REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: IN002B1760

Product name(s): Cymofil

Chemical active substances:

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)

September 2023, updated February 2024

April 2024, updated May 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 televant information are ~~struck through~~ and shaded for transparency.
September 2023	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.
January 2024	Applicant updates in potato *Phytophthora infestans* efficacy data - highlighted in turquoise.
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.
May 2024	Final report (National Assessment updated after the correction of Appendix 4 prepared by the Applicant) In order to facilitate tracking of changes in the Lists of data considered for national authorization (Appendix 4), amendments are highlighted in blue, while not agreed use pattern is ~~struck through~~ and shaded.

Table of Contents

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

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

Comments of zRMS:

Conclusions from the assessment were prepared using grey commenting boxes placed at the end of each chapter. Textual changes were done using grey highlights in the text. The parts of the text amended or added by the zRMS evaluator are highlighted in grey, whereas the parts struck off are ~~visibly marked with the grey font~~.

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

Abstract

Abstract of the evaluation, by the zRMS:

This application has been submitted for the authorization of new product IN002B1760 (Cymofil) in Poland, Germany, Czech Republic, Belgium, Netherlands, Austria, Slovenia and Ireland. IN002B1760 contains one active substance: cymoxanil (450 g/kg). This product is indicated to use as fungicide in potato.

MED
A total of ~~8~~ 13 valid field trials have been submitted to determine minimum effective dose to control of *Phytophthora infestans* on potato in the North-East and Maritime EPPO climatic zones. IN002B1760 applied at dose rate of 0,25 ~~0,33~~ kg/ha presented sufficient effectiveness to accept as MED in the NE zone. In previous trials, moderate effectiveness was achieved at lower disease pressure for both claimed doses in the MAR zone. In two additional trials conducted in 2023, good control was achieved for pest severity (<10%) and moderate control for the higher pest severity (52,5%). The cMS Netherlands is kindly asked to consider this use again, however no additional trials from Ireland or Netherlands have been submitted. ~~Limited number of trials was available in the MAR and~~ No efficacy trials were available in the SE zones. The cMSs are kindly asked to extrapolate the trial results from other zone and consider this use on national level.

Efficacy
The trial results showed that IN002B1760 ~~is effective on medium level for control of *Phytophthora infestans* on potato. However due to limited number of trials and insufficient support for the lower dose rate of 0,25 kg/ha, zRMS decided to consider only dose rate of 0,33 kg/ha.~~ at 0,25-0,33 kg/ha is effective for control of PHYTIN with lower disease pressure in the NE zone. Moderate effectiveness was achieved at higher disease pressure. In the previous trials in the MAR zone, the test product presented moderate control at lower disease pressure. In two additional trials conducted in 2023, good control was achieved for pest severity (<10%) and moderate control for the higher pest severity (52,5%). ~~Moreover,~~ According to the submitted trial results, the test product is intended to use for preventive and curative protection at lower disease pressure. The cMSs are kindly asked to consider this solution on national level.*

Selectivity
No special selectivity trials were available. The phytotoxicity assessment has been provided in ~~8~~ 13 efficacy trials (also 2 additional trials conducted in the United Kingdom which were not used in the efficacy evaluation). No negative impact on potato was observed in all submitted trials.

Resistance risk
The resistance management strategy for IN002B1760 is based on limited number of applications (half of the total number of applications) and use of alternation with products containing actives with different MoA. The general anti-resistance recommendations are presented in the chapter 3.3.

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*Please note, that where a particular use is marked blue in the GAP table, it means that taking individual decision on that use by the respective cMS is welcome. It should not be meant as an off-loading, of the decision-taking, by the zRMS to the cMS. Instead, it aims at allowing the cMSs to take decisions different from that taken by zRMS for their own country, in recognition of the cMSs` different national requirements or preferences. Bearing that in mind, zRMS has discussed, in the

commenting boxes, any doubtful issues, highlighting positive efficacy results where relevant, while also sharing with cMSs the reasons for which taking different decisions may be justified in different zones.
In case of the draft Registration Report there is still time for any cMS to express their view and argue, in favour or against the authorization in their country. That is why the zRMS is kindly asking the cMSs to not only take their decisions, but also to share the underlying information with the zRMS PL, within the commenting period framework. Only then will the zRMS be able to complete the GAP table unambiguously, in the final Registration Report, for all the EPPO zones and for all the concerned Member States, for which the present dossier has been submitted.

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ****	**Pests or Group of pests controlled** (additionally: devel-opmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	**zRMS Conclusion (efficacy)**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L prod-uct / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg 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	~~CEU~~ PL, DE, CZ, BE, NL, AT, SI, IE	Potato	F	Late blight (*Phythophtora in-festans*)	Foliar spray	BBCH 12-95	6	5-10	a) 0.33 b) 1.98	a) 148.5 b) 891	~~150~~ 300-~~1000~~ 500	7	250-330 g product/ha	A (PL, DE, ~~AT~~ CZ) N (NL) C (~~CZ~~, BE, NL, SI, IE, AT)
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
~~2~~	~~CEU~~	~~Tomato, auber-gine~~	~~G~~	~~Late blight (*Phythophtora in-festans*)~~	~~Foliar spray~~	~~BBCH 12-89~~	~~5~~	~~7-10~~	~~a) 0.33 b) 1.65~~	~~a) 148.5 b) 742.5~~	~~600-1500~~	~~3~~	~~250-330 g product/ha~~	
Minor uses according to Article 51 (field uses)														
-														
Minor uses according to Article 51 (interzonal uses)														
-														

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

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

Column 15: zRMS conclusion.

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

3.2 Efficacy data (KCP 6)

Introduction

This document summarises the information related to the efficacy of the plant protection product IN002B1760, containing the active substance Cymoxanil which was included into Annex I of Reg. (EC) No 1107/2009 (Reg. (EU) No 540/2011 for Cymoxanil).

The SANCO report for Cymoxanil (SANCO/179/08 – rev. 1, 09/07/2010) is considered to provide the relevant review information. is considered to provide the relevant review information or a reference to where such information can be found.

The Annex I Inclusion Directive for Cymoxanil (Reg. No 540/2011 (EU)) 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 of Annex VI, the conclusions of the review report on the Cymoxanil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28/10/2008 shall be taken into account. Consideration of active substances for Annex I inclusion does not include an evaluation of efficacy. Therefore, there are no concerns to address arising from the inclusion directive of cymoxanil relating to efficacy.

Appendix 1 of this document contains the list of references included in this document in support of the evaluation.

Description of active substances

Developed by DuPont and first introduced in 1977, cymoxanil gives protective and curative control of a range of fungal pathogen through contact and local systemic activity, and also inhibition of sporulation. It is included in a range of products currently approved for use in many EU countries for the control of pathogens belonging to the order Peronosporales, namely Phytophthora, Plasmopara and Peronospora species, which cause Downy mildew and Blight in a wide range of crops, including grapevine, potato, tomato, sugar beet and various vegetable crops.

Further information on the identity of cymoxanil is available in the Biological Assessment Dossier (KCP 6.0-01).

Mode of action

Whilst the primary mode of action and target site of cymoxanil is unknown, it has been proposed to inhibit nucleic acid synthesis, reduce membrane permeability and mycelial respiration and disrupt cysteine, glycine and serine synthesis. This leads to inhibition of mycelial and germ tube growth and reduced sporulation.

Cymoxanil is capable of penetrating into plant tissue, also redistributing in the foliage, and exhibits curative properties. When the compound penetrates through the leaves and when inside, it cannot be washed off by rain. It controls diseases during the incubation period and prevents the appearance of damage on the crop.

Specific details about cymoxanil mode of action are provided in point 3.3.1.

Table 3.2-1: Details of the active substance

Active substance	**cymoxanil**
Product code	IN002B1760
Concentration	450 g/kg
Chemical group	Cyanoacetamide oxime
Mode of action	unknown

Description of the plant protection product

IN002B1760 is a water dispersible granules (WG) formulation containing 45% (450 g/kg) of the active substance cymoxanil, to be used as preventive and curative fungicide in potato (SOLTU)~~, greenhouse tomato (LYPES) and aubergine (SOLME)~~ for use against late blight (PHYTIN).

Information on the detailed composition of IN002B1760 can be found in the confidential dossier of this submission (Registration Report - Part C).

Table 3.2-2: Examples of current registrations of straight cymoxanil formulations in EU Countries (Central zone and Southern zone)

Country	Product	Reg. No.	Crop
Austria	CYMBAL 45	3476-0	potato
	DAUPHIN 45 WDG	3288-0	potato
Belgium	CYMOX 45 WG	1388P/P	potato
	SACRON WG	10731P/B	potato
Croatia	CYMBAL FLOW (225 g/L)	UP/I-320-20/14-01/161	potato
	CURZATE 60 WG (600 g/kg)	UP/I-320-20/19-03/84	tomato (F/G), cucumber (F/G), melon (F/G), watermelon (F/G), pumpkin (F), lettuce (F), onion
France	CYMOXIL 450 WG	2190266	potato
	CYMBAL 45	2120067	potato
Germany	CYMOX WG	00A112-60	potato
	CURZATE 60 WG	00A112-00/00-001	potato
Greece	DRUM 45 WG	60447	potato
	SACRON 45 WG	60483	potato, tomato, grapes
Italy	XANILO 45 WG	12548	grape, potato, tomato, cucumber, aubergine, melon, watermelon, pumpkin, lettuce, onion, spinach, artichoke,
Malta	CURZATE 60 WG	2020-05-29 P01	tomato, potato, cucumber, gherkin, courgette, melon, watermelon, pumpkin, lettuce, onion
	CYMBAL	2010-03-16 P01	grape, artichoke, lettuce, spinach, melon, squash, cucumber (G), peas, garlic, onion, leek, potato, tomato, tobacco, rose
Netherlands	CYMBAL	14003	potato
	SACRON WG	15281	potato
Slovakia	SACRON WG	20-00891-AU	potato
	CURZATE 60 WG	20-00789-AU	potato
Spain	XANILO 45 WG	24128	artichoke, courgette, cucurbits with edible peel, cucurbits with inedible peel, lettuce, spinach, potato, tomato, grape
	CYMBAL 45 WG	25762	potato
	SACRON	ES-00321	potato, tomato, grape
UK	CURZATE 60 WG	19603	potato
	CYMBAL 45	16647	potato

Many cymoxanil straight formulations are currently available in EU market, some of them authorized from the ’80s. In CEU, straight cymoxanil products are authorized for use on potato against potato late blight (*Phytophthora infestans*), while in SEU, many other uses are authorized, such as grape, tomato, cucumber, gherkin, aubergine, courgette, melon, watermelon, pumpkin, lettuce, onion, garlic, spinach, peas, leek, artichoke, and some others.

Table 3.2-3: Simplified table of requested uses for IN002B1760

Crop / Pest	Application method	Spray volume (L/ha)	Application rate (kg f.p./ha)	Max. number of applications	Application timing (*e.g.* BBCH)
Potato *Phytophthora infestans*	foliar spray	150-1000	0.33	6	BBCH 12-95
~~**Tomato** *Phytophthora infestans*~~	~~foliar spray~~	~~150-1000 (F) 600-1500 (G)~~	~~0.33~~	~~5~~	~~BBCH 12-89~~
~~**Aubergine** *Phytophthora infestans*~~	~~foliar spray~~	~~150-1000 (F) 600-1500 (G)~~	~~0.33~~	~~5~~	~~BBCH 12-89~~

Description of the target pests

Phytophthora infestans (PHYTIN) on potato (SOLTU)~~, tomato (LYPES) and aubergine (SOLME)~~

Phytophthora infestans causes serious losses of potato crops worldwide and is probably the most important pathogen of potato and tomato.

Late blight is caused by the fungus-like oomycete pathogen *P. infestans*. It can infect and destroy the leaves, stems, fruits, and tubers of potato and tomato plants, as well as other Solanaceae. On potato, symptoms are first seen as damp areas on the lower leaves of plants. These areas may fuse to form a large brown area of dead or damaged tissue. The pathogen grows out of the leaves on the lower surfaces of the leaves where it is seen as a white downy mass. The disease is most aggressive under wet conditions and will rapidly kill all aerial parts of a plant.

Rots of the tuber also develop and are characterized by slightly sunken areas that have a brown to purplish skin. On young tubers, infections are dark, reddish brown and 5 to 15 mm deep. In stored tubers, rots are sunken, dry, and light brown but infected areas are not distinct from healthy tissue. Secondary fungal and bacterial invasion frequently occurs and the entire tuber becomes rotten.

On tomato fruits, lesions are firm, large, irregular, brownish-green blotches; the lesion surface has a greasy, rough appearance.

Disease development (growth and reproduction of the pathogen) is favoured by moderate temperatures and wet conditions. The disease is caused by zoospores. These spores can overwinter on potato tubers and can be very widely dispersed by wind or rain. On potatoes, the *mycelia* proliferate the whole leaf tissue. Spores develop on leaves and rain can wash them into the soil where they infect young tubers. Else spores can be blown to other areas by the wind. Epidemics can be rapid and devastating because of the high reproductive potential of this pathogen. Individual lesions can produce 100,000 to 300,000 *sporangia* per day. Each *sporangium* is capable of initiating a new infection that will become visible within three to four days and produce sporangia within another day or two under optimal conditions.

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

EPPO code	Scientific name	Common name
PHYTIN	*Phytophthora infestans*	Late blight

Table 3.2-5: Major / minor status of intended uses (for all cMS and zRMS).

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	Minor		Major	Minor
Potato	CEU	-	Late blight	CEU	-
~~Tomato~~	~~-~~	~~CEU~~	~~Late blight~~	~~CEU~~	~~-~~

Compliance with the Uniform Principles

The efficacy assessment of IN002B1760 was performed according to the Uniform Principles. All the submitted efficacy trials in Maritime, and North-East ~~and Mediterranean~~ EPPO zone were conducted in Good Experimental Practice (GEP) conditions.

Information on trials submitted (3.1 Efficacy data)

To support the registration of IN002B1760 in the claimed use~~s~~, field trials have been set up in potato ~~and greenhouse trials (interzonal) were performed in tomato~~. In potato trials, the formulation IN002B1760 was compared to Banjo 500 SC (Poland), Cymbal 45 (UK and Czech Republic) and Curzate 60 WG (Germany). ~~In tomato trials, IN002B1760 was compared to Xanilo 45 WG (Italy) and Miedzian 50 WG (Poland) and Sancron 45 WG (Greece).~~ All the reference products are currently on the market in the respective Countries. Further details are available in Table 3.2-7. The trials were conducted in 2021 (Maritime and North-East EPPO zone ~~+ greenhouse trials~~).

Furthermore, the above-mentioned results from 2021 were supplemented in this dossier by additional trials carried out on potato for *Phytophthora infestans* control in the Maritime and North-East EPPO zone in 2023. In these trials, the formulation of the tested product was compared to Controlla 450 WG (Poland and Germany) and Infinito (Czech Republic).

Data are presented from a total of ~~12~~ 8 efficacy trials, conducted with IN002B1760 in potato ~~(8) and tomato (4)~~ conducted with IN002B1760 in 2021. And the data from the additional 5 potato efficacy trials from 2023.

Table 3.2-6: Presentation of trials (efficacy trials)

Crop(s)	Target(s)	Country	Years	Type of trial	Number of trials (number of valid trials)			GEP, non-GEP, official
					Maritime zone	~~South~~ North-East zone	~~Interzonal~~	
Potato	Late blight	UK	2021	MED + E	2 (0)	-	-	GEP
		Germany	2021	MED + E	2 (2)	-	-	GEP
			2023	MED + E	1 (1)	-	-	GEP
		Czech Republic	2021	MED + E	2 (2)	-	-	GEP
			2023	MED + E	1 (1)	-	-	GEP
		Poland	2021	MED + E	-	4 (4)	-	GEP
			2023	MED + E	-	3 (3)	-	GEP
	TOTAL	-	2021	-	4	4	-	
		-	2023	-	2	3	-	
~~Tomato (greenhouse)~~	~~Late blight~~	~~Italy~~	~~2021~~	~~MED + E~~	~~-~~	~~-~~	~~2 (2)~~	~~GEP~~
		~~Poland~~	~~2021~~	~~MED + E~~	~~-~~	~~-~~	~~2 (2)~~	~~GEP~~
		~~France~~	~~2021~~	~~MED + E~~	~~-~~	~~-~~	~~1 (1)~~	~~GEP~~
		~~Greece~~	~~2021-2022~~	~~MED + E~~	~~-~~	~~-~~	~~1[1]~~	~~GEP~~
	~~TOTAL~~	~~-~~		~~-~~	~~-~~	~~-~~	~~5~~	
TOTAL	-	-		-	~~4~~ 6	~~4~~ 7	~~5~~	

MED = minimum effective dose, E = efficacy trial; GEP: Good Experimental Practices.
[1] trial is still ongoing.

Table 3.2-7: Presentation of reference standards used in efficacy trials in 2021:

Crop (s)	Reference standard	Country(ies) where the product is registered (1)	Authorization number	Active substance(s)	Formulation		Registered application rate(3)	Application rate in trials (per treatment)	Remark(4)
					Type (2)	Concentration of a.s.			

Crop (s)	Reference standard	Country(ies) where the product is registered (1)	Authorization number	Active sub-stance(s)	Formulation		Registered application rate(3)	Application rate in trials (per treatment)	Remark(4)
					Type (2)	Concentration of a.s.			
Potato	CYMBAL 45	UK	16647	Cymoxanil	WG	450 g/kg	250 g/ha	250 g/ha	
		Czech Republic	4924-0						
	BANJO 500 SC	Poland	R-21/2013	Fluazinam	SC	500 g/L	0.4 L/ha	0.4 L/ha	
	CURZATE 60 WG	Germany	00A112-00	Cymoxanil	WG	600 g/kg	0.2 kg/ha	0.2 kg/ha	
~~Tomato~~	~~XANILO 45 WG~~	~~Italy~~	~~12548~~	~~Cymoxanil~~	~~WG~~	~~450 g/kg~~	~~300-330 g/ha~~	~~330 g/ha~~	
	~~MIEDZIAN 50 WG~~	~~Poland~~	~~R-134/2015~~	~~Copper~~	~~WG~~	~~500 g/kg~~	~~1.5 kg/ha~~	~~1.5 kg/ha~~	
	~~BOUILLIE BORDE-LAISE RSR DISPERSS~~	~~France~~	~~9500452~~	~~Copper~~	~~WG~~	~~200 g/kg~~	~~3.75 kg/ha~~	~~3.75 kg/ha~~	
	~~SACRON 45 WG~~	~~Greece~~	~~2002595~~	~~Cymoxanil~~	~~WG~~	~~450 g/kg~~	~~0,22—0,27 kg/ha~~	~~0,27 kg/ha~~	

(1) only on use(s) applied for (with the test product).
(2) e.g. WP (wettable powder), EC (emulsifiable concentrate), etc.
(3) dose(s) / dose range authorized on that use in the country.
(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application, etc.).

Table 3.2-7a: Presentation of reference standards used in efficacy trials in 2023

Crop(s)	Reference standard	Country(ies) where the product is registered (1)	Authorization number	Active substance(s)	Formulation		Registered application rate(3)	Application rate in trials (per treatment)	Remark(4)
					Type(2)	Concentration of a.s.			
Potato	Controlla 450 WG	Poland	R-187/2020	Cymoxanil	WG	450 g/kg	250 g/ha	250 g/ha	
		Germany	00B026-00/01						
	Infinito	Czech Republic	4602-2	Propamocarb-hydrochlorid + Fluopico-lide	SC	625 g/L + 62,5 g/L	1,2-1,6 L/ha	1,0 L/ha	

(1) only on use(s) applied for (with the test product).
(2) e.g. WP (wettable powder), EC (emulsifiable concentrate), etc.
(3) dose(s) / dose range authorized on that use in the country.
(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application, etc.).

~~**Extrapolation**~~

~~The data package submitted for this dossier is substantial. However, it is justifiable to extrapolate from a strong database of one crop to support registration of another crop if certain conditions are met.~~

~~An extrapolation from data obtained on tomato to aubergine is proposed.~~

~~EPPO guideline PP 1/257(2) provides decision guidance for the extrapolation of fungicides data (Appendix 1). According to the decision support scheme, the claimed extrapolation is feasible.~~

~~Further details are given in the Biological Assessment dossier (KCP 6.0-01).~~

3.2.1 Preliminary tests (KCP 6.1)

Preliminary range-finding tests trials are not included in this biological dossier. The formulations IN002B1760 contains 450 g/kg of the active substance cymoxanil, and a lot of similar products have been registered and commercialized in many EU Member States for decades. The necessary application rates to obtain optimum control of the already registered target pests (*i.e. Phytophthora infestans*) are already known and they have been considered on the basis of the technical information available and on the effective registrations granted in EU Member States. Therefore, preliminary tests to assess the biological activity or dose range of the active substance were not deemed necessary for this registration purpose.

Little variations on application rates can be observed comparing similar cymoxanil formulations, However, the proposed GAP for IN002B1760 is compliant to the EU GAP for cymoxanil.

Comments of zRMS:

Accepted. The active substance cymoxanil is known for protection of potato against *Phytophthora infestans* in many EU Member States.

3.2.2 Minimum effective dose tests (KCP 6.2)

Field trials were established in order to determine the minimum effective dose for the control of *Phytophthora infestans* on potato ~~and tomato~~.

In potato ~~and tomato~~ trials, IN002B1760 was applied at the rate of 0.33 kg/ha, 0.25 kg/ha and 0.165 kg/ha, corresponding to 100%, 75% and 50% of the full recommended application rate, in accordance with the EPPO standard PP 1/225(2) 'Minimum effective dose'.

Efficacy was tested in field trials between in 2021 under a range of environmental conditions to fully challenge the product. ~~Tomato trials were conducted in greenhouse conditions, that represent the worst-case scenario for *Phytophthora infestans* control, however, some field trials conducted in Southern Zone are presented as additional data and discussed later~~

Furthermore, to support the results from the 2021, additional efficacy results data obtained in 2023 on potato *Phytophthora infestans* control are presented in the following dossier

The justification of the claimed rates 0.33 kg/ha on potato~~, tomato and aubergine~~ for IN002B1760 against the target disease is supported by data generated on the efficacy of the application of IN002B1760 at different rates in all the efficacy trials.

IN002B1760 is intended to be applied as foliar spray, with application volume ranging from 150 to 1000 L water/ha in ~~filed~~ field uses ~~and from 600 to 1500 l water/ha for greenhouse uses~~.

For details on the protocol, please refer to Table 3.2-14.

Many cymoxanil straight formulations are authorised and currently commercialised in EU, as described in Table 3.2-2. For efficacy and resistance concerns, in common practice, solo cymoxanil-based products are always applied together or in sequence with other products delivering different active substances. However, in trials conducted for registration purposes, the product must be applied alone to prove that the effectiveness is related to that product and not to partners.

Therefore, a moderate efficacy is expected, as well as a reduced or very reduced efficacy of late applications, where the disease severity is high. On the other hand, the expected efficacy is similar to that of other comparable formulations (or any other cymoxanil straight) used as reference. The aim of the present dossier is to demonstrate that IN002B1760 provide disease control comparable to similar cymoxanil-based products.

Similarly, despite the proposed number of applications for IN002B1760 is 6 for potato ~~and 5 for grape, tomato and aubergine,~~ a slight higher number of applications was performed in efficacy trials, in order

to cover, as much as possible, the disease period. In fact, in common practice, a higher number of applications are made during the growing season. In any case, assessments after each application or reduced number of applications are available in single trial reports and in Appendix 4.

In order to compare data of several trials that showed different disease level, as well as different disease appearance timings, results were grouped by range of pest severity. In fact, pest severity should be considered as the most important factor to evaluate the product's effectiveness. Therefore, efficacy results were analysed grouping them in ranges of ten to ten % of pest severity (*e.g.* 10-19.9%). In this way, it is possible to appreciate the efficacy of IN002B1760 related to the disease level.

Other ways to present data, *e.g.* efficacy after a fixed number of applications, could lead to unreliable analysis, also considering that cymoxanil is applied preventatively and the disease can therefore appear in different timing depending on the climatic conditions and many other factors.

Where pest incidence data were available (grape trials, both on leaves and bunches), data are even so presented by pest severity ranges, to have a consistent analysis.

Potato

The following tables show results obtained with IN002B1760 applied at 0.165 kg/ha, 0.25 kg/ha and 0.33 kg/ha against *Phytophthora infestans* on potato. Results are separated by EPPO climatic zone. Results related to all trials conducted in Central zone are also presented.

Table 3.2-8: Minimum effective dose. Efficacy of IN002B1760 on pest severity (PESSEV) at the proposed maximum label rate, 75% and 50% in EPPO Maritime zone in 2021

Pest severity%	No. of trials	Disease in UTC (PESSEV) %	Efficacy obtained with IN002B1760 Mean (min-max)		
			0.165 kg/ha	0.25 kg/ha	0.33 kg/ha
< 10%	2	6.3 (4.1-8.5)	53,3 (38,3-68,3)	61.7 (46.7-76.7)	57.8 (30-85.5)
10-19.9%	3	11.2 (10-12.3)	47,8 (41,7-53,3)	37.1 48.2 (0 33.33-64.6)	60 (54.2-71.7)
20-29.9%	1	27.5	37,5	52.5	56.7
30-39.9%	2	33.1 (31.3-35)	31,3 (28,1-34,4)	33.7 (21.9-45.4)	42 (31.3-52.7)
40-49.9%	1	40	14,4	39	36.7
50-59.9%	1	52.5	71	71.1	74.8
60-69.9%	-	-	-	-	-
70-79.9%	2	74.2 (71.3-77)	27,8 (26-29,6)	20 23.6 (0 7.2-40.1)	37 (20.9-53)
80-89.9%	2	84.9 (83.5-86.3)	16,5 (5,6-27,3)	10.1 (10.1-10.2)	14.5 (8.4-20.6)
90-99.9%	1	95	6,6	14.5	17.1
100%	3	100	0	0.1 (0-0.3)	0.8 (0-2.3)
Mean of all assessments		52.5	31.2	31.7	39.4

Despite no clear dose response was always evident, statistical differences among rates were observed in 5 assessments.

Table 3.2-9a: Minimum effective dose. Efficacy of IN002B1760 on pest severity (PESSEV) at the proposed maximum label rate, 75% and 50% in EPPO Maritime zone in 2023

Pest severity%	No. of trials	Disease in UTC (PESSEV) %	Efficacy obtained with IN002B1760 Mean (min-max)		
			0.165 kg/ha	0.25 kg/ha	0.33 kg/ha
< 10%	1	5,0	95,0	100,0	100,0
10-19.9%	-	-	-	-	-
20-29.9%	-	-	-	-	-
30-39.9%	-	-	-	-	-
40-49.9%	-	-	-	-	-
50-59.9%	1	52,5	51,7	59,0	62,5
60-69.9%	-	-	-	-	-
70-79.9%	-	-	-	-	-
80-89.9%	-	-	-	-	-
90-99.9%	-	-	-	-	-
100%	-	-	-	-	-

Table 3.2-8b: Minimum effective dose. Efficacy of IN002B1760 on pest severity (PESSEV) at the proposed maximum label rate, 75% and 50% in EPPO Maritime zone in 2021 and 2023 (Germany and Czech Republic)

Pest severity %	No. of trials	Untreated (PESSEV%)			Efficacy Mean (min-max) IN002B1760								
					0,165 kg/ha			0.25 kg/ha			0.33 kg/ha		
		Mean	min	max	Mean	min	max	Mean	min	max	Mean	min	max
< 10%	3	**5,9**	4,1	8,5	**67,2**	38,3	95,0	**74,5**	46,7	100,0	**71,8**	30,0	100,0
10-19.9%	3	**11,2**	10,0	12,3	**47,8**	41,7	53,3	**37,1**	0,0	64,6	**60,0**	54,2	71,7
20-29.9%	1	**27,5**	27,5	27,5	**37,5**	37,5	37,5	**52,5**	52,5	52,5	**56,7**	56,7	56,7
30-39.9%	2	**33,1**	31,3	35,0	**31,3**	28,1	34,4	**33,7**	21,9	45,4	**42,0**	31,3	52,7
40-49.9%	1	**40,0**	40,0	40,0	**14,4**	14,4	14,4	**39,0**	39,0	39,0	**36,7**	36,7	36,7
50-59.9%	2	**52,5**	52,5	52,5	**61,4**	51,7	71,0	**65,1**	59,0	71,1	**68,7**	62,5	74,8
60-69.9%	-	-	-	-	-	-	-	-	-	-	-	-	-
70-79.9%	2	**74,2**	71,3	77,0	**27,8**	26,0	29,6	**20,0**	0,0	40,1	**37,0**	20,9	53,0
80-89.9%	2	**84,9**	83,5	86,3	**16,5**	5,6	27,3	**10,1**	10,1	10,2	**14,5**	8,4	20,6
90-99.9%	1	**95,0**	95,0	95,0	**6,6**	6,6	6,6	**14,5**	14,5	14,5	**17,1**	17,1	17,1
100%	3	**100,0**	100,0	100,0	**0,0**	0,0	0,0	**0,1**	0,0	0,3	**0,8**	0,0	2,3
Mean of two key assessments		50,1			57,5			63,5			66		

Table 3.2-10: Minimum effective dose. Efficacy of IN002B1760 on pest severity (PESSEV) at the proposed maximum label rate, 75% and 50% in EPPO North-East zone in 2021

Pest severity%	No. of trials	Disease in UTC (PESSEV) %	Efficacy obtained with IN002B1760 Mean (min-max)		
			0.165 kg/ha	0.25 kg/ha	0.33 kg/ha
< 10%	1	5.0	65.0	100	85.0
10-19.9%	3	15.4 (15-16.3)	40,4 (18,3-69,6)	64.6 (43.3-79.2)	61.8 (54.2-66.7)
20-29.9%	3	23.3 (20-25)	33,2 (14,2-64,1)	47.3 (28.3-70.4)	59.2 (49.2-71.8)
30-39.9%	-	-	-	-	-
40-49.9%	2	44.4 (42.5-46.3)	44,2 (20,6-67,8)	52.6 (38.1-67.2)	57.8 (50-65.5)
50-59.9%	-	-	-	-	-
60-69.9%	3	62.1 (60-66.3)	32,4 (16,7-60)	39.9 (20.8-62.3)	42.5 (25-58.2)
70-79.9%	1	76.3	18	18	22.7
80-89.9%	2	80.6 (80-81.3)	20,7 (15,6-25,8)	28.4 (25-31.7)	23.7 (12.5-34.9)
90-99.9%	2	93.2 (91.3-95)	31,6 (17-46,3)	40.4 (26-54.8)	39 (24.8-53.2)
100%	2	100	0	0 (0-0)	0 (0-0)
Mean of all assessments		56.4	31.1	42.1	44.4

Table 3.2-11a: Minimum effective dose. Efficacy of IN002B1760 on pest severity (PESSEV) at the proposed maximum label rate, 75% and 50% in EPPO North-East zone in 2023

Pest severity%	No. of trials	Disease in UTC (PESSEV) %	Efficacy obtained with IN002B1760 Mean (min-max)		
			0.165 kg/ha	0.25 kg/ha	0.33 kg/ha
< 10%	2	7,3	82,95 (82,2-83,7)	96,4 (94,4-98,4)	98,3 (98,2-98,4)
10-19.9%	2	13,3	84,3 (83-85,5)	95,4 (92,9-97,8)	97,9 (97,7-98,1)
20-29.9%	1	26,5	37,4	66,1	75,4
30-39.9%	1	39,3	38,2	75,1	74,8
40-49.9%	-	-	-	-	-
50-59.9%	-	-	-	-	-
60-69.9%	-	-	-	-	-
70-79.9%	-	-	-	-	-
80-89.9%	-	-	-	-	-
90-99.9%	-	-	-	-	-
100%	-	-	-	-	-

Table 3.2-9b: Minimum effective dose. Efficacy of IN002B1760 on pest severity (PESSEV) at the proposed maximum label rate, 75% and 50% in EPPO North-East zone in 2021 and 2023

Pest severity %	No. of trials	Untreated (PESSEV%)			Efficacy Mean (min-max) IN002B1760								
					0,165 kg/ha			0.25 kg/ha			0.33 kg/ha		
		Mean	min	max	Mean	min	max	Mean	min	max	Mean	min	max
< 10%	2	**7,3**	7,0	7,5	**83,0**	82,2	83,7	**96,4**	94,4	98,4	**98,3**	98,2	98,4
10-19.9%	5	**14,6**	12,8	16,3	**55,0**	18,3	85,5	**76,9**	43,3	97,8	**76,2**	54,2	98,1
20-29.9%	4	**24,1**	20,0	26,5	**24,3**	14,2	37,4	**52,0**	28,3	70,4	**63,3**	49,2	75,4
30-39.9%	1	**39,3**	39,3	39,3	**38,2**	38,2	38,2	**75,1**	75,1	75,1	**74,8**	74,8	74,8
40-49.9%	2	**39,3**	42,5	46,3	**44,2**	20,6	67,8	**52,6**	38,1	67,2	**57,8**	50,0	65,5
50-59.9%	-	-	-	-	-	-	-	-	-	-	-	-	-
60-69.9%	3	**62,1**	60,0	66,3	**32,4**	16,7	60,0	**39,9**	20,8	62,3	**42,5**	25,0	58,2
70-79.9%	1	**76,3**	76,3	76,3	**18,0**	18,0	18,0	**18,0**	18,0	18,0	**22,7**	22,7	53,0
80-89.9%	2	**80,6**	80,0	81,3	**20,7**	15,6	25,8	**28,4**	25,0	31,7	**23,7**	12,5	34,9
90-99.9%	2	**93,2**	91,3	95,0	**31,6**	17,0	46,3	**40,4**	26,0	54,8	**39,0**	24,8	53,2
100%	2	**100,0**	100,0	100,0	**0,0**	0,0	0,0	**0,0**	0,0	0,0	**0,0**	0,0	0,0
Mean of two key assessments		46,6			69			86,65			87,25		

Numerical dose response was generally observed. Statistical differences were observed in some assessments among 0.165 kg/ha and higher rates, as well as among 0.33 kg/ha and both lower rates.

Moreover, it was also confirmed by the trials carried out in 2023. In these trials, statistical differences between the lowest dose of 0.165 kg/ha and the highest doses were also observed in most assessments.

Overall, considering the results and that IN002B1760 showed an efficacy fully comparable to that of cymoxanil references used in the trials conducted in Maritime zone (see point 3.2.3 Efficacy tests), it is considered that the rate of 0.25 kg/ha should be considered as the minimum effective dose, and that an application rate range of 0.25-0.33 kg/ha should be suggested, as discussed later.

~~Tomato~~

~~Results obtained with IN002B1760 against *P. infestans* on tomato in greenhouse (interzonal) are presented below.~~

~~Results of field trials conducted in Mediterranean EPPO zone are also presented as additional supportive trials as it is considered that climatic conditions in the field in Southern zone Countries (*e.g.* Italy, Spain, Portugal and Greece) are very similar to indoor conditions of greenhouses of Central zone (climatic data recorded inside greenhouse are availbale for Polish trials, in each trial report). Furthermore, looking at the disease level encountered in the trials, it can be observed that field trials in Mediterranean EPPO zone can be considered as worst case, thus representing more challenging situations to test the product's effectiveness.~~

~~**Table 3.2-12: Minimum effective dose. Efficacy of IN002B1760 on pest severity (PESSEV) at the proposed maximum label rate, 75% and 50% in greenhouse trials (interzonal)**~~

~~Pest severity%~~	~~No. of trials~~	~~Disease in UTC (PESSEV) %~~	~~Efficacy obtained with IN002B1760 Mean (min-max)~~		
			~~0.165 kg/ha~~	~~0.25 kg/ha~~	~~0.33 kg/ha~~
~~< 10%~~	~~2~~	~~7.9 (6.3-9.5)~~	~~92.1 (87.4-96.8)~~	~~97.2 (94.4-100)~~	~~99.4 (98.9-100)~~
~~10-19.9%~~	~~1~~	~~15~~	~~69.2~~	~~71.3~~	~~82.5~~
~~20-29.9%~~	~~3~~	~~21.7 (20-23.8)~~	~~61.8 (35.8-82.4)~~	~~73.8 (46.3-95.6)~~	~~81.9 (60.8-99)~~
~~30-39.9%~~	~~1~~	~~43.2~~	~~49.7~~	~~59.1~~	~~82.9~~
~~40-49.9%~~	~~-~~	~~-~~	~~-~~	~~-~~	~~-~~

Pest severity%	No. of trials	Disease in UTC (PESSEV) %	Efficacy obtained with IN002B1760 Mean (min-max)		
			0.165 kg/ha	0.25 kg/ha	0.33 kg/ha
50-59.9%	-	-	-	-	-
60-69.9%	-	-	-	-	-
70-79.9%	-	-	-	-	-
80-89.9%	1	87.1	49.5	52.7	75.2
90-99.9%	1	99.4	6.7	11	19.4
100%	-	-	-	-	-
Mean of all assessments		36.2	60.5	67.8	78.3

Pest severity %	No. of trials	Untreated (PESSEV%)			Efficacy Mean (min-max) IN002B1760								
					0.165 kg/ha			0.25 kg/ha			0.33 kg/ha		
		Mean	min	max	Mean	min	max	Mean	min	max	Mean	min	max
< 10%	2	7,9	6,2	9,5	92,1	87,4	96,9	97,2	94,4	100,0	99,4	98,9	100,0
10-19.9%	2	13,4	11,8	15,0	70,7	69,2	72,2	84,0	71,2	96,9	89,0	82,5	95,5
20-29.9%	3	21,7	20,0	23,8	61,8	35,8	82,4	73,8	46,3	95,6	81,9	60,8	99,0
30-39.9%	1	36,4	36,4	36,4	84,0	84,0	84,0	97,3	97,3	97,3	97,2	97,2	97,2
40-49.9%	1	43,2	43,2	43,2	49,7	49,7	49,7	59,1	59,1	59,1	82,9	82,9	82,9
50-59.9%													
60-69.9%													
70-79.9%													
80-89.9%	1	87,1	87,1	87,1	49,5	49,5	49,5	52,7	52,7	52,7	75,2	75,2	75,2
90-99.9%	1	99,4	99,4	99,4	6,7	6,7	6,7	11,0	11,0	11,0	19,4	19,4	19,4
100%													
Mean of all assessments		34,0			63,7			73,1			81,6		

Besides the numerical dose-response, the lower rate of 0.165 kg/ha resulted in a statistically inferior efficacy compared to higher rates, in 2 trials out of 5.

Table 3.2-13: Minimum effective dose. Efficacy of IN002B1760 on pest severity (PESSEV) at the proposed maximum label rate, 75% and 50% in EPPO Mediterranean zone

Pest severity%	No. of trials	Disease in UTC (PESSEV) %	Efficacy obtained with IN002B1760 Mean (min-max)		
			0.165 kg/ha	0.25 kg/ha	0.33 kg/ha
< 10%	3	6.1 (3.2-7.9)	62.1 (53.8-66.2)	67.4 (51.9-83.3)	68.8 (47.3-83.7)
10-19.9%	5	15 (11.8-17.1)	46 (9-68.1)	56.5 (9-90.3)	56 (9-87.7)
20-29.9%	3	25.8 (24.9-27.5)	55.1 (46.1-63.3)	66.4 (54.3-78.6)	72.9 (59.3-85.9)
30-39.9%	1	32.9	57.2	71.9	79.1
40-49.9%	1	42.9	53.3	53.4	52.6
50-59.9%	-	-	-	-	-
60-69.9%	-	-	-	-	-
70-79.9%	1	77	40.2	37.1	46.5
80-89.9%	-	-	-	-	-
90-99.9%	1	90.4	43.5	41.2	47.5
100%	-	-	-	-	-
Mean of all assessments		27.6	45.6	52.2	54.8

Despite a statistical dose response was not evidenced, a numerical trend can be observed.

~~Basing on field and greenhouse trials conducted in tomato against *Phytophthora infestans*, and taking into account results obtained also in potato against the same target disease, it is considered that the rate of 0.25 kg/ha should be considered as the minimum effective dose and that the application rate range of 0.25-0.33 kg/ha of IN002B1760 should be suggested as application rate to guarantee a good control in a broad range of situations.~~

Summary and conclusions on the minimum effective dose

According to the presented results, the application rate of 0.25-0.33 kg/ha of IN002B1760 (corresponding to 112.5-148.5 g/ha cymoxanil) provided a satisfying control of the disease caused by *Phytophthora infestans* in potato ~~and tomato~~, showing control numerically, and in some cases also statistically, superior to lower dose and should be considered as the minimum effective dose on potato ~~and tomato~~.

Comments of zRMS:

A total of ~~8~~ 13 field efficacy trials have been submitted to determine minimum effective dose to control of *Phytophthora infestans* on potato.
4 valid trials were available in **the Maritime EPPO climatic zone**. IN002B1760 applied at dose rate of 0,33 kg/ha achieved superior effectiveness compared to lower doses. The mean efficacy at least 60% has been achieved only ~~by~~ with lower pest severity (10-19,9%). Insufficient results were noted in other assessments. ~~Furthermore limited number of trials has been submitted in the MAR zone. Currently, in opinion of zRMS there are not basis to accept this use. However the cMSs are kindly asked to extrapolate trials from the NE zone and consider this use on national level.~~ 2 additional efficacy trials conducted in 2023 have been submitted in the MAR zone. Moderate level of control at ~~low~~ high pest severity (~~< 10~~ 52,5%) has been noted in these trials. Good control was achieved for pest severity (<10%) in the 2023 MAR trials. Moreover, similar effect has been achieved for both claimed doses. Taking into account all available dataset, the cMS Netherlands is kindly asked to consider again this use on national level. However, also the additional trials were not conducted under worst case conditions (which would generally be IE or NL in case of *Phytophthora infestans* according to the cMS NL comment in the commenting period of evaluation).
4 trials were carried out in **the North-East EPPO climatic zone**. IN002B1760 achieved very limited effectiveness. The dose rate of 0,165 kg/ha had significant inferior results compared to higher doses. The test product at 0,25 and 0,33 kg/ha presented superior mean efficacy however still on a low level. Sufficient results were observed only in case of lower pest severity (<10% or 10-19,9%). ~~Because the number of available trials is limited in the NE zone, zRMS decided to extrapolate also results from the neighboring countries in the Maritime zone (Germany and Czech Republic). Sufficient effectiveness has been confirmed for dose rate of 0,33 kg/ha in all approved trials and therefore it can be considered MED but it should be noted that only on medium level.~~ 3 additional efficacy trials conducted in 2023 have been submitted for the NE zone. Comparability of both claimed doses is visible. Sufficient level of control was observed mainly at lower disease pressure (<20%). Taking into account all submitted trials, the dose rate of 0,25 kg/ha can be determined MED for control *Phytophthora infestans* on potato in the NE zone. However, moderate effectiveness was achieved at higher pest severity for both claimed doses and this information should be included in the product label.
No efficacy trials have been submitted in the South-East EPPO zone. The cMS Slovenia is kindly asked to extrapolate trial results from other EPPO zones and consider this use on national level.
~~Taking into account all submitted trials, the dose rate of 0,33 kg/ha can be determine as minimum effective dose rate for control of *P.infestans* on potato. Comparability of results was visible between 0,25 kg/ha and 0,33 kg/ha, however significant differences have been observed in case of PESSEV 20-29,9% (Polish trials) and 10-19,9% (trials from the MAR zone). The higher dose was superior in most trials. With high pathogen pressure, the dose rate of 0,25 kg/ha can be insufficient.~~

3.2.3 Efficacy tests (KCP 6.2)

Trials in this dossier have been carried out by contractor companies that follow the EPPO guidelines and are officially recognized by the Competent Authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The GEP certificates of the official testing organization are reported in point 3.7.

IN002B1760 is intended for use on potato (field use)~~, tomato and aubergine (greenhouse use)~~ at 0.25-

0.33 kg/ha.

Efficacy data include the results of 8 valid trials on potato (4 in EPPO Maritime zone + 4 in EPPO North-East zone) ~~and 5 valid efficacy trials on tomato (5 greenhouse trials, 1 further trial is still ongoing)~~ conducted with IN002B1760 in 2021.

Furthermore, the efficacy results of *Phytophthora infestans* potato control data were supplemented with results of 5 valid trials conducted in the EPPO Maritime zone (2) and in EPPO Nort-East zone (3) in 2023.

For full and schematic details of the studies, please refer also to Appendix 3 and Appendix 4.

Table 3.2-14: Details on trial methodology (2021)

Guidelines	General guidelines	EPPO PP 1/135(4) 'Phytotoxicity assessment, PP 1/152(4) 'Design & analysis of efficacy evaluation trials', PP 1/181(4) 'Conduct and reporting of efficacy evaluation trials including good experimental practice', PP 1/225(2) 'Minimum effective dose'
	Specific guidelines	EPPO PP 1/002(4) 'Phytophthora infestans on potato', PP 1/065(3) 'Downy mildews of lettuce and other vegetables'
Experimental design	Plot design	RCBD
	Plot size	Potato: 18-25.2 m² ~~Tomato (greenhouse): 5.3-11 m²~~
	Number of replications	4
Crops	Trials per crop	Potato (8) ~~Tomato (5)~~
	Varieties per crop	Potato: Sagitta*, Marabella, Melody, Bila, Tajfun, Jelly, Denar, Solara ~~Tomato: ug11239, Gigawak, Pink Wave F1 (CRX78254), Luciplus, Cobra~~ [*variety tested in trials judged as not valid for efficacy, but usable for observation on phytotoxicity]
Application	Crop stage (BBCH) at application	Potato: BBCH 14 to BBCH 91 ~~Tomato (greenhouse): BBCH 15 to BBCH 81~~
	Number of applications Intervals between applications	Potato: 8-10 (6-15 days interval) ~~Tomato (greenhouse): 7-9 (7-10 days interval)~~
	Spray volumes	Potato: 200-500 L/ha ~~Tomato (greenhouse): 600-1200 L/ha~~
Assessment	Assessment types	Pest-incidence, pest-severity, general phytotoxicity/injury
	Assessment dates	After each application
Other relevant information	e.g. Soil type, pH (in case of soil active substance …)	Soil type Potato: clay sandy loam (1), clay loam (1), loamy fine sand (1), loam (1), sandy loam (2), silty clay (1), loamy clay (1) ~~Tomato: loam (1), clay (1), loamy sand (1), sandy loam (1), loamy clay sand (1)~~
	e.g. Natural / artificial inoculation…	Natural infection
	e.g. Field / Greenhouse...	Field (8) ~~Greenhouse (5)~~

Table 3.2-12a: Details on trial methodology (2023)

Guidelines	General guidelines	EPPO PP 1/135(4) 'Phytotoxicity assessment, PP 1/152(4) 'Design & analysis of efficacy evaluation trials', PP 1/181(4) 'Conduct and reporting of efficacy evaluation trials including good experimental practice', PP 1/225(2) 'Minimum effective dose'
	Specific guidelines	2023: PP 1/2(5)/ PP 1/2(4) 'Phytophthora infestans on potato'

Experimental design	Plot design	RCBD
	Plot size	Potato: 18-25 m²
	Number of replications	4
Crops	Trials per crop	Potato (5)
	Varieties per crop	Potato: Marabel, Lady Rosetta, Melody, Ricarda, Hermes
Application	Crop stage (BBCH) at application	Potato: BBCH 37 to BBCH 92
	Number of applications Intervals between applications	Potato: 6-11 (5-15 days interval)
	Spray volumes	Potato: 200-400 L/ha
Assessment	Assessment types	Pest-incidence, pest-severity, general phytotoxicity/injury
	Assessment dates	After each application
Other relevant information	e.g. Soil type, pH (in case of soil active substance …)	Soil type Potato: sandy clay (1); sandy loam (3), silty clay (1)
	e.g. Natural / artificial inoculation…	Natural infection
	e.g. Field / Greenhouse...	Field (5)

Efficacy trials application details, as well as efficacy trials location and crop details, are provided in the Biological Assessment dossier (KCP 6.0-01).

Introduction

Many cymoxanil straight formulations are authorised and currently commercialised in EU, as described in Table 3.2-2. For efficacy and resistance concerns, in common practice, cymoxanil-based products are always applied together or in sequence with other products delivering different active substances. However, in trials conducted for registration purposes, the product must be applied alone to prove that the effectiveness is related to that product and not to partners.

Therefore, a moderate efficacy is expected, as well as a reduced or very reduced efficacy of late applications, where the disease severity is high. On the other hand, the expected efficacy is similar to that of other comparable formulations (or any other cymoxanil straight) used as reference. The main aim of the present dossier is to demonstrate that IN002B1760 provide disease control comparable to similar cymoxanil-based products.

Similarly, despite the proposed number of applications for IN002B1760 is 6 for potato ~~and 5 for tomato and aubergine,~~ a slight higher number of applications was performed in efficacy trials, in order to cover, as much as possible, the disease period. In fact, in common practice, a higher number of applications are made during the growing season. In any case, assessments after each application or reduced number of applications are available in single trial reports and in Appendix 4.

In order to compare data of several trials that showed different disease level, as well as different disease appearance timings, results were grouped by range of pest severity. In fact, pest severity should be considered as the most important factor to evaluate the product's effectiveness. Therefore, efficacy results were analysed grouping them in ranges of ten to ten % of pest severity (*e.g.* 10-19.9%). In this way, it is possible to appreciate the efficacy of IN002B1760 related to the disease level.

Other ways to present data, *e.g.* efficacy after a fixed number of applications, could lead to unreliable analysis, also considering that cymoxanil is applied preventatively and the disease can therefore appear in different timing depending on the climatic conditions and many other factors.

Where pest incidence data were available ~~(tomato trials)~~, data are even so presented by pest severity ranges, to have a consistent analysis.

~~Thirteen~~ Eight valid efficacy trials were conducted in 2021 in EPPO Maritime and EPPO North-East zone, as part of the Regulatory Central zone~~, as well as in greenhouse (interzonal trials), to support the claimed GAP~~.

To substantiate the effectiveness of the tested product, this dossier was further enriched by 5 additional valid efficacy trials carried out in potato for *Phytophthora infestans* control at EPPO Maritime and EPPO North-East zones in 2023.

Results are presented hereafter separated by ~~crop and by~~ EPPO zone.

As the lower rates applied in the efficacy trials (0.165 kg/ha) resulted poorly effective and, in many cases, statistically lower than the higher rates, in all the summary tables presented below, the efficacy of IN002B1760 at 0.25 kg/ha and 0.33 kg/ha compared to reference standards is shown, indicating the number of trials where IN002B1760 at 0.25 kg/ha resulted statistically comparable, superior or inferior. A further column was added to limit the comparison only to cymoxanil-based reference standard (the number of cymoxanil references is indicated in brackets).

Only assessment with a sufficient disease pressure in the untreated plot were considered as valid (pest severity ▪ 5% or pest incidence ▪ 10%).

Potato

Ten field trials were conducted on potato in 2021 to support the use in Central zone. Trials were set up in EPPO Maritime zone (UK, Germany and Czech Republic) and in EPPO North-East zone (Poland). Unfortunately, two trials conducted in UK are considered as not valid because the disease infection spread very fast and the test product and the reference standard did not perform as expected. Efficacy results of these trials were excluded from the analysis.

Furthermore, five additional trials on potato were conducted in 2023. These trials were carried out at the EPPO Maritime Zone (Germany and Czech Republic) and the EPPO North-East Zone (Poland).

IN002B1760 was sprayed at 2.5 kg/ha and 3.3 kg/ha (with a water volume of 200-500 L/ha) with a series of application (8-10) at BBCH 14 to BBCH 91.

Meanwhile, in the potato trials carried out in 2023, tested product IN002B1760 was sprayed at 0.25 kg/ha and 0.33 kg/ha (with a water volume of 200-400 L/ha) with a series of application (6-11) at BBCH 37 to BBCH 92.

Results at different ranges of pest severity are presented in Table 3.2-15 to

Table 3.**2-13a: Efficacy of IN002B1760 at 0.25 and 0.33 kg/ha and reference product (cymoxanil) against *Phytophthora infestans* on potato, in EPPO Maritime zone in 2023 (Germany and Czech Republic) (43 DA-A)**

Pest severity %	No. of trials	Untreated (PESSEV%)			Efficacy Mean (min-max) IN002B1760 0.25 kg/ha			IN002B1760 0.33 kg/ha			Reference Label rate			Stat. Sign. Vs Cymoxanil <	=	>
		Mean	min	max	Mean	min	max	Mean	min	max	Mean	min	max			
< 10%	1	5,0	5,0	5,0	100,0	100,0	100,0	100,0	100,0	100,0	100,0	100,0	100,0		1	
10-19.9%	-	-	-	-	-	-	-	-	-	-	-	-	-			
20-29.9%	-	-	-	-	-	-	-	-	-	-	-	-	-			
30-39.9%	-	-	-	-	-	-	-	-	-	-	-	-	-			

40-49.9%	-	-	-	-	-	-	-	-	-	-	-	-	-			
50-59.9%	1	**52,5**	52,5	52,5	**59,0**	59,0	59,0	**62,5**	62,5	62,5	**52,1**	52,1	52,1		**1**	
60-69.9%	-	-	-	-	-	-	-	-	-	-	-	-	-			
70-79.9%	-	-	-	-	-	-	-	-	-	-	-	-	-			
80-89.9%	-	-	-	-	-	-	-	-	-	-	-	-	-			
90-99.9%	-	-	-	-	-	-	-	-	-	-	-	-	-			
100%	-	-	-	-	-	-	-	-	-	-	-	-	-			

Table 3.2-13b: Efficacy of IN002B1760 at 0.25 and 0.33 kg/ha and reference product (cymoxanil) against *Phytophthora infestans* on potato, in EPPO Maritime zone in 2021 and 2023 (Germany and Czech Republic)

Pest severity %	No. of trials	Untreated (PESSEV%)			Efficacy Mean (min-max) IN002B1760 0.25 kg/ha			IN002B1760 0.33 kg/ha			Reference Label rate			Stat. Sign. Vs Cymoxanil <	=	>
		Mean	min	max	Mean	min	max	Mean	min	max	Mean	min	max			
< 10%	3	**5,9**	4,1	8,5	**74,5**	46,7	100,0	**71,8**	30,0	100,0	**68,7**	27,5	100,0		**3**	
10-19.9%	3	**11,2**	10,0	12,3	**37,1**	0,0	64,6	**60,0**	54,2	71,7	**63,6**	61,7	65,8		**3**	
20-29.9%	1	**27,5**	27,5	27,5	**52,5**	52,5	52,5	**56,7**	56,7	56,7	**69,0**	69,0	69,0		**1**	
30-39.9%	2	**33,1**	31,3	35,0	**33,7**	21,9	45,4	**42,0**	31,3	52,7	**32,0**	31,3	32,7		**2**	
40-49.9%	1	**40,0**	40,0	40,0	**39,0**	39,0	39,0	**36,7**	36,7	36,7	**42,3**	42,3	42,3		**1**	
50-59.9%	2	**52,5**	52,5	52,5	**65,1**	59,0	71,1	**68,7**	62,5	74,8	**60,8**	52,1	69,6		**2**	
60-69.9%	-	-	-	-	-	-	-	-	-	-	-	-	-			
70-79.9%	2	**74,2**	71,3	77,0	**20,0**	0,0	40,1	**37,0**	20,9	53,0	**22,3**	3,9	40,7		**2**	
80-89.9%	2	**84,9**	83,5	86,3	**10,1**	10,1	10,2	**14,5**	8,4	20,6	**10,1**	10,1	10,2		**2**	
90-99.9%	1	**95,0**	95,0	95,0	**14,5**	14,5	14,5	**17,1**	17,1	17,1	**18,4**	18,4	18,4		**1**	
100%	3	**100,0**	100,0	100,0	**0,1**	0,0	0,3	**0,8**	0,0	2,3	**0,2**	0,0	0,5		**3**	

Table 3.2-16

Table 3.2-15: Efficacy of IN002B1760 at 0.25 and 0.33 kg/ha and reference product (cymoxanil) against *Phytophthora infestans* on potato, in EPPO Maritime zone in 2021

Pest severity %	No. of trials	Untreated (PESSEV%)	Efficacy Mean (min-max) IN002B1760 0.25 kg/ha	IN002B1760 0.33 kg/ha	Reference Label rate	Stat. Sign. *Vs* Cymoxanil <	=	>
< 10%	2	6.3 (4.1-8.5)	61.7 (46.7-76.7)	57.8 (30-85.5)	53 (27.5-78.6)		2	
10-19.9%	3	11.2 (10-12.3)	37.1 48.2 (0 33.33-64.6)	60 (54.2-71.7)	63.6 (61.7-65.8)		3	
20-29.9%	1	27.5	52.5	56.7	69		1	
30-39.9%	2	33.1 (31.3-35)	33.7 (21.9-45.4)	42 (31.3-52.7)	32 (31.3-32.7)		2	
40-49.9%	1	40	39	36.7	42.3		1	

Pest severity %	No. of trials	Untreated (PESSEV%)	Efficacy Mean (min-max)			Stat. Sign. *Vs* Cymoxanil		
			IN002B1760		Reference			
			0.25 kg/ha	0.33 kg/ha	Label rate	<	=	>
50-59.9%	1	52.5	71.1	74.8	69.6		1	
60-69.9%	-	-	-	-	-			
70-79.9%	2	74.2 (71.3-77)	~~20~~ 23.6 (~~0~~ 7.2-40.1)	37 (20.9-53)	22.3 (3.9-40.7)		2	
80-89.9%	2	84.9 (83.5-86.3)	10.1 (10.1-10.2)	14.5 (8.4-20.6)	10.1 (10.1-10.2)		2	
90-99.9%	1	95	14.5	17.1	18.4		1	
100%	3	100	0.1 (0-0.3)	0.8 (0-2.3)	0.2 (0-0.5)		3	

Table 3.2-13a: Efficacy of IN002B1760 at 0.25 and 0.33 kg/ha and reference product (cymoxanil) against *Phytophthora infestans* on potato, in EPPO Maritime zone in 2023 (Germany and Czech Republic) (43 DA-A)

Pest severity %	No. of trials	Untreated (PESSEV%)			Efficacy Mean (min-max)									Stat. Sign. Vs Cymoxanil		
					IN002B1760						Reference					
					0.25 kg/ha			0.33 kg/ha			Label rate			<	=	>
		Mean	min	max	Mean	min	max	Mean	min	max	Mean	min	max			
< 10%	1	**5,0**	5,0	5,0	**100,0**	100,0	100,0	**100,0**	100,0	100,0	**100,0**	100,0	100,0		**1**	
10-19.9%	-	-	-	-	-	-	-	-	-	-	-	-	-			
20-29.9%	-	-	-	-	-	-	-	-	-	-	-	-	-			
30-39.9%	-	-	-	-	-	-	-	-	-	-	-	-	-			
40-49.9%	-	-	-	-	-	-	-	-	-	-	-	-	-			
50-59.9%	1	**52,5**	52,5	52,5	**59,0**	59,0	59,0	**62,5**	62,5	62,5	**52,1**	52,1	52,1		**1**	
60-69.9%	-	-	-	-	-	-	-	-	-	-	-	-	-			
70-79.9%	-	-	-	-	-	-	-	-	-	-	-	-	-			
80-89.9%	-	-	-	-	-	-	-	-	-	-	-	-	-			
90-99.9%	-	-	-	-	-	-	-	-	-	-	-	-	-			
100%	-	-	-	-	-	-	-	-	-	-	-	-	-			

Table 3.2-13b: Efficacy of IN002B1760 at 0.25 and 0.33 kg/ha and reference product (cymoxanil) against *Phytophthora infestans* on potato, in EPPO Maritime zone in 2021 and 2023 (Germany and Czech Republic)

Pest severity %	No. of trials	Untreated (PESSEV%)			Efficacy Mean (min-max)									Stat. Sign. Vs Cymoxanil		
					IN002B1760						Reference					
					0.25 kg/ha			0.33 kg/ha			Label rate			<	=	>
		Mean	min	max	Mean	min	max	Mean	min	max	Mean	min	max			
< 10%	3	**5,9**	4,1	8,5	**74,5**	46,7	100,0	**71,8**	30,0	100,0	**68,7**	27,5	100,0		**3**	
10-	3	**11,2**	10,0	12,3	**37,1**	0,0	64,6	**60,0**	54,	71,7	**63,6**	61,	65,8		**3**	

19.9%										2			7			
20-29.9%	1	**27,5**	27,5	27,5	**52,5**	52,5	52,5	**56,7**	56,7	56,7	**69,0**	69,0	69,0		**1**	
30-39.9%	2	**33,1**	31,3	35,0	**33,7**	21,9	45,4	**42,0**	31,3	52,7	**32,0**	31,3	32,7		**2**	
40-49.9%	1	**40,0**	40,0	40,0	**39,0**	39,0	39,0	**36,7**	36,7	36,7	**42,3**	42,3	42,3		**1**	
50-59.9%	2	**52,5**	52,5	52,5	**65,1**	59,0	71,1	**68,7**	62,5	74,8	**60,8**	52,1	69,6		**2**	
60-69.9%	-	-	-	-	-	-	-	-	-	-	-	-	-			
70-79.9%	2	**74,2**	71,3	77,0	**20,0**	0,0	40,1	**37,0**	20,9	53,0	**22,3**	3,9	40,7		**2**	
80-89.9%	2	**84,9**	83,5	86,3	**10,1**	10,1	10,2	**14,5**	8,4	20,6	**10,1**	10,1	10,2		**2**	
90-99.9%	1	**95,0**	95,0	95,0	**14,5**	14,5	14,5	**17,1**	17,1	17,1	**18,4**	18,4	18,4		**1**	
100%	3	**100,0**	100,0	100,0	**0,1**	0,0	0,3	**0,8**	0,0	2,3	**0,2**	0,0	0,5		**3**	

Table 3.2-16: **Efficacy of IN002B1760 at 0.25 and 0.33 kg/ha and reference product (copper compounds) against *Phytophthora infestans* on potato, in EPPO North-East zone in 2021**

Pest severity %	No. of trials	Untreated (PESSEV%)	Efficacy Mean (min-max)			Stat. Sign. *Vs* fluazinam		
			IN002B1760		Reference			
			0.25 kg/ha	0.33 kg/ha	Label rate	<	=	>
< 10%	1	5.0	100	85.0	100		1	
10-19.9%	3	15.4 (15-16.3)	64.6 (43.3-79.2)	61.8 (54.2-66.7)	91.9 (86.7-100)	3		
20-29.9%	3	23.3 (20-25)	47.3 (28.3-70.4)	59.2 (49.2-71.8)	80.5 (69.6-86.7)	1	2	
30-39.9%	-	-	-	-	-			
40-49.9%	2	44.4 (42.5-46.3)	52.6 (38.1-67.2)	57.8 (50-65.5)	77.7 (67.5-88)	2		
50-59.9%	-	-	-	-	-			
60-69.9%	3	62.1 (60-66.3)	39.9 (20.8-62.3)	42.5 (25-58.2)	81.4 (68.3-88.6)	3		
70-79.9%	1	76.3	18	22.7	85.3	1		
80-89.9%	2	80.6 (80-81.3)	28.4 (25-31.7)	23.7 (12.5-34.9)	60.5 (55.5-65.6)	2		
90-99.9%	2	93.2 (91.3-95)	40.4 (26-54.8)	39 (24.8-53.2)	68.8 (47.3-90.3)	2		
100%	2	100	0 (0-0)	0 (0-0)	25 (12.5-37.5)	2		

Table 3.2-14a: **Efficacy of IN002B1760 at 0.25 and 0.33 kg/ha and reference product against *Phytophthora infestans* on potato, in EPPO North-East zone in 2023 (Poland) (37-70 DA-A)**

Pest severity %	No. of trials	Untreated (PESSEV%)			Efficacy Mean (min-max)									Stat. Sign. Vs Cymoxanil		
					IN002B1760						Reference					
					0.25 kg/ha			0.33 kg/ha			Label rate			<	=	>
		Mean	min	max	Mean	min	max	Mean	min	max	Mean	min	max			
< 10%	2	**7,3**	7,0	7,5	**96,4**	94,4	98,4	**98,3**	98,2	98,4	**96,3**	94,1	98,4		**2**	
10-19.9%	2	**13,3**	12,8	13,8	**95,4**	92,9	97,8	**97,9**	97,7	98,1	**97,9**	97,5	98,2		**2**	

20-29.9%	1	**26,5**	**26,5**	26,5	**66,1**	66,1	66,1	**75,4**	75,4	75,4	**70,9**	70,9	70,9		**1**	
30-39.9%	1	**39,3**	39,3	39,3	**75,1**	75,1	75,1	**74,8**	74,8	74,8	**70,9**	70,9	70,9		**1**	
40-49.9%	-	-	-	-	-	-	-	-	-	-	-	-	-			
50-59.9%	-	-	-	-	-	-	-	-	-	-	-	-	-			
60-69.9%	-	-	-	-	-	-	-	-	-	-	-	-	-			
70-79.9%	-	-	-	-	-	-	-	-	-	-	-	-	-			
80-89.9%	-	-	-	-	-	-	-	-	-	-	-	-	-			
90-99.9%	-	-	-	-	-	-	-	-	-	-	-	-	-			
100%	-	-	-	-	-	-	-	-	-	-	-	-	-			

Table 3.2-14b: Efficacy of IN002B1760 at 0.25 and 0.33 kg/ha and reference product against *Phytophthora infestans* on potato, in EPPO North-East zone in 2021 and 2023 (Poland)

Pest severity %	No. of trials	Untreated (PESSEV%)			Efficacy Mean (min-max) IN002B1760 0.25 kg/ha			IN002B1760 0.33 kg/ha			Reference Label rate			Stat. Sign. Vs Cymoxanil <	=	>
		Mean	min	max	Mean	min	max	Mean	min	max	Mean	min	max			
< 10%	2	**7,3**	7,0	7,5	**96,4**	94,4	98,4	**98,3**	98,2	98,4	**96,3**	94,1	98,4		**2**	
10-19.9%	5	**14,6**	12,8	16,3	**76,9**	43,3	97,8	**76,2**	54,2	98,1	**94,3**	86,7	100,0	**2**	**3**	
20-29.9%	4	**24,1**	20,0	26,5	**52,0**	28,3	70,4	**63,3**	49,2	75,4	**77,8**	69,6	86,7	**2**	**2**	
30-39.9%	1	**39,3**	39,3	39,3	**75,1**	75,1	75,1	**74,8**	74,8	74,8	**70,9**	70,9	70,9		**1**	
40-49.9%	2	**39,3**	42,5	46,3	**52,6**	38,1	67,2	**57,8**	50,0	65,5	**77,7**	67,5	88,0	**2**		
50-59.9%	-	-	-	-	-	-	-	-	-	-	-	-	-			
60-69.9%	3	**62,1**	60,0	66,3	**39,9**	20,8	62,3	**42,5**	25,0	58,2	**81,4**	68,3	88,6	**3**		
70-79.9%	1	**76,3**	76,3	76,3	**18,0**	18,0	18,0	**22,7**	22,7	53,0	**85,3**	85,3	85,3	**1**		
80-89.9%	2	**80,6**	80,0	81,3	**28,4**	25,0	31,7	**23,7**	12,5	34,9	**60,5**	55,5	65,6	**2**		
90-99.9%	2	**93,2**	91,3	95,0	**40,4**	26,0	54,8	**39,0**	24,8	53,2	**68,8**	47,3	90,3	**2**		
100%	2	**100,0**	100,0	100,0	**0,0**	0,0	0,0	**0,0**	0,0	0,0	**25,0**	12,5	37,5	**2**		

IN002B1760 showed a moderate to good efficacy in presence of low-moderate disease pressure, both in Maritime and in South-East climate. As stated in the introduction above, this is expected for cymoxanil-based products. In present of high disease level, or in case of quick disease developing, the efficacy of cymoxanil became insufficient. For this reason, together with resistance management concerns, cymoxanil products are always applied in combination or in alternation to products containing other active ingredients.

Furthermore, IN002B1760 resulted always at least as effective as the cymoxanil reference product (Maritime zone trials). The lower efficacy compared to fluazinam reference products (South-East zone trials) was expected, too. This is also reported in the corresponding single trials reports.

Regarding the trials carried out in the Maritime and North-East EPPO zones in 2023, the efficacy of

IN002B1760 was mostly at least comparable to cymoxanil used as a reference product (no statistically significant differences were observed).

The showed efficacy should be therefore considered as sufficient. According to EPPO PP1/214(4) '*Principles of acceptable efficacy*', the primary criterion of acceptable efficacy is that the product should show results that are significantly superior to those recorded in the untreated control, and this condition was always met in the presented trials. The secondary criterion is that the performance of the test product compares with that of the reference product, and also this condition was fully met in case of similar cymoxanil formulations.

An application range of 0.25-0.33 kg/ha is suggested in order to guarantee a sufficient efficacy with different disease pressure. The maximum rate of 0.33 kg/ha is compliant to the EU GAP of the a.s. cymoxanil renewal.

It is considered that the submitted number of efficacy trials (4 in Maritime zone + 4 in South-East zone) can be considered sufficient to support the claimed use on potato, in accordance with EPPO PP1/226(3) '*Number of efficacy trials*'. In fact, a reduced number of efficacy trials could be accepted where there is a large amount of supporting evidence from use of the product, or of similar products with the same active substance, on closely related pests or against the same pests on different crops. Similarly, according to the same EPPO guideline, trials conducted in only one season can be considered as adequate. Cymoxanil should be considered as a very well-known active ingredient is well-known and sufficient experience has been gained in decades of uses in CEU Countries. Despite the fact that the number of studies conducted in 2021 were sufficient accordance with EPPO requirements, additional five trials were carried out in 2023 to confirm the efficacy of the tested product.

As further supporting evidences, results of 4 efficacy trials conducted on potato in Mediterranean EPPO zone are reported below. The applicant is aware that these trials cannot directly support the use in Central zone, however, they can contribute to demonstrate that IN002B1760 behaviour is the same of similar cymoxanil based products authorized, independently of the climatic conditions.

Moreover, trials conducted on tomato in greenhouse (interzonal use) and in the field in Mediterranean EPPO zone, also demonstrate the efficacy of IN002B1760 against the same pest (*Phytophthora infestans*) and should be taken into account, as discussed in the next paragraph.

Table 3.2-17: Efficacy of IN002B1760 at 0.25 and 0.33 kg/ha and reference product against *Phytophthora infestans* on potato, in EPPO Mediterranean zone

Pest severity %	No. of trials	Untreated (PESSEV%)	Efficacy Mean (min-max)			Stat. Sign. *Vs* Cymoxanil		
			IN002B1760		Reference			
			0.25 kg/ha	0.33 kg/ha	Label rate	<	=	>
< 10%	2	*8.1 (7.5-8.8)*	72.9 (70.8-75)	89.6 (87.5-91.7)	80.2 (77.1-83.3)		1	
10-19.9%	2	*15 (11.9-18.1)*	79.1 (78.8-79.5)	78.2 (73.8-82.6)	62.1 (55.4-68.8)		1	1
20-29.9%	3	*23.5 (21.3-26.3)*	54 (28.3-70.3)	57.1 (25.8-75.6)	53.9 (45.6-65.2)		2	1
30-39.9%	3	*34 (31.9-37.5)*	43.9 (26-64.4)	59.3 (51.3-74.6)	34.9 (20.6-63.2)		3	
40-49.9%	1	*44.4*	71.7	79	53.7			1
50-59.9%	1	*58.1*	66.5	74.1	45.1			1
60-69.9%	1	*67.5*	18.8	11.5	31.3		1	
70-79.9%	1	*70*	21.5	13.2	29.5		1	
80-89.9%	1	*87.5*	17.3	25.7	11		1	
90-100%	1	*95*	11.9	21.1	7.8		1	

Tomato (greenhouse use)

Six Five trials were conducted on greenhouse tomato in 2021. Trials were set up in greenhouses in Poland (2), Italy (2) and France (1) and Greece (1) to support the interzonal use. One further trial is still ongoing. The present document will be update as soon results will be available.

IN002B1760 was sprayed at 2.5 kg/ha and 3.3 kg/ha (with a water volume of 600-1200 L/ha) with a series of application (7-10) at BBCH 15 to BBC 81.

Results at different ranges of pest severity are presented in Table 3.2-18.

Table 3.2-18: Efficacy on pest severity (PESSEV) of IN002B1760 at 0.25 and 0.33 kg/ha and reference product against *Phytophthora infestans* on greenhouse tomato (interzonal use)

Pest severity %	No. of trials	Untreated (PESSEV%)	Efficacy Mean (min-max)				Stat. Sign. Vs Cymoxanil		
			IN002B1760		Reference Product				
			0.25 kg/ha	0.33 kg/ha	All References	Cymoxanil ref. (No.)	<	=	>
< 10%	2	7.9 (6.3-9.5)	97.2 (94.4-100)	99.4 (98.9-100)	98.3 (96.6-100)	98.3 (96.6-100) (2)		2	
10-19.9%	1	15	71.3	82.5	84.6	-			
20-29.9%	3	21.7 (20-23.8)	73.8 (46.3-95.6)	81.9 (60.8-99)	80.5 (54.6-97.5)	97.5 (1)		1	
30-39.9%	1	43.2	59.1	82.9	96.4	-			
40-49.9%	-	-	-	-	-	-			
50-59.9%	-	-	-	-	-	-			
60-69.9%	-	-	-	-	-	-			
70-79.9%	-	-	-	-	-	-			
80-89.9%	1	87.1	52.7	75.2	93.6	-			
90-99.9%	1	99.4	11	19.4	56.5	-			
100%	-	-	-	-	-	-			

Pest severity %	No. of trials	Untreated			Efficacy													Stat. Sign. Vs Cymoxanil		
		(PESSEV%)			Mean (min-max)															
					IN002B1760						Reference									
					0.25 kg/ha			0.33 kg/ha			All References			Cymoxanil ref. (No.)			<	=	>
		Mean	min	max	Mean	min	max	Mean	min	max	Mean	min	max	Mean	min	max			
< 10%	2	7.9	6.3	9.5	97.2	94.4	100	99.4	98.9	100	98.3	96.6	100	98.3 (2)	96.6	100		2	
10-19.9%	2	13.4	11.8	15.0	84.0	71.3	96.8	89.0	82.5	95.5	84.6	84.6	84.6	99.03 (1)	99.0	99.0		2	
20-29.9%	2	21.7	20.0	23.8	73.8	46.3	95.6	81.9	60.8	99.0	80.5	54.6	97.5	97.5 (1)	97.5	97.5		2	
30-39.9%	1	26.4	26.4	26.4	97.2	97.2	97.2	97.2	97.2	97.2	98.9	98.9	98.9	98.9 (1)	98.9	98.9		1	
40-49.9%	1	43.2	43.2	43.2	59.1	59.1	59.1	82.9	82.9	82.9	96.4	96.4	96.4					1	
50-59.9%																			

60-69.9 %																			
70-79.9 %																			
80-89.9 %	1	87,1	87,1	87,1	52,7	52,7	52,7	75,2	75,2	75,2	93,6	93,6	93,6				1		
90-99.9 %	1	99,4	99,4	99,4	11,0	11,0	11,0	19,4	19,4	19,4	56,5	56,5	56,5				1		
100%																			

IN002B1760 showed very good efficacy in presence of low-moderate disease pressure in greenhouse conditions. IN002B1760 resulted always as effective as the cymoxanil reference product.

An application range of 0.25-0.33 kg/ha is suggested in order to guarantee a sufficient efficacy with different disease pressure. The maximum rate of 0.33 kg/ha is compliant to the EU GAP of the a.s. cymoxanil renewal.

It is considered that the submitted number of efficacy trials (6 5 trials in greenhouse + 1 further ongoing trial) can be considered sufficient to support the claimed use on greenhouse tomato, in accordance with EPPO PP1/226(3) '*Number of efficacy trials*', also considering that results of field trials (6 trials) conducted in Mediterranean EPPO zone. Furthermore, there is a large amount of supporting evidence from use of the same product against the same target (*Phytophthora infestans*) on potato, as well as from the use of similar cymoxanil based products. According to the same EPPO guideline, trials conducted in one season are adequate to a greenhouse use claim.

Results of 6 field trials conducted in Mediterranean EPPO zone are hereunder presented as additional supportive trials as it is considered that climatic conditions in the field in Southern zone Countries (*e.g.* Italy, Spain, Portugal and Greece) are very similar to indoor conditions of greenhouses (climatic data recorded inside greenhouse in Poland are availbale in each trial report). Moreover, looking at the disease level encountered in the trials, it can be observed that field trials in Mediterranean EPPO zone can be considered as worst case, thus representing more challenging situations to test the product's effectiveness.

Trials were set up in EPPO Mediterranean zone in Italy (2), Spain (2), Portugal (1) and Greece (1). IN002B1760 was sprayed at 2.5 kg/ha and 3.3 kg/ha (with a water volume of 500-1000 L/ha) with a series of application (7-8) at BBCH 12 to BBC 83.

Results at different timings are presented in Table 3.2-19 and

Table 3.2-20.

Table 3.2-19: Efficacy on pest incidence (PESINC) of IN002B1760 at 0.25 and 0.33 kg/ha and reference product against *Phytophthora infestans* on field tomato, in EPPO Mediterranean zone

Pest severity %	No. of trials	Untreated (PESSEV%)	Efficacy Mean (min-max)				Stat. Sign. *Vs* Cymoxanil		
			IN002B1760		Reference Product				
			0.25 kg/ha	0.33 kg/ha	All References	Cymoxanil ref. (No.)	<	=	>
< 10%	3	20.3 (14-29.5)	30.4 (17.4-45.9)	31.7 (17-49.6)	31 (11.8-60.2)	31 (11.8-60.2)		3	
10-19.9%	4	25.3 (20-33.5)	42 (30.9-67.8)	36.8 (25.9-61.9)	38.5 (25.4-56.6)	38.5 (25.4-56.6) (4)		4	
20-29.9%	2	45.5 (44.7-46.3)	43.4 (35.6-51.3)	42.1 (26.9-57.3)	49.5 (35.5-63.5)	49.5 (35.5-63.5) (2)		2	
30-39.9%	1	49.8	56.9	62.4	42.5	42.5 (1)		1	

Pest severity %	No. of trials	Untreated (PESSEV%)	Efficacy Mean (min-max)				Stat. Sign. *Vs* Cy-moxanil		
			IN002B1760		Reference Product				
			0.25 kg/ha	0.33 kg/ha	All References	Cymoxanil ref. (No.)	<	=	>
40-49.9%	-	-	-	-	-	-			
50-59.9%	-	-	-	-	-	-			
60-69.9%	-	-	-	-	-	-			
70-79.9%	-	-	-	-	-	-			
80-89.9%	-	-	-	-	-	-			
90-99.9%	-	-	-	-	-	-			
100%	-	-	-	-	-	-			

Table 3.2.20: Efficacy on pest severity (PESSEV) of IN002B1760 at 0.25 and 0.33 kg/ha and reference product against *Phytophthora infestans* on field tomato, in EPPO Mediterranean zone

Pest severity %	No. of trials	Untreated (PESSEV%)	Efficacy Mean (min-max)				Stat. Sign. *Vs* Cy-moxanil		
			IN002B1760		Reference Product				
			0.25 kg/ha	0.33 kg/ha	All References	Cymoxanil ref. (No.)	<	=	>
< 10%	3	6.1 (3.2-7.9)	67.4 (51.9-83.3)	68.8 (47.3-83.7)	65.9 (43-84.4)	65.9 (43-84.4) (4)		3	
10-19.9%	5	15 (11.8-17.1)	56.5 (9-90.3)	56 (9-87.7)	54.4 (9-85.5)	54.4 (9-85.5) (5)		5	
20-29.9%	3	25.8 (24.9-27.5)	66.4 (54.3-78.6)	72.9 (59.3-85.9)	70.1 (58.4-81.1)	70.1 (58.4-81.1) (3)		3	
30-39.9%	1	32.9	71.9	79.1	71.4	71.4 (1)		1	
40-49.9%	1	42.9	53.4	52.6	64.6	-			
50-59.9%	-	-	-	-	-	-			
60-69.9%	-	-	-	-	-	-			
70-79.9%	1	77	37.1	46.5	57.4	-			
80-89.9%	-	-	-	-	-	-			
90-99.9%	1	90.4	41.2	47.5	59.6	-			
100%	-	-	-	-	-	-			

IN002B1760 showed a good efficacy in presence of low-moderate disease pressure in Mediterranean climate. This behaviour is expected for cymoxanil straight products.

IN002B1760 resulted always as effective as the cymoxanil reference product.

Aubergine

According to EPPO extrapolation table 14/19575 '*Disease on fruiting vegetables of Solanaceae*', data obtained on the indicator crop tomato on late blight caused by *Phytophthora infestans* can be extrapolated to aubergine.

Summary and conclusion on the efficacy of IN002B1760

Based on the results of a total of 13 8 valid trials carried out in 2021 to support the claimed GAP of the product IN002B1760, the following can be concluded for the intended uses:

- IN002B1760 provides a sufficient level of control of the target diseases in a wide range of conditions and pest severity;
- The efficacy obtained with IN002B1760 is fully comparable to that of the other cymoxanil products used as reference standard in the submitted trials;
- The number of submitted trials can be considered as sufficient considering that several similar cymoxanil products have been registered and commercialized in many EU Countries, with similar application rates.

Futuremore, an additional five trials conducted on potato in 2023 to confirm the susceptible effectiveness of the tested product IN002B1760 and provides sufficient control of target diseases and pest severity. In these trials, the test product showed comparable efficacy to standard products.

Therefore, summarising the data from trials carried out in 2021 and 2023, it can be concluded that the test product IN002B1760 effectively (comparably or better to the reference products) controlled the Phytophthora infestans on potato.

Consequently, the claim of the use of IN002B1760 on potato at the application rate of 0.25-0.33 kg/ha~~, on glasshouse tomato/aubergine at the application rate of 0.25-0.33 kg/ha,~~ is justified.

Comments of zRMS:

A total of ~~8~~ 13 field efficacy trials have been submitted in the Maritime and North-East EPPO climatic zone to control of *Phytophthora infestans* on potato.
In total of 4 field trials in **the Maritime EPPO zone** (Germany and Czech Republic in 2021), IN002B1760 presented low effectiveness. The mean efficacy at least 60% was observed only ~~by~~ at low disease pressure. The trial results show that the test product is insufficient ~~by~~ at high pathogen severity. No significant differences between IN002B1760 and the reference product containing also cymoxanil have been noted. ~~In opinion of zRMS, it should be considered whether another product containing cymoxanil with limited effectiveness is needed in the MAR zone countries. Due to limited number of trials, the cMSs are kindly asked to extrapolate trial results from the NE zone and consider this use on national level.~~
The applicant has submitted two additional efficacy trials in the MAR zone (conducted in Germany and Czech Republic in 2023). IN002B1760 presented a high level of effectiveness in the first trial, however at low pest pressure (5%). Limited control was observed in the second trial when infestation increases. The test product achieved the effectiveness of 59% (0,25 l/ha) and 62,5% (0,33 l/ha) at high disease pressure (52,5%). Taking into account a total of 6 efficacy trials, it can be concluded that IN002B1760 at 0,25-0,33 kg/ha is moderately effective for control of PHYTIN at high disease severity in potato in the MAR zone. However, good control was achieved for pest severity (<10%) in the 2023 MAR trials.
4 efficacy trials were carried out in 2021 in Poland belonging to **the North-East EPPO zone**. Medium level of control is visible for IN002B1760 at dose rate of 0,33 kg/ha in some trials. However, the test product is effective only in case of lower disease pressure. Significant differences between IN002B1760 and the reference product containing copper compounds were observed. The reference product achieved superior control, either for low and higher pathogen severity. Due to limited number of trials in the NE zone, the zRMS decided to extrapolate trial results from the neighboring countries in the MAR zone. Taking into account all results, it can be concluded that IN002B1760 at 0,33 kg/ha is effective on medium level. In opinion of zRMS, the recommendation to use this product also as a preventive tool is justified.
Also 3 additional trials have been submitted in the NE zone (conducted in Poland in 2023). IN002B1760 at 0,25-0,33 kg/ha achieved a high effectiveness at lower disease pressure in 2 trials. However moderate control have been observed at higher pest pressure (>20%) in one trial. Comparability of results between dose rates of 0,25 kg/ha and 0,33 kg/ha is visible in the additional trials. The reference product presented similar effectiveness compared to the test product. Based on the additional trials either from the NE zone and the MAR zone, zRMS decided to consider both claimed dose rates of 0,25 and 0,33 kg/ha. Taking into account all submitted dataset, it can be concluded that IN002B1760 at 0,25-0,33 kg/ha is effective for control of PHYTIN in potato in the NE zone. However, it should be noted in the product label that moderately effective is presented at higher PESSEV.
No efficacy trials in the South-East EPPO zone were available. The cMS Slovenia is kindly asked to extrapolate reults from other zones and consider this use on national level.

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

An analysis of the possible development of resistance or cross-resistance was made according to EPPO guideline PP1/213.

3.3.1 Mode of action

Cymoxanil acts as a foliar fungicide with protective and curative action. It has contact and local systemic activity, and also inhibits sporulation. It is classified by the Fungicide Resistance Action Committee (FRAC) in 'unknown' mode of action with FRAC code 27 and it belongs to low to medium risk group, resistance management is required.

3.3.2 Evidence of resistance

A list of all current recorded cases of plant pathogens that have shown some form of resistance to code 27 fungicides world-wide is given in Table 3.3-1 (List of first confirmed cases of plant pathogenic organisms resistant to disease control agents, Revised May 2020).

Table 3.3-1: Plant pathogens resistant to chemical group of Cyanoacetamide-oxime (code 27)

No	FRAC Group code	Common name	Scientific name	Crop	Reference
1	27	Downy mildew	*Plasmopara viticola*	Grapevine	Gullino et al. 1997 (field)

Only one case of resistance is reported so far, related to *Plasmopara viticola* on grapevine.

The plant pathogen *Plasmopara viticola* on grapevine is classified as showing a high risk of development of resistance to fungicides. A list of all current recorded cases of resistance of *Plasmopara viticola* on grapevine to fungicides world-wide is given in Table 3.3-2 (List of first confirmed cases of plant pathogenic organisms resistant to disease control agents, Revised May 2020).

Table 3.3-2: Cases of resistance of PLASVI on grapevine to fungicides

No	MOA Code (Target Site)	FRAC Group code	Group name	Reference
1	A1 (RNA polymerase I)	4	PA-fungicides (PhenylAmides)	Staub & Sozzi 1981, Bosshard & Schuepp 1983 (field), Leroux & Clerjeau 1985 (field)
2	C3 (Complex III: cytochrome bc1 (ubiquinol oxidase) at Qo site)	11	QoI-fungicides (Quinone outside Inhibitors)	Heaney *et al*. 2000 (field), Gullino *et al*. 2004 (field), Sierotzki *et al*. 2005 (review)
3	H5 (Cellulose synthase)	40	CAA-fungicides (Carboxylic Acid Amides)	Gisi *et al*. 2007 (inheritance of resistance), Blum *et al*. 2010 (resistance mechanism)
4	U (unknown)	33	Phosphonates	Khilare *et al*. 2003 (field)

3.3.3 Mechanism of resistance

Fungicide resistance mechanism include: alteration of the biochemical target site so that it is no longer sensitive; increased production of the target protein; developing an alternative metabolic pathway that bypasses the target site; metabolic breakdown of the fungicide; exclusion or expulsion of the fungicide through ATP-ase dependent transporter proteins.

In general, systemic fungicides have been associated with resistance problems to a much greater extent than have non-systemic ('protectant') fungicides. However, there are some exceptions. Cases of resistance to systemic fungicides can generally be explained through other properties which accompany their ability to be translocated in plants. These are more persistent protective action, eradicate action, and specific biochemical mechanisms of action. However, these associations between resistance and site-specificity and between a particular mechanism of action and a particular risk of resistance are not absolute.

The mechanism of resistance of cymoxanil is not known.

3.3.4 Cross-resistance

In general, the occurrence of cross-resistance of pathogen strains to a range of different fungicides correlates with the existence of a common mode of action which is shared by these particular fungicides.

Cymoxanil is classified with FRAC code 27 and acts with "unknown" mode of action. Therefore, risk of cross resistance is deemed to be low to medium. Straight cymoxanil product are usually used in combination with other fungicides. Exposure of pathogens to two fungicides that exhibit negative cross-resistance should greatly reduce any resistance risk associated with either component as a shift to resistance against one automatically confers sensitivity against the other.

3.3.5 Sensitivity data

Baseline sensitivity data of the pest species are not available. Considering that the active substance cymoxanil included in IN002B1760 is already widely approved and used in Europe, assessing the current level of sensitivity to this active ingredient is based primarily on information derived from monitoring its effectiveness in the field.

3.3.6 Use pattern

IN002B1760 is intended for use as fungicide for the control of *Phytophthora infestans* on potato~~, tomato and aubergine~~. The maximum number of applications is ~~five~~ six for ~~all crops, except for~~ potato~~, where six applications are claimed~~. This is in line with FRAC recommendations for cymoxanil.

3.3.7 Analysis of the risk of resistance

Risk inherent to the fungicide

Despite widespread use of Cyanoacetamide-oxime fungicides for many years, there has been one recorded cases of resistance of *Plasmopara viticola* in grapevine against these sites of action. Aside from that, control of IN002B1760 of the target pathogen in conducted efficacy trials showed overall moderate to very good efficacy.

Risk inherent to the pathogen

According to FRAC pathogen risk list (September 2019), *Phytophthora infestans* is classified as showing a medium risk of development of resistance to fungicides.

Risk inherent to the agronomic practices

The label recommendation is for multiple applications with a maximum of ~~5 treatments per season on tomato and aubergine and~~ 6 treatments per season on potato, with a maximum application rate of 0.33 kg/ha, according to the EU GAP.

Cymoxanil-based products are applied preventively, reducing the risk inherent to agronomic practices. Therefore, the risk inherent to the agronomic practices could be considered as medium.

Combined risk

The combined resistance risk based on inherent fungicide risk, inherent pathogen risk, and agronomic risk, is calculated in 1-4 for *P. infestans*.

3.3.8 Acceptability of the resistance risk

IN002B1760 is intended for use as fungicide for the control of *Phytophthora infestans* on potato (max. 6 applications per year)~~, tomato and aubergine (max. 5 applications per year)~~.

The risk arising from the use of IN002B1760 is considered low to medium.

Taking all relevant factors into consideration, the overall risk of resistance for IN002B1760 when applied according to label recommendations and following "Good agricultural practise", is considered to be acceptable.

3.3.9 Resistance Management for IN002B1760

The risk management strategy is based on current measures advocated by the FRAC. The integrated use of combinations of different strategies is feasible, beneficial, and often implemented:

- Use in mixture with another fungicide active on the target disease;
- Apply preventatively;
- The number of applications of cymoxanil-containing products should be restricted:
    - Potato ~~and tomato~~: 6 applications per year;
- Always follow product specific recommendations for resistance management.

3.3.10 Monitoring and reporting changes in performance

Any confirmed occurrence of resistance or change of performance should be reported to the National Competent Authorities.

Comments of zRMS:

IN002B1760 contains one active substance cymoxanil belonging to the chemical group cyanoacetamideoxime. According to FRAC cymoxanil was classified to the FRAC code 27 and has low to medium resistance risk. *Phytophthora infestans* was described as plant pathogen accepted as showing a medium risk of development of resistance to fungicides (Pathogen Risk List, FRAC, September 2019). Due to that resistance management is required. In order to prevent resistance development in the target pathogen, it is recommended to:
- included in the potato late blight control program, products containing active substances of different MoA
- use the product in tank-mix with products containing actives with different MoA, intended to combat the same pathogens and at doses ensuring full protection against fungal diseases
- use cymoxanil-containing fungicides to maximum of half to the total number of applocations during the whole growth season.

3.4 Adverse effects on treated crops (KCP 6.4)

All the trials carried out and presented in the efficacy evaluation chapter have been monitored for phytotoxicity of IN002B1760.

Observations for phytotoxic effects related to the submitted efficacy trials are reported below.

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

The crop safety of IN002B1760 was assessed in all ~~13~~ 8 valid efficacy trials (and in 2 trials not valid for efficacy), where IN002B1760 was applied up to 0.33 kg/ha on potato with a maximum of 10 applications ~~and up to 0.33 kg/ha on tomato with a maximum of 9 applications per season~~. Crop safety of IN002B1760 was also assessed in additional 5 valid efficacy trials conducted in 2023.

The applied water spray volume was 200-500 L/ha in potato trials ~~and 600-1200 L/ha in tomato trials~~.

IN002B1760 was tested on the following varieties:

- Potato (2021): Sagitta, Marabella, Melody, Bila, Tajfun, Jelly, Denar, Solara
- Potato (2023): Marabel, Lady Rosetta, Ricarda, Hermes
- ~~Tomato: ug11239, Gigawak, Pink Wave F1 (CRX78254), Luciplus, Cobra.~~

For details on efficacy trial methodology and distribution, please refer to Table 3.2-14 presented above.

The following tables provide a summary of the phytotoxicity effects observed during the trials conducted in 2021 on the commercially available varieties listed above.

Table 3.4-1: Phytotoxicity of SIP 31664 on potato in 2021:

		Efficacy trials (8+2 trials)			
		IN002B1760			Ref. Standard
		0.165 kg/ha	0.25 kg/ha	0.33 kg/ha	Label rate
Maximum of phytotoxicity recorded during the trials	0 % to 5 %	10	10	10	10
	>5 % to 10 %	-	-	-	-
	>10 % to 15 %	-	-	-	-
	>15 %	-	-	-	-
Level of symptoms at the last assessments	0 % to 5 %	10	10	10	10
	>5 % to 10 %	-	-	-	-
	>10 % to 15 %	-	-	-	-
	>15 %	-	-	-	-

Table 3.4-1a: Phytotoxicity of IN002B1760 on potato in 2021 and 2023:

		Efficacy trials (13+2 trials)			
		IN002B1760			Ref. Standard
		0.165 kg/ha	0.25 kg/ha	0.33 kg/ha	Label rate
Maximum of phytotoxicity recorded during the trials	0 % to 5 %	15	15	15	15
	>5 % to 10 %	-	-	-	-
	>10 % to 15 %	-	-	-	-
	>15 %	-	-	-	-
Level of symptoms at the last assessments	0 % to 5 %	15	15	15	15
	>5 % to 10 %	-	-	-	-
	>10 % to 15 %	-	-	-	-
	>15 %	-	-	-	-

No phytotoxicity symptoms were observed in any of the efficacy trial conducted on potato.

IN002B1760 can therefore be considered as fully selective on potato at application rates up to 0.33 kg/ha.

~~Table 3.4.2: Phytotoxicity of SIP 31664 on tomato:~~

		~~Efficacy trials (5 trials)~~			
		~~IN002B1760~~			~~Ref. Standard~~
		~~0.165 kg/ha~~	~~0.25 kg/ha~~	~~0.33 kg/ha~~	~~Label rate~~
~~Maximum of phytotoxicity recorded during the trials~~	~~0 % to 5 %~~	~~5~~	~~5~~	~~5~~	~~5~~
	~~>5 % to 10 %~~	~~-~~	~~-~~	~~-~~	~~-~~
	~~>10 % to 15 %~~	~~-~~	~~-~~	~~-~~	~~-~~
	~~>15 %~~	~~-~~	~~-~~	~~-~~	~~-~~
~~Level of symptoms at the last assessments~~	~~0 % to 5 %~~	~~5~~	~~5~~	~~5~~	~~5~~
	~~>5 % to 10 %~~	~~-~~	~~-~~	~~-~~	~~-~~
	~~>10 % to 15 %~~	~~-~~	~~-~~	~~-~~	~~-~~
	~~>15 %~~	~~-~~	~~-~~	~~-~~	~~-~~

~~No phytotoxicity symptoms were observed in any of the efficacy trial conducted on tomato.~~

~~IN002B1760 can therefore be considered as fully selective on tomato at application rates up to 0.33 kg/ha.~~

Phytotoxicity summary and conclusions

A total of ~~15~~ 10 efficacy trials were carried out on potato ~~(10) and tomato (5)~~ on commercially grown varieties in order to demonstrate the crop safety of the formulation IN002B1760 applied according to the proposed GAP.

Additional 5 efficacy trials were carried out in potato in 2023 on commercial grown varieties in order to demostrate the crop safety of the formulation IN002B1760.

No phytotoxicity symptoms were observed in any trial.

In conclusion, the product IN002B1760 can be considered as perfectly selective for ~~all~~ the claimed crop~~s~~.

Comments of zRMS:

No special selectivity trials have been submitted. The phytotoxicity observations were included in the efficacy trials. ~~8~~ 12 varieties were tested in these trials. No negative impact has been detected in any trials. IN002B1760 applied at dose rate of 0,165-0,33 kg/ha is safe for potato.
Any negative effects was observed in the additional efficacy trials. Taking into account all submitted trials, it can be concluded the test product is selective for the intended crop.

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

Yield evaluation is not strictly required according to the specific EPPO standards followed for the claimed uses.

Anyway, yield data were recorded for most of the potato trials to demonstrate that IN002B1760 does not imply any negative effect on the yield of treated plants. In particular, seven trials were harvested (trials PL 21 061 PL1, PL 21 061 PL2, PL 21 063 and PL1 PL 21 061 PL4 conducted in Poland, trials K-111-QUI-21-288 and K-111-QUI-21-289 conducted in Germany and trial EU 21 280 CZ2 conducted in Czech Republic).

The results were suplemented by additional studies from 2023 (021GPSE202301, 021GPSE202302, 021GPSE202303 conducted in Poland, CT23-4-73DE2, conducted in Germany, and study 11-GP2023-01, conducted in the Czech Republic.

Yield results are presented hereunder, as kg/plot and tons per hectare. The relative yield percentage compared to untreated plot (untreated = 100%) are also indicated. Yield obtained in untreated plot, plots treated with IN002B1760 at 0.165, 0.25 and 0.33 kg/ha, as well as in plot treated with reference product, are compared.

Table 3.4-3: Yield obtained with IN002B1760 and reference product compared to untreated plot (~~Mediterranean and~~ Maritime EPPO zones in 2021)

Yield	Untreated plot	Yield obtained with IN002B1760 Mean (min-max)			Reference
		0.165 kg/ha	0.25 kg/ha	0.33 kg/ha	Label rate
kg/plot	29.5 (22.2-38.8)	32.7 (22.2-40.5)	33 (23.3-40.9)	34.1 (22.6-43.2)	30.7 (22.7-39.7)
t/ha	26.1 (22.5-32.3)	28.9 (23.1-33.8)	29.2 (24.3-34)	30.2 (23.5-36)	27.2 (23.6-33.1)
relative % compared to UTC	100	111.4 (99.9-126.9)	112.7 (104.6-133.9)	116 (101.6-128.4)	104.3 (102-107.1)

Table 3.4-3a: Yield obtained with IN002B1760 and reference product compared to untreated plot (~~Mediterranean and~~ Maritime EPPO zones in 2021 and 2023):

Yield	Untreated plot	Yield obtained with IN002B1760 Mean (min-max)			Reference
		0.165 kg/ha	0.25 kg/ha	0.33 kg/ha	Label rate
kg/plot	32.5	33.71	35.14	34.56	34.34
	22.2-38.8	22.2-40.5	23.3-40.9	22.6-43.2	22.7-39.7
t/ha	27.29	28.29	29.49	29.05	28.79
	22.5-32.3	23.1-33.8	24.3-34	23.5-36	23.6-33.1
relative % compared to UTC	100	104.09	108.67	107.05	105.77
		99.9-126.9	103.2-133.9	100.9-128.4	102-109.8

Table 3.4-4: Yield obtained with IN002B1760 and reference product compared to untreated plot (Maritime and North-East EPPO zones in 2021)

Yield	Untreated plot	Yield obtained with IN002B1760 Mean (min-max)			Reference
		0.165 kg/ha	0.25 kg/ha	0.33 kg/ha	Label rate
kg/plot	28 (20.2-33.4)	30.9 (22.9-34.6)	31.8 (22.3-36.1)	32.5 (20.7-37.6)	34.4 (23.1-43.8)
t/ha	25.3 (16.8-33)	27.9 (19.1-33.8)	28.6 (18.6-33.7)	29.3 (17.3-37.6)	31.1 (19.2-43.8)
relative % compared to UTC	100	111.9 (90.4-126.9)	114.9 (102.2-134.3)	116.9 (94.3-137.1)	123.7 (104.6-177.8)

Table 3.4-4a: Yield obtained with IN002B1760 and reference product compared to untreated plot (Maritime and North-East EPPO zones in 2021 and 2023):

Yield	Untreated plot	Yield obtained with IN002B1760 Mean (min-max)	Reference

		0.165 kg/ha	0.25 kg/ha	0.33 kg/ha	Label rate
kg/plot	36.02	36.26	38.18	39.58	39.56
	20.2-57.07	22.9-58.96	22.3-54.53	20.7-64.01	23.1-61.95
t/ha	30.18	31.78	31.98	33.17	33.18
	16.8-47.6	19.1-49.1	18.6-45.4	17.3-53.3	19.2-51.6
relative % compared to UTC	100	106.01	107.86	111.38	110.57
		90.4-126.9	95.3-134.3	94.3-137.1	104.6-177.8

In all the trials, yield in plots treated IN002B1760 resulted always comparable or higher than that of untreated plots (statistically comparable or better than untreated). Overall, an increase of potato yield percentage compared to untreated was observed.

Similarly, in additional 2023 trials, no negative effects on yield were ~~observed~~ observed after the application of IN002B1760.

No negative effects on the yield of the treated plants are expected applying IN002B1760 according to the proposed GAP.

Comments of zRMS:

No negative impact on yield of potato were observed in the submitted trials. Also no significant differences between test and reference products have been noted in the additional trials. IN002B1760 is safe for this crop.

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

The active ingredient cymoxanil is well-known and many years of practical experience have shown that no adverse effects on the quality of treated plants or plant products are expected. In the various efficacy trials submitted for the present registration, no adverse effects concerning the quality of the plant or of the yield have been reported.

Cymoxanil based products have been in use for many years in a number of Countries throughout Europe and no reports of negative impacts on crop quality or taint have been reported. In the same way, current registrations for cymoxanil containing products have no label restrictions with regards to plant quality or taint.

Therefore, it can be safely concluded that the risk of negative impact on quality or taint due to the use of IN002B1760 according to the proposed GAP is very low and specific testing are unnecessary.

In addition, the fact that the residues of cymoxanil at harvest are very low (close to or below the LOQ of 0.01 mg/kg) supports the low risk profile of IN002B1760 for taint in the claimed crops.

Comments of zRMS:

Accepted.

3.4.4 Effects on transformation processes (KCP 6.4.4)

No negative effects on the processing procedures (*i.e.* wine-making) were reported in decades of use of cymoxanil-based products.

Among the crops on which the use of IN002B1760 is claimed, only grapes in involved on processed

that depend on biological activity.

Potato, tomato and aubergine are not subject to transformation that can be affected by the use of a fungicide, therefore no data are presented.

In part B, Section 7 (Metabolism and Residues) it is indicated that no residues were found on grape at harvest. Therefore, according to EPPO PP 1/243(2) '*Effects of plant protection products on transformation processes*', no further data are required.

Comments of zRMS:

Accepted.

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

Submission of data is not considered as mandatory due to the fungicidal nature of the product (EPPO guideline PP 1/135(3)). According to EPPO PP 1/135(3) 'Phytotoxicity assessment', data on plant parts used for propagating purposes are not considered to be required in terms of fungicides being applied to crops that are propagated by cuttings, runners and bulbs or corms, and are required for other parent plant part (as seeds) only in case the plant protection product has systemic activity, is applied close to harvest and some phytotoxic effects are seen on some crops.

These conditions are not met, as IN002B1760 did not show any phytotoxicity.

Therefore, no adverse effects are expected when IN002B1760 is applied according to label recommendations.

Comments of zRMS:

Accepted.

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

3.5.1 Impact on succeeding crops (KCP 6.5.1)

A step-wise approach was followed, according to the EPPO Standard PP 1/207(2) '*Effects on succeeding crops*'. A summary and a conclusion of this step-wise approach is presented hereafter.

No phytotoxicity symptoms were detected in any efficacy trials conducted on potato and tomato, and it was demonstrated that the active substance did not significantly affect germination (reference is made to Part B, Section 9 (Ecotoxicology), seedling emergence test), therefore, no further testing is necessary.

Given the absence of phytotoxicity and considering that cymoxanil-based products have been used for decades without observation of negative impact on succeeding crops, no unacceptable effects are expected when IN002B1760 is applied according to label recommendations.

Comments of zRMS:

Accepted.

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

A step-wise approach was followed, according to the EPPO Standard PP 1/256(1) '*Effects on adjacent crops'*. A summary and a conclusion of this step-wise approach is presented hereafter.

No phytotoxicity symptoms were detected in any efficacy trials conducted on potato ~~and tomato~~. Furthrmore, the risk for non-target plants has been assessed in Part B, Section 9 (Ecotoxicology) of the present Registration Report showing no unacceptable effect.

Therefore, no further testing is necessary, and the tiered approach can stop.

In addition, IN002B1760 is a fungicide and is not expected to exhibit herbicidal activity. Products based on the active substance cymoxanil are already registered throughout Europe. Based on the years of experience with cymoxanil-based product on various crops, without any reporting of negative impact on other plants including adjacent crops, the risk on adverse effects is estimated to be very low.

Tank cleaning

According to EPPO PP 1/292(1) 'Cleaning pesticide application equipment (PAE) – efficacy aspects', if no phytotoxic symptoms are observed on tested crops then no further testing is necessary.

Similar cymoxanil products are already registered in many crops in the Countries where registration is sought without known issues of phytotoxicity; therefore, no issues related to tank cleaning are expected.

Comments of zRMS:

Accepted.

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

Based on experience in the practice from the already registered product containing cymoxanil, adverse effects on beneficial and other non-target organisms are not to be expected. Furthermore, no adverse effects on beneficials or other non-target organisms were noted during the efficacy trials.

Detailed information on the possible adverse effects to beneficial organisms is available in Part B, Section 9 (Ecotoxicology).

Summary and conclusion

No undesirable or unintended side-effects are expected applying IN002B1760 following the proposed GAP.

Comments of zRMS:

Accepted.

3.6 Other/special studies

No other studies were submitted.

3.7 List of test facilities including the corresponding certificates

Table 3.7-1: List of test facilities.

Test facility	Address	Certificate (Yes or No)
OAT Oxford Agricultural Trials	West Farm Barns, Launton Road, Stratton Audley OX27 9AS Bicester, Oxfordshire United Kingdom	Yes

Test facility	Address	Certificate (Yes or No)
ANADIAG SA, CZ osp.	Chleny 46, 517 45 Chleny Czech Republic	Yes
~~ANADIAG SAS~~	~~174, Impasse du Plan d'Eau 38300 Ruy Monteeau France~~	~~Yes~~
QUINTUS GmbH	Liepen 7, 17194 Hohen Wangelin Germany	Yes
~~STAPHYT~~	~~C. Sevilla, 21 41960 Gines, Sevilla Spain~~	~~Yes~~
~~ANADIAG IBÉRICA S.L~~	~~C. Falgueres, 15 17460 Celrà, Girona Spain~~	~~Yes~~
~~ANADIAG ITALIA SRL~~	~~Strada Savonesa 9, Fraz. Rivalta Scrivia 15057 Tortona Italy~~	~~Yes~~
ANADIAG SAS Oddzial w Polsce	Sadowa 16/22 95-100 Zgierz Poland	Yes
~~ANADIAG SA – Sucursal em Portugal~~	~~Rua dos Olivais 3, Loja B 3780-229 Anadia Portugal~~	~~Yes~~
ZS Nechanice	Štolbova 319, 503 15 Nechanice, Czech Republic	Yes
CropTrials GmbH	Ehlbeek 2 30938 Burgwedel Germany	Yes
Green & Property Consulting Anna Huszcza-Podgórska	ul. Na Stoku, nr 6/6, 26-600 Radom, Poland	Yes

The corresponding certificates are located in the Biological Assessment Dossier (KCP 6.0-01).

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Annex point	Author(s)	Year	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or Unpublished**	Data protection claimed Y/N	Owner
KCP 6.0-01	Anonymous	2021	Biological Assessment Dossier: ~~SIP 31664 – EU Southern Zone~~ IN002B1760–EU Central Zone - Unpublished	Y	Indofil Industries (Netherlands) B.V.
KCP 6.2-01	Guillaume Cardiet	2021	Efficacy of cymoxanil against *Phytophthora infestans* in potato ANADIAG SAS Oddzial w Polsce Trial ID: PL 21 061 PL1 GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.
KCP 6.2-02	Guillaume Cardiet	2021	Efficacy of cymoxanil against *Phytophthora infestans* in potato ANADIAG SAS Oddział w Polsce Trial ID: PL 21 061 PL2 GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.
KCP 6.2-03	Guillaume Cardiet	2021	Efficacy of cymoxanil against *Phytophthora infestans* in potato ANADIAG SAS Oddział w Polsce Trial ID: PL 21 061 PL3 GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.
KCP 6.2-04	Guillaume Cardiet	2021	Efficacy of cymoxanil against *Phytophthora infestans* in potato ANADIAG SAS Oddział w Polsce Trial ID: PL 21 061 PL4 GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.
KCP 6.2-05	Guillaume Cardiet	2021	Efficacy of cymoxanil against *Phytophthora infestans* in potato ANADIAG SA, CZ osp. Trial ID: EU 21 280 CZ1 GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.

Annex point	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2-06	Guillaume Cardiet	2021	Efficacy of cymoxanil against *Phytophthora infestans* in potato ANADIAG SA, CZ osp. Trial ID: EU 21 280 CZ2 GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.
KCP 6.2-07	Guillaume Cardiet	2021	Efficacy of cymoxanil against *Phytophthora infestans* in potato QUINTUS GmbH Trial ID: K-111-QUI-21-288 GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.
KCP 6.2-08	Guillaume Cardiet	2021	Efficacy of cymoxanil against *Phytophthora infestans* in potato QUINTUS GmbH Trial ID: K-111-QUI-21-289 GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.
~~KCP 6.2-09~~	~~Alessandro Spagnolo~~	~~2021~~	~~Efficacy of cymoxanil against *Phytophthora infestans* in potato~~ ~~ANADIAG SAS~~ ~~Trial ID: EU21280JP103~~ ~~GEP: Yes~~ ~~Unpublished~~	~~Y~~	~~Indofil Industries (Netherlands) B.V.~~
~~KCP 6.2-10~~	~~Alessandro Spagnolo~~	~~2021~~	~~Efficacy of cymoxanil against *Phytophthora infestans* in potato~~ ~~ANADIAG SAS~~ ~~Trial ID: EU21280XA110~~ ~~GEP: Yes~~ ~~Unpublished~~	~~Y~~	~~Indofil Industries (Netherlands) B.V.~~
~~KCP 6.2-11~~	~~Sofía Camuñez~~	~~2021~~	~~Efficacy of IN002B1760 against agaisnt *Phythophtora infestans* on potato.~~ ~~STAPHYT~~ ~~Trial ID: SCZ-21-51097-IT01~~ ~~GEP: Yes~~ ~~Unpublished~~	~~Y~~	~~Indofil Industries (Netherlands) B.V.~~
~~KCP 6.2-12~~	~~Sofía Camuñez~~	~~2021~~	~~Efficacy of IN002B1760 against agaisnt *Phythophtora infestans* on potato.~~ ~~STAPHYT~~ ~~Trial ID: SCZ-21-51097-IT02~~ ~~GEP: Yes~~ ~~Unpublished~~	~~Y~~	~~Indofil Industries (Netherlands) B.V.~~
KCP 6.2-13	Guillaume Cardiet	2021	Efficacy of cymoxanil against *Phytophthora infestans* in potato OAT Scotland	Y	Indofil Industries (Netherlands) B.V.

Annex point	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
			Trial ID: 1362A-21-ANA GEP: Yes Unpublished		
KCP 6.2-14	Guillaume Cardiet	2021	Efficacy of cymoxanil against *Phytophthora infestans* in potato OAT South West Trial ID: 1362B-21-ANA GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.
~~KCP 6.2-15~~	~~Guillaume Cardiet~~	~~2021~~	~~Efficacy of cymoxanil against *Phytophthora infestans* in Greenhouse tomato~~ ~~ANADIAG ITALIA SRL~~ ~~Trial ID: ITA-21132-TO1~~ ~~GEP: Yes~~ ~~Unpublished~~	~~Y~~	~~Indofil Industries (Netherlands) B.V.~~
~~KCP 6.2-16~~	~~Guillaume Cardiet~~	~~2021~~	~~Efficacy of cymoxanil against *Phytophthora infestans* in Greenhouse tomato~~ ~~ANADIAG ITALIA SRL~~ ~~Trial ID: ITA-21133-TO1~~ ~~GEP: Yes~~ ~~Unpublished~~	~~Y~~	~~Indofil Industries (Netherlands) B.V.~~
~~KCP 6.2-17~~	~~Guillaume Cardiet~~	~~2021~~	~~Efficacy of cymoxanil against *Phytophthora infestans* in Greenhouse tomato~~ ~~ANADIAG SAS Oddzial w Polsce~~ ~~Trial ID: PL-21-062-PL1~~ ~~GEP: Yes~~ ~~Unpublished~~	~~Y~~	~~Indofil Industries (Netherlands) B.V.~~
~~KCP 6.2-18~~	~~Guillaume Cardiet~~	~~2021~~	~~Efficacy of cymoxanil against *Phytophthora infestans* in Greenhouse tomato~~ ~~ANADIAG SAS Oddzial w Polsce~~ ~~Trial ID: PL-21-062-PL2~~ ~~GEP: Yes~~ ~~Unpublished~~	~~Y~~	~~Indofil Industries (Netherlands) B.V.~~
~~KCP 6.2-19~~	~~Sofia Camuñez~~	~~2021~~	~~Efficacy of IN002B1760 against *Phythophtora infestans* on tomato in green-house.~~ ~~STAPHYT~~ ~~Trial ID: SCZ-21-51099-FR01~~ ~~GEP: Yes~~ ~~Unpublished~~	~~Y~~	~~Indofil Industries (Netherlands) B.V.~~
~~KCP 6.2-20~~	~~Guillaume Cardiet~~	~~2021-2022~~	~~Efficacy of cymoxanil against *Phytophthora infestans* in Greenhouse tomato~~ ~~Anadiag International~~ ~~Trial ID: 21GR-283~~	~~Y~~	~~Indofil Industries (Netherlands) B.V.~~

Annex point	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
			GEP: Yes Trial ongoing (January 2022)		
KCP 6.2 21	Guillaume Cardiet	2021	Efficacy of cymoxanil against *Phytophthora infestans* in open field tomato Anadiag SA Sucursal em Portugal Trial ID: PO 210 35 PO1 GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.
KCP 6.2 22	Magalí Adarnius Blanch	2021	Efficacy of cymoxanil against *Phytophthora infestans* in open field tomato ANADIAG IBÉRICA S.L Trial ID: 21195 AF GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.
KCP 6.2 23	Magalí Adarnius Blanch	2021	Efficacy of cymoxanil against *Phytophthora infestans* in open field tomato ANADIAG IBÉRICA S.L Trial ID: 21196 RJ GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.
KCP 6.2 24	Guillaume Cardiet	2021	Efficacy of cymoxanil against *Phytophthora infestans* in open field tomato Anadiag International Trial ID: 21GR 199 GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.
KCP 6.2 25	Guillaume Cardiet	2021	Efficacy of cymoxanil against *Phytophthora infestans* in open field tomato ANADIAG ITALIA SRL Trial ID: ITA 21131 TO1 GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.
KCP 6.2 30	Sofía Camuñez	2021	Efficacy of IN002B1760 agaisnt *Phythophtora infestans* on tomato in open field. STAPHYT Trial ID: SCZ 21 51098 IT01 GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.
KCP 6.2-27	Lenka Vašátková Štanclová	2023	Evaluation of efficacy of cymoxanil against Phytophthora infestans on potato in Czech Republic. Essais+ 11-GP2023-01	Y	Indofil Industries (Netherlands) BV

Annex point	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
			GEP Unpublished		
KCP 6.2-28	Kirsten Heitsch	2023	An evaluation of the efficacy of IN002BI760 against Phytophthora infestans on potato following sequential applications in Germany, the EPPO climatic zone Maritime in 2023 Essais+ CT23-4-73DE2 GEP Unpublished	y	Indofil Industries (Netherlands) BV
KCP 6.2-29	Radosław Ptaszek	2023	Evaluation of efficacy of cymoxanil against Phytophthora infestans on potato in Poland 2023 Green & Property Consulting 021GPSE202301 GPE Unpublished	Y	Indofil Industries (Netherlands) BV
KCP 6.2-30	Anna Huszcza-Podgórska	2023	Evaluation of efficacy of cymoxanil against Phytophthora infestans on potato in Poland 2023 Green & Property Consulting 021GPSE202302 GPE Unpublished	Y	Indofil Industries (Netherlands) BV
KCP 6.2-31	Anna Huszcza-Podgórska	2023	Evaluation of efficacy of cymoxanil against Phytoftora infestans on potato in Poland 2023. Green & Property Consulting 021GPSE202303 GPE Unpublished	Y	Indofil Industries (Netherlands) BV

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

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

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2-09	Alessandro Spagnolo	2021	Efficacy of cymoxanil against *Phytophthora infestans* in potato ANADIAG SAS Trial ID: EU21280JP103 GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.
KCP 6.2-10	Alessandro Spagnolo	2021	Efficacy of cymoxanil against *Phytophthora infestans* in potato ANADIAG SAS Trial ID: EU21280XA110 GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.
KCP 6.2-11	Sofía Camuñez	2021	Efficacy of IN002B1760 agaisnt *Phythophtora infestans* on potato. STAPHYT Trial ID: SCZ-21-51097-IT01 GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.
KCP 6.2-12	Sofía Camuñez	2021	Efficacy of IN002B1760 agaisnt *Phythophtora infestans* on potato. STAPHYT Trial ID: SCZ-21-51097-IT02 GEP: Yes Unpublished	Y	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
KCP 6.2-15	Guillaume Cardiet	2021	Efficacy of cymoxanil against *Phytophthora infestans* in Greenhouse tomato ANADIAG ITALIA SRL Trial ID: ITA 21132 TO1 GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.
KCP 6.2-16	Guillaume Cardiet	2021	Efficacy of cymoxanil against *Phytophthora infestans* in Greenhouse tomato ANADIAG ITALIA SRL Trial ID: ITA 21133 TO1 GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.
KCP 6.2-17	Guillaume Cardiet	2021	Efficacy of cymoxanil against *Phytophthora infestans* in Greenhouse tomato ANADIAG SAS Oddzial w Polsce Trial ID: PL 21 062 PL1 GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.
KCP 6.2-18	Guillaume Cardiet	2021	Efficacy of cymoxanil against *Phytophthora infestans* in Greenhouse tomato ANADIAG SAS Oddział w Polsce Trial ID: PL 21 062 PL2 GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.
KCP 6.2-19	Sofía Camuñez	2021	Efficacy of IN002B1760 against *Phythophtora infestans* on tomato in greenhouse. STAPHYT Trial ID: SCZ-21-51099-FR01 GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.
KCP 6.2-20	Guillaume Cardiet	2021-2022	Efficacy of cymoxanil against *Phytophthora infestans* in Greenhouse tomato Anadiag International Trial ID: 21GR-283 GEP: Yes Trial ongoing (January 2022)	Y	Indofil Industries (Netherlands) B.V.
KCP 6.2-21	Guillaume Cardiet	2021	Efficacy of cymoxanil against *Phytophthora infestans* in open field tomato Anadiag SA-Sucursal em Portugal	Y	Indofil Industries (Nether-

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
			Trial ID: PO 210 35 PO1 GEP: Yes Unpublished		lands) B.V.
KCP 6.2-22	Magalí Adarnius Blanch	2021	Efficacy of cymoxanil against *Phytophthora infestans* in open field tomato ANADIAG IBÉRICA S.L Trial ID: 21195 AF GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.
KCP 6.2-23	Magalí Adarnius Blanch	2021	Efficacy of cymoxanil against *Phytophthora infestans* in open field tomato ANADIAG IBÉRICA S.L Trial ID: 21196 RJ GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.
KCP 6.2-24	Guillaume Cardiet	2021	Efficacy of cymoxanil against *Phytophthora infestans* in open field tomato Anadiag International Trial ID: 21GR-199 GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.
KCP 6.2-25	Guillaume Cardiet	2021	Efficacy of cymoxanil against *Phytophthora infestans* in open field tomato ANADIAG ITALIA SRL Trial ID: ITA 21131 TO1 GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.
KCP 6.2-26	Sofía Camuñez	2021	Efficacy of IN002B1760 agaisnt *Phythophtora infestans* on tomato in open field. STAPHYT Trial ID: SCZ-21-51098-IT01 GEP: Yes Unpublished	Y	Indofil Industries (Netherlands) B.V.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
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List with references (PPP) according SANCO/12580/2012 – rev. 4, 22 March 2019

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	Previously used Y/N If yes, for which data point?
KCP 6.2-01	G.Cardiet	2021	Efficacy of cymoxanil against *Phytophtora infestans* in potato Report No. PL 21 061 PL1 Source: ANADIAG POLSKA, Poland GLP No GEP Yes not published	N	Y	Data/study report never submitted before to Poland	Indofil Industries (Nether-lands) B.V.	N
KCP 6.2-02	G.Cardiet	2021	Efficacy of cymoxanil against *Phytophtora infestans* in potato Report No. PL 21 061 PL2 Source: ANADIAG POLSKA, Poland GLP No GEP Yes not published	N	Y	Data/study report never submitted before to Poland	Indofil Industries (Nether-lands) B.V.	N
KCP 6.2-03	G.Cardiet	2021	Efficacy of cymoxanil against *Phytophtora infestans* in potato Report No. PL 21 061 PL3 Source: ANADIAG POLSKA, Poland GLP No GEP Yes not published	N	Y	Data/study report never submitted before to Poland	Indofil Industries (Nether-lands) B.V.	N
KCP 6.2-04	G.Cardiet	2021	Efficacy of cymoxanil against *Phytophtora infestans* in potato Report No. PL 21 061 PL4 Source: ANADIAG POLSKA, Poland GLP No GEP Yes not published	N	Y	Data/study report never submitted before to Poland	Indofil Industries (Nether-lands) B.V.	N

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	Previously used Y/N If yes, for which data point?
KCP 6.2-05	G.Cardiet	2021	Efficacy of cymoxanil against *Phytophtora infestans* in potato Report No. EU21280CZ1 Source: ANADIAG SA, CZ osp., Czech Republic GLP No GEP Yes not published	N	Y	Data/study report never submitted before to Poland	Indofil Industries (Nether-lands) B.V.	N
KCP 6.2-06	G.Cardiet	2021	Efficacy of cymoxanil against *Phytophtora infestans* in potato Report No. EU21280CZ2 Source: ANADIAG SA, CZ osp., Czech Republic GLP No GEP Yes not published	N	Y	Data/study report never submitted before to Poland	Indofil Industries (Nether-lands) B.V.	N
KCP 6.2-07	G.Cardiet	2021	Efficacy of cymoxanil against *Phytophthora infestans* in potato Report No. K-111-QUI-21-288 Source: QUINTUS GMBH, Germany GLP No GEP Yes not published	N	Y	Data/study report never submitted before to Poland	Indofil Industries (Nether-lands) B.V.	N
KCP 6.2-08	G.Cardiet	2021	Efficacy of cymoxanil against *Phytophthora infestans* in potato Report No. K-111-QUI-21-289 Source: QUINTUS GMBH, Germany GLP No GEP Yes not published	N	Y	Data/study report never submitted before to Poland	Indofil Industries (Nether-lands) B.V.	N
KCP 6.2-13	G.Cardiet	2021	Efficacy of cymoxanil against *Phytophtora infestans* in potato Report No. 1362A-21-ANA Source: Oxford Agricultural Trials Limited, United Kingdom GLP No GEP Yes not published	N	Y	Data/study report never submitted before to Poland	Indofil Industries (Nether-lands) B.V.	N
KCP 6.2-14	G.Cardiet	2021	Efficacy of cymoxanil against *Phytophtora infestans* in potato Report No. 1362B-21-ANA Source: Oxford Agricultural Trials Limited, United Kingdom GLP No GEP Yes not published	N	Y	Data/study report never submitted before to Poland	Indofil Industries (Nether-lands) B.V.	N

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	Previously used Y/N If yes, for which data point?
KCP 6.2-09	A.Spagnolo	2021	Efficacy of cymoxanil against *Phytophtora infestans* in potato Report No. EU21280JP103 Source: ANADIAG SAS, France GLP No GEP Yes not published	N	Y	Data/study report never submitted before to Poland	Indofil Industries (Nether-lands) B.V.	N
KCP 6.2-10	A.Spagnolo	2021	Efficacy of cymoxanil against *Phytophtora infestans* in potato Report No. EU21280XA110 Source: ANADIAG SAS, France GLP No GEP Yes not published	N	Y	Data/study report never submitted before to Poland	Indofil Industries (Nether-lands) B.V.	N
KCP 6.2-11	S.Camuñez	2021	Efficacy of IN002B1760 against *Phytophthora infestans* on potato GEP Trial, ITALY, 2021 Report No. RA 21 087 BPS IT 01/ SCZ-21-51097-IT01 Source: Res Agraria s.r.l., Italy GLP No GEP Yes not published	N	Y	Data/study report never submitted before to Poland	Indofil Industries (Nether-lands) B.V.	N
KCP 6.2-12	S.Camuñez	2021	Efficacy of IN002B1760 against *Phytophthora infestans* on potato GEP Trial, ITALY, 2021 Report No. RA 21 087 BPS IT 02/ SCZ-21-51097-IT02 Source: Res Agraria s.r.l., Italy GLP No GEP Yes not published	N	Y	Data/study report never submitted before to Poland	Indofil Industries (Nether-lands) B.V.	N
KCP 6.2-15	G.Cardiet	2021	Efficacy of cymoxanil against *Phytophtora infestans* on greenhouse tomato Report No. ITA 21132 TO1 Source: ANADIAG ITALIA SRL, Italy GLP No GEP Yes not published	N	Y	Data/study report never submitted before to Poland	Indofil Industries (Nether-lands) B.V.	N

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	Previously used Y/N If yes, for which data point?
KCP 6.2-16	G.Cardiet	2021	Efficacy of cymoxanil against *Phytophtora infestans* on greenhouse tomato Report No. ITA 21133 TO1 Source: ANADIAG ITALIA SRL, Italy GLP No GEP Yes not published	N	Y	Data/study report never submitted before to Poland	Indofil Industries (Nether-lands) B.V.	N
KCP 6.2-17	G.Cardiet	2021	Efficacy of cymoxanil against *Phytophtora infestans* on greenhouse tomato Report No. PL 21 062 PL1 Source: ANADIAG POLSKA, Poland GLP No GEP Yes not published	N	Y	Data/study report never submitted before to Poland	Indofil Industries (Nether-lands) B.V.	N
KCP 6.2-18	G.Cardiet	2021	Efficacy of cymoxanil against *Phytophtora infestans* on greenhouse tomato Report No. PL 21 062 PL2 Source: ANADIAG POLSKA, Poland GLP No GEP Yes not published	N	Y	Data/study report never submitted before to Poland	Indofil Industries (Nether-lands) B.V.	N
KCP 6.2-19	S.Camuñez	2021	Efficacy of IN002B1760 against *Phytophthora infestans* on tomato in greenhouse, GEP Trial, FRANCE, 2021 Report No. OR20210903674/SCZ-21-51099-FR01 Source: STAPHYT, France GLP No GEP Yes not published	N	Y	Data/study report never submitted before to Poland	Indofil Industries (Nether-lands) B.V.	N
KCP 6.2-20	G.Cardiet	2021	Efficacy of cymoxanil against *Phytophtora infestans* on greenhouse tomato Report No. 21GR-283 Source: ANADIAG HELLAS LTD, Greece GLP No GEP Yes not published	N	Y	Data/study report never submitted before to Poland	Indofil Industries (Nether-lands) B.V.	N

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KCP 6.2-21	G.Cardiet	2021	Efficacy of cymoxanil against *Phytophtora infestans* on open field tomato Report No. PO 21 035 PO1 Source: ANADIAG PORTUGAL, Portugal GLP No GEP Yes not published	N	Y	Data/study report never submitted before to Poland	Indofil Industries (Nether-lands) B.V.	N
KCP 6.2-22	Magalí Adarnius Blanch	2021	Efficacy of cymoxanil against *Phytophtora infestans* on open field tomato Report No. 21195 AF Source: ANADIAG IBÉRICA, SL, Spain GLP No GEP Yes not published	N	Y	Data/study report never submitted before to Poland	Indofil Industries (Nether-lands) B.V.	N
KCP 6.2-23	Magalí Adarnius Blanch	2021	Efficacy of cymoxanil against *Phytophtora infestans* on open field tomato Report No. 21196 RJ Source: ANADIAG IBÉRICA, SL, Spain GLP No GEP Yes not published	N	Y	Data/study report never submitted before to Poland	Indofil Industries (Nether-lands) B.V.	N
KCP 6.2-24	G.Cardiet	2021	Efficacy of cymoxanil against *Phytophtora infestans* on open field tomato Report No. 21GR-199 Source: ANADIAG HELLAS LTD, Greece GLP No GEP Yes not published	N	Y	Data/study report never submitted before to Poland	Indofil Industries (Nether-lands) B.V.	N
KCP 6.2-25	G.Cardiet	2021	Efficacy of cymoxanil against *Phytophtora infestans* on open field tomato Report No. ITA 21131 TO1 Source: ANADIAG ITALIA SRL, Italy GLP No GEP Yes not published	N	Y	Data/study report never submitted before to Poland	Indofil Industries (Nether-lands) B.V.	N

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	Previously used Y/N If yes, for which data point?
KCP 6.2-26	S.Camuñez	2021	Efficacy of IN002B1760 against *Phytophthora infestans* on tomato in open field, GEP Trial, ITALY, 2021 Report No. RA 21 089 BPS IT01/SCZ-21-51098-IT01 Source: Res Agraria s.r.l. , Italy GLP No GEP Yes not published	N	Y	Data/study report never submitted before to Poland	Indofil Industries (Netherlands) B.V.	N
KCP 6.2-27	Lenka Vašátková Štanclová	2023	Evaluation of efficacy of cymoxanil against Phytophthora infestans on potato in Czech Republic. Essais+ 11-GP2023-01 GEP Unpublished	Y	Indofil Industries (Netherlands) BV	KCP 6.2-27	~~Lenka Vašátková Štanclová~~ Indofil Industries (Netherlands) B.V.	2023
KCP 6.2-28	Kirsten Heitsch	2023	An evaluation of the efficacy of IN002BI760 against Phytophthora infestans on potato following sequential applications in Germany, the EPPO climatic zone Maritime in 2023 Essais+ CT23-4-73DE2 GEP Unpublished	y	Indofil Industries (Netherlands) BV	KCP 6.2-28	~~Kirsten Heitsch~~ Indofil Industries (Netherlands) B.V.	2023
KCP 6.2-29	Radosław Ptaszek	2023	Evaluation of efficacy of cymoxanil against Phytophthora infestans on potato in Poland 2023 Green & Property Consulting 021GPSE202301 GPE Unpublished	Y	Indofil Industries (Netherlands) BV	KCP 6.2-29	~~Radosław Ptaszek~~ Indofil Industries (Netherlands) B.V.	2023
KCP 6.2-30	Anna Huszcza-Podgórska	2023	Evaluation of efficacy of cymoxanil against Phytophthora infestans on potato in Poland 2023 Green & Property Consulting 021GPSE202302 GPE Unpublished	Y	Indofil Industries (Netherlands) BV	KCP 6.2-30	~~Anna Huszcza-Podgórska~~ Indofil Industries (Netherlands) B.V.	2023

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	Previously used Y/N If yes, for which data point?
KCP 6.2-31	Anna Huszcza-Podgórska	2023	Evaluation of efficacy of cymoxanil against Phytoftora infestans on potato in Poland 2023. Green & Property Consulting 021GPSE202303 GPE Unpublished	Y	Indofil Industries (Netherlands) BV	KCP 6.2-31	~~Anna Huszcza-Podgórska~~ Indofil Industries (Netherlands) B.V.	2023