

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: IN005B1570

Product name: Difenoconazole 250 G/L EC greener

Chemical active substance:

Difenoconazole, 250 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT country

(Article 33: Application for authorisation)

Applicant: Indofil Industries (Netherlands) B.V.

Submission date: January 2022

Update: 10.2023

MS Finalisation date: 08.2023; 01.2024; 05.2024; 08.2024; 08.2025

Version history

When	What
January 2022	V0 – Original version from applicant Indofil Industries (Netherlands) B.V. for submission to z-RMS, Poland, in the frame of the PPP Authorization according to Article 33 of Regulation (EC) No. 1107/2009
August 2023	ZRMs evaluated submitted dRR by Applicant.
October 2023	Applicant inclusion of final reports of studies underway at time of original submission
January 2024	zRMS revision after changes and evaluation according to the Reg. 2023/574
February 2024	Applicant dRR update commenting period
May 2024	ZRMs made changes in line to reviewed comments.
August 2024	ZRMs made changes in RR in line to reviewed coments during 3 rd round
August 2025	Revision of the fRR regarding the use of the product in the protection of carrots up to BBCH phase 49.

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted in order to allow the registration of product IN005B1570, an emulsifiable concentrate formulation containing 250 g/L difenoconazole for use on oilseed rape, pome fruits, carrot, , cauliflower, broccoli and cabbage. Difenoconazole was first included in Annex I to Directive 91/414/EEC by Commission Directive 2008/69/EC of 1 July 2008 in Central Zone. Full details of all intended uses are summarized in GAP table, point 2.6.

A full risk assessment according to Uniform Principles is provided which demonstrates that the product is safe for the environment. Where appropriate this document refers to the conclusion of the EU review for difenoconazole. This will be where:

- The active substance data are relied upon in the risk assessment of the formulation; or when
- the EU review concluded that the additional data/information should be considered at national re-registration.

Note: this Part B document only reviews data (Annex II or Annex III) and additional information that has not previously been considered within the EU review process, as part of the Annex I inclusion decision. New annex II data must only be included if they are considered essential for the evaluation and in this case a full study summary must be provided. In the case where the formulation has been previously evaluated, at European level, detailed summaries have not been provided.

This product was not the representative formulation and has not been previously evaluated according to the Uniform Principles.

The EFSA Scientific report for Difenoconazole (EFSA Scientific Report, 2011; 9(1):1967) is considered to provide the relevant review information or a reference to where such information can be found.

The Commission Implementation Regulation for Difenoconazole (540/2011) provides specific provisions under part B 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 conclusion of the review report for Difenoconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.

In this overall assessment Member States must pay particular attention to:

- The protection of aquatic organisms.

Conditions of use shall include adequate risk mitigation measures, where appropriate.

The Commission Implementation Regulation (1100/2011) amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of Difenoconazole provides specific provisions under part B 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 27 September 2011 shall be taken into account.

In this overall assessment Member States shall pay particular attention to the protection of aquatic organisms.

Conditions of use shall include adequate risk mitigation measures, where appropriate.

The notifier shall submit confirmatory information as regards:

- (a) further data on the specification of the technical material;
- (b) residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops, processed commodities and products of animal origin;
- (c) the potential for endocrine disrupting effects on fish (fish full life cycle study) and the chronic risk to earthworms from the active substance and the metabolite CGA 205375 (1);
- (d) the possible impact of the variable isomer-ratio in the technical material and of the preferential degradation and/or conversion of the mixture of isomers on the worker risk assessment, the consumer risk assessment and on the environment.

The notifier shall submit to the Member States, the Commission and the Authority the information set out in point (a) by 31 May 2012, the information set out in points (b) and (c) by 30 November 2013 and the information set out in point (d) within 2 years from the adoption of specific guidance.'

Information on the detailed composition of IN005B1570 can be found in the confidential dossier of this submission (Registration Report – Part C).

1.2 Letters of Access

Not required

1.3 Justification for submission of tests and studies

The study reports submitted within this application are in agreement with the data requirements of the Regulation 284/2013.

1.4 Data protection claims

Indofil Industries (Netherlands) B.V. is claiming data protection in accordance with Article 59 of Regulation (EC) No 1107/2009 for the submitted studies. Please refer to the reference list in Appendix 4 for

more information

2 Details of the authorization decision

2.1 Product identity

Product code	INDOFIL Difenoconazole 250 g/L EC Greener (IN005B1570)
Product name in MS	Difenoconazole 250 G/L EC greener
Authorization number	-
Function	fungicide
Applicant	Indofil Industries (Netherlands) B.V
Active substance(s) (incl. content)	Difenoconazole; 250 g/L
Formulation type	Emulsifiable concentrate [Code: EC]
Packaging	0.25L, 0.5L, 1L, 5L, 10L, 20L bottle Polyamide / High Density Polyethylene professional user
Coformulants of concern for national authorizations	Not applicable
Restrictions related to identity	Not applicable
Mandatory tank mixtures	Not applicable
Recommended tank mixtures	Not applicable

2.2 Conclusion

The evaluation of the application for **Difenoconazole 250 G/L EC greener** resulted in the decision to grant the authorization.

Physical and chemical properties: ~~data gap — 2 years study is on going. Based on the composition of the formulation and results of the accelerated storage study, two years conditional registration of the product is proposed. Final registration will be possible after submission of the 2 year shelf life study.~~
Shelf life: 2 years

Efficacy section:

Difenoconazole greener 250 EC / IN005B1570 in Poland can be registered against SCLESC (spring once application) on winter oilseed rape, ALTEDA on carrot (3 times per season) and can be **conditionally** registered against VENTIN on apple (max 3 times per season). Pear against VENTPI, carrot against AL-TERA and ERY SHE and brassica crops (cabbage, broccoli, cauliflower) against ALTEBI and MY-COBR can be registered only in line to Article 51. **Recommended application window for brassicas crops in line to Article 51 should be 19-49 BBCH, instead of 19-39.**

Metabolism and residues:

All uses applied for were authorised **except for use(s) on cauliflower, broccoli and cabbage due to lack of residue trials.**

Additional storage stability data are accepted.

The residue trials presented by the applicant allow for the acceptance of the use of the product in the protection of carrots up to BBCH 49 phase.

Section 8. Fate and behaviour: In accordance with proposed pattern use in GAP no risk for groundwa-ter is expected.

Ecotoxicology section:

Difenconazole greener 250 EC/IN005B1570 can be registered in Poland in oilseed rape, orchards and carrots. Final decision in leafy crops is left to each CMS on the basis on submitted documentation.

PECs for the metabolite CGA 71019 was corrected according to dRR Part B8 based on $DT_{50} = 346.6$ d (CRD, 2014; EFSA 2018). For the metabolite CGA 71019 the risk assessment for earthworms and *F.candida* did not meet the trigger value of 5 for leafy crops. The risk for leafy crops in terms of soil organisms such as earthworms and *F.candida* is unacceptable. Refinement risk assessment for soil organisms such as earthworms and *F.candida* for leafy crops is required. It should be considered by MSs level.

The risk mitigation measures should be applied for aquatic organisms. It should be considered at MSs members.

According to Commission regulation (EU) No 284/2013, point 10.3.1. (Effects on bees) the Applicant provided also the chronic study for adult bees and the chronic test for larvae for formulated product. The studies were accepted by zRMS.

The evaluator also verified whether the co-formulants contained in plant protection product **Difenconazole 250 G/L EC greener** are listed in Annex III to Regulation (EC) No 1107/2009 and/or could be considered unacceptable based on the criteria indicated in the Annex to the Commission Implementing Regulation (EU) 2023/574 of 13 March 2023.

Based on the currently available MSDSs and other information provided by applicant or manufacturer of co-formulant, the product **Difenconazole 250 G/L EC greener** does not contain any unacceptable co-formulant/ingredient listed in the **Commission Regulation (EU) 2021/383** amending **Annex III** to Regulation (EC) No 1107/2009.

According to the current knowledge and available information none of the co-formulants in the plant protection product **Difenconazole 250 G/L EC greener** meets the Annex to **Regulation (EU) 2023/574** criteria for identification of co-formulants that are unacceptable for inclusion in a plant protection products. Taking this into account, none of the co-formulants/ingredients in this product is considered to be a candidate for inclusion in Annex III of Regulation (EU) 1107/2009.

Detailed assessment of co-formulants according to Article 3 of Regulation (EU) 2023/574 can be found in RR Part C or annex to Part C of this submission (section 1.2.2).

2.3 Substances of concern for national monitoring

Not applicable

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Eye irritation (Category 2) Carcinogenicity (Category 2, Aquatic Acute Category 1 Aquatic Chronic Category 1
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	GHS07 GHS08 GHS09
Signal word:	Warning
Hazard statement(s):	H319: Causes serious eye irritation. H351: Suspected of causing cancer. H400 : Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects H411: Toxic to aquatic life with long lasting effect
Precautionary statement(s):	WARNING SECTION OF THE LABEL (first page): P201: Obtain special instructions before use. P280: Wear protective gloves, eye protection/face protection. P273: Avoid release to the environment P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308+PP313: IF exposed or concerned: Get medical advice/attention. P391: Collect spillage. Other section of the label: P270 – Do not eat, drink or smoke when using this product. P405: Store locked up. P501: Dispose of contents/container in accordance with national regulation. And P280 as follows: Operator: „Stosować rękawice ochronne, ochronę oczu lub twarzy oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy roboczej oraz rękawice ochronne i odzież roboczą w trakcie wykonywania zabiegu” “Wear protective gloves, eye/face shield and work wear (coverall) during mixing/loading and protective gloves and work wear during application”. Worker: „Stosować odzież roboczą (długie spodnie, koszula z długim rękawem) oraz rękawice ochronne podczas prac wykonywanych na terenie poddanym zabiegowi.” “Wear workwear (long trousers, long-sleeve shirt) and protective gloves during field work carried out in the treated area.” Section “First aid”: P101: If medical advice is needed, have product container or label at hand. P308+PP313: IF exposed or concerned: Get medical advice/attention. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313: If eye irritation persists: Get medical advice/attention.

Additional labelling phrases:	To avoid risks to human health and the environment, comply with the instructions for use. [EUH401] 15 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity.
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Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
-	-

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

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
-	-

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

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2.5 Risk management

2.5.1 Restrictions linked to the PPP

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

Operator protection:					
Acceptable	Exposure assessment: No PPE required Classification: eye/face protection, protective gloves, work wear				
Worker protection:					
Acceptable	No PPE required (only work wear) Recommendation: protective gloves				
Integrated pest management (IPM)/sustainable use:					
-	No specific restrictions				
Environmental protection					
respective code if available	To protect aquatic organisms respect the following mitigation measures: Poland (D3, D4 and R1 are characteristic scenarios for Poland)				
	<table> <tr> <th>Crop</th><th>Mitigation measure</th></tr> <tr> <td></td><td></td></tr> </table>	Crop	Mitigation measure		
Crop	Mitigation measure				

	Oilseed rape	5m no spray buffer zone
	Orchards	25 m no-spray buffer zone
	Carrot	10 m no-spray buffer zone and 10 m vegetative filter strip
	Leafy vegetables (cauliflower, broccoli, cabbage)	20 m no-spray buffer zone and 20 m vegetative filter strip
Other specific restrictions		
respective code if available	-	

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

Integrated pest management (IPM)/sustainable use:	
-	-

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
-	-	-
Environmental protection:		Relevant for use no.
-	-	-

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code): INDOFIL Difenconazole 250 EC / IN005B1570
Active substance 1: Difenconazole
Applicant: Indofil Industries (Netherlands) B.V.
Zone(s): CEU ^(d)
Verified by MS: yes/no
Field of use: Fungicide

GAP rev. 1, date: 2021-August-23
Formulation type: EC ^(a, b)
Conc. of as 1: 250 g/L ^(c)
Professional use: ☒
Non professional use: ☐

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/synergist per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL	BRSNW (OSR)	F	LEPTMA (Leptosphaeria maculans) SCLESCS (Sclerotinia sclerotiorum), ALTEBI (Alternaria brassicac)	foliar spray	Autumn and Spring applica- tions at BBCH 60-69 BBCH 14-18 and BBCH 30-69	2 (1 in autumn and 1 in spring or 2 in autumn)	21 n.a	a) 0.5 b) 1-0.5	a) 125 b) 250 125	400-500 200-300	NA	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 au- tumn)
2	PL	MABSD, PYUCO (Apples, Pears)	F	VENTIN, VENTPI (Venturia inaequalis, Venturia pyrina)	foliar spray	BBCH 57-78 84	3	7	a) 0.25 0.2 b) 0.5 0.6	a) 50.0 50.0 b) 100.0 150.0	400-1500 300=1000 PL, CZ, SI 100-1000	21	Proposed LWA rate 0.15 0.15 L/10000 m² LWA with a maximum of 0.225 L/ha in for DE, AT, BE, NL, (UK) and maximum of 0,2 L/ha in PL, CZ, SI

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
													Dose rate Formulated Product:: Scab 0,015 L/ha / 0,225 L/ha PL, CZ, SI 0,2 L/ha Interval between applications: 7 10 days

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
3	PL	DAUCS (Garden carrot)	F	Leaf blight of carrot - ALTEDA (Alternaria dauci) Black rot of carrot - ALTERA (Alternaria radicina) Powdery mildew of carrot ERYSHE (Erysiphe heraclei)	foliar spray	from BBCH 39- 40-49	3	14	a) 0.5 b) 1.5	a) 125 b) 375	200-1000 200-600	14	Dose rate range Formulated Product in label:: 0,4 - 0,5 L/ha 0,4 L/ha in DE, AT (0,3 L/ha UK)
4	PL	BRSOB (cauliflower)	F	ALTEBI (Alternaria brassicicola) MYCOBR (Mycosphaerella brassicicola)	foliar spray	BBCH 20-39	3	14	a) 0.5 b) 1.5	a) 125 b) 375	200-1000	14	Efficacy section: Use not accepted in PL in line to Art. 33 (only registration in line to Article 51 is possible). Accepted BBCH will be 19-49 and water volume 200-600 L/ha. Metabolism and residues: Use not accepted Ecotoxicology sec- tion: Use not accept- ed. Recommended BBCH – 20-39.
5	PL	BRSOK (broccoli)	F	ALTEBI (Alternaria brassicicola) MYCOBR (Mycosphaerella brassicicola)	foliar spray	BBCH 20-39	3	7	a) 0.5 b) 1.5	a) 125 b) 375	200-1000	14	Efficacy section: Use not accepted in PL in line to Art. 33 (only registration in line to Article 51 is possible). Accepted BBCH will be 19-49 and water volume 200-600 L/ha. Interval between applications: 7 – 10 days Metabolism and

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/synergist per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
													residues: Use not accepted. Ecotoxicology sec- tion: Use not accept- ed. Recommended BBCH – 20-39.
6	PL	BRSOL (cabbage)	F	ALTEBI (Alternaria brassicicola) MYCOBR (Mycosphaerella brassicicola)	foliar spray	BBCH 20-39	3	7	a) 0.5 b) 1.5	a) 125 b) 375	200-1000	24	Efficacy section: Use not accepted in PL in line to Art. 33 (only registration in line to Article 51 is possible) Accepted BBCH will be 19-49 and water volume 200-600 L/ha. Interval between applications: 7 – 10 days Metabolism and residues: Use not accepted Ecotoxicology sec- tion: Use not accept- ed. Recommended BBCH – 20-39.

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l

(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

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

3 Background of authorization decision and risk management

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of dark yellow liquid, with an aromatic odour. It is not explosive, has no oxidising properties. The product is not flammable/has a flash point of 102 °C. It has a self-ignition temperature of 336 °C. In aqueous solution, it has a pH value around 5.9 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. Accelerated storage data and 2 year shelf life indicate a shelf life of 2 years at ambient temperature when stored in PA/HDPE bottles (see KCP 2.7.5 in Part B1-2&4). Its technical characteristics are acceptable for an emulsifiable concentrate formulation.

The intended concentration of use is 0.04 g/L to 1.25 g/L, 0.02 to 0.25 %.

~~No tank mixtures are recommended.~~

Difenconazole 250 G/L EC greener was tested with various potential tank mix partners and all tested combinations are considered compatible. Thus, the formulation has good miscibility with water and other products.

The formulation used for tests has the same composition as the one cited in Part C.

3.2 Efficacy (Part B, Section 3)

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

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.

3.3 Efficacy data

No specific preliminary range-finding tests were deemed necessary as the fungicidal activity of difenconazole has been widely researched and proven in commercial use in several countries across Europe and similar formulations have been registered and commercialized in many EU Member States for decades.


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 accordance with EPPO 1/225 (2).

During field tests Applicant used different doses containing difenconazole. 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).

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.


On *winter oilseed rape* 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.

On **apple** 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  studied in N-E EPPO zone **in 4 additional trials carried out in 2023** 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.

On **carrot** 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.



On **brassicas** 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.

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.

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.

Efficacy

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.

Applicant submitted in total  53 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 ( 15 trials). Only one growing season was studied for brassicas (5 trials) 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).**

Those efficacy trials were performed in Maritime EPPO zone ( 34-31 trials), N-E EPPO zone (14 trials+ 2 additional apple trials **from 2022 + 4 additional trials from 2023**) and S-E EPPO zone (2 trials).

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).

The following efficacy scale was used:

- L – limiting (0-60% efficacy)
- ME – moderately efficiency (60-80%)

- E – efficiently (>80%)

Oilseed rape – 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).

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. No changes in the GAP were made.

Apple – 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 11: 5 + 2 additional trials from 2022 + 4 additional trials from 2023). 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 – 14 trials (DE-3 and PL-5+2 additional trials from 2022 + 4 additional trials from 2023).

Brassicas – 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.

Carrot – both, in Maritime (9 trials: FR-4, 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 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 used 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 four 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 four 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 aples against VENTIN.

Below, ZRMs presented briefly summary form each presented additional 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 m² LWA, 0.225 L/10000 m² 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 m² 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 m² LWA, 0.225 L/10000 m² 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 m² 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 m² LWA, 0.225 L/10000 m² 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 m² 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 m² LWA, 0.225 L/10000 m² 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 m² 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 /	Untreated	IN005B1570			IN005B1570		IN005B1570		IN005B1570		DIFENO			
	Index	check	0.2 L/ha			0.225 L/ha		calc.[0.113-0.168] L/ha LWA		[0.15-0.2] L/ha		[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 /	%	Rate applied
		Severity index	Severity index	Control	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	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
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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 /	Untreated	IN005B1570			IN005B1570		IN005B1570		IN005B1570		DIFENO		
	Index	check	0.2 L/ha			0.225 L/ha		calc.[0.113-0.168] L/ha LWA		[0.15-0.2] L/ha		[0.15-0.2] L/ha		
		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	Severity index		Control
003GPSE202301	Class 1	373	400	-	400	-	400	-	400	-	400	-	0.20 L/ha	
003GPSE202301	Class 2	14	0	-	0	-	0	-	0	-	0	-		
003GPSE202301	Class 3	13	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		
003GPSE202302	Class 1	365	400	-	400	-	400	-	400	-	400	-	0.20 L/ha	
003GPSE202302	Class 2	19	0	-	0	-	0	-	0	-	0	-		
003GPSE202302	Class 3	16	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		
003GPSE202303	Class 1	359	394	-	387	-	387	-	394	-	398	-	0.20 L/ha	
003GPSE202303	Class 2	28	4	-	10	-	10	-	4	-	2	-		
003GPSE202303	Class 3	13	2	-	3	-	3	-	2	-	0	-		
003GPSE202303	TH calcul	6.8	1.0	85.2	2.0	70.4	2.0	70.4	1.0	85.2	0.3	96.3		
003GPSE202304	Class 1	363	394	-	391	-	391	-	394	-	398	-	0.20 L/ha	
003GPSE202304	Class 2	28	4	-	8	-	8	-	4	-	2	-		
003GPSE202304	Class 3	9	2	-	1	-	1	-	2	-	0	-		
003GPSE202304	TH calcul	5.8	1.0	82.6	1.3	78.3	1.3	78.3	1.0	82.6	0.3	95.7		

ZRMs recommends conditional registration against VENTIN on apples in Poland. Additional studies should be submitted by the applicant within 24 months of obtaining conditional product registration. At least 3-4 efficacy experiments in order to supplement the information of IN005B1570-250EC on apples against VENTIN, taking into account 3 applications should be presented by Applicant.

The applicant wishes to cite the original registrant's data on difenoconazole now out of protection in support of those recommendations on the draft label that are not adequately supported. Such extrapolations should be considered by individual member states on a national level based on current registration, data protection and experience with similar difenoconazole products. The spectrum of fungal disease (against VENTIN) should be checked with label claims on these reference products. In Poland this approach is not acceptable. In conclusion, use on apple should be approved conditionally in PL based on the documentation provided (in the opinion of ZRM).

Each cMS should consider possibility of extrapolating results from N-E EPPO zone or accepted limited number of trials for Maritime EPPO zone. Also, each cMS should accepted the informations that efficacy was not assessed after 3rd application in Maritime trials but after 9 and 10 application of tested product. With this approach, the true effectiveness of the product being evaluated cannot be assessed. Because, the presented effectiveness also includes previous applications, which makes it difficult to evaluate the product for the requested application presented in the GAP table. So, final decision is left to each cMS. If this approach will be accepted, then VENTIN on apples should be classified as moderately sensitive against dose 0.225 L/ha of IN005B1570. Also, cMS can consider possibility of usage results from 4 additional trial carried out in PL (N-E) in which 3 application of product in line to proposed GAP table were studied. What is important, in those trials also dose recommended for Maritime EPPO zone was studied (0,225 L/ha). The field trials noticed that tested product IN005B1570 effectively control VENTIN on apples. So, it can be concluded that tested product moderately (in Maritime trials) to effectively (in additional trials from N-E) control VENTIN on apples leaves and fruits.

For Poland, it can be concluded that product effectively control VENTIN on apples.

Apple/Pear – in Germany other products with the same active ingredients and same amount of it are used at the same application dose, timing and number of applications as tested IN005B1570 250 EC. Proposed water amount and application window are accepted. The number of trials is a bit too low, but the active ingredients is well known and in this case, we could accept the lack of one trial. This use is acceptable for DE.

AT – not accepted use against apple and pear. 5 standing alone efficacy trials for VENTIN are not sufficient for a major use. Data from the North-East EPPO zone will not be extrapolated for high growing crops, as the crop structure might be too different.

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 ap-

plied 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	tLWA m² of orchard	L/ha LWA	L/ha LWA	
FEU-AGR-004-20-SCAP-FR001	11	1.7	3.6	600	9444	-	0.238	0.159
FEU-AGR-001-21-SCAP1-FR06	10	2.0	4.0	600	10000	-	0.225	0.150
FEU-AGR-001-21-SCAP-DE01	10	2.1	3.5	1000	12000	-	0.188	0.125
FEU-AGR-001-21-SCAP-DE04	14	2.5	3.4	600	14706	-	0.153	0.153
FEU-AGR-001-21-SCAP1-DE05	10	2.0	2.0	1000	20000	-	0.113	0.113
FEU-AGR-001-21-SCAP2-PL08	16	2.5	3.7	1000	13514	0.148	-	0.148
FEU-AGR-001-21-SCAP2-PL09	10	2.1	3.5	750	12000	0.167	-	0.167
FEU-AGR-001-21-SCAP2-PL10	10	1.7	3.8	700	8947	0.224	-	0.168
FEU-AGR-001-21-SCAP2-PL11	10	2.6	3.5	1000	14857	0.135	-	0.135
FEU-AGR-001-21-SCAP2-PL12	10	2.5	4.0	500	12500	0.160	-	0.160
22SAG01062-I – additional test 1	12	2.2	4.0	1000	11500	0.174		0.174
7334.F.SAG22 -additional test 2	12	2.2	3.8	1000	14529.12105	0.173		0.173

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	tLWA m² of orchard	L/ha LWA	L/ha LWA	
003GPSE202301 – additional trial	3	2.4	4.0	700	12000	0.165		0.165
003GPSE202302 – additional trial	3	2.4	3.5	750	13714	0.167	0.188	0.167
003GPSE202303 – additional trial	3	2.5	3.4	800	14706	0.145	0.164	0.164
003GPSE202304 – additional trial	3	2.5	3.2	800	15625	0.136	0.153	0.153
						0.128	0.144	0.144

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 ~~0,14~~ **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 brassicas 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 BRBOK or Brussels sprouts BRBOK 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). However, 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 19-39.

Recommended water volume according to submitted trials should be 200-600 L/ha, not 200-1000 L/ha.

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.

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.

against MYCOBR (*Mycosphaerella brassicicola*) – 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 *Mycosphaerella brassicicola* on brassicas (cauliflower, head cabbage and broccoli). DE – accepted this use. NL- minor use (Art. 51). However, 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 in-stead of 39. ZRMs efficacy section accepted the BBCH 19-49 for brassicas crops, instead of 19-39.

Recommended water volume according to submitted trials should be 200-600 L/ha, not 200-1000 L/ha.

- Carrot

against Alternaria dauci – 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. DE and NL – accepted this use.

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.

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. < 40%) and moderately efficiency control the disease severity on leaves (eff. 72-80%).

against Erysiphe heraclei – 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 *Erysiphe heraclei*. So, CMS from those zones should consider extrapolating results from other EPPO zone or registration control *Erysiphe heraclei* on carrot according to Article 51 (without any trial), if carrot is a minor crop. In Poland, only registration according to Article 51 against *Erysiphe heraclei* on carrot is possible. DE and NL – accepted this use.

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.

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. >90%).

against *Alternaria radicina* – 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 *Alternaria dauci*. In Poland only registration according to Article 51 will be possible for *Alternaria radicina* on carrot. DE and NL– accepted this use.

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

Difenconazole is a DMI Triazole systemic fungicide. It provides prevention and cure. It is absorbed by the leaves with acropetally and shows strong translaminar translocation. It stops the development of fungi by interfering with the biosynthesis of sterols in cell membranes.

Difenconazole 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 difenconazole as active ingredient should be used in tank mixes and / or spray programs in alternation with fungicides with different MoA's and azole compounds.

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 re-cent 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 Difenconazole 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 al-ternation 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.

The agronomic risk for active ingredients which include IN005B1570 250EC is estimated as medium for difenconazole.

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.

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.

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.

3.3.2 Adverse effects on treated crops

No phytotoxicity symptoms were observed in any trial and no negative impact on yield and quality was observed, too.

No negative effects are therefore expected applying IN005B1570 according to the proposed GAP.

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.

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.

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).

Applicant submitted in total ~~65~~ 71 phytotoxicity trials carried out in the Maritime EPPO zone (45 trial), N-E EPPO zone (16 trials + 2 trials from 2022 + 4 trials from 2023) and S-E EPPO zone (4 trials). Sub-

mitted 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).

Oilseed rape: 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

Apple: 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.

Pear: 0 trials MAR; 0 trials N-E; 0 trials S-E. Pear can be accepted only in case 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).

Carrot: 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.

Brassicas: 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.

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: **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.**

Yield:

Winter oilseed rape: 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.

Table 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 ⁽¹⁾ > , = , IN005B1570 250EC at 0.5 L/ha vs. DIFENO 0.5 L/ha
						IN005B1570 250EC 0.5 L/ha				DIFENO 0.5 L/ha				
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	
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<

Apple: 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 resetting was not studied.

Table 3.3-1: Detailed results: Effect of IN005B1570 250EC on apple russetting - % of fruits without russetting - Efficacy trials

Trial code	EPPO climatic zone	Crop Cultivar	Days after application	Crop stage at assessments	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	Rate applied
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	-	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	-	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	-	89.5 [65.5-100.0] 12.7	-	

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

Grey lines: **Mean control** [Minimum efficacy noted in all trials - Maximum efficacy noted in all trials] - S.D: Standard deviation.

Table 3.3-2: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 > , = , < IN005B1570 a [0.15-0.2] L/ha vs. [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.	
Russeting	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.

Carrots: Applicant presented in total 7 trials: MAR 3 (DE-1, FR-1, UK-1) and N-E 4 (PL). 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 ERY SHE. In fact, there was an 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 an 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.

Table 3.3-3: 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 ⁽¹⁾ > , = , < 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	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 + ERY SHE	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	-	-	-	-	-	-	-	-	-	-

Brassicas: Applicant submitted in total 2 trials carried out in MAR (France). 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.

Table 3.3-4: 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	% Contr ol	t/ha	Stat	% Contr ol
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	BRSOB	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		

Summary: 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.**

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.

ZRMs agree with Applicant that: *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.*

3.3.3 Observations on other undesirable or unintended side-effects

Difenconazole 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 difenconazole soil (PECsoil) should be shown in report B, Section 5.

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 difenconazole products at fruit trees, vegetable or brassicas have not been reported.

Also, no impact of IN005B1570 250 EC EC on succeeding crops is not conceivable as crop rotation is not usual in orchards (apple, pear). **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 and adjacent crops.**

3.4 Methods of analysis (Part B, Section 5)

Methods of analysis for the quantification of difenconazole and its impurity in the plant protection product and relevant commodities have been submitted and are fully validated according to the applicable guideline.

3.4.1 Analytical method for the formulation

Methods of analysis for the quantification of difenconazole and its impurities have been submitted. The validation data demonstrate those methods are suitable for the determination of this active substance and impurities in INDOFIL Difenconazole 250 g/L EC Greener (IN005B1570) product. The methods are fully validated according to SANCO/3030/99 rev. 5.

3.4.2 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

Noticed data gaps are:

- An independent laboratory validation (ILV) of the analytical method for difenconazole in drinking water is required according to Regulation (EC) No 283/2013 (post registration requirement in Poland - after renewal of active substance).

- An analytical method for difenoconazole in body fluids is required according to Regulation (EC) No 283/2013 (post registration requirement in Poland - after renewal of active substance)
- Information on analytical methods for determining difenoconazole residues in animal matrices compliant with SANTE/2020/12830 rev. 2 (post registration requirement in Poland – after renewal of active substance).

Deadline for completion all above mentioned requirements may be considered at the Member State level (pre or post registration requirements).

Commodity/crop	Supported/ Not supported
Oilseed rape	Supported
Apple	Supported
Carrot	Supported
Tomato	Supported

3.5 Mammalian toxicology (Part B, Section 6)

The toxicological evaluation for INDOFIL Difenoconazole 250 g/L EC Greener (IN005B1570) is derived from the classification of the active substance Difenoconazole and co-formulants.

INDOFIL Difenoconazole 250 g/L EC Greener (IN005B1570) has a predicted low oral toxicity and is predicted as not toxic via the dermal or inhalation routes. INDOFIL Difenoconazole 250 g/L EC Greener (IN005B1570) is classified for eye irritation (Eye Irrit 2, H319) and carcinogenicity (Carc. 2, H351). Details of the co-formulants and their classification and the calculation methodology are presented in the confidential dossier of this submission (Registration Report - Part C) and in part B.6.

3.5.1 Acute toxicity

Acute toxicity studies for INDOFIL Difenoconazole 250 g/L EC Greener (IN005B1570) were not evaluated as part of the EU review of Difenoconazole. Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of INDOFIL Difenoconazole 250 g/L EC Greener (IN005B1570) can be found in the confidential dossier of this submission (Registration Report - Part C).

Taking into account the composition of the product, the formulation INDOFIL Difenoconazole 250 g/L EC Greener (IN005B1570) does not require classification in regards to oral acute, dermal and inhalation toxicity. The formulation IN005B1570 does not contain ingredients classified in regards to skin irritation and therefore does not require classification for this health hazard. INDOFIL Difenoconazole 250 g/L EC Greener (IN005B1570) is not considered a potential skin sensitiser and does not require classification for this endpoint according to Regulation (EC) No 1272/2008.

According to Regulation (EC) no. 1272/2008 INDOFIL Difenoconazole 250 g/L EC Greener (IN005B1570) should be classified as:

- **eye irritant** (Eye Irrit. 2, H319) and Signal word “Warning” with the hazard statement “**H319: Causes serious eye irritation**” and the pictogram GHS07 is required.
- **Carcinogen** (Carc. 2, H351) and Signal word “Warning” with the hazard statement “**H351: Suspected of causing cancer.**” and the pictogram GHS08 is required.

No signal word or hazard statement is required.

No signal word or hazard statement is required.

3.5.2 Operator exposure

According to the estimation based on AOEM, the use of IN005B1570 containing difenoconazole (250 g/kg) causes acceptable health risk for unprotected operator (arms, body and legs covered).

However, taking into account the classification of the product (Eye Irrit. 2, H319), eye/face shield are mandatory during handling the undiluted product.

Consequently, the following sentence regarding the use of PPE is recommended by the evaluator to be placed in the label:

„Stosować rękawice ochronne, ochronę oczu lub twarzy oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy roboczej oraz rękawice ochronne i odzież roboczą w trakcie wykonywania zabiegu.”

“Wear protective gloves, eye/face shield and work wear (coverall) during mixing/loading and protective gloves and work wear during application”.

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and consideration of the above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

3.5.3 Worker exposure

According to the estimation results, the use of IN005B1570 containing difenoconazole (250 g/kg) does not cause unacceptable health risk for a worker wearing work wear (arms, body and legs covered).

Nevertheless, it is forbidden to re-enter area treated with IN005B1570 until spray deposit on plant surfaces has dried. Taking into account the hygienic rules during handling of the PPPs, the protective gloves are strongly recommended.

Following sentence regarding the use of PPE is recommended by the evaluator to be placed in the section of precautions for the workers:

„Stosować odzież roboczą (długie spodnie, koszula z długim rękawem) oraz rękawice ochronne podczas prac wykonywanych na terenie poddanym zabiegowi.”

“Wear workwear (long trousers, long-sleeve shirt) and protective gloves during field work carried out in the treated area.”

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mention PPE, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

3.5.4 Bystander and resident exposure

The results of the exposure estimations suggest that the use of IN005B1570 according to the list of intended uses presented in GAP Table cause acceptable health risk for bystander and resident (adult and child) according AOEM.

Since the resident and/or bystander exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for Difenoconazole will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of resident/bystander exposure was not necessary and was therefore not performed.

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

3.6.1 Residues

Storage stability

Difenoconazole

According to EFSA Journal 2011;9(1):1967, residues of difenoconazole were found to be stable up to 24 months in potato, tomato, cotton (cottonseed oil) and wheat (straw, forage and grain) and up to 12 months in lettuce (head), soybean (beans) and banana when stored frozen at -20°C. Residues of difenoconazole were found to be stable at least 12 months in animal matrices (eggs, milk, poultry breast and beef liver) when stored frozen at -20°C. And difenoconazole and difenoconazole alcohol (CGA-205375) were found to be stable at least 10 months in animal matrices (milk, liver, kidney, fat and muscle) when stored frozen at -18°C.

TMDs

Storage stability data for TDMs are presented in EFSA Journal 2018;16(7):5376.

Plant products (Category)	Commodity	Stability (Months)			
		1,2,4-Triazole	TA	TAA	TLA
High water content	Apples, tomatoes, mustard leaves, wheat forage, radishes tops/roots, turnips roots, sugar beet roots, cabbages, lettuces	6	53	53	48 ((lettuce only)
High starch content	Barley, wheat	12	26	26	48
High oil content	Oilseed rape (seed), soya beans	12 (soya bean only; not stable in rape seed)	26 (soya bean only; not stable in rape seed)	53	48
High protein content	Peas, dry; Navy beans	No data	15	25	48
High acid content	Oranges	No data	No data	No data	48
Others	Cereal straw	12	53	40	No data
Animal	Animal commodity	Stability (Month/Year)			
	Muscle	No data	No data	No data	No data
	Liver	No data	No data	No data	No data
	Kidney	No data	No data	No data	No data
	Milk	No data	No data	No data	No data
	Egg	No data	No data	No data	No data

The available storage stability data are sufficient to demonstrate the stability of residues of difenconazole but regarding TDMs, a new study (Longhi, D. 2021. GLP-STUDY-21-124) was performed to assess the storage stability of triazole derivatives metabolites in high water (wheat forage, apple, tomato and carrot), in high oil (oilseed rape seeds), in high start (wheat grain), and in dry (wheat straw) commodities. After 7 months of storage, the obtained results for recovery are in compliance with the requirements of the SANTE/2020/12830 rev.1, with mean recovery in the range of 70-120% for the level of 0.1 mg/kg. For any detail about the study, reference is made to Appendix 2.

The studies demonstrated residue stability in all the matrices stored at -18°C for a period of 7 months for all TMDs, thus covering the storage periods of the supervised residue trials on various crops.

The study is acceptable.

The storage time of samples from field trials is acceptable in relation to storage stability data.

Metabolism in plants and animals

Plant residue definition for monitoring Difenconazole Reg. (EU) 2019/552

Plant residue definition for risk assessment separate residue definitions (Difenconazole, SANCO/830/08 – rev. 3, 13 December 2013, 18 May 2020:

- 1) Difenconazole
- 2) TA and TLA, since these compounds share the same toxicity;
- 3) TAA
- 4) 1,2,4-T

Animal residue definition for monitoring: difenconazole Reg. (EU) 2019/552

Animal residue definition for risk assessment

- 1) Difenconazole
- 2) TA and TLA, since these compounds share the same toxicity;
- 3) TAA
- 4) 1,2,4-T

Magnitude of residues in plants

Oilseed rape

Proposed GAP:

Max. 2 applications (1 in autumn and 1 in spring or 2 in autumn);

BBCH: Spring applications BBCH 14-18 and BBCH 30-69;

0.125 kg a.s/ha per treatment;

PHI – not required.

New study on the magnitude of residues has been submitted by the applicant in the framework of this application (investigating difenconazole and TDMs)

Trials GAP: 2 x 0.125 kg a.s/ha, outdoor

Residues (NEU, difenconazole; E, RA): 6x<0.01, 0.01 mg/kg

The study is accepted. The trials are independent and valid with regard to storage stability data for difenconazole. Analytical method used is accepted.

Although 7 instead of 8 northern European trials are presented, they are sufficient to support the proposed use. The residues arising from the proposed use will not exceed the MRLs for difenconazole established

for oilseed rape (0.5 mg/kg; Reg. (EU) 2019/552).

Trials from the southern zone of Europe were not included in the evaluation.

NL comment:

Considering the use on oilseed rape, 7 trials are available to support the intended use. However, according to SANTE/2019/12752, oilseed rape is a major crop and therefore 8 trials are required.

zRMS acknowledges that only 7 trials are available but considers this sufficient to support the intended use. However, both the applicant and zRMS do not further explain why this is considered acceptable. The Netherlands concludes that 8 trials are required, and the use can therefore not be considered sufficiently supported. An additional trial is required.

zRMS: 7 trials are enough since residues in these trials practically do not vary and 6 of them are below LOQ (0.01 mg/kg) and the last one are at LOQ. The residues arising from the proposed use will not exceed the MRLs.

Non-acceptance of this use due to the need to conduct additional study may be considered at Member State level.

According to the applicant another residue trial in OSR is ongoing in NEU and if requested it would be submitted post registration as confirmatory data.

The information has been added.

Use is accepted in Poland.

Applicant's statement:

7 trials are enough since residues in these trials practically do not vary.

Other 8 residue trials have been performed in SEU and the conclusion is the same (four of the SEU residue zone studies were carried out in north of Italy, bordering the NEU residue zone, thus similar climatic conditions might be extrapolated. These trials were considered valid).

Another residue trials in OSR is ongoing in NEU and if requested it would be submitted post registration as confirmatory data.

TDMs: Triazole alanine

Data (NEU): 1.566, 1x<0.002, 0.205, 0.299, 0.537, 0.1198, 0.113 mg/kg

TDMs: Triazole lactic acid

Data (NEU): <0.002, 0.0044, 0.0114, 0.0207, 0.025, 0.0317, 0.0628 mg/kg

Triazole acetic acid

Data (NEU): 4x<0.002, 0.0059, 0.0123, 0.013 mg/kg

1,2,4-Triazole

Data (NEU): 6x<0.01, 0.0129 mg/kg

Data gap: storage stability data for 1,2,4 Triazole and TA in high oil content matrix (post registration requirement).

Apples, Pears

Proposed GAP:

Max. 3 applications; BBCH: 57-84; 0.05625 kg a.s/ha; PHI – 21

New study on the magnitude of residues has been submitted by the applicant in the framework of this application (investigating difenoconazole and TDMs)

Trials GAP: 3 x 0.05625 kg as/ha per treatment, PHI 21d, outdoor

Residues (NEU, apples; difenoconazole): 0.0186, 0.0264, 0.0268, 0.0322, 0.0474, 0.0585, 0.0937, 0.1058 mg/kg

TDMs: Triazole alanine: (NEU) 0.0013, 4x<0.002, 0.0044, 0.0266, 0.0299 mg/kg

TDMs: Triazole lactic acid (NEU): 0.0008, 4x<0.002, 0.003, 0.0187, 0.0222 mg/kg

Triazole acetic acid (NEU): 4x<0.002, 0.0059, 0.0123, 0.013 mg/kg

1,2,4-Triazole (NEU): 8x<0.002 mg/kg

The study is accepted. The trials are independent and valid with regard to storage stability. Analytical method used is accepted.

The residues arising from the proposed use will not exceed the MRLs for difenoconazole established for apples and pears (0.8 mg/kg; Reg. (EU) 2019/552).

According to SANTE/2019/12752 extrapolation from apples to pears is possible.

Sufficient new trials on apples are available to support the proposed uses.

Carrot

Proposed GAP:

Max. 3-4 applications; BBCH: 39-40; max. 0.125kg a.s/ha per treatment; PHI – 14

New studies on the magnitude of residues have been submitted by the applicant in the framework of this application (investigating difenoconazole and TDMs)

Trials GAP: 3 x 0.125 kg as/ha, PHI 14d, outdoor

Residues (carrot; difenoconazole): 0.02597, 0.02824, 0.05418, 0.05666, 0.0577, 0.06944, 0.1118, 0.1153 mg/kg

TDMs: Triazole alanine: 0.00169, <0.002, 0.0037, 0.00813, 0.00835, 0.00936, 0.01441, 0.01479 mg/kg

TDMs: Triazole lactic acid: 0.00056, 0.00114, 3x<0.002, 0.00222, 0.00321, 0.0037 mg/kg

Triazole acetic acid: 7x<0.002, 0.00356 mg/kg

1,2,4-Triazole: 8x<0.002 mg/kg

The study is accepted. The trials are independent and valid with regard to storage stability. Analytical method used is accepted.

The residues arising from the proposed use will not exceed the MRLs for difenoconazole established for carrot (0.4 mg/kg; Reg. (EU) 2019/552).

Additionally applicant refers to unprotected EU data: Sweden, 2006 N-EU GAP on which EU a.s. assessment is based: 3 x 0.125 kg as/ha, PHI 14d, outdoor

Residues: 2x 0.02, 0.03, 0.04, 0.05, 0.07, 0.11, 0.12 mg/kg

Sufficient trials on carrots are available to support the proposed use with max. number of applications of 3. There is no data to cover max. number of applications of 4.

The residue trials presented by the applicant allow for the acceptance of the use of the product in the protection of carrots up to BBCH 49 phase.

Cauliflower, broccoli

Applicants refers to the 6 outdoor field trials on broccoli in N-EU and 12 outdoor field trials on cauliflower in N-EU, all of which were reviewed by the JMPR (JMPR, 2007).

~~Data presented by the applicant are insufficient to cover proposed uses. The studies were not evaluated at EU level.~~

~~Proposed uses are not accepted.~~

March 2024

The applicant provided new data: 4 outdoor field new trials on broccoli in N-EU and 4 outdoor field new trials on cauliflower in N-EU (Germany, Belgium, The Netherlands, Austria, Czech Republic and Poland).

Trials are acceptable.

Maximum freezer storage period between sampling and analysis: 76 days (difenconazole) and 72 (TMDS).

Trials are independent.

Application time is later than proposed but can be accepted as worst case. Other application parameters are consistent with GAP.

Trial GAP: 3 x 125 g as/ha, BBCH 41-45, PHI 14 d, outdoor

E, RA: (difenconazole) 5x<0.01, 0.02, 0.04, 0.13 mg/kg

The residues arising from the proposed use will not exceed the MRLs for difenconazole established for cauliflower and broccoli (Reg. (EU) 2019/552).

Triazole alanine data: 2x <0.01, 4x 0.02, 0.03, 0.04 mg/kg

Triazole lactic acid data: 8x<0.01 mg/kg

Triazole acetic acid data: 8x<0.01 mg/kg

1,2,4-Triazole data: 8x<0.01 mg/kg

According to SANTE/2019/12752 rev.1 4 trials on cauliflower plus 4 trials on broccoli can be extrapolated to the subgroup of flowering brassica. According to the available data, the uses on cauliflower and broccoli are considered acceptable.

Cabbage

~~Applicants refers to the 15 outdoor field trials in N-EU, all of which were reviewed by the JMPR (JMPR, 2007).~~

~~Data presented by the applicant are insufficient to cover proposed uses. The studies were not evaluated at EU level.~~

~~Proposed uses are not accepted.~~

March 2024

The applicant provided new data: 8 outdoor field new trials on cabbage in N-EU (Belgium, The Netherlands, Germany, Czech Republic and Northern France).

Trials are acceptable.

Maximum freezer storage period between sampling and analysis: 64 days.

Trials are independent.

Trial GAP: 3 x 125 g as/ha, BBCH 43-47, PHI 21 d, outdoor

E, RA: (difenconazole): 2x <0.01, 4x 0.01, 0.04, 0.07 mg/kg

The residues arising from the proposed use will not exceed the MRLs for difenconazole established for cabbage (Reg. (EU) 2019/552).

Triazole alanine data: 2x <0.01, 4x 0.02, 0.03, 0.04 mg/kg

Triazole lactic acid data: 8x<0.01 mg/kg

Triazole acetic acid data: 8x<0.01 mg/kg

1,2,4-Triazole data: 8x<0.01 mg/kg

According to the available data, the use on head cabbage is considered acceptable.

Magnitude of residues in livestock

Difenoconazole

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

TMDs

EFSA Journal 2018;16(7):5376:

Data Gap: Poultry and ruminant feeding studies conducted with TLA or, alternatively, metabolism studies performed in accordance with the current recommendations as a surrogate to these feeding studies to determine the magnitude of TLA residues in products of animal origin.

The above requirement applies to the active substance.

Processing studies

Data are available at EU level on apple, carrot, tomatoes and from acceptable new studies on oilseed rape, apple, tomatoes. The new studies investigated both difenoconazole than TDMs.

Regarding difenoconazole, it was possible to derive some PF for apple, washed and dried and for tomato, dried whereas for the other commodities, results were under LOQ (or even under LOD), so it is not possible to derive consistent conclusions.

Regarding TDMs, in the majority of the cases, data are below the LOQ in raw commodity as well as in all processed fractions, therefore calculations were not performed.

Magnitude of residues in representative succeeding crops

Difenoconazole

Waiting periods before planting following succeeding crops: not required.

TMDs:

Addendum – Confirmatory Data, UK, 2018:

EFSA Journal 2018;16(7):5376: *Rotational crop field trials on cereals small grain, carrots and lettuces were submitted for the determination of all the TDMs at different plant back intervals. The maximum storage time interval of the residue samples of the trials in primary and rotational crops, however, was not provided and is required to conclude on the validity of these trials (data gap).*

The above requirement applies to the active substance.

Other / special studies

~~Oilseed rape is a melliferous crop foraged by bees. A study to determine the residues in honey and bee products is required (post registration requirement).~~

Studies were already submitted for its evaluation.

The residues of difenoconazole and the triazole-derivative metabolites (TDMs): triazole-alanine (TA), 1,2,4-triazole (1,2,4-T), triazole lactic acid (TLA), triazole acetic acid (TAA) are not above the LOD and/or LOQ, and therefore are not a risk for the consumer.

Therefore, this data gap is already covered.

Noticed data gaps are:

- storage stability data for 1,2,4 Triazole and TA in high oil content matrix (post registration requirement);
- Residue trials on cauliflower, broccoli and cabbage
- A study to determine the residues in honey and bee products is required (oil seed rape; post registration requirement);

3.6.2 Consumer exposure

Risk assessment residue definition 1: Difenoconazole

Table 3.6-1: Consumer risk assessment – risk assessment residue definition 1: difenoconazole

IEDI (% ADI) according to EFSA PRIMo rev.3.1	74 % (based on GEMS/ Food G06 NL-toddler) 1 st contributor: table grapes 8% tomatoes 26% 2 nd contributor: tomatoes 7% table grapes 8%
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<p>TESTI (% ARfD) according to EFSA PRIMo*rev.3.1</p>	<p><u>Unprocessed commodities:</u></p> <p><u>Children:</u></p> <p>11% Broccoli</p> <p>10% Pears</p> <p>7% Apples</p> <p>7% Cauliflowers</p> <p>5% Head cabbages</p> <p>0,01% Rapeseeds/canola seeds</p> <p><u>Adults:</u></p> <p>6% Broccoli</p> <p>5% Head cabbages</p> <p>3% Cauliflowers</p> <p>2% Apples</p> <p>2% Pears</p> <p>0,00% Rapeseeds/canola seeds</p> <p><u>Processed commodities:</u></p> <p><u>Children:</u></p> <p>20% Broccoli / boiled</p> <p>9% Cauliflowers / boiled</p> <p>1% Apples / juice</p> <p>0,1% Head cabbages / canned</p> <p>0,0% Rapeseeds / oils</p> <p><u>Adults:</u></p> <p>6% Broccoli / boiled</p> <p>5% Cauliflowers / boiled</p> <p>0,8% Apples / juice</p> <p>0,8% Pears / juice</p> <p>0,1% Head cabbages / canned</p> <p><u>Unprocessed commodities:</u></p> <p><u>Children:</u></p> <p>10% Pears</p> <p>7% Apples</p> <p>5% Carrots</p> <p>5% Cauliflowers</p> <p>3% Broccoli</p> <p>2% Head cabbages</p> <p>0,01% Rapeseeds/canola seeds</p> <p><u>Adults:</u></p> <p>2% Pears</p> <p>2% Broccoli</p> <p>2% Apples</p> <p>2% Cauliflowers</p> <p>2% Head Cabbages</p> <p>1% Carrots</p> <p>0,00% Rapeseeds/canola seeds</p> <p><u>Processed commodities:</u></p> <p><u>Children:</u></p> <p>6% Broccoli / boiled</p> <p>6% Cauliflowers / boiled</p> <p>1% Carrots/ juice</p> <p>0,8% Pears/ juice</p> <p>0,0% Head cabbages / canned</p> <p>0,0% Rapeseeds / oils</p> <p><u>Adults:</u></p> <p>3% Cauliflowers / boiled</p> <p>2% Broccoli / boiled</p> <p>0,8% Apples / juice</p> <p>0,3 Carrots / juice</p>
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	0,06% Head cabbages / canned
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Risk assessment residue definition 2: Triazole alanine and triazole lactic acid

Risk assessment residue definition 3: Triazole acetic acid

Risk assessment residue definition 4: 1,2,4-triazole

The chronic and acute consumer risk assessment was performed using the EFSA PRIMo rev 3.1 model. The input values in the PRIMo model were STMR and HR values for the crops included in the GAP, as determined from new studies on oilseed rape, pome fruits, cauliflower, broccoli, head cabbage and carrot.

Chronic exposure: exposure was calculated using EFSA PRIMo model rev. 3.1 using the input data reported in Table 7.2-21.

The results ranged from 0.003% 0.004% of ADI for RA3 definition to 0.11% for RA2 0.16% R4 definition, being NL toddler the diet with the highest %ADI for all the residue definitions

Acute exposure: RA2 gave the highest values for raw commodities, head cabbage carrots being for children and adults the raw commodity with the highest % of ARfD/ADI (5 and 2% respectively for TA). For processed commodities, R2 gave the highest value for children broccoli/boiled was the commodity with the highest % of ARfD/ADI 1%. And RA4 gave the highest values for adults cauliflower/ boiled was the commodity with the highest % of ARfD/ADI 0.37%. for both children and adults apples / juice was the commodity with the highest % of ARfD/ADI (1 and 0.7%, respectively).

Table 3.6-2: Consumer risk assessment – risk assessment residue definition 2, 3, 4

IEDI (% ADI) according to EFSA PRIMo	RA2 – TA + TLA: 0.1% +0.024% (based on NL toddler)
	RA3 - TAA: 0.003% 0.004% (NL toddler)
	RA4 – 1,2,4-T: 0.16% (NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	RA2 – TA + TLA: <u>Unprocessed commodities:</u> Children: TA: Carrots 5% (based on UK infant) TLA: Pears 1% (based on NL toddler) Adults: TA: Carrots 2% (based on NL general population) TLA: Pears 0.2% (based on NL general population) <u>Processed commodities:</u> Children: TA: Carrots / juice 0.1% (based on DE child) TLA: Apples / juice 0.04% (based on DE child) Adults: TA: Apples / juice 0.03% (based on NL general population) TLA: Apples / juice 0.02% (based on NL general population) <u>Unprocessed commodities:</u> Children: TA: Head cabbages 2% (based on BE toddlers) TLA: Pears 0.5% (based on NL toddler) Adults: TA: Head cabbages 2% (based on CZ females 15-17 years) TLA: Pears 0.1% (based on CZ females 15-17 years) <u>Processed commodities:</u> Children: TA: Broccoli/ boiled 1% (based on NL toddler) TLA: Broccoli/ boiled 0.1% (NL toddler) Adults: TA: Cauliflower/ boiled 0.6% (based on NL general population) TLA: Cauliflower/ boiled 0.03% (based on NL general population)
	RA3 - TAA: <u>Unprocessed commodities:</u> Children: Pears 0.1% (based on NL toddler) Adults: Pears 0.02% (based on NL general population) <u>Processed commodities:</u> Children: Apples / juice 0.01% (based on DE child)

	Adults: Apples / juice 0.01% (based on NL general population)
	Unprocessed commodities: Children: Pears 0.1% (based on NL toddler) Adults: Pears 0.03% (based on NL general population) Processed commodities Children: Broccoli/ boiled 0.03% (based on NL toddler) Adults: Cauliflower/ boiled 0.02% (based on NL general population)
	RA4 – 1,2,4-T: Unprocessed commodities: Children: Pears 3% (based on NL toddler) Adults: Pears 0.6% (based on NL general population) Processed commodities: Children: Apples / juice 1% (based on DE child) Adults: Apple / juice 0.7% (based on NL general population) Unprocessed commodities: Children: Cauliflowers 0.5% (based on UK infant) Adults: Broccoli 0.2% (based on NL general population) Processed commodities: Children: Broccoli/ boiled 0.7% (based on NL toddler) Adults: Cauliflower/ boiled 0.37% (based on NL general population)

Even if there is lack of information at EU level regarding TDMs, it is clear that the proposed uses will account for a minor contribution to the overall intake regarding those compounds.

Overall conclusion

The accepted uses of Difenconazole in the formulation IN005B1570 do not represent unacceptable acute and chronic risks for the consumer.

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

No new studies are presented, since it is possible to extrapolate from data obtained with the active substances. Appropriate endpoints from the EU review were used to calculate PEC for Difenconazole and its metabolites in soil, surface water and groundwater for the intended use patterns.

Active substance and metabolites considered in the assessment.

Code number/name	Relevant compartments
Difenconazole	Soil, groundwater, surface water
CGA 205375 Difenconazole alcohol	Soil, groundwater, surface water
CGA 71019 1,2,4-triazole	Soil, groundwater, surface water

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

The EU agreed endpoints were used (EFSA Journal 2011;9(1):1967). The predicted environmental concentrations in soil were calculated for the active substance difenconazole and its metabolites according to recommendations by the “FOCUS” group (FOCUS report, 29.02.1997). Calculations were based on a simple first tier approach (Excel sheet).

A soil depth of 5 cm and a soil density of 1.5 g/cm³ were used for all calculations. For calculations of plateau concentrations following multiple years of applications, a soil depth of 20 cm was used for all

field crops (to account for tillage) and a soil depth of 5 cm was used for permanent crops (no tillage). The $PEC_{accumulation}$ value was calculated by adding the initial PEC_{soil} value to the minimum plateau value (*i.e.* the PEC_{soil} immediately before each year's application).

Compound	Difenoconazole	CGA-205375	CGA-71019
Max. occurrence	-	11.9	23.4
DT ₅₀ (days)	265	152	12.0

Use	Max. PEC_{soil} for parent (mg/kg)	Maximum PEC_{soil} (mg/kg)	
		CGA-205375	CGA-71019
Oilseed rape (2 x 125 g/ha, 21 d int., 40% intercept)	0.227	0.023	0.009
Pome/stone fruit (3 x 56.25 g/ha, 7 d int., 60% intercept)	0.145	0.015	0.006
Carrots (3 x 125 g/ha, 14 d int., 60% intercept)	0.225	0.023	0.009
Potatoes (4 x 125 g/ha, 7 d int., 85% intercept)	0.113	0.012	0.004
Leafy veg. (3 x 125 g/ha, 7 d int., 25% intercept)	0.428	0.044	0.017

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

Predicted environmental concentrations in groundwater (at a soil depth of 1 m) were calculated for the active substance difenoconazole and its metabolites for all representative use patterns derived from GAP information. The PEC_{GW} values for difenoconazole and its metabolites were calculated using FOCUS modelling - FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5 .

To define the application dates, considered in modelling, the AppDate (v3.06) software (M. Klein, 2019. Fraunhofer IME, Germany) was used, which calculates application dates based on growth development stages (BBCH) of each crop in the different FOCUS groundwater and surface water scenarios. For Oilseed rape, the first application date considered was BBCH 14 in autumn and BBCH 30 in spring; for carrots, it was BBCH 39; and for Leafy vegetables, it was BBCH 19.

The risk to groundwater is considered acceptable if the 80th percentile annual leaching concentration at 1 m depth is < 0.1 µg/L.

Thus, the Predicted Environmental Concentrations in groundwater calculated, using the FOCUS groundwater scenarios, are significantly lower than the regulatory threshold of 0.1 µg/L for the active substance Difenoconazole and its metabolites demonstrating a negligible risk of contamination of groundwater after IN005B1570 application in all intended uses.

PEC_{gw} calculations were performed with the FOCUS scenarios relevant for Poland: Châteaudun, Hamburg, Kremsmünster.

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

The PEC_{SW} and PEC_{SED} values for difenoconazole and its metabolites were calculated using FOCUS modelling. FOCUS Step 1-2 in calculations were conducted for difenoconazole and its two major metabolites. Further assessment at Step 3 and 4 was required for parent difenoconazole only.

To define the application dates, considered in modelling, the AppDate (v3.06) software (M. Klein, 2019. Fraunhofer IME, Germany) was used.

For all uses, the max PEC_{sw} for the parent are above the RAC with Step 1-2 calculations. Therefore, STEP 3 and 4 were simulated. The calculations was done for important scenarios for Poland: D3, D4 and R1.

For all intended uses, the max PEC_{sw} for the metabolites are below the RAC with Step 1-2 calculations, therefore, with no need for the simulation of further Steps.

Due to the fact that the applicant did not submit NA for Poland, zRMS presents below the PEC_{sw} /sed values obtained in step 4 (from B8) for scenarios relevant for Poland D3, D4, R1.

At the same time, zRMS indicates the lack of PEC_{sw} /sed for D4 for use in carrot. After analysis performed by zRMS PEC_{sw}/sed calculated for leafy vegetables for D4 scenario can be used as worse case in risk assessment.

STEP 4 – PEC_{sw}/sed

Winter oilseed rape (1 x 125 g/ha or 2 x 62.5 g/ha, 21-day interval, autumn application)

Vegetative strip:		None			
No spray buffer:		5 m			
No. applications:		Multiple (2 x 62.5 g/ha)		Single (1 x 125 g/ha)	
Scenario	Water body	Max PEC_{sw} (µg/L)*	Max PEC_{sed} (µg/kg)	Max PEC_{sw} (µg/L)*	Max PEC_{sed} (µg/kg)
D3	ditch	0.090	0.156	0.214	0.231
D4	pond	0.015	0.289	0.023	0.339
D4	stream	0.104	0.052	0.248	0.054
R1	pond	0.049	1.130	0.048	1.122
R1	stream	0.239	1.078	0.230	0.953

Winter oilseed rape (1 x 125 g/ha in autumn + 1 x 125 g/ha in spring) – 10 m buffer

Vegetative strip:		10 m			
No spray buffer:		10 m			
Scenario	Water body	Max PEC_{sw} (µg/L)		Max PEC_{sed} (µg/kg)	
		Multiple		Multiple	
D3	ditch	0.093		0.110	
D4	pond	0.021		0.411	
D4	stream	0.108		0.079	
R1	pond	0.026		0.776	
R1	stream	0.144		0.467	

Pome/stone fruit - early application (3 x 56.5 g/ha, 7-d interval) – 20 m spray buffer

Vegetative strip:		None			
No spray buffer:		20 m			
Scenario	Water body	Max PEC_{sw} (µg/L)*		Max PEC_{sed} (µg/kg)	
		Multiple	Single	Multiple	Single
D3	ditch	0.414	0.480	0.980	0.484
D4	pond	0.100	0.053	1.325	0.596
D4	stream	0.477	0.557	0.242	0.115
R1	pond	0.102	0.053	1.319	0.590

R1	stream	0.366	0.427	0.944	0.408
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Pome/stone fruit - early application (3 x 56.5 g/ha, 7-d interval) – 25 m spray buffer

Vegetative strip:		None			
No spray buffer:		25 m			
Scenario	Water body	Max PEC _{sw} (µg/L)		Max PEC _{sed} (µg/kg)	
		Multiple	Single	Multiple	Single
D3	ditch	0.226	0.283	0.549	0.287
D4	pond	0.063	0.035	0.855	0.408
D4	stream	0.261	0.328	0.135	0.068
R1	pond	0.069	0.035	0.916	0.429
R1	stream	0.212	0.251	0.903	0.397

FOCUS Step 4 PEC_{sw} for difenoconazole following application to carrots (3 x 125 g/ha, 14-d interval) – 10 m buffer

Vegetative strip:		10 m			
No spray buffer:		10 m			
Scenario	Water body	Max PEC _{sw} (µg/L)*		Max PEC _{sed} (µg/kg)	
		Multiple	Single	Multiple	Single
D3	ditch	0.080	0.113	0.118	0.079
D4*	pond	0.034	0.017	0.583	0.225
D4*	stream	0.144	0.116	0.137	0.036
R1	pond	0.075	0.034	2.202	0.893
R1	stream	0.244	0.106	2.156	1.001
R4	stream	0.516	0.162	2.418	0.924

Carrots (3 x 125 g/ha, 14-d interval) – 20 m buffer

Vegetative strip:		20 m			
No spray buffer:		20 m			
Scenario	Water body	Max PEC _{sw} (µg/L)*		Max PEC _{sed} (µg/kg)	
		Multiple		Multiple	
D3	ditch	0.041		0.062	
D4*	pond	0.032		0.484	
D4*	stream	0.144		0.136	
R1	pond	0.039		1.184	
R1	stream	0.127		0.807	

Leafy vegetables (3 x 125 g/ha, 7-d interval) – 10 m buffer

Vegetative strip:		10 m			
No spray buffer:		10 m			

Scenario	Water body	Max PEC _{sw} (µg/L)*		Max PEC _{sed} (µg/kg)	
		Multiple	Single	Multiple	Single
D3	ditch	0.080	0.113	0.132	0.087
D4	pond	0.034	0.017	0.583	0.225
D4	stream	0.144	0.116	0.137	0.036
R1	pond	0.135	0.040	3.342	1.100
R1	stream	0.252	0.101	8.815	3.301

Leafy vegetables (3 x 125 g/ha, 7-d interval) – 20 m buffer

Vegetative strip:		20 m			
No spray buffer:		20 m			
Scenario	Water body	Max PEC _{sw} (µg/L)*		Max PEC _{sed} (µg/kg)	
		Multiple		Multiple	
D3	ditch	0.041		0.070	
D4	pond	0.032		0.484	
D4	stream	0.144		0.136	
R1	pond	0.069		1.758	
R1	stream	0.132		3.060	

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

The vapor pressure at 20 °C of the active substance difenconazole is < 10⁻⁵ Pa. Hence the active substance difenconazole is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance difenconazole due to volatilization with subsequent deposition is not required.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

Effects on birds

zRMS accept the toxicity endpoints for difenconazole according to EFSA Conclusion Report 2011; 9(1):1967. The toxicity data for acute and long-term risk were agreed at the EU level. For acute risk assessment, the short-term dietary LDD₅₀ = 349 mg/kg bw/d was taken into account. In addition the metabolite, CGA131013, is formed in plants. Applicant provided a risk assessment for the metabolite - CGA131013. However, according to the RMS, it is not necessary. The risk assessment for the active substance difenconazole will cover the risk for the metabolite - CGA131013. The short-term avian LC₅₀ for CGA131013 is > 1342 mg/kg b.w./day, and therefore clearly has a lower dietary toxicity to birds compared to the parent compound difenconazole, for which a 5-day LC₅₀ value of >349 mg/kg bw/day has been determined. Since the acute and long-term risk assessments below demonstrate acceptable risk to the parent compound, the ecological risks from potential exposure to this metabolite are expected to be negli-

gible, thus CGA131013 will not be considered further in the risk assessment, which is in line with the residue definition for difenconazole. Negligible exposure to this metabolite is expected when applied by foliar spray. The acute risk assessment for difenconazole for screening step have been accepted by zRMS. The long-term risk assessment for difenconazole for screening step have been accepted by zRMS. The long-term risk assessment for difenconazole for 1-tier step have been accepted by zRMS. The TER_{it} value for medium herbivorous/granivorous bird "pigeon" is below the trigger value of 5 and should be refinement. zRMS considers unacceptable the use of a DP value of 0.6 in oilseed rape. According to EFSA (2009) estimation of residues on undergrowth vegetation using FOCUS interception factors becomes increasingly uncertain with decreasing soil cover of the crop and increasing height of weeds. Thus, reliable predictions are only deemed possible where the largest part of the soil surface is actually covered by the crop and the undergrowth vegetation is clearly smaller than the crop (such as plants orchards, vineyards or crop plants in the late growth stage).

Higher tier assessment was performed by zRMS

Based on Prosser, 2010 for winter oilseed rape at autumn (BBCH 14-18, September - November) and spring OSR (BBCH 14-18, March-May) the relevant PT values were taken into consideration. The $PT = 0.29$ and $PT = 0.84$ (90th percentile, consumers only) were used for winter OSR and spring OSR, respectively. The application rate of 2 x 125 g a.s./ha confirm the safe use of IN005B1570 in winter and spring oilseed rape. In the higher tier assessment of the reproductive risk for birds for difenconazole due the use of IN005B1570 in all crop uses, the resulting TER is above the trigger value of 5. Therefore, acceptable risks to the outstanding generic focal species are demonstrated for all intended uses.

Acceptable risk for birds due to drinking water exposure was demonstrated. In the risk assessment for earthworm-eating birds and fish-eating birds via secondary poisoning, the TER values are greater than the trigger of 5, indicating acceptable risk for birds and indicating therefore no need for further refinement.

Effects on terrestrial vertebrates other than birds

zRMS accept the toxicity endpoints for difenconazole for mammals according to EFSA Conclusion Report 2011; 9(1):1967. In addition the metabolite, CGA131013, is formed in plants. However, according to the RMS, it is not necessary. The risk assessment for the active substance difenconazole will cover the risk for the metabolite - CGA131013. Studies in mammals have shown low toxicity from CGA131013, with acute LD_{50} values in both rats and mice of $>5\ 000$ mg a.s./kg food and a lowest NOAEL of 100 mg a.s./kg bw/day in reproductive toxicity studies in rats. Toxicity of the metabolite is significantly lower than for the parent compound difenconazole which has an acute LD_{50} of 1 453 mg a.s./kg bw/day and long-term NOAEL of 17.3 mg a.s./kg bw/day in rat.

The screening TER_a values for difenconazole for all proposed uses of IN005B1570 are greater than the Commission Regulation (EU) No. 546/2011 trigger of 10, indicating that acute risk to mammals is acceptable following use according to the proposed use pattern for these crops.

The refined risk assessment have been corrected by zRMS. Further refined risk assessment for vole is not necessary.

The TER_{it} for vole is lower than the trigger of 5 for leafy vegetables (BBCH 40-49). The Applicant used $DF = 0.6$. However, according to EFSA Guidance Document to obtain DegT50 values (EFSA Journal 2014;12(5):3662), the interception for leafy vegetables BBCH 40-49 would be 70%, which would mean that 30% of the total applied product would end up in the grass.

The refined risk assessment have been corrected by zRMS. Further refined risk assessment for vole is not necessary.

The TER_{it} for vole is lower than the trigger of 5 for leafy vegetables (BBCH 40-49). The Applicant used $DF = 0.6$. However, according to EFSA Guidance Document to obtain DegT50 values (EFSA Journal 2014;12(5):3662), the interception for leafy vegetables BBCH 40-49 would be 70%, which would mean

that 30% of the total applied product would end up in the grass.

The relevance of the “vole” for the scenario of small herbivorous mammals in higher tier risk assessment is highly discussed by the different Member States on EU level. Therefore, it is proposed to conclude on the overall relevance of the “vole” scenario for the higher tier risk assessment on Member State level.

Acceptable reproductive risks to mammals have been demonstrated for all uses.

Acceptable risk for mammals due to drinking water exposure was demonstrated. In the risk assessment for earthworm-eating mammals and fish-eating mammals via secondary poisoning, the TER values are greater than the trigger of 5, indicating acceptable risk for mammals and indicating therefore no need for further refinement.

Updated April 2024

Birds

According CZ comments: For the completeness of the risk assessment, the following scenarios should be mentioned in first tier of reproductive risk for birds in leafy vegetables: BBCH 10-19 medium herbivorous/granivorous bird, BBCH 10-19 small insectivorous bird. From the risk assessment of medium herbivorous bird, the unacceptable risk can be concluded, therefore the higher tier is needed.

The refined risk assessment for medium herbivorous/granivorous bird in leafy vegetables scenario should be resolved. The focal species in the OSR and leafy vegetables scenario should be supported by scientific literature or a monitoring study. The Applicant not provided the data for further refinement. Therefore, in this case, as the application is intended only in BBCH from 19, it can reasonably be assumed that the risk assessment for medium herbivorous//granivorous birds is also accepted in leafy crops for BBCH from 20.

The risk assessment is acceptable for birds in leafy crops in BBCH from 20.

Mammals

According NL comments: zRMS still proposes to use a deposition factor of 0.3 for leafy vegetables. However, according to Appendix E of the EFSA guidance document birds & mammals (2009), the relevant BBCH growth stage for which a DF can be applied in leafy vegetables is BBCH ≥ 50 . Hence, for leafy vegetables at BBCH 40-49 interception cannot be used in the risk assessment. Furthermore, NL does not accept a trigger value of 2. Could you please take these considerations into account in the risk assessment for mammals?

According to the comment by NL DF of 0.3 can be applied in leafy vegetables is BBCH ≥ 50 . Hence, for leafy vegetables at BBCH 40-49 interception cannot be used in the risk assessment. Therefore, the refined risk assessment for mammals presented is only sufficient for leafy crops only for BBCH ≥ 50 .

However, a long-term risk for small herbivorous mammal "vole", leafy vegetables, application crop directed (BBCH 40-49) was observed. As the application is intended only in BBCH from 19, it can reasonably be assumed that the risk assessment for vole is also accepted in leafy crops for BBCH 19-39.

Conclusion: Risk assessment for mammals for leafy crops is accepted only for BBCH 19-39 or BBCH ≥ 50 .

Risk assessment for birds and mammals for leafy crops is accepted only for BBCH 20-39 or BBCH ≥ 50 .

3.8.2 Effects on aquatic species

No unacceptable risk to aquatic organisms is seen following step 1 for the metabolites CGA 71019 and CGA 205375 following application of the formulation IN005B1570 on all intended groups. For all proposed uses, an acceptable risk for the active substance is seen after FOCUS step 4, concluding an acceptable risk for the formulation IN005B1570 to aquatic organisms considering the following mitigation measures:

Poland (D3, D4 and R1 are characteristic scenarios for Poland)

Crop	Mitigation measure
Oilseed rape	5m no spray buffer zone
Orchards	25 m no-spray buffer zone
Carrot	10 m no-spray buffer zone and 10 m vegetative filter strip
Leafy vegetables (cauliflower, broccoli, cabbage)	20 m no-spray buffer zone and 20 m vegetative filter strip

3.8.3 Effects on bees

The risk assessment performed for both the active substance and the formulated product derived hazard quotients lower than 50, indicating that the active substance as well as the formulation IN005B1570 pose an acceptable risk to bees from oral and contact exposure according to the proposed use.

According to Commission regulation (EU) No 284/2013, point 10.3.1. (Effects on bees) the Applicant should provide also the chronic study for adult bees and the chronic test for larvae for formulated product. The risk assessment based on this study should be considered when GD for Bees, 2013 is implemented at EU level.

Updated April 2024

To address the data requirements for chronic and larval toxicity to bees the applicant as shared with the zRMS the following studies, as well as the updated dRR Part B9, B5 and Part A:

- Chronic oral bee study (KCP 10.3.1.2)
 - Larvae bee studies (KCP 10.3.1.3)
 - Validation of the analytical method (KCP 5.1.2.16) Additionally, the applicant has shared the studies directly with the cMS that requested them. The chronic studies for bees were accepted by zRMS.
- Based on the acute risk assessment with the consideration SANCO/10329/2002 rev.2 (final), October 17, 2002), HQ values for adult bees from exposure of IN005B1570 are < 50, indicating an acceptable risk to adult bees.

3.8.4 Effects on other arthropod species other than bees

In-field HQ values based on first tier laboratory studies with *Aphidius rhopalosiphi* and *Typhlodromus pyri* were below the trigger value of 2, and therefore an acceptable risk is concluded following use according to the proposed use pattern.

Risk assessment for off-field exposure was not performed by Applicant. The risk assessment for off-field exposure was performed by zRMS.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group “field crops” also covers the risk for non-target arthropods from intended uses in groups “oilseed rape”, “cauliflower”, “carrots”, “cabbage” and “broccoli”. The assessment for the use group “fruit crop” also covers the risk in groups “apple, pear

The 1-tier studies for the indicator species *A.rhopalosiphi* and *T.pyri* was provided by Applicant.

The risk off-field for NTA for laboratory test for *A.rhopalosiphi* and *T.pyri* is considered acceptable (HQ values were below 2 for these species). To achieve a complete risk assessment, the risk envelope approach have been applied.

In addition, no unacceptable in and off-field risk were obtained after risk assessment with IN005B1570 formulation.

3.8.5 Effects on soil organisms

Effects on non-target soil meso- and macrofauna

The chronic TER values for earthworms and other non-target soil organisms (meso- and macrofauna) exposed to difenoconazole, its relevant metabolite CGA 71019 and the formulation IN005B1570 are greater than the trigger of 5, indicating that the risk to earthworms and other non-target soil organisms (meso- and macrofauna) is acceptable following use of IN005B1570 according to the proposed use pattern.

Effects on soil microbial activity

Effects at expected soil concentrations for proposed uses of IN005B1570 are below the Commission Regulation (EU) No. 546/2011 triggers of 25%, indicating that the risk to soil micro-organisms is acceptable following use of IN005B1570 according to the proposed use pattern.

Updated April 2024

PECs for the metabolite CGA 71019 was corrected according to dRR Part B8 based on $DT_{50} = 346.6$ d (CRD, 2014; EFSA 2018). For the metabolite CGA 71019 the risk assessment for earthworms and *F.candida* did not meet the trigger value of 5 for leafy crops. The risk for leafy crops in terms of soil organisms such as earthworms and *F.candida* is unacceptable. Refinement risk assessment for soil organisms such as earthworms and *F.candida* for leafy crops is required.

Risk assessment for earthworms and other soil macroorganisms such as *F.candida* as well as *H. aculeifer* for metabolite CGA 71019 for winter oilseed rape, orchards and carrots is acceptable.

Risk assessment for earthworms and other soil macroorganisms such as *F.candida* for metabolite CGA-20535 was performed by zRMS. The risk assessment for earthworms and other soil macroorganisms such as *F.candida* for metabolite CGA-20535 is low.

3.8.6 Effects on non-target terrestrial plants

The worst-case TER values are well greater than the trigger value of 5 and therefore it is considered that risks to non-target plants after IN005B1570 applications are acceptable.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

No data available.

3.9 Relevance of metabolites (Part B, Section 10)

Both metabolites CGA-205375 and CGA 71019 predicted to occur in groundwater will occur at concentrations below 0.1 µg/L (see chapter 8.8.2 in dRR Part B, Section 8). Assessment of the relevance of this metabolite according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required.

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

Insert summary of the outcome of the national comparative assessment. Delete as appropriate:

Product name contains active substance which is approved as a candidate for substitution because low ADI, ARfD or AOEL; two of PBT; significant proportion of non-active isomers; classified Carcinogen 1A or 1B; classified as toxic for reproduction 1A or 1B; endocrine disruption; other reasons for concern

As a conclusion of the comparative assessment

use(s) use number(s) from GAP table in 2.6 is/is not / are/are not suitable for substitution because

Specify your conclusion for each use assessed

As a conclusion of the comparative assessment, use use number from GAP table in 2.6 is not suitable for substitution because there is/are only insert number alternative mode(s) of action available amongst alternative products and thus the chemical diversity remaining is not sufficient to minimise the occurrence of resistance.

or

As a conclusion of the comparative assessment, use use number from GAP table in 2.6 is suitable for substitution because another product (other product name) is a significantly safer alternative with no significant economic or practical disadvantages. Sufficient alternatives remain available to minimise the occurrence of resistance and there are no adverse consequences for minor use authorizations.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Insert any data that the notifier needs to submit following authorization. As a rule, this is restricted to storage stability and monitoring data.

Insert the data that is still required for the evaluation of the product in the case where the product authorization is not granted.

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

Appendix 2 Copy of the product label

Sekcja fizykochemii: brak uwag Termin ważności: 2 lata

Skuteczność:

Rzepak ozimy – tylko zastosowanie przeciwko zgniliznie twardzikowej (wiosenna aplikacja, raz na sezon w dawce 0,5 L/ha); jabłoń – parch jabłoni, marchew przeciwko alternariozie naci marchwi zostało zaakceptowane. ~~Zmieniono dawkę 1 L/ha dla jabłoni z 0,15 L/ha 1 L/ha na 0,14 L/ha 1 L/ha.~~ Zmodyfikowano okienka aplikacyjne oraz zalecaną ilość wody. Dodano stopień zwalczania do etykiety dla zaakceptowanych zastosowań. Pozostałe zapisy – zaakceptowano. W etykiecie informacja nt. następstwa roślin – niewymagana. Grusza przeciw parchowi gruszy, marchew przeciwko czarnej zgniliznie korzeni i mączniakowi prawdziwemu baldaszkowatych, a także kapusta, kalafior i brokuł przeciwko czerni krzyżowych i plamistości pierścieniowej kapustnych mogą być tylko zarejestrowane w trybie Artykułu 51 (dlatego zostały wykreślone z głównej części etykiety). Zaakceptowane fazy BBCH dla kalafiora, brokułu i kapusty w art. 51 to BBCH 19-49, zamiast 19-39. Uprawy pod osłonami nie były oceniane, ponieważ nie uwzględniono ich w tabeli GAP dla upraw polowych, dlatego zostały wykreślone z etykiety. Zapis dot. stopnia zwalczania w marchwi przeniesiono do innego punktu etykiety.

Metabolizm i pozostałości:

Brak zgody na zastosowanie na;

Brokuły, kapustę, kalafior – brak badań polowych

Pomidor, osterżyna, papryka, ogórek – brak tych upraw w ocenianym GAP

Wprowadzono zapis: Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie:

Nie wymagany.

Los i zachowanie w środowisku: brak uwag

Ekotoksykologia: Zastosowanie w uprawie kalafiora, brokułu i kapusty zostało wykreślone z etykiety (wymagane uściślenie dla dżdżownic i *F.candida* dla metabolitu CGA 71019).

W przypadku uprawy rzepaku ozimego:

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 5 metrów od zbiorników i cieków wodnych.

W przypadku upraw jabłoni, gruszy:

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 25 metrów od zbiorników i cieków wodnych.

W przypadku upraw marchwi:

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 10 metrów, zadarnionej na szerokości 10 metrów od zbiorników i cieków wodnych.

W przypadku uprawy kalafiora, brokuła i kapusty:

~~W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 20 metrów, zadarnionej na szerokości 20 metrów od zbiorników i cieków wodnych.~~

Załącznik do zezwolenia MRiRW nr R - /2022 z dnia . .2022 r.

Posiadacz zezwolenia:

Indofil Industries (Netherlands) B.V., Piet Heinkade 55, 1019 GM Amsterdam, Holandia, tel.: +31 (0) 20 217 0971, fax: +31 (0) 20 217 0970, e-mail: indofil-inlbv@modi.com


DIFENOCONAZOLE 250 G/L EC greener

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

difenokonazol (związek z grupy triazoli) - 250 g/l (22,73%)

Zezwolenie MRiRW nr R - /2022 z dnia . .2022 r.

	
Uwaga	
H319 H351 H410	Działa drażniąco na oczy. Podejrzewa się, że powoduje raka. Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia. Mieszanina zawiera 15% składników o nieznanej toksyczności ostrej przez drogi oddechowe.
P270 P201 P273 P280 P305+P351+P338 P308+P313 P337+P313	Nie jeść, nie pić i nie palić podczas używania produktu. Przed użyciem zapoznać się ze specjalnymi środkami ostrożności Unikać uwolnienia do środowiska. Stosować rękawice ochronne, ochronę oczu/twarzy. W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać. W przypadku narażenia lub styczości: Zasięgnąć porady/zgłosić się pod opiekę lekarza. W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

P391	Zebrać wyciek.
P501	Zawartość/pojemnik usuwać zgodnie z lokalnymi przepisami.

OPIS DZIAŁANIA

FUNGICYD w formie koncentratu do sporządzania emulsji wodnej (EC) o działaniu systemicznym do stosowania zapobiegawczego i interwencyjnego przed chorobami grzybowymi.

Zgodnie z klasyfikacją FRAC substancja czynna difenokonazol zaliczana jest do grupy 3.

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy sadow-nicznych lub polowych oraz opryskiwaczy ręcznych.

Rzepak ozimy

~~Sucha zgnilizna kapustnych, zgnilizna twardzikowa~~ (ograniczona skuteczność zwalczania nasilenia choroby na lodygach), ~~czarna krzyżówek~~

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,5 l/ha

Termin stosowania: Zabiegi wykonywać od początku fazy kwitnienia (BBCH 60) do jej zakończenia (BBCH 69).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Zalecana ilość wody: 200-300 l/ha.

Zalecane opryskiwanie: średniokropliste.

~~Schemat 1 (dwa zabiegi – jesień)~~

~~pierwszy zabieg:~~

~~Maksymalna /zalecana dawka środka dla jednorazowego zastosowania: 0,25 l/ha~~

~~drugi zabieg:~~

~~Maksymalna /zalecana dawka środka dla jednorazowego zastosowania: 0,25 l/ha~~

~~Termin stosowania: Zabiegi wykonać jesienią w fazie od czwartego do ósmego liścia (BBCH 14-18).~~

~~Środek stosować zapobiegawczo lub natychmiast po zauważeniu pierwszych objawów chorób.~~

~~Liczba zabiegów: 2~~

~~Schemat 2 (dwa zabiegi – jesień i wiosna)~~

~~Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,5 l/ha~~

~~Termin stosowania: Pierwszy zabieg wykonać jesienią od fazy czwartego liścia do fazy ósmego liścia (BBCH 14-18). Drugi zabieg wykonać wiosną, w fazie wydłużania pędu głównego (początek wydłużania pędu), do fazy końca kwitnienia (BBCH 30-69). Środek stosować zapobiegawczo lub natychmiast po zauważeniu pierwszych objawów chorób.~~

~~Liczba zabiegów: 2~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2~~

~~Odstęp między zabiegami: co najmniej 21 dni.~~

~~Zalecana ilość wody: 100-500 l/ha.~~

~~Zalecane opryskiwanie: średniokropliste.~~

Jabłoń, grusza

~~Parch jabłoni, parch gruszy~~ (ograniczenie częstotliwości występowania choroby)

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,2 l/ha (0,15 0,15 L/10 000 m² LWA)

Termin stosowania: Zabiegi wykonywać od początku fazy różowego pąka kwiatowego do fazy ~~dojrza-~~wania owoców (BBCH 57-84) gdy owoc osiąga 80% typowej wielkości. Środek stosować zapobiegawczo co 7-10 dni.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 3.

Odstęp między zabiegami: co najmniej 7-10 dni.

Zalecana ilość wody: 100-1000 300-1000 l/ha.

Zalecane opryskiwanie: średniokropliste.

Marchew

Alternarioza naci marchwi ograniczona częstotliwość występowania choroby na liściach i umiarkowana skuteczność zwalczania nasilenia choroby na liściach. ~~czarna zgnilizna korzeni, mączniak prawdziwy bal-daszgowaty~~

Maksymalna dawka dla jednorazowego zastosowania: 0,5 l/ha.

Zalecana dawka dla jednorazowego zastosowania: ~~0,4~~ 0,5 l/ha.

Termin stosowania: Środek stosować od początku fazy rozwoju części przeznaczonych do zbioru do momentu gdy korzeń osiąga typową wielkość i kształt (BBCH ~~39-40-49~~).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 3.

Odstęp między zabiegami: co najmniej 14 dni.

Zalecana ilość wody: ~~200-1000~~ 200-600 l/ha.

Zalecane opryskiwanie: średniokropliste.

Kalafior

Czerń krzyżowych, plamistość pierścieniowa kapustnych

~~Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,5 l/ha.~~

~~Termin stosowania: Środek stosować od fazy 9 lub więcej liści (BBCH 19).~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 3.~~

~~Odstęp między zabiegami: co najmniej 14 dni.~~

~~Zalecana ilość wody: 200-1000 l/ha.~~

~~Zalecane opryskiwanie: średniokropliste.~~

Brokuł

Czerń krzyżowych, plamistość pierścieniowa kapustnych

~~Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,5 l/ha.~~

~~Termin stosowania: Środek stosować od fazy 9 lub więcej liści, na początku fazy rozwoju pędów bocznych (BBCH 19-21).~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 3.~~

~~Odstęp między zabiegami: co najmniej 7-10 dni.~~

~~Zalecana ilość wody: 200-1000 l/ha.~~

~~Zalecane opryskiwanie: średniokropliste.~~

Kapusta

Czerń krzyżowych, plamistość pierścieniowa kapustnych

~~Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,5 l/ha.~~

~~Termin stosowania: Środek stosować od fazy 9 lub więcej liści (BBCH 19).~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 3.~~

~~Odstęp między zabiegami: co najmniej 7-10 dni.~~

~~Zalecana ilość wody: 200-1000 l/ha.
Zalecane opryskiwanie: średniokropliste.~~

Pomidor, oherżyna (uprawa pod osłonami)

~~Alternarioza, mączniak prawdziwy~~

~~Maksymalna dawka dla jednorazowego zastosowania: 0,5 l/ha (0,35 L/10 000 m² LWA).~~

~~Zalecana dawka dla jednorazowego zastosowania: 0,4 – 0,5 l/ha.~~

~~Termin stosowania: Środek stosować od początku fazy rozwiniętych 9 lub więcej liści na pędzie głównym, na początku fazy rozwoju pędów bocznych (BBCH 19-20).~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 3.~~

~~Odstęp między zabiegami: co najmniej 7-10 dni.~~

~~Zalecana ilość wody: 200-1200 l/ha.~~

~~Zalecane opryskiwanie: średniokropliste.~~

Papryka (uprawa pod osłonami)

~~Alternarioza, mączniak prawdziwy~~

~~Maksymalna dawka dla jednorazowego zastosowania: 0,5 l/ha (0,35 L/10 000 m² LWA).~~

~~Zalecana dawka dla jednorazowego zastosowania: 0,4 – 0,5 l/ha.~~

~~Termin stosowania: Środek stosować od początku fazy rozwiniętych 9 lub więcej liści na pędzie głównym, na początku fazy rozwoju pędów bocznych (BBCH 19-20).~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2.~~

~~Odstęp między zabiegami: co najmniej 7-10 dni.~~

~~Zalecana ilość wody: 200-1200 l/ha.~~

~~Zalecane opryskiwanie: średniokropliste.~~

Ogórek (uprawa pod osłonami)

~~Alternarioza, mączniak prawdziwy~~

~~Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,5 l/ha (0,35 L/10 000 m² LWA).~~

~~Termin stosowania: Środek stosować od fazy, gdy na pędzie głównym widocznych 9 lub więcej zawiązków pąków kwiatowych na wydłużonej szypułce, na początku fazy kwitnienia, gdy na pędzie głównym otwarty pierwszy kwiat (BBCH 59-61).~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 3.~~

~~Odstęp między zabiegami: co najmniej 8-10 dni.~~

~~Zalecana ilość wody: 200-1000 l/ha.~~

~~Zalecane opryskiwanie: średniokropliste.~~

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

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

Jabłoń, grusza, kapusta - 21 dni,

Marchew, kalafior, brokuł - 14 dni,

Pomidor, oherżyna, papryka, ogórek - 3 dni,

Rzepak: nie wymagany

1. Środek stosować w temperaturze powietrza powyżej 12°C.

2. Środek zawiera substancję czynną difenokonazol, związek triazolowy, należący do grupy inhibitorów syntezy steroli - SBI (wg FRAC Grupa 3). W ramach strategii przeciwdziałania odporności zaleca się m.in. stosowanie środka:
 - w terminie i dawce zgodnie z etykietą,
 - przemiennie ze środkami grzybobójczymi zawierającymi substancje czynne z innych grup, o odmiennym mechanizmie działania.
3. Podczas stosowania środka nie dopuścić do:
 - znoszenia cieczy użytkowej na sąsiadujące rośliny uprawne oraz
 - nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.
4. Alternarioza naci marchwi – ograniczona częstość występowania choroby na liściach i umiarkowana skuteczność zwalczania nasilenia choroby na liściach po zastosowaniu produktu.

Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie:

Nie wymagany

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość. Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem) i uzupełnić wodą do potrzebnej ilości. Po wlewaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz w zbiorniku mechanicznie wymieszać. Opryskiwać z włączonym mieszadłem.

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową.

W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy należy dokładnie wymieszać ciecz użytkową w zbiorniku opryskiwacza.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy:

- po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, jeżeli jest to możliwe, lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

Uprawy polowe:

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

Pracownik polowy: Stosować odzież roboczą (długie spodnie, koszula z długim rękawem) oraz rękawice ochronne podczas prac wykonywanych na terenie poddanym zabiegowi.

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

W przypadku uprawy rzepaku ozimego:

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 10 metrów, zadarnionej na szerokości 10 metrów od zbiorników i cieków wodnych.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 5 metrów od zbiorników i cieków wodnych.

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo.

W przypadku upraw jabłoni, gruszy:

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 25 metrów od zbiorników i cieków wodnych.

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 3 m od terenów nieużytkowanych rolniczo.

W przypadku upraw marchwi, kalafiora, brokuła i kapusty:

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 20 metrów, zadarnionej na szerokości 20 metrów od zbiorników i cieków wodnych.

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo.

W przypadku upraw marchwi:

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 10 metrów, zadarnionej na szerokości 10 metrów od zbiorników i cieków wodnych.

W przypadku uprawy kalafiora, brokuła i kapusty:

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 20 metrów, zadarnionej na szerokości 20 metrów od zbiorników i cieków wodnych.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):

Nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- pod zamknięciem,
- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
- w chłodnym, dobrze wentylowanym miejscu,
- szczelnie zamkniętym pojemniku.

Chronić przed wilgocią.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W przypadku dostania się do oczu: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.

W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

Not necessary

Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1	Urbani, M.	2021b	Difenoconazole 250 g/L EC greener – IN005B1570: Determination of the Physico-chemical Properties Report No CH – 0329/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 2.2.1	Urbani, M.	2021b	Difenoconazole 250 g/L EC greener – IN005B1570: Determination of the Physico-chemical Properties Report No CH – 0329/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 2.2.2	Urbani, M.	2021b	Difenoconazole 250 g/L EC greener – IN005B1570: Determination of the Physico-chemical Properties Report No CH – 0329/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 2.3.1	Urbani, M.	2021b	Difenoconazole 250 g/L EC greener – IN005B1570: Determination of the Physico-chemical Properties	N	Y	Data/study report never	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report No CH – 0329/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished			submitted before to Poland	
KCP 2.3.3	Urbani, M.	2021b	Difenconazole 250 g/L EC greener – IN005B1570: Determination of the Physico-chemical Properties Report No CH – 0329/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 2.4.2	Urbani, M.	2021b	Difenconazole 250 g/L EC greener – IN005B1570: Determination of the Physico-chemical Properties Report No CH – 0329/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 2.5.1	Urbani, M.	2021b	Difenconazole 250 g/L EC greener – IN005B1570: Determination of the Physico-chemical Properties Report No CH – 0329/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 2.5.2	Urbani, M.	2021b	Difenconazole 250 g/L EC greener – IN005B1570: Determination of the Physico-chemical Properties Report No CH – 0329/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 2.6.1	Urbani, M.	2021b	Difenconazole 250 g/L EC greener – IN005B1570: Determination of the Physico-chemical Properties	N	Y	Data/study report never	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report No CH – 0329/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished			submitted before to Poland	
KCP 2.7.1	Urbani, M.	2021a	Difenconazole 250 g/L EC greener – IN005B1570: Determination of the Accelerated Storage Stability and Corrosion Characteristics Report No CH – 0332/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 2.7.2	Urbani, M. Nichetti, S.	2021a 2023	Difenconazole 250 g/L EC greener – IN005B1570: Two Years Storage Stability and Corrosion Characteristics. FINAL REPORT Study Plan No CH – 0333/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 2.7.3	Urbani, M.	2021a	Difenconazole 250 g/L EC greener – IN005B1570: Determination of the Accelerated Storage Stability and Corrosion Characteristics Report No CH – 0332/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 2.7.4	Urbani, M.	2021b	Difenconazole 250 g/L EC greener – IN005B1570: Determination of the Physico-chemical Properties Report No CH – 0329/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 2.7.5	Urbani, M.	2021c	Difenconazole 250 g/L EC greener – IN005B1570: Two Years Storage Stability and Corrosion Characteristics	N	Y	Data/study report never	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Study Plan No CH – 0333/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished			submitted before to Poland	
KCP 2.8.2	Urbani, M.	2021b	Difenconazole 250 g/L EC greener – IN005B1570: Determination of the Physico-chemical Properties Report No CH – 0329/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 2.8.6.1	Urbani, M.	2021b	Difenconazole 250 g/L EC greener – IN005B1570: Determination of the Physico-chemical Properties Report No CH – 0329/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 2.8.6.3	Urbani, M.	2021b	Difenconazole 250 g/L EC greener – IN005B1570: Determination of the Physico-chemical Properties Report No CH – 0329/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 2.9.1-1 (KCP 2.9.2)	Narkiewicz-Jodko, J.	2024a	Field miscibility study of difenconazole 250 EC (IN005B1570) evaluation-Tank-mix partners Report No. TMC19122023GP/01 Green & Property Consulting GEP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 2.9.1-2	Narkiewicz-Jodko, J.	2024b	Laboratory miscibility study of Difenconazole 250 EC (IN005B1570) with tank-mix partner	N	Y	Data/study report never	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
(KCP 2.9.2)			Report No. TMC19122023GP/02 Green & Property Consulting GEP Unpublished			submitted before to Poland	
KCP 2.11	Urbani, M.	2021a	Difenconazole 250 g/L EC greener – IN005B1570: Determination of the Accelerated Storage Stability and Corrosion Characteristics Report No CH – 0332/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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, Udem, Germany, Report No. GE21-IBV-105-07 Indofil GEP	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
3.2.2 3.2.3 3.4.1 #006	Teresiak-Baumgart, P.	2021	Evaluate the efficacy of IN233C1560 and IN005B1570 against Phoma on OSR. Agro-check, Lentzke, Germany, Report No. AC/21/062 Report No. GE21-IBV-106-02 Indofil Not GEP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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, Udem, Germany, Report No. PL21-IBV-105-13 Indofil GEP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
3.2.2	Kolditz,	2021	Evaluate the efficacy of IN233C1560 and IN005B1570 against Phoma on	N	Y	Data/study	INDOFIL Industries

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
3.2.3 3.4.1 #008	M.		OSR. BioChem agrar Polska Spółka z o.o., Urbanowice, Poland, Report No. 21 1068 1216 Report No. PL21-IBV-106-03 Indofil GEP Unpublished			report never submitted before to Poland	(Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
3.2.2 3.2.3	Camunez, S.	2021	Efficacy of Prothio + Difeno RMIX against Phoma on OSR GEP Trial, FRANCE, 2020	N	Y	Data/study report never	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
3.4.1 #012			Staphyt, Inchy-en-Artois, France, Report No. SCZ-20-45428-FR01 Indofil Not GEP Unpublished			submitted before to Poland	
3.2.2 3.2.3 3.4.1 #013	Camunez, S.	2021	Efficacy of Prothio + Difeno RMX against Phoma on OSR Staphyt, Urziceni, Romania, Report No. SCZ-20-45428-RO07 Indofil GEP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Indofil GEP Unpublished				
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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 Indofil GEP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
3.4.1 #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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
3.4.1 3.4.3	George, F.	2021	Evaluate the efficacy of IN233C1560 and IN005B1560 against Sclerotinia on OSR.	N	Y	Data/study report never	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
#025			SC Agrotest Romania SRL, Județele Timiș, Romania, Report No. RO21-IBV-105-17 Indofil GEP Unpublished			submitted before to Poland	
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
3.4.1	Camunez,	2021	Efficacy of Prothio + Difeno RMIX against Phoma on OSR. GEP Trial,	N	Y	Data/study	INDOFIL Industries

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
#030	S.		United Kingdom, 2020 Staphyt, Bicester, United Kingdom, Report No. SCZ-20-45428-GB05 Indofil GEP Unpublished			report never submitted before to Poland	(Netherlands) B.V.
3.4.1 #031	Camunez, S.	2021	Efficacy of Prothio + Difeno RMX against Phoma on OSR. GEP Trial, POLAND, 2020 Staphyt, Poznan, Poland, Report No. SCZ-20-45428-PL06 Indofil GEP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	N	Y	Data/study report never submitted before to	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Indofil GEP Unpublished			Poland	
3.2.2 3.2.3 3.4.1 #035	Lunzen-fichter, 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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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 GEP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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, Kosciuszko, Poland, Report No. DPE21/059/FOW-02 Report No. FEU-AGR-001-21-SCAP2-PL08	N	Y	Data/study report never submitted before to	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Indofil GEP Unpublished			Poland	
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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 Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
3.4.1 #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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	N	Y	Data/study report never submitted before to	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Indofil GEP Unpublished			Poland	
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
3.2.2 3.2.3 3.4.1 #055	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_327 Report No. FEU-AGR-005-21-ALTCAR-PL04 Indofil GEP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
3.2.2 3.2.3 3.4.1 #056	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	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
3.2.2 3.2.3 3.4.1 #057	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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
3.2.2 3.2.3 3.4.1 #058	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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
3.2.2 3.2.3 3.4.1 #059	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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
3.4.1 #060	Kohrman, E.	2021	Evaluation of the efficacy of IN005B1570 against <i>Alternaria</i> sp. on carrot in the Netherlands Verify, A compléter, Netherlands, Report No. 210596 Report No. FEU-AGR-003-21-ALTCAR-NL04 Indofil GEP	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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>Myco-sphaerella</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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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>Myco-sphaerella</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	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
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>Myco-sphaerella</i> on cabbage Essais+, Boyelles, France, Report No. 2040F06 Report No. FEU-AGR-028-20-ALMYCAB-FR001 Indofil GEP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
3.2.2 3.2.3 3.4.1 #065	Issakof, J.	2020	Evaluation of the efficacy of IN005B1570 against <i>Alternaria</i> or <i>Myco-sphaerella</i> on cabbage Cerestis, Saint Léger sous Brienne, France, Report No. CEE-20281 Report No. FEU-AGR-028-20-ALMYCAB-FR002 Indofil GEP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 5.1.1/01	Urbani, M.	2021a	Difenconazole 250 g/L EC greener – IN005B1570: Validation of the Analytical Method for the Determination of the Active Ingredient Content Report No CH – 0330/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 5.1.1/02	Urbani, M.	2021b	Difenconazole 250 g/L EC greener – IN005B1570: Validation of the Analytical Method for the Determination of Toluene as Relevant Impurity Content Report No CH – 0331/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 5.1.2/01	Longhi, D.	2021a	Validation of an analytical method for the quantification of Difenconazole and Prothioconazole-desthio in wheat, barley, oilseed rape and processed commodities Report No GLP-STUDY-21-31 LabAnalysis s.r.l. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 5.1.2/02	Longhi, D.	2021b	Validation of an analytical method for the quantification of Difenconazole in apple, carrot, tomato and processed commodities Report No GLP-STUDY-21-32	N	Y	Data/study report never submitted	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			LabAnalysis s.r.l. GLP Unpublished			before to Poland	
KCP 5.1.2/03	Rigamonti, E.	2022a	Independent Laboratory Validation (ILV) of the Analytical Method for the Determination of Difenconazole in Dried apples Report No 1079/2021 LabAnalysis s.r.l. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 5.1.2/04	Rigamonti, E.	2022b	Independent Laboratory Validation (ILV) of the Analytical Method for the Determination of Difenconazole in Dried tomatoes Report No 1080/2021 LabAnalysis s.r.l. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 5.1.2/05	Longhi, D.	2021c	Validation of an analytical method for the quantification of Triazole Derivative Metabolites (TDMs) in wheat, barley, oilseed rape and processed commodities Report No GLP-STUDY-21-108 LabAnalysis s.r.l. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 5.1.2/06	Rigamonti, E.	2022c	Independent Laboratory Validation (ILV) of the Analytical Method for the Determination of TDM in Whole Plant (Rapeseed) Report No GLP-STUDY-1085/2021 LabAnalysis s.r.l. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 5.1.2/07	Rigamonti, E.	2022d	Independent Laboratory Validation (ILV) of the Analytical Method for the Determination of TDM in Rapeseed seeds	N	Y	Data/study report never	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report No GLP-STUDY-1090/2021 LabAnalysis s.r.l. GLP Unpublished			submitted before to Poland	
KCP 5.1.2/08	Longhi, D.	2021d	Validation of an analytical method for the quantification of Triazole Derivative Metabolites (TDMs) in apple, carrot, tomato and processed commodities Report No GLP-STUDY-21-109 LabAnalysis s.r.l. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 5.1.2/09	Rigamonti, E.	2022e	Independent Laboratory Validation (ILV) of the Analytical Method for the Determination of TDM in Dried apples Report No GLP-STUDY-1088/2021 LabAnalysis s.r.l. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 5.1.2/10	Rigamonti, E.	2022f	Independent Laboratory Validation (ILV) of the Analytical Method for the Determination of TDM in Dried tomatoes Report No GLP-STUDY-1089/2021 LabAnalysis s.r.l. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 5.1.2/11	Garagna, D.	2021a	Validation of the Analytical Method for the Determination of Difenconazole residues in soil samples of Difenconazole 250 g/L EC greener – IN005B1570 coming from the Ecotoxicological tests Report No. 0368/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2/12	Garagna, D.	2021b	Validation of the Analytical Method for the Determination of Difenconazole content in Stock Solutions of Difenconazole 250 g/L EC greener – IN005B1570 coming from the Ecotoxicological tests Garagna, D. 2021 Report No. 0782/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 5.1.2/13	Garagna, D.	2021c	Validation of the Analytical Method for the Determination of Difenconazole residues in aqueous samples of Difenconazole 250 g/L EC greener – IN005B1570 coming from the Ecotoxicological tests Report No. 0367/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 5.1.2/14	Nichetti, S.	2022a	Independent Laboratory Validation (ILV) of the Analytical Method for the Determination of Difenconazole and Prothio-desthio in Whole Plant (Rapeseed) Report No CH-1084/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 5.1.2/15	Nichetti, S.	2022b	Independent Laboratory Validation (ILV) of the Analytical Method for the Determination of Difenconazole and Prothio-desthio in Rapeseed seeds Report No CH-1083/2021 ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 5.2/01	Rovetto, I.	2023	Magnitude of the residue of difenconazole, prothioconazole, prothioconazole-desthio and triazole-derivative metabolites (TDMs) in	N	Y	Data/study report never	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			honey after one application of IN233C1560 380 EC on Phacelia crop under semi field conditions in four trials in Northern Europe and Southern Europe – 2023 Study code: 1111.4F.SAG23 GLP Not Published			submitted before to Poland	
KCP 5.2/02	Mattioli, B.	2023	Independent Laboratory Validation (ILV) of the Analytical Method for the Determination of Difenconazole, Prothioconazole, Prothioconazole-desthio and Triazole Derivative Metabolites (TDMs) residue in Honey Study No. CH – 0859-2023 GLP Not Published	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCA 6.1-01	Longhi, Diego	2021	Validation of an analytical method for the quantification of Difenconazole and Prothioconazole-desthio in wheat, barley, oilseed rape and processed commodities GLP-STUDY-21-31 LabAnalysis srl GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCA 6.1-02	Longhi, Diego	2021	Validation of an analytical method for the quantification of Difenconazole in apple, carrot, tomato and processed commodities GLP-STUDY-21-32 LabAnalysis srl GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCA 6.1-03	Longhi, Diego	2022	Storage stability of Triazole Derivative Metabolites (TDM) in wheat forage, wheat grain, rapeseed seeds, wheat straw, apple, tomato, carrot GLP-STUDY-21-124 LabAnalysis srl GLP	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCA 6.3-01	Longhi, Diego	2022	Determination of difenoconazole, prothioconazole-desthio and Triazole Derivative Metabolites (TDMs) residues in raw agricultural commodity of oilseed rape and processed (oilseed rape oil) following two applications of the formulated products IN233C1560 and IN005B1570 (Northern and Southern Europe – 16 trials + processed, year 2021 – open field) GLP-STUDY-21-26 LabAnalysis srl GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCA 6.3-02	Longhi, Diego	2022	Determination of difenoconazole and Triazole Derivative Metabolites (TDMs) residues in raw agricultural commodity of apple and processed commodities (dry apple and apple juice) following three applications of the formulated product IN005B1570 (Northern and Southern Europe – 16 trials, year 2021 – open field) GLP-STUDY-21-28 LabAnalysis srl GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCA 6.3-03	Longhi, Diego	2022	Determination of difenoconazole and Triazole Derivative Metabolites (TDMs) residues in raw agricultural commodity carrot following three applications of the formulated product IN005B1570 250 EC (Difenoconazole 250 g/L) (Northern and Southern Europe – 16 trials, year 2021 – open field) GLP-STUDY-21-27 LabAnalysis srl GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCA 6.3-	Longhi,	2022	Determination of difenoconazole and Triazole Derivative Metabolites	N	Y	Data/study	INDOFIL Industries

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04	Diego		(TDMs) residues in raw agricultural commodity of tomato and processed following three applications of the formulated product IN005B1570 (Southern Europe – 8 trials, year 2021 – open field) GLP-STUDY-21-29 LabAnalysis srl GLP Unpublished			report never submitted before to Poland	(Netherlands) B.V.
KCA 6.3-05	Longhi, Diego	2022	Determination of difenoconazole and Triazole Derivative Metabolites (TDMs) residues in raw agricultural commodity of tomato following three applications of the formulated product IN005B1570 (Southern Europe – 8 trials, year 2021 – greenhouse) GLP-STUDY-21-30 LabAnalysis srl GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCA 6.3-06	Longhi, D.	2024a	Determination of Difenconazole and Triazole Derivative Metabolites (TDMs) residues in raw agricultural commodity of cabbage after three applications of the formulated product IN005B1570 (North Europe – 4 trials, 2023) LBN-0121-2023 LabAnalysis srl GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCA 6.3-07.1	Longhi, D.	2024b	Determination of Difenconazole and Triazole Derivative Metabolites (TDMs) residues in head cabbage following foliar applications with IN005B1570 under field conditions in Northern Europe in 2023. Analytical phase report. LBN-0120-2023 LabAnalysis srl GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3-07.2	Thomas-Delille, E.	2024	Determination of Difenconazole and Triazole Derivative Metabolites (TDMs) residues in head cabbage following foliar applications with IN005B1570 under field conditions in Northern Europe in 2023. Field phase report. C3165 ANADIAG GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCA 6.3-08	Longhi, D.	2024c	Determination of Difenconazole and Triazole Derivative Metabolites (TDMs) residues in raw agricultural commodity of broccoli and cauliflower after three applications of the formulated product IN005B1570 (North Europe – 8 trials, 2023). LBN-0122-2023 LabAnalysis srl GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCA 6.10-01	Rovetto, I.	2023	Magnitude of the residue of difenconazole, prothioconazole, prothioconazole-desthio and triazole-derivative metabolites (TDMs) in honey after one application of IN233C1560 380 EC on Phacelia crop under semi field conditions in four trials in Northern Europe and Southern Europe – 2023 Study code: 1111.4F.SAG23 SAGEA Centro di Saggio s.r.l GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 7.3	Karishma R. Desai	2022	<i>In vitro</i> dermal absorption of difenconazole from difenconazole 250 g/l ec greener – in005b1570 using human split-thickness skin in a flow through diffusion system. JRF Study Number: 617-1-06-29170 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2.1/01	Noe, F.	2021	Difenconazole 250 g/L EC greener – IN005B1570: Acute Toxicity to <i>Daphnia magna</i> in a 48-hour Immobilization Test under Semi-Static Exposure ChemService Study No. CH – 0249/2021 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 10.2.1/02	Noe, F.	2021	Difenconazole 250 g/L EC greener – IN005B1570: Toxicity to Green Algae <i>Pseudokirchneriella subcapitata</i> in a Growth Inhibition Study ChemService Study No. CH – 0250/2021 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 10.2.1/03	■■■	2021	Difenconazole 250 g/L EC greener – IN005B1570: ■■■ Unpublished	Y	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 10.3.1.1.1	Ponti, B.	2021	Difenconazole 250 g/L EC greener – IN005B1570.: Acute Contact and Oral Toxicity to adult worker honeybees <i>Apis mellifera</i> L. ChemService Study No. CH – 0251/2021 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 10.3.2.1/01	Dini, R	2021	Difenconazole 250 g/L EC greener – IN005B1570: Effects on the Parasitoid <i>Aphidius rhopalosiphii</i> De Stefani Perez (Hymenoptera, Braconidae) under laboratory conditions ChemService Study No. CH – 0253/2021 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.2.1/02	Dini, R	2021	Difenconazole 250 g/L EC greener – IN005B1570: Effects on the predatory mite <i>Typhlodromus pyri</i> Scheuten (Acari: Phytoseiidae) under laboratory conditions ChemService Study No. CH – 0252/2021 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 10.4.1.1	Dini, R	2021	Difenconazole 250 g/L EC greener – IN005B1570: Effects on Reproduction of Earthworm <i>Eisenia fetida</i> in an Artificial Soil Study ChemService Study No. CH – 0254/2021 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 10.4.2.1/01	Dini, R	2021	Difenconazole 250 g/L EC greener – IN005B1570: Effects on Collembolan Reproduction in an Artificial Soil Study ChemService Study No. CH – 0255/2021 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 10.4.2.1/02	Dini, R	2021	Difenconazole 250 g/L EC greener – IN005B1570: Effects on <i>Hypoaspis (Geolaelaps) aculeifer</i> Reproduction in an Artificial Soil Study ChemService Study No. CH – 0256/2021 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 10.5	Tediosi, E	2022	Difenconazole 250 g/L EC greener – IN005B1570: Effects on Soil Microorganisms - Nitrogen Transformation Test ChemService Study No. CH – 0770/2021 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.6.2/01	Noe, F.	2022	Difenoconazole 250 g/L EC greener – IN005B1570: Vegetative Vigour Test of Terrestrial Plants ChemService Study No. CH – 0772/2021 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.
KCP 10.6.2/02	Noe, F.	2022	Difenoconazole 250 g/L EC greener – IN005B1570: Seedling Emergence and Seedling Growth Test of Terrestrial Plants ChemService Study No. CH – 0771/2021 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	INDOFIL Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
n.a. Reference only	EFSA (European Food Safety Authority)	2010	Modification of the existing MRLs for difenoconazole in swedes and turnips on request from the European Commission. EFSA Journal 2010;8(2):1510. [36 pp.]. doi:10.2903/j.efsa.2010.1510. Available online: www.efsa.europa.eu Published	N	n.a.
n.a. Reference only	EFSA (European Food Safety Authority)	2010	Modification of the existing MRLs for difenoconazole in peppers and aubergines. EFSA Journal 2010; 8(6):1651. [27 pp.]. doi:10.2903/j.efsa.2010.1651. Available online: www.efsa.europa.eu Published	N	n.a.
n.a. Reference only	EFSA (European Food Safety Authority)	2011	Conclusion on the peer review of the pesticide risk assessment of the active substance difenoconazole. EFSA Journal 2011;9(11):1967. [71 pp.]. doi:10.2903/j.efsa.2011.1967. Available online:	N	n.a.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
	ty)		www.efsa.europa.eu/efsajournal.htm Published		
n.a. Reference only	EFSA (European Food Safety Authority)	2012	Reasoned opinion on the modification of the existing MRLs for difenoconazole in raspberries, blackberries and cucurbits (edible peel). EFSA Journal 2012;10(8):2867. [30 pp.] doi:10.2903/j.efsa.2012.2867. Available online: www.efsa.europa.eu/efsajournal Published	N	n.a.
n.a. Reference only	EFSA (European Food Safety Authority)	2018	Conclusion on the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted. EFSA Journal 2018;16(7):5376, 20 pp. https://doi.org/10.2903/j.efsa.2018.5376 Published	N	n.a.
n.a. Reference only	EFSA (European Food Safety Authority)	2018	Modification of the existing maximum residue levels for difenoconazole in leafy brassica. EFSA Journal 2021;19(2):6407. https://doi.org/10.2903/j.efsa.2021.6407 Published	N	n.a.
n.a. Reference only	EFSA (European Food Safety Authority)	2021	Modification of the existing maximum residue levels for difenoconazole in leafy brassica. EFSA Journal 2021;19(2):6407. https://doi.org/10.2903/j.efsa.2021.6407 Published	N	n.a.
n.a. Reference only	European Commission	2008	Expert meetings report (for establishing Annexes to Regulation (EC) No 396/2005.28–31 Published	N	n.a.
n.a. Reference only	FAO (Food and Agriculture Organization of the United Nations)	2007	Joint FAO/WHO Meeting on Pesticides Residues (JMPR): Evaluations 2007 Published	N	n.a.
n.a. Reference only	Spain	2019	Draft Renewal Assessment Report on the active substance Difenoconazole prepared according to the Commission Regulation (EU) No 1107/2009 Published	N	n.a.
n.a. Reference only	Sweden	2006	Draft assessment report on the active substance difenoconazole prepared by the rapporteur Member State	N	n.a.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
ence only			Sweden in the framework of Council Directive 91/414/EEC Published		
n.a. Reference only	Sweden	2010	Final Addendum to the Draft assessment report on the active substance difenoconazole prepared by the rapporteur Member State Sweden in the framework of Council Directive 91/414/EEC Published	N	n.a.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	Owner

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	Owner

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	Owner