

# FINAL REGISTRATION REPORT

## Part B

### Section 3

#### Efficacy Data and Information

Concise summary

Product code: IN005B1570

Product name: ~~INDOFIL~~ Difenoconazole 250 G/L EC greener

Chemical active substance:

Difenoconazole, 250 g/L ~~250 g/L~~

Central registration zone

Zonal Rapporteur Member State: Poland

#### CORE ASSESSMENT

(Authorisation)

Applicant: Indofil Industries (Netherlands) B.V.

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## Version history

When	What
June 2023	ZRMs evaluated drr submitted by Applicant.
February 2024	Applicant's update new efficacy trials on apple
May 2024	ZRMs made changes in RR in line to reviewd comments during commenting periods.
July 2024	ZRMs made changes in RR in line to reviewed coments during 3 <sup>rd</sup> round

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

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

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

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

Comments of zRMS:	Comments of zRMS are in commenting boxes at the end of each chapter. The text of dRR was generally not changed or rewritten (small changes in the document are in grey). Changes made during commenting period are marked by turquoise and by 3 <sup>rd</sup> round by blue colour.
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##### **Summary**

##### **Abstract**

Comments of zRMS: Overall summaries are not necessary here. It was provided at the end of each chapter of the dRR.

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use - No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fnp, G, Gn, Gnp or I **	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application dose			PHI (days)	Remarks:  e.g. g safener/ synergist per ha, other dose expression, dose range (min - max)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between applications (days)	L product / ha a) max. dose per appl. b) max. total dose per crop/season	g a.s./ha a) max. dose per appl. b) max. total dose per crop/season	Water L/ha min / max			
Central registration zone uses														
1	AT, BE, CZ, DE, IE, NL, PL, SI	Oilseed rape (BRNSW)	F	LEPTMA Phoma leaf spot / Stem canker ( <i>Leptosphaeria maculans</i> / <i>L. biglobosa</i> ), SCLESC Sclerotinia stem rot ( <i>Sclerotinia sclerotiorum</i> ), ALTEBI <i>Alternaria brassicae</i>	foliar spray	Autumn and Spring applications BBCH 14-18 and BBCH 30-69	2 (1 in autumn and 1 in spring or 2 in autumn)	21	a) 0.5 b) 1	a) 125 b) 250	100-500 200-300	NA	Dose rate: 125 g a.s./ha 0.5 L/ha Formulated Product (or 0.25 L/ha per single application if 2 applications in autumn)	In PL – only spring application against SCLESC is accepted at dose 0.5 L/ha applied once a season. cMS should consider proposed application window and water volume DE and AT – not accepted use against LEPTMA (autumn and spring application), ALTEBI (autumn and spring application), SCLEC (autumn application). DE and AT – accepted only spring application against SCLESC.
2	AT, BE, DE, IE,	Apple (MABSD)	F	VENTIN, VENTPI Scab	foliar spray	BBCH 57-84	3	7	a) 0.225	a) 56.25	100-1500	21	Spray interval from 7 to 14 days	cMS should consider



	NL	Pear (PYUCO)		( <i>Venturia inaequalis</i> , <i>Venturia pyrina</i> )		57-78			b) 0.675	b) 168.75	300-1000		10 days Other rate expressions: 0.15 L/10 000 m² LWA Or 0.015 L/hL	proposed application window and water volume. DE and NL accepted this use. AT – not accepted this use. NL – accepted only use on apples.
3	CZ, PL, SI	Apple (MABSD) Pear (PYUCO)	F	VENTIN, VENTPI Scab ( <i>Venturia inaequalis</i> , <i>Venturia pyrina</i> )	foliar spray	BBCH 57-84 57-78	3	7	a) 0.2 b) 0.6	a) 50.0 b) 150.0	100-1000 300-1000	21	Spray interval from 7 to 10 days Other rate expressions: 0.15 L/10 000 m² LWA Or 0.015 L/hL In PL – 0.15 L – 150.000 m² LWA	In PL pear as minor crop according to Article 51 can be accepted.. Apple at BBCH 57-78. PL – accepted. CMS should consider that application window and proposed water volume.
4	BE, CZ, IE, NL, PL, SI	Carrot (DAUCS)	F	ALTEDA Leaf bligh ( <i>Alternaria dauci</i> ), ALTERA Black-rot ( <i>Alternaria radicina</i> ), ERYSHE Oidium ( <i>Erysiphe heraclei</i> )	foliar spray	from BBCH 39-40 40-49	3	14	a) 0.5 b) 1.5	a) 125 b) 375	200-1000 200-600	14	Dose rate range in label 0.4-0.5 L/ha	In PL – ERY SHE and ALTERA can be accepted only according to Article 51 CMS should consider proposed appication window and

														water volume NL – accepted use
5	AT - DE	Carrot (DAUCS)	F	ALTEDA Leaf bligh ( <i>Alternaria dauci</i> ), ALTERA Black-rot ( <i>Alternaria radicina</i> ), ERYSHE Oidium ( <i>Erysiphe heraclei</i> )	foliar spray	from BBCH <del>39-40</del> 40-49	3	14	a) 0.4 b) 1.2	a) 100 b) 300	<del>200-1000</del> 200-600	14	-	cMS should consider proposed application window and water volume DE-use accepted
6	AT, BE, CZ, DE, IE, NL (minor use, art. 51), PL, SI	Cauliflower (BRSOB)	F	ALTEBI <i>Alternaria spp.</i> , MYCOBR Ring spot ( <i>Mycosphaerella brassicicola</i> )	foliar spray	from BBCH 19-49 <del>39</del>	3	14	a) 0.5 b) 1.5	a) 125 b) 375	<del>200-1000</del> 200-600	14	-	In PL only as minor crop according to Article 51 can be accepted. cMS should consider proposed application window and water volume Recommended application window: BBCH 19-49. DE-use accepted
7	AT, BE, CZ, DE, IE, NL (minor use, art. 51), PL, SI	Broccoli (BRSOK)	F	ALTEBI <i>Alternaria spp.</i> , MYCOBR Ring spot ( <i>Mycosphaerella brassicicola</i> )	foliar spray	from BBCH <del>19-21</del> 19-49 <del>39</del>	3	7	a) 0.5 b) 1.5	a) 125 b) 375	<del>200-1000</del> 200-600	14	Interval between applications: 7 <del>10</del> days	In PL only as minor crop according to Article 51 can be accepted cMS should consider proposed application window and water volume Recommended application window: BBCH 19-49. DE-use

														accepted
8	AT, BE, CZ, DE, IE, NL (minor use, art. 51), PL, SI	Cabbage (BRSOL)	F	ALTEBI <i>Alternaria spp.</i> MYCOBR Ring spot ( <i>Mycosphaerella brassicicola</i> )	foliar spray	from BBCH 19-49	3	7	a) 0.5 b) 1.5	a) 125 b) 375	<del>200-1000</del> 200-600	14	Interval between applications: 7-10 days	In PL only as minor crop according to Article 51 can be accepted. cMS should consider proposed application window and water volume Recommended application window: BBCH 19-49. DE-use accepted.

\* 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, Fpn: professional and non - professional field use, G: professional greenhouse use, Gn: non - professional greenhouse use, Gpn: professional and non - professional greenhouse use, I: indoor application.

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 IN005B1570 250EC containing difenoconazole (250 g/L) which were included Annex I of Directive 91/414 (inclusion directive 2009/70/CE, dated 25/06/2009). The SANCO report for difenoconazole (SANCO/830/08 – rev.3 – 18/05/2020) is considered to provide the relevant review information, or a reference, to where such information can be found.

The Annex (Part A) to Commission Implementing Regulation (EU) No 540/2011 provides specific provisions which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on difenoconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 March 2009 shall be taken into account.

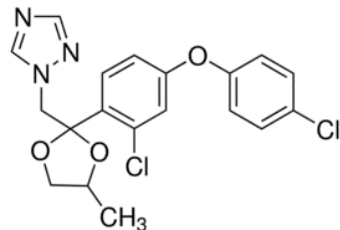
In fact, this Biological Assessment Dossier (BAD) supports submission for authorisation of the new product IN005B1570 250EC as a EC (Emulsifiable Concentrate) formulation for the control of diseases in various crops in the Central registration zone. IN005B1570 250EC is a new formulation with difenoconazole 250 g/L. Several difenoconazole 250 g/L based products are currently registered in Europe, notably, in Austria, Belgium, Czech Republic, Germany, Poland, Slovenia, The Netherlands and Ireland to control fungus in various crops. Therefore, the objective of this BAD is to justify the similarity between IN005B1570 250EC and these difenoconazole based products at the same dose rate.

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

### Description of active substance

Active substance properties are summarised in Table 3.2-1.

**Table 3.2-1: Details of the active substance**

Active substance	Difenoconazole
Concentration (Unit: g/kg or g/L...)	250 g/L
Chemical name (IUPAC)	Difenoconazole
CAS No	119446-68-3
Molecular formula	C <sub>19</sub> H <sub>17</sub> Cl <sub>2</sub> N <sub>3</sub> O <sub>3</sub>
Molecular mass	406.3 g/mol
Chemical group	Triazole
FRAC Group	G1 Group 3
Mode of action	C14 - demethylase in sterol biosynthesis
Biological action	Systemic with preventative and curative action. Disrupts membrane function - inhibition of demethylation during ergosterol synthesis.
Structural formula	

## Mode of action

Difenoconazole is a fungicide used in agriculture for the control of various diseases including Powdery mildews (e.g. *Erysiphe heraclei*, *E. communis*), scab (*Venturia inaequalis*, *V. pyrina*), *Alternaria* spp. (*A. solani*, *A. alternata*, *A. dauci*) and bunt (*Tilletia caries*, *T. controversa*) in a range of crops. Difenoconazole is a systemic pesticide belonging to the group of triazoles.

Difenoconazole is a translaminar (weakly xylem-mobile) fungicide with long-lasting preventative and curative broad-spectrum control, including leaf spot diseases, powdery mildews, rusts and scab of annual and perennial crops. It is active against plant pathogens belonging to the Deuteromycota, Basidiomycota and Ascomycota.

Difenoconazole is from the triazole class of chemistry and its mode of action is similar to other triazoles (sterol demethylation inhibitors = DMIs), i.e. its main biochemical mode of action is the inhibition of cytochrome P-450 sterol 14 $\alpha$ -demethylase (P-45014DM), a key enzyme of the sterol biosynthetic pathway of fungi, which stops the development of fungi by interfering with the biosynthesis of sterols in cell membranes.

Triazole fungicides are systemic or translaminar compounds with quick uptake and acropetal translocation in the xylem, resulting in good distribution in the plant tissue and protection from being washed off. When taken up by the plant, difenoconazole acts on the fungal pathogen during penetration and haustoria formation. It stops the development of fungi by interfering with the biosynthesis of sterols in cell membranes. Interference with sterol biosynthesis leads to disruption of membrane function, leakage of cytoplasmic contents and hyphal death.

## Description of the plant protection product

IN005B1570 250EC is a Emulsifiable Concentrate (EC) preparation containing difenoconazole (250 g/L) addressed to control a range of diseases of diverse crops by foliar application method.

In all requested countries of the Central regulatory zone, several preparations containing difenoconazole are currently registered and sold under many trade names in Europe for the control of diseases in arable and speciality crops, e.g.: SCORE, DIFCOR, DIFO 25%EC, NARITA etc...

Principals requested uses (mainly SCORE as is the reference product used in protocols or other preparations containing difenoconazole straight or in mixture on uses where SCORE is not registered) are presented in Table 3.2-2.

**Table 3.2-2: Products containing difenoconazole registered in the Central registration zone against a range of diseases - List of authorizations granted**

Country	Registration No.	Product name	Owner	Active substance	Rate of active substance	Formulation	Crop	Pest	Registered dose rate	Rate a.s. (g/ha or g/hL)
Austria	3255-0	SCORE	Syngenta	Difenoconazole	250.0 g/L	EC	Oilseed rape	<i>Leptosphaeria maculans</i>	0.5 L/ha	125 g a.s/ha
								<i>Sclerotinia sclerotiorum</i>	Not registered	-
								<i>Alternaria brassicae</i>		
							Carrot	<i>Alternaria dauci</i> <i>Alternaria radicina</i> <i>Erysiphe heraclei</i>	0.4 L/ha	100 g a.s/ha
							Cauliflower	<i>Alternaria spp.</i> <i>Mycosphaerella brassicicola</i>	0.4 L/ha	100 g a.s/ha
	4000-0	DIFENOFIN	Finchimica S.p.A.	Difenoconazole	250.0 g/L	EC	Apple	<i>Venturia inaequalis</i>	0.075 L/ha m CH Max 0.225 L/ha	18.75 g a.s/ha m CH Max 56.25 g a.s/ha
Belgium	9454P/B	DIFCOR	Globachem nv	Difenoconazole	250.0 g/L	EC	Oilseed rape	<i>Leptosphaeria maculans</i> <i>Sclerotinia sclerotiorum</i> <i>Alternaria brassicae</i>	0.5 L/ha	125 g a.s/ha
								<i>Venturia inaequalis</i>	0.1 L/ha m CH	25.0 g a.s/ha m CH
							Carrot	<i>Alternaria dauci</i> <i>Alternaria radicina</i> <i>Erysiphe heraclei</i>	0.5 L/ha	125 g a.s/ha
							Cauliflower Broccoli Cabbage	<i>Alternaria spp.</i> <i>Mycosphaerella brassicicola</i>	0.5 L/ha	125 g a.s/ha
Czech Republic	4747-0	Difcor 250 EC	Globachem nv	Difenoconazole	250.0 g/L	EC	Oilseed rape	<i>Leptosphaeria maculans</i> <i>Sclerotinia sclerotiorum</i> <i>Alternaria brassicae</i>	0.5 L/ha	125 g a.s/ha
	5274-1	Rekin 250 EC	INNVIKO Sp. z o.o.	Difenoconazole	250.0 g/L	EC	Apple	<i>Venturia inaequalis</i>	0.2 L/ha	50 g a.s/ha
	5414-0	Dagonis	BASF	Fluxapyroxad, Difenoconazole	75 g/L 50 g/L	SC	Carrot	<i>Alternaria dauci</i> <i>Alternaria radicina</i> <i>Erysiphe heraclei</i>	0.2 L/ha	15 g a.s/ha 10 g a.s/ha
							Broccoli Cabbage	<i>Alternaria spp.</i> <i>Mycosphaerella brassicicola</i>	1.0 L/ha	75 g a.s/ha 50 g a.s/ha
Germany	024353-00	SCORE	Syngenta	Difenoconazole	250.0 g/L	EC	Oilseed rape	<i>Leptosphaeria maculans</i>	0.5 L/ha	125 g a.s/ha
								<i>Sclerotinia sclerotiorum</i>	Not registered	-
								<i>Alternaria brassicae</i>	Not registered	-
							Pome fruit	<i>Venturia spp.</i>	0.075 L/ha m CH	18.75 g a.s /ha m CH
							Carrot	<i>Alternaria dauci</i> <i>Alternaria radicina</i> <i>Erysiphe heraclei</i>	0.4 L/ha	100 g a.s/ha
							Cauliflower	<i>Alternaria spp.</i> <i>Mycosphaerella brassicicola</i>	0.4 L/ha	100 g a.s/ha

Country	Registration No.	Product name	Owner	Active substance	Rate of active substance	Formulation	Crop	Pest	Registered dose rate	Rate a.s. (g/ha or g/hL)
Ireland	04566	SCORE 250 EC	Syngenta	Difenoconazole	250.0 g/L	EC	Oilseed rape	<i>Leptosphaeria maculans</i> <i>Sclerotinia sclerotiorum</i> <i>Alternaria brassicae</i>	0.5 L/ha	<b>125 g a.s/ha</b>
							Cauliflower Broccoli Cabbage	<i>Alternaria spp.</i> , <i>Mycosphaerella brassicicola</i>	0.5 L/ha	<b>125 g a.s/ha</b>
	04891	DIFO 25% EC	Sharda Europe b.v.b.a	Difenoconazole	250.0 g/L	EC	Pome fruit	<i>Venturia inaequalis</i>	0.2 L/ha	<b>50 g a.s/ha</b>
	06476	PERSEUS	BASF	Fluxapyroxad, <b>Difenoconazole</b>	75 g/L <b>50 g/L</b>	SC	Carrot	<i>Alternaria dauci</i> <i>Alternaria radicina</i> <i>Erysiphe heraclei</i>	1.0 L/ha	75 g a.s/ha <b>50 g a.s/ha</b>
Netherlands	11453	SCORE	Syngenta	Difenoconazole	250.0 g/L	EC	Oilseed rape	<i>Leptosphaeria maculans</i>	0.5 L/ha	<b>125 g a.s/ha</b>
								<i>Sclerotinia sclerotiorum</i> <i>Alternaria brassicae</i>	Not registered	-
							Apple Pear	<i>Venturia inaequalis</i> <i>Venturia pyrina</i>	0.015 L/hL Max 0.225 L/ha	<b>3.75 g a.s/hL</b> <b>56.25 g a.s/ha</b>
							Carrot	<i>Alternaria dauci</i>	0.5 L/ha	<b>125 g a.s/ha</b>
							Cabbage	<i>Alternaria spp.</i> , <i>Mycosphaerella brassicicola</i>	0.5 L/ha	<b>125 g a.s/ha</b>
Poland	R-100-2014	SCORE 250 EC	Syngenta	Difenoconazole	250.0 g/L	EC	Apple	<i>Venturia inaequalis</i>	0.2 L/ha	<b>50 g a.s/ha</b>
	R-140/2014	DIFO 250 EC	Globachem	Difenoconazole	250.0 g/L	EC	Oilseed rape	<i>Leptosphaeria maculans</i> <i>Alternaria brassicae</i>	0.5 L/ha	<b>125 g a.s/ha</b>
								<i>Sclerotinia sclerotiorum</i>	Not registered	-
							Apple Pear	<i>Venturia inaequalis</i>	0.2 L/ha	<b>50 g a.s/ha</b>
							Carrot	<i>Alternaria dauci</i> <i>Alternaria radicina</i> <i>Erysiphe heraclei</i>	0.5 L/ha	<b>125 g a.s/ha</b>
							Broccoli Cauliflower	<i>Alternaria sp.</i>	0.5 L/ha	<b>125 g a.s/ha</b>
Slovenia	SFS 9147	SCORE 250 EC	Syngenta	Difenoconazole	250.0 g/L	EC	Oilseed rape	<i>Leptosphaeria maculans</i> <i>Alternaria brassicae</i>	0.5 L/ha	<b>125 g a.s/ha</b>
								<i>Sclerotinia sclerotiorum</i>	Not registered	-
							Apple Pear	<i>Venturia inaequalis</i> <i>Venturia pyrina</i>	0.2 L/ha	<b>50 g a.s/ha</b>
							Cauliflower Broccoli Cabbage	<i>Alternaria spp.</i> , <i>Mycosphaerella brassicicola</i>	0.5 L/ha	<b>125 g a.s/ha</b>
	U34330-173/15/13	SERCADIS PLUS	BASF	Fluxapyroxad, <b>Difenoconazole</b>	75 g/L <b>50 g/L</b>	SC	Carrot	<i>Alternaria dauci</i>	1.0 L/ha	75 g a.s/ha <b>50 g a.s/ha</b>

### **Requested uses**

The simplified recommendations proposed for IN005B1570 250EC are presented in Table 3.2-3. Further details are in the table “All intended uses” in Part B - Section 0.



**Table 3.2-3: Simplified table of requested dose rate for IN005B1570 250EC by Applicant**

Crop	Target	Member state	Requested registration			Comments / other relevant details on GAPs
			Requested dose per application	Application number	Application crop stage	
Oilseed rape (BRNSW)	Stem canker - LEPTMA ( <i>Leptosphaeria maculans</i> ) Sclerotinia stem rot - SCLESC ( <i>Sclerotinia sclerotiorum</i> ) Black spot of rape - ALTEBI ( <i>Alternaria brassicae</i> )	PL - DE - CZ - BE - NL - AT - SI - IE	0.5 L/ha	2	BBCH 14-18 (Autumn application) BBCH 30-69 (Spring application)	100-500 L/ha  Dose rate: 125 g a.i./ha 0,5 L/ha Formulated Product (or 0,25 L/ha per single application if 2 applications in autumn)
Apple (MABSD) Pear (PYUCO)	Scab - VENTIN, VENTPI ( <i>Venturia inaequalis</i> , <i>Venturia pyrina</i> )	DE - BE - NL - AT - IE	0.225 L/ha	3	BBCH 57-84	100-1500 L/ha
		PL - CZ - SI	0.2 L/ha			100-1000 L/ha
Carrot (DAUCS)	Leaf blight of carrot - ALTEDA ( <i>Alternaria dauci</i> ) Black rot of carrot - ALTERA ( <i>Alternaria radicina</i> ) Powdery mildew of carrot - ERYSHS ( <i>Erysiphe heraclei</i> )	PL - CZ - BE - NL - SI - IE	0.5 L/ha	3	BBCH 39-40	200-1000 L/ha
		AT - DE	0.4 L/ha			
Brassicas crops (Cauliflower - BRSOB, Broccoli - BRSOK and Cabbage - BRSOL)	Leaf spot - ALTESP <i>Alternaria spp</i> Ring spot -MYCOBR <i>Mycosphaerella brassicicola</i>	PL - DE - CZ - BE - NL - AT - SI - IE	0.5 L/ha	3	From BBCH 19	200-1000 L/ha

## Description of the target pest

The disease concerned by this dossier is summarised in the following Table 3.2-4.

**Table 3.2-4: Glossary of pests mentioned in the trials**

Crop	Disease	Pathogens (Latin name)	EPPO code
Oilseed rape	Stem canker Sclerotinia stem rot Black spot of rape Cylindrosporium	<i>Leptosphaeria maculans</i> <i>Sclerotinia sclerotiorum</i> <i>Alternaria brassicae</i> <i>Cylindrosporium sp.</i>	LEPTMA SCLESC ALTEBI CYLSSP
Pome fruits (Apple and pear)	Apple scab Pear scab	<i>Venturia inaequalis</i> , <i>Venturia pirina</i>	VENTIN VENTPI
Garden carrot	Powdery mildew Leaf blight of carrot	<i>Erysiphe heraclei</i> <i>Alternaria dauca</i> <i>Alternaria spp</i>	ERYSHE ALTEDA ALTESP
Brassicae crop (Cauliflower, broccoli and cabbage)	Leaf spot Ring spot	<i>Alternaria brassicicola</i> <i>Mycosphaerella brassicicola</i>	ALTEBI MYCOBR

Fungal diseases can cause considerable yield and quality losses on crops, which can be reduced using appropriate disease control strategies including the application of fungicides relevant to the particular disease situation. The use of IN005B1570 250EC provides a product with a broad spectrum of activity for use on vegetable crops, oilseed rape and pome fruits. Below is a short description of each of the diseases that IN005B1570 250EC will control when applied as a foliar spray to pome fruits, vegetable crops such as carrots and brassicae and oilseed rape.

### 1) Oilseed rape

Stem canker or Phoma leaf spot (*Leptosphaeria maculans* and *L. biglobosa*):

Caused by two closely related pathogens – *Leptosphaeria maculans* and *L. biglobosa* – phoma goes through one infection cycle per season (a monocyclic disease). During periods of warm, wet and humid weather in the autumn, infected stubble releases airborne spores (ascospores). When these spores land on the leaves of young (from emergence onwards), susceptible plants, infection occurs.

Phoma spotting symptoms:

Generally, spots start to show on infected leaves after at least 20 days of rainfall. Each of the pathogens that cause phoma has its own distinct leaf-spotting symptoms. For *L. maculans*, symptoms are typically, tawny-coloured spots with dark specks (asexual fruiting bodies – pycnidia) and *L. biglobosa*, it is usually, darker spots with few (if any) dark specks (pycnidia).

Spots develop on the upper side of the leaf, with the underside clear of fungal growth (unlike the white fungal growth associated with downy mildew). Some spots may have a yellow halo and cause browning of leaf veins. Leaf spots have minimal impact on crop growth and yield, except when severe infection of cotyledons kills seedlings.

Phoma canker symptoms:

From the leaf, the pathogen grows along the leaf petiole to the stem, invading and killing plant tissue cells. Classic canker symptoms often form around the leaf scars at the stem-base. These develop further and girdle the stem, restricting water and nutrient transport. This can result in premature senescence. In extreme cases, the stem can be severed, the crop can lodge and plants can die. The earliest infections are associated with the largest cankers. *L. maculans*, typically, causes relatively severe stem-base cankers and *L. biglobosa*: usually causes lesions to develop on the upper stem. Symptoms of infection can also show in flowers, buds and pods. In the latter, brown pod lesions may occur, along with pycnidia and a black margin.

After harvest, the pathogen continues to develop on the stubble. However, symptoms gradually disappear, as the fungus enters its sexual stage on stems and roots.

#### Sclerotinia stem rot (*Sclerotinia sclerotiorum*):

*Sclerotinia sclerotiorum* (SCLESC) is the causal agent of Sclerotinia stem rot affecting a wide range of crops. SCLESC is a soil born disease surviving in the soil by the mean of sclerotia, black dots of 1-10 mm size which can rest for 10 years in the soil.

In the spring, sclerotia can germinate (soil moisture and temperatures >10°C), produce apothecia and when mature these apothecia release spores which contaminate the plant surface, particularly petals. Petal contamination is essential in the spread of the disease as it sticks to the leaf of stem surface and provides a growing medium allowing spores to germinate and penetrate the plant.

Rapidly the first symptoms, pale brown patches, develop but the symptoms more typical of the disease appear later in the season: large white lesions on stems sometimes with black sclerotia visible on the surface and plenty more sclerotia inside the stem or root cavity. These lesions cause premature ripening of the pod by disruption of nutrient and water supply. The sclerotia produced during the crop cycle represent a new source of contamination for the soil and of other crop by contamination of the harvest. Conditions favouring the disease are a history of soil contamination, sufficient temperature and showery conditions during flowering to allow the fallen petals to stick during the contamination period. The critical period for the protection of the crop against sclerotinia is the early to mid-flowering.

In the UK, the economic threshold for intervention was estimated at 10% plants contaminated.<sup>1</sup> The importance of this disease is also growing in other countries of Europe like Germany and is directly linked to the intensive cultivation and limited crop rotation. In the coastal region of the north east of Germany (Mecklenburg-Western Pomerania), up to 30% yield loss can occur according to S.Koch and al. This article also revisited the conditions required for ascospore infection and reduced the minimum temperature required to 7-11°C with 80-86% humidity and confirmed the significant correlation between OSR cropping frequency and intensity of disease outbreaks.<sup>2</sup>

## **2) Pome fruits**

#### Apple scab (*Venturia inaequalis*)

Apple scab caused by the fungus *Venturia inaequalis* is a destructive disease of apple trees. Apple scab is of major economic importance in all apple growing regions with temperate climates. Losses result directly from fruit infections which affect yield, fruit quality, marketability and storability or indirectly from defoliation which can affect tree vigor and winter survival. If not controlled, apple scab can result in 100% crop loss where humid, cool weather occurs during the spring months. The pathogen is a facultative saprophyte that grows subcuticularly on the host. *V. inaequalis* must obtain nutrients through an active mean. The fungus grows as a stroma of thick-walled cells between the cuticle and the outer wall of the host epidermis. Temperatures from 17 to 24°C are optimal for fungus growth.

Apple scab can be observed on leaves, petioles, blossoms, sepals, fruit, pedicels, and less frequently, on young shoots and bud scales. The disease manifests as velvety brown to olive lesions and has feathery, indistinct margins. With time, the margins become distinct, but they may be obscured if several lesions coalesce. As an infected leaf ages, the tissue adjacent to the lesion thicken, and the leaf

<sup>1</sup> <http://adlib.everysite.co.uk/adlib/defra/content.aspx?doc=2279&id=2329>

<sup>2</sup> <http://apsjournals.apsnet.org/doi/pdf/10.1094/PHYTO-97-9-1186>

surface becomes deformed. Young leaves may become curled, dwarfed, and distorted when infections are numerous. Lesions on young fruits appear similar to those on leaves, but as the infected fruit enlarge, the lesions become brown and corky. Infections early in the season can cause fruit to develop unevenly as uninfected portions continue to grow. Cracks then appear in the skin and flesh, or the fruit may become deformed. Fruit infections that occur in late summer or early fall may not be visible until the fruit are in storage.

The disease cycle of apple scab is characterized by two distinct but temporally overlapping spore stages. The primary stage is defined by the period of ascospore release. *V. inaequalis* overwinters as pseudothecia in fallen infected leaves, and ascospore maturity and release occur over a time period generally beginning at bud break in early spring and continuing until the ascospore supply is exhausted. The peak release of ascospores typically occurs shortly before or during blooming. The length of time required for infection to occur depends on the number of hours with continuous wetness and temperature during the wet period.

The secondary stage corresponds with the production of conidia and results in the classic polycyclic spread of disease, with rainfalls. The first conidia are produced 2 to 4 weeks after the initial ascospore infections have completed their latent period.

### 3) Vegetables

#### Leaf blight of carrot (*Alternaria dauci* and *radicina*):

Two species of *Alternaria* cause disease of carrots-*A. dauci* and *A. radicina*. *A. dauci* causes leaf spot and blight, and is present in all carrot production areas of the world, and is capable of rapidly causing severe foliar epidemics. *A. radicina* causes damping-off and petiole and crown infection of seedlings, necrosis of roots and crowns, foliar blight, seed/umbel blight, and storage rot. Also present in all parts of the world where carrot are grown, *A. radicina* infects celery, celeriac, caraway, dill, fennel, parsley, and parsnips.

*Alternaria dauci* leaf blight is the main carrot foliar disease. Foliar symptoms of *A. dauci* first appear along leaflet margins as greenish-brown, water-soaked lesions which enlarge, turn brown to black, and often develop a yellow halo. Older leaves are more susceptible to infection. When about 40% of the leaf is infected, the leaf yellows, collapses, and dies. Petiole lesions are common, elongate, and can quickly kill entire leaves.

#### Life Cycle:

*A. dauci* occurs on the seed as spores and within the seed as dormant mycelium and/or spores; seedborne inoculum is important in the spread of this disease to new production areas. *A. dauci* is favored by moderate to warm conditions and prolonged periods of leaf wetness. The fungus survives in the soil on crop debris but dies when the residue decomposes. Initially, infection may occur on the petioles as shallow, black lesions which later spread into the crown and down the root. *A. radicina* is seed-borne and also survives in the soil both in association with plant residues and as free spores. It can persist in soil for up to 8 years.

#### Crop Injury:

*Alternaria* leaf blight leads to yield losses directly by reducing foliage and indirectly by causing carrots to be left in the ground during mechanical harvesting. *A. radicina* causes seed decay, damping-off, blackened hypocotyls, and deformed roots. A dry, mealy, black decay may develop when carrot roots are held in storage. Foliar symptoms caused by *A. radicina* are less severe than those caused by *A. dauci*; however, lesions on petioles can extend to the vascular system and cause yellowing, wilting, and plant death.

### Powdery mildew of carrot (*Erysiphe heraclei*)<sup>3</sup>:

*Erysiphe heraclei* is a pathogen of many members of the *Apiaceae* including carrot (*Daucus carotae*). In the case of carrot powdery mildew, the disease can cause yield loss as well as a reduction in the ability to mechanically pull carrots from the ground due to leaf damage. Disease has the most effect on yield with early infections. Yield of seed can be reduced in seed production systems. In carrots there are differences in disease expression and severity across cultivars. The disease appears to be severe in temperatures typically found in summer and autumn.

The symptoms are typical of powdery mildews, with typical white fungal growth covering all leaf surfaces. Conidia are cylindrical and produced singly. Powdery mildew growth is difficult to observe early in infection due to the fine leaflets of the carrot, as with other powdery mildews the disease increases and spreads rapidly.

## **4) Brassicas**

### Alternaria leaf spot of cole crops (*Alternaria brassicicola*)<sup>4</sup>:

This disease is caused by the fungus *Alternaria brassicicola*, and occurs during warm, moist conditions. On seedlings, the symptoms are small dark spots on the stem that can cause damping-off or stunting of the plant. On older plants, the bottom leaves are infected first with brown circular spots on the leaves. Spots have characteristic concentric rings (target spots). Blackened areas may develop on cauliflower curds and on broccoli heads. Infected leaves soon turn yellow and drop. Bright sunshine, frequent dews or showers, and temperatures between 15 and 30°C favor disease development.

### Ring spot of cole crops (*Mycosphaerella brassicicola*)<sup>5</sup>:

Leaf spots caused by ring spot fungus look similar to those caused by *Alternaria* species. The main difference is that ring spot lesions are grey and contain black, pinheads dots in concentric rings. This spot does not damage cauliflower curds or broccoli heads but can render cabbage heads unsaleable unless heavily trimmed.

## **Description of the crops**

Table 3.2-5 presents the details of the production area per crop per cMS.

**Table 3.2-5: Production area (1000 ha) used for all crops in the Central regulatory zone in 2020<sup>(6)</sup>**

Crop	Country							
	Austria (AT)	Belgium (BE)	Czech republic (CZ)	Germany (DE)	Ireland (IE)	The Netherlands (NL)	Poland (PL)	Slovenia (SI)
Oilseed rape	165.74	8.39	450.21	1,031.30	10.38	-	1,039.30	9.76
Apples	6.43	5.48	7.19	33.98	0.71	6.20	152.00	2.18
Pears	0.54	10.66	0.83	2.14	0.00	10.00	5.10	0.23
Pome fruits	6.97	16.14	8.02	36.12	0.71	16.20	157.10	2.41
Carrots	1.87	5.08	0.84	13.79	0.77	9.59	17.90	0.28
Cauliflower and broccoli	0.32	6.03	0.33	5.80	0.86	4.88	10.10	0.14
Cabbages	0.77	1.00	1.15	9.02	0.69	2.71	13.60	0.65
Brassicas	1.09	7.03	1.48	14.82	1.55	7.59	23.70	0.79

<sup>3</sup> Source : <https://www.appsnet.org/Publications/potm/pdf/Sep11.pdf>

<sup>4</sup> Source : <https://hgic.clemson.edu/factsheet/cabbage-broccoli-other-cole-crop-diseases/>

<sup>5</sup> Source : <https://www.agric.wa.gov.au/broccoli/diseases-vegetable-brassicas?page=0%2C1>

<sup>6</sup> Source: <http://ec.europa.eu/eurostat/data/database>

Table 3.2-6 presents the status of each crop and each use in the concerned Member States.

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

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	Minor		Major	Minor
<b>Oilseed rape</b> (BRSNW)	PL - DE - CZ - BE - AT - SI - IE	NL	Stem canker - LEPTMA ( <i>Leptosphaeria maculans</i> ) Sclerotinia stem rot - SCLECS ( <i>Sclerotinia sclerotiorum</i> ) Black spot of rape - ALTEBI ( <i>Alternaria brassicae</i> )	PL - DE - CZ - BE - NL - AT - SI - IE	-
<b>Pome fruits</b> Apple (MABSD)	PL - DE - CZ - BE - NL - AT	IE - SI	Scab - VENTIN, VENTPI ( <i>Venturia inaequalis</i> , <i>Venturia pyrina</i> )	PL - DE - CZ - BE - NL - AT - SI - IE	-
<b>Pome fruits</b> Pear (PYUCO)	PL - DE - CZ - BE - NL - AT	PL IE - SI	Scab - VENTIN, VENTPI ( <i>Venturia inaequalis</i> , <i>Venturia pyrina</i> )	PL - DE - CZ - BE - NL - AT - SI - IE	-
<b>Root vegetables</b> Carrot (DAUCS)	PL - <del>BE</del> - BE - NL - AT	CZ - IE - SI - PL-DE	Leaf blight of carrot - ALTEDA ( <i>Alternaria dauci</i> ) Black rot of carrot - ALTERA ( <i>Alternaria radicina</i> ) Powdery mildew of carrot - ERYSHE ( <i>Erysiphe heraclei</i> )	PL - <del>BE</del> - CZ - BE - NL - AT - SI - IE	DE
<b>Brassicas crops</b> Cauliflower - BRSOB	PL - <del>BE</del> - CZ - BE - <del>SI</del> - IE	AT - SI - PL - DE- NL	Leaf spot - ALTESP <i>Alternaria spp</i> Ring spot -MYCOBR <i>Mycosphaerella brassicicola</i>	PL - <del>BE</del> - CZ - BE - NL - AT - SI - IE	DE
<b>Brassicas crops</b> Broccoli BRBOK	PL - <del>BE</del> - BE - NL - IE	AT - CZ - SI - PL- DE- NL	Leaf spot - ALTESP <i>Alternaria spp</i> Ring spot -MYCOBR <i>Mycosphaerella brassicicola</i>	PL - <del>BE</del> - CZ - BE - NL - AT - SI - IE	DE
<b>Brassicas crops</b> Cabbage - BRBOL	PL - <del>BE</del> - CZ - BE - <del>SI</del> - IE	AT - SI - PL - DE- NL	Leaf spot - ALTESP <i>Alternaria spp</i> Ring spot -MYCOBR <i>Mycosphaerella brassicicola</i>	PL - <del>BE</del> - CZ - BE - NL - AT - SI - IE	DE

### Compliance with the Uniform Principles

The overall assessment was performed according to the uniform principles.

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

The testing facilities responsible for the conduct of these trials and a copy of their official compliance certificates are presented in Section 3.7 “List of test facilities including the corresponding certificates”.

The efficacy GEP trials followed the requirements of the general EPPO standards:

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

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

EPPO 1/307(2) describes the development of a new product which is to be based on the principle of comparing with, and ‘bridging’ to, an existing formulation. The existing authorized formulation should

have a full underlying supporting data package. The location of trials should reflect challenging conditions based on crop/pest and environment. Moreover, testing in different zones may be more likely where the diversity of uses or crops is such that they are insufficiently represented in any one EPPO climate region.

According to this standard EPPO 1/307(2), data from other registration zones were used in this dossier. Moreover, according to EPPO PP 1/24(1) zones, the Central registration zone is composed of 3 EPPO climatic zones: Maritime, North-East and South-East zone.

Similar trial methodologies were used in all countries (Czech Republic, France, German, Netherlands, United Kingdom, Poland and Romania). All trials are in compliance with GEP and were undertaken by official or officially recognised testing facilities in accordance with the relevant EPPO guideline. Furthermore, identical methods of assessment for efficacy and crop tolerance were employed.

Trial sites were selected on the basis of known disease infestations and located within a commercial area in each respective country, grown according to the principles of good agricultural practice (GAP). These areas have been found to be particularly suitable for all crops due to their innate similarity in terms of soil type and climate.

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

Data to confirm the efficacy claims for the applications of IN005B1570 250EC in vegetable crops, oilseed rape and pome fruit against fungal diseases were taken from a set of 65 efficacy trials carried out in Maritime (45 trials), North-East (16 trials) and South-East (4 trials) EPPO climatic zones from 2020 to 2021.

Two additional efficacy trial has been presented by applicant in 2022 in North-East EPPO climatic zone to support efficacy claim of IN005B1570 250EC in pome fruit in regards to GAP. Those trials were carried out on apples. Lack of trials for pear.

Furthermore additional 4 efficacy trials has been carried out in North-East (4 trials) EPPO climatic zone in 2023 to confirm efficacy of IN005B1570 250EC in pome fruit in regards to GAP and resistance management requirements claims. Those trials were carried out on apples. Lack of trials for pear.

To cover the largest spectrum of climatic, soil conditions and crop varieties, trials were located in the main growing areas of each requested crop of Maritime, North-East and South-East EPPO climatic zones in Czech Republic, France, Germany, The Netherlands, United Kingdom, Poland and Romania. Table 3.2-7 presents the efficacy trials repartition.

**Table 3.2-7: Trials repartition**

Crop	Year	EPPO climatic zone							Total
		Maritime					North-East	South-East	
		Czech Re-public	France	Germany	Netherlands	United Kingdom	Poland	Romania	
Oilseed rape	2020	-	3 (2)	2 (0)	-	1 (0)	2 (1)	2 (1)	10 (4)
BRNSW	2021	1 (1)	4 (1)	7 (4)	-	4 (4)	3 (2)	2 (1)	21 (13)
Total Oilseed rape		1 (1)	7 (3)	9 (4)	-	5 (4)	5 (3)	4 (2)	31 (17)
Apple	2020	-	1 (1)	-	-	-	-	-	1 (1)
MABSD	2021	-	2 (1)	5 (3)	-	-	5 (5)	-	12 (9)
	2022	-	-	-	-	-	2 (2)	-	2 (2)
	2023	-	-	-	-	-	4 (4)	-	4 (4)
Total Apple		-	3 (2)	5 (3)	-	-	11 (11)	-	19 (16)
Cauliflower	2020	-	2 (2)	-	-	-	-	-	2 (2)
BRSOB	2020	-	1 (1)	-	-	-	-	-	1 (1)
Broccoli	2020	-	2 (2)	-	-	-	-	-	2 (2)
BRSOK	2020	-	-	-	-	-	-	-	-
Head cabbage	2020	-	-	-	-	-	-	-	-
BRSOL	2020	-	-	-	-	-	-	-	-
Total Brassicas		-	5 (5)	-	-	-	-	-	5 (5)
Carrot	2020	-	4 (4)	-	-	-	-	-	4 (4)
DAUCS	2021	-	-	2 (2)	2 (1)	2 (2)	6 (6)	-	12 (11)

<b>Total Vegetables</b>	<b>-</b>	<b>9 (9)</b>	<b>2 (2)</b>	<b>2 (1)</b>	<b>2 (2)</b>	<b>6 (6)</b>	<b>-</b>	<b>21 (20)</b>
<b>TOTAL</b>	<b>1 (1)</b>	<b>19 (14)</b>	<b>16 (9)</b>	<b>2 (1)</b>	<b>7 (6)</b>	<b>20 (18)</b>	<b>4 (2)</b>	<b>71 (53)</b>

In bracket, number of valid trials.

An overview of available trials is provided in :

- Table 3.2-8 for **Oilseed rape** and a summary of data on trial sites. Figure 3.2-1 presents the efficacy trials repartition for Oilseed rape trials;
- Table 3.2-9 for **Apples** and a summary of data on trial sites. Figure 3.2-2 presents the efficacy trials repartition for Apples trials;
- Table 3.2-10 for **Vegetables** and a summary of data on trial sites. Figure 3.2-3 presents the efficacy trials repartition for Vegetables trials;

**Table 3.2-8: Presentation of efficacy trials - Oilseed rape**

Crop(s) <sup>(1)</sup>	Target(s) <sup>(1)</sup>	EPPO climatic zone <sup>(2)</sup>	Country	Year	Number of trials	Type of trial <sup>(3)</sup>	GEP, non-GEP, official <sup>(4)</sup>	Comments (any other relevant information)
Winter rape	CYLSSP	South-East	Romania	2021	1 trial	S + Y	GEP	Not selected on efficacy part
	LEPTMA	Maritime	France	2021	1 trial	S	GEP	Not selected on efficacy part
			Germany	2020	2 trials	S	GEP	Not selected on efficacy part
			United Kingdom	2021	1 trial	MED + E + S	GEP	-
				2020	1 trial	S	GEP	Not selected on efficacy part
				2021	2 trials	MED + E + S	GEP	-
		North-East	Poland	2020	1 trial	S	GEP	Not selected on efficacy part
				2021	1 trial	MED + E + S	GEP	-
		South-East	Romania	2020	1 trial	MED + E + S	GEP	-
				2021	1 trial	MED + E + S	GEP	-
	LEPTMA + ALTEBA	Maritime	France	2020	1 trial	MED + E + S	GEP	-
	SCLESC	Maritime	Czech Republic	2021	1 trial	MED + E + S + Y	GEP	-
				2021	2 trials	S	GEP	Not selected on efficacy part
			France	2021	1 trial	MED + E + S	GEP	-
					3 trials	S	GEP	Not selected on efficacy part
					2 trials	MED + E + S	GEP	-
			Germany	2021	1 trial	MED + E + S + Y	GEP	-
					1 trial	MED + E + S + Y	GEP	-
					1 trial	MED + E + S + Y	GEP	-
			United Kingdom	2021	1 trial	MED + E + S	GEP	-
					1 trial	MED + E + S	GEP	-
		North-East	Poland	2021	1 trial	MED + E + S + Y	GEP	-
		South-East	Romania	2020	1 trial	S + Y	GEP	-
					1 trial	S	GEP	Not selected on efficacy part
	SCLESC + ALTEBA	Maritime	France	2020	1 trial	MED + E + S	GEP	-
	SCLESC + CYLSSP				1 trial	S	GEP	Not selected on efficacy part
	SCLESC + LEPTMA	North-East	Poland	2020	1 trial	MED + E + S	GEP	-

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

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

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

**Table 3.2-9: Presentation of efficacy trials - Apple**

Crop(s) <sup>(1)</sup>	Target(s) <sup>(1)</sup>	EPPO climatic zone <sup>(2)</sup>	Country	Year	Number of trials	Type of trial <sup>(3)</sup>	GEP, non-GEP, official <sup>(4)</sup>	Comments (any other relevant information)
Apple	VENTIN	Maritime	France	2020	1 trial	MED + E + S	GEP	-
				2021	1 trial	MED + E + S	GEP	-
					1 trial	S	GEP	-
			Germany	2021	3 trials	MED + E + S	GEP	-
					2 trials	S	GEP	-
					1 trial	S	GEP	-



Crop(s) <sup>(1)</sup>	Target(s) <sup>(1)</sup>	EPPO climatic zone <sup>(2)</sup>	Country	Year	Number of trials	Type of trial <sup>(3)</sup>	GEP, non-GEP, official <sup>(4)</sup>	Comments (any other relevant information)
		North-East	Poland	2021	5 trials	MED + E + S	GEP	-
				2022	2 trials	MED + E + S	GEP	-
				2023	4 trials	MED + E + S	GEP	-

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

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

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

**Table 3.2-10: Presentation of efficacy trials - Vegetables**

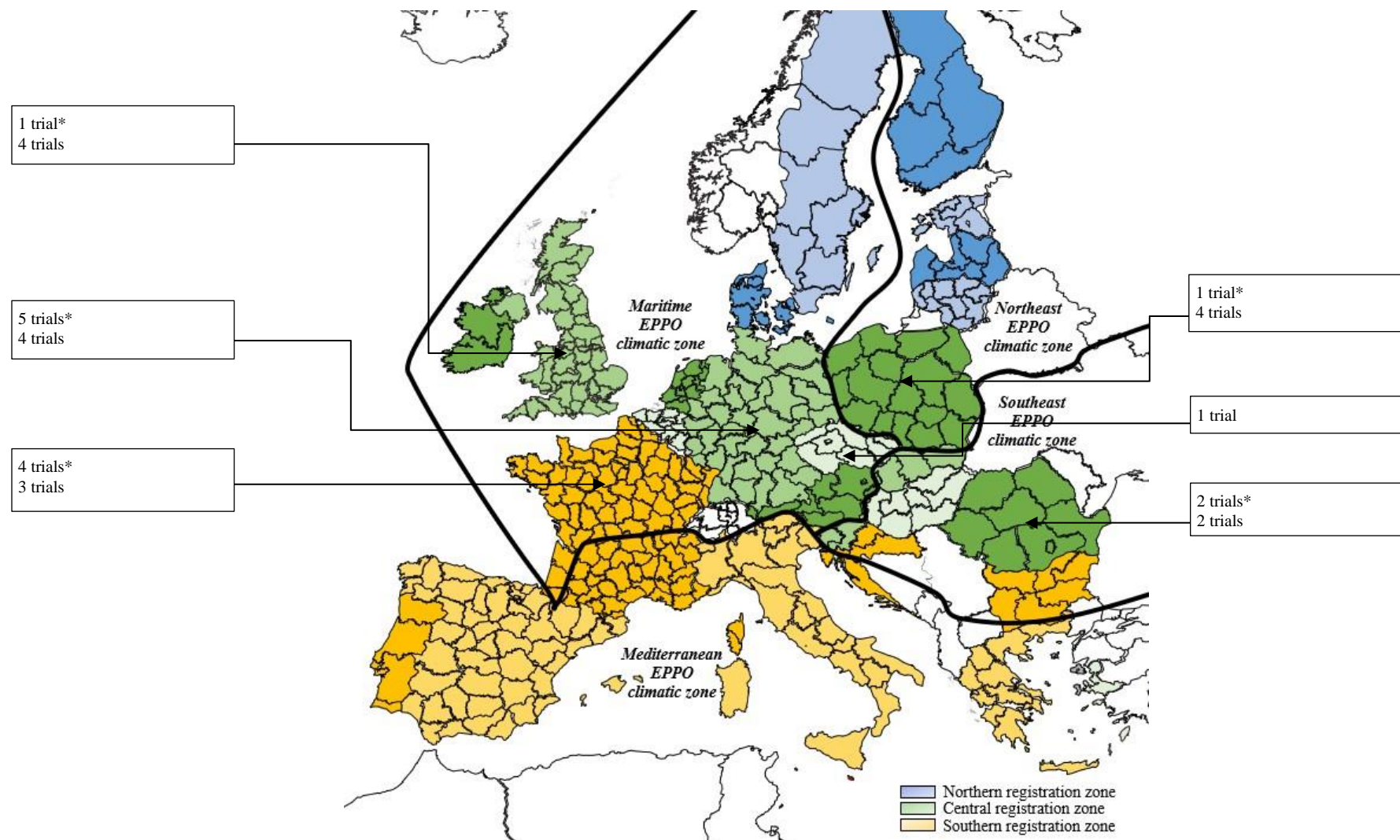
Crop(s) <sup>(1)</sup>	Target(s) <sup>(1)</sup>	EPPO climatic zone <sup>(2)</sup>	Country	Year	Number of trials	Type of trial <sup>(3)</sup>	GEP, non-official <sup>(4)</sup>	Comments (any other relevant information)
Cauliflower	ALTEBI	Maritime	France	2020	1 trial	MED + E + S + Y	GEP	-
					1 trial	MED + E + S	GEP	-
Broccoli	ALTEBI	Maritime	France	2020	1 trial	MED + E + S + Y	GEP	-
Head cabbage	ALTEBI	Maritime	France	2020	1 trial	MED + E + S	GEP	-
	ALTEBI + MYCOBR	Maritime	France	2020	1 trial	MED + E + S	GEP	-
Carrot	ALTEDA	Maritime	France	2020	1 trial	MED + E + S	GEP	-
			Germany	2021	1 trial	MED + E + S + Y	GEP	-
			Netherlands	2021	1 trial	S	GEP	Not valid on efficacy
			United Kingdom	2021	1 trial	MED + E + S	GEP	-
					1 trial	MED + E + S + Y	GEP	-
		North-East	Poland	2021	4 trials	MED + E + S + Y	GEP	-
					2 trials	MED + E + S	GEP	-
	ALTEDA + ERY SHE	Maritime	France	2020	1 trial	MED + E + S + Y	GEP	-
					1 trial	MED + E + S	GEP	-
			Germany	2021	1 trial	MED + E + S	GEP	-
			Netherlands	2021	1 trial	MED + E + S	GEP	-
			France	2020	1 trial	MED + E + S	GEP	-

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

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

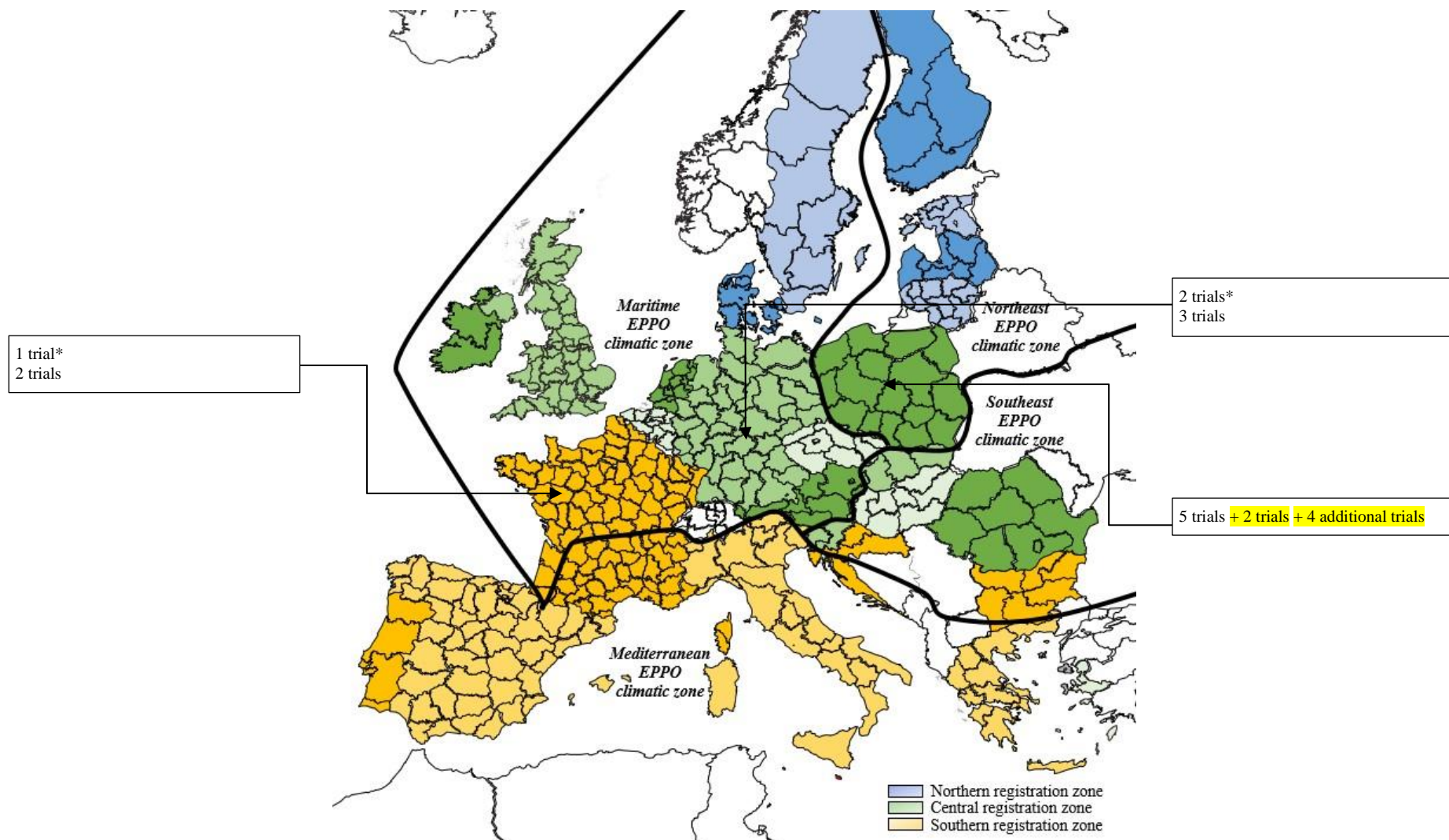
<sup>(4)</sup> GEP: Good Experimental Practices. Official: carried out by a national official organisation.

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



\*Invalid efficacy trial

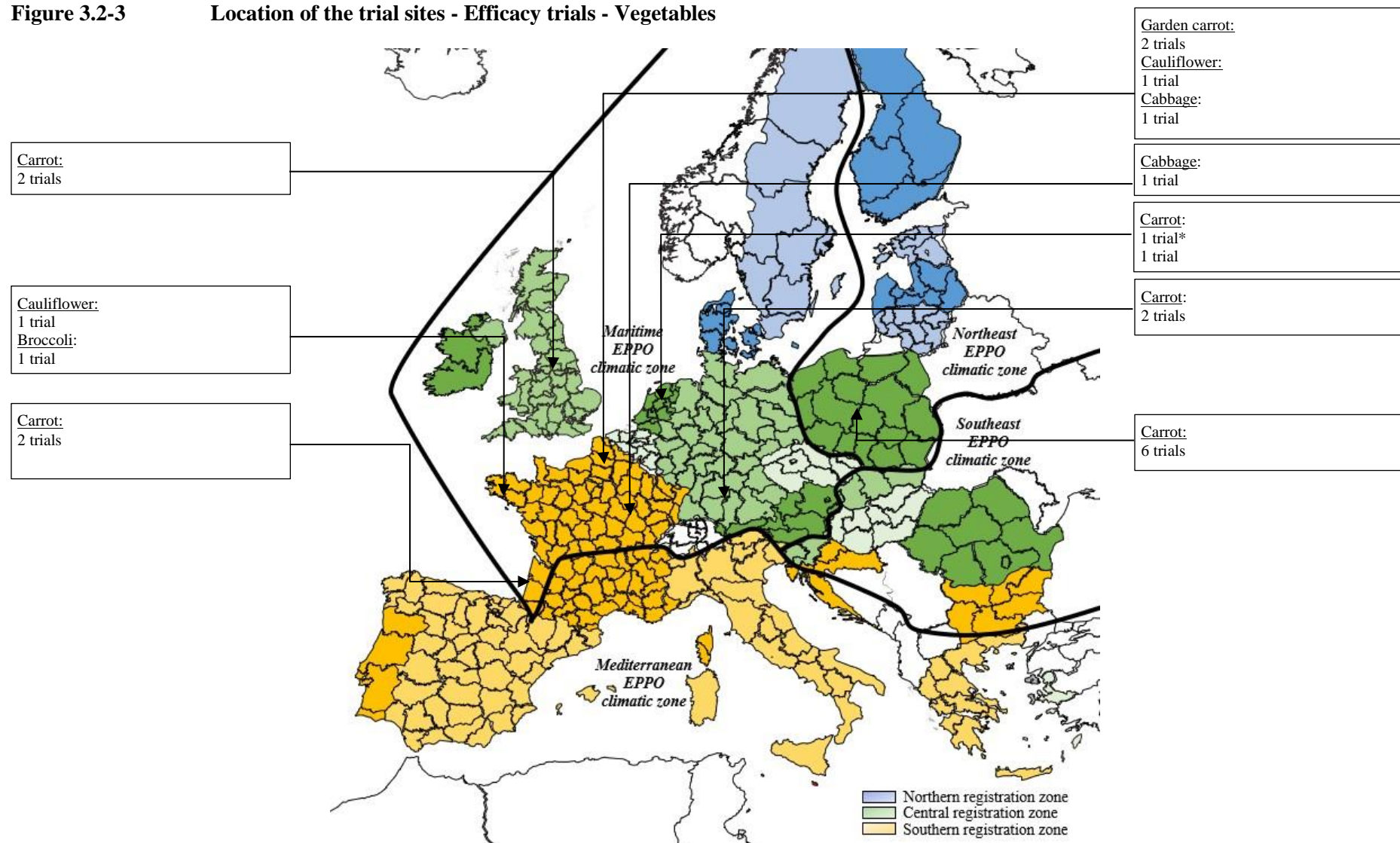
**Figure 3.2-2 Location of the trial sites - Efficacy trials - Apple**



\*Invalid efficacy trial



**Figure 3.2-3 Location of the trial sites - Efficacy trials - Vegetables**



\*Invalid efficacy trial

**Table 3.2-11: Presentation of reference standards used in efficacy trials - All crops**

Product name	Active substance(s)	Formulation		Country(ies) where the product is registered <sup>(1)</sup>	Registration number	Crop(s)	Registered application dose <sup>(3)</sup>	Dose rate in trials (per treatment)	Rate of active substance per ha	Remark
		Type <sup>(2)</sup>	Concentration of a.s.							
GEYSER / SCORE*	Difenoconazole	EC	250 g/L	CZ	Not registered	Oilseed rape	-	0.5 L/ha	125.0 g a.s./ha	-
				DE	024353-00	Oilseed rape	0.5 L/ha against LEPTMA	0.5 L/ha	125.0 g a.s./ha	-
						Pome fruit	0.15 L/ha	0.15 L/ha	37.5 g a.s./ha	-
						Carrot	0.4 L/ha	0.4 L/ha	100.0 g a.s./ha	-
				FR	880841	Oilseed rape	-	0.5 L/ha	125.0 g a.s./ha	-
						Pome fruit	0.15 L/ha	0.15 L/ha	37.5 g a.s./ha	-
						Carrot	0.5 L/ha	0.5 L/ha	125.0 g a.s./ha	-
						Brassicaes	0.5 L/ha	0.5 L/ha	125.0 g a.s./ha	-
				NL	11453	Carrot	0.5 L/ha	0.4 L/ha	100.0 g a.s./ha	-
				PL	R-100-2014	Oilseed rape	-	0.5 L/ha	125.0 g a.s./ha	-
						Pome fruit	0.2 L/ha	0.20 L/ha	50.0 g a.s./ha	-
						Carrot	0.5 L/ha	0.5 L/ha	125.0 g a.s./ha	-
				RO	1165	Oilseed rape	0.5 L/ha	0.5 L/ha	125.0 g a.s./ha	-
				UK	04566	Oilseed rape	0.5 L/ha	0.5 L/ha	125.0 g a.s./ha	-
						Carrot	-	0.5 L/ha	125.0 g a.s./ha	-
TOLEDO	Tebuconazole	SC	430 g/L	UK	04566	Carrot	0.6 L/ha	0.6 L/ha	258.0 g a.s./ha	-
CARAMBA 60SL	Metconazole	SL	60 g/L	PL	R-45/2010	Oilseed rape	1.0 L/ha	1.0 L/ha	60 g a.s./ha	-
AURELIA 250EC	Prothioconazole	EC	250 g/L	UK	19350	Oilseed rape	0.7 L/ha	0.7 L/ha	175 g a.s./ha	-
CURBATOR				DE	025287-60	Oilseed rape				-
JOAO				FR	2060116	Oilseed rape				
PRAKTIS				PL	R-222/2019	Oilseed rape				
PROLINE				CZ	4523-1	Oilseed rape				
				DE	025287-00	Oilseed rape				
			275	UK	14790	Oilseed rape	0.63 L/ha	0.63 L/ha	173 g a.s./ha	-
Folicur Solo 250 EW	Tebuconazole	EW	250 g/L	RO	1794/7.08.19 97	Oilseed rape	0.5-1.0 L/ha	1.0 L/ha	250 g a.s./ha	-
JUVENTUS	Metconazole	EC	90 g/L	FR	2010280	Oilseed rape	0.6-0.8 L/ha	0.6 L/ha	54 g a.s./ha	-
PROTENDO 250 EC	Prothioconazole	EC	250 g/L	DE	00A469-00/00-040	Oilseed rape	0.7 L/ha	0.7 L/ha	175 g a.s./ha	-
PABI 300 EC	Prothioconazole	EC	300 g/L	PL	R-27/2020	Oilseed rape	0.6 L/ha	0.6 L/ha	180 g a.s./ha	-

\* Geyser and Score are the trade names used in the different countries for the same Difenoconazole 250 g/L EC product registered by Syngenta.

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

Comments of zRMS:	<p>This document was prepared by Applicant for registration IN005B1570 250EC (product code) containing difenoconazole (250 g/L). The formulation of this product is an emulsifiable concentrate (EC). In Poland, this tested plant protection product will be sold as DIFENOCONAZOLE 250 G/L EC greener.</p> <p>Difenoconazole is a systemic triazole fungicide used for long-lasting preventative and curative broad-spectrum control of cereal, fruit and vegetable diseases including powdery mildew, rust, scab, and leaf spots. It acts by interference with the ergosterol biosynthesis in target fungi by inhibition of the C-14-demethylation of sterols, which leads to morphological and functional changes of fungal cell membrane.</p> <p>IN005B1570 250EC (product code) containing difenoconazole (250 g/L) by Indofil Industries Limited has not been previously evaluated in any country according to Uniform Principles. Poland is a ZRMs. cMS are: Austria, Belgium, Czech Republic, Germany, Ireland, The Netherlands and Slovenia</p> <p>In Poland <del>94</del> 92 plant protection products containing difenoconazole are already registered, according to the register of plant protection products dated <del>31.05.2023</del> 29.02.2024.</p> <p>All necessary information's about tested plant protection product, active substances, studied fungal diseases, reference products, etc. are correctly presented in this drr by Applicant.</p> <p>cMS should check major / minor status of intended uses.</p>
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### 3.2.1 Preliminary tests (KCP 6.1)

IN005B1570 250EC contains 250 g/L of difenoconazole that has been approved for the control of a range of diseases since 1988. The fungicidal activity of this compound has therefore been widely researched and proven in commercial use in several countries across Europe. Based on this, the chemistry and biology of the active ingredient is well understood. Therefore, no specific, preliminary/screening tests have been undertaken with IN005B1570 250EC.


Comments of zRMS:	<p>Difenoconazole 250 EC formulations are already registered and currently used in Europe. Therefore, no preliminary range-finding tests have been performed. Difenoconazol is a well-known as an active ingredient, therefore it is justified to drop preliminary range finding tests.</p>
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### 3.2.2 Minimum effective dose tests (KCP 6.2)

IN005B1570 250EC contains 250 g/L of difenoconazole which has been approved for the control of a range of diseases since 1988. Similar fungicides with same formulation and same quantity of active ingredient (difenoconazole, 250 g/L EC) have been developed and approved for use in agriculture for many years. Therefore the minimum effective dose of IN005B1570 250EC is already known (cf. Table 3.2-2). However, to deepen the knowledge on IN005B1570 250EC, different doses were studied in efficacy trials in 2020, 2021 and 2023.

These results are presented in 3.2.3.

Comments of zRMS:	<p>To provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least two lower dose(s) than recommended dose. In the appropriate research of efficacy were tested differ doses and to register was chosen the lowest effective, which is in</p>
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	<p>accordance with EPPO 1/225 (2).</p> <p>During field tests Applicant used different doses containing difenoconazole. So, in the appropriate research of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance with EPPO 1/225 (2).</p> <p>All trials were carried out under GEP conditions by officially recognized testing organisations. Test product was applied at intended dose rate and different lower dose rates.</p> <p>On <i>winter oilseed rape</i> following doses were studied: 0,312 L/ha; 0,36 L/ha and 0,5 L/ha (N dose) for single application. Those doses were applied once a season. Autumn and spring application was studied. Two application per season were studied only at autumn application for dose 0,25 L/ha. All results were compared to standard reference products. Recommended dose is 0,5 L/ha applied once a season as most effective. Applicant would like to register also dose 0,25 L/ha applied twice a season. However, during trials only two applications in autumn were studied. So, in the opinion of ZRMs two applications: one in autumn and two in spring were not justified by submitted trials.</p> <p>On <i>apple</i> trees following doses were studied: 0,10 L/ha; 0,15 L/ha; 0,2 L/ha and 0,225 L/ha. Lack of trials for pear. In the Maritime EPPO zone the dose 0,225 L/ha (dose 0,2 L/ha was not studied) is recommended and in N-E EPPO zone – dose 0,2 L/ha (dose 0,225 L/ha was not studied) as most effective. Dose 0,225 L/ha was <b>not</b> studied in N-E EPPO zone <b>in 4 additional trials carried out in 2023</b> and dose 0,2 L/ha was not studied in Maritime EPPO zone. MED dose for S-E EPPO zone was not justified according to lack of trials for this zone</p> <p>On <i>carrot</i> following doses were studied: 0,3 L/ha; 0,4 L/ha and 0,5 L/ha. The most effective dose was 0,5 L/ha. However, in AT and DE – Applicant would like to register dose 0,4 L/ha (this dose was characterized by lower efficacy than 0,5 L/ha, however that dose was still efficient). The requested different dosage is probably due to environmental or other restrictions in these member countries for the active substance difenoconazole and/or is in line with previously registered plant protection products. MED dose for S-E EPPO zone was not justified according to lack of trials for this zone.</p> <p>On <i>brassicas</i> following doses were studied: 0,3 L/ha; 0,4 L/ha and 0,5 L/ha (N dose). The most effective dose was 0,5 L/ha. Those trials were carried only in Maritime EPPO zone, so MED dose for N-E EPPO zone and S-E EPPO zone was not justified by Applicant.</p> <p><b>Based on the results from  53 valid efficacy trials, a dose response was shown. Supported by the trials and by the knowledge of difenoconazole - which is already registered and in common use - a minimum effective dose rate of 0,5 L/ha for brassicas, 0,4 l/ha for AT, DE and 0,5 L/ha for BE, CZ, IE, NL, PL, SI on carrot; 0,5 L/ha for winter oilseed rape and 0,225 l/ha for AT, DE, BE, IE, NL and 0,2 L/ha for PL, CZ and SI on apple is justified. Two application of 0,25 L/ha on winter oilseed rape was justified for autumn application. Two applications: one in spring and second in autumn were not studied and not justified by Applicant.</b></p> <p>cMs should consider in case of limiting documentation – using of data from other fungicides containing difenoconazole, if their data are unprotected and national regulations allow it.</p>
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### 3.2.3 Efficacy tests (KCP 6.2)

#### 3.2.3.1 Efficacy trials in oilseed rape

A total of 31 efficacy trials were carried out in 2020 and 2021 to justify the interest of IN005B1570 250EC applied from 0.312 L/ha to 0.5 L/ha for the control of *Leptosphaeria maculans*, *Sclerotinia sclerotiorum* and *Alternaria brassicae* in oilseed rape. All trials were carried out in the Maritime (Czech Republic (1 trial), France (7 trials), Germany (9 trials) and the United Kingdom (5 trials)), in the North-East (5 trials in Poland) and in the South-East EPPO climatic zone in Romania (4 trials). In fourteen trials insufficient disease developed or abnormal behaviour of the local reference occurred, so their efficacy data are not discussed further, but are included to the discussion of crop selectivity in Section 3.4 “Adverse effects on treated crops (KCP 6.4)”. So, only 17 valid trials were presented for oilseed rape (12 maritime: CZ-1, FR-3, DE-4, UK-4), N-E – 3 trials (PL) and S-E – 2 trials (RO).

##### 3.2.3.1.1 Material and Methods

#### Experimental details

All the trials presented in Table 3.2-8 were carried out by officially recognised organisations in accordance with the Principles of Good Experimental Practice (GEP). These trials were performed following EPPO guidelines or trial method recommendations published by the French CEB (“Commission des Essais Biologiques”). The “CEB” methods are in accordance with EPPO directives.

Main characteristics are summarised in Table 3.2-12 (Spring application) and in

Table 3.2-13 (Autumn application).

**Table 3.2-12: Details on trial methodology - Efficacy trials - Oilseed rape - Spring application**

<b>Guidelines</b>	General guidelines	PP1/135(4): “ <i>Phytotoxicity assessment</i> ”. PP1/152(4): “ <i>Design and analysis of efficacy evaluation trials</i> ”. PP1/181(4): “ <i>Conduct and reporting of efficacy evaluation trials, including good experimental practice</i> ”.
	Specific guidelines	PP1/78(3): “ <i>Root, stem, foliar and pod diseases of rape</i> ”
<b>Experimental design</b>	Plot design	Randomized Complete Block (RCB)
	Plot size	20-42 m <sup>2</sup>
	Number of replications	4 replications.
<b>Crop</b>	Number of trials	10 valid efficacy trials and 9 non valid efficacy trials
	Varieties	<i>Ambassador (1), Aspire (1), Avatar (1), Barbados(1), Cristiano KWS (1),DK Excalibur (1), DK Exception (1), DK Expansion (1), Grizzly (1), KWS Roberto (1), Pioneer PX 113 (1), PR46W14 (1), Quizz (1), Safran (1), SY Aganos (1), SY Alibaba (1),SY Florida (1), Tempo (1), Umberto (1)</i>
<b>Application</b>	Application timing	1 application between BBCH 63-65 (From April to May) - just before mid flowering.
	Spray volumes	Foliar spraying: 200-300 L/ha.
<b>Assessment</b>	Assessment dates	Around 3 weeks after the application on leaves, at around BBCH 70-85 on stems and before harvest on pods
	Assessment types	Disease incidence and disease severity on leaves, stem and pods. Phytotoxicity and Yield (6 trials)
<b>Results &amp; Analysis</b>	Statistical analysis	ANOVA - Newman - Keuls test (5%).

**Table 3.2-13: Details on trial methodology - Efficacy trials - Oilseed rape - Autumn application**

<b>Guidelines</b>	General guidelines	PP1/135(4): “ <i>Phytotoxicity assessment</i> ”. PP1/152(4): “ <i>Design and analysis of efficacy evaluation trials</i> ”. PP1/181(4): “ <i>Conduct and reporting of efficacy evaluation trials, including good experimental practice</i> ”.
	Specific guidelines	PP1/78(3): “ <i>Root, stem, foliar and pod diseases of rape</i> ”
<b>Experimental design</b>	Plot design	Randomized Complete Block (RCB)
	Plot size	20-54 m <sup>2</sup>
	Number of replications	4 replications.
<b>Crop</b>	Number of trials	7 valid efficacy trials and 5 non valid efficacy trials
	Varieties	<i>Acacia (1), Alexander (1), Alledor (1), Campus (2), Extremus (1), Feliciano (1), LG Ambassador (1), LG Architekt (1), RAGT Gazetta (1), Smaragd (1), SY Florida (1)</i>
<b>Application</b>	Application timing	1 application between BBCH 14-19 (From September to November).
	Spray volumes	Foliar spraying: 200-300 L/ha.
<b>Assessment</b>	Assessment dates	Around 3 weeks after the application on leaves, at around BBCH 70-85 on stems and before harvest on pods
	Assessment types	Disease incidence and disease severity on leaves, stems, roots and pods. Phytotoxicity
<b>Results &amp; Analysis</b>	Statistical analysis	ANOVA - Newman - Keuls test (5%).

14 trials were not selected for the following reasons:

**Table 3.2-14: Trials not valid on the efficacy part in oilseed rape**

<b>Trials codes</b>	<b>Validity explanation</b>	<b>Other relevant comments</b>
1 trial	Disease not requested assessed (CYLSP)	Presented in phytotoxicity part and yield in efficacy part
2 trials	Not selected because the local reference was applied twice and too high infestation	Presented in phytotoxicity part
1 trial	Not selected because the local reference was applied twice and behavior of the reference abnormal (efficacy <15%)	Presented in phytotoxicity part
4 trials	Behavior of the local reference abnormal (efficacy <50%)	Presented in phytotoxicity part
4 trials	Too low infestation	Presented in phytotoxicity part
2 trials	No infestation	Presented in phytotoxicity part

### Treatments and reference standards

In all efficacy trials, the efficacy of IN005B1570 250EC applied at 0.312 - 0.36 - 0.5 L/ha and twice at 0.25 L/ha was compared to the reference standard SCORE applied 0.5 L/ha and a local reference (Table 3.2-11). This rate reflects 62 and 72% of the maximum dose of IN005B1570 250EC requested (0.5 L/ha is the maximum dose of IN005B1570 250EC requested). In trials with the applications performed in autumn, IN005B1570 250EC was applied twice at 0.25 L/ha (split application, 21 days after the first or longer). All protocols are summarised in Table 3.2-16.

Table 3.2-15 below presents the plant protection products and the rates used in this part.

**Table 3.2-15: Plant protection products used in efficacy trials - Oilseed rape**

Product name	Active substance(s)	Formulation		Application dose in trials (per treatment)	Country	Rate of active substance per ha	Remark
		Type <sup>[1]</sup>	Concentration of a.s.				
IN005B1570 250EC	Difenoconazole	EC	250 g/L	0.25 L/ha* 0.312 L/ha 0.36 L/ha 0.5 L/ha	-	62.5 g a.s./ha 78.0 g a.s./ha 90.0 g a.s./ha 125.0 g a.s./ha	-
SCORE	Difenoconazole	EC	250 g/L	0.5 L/ha	FR-DE-UK-PL-RO-CZ	125.0 g a.s./ha	Named <b>DIFENO</b> in this dRR

<sup>[1]</sup> EC: Emulsionate Concentrate \* 2 applications in autumn

**Table 3.2-16: Protocol used in efficacy trials - Oilseed rape**

Number of trials	Year	Autumn (A) or Spring (S) application	IN005B1570 250EC				SCORE 0.5 L/ha [A]	Local reference [A]
			0.25 L/ha [AB]	0.312 L/ha [A]	0.36 L/ha [A]	0.5 L/ha [A]		
6 trials	2021	A	X	X	X	X	X	X
6 trials	2020	A	X	X	X	X	X	X
15 trials	2021	S	-	X	X	X	X	X
4 trials	2020	S	-	X	X	X	X	X

### Assessment methods

In all trials, efficacy was assessed according to EPPO guidelines (1/78(3)). Assessments of efficacy were made on different plant parts. Plant parts assessed were one or both of the following: leaf, stem and pods.

*Leptosphaeria maculans*, *Sclerotinia sclerotiorum* and *Alternaria brassicae*:

Data was recorded on either 25, 50 or 100 randomly plants as either percentage of visual infection of disease (disease severity) on specified plant parts or as percentage of incidence or occurrence (disease incidence).

Disease severity: (PESSEV)

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

Disease incidence: (PESINC)

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

Efficacy was calculated according to the formula of Abbott.

### Phytotoxicity assessments

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

### Statistical analyses

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

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

## Results layout

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

On LEPTMA, the last valid assessments where the pest severity (PESSEV) in the untreated reached at least 5% of leaves and roots were considered. In order to enlarge the data package, assessments where the incidence reached at least 30% on leaves were considered as valid. On stems, only assessments where the pest incidence (PESINC) in the untreated reached at least 10% of infected stems were considered as valid. Also, only assessments where the local reference standard reached a normal efficacy (>50% control compared to untreated) were considered as valid. The assessments with data below either thresholds were not taken into account in the calculation of means. Considering that, no data on stems and roots have been presented in this part.

For LEPTMA, 1 valid assessment on leaves were selected and summarised in this part. This selected assessment is the most representative according to the disease and oilseed rape development:

- Assessment on leaves: assessment carried out between BBCH 19-25 and 2 weeks after the last application for the autumn applications and around 5 weeks for the spring application.

On SCLESC and ALTEBA, only assessments where the pest incidence (PESINC) in the untreated reached at least 10% (according to the French Method CEB 220) of infected stems and pods were considered as valid. As well, on leaves only assessments where the area infected (PESSEV) in the untreated reached at least 10% were summarized.

Also, only assessments where the local reference standard reached a normal efficacy (>50% control on compared to untreated) were considered as valid. The assessments with data below either thresholds were not taken into account in the calculation of means. Considering that, no data on roots have been presented in this part.

For SCLESC, 1 valid assessment on stems, pods and leaves were selected and summarised in this part. These 3 selected assessments are the most representative according to the disease and oilseed rape development:

- Assessment on stems: assessment carried out between BBCH 67-85.
- Assessment on pods: assessment carried out between BBCH 79-83.
- Assessment on leaves: assessment carried out around 3-4 weeks after the treatment.

If in one trial, notably on stems, 2 valid assessments were carried out in the same interval, the valid assessment the most logical and nearest of the group name value is taken into account to calculate the mean across trials.

### 3.2.3.1.1 Efficacy trials results for the control of *Leptosphaeria maculans* in oilseed rape

A total of 8 valid efficacy trials were carried out to evaluate the efficacy of IN005B1570 250EC in the Central registration zone applied at 0.312-0.36-0.5 L/ha and 0.25 L/ha applied twice for the control of *Leptosphaeria maculans* on oilseed rape in comparison to the reference standard named DIFENO at 0.5 L/ha. The full list of these trials is presented in Table 3.2-8.

The summary results of the effect of IN005B1570 250EC applied at 0.5 L/ha compared to reference standard and the other rates are shown in Table 3.2-17.

**Table 3.2-17: Efficacy of IN005B1570 250EC against *Leptosphaeria maculans* on oilseed rape - Mean control**

Parts	EPPO climatic zone	No. of trials	Untreated control				Mean control (%)																				No. of assessments significantly <sup>(1)</sup> > , = , < IN005B1570 250EC			
							IN005B1570 0.312 L/ha [A]				IN005B1570 0.36 L/ha [A]				IN005B1570 0.5 L/ha [A]				IN005B1570 0.25 L/ha [AB]				DIFENO 0.5 L/ha [A]				at 0.5 L/ha vs. IN005B1570 250EC and		At 0.25 L/ha [AB] vs.	
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	At 0.312 L/ha [A]	At 0.36 L/ha[A]	DIFENO 0.5 L/ha	DIFENO 0.5 L/ha	
Disease severity on leaves - Autumn	Maritime	3	9.9	5.2	14.4	53.6	45.5	61.9	6.7	55.1	48.8	63.7	6.3	62.9	55.2	76.0	9.3	59.5	50.1	74.5	10.7	60.8	42.1	79.6	15.3	1> ; 2= ; 0<	1> ; 2= ; 0<	1> ; 2= ; 0<	1> ; 2= ; 0<	
	North-East	2	3.9	1.7	6.0	74.9	69.1	80.7	5.8	74.5	68.5	80.4	5.9	82.2	81.9	82.6	0.4	83.5	82.2	84.7	1.2	81.1	80.7	81.5	0.4	1> ; 1= ; 0<	1> ; 1= ; 0<	0> ; 2= ; 0<	0> ; 2= ; 0<	
	South-East	2	11.9	2.8	21.0	58.7	34.8	82.6	23.9	54.2	30.3	78.0	23.9	66.3	54.9	77.8	11.4	63.1	44.6	81.6	18.5	73.3	52.3	94.3	21.0	0> ; 2= ; 0<	0> ; 2= ; 0<	0> ; 1= ; 1<	0> ; 1= ; 1<	
	All zones	7	8.8	1.7	21.0	61.1	34.8	82.6	16.5	60.3	30.3	80.4	16.4	69.4	54.9	82.6	11.9	67.4	44.6	84.7	15.9	70.2	42.1	94.3	17.4	2> ; 5= ; 0<	2> ; 5= ; 0<	1> ; 5= ; 1<	1> ; 5= ; 1<	
Disease incidence on leaves- Autumn	Maritime	3	93.7	82.0	100.0	13.7	3.0	24.0	8.6	15.9	4.0	31.7	11.6	20.2	3.0	40.2	15.3	21.9	8.0	36.4	11.6	25.2	12.0	44.0	13.7	1> ; 2= ; 0<	0> ; 3= ; 0<	0> ; 3= ; 0<	0> ; 3= ; 0<	
	North-East	2	59.3	48.5	70.0	52.7	48.7	56.7	4.0	50.5	48.4	52.6	2.1	57.8	56.7	58.8	1.1	62.3	58.8	65.8	3.5	58.8	56.7	60.8	2.1	0> ; 2= ; 0<	0> ; 2= ; 0<	0> ; 2= ; 0<	0> ; 2= ; 0<	
	South-East	2	85.0	71.0	99.0	41.9	7.0	76.8	34.9	34.9	5.0	64.8	29.9	34.8	4.0	65.5	30.8	35.7	1.0	70.4	34.7	44.5	3.0	85.9	41.5	0> ; 2= ; 0<	0> ; 2= ; 0<	0> ; 1= ; 1<	0> ; 1= ; 1<	
	All zones	7	81.4	48.5	100.0	32.9	3.0	76.8	26.0	31.2	4.0	64.8	22.9	35.1	3.0	65.5	24.8	37.4	1.0	70.4	26.2	40.3	3.0	85.9	27.8	1> ; 6= ; 0<	0> ; 7= ; 0<	0> ; 6= ; 1<	0> ; 6= ; 1<	
Disease severity on leaves - Spring	North-East	1	11.0	-	-	67.7	-	-	-	70.3	-	-	-	78.2	-	-	-	-	-	-	-	78.2	-	-	-	1> ; 0= ; 0<	1> ; 0= ; 0<	0> ; 1= ; 0<	-	
Disease incidence on leaves- Spring	North-East	1	73.0	-	-	45.2	-	-	-	47.3	-	-	-	56.2	-	-	-	-	-	-	-	54.8	-	-	-	1> ; 0= ; 0<	1> ; 0= ; 0<	0> ; 1= ; 0<	-	

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

A total of 8 valid efficacy trials (3 trials in the Maritime, 3 trials in the North-East and 2 trials in South-East EPPO climatic zones) are available. IN005B1570 250EC applied once at 0.5 L/ha and twice at 0.25 L/ha was compared to DIFENO applied at 0.5 L/ha.

### **Efficacy results on leaves - Autumn application**

On leaves, a total of 7 trials were assessed and the infestation level reached around 9% of leaves infected in untreated control, ranged from 1.7% to 21%.

#### *Minimum effective dose results:*

In the Maritime EPPO climatic zone, on disease severity, IN005B1570 250EC applied at 0.5 L/ha showed a moderate control (63%) slightly higher than IN005B1570 250EC applied at 0.36 L/ha (55%, with a significant difference in 1 out of 3 trials) and IN005B1570 250EC applied at 0.312 L/ha (54%, with a significant difference in 1 out of 3 trials). On disease incidence, even if the level of efficacy was low due to a high infestation on the incidence, these results were confirmed (20% mean control at 0.5 L/ha vs. 14-16% mean control for the lower tested doses).

In the North-East EPPO climatic zone, on disease severity, IN005B1570 250EC applied at 0.5 L/ha showed a good control (82%) slightly higher than IN005B1570 250EC applied at 0.36 L/ha (75%, with a significant difference in 1 out of 2 trials) and IN005B1570 250EC applied at 0.312 L/ha (75%, with a significant difference in 1 out of 2 trials). On disease incidence, even if the level of efficacy was moderate, these results were confirmed (58% mean control at 0.5 L/ha vs. 51-53% mean control for the lower tested doses).

In the South-East EPPO climatic zone, on disease severity, IN005B1570 250EC applied at 0.5 L/ha showed a moderate control (66%) higher than IN005B1570 250EC applied at 0.36 L/ha (54%) and IN005B1570 250EC applied at 0.312 L/ha (59%). On disease incidence, even if the level of efficacy was low due to a high infestation on the incidence, these results were confirmed (35% mean control at 0.5 L/ha vs. 35-42% mean control for the lower tested doses).

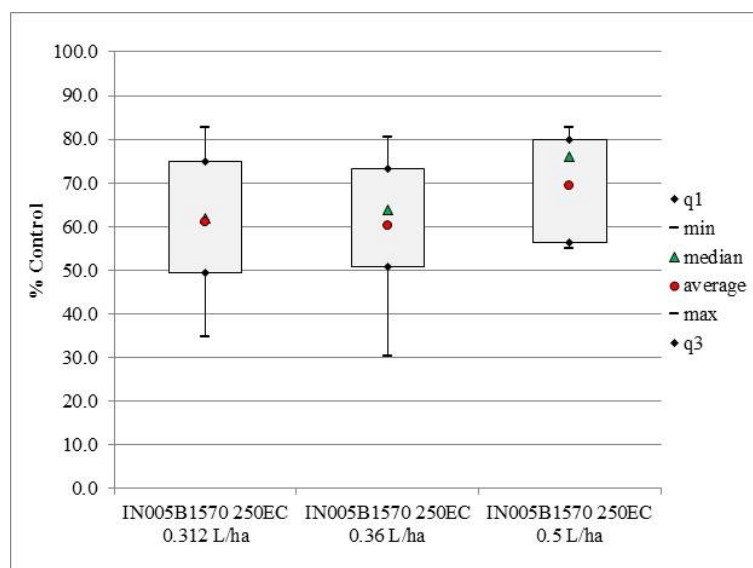
On all zones, similar trends were observed both on incidence and severity on 7 trials: on the severity, IN005B1570 250EC applied at 0.5 L/ha showed a moderate control (69%) slightly higher than IN005B1570 250EC applied at 0.36 L/ha (60%, with a significant difference in 1 out of 7 trials) and IN005B1570 250EC applied at 0.312 L/ha (61%, with a significant difference in 1 out of 7 trials) and on the incidence, these results were confirmed (35% mean control at 0.5 L/ha vs. 31-33% mean control for the lower tested doses with a significant difference in 1 out of 7 trials for the lowest tested dose).

These results demonstrated that an increased dose rate provides an increased control.

The difference between the dose rates of IN005B1570 250EC at 0.312, 0.36 and 0.5 L/ha can be illustrated by box plot graphic on the disease severity on leaves (Figure 3.2-4).

**Figure 3.2-4**

**Efficacy of IN005B1570 250EC at 0.312, 0.36 and 0.5 L/ha on leaves against *Leptosphaeria maculans* - Disease severity - All EPPO climatic zones - Box plot graphics (7 trials)**



*Efficacy results:*

In the Maritime EPPO climatic zone, on disease severity, IN005B1570 250EC applied at 0.5 L/ha and twice at 0.25 L/ha showed a similar control than the reference standard DIFENO (respectively 63% and 60 vs. 61% mean control). No significant difference was observed in 2 out of 3 trials between both rates of IN005B1570 250EC and the reference DIFENO. These results were confirmed on the disease incidence with 20% mean control for IN005B1570 250EC applied at 0.5 L/ha and 22% mean control for IN005B1570 250EC applied twice at 0.25 L/ha vs. 25% mean control for the reference standard DIFENO.

In the North-East EPPO climatic zone, on disease severity, IN005B1570 250EC applied at 0.5 L/ha and twice at 0.25 L/ha showed a similar control than the reference standard DIFENO (respectively 82% and 84 vs. 81% mean control). No significant difference was observed in both trials between both rates of IN005B1570 250EC and the reference DIFENO. These results were confirmed on the disease incidence with 58% mean control for IN005B1570 250EC applied at 0.5 L/ha and 62% mean control for IN005B1570 250EC applied twice at 0.25 L/ha vs. 59% mean control for the reference standard DIFENO.

In the South-East EPPO climatic zone, on disease severity, IN005B1570 250EC applied at 0.5 L/ha and twice at 0.25 L/ha showed a slightly lower control than the reference standard DIFENO (respectively 66% and 63 vs. 73% mean control). However, no significant difference was observed in 1 out of 2 trials between both rates of IN005B1570 250EC and the reference DIFENO. These results were confirmed on the disease incidence with 35% mean control for IN005B1570 250EC applied at 0.5 L/ha and 36% mean control for IN005B1570 250EC applied twice at 0.25 L/ha vs. 45% mean control for the reference standard DIFENO.

In all EPPO climatic zones, on disease severity, IN005B1570 250EC applied at 0.5 L/ha and twice at 0.25 L/ha showed a similar control than the reference standard DIFENO (respectively 69% and 67% vs. 70% mean control). No significant difference was observed in 5 out of 7 trials between both rates of IN005B1570 250EC and the reference DIFENO. These results were confirmed on the disease incidence with 35% mean control for IN005B1570 250EC applied at 0.5 L/ha and 37% mean control for IN005B1570 250EC applied twice at 0.25 L/ha vs. 40% mean control for the reference standard DIFENO.



### **Efficacy results on leaves - Spring application**

For information, 1 valid efficacy trial was assessed and the infestation level reached around 11% of leaves infected in untreated control.

- *Minimum effective dose results*

In the North-East EPPO climatic zone, on disease severity, IN005B1570 250EC applied at 0.5 L/ha showed a good control (78%) slightly higher than IN005B1570 250EC applied at 0.36 L/ha (70%) and IN005B1570 250EC applied at 0.312 L/ha (68%). This result was confirmed on disease incidence: IN005B1570 250EC applied at 0.5 L/ha showed a moderate control (56%) slightly higher than IN005B1570 250EC applied at 0.36 L/ha (47%) and IN005B1570 250EC applied at 0.312 L/ha (45%).

This result demonstrated that an increased dose rate provides an increased control.

- *Efficacy results*

In the North-East EPPO climatic zone, on disease severity, IN005B1570 250EC applied at 0.5 L/ha showed an equivalent control than the reference standard DIFENO (respectively 78% vs. 78% mean control). No significant difference was observed in the trial between IN005B1570 250EC applied at 0.5 L/ha and the reference DIFENO. This result was confirmed on disease incidence with 56% mean control for IN005B1570 250EC applied at 0.5 L/ha vs. 55% mean control for the reference standard DIFENO.

Thus, according to these results, IN005B1570 250EC applied at 0.5 L/ha showed a moderate to good control of *Leptosphaeria maculans* higher than the lower dose rates of IN005B1570 250EC applied at 0.312 L/ha and 0.36 L/ha and an equivalent control of *Leptosphaeria maculans* to the reference standard DIFENO and the split application at 0.25 L/ha. So, IN005B1570 250EC at 0.5 L/ha and applied twice at 0.25 L/ha perform as well as the standard DIFENO applied at the same rate.

**Therefore, by and large, with a moderate level of infestation, IN005B1570 250EC at 0.5 L/ha and applied twice at 0.25 L/ha showed an acceptable level of control on LEPTMA in the Central registration zone and was equivalent to the reference DIFENO. Therefore, a rate of 0.5 L/ha or 0.25 L/ha if 2 applications in autumn will be recommended on the product label for Austria, Belgium, Czech Republic, Ireland, Germany, The Netherlands, Poland and Slovenia.**

#### **3.2.3.1.2 Efficacy trials results for the control of *Sclerotinia sclerotiorum* in oilseed rape**

A total of 11 valid efficacy trials were carried out to evaluate the efficacy of IN005B1570 250EC in the Central registration zone applied at 0.312, 0.36 and 0.5 L/ha for the control of *Sclerotinia sclerotiorum* on oilseed rape in comparison to the reference standard named DIFENO at 0.5 L/ha. The full list of these trials is presented in Table 3.2-8.

The summary results of the effect of IN005B1570 250EC applied at 0.5 L/ha compared to reference standard and the other rates are shown in Table 3.2-18.

**Table 3.2-18: Efficacy of IN005B1570 250EC against *Sclerotinia sclerotiorum* on oilseed rape - Mean control**

Parts	EPPO climatic zone	No. of trials	Untreated control			Mean control (%)																No. of assessments significantly <sup>(1)</sup> > , = , < IN005B1570 250EC at 0.5 L/ha vs.		
						IN005B1570 0.312 L/ha				IN005B1570 0.36 L/ha				IN005B1570 0.5 L/ha				DIFENO 0.5 L/ha						
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	IN005B1570 0.312 L/ha	IN005B1570 0.36 L/ha	DIFENO 0.5 L/ha
Disease incidence on stems	Maritime	7	44.7	20.0	63.0	49.0	29.8	73.5	13.8	45.4	16.0	57.9	13.8	52.4	30.5	61.4	10.2	49.5	20.0	67.3	15.1	1> ; 6= ; 0<	1> ; 6= ; 0<	0> ; 7= ; 0<
	North-East	2	36.8	35.0	38.5	42.3	40.3	44.3	2.0	38.1	36.4	39.9	1.8	53.2	42.9	63.5	10.4	58.3	42.9	73.8	15.5	0> ; 2= ; 0<	0> ; 2= ; 0<	0> ; 2= ; 0<
	All zones	9	43.0	20.0	63.0	47.5	29.8	73.5	12.5	43.8	16.0	57.9	12.6	52.6	30.5	63.5	10.3	51.4	20.0	73.8	15.7	1> ; 8= ; 0<	1> ; 8= ; 0<	0> ; 9= ; 0<
Disease severity on stems	Maritime	7	22.7	7.4	37.3	55.2	29.8	77.2	16.4	52.3	21.2	79.7	17.9	59.2	34.7	79.3	12.9	55.6	23.7	76.9	17.0	1> ; 6= ; 0<	2> ; 5= ; 0<	0> ; 7= ; 0<
	North-East	2	28.4	21.9	34.8	50.7	45.9	55.4	4.8	49.3	41.9	56.7	7.4	64.6	63.8	65.4	0.8	66.5	59.4	73.7	7.2	0> ; 2= ; 0<	0> ; 2= ; 0<	0> ; 2= ; 0<
	All zones	9	24.0	7.4	37.3	54.2	29.8	77.2	14.8	51.7	21.2	79.7	16.2	60.4	34.7	79.3	11.6	58.0	23.7	76.9	16.0	1> ; 8= ; 0<	2> ; 7= ; 0<	0> ; 9= ; 0<
Disease incidence on pods	Maritime	2	16.0	10.0	22.0	51.7	45.8	57.5	5.8	47.1	40.0	54.2	7.1	63.3	60.0	66.7	3.3	48.1	37.9	58.3	10.2	0> ; 2= ; 0<	0> ; 2= ; 0<	0> ; 2= ; 0<
Disease severity on pods	Maritime	2	11.3	0.5	22.0	71.5	57.5	85.6	14.0	67.5	44.3	90.8	23.3	77.9	72.4	83.3	5.5	63.6	41.8	85.3	21.7	0> ; 2= ; 0<	0> ; 2= ; 0<	0> ; 2= ; 0<
Disease severity on leaves	North-East	1	15.5	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	0> ; 1= ; 0<
Disease incidence on leaves	North-East	1	30.0	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	0> ; 1= ; 0<

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

A total of 11 valid efficacy trials (8 trials in the Maritime and 3 trials in the North-East EPPO climatic zones) are available. IN005B1570 250EC applied at 0.5 L/ha was compared to DIFENO applied at 0.5 L/ha.

### **Efficacy results on stems**

On stems, a total of 9 trials were assessed and the infestation level reached around 43% of leaves infected in untreated control, ranged from 20% to 63%.

#### *Minimum effective dose results:*

In the Maritime EPPO climatic zone, on disease incidence, IN005B1570 250EC applied at 0.5 L/ha showed a moderate control (52%) slightly higher than IN005B1570 250EC applied at 0.36 L/ha (45%, with a significant difference in 1 out of 7 trials) and IN005B1570 250EC applied at 0.312 L/ha (49%, with a significant difference in 1 out of 7 trials). On disease severity, even if the level of efficacy was moderate due to a high infestation on the incidence, these results were confirmed (59% mean control at 0.5 L/ha vs. 52-55% mean control for the lower tested doses).

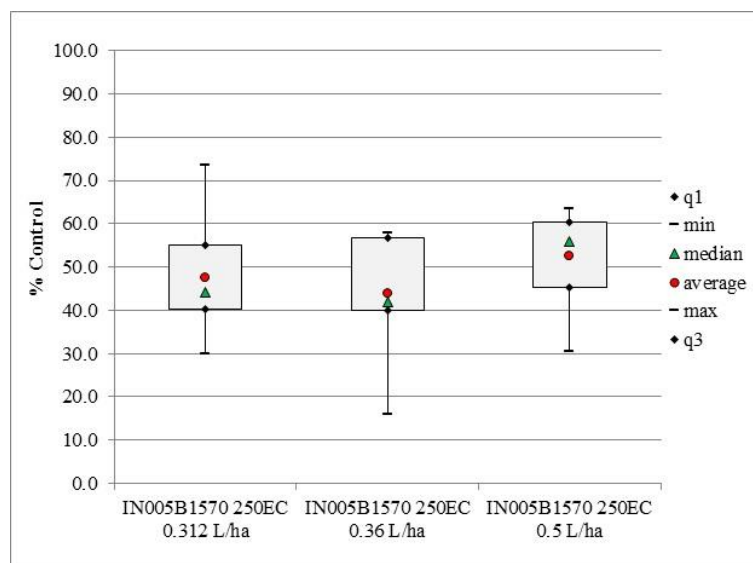
In the North-East EPPO climatic zone, on disease incidence, IN005B1570 250EC applied at 0.5 L/ha showed a moderate control (53%) slightly higher than IN005B1570 250EC applied at 0.36 L/ha (38%, with no significant difference in all trials) and IN005B1570 250EC applied at 0.312 L/ha (42%, with no significant difference in all trials). On disease severity, even if the level of efficacy was moderate, these results were confirmed (65% mean control at 0.5 L/ha vs. 49-51% mean control for the lower tested doses).

On all zones, similar trends were observed both on incidence and severity on 9 trials: on the incidence, IN005B1570 250EC applied at 0.5 L/ha showed a moderate control (53%) slightly higher than IN005B1570 250EC applied at 0.36 L/ha (44%, with a significant difference in 1 out of 9 trials) and IN005B1570 250EC applied at 0.312 L/ha (48%, with a significant difference in 1 out of 9 trials) and on the severity, these results were confirmed (60% mean control at 0.5 L/ha vs. 52-54% mean control for the lower tested doses with a significant difference in 1 out of 9 trials for IN005B1570 250EC applied at 0.312 L/ha and in 2 out of 9 trials for IN005B1570 250EC applied at 0.36 L/ha).

These results demonstrated that an increased dose rate provides an increased control.

The difference between the dose rates of IN005B1570 250EC at 0.312, 0.36 and 0.5 L/ha can be illustrated by box plot graphic on the disease incidence on stems (Figure 3.2-5).

**Figure 3.2-5 Efficacy of IN005B1570 250EC at 0.312, 0.36 and 0.5 L/ha on stems against *Sclerotinia sclerotiorum* - Disease incidence - All EPPO climatic zones - Box plot graphics (9 trials)**



*Efficacy results:*

In the Maritime EPPO climatic zone, on disease incidence, IN005B1570 250EC applied at 0.5 L/ha showed a similar control than the reference standard DIFENO (respectively 52% vs. 50% mean control). No significant difference was observed in all trials between IN005B1570 250EC applied at 0.5 L/ha and the reference DIFENO. These results were confirmed on the disease severity with 59% mean control for IN005B1570 250EC applied at 0.5 L/ha vs. 56% mean control for the reference standard DIFENO.

In the North-East EPPO climatic zone, on disease incidence, IN005B1570 250EC applied at 0.5 L/ha showed a slightly lower control than the reference standard DIFENO (respectively 53% vs. 58% mean control) but no significant difference was observed in all trials between IN005B1570 250EC applied at 0.5 L/ha and the reference DIFENO. These results were confirmed on the disease severity with 65% mean control for IN005B1570 250EC applied at 0.5 L/ha vs. 67% mean control for the reference standard DIFENO.

In all EPPO climatic zones, on the disease incidence, IN005B1570 250EC applied at 0.5 L/ha showed a similar control than the reference standard DIFENO (respectively 53% vs. 51% mean control). No significant difference was observed in all trials between IN005B1570 250EC applied at 0.5 L/ha and the reference DIFENO. These results were confirmed on the disease severity with 60% mean control for IN005B1570 250EC applied at 0.5 L/ha vs. 58% mean control for the reference standard DIFENO.

**Efficacy results on pods**

A total of 2 trials were assessed and the infestation level reached around 16% of pods infected in untreated control, ranged from 10% to 22%.

- *Minimum effective dose results*

In the Maritime EPPO climatic zone, on disease incidence, even if no significant difference was observed between all trials, IN005B1570 250EC applied at 0.5 L/ha showed a moderate control (63%) slightly higher than IN005B1570 250EC applied at 0.36 L/ha (47%) and IN005B1570 250EC applied at 0.312 L/ha (52%). These results were confirmed on disease severity: IN005B1570 250EC applied at 0.5 L/ha showed a good control (81%) a slightly higher than IN005B1570 250EC applied at 0.36 L/ha (77%) and IN005B1570 250EC applied at 0.312 L/ha (76%).

These results demonstrated that an increased dose rate provides an increased control.

- *Efficacy results*

In the Maritime EPPO climatic zone, on disease incidence, IN005B1570 250EC applied at 0.5 L/ha showed a higher control than the reference standard DIFENO (respectively 63% vs. 48% mean control). No significant difference was observed in all trials between IN005B1570 250EC applied at 0.5 L/ha and the reference DIFENO. These results were confirmed on disease severity with 78% mean control for IN005B1570 250EC applied at 0.5 L/ha vs. 64% mean control for the reference standard DIFENO.

**Efficacy results on leaves**

For information, a total of 1 trial was assessed and the level of disease reached 16% leaves area infected in untreated control.

In the North-East EPPO climatic zone, on disease severity, IN005B1570 250EC applied at 0.5 L/ha showed a similar control than the reference standard DIFENO (respectively 100% vs. 100% mean control). No significant difference was observed in the trial between IN005B1570 250EC applied at 0.5 L/ha and the reference DIFENO. These results were also confirmed on disease incidence.

Thus, according to these results, IN005B1570 250EC applied at 0.5 L/ha showed a moderate to good control of *Sclerotinia sclerotiorum* higher than the lower dose rates of IN005B1570 250EC applied at 0.312 L/ha and 0.36 L/ha and an equivalent control of *Sclerotinia sclerotiorum* to the reference standard DIFENO. So, IN005B1570 250EC performs as well as the standard DIFENO applied at the same rate.

**Therefore, by and large, with a good level of infestation, IN005B1570 250EC applied at 0.5 L/ha showed an acceptable level of control on SCLESC in the Central registration zone and was equivalent to the reference DIFENO. Therefore, a rate of 0.5 L/ha will be recommended on the product label for Austria, Belgium, Czech Republic, Ireland, Germany, The Netherlands, Poland and Slovenia.**

**3.2.3.1.3 Efficacy trials results for the control of *Alternaria brassicae* in oilseed rape**

For information, 2 trials performed in Maritime EPPO climatic zone in 2020 are provided as supportive data to evaluate the efficacy of IN005B1570 250EC at 0.5 L/ha for the control of *Alternaria brassicae* in oilseed rape in comparison to the reference standard DIFENO at 0.5 L/ha. Applications were performed at different timing:

- In 1 trial, with 2 applications A and B performed at BBCH 16 and 18 (Autumn application);
- In 1 trial, with 1 application performed at BBCH 65 (Spring application).

On pods, one valid assessment was available per trial and performed at BBCH 83 for the control of *Alternaria brassicae* in oilseed rape. These supportive data are shown in Table 3.2-19.

**Table 3.2-19: Efficacy of IN005B1570 250EC against *Alternaria brassicae* on oilseed rape on pods - Efficacy trial - Maritime EPPO climatic zone**

Parts	Number of trials	Days after appli.	Crop stage at assess.	Untreated check		IN005B1570 0.312 L/ha [A]			IN005B1570 0.36 L/ha [A]			IN005B1570 0.5 L/ha [A]			IN005B1570 0.25 L/ha [AB]			DIFENO 0.5 L/ha [A]			Local reference			Reference description
				Raw data	Stat	Raw data	Stat	% Cont.	Raw data	Stat	% Cont.	Raw data	Stat	% Cont.	Raw data	Stat	% Cont.	Raw data	Stat	% Cont.	Raw data	Stat	% Cont.	
Disease incidence on pods <b>Autumn application</b>	1 trial	259 DA-A	83	85.3	a	71.8	a	15.8	59.3	a	30.5	64.0	a	25.0	66.5	a	22.0	63.3	a	25.8	65.8	a	22.9	Metco EC 0.9 L/ha
Disease severity on pods <b>Autumn application</b>	1 trial	259 DA-A	83	29.9	a	13.5	a	48.4	9.1	a	57.5	11.2	a	47.6	10.4	a	55.0	10.0	a	54.4	11.1	a	51.1	Metco EC 0.9 L/ha
Disease incidence on pods <b>Spring application</b>	1 trial	52 DA-A	83	88.5	a	36.5	b	58.8	38.5	b	56.5	30.5	b	65.5	-	-	-	63.3	a	25.8	40.5	b	54.2	Prothio 250EC 0.7 L/ha
Disease severity on pods <b>Spring application</b>	1 trial	52 DA-A	83	4.3	a	0.7	b	73.9	0.8	b	77.8	0.5	b	82.9	-	-	-	0.7	b	81.6	0.8	b	78.5	Prothio 250EC 0.7 L/ha

Stat: Student-Newman-Keuls test at 5% - % Control: Mean control (% efficacy).

On disease severity, IN005B1570 250EC applied at 0.5 L/ha showed a moderate to good control and equivalent to the reference standard DIFENO (respectively 48% vs. 54% mean control at autumn application and 83% vs. 82% mean control at spring application).

Thus, according to this results, under a good infestation level, IN005B1570 250EC at 0.5 L/ha achieved an acceptable control of *Alternaria brassicae* on oilseed rape on pod and performed as well as the standard DIFENO applied at the same rate.

Overall, very few data from field on oilseed rape are available (2 trials) for this disease for which proposed label claims are made for control with IN005B1570 250EC at 0.5 L/ha. However, other data (5 trials) are available from trials conducted on brassicas crops included in the section 3.2.3.3.3. It is asserted that these data provides additional information and assurance that IN005B1570 250EC SC will work on this disease as well as it does on other host crops of alternaria for which data have been presented.

**Therefore, and with regard to the results in oilseed rape presented in this dossier and the knowledge of difenoconazole - which is already registered at the same dose rate and in use in oilseed rape - the registration of IN005B1570 250EC at 0.5 L/ha in oilseed rape to control ALTEBI is recommended on the product label for Austria, Belgium, Czech Republic, Ireland, Germany, The Netherlands, Poland and Slovenia.**

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

A total of 6 efficacy trials were harvested in 2021 in the Maritime (1 trial in Czech republic, 1 trial in Germany and 1 trial in United Kingdom), in the North-East (2 trials in Poland) and in the South-East (1 trial in Romania) EPPOclimatic zones. The objective was to confirm the yield response of IN005B1570 250EC in the presence of fungi diseases in oilseed rape crop.

Table 3.2-20 shows a summary of positive effect on the yield of IN005B1570 250EC applied at 0.4 and 0.5 L/ha compared to the reference standard DIFENO.



**Table 3.2-20: Positive effect on the yield of IN005B1570 250EC - Comparison with the reference standard - Efficacy trials - Oilseed rape**

Target	EPPO climatic zone	No. of trials	Untreated control			Mean control (%)								No. of assessments significantly <sup>(1)</sup> > , = , < IN005B1570 250EC at 0.5 L/ha vs.
						IN005B1570 250EC 0.5 L/ha				DIFENO 0.5 L/ha				
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	DIFENO 0.5 L/ha
SCLESC	Maritime zone	3	4.1	3.3	5.2	104.4	101.2	109.8	3.9	103.7	99.6	107.7	3.3	0> ; 3= ; 0<
	North-East zone	2	3.5	3.3	3.6	102.6	98.8	106.4	3.8	102.5	99.4	105.5	3.1	0> ; 2= ; 0<
	Mar.&North-East zones	5	3.8	3.3	5.2	103.7	98.8	109.8	3.9	103.2	99.4	107.7	3.3	0> ; 5= ; 0<
CYLSSP	South-East zone	1	3.2	-	-	104.4	-	-	-	108.2	-	-	-	0> ; 1= ; 0<
All diseases	All zones	6	3.7	3.2	5.2	103.8	98.8	109.8	3.6	104.0	99.4	108.2	3.5	0> ; 6= ; 0<

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

In all EPPO climatic zones, the average yield reached 3.7 t/ha in the untreated plot (ranging from 3.2 t/ha to 5.2 t/ha in the individual trials).

In the Maritime EPPO climatic zone, IN005B1570 250EC at 0.5 L/ha had a positive effect on the yield of oilseed rape in the presence of SCLESC. In fact, there was an 4 % increase in yield over the untreated. Overall, no significant difference was observed between IN005B1570 250EC and the reference standards DIFENO. As well, in the North-East EPPO climatic zone, IN005B1570 250EC at 0.5 L/ha had a positive effect on the yield of oilseed rape in the presence of SCLESC (3% increase in yield over the untreated). In both EPPO climatic zones, IN005B1570 250EC at 0.5 L/ha had a positive effect on the yield and no no significant difference was observed between IN005B1570 250EC and the reference standards DIFENO.

In all EPPO climatic zones, IN005B1570 250EC at 0.5 L/ha had a positive effect on the yield of oilseed rape in the presence of diseases. In fact, there was an 4 % increase in yield over the untreated, a similar increase than the reference standard DIFENO.

### 3.2.3.1.5 Conclusion on oilseed rape

A total of 17 valid efficacy trials conducted in the Maritime, North-East and South-East EPPO climatic zones (Czech Republic, France, Germany, The Netherlands, Poland, Romania and The United Kingdom) evaluated the efficacy of IN005B1570 250EC at 0.5 L/ha and applied twice at 0.25 L/ha against *Leptosphaeria maculans*, *Sclerotinia sclerotiorum* and *Alternaria brassicae* in oilseed rape.

In summary, the large set of data submitted on oilseed rape, showing a consistent control of *Leptosphaeria maculans*, *Sclerotinia sclerotiorum* and *Alternaria brassicae*, can fully support the requested dose rates for IN005B1570 250EC. Moreover, data demonstrated that the efficacy provided by IN005B1570 250EC at the different proposed rates was overall comparable to the efficacy provided by the reference products DIFENO.

Table 3.2-21 below summarises the results from the efficacy trials.

**Table 3.2-21: Overall summary of efficacy of IN005B1570 250EC on oilseed rape in Central registration zone**

Pathogen / Crop	Pest species (EPPO code)	Part ass.	Nb of trials	Efficacy (%) in Oilseed rape of			No. of assessments significantly <sup>(1)</sup> > , = , < DIFENO at 0.5 L/ha vs.	
				IN005B1570 250EC at		DIFENO at	IN005B1570 250EC	
				0.25 L/ha [AB]	0.5 L/ha [A]	0.5 L/ha [A]	At 0.25 L/ha [AB]	At 0.5 L/ha [A]
Stem canker <i>Leptosphaeria maculans</i>	LEPTMA / BRSNW	Disease severity on leaves <b>Autumn</b>	7	67.4	69.4	70.2	1> ; 5= ; 1<	1> ; 5= ; 1<
		Disease incidence on leaves <b>Autumn</b>	7	37.4	35.1	40.3	0> ; 6= ; 1<	0> ; 6= ; 1<
		Disease severity on leaves - <b>Spring</b>	1	-	78.2	78.2	-	0> ; 1= ; 0<
		Disease incidence on leaves <b>Spring</b>	1	-	56.2	54.8	-	0> ; 1= ; 0<
Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i>	SCLECS / BRSNW	Disease incidence on stems	9	-	52.6	51.4	-	0> ; 9= ; 0<
		Disease severity on stems	9	-	60.4	58.0	-	0> ; 9= ; 0<
		Disease incidence on pods	2	-	63.3	48.1	-	0> ; 2= ; 0<
		Disease severity on pods	2	-	77.9	63.6	-	0> ; 2= ; 0<
		Disease severity on leaves	1	-	100.0	100.0	-	0> ; 1= ; 0<

		Disease incidence on leaves	1	-	100.0	100.0	-	0> ; 1= ; 0<
Black spot of rape <i>Alternaria brassicae</i>	ALTEBI / BRSNW	Disease incidence on pods <b>Autumn</b>	1	22.0	25.0	25.8	0> ; 1= ; 0<	0> ; 1= ; 0<
		Disease severity on pods <b>Autumn</b>	1	55.0	47.6	54.4	0> ; 1= ; 0<	0> ; 1= ; 0<
		Disease incidence on pods <b>Spring</b>	1	-	65.5	25.8	-	1> ; 0= ; 0<
		Disease severity on pods <b>Spring</b>	1	-	82.9	81.6	-	0> ; 1= ; 0<

### 3.2.3.2 Efficacy trials in pome fruit

#### Justification for approval of multiple applications of IN005B1570 250EC for the control of *Venturia inaequalis* in apple

The data within this section demonstrates the efficacy of IN005B1570 250EC for the control of *Venturia inaequalis* on apple applied as multiple sequential applications. Although the GAP claims a maximum of 3 applications per crop per season, the regulatory advice in most test countries is to apply multiple applications based on the recommended GAP interval between treatments in order to demonstrate efficacy of the product, *Venturia inaequalis* pressure may be season long. Repeated applications will ensure that efficacy can be demonstrated on at least one of the actively damaging cycles per season and has the advantage over programmes consisting of other products in respect of demonstrating only the efficacy of the active ingredient under test.

Therefore, the justification for use of multiple applications of IN005B1570 250EC is that infection pressure continues through the growing season, with the most critical period for epidemic disease development coinciding with rapid vegetative growth of pome fruit trees. IN005B1570 250EC is a preventative and curative fungicide with a period of protection of 7-10 days based on diseases and conditions. Therefore, to cover the *Venturia inaequalis* infection period during the growing season, multiple applications are required. However, due to resistance management requirements, it is deemed that the maximum number of applications of IN005B1570 250EC per season should not be more than 3.

A total of 10 valid efficacy trials were carried out in 2020 and 2021 + 2 additional efficacy trials from 2022 + 4 additional trials from 2023 to justify the interest of IN005B1570 250EC applied from 0.10 L/ha to 0.225 L/ha for the control of *Venturia inaequalis* in apple. All trials were carried out in Maritime EPPO climatic zone in France (2 trials) and Germany (3 trials) and North-East EPPO climatic zone in Poland (5 + 2 + 4 trials). In three trials, insufficient disease developed, so their efficacy data is not discussed further, but is included to the discussion of crop selectivity in Section 3.4 “Adverse effects on treated crops (KCP 6.4)”.

Additional data package has been added to the section to demonstrate efficacy of IN005B1570 250EC for the control of *Venturia inaequalis* on apple accordingly to the GAP presented in **Błąd! Nie można odnaleźć źródła odwołania..** The results obtained from this additional trials support the claim of effectiveness of the IN005B1570 250EC when applied maximum 3 times per season accordingly to the GAP and resistance management requirements.

This addition consists of 4 efficacy trials that were carried out in 2023 to justify efficacy of IN005B1570 250EC applied from 0.10 L/ha to 0.225 L/ha for the control of *Venturia inaequalis* in apple. All trials were carried out in North-East EPPO climatic zone in Poland (4 trials).

### 3.2.3.2.1 Material and Methods

#### Experimental details

All the trials presented in Table 3.2-9 were carried out by officially recognised organisations in accordance with the Principles of Good Experimental Practice (GEP). These trials were performed following EPPO guidelines or trial method recommendations published by the CEB (“Commission des Essais Biologiques”). The “CEB” methods are in accordance with EPPO directives.

Main characteristics are summarised in Table 3.2-22.

**Table 3.2-22: Details on trial methodology - Efficacy trials - Pome fruits**

Guidelines	General guidelines	PP1/135(4): “Phytotoxicity assessment”. PP1/152(4): “Design and analysis of efficacy evaluation trials”. PP1/181(4): “Conduct and reporting of efficacy evaluation trials, including good experimental practice”.	
	Specific guidelines	PP1/5(3): “Efficacy evaluation of fungicides - <i>Venturia inaequalis</i> and <i>V. pyrina</i> ”.	
Experimental design	Plot design	Randomized Complete Block (RCB) - Included untreated (13 trials).	
	Plot size	Plot area: from 11 to 40 m²	
	Number of replications	4 replicates.	
Crop	Number of trials	Valid efficacy trials : 16 trials. Not valid efficacy trials : 3 trials.	
	Varieties	Apple (MABSD): <i>Boskoop</i> (1), <i>Cox Orange</i> (1), <i>Elstar</i> (2), <i>Gala</i> (2), <i>Golden</i> (1), <i>Golden Delicious</i> (3), <i>Idared</i> (1), <i>Jonagold</i> (2), <i>Melrose</i> (1), <i>Najdared</i> (1), <i>Red Jonaprince</i> (1), <i>Sunrise</i> (1), <i>Szampion</i> (2).	
Application	Application timing	Apple (MABSD): Between BBCH 19-81 (From March to August) with an interval between application of 3-19 days.	
	Number of applications	Apple (MABSD): 10 applications: 9 trials with intervals of 6-19 days 11 applications: 3 trial with intervals of 7-10 days 12 applications: 1 trial with intervals of 4-16 days 14 applications: 1 trial with intervals of 3-14 days 16 applications: 1 trial with intervals of 7-11 days 3 applications: 4 trials with intervals of 5-9 days	
		Spray volumes	Foliar spraying: 300 - 1000 L/ha.
		Assessment	Assessment types
Assessment date			From first symptoms and according to disease evolution.
Results & Analysis		Statistical analysis	ANOVA - Newman - Keuls test (5%).

In 3 trials carried out in the Maritime EPPO climatic zone, the disease infestation was too low. These trials without disease are considered as not valid for efficacy part but are used to justify the selectivity and quality parameters on russetting in Section 3.4 “Adverse effects on treated crops (KCP 6.4)”.

In 2 trials, a short and long spray interval of 3 to 19 days were performed because important and long period of rainfall occurred on the trials sites.

#### Dose expression in trials

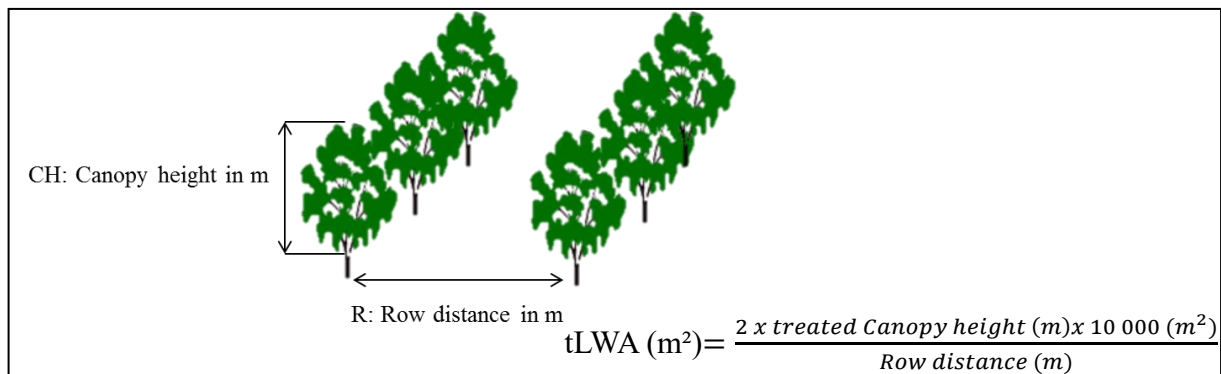
According to the protocols, the products were applied according to 3 different doses expression in efficacy trials:

- Ground area (L/ha)
- Dose Leaf Wall Height (L/h/ha/1m of CH)
- Leaf wall area (L/10 000 m<sup>2</sup> LWA = L/ha LWA)

In this dossier, for the control of apple scab, the rate expression chosen is the ground area (L/ha) for all countries. However, the LWA is a rate expression more and more agreed by the countries to reach an harmonisation of dose expression between European countries.

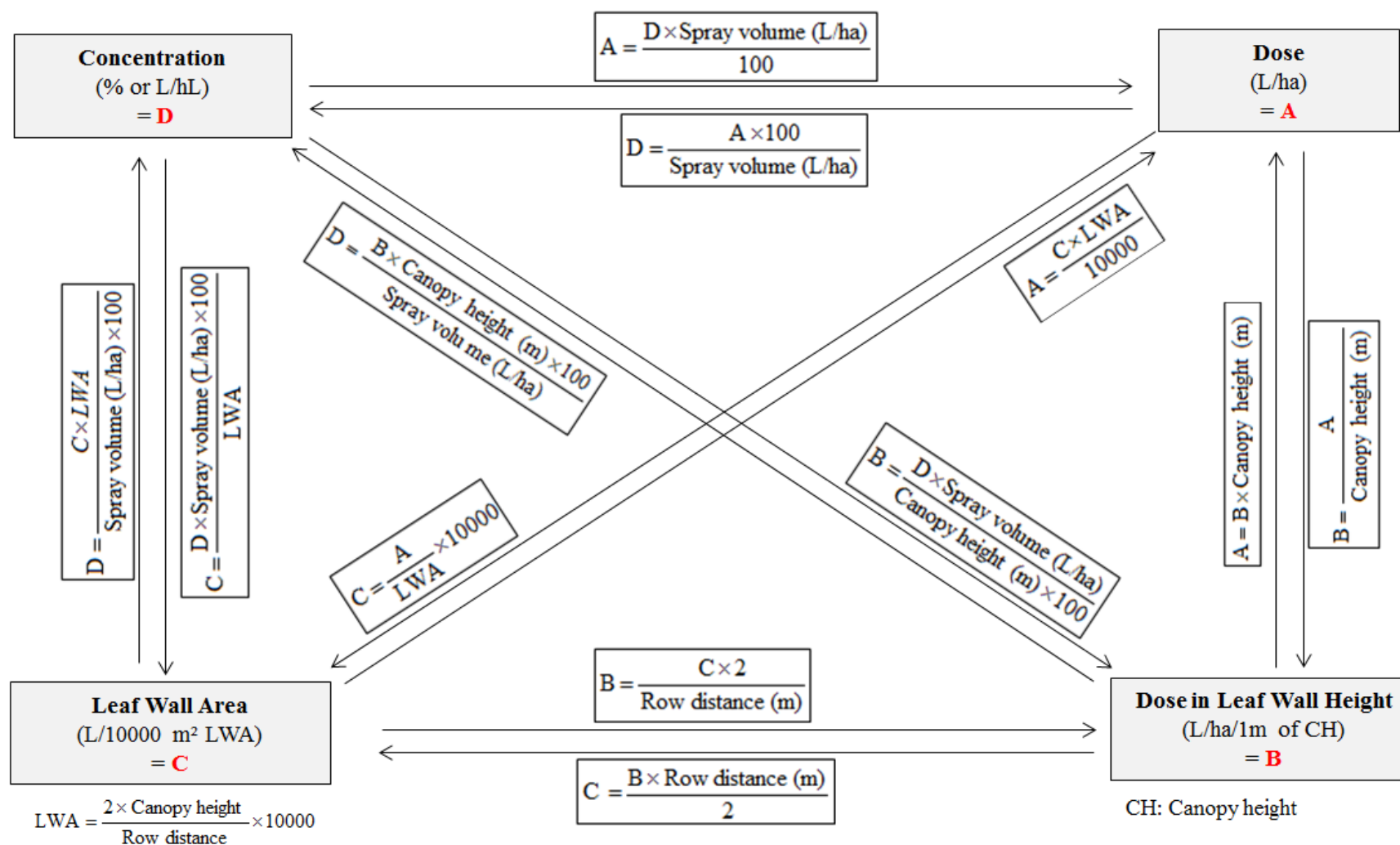
The following Figure 3.2-6 and Figure 3.2-7 present the calculation formulas of the treated Leaf Wall Area (tLWA) and conversion between the different expression rates.

**Figure 3.2-6 Formula of the tLWA (treated Leaf Wall Area)**



In this dossier the tLWA is expressed in m².

**Figure 3.2-7 Conversion formulas between the different expression rates of application**



In order to allow each country to visualize the rates, Table 3.2-23 below present the rates of the products used in the efficacy trials according to the various rate expressions.

In all protocols for apple scab, different dose rates in L/10 000 m<sup>2</sup> LWA (L/ha LWA) were included in the protocols to be used uniformly in all the trials, but it is not presented in this dossier because it does not fit with the final GAP. However, from the different dose rates available in the protocols, a dose in LWA expression was calculated in order to obtain the nearest dose rate requested in the GAP (0.15 L/ha LWA). The conversion tables below allowed to determine a dose range:

- The most logical and nearest value was selected across the treatments in L/ha.

This calculated dose rate is presented in the efficacy tables hereafter.

In this way, the rate expression in L/ha LWA is also used and proposed in the efficacy tables in this dossier. Indeed, this rate is the rate expression mainly used currently in the countries on the respective registered labels.

**Table 3.2-23: IN005B1570 250EC rates used in efficacy trials according to various rate expression - VENTIN**

Trial	Selected Appli.	Appli.	Orchard parameters				IN005B1570 0.1 L/ha	IN005B1570 0.15 L/ha	IN005B1570 0.2 L/ha	IN005B1570 0.225 L/ha	IN005B1570 calc.[0.113-0.168] L/ha LWA
			Treated foliage height (m)	Row distance (m)	Spray volume L/ha	tLWA m² of orchard	L/ha LWA	L/ha LWA	L/ha LWA	L/ha LWA	
FEU-AGR-004-20-SCAP-FR001	X	K	1.7	3.6	600	9444	0.106	<b>0.159</b>	-	0.238	<b>0.159</b>
FEU-AGR-001-21-SCAP1-FR06	X	J	2	4	600	10000	0.1	<b>0.15</b>	-	0.225	<b>0.15</b>
FEU-AGR-001-21-SCAP-DE01	X	J	2.1	3.5	1000	12000	0.083	<b>0.125</b>	-	0.188	<b>0.125</b>
FEU-AGR-001-21-SCAP-DE04	X	N	2.5	3.4	600	14706	0.068	0.102	-	<b>0.153</b>	<b>0.153</b>
FEU-AGR-001-21-SCAP1-DE05	X	J	2	2	1000	20000	0.05	0.075	-	<b>0.113</b>	<b>0.113</b>
FEU-AGR-001-21-SCAP2-PL08	X	P	2.5	3.7	1000	13514	0.074	0.111	<b>0.148</b>	-	<b>0.148</b>
FEU-AGR-001-21-SCAP2-PL09	X	J	2.1	3.5	750	12000	0.083	0.125	<b>0.167</b>	-	<b>0.167</b>
FEU-AGR-001-21-SCAP2-PL10	X	J	1.7	3.8	700	8947	0.112	<b>0.168</b>	0.224	-	<b>0.168</b>
FEU-AGR-001-21-SCAP2-PL11	X	J	2.6	3.5	1000	14857	0.067	0.101	<b>0.135</b>	-	<b>0.135</b>
FEU-AGR-001-21-SCAP2-PL12	X	J	2.5	4	500	12500	0.08	0.12	<b>0.16</b>	-	<b>0.16</b>
7333.F.SAG22	X	K	2.3	4	1000	11500	-	-	<b>0.174</b>	-	<b>0.174</b>
7334.F.SAG22	X	K	2.3	3.8	1000	12105	-	-	<b>0.165</b>	-	<b>0.165</b>
003GPSE202301	X	C	2.4	4	700	12000	0.08	0.125	<b>0.167</b>	0.188	<b>0.167</b>
003GPSE202302	X	C	2.4	3.5	750	13714	0.07	0.109	0.145	<b>0.164</b>	<b>0.164</b>
003GPSE202303	X	C	2.5	3.4	800	14706	0.07	0.102	0.136	<b>0.153</b>	<b>0.153</b>
003GPSE202304	X	C	2.5	3.2	800	15625	0.06	0.096	0.128	<b>0.144</b>	<b>0.144</b>

X= Selected application according to the selected assessment. - NS = Not selected.



## Treatments and reference standards

In all efficacy trials, the efficacy of IN005B1570 250EC applied at different dose rates was compared to the reference standard GEYSER or SCORE (Table 3.2-11). These rates reflect 44%, 67% and 89% (0.225 L/ha is the maximum dose of IN005B1570 250EC requested) in accordance with the EPPO guideline PP 1/225(1) “*Minimum effective rate*”.

Table 3.2-24 below presents the plant protection products and the rates used in this part.

**Table 3.2-24: Plant protection products used in efficacy trials - VENTIN**

Product name	Active substance(s)	Formulation		Application dose in trials (per treatment)	Country	Rate of active substance per ha	Remark
		Type <sup>[1]</sup>	Concentration of a.s.				
IN005B1570 250EC	Difenoconazole	EC	250 g/L	0.10 L/ha 0.15 L/ha 0.20 L/ha 0.225 L/ha		25.0 g a.s./ha 37.5 g a.s./ha 50.0 g a.s./ha 56.25 g a.s./ha	-
GEYSER / SCORE*	Difenoconazole	EC	250 g/L	0.15 L/ha	DE** - FR	37.5 g a.s./ha	Named <b>DIFENO</b> in this dRR
				0.20 L/ha	PL	50.0 g a.s./ha	

<sup>[1]</sup> EC: Emulsionate Concentrate

\* Geyser and Score are the trade names used in the different countries for the same Difenoconazole 250 g/L EC product registered by Syngenta

\*\*At 0.15 L/ha, according to the conversion formulas, the converted rate reaches as maximum 0.075 L/ha/1m of CH (registered rate).

The two tested dose rates 0.15 and 0.2 L/ha of the reference standard DIFENO were tested in two different protocols. In order to have a maximum of merging data, these two rates were gathered together and compared to the same rates of active substance of IN005B1570 250EC in the efficacy part.

## Assessment methods

### Venturia inaequalis (Scab):

In all trials, efficacy was assessed according to EPPO guidelines PP 1/5(3) *Venturia inaequalis* and *V. pirina*.

Concerning *Venturia inaequalis*, the disease progression was evaluated as percent incidence and percent severity on leaves per plot after each significant expression of spotting symptoms (percentage and area of infected leaves) and on fruits from the fifth application until the harvest. Infected fruits were ranked according to a scale:

- Class 1= no attack
- Class 2= 1-3 spots per fruit
- Class 3=> 3 spots per fruit.

The data regarding disease severity on fruits were processed according to the Townsend-Heuberger formula to calculate the percentage of infection (P%):

$$P\% = \frac{\sum n*(v-1)}{(V_{max}-1)*N} * 100$$

where P% = percentage of infection; n = number of leaves in each class; v = class value; Vmax = highest class value; N = total amount of assessed leaves.

Sample size was carried out in accordance with EPPO recommendations using at least 200 leaves per plot or all leaves of 20 elongating shoots (excluding the tip, young leaves of the shoot) and a minimum of 100 fruits per plot (from central part of the tree top, all around the tree).

Assessments of efficacy were made at regular interval to monitor the disease development.

In all efficacy trials, efficacy was calculated according to Abbott's formula.

### **Phytotoxicity assessments**

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

### **Statistical analyses**

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

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

### **Quality parameters**

Assessments were carried out on russetting for susceptible varieties on 100 fruits at harvest according to a scale : Class 1 "No russet" - Class 2 "Minor russet" and Class 3 "High russet".

### **Results layout**

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

#### *Venturia inaequalis* (Scab):

Only assessments where pest incidence in the untreated reached at least 20% incidence on leaves and 10% incidence on fruits was summarised. Only the more pertinent assessment by trial was summarised according to the disease and pome fruit development.

For VENTIN, 1 valid assessment on leaves and 2 valid assessments on fruits were selected and summarised in this part. These 3 selected assessments are the most representative according to the disease and pome fruit development:

- Assessment on leaves: assessment carried out between BBCH 71-79.
- Assessment on fruits: the first valid assessment carried out between BBCH 72-79.
- Assessment on fruits: the last valid assessment before harvest.

If in one trial, notably on fruits, 2 valid assessments were carried out in the same interval, the valid assessment, the most logical and nearest of the group name value is taken into account to calculate the mean across trials.

### **3.2.3.2.2 Efficacy trials results for the control of *Venturia inaequalis* in apples**

#### **A. Minimum effective dose results for the control of *Venturia inaequalis* in apples**

A total of 13 valid efficacy trials in apple were carried in 2020 and 2021 to evaluate the minimum effective dose of IN005B1570 250EC applied at 0.10, 0.15, 0.2 and 0.225 L/ha for the control of *Venturia inaequalis* on apple fruit in comparison to the reference standard DIFENO at 0.15 and 0.2 L/ha.

However, in three trials, insufficient disease developed, so there is no efficacy data presented in this section.

Additional 4 efficacy trials in apple were carried in 2023 to evaluate the minimum effective dose of IN005B1570 250EC applied at 0.10, 0.15, 0.2 and 0.225 L/ha for the control of *Venturia inaequalis* on apple fruit in comparison to the reference standard DIFENO at 0.15 and 0.2 L/ha.

The full list of these trials is presented in Table 3.2-9.

The summary results of the dose response are shown in Table 3.2-25.

**Table 3.2-25: Minimum effective dose of IN005B1570 250EC against *Venturia inaequalis* on apple - Mean control**

Parts	EPPO climatic zone	Target	No. of trials	Untreated control			Mean control (%)																No. of assessments significantly <sup>(1)</sup> > , = , < IN005B1570 at 0.20 or 0.225 L/ha vs.	
							IN005B1570 0.10 L/ha				IN005B1570 0.15 L/ha				IN005B1570 0.20 L/ha				IN005B1570 0.225 L/ha					
				Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	0.10 L/ha	0.15 L/ha
Disease incidence on leaves	Maritime	VENTIN	4	77.7	50.3	95.1	53	41.1	66.9	9.4	66	47.5	76.6	11.4	-	-	-	-	75.5	63.3	82.6	7.3	3> ; 1= ; 0<	1> ; 3= ; 0<
	North-East	VENTIN	9	44.5	6.8	96	58.1	26.6	85.4	24.3	67.5	31.1	94.7	24.9	75	37.1	98	22	-	-	-	-	4> ; 5= ; 0<	3> ; 6= ; 0<
	All zones	VENTIN	13	54.7	6.8	96	56.5	26.6	85.4	20.7	67	31.1	94.7	21.4	-	-	-	-	79.7*	37.1	99	18.3	7> ; 6= ; 0<	4> ; 9= ; 0<
Disease severity on leaves	Maritime	VENTIN	4	17.7	3.6	34.3	78	63.2	87.2	9.3	85.1	67.6	94.5	12.4	-	-	-	-	91.2	83.4	97.2	7	3> ; 1= ; 0<	0> ; 4= ; 0<
	North-East	VENTIN	9	11.8	5.1	29.4	63.3	48.5	82.6	10.3	78.6	68.1	91.3	7.6	85.2	68.9	98.3	8.5	-	-	-	-	6> ; 3= ; 0<	3> ; 6= ; 0<
	All zones	VENTIN	13	13.1	3.6	34.3	67.9	48.5	87.2	12.2	80.6	67.6	94.5	9.3	-	-	-	-	88.9*	68.9	98.3	8.1	8> ; 5= ; 0<	3> ; 10= ; 0<
Disease incidence on fruits First ass..	Maritime	VENTIN	5	45.8	13.5	97.8	73.2	36.9	92.9	20.4	75.6	49.7	100	22.2	-	-	-	-	81.1	47.3	99.6	18.9	1> ; 4= ; 0<	1> ; 4= ; 0<
	North-East	VENTIN	6	37.6	6	91.8	53.9	21.4	74	21.3	68.3	51.8	83.7	10.5	82.8	78	87.9	4.4	-	-	-	-	3> ; 3= ; 0<	3> ; 3= ; 0<
	All zones	VENTIN	11	41.3	6	97.8	62.7	21.4	92.9	23.1	71.6	49.7	100	17.78	-	-	-	-	82.9*	47.3	99.6	13.3	4> ; 7= ; 0<	4> ; 7= ; 0<
Index severity on fruits First ass	Maritime	VENTIN	5	39.3	10.4	94.9	76.8	52.7	92.7	14.3	81	56.6	100	20.2	-	-	-	-	88.2	68.7	99.4	12.5	-	-
	North-East	VENTIN	6	30.3	4.1	79.5	58.8	40.2	74.7	13.2	73.2	68.2	81.8	5	84	78.8	90.4	4.3	-	-	-	-	-	-
	All zones	VENTIN	11	34.4	4.1	94.9	67	40.2	92.7	16.7	76.7	56.6	100	13.8	-	-	-	-	86.4*	68.7	99.4	8.1	-	-
Disease incidence on fruits Last ass.	Maritime	VENTIN	5	56.8	15.5	100	59.4	15.1	89.5	27.5	71.1	16.8	94.6	31	-	-	-	-	81.1	47.9	98.9	21.3	3> ; 2= ; 0<	1> ; 4= ; 0<
	North-East	VENTIN	9	38.1	6.8	100	51.8	22.8	86.7	23.7	70.5	40.3	90.8	16.7	79.1	46.7	100	18.6	-	-	-	-	4> ; 5= ; 0<	3> ; 6= ; 0<
	All zones	VENTIN	14	44.7	6.8	100	54.5	15.1	89.5	24.3	70.7	16.8	94.6	21.6	-	-	-	-	80.6*	46.7	100	18.5	7> ; 7= ; 0<	4> ; 10= ; 0<
Index severity on fruit Last ass.	Maritime	VENTIN	5	52.8	11.5	100	63.7	22.2	88.4	25.7	73	26.1	96.1	27.9	-	-	-	-	86.3	59.1	99.2	16.5	-	-
	North-East	VENTIN	9	32.2	5	100	58	32.6	88.2	18.7	75.3	41.1	94	15.8	81.5	45.3	100	18.2	-	-	-	-	-	-
	All zones	VENTIN	14	39.5	5	100	60.1	22.2	88.4	20.6	74.5	26.1	96.1	19.9	-	-	-	-	83.2	45.3	100	16.4	-	-

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

\* Average on the dose rates 0.2 and 0.225 L/ha merged.

A total of 16 valid efficacy trials conducted in 2020, 2021, 2022 and 2023 (5 trials in Maritime and 11 trials in North-East EPPO climatic zones) are available. IN005B1570 250EC applied from 0.10 to 0.225 L/ha was compared to the reference standard DIFENO applied at 0.15 and 0.20 L/ha.

### **Minimum effective dose results on leaves**

On leaves, a total of 13 trials were assessed and the infestation level reached around 54.8% of leaves infected in untreated control, ranged from 42% to 96%. The level of attack by apple scab reached in average 16%.

#### *Maritime EPPO climatic zone:*

On disease incidence, IN005B1570 250EC applied at 0.225 L/ha showed a good control (76%) superior to IN005B1570 250EC at 0.15 L/ha (66%) or 0.10 L/ha (53%). This difference was significant in 3 out of 4 trials between the dose 0.10 L/ha and 0.225 L/ha and in 1 out of 4 trials between the rate 0.15 L/ha and 0.225 L/ha. These results demonstrated that an increased dose rate provided an increased control. Moreover, these results were confirmed on the disease severity. (91% mean control at 0.225 L/ha vs. 78-85% mean control for the lower tested doses) This difference was significant in 3 out of 4 trials between the dose 0.10 L/ha and 0.225 L/ha.

#### *North-East EPPO climatic zone:*

On disease incidence, IN005B1570 250EC applied at 0.20 L/ha showed a good control (75%) and superior to IN005B1570 250EC at 0.15 L/ha (67.5%) or 0.10 L/ha (58.1%). This difference was significant in 4 out of 9 trials between the doses 0.10 and 0.20 L/ha and in 3 out of 9 trials between the doses 0.15 L/ha and 0.20 L/ha.

In set of trials performed in 2023 IN005B1570 250EC applied at 0.20 L/ha showed a very good control (93.4%) and superior to IN005B1570 250EC at 0.15 L/ha (88.5%) or 0.10 L/ha (58.1%). This difference was significant in 1 out of 4 trials between the doses 0.10 and 0.20 L/ha.

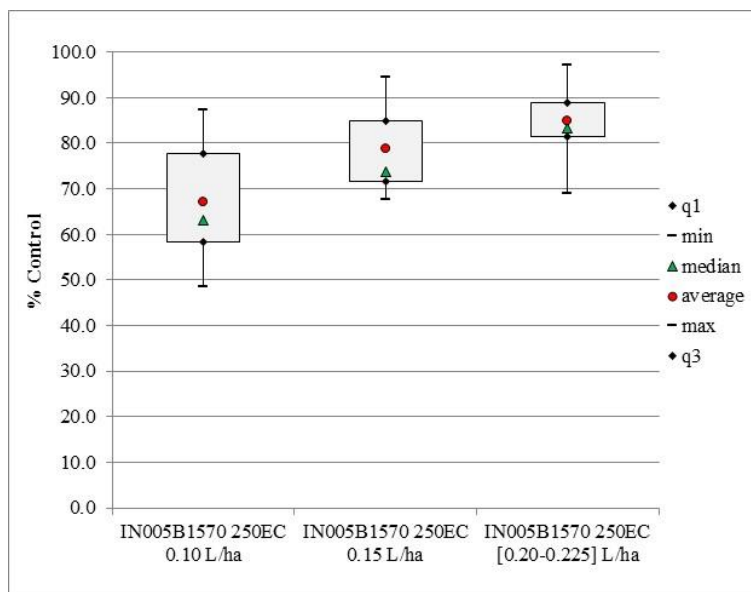
These results demonstrated that an increased dose rate provided an increased control. Moreover, these results were confirmed on the disease severity (85.2% mean control at 0.20 L/ha vs. 63.3-78.6% mean control for the lower tested doses). This difference was significant in 5 out of 9 trials between the dose 0.10 L/ha and 0.20 L/ha and in 3 out of 9 trials between the rate 0.15 L/ha and 0.20 L/ha.

In all zones, on disease incidence, IN005B1570 250EC applied at 0.20 L/ha showed a good control (80%) and superior to IN005B1570 250EC at 0.15 L/ha (67%) or 0.10 L/ha (56.5%). This difference was significant in 7 out of 13 trials between the dose 0.10 L/ha and [0.20-0.225] L/ha and in 4 out of 13 trials between the rate 0.15 L/ha and [0.20-0.225] L/ha. These results demonstrated that an increased dose rate provided an increased control. Moreover, these results were confirmed on the disease severity (89% mean control at [0.20-0.225] L/ha vs. 68-81% mean control for the lower tested doses). This difference was significant in 8 out of 13 trials between the dose 0.10 L/ha and in 3 out of 13 trials between the rate 0.15 L/ha and [0.20-0.225] L/ha.

The difference between the dose rates of IN005B1570 250EC at 0.10, 0.15 and [0.20-0.225] L/ha can be illustrated by box plot graphic on the disease severity on leaves (Figure 3.2-8).

**Figure 3.2-8**

**Minimum effective dose of IN005B1570 250EC at 0.10, 0.15 and [0.20-0.225] L/ha on leaves against *Venturia inaequalis* - Disease severity - North-East EPPO climatic zone - Box plot graphics (9 trials)**



#### **Minimum effective dose results on fruits**

##### *- First assessment*

A total of 11 trials were assessed on fruits and the the level of apple scab at the first assessment ranged from 2 to 98% fruits infected in untreated control.

##### *Maritime EPPO climatic zone:*

On disease incidence, IN005B1570 250EC applied at 0.225 L/ha showed a good control (81%) superior to IN005B1570 250EC at 0.15 L/ha (76%) or 0.10 L/ha (73%). These results demonstrated that an increased dose rate provided an increased control. These results were confirmed on disease severity calculated from the infection classes 1 to 3 with 88% mean control at 0.225 L/ha vs. 77-81% mean control for the lower tested doses. A significant difference was observed in 1 out of 5 trials between the lower tested doses and 0.225 L/ha.

##### *North-East EPPO climatic zone:*

On disease incidence, IN005B1570 250EC applied at 0.20 L/ha showed a good control (83%) and superior to IN005B1570 250EC at 0.15 L/ha (68%) or 0.10 L/ha (54%).

In trials performed in 2023 IN005B1570 250EC applied at 0.20 L/ha showed a good control (83%) and superior to IN005B1570 250EC at 0.15 L/ha (76%) or 0.10 L/ha (69%).

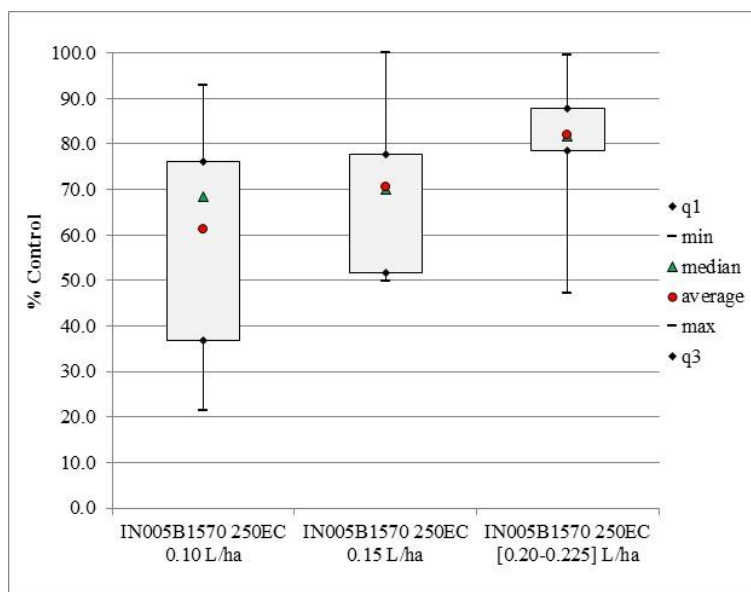
These results demonstrated that an increased dose rate provided an increased control. These results were confirmed on disease severity calculated from the infection classes 1 to 3 with 84% mean control at 0.20 L/ha vs. 59-73% mean control for the lower tested doses.

In all zones, on disease incidence, IN005B1570 250EC applied at [0.20-0.225] L/ha showed a good control (83%) superior to IN005B1570 250EC at 0.15 L/ha (72%) or 0.10 L/ha (63%). These results demonstrated that an increased dose rate provided an increased control. These results were confirmed on disease severity calculated from the infection classes 1 to 3 with 86% mean control at [0.20-0.225] L/ha vs. 67-77% mean control for the lower tested doses.

The difference between the dose rates of IN005B1570 250EC at 0.10, 0.15 and [0.20-0.225] L/ha can be illustrated by box plot graphic on the disease incidence on fruits (Figure 3.2-9).

**Figure 3.2-9**

**Minimum effective dose of IN005B1570 250EC at 0.10, 0.15 and [0.20-0.225] L/ha on fruits against *Venturia inaequalis* - Disease incidence - Maritime EPPO climatic zone - Box plot graphics (9 trials)**



- Last assessment

A total of 14 trials were assessed on fruits close to the harvest and the the level of apple scab ranged then from 7 to 100% fruits infected in untreated control.

*Maritime EPPO climatic zone:*

On disease incidence, IN005B1570 250EC applied at 0.225 L/ha showed a good control (81%) superior to IN005B1570 250EC at 0.15 L/ha (71%) or 0.10 L/ha (59%). These results demonstrated that an increased dose rate provided an increased control. These results were confirmed on disease severity calculated from the infection classes 1 to 3 with 86% mean control at 0.225 L/ha vs. 64-73% mean control for the lower tested doses. A significant difference was observed in 3 out of 5 trials between the dose 0.10 L/ha and 0.225 L/ha and in 1 out of 5 trials between the dose 0.15 L/ha and 0.225 L/ha.

*North-East EPPO climatic zone:*

On disease incidence, IN005B1570 250EC applied at 0.20 L/ha showed a good control (79%) which is better than IN005B1570 250EC at 0.15 L/ha (71%) and superior to 0.10 L/ha (52%).

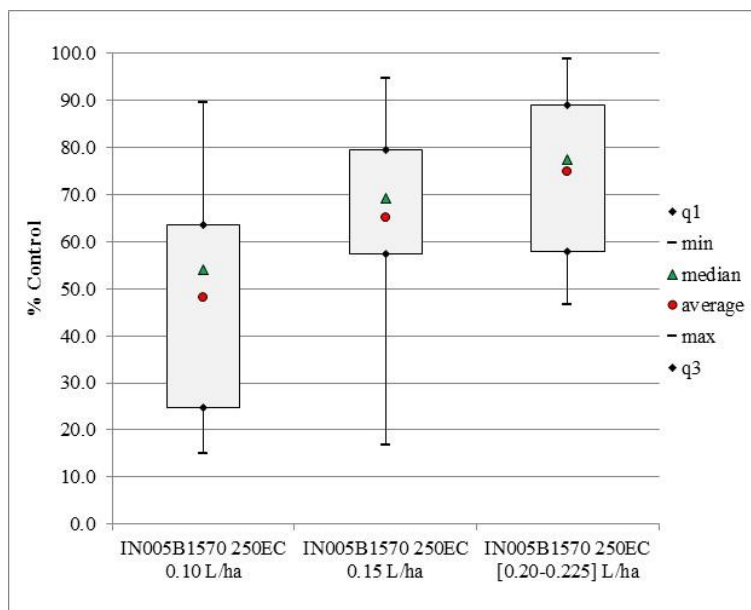
In set of trials performed in 2023 IN005B1570 250EC applied at 0.20 L/ha showed a very good control (92.2%) and superior to IN005B1570 250EC at 0.15 L/ha (84.6%) or 0.10 L/ha (70.4%).

These results demonstrated that an increased dose rate provided an increased control. These results were confirmed on disease severity calculated from the infection classes 1 to 3 with 82% mean control at 0.20 L/ha vs. 58-75% mean control for the lower tested doses.

In all zones, on disease incidence, IN005B1570 250EC applied at [0.20-0.225] L/ha showed a good level of control (81%) superior to IN005B1570 250EC at 0.15 L/ha (71%) or 0.10 L/ha (55%). These results demonstrated that an increased dose rate provided an increased control. These results were confirmed on disease severity calculated from the infection classes 1 to 3 with 83% mean control at [0.20-0.225] L/ha vs. 60-75% mean control for the lower tested doses.

The difference between the dose rates of IN005B1570 250EC at 0.10, 0.15 and [0.20-0.225] L/ha can be illustrated by box plot graphic on the disease incidence on fruits (Figure 3.2-10).

**Figure 3.2-10 Minimum effective dose of IN005B1570 250EC at 0.10, 0.15 and [0.20-0.225] L/ha on fruits against *Venturia inaequalis* - Disease incidence - Maritime EPPO climatic zone - Box plot graphics (10 trials)**



To conclude, the higher the dose of IN005B1570 250EC, the higher the efficacy and the lower the dispersion and variations among means.

Therefore, it can be concluded that the intended dose rate for IN005B1570 250EC of 0.2 and 0.225 L/ha in pome fruit are confirmed as minimum effective dose to obtain a consistent control of *Venturia inaequalis* and *Venturia pirina*.



*B. Efficacy trials results*

A total of 19 efficacy trials in apple were carried in 2020, 2021, 2022 and 2023 to evaluate the efficacy of IN005B1570 250EC applied at [0.15-0.2] L/ha for the control of *Venturia inaequalis* on apple fruit in comparison to the reference standard DIFENO at [0.15-0.2] L/ha.

However, in three trials, insufficient disease developed, so there is no efficacy data presented in this section.

The full list of these trials is presented in Table 3.2-9

The summary results of the efficacy of IN005B1570 250EC applied at [0.15-0.2] L/ha compared to the reference standard DIFENO at [0.15-0.2] L/ha are shown in Table 3.2-26. IN005B1570 250EC applied at 0.2 L/ha, 0.225 L/ha and at calculated rate of [0.113-0.168] L/ha LWA were also presented for information.

**Table 3.2-26: Efficacy of IN005B1570 250EC against *Venturia inaequalis* on apple - Mean control**

Parts	EPPO climatic zone	Target	No. of trials	Untreated control			Mean control (%)																				No. of assessments significantly <sup>(1)</sup> > , = , < IN005B1570 at [0.15-0.2] L/ha vs.	
							IN005B1570 0.2 L/ha				IN005B1570 0.225 L/ha				IN005B1570 calc.[0.113-0.168] L/ha LWA				IN005B1570 [0.15-0.2] L/ha				DIFENO [0.15-0.2] L/ha					
				Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max		S.D.
				[0.15-0.2] L/ha																								
Disease incidence on leaves	Maritime	VENTIN	4	77.7	50.3	95.1	-	-	-	-	75.5	63.3	82.6	8.5	70.6	63.3	79.3	7.4	66	47.5	76.6	13.2	65.7	53.3	74.9	10.9	0> ; 4= ; 0<	
	North-East	VENTIN	9	44.6	7.6	96	75	37.1	98	22	-	-	-	-	73	31.1	100	26	75	37.1	97.5	22	70.8	32.3	99.1	27.6	2> ; 7= ; 0<	
	All zones	VENTIN	13	54.8	7.6	96	-	-	-	-	79.8*	37.1	99	18.3	72.3	31.1	100	21.5	72.2	37.1	97.5	19.6	69.3	32.3	99.1	23.3	2> ; 11= ; 0<	
Disease severity on leaves	Maritime	VENTIN	4	17.7	3.6	34.3	-	-	-	-	91.5	83.4	97.2	7	89.6	83.4	94.5	5.3	85.1	67.6	94.5	12.4	85.3	71.2	95	10.6	0> ; 4= ; 0<	
	North-East	VENTIN	9	11.8	5.1	29.4	85.2	68.9	98.2	8.5	-	-	-	-	83.5	68.1	98.2	10.2	85.2	68.9	98.3	8.5	83.7	71.8	98.3	10.9	1> ; 8= ; 0<	
	All zones	VENTIN	13	13.6	3.6	34.3	-	-	-	-	88.9*	68.9	98.2	8.1	85.4	68.1	98.2	9.2	85.2	68	98.3	9.3	84.2	71.2	98.3	10.4	1> ; 12= ; 0<	
Disease incidence on fruits First ass.	Maritime	VENTIN	5	45.8	13.5	97.8	-	-	-	-	81.1	47.3	99.6	21.2	82.1	50.8	100	20.1	75.6	50	100	24.8	80.4	61.5	98.3	16.7	0> ; 5= ; 0<	
	North-East	VENTIN	6	37.6	6	91.8	82.8	78	87.9	4.4	-	-	-	-	81.6	62.9	87.9	9.9	82.8	78	87.9	4.4	84.1	70.5	92.7	8.7	1> ; 5= ; 0<	
	All zones	VENTIN	11	41.3	6	97.8	-	-	-	-	82.9*	47.3	99.6	13.3	81.8	50.8	100	14.5	79.5	49.7	100	16.4	82.4	62	98.3	12.4	1> ; 10= ; 0<	
Index severity on fruits First ass	Maritime	VENTIN	5	39.3	10.4	94.9	-	-	-	-	88.2	68.7	99.4	12.5	86	56.6	100	17.6	83.4	63.4	100	17	86.8	73	98.9	11.3	-	
	North-East	VENTIN	6	30.3	4.1	79.5	84	79	90	4.3	-	-	-	-	84.8	69.8	90.9	8	84	79	90	4.3	80.1	55	95.1	14.2	-	
	All zones	VENTIN	11	34.4	4.1	94.9	-	-	-	-	86.4*	68.7	99.4	8.1	85.3	56.6	100	12.5	83.7	63	100	11.2	83.2	55	98.9	12.8	-	
Disease incidence on fruits Last ass.	Maritime	VENTIN	5	56.8	15.5	100	-	-	-	-	81.1	47	99.6	21.1	79.1	47.9	94.6	18.4	71.1	16.8	94.6	31	66.6	19.3	94.4	29.1	0> ; 5= ; 0<	
	North-East	VENTIN	9	38.1	6.8	100	79.1	46.7	100	18.6	-	-	-	-	73.1	46.7	100	20.2	79.1	46.7	100	18.6	81.5	47.8	100	18.9	1> ; 7= ; 1<	
	All zones	VENTIN	14	44.7	6.8	100	-	-	-	-	80.6*	46.7	100	18.5	75.3	47	100	19.1	76.3	16.8	100	22.9	76.2	19.3	100	23.1	1> ; 12= ; 1<	
Index severity on fruit Last ass.	Maritime	VENTIN	5	52.8	11.5	100	-	-	-	-	86.3	59.1	99.2	16.5	83.8	59.1	96.1	14.7	73	26.1	96.1	27.9	73	29.9	95.3	25.7	-	
	North-East	VENTIN	9	32.2	5	100	81.5	45.3	100	18.2	-	-	-	-	77.7	45.3	100	18.9	81.5	45.3	100	18.2	85	49.5	100	17.4	-	
	All zones	VENTIN	14	39.5	5	100	-	-	-	-	83.2	45.3	100	16.4	79.9	45	100	17.2	78.5	26.1	100	21.5	80.7	29.9	100	20.6	-	

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

\* Average on the dose rates 0.2 and 0.225 L/ha merged.

A total of 16 valid efficacy trials conducted in 2020, 2021, 2022 and 2023 (5 trials in Maritime and 11 trials in North-East EPPO climatic zones) are available. IN005B1570 250EC applied at [0.15-0.2] L/ha was compared to the reference standard DIFENO applied at [0.15-0.2] L/ha (transversal reference across the countries). IN005B1570 250EC applied at 0.2 L/ha, 0.225 L/ha and at calculated rate of [0.113-0.168] L/ha LWA were also presented for information.

### **Efficacy results on leaves**

On leaves, a total of 13 trials were assessed and the attack level by apple scab ranged from 7 to 96% leaves infected in untreated control.

On disease incidence, in all EPPO climatic zones on pome fruit, IN005B1570 250EC applied at [0.15-0.2] L/ha showed a good control (75%) slightly superior to DIFENO at [0.15-0.2] L/ha (71%). This difference was significant in 2 trials and in 11 out of 13 trials no significant difference was observed. These results were confirmed on disease severity showing a good control with respectively 85% vs. 83% and no significant difference was observed in 12 out of 13 trials.

In the Maritime EPPO climatic zone, IN005B1570 250EC applied at 0.225 L/ha showed a good control with 76% of control on the disease incidence and 91% of control on the severity, in 4 trials. Likewise, in the North-East EPPO climatic zone, IN005B1570 250EC applied at 0.2 L/ha demonstrated a good control with 75% on the incidence and 84% of control on the severity in 9 trials. For information, IN005B1570 250EC applied at calculated rate [0.113-0.168] L/ha LWA demonstrated a good control (72% on the incidence and 86% on the severity).

Additionally in trials performed in 2023 IN005B1570 250EC applied at 0.20 L/ha showed a very good control (93.4%) and fully comparable to DIFENO at [0.15-0.2] L/ha (94.7%). These results were confirmed on disease severity showing a good control with respectively 92% vs. 93% and no significant difference was observed.

### **Efficacy results on fruits**

#### *- First assessment*

A total of 11 trials were assessed on fruits and the the level of apple scab at the first assessment ranged from 6 to 98% fruits infected in untreated control.

On disease incidence, in all EPPO climatic zones on pome fruit, IN005B1570 250EC applied at [0.15-0.2] L/ha showed a good control (80%) equivalent to DIFENO at [0.15-0.2] L/ha (82%). No significant difference was observed in 10 out of 11 trials. These results were confirmed on the disease severity calculated from the infection classes 1 to 3 showing a good control with respectively 84% vs. 83%.

In the Maritime EPPO climatic zone, IN005B1570 250EC applied at 0.225 L/ha showed a good control with 81% of control on the disease incidence and 88% of control on the severity, in 5 trials. Likewise, in the North-East EPPO climatic zone, IN005B1570 250EC applied at 0.2 L/ha demonstrated a good control with 83% on the incidence and 84% of control on the severity in 6 trials. For information, IN005B1570 250EC applied at calculated rate [0.113-0.168] L/ha LWA demonstrated an equivalent control (82% on the incidence and 85% on the severity)

Additionally in trials performed in 2023 IN005B1570 250EC applied at 0.20 L/ha showed a very good control (83%) and slightly inferior to DIFENO at [0.15-0.2] L/ha (92%). Results showed a good control with no significant difference between IN005B1570 250EC and DIFENO.

#### *- Last assessment*

A total of 14 trials were assessed on fruits close to the harvest and the level of disease at the last assessment was ranging from 7 to 100% fruits infected in untreated control.

On disease incidence, in all EPPO climatic zones on apple, IN005B1570 250EC applied at [0.15-0.2] L/ha showed a good control (76%) equivalent to DIFENO at [0.15-0.2] L/ha (76%). No significant difference was observed in 12 out of 14 trials. These results were confirmed on the disease severity calculated from the infection classes 1 to 3 showing a good control with respectively 79% vs. 81%.

In the Maritime EPPO climatic zone, IN005B1570 250EC applied at 0.225 L/ha showed a good control with 81% of control on the disease incidence and 86% of control on the severity, in 5 trials. Likewise, in the North-East EPPO climatic zone, IN005B1570 250EC applied at 0.2 L/ha demonstrated a good control with 79% on the incidence and 81% of control on the severity in 9 trials. For information, IN005B1570 250EC applied at calculated rate [0.113-0.168] L/ha LWA demonstrated a similar control (75% on the incidence and 80% on the severity).

Additionally in trials performed in 2023 IN005B1570 250EC applied at 0.20 L/ha showed a very good control (92%) and presented slightly weaker results, however, the differences were not statistically significant to DIFENO at [0.15-0.2] L/ha (97%). Results showed that IN005B1570 250EC applied at 0.20 L/ha obtained a very good control against *Venturia inaequalis* with no statistical difference between IN005B1570 250EC and DIFENO.

Separate summary has been performed to include trials performed in 2022 and provide additional proof of effectiveness of IN005B1570 250EC applied at 0.20 L/ha in direct comparison to DIFENO at [0.2] L/ha applied in sequence within the spray program against scab of apple.

It is well known that planning an experimental programme in apples is difficult. Having the disease present in the trials at the right time and the right severity involves an element of chance, and this makes planning and conducting a trials programme difficult. In general, the EPPO specific standard PP 1/5 for VENTIN applies. The application window requested should be tested, the number of applications can be higher, but the evaluation of efficacy should be made - at least after three applications, with an infestation level of min >5%.

Therefore the applicant has re-organised the efficacy data to incorporate the two trials conducted in Poland in 2022, with efficacy presented for the following general evaluation points, *i.e.* the last week of May (usually the first evaluation date in the report); mid-June (usually the second evaluation date in the report) and mid July (the third evaluation date in the report). These are the evaluation dates closest to the postulated three applications. Assessment from the first observations show the effectiveness after three applications of the product. The other assessment points show the long-term performance of the product.

In addition the final assessment of efficacy on fruits is also re-organised, to include the data from trial 7333.F.DAG23 which was conducted in 2022. There were no fruit in trial 7334.F.DAG23 due to unfavorable weather conditions (frost on May 18<sup>th</sup>) and an early intense "June drop" which meant that very little fruit remained on the trees, although efficacy on leaves was assessed.

Only data from the North-eastern EPPO zone are re-organised here; the data from the Maritime zone are unaffected by these changes.

Only assessments in which the result in the untreated plots was >5% are included.

**Table 3.2-27a: Efficacy of IN005B1570 250EC against *Venturia inaequalis* on apple - Mean control, May assessments**

				Name	UTC	IN005B1570	SCORE					
				Conc		250	250					
				Unit		g/L	g/L					
				Type		EC	EC					
				Rate		0.2	0.2					
Trial	Rating Date	Plant part	Description	Unit	% infection	L/ha	L/ha	LSD P=.05	SD	CV	IN005B1570 compared to Score	
FEU-AGR-001-21-SCAP2-PL09	25/05/2021	LEAF	Disease severity	% CONTROL	5.28	86.27	84.38	4.75	3.15	3.90		
FEU-AGR-001-21-SCAP2-PL12	31/05/2021	LEAF	Disease incidence	% CONTROL	6.38	55.28	50.99	15.75	10.45	22.64		
FEU-AGR-001-21-SCAP2-PL10	25/05/2021	LEAF	Disease incidence	% CONTROL	33.75	50.45	41.30	10.53	6.98	22.13		
FEU-AGR-001-21-SCAP2-PL09	25/05/2021	LEAF	Disease incidence	% CONTROL	41.00	59.69	52.33	12.77	8.47	19.75		
				Mean	27.04	55.14	48.21					
				Min	6.38	50.45	41.30					
				Max	41.00	59.69	52.33					
				Count	3	3	3					

**Table 3.2-28b: Efficacy of IN005B1570 250EC against *Venturia inaequalis* on apple - Mean control, mid-trial assessments**

				Name	UTC	IN005B1570	SCORE					
				Conc		250	250					
				Unit		g/L	g/L					
				Type		EC	EC					
				Rate		0.2	0.2					
Trial	Rating Date	Plant part	Description	Unit	% infection	L/ha	L/ha	LSD P=.05	SD	CV	IN005B1570 </> compared to Score	
FEU-AGR-001-21-SCAP2-PL09	15/06/2021	LEAF	Disease incidence	% CONTROL	56.38	41.47	35.63	12.30	8.16	27.78	=	
FEU-AGR-001-21-SCAP2-PL10	16/06/2021	LEAF	Disease incidence	% CONTROL	58.75	37.52	40.13	8.467	5.62	16.99	=	
FEU-AGR-001-21-SCAP2-PL11	18/06/2021	LEAF	Disease incidence	% CONTROL	38.00	87.24	88.26	3.56	2.36	2.91	=	
FEU-AGR-001-21-SCAP2-PL12	22/06/2021	LEAF	Disease incidence	% CONTROL	34.88	73.68	62.65	13.44	8.92	14.13	=	
7333.F.DAG22	01/07/2022	LEAF	Disease incidence	% CONTROL	25.80	87.3	86.5	8.70	5.44	6.18	=	
7334.F.DAG22	02/07/2022	LEAF	Disease incidence	% CONTROL	25.80	86.4	84.9	8.41	5.26	5.88	=	
				Mean	39.94	68.94	66.35					
				Min	25.80	37.52	35.63					
				Max	58.75	87.30	88.26					
				Count	6	6	6					
FEU-AGR-001-21-SCAP2-PL09	15/06/2021	LEAF	Disease severity	% CONTROL	9.09	84.22	82.87	4.15	2.76	3.68	=	
FEU-AGR-001-21-SCAP2-PL10	16/06/2021	LEAF	Disease severity	% CONTROL	11.61	85.00	84.53	4.20	2.79	3.63	=	
				Mean	10.35	84.61	83.70					
				Min	9.09	84.22	82.87					
				Max	11.61	85.00	84.53					
				Count	2	2	2					

**Table 3.2-29c: Efficacy of IN005B1570 250EC against *Venturia inaequalis* on apple - Mean control, long-term assessments mid-late July**

				Name	UTC	IN005B1570	SCORE					
				Conc		250	250					
				Unit		g/L	g/L					
				Type		EC	EC					
				Rate		0.2	0.2					
Trial	Rating Date	Plant part	Description	Unit	% infection	L/ha	L/ha	LSD P=.05	SD	CV	IN005B1570 compared to Score	
FEU-AGR-001-21-SCAP2-PL11	08/07/2021	LEAF	Disease incidence	% CONTROL	45.75	84.73	85.84	3.36	2.23	2.79	=	
FEU-AGR-001-21-SCAP2-PL09	15/07/2021	LEAF	Disease incidence	% CONTROL	96.00	57.27	32.26	8.52	5.56	14.52	>	
FEU-AGR-001-21-SCAP2-PL10	16/07/2021	LEAF	Disease incidence	% CONTROL	84.75	52.49	39.80	9.70	6.43	18.77	>	
FEU-AGR-001-21-SCAP2-PL12	30/07/2021	LEAF	Disease incidence	% CONTROL	42.13	69.10	58.97	12.71	8.43	13.96	=	
7334.F.DAG22	20/07/2022	LEAF	Disease incidence	% CONTROL	30.10	83.8	82.2	6.62	4.14	4.75	=	
7333.F.DAG22	20/07/2022	LEAF	Disease incidence	% CONTROL	43.50	86.1	87.8	4.26	2.66	3.03	=	
				Mean	57.04	72.25	64.48					
				Min	30.10	52.49	32.26					
				Max	96.00	86.10	87.80					
				Count	6	6	6					
FEU-AGR-001-21-SCAP2-PL11	08/07/2021	LEAF	Disease severity	% CONTROL	5.06	88.94	89.39	3.28	2.17	2.59	=	
FEU-AGR-001-21-SCAP2-PL09	15/07/2021	LEAF	Disease severity	% CONTROL	29.38	81.47	74.87	5.46	3.62	5.18	=	
FEU-AGR-001-21-SCAP2-PL10	16/07/2021	LEAF	Disease severity	% CONTROL	26.02	83.17	71.83	4.25	2.82	4.26	>	
FEU-AGR-001-21-SCAP2-PL12	30/07/2021	LEAF	Disease severity	% CONTROL	9.83	77.98	75.24	10.43	6.92	9.67	=	
7333.F.DAG22	20/07/2022	LEAF	Disease severity	% CONTROL	6.20	90.1	90.2	2.41	1.50	1.62	=	
				Mean	15.30	84.33	80.31					
				Min	5.06	77.98	71.83					
				Max	29.38	90.10	90.20					
				Count	5	5	5					

**Table 3.2-30d: Efficacy of IN005B1570 250EC against *Venturia inaequalis* on apple - Mean control, final fruit assessments**

				Name	UTC	IN005B1570	SCORE				
				Conc		250	250				
				Unit		g/L	g/L				
				Type		EC	EC				
				Rate		0.2	0.2				
Trial	Rating Date	Plant part	Description	Unit	% infection	L/ha	L/ha	LSD P=,05	SD	CV	IN005B1570 </=> compared to Score
7333.F.DAG23	20/07/2022	FRUIT	Disease incidence	% CONTROL	9.80	87.6	86.6	6.02	3.76	4.22	
FEU-AGR-001-21-SCAP2-PL08	24/09/2021	FRUIT	Disease incidence	% CONTROL	21.75	53.00	65.54	18.70	12.41	23.13	
FEU-AGR-001-21-SCAP2-PL09	24/08/2021	FRUIT	Disease incidence	% CONTROL	100.00	80.25	79.75	4.91	3.26	5.36	
FEU-AGR-001-21-SCAP2-PL10	13/10/2021	FRUIT	Disease incidence	% CONTROL	100.00	74.50	61.75	5.70	3.78	7.77	>
FEU-AGR-001-21-SCAP2-PL11	04/10/2021	FRUIT	Disease incidence	% CONTROL	29.50	89.01	89.79	4.30	2.92	3.65	
FEU-AGR-001-21-SCAP2-PL12	29/09/2021	FRUIT	Disease incidence	% CONTROL	56.00	46.73	47.82	7.32	4.85	10.56	
				Mean	52.84	71.85	71.88				
				Min	9.80	46.73	47.82				
				Max	100.00	89.01	89.79				
				Count	6	6	6				



Results presented in Tables 3.2-26a to 3.2-26c indicate that IN005B1570 250EC applied at 0.2 L/ha achieves good levels of initial control of VENTIN on leaves with excellent long-term effects, equivalent or superior to those achieved by the reference product.

At the first assessment timing (Table 3.2-26a) control of VENTIN incidence achieved by IN005B1570 in three trials was a mean of 55%, equivalent statistically to the control levels achieved by the reference product.

Mid-term control of VENTIN incidence achieved by IN005B1570 in six trials was a mean of 68%, equivalent statistically to the control levels achieved by the reference product (Table 3.2-26b). Control of disease severity was 84% from IN005B1570 in three trials.

Final assessments of long-term control on leaves (Table 3.2-26c) showed that IN005B1570 achieved 72% control of disease incidence (six trials, two of them with statistically superior performance when compared to the reference). Control of disease severity was a mean of 84% from five trials, with one of these results being statistically superior to the reference.

The control of disease on apples is also at a high level, with a mean level of control of 71.9% from six trials. One of these had statistically superior performance compared to the reference product (Table 3.2-26d).

In the requested application the applicant proposes a wide application window of crop BBCH 57-82. In many registered difenoconazole-based products in Poland, the application window is often a little narrower BBCH 57-72. However, the trials included in this submission included applications made from crop BBCH 53 to crop BBCH 81. As the difference between crop BBCH81 and BBCH 82 is so minor, it is reasonable to apply IN005B1570 according to the proposed GAP of crop BBCH 57-82.

To conclude, IN005B1570 250EC applied at [0.15-0.2] L/ha in apple has showed good and equivalent control of *Venturia inaequalis* to the reference DIFENO at the registered dose [0.15-0.2] L/ha. So, IN005B1570 250EC performs as well as the standard DIFENO applied at the same rate. However, overall, IN005B1570 250EC applied at a maximum rate of 0.225 L/ha increases the control of the disease compared to the standard at 0.15 or 0.2 L/ha.

**Therefore the data confirm that IN005B1570 250EC applied from 0.2 L/ha to 0.225 L/ha is effective to control scab in apple. Moreover, it is possible to use a dose rate of IN005B1570 250EC following the treated canopy at 0.15 L/10 000 m<sup>2</sup> LWA. Therefore, a maximum rate of 0.225 L/ha will be recommended on the product label for Austria, Belgium, Ireland, Germany and The Netherlands, and a rate at 0.2 L/ha will be recommended on the product label for Czech Republic, Poland and Slovenia.**

### **3.2.3.2.3 Impact of IN005B1570 250EC on fruit russetting**

Skin russet is a light brown colour and rough to the touch. Cultivars with thin cuticles are most likely to russet. Skin russetting does not affect flavour or eating quality of the fruit, but russeted fruits may shrivel in storage and can present a serious defect in the marketing of some varieties of apples. Russetting is a characteristic of some cultivars grown under certain environmental conditions and sometimes the severity can be exacerbated by spraying certain plant protection products. Russetting sensitive stages are from BBCH 59 (most flowers with petals forming a hollow ball) to 8 weeks later (about BBCH 79 - fruit about 90% of final size) with a sensitive peak between BBCH 65 (full flowering) and BBCH 74 (fruit erect).

The summary of the results to study the impact of IN005B1570 250EC on apple fruit russetting are shown in Table 3.2-31.

**Table 3.2-31: Effect of IN005B1570 250EC on apple russetting - % of fruits without russetting - Mean control**

Part	EPPO climatic zone	No. of trials	Untreated check			IN005B1570 0.2 L/ha				IN005B1570 0.225 L/ha				IN005B1570 calc.[0.113-0.168] L/ha LWA				IN005B1570 [0.15-0.2] L/ha				DIFENO [0.15-0.2] L/ha				No. of assessments significantly <sup>(1)</sup> > , = , < IN005B1570 at [0.15-0.2] L/ha vs. [0.15-0.2] L/ha
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	
Russetting	Maritime	3	92.0	76.0	100.0	-	-	-	-	92.9	78.7	100.0	10.4	93.8	81.3	100.0	8.8	93.8	81.3	100.0	8.8	93.0	79.0	100.0	9.9	0> ; 3= ; 0<
	North-East	4	87.8	71.0	100.0	86.6	65.5	100.0	14.5	-	-	-	-	86.6	65.5	100.0	14.5	86.6	65.5	100.0	14.5	86.9	65.5	100.0	13.8	0> ; 4= ; 0<
	All zones	7	89.6	71.0	100.0	-	-	-	-	89.3	65.5	100.0	13.1	89.6	65.5	100.0	12.9	89.6	65.5	100.0	12.9	89.5	65.5	100.0	12.7	0> ; 7= ; 0<

In all trials, IN005B1570 250EC at [0.15-0.2] L/ha showed similar ratios of fruit without russetting than untreated and the reference standard at the same rate. Similar results were observed between IN005B1570 250EC applied at 0.225 L/ha or at equivalent rate 0.156-0.169 L/ha LWA. Thus it is concluded that IN005B1570 250EC has no negative impact on apple russetting.

### **3.2.3.2.1 Efficacy trials results for the control of *Venturia pirina* in pears**

#### **Extrapolation of IN005B1570 250EC efficacy on pear (PUYCO) against *Venturia pirina***

On pear, no trial was carried out to evaluate the efficacy of IN005B1570 250EC for the control of *Venturia pirina* in the Central registration zone. Nevertheless, for this use, an extrapolation from apple to pome fruit permits to justify the request. Indeed, by extrapolation, it can be considered that the efficacy of IN005B1570 250EC against *Venturia pirina* on pear will be similar to the efficacy against *Venturia inaequalis* on apple as all crops are generally regarded as proper host plants for this fungal pathogen. Moreover, this extrapolation is in agreement with the extrapolation table published by EPPO (Table No. 14/20152, “Extrapolation table for effectiveness of fungicides, Diseases on pome fruit”).

**Therefore, and with regards to the results in apples presented in this dossier and the knowledge of difenoconazole - which is already registered at the same dose rate and in use in pome fruits - the registration of IN005B1570 250EC at 0.2 and 0.225 L/ha in pear is recommended. Thus, a maximum rate of 0.225 L/ha will be recommended on the product label for Austria, Belgium, Ireland, Germany and The Netherlands, and a rate at 0.2 L/ha will be recommended on the product label for Czech Republic, Poland and Slovenia. Moreover, it is possible to use a dose rate of IN005B1570 250EC following the treated canopy at 0.15 L/10 000 m<sup>2</sup> LWA.**

### 3.2.3.3 Efficacy trials in vegetables

A total of 20 valid efficacy trials were carried out in 2020 and 2021 to justify the interest of IN005B1570 250EC applied from 0.3 L/ha to 0.5 L/ha for the control of diseases in carrot and brassicae crops. All trials were carried out either in the Maritime EPPO climatic zone including France, Germany, the Netherlands and the United Kingdom (14 trials) and the North-East EPPO climatic zone in Poland (6 trials).

In one trial insufficient disease developed, so the efficacy data is not discussed further, but it is included to the discussion of crop selectivity in Section 3.4 “Adverse effects on treated crops (KCP 6.4)”.

#### 3.2.3.3.1 Material and Methods

##### Experimental details

All the trials presented in Table 3.2-10 were carried out by officially recognised organisations in accordance with the Principles of Good Experimental Practice (GEP). These trials were performed following EPPO guidelines or trial method recommendations published by the French CEB (“Commission des Essais Biologiques”). The “CEB” methods are in accordance with EPPO directives.

Main characteristics are summarised in Table 3.2-32 (Carrot crop), and Table 3.2-33 (Brassicas crop).

**Table 3.2-32: Details on trial methodology - Efficacy trials - Carrot**

<b>Guidelines</b>	General guidelines	PP1/135(4): “Phytotoxicity assessment”. PP1/152(4): “Design and analysis of efficacy evaluation trials”. PP1/181(4): “Conduct and reporting of efficacy evaluation trials, including good experimental practice”.
	Specific guidelines	PP 1/57(3): “Powdery mildews on cucurbits and other vegetables”. PP 1/121(2): “Leafspots of vegetables”.
<b>Experimental design</b>	Plot design	Randomized Complete Block (RCB)
	Plot size	11-27 m <sup>2</sup>
	Number of replications	4 replications
<b>Crop</b>	Number of trials	15 valid efficacy trials and 1 trial not valid
	Varieties	Bangor (1), Carvora (1), Farah (1), Galicja (1), Mello Yello (1), Nairobi (2), Nerac (1), Norway (1), Presto (2), Robila (1), Texto (1), Salsa (1), Volcano (2)
<b>Application</b>	Application timing	<u>Alternaria</u> : BBCH 41-49 with an interval between application of 11-21 days <u>Erysiphe heraclei</u> : BBCH 42-47 with an interval between application of 6-10 days
	Number of applications	<u>Alternaria</u> : 5 applications (3 trials) with an interval between application of 12-15 days 6 applications (11 trials) with an interval between application of 12-21 days <u>Erysiphe heraclei</u> : 6 applications (1 trial) with an interval between application of 6-10 days 7 applications (1 trial) with an interval between application of 7-10 days
	Spray volumes	200-600 L/ha
	Assessment dates	From appearance of the first symptoms in the untreated and according to disease development.
<b>Assessment</b>	Assessment types	Disease severity, disease incidence on leaves Yield (t/ha) (6 trials) Phytotoxicity
<b>Results &amp; Analysis</b>	Statistical analysis	ANOVA - Newman - Keuls test (5%).

In one trial carried out in the Maritime EPPO climatic zone, there was too low disease infestation. This trial without disease is considered as not valid for efficacy part but is used to justify the selectivity.

**Table 3.2-33: Details on trial methodology - Efficacy trials - Brassicas crop**

<b>Guidelines</b>	General guidelines	PP1/135(4): “ <i>Phytotoxicity assessment</i> ”. PP1/152(4): “ <i>Design and analysis of efficacy evaluation trials</i> ”. PP1/181(4): “ <i>Conduct and reporting of efficacy evaluation trials, including good experimental practice</i> ”.
	Specific guidelines	PP 1/121(2): “ <i>Leafspots of vegetables</i> ”.
<b>Experimental design</b>	Plot design	Randomized Complete Block (RCB)
	Plot size	15-30 m <sup>2</sup>
	Number of replications	4 replications
<b>Crop</b>	Number of trials	5 valid efficacy trials
	Varieties	<u>Cauliflower (BRSOB)</u> : <i>Cariance Verimark (1), Damsel (1)</i> <u>Broccoli (BRSOK)</u> : <i>Titanium (1)</i> <u>Head cabbage (BRSOL)</u> : <i>Brigadier (1), Manitoba (1)</i>
<b>Application</b>	Application timing	<u>Cauliflower (BRSOB)</u> : BBCH 19-74 with an interval between application of 13-15 days <u>Broccoli (BRSOK)</u> : BBCH 19-43 with an interval between application of 6-8 days <u>Head cabbage (BRSOL)</u> : BBCH 20-47 with an interval between application of 7-16 days
	Number of applications	<u>Cauliflower (BRSOB)</u> : 4 applications (1 trial) with an interval between application of 14 days 6 applications (1 trial) with an interval between application of 13-15 days <u>Broccoli (BRSOK)</u> : 6 applications (1 trial) with an interval between application of 6-8 days <u>Head cabbage (BRSOL)</u> : 9 applications (1 trial) with an interval between application of 7-16 days 11 applications (1 trial) with an interval between application of 8-10 days
	Spray volumes	200-600 L/ha
	Assessment dates	From appearance of the first symptoms in the untreated
<b>Assessment</b>	Assessment types	Disease severity, disease incidence on leaves, number of infested leaves per plot Yield (2 trials) Phytotoxicity
<b>Results &amp; Analysis</b>	Statistical analysis	ANOVA - Newman - Keuls test (5%).

## Treatments and reference standards

### Carrot crop:

In all efficacy trials, the efficacy of IN005B1570 250EC applied at 0.3, 0.4 and 0.5 L/ha was compared to the reference standard GEYSER or SCORE applied 0.5 L/ha (Table 3.2-11). These rates reflect 60% and 80% (0.5 L/ha is the maximum dose of IN005B1570 250EC requested) in accordance with the EPPO guideline PP 1/225(1) “*Minimum effective rate*”.

Table 3.2-34 below presents the plant protection products and the rates used in this part.

**Table 3.2-34: Plant protection products used in efficacy trials - Carrot**

Product name	Active substance(s)	Formulation		Application dose in trials (per treatment)	Country	Rate of active substance per ha	Remark
		Type <sup>[1]</sup>	Concentration of a.s.				
IN005B1570 250EC	Difenoconazole	EC	250 g/L	0.3 L/ha 0.4 L/ha 0.5 L/ha	-	75.0 g a.s./ha 100.0 g a.s./ha 125.0 g a.s./ha	-
GEYSER / SCORE*	Difenoconazole	EC	250 g/L	0.4 L/ha	DE - PL	100.0 g a.s./ha	Named <b>DIFENO</b> in this dRR
				0.5 L/ha	FR - NL - UK	125.0 g a.s./ha	

<sup>[1]</sup> EC: Emulsionate Concentrate - \* Geyser and Score are the trade names used in the different countries for the same Difenoconazole 250 g/L EC product registered by Syngenta

### Brassicac crops (cauliflower, broccoli and cabbage):

In all efficacy trials, the efficacy of IN005B1570 250EC applied et 0.3, 0.4 and 0.5 L/ha was compared to the reference standard GEYSER or SCORE applied 0.5 L/ha (Table 3.2-11). These rates reflect 60% and 80% (0.5 L/ha is the maximum dose of IN005B1570 250EC requested) in accordance with the EPPO guideline PP 1/225(1) “*Minimum effective rate*”.

Table 3.2-35 below presents the plant protection products and the rates used in this part.

**Table 3.2-35: Plant protection products used in open field efficacy trials - Brassicas**

Product name	Active substance(s)	Formulation		Application dose in trials (per treatment)	Country	Rate of active substance per ha	Remark
		Type <sup>[1]</sup>	Concentration of a.s.				
IN005B1570 250EC	Difenoconazole	EC	250 g/L	0.3 L/ha 0.4 L/ha 0.5 L/ha	-	75.0 g a.s./ha 100.0 g a.s./ha 125.0 g a.s./ha	-
GEYSER	Difenoconazole	EC	250 g/L	0.5 L/ha	FR	125.0 g a.s./ha	Named <b>DIFENO</b> in this dRR

<sup>[1]</sup> EC: Emulsionate Concentrate

### **Assessment methods**

#### *Alternaria dauci* and *Erysiphe heraclei*:

In accordance with the EPPO guidelines, the symptoms were assessed on 30-50 leaves per plot from appearance of the first symptoms in the untreated (disease severity and incidence expressed in percentage) and depending of the development of the disease until 3 weeks after the last applications.

#### *Alternaria brassicicola* and *Mycosphaerella brassicicola*:

In accordance with the EPPO guidelines, the symptoms were assessed on the crown of leaves of same ages on 20 plants per plot from appearance of the first symptoms in the untreated (disease severity and incidence expressed in percentage) and depending of the development of the disease until 10-14 days after the last applications. The number of infested leaves per plant on 20 plants per plot was also assessed.

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

### **Phytotoxicity assessments**

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

### **Statistical analyses**

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

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

### **Results layout**

All treatments of each trial are not systematically presented in this dossier, only relevant treatments are

summarised. All data are available in individual trial reports in Document K.

Indeed, for ALTEDA, ERYSHE, ALTEBI and MYCOBR, only the last valid assessments on leaves where pest severity in the untreated reached at least 5% infestation was summarised. Also, only assessments where reference standard reached a normal behavior were considered as valid. Only the more pertinent assessment by trial was summarised according to the disease and crop development.

For ALTEDA, assessments where the disease infection is too high (>80%) were not selected.

For ERYSHE, assessments were selected according to the disease development and when the disease was the highest.

All other assessments are available in individual trials reports.

### 3.2.3.3.2 Efficacy trials results for the control of diseases in carrot

#### A. *Alternaria dauci*

A total of 15 efficacy trials were carried in 2020 and 2021 to evaluate the efficacy of IN005B1570 250EC in the Central registration zones applied from 0.3 L/ha to 0.5 L/ha for the control of *Alternaria dauci* on carrot in comparison with the reference standard DIFENO at 0.4 and 0.5 L/ha. The trials were performed in the Maritime (3 trials in France, 2 trials in Germany, 2 trials in the Netherlands and 2 trials in the United-Kingdom) and in the North-East (6 trials in Poland) EPPO climatic zones.

However, in one trial, insufficient disease developed, so its efficacy data are not presented in this section.

The full list of these trials is presented in Table 3.2-10.

The summary results of the efficacy of IN005B1570 250EC applied at 0.4 and 0.5 L/ha compared to the reference standard DIFENO at 0.4 and 0.5 L/ha are shown in Table 3.2-36.



**Table 3.2-36: Efficacy of IN005B1570 250EC against *Alternaria dauci* on carrot - Mean control**

Parts	EPPO climatic zone	No. of trials	Untreated control			Mean control (%)																				No. of assessments significantly <sup>(1)</sup> >, =, < IN005B1570 250EC at			
						IN005B1570 250EC 0.3 L/ha				IN005B1570 250EC 0.4 L/ha				IN005B1570 250EC 0.5 L/ha				DIFENO 0.4 L/ha				DIFENO 0.5 L/ha				0.5 L/ha vs.		0.4 L/ha vs.	
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	IN005B1570 250EC		DIFENO	
																										0.3 L/ha	0.4 L/ha	0.5 L/ha	0.4 L/ha
Disease severity on leaves	Maritime	8	34.2	7.6	69.3	65.6	30.1	99.4	20.4	70.7	50.6	99.2	17.5	78.1	60.4	99.3	14.6	-	-	-	-	-	-	-	-	2> ; 6= ; 0<	2> ; 6= ; 0<	-	-
		2	46.4	23.4	69.3	76.9	54.4	99.4	22.5	87.5	75.9	99.2	11.6	91.7	84.2	99.3	7.6	76.6	53.6	99.6	23.0	-	-	-	-	-	-	-	0> ; 2= ; 0<
		6	30.1	7.6	60.6	61.8	30.1	84.6	18.2	65.1	50.6	87.8	15.4	73.6	60.4	93.8	13.5	-	-	-	-	72.2	57.8	92.4	14.2	-	-	1> ; 5= ; 0<	-
	North-East	6	22.7	6.3	45.0	72.3	52.1	84.3	11.1	78.3	46.0	94.7	15.9	82.5	53.3	96.8	13.9	80.0	50.6	94.7	14.2	-	-	-	-	5> ; 1= ; 0<	2> ; 4= ; 0<	-	1> ; 5= ; 0<
	All zones	14	29.3	6.3	69.3	68.5	30.1	99.4	17.4	73.9	46.0	99.2	17.3	80.0	53.3	99.3	14.5	-	-	-	-	-	-	-	-	7> ; 7= ; 0<	4> ; 10= ; 0<	-	-
		8	28.6	6.3	69.3	73.4	52.1	99.4	14.9	80.6	46.0	99.2	15.5	84.8	53.3	99.3	13.2	79.1	50.6	99.6	16.9	-	-	-	-	-	-	-	1> ; 7= ; 0<
Disease incidence on leaves	Maritime	8	90.7	56.7	100.0	25.9	0.0	89.2	28.5	29.3	0.0	87.5	28.3	33.8	0.0	90.8	30.5	-	-	-	-	-	-	-	-	2> ; 6= ; 0<	1> ; 7= ; 0<	-	-
		2	100.0	100.0	100.0	51.7	14.2	89.2	37.5	56.3	25.0	87.5	31.3	59.6	28.3	90.8	31.3	48.3	4.2	92.5	44.2	-	-	-	-	-	-	-	0> ; 2= ; 0<
		6	87.6	56.7	100.0	17.3	0.0	48.7	17.9	20.3	0.0	55.8	20.5	25.2	0.0	72.9	24.8	-	-	-	-	24.0	0.0	58.5	20.7	-	-	0> ; 6= ; 0<	-
	North-East	6	81.3	60.8	100.0	30.5	0.0	62.7	21.9	38.9	2.5	75.9	25.7	44.3	2.5	80.7	25.6	39.8	0.0	75.9	25.0	-	-	-	-	4> ; 2= ; 0<	1> ; 5= ; 0<	-	0> ; 6= ; 0<
	All zones	14	86.7	56.7	100.0	27.9	0.0	89.2	26.0	33.4	0.0	87.5	27.6	38.3	0.0	90.8	28.9	-	-	-	-	-	-	-	-	6> ; 8= ; 0<	2> ; 12= ; 0<	-	-
		8	85.9	60.8	100.0	35.8	0.0	89.2	28.2	43.2	2.5	87.5	28.2	48.1	2.5	90.8	27.9	41.9	0.0	92.5	31.1	-	-	-	-	-	-	-	0> ; 8= ; 0<

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

### **Efficacy results on leaves**

In the Central registration zone, at the last application, the infestation on leaves in untreated plots reached until 69% in the efficacy trials.

In the Maritime EPPO climatic zone, on the disease severity, IN005B1570 250EC at 0.5 L/ha showed a good control (78%) higher than IN005B1570 250EC at 0.4 L/ha (71%) and IN005B1570 250EC at 0.3 L/ha (66%). These results demonstrated that an increased dose rate provides an increased control. This difference was significant in 2 out of 8 trials between IN005B1570 250EC at 0.5 L/ha and the lower tested doses 0.3-0.4 L/ha.

On disease incidence, even if the level of efficacy was low due to a high infestation, these results were confirmed (34% mean control at 0.5 L/ha vs. 26-29% mean control for the lower tested doses).

IN005B1570 250EC at 0.4 L/ha expressed a higher control than the reference standard DIFENO at 0.4 L/ha (respectively 88% vs. 77% mean control in 2 trials) even if no significant difference was noted in both trials. On the other hand, IN005B1570 250EC at 0.5 L/ha was similar than the reference DIFENO at 0.5 L/ha and demonstrated a good control (respectively 74% vs. 72% mean control in 6 trials). A significant difference was noted in 1 out of 6 trials between IN005B1570 250EC at 0.5 L/ha and DIFENO at 0.5 L/ha. These results were confirmed on disease incidence with respectively 56% vs. 48% mean control between IN005B1570 250EC at 0.4 L/ha and the standard at 0.4 L/ha in 2 trials and 25% vs. 24% mean control between IN005B1570 250EC at 0.5 L/ha and the standard at 0.5 L/ha in 6 trials.

In the North-East EPPO climatic zone, on the disease severity, IN005B1570 250EC at 0.5 L/ha showed a good control (83%) higher than IN005B1570 250EC at 0.4 L/ha (78%) and IN005B1570 250EC at 0.3 L/ha (72%). These results demonstrated that an increased dose rate provided an increase control. This difference was significant in 2 out of 6 trials between IN005B1570 250EC at 0.5 L/ha and 0.4 L/ha, and in 5 out of 6 trials between IN005B1570 250EC at 0.5 L/ha and 0.3 L/ha.

On disease incidence, even if the level of efficacy was low due to a high infestation, these results were confirmed (44% mean control at 0.5 L/ha vs. 31-39% mean control for the lower tested doses).

IN005B1570 250EC at 0.4 L/ha expressed at least a similar control than the reference standard DIFENO at 0.4 L/ha (respectively 78% vs. 80% mean control in 6 trials) and this difference was significant in 1 out of 6 trials.

In all zones, on the disease severity on 14 trials, IN005B1570 250EC at 0.5 L/ha showed a good control (80%) higher than IN005B1570 250EC at 0.4 L/ha (74%) and IN005B1570 250EC at 0.3 L/ha (69%). These results demonstrated that an increased dose rate provides an increased control. Moreover, this difference was significant in 4 out of 14 trials between IN005B1570 250EC at 0.5 L/ha and 0.4 L/ha and in 7 out of 14 trials between IN005B1570 250EC at 0.5 L/ha and 0.3 L/ha.

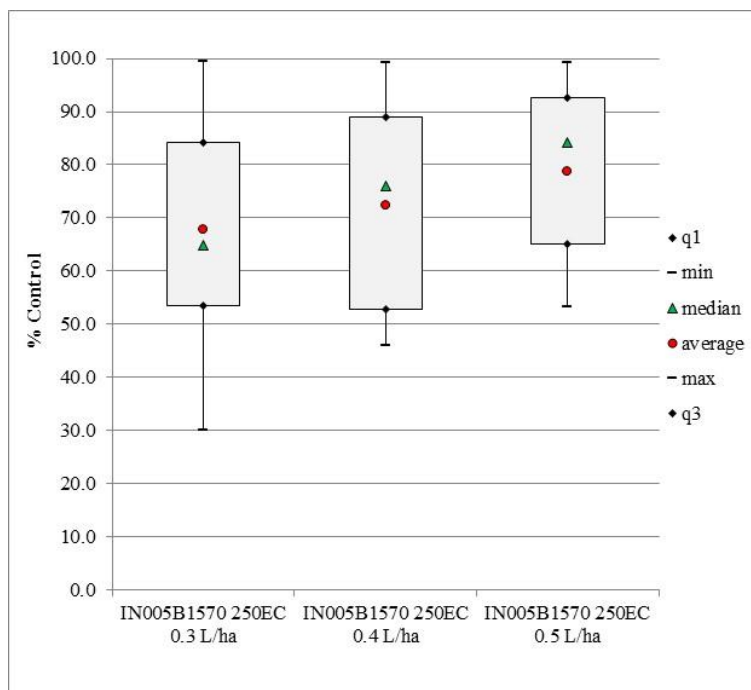
On disease incidence, even if the level of efficacy was low due to a high infestation, these results were confirmed (38% mean control at 0.5 L/ha vs. 28-33% mean control for the lower tested doses).

IN005B1570 250EC at 0.4 L/ha expressed a similar control than the reference standard DIFENO at 0.4 L/ha (respectively 81% vs. 79% mean control in 8 trials) and this difference was significant in 1 out of 8 trials.

These results were similar on disease incidence with respectively 43% vs. 42% mean control.

The difference between the dose rates of IN005B1570 250EC at 0.3, 0.4 and 0.5 L/ha can be illustrated by box plot graphic on the disease severity on leaves (Figure 3.2-11).

**Figure 3.2-11**      **Efficacy of IN005B1570 250EC at 0.3, 0.4 and 0.5 L/ha on leaves against *Alternaria dauci* - Disease severity on leaves - All EPPO climatic zone - Box plot graphics (14 trials - All zones)**



To conclude, IN005B1570 250EC applied at 0.5 L/ha on carrot crop showed a good level of control of *Alternaria dauci* similar to the reference DIFENO at the registered dose 0.5 L/ha. In addition, the higher the dose of IN005B1570 250EC, the higher the efficacy and the lower the dispersion and variations between means.

Moreover, overall, IN005B1570 250EC applied at 0.4 L/ha was equivalent to the reference DIFENO at the registered dose 0.4 L/ha and showed an acceptable and good control.

**Therefore, by and large, with a good level of infestation, IN005B1570 250EC at 0.5 L/ha showed a good level of control on ALTEDA in the Central registration zone and was equivalent to the reference DIFENO. Then, following the disease pressure, it is possible to use a lower rate of IN005B1570 250EC. Therefore, a rate ranging from 0.4 to 0.5 L/ha will be recommended on the product label for Belgium, Czech Republic, Ireland, The Netherlands, Poland and Slovenia and a rate at 0.4 L/ha will be recommended on the product label for Austria and Germany for the control of ALTEDA and ALTERA.**

*B. Erysiphe heracleii*

A total of 5 efficacy trials were carried in 2020 and 2021 to evaluate the efficacy of IN005B1570 250EC in the Central and Southern registration zone applied from 0.3 L/ha to 0.5 L/ha for the control of *Erysiphe heraclei* on carrot in comparison to the reference standard DIFENO at 0.4 and 0.5 L/ha. The trials were performed in the Maritime (3 trials in France, 1 trial in Germany and 1 trial in the Netherlands) EPPO climatic zone.

The full list of these trials is presented in Table 3.2-10.

The summary results of the efficacy of IN005B1570 250EC applied at 0.3-0.4-0.5 L/ha compared to the reference standard DIFENO at 0.4 and 0.5 L/ha are shown in Table 3.2-37.

**Table 3.2-37: Efficacy of IN005B1570 250EC against *Erysiphe heraclei* on carrot - Mean control**

Parts	EPPO climatic zone	No. of trials	Untreated control			Mean control (%)																				No. of assessments significantly <sup>(1)</sup> > , = , < IN005B1570 250EC at				
						IN005B1570 250EC 0.3 L/ha				IN005B1570 250EC 0.4 L/ha				IN005B1570 250EC 0.5 L/ha				DIFENO 0.4 L/ha				DIFENO 0.5 L/ha				0.5 L/ha vs.		0.4 L/ha vs.		
			Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	IN005B1570 250EC		DIFENO	
																											0.3 L/ha	0.4 L/ha	0.5 L/ha	0.4 L/ha
Disease severity on leaves	Maritime	5	28.8	19.3	54.3	87.6	78.8	100.0	7.7	90.8	79.8	100.0	8.0	94.2	84.7	99.2	5.6	-	-	-	-	-	-	-	-	-	1> ; 4= ; 0<	0> ; 5= ; 0<	-	-
		1	27.6	-	-	91.8	-	-	-	98.1	-	-	-	98.9	-	-	-	96.7	-	-	-	-	-	-	-	-	-	-	-	0> ; 1= ; 0<
		4	29.0	19.3	54.3	86.5	78.8	100.0	8.2	89.0	79.8	100.0	7.9	93.0	84.7	99.2	5.6	-	-	-	-	91.3	82.1	100.0	8.3	-	-	0> ; 4= ; 0<	-	
Disease incidence on leaves	Maritime	5	84.6	58.3	100.0	40.6	0.0	100.0	35.5	66.0	15.0	85.9	26.3	57.6	5.8	100.0	31.7	-	-	-	-	-	-	-	-	1> ; 4= ; 0<	0> ; 5= ; 0<	-	-	
		1	100.0	-	-	51.7	-	-	-	79.2	-	-	-	85.0	-	-	-	73.3	-	-	-	-	-	-	-	-	-	-	0> ; 1= ; 0<	
		4	80.7	58.3	100.0	37.8	0.0	100.0	39.2	52.2	5.8	100.0	33.3	61.3	15.0	85.9	27.4	-	-	-	-	50.0	8.3	100.0	32.8	-	-	0> ; 4= ; 0<	-	

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

### **Efficacy results on leaves**

In the Central registration zone, at the last application, the infestation on leaves in untreated plot reached until 54% in the efficacy trials.

In the Maritime EPPO climatic zone, on the disease severity, IN005B1570 250EC at 0.5 L/ha showed a very good control (94%) higher than IN005B1570 250EC at 0.4 L/ha (91%) and IN005B1570 250EC at 0.3 L/ha (88%) in 5 trials. These results demonstrated that an increased dose rate provides an increased control. No significant difference was noted in all trials between IN005B1570 250EC at 0.5 L/ha and 0.4 L/ha. However, this difference is significant in 1 out of 5 between IN005B1570 250EC at 0.5 L/ha and 0.3 L/ha.

On disease incidence, even if the level of efficacy was moderate due to a high infestation, these results were confirmed (66% mean control at 0.5 L/ha vs. 41-58% mean control for the lower tested doses).

IN005B1570 250EC at 0.4 L/ha expressed at least a similar control than the reference standard DIFENO at 0.5 L/ha (respectively 89% vs. 91% mean control in 4 trials) and no significant difference was noted in all trials. On the other hand, IN005B1570 250EC at 0.5 L/ha showed a similar control than the reference DIFENO at 0.5 L/ha and demonstrated an excellent control (respectively 93% vs. 91% mean control in 4 trials). No significant difference was noted in all trials.

To conclude, IN005B1570 250EC applied at 0.5 L/ha on carrot crop showed a very good level of control of *Erysiphe heracleii* similar to the reference DIFENO at the registered dose 0.5 L/ha. In addition, the higher the dose of IN005B1570 250EC, the higher the efficacy and the lower the dispersion and variations between means. Moreover, overall, IN005B1570 250EC applied at 0.4 L/ha was equivalent to the reference DIFENO at the registered dose 0.5 L/ha and showed an acceptable and good control.

**Therefore, by and large, with a good level of infestation, IN005B1570 250EC at 0.5 L/ha showed a very good level of control on ERYSHE in the Central registration zone and was equivalent to the reference DIFENO. Then, following the disease pressure, it is possible to use a lower rate of IN005B1570 250EC. Therefore, a rate ranging from 0.4 to 0.5 L/ha will be recommended on the product label for Belgium, Czech Republic, Ireland, The Netherlands, Poland and Slovenia, and a rate at 0.4 L/ha will be recommended on the product label for Austria and Germany for the control of ERYSHE.**

#### **C. Effect on the yield in presence of carrot diseases**

A total of 7 efficacy trials were harvested in 2020 and 2021 in the Maritime (1 trial in France, 1 trial in Germany and 1 in The United-Kingdom) and in the North-East (4 trials in Poland) EPPO climatic zones. The objective was to confirm the yield response of IN005B1570 250EC in the presence of fungi diseases in carrot crop.

Table 3.2-38 shows a summary of positive effect on the yield of IN005B1570 250EC applied at 0.4 and 0.5 L/ha compared to the reference standard DIFENO.

**Table 3.2-38: Positive effect on the yield of IN005B1570 250EC compared to the reference standard - Efficacy trials - Carrot**

Parts	EPPO climatic zone	No. of trials	Untreated control t/ha			Mean control (%)																No. of assessments significantly <sup>(1)</sup> > , = , < IN005B1570 250EC	
						IN005B1570 250EC 0.4 L/ha				IN005B1570 250EC 0.5 L/ha				DIFENO 0.4 L/ha				DIFENO 0.5 L/ha				at 0.4 L/ha vs.	at 0.5 L/ha vs.
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	DIFENO 0.4 L/ha	DIFENO 0.5 L/ha
ALTEDA + ERYSH	Maritime	1	68.4	-	-	115.9	-	-	-	135.5	-	-	-	119.9	-	-	-	119.9	-	-	-	-	1> ; 0= ; 0<
ALTEDA	Maritime	1	89.9	-	-	94.4	-	-	-	91.0	-	-	-	-	-	-	-	96.9	-	-	-	-	0> ; 1= ; 0<
	Maritime	1	54.0	-	-	107.4	-	-	-	108.2	-	-	-	104.3	-	-	-	-	-	-	-	0> ; 1= ; 0<	-
	North-East	4	71.7	60.4	85.2	106.8	99.3	116.1	6.1	108.2	100.0	120.5	7.6	109.9	100.1	119.0	6.7	-	-	-	-	0> ; 4= ; 0<	-
All diseases	All zones	5	68.1	54.0	85.2	106.9	99.3	116.1	5.5	108.2	100.0	120.5	6.8	108.8	100.1	119.0	6.4	-	-	-	-	0> ; 5= ; 0<	-
		7	68.2	54.0	85.2	106.4	94.4	116.1	7.4	109.6	91.0	135.5	13.4	-	-	-	-	-	-	-	-	-	-

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

In the Maritime EPPO climatic zone, the average yield reached 68 t/ha in the untreated plot.

IN005B1570 250EC at 0.5 L/ha had a positive effect on the yield of carrot in the presence of ALTEDA and ERYSHE. In fact, there was a 35% increase in yield over the untreated with a significant difference between IN005B1570 250EC and the reference standard DIFENO at 0.5 L/ha.

IN005B1570 250EC at 0.4 L/ha had also a positive effect on the yield of carrot in the presence of ALTEDA. In fact, there was a 7% increase in yield over the untreated in 4 trials. Overall, no significant difference was observed between IN005B1570 250EC and the reference standard DIFENO at 0.4 L/ha in all trials.

Overall, in all trials, IN005B1570 250EC at 0.5 L/ha had a positive effect on the yield of carrot in the presence of foliar diseases. In fact, there was a 10% increase in yield over the untreated.

### **3.2.3.3.3 Efficacy trials results for the control of diseases in Brassicas crops (cauliflower, broccoli and cabbage)**

#### **A. *Alternaria spp.***

A total of 5 efficacy trials were carried in 2020 to evaluate the efficacy of IN005B1570 250EC in the Maritime EPPO climatic zone applied from 0.3 to 0.5 L/ha for the control of *Alternaria brassicicola* on brassicas crop (2 trials on cauliflower crops, 1 trial on broccoli crop and 2 trials on cabbage crops) in comparison with the reference standard DIFENO at 0.5 L/ha. The trials were performed in the Maritime EPPO climatic zone (5 trials in France).

The full list of these trials is presented in Table 3.2-10.

The summary results of the efficacy of IN005B1570 250EC applied at 0.3-0.4-0.5 L/ha compared to the reference standard DIFENO at 0.5 L/ha are shown in Table 3.2-39.



**Table 3.2-39: Efficacy of IN005B1570 250EC against *Alternaria brassicicola* in brassicas crop in the Maritime EPPO climatic zone - Mean control**

Parts	Crop	No. of trials	Untreated control			Mean control (%)																No. of assessments significantly <sup>(1)</sup> > , = , < IN005B1570 250EC at 0.5 L/ha vs.		
						IN005B1570 0.3 L/ha				IN005B1570 0.4 L/ha				IN005B1570 0.5 L/ha				DIFENO 0.5 L/ha						
			Mean	Min	Max	Mea n	Min	Max	S.D.	Mea n	Min	Max	S.D.	Mea n	Min	Max	S.D.	Mea n	Min	Max	S.D.	IN005B1570 0.3 L/ha	IN005B1570 0.4 L/ha	DIFENO 0.5 L/ha
Disease severity on leaves	BRSOK	1	16.7	-	-	63.4	-	-	-	78.5	-	-	-	82.2	-	-	-	75.5	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<	0> ; 1= ; 0<
	BRSOL	2	7.8	7.6	8.1	65.3	50.5	80.1	14.8	73.0	70.0	76.0	3.0	79.4	76.8	81.9	2.5	79.2	75.8	82.6	3.4	0> ; 2= ; 0<	0> ; 2= ; 0<	0> ; 2= ; 0<
	BRSOB	2	15.2	10.3	20.0	66.8	61.1	72.5	5.8	76.2	65.8	86.5	10.3	83.0	78.9	87.2	4.2	86.9	80.2	93.5	6.6	1> ; 1= ; 0<	1> ; 1= ; 0<	0> ; 1= ; 1<
	All brassicas	5	12.5	7.6	20.0	65.5	50.5	80.1	10.1	75.4	65.8	86.5	7.1	81.4	76.8	87.2	3.5	81.5	75.5	93.5	6.6	2> ; 3= ; 0<	1> ; 4= ; 0<	0> ; 4= ; 1<
Disease incidence on leaves	BRSOK	1	100.0			21.3	-	-	-	37.5	-	-	-	44.5	-	-	-	28.8	-	-	-	1> ; 0= ; 0<	1> ; 0= ; 0<	1> ; 0= ; 0<
	BRSOL	2	91.9	85.0	98.8	23.5	21.5	25.5	2.0	29.6	16.4	42.7	13.2	39.2	29.0	49.5	10.3	38.9	29.1	48.7	9.8	1> ; 1= ; 0<	0> ; 2= ; 0<	0> ; 2= ; 0<
	BRSOB	2	95.6	91.3	100.0	10.3	0.0	20.5	10.3	14.5	4.5	24.5	10.0	21.9	0.0	43.8	21.9	32.4	18.3	46.6	14.2	1> ; 1= ; 0<	1> ; 1= ; 0<	0> ; 1= ; 1<
	All brassicas	5	95.0	85.0	100.0	17.8	0.0	25.5	9.1	25.1	4.5	42.7	13.9	33.3	0.0	49.5	18.0	34.3	18.3	48.7	11.6	3 ; 2= ; 0<	2> ; 3= ; 0<	1> ; 3= ; 1<
Average number of infested leaves per plot	BRSOK	1	12.0	-	-	57.7	-	-	-	64.0	-	-	-	76.0	-	-	-	63.8				1> ; 0= ; 0<	1> ; 0= ; 0<	1> ; 0= ; 0<
	BRSOL	2	3.5	2.4	4.5	52.0	44.7	59.3	7.3	55.0	38.3	71.7	16.7	66.2	54.9	77.5	11.3	63.7	51.4	76.0	12.3	0> ; 2= ; 0<	0> ; 2= ; 0<	0> ; 2= ; 0<
	BRSOB	2	6.9	4.1	9.6	34.1	13.9	54.2	20.2	42.1	24.8	59.5	17.3	56.7	40.2	73.1	16.4	58.5	42.0	75.1	16.6	2> ; 0= ; 0<	2> ; 0= ; 0<	0> ; 2= ; 0<
	All brassicas	5	6.5	2.4	12.0	46.0	13.9	59.3	16.8	51.7	24.8	71.7	17.4	64.4	40.2	77.5	14.6	61.7	42.0	76.0	13.3	3> ; 2= ; 0<	3> ; 2= ; 0<	1> ; 4= ; 0<

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

In the Maritime EPPO climatic zone, at the last application, the infestation in untreated plot on leaves reached until 13% in all brassicas trials.

On the disease severity, IN005B1570 250EC at 0.5 L/ha showed a good control (81%) higher than IN005B1570 250EC at 0.4 L/ha (75%) and IN005B1570 250EC at 0.3 L/ha (66%). These results demonstrated that an increased dose rate provides an increased control. Moreover, the efficacy of IN005B1570 250EC at 0.5 L/ha in all brassicas was similar to the reference DIFENO at 0.5 L/ha and demonstrated a good control (respectively 81% vs. 82% mean control). No significant difference was noted in 4 out of 5 trials.

These results were similar on disease incidence with respectively 33% vs. 34% mean control.

On the number of infested leaves, IN005B1570 250EC at 0.5 L/ha showed a moderate control (64%) higher than IN005B1570 250EC at 0.4 L/ha (52%) and IN005B1570 250EC at 0.3 L/ha (46%). Moreover, the efficacy of IN005B1570 250EC at 0.5 L/ha in all brassicas was slightly superior to the reference DIFENO at 0.5 L/ha (respectively 64% vs. 62% mean control). No significant difference was noted in 4 out of 5 trials.

Overall, few data from field on cauliflower, broccoli and cabbage are available (5 trials) for this disease for which proposed label claims are made for control with IN005B1570 250EC at 0.5 L/ha. However, a significant quantity of data is available from trials conducted on vegetables included in the section 3.2.3.3. It is asserted that these data provides sufficient information and assurance that IN005B1570 250EC SC will work on this disease as well as it does on other host crops of alternaria. for which data have been presented. Moreover, in all requested countries of Central regulatory zone, several preparations containing difenoconazole are currently registered on this use. Principals requested use are presented in Table 3.2-2.

**Therefore, by and large, with a moderate level of infestation, IN005B1570 250EC at 0.5 L/ha showed a good level of control on ALTEBI in the Maritime EPPO climatic zone and was equivalent to the reference DIFENO. In addition, the higher the dose of IN005B1570 250EC, the higher the efficacy. Therefore, a rate of 0.5 L/ha will be recommended on the product label for Austria, Belgium, Czech Republic, Ireland, Germany, The Netherlands, Poland and Slovenia.**

*B. Mycosphaerella brassicicola*

A total of 1 efficacy trial was carried in 2020 to evaluate the efficacy of IN005B1570 250EC in the Maritime EPPO climatic zone applied at 0.5 L/ha for the control of *Mycosphaerella brassicicola* in cabbage in comparison with the reference standard GEYSER, named DIFENO, at 0.5 L/ha. The trial was performed in France.

The full list of this trial is presented in Table 3.2-10.

The summary results of the efficacy of IN005B1570 250EC applied at 0.3-0.4-0.5 L/ha compared to the reference standard DIFENO at 0.5 L/ha are shown in Table 3.2-40.

**Table 3.2-40: Efficacy of IN005B1570 250EC against *Mycosphaerella brassicicola* in cabbage in Maritime EPPO climatic zone - Mean control**

Parts	Crop	No. of trials	Untreated control			Mean control (%)																No. of assessments significantly <sup>(1)</sup> > , = , < IN005B1570 250EC at 0.5 L/ha vs.		
						IN005B1570 0.3 L/ha				IN005B1570 0.4 L/ha				IN005B1570 0.5 L/ha				DIFENO 0.5 L/ha						
			Mean	Min	Max	Mea n	Min	Max	S.D.	Mea n	Min	Max	S.D.	Mea n	Min	Max	S.D.	Mea n	Min	Max	S.D.	IN005B1570 0.3 L/ha	IN005B1570 0.4 L/ha	DIFENO 0.5 L/ha
Disease severity on leaves	BRSOL	1	17.3	-	-	93.6	-	-	-	92.8	-	-	-	97.0	-	-	-	96.5	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	0> ; 1= ; 0<
Disease incidence on leaves		1	100.0	-	-	68.8	-	-	-	65.0	-	-	-	83.8	-	-	-	73.8	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	0> ; 1= ; 0<
Average number of infested leaves per plot		1	8.8	-	-	93.6	-	-	-	93.8	-	-	-	97.0	-	-	-	95.6	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	0> ; 1= ; 0<

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

For information, in the only trial performed in the Maritime EPPO climatic zone, at the last application, the infestation in untreated plot on leaves reached until 17% in cabbage.

On the disease severity, the efficacy of IN005B1570 250EC at 0.5 L/ha was similar to the reference DIFENO at 0.5 L/ha and demonstrated a very good control (respectively 97% vs. 97% mean control). No significant difference was noted in the trial. On the disease incidence, the efficacy of IN005B1570 250EC at 0.5 L/ha was superior to the reference DIFENO at 0.5 L/ha and demonstrated a good control (respectively 84% vs. 74% mean control). No significant difference was noted in the trial.

These results were similar on the number of infested leaves with respectively 97% vs. 96% mean control.

Overall, few data from field on cabbage are available (1 trial) for this disease for which proposed label claims are made for control with IN005B1570 250EC at 0.5 L/ha. However, a significant quantity of data is available from trials conducted on vegetables included in the section 3.2.3.3. It is asserted that these data provided additional information and assurance that IN005B1570 250EC SC work on various diseases as well as the reference product. Moreover, in all requested countries of Central regulatory zone, several preparations containing difenoconazole are currently registered on this use. Principals requested use are presented in Table 3.2-2.

**Therefore, by and large, with a moderate level of infestation, IN005B1570 250EC at 0.5 L/ha showed a good level of control on MYCOBR in the Central registration zone and was equivalent to the reference DIFENO. Therefore, a rate of 0.5 L/ha will be recommended on the product label for Austria, Belgium, Czech Republic, Ireland, Germany, The Netherlands, Poland and Slovenia.**

*C. Effect on the yield in presence of Brassicas crops diseases*

A total of 2 efficacy trials were harvested in 2020 in Maritime EPPO climatic zone (2 trials in France). The objective was to confirm the yield response of IN005B1570 250EC in the presence of fungi diseases in cole crop.

Table 3.2-41 shows a summary of positive effect on the yield of IN005B1570 250EC applied at 0.3, 0.4 and 0.5 L/ha compared to the reference standard DIFENO.

**Table 3.2-41: Positive effect on the yield of IN005B1570 250EC compared to the reference standard - Efficacy trials - Brassicas crop**

Target	EPPO climatic zone	No. of trials	Untreated control <i>t/ha</i>			Mean control (%)								No. of assessments significantly <sup>(1)</sup> > , = , < IN005B1570 250EC at 0.5 L/ha vs.
						IN005B1570 250EC 0.5 L/ha				DIFENO 0.5 L/ha				
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	DIFENO 0.5 L/ha
ALTEBI	Maritime	2	35.3	26.7	43.8	102.6	95.3	109.9	7.3	102.7	96.4	109.0	6.3	0> ; 2= ; 0<

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

In the Maritime EPPO climatic zone, the average yield reached 35 t/ha in the untreated plot (ranging from 27 t/ha to 44 t/ha in the individual trials).

IN005B1570 250EC at 0.5 L/ha had a positive effect on the yield of cole crop in the presence of ALTEBI. In fact, there was a 3 % increase in yield over the untreated. Overall, no significant difference was observed between IN005B1570 250EC and the reference standards DIFENO in all trials.

### 3.2.3.3.4 Conclusion on vegetables

A total of 20 valid efficacy trials conducted in the Maritime and North-East EPPO climatic zones (France, Germany, The Netherlands, Poland and The United Kingdom) evaluated the efficacy of IN005B1570 250EC at 0.4-0.5 L/ha against various diseases on carrot and brassicas crops.

In summary, the large set of data submitted on vegetables, showing a consistent control of a range of diseases, can fully support the requested dose rates for IN005B1570 250EC. Moreover, data demonstrated that the efficacy provided by IN005B1570 250EC at the different proposed rates was overall comparable to the efficacy provided by the reference products DIFENO.

Table 3.2-42 below summarises the results from the efficacy trials.

**Table 3.2-42: Overall summary of efficacy of IN005B1570 250EC on vegetables in Central registration zone**

Pathogen / Crop	Pest species (EPPO code)	Part ass.	Nb of trials	Efficacy (%) in Vegetables of				No. of assessments significantly <sup>(1)</sup> >, =, < IN005B1570 250EC at	
				IN005B1570 250EC at		DIFENO at		0.4 L/ha vs. DIFENO 0.4 L/ha	0.5 L/ha vs. DIFENO 0.5 L/ha
				0.4 L/ha	0.5 L/ha	0.4 L/ha	0.5 L/ha		
Leaf blight <i>Alternaria dauci</i> . Carrot	ALTEDA / DAUCS	Disease severity on leaves	8	80.6	-	79.1	-	1> ; 7= ; 0<	-
			6	-	73.6	-	72.2	-	1> ; 5= ; 0<
		Disease incidence on leaves	8	43.2	-	41.9	-	0> ; 8= ; 0<	-
			6	-	25.2	-	24.0	-	0> ; 6= ; 0<
Powdery mildew <i>Erysiphe heraclei</i> Carrot	ERYSHE / DAUCS	Disease severity on leaves	1	98.1	-	96.7	-	0> ; 1= ; 0<	-
			4	89.0	93.0	-	91.3	-	0> ; 4= ; 0<
		Disease incidence on leaves	1	79.2	-	73.3	-	0> ; 1= ; 0<	-
			4	52.2	61.3	-	50.0	-	0> ; 4= ; 0<
Leaf spot <i>Alternaria spp.</i> Brassicas crop	ALTESP / BRSOK - BRSOL - BRSOB	Disease severity on leaves	5	-	81.4	-	81.5	-	0> ; 4= ; 1<
		Disease incidence on leaves	5	-	33.3	-	34.3	-	1> ; 3= ; 1<
		Average number of infested leaves per plot	5	-	64.4	-	61.7	-	1> ; 4= ; 0<
Ring spot <i>Mycosphaerella brassicicola</i> Brassicas crop	MYCOBR / BRSOK - BRSOL - BRSOB	Disease severity on leaves	1	-	97.0	-	96.5	-	0> ; 1= ; 0<
		Disease incidence on leaves	1	-	83.8	-	73.8	-	0> ; 1= ; 0<
		Average number of infested leaves per plot	1	-	97.0	-	95.6	-	0> ; 1= ; 0<

Comments of zRMS:	<p>Details of experiment are presented above by Applicant. All used methodology is in accordance with GEP rules, in exception of EPPO 1/181 (4) for brassicas (trials on them were performed only in 2020). However, this exception can be accepted if brassicas can be treated as minor crops. And taking into account that the effectiveness of difenoconazole has already been confirmed in many studies.</p> <p>Applicant submitted in total <b>53</b> valid field trials showing the results in research into product efficacy carried out during two growing seasons (2020 and 2021) in winter oilseed rape (17 trials), apple (10 trials), carrot (<b>15</b> trials). Only one growing season was studied for brassicas (<b>5 trials</b>) in 2020. Also, Applicant presented 2 additional trials from 2022 performed on apple in PL (N-E) to validate the claimed use in the GAP. During commenting period Applicant submitted another 4 additional efficacy trials carried out on apples in PL (N-E) in 2023. So, in total Applicant submitted 16 valid trials for apple in four growing seasons (2020, 2021, 2022, 2023).</p> <p>Those efficacy trials were performed in Maritime EPPO zone (<b>31</b> trials), N-E EPPO zone (14 trials+ 2 additional apple trials <b>from 2022 + 4 additional trials from 2023</b>) and S-E EPPO zone (2 trials).</p> <p>We are dealing with the active substances used commonly for many years in many countries. We must emphasize that each pest should be representative by sufficient number of field efficacy tests (at least 6 for major pest and at least 3 for minor pest).</p> <p>The following efficacy scale was used:</p> <ul style="list-style-type: none"> <li>- L – limiting (0-60% efficacy)</li> <li>- ME – moderately efficiency (60-80%)</li> <li>- E – efficiently (&gt;80%)</li> </ul> <p><b>Oilseed rape</b> – only in Maritime EPPO zone enough trials was presented (CZ-1, FR-3, DE-4, UK-4). cMS from N-E EPPO zone (3 trials: PL) and S-E EPPO zone (2 trials: RO) should decide if limited number of trials can be accepted. Extrapolating results from other EPPO zone should be also consider. For Poland – required number of trials was presented (also results from neighbouring countries are acceptable from other EPPO zone): in total – 8 trials (CZ-1; DE-4 and PL-3).</p> <p>For Germany, the applicant would like to replace winter oilseed rape with oilseed rape. However, studies were carried only on winter oilseed rape. Lack of trials for spring oilseed rape. Such decision should be done on national level in line to national rules. For example, in PL such extrapolation without any trials is not possible. So, cMS should decide about possibility of extrapolation results between winter and spring oilseed rape at national level.</p> <p><b>Apple</b> – Maritime EPPO zone was not represented by the right number of trials. So, cMS from Maritime should decide if limited number of trials (5) can be accepted or consider extrapolating results from other EPPO zone. For N-E – Applicant submitted enough number of trials (in total <b>11</b>: 5 + 2 additional trials <b>from 2022 + 4 additional trials from 2023</b>). cMS from S-E should consider extrapolating results from other EPPO zone due to lack of trials. For Poland – required number of trials was presented (also results from neighbouring countries from other EPPO zone can be used): in total – <b>14</b> trials (DE-3 and PL-5+2 additional trials <b>from 2022 + 4 additional trials from 2023</b>).</p> <p><b>Brassicas</b> – only in Maritime EPPO zone enough trials was presented (FR-5) if we consider brassicas as minor crops. For cauliflower and head cabbage Applicant presented 2 trials and for broccoli – 1 trial. cMS from N-E and S-E EPPO zone should consider extrapolating results from other EPPO zone. In Poland, registration brassicas according to Article 33 is not possible. In the Polish label brassicas can be accepted only as minor crops according to Article 51 without any trial.</p> <p><b>Carrot</b> – both, in Maritime (<b>9</b> trials: FR-<b>4</b>, DE-2, NL-1, UK-2) and N-E EPPO zone (6 trials: PL) enough trials was presented. cMS from S-E should consider extrapolating results</p>
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from other EPPO zone due to lack of trials. For Poland – required number of trials was presented (also results from neighbouring countries from other EPPO zone are acceptable): in total – 8 trials (DE-2 and PL-6).

Not only the number of tests for individual crops is important, but also for disease units and timing of application (spring or autumn). Each important disease should be tested in at least 6 valid trials, and a disease of local importance should be tested in at least 3 trials.

Number of trials for each fungal disease:

- **winter oilseed rape**

**CYLSSP** – only one valid trial from S-E EPPO zone. This disease should be deleted from GAP table and label project due to not sufficient documentation. However, final decision is left to cMS. Registration of this use in Poland is not possible. **DE, AT and NL – not accepted. This use was not included in GAP table by Applicant.**

**LEPTMA – autumn** application: Maritime (4 trials: DE-1, UK-2, CZ-1, N-E EPPO zone (PL-1); S-E EPPO zone (RO-2). Each cMS should decide if limited number of trials can be accepted. In Poland registration for control LEPTMA at autumn application in winter oilseed rape is not possible. It is a major disease, so at least 6 valid trials are required. **DE and AT and NL – not accepted autumn application against LEPTMA.**

Applicant also studied two application of dose 0,25 L/ha per season. Those mentioned 2 applications were made in autumn in MAR (3 trials: UK-2, DE-1), N-E (2 trials: PL) and S-E (2 trials: RO), so it is not recommended for applied tested product once in autumn and twice in spring (when it was not studied). Final decision about acceptance of two applications is left to cMS. In Poland it is not acceptable due to not enough trials.

**LEPTMA – spring** application: N-E EPPO zone (PL-1). This disease should be deleted from GAP table and label project due to lack or very limited number of trials. However, final decision is left to cMS. In Poland registration for control LEPTMA at spring application in winter oilseed rape is not possible. It is a major disease, so at least 6 valid trials are required. Also, two applications per season were not studied. **DE and AT and NL – not accepted autumn application against LEPTMA.**

**ALTEBI – autumn** application: Maritime (FR-1). This disease should be deleted from GAP table and label project due to lack or very limited number of trials. However, final decision is left to cMS. In Poland registration for control ALTEBI at autumn application in winter oilseed rape is not possible. It is a major disease, so at least 6 valid trials are required. Also, two applications per season were not studied. **DE and AT and NL – not accepted autumn application against LEPTMA.**

**ALTEBI – spring** application: Maritime (FR-1). This disease should be deleted from GAP table and label project due to lack or very limited number of trials. However, final decision is left to cMS. In Poland registration for control ALTEBI at spring application in winter oilseed rape is not possible. It is a major disease, so at least 6 valid trials are required. Also, two applications per season were not studied. **DE and AT and NL – not accepted autumn application against LEPTMA.**

**SCLESC – spring** application on stems in Maritime (7 trials: CZ-1, FR-1, DE-3, UK-2) and N-E EPPO zone (PL-2). Enough trials were presented for Maritime EPPO zone. cMS from N-E should decide if limited number of trials can be acceptable or consider extrapolating results from other EPPO zone. cMS from S-E should consider extrapolating results from other EPPO zone due to lack of trials. For Poland – required number of trials was presented (also results from neighboring countries are acceptable): in total – 6 trials (DE-3, CZ-1 and PL-2). Only during 2 trials (DE) efficacy on pods was assessed and only in one trial (PL) on leaves. In the opinion, of ZRMs pods and leaves should be deleted from GAP table. However, final decision is left to each cMS. **In Poland only registration against SCLESC at spring application on stem is possible. DE and AT accepted this use only with restrictions**



(use at BBCH 60-69). NL – moderate efficacy is insufficient for NL to accept, irrespective of the limited number of trials. Oilseed rape will not be included in the label.

Applicant applied for BBCH application window: 30-69. However, in trials when SCLESC was studied only following BBCH was studied: 61-67. In the opinion of ZRMs, application window should be only for flowering (BBCH 60-69). Such wide application BBCH 30-69 is not accepted without trials.

In the Maritime EPPO climatic zone, on disease incidence, IN005B1570 250EC applied at 0.5 L/ha showed a similar control than the reference standard DIFENO (respectively 52% vs. 50% mean control). No significant difference was observed in all trials between IN005B1570 250EC applied at 0.5 L/ha and the reference DIFENO. These results were confirmed on the disease severity with 59% mean control for IN005B1570 250EC applied at 0.5 L/ha vs. 56% mean control for the reference standard DIFENO.

In the North-East EPPO climatic zone, on disease incidence, IN005B1570 250EC applied at 0.5 L/ha showed a slightly lower control than the reference standard DIFENO (respectively 53% vs. 58% mean control) but no significant difference was observed in all trials between IN005B1570 250EC applied at 0.5 L/ha and the reference DIFENO. These results were confirmed on the disease severity with 65% mean control for IN005B1570 250EC applied at 0.5 L/ha vs. 67% mean control for the reference standard DIFENO. In the Polish label, IN005B1570 250EC can be registered to limited SCLESC on winter oilseed rape stems at dose 0,5 L/ha applied once a season. Two applications can not be accepted due to lack of trials for 0,25 L/ha dose applied twice a season.

**SCLESC – autumn** application. Lack of trials. This use should be excluded from GAP table and label project. However, final decision is left to cMS. In Poland registration for control SCLESC at autumn application in winter oilseed rape is not possible. It is a major disease, so at least 6 valid trials are required. Also, two applications per season were not studied

Accepted water volume according to presented trials should be: 200-300 L/ha, not 100-500 L/ha. DE and AT and NL– not accepted this use.

- **Apple**


**VENTIN** is a major fungal disease in apple crops, so at least 6 valid trials are required. For Maritime EPPO zone Applicant submitted 5 trials against VENTIN on apple (recommended and studied dose was 0,225 L/ha) and for N-E EPPO zone – in total 11 trials: 5 + 2 additional valid trials (recommended and studied dose was 0,2 L/ha from 2022) + 4 additional valid trials (recommended dose was studied: 0,2 L/ha and 0,225 L/ha from 2023). The number of studies was too small for Maritime EPPO zone (at least 6 are required). Also, different doses were tested in two zones and the recorded effectiveness between zones had some discrepancies. Therefore, ZRMs will not use results from another zone for Poland (they can be use only as supportive). cMS from Maritime should decide if trials from PL with slightly different dose studied can be valid. In addition, the GAP table requests that the tested plant protection product can be registered for a maximum of 3 applications per season. Nonetheless, in the statements of efficacy studies, the Applicant has given efficacy from the first and last evaluation. The timing and number of treatments are related to aspects of resistance to difenoconazole against apple scab, however the nature of VENTIN control in practice requires more than 3 applications, therefore the relevant test protocol has been designed to clearly meet the requirements of the EPPO PP1/005 methodologies (3) *Venturia inaequalis* and *V. pyrina*. In studies conducted in Poland in 2021, the first evaluations on leaves were made after the third application - C : FEU-AGR-001-21-SCAP2-PL09 - 10 DA-C, FEU-AGR-001-21-SCAP2-PL10 - 6 DA-C and after the fourth application - D : FEU-AGR-001-21-SCAP2-PL11 - 6DA-D, FEU-AGR-001-21-SCAP2 - 10 DA-D.

It should be noted a very important issue of the technical application of the product, which


often makes it difficult to accurately confirm the recommended range of application of plant protection products (GAP table). These are pathogenic factors occurring in nature and biology, as well as the environment in which it multiplies and weather conditions that are necessary for its development, thus reaching the threshold of paralysis (in experimentation) and in practice (threshold of economic harmfulness). Temperatures from 17 to 24°C are optimal for the development of the VENTIN pathogen. The peak of ascospore release usually occurs shortly before or during flowering. The length of time it takes for infection to occur depends on the number of hours with continuous moisture and the temperature during the wet season. The secondary stage corresponds to the production of conidia and causes classic polycritical spread of the disease with rainfall. The first conidia are produced 2 to 4 weeks after the initial ascospore infections have completed their latent period.

According to EPPO PP1/005(3) Assessment on leaves: the first assessment is made when lesions appear corresponding to the period of primary scab infection. Further assessments should be made after later periods of infection if treatments are continued throughout the season. Bark assessment (if necessary): before the first application, record the number of bark lesions or the number of conidia on long shoots that grew in the previous season; repeat at harvest on long shoots that have grown in the current season.

Assessment on fruits: after the appearance of lesions (optional), second at harvest. All apple treatments in the MAR and N-East EPPO experiments were started according to the target GAP table, BBCH 51/57, with a 7-day interval between treatments. The assessment was made in accordance with PP1/005 (3) *Venturia inaequalis* and *V. pyrina* when the obtained level of VENTIN infestation required >5%. Taking into account the above information and the nature of the VENTIN biology, correlated with the weather conditions and the development of the disease in 2021/2022, the applicant was not able to provide the results of the assessments for the first three applications made in the apple cultivation trial programme.

The exceptions are  studies carried out in Poland in 2021, where the first evaluations on the leaves were made after the third application - C : FEU-AGR-001-21-SCAP2-PL09 - 10 DA-C, FEU-AGR-001-21-SCAP2 -PL10 - 6 DA-C and after the fourth application - D : FEU-AGR-001-21-SCAP2-PL11 - 6DA-D, FEU-AGR-001-21-SCAP2 - 10 DA-D.

Summarizing the arguments presented, the ZRMs requests – conditional approval of the use for the control of apple scab (VENRIN), based on the presented package of data specific to Poland:

- ✓ 2021 (5 E+M+S trials) + 2022 (2 E+M+S) - made in Poland in support of 0.200 L/ha of measure IN005B1570 250EC
- ✓ Germany 2021( 3 E+M+S) - made in Germany with the tested dose of N 0.225 L/ha, The fact that in the German studies the target dose of N was considered to be 0.225 L/ha of the IN005B1570 250EC preparation should be treated as a supporting data package for the Polish studies, where the tested dose of N of the IN005B1570 250EC preparation was 0.200 L/ha. The differences between the tested doses of N are in fact only 12%, which should be considered fully comparable from the point of view of effectiveness and agricultural practice.

These experiences prove the effectiveness of the product IN005B1570 250EC in three applications and are consistent with the GAP table recommended by the applicant.

The requested application window does not match the scores included in the detailed reports. Applications 1-3 were made at BBCH 57-84. The dates in which the assessments were made during the studies carried out in Poland: BBCH 71-80 were maintained in the range of recommended application dates, presented by the applicant in the GAP table, BBCH 57-85. However, given VENTIN's biology, weather conditions in 2021 and 2022, the level of scab infestation did not allow for earlier assessment dates that could confirm the product's effectiveness in the earlier stages of BBCH cultivation - BBCH 57-78. However,

the application dates shown in the submitted study reports reflect the most critical and common application timing relevant to apple scab control. Therefore, the application period should be BBCH phases 57-78.

Considering the level of effectiveness of IN005B1570 250EC obtained and presented in studies where evaluations were carried out after 3 and 4 applications, information on reducing the disease / infection of apple scab at the maximum recommended dose 0.200 L/ha at the time of application of BBCH 57-78.

Recommended water volume according to submitted trials should be 300-1000 L/ha, not 100-1500 L/ha.

During commenting period Applicant submitted 4 additional trials carried out on apple in PL (N-E) in which 3 applications of IN005B1570 were studied at BBCH 57-75. IN005B1570 was studied at dose 0,1 l/ha; 0,15 l/ha. 0,2 l/ha and 0,225 l/ha. So, ZRMs dropped from conditional registration. **In the opinion of ZRMs, new additional trials allowed to normal registration in Poland on apples against VENTIN.**

Below, ZRMs presented briefly summary form each preseneted adiotional trials.

**1) Trial 003GPSE202303**

The disease was present in untreated plots achieving 40.25% PESINC and 10.0% PESSEV on leaves and 10.3% PESINC on fruits. No symptoms of VENTIN were recorded on bark or shoots. The experimental formulation IN005B1570 showed a significant reduction in the pest incidence and severity when compared to the untreated check at almost all tested dose rate with exception of 0.1 L/ha dose rate which show insufficient efficacy levels. The results for dose rates of: 0.15 L/ha, 0.2 L/ha and 0.225 L/ha and 0.2 L/10000 m<sup>2</sup> LWA, 0.225 L/10000 m<sup>2</sup> LWA were statistically comparable to the reference of Score 250 EC at dose rate of 0.2 L/ha. Score 250 EC applied at dose rate of 0.075 L/10000 m<sup>2</sup> LWA provide insufficient level of VENTIN control. No symptoms of crop phytotoxicity effects nor impact on non-target organisms were observed following any treatment at any stage.

**2) Trial 003GPSE202304**

The disease was present in untreated plots achieving 28.0% PESINC and 8.25% PESSEV on leaves and 9.3% PESINC on fruits. No symptoms of VENTIN were recorded on bark or shoots. The experimental formulation IN005B1570 showed a significant reduction in the pest incidence and severity when compared to the untreated check at almost all tested dose rate with exception of 0.1 L/ha dose rate which show insufficient efficacy levels. The results for dose rates of: 0.15 L/ha, 0.2 L/ha and 0.225 L/ha and 0.2 L/10000 m<sup>2</sup> LWA, 0.225 L/10000 m<sup>2</sup> LWA were statistically comparable to the reference of Score 250 EC at dose rate of 0.2 L/ha. Score 250 EC applied at dose rate of 0.075 L/10000 m<sup>2</sup> LWA provide insufficient level of VENTIN control. No symptoms of crop phytotoxicity effects nor impact on non-target organisms were observed following any treatment at any stage.

**3) Trial 003GPSE202302**

The disease was present in untreated plots achieving 6.8% PESINC and 6.5% PESSEV on leaves at 14 DA-C and 8.8% PESINC on fruits during the harvest. No symptoms of VENTIN were recorded on bark or shoots. The experimental formulation IN005B1570 showed a significant reduction in the pest incidence and severity when compared to the untreated check at almost all tested dose rate with exception of 0.1 L/ha dose rate which show insufficient efficacy levels. The results for dose rates of: 0.15 L/ha, 0.2 L/ha and 0.225 L/ha and 0.2 L/10000 m<sup>2</sup> LWA, 0.225 L/10000 m<sup>2</sup> LWA were statistically comparable to the reference of Score 250 EC at dose rate of 0.2 L/ha. Score 250 EC applied at dose rate of 0.075 L/10000 m<sup>2</sup> LWA provide insufficient level of VENTIN control. No symptoms of crop phytotoxicity effects nor impact on non-target organisms were observed following any treatment at any stage.

**4) Trial 003GPSE202301**

The disease was present in untreated plots achieving 14.4% PESINC and 5.8% PESSEV on leaves at 12 DA-C and 6.8% PESINC on fruits. No symptoms of VENTIN were recorded on bark or shoots. The experimental formulation IN005B1570 showed a significant reduction in the pest incidence and severity when compared to the untreated check at almost all tested dose rate with exception of 0.1 L/ha dose rate which show insufficient efficacy levels. The results for dose rates of: 0.15 L/ha, 0.2

L/ha and 0.225 L/ha and 0.2 L/10000 m<sup>2</sup> LWA, 0.225 L/10000 m<sup>2</sup> LWA were statistically comparable to the reference of Score 250 EC at dose rate of 0.2 L/ha. Score 250 EC applied at dose rate of 0.075 L/10000 m<sup>2</sup> LWA provide insufficient level of VENTIN control. No symptoms of crop phytotoxicity effects nor impact on non-target organisms were observed following any treatment at any stage.

Below, ZRMs presented detailed results from additional trials. Assessment was made on leaves and fruits. Those trials are valid for Poland but may also be use by cMS (for example by DE).

**Efficacy of IN005B1570 250EC against *Venturia inaequalis* on apple - Disease incidence on leaves – additional 4 efficacy trials:**

Trial code	Untreated check		IN005B1570 0.2 L/ha			IN005B1570 0.225 L/ha			IN005B1570 calc.[0.113-0.168] L/ha LWA			IN005B1570 [0.15-0.2] L/ha			DIFENO [0.15-0.2] L/ha			
	Raw data	Stat	Raw data	Stat	% Cont	Raw data	Stat	% Cont	Raw data	Stat	% Cont	Raw data	Stat	% Cont	Raw data	Stat	% Cont	Rate applied
003GPSE202301	14.4	a	0.9	c	93.9	0.6	c	95.7	0.9	c	93.9	0.9	c	93.9	0.6	c	95.7	0.20 L/ha
003GPSE202302	6.8	a	1.0	b	85.2	1.0	b	85.2	1.0	b	85.2	1.0	b	85.2	1.0	b	85.2	0.20 L/ha
003GPSE202303	40.3	a	1.3	c	97.5	0.3	c	99.5	0.3	c	99.5	1.3	c	97.5	0.3	c	99.1	0.20 L/ha
003GPSE202304	28.0	a	1.0	c	97.1	0.3	c	98.4	0.3	c	98.4	1.0	c	97.1	0.3	c	98.8	0.20 L/ha

**Efficacy of IN005B1570 250EC against *Venturia inaequalis* on apple - Disease severity on leaves – additional 4 efficacy trials**

Trial code	Untreated check		IN005B1570 0.2 L/ha			IN005B1570 0.225 L/ha			IN005B1570 calc.[0.113-0.168] L/ha LWA			IN005B1570 [0.15-0.2] L/ha			DIFENO [0.15-0.2] L/ha			
	Raw data	Stat	Raw data	Stat	% Cont	Raw data	Stat	% Cont	Raw data	Stat	% Cont	Raw data	Stat	% Cont	Raw data	Stat	% Cont	Rate applied
003GPSE202301	5.8	a	0.1	c	98.3	0.1	c	98.3	0.1	c	98.3	0.1	c	98.3	0.1	c	98.3	0.20 L/ha
003GPSE202302	6.5	a	0.6	c	90.8	0.2	c	96.9	0.6	c	90.8	0.6	c	90.8	0.2	c	96.9	0.20 L/ha
003GPSE202303	10.0	a	1.0	b	89.2	1.0	b	92.3	1.0	b	89.2	1.0	b	89.2	1.0	b	89.2	0.20 L/ha
003GPSE202304	8.3	a	1.0	b	87.9	0.8	b	92.5	1.0	b	87.9	1.0	b	87.9	1.0	b	87.3	0.20 L/ha

**Efficacy of IN005B1570 250EC in against *Venturia inaequalis* on apple - Disease incidence on fruits - First assessment**

Trial code	Untreated check		IN005B1570 0.2 L/ha			IN005B1570 0.225 L/ha			IN005B1570 calc.[0.113-0.168] L/ha LWA			IN005B1570 [0.15-0.2] L/ha			DIFENO [0.15-0.2] L/ha			
	Raw data	Stat	Raw data	Stat	% Cont	Raw data	Stat	% Cont	Raw data	Stat	% Cont	Raw data	Stat	% Cont	Raw data	Stat	% Cont	Rate applied
003GPSE202303	7.8	a	1.3	c	85.2	1.0	c	87.1	1.0	c	87.1	1.3	c	85.2	0.5	c	92.7	0.20 L/ha
003GPSE202304	6.0	a	1.3	bc	80.1	0.8	c	86.7	0.8	c	86.7	1.3	bc	80.1	0.5	c	91.7	0.20 L/ha

**Efficacy of IN005B1570 250EC against *Venturia inaequalis* on apple calculated on the total number of fruits per class per treatment - Index severity on fruits - First assessment**

Trial code	Class / Index	Untreated check	IN005B1570 0.2 L/ha			IN005B1570 0.225 L/ha			IN005B1570 calc.[0.113-0.168] L/ha LWA			IN005B1570 [0.15-0.2] L/ha			DIFENO [0.15-0.2] L/ha			
			No. of fruit /	No. of fruit /	%	No. of fruit /	No. of fruit /	%	No. of fruit /	No. of fruit /	%	No. of fruit /	No. of fruit /	%	No. of fruit /	No. of fruit /	%	Rate applied

		Severity index	Severity index	Control	Severity index	Control	Severity index	Control	Severity index	Control	Severity index	Control							
003GPSE202303	Class 1	369	395	-	396	-	396	-	395	-	398	-	0.20 L/ha						
003GPSE202303	Class 2	21	3	-	3	-	3	-	3	-	2	-							
003GPSE202303	Class 3	10	2	-	1	-	1	-	2	-	0	-							
003GPSE202303	TH calcul	5.1	0.9	82.9	0.6	87.8	0.6	87.8	0.9	82.9	0.3	95.1							
003GPSE202304	Class 1	376	395	-	397	-	397	-	395	-	390	-	0.20 L/ha						
003GPSE202304	Class 2	15	3	-	3	-	3	-	3	-	5	-							
003GPSE202304	Class 3	9	2	-	0	-	0	-	2	-	5	-							
003GPSE202304	TH calcul	4.1	0.9	78.8	0.4	90.9	0.4	90.9	0.9	78.8	1.9	54.5							
Efficacy of IN005B1570 250EC in against Venturia inaequalis on apple - Disease incidence on fruits - Last assessment																			
Trial code	Crop stage at assess.	Untreated check		IN005B1570 0.2 L/ha			IN005B1570 0.225 L/ha			IN005B1570 calc.[0.113-0.168] L/ha LWA			IN005B1570 [0.15-0.2] L/ha			DIFENO [0.15-0.2] L/ha			Rate applied
		Raw data	Stat	Raw data	Stat	% Cont	Raw data	Stat	% Cont	Raw data	Stat	% Cont	Raw data	Stat	% Cont	Raw data	Stat	% Cont	
003GPSE202301	87	6.8	a	0.0	c	100.0	0.0	c	100.0	0.0	c	100.0	0.0	c	100.0	0.0	c	100.0	0.20 L/ha
003GPSE202302	87	8.8	a	0.0	c	100.0	0.0	c	100.0	0.0	c	100.0	0.0	c	100.0	0.0	c	100.0	0.20 L/ha
003GPSE202303	87	10.3	a	1.5	bc	85.4	3.3	bc	61.9	3.3	bc	61.9	1.5	bc	85.4	0.5	c	94.2	0.20 L/ha
003GPSE202304	87	9.3	a	1.5	b	83.3	2.3	bc	71.0	2.3	bc	71.0	1.5	b	83.3	0.5	c	94.2	0.20 L/ha
Efficacy of IN005B1570 250EC against Venturia inaequalis on apple calculated on the total number of fruits per class per treatment - Index severity on fruits - Last assessment																			
Trial code	Class / Index	Untreat-ed	IN005B1570 0.2 L/ha			IN005B1570 0.225 L/ha			IN005B1570 calc.[0.113-0.168] L/ha LWA			IN005B1570 [0.15-0.2] L/ha			DIFENO [0.15-0.2] L/ha			Rate applied	
		check																	
	No. of fruit / Severity index	No. of fruit / Severity index	% Control	No. of fruit / Severity index	% Control	No. of fruit / Severity index	% Control	No. of fruit / Severity index	% Control	No. of fruit / Severity index	% Control	No. of fruit / Severity index	% Control	No. of fruit / Severity index	% Control				
003GPSE202301	Class 1	373	400	-	400	-	400	-	400	-	400	-	400	-	400	-	0.20 L/ha		
003GPSE202301	Class 2	14	0	-	0	-	0	-	0	-	0	-	0	-	0	-			
003GPSE202301	Class 3	13	0	-	0	-	0	-	0	-	0	-	0	-	0	-			
003GPSE202301	TH calcul	5.0	0.0	100	0.0	100	0.0	100	0.0	100	0.0	100	0.0	100	0.0	100			
003GPSE202302	Class 1	365	400	-	400	-	400	-	400	-	400	-	400	-	400	-	0.20 L/ha		
003GPSE202302	Class 2	19	0	-	0	-	0	-	0	-	0	-	0	-	0	-			
003GPSE202302	Class 3	16	0	-	0	-	0	-	0	-	0	-	0	-	0	-			
003GPSE202302	TH calcul	6.4	0.0	100	0.0	100	0.0	100	0.0	100	0.0	100	0.0	100	0.0	100			
003GPSE202303	Class 1	359	394	-	387	-	387	-	394	-	398	-	398	-	398	-	0.20 L/ha		
003GPSE202303	Class 2	28	4	-	10	-	10	-	4	-	2	-	2	-	2	-			



NL – multiple sequential applications have applied instead of the 3 mentioned in the GAP. NL agrees with the zRMS that this may be acceptable. NL could include a sentence on the label indicating that to obtain a balanced spraying scheme IN005B1570 should be alternated with fungicides with a different mode of action. NL agrees on the point risen by the zRMS

that it is not accurate to assess after 9 and 10 application of tested product, instead of 3, which will be claimed on the label. However, given the very similar results after first application compared to later, NL accepts this approach. Also because in practice spraying will be performed more than 3 times, but with fungicides with different mode of action, the effectiveness after three subsequent applications is not practically valid. Rate of the reference tested (0.15 and 0.2) was lower than that of the minimum effective dose rate as established for the maritime zone (0.225). For that reason the results cannot be compared directly. In the maritime zone also the dose rate of 0.2 was tested and those results can be compared to those of the reference. However, that is only valid assuming that the reference would also give similar results to IN005B1570 at rate of 0.225. In addition, the number of trials is too low: 4 or 5 valid trials, where EPPO standards require 6 valid trials. Comparing the results for the N-E zone to those in the maritime zone suggest that the trials performed in Poland could be accepted as additional trials. However, those are also performed at the lower dose rate of 0.2. Given the results across dose rates, and given the fact that the active substance has an extensive track record, NL can consider including the results from Poland in the number of valid trials for validating the efficacy of IN005B1570.

**Below, we present the Applicant's arguments for cMs in support of accepting the documentation presented in this report:** *“The data within this section demonstrates the efficacy of IN005B1570 250EC for the control of Venturia inaequalis on apple applied as multiple sequential applications. Although the GAP claims a maximum of 3 applications per crop per season, the regulatory advice in most test countries is to apply multiple applications based on the recommended GAP interval between treatments in order to demonstrate efficacy of the product, Venturia inaequalis pressure may be season long. Repeated applications will ensure that efficacy can be demonstrated on at least one of the actively damaging cycles per season and has the advantage over programmes consisting of other products in respect of demonstrating only the efficacy of the active ingredient under test.*

*Therefore, the justification for use of multiple applications of IN005B1570 250EC is that infection pressure continues through the growing season, with the most critical period for epidemic disease development coinciding with rapid vegetative growth of pome fruit trees. IN005B1570 250EC is a preventative and curative fungicide with a period of protection of 7-10 days based on diseases and conditions. Therefore, to cover the Venturia inaequalis infection period during the growing season, multiple applications are required. However, due to resistance management requirements, it is deemed that the maximum number of applications of IN005B1570 250EC per season should not be more than 3.*

*The applicant acknowledges that the data submitted with the initial application may appear unclear. The nature of the trial's programmes required for multi-application fungicide (and insecticide) products is that it is frequently necessary to apply the experimental products in a manner that does not exactly match the label or GAP recommendations, in order to obtain the necessary information regarding protectant and curative activity, and to gain information on all relevant plant organs (e.g., leaves and fruit).*

*To conduct trials in which only three applications were made would expose growers to the risk of severe disease infection, as the trial area would have to remain unsprayed until late in the season. This is unacceptable to most commercial growers, particularly when there is the risk of inoculum carry-over in infected leaves in orchards. Alternatively, to prevent this a commercial programme would have to be applied across the entire trial area, including the untreated plots, which would inhibit the development of disease and may render all trial results worthless.*

*Continuous application of the experimental treatments to the same plots over the course of the growing season is in some senses an artificial situation but does permit direct comparisons of the performance of experimental and reference treatments and has the advantage, over programmes consisting of the evaluation of other products, in respect of demonstrating only the efficacy of the product under test under different conditions and growth stages. It*

also allows the trial investigators to gain the maximum amount of information from small plot trials.

*It is impossible to test a product in all possible commercial combinations and sequences. Representative programmes may be tested, but these will only ever provide a snapshot of the place of the experimental product over a limited time frame. Therefore, in the experimental phase of the testing process the product must be applied alone if we are to understand the nature of its activity against key diseases.*

#### **EFFECTIVENESS ACCORDING TO LWA APPROACH:**

According to EPPO PP 1/239, the application rate should be calculated per treated leaf wall area unit (LWA) and results of the test product should be presented and interpreted according to LWA by the applicant. From efficacy's point of view, the reference to ha ground area is not sufficient anymore (EPPO PP 1/239). Therefore, the Evaluator calculated the LWA for IN005B1570, using the treated canopy height as well as the row distance between the rows from the single trial reports (where these parameters were available).

#### **Conversion of the application dose in L/ha LWA:**

According to the EPPO guideline PP 1/239(2) “great efforts are being made to obtain optimum efficacy from the applied product and to avoid unnecessary emission of products into the environment and residues in feed and food” and “the best way to achieve this is to adapt dose rate to the area where the treatment is needed (e.g., crop canopy) and its structure.

An easy way to establish correct application dose in three-dimensional crops is to use dose per treated leaf area unit (LWA).

To calculate LWA is needed to know distance between rows and treated foliage height.

#### **Calculation of LWA:**

$$\text{Leaf Wall Area (LWA)} = \frac{2 \times \text{tree height [m]}}{\text{distance between rows [m]}} \times 10\,000 \text{ m}^2/\text{ha}$$

For determining the dose per ha ground for every m canopy height we should dose per ha LWA \* conversion factor (the conversion factor is calculated by dividing the leaf wall area by 10 000) \* canopy height (m) = ‘dose per ha ground per m canopy height).

Trial	Appli.	Orchard parameters				IN005B1570 0.2 L/ha	IN005B1570 0.225 L/ha	IN005B1570 calc.[0.113- 0.168] L/ha LWA
		Treated foliage height (m)	Row distance (m)	Spray volume L/ha	LWA m <sup>2</sup> of orchard	L/ha LWA	L/ha LWA	
FEU-AGR-004-20-SCAP-FR001	11	1.7	3.6	600	9444	-	0.238	<b>0.159</b>
FEU-AGR-001-21-SCAP1-FR06	10	2.0	4.0	600	10000	-	0.225	<b>0.150</b>
FEU-AGR-001-21-SCAP-DE01	10	2.1	3.5	1000	12000	-	0.188	<b>0.125</b>
FEU-AGR-001-21-SCAP-DE04	14	2.5	3.4	600	14706	-	<b>0.153</b>	<b>0.153</b>
FEU-AGR-001-21-SCAP1-DE05	10	2.0	2.0	1000	20000	-	<b>0.113</b>	<b>0.113</b>
FEU-AGR-001-21-SCAP2-PL08	16	2.5	3.7	1000	13514	<b>0.148</b>	-	<b>0.148</b>
FEU-AGR-001-21-SCAP2-PL09	10	2.1	3.5	750	12000	<b>0.167</b>	-	<b>0.167</b>
FEU-AGR-001-21-SCAP2-PL10	10	1.7	3.8	700	8947	0.224	-	<b>0.168</b>
FEU-AGR-001-21-SCAP2-PL11	10	2.6	3.5	1000	14857	<b>0.135</b>	-	<b>0.135</b>
FEU-AGR-001-21-SCAP2-PL12	10	2.5	4.0	500	12500	<b>0.160</b>	-	<b>0.160</b>
22SAG01062-1 – additional test 1	12	2.2	4.0	1000	11500	<b>0.174</b>		<b>0.174</b>
7334.F.SAG22 -additional test 2	12	2.2	3.8	1000	11500	<b>0.174</b>		<b>0.174</b>
003GPSE202301 – additional trial	3	2.4	4.0	700	12000	<b>0.167</b>	0.188	<b>0.167</b>
003GPSE202302 – additional trial	3	2.4	3.5	750	13714	<b>0.145</b>	0.164	<b>0.164</b>
003GPSE202303 – additional trial	3	2.5	3.4	800	14706	<b>0.136</b>	0.153	<b>0.153</b>
003GPSE202304 – additional trial	3	2.5	3.2	800	15625	<b>0.128</b>	0.144	<b>0.144</b>



According to submitted trials by Applicant dose LWA for Maritime EPPO zone should be 0,14 L/ha LWA (as an average from 5 trials) and for N-E EPPO zone should be 0,15 L/ha LWA. In GAP table, Applicant proposed average from MAR and N-E: 0,15 L/ha. However, in the opinion of ZRMs for each EPPO zone should be presented recommended dose. Especially when the recorded effectiveness between zones differed and the same dose was not tested in both climate zones. However, final decision is left to each cMS.

- *Pear*

No trials were provided for scab in pear. According to EPPO it is justified to extrapolate from apple to pear if the database in apple is sufficient. The apple trials could be used as a database for the application in pear. An extrapolation is possible. Countries in other EPPO zones have to decide if data are sufficient for registration a pear. In the opinion of ZRMs, extrapolating results from apple should be possible only in case of sufficient documentation for apple which did not happen in this case. So, final decision about pear is left to each cMS. In Poland registration pear is possible only in line to Article 51 as a minor crop without any trial. For extrapolation results from apple at least 1-2 efficacy trials carried out in N-E or country neighboring to Poland from other EPPO zone. So, registration pear in accordance with Article 33 is not possible. DE – accepted this use. NL and AT – not accepted use.

EFFECTIVENESS ACCORDING TO LWA APPROACH:

Since no studies have been presented for pear, cMS should consider extrapolating the LWA dose from apple trees. However, it should be kept in mind that pear trees can vary in height and distance between rows, which can affect the LWA value. Therefore, cMS, should consider the LWA dose for pear based on standard growing conditions. For example, in Poland the average LWA for pear is usually between 10000-12000 (average: 11000), which corresponds to 0,18 L/ha LWA (it corresponds to dose per ground 0,2 L/ha) and 0,20 L/ha LWA (which corresponds to dose 0,225 L/ha per ground). Recommended water volume according to submitted trials should be 300-1000 L/ha, not 100-1500 L/ha.

- *Brassicas*

**against ALTEBI:** Applicant submitted 5 valid trials for brassicas carried out in one EPPO zone - Maritime (FR). Lack of trials for N-E EPPO zone and S-E EPPO zone. During French trials one fungal disease was studied: *Alternaria brassicicola*. Three different brassica crops were studied during trials: broccoli (1 trial), head cabbage (2 trials), cauliflower (2 trials). If brassicas are major crops, documentation is not acceptable. In the opinion of ZRMs, if brassicas in MAR have minor status, the documentation for registration is possible. According to EPPO extrapolating results for minor uses, the indicator crop could be: cauliflower BRSOB or broccoli BRSOK or Brussels sprouts BRSOB and from them extrapolating results to leafy and flower head and root brassicas is possible. So, all brassicas crop group could be registered in MAR. However, final decision is left to cMS. In the opinion of ZRMs, cMS from S-E and N-E EPPO zone should consider extrapolating results from MAR or could consider registration according to Article 51 without any trials. In Poland, only registration according to Article 51 for brassicas against ALTEBI will be possible. DE – accepted this use. NL- minor use (Art. 51).

Applicant proposed 3 applications per season. However, proposed application window BBCH 19-21 applies only to one application (the first) and does not take into account the use of two more applications recommended. In the opinion of ZRMs application window for all brassicas should be the same and in line with the research presented. So, accepted application window should be as follows: BBCH 19-39 (from the stage of development of lateral shoots to the stage of visible 9 or more internodes). The applicant submitted 8 residue trials in cabbage, 4 in broccoli and 4 in cauliflower. However, the final reports as well as the updated sections of the dossier (Part B7 and Part A) have been evaluated by zRMS residue

	<p>specialist and considered acceptable (see notes from zRMS in residue section). Therefore, the applicant kindly asks to extend application window to 19-49 instead of 39. ZRMs efficacy section accepted the BBCH 19-49 for brassicas crops, instead of BBCH 19-39.</p> <p>Recommended water volume according to submitted trials should be 200-600 L/ha, not 200-1000 L/ha.</p> <p>In cauliflower, 7 days intervals between second and third application was studied, only between first and second application was 14 days. In broccoli and head cabbage – 7 days intervals were studied. ZRMs accepted proposed interval days for brassicas crops proposed by Applicant.</p> <p>Applicant in the tables presented efficacy results after last assessment, which was after 4 applications (3 trials), 10 applications (1 trial) and 6 applications (1 trial) not 3 applications as requested in the GAP table. So, cMS should decide if 3 application per season can be accepted without assessment at this timing. Product was characterized by moderately efficiency considering the effectiveness at disease severity on leaves (81.4% eff.), disease incidence on leaves (33.3% eff.) and average number of infested leaves per plot (64.4% eff.). All results were comparable to standard reference products used during trials.</p> <p><b>against MYCOBR</b> (<i>Mycosphaerella brassicicola</i>) – only one trial carried out on cabbage for this disease was presented by Applicant in the Maritime EPPO zone. Each cMS should decide if registration this use can be accepted on the basis on very limited number of trials. In Poland only registration according to Article 51 will be possible for <i>Mycosphaerella brassicicola</i> on brassicas (cauliflower, head cabbage and broccoli). <b>DE – accepted this use. NL- minor use (Art. 51).</b> The final reports as well as the updated sections of the dossier (Part B7 and Part A) have been evaluated by zRMS residue specialist and considered acceptable (see notes from zRMS in residue section). Therefore, the applicant kindly asks to extend application window to 19-49 instead of 39. ZRMs efficacy section accepted the BBCH 19-49 for brassicas crops, instead of BBCH 19-39.</p> <p>Recommended water volume according to submitted trials should be 200-600 L/ha, not 200-1000 L/ha.</p> <p>- <b>Carrot</b></p> <p><b>against Alternaria dauci</b> – Applicant submitted in total 15 trials: MAR 8 trials (FR-3, DE-2, UK-2, NL-2) and N-E 6 trials (PL). According to submitted documentation registration in Maritime and N-E EPPO zone is possible. cMS from S-E should consider extrapolating results from other EPPO zone or registration carrot according to Article 51, if it is a minor crop. <b>DE and NL – accepted this use.</b></p> <p>Applicant proposed following application window: BBCH 39-40. However, during trials following BBCH was studied (between first and third application) 42-49. In the opinion of ZRMs accepted application window for carrot should be for BBCH 40-49 (development of plant parts for harvesting). 14 days of interval is accepted.</p> <p>Efficacy was assessed after 3 applications in 13 trials (only in one French trials efficacy was assessed after 5 application). On the basis on submitted documentation it can be consider that IN005B1570 limited disease incidence on leaves (eff. &lt; 40%) and moderately efficiency control the disease severity on leaves (eff. 72-80%).</p> <p><b>against Erysiphe heraclei</b> – Applicant submitted in total 5 trials. All trials were carried out only in one EPPO zone – Maritime (FR-3, DE-1, NL-1). Lack of trials performed in N-E and S-E EPPO zone on carrot against <i>Erysiphe heraclei</i>. So, cMS from those zones should consider extrapolating results from other EPPO zone or registration control <i>Erysiphe heraclei</i> on carrot according to Article 51 (without any trial), if carrot is a minor crop. In Poland, only registration according to Article 51 against <i>Erysiphe heraclei</i> on carrot is possible. <b>DE and NL – accepted this use.</b></p>
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	<p>Applicant proposed following application window: BBCH 39-40. However, during trials following BBCH was studied (between first and third application) 42-47. In the opinion of ZRMs accepted application window for carrot should be for BBCH 40-49 (development of plant parts for harvesting). 14 days of interval is accepted.</p> <p>During 3 trials efficacy after 3 applications were assessed and during 2 trials – after 5 applications (DE, FR). On the basis on submitted documentation it can be consider that IN005B1570 limited disease incidence on leaves and efficiency control the disease severity on leaves (eff. &gt;90%).</p> <p><b>against <i>Alternaria radicina</i></b> – Lack of trials for this disease was presented by Applicant. Each cMS should decide if registration this use can be accepted without any trial or can consider extrapolating results from <i>Alternaria dauci</i>. In Poland only registration according to Article 51 will be possible for <i>Alternaria radicina</i> on carrot. <b>DE and NL– accepted this use.</b></p>
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### 3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

IN005B1570 250EC is a fungicide for the control of different diseases on several crops (pome fruits, vegetables and brassicas) at different dose rates according to the requested uses.

The formulation contains 250 g/L difenoconazole as active substance. A resistance risk analysis has been conducted in accordance to EPPO guideline PP1/213(3) ‘Resistance risk analysis’.

#### 3.3.1 Mode of Action

Difenoconazole is a fungicide used in agriculture for the control of various diseases including Powdery mildews (e.g. *Erysiphe heraclei*, *E. communis*), scab (*Venturia inaequalis*, *V. pyrina*), *Alternaria spp.* (*A. solani*, *A. alternata*, *A. dauci*) and bunt (*Tilletia caries*, *T. controversa*) in a range of crops. Difenoconazole is a systemic pesticide belonging to the group of triazoles.

Difenoconazole is a translaminar (weakly xylem-mobile) fungicide with long-lasting preventative and curative broad-spectrum control, including leaf spot diseases, powdery mildews, rusts and scab of annual and perennial crops. It is active against plant pathogens belonging to the Deuteromycota, Basidiomycota and Ascomycota.

Difenoconazole is from the triazole class of chemistry, and its mode of action is similar to other triazoles (sterol demethylation inhibitors = DMIs, group G1), i.e. its main biochemical mode of action is the inhibition of cytochrome P-450 sterol 14 $\alpha$ -demethylase (P-45014DM), a key enzyme of the sterol biosynthetic pathway of fungi, which stops the development of fungi by interfering with the biosynthesis of sterols in cell membranes.

Triazole fungicides are systemic or translaminar compounds with quick uptake and acropetal translocation in the xylem, resulting in good distribution in the plant tissue and protection from being washed off. When taken up by the plant, difenoconazole acts on the fungal pathogen during penetration and haustoria formation. It stops the development of fungi by interfering with the biosynthesis of sterols in cell membranes. Interference with sterol biosynthesis leads to disruption of membrane function, leakage of cytoplasmic contents and hyphal death.

Based on the FRAC classification, the DMI's (FRAC code 3) are considered as a medium-risk group to fungicide resistance development.

### 3.3.2 Mechanism of resistance

In general, DMI fungicides are considered to have a medium risk of resistance development.

More than 40 sterol biosynthesis inhibitor fungicides are available to control a big variety of plant pathogens. Because the mechanism of resistance is mostly controlled by the accumulation of several independent mutations and is referred to as "quantitative resistance", the inherent resistance risk to DMI fungicides has been classified as a medium risk. The resistance factors associated to single mutations at target gene (*cyp51*) are relatively small. Resistance to DMI's has been shown to be in the form of small shifts occurring over a long period of time and the phenotype correspond rather to reduced sensitivity than to resistance. Only in rare cases truly resistant isolates have been found in a few species.

Prominent examples for the shifting behaviour of DMI fungicides are *Zymoseptoria tritici* (aka *Mycosphaerella graminicola*) and *Venturia inaequalis*. There are ample reports for shifting in *Erysiphe* species on cereals and *Cercospora beticola* in sugar beet. To our knowledge, no reports on sensitivity shift for *Alternaria* species have been described. DMI sensitivity of apple scab causal agent *Venturia inaequalis* is stable since many years after having experienced a sensitivity shift in the past. The potential mechanism of this shift is reported to be due to insertions in the promoter of the *cyp51* in *V. inaequalis* leading to overexpression of the enzyme. Phoma leaf spot and stem canker (*Leptosphaeria maculans* and *biglobosa*) monitoring showed a stable DMI sensitivity range from 2006 to 2015 in Europe.

Several resistance mechanisms to DMIs are known, including a number of target site mutations on the *cyp51* gene (cytochrome p450), overexpression of the *cyp51* gene and effects on ABC transporters. DMIs have no cross resistance to any of the other major fungicide classes e.g. MBC, QoIs, or SDHIs.

*Z. tritici* has become a model organism to study plant pathogen fungicide resistance evolution. Changes in DMI sensitivity in *Z. tritici* were studied extensively during the last years and the mechanisms involved were largely elucidated, as described below. These findings are of interest as general information concerning the mechanisms involved in DMI sensitivity shift, although this pathogen is not directly relevant to this submission. In *Z. tritici*, mutations in the *cyp51* gene were detected at several positions leading to six genotype groups. They carry different combinations of mutations in the *cyp51* gene and express varying degrees of sensitivity to DMIs ranging from: i) very high sensitivity (wild-type isolates, genotype I), ii) slightly reduced sensitivity (type II, Y137F), iii) moderately reduced sensitivity (type III, heterogeneous genotype), iv) significantly reduced sensitivity (type IV, V136A; type V, I381V; type VI, A379G plus I381V). Most mutations when occurring singly had only small impact on sensitivity in a particular isolate, and no isolates with complete resistance have been found in field populations up to now. The composition of *cyp51* genotypes in field populations changed significantly over the last two decades, wild-type isolates disappeared, whereas genotypes III to VI predominate in recent populations.

### 3.3.3 Evidence of resistance

Resistance development towards DMI fungicides was observed for *Venturia inaequalis* in apple, which are amongst others, the claimed targets in this dossier.

According to FRAC<sup>7</sup>, *Venturia inaequalis*, is considered to be a high risk pathogen. This pathogen has evolved resistance to fungicides in a time span sufficiently short to be a serious threat to the commercial success of more than one fungicide class.

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<sup>7</sup> <https://www.frac.info/docs/default-source/publications/pathogen-risk/frac-pathogen-list-2019.pdf>

**Table 3.3-1: Pathogens resistant to DMI Fungicides, reported by FRAC**

MOA Code	FRAC Group Code	Pathogen	Common name	Crop	Reference	Remarks
G1	3	<i>Aspergillus nidulans</i>	-	-	De Waard & van Nistelrooy 1979	Genetic study
		<i>Blumeriella jaapii</i>	Leaf spot	Cherry	Proffer <i>et al.</i> 2006	Field
		<i>Botrytis cinerea</i>	Grey mold	Vegetables Various	Elad 1992 Stehmann & De Waard 1996	Field Laboratory investigation of lack of intrinsic activity
		<i>Calonectria pauciramosa</i>		Nurseries	Guarnaccia <i>et al.</i> 2014	Field
		<i>Calonectria polizzii</i>		Nurseries	Guarnaccia <i>et al.</i> 2014	Field
		<i>Cercospora beticola</i>	Leaf spot	Sugar beet	Henry & Trivellas 1989 Karaoglanidis <i>et al.</i> 2000 Budakov <i>et al.</i> 2014	Laboratory mutants Field isolates Field
		<i>Cladosporium caryigenum</i>	Scab	Pecan	Reynolds <i>et al.</i> 1997	Cross resistance, laboratory
		<i>Colletotrichum gloeosporioides</i>	Anthraxnose	Mango	Gutierrez-Alonso <i>et al.</i> 2003	Postharvest / laboratory
		<i>Erysiphe graminis f.sp. hordei</i>	Powdery mildew	Barley	Fletcher & Wolfe 1981	Field
		<i>Erysiphe graminis f.sp. tritici</i>	Powdery mildew	Wheat	De Waard <i>et al.</i> 1986	Field
		<i>Fusarium asiaticum</i> <i>Fusarium graminearum</i>	Fusarium head blight	Wheat	Yin <i>et al.</i> 2009	Lab study on isolates from China
		<i>Fusarium graminearum</i>	Head blight	Wheat	Spolti <i>et al.</i> 2014	Field
		<i>Fusarium fujikuroi</i>	-	-	Zhao Zhi-hua <i>et al.</i> 2007	Laboratory mutation (prochloraz)
		<i>Fusarium monilifore</i>	Bakanae	Rice	Yanh HongFu <i>et al.</i> 2013	Field
		<i>Fusarium verticillioides</i>	Fusarium	Corn	Fan <i>et al.</i> 2014	Laboratory
		<i>Microdochium (Fusarium) nivale</i>	-	-	Cristani & Gambogi 1993	Laboratory
		<i>Monilinia fructicola</i> *	Twig blight, brown rot	Stone fruits	Nuninger-Ney <i>et al.</i> 1989 Elmer <i>et al.</i> 1992 Chen <i>et al.</i> 2013	Laboratory Field Field
		<i>Mycosphaerella fijiensis</i>	Sigatoka	Banana	Anonymous 1992	
		<i>Mycosphaerella graminicola</i> / <i>Septoria tritici</i>	Leaf spot	Wheat	Metcalfe <i>et al.</i> 2000 Mavroedi & Shaw 2005 HGCA 2005 Cools <i>et al.</i> 2005	Field experiments Field experiments Field Laboratory
		<i>Mycovellosiella natrassii</i>	Leaf mold	Eggplant	Yamaguchi <i>et al.</i> 2000	Field
		<i>Nectria haematococca</i> var. <i>cucurbitae</i>	Foot rot	Cucurbits	Kalamarakis <i>et al.</i> 1991	Laboratory genetics
		<i>Penicillium digitatum</i>	Green mold	Citrus	Eckert 1987 Wang Jinlong <i>et al.</i> 2014	Laboratory Selection Storage
		<i>Penicillium italicum</i>	Blue mold	-	De Waard <i>et al.</i> 1982	Laboratory
		<i>Pseudocercospora herpotrichoides</i> Lente or R type	Eyespot	Wheat	Leroux & Marchegay 199	Field
		<i>Puccinia horiana</i>	White rust	Chrysanthemum	Cevat 1992 Cook 2001	Field Field
		<i>Puccinia striiformis</i>	Yellow / stripe rust	Wheat	Bayles <i>et al.</i> 2000 Napier <i>et al.</i> 2000	Sensitivity shift Laboratory
		<i>Pyrenophora teres</i>	Net blotch	Barley	Sheridan <i>et al.</i> 1985	Field
		<i>Pyrenophora tritici-repentis</i>	Tan spot	Wheat	Reimann & Deising 2005	Field
		<i>Rhizoctonia solani</i>	Rhizoctonia leafspot	Rice	Manish Agrawal <i>et al.</i> 2013	Field
		<i>Rhynchosporium secalis</i>	Leaf blotch, scald	Barley	Hunter <i>et al.</i> 1986 Kendall & Hollomon 1990 Kendall <i>et al.</i> 1993 Cooke <i>et al.</i> 2004	Glasshouse Field Field isolates Field
		<i>Sclerotinia homoeocarpa</i>	- Dollar spo	- Turfgrass	Vargas <i>et al.</i> 1992 Ma & Tredway 2013	Laboratory Field
		<i>Sphaerotheca fuliginea</i>	Powdery mildew	Cucumber	Schepers 1983, 1985a, 1985b	Field
		<i>Sphaerotheca mors-uvae</i>	Powdery mildew	Blackcurrant	Goszczynski <i>et al.</i>	Field

MOA Code	FRAC Group Code	Pathogen	Common name	Crop	Reference	Remarks
					1988	
		<i>Sphaerotheca pannosa</i> *	Powdery mildew	Nectarine	Reuveni 2001	Field
		<i>Trichoderma koningii</i>	-	-	Figueras-Roca <i>et al.</i> 1996	Laboratory
		<i>Erysiphe necator/ Uncinula necator</i> *	Powdery mildew	Grapevine	Steva <i>et al.</i> 1990 Reidi & Steinkellner 1996 Miller & Gubler 2003	Field Field Field
		<i>Ustilago avenae</i>	Loose smut	Oats	Hippe & Koller 1986	Laboratory
		<i>Ustilago maydis</i>	Smut / blister smut	Maize	Walsh & Sisler 1981	Laboratory
		<i>Venturia inaequalis</i> *	Scab	Apple	Stanis & Jones 1985; Köller <i>et al.</i> 1991	Field Laboratory
		<i>Venturia nashicola</i>	Japanese pear scab	Pear	Tomita & Ishii 1998	Field

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

Source: FRAC List of first confirmed cases of plant pathogenic organisms resistant to disease control agents, revised May 2020

(<http://www.frac.info/publications>).

Details of resistance of the target pathogens for this submission, as reported by FRAC, are given in Table 3.3-2.

**Table 3.3-2: Resistance of different targets against different classes of fungicides, reported by FRAC**

Fungicide group	MOA Code	FRAC Group code	Pathogen	Crop	Reference	Remarks
SDHI fungicides (Succinate dehydrogenase inhibitors) : Complex II succinate-dehydrogenase	C2	7	<i>Venturia inaequalis</i>	Apple	FRAC 2014	Field
QoI fungicides (Quinone outside Inhib.): Complex III cytochrome bc1 (ubiquinol oxidase) at Qo site (cyt b gene)	C3	11	<i>Venturia inaequalis</i>	Apple	Zheng <i>et al.</i> 2000 Farber <i>et al.</i> 2002 Steinfeld <i>et al.</i> 2002 Dux <i>et al.</i> 2005	Laboratory mutants Field trial Field Field
AP fungicides (Anilinopyrimidines) Methionine biosynthesis (proposed) (cgs gene)	D1	9	<i>Venturia inaequalis</i>	Apple	FRAC 2014	Field
DMI Fungicides (DeMethylation Inhibitors) SBI Class I. C14-demethylase in sterol biosynthesis (erg11 / cyp 51)	G1	3	<i>Venturia inaequalis</i>	Apple	Stanis & Jones 1985; Köller <i>et al.</i> 1991	Field laboratory
Bis-guanidines, (membrane disruptors, detergents)	M	M07	<i>Venturia inaequalis</i>	Apple	Szkolnik & Gilpatrick 1969, 1971	Dodine
MBC fungicides (Methyl Benzimidazole Carbamates), $\beta$ -tubulin assembly in mitosis	B1	1	<i>Venturia pirina</i>	Pome fruits	Shabi & Ben-Yephet 1976	Field
-	-	-	<i>Podosphaera leucotricha</i>	-	-	-
MBC fungicides (Methyl Benzimidazole Carbamates), $\beta$ -tubulin assembly in mitosis	B1	1	<i>Sphaerotheca pannosa</i>	Rosa / Peach tree	Jarvis & Slingsby 1975	Field
DMI Fungicides (DeMethylation Inhibitors) SBI Class I. C14-demethylase in sterol biosynthesis (erg11 / cyp 51)	G1	3	<i>Sphaerotheca pannosa</i>	Nectarine	Reuveni 2001	Field
MBC fungicides (Methyl Benzimidazole Carbamates), $\beta$ -tubulin assembly in mitosis	B1	1	<i>Monilinia fruticola</i>	Pome fruits	Jones & Ehret 1976	Field
SDHI fungicides (Succinate dehydrogenase inhibitors) : Complex II succinate-dehydrogenase	C2	7	<i>Monilinia fruticola</i>	Peach	Chen <i>et al.</i> 2013	Field
Dicarboximides. MAP / Histidine-kinase in osmotic signal transduction (os-1,	E3	2	<i>Monilinia fruticola</i>	Stone fruits	Penrose <i>et al.</i> 1985 Elmer & Gaunt 1994	Field



Fungicide group	MOA Code	FRAC Group code	Pathogen	Crop	Reference	Remarks
Daf1)						
DMI Fungicides (DeMethylation Inhibitors) SBI Class I. C14-demethylase in sterol biosynthesis (erg11 / cyp 51)	G1	3	<i>Monilinia fruticola</i>	Stone fruits	Nuninger-Ney et al. 1989 Elmer et al. 1992 Chen et al. 2013	Laboratory Field Field
MBC fungicides (Methyl Benzimidazole Carbamates), $\beta$ -tubulin assembly in mitosis	B1	1	<i>Monilinia laxa</i>	Pome fruits	Ogawa et al. 1981	Field
QoI fungicides (Quinone outside Inhib.): Complex III cytochrome bc1 (ubiquinol oxidase) at Qo site (cyt b gene)	C3	11	<i>Monilinia laxa</i> <i>M. fruticola</i>	Fruit	Meissner & Stammler 2010	Not resistance but evidence of an intron
Dicarboximides. MAP / Histidine-kinase in osmotic signal transduction (os-1, Daf1)	E3	2	<i>Monilinia laxa</i>	Apple	Katan & Shabi 1981	Laboratory
KRI fungicides (KetoReductase Inhibitors), (SBI class III). 3-keto reductase C4-demethylation (erg27)	G3	17	<i>Monilinia laxa</i>	Apple / stone fruits	Malandrakis et al. 2013	Field
-	-	-	<i>Taphrina deformans</i>	-	-	-
MBC fungicides (Methyl Benzimidazole Carbamates), $\beta$ -tubulin assembly in mitosis	B1	1	<i>Leveillula taurica</i>	Tomato	Jones & Thompson 1982	Field
SDHI fungicides (Succinate dehydrogenase inhibitors) : Complex II succinate-dehydrogenase	C2	7	<i>Alternaria solani</i>	Potato	Mallik et al. 2014 Miles et al. 2014	Laboratory Field
Dicarboximides. MAP / Histidine-kinase in osmotic signal transduction (os-1, Daf1)	E3	2	<i>Alternaria daucii</i>	Carrot	Strandberg 1984 Fancelli & Kimati 1991	Laboratory
-	-	-	<i>Alternaria radicina</i>	-	-	-
-	-	-	<i>Erysiphe heraclei</i>	-	-	-
-	-	-	<i>Golovinomyces cichoracearum</i>	-	-	-
Dicarboximides. MAP / Histidine-kinase in osmotic signal transduction (os-1, Daf1)	E3	2	<i>Alternaria brassicicola</i>	Brassicas	Avenot et al. 2005	Field / laboratory resistance mechanism
PP fungicides (Phenylpyrroles). MAP / Histidine-kinase in osmotic signal transduction (os-2, HOG1)	E2	12	<i>Alternaria brassicicola</i>	Brassicas	Avenot et al. 2005	Field / laboratory resistance mechanism
MBC fungicides (Methyl Benzimidazole Carbamates), $\beta$ -tubulin assembly in mitosis	B1	1	<i>Mycosphaerella brassicicola</i>	Brassicas	-	-
MBC fungicides (Methyl Benzimidazole Carbamates), $\beta$ -tubulin assembly in mitosis	B1	1	<i>Erysiphe necator</i>	Grapes / Vines	Naegler et al. 1977; Pearson 1980 Pearson & Taschenberg 1980	Field
QoI fungicides (Quinone outside Inhib.): Complex III cytochrome bc1 (ubiquinol oxidase) at Qo site (cyt b gene)	C3	11	<i>Erysiphe necator</i>	Grapevine	Wilcox et al. 2003	Field
AZN: Aza-naphthalenes. Signal transduction (mechanism unknown)	E1	13	<i>Erysiphe necator</i>	Wheat Grapevine	Genet & Jaworska 2009	Baseline, cross resistance studies
DMI Fungicides (DeMethylation Inhibitors) SBI Class I. C14-demethylase in sterol biosynthesis (erg11 / cyp 51)	G1	3	<i>Erysiphe necator</i>	Grapevine	Steva et al. 1990 Reidi & Steinkellner 1996 Miller & Gubler 2003	Field Field Field
-	-	-	<i>Guignardia bidwellii</i>	-	-	-

Source: FRAC List of first confirmed cases of plant pathogenic organisms resistant to disease control agents, revised May 2020  
(<http://www.frac.info/publications>).

### 3.3.4 Cross-resistance

All DMI fungicides inhibit pathogens by interacting with the same target site (C14-demethylase) and are therefore considered to be cross-resistant with each other. Generally, compounds within each subgroup of SBI's (DMI's, amines, KRI's) are cross-resistant with other members within the same group, but there is no cross-resistance between members of different groups.

### 3.3.5 Sensitivity data

There is an annual meeting of the SBI Working Group of FRAC<sup>8</sup>, where current monitoring data are discussed and decision is made whether changes to the next year's use recommendations are required.

The monitoring data derives from several industrial plant protection product manufacturers and the results are published on the FRAC webpage. According to the intended pathogens for which activity of IN005B1570 250EC is claimed, monitoring data for *Leptosphaeria maculans* and *Sclerotinia sclerotiorum* in oilseed rape, *Venturia inaequalis* in apple, *Alternaria solani*, *A. alternata* and *Alternaria* species in broccoli, cabbage, carrots, and cauliflower are presented.

Concerning *Leptosphaeria maculans* in oilseed rape, monitoring data from 2018 to 2020 derived from several countries of the Central Zone (Czech Republic, Germany, Hungary, Ireland, , Poland, Romania, Slovakia, Sweden and United Kingdom) as well as the North Zone (Finland, Latvia and Lithuania) and Southern Zone in France.

Overall, the sensitivity in European populations remains unchanged since around a decade.

Concerning *Sclerotinia sclerotiorum* in oilseed rape, the disease pressure from 2016 to 2019 was low to moderate.

Monitoring data from 2016 to 2019 derived from several countries of the Central Zone (Czech Republic, , Germany, Poland, Slovakia and United Kingdom) as well as the North Zone (Denmark, Latvia and Lithuania) and Southern Zone (Bulgaria and France). Monitoring data from the five years showed a stable and narrow sensitivity range with no geographical differences.

Concerning *Venturia inaequalis*, the disease pressure in 2019 was low to moderate and disease onset started late in the season across Europe. The performance of DMI's was good on this disease when compounds were used according to the manufacturers' and FRAC recommendations within spraying programmes.

Monitoring data from 2017 to 2020 derived from several countries of the Central Zone (Belgium, Germany, Hungary, the Netherlands, Poland, Slovenia and Switzerland) as well as the Southern Zone (Bulgaria, Croatia, Greece, Italy, Portugal and Spain).

Overall, the sensitivity in European populations remains unchanged since around a decade.

Regarding *Alternaria solani* and *Alternaria alternata* monitoring data derived from several countries of the Central Zone (Belgium, Denmark, Germany, Hungary, Poland and Serbia) as well as the Southern Zone (Bulgaria, Croatia, France, Italy and Spain) on potato and tomato. All strains collected in 2019 in tomato and potato are in the same range of sensitivity as in the previous 6 years. In 2020, a homogenous sensitivity of both pathogens was observed comparable to previous years

In *Alternaria tomatophila* on tomato, initial sensitivity studies performed in 2018 by Syngenta with limited number of *strains* indicated high and homogenous sensitivity in USA.

Concerning *Alternaria* species on vegetables (broccoli, cabbage, carrots, cauliflower), several crops and species were analysed in 2017 for the first time. In 2019, monitoring data of *A. alternata*, *A. brassicae*, *A. brassicicola* and *A. dauci* on broccoli, cabbage and carrots derived from several countries of

<sup>8</sup> Source : [https://www.frac.info/docs/default-source/working-groups/sbi-fungicides/group/minutes-of-the-2021-sbi-telco-meeting-recommendations-for-2021-from-3rd-of-march-2021.pdf?sfvrsn=55f3499a\\_2](https://www.frac.info/docs/default-source/working-groups/sbi-fungicides/group/minutes-of-the-2021-sbi-telco-meeting-recommendations-for-2021-from-3rd-of-march-2021.pdf?sfvrsn=55f3499a_2)



the Central zone (Belgium, Hungary, and Poland) as well as the Southern Zone (Croatia, France, Greece, Italy, Portugal and Spain). There is no indication of a decreased sensitivity across all crops, countries, and species.

### 3.3.6 Use pattern

IN005B1570 250EC is used in a wide range of crops and the maximum number of applications goes from 2 to 4 depending on the crop. The target diseases normally need a large number of applications during the full season, so IN005B1570 250EC is usually applied as part of multiple, season-long spray program. It will be mainly applied in conjunction or sequences with other fungicides with different modes of action in order to avoid the resistance development.

### 3.3.7 Resistance risk assessment of unrestricted use pattern

This analysis is conducted according to the EPPO guidance document PP/213 “Resistance risk analysis”. The actual risk for the evolution of resistance towards difenoconazole depends on three different parameters: mechanism of resistance against the compound (intrinsic fungicide risk), biology of the pathogen (pathogen risk) and on agronomical factors (agronomic risk).

#### Inherent active substance associated risk

According to FRAC, the DMI fungicide difenoconazole is classified as substance exerting a medium risk of resistance development.

#### Inherent pathogen associated risk

Large differences in pathogen risk can be found among certain genera and species of plant pathogens. Factors relating directly to disease epidemiology combined with genetic factors can influence the pathogen risk. The most important factors determining pathogen risk appear to be:

- Life cycle of pathogen; the shorter the generation time, the more frequent the need for exposure to the fungicide and the faster the build - up of resistance;
- Abundance of sporulation; the more spores that are released in the crop the greater the availability of individual genomes for mutation and selection, and the faster the spread of resistant mutants;
- Ability of spores to spread between plants, crops and regions;
- Ability to infect at all crops stages, requiring repeated fungicide treatment;
- Occurrence of a sexual stage in the life cycle; this could either favour or hinder resistance development;
- Ability to mutate or express mutant genes; certain pathogens seem to produce fit mutants more readily than others (FRAC, 2007)

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

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

**Table 3.3-3: Pathogen risk summary**

Pathogen	Crop	Risk	Risk class
<i>Alternaria alternata</i>	Various	High	3
<i>Venturia inaequalis</i>	Apple	High	3
<i>Alternaria brassicicola</i> , <i>A. brassicae</i>	Oilseed rape and cabbage	Medium	2

<i>Venturia pirina</i>	Pear	Medium	2
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\*The EPPO Guideline lists these pathogens as high risk pathogens of which baseline sensitivity is normally requested

### Inherent combined risk

When the pathogen risk is reported in a table with the inherent resistance risk of the DMIs group, the combined resistance risk for each pathogen/fungicide combination can be estimated as follow (FRAC, 2016).

**Table 3.3-4: Combined Inherent risk for IN005B1570 250EC**

Molecule Risk ↓	Combined Risk		
High = 3	3	6	9
Medium = 2 difenoconazole	2	4	6
Low=1	1	2	3
Pathogen risk →	Low =1	Medium = 2	High = 3
Pathogen →	-	<i>Alternaria spp.</i> (ALTEBI, ALTEBA, ALTESO) <i>Venturia pirina</i>	<i>Alternaria alternata</i> <i>Venturia inaequalis</i>

Combined Risk: 1 = low, 2 to 6 medium, 9 high (FRAC, 2016)

According to the Table 3.3-4, the combined inherent risk for difenoconazole is medium for the diseases that a registration demand is asked. However this table does not take into account the agronomy risk.

The actual risk of resistance depends not only on the inherent risk of a particular fungicide - pathogen combination, as indicated in the previous table, but also on the conditions of fungicide use. In fact, there are important parameters of resistance risk in practice that must be included in an integral part of resistance risk assessment.

The most important conditions of use that can affect resistance risk are:

- Number of repeated applications of the fungicide; the more frequent the product is applied to the pathogen, the more rapid the selection of mutants
- Exclusivity of the product, the more exclusive the products with the same mode of action, the more sustained the selection pressure; alternation or combined application with other types of fungicides with different mechanisms of action can reduce resistance risk
- Amounts of pathogen exposed to the fungicide; if disease incidence is relatively low or irregular from season to season, then occurrence and selection of possible resistant mutants is reduced.

Table 3.3-5 reports the combined risk for IN005B1570 250EC by taking into account the agronomic risk.

**Table 3.3-5: Possible combined risk for IN005B1570 250EC in relation with the agronomic risk level**

Molecule Risk	Combined risk			Agronomic Risk
High = 6	6 3 1.5	12 6 3	18 9 4.5	High =1 Medium = 0.5 Low = 0.25
Medium=4 (difenoconazole)	4 <u>2</u> 1	8 <u>4</u> 2	12 <u>6</u> 3	High =1 <b>Medium = 0.5</b> Low = 0.25
Low=1	1 0,5 0,25	2 1 0,5	3 1,5 0,75	High =1 Medium = 0.5 Low = 0.25
Pathogen risk →	Low =1	Medium = 2	High = 3	
Pathogen	-	<i>Alternaria spp.</i> (ALTEBI,	<i>Alternaria alternata</i>	

		ALTEBA, ALTESO) <i>Venturia pirina</i>	<i>Venturia inaequalis</i>	
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Highest possible value = 18 (high molecule risk high pathogen risk and high agronomy risk).

For all those diseases, fungicides are not systematically applied. Application is performed according to the disease contamination level and is based on the assessment carried out by the plant protection technical department of various partners like SRAL, Arvalis.... Those assessments are completed by modelling systems which refine the date of application. All the results are communicated to farmers through various supports like email, fax, technical bulletin... This process avoids excessive number of applications on pathogens.

According to the Good Agricultural Practices, IN005B1570 250EC is applied 2 to 4 times depending on the different crops considering on this submission, in consequence the agronomic risk on those diseases is medium (0.5). By taking into account the agronomic risk, the combined risk adapted to the use of IN005B1570 250EC is the following one:

**Table 3.3-6: Summary of the combined risk for IN005B1570 250EC**

Pathogen	Crop	Combined Risk
<i>Alternaria spp.</i>	Carrots, cabbage crops	4
<i>Venturia pirina</i>	Pome fruits	4
<i>Venturia inaequalis</i>	Pome fruits	6

In conclusion the combined risk is medium to high depending in the pathogen: *Alternaria spp.*, *Venturia pirina* are pathogens with medium combined risk, while *Alternaria alternata* and *Venturia inaequalis* are pathogens with a medium to high combined risk.

The resistance risk is therefore acceptable.

### 3.3.8 Management strategy

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

Utilization of fungicide resistance management strategies in practice is one of the most important tools to slow down the evolution of fungicide resistant plant pathogens. FRAC gives some general recommendations for resistance management for all the crops and also some specific ones for *Venturia inaequalis*.

Regarding the general recommendations for SBI fungicides on all crops:

The SBI fungicides represent one of the most potent classes of fungicides available to the grower for the control of many economically important pathogens. It is in the best interest of all those involved in recommending and using these fungicides that they are utilised in such a way that their effectiveness is maintained.

The following general recommendations can be made:

- Repeated application of SBI fungicides alone should not be used on the same crop in one season against a high-risk pathogen in areas of high disease pressure for that particular pathogen.
- For crop/pathogen situations where repeated spray applications (e.g. orchard crops/powdery mildew) are made during the season, alternation (block sprays or in sequence) or mixtures with an effective non cross-resistant fungicide are recommended.
- Where alternation or the use of mixtures is not feasible because of a lack of effective or compatible non cross-resistant partner fungicides, then input of SBI's should be reserved for critical parts of the season or crop growth stage.

- If the performance of SBIs should decline and sensitivity testing has confirmed the presence of less sensitive isolates, SBIs should only be used in mixture or alternation with effective non cross-resistant partner fungicides.
- The introduction of new classes of chemistry offers opportunities for more effective resistance management. The use of different modes of action should be maximized for the most effective resistance management strategies.
- Users must adhere to the manufacturers' recommendations. In many cases, reports of "resistance" have, on investigation, been attributed to cutting recommended use rates, or to poorly timed applications.
- Fungicide input is only one aspect of crop management. Fungicide use does not replace the need for resistant crop varieties, good agronomic practice, plant hygiene/sanitation, etc.
- Exclusive frequency measurements of single cyp51 mutations are not sufficient to describe the sensitivity situation towards DMIs but can help to better understand the background of sensitivity shifts.

Concerning the specific recommendations:

*Venturia inaequalis* in Apple:

- DMI fungicides are not recommended for season long use and a maximum of 4 DMI sprays either alone or in mixture is recommended.
- DMIs should be used in mixtures or (block) alternations with a non-cross resistant fungicide. Application of recommended label rates is important.
- Preventative applications should always be the first choice with DMIs. Curative applications are only recommended when accurate disease warning systems are available.

Comments of zRMS:	<p>Difenoconazole is a DMI Triazole systemic fungicide. It provides prevention and cure. It is absorbed by the leaves with acropetally and shows strong trans-laminar translocation. It stops the development of fungi by interfering with the biosynthesis of sterols in cell membranes.</p> <p>Difenoconazole is a demethylation inhibitor (DMI) fungicide, which shares its mode of action with other sterol biosynthesis inhibitors. It belongs to FRAC MOA Code G1 Group Code 3 which are considered at medium risk to fungicide resistance development. A resistance management strategy is required. IN005B1570 250EC with the triazole difenoconazole as active ingredient should be used in tank mixes and / or spray programs in alternation with fungicides with different MoA's and azole compounds.</p> <p>Despite of the combined risk for resistance development according to the FRAC classification, it must be noted that there are regional differences in sensitivity across Europe. On the other hand, monitoring results from recent years indicate that resistance levels are stable. However, trial results in this dossier clearly show that in most cases, sufficient levels of control are given. IN005B1570 250EC with the Triazole Difenoconazole as active ingredient is therefore regarded to be an important tool of resistance management and should be used in tank mixes and / or spray programs in alternation with fungicides with different MoA's and Azole compounds. As a result, it can be stated that, if IN005B1570 250EC is used according to the use instructions and under consideration of the proposed anti-resistance modifiers, the resistance risk of the target pathogen to develop resistance to IN005B1570 250EC is considered medium to high but can be reduced by adherence of the management strategy.</p>
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	<p>The agronomic risk for active ingredients which include IN005B1570 250EC is estimated as medium for difenoconazole.</p> <p>The resistance management is coordinated by FRAC recommendations. Applying the anti-resistance use recommendations, development of resistance can be considerably decreased or avoided. The restriction should be put on the label.</p> <p>Since the agronomic factors influencing the risk of resistance development tend to vary between the member states, the individual and detailed assessment of the resistance risk (Evaluation of the Agronomic risk of resistance, Management of resistance, Use pattern, Proposed Risk Modifiers) has to be finalised on national level.</p>
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### 3.4 Adverse effects on treated crops (KCP 6.4)

#### Information on trials submitted (3.4 Adverse effects on treated crops)

As IN005B1570 250EC showed no herbicidal activity, no dedicated crop safety trial was necessary (in accordance with EPPO standard PP1/135(4)). Moreover, difenoconazole has been approved for the control of a range of diseases since 1988. Then, similar fungicides with same formulation and same quantity of active ingredient (difenoconazole, 250 g/L EC) have been developed and approved for use in agriculture for many years (cf. Table 3.2 2).

In addition, the crop sensitivity of IN005B1570 250EC was studied in presence (or not) of foliar diseases from a set of 71 efficacy trials implemented in 2020, 2021, 2022 and 2023 in:

- Oilseed rape crop in the Maritime (Czech Republic (1 trial), France (7 trials), Germany (9 trials) and the United Kingdom (5 trials)), in the North-East (5 trials in Poland) and in the South-East EPPO (Romania (4 trials)) climatic zones;
- Apple crop in the Maritime (8 trials in France and Germany) and in the North-East (11 trials in Poland) EPPO climatic zones;
- Vegetables in the Maritime (15 trials in France, Germany, The Netherlands and The United Kingdom) and in the North-East (6 trials in Poland) EPPO climatic zones;

Materials and methods of these trials are presented in Section 3.2.3 “Efficacy test” and are not duplicated here.

#### 3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

##### 3.4.1.1 Oilseed rape

The crop sensitivity was assessed in 31 efficacy trials on oilseed rape in the Maritime (22 trials), North-East (5 trials) and the South-East (4 trials) EPPO climatic zones. These trials were performed in 2020 and 2021. In all trials, no phytotoxicity symptom was observed after the application of IN005B1570 250EC at the requested rate except in two trial but remained very low (under 2%).

**Table 3.4-1: Phytotoxicity assessments of IN005B1570 250EC - Efficacy trials - Oilseed rape**

Number of trials with...		IN005B1570 250EC 0.5 L/ha	DIFENO 0.5 L/ha
Maximum of phytotoxicity recorded during	0%	29	31
	>0 - 4.9%	2	0
	5 - 9.9%	0	0

Number of trials with...		IN005B1570 250EC 0.5 L/ha	DIFENO 0.5 L/ha
the trials	10 - 14.9%	0	0
	15% and more	0	0
Level of symptoms at the last assessments	0%	29	31
	>0 - 4.9%	2	0
	5 - 9.9%	0	0
	10 - 14.9%	0	0
	15% and more	0	0

In 29 trials of the oilseed rape crops, any phytotoxicity symptoms was observed when IN005B1570 250EC was applied.

The potential impact of variety on the occurrence of phytotoxicity was tested in 29 different varieties of oilseed rape (Table 3.4-2).

**Table 3.4-2: Phytotoxicity assessments of IN005B1570 250EC - Varieties tested in efficacy trials - Oilseed rape**

Crop	No of trials	No of varieties	Variety names (No of trials) without phytotoxicity
Oilseed rape	31	29	Acacia (1), Alexander (1), Alledor (1), Ambassador (1), Aspire (1), Avatar (1), Barbados (1), Campus (2), Cristiano KWS (1), DK Excalibur (1), DK Exception (1), DK Expansion (1), Extremus (1), Feliciano (1), Grizzly (1), KWS Roberto (1), LG Ambassador (1), LG Architekt, (1), Pioneer PX 113 (1), PR46W14 1), Quizz (1), RAGT Gazetta, (1), Safran (1), Smaragd (1), SY Aganos (1), SY Alibaba (1), SY Florida (2), Tempo (1), Umberto (1)

**Therefore, no unacceptable phytotoxicity symptom is expected on oilseed rape if IN005B1570 250EC is used according to the Good Agricultural Practices and label recommendations.**

### 3.4.1.2 Apple

The crop sensitivity was assessed in 19 efficacy trials in the Maritime (8 trials) and the North-East (11 trials) EPPO climatic zones. These trials were performed in 2020, 2021, 2022 and 2023. In the 19 trials, no phytotoxicity symptom was observed after repeated applications of IN005B1570 250EC at the requested rate. In 4 additional trials in N-E (PL) also dose 0.225 L/ha was studied, so total number for this dose is 12 (8 Maritime + 4 N-E).

**Table 3.4-3: Phytotoxicity assessments of IN005B1570 250EC - Efficacy trials - Apple**

Number of trials with...		IN005B1570 250EC		DIFENO	
		0.20 L/ha	0.225 L/ha	0.15-0.2 L/ha	0.225 L/ha
Maximum of phytotoxicity recorded during the trials	0%	11	12	14	9
	>0 - 4.9%	0	0	0	0
	5 - 9.9%	0	0	0	0
	10 - 14.9%	0	0	0	0
	15% and more	0	0	0	0
Level of symptoms at the last assessments	0%	11	12	14	9
	>0 - 4.9%	0	0	0	0
	5 - 9.9%	0	0	0	0
	10 - 14.9%	0	0	0	0
	15% and more	0	0	0	0

In none of the Apple crops were any phytotoxicity symptoms observed when IN005B1570 250EC was applied.

The potential impact of variety on the occurrence of phytotoxicity was tested in 10 different varieties of apple (Table 3.4-4).

**Table 3.4-4: Phytotoxicity assessments of IN005B1570 250EC - Varieties tested in efficacy trials - Apple**

Crop	No of trials	No of varieties	Variety names (No of trials) without phytotoxicity
Apple	19	13	Boskoop (1), Cox Orange (1), Elstar (2), Gala (2), Golden (1), Golden Delicious (3), Idared (1), Jonagold (2), Melrose (1), Najdared (1), Red Jonaprince (1), Sunrise (1), Szampion(2).

**Therefore, no unacceptable phytotoxicity symptom is expected on pome fruit if IN005B1570 250EC is used according to the Good Agricultural Practices and label recommendations.**

### 3.4.1.3 Vegetables

The crop sensitivity was assessed in 21 efficacy trials in the Maritime EPPO climatic zone France, Germany, The Netherlands and The united Kingdom (15 trials) and the North-East EPPO climatic zone in Poland (6 trials). These trials were performed in 2020 and 2021. In the all trials, no phytotoxicity symptom was observed after repeated applications of IN005B1570 250EC at the requested rate.

**Table 3.4-5: Phytotoxicity assessments of IN005B1570 250EC - Efficacy trials - Vegetables**

Number of trials with...		IN005B1570 250EC 0.5 L/ha	DIFENO 0.4 L/ha	DIFENO 0.5 L/ha
Maximum of phytotoxicity recorded during the trials	0%	21	8	13
	>0 - 4.9%	0		0
	5 - 9.9%	0		0
	10 - 14.9%	0		0
	15% and more	0		0
Level of symptoms at the last assessments	0%	21	8	13
	>0 - 4.9%	0		0
	5 - 9.9%	0		0
	10 - 14.9%	0		0
	15% and more	0		0



In none of the vegetables crops were any phytotoxicity symptoms observed when IN005B1570 250EC was applied.

The potential impact of variety on the occurrence of phytotoxicity was tested in 18 different varieties of vegetables (Table 3.4-6).

**Table 3.4-6: Phytotoxicity assessments of IN005B1570 250EC - Varieties tested in efficacy trials - Vegetables**

Crop	No of trials	No of varieties	Variety names (No of trials) without phytotoxicity
Carrot	16	13	<i>Bangor (1), Carvora (1), Farah (1), Galicja (1), Mello Yello (1), Nairobi (2), Nerac (1), Norway (1), Presto (2), Robila (1), Texto (1), Salsa (1), Volcano (2)</i>
Brassicas crop	5	5	<i>Cauliflower (BRSOB): Cariance Verimark (1), Damsel (1) Broccoli (BRSOK): Titanium (1) Head cabbage (BRSOL): Brigadier (1), Manitoba (1)</i>

**Therefore, no unacceptable phytotoxicity symptom is expected on carrot and brassicas crops if IN005B1570 250EC is used according to the Good Agricultural Practices and label recommendations.**

Comments of zRMS:	<p>The phytotoxicity trials about tested plant protection product (fungicide) have been carried out in accordance with EPPO Guidelines (1/181 (4)). The conduct of the field work is principally compliant with “Good Agricultural Practice” and in accordance with EPPO Guidelines PP 1/135.</p> <p>The trials were performed with the use of different agricultural practice in North-East EPPO zone, South-East EPPO zone and Maritime EPPO zone. All presented trials were performed with the use of cultivars, differing in growth strength as well as soil and water requirements. The appropriate experimental design was applied. In all trials studied product was compared to the standard reference products. Statistical analysis of the data was performed. Also, quality of yield was evaluated in some trials.</p> <p>Both EU Directive 91/414 (EU, 1991) and EPPO PP 1/226 (3) – Number of efficacy trials requires testing phytotoxicity at normal (N) and double (2N) recommended dose. However, EPPO 1/135 (3) – Phytotoxicity assessment states: ‘EPPO Standards on fungicides, insecticides and plant growth regulators or seed treatments, on the other hand, include only a relatively simple special section on phytotoxicity assessment, because, for these types of plant protection products, phytotoxic effects will be less frequent’. Selectivity trials and studied dose 2N were not required, which is in accordance with EPPO 1/135 (3).</p> <p>Applicant submitted in total  71 phytotoxicity trials carried out in the Maritime EPPO zone (45 trial), N-E EPPO zone (16 + 2 trials from 2022 + 4 trials from 2023) and S-E EPPO zone (4 trials). Submitted trials were carried out on winter oilseed rape (31 trials), apple (13 trials + 2 additional trials from 2022+4 additional trials from 2023) and vegetable crops (16 trials performed on carrot and 5 performed on brassicas).</p> <p><i>Oilseed rape</i>: 22 trials MAR (CZ-1, FR-7, DE-9, UK- 5); 5 trials N-E (PL) and 4 trials S-E (RO). No negative effects were observed during all trials. Results for MAR, S-E and N-E are sufficient</p> <p><i>Apple</i>: 8 trials MAR (FR-3, DE-5), 5 trials N-E (PL) + 2 additional trials from 2022 + 4 additional trials from 2023, 0 trials S-E. No negative effects were observed during all trials. cMS from S-E should decide if lack of data for this zone can be accepted. Results for MAR and N-E are sufficient.</p> <p><i>Pear</i>: 0 trials MAR; 0 trials N-E; 0 trials S-E. Pear can be accepted only in case</p>
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	<p>of extrapolating results from apple. Each cMS should decide if this approach can be accepted. In Poland pear cannot be accepted due to lack of phytotoxicity and efficacy trials (at least 1-2 are required for possibility extrapolating results from apple).</p> <p><i>Carrot:</i> 10 trials MAR (FR-4, DE-2, NL-2, UK-2); 6 trials N-E (PL); 0 trials S-E. cMS from S-E should decide if lack of data for this zone can be accepted. Results for MAR and N-E are sufficient.</p> <p><i>Brassicas:</i> 5 trials MAR (FR); 0 trials N-E; 0 trials S-E. cMS from S-E and N-E should decide if lack of data for those zones can be accepted. Results for MAR are sufficient. In Poland brassicas due to lack of phytotoxicity and efficacy trials could be registered only in line to Article 51.</p> <p>There were not observed any phytotoxicity symptoms caused by tested plant protection product – IN005B1570 250EC during all trials. So, ZRM s agree with Applicant that: <b><i>no unacceptable phytotoxicity symptom is expected on carrot and brassicas crops if IN005B1570 250EC is used according to the Good Agricultural Practices and label recommendations.</i></b></p>
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### 3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

Many products containing difenoconazole have been approved and widely used in many countries of Europe for the control of several diseases and proven to have no effect on the yield of the different crops where it is applied. Therefore, no data on the possible effect on the yield is provided in this dossier.

However, assessments on yield were made in the efficacy trials on carrot and brassicas crops. Results are presented in section 3.2.3.3. In these trials, increases in yield were observed due to the effective disease control. No symptoms of phytotoxicity of IN005B1570 250EC were observed in any of the efficacy trials in all crops. Therefore, negative effects on yield following application with IN005B1570 250EC are considered highly unlikely.

**Therefore, no effect on the yield is expected when IN005B1570 250EC is applied according to the Good Agricultural Practices and label recommendations.**

Comments of zRMS:	<p><b>Winter oilseed rape:</b> 6 efficacy trials were harvested in 2021. Applicant submitted in total 6 trials for yield: MAR 3 (CZ-1, DE-1, UK-1); N-E 2 (PL) and S-E 1 (RO). In all EPPO climatic zones, the average yield reached 3.7 t/ha in the untreated plot (ranging from 3.2 t/ha to 5.2 t/ha in the individual trials). In the Maritime EPPO climatic zone, IN005B1570 250EC at 0.5 L/ha had a positive effect on the yield of oilseed rape in the presence of SCLESC. In fact, there was an 4 % increase in yield over the untreated. Overall, no significant difference was observed between IN005B1570 250EC and the reference standards DIFENO. As well, in the North-East EPPO climatic zone, IN005B1570 250EC at 0.5 L/ha had a positive effect on the yield of oilseed rape in the presence of SCLESC (3% increase in yield over the untreated). In both EPPO climatic zones, IN005B1570 250EC at 0.5 L/ha had a positive effect on the yield and no significant difference was observed between IN005B1570 250EC and the reference standards DIFENO. In all EPPO climatic zones, IN005B1570 250EC at 0.5 L/ha had a positive effect on the yield of oilseed rape in the presence of diseases. In fact, there was an 4 % increase in yield over the untreated, a similar increase than the reference standard DIFENO.</p> <p><b>Table</b> Positive effect on the yield of IN005B1570 250EC - Comparison with the reference standard - Efficacy trials - Oilseed rape</p> <table> <tr> <th rowspan="2">Target</th><th rowspan="2">EPPO climatic zone</th><th rowspan="2">No. of trials</th><th rowspan="2">Untreated control</th><th colspan="2">Mean control (%)</th><th rowspan="2">No. of assessments significantly<sup>(1)</sup> &gt; , =</th></tr> <tr> <th>IN005B1570 250EC</th><th>DIFENO</th></tr> </table>						Target	EPPO climatic zone	No. of trials	Untreated control	Mean control (%)		No. of assessments significantly <sup>(1)</sup> > , =	IN005B1570 250EC	DIFENO
Target	EPPO climatic zone	No. of trials	Untreated control	Mean control (%)		No. of assessments significantly <sup>(1)</sup> > , =									
				IN005B1570 250EC	DIFENO										

							0.5 L/ha				0.5 L/ha				, < IN005B1570 250EC at 0.5 L/ha vs.		
				Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	DIFENO 0.5 L/ha		
SCLESC	Maritime zone	3	4.1	3.3	5.2	104.4	101.2	109.8	3.9	103.7	99.6	107.7	3.3	0> ; 3= ; 0<			
	North-East zone	2	3.5	3.3	3.6	102.6	98.8	106.4	3.8	102.5	99.4	105.5	3.1	0> ; 2= ; 0<			
	Mar.&North-East zones	5	3.8	3.3	5.2	103.7	98.8	109.8	3.9	103.2	99.4	107.7	3.3	0> ; 5= ; 0<			
CYLSSP	South-East zone	1	3.2	-	-	104.4	-	-	-	108.2	-	-	-	0> ; 1= ; 0<			
All diseases	All zones	6	3.7	3.2	5.2	103.8	98.8	109.8	3.6	104.0	99.4	108.2	3.5	0> ; 6= ; 0<			
<p><b>Apple:</b> apple fruit russetting, assessments were carried out in 7 efficacy trials. Table 3.2 50 below presents, in each trial, the percentage of fruits without russetting. The summary of the results to study the impact of IN005B1570 250EC on apple fruit russetting are shown in Table 3.2 51. Trials (in total 7) were carried out on MAR 3 (DE-1, FR-2) and N-E 4 (PL). During additional trials (2 from 2022 and 4 from 2023) – impact on russetting was not studied.</p>																	
<p><b>Table 3.4-7:</b> Detailed results: Effect of IN005B1570 250EC on apple russetting - % of fruits without russetting - Efficacy trials</p>																	
Trial code	EPPO climatic zone	Crop Cultivar	Days after application	Crop stage at assessment.	Untreated check		IN005B1570 0.2 L/ha		IN005B1570 0.225 L/ha		IN005B1570 calc.[0.113-0.168] L/ha LWA		IN005B1570 [0.15-0.2] L/ha		DIFENO [0.15-0.2] L/ha		
					Raw data	Stat	Raw data	Stat	Raw data	Stat	Raw data	Stat	Raw data	Stat	Raw data	Stat	Raw data
FEU-AGR-004-20-SCAP-FR001	Maritime	Melrose	84 DA-K	87	76.0	a	-	-	78.7	a	81.3	a	81.3	a	79.0	a	0.15 L/ha
FEU-AGR-001-21-SCAP1-FR06	Maritime	Golden	80 DA-J	89	100.0	a	-	-	100.0	a	100.0	a	100.0	a	100.0	a	0.15 L/ha
FEU-AGR-001-21-SCAP1-DE04	Maritime	Jonagold	87 DA-N	87	100.0	a	-	-	100.0	a	100.0	a	100.0	a	100.0	a	0.15 L/ha
FEU-AGR-001-21-SCAP2-PL08	North-East	Szampion	28 DA-P	87	100.0	a	100.0	a	-	-	100.0	a	100.0	a	100.0	a	0.20 L/ha
FEU-AGR-001-21-SCAP2-PL09	North-East	Sunrise	47 DA-J	87	80.0	a	80.8	a	-	-	80.8	a	80.8	a	80.0	a	0.20 L/ha
FEU-AGR-001-21-SCAP2-PL11	North-East	Golden delicious	102 DA-J	87	71.0	a	65.5	a	-	-	65.5	a	65.5	a	67.5	a	0.20 L/ha
FEU-AGR-001-21-SCAP2-PL12	North-East	Golden delicious	97 DA-J	87	100.0	a	100.0	a	-	-	100.0	a	100.0	a	100.0	a	0.20 L/ha
Mean control (%) [Min-Max] S.D	Maritime zone	MABSD	3 trials	[87-89]	92.0 [76.0-100.0]	-	-	-	92.9 [78.7-100.0]	10.4	93.8 [81.3-100.0]	8.8	93.8 [81.3-100.0]	8.8	93.0 [79.0-100.0]	9.9	
	North-East zone	MABSD	4 trials	87	87.8 [71.0-100.0]	-	-	-	86.6 [65.5-100.0]	14.5	86.6 [65.5-100.0]	14.5	86.6 [65.5-100.0]	14.5	86.9 [65.5-100.0]	13.8	
	All zones	MABSD	7 trials	[87-89]	89.6 [71.0-100.0]	-	-	-	89.3 [65.5-100.0]	13.1	89.6 [65.5-100.0]	12.9	89.6 [65.5-100.0]	12.9	89.5 [65.5-100.0]	12.7	
<p>Stat: Student-Newman-Keuls test at 5% - % Control: Mean control (% efficacy). Grey lines: <b>Mean control</b> [Minimum efficacy noted in all trials - Maximum efficacy noted in all trials] - S.D: Standard deviation.</p>																	
<p><b>Table 3.4-8:</b>Effect of IN005B1570 250EC on apple russetting - % of fruits without russetting - Mean control</p>																	
Part	EPPO climatic zone	No. of trials	Untreated check	IN005B1570 0.2 L/ha	IN005B1570 0.225 L/ha	IN005B1570 calc.[0.113-0.168] L/ha LWA	IN005B1570 [0.15-0.2] L/ha	DIFENO [0.15-0.2] L/ha	No. of assessments significantly <sup>1)</sup> > , = , < IN005B1570 at								

**Table 3.4-10:** Detailed results: Positive effect on the yield of IN005B1570 250EC compared to the reference standard - Efficacy trials - Brassicas crop

	Trial code	Target	EPPO climatic zone	Part	Crop	Days after application	Crop stage at assess.	Untreated check		IN005B1570 0.5 L/ha			DIFENO 0.5 L/ha		
								t/ha	Stat	t/ha	Stat	% Control	t/ha	Stat	% Control
	FEU-AGR-026-20-ALMYCAU-FR001	ALTEBI	Maritime	FRUIT	BRSOB	13 DA-D	79	43.8	a	48.2	a	109.9	47.7	a	109.0
	FEU-AGR-027-20-ALMYBRO-FR002	ALTEBI	Maritime	FRUIT	BRSOBK	20 DA-F	49	26.7	a	25.5	a	95.3	25.7	a	96.4
	Mean control (%)	ALTEBI	Maritime zone	FRUIT	All brassicas	1 trial	49	17.3		102.6 [95.3-109.9] 7.3			102.7 [96.4-109.0] 6.3		
<b>Summary:</b> In these trials, increases in yield were observed due to the effective disease control. No symptoms of phytotoxicity of IN005B1570 250EC were observed in any of the efficacy trials in all crops. Therefore, negative effects on yield following application with IN005B1570 250EC are considered highly unlikely. <b>Therefore, no effect on the yield is expected when IN005B1570 250EC is applied according to the Good Agricultural Practices and label recommendations.</b>															

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

Many products containing difenoconazole have been approved and widely used in many countries of Europe for the control of several diseases and proven to have no effect on the quality of plants or plant products of the different crops where it is applied. For these reasons and based on the data provided, we can expect no adverse effect on the quality parameters.

However, to deepen the knowledge on IN005B1570 250EC, several trials were carried out to evaluate the unintentional effects of IN005B1570 250EC compared to the reference standard DIFENO at the requested dose.

#### 3.4.3.1 Material and Methods

Material and Methods used in efficacy trials are given within section 3.2.3.1 and is not repeated here.

#### 3.4.3.2 Effects on the quality of oilseed rape

The possible impact of IN005B1570 250EC on the quality was studied in 6 efficacy trials in oilseed rape. All trials were carried out by testing facilities officially recognised according to Good Experimental Practice (GEP).

Different quality parameters (moist content, specific weight or oil content) were measured in 6 efficacy trials performed in the Maritime EPPO climatic zone (1 trial in Czech Republic, 1 in Germany and 1 trial in United Kingdom), North-East (2 trials in Poland) and in South-East (1 trial in Romania) EPPO climatic zones in 2021.

All quality results are summarised in Table 3.4-11 (compared to the reference DIFENO).

**Table 3.4-11: Effect on the quality parameters of IN005B1570 250EC at 0.5 L/ha - Comparison with the reference standard - Efficacy trials - Oilseed rape**

Quality parameters	EPPO climatic zone	No. of trials	Untreated control			IN005B1570 250EC 0.5 L/ha				DIFENO 0.5 L/ha				No. of assessments significantly > , = , < IN005B1570 250EC - 0.5 L/ha vs.
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	
			Moist content (%)			Percentage of untreated control				DIFENO at 0.5 L/ha				
Moist content	Maritime	3	8.8	6.5	11.4	100.0	98.8	101.2	1.0	99.3	98.0	100.0	0.9	0> ; 3= ; 0<
	North-East	2	6.4	6.4	8.9	100.2	100.4	101.6	0.6	98.8	95.3	102.3	3.5	0> ; 2= ; 0<
	South-East	1	9.1	-	-	99.4	-	-	-	100.0	-	-	-	0> ; 1= ; 0<
	All zones	6	7.8	5.3	11.4	100.2	98.8	101.6	1.0	99.3	95.3	102.3	2.2	0> ; 6= ; 0<
Specific weight	HLW (kg/hL)			Percentage of untreated control				DIFENO at 0.5 L/ha						
	Maritime	1	65.3	-	-	99.7	-	-	-	99.3	-	-	-	0> ; 1= ; 0<
	South-East	1	68.1	-	-	99.4	-	-	-	98.2	-	-	-	0> ; 1= ; 0<
	All zones	2	66.7	65.3	68.1	99.6	99.4	99.7	0.2	98.8	98.2	99.3	0.6	0> ; 2= ; 0<
Thousand grain weight	TGW (g)			Percentage of untreated control				DIFENO at 0.5 L/ha						
	Maritime	1	4.3	-	-	106.7	-	-	-	103.0	-	-	-	0> ; 1= ; 0<
	North-East	1	5.1	-	-	101.2	-	-	-	100.8	-	-	-	0> ; 1= ; 0<
	South-East	1	4.0	-	-	101.0	-	-	-	101.5	-	-	-	0> ; 1= ; 0<
	All zones	3	4.5	4.3	5.1	103.0	101.0	106.7	2.6	101.8	100.8	103.0	0.9	0> ; 3= ; 0<
Oil content	Oil content (%)			Percentage of untreated control				DIFENO at 0.5 L/ha						
	Maritime	1	44.8	-	-	100.3	-	-	-	100.3	-	-	-	0> ; 1= ; 0<
	North-East	1	37.1	-	-	103.9	-	-	-	102.4	-	-	-	0> ; 1= ; 0<
	South-East	1	43.4	-	-	104.3	-	-	-	101.0	-	-	-	0> ; 1= ; 0<
	All zones	2	41.8	37.1	44.8	102.8	100.3	104.3	1.8	101.2	100.3	102.4	0.8	0> ; 3= ; 0<

Because IN005B1570 250EC is a fungicide, no determination of oil content was necessary and this was just done in 3 trials to confirm the assumption that IN005B1570 250EC would have no impact on quality parameters for oilseed rape. Moreover no negative effect on moist content, specific weight and thousand grain weight was noted after an application of IN005B1570 250EC at 0.5 L/ha. Finally, no significant difference was noted with the reference standard DIFENO at 0.5 L/ha in all trials on all quality parameters. No significant difference was also noted with the local reference product.

**Therefore, no negative effect on quality of oilseed rape is expected if IN005B1570 250EC is applied at the requested rate of 0.5 L/ha according to the Good Agricultural Practices and label recommendations.**

Comments of zRMS:	<p>Quality of yield was studied only for winter oilseed rape trials during 6 trials (MAR 3: DE-1, UK-1, CZ-1 and N-E 2: PL and S-E 1: RO). Applicant studied: moisture content (MAR-3: DE-1, UK-1, CZ-1; N-E-2: PL; S-E-1: RO), specific weight (MAR-1: CZ, S-E-1: RO, thousand grain weight (MAR-1:CZ, N-E-1: PL, S-E-1: RO) and oil content (MAR-1:DE, N-E-1:PL, S-E-1:RO). Because IN005B1570 250EC is a fungicide, no determination of oil content was necessary, and this was just done in 3 trials to confirm the assumption that IN005B1570 250EC would have no impact on quality parameters for oilseed rape. Moreover, no negative effect on moist content, specific weight and thousand grain weight was noted after an application of IN005B1570 250EC at 0.5 L/ha. Finally, no significant difference was noted with the reference standard DIFENO at 0.5 L/ha in all trials on all quality parameters. No significant difference was also noted with the local reference product.</p> <p>ZRMs agree with Applicant that: <i>no negative effect on quality of oilseed rape is expected if IN005B1570 250EC is applied at the requested rate of 0.5 L/ha according to the Good Agricultural Practices and label recommendations.</i></p>
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### 3.4.4 Effects on transformation processes (KCP 6.4.4)

Many products containing difenoconazole have been approved and widely used in many countries of Europe for the control of several diseases and proven to have no effect on the transformation processes of the different crops where it is applied. Therefore, no data on the possible effect on the transformation processes is provided in this dossier.

No effect on transformation processes is expected when IN005B1570 250EC is applied according to the Good Agricultural Practices and label recommendations.

Comments of zRMS:	<p>No trials have been presented by Applicant about effects on transformation processes. According to EPPO PP1/243 (2) on effects of plant protection products on transformation process, if the applicant can demonstrate that residues are undetectable, it may be sufficient to address these requirements. No data about residue for example in apple juice were presented by Applicant, so ZRMs could not exclude the impact on production. cMS should decide for themselves if the remark “no data available for influence on apple juice and processing procedures and their products” is necessary on the label.</p> <p>Still, no phytotoxicity symptoms occurring during the field trials suggest that product application in accordance with label recommendation has no negative impact on parts of plant used for propagating purposes. Also, this active compound – difenoconazole is known and commercially used in Poland (zRMS) and other countries from EU. <b>Therefore, it is not expected to adversely affect the processing operations in the opinion of Evaluator.</b></p>
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### 3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

IN005B1570 250EC is a fungicide and has no herbicidal activity. Therefore, there is no requirement for the evaluation of secondary effect on plants for propagating purposes.

In addition, many products containing difenoconazole have been approved and widely used in many countries of Europe for the control of several diseases and proven to have no impact on treated plants or plant products to be used for propagation.

**Therefore, no impact on treated plants or plant products to be used for propagation is expected if IN005B1570 250EC is used in accordance with good agricultural practices, including label instructions.**

Comments of zRMS:	<p>Azoles generally may influence the hormone system of the plant. Influences on propagation are not excludable. For that special item propagating, no problems have been recorded here for other authorised difenoconazole products. No adverse effects on apple and pear are to be expected. About a remark at label may be decided as nationally usual.</p> <p>No indication from agricultural practice is known that fungicides with the active substances difenoconazole have affected vegetables or brassicas used for propagation purposes. No negative influence of the product IN005B1570 250EC is to be expected when applied at the intended dose rate and used according to the label recommendations.</p> <p>Information provided by the Applicant was limited due to fact that there is no information available pointing to presence of any limitations to using difenoconazole. Also, <b>no phytotoxicity symptoms occurring during the field trials suggested that product (IN005B1570 250EC) application in accordance with label recommendation has no negative impact on parts of plant used for propagating purposes.</b></p>
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### 3.5 Observations on other undesirable or unintended side - effects (KCP 6.5)

#### 3.5.1 Impact on succeeding crops (KCP 6.5.1)

Fungicides usually do not exhibit herbicidal activity. No symptoms of phytotoxicity of IN005B1570 250EC were observed in any of the efficacy trials in all crops. For more details on phytotoxicity results, please refer to Section 3.4.1.

In addition, any potential impact of IN005B1570 250EC on succeeding crops would principally be related to the active substances. Difenoconazole is used in Europe for many years and no effect on succeeding crops is known in Europe.

**Therefore, no impact is expected on succeeding crops if IN005B1570 250EC is used according to the Good Agricultural Practices and label recommendations.**

Comments of zRMS:	<p>The Applicant initially did not provide a sufficient level of information to address the impact on succeeding crops in accordance with EPPO PP 1/207. Typical soil degradation in days is about 130 for difenoconazole.</p> <p>Difenoconazole is a fungicide used for disease control in many fruits, vegetables, cereals, and other field crops. Although potentially a mobile molecule it is unlikely to leach due to its low aqueous solubility. It does however have poten-</p>
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	<p>tial for particle bound transport. It is slightly volatile, persistent in soil and in the aquatic environment. There are some concerns regarding its potential for bioaccumulation. Moderately toxic to humans, mammals, birds, and most aquatic organisms. Predicted concentration of difenoconazole soil (PECsoil) should be shown in report B, Section 5.</p> <p>Normally no special data for fungicides are prepared and submitted for that point if no persistence of the product is known or in discussion. Some data can be described at other parts of this section or in other sections (persistence situation of the applied substances). However, problems from other authorisations of difenoconazole products at fruit trees, vegetable or brassicas have not been reported.</p> <p>Also, no impact of IN005B1570 250 EC EC on succeeding crops is not conceivable as crop rotation is not usual in orchards (apple, pear). <b>Lack of phytotoxicity symptoms recorded during the field trials suggested that product (IN005B1570 250 EC EC) application in accordance with label recommendation shall not adversely impact on succeeding crops.</b></p>
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### 3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

IN005B1570 250EC is a fungicide and is not expected to have any significant herbicidal activity.

In addition, many products containing difenoconazole have been approved and widely used in many countries of Europe for the control of several diseases and proven to have no effects on adjacent crops.

**Therefore, no impact on adjacent crops is expected if IN005B1570 250EC is used according to the Good Agricultural Practices and label recommendations.**

Comments of zRMS:	<p>The Applicant initially did not provide a sufficient level of information to address the impact on succeeding crops in accordance with EPPO PP 1/207. Typical soil degradation in days is about 130 for difenoconazole.</p> <p>Difenoconazole is a fungicide used for disease control in many fruits, vegetables, cereals, and other field crops. Although potentially a mobile molecule it is unlikely to leach due to its low aqueous solubility. It does however have potential for particle bound transport. It is slightly volatile, persistent in soil and in the aquatic environment. There are some concerns regarding its potential for bioaccumulation. Moderately toxic to humans, mammals, birds, and most aquatic organisms. Predicted concentration of difenoconazole soil (PECsoil) should be shown in report B, Section 5.</p> <p>Normally no special data for fungicides are prepared and submitted for that point if no persistence of the product is known or in discussion. Some data can be described at other parts of this section or in other sections (persistence situation of the applied substances). However, problems from other authorisations of difenoconazole products at fruit trees, vegetable or brassicas have not been reported.</p> <p>Also, no impact of IN005B1570 250 EC EC on succeeding crops is not conceivable as crop rotation is not usual in orchards (apple, pear). <b>Lack of phytotoxicity symptoms recorded during the field trials suggested that product (IN005B1570 250 EC EC) application in accordance with label recommendation shall not adversely impact on adjacent crops.</b></p>
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### 3.6 Other/special studies

No further information is available.

Comments of zRMS:	ZRM s agree.
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### 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 recognized as organizations for efficacy testing of plant protection products according to the Directive 93/71/EC, are available in the GEP certibase (www.gepcertibase.eu).

**Table 3.7-1: List of test facilities**

Testing facilities	Adress	Years of trials	GEP Statues	Link of GEP Certibase
Agreco sp. z o.o.	Gac 64A, Olawa	2022	GEP	<a href="http://gepcertibase.eu/documents/2553%20DECYZJA-DPE-Nr-32021_EN.pdf">http://gepcertibase.eu/documents/2553%20DECYZJA-DPE-Nr-32021_EN.pdf</a>
Agro-check	Dorfstr. 15 D-16833 Lentzke Germany	2021	GEP	<a href="#">1d693b91d51</a>
Agrochemex Environmental	Aldhams Farm/Dead La, Manningtree CO11 2NF, United kingdom	2021	GEP	<a href="#">1d69437c65e</a>
Agrotest France	ZI de la Pomme - 17, avenue Marie Curie 31250 Revel France	2020	GEP	<a href="#">1d656d02b17</a>
Antedis	48 Rue de la Madeleine, 60000 Beauvais France	2021	GEP	<a href="#">1d69437c6e2</a>
BioChem Agrar GmbH	Kupferstraße 6 ,D-04827 Machern OT Gerichshain Germany	2021	GEP	<a href="#">1d693b91f52</a>
	Bünnert 72, D-47589 Uedem Germany	2021	GEP	<a href="#">1d693b92087</a>
BioChem Agrar Poland	Urbanowice, ul. Kozielska 48 ; 47-260 Poland	2021	GEP	<a href="#">1d693b91dcd</a>
Biotek Agriculture	Route de Viélaines 10120 Saint Pouange France	2021	GEP	<a href="#">1d693b9200f</a>
Cerestis	La Ferme du Parc ZI de Saint Christophe 10500 Saint Léger sous Brienne France	2020	GEP	<a href="#">1d617b11b95</a>
Cultus Crop Research	Denenweg 19b, 5962 NC Melderslo Netherlands	2021	GEP	<a href="#">1d6c959745e</a>
Essais+	1 rue du 8 mai 62128 Boyelles France	2020 2021	GEP	<a href="#">1d656d02a6c</a>
Fertico Sp. z o.o.	ul. Goliany 43 05-620 Błędów Poland	2021	GEP	<a href="#">1d693b92021</a>
Fieldarm Limited	Willow Fields The street, Ramsey, Harwich CO12 HL United Kingdom	2021	GEP	<a href="#">1d69437c6d8</a>
Field Research Support	Max-Planck-Straße 5, 31515 Wunstorf Germany	2021	GEP	<a href="#">1d693b9212b</a>
	Dworcowa 2, 64-000 Kościan Poland	2021	GEP	<a href="#">1d693b91da9</a>
Field Trial Services S.L.L.	C/ Platino, 1a planta, puerta 22 41909 Salteras (Sevilla) Spain	2020	GEP	<a href="#">1d691eac904</a>
Green & Property consulting Anna Huszcza-Podgórska	Ul. Na Stoku 6/6 26-600 Radom Poland	2023	GEP	<a href="#">k8DNKe1pmA</a>
Heliophyt	17, la Péree aux Naux	2020	GEP	<a href="#">1d5e0c4220d</a>

Testing facilities	Adress	Years of trials	GEP Statues	Link of GEP Certibase
	37130 Lignières-de-Touraine France			
Hetterich Field-work GbR	Bamberger Str. 50, 97359 Schwarzach am Main Germany	2021	GEP	<a href="#">1d693b9201c</a>
Invenio	Maison Jeannette 24140 Douville France	2020	GEP	<a href="#">1d691f0e40b</a>
Oxford Agricultural Trials Ltd	1 Abbey St, Eynsham, Witney OX29 4TB United Kingdom	2021	GEP	<a href="#">1d693b91f2b</a>
Prime Crop Research	Honingham Thorpe, Colton, Norwich, NR9 5BZ United Kingdom	2021	GEP	<a href="#">1d693b91f56</a>
Qualiphyt	80 chemin de Riboulin 26270 Loriol sur Drôme France	2021	GEP	<a href="#">1d693b92016</a>
Quintus GmbH	Liepen 7, 17194 Hohen Wangelin Germany	2021	GEP	<a href="#">1d693b92078</a>
S.C. Agrotest Romania SRL	Comuna Voiteg 307470 Județele Timiș Romania	2021	GEP	<a href="#">1d693b91d8e</a>
SARL Vert-Marine	Kerloroc 29830 Ploudalmezeau France	2020	GEP	<a href="#">1d691eac8ee</a>
Staphyt GmbH	Langenburger Str. 35, 74572 Blaufelden Germany	2021	GEP	<a href="#">1d693b920cb</a>
Staphyt Ltd	Cromwell Office Park, York Road, Wetherby, LS22 7SU United Kingdom	2021	GEP	<a href="#">1d693b91f62</a>
Staphyt s.r.o.	Antala Staška 1859/34, 140 00 Praha 4 Czech Republik	2021	GEP	<a href="#">1d693b91e58</a>
Staphyt Sp. z o.o.	ul. Ziębicka 2, 60-164 Poznań	2020 2021	GEP	<a href="#">1d6c94bbaae</a>
Staphyt SRL	Str. Petrolistilor nr. 18 925300, Urziceni Romania	2020	GEP	<a href="#">1d693b920ca</a>
Staphyt (France)	23 Route de Moeuvres 62860 Inchy en Artois France	2020	GEP	<a href="#">1d5a52ade17</a>
Verify	Tolweg 13, 1681 ND Zwaagdijk The Netherlands	2021	GEP	<a href="#">1d693b92108</a>
ZZS Kujavy, s.r.o.	Kujavy 48, 742 45 Kujavy Czech Republik	2021	GEP	<a href="#">1d693b920c9</a>

## Appendix 1 Lists of data considered in support of the evaluation

### List of data submitted

Annex point/reference number (OECD-Format)	Author	Year	Title Source (where different from company), Report No. Company Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
3.2.2 3.2.3 3.4.1 3.4.3 #001	Dana, P.	2021	Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. ZZS Kujavy, s.r.o., Kujavy, Czech Republik, Report No. CZ21-IBV-105-03 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #002	Barou, J-L.	2021	Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. AGROTEST France, Revel, France, Report No. FR21-IBV-105-04 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #003	Zickart, U.	2021	Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. BioChem agrar GmbH, Uedem, Germany, Report No. GE21-IBV-105-07 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 3.4.3 #004	Hetterich, A.	2021	Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. Hetterich Fieldwork GbR, Schwarzach am Main, Germany, Report No. GE21-IBV-105-08 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #005	Hetterich, A.	2021	Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. Hetterich Fieldwork GbR, Schwarzach am Main, Germany, Report No. GE21-IBV-105-12 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3	Teresiak-Baumgart, P.	2021	Evaluate the efficacy of IN233C1560 and IN005B1570 against Phoma on OSR. Agro-check, Lentzke, Germany, Report No. AC/21/062	N	Y	New study	Indofil

Annex point/reference number (OECD-Format)	Author	Year	Title Source (where different from company), Report No. Company Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
3.4.1 #006			Report No. GE21-IBV-106-02 Indofil Not GEP Unpublished				
3.2.2 3.2.3 3.4.1 3.4.3 #007	Kolditz, M.	2021	Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. BioChem agrar GmbH, Uedem, Germany, Report No. PL21-IBV-105-13 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #008	Kolditz, M.	2021	Evaluate the efficacy of IN233C1560 and IN005B1570 against Phoma on OSR. BioChem agrar Polska Spółka z o.o., Urbanowice, Poland, Report No. 21 1068 1216 Report No. PL21-IBV-106-03 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #009	Fora Ciprian, G.	2021	Evaluate the efficacy of IN233C1560 and IN005B1570 against Phoma on OSR. S.C. Agrotest Romania SRL, Județele Timiș, Romania, Report No. Atr 2022.1 Report No. RO21-IBV-106-07 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #010	Camunez, S.	2020	Efficacy of Prothio + Difeno RMIX against Sclerotinia on OSR. GEP Trial, FRANCE, 2020 Staphyt, Inchy-en-Artois, France, Report No. SCZ-20-44463-FR01 Report No. SCZ-20-44463-FR01 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #011	Camunez, S.	2020	Efficacy of Prothio + Difeno RMIX against Sclerotinia on OSR. Staphyt, Poznan, Poland, Report No. SCZ-20-44463-PL06 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3	Camunez, S.	2021	Efficacy of Prothio + Difeno RMIX against Phoma on OSR GEP Trial, FRANCE, 2020 Staphyt, Inchy-en-Artois, France,	N	Y	New study	Indofil

Annex point/reference number (OECD-Format)	Author	Year	Title Source (where different from company), Report No. Company Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
3.4.1 #012			Report No. SCZ-20-45428-FR01 Indofil Not GEP Unpublished				
3.2.2 3.2.3 3.4.1 #013	Camunez, S.	2021	Efficacy of Prothio + Difeno RMIX against Phoma on OSR Staphyt, Urziceni, Romania, Report No. SCZ-20-45428-RO07 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 3.4.3 #014	McCabe, T.	2021	Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. Prime Crop Research, Norwich, United Kingdom, Report No. UK21-IBV-105-18 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #015	McCabe, T.	2021	Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. Prime Crop Research, Norwich, United Kingdom Report No. UK21-IBV-105-19 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #016	Pralea, M.	2021	Evaluate the efficacy of IN233C1560 and IN005B1570 against phoma on OSR. Agrochemex Environmental, Manningtree, United Kingdom, Report No. ACE21-507 Report No. UK21-IBV-106-04 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #017	Haigh, I.	2021	Evaluate the efficacy of IN233C1560 and IN005B1560 against Phoma on OSR. Fieldarm Limited, Harwich, United Kingdom, Report No. F21052 T1 Report No. UK21-IBV-106-05 Indofil GEP Unpublished	N	Y	New study	Indofil
3.4.1 #018	Rivet, J.	2021	Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. Essais+, Boyelles, France Report No. FR21-IBV-105-01	N	Y	New study	Indofil

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			Indofil GEP Unpublished				
3.4.1 #019	Crepin, D.	2021	Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. Essais+, Boyelles, Report No. FR21-IBV-105-02 Indofil GEP Unpublished	N	Y	New study	Indofil
3.4.1 #020	Negrini, P.	2021	Evaluate the efficacy of IN233C1560 AND IN005B1570 against phoma, sclerotinia on OSR - 2021 ANTEDIS, Beauvais, France, Report No. RED-FE22CO-00006-CO Report No. FR21-IBV-106-01 Indofil GEP Unpublished	N	Y	New study	Indofil
3.4.1 #021	Teresiak, H.	2021	Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. Agro-check, Lentzke , Germany Report No. GE21-IBV-105-05 Indofil GEP Unpublished	N	Y	New study	Indofil
3.4.1 #022	Seifert, M.	2021	Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. BioChem agrar GmbH, Gerichshain, Germany Report No. GE21-IBV-105-06 Indofil GEP Unpublished	N	Y	New study	Indofil
3.4.1 #023	Hetterich, A.	2021	Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. Hetterich Fieldwork GbR, Schwarzach am Main, Germany Report No. GE21-IBV-105-09 Indofil GEP Unpublished	N	Y	New study	Indofil
3.4.1 3.4.3 #024	Rusek, K.	2021	Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. Fertico, Błędów, Poland, Report No. PL21-IBV-105-14 Indofil	N	Y	New study	Indofil

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			GEP Unpublished				
3.4.1 3.4.3 #025	George, F.	2021	Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR. SC Agrotest Romania SRL, Judeţele Timiş, Romania, Report No. RO21-IBV-105-17 Indofil GEP Unpublished	N	Y	New study	Indofil
3.4.1 #026	Camunez, S.	2020	Efficacy of Prothio + Difeno RMIX against Sclerotinia on OSR. Staphyt, Inchy-en-Artois, France, Report No. SCZ-20-44463-FR02 Indofil GEP Unpublished	N	Y	New study	Indofil
3.4.1 #027	Camunez, S.	2020	Efficacy of Prothio + Difeno RMIX against Sclerotinia on OSR. Staphyt, Urziceni, Romania, Report No. SCZ-20-44463-RO07 Indofil GEP Unpublished	N	Y	New study	Indofil
3.4.1 #028	Camunez, S.	2021	Efficacy of Prothio + Difeno RMIX against Phoma on OSR. Version 2 Staphyt, Blaufelden-Herrentierbach, Germany, Report No. SCZ-20-45428-DE03 Indofil GEP Unpublished	N	Y	New study	Indofil
3.4.1 #029	Camunez, S.	2021	Efficacy of Prothio + Difeno RMIX against Phoma on OSR. Version 2 Staphyt, Blaufelden-Herrentierbach, Germany, Report No. SCZ-20-45428-DE04 Indofil GEP Unpublished	N	Y	New study	Indofil
3.4.1 #030	Camunez, S.	2021	Efficacy of Prothio + Difeno RMIX against Phoma on OSR. GEP Trial, United Kingdom, 2020 Staphyt, Bicester, United Kingdom, Report No. SCZ-20-45428-GB05 Indofil	N	Y	New study	Indofil

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			GEP Unpublished				
3.4.1 #031	Camunez, S.	2021	Efficacy of Prothio + Difeno RMIX against Phoma on OSR. GEP Trial, POLAND, 2020 Staphyt, Poznan, Poland, Report No. SCZ-20-45428-PL06 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #032	Rump, K.	2021	Evaluate the efficacy of IN005B1570 on apple trees against <i>Venturia inaequalis</i> Field Research Support, Wunstorf, Germany, Report No. FRS200/21-V1 Report No. FEU-AGR-001-21-SCAP-DE01 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #033	Koppi, M.	2021	Evaluation of the efficacy of IN005B1570 on apple trees against Apple scab Hetterich Fieldwork GbR, Schwarzach am Main, Germany, Report No. FEU-AGR-001-21-SCAP1-DE04 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #034	Hüttenrauch, J.	2021	Evaluation of the efficacy of IN005B1570 on apple trees against Apple scab Quintus GmbH, Hohen Wangelin, Germany, Report No. K-150-QUI-21-251 Report No. FEU-AGR-001-21-SCAP1-DE05 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #035	Lunzenfichter, D.	2021	Evaluation of the efficacy of IN005B1570 on apple trees against Apple scab, France, 2021. Qualiphyt, Lorient sur Drôme, France, Report No. QUALI21112B17 Report No. FEU-AGR-001-21-SCAP1-FR06 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #036	Pietryga, A.	2021	Evaluation of the efficacy of IN005B1570 on apple trees against Apple scab in Poland Biotek Agriculture Polska Sp. z o.o., Kozielska, Poland, Report No. DPE21/059/FOW-01 Report No. FEU-AGR-001-21-SCAP2-PL09 Indofil	N	Y	New study	Indofil



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			GEP Unpublished				
3.2.2 3.2.3 3.4.1 #037	Pietryga, A.	2021	Evaluation of the efficacy of IN005B1570 on apple trees against Apple scab in Poland Biotek Agriculture Polska Sp. z o.o., Kozielska, Poland, Report No. DPE21/059/FOW-02 Report No. FEU-AGR-001-21-SCAP2-PL10 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #038	Ciemniak, W.	2021	Evaluation of the efficacy of IN005B1570 on apple trees against Apple scab in Poland Field Research Support, Koscian, Poland, Report No. DPE21/059/FOW-02 Report No. FEU-AGR-001-21-SCAP2-PL08 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #039	Sowińska, P.	2021	Evaluation of the efficacy of IN005B1570 on apple trees against Apple scab in Poland Fertico sp. zo.o, Błędów, Poland, Report No. 156_01_F21_323 Report No. FEU-AGR-001-21-SCAP2-PL11 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #040	Sowińska, P.	2021	Evaluation of the efficacy of IN005B1570 on apple trees against Apple scab in Poland Fertico sp. zo.o, Błędów, Poland, Report No. 156_01_F21_323 Report No. FEU-AGR-001-21-SCAP2-PL12 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #041	Romium, M.	2020	Evaluation of the efficacy of IN005B1570 on apple trees against Apple scab Heliophyt, Lignières-de-Touraine, France, Report No. Helio20-002 Report No. FEU-AGR-004-20-SCAP-FR001 Indofil GEP Unpublished	N	Y	New study	Indofil
3.4.1 #042	Rump, K.	2021	Evaluate the efficacy of IN005B1570 on apple trees against <i>Venturia inaequalis</i> Field Research Support, Wunstorf, Germany, Report No. FRS200/21-V2 Report No. FEU-AGR-001-21-SCAP-DE02 Indofil GEP	N	Y	New study	Indofil

Annex point/reference number (OECD-Format)	Author	Year	Title Source (where different from company), Report No. Company Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
3.4.1 #043	Koppi, M.	2021	Evaluation of the efficacy of IN005B1570 on apple trees against Apple scab Hetterich Fieldwork GbR, Schwarzach am, Germany, Report No. FEU-AGR-001-21-SCAP1-DE03 Indofil GEP Unpublished	N	Y	New study	Indofil
3.4.1 #044	Gouaille, L.	2021	Evaluation of the efficacy of IN005B1570 on apple trees against Apple scab Biotek Agriculture, Saint Pouange, France, Report No. BPE21/219/FAR01 Report No. FEU-AGR-001-21-SCAP1-FR07 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #045	Crepin, D.	2020	Evaluation of the efficacy of IN005B1570 against <i>Alternaria sp.</i> on carrot Essais +, Boyelles, France, Report No. 2040F02 Report No. FEU-AGR-022-20-ALTCAR-FR001 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #046	Galland, R.	2020	Evaluation of the efficacy of IN005B1570 against <i>Alternaria sp.</i> on carrot Invenio, Douville, France, Report No. 80881 Report No. FEU-AGR-022-20-ALTCAR-FR002 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #047	Crepin, D.	2020	Evaluation of the efficacy of IN005B1570 against <i>Erysiphe heraclei</i> on carrot Essais +, Boyelles, France, Report No. 2040F03 Report No. FEU-AGR-023-20-ERYCAR-FR001 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #048	Galland, R.	2020	Evaluation of the efficacy of IN005B1570 against <i>Erysiphe heraclei</i> on carrot Invenio, Douville, France, Report No. 80882 Report No. FEU-AGR-023-20-ERYCAR-FR002 Indofil GEP Unpublished	N	Y	New study	Indofil

Annex point/reference number (OECD-Format)	Author	Year	Title Source (where different from company), Report No. Company Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
3.2.2 3.2.3 3.4.1 #049	Rump, K.	2021	Evaluate the efficacy of IN005B1570 on carrot against <i>Alternaria</i> sp. Field Research Support, Wunstorf, Germany, Report No. FRS201/21 Report No. FEU-AGR-002-21-ALTCAR-DE01 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #050	Hüttenrauch, J.	2021	Evaluate the efficacy of IN005B1570 on carrot against <i>Alternaria</i> sp. Quintus GmbH, Wunstorf, Germany, Report No. FEU-AGR-002-21-ALTCAR-DE02 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #051	Kohrman, E.	2021	Evaluate the efficacy of IN005B1570 on carrot against <i>Alternaria</i> sp. Cultus, Melderslo, Netherlands, Report No. R21-132-64F-1 Report No. FEU-AGR-003-21-ALTCAR-NL03 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #052	Wojciech, C.	2021	Evaluation of the efficacy of IN005B1570 against <i>Alternaria</i> sp. on carrot in Poland Field Research Support, Kościan, Poland, Report No. FRS 201/21-V2-PL Report No. FEU-AGR-005-21-ALTCAR-PL01 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #053	Sowińska, P.	2021	Evaluation of the efficacy of IN005B1570 against <i>Alternaria</i> sp. on carrot in Poland Fertico sp. z o.o, Błędów, Poland, Report No. 157_01_F21_325 Report No. FEU-AGR-005-21-ALTCAR-PL02 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #054	Sowińska, P.	2021	Evaluation of the efficacy of IN005B1570 against <i>Alternaria</i> sp. on carrot in Poland Fertico sp. z o.o, Błędów, Poland, Report No. 157_02_F21_326 Report No. FEU-AGR-005-21-ALTCAR-PL03 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2	Sowińska, P.	2021	Evaluation of the efficacy of IN005B1570 against <i>Alternaria</i> sp. on carrot in Poland	N	Y	New study	Indofil

Annex point/reference number (OECD-Format)	Author	Year	Title Source (where different from company), Report No. Company Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
3.2.3 3.4.1 <b>#055</b>			Fertico sp. z o.o, Błędów, Poland, Report No. 157_02_F21_327 Report No. FEU-AGR-005-21-ALTCAR-PL04 Indofil GEP Unpublished				
3.2.2 3.2.3 3.4.1 <b>#056</b>	Pietryga, A.	2021	Evaluation of the efficacy of IN005B1570 against <i>Alternaria</i> sp. on carrot in Poland Biotek Agriculture, Kozielska, Poland, Report No. DPE21/060/FWA-01 Report No. FEU-AGR-005-21-ALTCAR-PL05 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 <b>#057</b>	Pietryga, A.	2021	Evaluation of the efficacy of IN005B1570 against <i>Alternaria</i> sp. on carrot in Poland Biotek Agriculture, Kozielska, Poland, Report No. DPE21/060/FWA-02 Report No. FEU-AGR-005-21-ALTCAR-PL06 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 <b>#058</b>	Carr, D.	2021	Evaluation of the efficacy of IN005B1570 against <i>Alternaria</i> sp. on carrot in the United Kingdom Oxford Agricultural Trials Limited, Witney, United Kingdom, Report No. OAT-AGR2021-1294 Report No. FEU-AGR-004-21-ALTCAR-UK05 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 <b>#059</b>	Hunt, A.	2021	Evaluation of the efficacy of IN005B1570 against <i>Alternaria</i> sp. on carrot in the United Kingdom Oxford Agricultural Trials Limited, Witney, United Kingdom, Report No. OAT-AGR2021-1294 Report No. FEU-AGR-004-21-ALTCAR-UK06 Indofil GEP Unpublished	N	Y	New study	Indofil
3.4.1 <b>#060</b>	Kohrman, E.	2021	Evaluation of the efficacy of IN005B1570 against <i>Alternaria</i> sp. on carrot in the Netherlands Vertify, A compléter, Netherlands, Report No. 210596 Report No. FEU-AGR-003-21-ALTCAR-NL04 Indofil	N	Y	New study	Indofil

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			GEP Unpublished				
3.2.2 3.2.3 3.4.1 #061	Crepin, D.	2020	Evaluation of the efficacy of IN005B1570 against <i>Alternaria</i> on cauliflower Essais+, Boyelles, France, Report No. 2040F04 Report No. FEU-AGR-026-20-ALMYCAU-FR001 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #062	Auges, C.	2020	Evaluation of the efficacy of IN005B1570 against <i>Alternaria</i> or <i>Mycosphaerella</i> on cauliflower SARL Vert-Marine, Ploudalmezeau, France, Report No. Agr20-FngChou-1 Report No. FEU-AGR-026-20-ALMYCAU-FR002 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #063	Auges, C.	2020	Evaluation of the efficacy of IN005B1570 against <i>Alternaria</i> or <i>Mycosphaerella</i> on broccoli SARL Vert-Marine, Ploudalmezeau, France, Report No. Agr20-FngBrocoli-1 Report No. FEU-AGR-027-20-ALMYBRO-FR002 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #064	Crepin, D.	2020	Evaluation of the efficacy of IN005B1570 against <i>Alternaria</i> or <i>Mycosphaerella</i> on cabbage Essais+, Boyelles, France, Report No. 2040F06 Report No. FEU-AGR-028-20-ALMYCAB-FR001 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #065	Issakof, J.	2020	Evaluation of the efficacy of IN005B1570 against <i>Alternaria</i> or <i>Mycosphaerella</i> on cabbage Ceresstis, Saint Léger sous Brienne, France, Report No. CEE-20281 Report No. FEU-AGR-028-20-ALMYCAB-FR002 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.3	Kukuła, A.	2022	Efficacy and selectivity evaluation of test product IN005B1570 (difenoconazole 250 G/L) applied alone or in strategy against <i>Venturia inaequalis</i> on apple - Poland 2022	N	Y	New study	Indofil

Annex point/reference number (OECD-Format)	Author	Year	Title Source (where different from company), Report No. Company Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
3.4.1 #066			Agreco sp. z o.o., Poland Report No. 7333.F.SAG22 Indofil GEP Unpublished				
3.2.3 3.4.1 #067	Kukuła, A.	2022	Efficacy and selectivity evaluation of test product IN005B1570 (difenoconazole 250 G/L) applied alone or in strategy against <i>Venturia inaequalis</i> on apple - Poland 2022 Agreco sp. z o.o., Poland Report No. 7334.F.SAG22 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #068	Ptaszek, R.	2023	Efficacy and selectivity of IN005B1570 against <i>Venturia inaequalis</i> in pome fruits. Green & Property Consulting, Poland Report No. 003GPSE202301 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #069	Ptaszek, R.	2023	Efficacy and selectivity of IN005B1570 against <i>Venturia inaequalis</i> in pome fruits. Green & Property Consulting, Poland Report No. 003GPSE202302 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #070	Ptaszek, R.	2023	Efficacy and selectivity of IN005B1570 against <i>Venturia inaequalis</i> in pome fruits. Green & Property Consulting, Poland Report No. 003GPSE202303 Indofil GEP Unpublished	N	Y	New study	Indofil
3.2.2 3.2.3 3.4.1 #071	Ptaszek, R.	2023	Efficacy and selectivity of IN005B1570 against <i>Venturia inaequalis</i> in pome fruits. Green & Property Consulting, Poland Report No. 003GPSE202304 Indofil GEP Unpublished	N	Y	New study	Indofil

