- base but pro- vided in the trial reports	10/02/2019-09/02/2024
Quintus GmbH	Liepen 7 17194 Hohen Wangelin Germany (DE)	Yes link	17/02/2021 - 16/02/2026
Staphyt*	23, rue de Moeuvres 62860 Incy-en-Artois France (FR)	Yes link	14/10/2021 – 13/06/2026
North-East EPPO zone			
BioTrials Baranowska S.K.A.	ul. Rubież 46 61-612 Poznań Poland (PL)	Yes Not available in the GEP certibase but provided in the trial reports	From 2021
Field Research Support PL	Ul. Dworcowa 2. 64-000 Kościan Poland (PL)	Yes link	From 07/06/2013

* Trials conducted by Philagro France, but the harvest was subcontracted to various subcontractors.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Owner
KCP 6/01	XXXX.	2023	Biological Assessment Dossier, Efficacy data and information, Detailed summary. Product code: Mandestrobin 40SC, Chemical active substance: Mandestrobin, 400 g/L. Central Zone, Zonal Rapporteur Member State: Poland. CORE ASSESSMENT (Article 33 authorisation). XXXX Not GEP Unpublished	N	N	XXXX
KCP 6.2/01 KCP 6.4.1	Zöllner, H.	2021	Field study to determinate the efficacy and crop safety of Mandestrobin 400 G/L SC (AE20-2) for the control of Sclerotinia sclerotiorum in oilseed rape in Germany EPPO maritime. SCAE2021FPAP0203 Field Research Support GEP Unpublished	N	Y	XXXX
KCP 6.2/02 KCP 6.4.1	Zöllner, H.	2021	Field study to determinate the efficacy and crop safety of Mandestrobin 400 G/L SC (AE20-2) for the control of Sclerotinia sclerotiorum in oilseed rape in Germany EPPO maritime. SCAE2021FPAP0204 Field Research Support GEP Unpublished	N	Y	XXXX
KCP 6.2/03 KCP 6.4.1	Ströbele, U.	2021	Evaluation of new mandestrobin formulation. SCAE2021FPAP0205 Quintus GmbH GEP Unpublished	N	Y	XXXX

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Owner
KCP 6.2/04 KCP 6.4.1	Ströbele, U.	2021	Evaluation of new mandestrobin formulation. SCAE2021FPAPO206 Quintus GmbH GEP Unpublished	N	Y	XXXX
KCP 6.2/05 KCP 6.4.1 KCP 6.4.3	Parizot, M. & Bouly, T.	2021	Evaluation of new mandestrobin formulation. SCAE2021FPAPO220 Philagro France GEP Unpublished	N	Y	XXXX
KCP 6.2/06 KCP 6.4.1 KCP 6.4.3	Parizot, M. & Bouly, T.	2021	Evaluation of new mandestrobin formulation. SCAE2021FPAPO221 Philagro France GEP Unpublished	N	Y	XXXX
KCP 6.2/07 KCP 6.4.1	Delas, N. & Bouly, T.	2021	Evaluation of new mandestrobin formulation. SCAE2021FPAPO222 Philagro France GEP Unpublished	N	Y	XXXX
KCP 6.2/08 KCP 6.4.1	Forest, P. & Bouly, T.	2021	Evaluation of new mandestrobin formulation. SCAE2021FPAPO223 Philagro France GEP Unpublished	N	Y	XXXX
KCP 6.2/09 KCP 6.4.1	Forest, P. & Bouly, T.	2021	Evaluation of new mandestrobin formulation. SCAE2021FPAPO224 Philagro France GEP Unpublished	N	Y	XXXX

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Owner
KCP 6.2/10 KCP 6.4.1 KCP 6.4.3	Uminski, P.	2021	Evaluation of new mandestrobin formulation. SCAE2021FPAPO235 Field Research Support GEP Unpublished	N	Y	XXXX
KCP 6.2/11 KCP 6.4.1 KCP 6.4.3	Uminski, P.	2021	Evaluation of new mandestrobin formulation. SCAE2021FPAPO236 Field Research Support GEP Unpublished	N	Y	XXXX
KCP 6.2/12 KCP 6.4.1 KCP 6.4.3	Uminski, P.	2021	Evaluation of new mandestrobin formulation. SCAE2021FPAPO237 Field Research Support GEP Unpublished	N	Y	XXXX
KCP 6.2/13 KCP 6.4.1	Siekaniec, L.	2021	Evaluation of new mandestrobin formulation. SCAE2021FPAPO238 BioTrials Baranowska S.K.A. GEP Unpublished	N	Y	XXXX
KCP 6.2/14 KCP 6.4.1	Uminski, P.	2021	Evaluation of new mandestrobin formulation. SCAE2022FPAPO031 Field Research Support GEP Unpublished	N	Y	XXXX
KCP 6.2/15 KCP 6.4.1	Siekaniec, L.	2022	Evaluation of new mandestrobin formulation. SCAE2022FPAPO032 BioTrials Baranowska S.K.A. GEP Unpublished	N	Y	XXXX

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Owner
KCP 6.2/16 KCP 6.4.1	Siekaniec, L.	2022	Evaluation of new mandestrobin formulation. SCAE2022FPAP0033 BioTrials Baranowska S.K.A. GEP Unpublished	N	Y	XXXX
KCP 6.2/17 KCP 6.4.1	Dupeuble, F.	2023	Statistical analysis: MANDES_BRIDGING_MAR_PESINC Lynxee Consulting Unpublished	N	Y	XXXX
KCP 6.2/18 KCP 6.4.1	Dupeuble, F.	2023	Statistical analysis: MANDES_BRIDGING_MAR_PESSEV Lynxee Consulting Unpublished	N	Y	XXXX
KCP 6.2/19 KCP 6.4.1	Dupeuble, F.	2023	Statistical analysis: MANDES_BRIDGING_NE_PESINC Lynxee Consulting Unpublished	N	Y	XXXX
KCP 6.2/20 KCP 6.4.1	Dupeuble, F.	2023	Statistical analysis: MANDES_BRIDGING_NE_PESSEV Lynxee Consulting Unpublished	N	Y	XXXX
KCP 6.2/21 KCP 6.4.1	Dupeuble, F.	2023	Statistical analysis: MANDES_EFF_MAR_PESINC Lynxee Consulting Unpublished	N	Y	XXXX
KCP 6.2/22 KCP 6.4.1	Dupeuble, F.	2023	Statistical analysis: MANDES_EFF_MAR_PESSEV Lynxee Consulting Unpublished	N	Y	XXXX
KCP 6.2/23 KCP 6.4.1	Dupeuble, F.	2023	Statistical analysis: MANDES_EFF_NE_PESINC Lynxee Consulting Unpublished	N	Y	XXXX
KCP 6.2/24 KCP 6.4.1	Dupeuble, F.	2023	Statistical analysis: MANDES_EFF_NE_PESSEV Lynxee Consulting Unpublished	N	Y	XXXX

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Owner
KCP 6.2/25 KCP 6.4.1	Dupeuble, F.	2023	Statistical analysis: MANDES_MED_MAR_PESINC Lynxee Consulting Unpublished	N	Y	XXXX
KCP 6.2/26 KCP 6.4.1	Dupeuble, F.	2023	Statistical analysis: MANDES_MED_MAR_PESSEV Lynxee Consulting Unpublished	N	Y	XXXX
KCP 6.2/27 KCP 6.4.1	Dupeuble, F.	2023	Statistical analysis: MANDES_MED_NE_PESINC Lynxee Consulting Unpublished	N	Y	XXXX
KCP 6.2/28 KCP 6.4.1	Dupeuble, F.	2023	Statistical analysis: MANDES_YIELD_MAR Lynxee Consulting Unpublished	N	Y	XXXX
KCP 6.2/29 KCP 6.4.1	Dupeuble, F.	2023	Statistical analysis: MANDES_YIELD_NE Lynxee Consulting Unpublished	N	Y	XXXX

* XXXX).

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title	Y/N	Owner

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished		