

REGISTRATION REPORT

Part A

Risk Management

Product code: IN002B1760

Product name(s): Cymofil

Chemical active substance:

Cymoxanil, 450 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland

(authorization)

Applicant: Indofil Industries (Netherlands) B.V.

Submission date: August 2022

MS Finalisation date: May 2023 (initial National Assessment)

January 2024, updated February 2024

April 2024, updated May 2024 (final National 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 In order to facilitate tracking of changes of the intended uses of the product due to the performed evaluation, amendments of the GAP table and in the product label (Appendix 2) and Lists of data considered for national authorization (Appendix 4) are highlighted in grey , while not agreed use pattern is struck through and shaded .
January 2024	National Assessment updated following the commenting period Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow .
February 2024	zRMS assessment after submission of the additional data in the scope of physical and chemical properties, analytical methods, efficacy, ecotoxicology (additional information/assessments included by the zRMS in the report are highlighted in green). Not agreed or not relevant information are struck through and shaded for transparency.
April 2024	Final report (National Assessment updated following the commenting period 2 nd tour) 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 turquoise , while not agreed use pattern is struck through and shaded .

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application is being submitted to support the authorisation of the new product IN002B1760 in accordance with Article 33 of Regulation (EC) n. 1107/2009. The product is a WG formulation containing 450 g/kg cymoxanil; it was not the representative formulation of the EU review, but it is a new product not previously evaluated.

Poland acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorization of this product in Poland and in other MSs of the Central zone for field uses.

This dossier is submitted in accordance with the Commission Regulation (EU) No 284/2013.

In the Central zone, IN002B1760 acts as fungicide for the control of late blight in potato.

Cymoxanil was included into Annex I of Directive 91/414 according to Commission Directive 2008/125/EC of 19 December 2008 and approved under Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009.

In support of this application, reference is made to active substance data, please refer to the list of endpoints (EFSA Scientific Report (2008) 167, 1-116; SANCO/179/08 – 09/07/2010; original DAR and Final Addendum to the Draft Assessment Report-updated September 2008).

1.2 Letters of Access

All data for the active substance are unprotected. A technical equivalence was assessed and established by UK for a new source of cymoxanil owned by Indofil Industries Limited (India) [COP 2017/02093]. Some studies on the active substance used in the present application are owned by Indofil Industries Limited.

1.3 Justification for submission of tests and studies

The tests and study reports are necessary in order to support the authorisation of IN002B1760 as a new product (i.e. first authorisation in the EU).

1.4 Data protection claims

IN002B1760 is a new product and therefore, for all data, data protection is claimed for 10 years starting at the date of authorisation in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

2 Details of the authorization decision

2.1 Product identity

Product code	IN002B1760
Product name in MS	To be decided
Authorization number	New authorisation
Function	Fungicide

Applicant	Indofil Industries (Netherlands) B.V.
Active substance(s) (incl. content)	Cymoxanil 450 g/kg
Formulation type	WG
Packaging	0.1-0.2-0.5-1-5 kg plastic bag, professional user (Polyethylene lined laminate paper bag/pouch)
Coformulants of concern for national authorizations	None
Restrictions related to identity	None
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for Cymofil resulted in the decision to grant the authorization

2.3 Substances of concern for national monitoring

Not applicable.

2.4 Classification and labelling

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

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

Hazard class(es), categories:	Acute oral tox cat.4 Skin Sens. 1, Repro. 2, STOT RE 2; Eye Irrit. 2, Aquatic Chronic 1,
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	GHS07 GHS08 GHS09
Signal word:	Warning
Hazard statement(s):	H302, H317, H361fd, H373, H319, H410
Precautionary statement(s):	P201, P260, P273, P280, P308+P313, P305 + P351 + P338, P391, P501
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
-	
-	

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
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2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

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2.5 Risk management

2.5.1 Restrictions linked to the PPP

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

Operator protection:	
-	Workwear is recommended in all the tasks. Gloves in the manual application with lance.
Worker protection:	
-	Potato: work wear for inspection and irrigation
Integrated pest management (IPM)/sustainable use:	
-	Maximum number of applications according to FRAC guidelines
Environmental protection	
-	-
Other specific restrictions	
-	-

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

Integrated pest management (IPM)/sustainable use:	
-	No restrictions

2.5.2 Specific restrictions linked to the intended uses

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

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

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code):
Active substance 1:
Applicant:
Zone(s):
Verified by MS:
Field of use:

IN002B1760
Cymoxanil
Indofil Industries (Netherlands) B.V.
SEU/Interzonal ^(d)
yes
fungicide

Formulation type:
Conc. of as 1:
Professional use:
Non professional use:

WG ^(a, b)
450 g/kg ^(c)
x
☐

GAP rev. 1, date: 2024-04 2023-05

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

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

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

- Remarks columns:**
- 1 Numeration necessary to allow references
 - 2 Use official codes/nomenclatures of EU Member States
 - 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
 - 4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
 - 5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
 - 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

* Explanation for column 15 "Overall conclusions"

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

- 7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- 8 The maximum number of application possible under practical conditions of use must be provided.
- 9 Minimum interval (in days) between applications of the same product
- 10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
- 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
- 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
- 13 PHI - minimum pre-harvest interval
- 14 Remarks may include: Extent of use/economic importance/restrictions
- 15 Overall conclusions - explanation for the column 15 is below *

3 Background of authorization decision and risk management

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a granular formulation, with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. In aqueous solution, it has a pH value around 5.2 at 20°C. ~~Ambient temperature study is currently ongoing, and should be provided upon completion.~~ There is no effect of high temperature on the stability of the formulation, since after 14 days at 54°C neither the active ingredient content nor the technical properties were changed. The stability data after accelerated and ambient storage indicates a shelf life of at least 2 years at ambient temperature when stored in polyethylene bag. Its technical characteristics are acceptable for a WG formulation.

The intended concentration of use is 0.066-0.11% ~~0.0166% to 0.22%.~~

~~The product is not intended to be mixed in the tank together with other products.~~

Cymoxanil 45 WG was tested with various potential tank mix partners (Enervin ® SC, Pergado SC ®, Ranman Top, Nando ® Maxi, Folpan 80 WDG, R6 Erresei Bordeaux WG, Orondis ®, Aliette ®, Copperfield 17 WG, Zoxium ® 240 SC, Ossiclor 50 PB Manica ®, Polyram ® DF, Century SL, R6 Erresei Albis ®, Previter) and all tested combinations are considered compatible. Thus, the formulation has good miscibility with water and other products.

The formulation is not classified for physical chemical aspect.

The product IN002B1760 complies with FAO specifications.

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

3.2 Efficacy (Part B, Section 3)

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) for use against late blight (PHYTIN).

Data are presented from a total of 8 efficacy trials, conducted with IN002B1760 in potato in Poland, Germany and Czech Republic. Also 2 trials not valid for efficacy have been submitted for phytotoxicity assessment. These trials were carried out in the UK.

3.3 Efficacy data

No specific preliminary range-finding tests were deemed necessary as 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. Plasmopara viticola and 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.

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

Efficacy data include the results of 8 13 valid efficacy trials on potato (4 7 in EPPO North-East zone + 4 6 in EPPO Maritime zone) conducted with IN002B1760 in 2021 and 2023.

Based on the results of a total of 8 13 valid trials carried out in 2021 and 2023 to support the claimed GAP of the product IN002B1760, it can be concluded that IN002B1760 provides a sufficient level of control of the target diseases with lower disease pressure in a wide range of conditions and pest severity and that the efficacy obtained with IN002B1760 is fully comparable to that of the other cymoxanil

products used as reference standard in the submitted trials. **Moderate level of control was observed with higher disease pressure and this information should be included in the national product label.**

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.

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

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

The overall risk of resistance for IN002B1760 when applied according to label recommendations and following “Good agricultural practise”, is considered to be acceptable.

The following risk management strategy should be adopted:

- 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: **max** 6 applications per year;
- Always follow product specific recommendations for resistance management.

3.3.2 Adverse effects on treated crops

No phytotoxicity symptoms were observed in any trial.

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

3.3.3 Observations on other undesirable or unintended side-effects

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

3.4 Methods of analysis (Part B, Section 5)

Adequate methodology exists for determination of cymoxanil in the plant protection product and in plants, animal tissue, milk and eggs, soil, water and air.

3.4.1 Analytical method for the formulation

Analytical method for the determination of cymoxanil in the formulation is available and validated. An HPLC/UV-DAD method used for active ingredient content determination in the test item, was validated according to SANCO 3030/99 rev.5 guidance document for specificity, interferences check, linearity of response, precision and recovery.

As the active substance cymoxanil does not contain any relevant impurity, no pertinent analytical method is required.

3.4.2 Analytical methods for residues

According to the SANTE/2020/12830, Rev.1, 24. February 2021 potato belongs to high water content commodities analytical group.

According to the EFSA Journal 2015;13(12):4355 *In the framework of the peer review under Directive 91/414/EEC, a method using GC-NPD was sufficiently validated with a limit of quantification (LOQ) of 0.04 mg/kg for the determination of cymoxanil in commodities with high water and high acid content, and*

with an LOQ of 0.1 mg/kg for the determination of cymoxanil in hops. A confirmatory method using GC-NPD is available for the determination of cymoxanil residues in commodities with high water and high acid content but is still missing for hops (EFSA, 2008).

Furthermore, the multi-residue QuEChERS method is also applicable for the determination of cymoxanil. The LC-MS/MS analyses cymoxanil residues in high water, high acid content and dry commodities with an LOQ of 0.01 mg/kg (CEN, 2008).

In addition, the RMS has evaluated the DFG S19 method for enforcement of cymoxanil in high oil content commodities. The HPLC-MS/MS was validated for enforcement of cymoxanil in high oil content commodities with an LOQ of 0.01 mg/kg (Austria, 2013). An ILV is not required for this method.

Hence, it is concluded that cymoxanil can be enforced in the four main plant matrices with an LOQ of 0.01 mg/kg. The enforcement of cymoxanil is also achievable in difficult matrices such as hops and herbal infusions (dried) with an LOQ of 0.1 mg/kg. This conclusion was confirmed by the EURLs during the Member States consultation. Nevertheless, a confirmatory method is still required for these specific matrices.

In accordance with Regulations 283/2013 and 284/2013 and guide SANTE/2020/12830, Rev.1, 24. February 2021, validated methods should be available for the determination of cymoxanil residues for monitoring purposes in all plant matrices. Generally, an LOQ of at least 0.01 mg/kg should be met, except for MRLs which have been established at an even lower level (e.g. for compounds with a very low toxicological reference value) which then has to be covered by the LOQ.

According to the current Reg. (EU) 2022 /1363 most of the MRLs are 0.01 mg/kg.

Data are available to the Applicant from a study on potatoes that was already evaluated by zRMS Greece in the context of an application for the authorisation of the product (Moximate 505 WG) in 2014. This study demonstrated a determined LOQ of 0.01 mg/kg.

Applicant submitted additional data supporting the MRL of 0.01 mg/kg for tomatoes from study GLP-STUDY-21-58, Sala A. 2021a. The results of an ILV study are available and the dRR was updated accordingly (CH-0061-2023, Pardo Martinez M.).

Analytical methods for determination of cymoxanil in high water content matrix have been assessed.

During the commenting period Applicant submitted additional information:

According to the agreed decision of the Interzonal Steering Committee of March 2023 on Data Gaps in EFSA Conclusions, as no data gaps were reported in the review report or EFSA Conclusions or requested at Member State level, "data gap is not to be considered at PPP level because it is not relevant".

Considering that no residues of cymoxanil above the LOQ were found in any of the raw commodities analysed in the dossier, no additional data have to be provided by the Applicant.

However, the Applicant is a component of the Task Force for the renewal of the active ingredient and studies were provided and are currently under evaluation in the renewal procedure.

The applicant resubmitted the Pardo-Martinez (2023) study to the BVL in Germany through the Portal on the 10/07/2023.

zRMS conclusion:

As the current Reg. (EU) 2022/1363 most of the MRLs are 0.01* mg/kg, new analytical methods (with confirmatory data and ILV) for food and feed of plant origin required for all matrix types are required. It should be noted that sufficiently validated methods have been submitted in the framework of active substance renewal.

Noticed data gaps are:

- ILV for drinking or ground water,
- fully validated method for the determination of cymoxanil in body fluids and tissues.
- new analytical method for the determination of residues of cymoxanil in soil,
- analytical methods for monitoring/enforcement purposes for food and feed of plant origin required for all matrix types with LOQ of 0.01* mg/kg.

zRMS-PL considers that these data gaps are anticipated to be addressed at active substance level in context with the renewal of cymoxanil and will be subject of the art.43 re-authorisation process for the product.

3.5 Mammalian toxicology (Part B, Section 6)

The following risk mitigation measures are required for field crops:

Operator:

Potato (max. 6 x 0.33 kg product/ha, interval 5 days)

- ⇒ Tractor-mounted boom sprayer, downwards: Work-wear during mixing/loading and application
- ⇒ Manual, hand-held application (lance and knapsack): Work wear during mixing/loading and application and gloves in case of application with lance

Workers:

Potato (max. 6 x 0.33 kg product/ha, interval 5 days)

- ⇒ Work wear (arms, body and legs covered) during all worker re-entry tasks

3.5.1 Acute toxicity

A summary of the toxicological evaluation for IN002B1760 is given in the following table. The justifications according to CLP calculation method are reported in detail in Appendix 2.

Table 3.5-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for IN002B1760

Endpoint	Result	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral	> 300 mg/kg bw and < 2000 mg/kg bw	H302	Calculation method
LD ₅₀ dermal	> 2000 mg/kg bw	None	Calculation method
LC ₅₀ inhalation	> 5.0 mg/L air	None	Calculation method
Skin irritation	Non-irritant	None	Calculation method
Eye irritation	Irritant	H319	Calculation method
Skin sensitisation	Skin sensitising	H317	Calculation method

According to the above toxicological conclusions the use of gloves and glasses are recommended for mixing and loading tasks due to the hazardous properties of the product.

3.5.2 Operator exposure

Based on the calculations, the operator exposure for the intended GAP uses of IN002B1760 is below the limit of 100% AOEL if the label restrictions indicated in section 3.5 are taken into account.

Protective clothing is always recommended; in addition protective gloves/eye protection/face protection for all tasks due to the hazardous properties of the product.

3.5.3 Worker exposure

In order to obtain an acceptable risk assessment some refinements are applied.

DFR (Dislodgeable foliar residue) was assumed to be 3 µg a.s./cm² /kg a.s./ha. This is a default value and it is assumed as a worst-case scenario for the intended uses of Cymoxanil 45 WG. Whereas unacceptable risk were found using the default DT₅₀ value of 30 days, for the risk assessment refinement, a “DT50”

(50% Dissipation Time) of 1 day was estimated based on experimental residue data obtained with residue and DFR trials and chosen as a worst-case assumption for the assessment.

Based on the calculations, the worker exposure for the intended GAP uses of IN002B1760 is below the limit of 100% AOEL if the label restrictions indicated in section 3.5 are taken into account.

3.5.4 Bystander and resident exposure

The calculations according to the EFSA model demonstrate that residents of any age are not at risk during and after application of IN002B1760 on potato in the field. The effects of cymoxanil are within the limits of 100% AOELs for all scenarios. A bystander risk assessment is not required for PPPs that do not have significant acute toxic effects or the potential to exert toxic effects after a single exposure.

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

The present application is intended for the authorisation of a new product containing cymoxanil, a solid formulation (WG) containing 45% of active ingredient.

3.6.1 Residues

Data were available to the applicant covering the requested use on potato. Potato is the major crop in northern Europe (EU Technical Guidelines Document SANTE/2019/12752). A minimum of eight trials are required. When the supervised residue trials show that the residue levels in plants or plant products are lower than the limit of quantification (LOQ), the number of independent trials may be reduced. The number of trials shall not be below the minimum of four per zone for major crops.

The intended GAP for cymoxanil for potato in Central Europe is 6x148.5 g a.s./ha with interval between applications of 5-10 days at BBCH 12-95 with PHI of 7 days.

New study on the magnitude of residue has been submitted by the Applicant in the framework of this application.

A total of 4 supervised residue trials on potato were performed in Northern Europe during 2007/2008.

1. Semrau; 2010, Report no.: 20074095/E1-FPPO - six applications, separated by a 4-6 days interval were made at 120 g ai/ha for cymoxanil. The actual application rate tested in residue trials was no less than ± 25 % of the intended maximum application rate.

The trials are supported by valid storage stability data and validated analytical methods.

Results:

In all trials no residues of cymoxanil were found in the treated and untreated field specimens of potato tubers above the limit of detection (0.003 mg/kg).

The residues arising from the proposed use will not exceed the MRL established for cymoxanil for potato of 0.01* mg/kg in Reg. (EU) 2022/1363.

The use is considered acceptable.

As residues of cymoxanil do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Conclusions

Data are available by the applicant supporting the intended use on potatoes. For potatoes, a situation of

non-residues is evidenced.

The data submitted show that no exceedance of the MRL will occur and the proposed use is considered acceptable.

3.6.2 Consumer exposure

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo rev.3.1). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population (EFSA, 2018).

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see section 7.1.2).

Current MRL values for cymoxanil according to the Reg. (EU) 2022/1363 have been taken into account as input values for the chronic assessment. For acute risk assessment, a refined assessment is presented, using the HR in potatoes and MRLs for animal commodities.

All MRLs for cymoxanil are based on the residue definition for monitoring/enforcement of parent cymoxanil only, which is also the residue definition for risk assessment. No Conversion Factor is required to account for the residue definitions, and no processing factors are required.

Long-term consumer intake concerns were not identified for any of the European diets incorporated in the EFSA PRIMo 3.1. The total calculated intake accounted for up to 21% of the ADI (based on GEMS/Food G06), see the following table.

TMDI (% ADI) according to EFSA PRIMo rev 3.1	21% (based on GEMS/Food G06) 1 st contributor: tomatoes 11% 2 nd contributor: watermelons 3% 3 rd contributor: melons 1%
IEDI (% ADI) according to EFSA PRIMo rev 3.1	Not necessary
IESTI (% ARfD) according to EFSA PRIMo rev 3.1	<u>Children</u> Primary commodities: Potatoes 2% Processed commodities: Potatoes / fried 1% <u>Adults</u> Primary commodities: Potatoes 0.05 0.4% Processed commodities: Potatoes / chips 0.1%
NTMDI (% ADI) **	Not necessary
NEDI (% ADI) **	Not necessary
NESTI (% ARfD) **	Not necessary

An acute consumer risk was not identified for consumption of potatoes. The acute consumer exposure was calculated to be 2% of the ARfD when potatoes is consumed by children and 0.05 0.4% of the ARfD by adult.

The chronic and the short-term intakes of cymoxanil residues are unlikely to present a public health concern.

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

Appropriate endpoints from the EU review and from Indofil studies were used to calculate PEC for active substance cymoxanil and its metabolites in soil, surface water and groundwater for the intended use patterns.

Active substance and metabolites considered in the assessment.

Code number/name	Relevant compartments
Cymoxanil	Soil, groundwater, surface water
IN-U3204 1-ethyl-6-iminodihydropyrimidine-	Soil, groundwater, surface water

Code number/name	Relevant compartments
2,4,5(3H)-trione 5-(O-methyloxime)	
IN-W3595 Cyano(methoxyimino)acetic acid	Soil, groundwater, surface water
IN-JX915 3-ethyl-4-(methoxyamino)-2,5-dioximidazolidine-4-carbonitrile	Soil, groundwater, surface water
IN-KQ960 3-ethyl-4-(methoxyamino)-2,5-dioximidazolidine-4-carboxamide	Groundwater, surface water
IN-T4226 1-ethylimidazolidine-2,4,5-trione	Surface water
IN-R3273 1-ethylimidazolidine-2,4,5-trione 5-(O-methyloxime)	Surface water
IN-KP533 {[(ethylamino)carbonyl]amino}(oxo)acetic acid	Surface water
M5 N-(aminocarbonyl)-2-(methoxyimino)malonamide	Surface water

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

Soil exposure for cymoxanil and its metabolites was calculated using approach described in respective FOCUS guidance for the intended uses of IN002B1760. For all compounds, EU agreed data were taken into account. Soil exposure for the formulated product was also calculated. The results for PEC_{soil} for the active substance and its metabolites were used for the ecotoxicological risk assessment.

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

The leaching behaviour of cymoxanil and its metabolites was assessed using FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5 on the basis of the EU agreed input parameters and intended use pattern of IN002B1760. Performed calculations resulted with PEC_{GW} for cymoxanil and metabolites IN-U3204, IN-JX915 and IN-W3596 with values below 0.1 µg/L in all relevant Polish scenarios following early and late application to potato. PEC_{GW} for metabolite IN-KQ960 were above >0.1 µg/L in almost all scenarios following late application in potato. As metabolite IN-KQ960 is toxicologically relevant, its concentrations must remain <0.1 µg/L. Further assessment for metabolite IN-KQ960 was conducted at Tier 2 based on data from DRAR Vol. 3CA and CP, B.8, January 2022 as a part of the confirmatory data for cymoxanil evaluated and agreed by the RMS (LT). On the basis of the obtained results at Tier 2 metabolite IN-KQ960 is not expected to migrate to groundwater at concentrations exceeding 0.1 µg/L following application of IN002B1760 to potato.

Overall, based on the performed evaluation no unacceptable risk to groundwater from cymoxanil and its metabolites is expected following the intended uses of IN002B1760.

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

The surface water modelling was performed for the intended use pattern of IN002B1760 in line with recommendations of respective FOCUS guidance documents using most up-to-date versions of the models. FOCUS Step 1-2 in calculations were conducted for cymoxanil and its metabolites. No further assessment at Step 3 and 4 was required for parent or for metabolites.

Obtained PEC_{SW/SED} values were used in the risk assessment for aquatic organisms.

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

The vapour pressure at 20°C of the active substance cymoxanil is between 10^{-5} and 10^{-4} Pa. Hence the active substance cymoxanil is regarded as slightly volatile, indicating that significant losses due to volatilization would not be expected. Calculations using the method of Atkinson for indirect photooxidation in the atmosphere through reaction with hydroxyl radicals resulted in an atmospheric half-life estimated at 21.3 hours (assuming an atmospheric hydroxyl radical concentration of 1.5×10^6 radicals cm^{-3}) indicating the small proportion of applied cymoxanil that will volatilize would be unlikely to be subject to long range atmospheric transport. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance cymoxanil due to volatilization with subsequent deposition should not be considered.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

The results of the acute risk assessments indicate acceptable risk to birds and mammals with TER values well above the trigger already at the screening step. For potatoes, the results of the long-term Tier-1 assessment showed acceptable risk for all the representative species and scenarios except for small herbivorous mammal “vole” and large herbivorous mammal “lagomorph”.

Nevertheless, a higher tier risk assessment has been provided in order to demonstrate that IN002B1760 poses a low risk to these focal species when applied according to the proposed used pattern. For voles, considering, the refined PD, DT₅₀ for cymoxanil and updated deposition factors (calculated up to BBCH 89), no unacceptable risk is concluded for proposed uses (12-95 BBCH) in potatoes for PL registration of the product.

For the long-term risk assessment of large herbivorous mammal “lagomorph” in treated potato fields, updated parameters such as DT₅₀, MAF and ftwa values have been also considered.

Overall, all the TER_{it} values exceed the trigger of 5, demonstrating that no unacceptable risk is expected due to the contamination of food items from spray application of IN002B1760.

No risk to birds and mammals is expected either following assumption of drinking water or via secondary poisoning.

It is possible to conclude that the exposure to cymoxanil following application of IN002B1760 according to the proposed use pattern doesn't pose unacceptable risks to birds and mammals.

During the EU evaluation of cymoxanil, no concern was identified for amphibians and reptiles. Considering that no harmonised test guidelines and risk assessment schemes are available to address this data point more thoroughly and in a consistent manner, no further action is deemed to be required.

3.8.2 Effects on aquatic species

For potato, the PEC/RAC ratios, using worst-case PEC_{SW} values for cymoxanil and its relevant metabolites are less than the trigger value of 1, indicating that the risk to aquatic organisms is acceptable and no mitigation measure is required.

3.8.3 Effects on bees

The result of the acute HQ calculation shows values well below the trigger, thus providing a wide safety margin to take into account any possible effect related to the formulation. In the same time chronic studies for ~~risk assessment for adult bees and larvae from~~ formulation IN002B1760 have been submitted by the Applicant according to EU Reg. 284/2009. ~~can be concluded.~~

3.8.4 Effects on other arthropod species other than bees

The quantitative risk assessment has been performed on the basis of the endpoints of IN002B1760 and was considered acceptable for population of non-target arthropods living in the in-field and off-field areas, and no mitigation measure is required.

3.8.5 Effects on soil organisms

The TER_{LT} values are above trigger of 5, demonstrating that no unacceptable long-term risk is expected following the application of IN002B1760 according to the proposed use pattern.

The risk to soil micro-organisms was evaluated by comparison of the maximum cymoxanil concentrations with effects $\leq 25\%$ derived from laboratory tests, with the highest PEC_{soil}. The effect levels exceeded the relevant PEC_{soil} values, indicating that no unacceptable risk to soil micro-organisms is expected following the applications of IN002B1760 according to the proposed use pattern.

3.8.6 Effects on non-target terrestrial plants

No unacceptable risk to non-target terrestrial plants in off-crop areas is expected following the use of IN002B1760 according to the proposed use pattern.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Potential risks to terrestrial organisms have been assessed considering a broad range of species. Further testing is not deemed to be required.

3.9 Relevance of metabolites (Part B, Section 10)

According to EFSA 2008, no information is available on the toxicological relevance of metabolite IN-W3595, because it is not needed. No groundwater relevance assessment was demanded. Only parent compound and IN-KQ960 were identified as toxicologically relevant compounds. IN-W3595 is not a toxicologically relevant compound, so 0.75 µg/L could be considered the threshold value for groundwater. Furthermore, only a few results are > 0.1 µg/L. Among these, it has to be considered that Jokioinen scenario is not relevant for the application in Southern Zone Member States. The slight exceedance found in Hamburg scenario under alkaline conditions is only theoretical and it is not expected to be found in practice, as the pH conditions associated with Hamburg scenario are acidic (pH 5.7, according to FOCUS 2002).

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

Cymoxanil is not a candidate for substitution active substance. Comparative assessment is therefore not required for IN002B1760.

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

~~None.~~

Analytical methods:

Noticed data gaps are:

- ILV for drinking or ground water,
- fully validated method for the determination of cymoxanil in body fluids and tissues,
- new analytical method for the determination of residues of cymoxanil in soil,
- analytical methods for monitoring/enforcement purposes for food and feed of plant origin required for all matrix types with LOQ of 0.01* mg/kg.

zRMS-PL considers that these data gaps are anticipated to be addressed at active substance level in context with the renewal of cymoxanil and will be subject of the art.43 re-authorisation process for the product.

Appendix 1 Copy of the product authorization

Appendix 2 Copy of the product label

Komentarz oceniających:

Etykieta została sprawdzona w zakresie fizykochemii, metod analitycznych, toksykologii i istotności toksykologicznej metabolitów, pozostałości, losu i zachowania, ekotoksykologii oraz skuteczności. Zmiany wynikające z oceny wprowadzono do poniższej etykiety w widoczny sposób, poprzez zaznaczenie ich szarym podświetleniem tekstu (fragmenty dodane) lub przekreśleniem i jasno szarą czeionką (fragmenty usunięte).

Zakres zmian jest następujący:

Z projektu etykiety zostało wykreślone zastosowanie w pomidorze i bakłażanie. Polska jako zRMS strefowy została wyznaczona do oceny wniosku tylko w zakresie zastosowania na ziemniaku uprawianym na polu. Ocena międzystrefowa zastosowań szklarniowych została zlecona zRMS Malta.

Sekcja właściwości fizykochemiczne:

1. Środek nie wykazuje właściwości wybuchowych i utleniających, znakowanie środka wynikające z wyżej wymienionych właściwości fizykochemicznych zgodne z zapisami Rozporządzenia Parlamentu Europejskiego i Rady (WE) NR 1272/2008 z dnia 16 grudnia 2008 r. nie jest wymagane.
2. Okres ważności: 2 lata na podstawie zaakceptowanych 2-letnich badań stabilności środka ochrony roślin przechowywanego w torebkach/woreczkach polietylenowych. Trwają 2 letnie badania stabilności. Można uznać warunkowo 2 letni okres przechowywania środka ochrony roślin w torebkach/woreczkach polietylenowych na podstawie zaakceptowanego 2 tygodniowego badania przyspieszonego starzenia w temperaturę 54°C. W związku z powyższym, wszystkie opakowania wymienione, w punktach 2.1 dokumentu A i 4.1 Sekcji 1,2,4 można uznać za odpowiednie do celów transportu i magazynowania środka ochrony roślin.
3. Brak uwag do punktów dotyczących warunków przechowywania i bezpiecznego usuwania środka ochrony roślin i opakowania oraz sporządzania cieczy użytkowej.
4. Brak uwag do zapisu nazwy substancji czynnej i jej zawartości.
5. Zgodnie z informacjami zawartymi w punktach IIIA 2.9.1 i IIIA 2.9.2 Sekcji 1.2.4 Raportu Rejestracyjnego środek nie jest dedykowany do łącznego stosowania. Cymoxanil 45 WG został przetestowany w mieszance zbiornikowej ze środkami ochrony roślin: Enervin SC, Pergado SC, Ranman Top, Nando Maxi, Folpan 80 WDG, R6 Erresei Bordeaux WG, Orondis, Aliette, Copperfield 17 WG, Zoxium 240 SC, Ossiclor 50 PB Manica, Polyram DF, Century SL, R6 Erresei Albis, Previter. Zgodnie z zapisami wytycznej ASTM E-1518-5 wszystkie badane kombinacje uznaje się za kompatybilne.

Sekcja skuteczność:

1. Na podstawie danych przedłożonych przez wnioskodawcę możliwa jest rejestracja środka Cymofil do ochrony ziemniaka przed zarzą ziemniaka w zakresie sekcji skuteczność.
2. W sumie przedłożono 4 badania prowadzone w Polsce. Dodatkowo dla wsparcia rejestracji uwzględniono 4 badania prowadzone w krajach sąsiednich (Niemczech i Czechach). Biorąc pod uwagę wszystkie wyniki dostępnych badań w opinii eksperta uzasadniona jest dawka środka Cymofil 0,33 kg/ha. Środek wykazywał średni poziom ochrony przed patogenem przy niskim nasileniu choroby. W przypadku badań prowadzonych w Polsce skuteczność dawek 0,25 i 0,33 kg/ha była podobna, niemniej jednak różnice zaobserwowano w badaniach wspierających z krajów sąsiednich. Względnie wyższą skuteczność wykazywała dawka 0,33 kg/ha. Z uwagi na fakt, że środek działał na średnim poziomie przy niewielkim nasileniu patogena, w etykiecie należy zaznaczyć, że przeznaczony jest on zarówno do zapobiegawczego jak i interwencyjnego zastosowania. W oparciu o cały dostępny zestaw badań (2021 i 2023) uznano, że środek jest skuteczny w początkowej fazie infekcji, gdy nasilenie patogenu nie przekracza 20%. Powyżej tego progu odnotowano średni poziom skuteczności, co widoczne było zarówno w badaniach krajowych jak i z krajów sąsiednich (Niemcy, Czechy). Wyższa skuteczność środka w początkowej fazie infekcji argumentuje zasadność zapisu o jego zapobiegawczym działaniu. Ponadto, w dodatkowych badaniach (2023) zaobserwować można było porównywalny poziom skuteczności obu wnioskowanych dawek 0,25 kg/ha i 0,33 kg/ha, co pozwala na ich akceptację względem pierwotnej oceny.
3. Usunięto zapis o wyłącznym stosowaniu środka w mieszaninie ze środkiem grzybobójczym o działaniu powierzchniowym (kontaktowym) w części dotyczącej zakresu stosowania środka z uwagi na to, że przedmiotem wniosku jest pojedyncze zastosowanie środka. Wnioskodawca nie przedstawił stosownych badań dla potwierdzenia skuteczności mieszanin. Zalecenie łącznego stosowania środka w mieszaninach zbiornikowych z innymi fungicydami o innych mechanizmach działania zgodnie z rekomendacją FRAC, może być wskazane jako jedno z narzędzi strategii antyodpornościowej. Zmodyfikowano zapisy dla strategii zarządzania odpornością.
4. Uzupełniono zapis o terminie stosowania środka.
5. Zmieniono zalecaną ilość wody.

Sekcja metody analityczne:

1. Brak uwag.

Sekcja toksykologia i istotność toksykologiczna metabolitów:

1. W części dotyczącej klasyfikacji zagrożeń wprowadzono zwrot P201 oraz P305 + P351 + P338. Zwrot P308+P313 został wykreślony ze względu na to że jest powtórzony w cz. Pierwsza pomoc
2. W części dotyczącej środków ostrożności dla osób stosujących środek odpowiedni zapis zmodyfikowano zgodnie z wymaganiami harmonizacyjnymi dotyczącymi oceny właściwości toksykologicznych oraz szacowania NDE (Min Rol RW wersja 26 10 2021).

Sekcja pozostałości:

1. Wprowadzono zapis do etykiety dotyczący roślin następczych: „Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie: nie ma ograniczeń co do okresu od ostatniego zastosowania środka do dnia, w którym można siać lub sadzić rośliny uprawiane następnie.”

Sekcja los i zachowanie w środowisku:

1. Brak uwag.

Sekcja ekotoksykologia:

1. Usunięto zwrot P 273.

Posiadacz zezwolenia:

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

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:

.....

Podmiot odpowiedzialny za końcowe etykietowanie środka ochrony roślin:

.....


Cymofil

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

cymoksanil (substancja z grupy iminoacetylomoczników) - 450 g/l (45%)

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

	
Uwaga	
H302	Działa szkodliwie po połknięciu.
H317	Może powodować reakcję alergiczną skóry.
H319	Działa drażniąco na oczy.
H361fd	Podejrzewa się, że działa szkodliwie na płodność. Podejrzewa się, że działa szkodliwie na dziecko w łonie matki.
H373	Może powodować uszkodzenie narządów (krew i grasica) poprzez długotrwałe lub narażenie powtarzane.
H410	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.

EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P201 P260 P273 P280 P308+P313 P305 + P351 + P338 P391 P501	Przed użyciem zapoznać się ze specjalnymi środkami ostrożności. Nie wdychać pyłu. Unikać uwolnienia do środowiska. Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy. W przypadku narażenia lub stężności: Zasięgnąć porady/zgłosić się pod opiekę lekarza. W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Kontynuować płukanie. Zebrać wyciek. Zawartość/pojemnik usuwać zgodnie z przepisami o substancjach niebezpiecznych.

OPIS DZIAŁANIA

FUNGICYD w postaci granul do sporządzania zawiesiny wodnej (WG). Środek o działaniu wgłębnym do stosowania **prewencyjnego oraz** interwencyjnego w ochronie przed chorobami grzybowymi.

Zgodnie z klasyfikacją FRAC substancja czynna cymoksanil zaliczana jest do grupy 27.

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieźnych lub ciągnikowych opryskiwaczy polowych oraz opryskiwaczy ręcznych.

Ziemniak

Zaraza ziemniaka

Maksymalna ~~Zalecana~~ dawka dla jednorazowego zastosowania: 0,33 kg/ha.

Zalecana dawka dla jednorazowego zastosowania: 0,25 - 0,33 kg/ha.

Termin stosowania: **Środek stosować zapobiegawczo lub bezpośrednio po zauważeniu pierwszych objawów**, od fazy rozwiniętego drugiego liścia na głównym pędzie (>4 cm), do fazy, gdy 50% liści brązowieje (BBCH 12-95).

Środek wykazuje średni poziom ochrony ziemniaka przed zarazą przy wysokim nasileniu patogenu.

~~Środek stosować wyłącznie w mieszaniu ze środkiem grzybobójczym o działaniu powierzchniowym (kontaktowym).~~

~~Środek o działaniu powierzchniowym należy zastosować w dawce zalecanej.~~

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 6.

Odstęp między zabiegami: 5-10 dni.

Zalecana ilość wody: 300-~~1000~~ **500** l/ha.

Zalecane opryskiwanie: drobnokropliste.

~~Pomidor, bakłażan (w uprawie szklarniowej)~~

~~Zaraza ziemniaka~~

~~Maksymalna dawka dla jednorazowego zastosowania: 0,33 kg/ha.~~

~~Zalecana dawka dla jednorazowego zastosowania: 0,25 – 0,33 kg/ha.~~

~~Termin stosowania: Środek stosować od fazy rozwiniętego drugiego liścia właściwego na pędzie głównym, do fazy pełnej dojrzałości, gdy owoce mają typową barwę (BBCH 12–89).~~

~~Środek stosować wyłącznie w mieszaniu ze środkiem grzybobójczym o działaniu powierzchniowym (kontaktowym).~~

~~Środek o działaniu powierzchniowym należy zastosować w dawce zalecanej.~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 5.~~

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

~~Zalecana ilość wody: 600-1500 l/ha.~~

~~Zalecane opryskiwanie: drobnokropliste.~~

ŚRODKI OSTROŻNOŚCI I SZCZEGÓLNE WARUNKI STOSOWANIA

Wielokrotne stosowanie środków grzybobójczych zawierających substancje czynne o tym samym mechanizmie działania może przyczynić się do wyselekcjonowania w populacji sprawcy choroby form odpornych i w konsekwencji do obniżenia skuteczności zabiegów

Z tego też względu w ramach strategii antyodpornościowej zaleca się:

- włączenie do programu ochrony środków zawierających substancje czynne o różnych mechanizmach działania,
- ~~stosowanie środka wyłącznie w mieszaniu ze środkiem grzybobójczym o działaniu kontaktowym (powierzchniowym)~~ środek stosować w mieszaninach ze środkami zawierającymi substancje czynne o innym mechanizmie działania, przeznaczonymi do zwalczania tych samych patogenów oraz w dawkach zapewniających pełną ochronę przed chorobami grzybowymi,
- wybór środków zawierających substancję czynną cymoksanil do maksymalnie połowy przewidzianych w sezonie zabiegów.

OKRESY KARENCJI

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

~~pomidor, bakłażan – 3 dni;~~

ziemniaki - 7 dni.

Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie: nie ma ograniczeń co do okresu od ostatniego zastosowania środka do dnia, w którym można siać lub sadzić rośliny uprawiane następnie.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka (Odważoną ilość środka wymieszać w osobnym naczyniu z małą ilością wody, następnie wlać przez sito) dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlewniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać.

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

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy:

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

Po pracy aparaturę dokładnie wymyć.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

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

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

Nie wdychać pyłu.

~~Stosować rękawice ochronne, ochronę oczu lub ochronę twarzy oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.~~

Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież ochronną zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):
nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

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

Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 1 m od zbiorników i cieków wodnych.

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

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0°C - 30°C.

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

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

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

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

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

W przypadku narażenia lub styczości: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

Not necessary.

Appendix 4 Lists of data considered for national authorization

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 2.2.1	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 2.2.2	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 2.3.2	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 2.3.3	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 2.4.2	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Unpublished				
KCP 2.6.2	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 2.7.1	Rigamonti, E	2021b	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Accelerated Storage Stability and Corrosion Characteristics Company Report No: CH-0527/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 2.7.3	Rigamonti, E	2021b	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Accelerated Storage Stability and Corrosion Characteristics Company Report No: CH-0527/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 2.7.5	Rigamonti, E	2023	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Two Years Storage Stability and Corrosion Characteristics Company Report CH – 0528/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 2.8.1	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 2.8.2	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 2.8.3.1	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the	N	Y	Study report never submitted before	Indofil

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
			Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished				Industries (Netherlands) B.V.
KCP 2.8.3.2	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 2.8.5.1.1	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 2.8.5.1.2	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 2.8.5.2.1	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 2.8.5.3	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche GLP Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 2.8.7.1	Rigamonti, E	2021a	Title: Cymoxanil 45 WG (IN 002B1760): Determination of the Physico-chemical Properties Company Report No: CH-0525/2021 Source: ChemService S.r.l. Controlli e Ricerche	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Unpublished				
KCP 2.9.1	Longhi, D.	2023	Title: Compatibility test of IN002B1760 (Cymoxanil 45WG) Company Report No: LBN-0124-2023 Source: LabAnalysis s.r.l. GLP Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 2.9.2	Longhi, D.	2023	Title: Compatibility test of IN002B1760 (Cymoxanil 45WG) Company Report No: LBN-0124-2023 Source: LabAnalysis s.r.l. GLP Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 2.11	Longhi, D.	2022	Title: IN002B1760 (Cymoxanil 45 WG): equipment cleaning procedure Company Report No: LBN-0065-2022, 02/12/2022 GLP Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 5.1.1_01	Rigamonti E.	2021	Cymoxanil 45 WG (IN 002B1760): Validation of the Analytical Method for the Determination of Active Ingredient Content Report N. CH-0526/2021 ChemService S.r.l. Controlli e Ricerche GLP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 5.1.2_01	Sala A.	2021a	Determination of cymoxanil in raw agricultural commodity tomato following five applications of the formulated product Cymoxanil 45 WG (Southern Europe – 2 open field trials year 2021) Report N. GLP-STUDY-21-58 LabAnalysis S.r.l. GLP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2_02	Sala A.	2021b	Determination of cymoxanil in raw agricultural commodity tomato following five applications of the formulated product Cymoxanil 45 WG in protected condition (Southern Europe – 2 greenhouse trial year 2021) Report N. GLP-STUDY-21-59 LabAnalysis S.r.l. GLP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 5.1.2_03a	Garagna D.	2021a	Validation of the Analytical Method for the Determination of Cymoxanil content in stock solutions of Cymoxanil 45 WG (IN 002B1760) coming from the Ecotoxicological tests Report N. CH-0351/2021 ChemService S.r.l. Controlli e Ricerche GLP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 5.1.2_03b	Garagna D.	2021b	Amendment N.1 to final report Validation of the Analytical Method for the Determination of Cymoxanil content in stock solutions of Cymoxanil 45 WG (IN 002B1760) coming from the Ecotoxicological tests Report N. CH-0351/2021 ChemService S.r.l. Controlli e Ricerche GLP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 5.1.2_04a	Garagna D.	2021b	Validation of the Analytical Method for the Determination of Cymoxanil Content in Feeding Solutions of Cymoxanil 45 WG (IN 002B1760) coming from the Ecotoxicological tests Report N. CH-0352/2021 ChemService S.r.l. Controlli e Ricerche GLP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 5.1.2_04b	Garagna D.	2021c	Amendment N.1 to final report Validation of the Analytical Method for the Determination of Cymoxanil Content in Feeding Solutions of Cymoxanil 45 WG (IN 002B1760) coming from the Ecotoxicological tests Report N. CH-0352/2021 ChemService S.r.l. Controlli e Ricerche GLP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 5.1.2_05a	Garagna D.	2021c	Validation of the Analytical Method for the Determination of	N	Y	Study report never submitted before	Indofil

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
			Cymoxanil Content in Soil Sample of Cymoxanil 45 WG (IN 002B1760) coming from the Ecotoxicological tests Report N. CH-0353/2021 ChemService S.r.l. Controlli e Ricerche GLP: Yes Unpublished				Industries (Netherlands) B.V.
KCP 5.1.2/05b	Garagna D.	2021a	Amendment N.1 to final report Validation of the Analytical Method for the Determination of Cymoxanil Content in Soil Sample of Cymoxanil 45 WG (IN 002B1760) coming from the Ecotoxicological tests Report N. CH-0353/2021 ChemService S.r.l. Controlli e Ricerche GLP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 5.1.2/06a; KCP 10.2.1/04	Venkanna, B.	2023a	Analytical report for the fresh water algae growth inhibition test with Cymoxanil 45% WG Vivo Bio Tech LTD Report N: 23/0177 GLP Unpublished	N	Y	Study report never submitted before	Vivo Bio Tech LTD Indofil Industries Limited (Netherlands) B.V.
KCP 5.1.2/06b	Venkanna, B.	2023b	Validation of the analytical method for determination of cymoxanil active ingredient in Cymoxanil 45% WG for the fresh water algae growth inhibition test with Cymoxanil 45% WG Vivo Bio Tech LTD Report N: 23/0181 GLP Unpublished	N	Y	Study report never submitted before	Vivo Bio Tech LTD Indofil Industries Limited (Netherlands) B.V.
KCP 5.2/01	Pardo Martinez M.	2023	Independent Laboratory Validation (ILV) of the Analytical Method for the Determination of Cymoxanil in Tomato Report N. CH-0061-2023 ChemService S.r.l. Controlli e Ricerche GLP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.0-01	Anonymous	2021	Biological Assessment Dossier: IN002B1760 – EU Central Southern Zone - Unpublished	N	Y	Data never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.2-05	Guillaume	2021	Efficacy of cymoxanil against <i>Phytophthora infestans</i> in potato	N	Y	Study report never submitted before	Indofil

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
	Cardiet		ANADIAG SA, CZ osp. Trial ID: EU 21 280 CZ1 GEP: Yes Unpublished				Industries (Netherlands) B.V.
KCP 6.2-06	Guillaume Cardiet	2021	Efficacy of cymoxanil against <i>Phytophthora infestans</i> in potato ANADIAG SA, CZ osp. Trial ID: EU 21 280 CZ2 GEP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.2-07	Guillaume Cardiet	2021	Efficacy of cymoxanil against <i>Phytophthora infestans</i> in potato QUINTUS GmbH Trial ID: K-111-QUI-21-288 GEP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.2-08	Guillaume Cardiet	2021	Efficacy of cymoxanil against <i>Phytophthora infestans</i> in potato QUINTUS GmbH Trial ID: K-111-QUI-21-289 GEP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.2-13	Guillaume Cardiet	2021	Efficacy of cymoxanil against <i>Phytophthora infestans</i> in potato OAT Scotland Trial ID: 1362A-21-ANA GEP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.2-14	Guillaume Cardiet	2021	Efficacy of cymoxanil against <i>Phytophthora infestans</i> in potato OAT South West Trial ID: 1362B-21-ANA GEP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.2-01	Guillaume Cardiet	2021	Efficacy of cymoxanil against <i>Phytophthora infestans</i> in potato ANADIAG SAS Oddział w Polsce Trial ID: PL 21 061 PL1 GEP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.2-02	Guillaume Cardiet	2021	Efficacy of cymoxanil against <i>Phytophthora infestans</i> in potato ANADIAG SAS Oddział w Polsce Trial ID: PL 21 061 PL2 GEP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-03	Guillaume Cardiet	2021	Efficacy of cymoxanil against <i>Phytophthora infestans</i> in potato ANADIAG SAS Oddział w Polsce Trial ID: PL 21 061 PL3 GEP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.2-04	Guillaume Cardiet	2021	Efficacy of cymoxanil against <i>Phytophthora infestans</i> in potato ANADIAG SAS Oddział w Polsce Trial ID: PL 21 061 PL4 GEP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.2-27	Lenka Vašítková Štanclová	2023	Evaluation of efficacy of cymoxanil against <i>Phytophthora infestans</i> on potato in Czech Republic. Essais+ 11-GP2023-01 GEP Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.2-28	Kirsten Heitsch	2023	An evaluation of the efficacy of IN002B1760 against <i>Phytophthora infestans</i> on potato following sequential applications in Germany, the EPPO climatic zone Maritime in 2023 Essais+ CT23-4-73DE2 GEP Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.2-29	Radosław Ptaszek	2023	Evaluation of efficacy of cymoxanil against <i>Phytophthora infestans</i> on potato in Poland 2023 Green & Property Consulting 021GPSE202301 GPE Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.2-30	Anna Huszcza-Podgórska	2023	Evaluation of efficacy of cymoxanil against <i>Phytophthora infestans</i> on potato in Poland 2023 Green & Property Consulting 021GPSE202302 GPE Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.2-31	Anna Huszcza-Podgórska	2023	Evaluation of efficacy of cymoxanil against <i>Phytophthora infestans</i> on potato in Poland 2023. Green & Property Consulting 021GPSE202303	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP Unpublished				
KCP 6.2-10	Alessandro Spagnolo	2021	Efficacy of cymoxanil against <i>Phytophthora infestans</i> in potato ANADIAG SAS Trial ID: EU21280XA110 GEP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCA 6.3-01	Koenings, L.	2009	Determination of Cymoxanil and Mancozeb Residues in Wine Grapes Following Treatment with WP 4.5/68 or WP 4/46.5 under Open Field Conditions in Northern and Southern Europe, 2007 Doc. No. 632-4003 Anadiag Report no. R A7115 GLP, Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries (Netherlands) B.V.
KCA 6.3-02	Semrau J.	2010	Determination of Residues of Cymoxanil and Mancozeb After Six Applications Cymoxanil/Mancozeb 4.5/68 % w/w in Field Potatoes, Northern Europe, 2007/2008 Eurofins Report no.: 20074095/E1-FPPO Doc. No. 634-1105 GLP, Unpublished	N	N Y	Study report never submitted before in Poland	Indofil Industries Limited (Netherlands) B.V.
KCA 6.3-03	Semrau J.	2010	Determination of Residues of Cymoxanil and Mancozeb After Six Applications of Cymoxanil/Mancozeb 4.5/68 % w/w WP or Cymoxanil/Mancozeb 4/46.5 % w/w WP in Field Potatoes, Southern Europe, 2007/2008 Eurofins Report no.: 20074095/E2-FPPO Doc. No. 634-1106 GLP, Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries (Netherlands) B.V.
KCA 6.3-04	Sala A.	2021	Determination of cymoxanil in raw agricultural commodity tomato following five applications of the formulated product IN002B1760 (Southern Europe – 2 open field trials year 2021) Lab Analysis Report no.: GLP STUDY 21-58 GLP, Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries (Netherlands) B.V.
KCA 6.3-05	Sala A.	2021	Determination of cymoxanil in raw agricultural commodity tomato following five applications of the formulated product IN002B1760 (Southern Europe – 2 greenhouse trials year 2021) Lab Analysis Report no.: GLP STUDY 21-59 GLP, Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries (Netherlands) B.V.
KCP 7.3		2022	In vitro dermal absorption of cymoxanil from Indofil cymoxanil 45 WG using human split-thickness skin in a flow through diffusion system	N	Y	Study report never submitted before in Poland	Indofil Industries (Netherlands)

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			<div></div> GLP; Unpublished				B.V.
KCP 9.2.4.1/01	Tan, N. & Brands, C.	2009	DETERMINATION OF THE AEROBIC DEGRADATION ROUTE (IN ONE SOIL) AND RATE (IN THREE SOILS) OF CYMOXANIL NOTOX B.V., 's Hertogenbosch, The Netherlands Report No.: 487663 183528/A GLP, unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries (Netherlands) B.V.
KCP 9.2.4.1/02	Hardy, I.A.J. & Patel, M.	2009	KINETIC MODELLING ANALYSIS OF CYMOXANIL AND ITS METABOLITES FROM AEROBIC SOIL DEGRADATION; HYDROLYSIS AND WATER/ SEDIMENT STUDIES Battelle UK Ltd., Essex, United Kingdom Report No.: OZ/09/003 Not GLP, unpublished	N	N	-	Indofil industries Limited
KCP 9.2.4.1/03	Isacco, L.	2021	Predicted Environmental Concentration in groundwater (PEC _{gw}) following the use of cymoxanil containing product in various crops 2021-E001, Expedia MRCC S.r.l. Not GLP, unpublished	N	N	-	Indofil Industries (Netherlands) B.V.
KCP 10.2.1/01	<div></div>	2009a	Acute toxicity of Moximate 505 WP to Zebra fish (<i>Danio rerio</i>) in a 96 hour study under semi static exposure. <div></div> GLP Unpublished	Y	Y	Study report never submitted before in Poland	Indofil Industries Ltd.
KCP 10.2.1/02	Neri, M.C.	2009b	Acute toxicity of Moximate 505 WP to <i>Daphnia magna</i> in a 48-hour immobilisation test under semi static exposure. Report No. CH E 004510/2009 (Doc. No. 822-004) Test Facility: ChemService S.r.l. Via Fratelli Beltrami, 15, 20026 Novate Milanese (MI), Italy GLP Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.
KCP 10.2.1/03	Neri, M.C.	2009c	Toxicity of Moximate 505 WP to green algae <i>Pseudokirchneriella subcapitata</i> determined in a growth inhibition study. Report No. CH E 004510/2009 (Doc. No. 823-004) Test Facility: ChemService S.r.l. Via Fratelli Beltrami, 15, 20026 Novate Milanese (MI), Italy	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.

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
			GLP Unpublished				
KCP 10.2.1/04; KCP 5.1.2/06a	Venkanna, B.	2024	Fresh water Algae Growth Inhibition Test with Cymoxanil 45% WG. Report No. 23/0177 Test Facility: Vivo Bio Tech Limited. Survey # 349/A, Pregnapur Village – 502311, Gajwel Mandal, District - Siddipet, Telangana (India) GLP Unpublished	N ^Y	Y	Study report never submitted before in Poland	Indofil Industries Ltd.
KCP 10.3.1.1/01	Schmitzer, S.	2007	Effects of Cymoxanil Technical (Acute Contact and Oral) on Honey Bees (<i>Apis mellifera</i> L.) in the Laboratory (Limit Test). Report No. 36571035 Test Facility: Institut für Biologische Analytik und Consulting IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany GLP Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.
KCP 10.3.1.1/02	Colli, M.	2009a	Effects, acute oral and acute contact toxicity of Moximate 505 WP on the honeybee <i>Apis mellifera</i> L. in the laboratory (dose response test). Report No. BT013/09 (Doc. No. 832-004) Test Facility: BIOTECNOLOGIE BT S.r.l., Fraz. Pantalla, 06050 Todi (PG), Italy GLP Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.
KCP 10.3.1.2/01	Ponti, B.	2021	Cymoxanil 45 WG (IN 002B1760): Chronic Oral Toxicity to adult worker honeybees <i>Apis mellifera</i> L. (10-day feeding). Report No. CH-0257/2021 Test Facility: ChemService S.r.l. Via Fratelli Beltrami, 15, 20026 Novate Milanese (MI), Italy GLP Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.
KCP 10.3.1.3/01	Noè, F.	2022	Cymoxanil 45 WG (IN 002B1760): Honey bees (<i>Apis mellifera</i> L.) Larval Toxicity Test with Repeated Exposure. Report No. CH-0258/2021 Test Facility: ChemService S.r.l. Via Fratelli Beltrami, 15, 20026 Novate Milanese (MI), Italy GLP Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.

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KCP 10.3.1.3/01a	Noè, F.	2022	STUDY PLAN AMENDMENT No. 1 to the report “Cymoxanil 45 WG (IN 002B1760): Honey bees (<i>Apis mellifera</i> L.) Larval Toxicity Test with Repeated Exposure.” Report No. Study Plan Amendment No. 1 CH–0258/2021 Test Facility: ChemService S.r.l. Via Fratelli Beltrami, 15, 20026 Novate Milanese (MI), Italy GLP Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.
KCP 10.3.2.1/01	Moll, M.	2008a	Effects of Cymoxanil 45 WG on the Parasitoid <i>Aphidius rhopalosiphi</i> in the Laboratory - Dose Response Test. Report No. 39701001 Test Facility: Institut für Biologische Analytik und Consulting IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany GLP Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.
KCP 10.3.2.1/02	Moll, M.	2008b	Effects of Cymoxanil 45 WG on the Predatory Mite <i>Typhlodromus pyri</i> in the Laboratory - Dose Response Test. Report No. 39702063 Test Facility: Institut für Biologische Analytik und Consulting IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany GLP Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.
KCP 10.3.2.2/01	Schmitzer, S.	2008	Effects of Cymoxanil 45 WG on the Carabid Beetle <i>Poecilus cupreus</i> L. - Extended Laboratory Study. Report No. 39703007 Test Facility: Institut für Biologische Analytik und Consulting IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany GLP Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.
KCP 10.3.2.2/02	Moll, M.	2008c	Effects of Cymoxanil 45 WG on the Lacewing <i>Chrysoperla carnea</i> under Extended Laboratory Conditions. Report No. 39704047 Test Facility: Institut für Biologische Analytik und Consulting IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany GLP Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.
KCP 10.3.2.2/03	Colli, M.	2009b	Effects of Moximate 505 WP on the predatory mite <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) under extended laboratory conditions (rate response test).	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.

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			Report No. BT039/09 (Doc. No. 834 006) Test Facility: BIOTECNOLOGIE BT S.r.l., Fraz. Pantalla, 06050 Todi (PG), Italy GLP Unpublished				
KCP 10.3.2.2/04	Colli, M.	2009e	Effects of Moximate 505 WP on the aphid parasitoid <i>Aphidius rhopalosiphi</i> De Stefani Perez (Hymenoptera, Braconidae) under extended laboratory conditions (rate response test). Report No. BT034/09 (Doc. No. 834 003) Test Facility: BIOTECNOLOGIE BT S.r.l., Fraz. Pantalla, 06050 Todi (PG), Italy GLP Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.
KCP 10.3.2.2/05	Colli, M.	2009d	Effect toxicity evaluation of Moximate 505 WP on the <i>Chrysoperla carnea</i> L. (Neuroptera, Chrysopidae) under extended laboratory conditions (rate response test). Report No. BT033/09 (Doc. No. 834 004) Test Facility: BIOTECNOLOGIE BT S.r.l., Fraz. Pantalla, 06050 Todi (PG), Italy GLP Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.
KCP 10.3.2.2/06	Colli, M.	2010	Effect of Moximate 505 WP on the plant dwelling insect <i>Coccinella septempunctata</i> L. (Coleoptera, Coccinellidae) under extended laboratory conditions (rate response test). Report No. BT032/09 (Doc. No. 834 005) Test Facility: BIOTECNOLOGIE BT S.r.l., Fraz. Pantalla, 06050 Todi (PG), Italy GLP, Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.
KCP 10.3.2.2/07	Rosenkranz, B. & Wirzinger, G.	2011	Statistical re-evaluation of effects of Moximate 505 WP on <i>Aphidius rhopalosiphi</i> and <i>Eisenia fetida</i> . Report No. not indicated (Doc. No.: 882 002) Test Facility: Scientific Consulting Company, Bad Kreuznach, Germany Not GLP, Unpublished	N	N	-	Indofil Industries Ltd.
KCP 10.3.2.4/01	Rosenkranz, B. & Schabio, S.	2009	Effects of Cymbal 45 WG on Predatory Mites (<i>Acari, Phytoseiidae</i>) under Field Conditions in Vine (4 Applications) Report No. 39706064 Test Facility: Institut für Biologische Analytik und Consulting IBACON GmbH, Industriestrasse 1, 64380 Rossdorf, Germany	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.

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			GLP Unpublished				
KCP 10.4.1.1/01	Dini, R.	2022a	Cymoxanil 45 WG (IN 002B1760): Effects on Reproduction of Earthworm <i>Eisenia fetida</i> in an Artificial Soil Study. Report No. CH-0259/2021 Test Facility: ChemService S.r.l. Via Fratelli Beltrami, 15, 20026 Novate Milanese (MI), Italy GLP Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.
KCP 10.4.2.1/01	Dini, R.	2022b	Cymoxanil 45 WG (IN 002B1760): Effects on Collembolan Reproduction in an Artificial Soil Study. Report No. CH-0260/2021 Test Facility: ChemService S.r.l. Via Fratelli Beltrami, 15, 20026 Novate Milanese (MI), Italy GLP Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.
KCP 10.4.2.1/02	Dini, R.	2022c	Cymoxanil 45 WG (IN 002B1760): Effects on <i>Hypoaspis (Geolaelaps) aculeifer</i> Reproduction in an Artificial Soil Study. Report No. CH-0261/2021 Test Facility: ChemService S.r.l. Via Fratelli Beltrami, 15, 20026 Novate Milanese (MI), Italy GLP Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.
KCP 10.5.1/01	Feil, N.	2008	Effects of Cymoxanil technical on the Activity of the Soil Microflora in the Laboratory. Report No. 41382080 Test Facility: Institut für Biologische Analytik und Consulting IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany GLP Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.
KCP 10.6.2/01	Bützler, R. & Meinerling, M.	2008	Effects of Cymoxanil 45 WG on Terrestrial (Non-Target) Plants: Vegetative Vigour Test. Report No. 39709087 Test Facility: Institut für Biologische Analytik und Consulting IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany GLP Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.
KCP 10.6.2/02	Noè, F.	2022	Cymoxanil 45 WG (IN 002B1760): Seedling Emergence and Seedling Growth Test of Terrestrial Plants.	N	Y	Study report never submitted before in Poland	Indofil Industries

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			Report No. CH-0262/2021 Test Facility: ChemService S.r.l. Via Fratelli Beltrami, 15, 20026 Novate Milanese (MI), Italy GLP Unpublished				Ltd.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 4.2.1/01	Kretschmer S., Class T.	1999	Method assessment and validation of an analytical multi-residue enforcement method (DFG S19 modified) for the determination of residues of cymoxanil in plant material (grape, potato, tomato, hops cones, post-cured tobacco). PRTL Europe Report N.: Dupont-2158 GLP Unpublished	N	N	--	DuPont
KCA 4.2.1/02	Linkerhägner M.	1999	Independent laboratory validation (ILV) of a multi-residue enforcement method (DFG S19 modified) for the determination of cymoxanil in dry, high water and oily crops. Dr. Specht & Partner, Germany Report N.: DuPont-2946 GLP Unpublished	N	N	--	DuPont
KCA 4.2.1/05	Freschi G.	2001a	Validation of the analytical method for determination of residues of cymoxanil in lettuce (plant) SIPCAM S.p.A. Salerano sul Lambro, Italy Report N.: SIP1279 GLP Unpublished	N	N	--	Oxon
KCA 4.2.1/06	Freschi G.	2001b	Validation of the analytical method for determination of residues of cymoxanil in potato (tuber) SIPCAM S.p.A. Salerano sul Lambro, Italy Report N.: SIP1277 GLP Unpublished	N	N	--	Oxon
KCA 4.2.1/07	Wasser C.	2002	Validation of the analytical method for determination of residues of cymoxanil in specimens of tomato, grapes, potatoes and lettuce. Anadiag S.A. Haguenau, France Report N.: A0087 GLP Unpublished	N	N	--	Oxon
KCA 4.2.2/01	Melkebeke T.	2000a	Validation of the analytical method for determination of residues of cymoxanil in soil. Notox B.V., 's-Hertogenbosch, The Netherlands Report N.: 281802	N	N	--	Oxon

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			GLP Unpublished				
KCA 4.2.3/01	Cabusas M.E.Y.	1999	Analytical method for the determination of cymoxanil in drinking, ground and surface water using liquid chromatography with ultraviolet detection. DupPont Experimental Station Report N.: DuPont-2126 GLP Unpublished	N	N	--	DuPont
KCA 4.2.4/01	Melkebeke T.	2000b	Validation of the analytical method for determination of cymoxanil in air. Notox B.V., 's-Hertogenbosch, The Netherlands Report N.: 257805 GLP Unpublished	N	N	--	Oxon
KCA 5.1.2-06	Semrau J.	2010	Determination of Residues of Cymoxanil and Mancozeb After Six Applications Cymoxanil/Mancozeb 4.5/68 % w/w in Field Potatoes, Northern Europe, 2007/2008 Eurofins Report no.: 20074095/E1-FPPO Doc. No. 634-1105 GLP, Unpublished	N	N	--	Indofil Industries Limited IND
IIA, 8.1.1		1996	Cymoxanil Technical acute oral toxicity (LD ₅₀) to the bobwhite quail. GLP: Yes Published: No	Y	N	--	Oxon
IIIA, 10.1.1		2003	Avian toxicity study of Cymoxanil 50 WP oral toxicity in the Japanese quail – limit test according to SETAC guideline document. GLP: Yes Published: No	Y	N	--	Oxon
IIA, 8.1.2		1999	5-Day dietary toxicity study in mallard duck GLP: Yes Published: No	Y	N	--	Oxon
IIA, 8.1.3		1996b	DPX-T3217-113 (cymoxanil): A reproduction study with the mallard	Y	N	--	DuPont

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			(<i>Anas platyrhynchos</i>) GLP: Yes [REDACTED] Published: No				
IIA, 5.2.1	[REDACTED]	1992	Acute oral toxicity study with DPX-T3217-113 (Cymoxanil) in male and female rats [REDACTED] GLP not published	Y	N	--	DuPont
IIIA, 7.1.1	[REDACTED]	1995a	Cymoxanil 50 % WP: Acute oral toxicity study to the rat [REDACTED] GLP Unpublished	Y	N	--	Oxon
IIIA, 7.1.1	[REDACTED]	1997a	Acute oral toxicity study with DPX-KP481-25 50WG in male and female rats [REDACTED] GLP Unpublished	Y	N	--	DuPont
IIA, 5.6.2	[REDACTED]	1993	Developmental toxicity study of DPX-T3217-113 (cymoxanil) in rats [REDACTED] GLP Unpublished	Y	N	--	DuPont
IIA, 8.2.1	[REDACTED]	1993b	Static, acute, 96-hour LC ₅₀ of DPX-T3217-113 (cymoxanil) to bluegill sunfish, <i>Lepomis macrochirus</i> [REDACTED] GLP: Yes Published: No	Y	N	--	DuPont
IIA, 8.2.1	[REDACTED]	2002b	IN-U3204: Static-renewal, acute, 96-hour limit test to rainbow trout, <i>Oncorhynchus mykiss</i> [REDACTED] GLP: Yes Published: No	Y	N	--	DuPont

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IIA, 8.2.1	██████	2002b	IN-W3595: Static, acute, 96-hour limit test to rainbow trout, <i>Oncorhynchus mykiss</i> ██████ GLP: Yes Published: No	Y	N	--	DuPont
IIA, 8.2.1	██████	2002a	IN-KQ960: Static, acute, 96-hour limit test to rainbow trout, <i>Oncorhynchus mykiss</i> ██████ GLP: Yes Published: No	Y	N	--	DuPont
IIA, 8.2.1	██████	2002a	IN-T4226: Static-renewal, acute, 96-hour limit test to rainbow trout, <i>Oncorhynchus mykiss</i> ██████ GLP: Yes Published: No	Y	N	--	DuPont
IIIA, 10.2.1	██████	1999a	96-hour acute toxicity study in rainbow trout with Cymoxanil 50 % WP (semi-static) ██████ GLP: Yes Published: No	Y	N	--	Oxon
IIIA, 10.2.1	██████	1997a	DPX-KP481-25 50WG: Flow-through, acute, 96- hour LC50 to rainbow trout, <i>Oncorhynchus mykiss</i> ██████ GLP: Yes Published: No	Y	N	--	DuPont
IIA, 8.2.2.2	██████	1996	DPX-T3217-113 (Cymoxanil): Early life-stage toxicity to rainbow trout, <i>Oncorhynchus mykiss</i> ██████ GLP: Yes Published: No	Y	N	--	DuPont
IIA, 8.2.4	Baer, K.N.	1993c	Static, acute, 48-hour EC ₅₀ of DPX-T3217-113 (cymoxanil) to <i>Daphnia magna</i> DuPont Haskell Laboratory	N	N	--	DuPont

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			HLR 736-92 GLP: Yes Published: No				
IIA, 8.2.4	Samel, A.	2002c	IN-U3204: Static-renewal, acute, 48-hour EC ₅₀ to <i>Daphnia magna</i> DuPont Haskell Laboratory DuPont-9557 GLP: Yes Published: No	N	N	--	DuPont
IIA, 8.2.4	Boeri, R.L., Wyskiel, D.C., Ward, T.J.	2002d	IN-W3595: Acute, 48-hour EC ₅₀ to <i>Daphnia magna</i> T. R. Wilbury Laboratories, Inc. DuPont-9383 GLP: Yes Published: No	N	N	--	DuPont
IIA, 8.2.4	Samel, A.	2002d	IN-KQ960: Static, acute, 48-hour EC ₅₀ to <i>Daphnia magna</i> DuPont Haskell Laboratory DuPont-9559 GLP: Yes Published: No	N	N	--	DuPont
IIA, 8.2.4	Boeri, R.L., Wyskiel, D.C., Ward, T.J.	2002c	IN-T4226: Acute, 48-hour EC ₅₀ to <i>Daphnia magna</i> T. R. Wilbury Laboratories, Inc. DuPont-9385 GLP: Yes Published: No	N	N	--	DuPont
IIIA, 10.2.1	Migchielsen, M.H.J.	1999	Acute toxicity study in <i>Daphnia magna</i> with Cymoxanil 50 % WP (semi-static) NOTOX B.V., The Netherlands Report 262439 GLP: Yes Published: No	N	N	--	Oxon
IIIA, 10.2.1	Brown, M.R.	1997b	DPX-KP481-25 50WG: Flow-through, acute, 48-hour EC ₅₀ to <i>Daphnia magna</i> DuPont Haskell Laboratory HL-1997-00437 GLP: Yes Published: No	N	N	--	DuPont
IIA, 8.2.5	Baer, K.N.	1993d	Chronic toxicity of DPX-T3217-113 (cymoxanil) to <i>Daphnia magna</i> : 24-Hour renewal DuPont Haskell Laboratory HLR 354-93, Revision No. 1	N	N	--	DuPont

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			GLP: Yes Published: No				
IIA, 8.2.5	Samel, A.	2003	IN-KQ960: 21-Day chronic toxicity to <i>Daphnia magna</i> DuPont Haskell Laboratory DuPont-11971 GLP: Yes Published: No	N	N	--	DuPont
IIA, 8.2.6	Hughes, J.S., Williams, T.L., Conder, L.A.	1996a	DPX-T3217-113 (cymoxanil): Influence on growth and reproduction of <i>Anabaena flos-aquae</i> Carolina Ecotox, Inc. AMR 4109-96 GLP: Yes Published: No	N	N	--	DuPont
IIA, 8.2.6	Sloman, T.L.	2001b	IN-W3595: Influence on growth and growth rate of the blue-green alga <i>Anabaena flos-aquae</i> DuPont Haskell Laboratory DuPont-3748 GLP: Yes Published: No	N	N	--	DuPont
IIA, 8.2.6	Sloman, T.L.	2001a	IN-T4226: Influence on growth and growth rate of the blue-green alga <i>Anabaena flos-aquae</i> DuPont Haskell Laboratory DuPont-3747 GLP: Yes Published: No	N	N	--	DuPont
IIIA, 10.2.1	Bogers M.	1999b	Fresh water algal growth inhibition test with Cymoxanil 50 % WP NOTOX B.V., The Netherlands, Report 262441 GLP: Yes Published: No	N	N	--	Oxon
IIIA, 10.2.1	Leva, S.E., Sloman, T.L.	1997	DPX-KX007: Influence on growth and growth rate of the green alga <i>Pseudokirchneriella subcapitata</i> (formerly called <i>Selenastrum capricornutum</i>) DuPont Stine Research Center AMR 4116-96 GLP: Yes Published: No	N	N	--	DuPont
IIA, 8.2.8	Leva, S.E., Sloman, T.L.	1996	Cymoxanil: Influence on growth and reproduction of <i>Lemna gibba</i> G3 DuPont Stine-Haskell Research Center	N	N	--	DuPont

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			AMR 3775-96 GLP: Yes Published: No				
IIA, 8.3.1.1	Schur, A.	1999	Assessment of side effects of cymoxanil technical to the honey bee, <i>Apis mellifera</i> L. in the laboratory GAB Biotechnologie GmbH and IFU Umweltanalytik GmbH 99063/01-BLEU GLP: Yes Published: No	N	N	--	Oxon
IIA, 8.3.2	Geuijen, W.H.C.	1999a	Effects of Cymoxanil 50% WP on survival and reproduction of the parasitic wasp <i>Aphidius rhopalosiphi</i> in the laboratory NOTOX BV. 257816 GLP: Yes Published: No	N	N	--	Oxon
IIA, 8.3.2	Geuijen, W.H.C.	2000	Effects of Cymoxanil 50% WP on survival and reproduction of the phytoseiid mite <i>Typhlodromus pyri</i> Scheuten NOTOX BV. 257827 GLP: Yes Published: No	N	N	--	Oxon
IIA, 8.3.2	Geuijen, W.H.C.	1999b	Effects of Cymoxanil 50% WP on survival of the carabid beetle <i>Poecilus cupreus</i> NOTOX BV. 257838 GLP: Yes Published: No	N	N	--	Oxon
IIA, 8.3.2	Müther, J.	2002	A field study to evaluate the effects of Cymoxanil 50% WP on predatory mites (Acari: phytoseiidae) in vines in France Arbeitsgemeinschaft GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, Germany 20021069/F1-NFTp GLP: Yes Published: No	N	N	--	Oxon
IIIA, 10.5.1	Kuehner, C.	1996b	DPX-KX007, a suspension concentrate (SC) formulation, containing JE874 (90 g/L) and cymoxanil (120 g/L): Acute toxicity to the predatory mite, <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) in the laboratory Report No. AMR 3530-95	N	N	--	DuPont

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
			GLP: Yes Published: No				
IIIA, 10.5.1	Kuehner, C.	1995	DPX-KX007, a suspension concentrate (SC) formulation, containing JE874 (90 g/L) and cymoxanil (120 g/L): Acute toxicity to the green lacewing, <i>Chrysoperla carnea</i> Steph. (Neuroptera, Chrysopidae) in the laboratory. Report No. AMR 3529-95 GLP: Yes Published: No	N	N	--	DuPont
IIIA, 10.5.1	Kuehner, C.	1996b	DPX-KX007, a suspension concentrate (SC) formulation, containing JE874 (90 g/L) and cymoxanil (120 g/L): Acute toxicity to the ground beetle, <i>Poecilus cupreus</i> L. (Coleoptera, Carabidae) in the laboratory Report No. AMR 3528-95 GLP: Yes Published: No	N	N	--	DuPont
IIIA, 10.5.1	Mead-Briggs, M.	1996	DPX-KX007, a suspension concentrate (SC) formulation, containing JE874 (90 g/L) and cymoxanil (120 g/L): An extended laboratory test to evaluate the effects on the parasitic wasp <i>Aphidius rhopalosiphi</i> when applied in up to six serial applications to tomato plants Report No. AMR 3593-95 GLP: Yes Published: No	N	N	--	DuPont
IIIA, 10.5.1	Grove, A.J.	1996a	Effects of DPX-KX007-03 on juvenile survival, reproduction and egg hatch success of <i>Typhlodromus pyri</i> (Acari: Phytoseiidae), following multiple applications on grapevine leaf: Extended laboratory test Report No. AMR 3571-95 GLP: Yes Published: No	N	N	--	DuPont
IIIA, 10.5.1	Grove, A.J.	1996b	Extended laboratory test comparing the effects of DPX-KX007 (containing DPX-JE874 and cymoxanil) WG and SC formulations on <i>Typhlodromus pyri</i> , following multiple applications on grapevine leaves under greenhouse conditions MITOX Stichting Bevordering Duurzame Plaagbestijding AMR 3812-96 GLP: Yes Published: No	N	N	--	DuPont

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
IIIA, 10.5.1	Nengel, S.	1996a	Assessment of side effects of DPX-KX007 20 SC on the hoverfly, <i>Episyrphus balteatus</i> DEG. (Diptera, Syrphidae): Extended lab test Report No. AMR 3569-95 GLP: Yes Published: No	N	N	--	DuPont
IIIA, 10.5.1	Nengel, S.	1996b	Assessment of side effects of DPX-KX007 20SC on the ground beetle, <i>Poecilus cupreus</i> L. (Coleoptera, Carabidae): Semi-field test Report No. AMR 3570-95 GLP: Yes Published: No	N	N	--	DuPont
IIIA, 10.5.1	Kuehner, C.	1997a	DPX-KP481, a water-dispersible granular (WG) formulation, containing JE874 (254 g ai/kg) and cymoxanil (266 g ai/kg): Acute toxicity to the hoverfly, <i>Episyrphus balteatus</i> Deg. (Diptera, Syrphidae) in the laboratory GAB Biotechnologie GmbH AMR 4232-96 GLP: Yes Published: No	N	N	--	DuPont
IIIA, 10.5.1	Kuehner, C.	1997b	DPX-KP481, a water-dispersible granular (WG) formulation, containing JE874 (254 g ai/kg) and cymoxanil (266 g ai/kg): Acute toxicity to the ground beetle, <i>Poecilus cupreus</i> L. (Coleoptera, Carabidae) in the laboratory GAB Biotechnologie GmbH AMR 4233-96 GLP: Yes Published: No	N	N	--	DuPont
IIIA, 10.5.1	Kuehner, C.	1997c	DPX-KP481, a water-dispersible granular (WG) formulation, containing JE874 (254 g ai/kg) and cymoxanil (266 g ai/kg): Acute toxicity to the green lacewing, <i>Chrysoperla carnea</i> Steph. (Neuroptera, Chrysopidae) in the laboratory GAB Biotechnologie GmbH AMR 4234-96 GLP: Yes Published: No	N	N	--	DuPont
IIIA, 10.5.1	Kuehner, C.	1997d	DPX-KP481, a water-dispersible granular (WG) formulation containing DPX-JE874 (254 g ai/kg) and cymoxanil (266 g ai/kg): Acute toxicity to the staphylinid beetle, <i>Aleochara bilineata</i> (Coleoptera, Staphylinidae) in the laboratory GAB Biotechnologie, GmbH	N	N	--	DuPont

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
			AMR 4235-96 GLP: Yes Published: No				
IIIA, 10.5.1	Beech, P. & Mead-Briggs, M.	1998	Cymoxanil/Famoxadone (DPX-KP481) 50 WG (25%:25%). An extended laboratory study to evaluate the effects on the ground beetle, <i>Poecilus cupreus</i> University of Southampton, Agrochemical Evaluation Unit (AEU) AMR 4539-97 GLP: Yes Published: No	N	N	--	DuPont
IIIA, 10.5.1	Thompson, B.	1999a	Cymoxanil/Famoxadone (DPX-KP481) 50 WG (25%:25%) an extended laboratory study to evaluate the effects on the hoverfly, <i>Episyrphus balteatus</i> University of Southampton, Agrochemical Evaluation Unit (AEU) AMR 4541-97 GLP: Yes Published: No	N	N	--	DuPont
IIIA, 10.5.1	Thompson, B.	1999c	Cymoxanil/Famoxadone (DPX-KP481) 50 WG (25%:25%). An extended laboratory study to evaluate the effects on the green lacewing, <i>Chrysoperla carnea</i> University of Southampton, Agrochemical Evaluation Unit (AEU) Report No.: AMR 4540-97 GLP: Yes Published: No	N	N	--	DuPont
IIIA, 10.5.1	Hermann, P.	2001	DPX-KP481-25: A semi-field study to evaluate the effects on the hoverfly, <i>Episyrphus balteatus</i> Deg. (Diptera, Syrphidae) GAB Biotechnologie, GmbH DuPont-3881 GLP: Yes Published: No	N	N	--	DuPont
IIIA, 10.5.1	Thompson, B.	1999b	Cymoxanil/Famoxadone (DPX-KP481) 50 WG (25%:25%): A semi-field study to evaluate the effects on aphid parasitoids, (Hymenoptera, Aphidiinae) in a potato crop University of Southampton, Agrochemical Evaluation Unit (AEU) Report No.: AMR 4542-97 GLP: Yes Published: No	N	N	--	DuPont

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
IIIA, 10.5.1	Kuehner, C.	1998	Cymoxanil/famoxadone (DPX-KX007) 52.5% WG (30% : 22.5%): An extended laboratory study (field aged residue) to evaluate the effects on the parasitoid <i>Trichogramma cacoeciae</i> Marchal (Hym., Trichogrammatidae) Report No.: AMR 4573-97 GLP: Yes Published: No	N	N	--	DuPont
IIIA, 10.5.1	Oberwalder, C.	1997	A field study to evaluate the effects of DPX-KX007 WG, a formulation containing DPX-JE874 (225 g ai/kg) and cymoxanil (300 g ai/kg), on the predatory mite <i>Typhlodromus pyri</i> in vines (two locations in Germany) Report No.: AMR 3969-96, Revision No.1 GLP: Yes Published: No	N	N	--	DuPont
IIA, 8.4.1	Rodgers, M.H., Cameron, D.M., Mansell, P.	1995	Cymoxanil technical acute toxicity (LC ₅₀) to the earthworm (<i>Eisenia foetida</i>) Huntingdon Life Sciences Ltd. OXN 78A/950675 GLP: Yes Published: No	N	N	--	Oxon
IIIA, 10.6.1.1	Rodgers, M.H.	1995	Cymoxanil 50 % WP - Acute toxicity (LC ₅₀) to the earthworm (<i>Eisenia foetida</i>) Huntingdon Research Centre Ltd., Huntingdon, Cambridgeshire, England OXN 81A/943245 GLP: Yes Published: No	N	N	--	Oxon
IIIA, 10.6.1.1	Wachter, S.	1997	Acute toxicity of DPX-KX007-5 on earthworms, <i>Eisenia foetida</i> using an artificial soil test GAB Biotechnologie, GmbH AMR 4136-96 GLP: Yes Published: N	N	N	--	DuPont
IIA, 8.4.2	Lührs, U.	2000	Cymoxanil/famoxadone (DPX-KP481): A dose response sublethal study to the earthworm, <i>Eisenia fetida</i> (Savigny 1826), in artificial soil IBACON DuPont-4611 GLP: Yes	N	N	--	DuPont

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
			Published: No				
IIA, 8.5	Kölzer, U.	2003	Assessment of the side effects of cymoxanil technical on the activity of the soil microflora Arbeitsgemeinschaft GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH. 20031314/01-ABMF GLP: Yes Published: No	N	N	--	Oxon
IIIA, 10.7	Carter, J.N.	1995	DPX-KX007 (20 SC) effects on soil non-target micro-organisms Report No.: AMR 3560-95 GLP: Yes Published: No	N	N	--	DuPont
IIA, 8.6	Balluff, M.	2003	Vegetative vigour limit test for non target plants following single rate application of Cymoxanil 50 WP Arbeitsgemeinschaft GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH. 20033057/S1-FGW GLP: Yes Published: No	N	N	--	Oxon
KCP 9.2.4.1/01	Tan, N. & Brands, C.	2009	DETERMINATION OF THE AEROBIC DEGRADATION ROUTE (IN ONE SOIL) AND RATE (IN THREE SOILS) OF CYMOXANIL NOTOX B.V., 's-Hertogenbosch, The Netherlands Report No.: 487663 183528/A GLP, unpublished	N	N	-	Belchim Crop Protection Indofil Industries Limited
KCP 9.2.4.1/02	Hardy, I.A.J & Patel, M.	2009	KINETIC MODELLING ANALYSIS OF CYMOXANIL AND ITS METABOLITES FROM AEROBIC SOIL DEGRADATION, HYDROLYSIS AND WATER/ SEDIMENT STUDIES Battelle UK Ltd., Essex, United Kingdom Report No.: OZ/09/003 Not GLP, unpublished	N	N	-	Belchim Crop Protection Indofil Industries Limited

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-09	Alessandro Spagnolo	2021	Efficacy of cymoxanil against <i>Phytophthora infestans</i> in potato ANADIAG SAS Trial ID: EU21280JP103 GEP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.2-10	Alessandro Spagnolo	2021	Efficacy of cymoxanil against <i>Phytophthora infestans</i> in potato ANADIAG SAS Trial ID: EU21280XA110 GEP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.2-11	Sofía Camuñez	2021	Efficacy of IN002B1760 against <i>Phytophthora infestans</i> on potato. STAPHYT Trial ID: SCZ-21-51097-IT01 GEP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.2-12	Sofía Camuñez	2021	Efficacy of IN002B1760 against <i>Phytophthora infestans</i> on potato. STAPHYT Trial ID: SCZ-21-51097-IT02 GEP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.2-15	Guillaume Cardiet	2021	Efficacy of cymoxanil against <i>Phytophthora infestans</i> in Greenhouse tomato ANADIAG ITALIA SRL Trial ID: ITA 21132 TO1 GEP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.2-16	Guillaume Cardiet	2021	Efficacy of cymoxanil against <i>Phytophthora infestans</i> in Greenhouse tomato ANADIAG ITALIA SRL Trial ID: ITA 21133 TO1 GEP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.2-17	Guillaume Cardiet	2021	Efficacy of cymoxanil against <i>Phytophthora infestans</i> in Greenhouse tomato ANADIAG SAS Oddział w Polsce	N	Y	Study report never submitted before	Indofil Industries (Netherlands)

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
			Trial ID: PL 21 062 PL1 GEP: Yes Unpublished				B.V.
KCP 6.2-18	Guillaume Cardiet	2021	Efficacy of cymoxanil against <i>Phytophthora infestans</i> in Greenhouse tomato ANADIAG SAS Oddział w Polsce Trial ID: PL 21 062 PL2 GEP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.2-19	Sofía Camuñez	2021	Efficacy of IN002B1760 against <i>Phytophthora infestans</i> on tomato in greenhouse. STAPHYT Trial ID: SCZ-21-51099-FR01 GEP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.2-20	Guillaume Cardiet	2021-2022	Efficacy of cymoxanil against <i>Phytophthora infestans</i> in Greenhouse tomato Anadiag International Trial ID: 21GR-283 GEP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.2-21	Guillaume Cardiet	2021	Efficacy of cymoxanil against <i>Phytophthora infestans</i> in open field tomato Anadiag SA-Sucursal em Portugal Trial ID: PO 210 35 PO1 GEP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.2-22	Magalí Adarnius Blanch	2021	Efficacy of cymoxanil against <i>Phytophthora infestans</i> in open field tomato ANADIAG IBÉRICA S.L Trial ID: 21195 AF GEP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.2-23	Magalí Adarnius Blanch	2021	Efficacy of cymoxanil against <i>Phytophthora infestans</i> in open field tomato ANADIAG IBÉRICA S.L Trial ID: 21196 RJ GEP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.

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KCP 6.2-24	Guillaume Cardiet	2021	Efficacy of cymoxanil against <i>Phytophthora infestans</i> in open field tomato Anadiag International Trial ID: 21GR-199 GEP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.2-25	Guillaume Cardiet	2021	Efficacy of cymoxanil against <i>Phytophthora infestans</i> in open field tomato ANADIAG ITALIA SRL Trial ID: ITA 21131 TO1 GEP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 6.2-26	Sofia Camuñez	2021	Efficacy of IN002B1760 against <i>Phytophthora infestans</i> on tomato in open field. STAPHYT Trial ID: SCZ-21-51098-IT01 GEP: Yes Unpublished	N	Y	Study report never submitted before	Indofil Industries (Netherlands) B.V.
KCP 10.2.1/01	Neri, M.C.	2009a	Acute toxicity of Moximate 505 WP to Zebra fish (<i>Danio rerio</i>) in a 96-hour study under semi-static exposure. Report No. CH-E-008/2009 (Doc. No. 821-006) Test Facility: ChemService S.r.l. Via Fratelli Beltrami, 15, 20026 Novate Milanese (MI), Italy GLP Unpublished	Y	Y	Study report never submitted before in Poland	Indofil Industries Ltd.
KCP 10.2.1/02	Neri, M.C.	2009b	Acute toxicity of Moximate 505 WP to <i>Daphnia magna</i> in a 48-hour immobilisation test under semi-static exposure. Report No. CH-E-009/2009 (Doc. No. 822-004) Test Facility: ChemService S.r.l. Via Fratelli Beltrami, 15, 20026 Novate Milanese (MI), Italy GLP Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.
KCP 10.2.1/03	Neri, M.C.	2009c	Toxicity of Moximate 505 WP to green algae <i>Pseudokirchneriella subcapitata</i> determined in a growth inhibition study. Report No. CH-E-010/2009 (Doc. No. 823-004) Test Facility: ChemService S.r.l. Via Fratelli Beltrami, 15, 20026 Novate Milanese (MI), Italy GLP Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.1.1/01	Schmitzer, S.	2007	Effects of Cymoxanil Technical (Acute Contact and Oral) on Honey Bees (<i>Apis mellifera</i> L.) in the Laboratory (Limit Test). Report No. 36571035 Test Facility: Institut für Biologische Analytik und Consulting IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany GLP Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.
KCP 10.3.1.1/02	Colli, M.	2009a	Effects, acute oral and acute contact toxicity of Moximate 505 WP on the honeybee <i>Apis mellifera</i> L. in the laboratory (dose response test). Report No. BT013/09 (Doc. No. 832-004) Test Facility: BIOTECNOLOGIE BT S.r.l., Fraz. Pantalla, 06050 Todi (PG), Italy GLP Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.
KCP 10.3.2.2/03	Colli, M.	2009b	Effects of Moximate 505 WP on the predatory mite <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) under extended laboratory conditions (rate response test). Report No. BT035/09 (Doc. No. 834-006) Test Facility: BIOTECNOLOGIE BT S.r.l., Fraz. Pantalla, 06050 Todi (PG), Italy GLP Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.
KCP 10.3.2.2/04	Colli, M.	2009c	Effects of Moximate 505 WP on the aphid parasitoid <i>Aphidius rhopalosiphii</i> De Stefani Perez (Hymenoptera, Braconidae) under extended laboratory conditions (rate response test). Report No. BT034/09 (Doc. No. 834-003) Test Facility: BIOTECNOLOGIE BT S.r.l., Fraz. Pantalla, 06050 Todi (PG), Italy GLP Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.
KCP 10.3.2.2/05	Colli, M.	2009d	Effect toxicity evaluation of Moximate 505 WP on the <i>Chrysoperla carnea</i> L. (Neuroptera, Chrysopidae) under extended laboratory conditions (rate response test). Report No. BT033/09 (Doc. No. 834-004) Test Facility: BIOTECNOLOGIE BT S.r.l., Fraz. Pantalla, 06050 Todi (PG), Italy GLP Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.2.2/06	Colli, M.	2010	Effect of Moximate 505 WP on the plant dwelling insect <i>Coccinella septempunctata</i> L. (Coleoptera, Coccinellidae) under extended laboratory conditions (rate response test). Report No. BT032/09 (Doc. No. 834-005) Test Facility: BIOTECNOLOGIE BT S.r.l., Fraz. Pantalla, 06050 Todi (PG), Italy GLP Unpublished	N	Y	Study report never submitted before in Poland	Indofil Industries Ltd.
KCP 10.3.2.2/07	Rosenkranz, B. & Wirzinger, G.	2011	Statistical re-evaluation of effects of Moximate 505 WP on <i>Aphidius rhopalosiphi</i> and <i>Eisenia fetida</i> . Report No. not indicated (Doc. No.: 882-002) Test Facility: Scientific Consulting Company, Bad Kreuznach, Germany Not GLP Unpublished	N	N	Study report never submitted before in Poland	Indofil Industries Ltd.

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

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-	-	-	-	-	-	-	-