

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: IN005B1570

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

Chemical active substance:

Difenoconazole, 250 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Article 33: Application for authorisation)

Applicant: Indofil Industries (Netherlands) B.V.

Submission date: January 2022

Update: 10.2023

MS Finalisation date: 08.2023; 12.2023; 05.2024; 08.2024

IN005B1570 / INDOFIL Difenoconazole 250 EC
Part B – Section 0 - Core Assessment
Applicant version

Version history

When	What
January 2022	V0 – Original version from applicant Indofil Industries (Netherlands) B.V. for submission to z-RMS, Malta, in the frame of the PPP Authorization according to Article 33 of Regulation (EC) No. 1107/2009
August 2023	ZRMs evaluated drr submitted by Applicant.
October 2023	Applicant inclusion of final reports of studies underway at time of original submission
December 2023	Assessment of additional data provided by the Applicant
May 2024	ZRMs made changes in RR in line to commenting period.
August 2024	ZRMs made changes in RR in line to reviewed coments during 3 rd round

Table of Contents

0	Product background, regulatory context and GAP information	4
0.1	Introduction.....	4
0.1.1	Reason for application	4
0.1.2	Details of zRMS(s) and concerned MS	4
0.1.3	Regulatory history of the active(s).....	5
0.1.4	Regulatory history of the product	7
0.2	zRMS conclusion.....	7
Appendix 1	ALL intended uses	10

0 Product background, regulatory context and GAP information

0.1 Introduction

This document presents the product background, regulatory context and GAP information for the product IN005B1570, an emulsifiable concentrate formulation containing 250 g/L difenoconazole for use on oilseed rape, pome fruits, carrot, cucumber, 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.

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.

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.

0.1.1 Reason for application

This application is made for the authorisation of IN005B1570 in accordance with Article 33 of Regulation (EC) No. 1107/2009. This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Northern zone	Not applicable	Not applicable
Central zone	Poland, INDOFIL Difenoconazole 250 G/L EC greener (IN005B1570) New product authorisation	Germany, INDOFIL Difenoconazole 250 EC (IN005B1570) Czech Republic, INDOFIL Difenoconazole 250 EC (IN005B1570) Belgium, INDOFIL Difenoconazole 250 EC (IN005B1570) The Netherlands, INDOFIL Difenoconazole 250 EC (IN005B1570)

IN005B1570 / INDOFIL Difenoconazole 250 EC
 Part B – Section 0 - Core Assessment
 Applicant version

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
		Austria, INDOFIL Difenoconazole 250 EC (IN005B1570) Slovenia, INDOFIL Difenoconazole 250 EC (IN005B1570) Ireland, INDOFIL Difenoconazole 250 EC (IN005B1570) New product authorisation in ALL
Southern zone	Malta, INDOFIL Difenoconazole 250 EC (IN005B1570) New product authorisation	Italy, INDOFIL Difenoconazole 250 EC (IN005B1570) Spain, INDOFIL Difenoconazole 250 EC (IN005B1570) France, INDOFIL Difenoconazole 250 EC (IN005B1570) Portugal, INDOFIL Difenoconazole 250 EC (IN005B1570) Greece, INDOFIL Difenoconazole 250 EC (IN005B1570) Cyprus, INDOFIL Difenoconazole 250 EC (IN005B1570) Croatia, INDOFIL Difenoconazole 250 EC (IN005B1570) New product authorisation in ALL
Inter-zonal	Not applicable	Not applicable

0.1.3 Regulatory history of the active(s)

Table 0.1-2: Summary of regulatory history of CAS No: 119446-68-3

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2008/69/EC
RMS	Spain
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.01.2009
Current expiration of approval	31.12.20222023 15.03.2026
Low risk substance or Candidate for Substitution?	CfS

Issues that need to be considered as part of the EU approval are listed below.

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

IN005B1570 / INDOFIL Difenoconazole 250 EC
 Part B – Section 0 - Core Assessment
 Applicant version

- 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.'

The SANCO report for difenoconazole (SANCO/830/08 – 18/05/2020) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 2011.

Table 0.1-3: Information on minimum purity of difenoconazole

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
<p>≥ 940g/kg</p> <p>The following manufacturing impurities are of toxicological</p>	<p>965 g/kg</p> <p>Equivalence report available: Y (20181552 PWSG approved on 11th December 2019)</p> <p>RMS: The Netherlands</p>

IN005B1570 / INDOFIL Difenconazole 250 EC
 Part B – Section 0 - Core Assessment
 Applicant version

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
concern and each of them must not exceed a certain amount in the technical material: - Toluene maximum content: 5 g/kg	970 g/kg Relevant impurity: toluene maximum content 5 g/kg Equivalence report available: Y (41185/22 approved on 4 th April 2022) RMS: Belgium

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

**, If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

For justification for used endpoints in the different sections please refer to the respective paragraphs in dRR Part B1-10.

0.1.4 Regulatory history of the product

Not relevant as the product has not yet been authorised

0.2 zRMS conclusion

Uses to be considered safe on the basis of EU methodology:

Insert relevant use number from GAP table in Appendix 1.

Efficacy section: all uses

Residues section: ~~4-3~~ 1-6

Mammalian toxicology: 1-6

Environmental fate and behavior section: all uses

Ecotoxicology section: all uses

Uses to be considered non-safe on the basis of EU methodology:

Insert relevant use number from GAP table in Appendix 1 and refer to relevant RR chapter with identified risk.

Efficacy section: none

Mammalian toxicology: none

Residues section: ~~4-6~~ none

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

Environmental fate and behavior section: none

IN005B1570 / INDOFIL Difenoconazole 250 EC
Part B – Section 0 - Core Assessment
Applicant version

Ecotoxicology section: none

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant cMS:

Residues section: none

Residues section: All uses/ GAPs are covered by established MRLs.

zRMS conclusions:

Physical-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~~

Efficacy section:

Conclusion for Poland: 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 ALTERA and ERY SHE and brassica crops (cabbage, broccoli, cauliflower) against ALTEBI and MYCOBR can be registered only in line to Article 51. Recommended application window for brassics crops in line to Art. 51 is BBCH 19-49, instead of 19-39. **Conclusion for cMS:** Final decision is left to each cMS on the basis on submitted documentation. Decision of cMS (AT, NL, DE) made during commenting period were added to GAP table.

Metabolism and residues

Noticed data gaps are: none

- ~~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);

Fate section:

In accordance with proposed pattern use in GAP no risk for groundwater is expected.

IN005B1570 / INDOFIL Difenoconazole 250 EC
Part B – Section 0 - Core Assessment
Applicant version

Section B6, Mammalian toxicology

Taking into account the composition of the product and the provisions of the Regulation EC No. 1272/2008, the formulation INDOFIL Difenoconazole 250 g/L EC Greener (IN005B1570) containing difenoconazole, (250 g/L) requires classification in regards to eye irritation (Eye Irrit. 2, H319) and carcinogenicity (Carc. 2, H351).

Exposure assessment:

Operator: According to the estimation based on OPEX version v.1.0.1, the use of INDOFIL Difenoconazole 250 g/L EC Greener (IN005B1570) containing difenoconazole (250 g/kg) causes acceptable health risk for operator wearing work wear (arms, body and legs covered) and protective gloves. Taking into account the classification of the product (Carc. 2, H351, Eye Irrit. 2, H319), eye/face shield are mandatory during handling the undiluted product.

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

Bystander/Resident: The results of the exposure estimations suggest that the use of INDOFIL Difenoconazole 250 g/L EC Greener (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.

Ecotoxicology section:

Difenoconazole greener 250 EC/IN005B1570 can be registered in Poland in oilseed rape, orchards and carrots. Final decision 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.

IN005B1570 / INDOFIL Difenconazole 250 EC
 Part B – Section 0 - Core Assessment
 Applicant version

Appendix 1 ALL intended uses

GAP rev. 1, date: 2021-August-23

PPP (product name/code): INDOFIL Difenconazole 250 EC / IN005B1570

Formulation type: EC ^(a, b)

Active substance 1: Difenconazole

Conc. of as 1: 250 g/L ^(c)

Applicant: Indofil Industries (Netherlands) B.V.

Professional use: ☒

Zone(s): CEU ^(d)

Non professional use: ☐

Verified by MS: yes/no

Field of use: Fungicide

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 safener/syner- gist per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

IN005B1570 / INDOFIL Difenconazole 250 EC

Part B – Section 0 - Core Assessment

Applicant version

Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL - DE, CZ ; BE, AT , AT, SI, IE Extra EU: UK	BRSNW (OSR)	F	LEPTMA (<i>Leptosphaeria maculans</i>) SCLESC (Sclerotinia sclerotiorum), ALTEBI (<i>Alternaria brassicae</i>)	foliar spray	Autumn and Spring applications BBCH 14-18 and BBCH 30-69	2 (1 in autumn and 1 in spring or 2 in autumn)	21	a) 0.5 b) 1	a) 125 b) 250	100-500 200-300	NA	<p>Dose rate: 125 g a.i./ha 0,5 L/ha Formulated Product (or 0,25 L/ha per single application if 2 applications in autumn) Eff. Section: In PL – only spring application against SCLESC is accepted at dose 0.5 L/ha applied once a season. Recommended BBCH: 60-69, water volume 200-300 L/ha cMS should consider proposed application window and water volume. DE and AT – not accepted use against LEPTMA (autumn and spring application), ALTEBI (autumn and spring application), SCLESC (autumn application). DE and AT – accepted only spring application against SCLESC.</p> <p>Metabolism and residues:</p> <p>Non-acceptance of this use due to the need to conduct additional study may be considered at Member State level.</p>
2	PL - DE,	MABSD, PYUCO	F	VENTIN, VENTPI	foliar	BBCH 57-84	3	7	a) 0.2* or 0,225	a) 50.0* or	100	21	Proposed LWA rate 0.15 L/10000 m2 LWA with a

IN005B1570 / INDOFIL Difenconazole 250 EC

Part B – Section 0 - Core Assessment

Applicant version

	CZ ; BE, NL, AT , SI, IE Extra EU: UK	(Apples, Pears)		(<i>Venturia inaequalis</i> , <i>Venturia pyrina</i>)	spray	57-78			b) 0.6* or 0.675	56,25 b) 150.0* or 168,75	1500 PL CZ, SI 100 1000 300- 1000	maximum of 0.225 L/ha in for DE, AT, BE, NL, (UK) and maximum of 0.2 L/ha in PL, CZ, SI In PL- 0.15 0.15 L/10 000 m² LWA Dose rate Formulated Product:: Scab 0,015 L/hl / 0,225 L/ha PL, CZ, SI 0,2 L/ha Interval between applica- tions: 7 10 days In PL pear as minor crop according to Article 51 can be accepted. Apple at BBCH 57-78. PL- accepted. Water vol- ume: 300-1000 L/ha. cMS should consider pro- posed application win- dow and water volume. DE and NL (only on apples) accepted this use.
--	------------------------------------------------------------------	-----------------	--	------------------------------------------------------------	-------	-------	--	--	------------------	---------------------------------	--------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

IN005B1570 / INDOFIL Difenconazole 250 EC

Part B – Section 0 - Core Assessment

Applicant version

3	PL - DE, CZ ; BE, NL, AT, SI, IE Extra EU: UK	DAUCS (Garden carrot)	F	Leaf blight of carrot - ALTEDA (Alternaria dauci) Black rot of carrot - ALTERA (Alternaria radicina) Powdery mildew of carrot - ERY SHE (Erysiphe heraclei)	foliar spray	from BBCH 39 40-49	3	14	a) 0.3* or 0.4** or 0.5 b) 0.9* or 1.2** or 1.5	a) 75* or 100** or 125 b) 225* or 300** or 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) Eff. section: In PL – ERY SHE and ALTERA can be accepted only according to Article 51. Recommended BBCH: 40-49 and 200-600 L/ha as a water volume. cMS should consider proposed application window and water volume. NL and DE – accepted use
4	Central EU: PL - DE, CZ ; BE, NL, AT, SI, IE Extra EU: UK	BRSOB (cawliflower)	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 200-600	14	Eff section: In PL only as minor crop according to Article 51 can be accepted Recommended BBCH – 19- 39-49 and water volume 200-600 L/ha. cMS should consider proposed application window and water volume. DE – accepted, NL as minor use (Art. 51) Metabolism and residues: Use not accepted Ecotoxicology section: Use not accepted. Recommended BBCH – 20-39

IN005B1570 / INDOFIL Difenconazole 250 EC
 Part B – Section 0 - Core Assessment
 Applicant version

5	Central EU: PL - DE, CZ ; BE, NL, AT, SI, IE Extra EU: UK	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 200- 600	14	<p>Interval between applications: 7 – 40 days Eff section: In PL only as minor crop according to Article 51 can be accepted Recommended BBCH – 19-39-49 and water volume 200-600 L/ha. cMS should consider proposed application window and water volume. DE – accepted, NL as minor use (Art. 51)</p> <p>Metabolism and residues: Use not accepted Ecotoxicology section: Use not accepted. Recommended BBCH – 20-39</p>
---	------------------------------------------------------------------------------------	---------------------	---	-----------------------------------------------------------------------------------	-----------------	------------	---	---	------------------	------------------	-----------------------------	----	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

IN005B1570 / INDOFIL Difenoconazole 250 EC

Part B – Section 0 - Core Assessment

Applicant version

6	Central EU: PL - DE, CZ ; BE, NL, AT, SI, IE Extra EU: UK	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 200- 600	21	Interval between ap- plications: 7 – 40 days Eff section: In PL only as minor crop ac- cording to Article 51 can be accepted Rec- ommended BBCH – 19-39-49 and water volume 200-600 L/ha cMS should consider proposed application window and water volume.. DE – ac- cepted, NL as minor use (Art. 51) Metabolism and resi- dues: Use not accepted Ecotoxicology sec- tion: Use not ac- cepted. 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 EPPG-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPG-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