REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: IN002B1760

Product name(s): Cymofil

Chemical active substance:

Cymoxanil, 450 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(New authorisation)

Applicant: Indofil Industries (Netherlands) B.V.

Submission date: August 2022

MS Finalisation date: May 2023 (initial Core Assessment)

January 2024, updated February 2024

April 2024 (final Core Assessment)

Version history

When	What
August 2022	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
May 2023	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.
January 2024	Core Assessment updated following the commenting period Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow.
February 2024	zRMS assessment after submission of the additional efficacy trials provided by the applicant in the efficacy section The updated report has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in green. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.
April 2024	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in purple. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.

Table of Contents

0 Product background, regulatory context and GAP information

0.1 Introduction

This document summarises the information related to the product background, the regulatory context and GAP information for the plant protection product IN002B1760 containing the active substance cymoxanil which was included into Annex of Reg. EU n. 540/2011, currently under renewal process. IN002B1760 is a WG formulation containing 450 g/kg cymoxanil and acts as fungicide.
This dossier is submitted in accordance with the Commission Regulation (EU) No 284/2013 and in accordance with Conclusion regarding the peer review of the pesticide risk assessment of the active substance cymoxanil, EFSA Scientific Report (2008) 167, 1-116.

Where appropriate this document refers to the conclusions of the EU review of cymoxanil. This will be where:

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

The product IN002B1760 is not the representative formulation of the EU review.

All the available documents on the active substance (Review Reports, EFSA Scientific Peer Review Conclusions, and their updates, together with original DAR and confirmatory data) are considered to provide the relevant review information or a reference to where such information can be found.

The dRR is for new authorisation of the product IN002B1760 for use as fungicide on different crops.

0.1.1 Reason for application

This dossier is submitted for the new authorisation of IN002B1760 in accordance with Article 33 of Regulation (EC) No. 1107/2009. The application is supported by studies owned by the applicant as well as references to the DAR, confirmatory data and different addenda of the active substance.
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

Details of zRMS and cMS are given in Table 0.1-1.

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 relevant	Not relevant
Central zone	PL - IN002B1760 (new product)	DE, CZ, BE, NL, AT, SI, IE - IN002B1760 (new product)
Southern zone	MT - IN002B1760 (new product)	IT, ES, FR, PT, EL, CY, HR - IN002B1760 (new product)
Inter-zonal	Not relevant	Not relevant

0.1.3 Regulatory history of the active substance cymoxanil

Table 0.1-2: Summary of regulatory history of CAS No: 57966-95-7

Status	
Approved in EU	Y
Original Inclusion Directive	Commission Directive 2008/125/EC
RMS	Austria (original inclusion)
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.09.2009
Current expiration of approval	~~31.08.2022~~ ~~2023~~ 15.08.2026
Low risk substance or Candidate for Substitution?	No

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:

- the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment;
- the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;
- the protection of aquatic organisms. Conditions of authorisation should include risk mitigation measures such as buffer zones, where appropriate.

The SANCO report for cymoxanil (SANCO/179/08 – 09/07/2010) 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 17/09/2008.

Table 0.1-3: Information on minimum purity of active substance cymoxanil

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 *, **
≥ 970 g/kg ≥ 980 g/kg	minimum purity of active substance ≥ 970 g/kg Equivalence report available: Y (COP 2017/02093) RMS: UK

* 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

See column 15 of the GAP table presented in Appendix 1 of this document.

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

See column 15 of the GAP table presented in Appendix 1 of this document.

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

See column 15 of the GAP table presented in Appendix 1 of this document.

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:

See column 15 of the GAP table presented in Appendix 1 of this document.

All uses/ GAPs are covered by established MRLs.

Appendix 1 ALL intended uses

GAP rev. 1, date: 2023-05

PPP (product name/code):	IN002B1760	Formulation type:	WG [a, b]
Active substance 1:	Cymoxanil	Conc. of as 1:	450 g/kg [c]
Applicant:	Indofil Industries (Netherlands) B.V.	Professional use:	X
Zone(s):	central [d]	Non professional use:	☐
Verified by MS:	yes		
Field of use:	fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15								
Use-No. [i]	**Member state(s)**	**Crop and/ or situa-tion** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests con-trolled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safen-er/synergist per ha [f]	**zRMS Conclusion**								
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter-val between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Phys-chem	Analytical methods	Toxicology	Residues	Groundwater	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
Zonal uses (field or outdoor uses, certain types of protected crops)																						
1	PL, DE, CZ, BE, NL, AT, SI, IE	Potato (0211000)	F	Late blight (*Phythophtora infestans*)	Foliar spray	BBCH 12-95	6	5-10	a) 0.33 b) 1.98	a) 148.5 b) 891	300-~~1000~~ 500	7	250-330 g product/ha	A	A	A	A	A	A C (Mammals)	A	A (PL, DE, ~~NL~~, CZ) N (NL) C (~~CZ~~, BE,NL, SI, IE, AT)

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
2 Use official codes/nomenclatures of EU Member States
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)
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
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.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
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
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions
15 Overall conclusions - explanation for the column 15 is below *

* Explanation for column 15 “Overall conclusions”

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible