REGISTRATION REPORT

**Part B**

**Section 8**

**Environmental Fate**

Detailed summary of the risk assessment

Product code: IN002B1760

Product name(s): Cymofil

Chemical active substance:

Cymoxanil, 450 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(New authorisation)

Applicant: Indofil Industries (Netherlands) B.V.

Submission date: August 2022

MS Finalisation date: May 2023 (initial Core Assessment)

April 2024 (final Core Assessment)

# Version History

| When | What |
|---|---|
| August 2022 | IN002B1760 product submission in the Central Zone – new authorisation |
| May 2023 | Initial zRMS assessment<br><br>The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency. |
| August 2023 | Final report (Core Assessment updated following the commenting period)<br><br>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. Information no longer relevant ~~is struck through~~ and shaded. |
| April 2024 | Final report (Core Assessment updated following the commenting period)<br><br>Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in blue. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency. |

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# 8 Fate and behaviour in the environment (KCP 9)

This document reviews the environmental fate summary and exposure calculations for the plant protection product IN002B1760, a formulation containing Cymoxanil, as relevant for a product submission in the Central Zone.

Cymoxanil, is included in the Annex of Regulation (EU) 540/2011 (former Annex I of Directive 91/414/EEC) with Commission Directive 2008/125/EC of 19 December 2008. A full risk assessment according to Uniform Principles is provided which demonstrates that the product is safe for the environment. Where appropriate this document refers to the conclusions of the EU review of Cymoxanil. This will be where the:

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

Note: This Part B document only reviews data (Annex II or Annex III) and additional information that has not previously been considered within the EU review process, as part of the Annex I inclusion decision. New Annex II data are only included if they are considered essential for the evaluation; in this case, full study summaries are provided.

The product IN002B1760 was not the representative formulation during EU review of the active substance. The product has not been previously evaluated in EU countries according to Uniform Principles of Annex VI of Directive 91/414/EEC (now Regulation (EU) 546/2011).

Where appropriate, this document refers to the concluded data of the active substances after EU review. The SANCO report for Cymoxanil (SANCO/179/08 rev.1, 9 July 2010) and the EFSA Scientific Report (2008) are considered to provide the relevant review information for Cymoxanil. Each section will begin with a table providing the EU endpoints to be used in this evaluation.

The Annex I Inclusion Directive for Cymoxanil (2008/125/EC) provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles of Reg (EU) 546/2011, the conclusions of the review report on Cymoxanil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 19/12/2008, shall be taken into account. In this overall assessment for Cymoxanil (as relevant to this dRR Part B8), Member States must pay particular attention to the:

- protection of groundwater when the active substance is applied in regions with vulnerable soil and/or climatic conditions
- protection of aquatic organisms and must ensure that the conditions of authorization include risk mitigation measures such as buffer zones where appropriate.

These concerns have been addressed within the current submission.

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

The present application supports the authorisation of a new formulation according to Art. 33 of Reg. EC n. 1107/2009.

# 8.1 Critical GAP and overall conclusions

**Table 8.1-1: Critical use pattern of the formulated product IN002B1760 concerning environmental fate**

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Use-No.* | Member state(s) | Crop and/or situation (crop destination /purpose of crop) | F, Fn, Fpn G, Gn, Gpn or I** | Pests or goup of pests controlled (developmental stages of the pest or pest group) | **Application** | | | | **Application rate** | | | PHI (d) *** | Remarks | **Conclusion** |
| | | | | | Method/ kind | Timing/growth stage of crop & season | Max. number a) per use b) per crop/season | Min. interval between appn. (d) | kg FP/ha a) max. rate per appn. b) max. total rate per crop/season | g as/ha a) max. rate per appn. b) max. total rate per crop/season | Water L/ha min/max | | | Groundwater |
| **Zonal uses (field or outdoor uses, certain types of protected crops)** | | | | | | | | | | | | | | |
| 2 | AT, BE, CZ, DE, IE, NL, PL, SI, UK | Potato | F | Downy mildew (*Phythophtora infestans*) | Foliar spray | BBCH 12-95 | 6 | 5 | a) 0.33<br>b) 1.98 | a) 148.5<br>b) 891 | 300-500<br>~~150-1000~~ | 7 | 250-330g FP/ha | A |

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
*** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop)

Explanation for column 15 "Conclusion"

| | |
|---|---|
| A | Safe use |
| R | Further refinement and/or risk mitigation measures required |
| C | To be confirmed by cMS |
| N | No safe use |

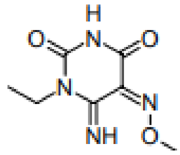
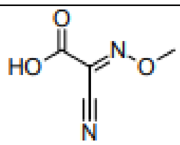
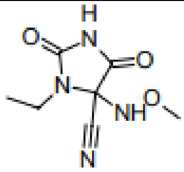
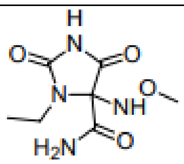
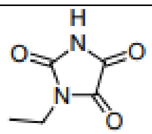
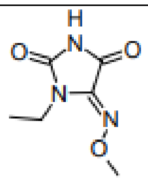
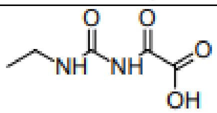
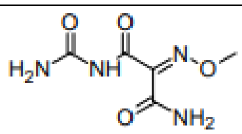
**Table 8.1-2: Assessed (critical) uses during approval of Cymoxanil concerning environmental fate**

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Use-No. * | 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 (developmental stages of the pest or pest group) | **Application** | | | | **Application rate** | | | PHI (d)*** | Remarks |
| | | | | | Method/kind | Timing/ growth stage of crop & season | Max. number a) per use b) per crop/ season | Min. interval between applications (d) | kg as/hL | g as/ha | Water L/ha min/max | | |
| - | SEU | Lettuce | F | *Bremia lactucae* | Foliar spray | BBCH 40-49 | 3-4 | 7 | 0.03-0.048 | 240 | 500-800 | 10 | Oxon |
| - | NEU | Potato | F | *Phytophthora infestans* | Foliar spray | BBCH 21-95 | 4 | 7-10 | 0.026-0.060 | 120 | 200-450 | 7 | Oxon |
| | SEU | | | | | | 5 | 7 | 0.012-0.024 | 120 | 500-1000 | 7 | Oxon |
| | NEU | | | | | | 6-8 | 7-10 | 0.029-0.058 | 175 | 300-600 | 14 | DuPont |
| | SEU | | | | | | | | | | | | |

* **Representative uses assessed at EU level are more critical than the ones requested in the current application for IN002B1760**
** 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
*** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop)

## 8.2 Metabolites considered in the assessment

**Table 8.2-1: Major (>5 AR) metabolites of Cymoxanil triggered for exposure assessment**

| Metabolite | Molar mass (g/mol) | Chemical structure | Maximum (% AR) in compartment | Exposure assessment |
|---|---|---|---|---|
| IN-U3204<br><br>1-ethyl-6-iminodihydro pyrimidine-2,4,5(3H)-trione 5-(O-methyloxime) | 198.2 |  | Soil:<br>24.7%<br><br>Water/sediment:<br>water 24.7%,<br>sediment 0.5%** | PECsoil<br>PECgw<br><br>PECsw |
| IN-W3595<br><br>Cyano(methoxyimino)acetic acid | 128.1 |  | Soil:<br>10.1%<br><br>Water/sediment:<br>water 26.1%,<br>sediment 2.3%** | PECsoil<br>PECgw<br><br>PECsw |
| IN-JX915<br><br>3-ethyl-4-(methoxyamino)-2,5-dioxoimidazolidine-4-car-bonitrile | 198.2 |  | Soil phot:<br>10.9%<br><br>Water/sediment:<br>water 7.2%,<br>sediment 1.2%** | PECsoil<br>PECgw<br><br>PECsw |
| IN-KQ960<br><br>3-ethyl-4-(methoxyamino)-2,5-dioxoimidazolidine-4-carboxamide | 216.2 |  | Soil:<br>6.3%*<br><br>Water/sediment:<br>water 13.0%,<br>sediment 5.5%** | PECgw<br><br>PECsw |
| IN-T4226<br><br>1-ethylimidazolidine-2,4,5-trione | 142.1 |  | Water/sediment:<br>water 11.1%,<br>sediment 1.0%** | PECsw |
| IN-R3273<br><br>1-ethylimidazolidine-2,4,5-trione 5-(Omethyloxime) | 171.2 |  | Water/sediment:<br>water 5.0%,<br>sediment 0.5%** | PECsw |
| IN-KP533<br><br>{[(ethylamino)car-bonyl]amino (oxo)acetic acid | 160.1 |  | Water/sediment:<br>water 20.5%,<br>sediment 6.5%** | PECsw |
| M5<br><br>N-(aminocarbonyl)-2-(methoxyimino)malonamide | 198.2 |  | Water/sediment:<br>water 22.9%,<br>sediment n.d** | PECsw |

* PECsoil not triggered since <10% AR (EFSA, 2008)
** PECsed not triggered since <10% AR (EFSA, 2008)

| **zRMS comments:** |
|---|
| Information regarding cymoxanil metabolites is in line with information presented in EFSA Scientific Report (2008) 167, 1-116. |

## 8.3 Rate of degradation in soil (KCP 9.1.1)

Studies on the laboratory degradation rate in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. A summary of the data is given below.

### 8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

The rate of degradation in soil of Cymoxanil and metabolites was evaluated during the Annex I Inclusion and additional data was not required as a result of the review.

~~Following the EU review, new laboratory studies have been performed (Tan & Brands, 2009, and Hardy & Patel, 2009) to generate further rate of degradation data for the IN-KQ960 metabolite, and the study is summarised in Appendix 2.~~

**Table 8.3-1: Summary of aerobic degradation rates for Cymoxanil - laboratory studies**

| **Cymoxanil, laboratory studies, aerobic conditions** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Soil type** | **pH** | **T°C/% MWHC** | **$DT_{50}/DT_{90}$ (d)** | **SFO-$DT_{50}$* (d) 20°C/pF2** | **$\chi^2$ error (%)** | **Method** | ~~**$DT_{50}$ (d) 20°C/ $Q_{10}$ 2.58**~~ | **Evaluated at EU level** |
| Sandy loam | 6.0 | 20°C/40% MWHC | 0.1/0.5 | 0.2 | 1.4 | FOMC | ~~0.2~~ | EFSA Scientific Report (2008) ~~Final Addendum to DAR – updated September 2008~~ |
| Sandy loam | 6.4 | 25°C/75% 1/3 bar | 1.2/18.8 | 5.8 ~~5.7~~ | 17.6 | FOMC | ~~6.4~~ | |
| Sandy clay loam | 6.8 | 25°C/50% MWHC | 0.2/0.8 | 0.4 ~~0.3~~ | 5.9 | FOMC | ~~0.5~~ | |
| Sandy loam | 6.5 | 20°C/50% MWHC | 2.3/13.1 | 3.1 ~~3.9~~ | 6.9 | FOMC | ~~3.1~~ | |
| Sandy loam | 7.8 | 20°C/50% MWHC | 0.7/2.3 | 0.6 ~~0.7~~ | 16.7 | FOMC | ~~0.6~~ | |
| Sandy clay loam | 5.7 | 20°C/50% MWHC | 2.5/33.3 | 7.3 ~~10~~ | 6.5 | FOMC | ~~7.3~~ | |
| Silt loam | 4.3 | 20°C/40% MWHC | 4.3/23.7 | 6.1 ~~7.1~~ | 4.3 | FOMC | ~~6.1~~ | |
| Silt loam | 6.4 | 20°C/40% MWHC | 0.9/3.1 | 0.8 ~~0.9~~ | 2.6 ~~3.0~~ | SFO | ~~0.8~~ | |
| Clay loam | 7.5 | 20°C/40% MWHC | 0.2/0.8 | 0.2 | 5.7 ~~7.3~~ | SFO | ~~0.2~~ | |
| Geometric mean (n=9) | | | | 1.2 | - | - | ~~1.2~~ | - |

* SFO-$DT_{50}$ re-calculated from FOMC-$DT_{90}$ by division with 3.32

**Table 8.3-2: Summary of aerobic degradation rates for IN-U3204 - laboratory studies**

| **IN-U3204, laboratory studies, aerobic conditions** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Soil type** | **pH** | **T°C/% MWHC** | **$DT_{50}/DT_{90}$ (d)** | **f.f. (from parent)** | **$DT_{50}$ (d) 20°C/pF2** | **$\chi^2$ error (%)** | **Method** | ~~**$DT_{50}$ (d) 20°C/ $Q_{10}$ 2.58**~~ | **Evaluated at EU level** |
| Sandy clay loam | 6.8 | 25°C/50% MWHC | 0.6/1.9 | 0.48 | 0.9 | 11.0 | SFO | ~~1.0~~ | EFSA Scientific Report (2008) ~~Final Addendum to DAR – updated September 2008~~ |
| Silt loam | 6.4 | 20°C/40% MWHC | 0.4/1.3 | 0.24 | 0.3 | 26.2 | SFO | ~~0.3~~ | |
| Clay loam | 7.5 | 20°C/40% MWHC | 0.2/0.6 | 0.36 | 0.2 | 12.2 | SFO | ~~0.2~~ | |
| Geometric mean (n=3)<br>Arithmetic mean | | | 0.4/1.1<br>-/- | -<br>0.36 | 0.4<br>- | - | - | ~~0.4~~ | - |

**Table 8.3-3: Summary of aerobic degradation rates for IN-W3595 - laboratory studies**

| IN-W3595, laboratory studies, aerobic conditions | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Soil type** | **pH** | **T°C/% MWHC** | **$DT_{50}/DT_{90}$ (d)** | **f.f. (from parent)** | **$DT_{50}$ (d) 20°C/pF2** | **$\chi^2$ error (%)** | **Method** | ~~**$DT_{50}$ (d) 20°C/ $Q_{10}$ 2.58**~~ | **Evaluated at EU level** |
| Sandy clay loam | 6.8 | 25°C/50% MWHC | 1.7/5.5 | 0.15 | 2.5 | 14.5 | SFO | ~~2.7~~ | EFSA Scientific Report (2008) ~~Final Addendum to DAR – updated September 2008~~ |
| Sandy loam | 7.8 | 20°C/50% MWHC | 2.8/9.4 | 0.07 | 2.2 | 69.3 | SFO | ~~2.2~~ | |
| Worst case (n=2) | | | 2.8/9.4 | 0.15 | 2.5 | - | - | ~~2.7~~ | - |

**Table 8.3-4: Summary of aerobic degradation rates for IN-JX915 - laboratory studies**

| IN-JX915, laboratory studies, aerobic conditions | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Soil type** | **pH** | **T°C/% MWHC** | **$DT_{50}/DT_{90}$ (d)** | **f.f. (from parent)** | **$DT_{50}$ (d) 20°C/pF2** | **$\chi^2$ error (%)** | **Method** | ~~**$DT_{50}$ (d) 20°C/ $Q_{10}$ 2.58**~~ | **Evaluated at EU level** |
| Sandy clay loam | 6.8 | 25°C/50% MWHC | 0.6/1.9 | 0.10 | 1.0 | 27 | SFO | ~~1.0~~ | EFSA Scientific Report (2008) ~~Final Addendum to DAR – updated September 2008~~ |

**Table 8.3-5: Summary of aerobic degradation rates for IN-KQ960 - laboratory studies**

| IN-KQ960, laboratory studies, aerobic conditions | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Soil type** | **pH** | **T°C/% MWHC** | **$DT_{50}/DT_{90}$ (d)** | **f.f. (from IN-U3204)** | **$DT_{50}$ (d) 20°C/pF2** | **$\chi^2$ error (%)** | **Method** | ~~**$DT_{50}$ (d) 20°C/ $Q_{10}$ 2.58**~~ | **Evaluated at EU level** |
| Sandy clay loam | 6.8 | 25°C/50% MWHC | 7.6/25.2 | 0.16 | 11.2 | 19.2 | SFO | ~~12.2~~ | EFSA Scientific Report (2008) ~~Final Addendum to DAR – updated September 2008~~ |
| ~~Silty clay loam~~ | ~~6.0~~ | ~~20°C/40% MWHC~~ | ~~1.5/4.9~~ | ~~-~~ | ~~1.3~~ | ~~5.5~~ | ~~SFO~~ | ~~1.4~~ | ~~Hardy & Patel, 2009~~ ~~Tan & Brands, 2009~~ |
| ~~Sandy loam~~ | ~~6.4~~ | ~~20°C/40% MWHC~~ | ~~1.6/5.4~~ | ~~-~~ | ~~1.3~~ | ~~21.3~~ | ~~SFO~~ | ~~1.3*~~ | |
| ~~Clay~~ | ~~7.2~~ | ~~20°C/40% MWHC~~ | ~~0.6/2.2~~ | ~~-~~ | ~~0.3~~ | ~~6.0~~ | ~~SFO~~ | ~~0.3~~ | |
| Worst case<br>Geometric mean (n=3) | | | | | | | | ~~12.2~~<br>~~1.7~~ | - |

* Not included in calculation of geometric mean, as not sufficiently robust

**zRMS comments:**

Soil degradation data for cymoxanil metabolites are in general in line with EU agreed endpoints reported in EFSA Scientific Report (2008) 167, 1-116. In Table 8.3-1 degradation rates for cymoxanil were corrected to be fully in line with EU agreed values.

It is noted that in Tables 8.3-1 to 8.3-5 the $DT_{50}$ values normalised with consideration of $Q_{10}$ of 2.58 are presented, in line with current FOCUS requirements. Although normalisation using $Q_{10}$ of 2.58 is currently required, in the exposure assessment endpoints as reported in the LoEP should be used, even if the EU agreed data were normalised using $Q_{10}$ of 2.2. Taking this into account, the $DT_{50}$ values with $Q_{10}$ of 2.58 were not validated by the zRMS and are struck through in tables above. Nevertheless, consideration of $DT_{50}$ values including data normalised with $Q_{10}$ of 2.58 in the exposure assessment will have no impact on the obtained results due to negligible deviation from the EU agreed endpoints based on degradation data normalised using $Q_{10}$ of 2.2.

It is noted that Applicant submitted additional studies on soil degradation of IN-KQ960 in soil (Tan & Brands, 2009 and Hardy & Patel, 2009) and it is considered to be a new active substance data. Although, in general, the product assessment should be carried out according to the currently agreed EU endpoints, the Working Document of the Central Zone in area of Section 8, identifies situation when new active substance data may be considered in the Core Assessments:

> *[...] Note that according to the guidance document on the evaluation of new active substance data post approval (SANCO/10328/2004– rev 8, 24.01.2012) new active substance/metabolite data should not be considered unless they are necessary in order to show a safe use, they are needed as additional uses/crops are applied for authorisation, or they are "adverse" data. [...]*

Nevertheless, studies Tan & Brands, 2009 and Hardy & Patel, 2009 have been already evaluated and agreed by the RMS (LT) as a part of the data submitted in support of the cymoxanil renewal process. Although the renewal process is not finalised yet, it is at the advanced stage with recent version of the DRAR issued in January 2022, after the discussion during the expert meetings. The valid degradation data of metabolite IN-KQ960 were available for 12 soils resulting with geometric mean $DT_{50}$ of 1.55 days, which is considerably shorter than currently EU agreed $DT_{50}$ of 11.2 days derived for the single soil, and may be considered as already peer-reviewed. As a member of the cymoxanil Task Force (CTF), the Applicant for IN002B1760 has full access to cymoxanil data considered during the renewal process.
Taking this into account, the new degradation data were not validated by the zRMS and are thus struck through in Table 8.3-5.
For relevant endpoints considered in exposure assessment, please refer to points 8.7 (soil), 8.8 (groundwater) and 8.9 (surface water) of this document.

### 8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Degradation rates in anaerobic soil have been calculated, where appropriate. However, these are not required for risk assessment and no further information is provided here.

**zRMS comments:**

No data were available on the route of degradation under anaerobic conditions according to EFSA Scientific Report (2008) 167, 1-116.

## 8.4 Field studies (KCP 9.1.1.2)

Due to the rapid degradation of Cymoxanil in laboratory studies, field dissipation studies were not triggered. No additional studies have been performed.

**zRMS comments:**

According to EFSA Scientific Report (2008) 167, 1-116, studies on field degradation of cymoxanil were not triggered.

### 8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

Not triggered or required.

**zRMS comments:**

Please, refer to point 8.4 above.

### 8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Not triggered or required.

**zRMS comments:**

Please, refer to point 8.4 above.

## 8.5 Mobility in soil (KCP 9.1.2)

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from sorption data obtained with the active substance. A summary of the sorption data is given below. For some metabolites, sorption data were obtained using an 'HPLC method' (EFSA, 2008) and a summary of the data is also provided.

**Table 8.5-1: Summary of soil sorption for Cymoxanil**

| Cymoxanil | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Soil name** | **Soil type** | **OC (%)** | **pH** | **Kf (mL/g)** | **Kfoc (mL/g)** | **1/n** | **Evaluated at EU level** |
| Speyer 2.1 | Sand | 0.59 | 6.9 | 0.090 | 15.1 | 0.88 | EFSA Scientific Report (2008) |
| Midwest 1 | Sandy loam | 1 | 5.7 | 0.910 | 87.1 | 0.87 | |
| Cranfield 115 | Clay loam | 1.6 | 8.1 | 0.462 | 28.9 | 0.81 | |
| Cranfield 164 | Silty loam | 2 | 7.2 | 0.856 | 43.4 | 0.87 | |
| Arithmetic mean (n=4) | | | | | 43.6 | 0.86 | |
| Geometric mean (n=4) | | | | | 35.8 | - | - |
| pH-dependency | | | | | No | | |

**Table 8.5-2: Summary of soil sorption for IN-W3595**

| IN-W3595 | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Soil name** | **Soil type** | **OC (%)** | **pH** | **Kf (mL/g)** | **Kfoc (mL/g)** | **1/n** | **Evaluated at EU level** |
| 'Bayboro' | Silty loam | 2.3 | 4.6 | - | 27.4 | - | EFSA Scientific Report (2008) |
| 'Chino' | Loam | 0.99 | 7.6 | - | 2.6 | - | |
| 'Fargo' | Silty clay loam | 3.2 | 7.8 | - | 2.3 | - | |
| 'Sassafras' | Sandy loam | 0.46 | 6.4 | - | 4.3 | - | |
| Arithmetic mean (n=4) | | | | | 9.2 | 1 | |
| Geometric mean (n=4) | | | | | 5.2 | - | - |
| pH-dependency | | | | | Yes | | |

The sorption of metabolite IN-W3595 was pH-dependent with higher $K_{OC}$ values found in acidic soils. The pH-dependent values obtained for Koc(acid) and Koc(base) were 33.3 and 2.3 mL/g, respectively, with a pKa of 5.2.

**Table 8.5-3: Summary of soil sorption for IN-JX915**

| IN-JX915 | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Soil name** | **Soil type** | **OC (%)** | **pH** | **Kf (mL/g)** | **Kfoc (mL/g)** | **1/n** | **Evaluated at EU level** |
| 'Bayboro' | Silty loam | 2.3 | 4.6 | - | 5.4 | - | EFSA Scientific Report (2008) |
| 'Chino' | Loam | 0.99 | 7.6 | - | 34.3 | - | |
| 'Fargo' | Silty clay loam | 3.2 | 7.8 | - | 20.6 | - | |
| 'Sassafras' | Sandy loam | 0.46 | 6.4 | - | 4.4 | - | |
| Arithmetic mean (n=4) | | | | | 16.2 | 1 | |
| Geometric mean (n=4) | | | | | 11.4 | - | - |
| pH-dependency | | | | | No | | |

**Table 8.5-4: Summary of soil sorption for IN-R3273**

| IN-R3273 | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Soil name** | **Soil type** | **OC (%)** | **pH** | **Kf (mL/g)** | **Kfoc (mL/g)** | **1/n** | **Evaluated at EU level** |
| 'Bayboro' | Silty loam | 2.3 | 4.6 | - | 25.7 | - | EFSA Scientific Report (2008) |
| 'Chino' | Loam | 0.99 | 7.6 | - | 49.5 | - | |
| 'Fargo' | Silty clay loam | 3.2 | 7.8 | - | 46.9 | - | |
| 'Sassafras' | Sandy loam | 0.46 | 6.4 | - | 45.7 | - | |
| Arithmetic mean (n=4) | | | | | 41.9 | 1 | |
| Geometric mean (n=4) | | | | | 40.6 | - | - |
| pH-dependency | | | | | No | | |

**Table 8.5-5: Summary of soil sorption for metabolites using 'HPLC method'**

| **Endpoint** | **IN-U3204** | **IN-KQ960** | **IN-T4226** | **IN-KP533** | **Evaluated at EU level** |
|---|---|---|---|---|---|
| Koc (mL/g) | 27.9 | 21.6 | 17.7 | 12.9 | EFSA Scientific Report (2008) |
| 1/n | 1* | 1* | 1* | 1* | |

a Default value when Freundlich data not available

Note that for metabolite M5, where no sorption data are available, surrogate Koc and 1/n values of 9.2 mL/g and 1 were assumed (as per IN-W3595) (EFSA, 2008).

**zRMS comments:**

Soil mobility data for cymoxanil and its metabolites presented in tables above are in line with EU agreed endpoints reported in EFSA Scientific Report (2008) 167, 1-116.
It is noted that the geometric mean Kfoc values were calculated by the Applicant, although in the EFSA conclusion only arithmetic mean values are reported and further used for groundwater and surface water modelling. The geometric mean values calculated by the Applicant were based on the individual Kfoc from the LoEP and are confirmed to be correct. The results of the modelling simulation were validated by the zRMS with consideration of the EU agreed arithmetic mean values.

## 8.5.1 Column leaching (KCP 9.1.2.1)

Column leaching studies have not been carried out.

**zRMS comments:**

According to EFSA Scientific Report (2008) 167, 1-116, column leaching studies with cymoxanil were not required.

### 8.5.2 Lysimeter studies (KCP 9.1.2.2)

Field lysimeter studies have been carried out and are reported (EFSA, 2008). However, they are not relevant to this submission and are not described further.

| zRMS comments: |
|---|
| According to EFSA Scientific Report (2008) 167, 1-116, lysimeter studies with cymoxanil were not required. |

### 8.5.3 Field leaching studies (KCP 9.1.2.3)

Field leaching studies have not been carried out.

| zRMS comments: |
|---|
| According to EFSA Scientific Report (2008) 167, 1-116, field leaching studies with cymoxanil were not required. |

## 8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

Studies on degradation in water/sediment systems with the formulation were not performed since it is possible to extrapolate from data obtained with the active substance. A summary of the data is given below.

**Table 8.6-1: Summary of degradation in water/sediment of Cymoxanil**

| Cymoxanil (max. sediment 3.9% AR after 1 d) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Water/sediment system** | **pH water** | **pH sediment** | **T°C** | **$DegT_{50}/DegT_{90}$ (d) whole sys.** | **$r^2$** | **$DegT_{50}/DegT_{90}$ (d) water** | **$r^2$** | **Method** | **Evaluated at EU level** |
| Sand | 7.4 | 7.0 | 20 | 0.5/1.7 | 1.00 | 0.5/1.7 | 1.00 | SFO | EFSA Scientific Report (2008) |
| Sand | 5.3 | 5.1 | 20 | 1.6/5.3 | 0.99 | 1.5/5.0 | 0.99 | SFO | |
| Silty clay loam | 8.3 | 7.5 | 20 | 0.1/0.2 | 1.00 | 0.1/0.2 | 1.00 | SFO | |
| Silt loam | 8.3 | 7.5 | 20 | 0.2/0.5 | 1.00 | 0.2/0.5 | 1.00 | SFO | |
| Geometric mean (n=4) | | | | 0.3/1.0 | - | 0.3/1.0 | | | - |

**Table 8.6-2: Summary of degradation in water/sediment of IN-U3204**

| IN-U3204 (max. water 24.7% AR after 0.13 d, max. sediment 0.5% AR after 3 d) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Water/sediment system** | **pH water** | **pH sediment** | **T°C** | **$DegT_{50}/DegT_{90}$ (d) whole sys.** | **$r^2$** | **$DegT_{50}/DegT_{90}$ (d) water** | **$r^2$** | **Method** | **Evaluated at EU level** |
| Sand | 7.4 | 7.0 | 20 | 0.6/2.0 | 0.92 | - | - | SFO | EFSA Scientific Report (2008) |
| Silty clay loam | 8.3 | 7.5 | 20 | 0.2/0.5 | 0.98 | - | - | SFO | |
| Silt loam | 8.3 | 7.5 | 20 | 0.5/1.7 | 0.96 | - | - | SFO | |
| Geometric mean (n=3) | | | | 0.4/1.2 | - | - | - | - | - |

**Table 8.6-3: Summary of degradation in water/sediment of IN-W3595**

| IN-W3595 (max. water 26.1% AR after 0.25 d, max. sediment 2.3% AR after 1 d) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Water/sediment system** | **pH water** | **pH sediment** | **T°C** | **$DegT_{50}/DegT_{90}$ (d) whole sys.** | **$r^2$** | **$DegT_{50}/DegT_{90}$ (d) water** | **$r^2$** | **Method** | **Evaluated at EU level** |
| Sand | 7.4 | 7.0 | 20 | 3.6/12.1 | 0.95 | - | - | SFO | EFSA Scientific Report (2008) |
| Silty clay loam | 8.3 | 7.5 | 20 | 2.7/9.0 | 0.99 | - | - | SFO | |
| Silt loam | 8.3 | 7.5 | 20 | 2.7/8.9 | 0.98 | - | - | SFO | |
| Geometric mean (n=3) | | | | 3.0/9.9 | - | - | - | - | - |

**Table 8.6-4: Summary of degradation in water/sediment of IN-JX915**

| IN-JX915 (max. water 7.2% AR after 1 d, max. sediment 1.2% AR after 1 d) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Water/sediment system** | **pH water** | **pH sediment** | **T°C** | **$DegT_{50}/DegT_{90}$ (d) whole sys.** | **$r^2$** | **$DegT_{50}/DegT_{90}$ (d) water** | **$r^2$** | **Method** | **Evaluated at EU level** |
| Sand | 7.4 | 7.0 | 20 | 2.5/8.3 | 0.79 | - | - | SFO | EFSA Scientific Report (2008) |
| Sand | 5.3 | 5.1 | 20 | 1.1/3.7 | 0.96 | - | - | SFO | |
| Silty clay loam | 8.3 | 7.5 | 20 | 2.1/7.1 | 0.88 | - | - | SFO | |
| Silt loam | 8.3 | 7. | 20 | 1.5/5.1 | 0.97 | - | - | SFO | |
| Geometric mean (n=4) | | | | 1.7/5.8 | - | - | - | - | - |

**Table 8.6-5: Summary of degradation in water/sediment of IN-KQ960**

| IN-KQ960 (max. water 13.0% AR after 1 d, max. sediment 5.5% AR after 30 d) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Water/sediment system** | **pH water** | **pH sediment** | **T°C** | **$DegT_{50}/DegT_{90}$ (d) whole sys.** | **$r^2$** | **$DegT_{50}/DegT_{90}$ (d) water** | **$r^2$** | **Method** | **Evaluated at EU level** |
| Sand | 7.4 | 7.0 | 20 | 154/521 | 0.76 | - | - | SFO | EFSA Scientific Report (2008) |
| Sand | 5.3 | 5.1 | 20 | 45.4/151 | 0.97 | - | - | SFO | |
| Silt loam | 8.3 | 7.5 | 20 | 15.2/50.5 | 0.98 | - | - | SFO | |
| Geometric mean (n=3) | | | | 47.4/158 | - | - | - | - | - |

**Table 8.6-6: Summary of degradation in water/sediment of IN-T4226**

| IN-T4226 (max. water 11.1% AR after 3 d, max. sediment 1.0% AR after 8 d) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Water/sediment system** | **pH water** | **pH sediment** | **T°C** | **$DegT_{50}/DegT_{90}$ (d) whole sys.** | **$r^2$** | **$DegT_{50}/DegT_{90}$ (d) water** | **$r^2$** | **Method** | **Evaluated at EU level** |
| Sand | 7.4 | 7.0 | 20 | 3.9/12.9 | 0.99 | - | - | SFO | EFSA Scientific Report (2008) |
| Sand | 5.3 | 5.1 | 20 | 5.4/17.9 | 0.91 | - | - | SFO | |
| Geometric mean (n=2) | | | | 4.6/15.2 | - | - | - | - | - |

**Table 8.6-7: Summary of degradation in water/sediment of IN-R3273**

| IN-R3273 (max. water 5.0% AR after 3 d, max. sediment 0.5% AR after 3 d) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Water/sediment system** | **pH water** | **pH sediment** | **T°C** | **$DegT_{50}/DegT_{90}$ (d) whole sys.** | **$r^2$** | **$DegT_{50}/DegT_{90}$ (d) water** | **$r^2$** | **Method** | **Evaluated at EU level** |
| Sand | 7.4 | 7.0 | 20 | 6.0/19.9 | 0.93 | - | - | SFO | EFSA Scientific Report (2008) |
| Sand | 5.3 | 5.1 | 20 | 6.7/22.2 | 0.98 | - | - | SFO | |
| Geometric mean (n=2) | | | | 6.3/21.0 | - | - | - | - | - |

**Table 8.6-8: Summary of degradation in water/sediment of IN-KP533**

| IN-KP533 (max. water 20.5% AR after 10 d, max. sediment 6.5% AR after 1 d)* | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Water/sediment system** | **pH water** | **pH sediment** | **T°C** | **$DegT_{50}/DegT_{90}$ (d) whole sys.** | **$r^2$** | **$DegT_{50}/DegT_{90}$ (d) water** | **$r^2$** | **Method** | **Evaluated at EU level** |
| Sand | 7.4 | 7.0/uk | 20 | 2.3/7.5 | 0.96 | - | - | SFO | EFSA Scientific Report (2008) |
| Sand | 5.3 | 5.1/uk | 20 | 3.0/10.0 | 0.97 | - | - | SFO | |
| Geometric mean (n=2) | | | | 2.6/8.7 | - | - | - | - | - |

* Worst-case assessment, individual amounts of IN-KP533 in two or four water/sediment systems not known (in two systems maximal 8.0% AR in the entire system)

**Table 8.6-9: Summary of degradation in water/sediment of metabolite fraction M5**

| M5 (max. water 22.9% AR after 1 d, max. sediment 0% AR) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Water/sediment system** | **pH water** | **pH sediment** | **T°C** | **$DegT_{50}/DegT_{90}$ (d) whole sys.** | **$r^2$** | **$DegT_{50}/DegT_{90}$ (d) water** | **$r^2$** | **Method** | **Evaluated at EU level** |
| Silty clay loam | 8.3 | 7.5/Ca | 20 | 1.2/4.0 | 1.00 | - | - | SFO | EFSA Scientific Report (2008) |
| Silt loam | 8.3 | 7.5/Ca | 20 | 1.6/5.2 | 1.00 | - | - | SFO | |
| Geometric mean (n=2) | | | | 1.4/4.6 | - | - | - | - | - |

**zRMS comments:**

Degradation data cymoxanil and its metabolites in water/sediment systems provided in table above are in line with EU agreed endpoints reported in EFSA Scientific Report (2008) 167, 1-116 and are relevant for the surface water exposure assessment.

## 8.7 Predicted environmental concentrations in soil (PECsoil) (KCP 9.1.3)

### 8.7.1 Justification for new endpoints

Agreed EU endpoints (EFSA, 2008) were used for the PECsoil calculations.

### 8.7.2 Active substance(s) and relevant metabolite(s)

**Table 8.7-1: Inputs related to application for PECsoil calculations**

| **Use no.** | **2** |
|---|---|
| Crop category | Potato |
| Open or enclosed | Field |
| Application rate (g as/ha) | 148.5 |
| Number of appn. | 6 |
| Appn. interval (d) | 5 |
| Appn. window | BBCH 12-95 |
| Crop interception (%)* | 15% (worst case for BBCH 12 and subsequent applications) |
| Soil depth (cm) | 5 |
| Soil density (g/cm$^3$) | 1.5 |

* AppDate 3.06 (June, 2019)

**Table 8.7-2: Inputs for Cymoxanil and metabolites for PECsoil calculation**

| **Compound** | **Molar mass (g/mol)** | **Max. soil (% AR)** | **Worst case SFO $DT_{50}$ (20°C/pF2/$Q_{10}$ 2.58) (d)** | **Evaluated at EU level** |
|---|---|---|---|---|
| Cymoxanil | 198.2 | - | 7.3*/7.3 | * EFSA Scientific Report (2008) Final Addendum to DAR – updated September 2008 |
| IN-U3204 | 198.2 | 24.7% | 0.9*/1.0 | |
| IN-W3595 | 128.1 | 10.1% | 2.5*/2.7 | |
| IN-JX915 | 198.2 | 10.9% | 1.0*/1.0 | |

* normalisation to 10 kPa or pF2, 20 °C with $Q_{10}$ of 2.2

Note that a PECsoil was not calculated for IN-KQ960 since it was <10% AR (EFSA, 2008).

PECsoil(acc) values were not calculated since none of the residues are considered persistent.

**Table 8.7-3: PECsoil for Cymoxanil on potato**

| PECsoil (mg/kg) | | Use no. 2 | | | |
|---|---|---|---|---|---|
| | | Single application | | Multiple applications | |
| | | Actual | TWA | Actual | TWA |
| Initial | | 0.168 | - | 0.419 | - |
| Short term | 1 d | 0.153 | 0.161 | 0.381 | 0.400 |
| | 2 d | 0.139 | 0.153 | 0.347 | 0.382 |
| | 4 d | 0.115 | 0.140 | 0.287 | 0.349 |
| Long term | 7 d | 0.087 | 0.123 | 0.216 | 0.306 |
| | 14 d | 0.045 | 0.093 | 0.111 | 0.232 |
| | 21 d | 0.023 | 0.073 | 0.057 | 0.182 |
| | 28 d | 0.012 | 0.059 | 0.029 | 0.147 |
| | 50 d | 0.001 | 0.035 | 0.004 | 0.088 |
| | 100 d | <0.001 | 0.018 | <0.001 | 0.044 |

**Table 8.7-4: PECsoil for IN-U3204 metabolite on potato**

| PECsoil (mg/kg) | | Use no. 2 | | | |
|---|---|---|---|---|---|
| | | Single application | | Multiple applications | |
| | | Actual | TWA | Actual | TWA |
| Initial | | 0.042 | - | 0.043 | - |
| Short term | 1 d | 0.021 | 0.030 | 0.021 | 0.031 |
| | 2 d | 0.010 | 0.022 | 0.011 | 0.023 |
| | 4 d | 0.003 | 0.014 | 0.003 | 0.015 |
| Long term | 7 d | <0.001 | 0.009 | <0.001 | 0.009 |
| | 14 d | <0.001 | 0.004 | <0.001 | 0.004 |
| | 21 d | <0.001 | 0.003 | <0.001 | 0.003 |
| | 28 d | <0.001 | 0.002 | <0.001 | 0.002 |
| | 50 d | <0.001 | 0.001 | <0.001 | 0.001 |
| | 100 d | <0.001 | 0.001 | <0.001 | 0.001 |

**Table 8.7-5: PECsoil for IN-W3595 metabolite on potato**

| PECsoil (mg/kg) | | Use no. 2 | | | |
|---|---|---|---|---|---|
| | | Single application | | Multiple applications | |
| | | Actual | TWA | Actual | TWA |
| Initial | | 0.011 | - | 0.015 | - |
| Short term | 1 d | 0.008 | 0.010 | 0.012 | 0.013 |
| | 2 d | 0.007 | 0.009 | 0.009 | 0.012 |
| | 4 d | 0.004 | 0.007 | 0.005 | 0.009 |
| Long term | 7 d | 0.002 | 0.005 | 0.003 | 0.007 |
| | 14 d | <0.001 | 0.003 | <0.001 | 0.004 |
| | 21 d | <0.001 | 0.002 | <0.001 | 0.003 |
| | 28 d | <0.001 | 0.002 | <0.001 | 0.002 |
| | 50 d | <0.001 | 0.001 | <0.001 | 0.001 |
| | 100 d | <0.001 | <0.001 | <0.001 | 0.001 |

**Table 8.7-6: PECsoil for IN-JX915 metabolite on potato**

| PECsoil (mg/kg) | | Use no. 2 | | | |
|---|---|---|---|---|---|
| | | Single application | | Multiple applications | |
| | | Actual | TWA | Actual | TWA |
| Initial | | 0.018 | - | 0.019 | - |
| Short term | 1 d | 0.009 | 0.013 | 0.009 | 0.014 |
| | 2 d | 0.005 | 0.010 | 0.005 | 0.010 |
| | 4 d | 0.001 | 0.006 | 0.001 | 0.006 |
| Long term | 7 d | <0.001 | 0.004 | <0.001 | 0.004 |
| | 14 d | <0.001 | 0.002 | <0.001 | 0.002 |
| | 21 d | <0.001 | 0.001 | <0.001 | 0.001 |
| | 28 d | <0.001 | 0.001 | <0.001 | 0.001 |
| | 50 d | <0.001 | 0.001 | <0.001 | 0.001 |
| | 100 d | <0.001 | <0.001 | <0.001 | <0.001 |

**zRMS comments:**

The application pattern presented in Table 8.7-1 and assumed in the soil exposure assessment is in line with the Central Zone GAP presented in Table 8.1-1. Relevant crop interception of 15% for potato in line with FOCUS groundwater guidance (2021) has been selected.

Input parameters presented in Table 8.7-2 for cymoxanil and its metabolites are in general in line with EU agreed parameters reported in EFSA Scientific Report (2008) 167, 1-116.
It is noted that for cymoxanil and its metabolites the geometric mean soil $DT_{50}$ values normalised with $Q_{10}$ of 2.58 were considered although the EU agreed endpoints were normalised with $Q_{10}$ of 2.2, the respective information was added to the Table 8.7-2. Nevertheless, the differences are negligible with no expected impact on the calculated $PEC_{SOIL}$. Morevoer, according to FOCUS groundwater guidance (2021), the recommended $Q_{10}$ factor is a default value of 2.58. Taking this into account, the soil $DT_{50}$ values considered by the Applicant are agreed by the zRMS

The soil exposure for cymoxanil and its metabolites has been independently validated by the zRMS using FOCUS methods and EU agreed endpoints. The calculated $PEC_{SOIL}$ values were in good agreement with these obtained by the Applicant. Therefore, results reported in tables above may be used for the soil risk assessment purposes.

## 8.7.3 Formulation

The formulation will not remain intact in soil after application due to breakdown of its individual components. Therefore, only an initial PECsoil was calculated for a single (not multiple) application and furthermore, time-aged values are not appropriate. The PECsoil was based upon an application rate of 330 g FP/ha with 15% interception for an application at BBCH 12 for potato.

**Table 8.7-7 PECsoil for IN002B1760 formulation**

| PECsoil (mg/kg) | Single application only |
|---|---|
| | Use no. 2 |
| Initial | 0.374 |

**zRMS comments:**

$PEC_{SOIL}$ value for the formulated product is agreed by the zRMS and may be used in the risk assessment for soil organisms.

## 8.8 Predicted environmental concentrations in groundwater (PECgw) (KCP 9.2.4)

### 8.8.1 Justification for new endpoints

Agreed EU endpoints (EFSA, 2008) were used for the PECgw calculations.

Following the EU review, new laboratory studies have been performed (Tan & Brands, 2009, and Hardy & Patel, 2009) to generate further rate of degradation data for the IN-KQ960 metabolite, and the study is summarised in Appendix 2.

### 8.8.2 Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1)

**Table 8.8-1: Inputs related to application for PECgw calculations**

| Use No. | 2 |
|---|---|
| Crop category | Potato |
| Application rate (g as/ha) | 148.5 |
| Number of appn. | 6 |
| Appn. interval (d) | 5 |
| Appn. Window | BBCH 12-95 |
| Crop interception (%)* | Early application:<br>1st and 2nd, 3rd 15%<br>~~3rd~~, 4th, 5st and 6nd applications; 60%<br>~~Early application: 15%~~<br>~~1st and 2nd applications; 60%~~<br>Late applications: 85% |
| Relative appn. date* | Early: 7 d post-emergence<br>Late: 33 d pre-harvest |
| Frequency of appn. | Annual |
| Models used | FOCUSPELMO 6.6.4 and<br>FOCUSPEARL 5.5.5 |

* AppDate 3.06 (June, 2019), worst case

The following report **(8.8.2/01)** provides the PECgw values for Cymoxanil and its metabolites when using the GAP and models described in Table 8.8-1.

| Reference: | **8.8.2/01** |
|---|---|
| Report: | Isacco, L. (2021): Predicted environmental concentration in groundwater (PECgw) following the use of Cymoxanil containing product in various crops.<br>2021-E001, Expedia MRCC S.r.l. |
| Guideline(s): | Recommendations of FOCUS groundwater workgroup |
| Deviations: | No |
| GLP: | No (model calculation) |
| Acceptability: | Yes |

**Table 8.8-2: Inputs related to Cymoxanil and its metabolites for PECgw calculations**

| Compound | Cymoxanil | IN-U3204 | IN-W3595 | IN-JX915 | IN-KQ960 | Evaluated at EU level |
|---|---|---|---|---|---|---|
| Molar mass (g/mol) | 198.2 | 198.2 | 128.1 | 198.2 | 216.2 | EFSA Scientific Report (2008) |
| Water solubility (mg/L) | 783<br>(20°C, pH7) | Parent as surrogate | Parent as surrogate | Parent as surrogate | Parent as surrogate | |
| Sat. vapour pressure (Pa) | $1.5 \times 10^{-4}$<br>(20°C) | Parent as surrogate | Parent as surrogate | Parent as surrogate | Parent as surrogate | |
| $DT_{50}$ soil (d) | 1.2<br>(geomean, 20°C/$Q_{10}$ 2.58/ pF2) | 0.4<br>(geomean, 20°C/$Q_{10}$ 2.58/ pF2) | 2.7<br>(geomean, 20°C/$Q_{10}$ 2.58/ pF2) | 1<br>(worst case, 20°C/$Q_{10}$ 2.58/ pF2) | 12.2*<br>(worst case, 20°C/$Q_{10}$ 2.58/ pF2) | For IN-KQ960 |

| Compound | Cymoxanil | IN-U3204 | IN-W3595 | IN-JX915 | IN-KQ960 | Evaluated at EU level |
|---|---|---|---|---|---|---|
| | | | | | 1.55 (geomean n=12)** ~~1.7** (geomean, 20°C/$Q_{10}$ 2.58/ pF2)~~ | soil $DT_{50}$: DRAR, January 2022 ~~Tan and Brands, 2009; Hardy and Patel, 2009~~ |
| Kfoc (mL/g) | 43.6 (arithmetic mean) | 27.9 (HPLC method) | Koc acid=33.3 Koc basic=2.3 pKa = 5.2 | 16.2 (arithmetic mean) | 21.6 (HPLC method) | |
| 1/n | 0.86 (arithmetic mean) | 1 | 1 | 1 | 1 | |
| Plant uptake factor | 0 | 0 | 0 | 0 | 0 | |
| Formation fraction | - | From Cymoxanil: 0.36 | From Cymoxanil: 0.15 | From Cymoxanil: 0.109 | From IN-U3204: 0.16 | |

* Tier 1
** Tier 2 with refined $DT_{50}$

**Table 8.8-3: PECgw for Cymoxanil and its metabolites on potato**

| FOCUS model | Scenario | 80th Percentile PECgw at 1 m soil depth (µg/L) | | | |
|---|---|---|---|---|---|
| | | Cymoxanil | IN-U3204 | IN-JX915 | IN-KQ960 |
| **Potatoes, early** | | | | | |
| PELMO 6.6.4 | Châteaudun | <0.001 | <0.001 | <0.001 | ~~0.031~~ / <0.001* |
| | Hamburg | <0.001 | <0.001 | <0.001 | ~~0.090~~ / <0.001* |
| | Jokioinen | <0.001 | <0.001 | <0.001 | ~~0.190~~ / <0.001* |
| | Kremsmünster | <0.001 | <0.001 | <0.001 | ~~0.070~~ / <0.001* |
| | Okehampton | <0.001 | <0.001 | <0.001 | ~~0.087~~ / <0.001* |
| | Piacenza | <0.001 | <0.001 | <0.001 | ~~0.023~~ / <0.001* |
| | Porto | <0 001 | <0 001 | <0 001 | ~~0.017~~ / <0.001* |
| | Sevilla | <0.001 | <0.001 | <0.001 | ~~0.002~~ / <0.001* |
| | Thiva | <0.001 | <0.001 | <0.001 | ~~0.005~~ / <0.001* |
| PEARL 5.5.5 | Châteaudun | <0.001 | <0.001 | <0.001 | ~~0.035~~ / <0.001* |
| | Hamburg | <0.001 | <0.001 | <0.001 | ~~0.096~~ / <0.001* |
| | Jokioinen | <0.001 | <0.001 | <0.001 | ~~0.132~~ / <0.001* |
| | Kremsmünster | <0.001 | <0.001 | <0.001 | ~~0.057~~ / <0.001* |
| | Okehampton | <0.001 | <0.001 | <0.001 | ~~0.067~~ / <0.001* |
| | Piacenza | <0.001 | <0.001 | <0.001 | ~~0.015~~ / <0.001* |
| | Porto | <0 001 | <0 001 | <0 001 | ~~0.009~~ / <0.001* |
| | Sevilla | <0.001 | <0.001 | <0.001 | ~~0.001~~ / <0.001* |
| | Thiva | <0.001 | <0.001 | <0.001 | ~~0.003~~ / <0.001* |
| **Potatoes, late** | | | | | |
| PELMO 6.6.4 | Châteaudun | <0.001 | <0.001 | <0.001 | 0.017 / <0.001* |
| | Hamburg | <0.001 | <0.001 | <0.001 | 0.400 / <0.001* |
| | Jokioinen | <0.001 | <0.001 | 0.001 | 0.492 / 0.002 |
| | Kremsmünster | <0.001 | <0.001 | <0.001 | 0.135 / <0.001* |
| | Okehampton | <0.001 | <0.001 | <0.001 | 0.156 / <0.001* |
| | Piacenza | <0.001 | <0.001 | <0.001 | 0.107 / <0.001* |
| | Porto | <0 001 | <0 001 | <0 001 | 0.011 / <0.001* |
| | Sevilla | <0.001 | <0.001 | <0.001 | <0.001 / <0.001* |
| | Thiva | <0.001 | <0.001 | <0.001 | 0.001 / <0.001* |
| PEARL 5.5.5 | Châteaudun | <0.001 | <0.001 | <0.001 | 0.009 / <0.001* |
| | Hamburg | <0.001 | <0.001 | <0.001 | 0.122 / <0.001* |

| | | | | | |
|---|---|---|---|---|---|
| | Jokioinen | <0.001 | <0.001 | <0.001 | 0.118 / <0.001* |
| | Kremsmünster | <0.001 | <0.001 | <0.001 | 0.045 / <0.001* |
| | Okehampton | <0.001 | <0.001 | <0.001 | 0.058 / <0.001* |
| | Piacenza | <0.001 | <0.001 | <0.001 | 0.046 / <0.001* |
| | Porto | <0 001 | <0 001 | <0 001 | 0.001 / <0.001* |
| | Sevilla | <0.001 | <0.001 | <0.001 | <0.001/ <0.001* |
| | Thiva | <0.001 | <0.001 | <0.001 | 0.001 / <0.001* |

* Tier 2 calculations performed with refined $DT_{50}$ for IN-KQ960 of 1.55 days

**Table 8.8-4: PECgw for IN-W3595 metabolite on potato when accounting for pH-dependence**

| FOCUS model | Scenario | 80th Percentile PECgw at 1 m soil depth (µg/L) | |
|---|---|---|---|
| | | IN-W3595 (acid Koc) | IN-W3595 (basic Koc) |
| **Potatoes, early** | | | |
| PELMO 6.6.4 | Châteaudun | <0.001 | <0.001 |
| | Hamburg | <0.001 | <0.001 |
| | Jokioinen | <0.001 | 0.006 |
| | Kremsmünster | <0.001 | 0.001 |
| | Okehampton | <0.001 | 0.004 |
| | Piacenza | <0.001 | 0.006 |
| | Porto | <0.001 | 0.019 |
| | Sevilla | <0.001 | 0.001 |
| | Thiva | <0.001 | <0.001 |
| PEARL 5.5.5 | Châteaudun | <0.001 | <0.001 |
| | Hamburg | <0.001 | <0.001 |
| | Jokioinen | <0.001 | 0.001 |
| | Kremsmünster | <0.001 | <0.001 |
| | Okehampton | <0.001 | 0.001 |
| | Piacenza | <0.001 | <0.001 |
| | Porto | <0.001 | 0.001 |
| | Sevilla | <0.001 | <0.001 |
| | Thiva | <0.001 | <0.001 |
| **Potatoes, late** | | | |
| PELMO 6.6.4 | Châteaudun | <0.001 | <0.001 |
| | Hamburg | 0.001 | 0.017 |
| | Jokioinen | 0.004 | 0.465 |
| | Kremsmünster | <0.001 | 0.008 |
| | Okehampton | <0.001 | 0.002 |
| | Piacenza | <0.001 | 0.006 |
| | Porto | <0.001 | <0.001 |
| | Sevilla | <0.001 | <0.001 |
| | Thiva | <0.001 | <0.001 |
| PEARL 5.5.5 | Châteaudun | <0.001 | <0.001 |
| | Hamburg | <0.001 | 0.009 |
| | Jokioinen | 0.001 | 0.050 |
| | Kremsmünster | <0.001 | 0.001 |
| | Okehampton | <0.001 | 0.001 |
| | Piacenza | <0.001 | 0.001 |
| | Porto | <0.001 | <0.001 |
| | Sevilla | <0.001 | <0.001 |
| | Thiva | <0.001 | <0.001 |

For IN-KQ960, the Tier 2 calculations using a refined $DT_{50}$ (1.7 days) lead to results well below the regulatory threshold value of 0.1 µg/L.

No information is available on the toxicological relevance of IN-W3595 since it was not triggered (EFSA, 2008), and no groundwater assessment was required. ~~IN-W3595 is not considered toxicologically relevant, so 0.75 µg/L could be considered the threshold PECgw~~. Furthermore, only a small number of results are >0.1 µg/L, especially Jokioinen which is not relevant for the Central Zone.

**zRMS comments:**

The application pattern presented in Table 8.8-1 and considered in ground water exposure assessment is in general in line with the Central Zone GAP and is protective for intended uses of IN002B1760 in potato.
It is noted that for the early application - first and second applications correspond with 15% crop interception and for the subsequent applications crop interception is 60% for Châteaudun, Kremsmünster, Piacenza. However for scenarios: Hamburg, Jokioinen, Okehampton, Porto, Sevilla and Thiva crop interception of 15% corresponds to first, second and 3rd application, whereas crop interception of 60% to 4th , 5th and 6th application. This information was corrected by the zRMS in Table 8.8-1 in order to be in line with the AppDate 3.06 (June, 2019). ~~and with modelling reports that show correct crop interception.~~

Tier 1
Input parameters for cymoxanil and its metabolites presented in Table 8.8-2 are in general in line with EU agreed parameters reported in EFSA Scientific Report (2008) 167, 1-116 with following exceptions:

- For cymoxanil and its metabolites the geometric mean soil $DT_{50}$ values normalised with $Q_{10}$ of 2.58 were considered although the EU agreed endpoints were normalised with $Q_{10}$ of 2.2. Nevertheless, the difference between the EU agreed $DT_{50}$ for metabolite IN-W3596 and IN-KQ960 (2.5 and 11.2 d, respectively) and this used in the modelling (2.7 and 12.2 d, respectively) is worst case. Taking this into account, the soil $DT_{50}$ values considered by the Applicant at Tier 1 calculations are agreed by the zRMS.

In all simulations PUF value of 0 was assumed, in line with recommendations of the most recent version of the FOCUS Groundwater Guidance.

The groundwater modelling was independently validated by the zRMS in additional modelling with FOCUS PEARL 5.5.5 and FOCUS PELMO 6.6.4 using the EU agreed input parameters and application dates as suggested by AppDate 3.06. Obtained results at Tier 1 were in good agreement with these derived by the Applicant for cymoxanil and its metabolites.
No unacceptable leaching of cymoxanil and metabolites IN-U3204 and IN-JX915 is expected following application of ADM.06001.H.2.B according to the intended Central Zone use pattern given in Table 8.1-1.
The $PEC_{GW}$ value for metabolite IN-W3596 is > 0.1 µg/L only in Jokioinen scenario for late application in potatoes. Since Jokioinen scenario is not relevant for the Central Zone no further assessment was necessary. However according to EFSA Scientific Report (2008) 167, 1-116 for this metabolite non information for toxicological relevance is available, and not needed.
The $PEC_{GW}$ values for toxicologically relevant metabolite IN-KQ960 were above 0.1 µg/L in almost all scenarios for late application in potatoes. Therefore, further modelling at Tier 2 was performed and is discussed by the zRMS below.

During the commenting period it was correctly noticed that wrong crop interception was assumed for the early application to potatoes. New groundwater modelling with correct crop interception and using the EU agreed input parameters was performed by the zRMS and no impact on the PECgw results for cymoxanil and its metabolites: IN-U3204, IN-W3595, and IN-JX915 were observed. Whereas the obtained results for metabolite IN-KQ960 at Tier 1 demonstrated potential leaching to groundwater at concentrations >0.1 µg/L in few scenarios for early application in potatoes. Since the groundwater exposure assessment for the metabolite IN-KQ960 at Tier 2 is still needed, in order to reduce the workload the previous results at Tier 1 for early application to potatoes have been struck through.

Tier 2
The groundwater modelling based on the EU agreed parameters at Tier 1 demonstrated potential leaching of cymoxanil metabolite IN-KQ960 to groundwater at concentrations >0.1 µg/L in almost all scenarios for late application in potatoes. As metabolite IN-KQ960 is toxicologically relevant, its concentrations must remain <0.1 µg/L in order to conclude acceptable groundwater exposure and for this reason further assessment was deemed necessary.

The data available from the first EU review were not sufficient to refine any of the input parameters and for IN-

KQ960 the soil $DT_{50}$ for only single soil was available from the EU review. For this reason the Applicant submitted additional studies on soil degradation of IN-KQ960 in soil (Tan & Brands, 2009 and Hardy & Patel, 2009) in support of the refined groundwater modelling following the intended uses of IN002B1760. Although, in general, the product assessment should be carried out according to the currently agreed EU endpoints, the Working Document of the Central Zone in area of Section 8, identifies situation when new active substance data may be considered in the Core Assessments:

*[...] Note that according to the guidance document on the evaluation of new active substance data post approval (SANCO/10328/2004– rev 8, 24.01.2012) new active substance/metabolite data should not be considered unless they are necessary in order to show a safe use, they are needed as additional uses/crops are applied for authorisation, or they are "adverse" data. [...]*

Nevertheless, before evaluation of the new studies, the zRMS checked if they were evaluated at the EU level in the course of the renewal process or as a part of the confirmatory data. It turned out that both studies were already evaluated and agreed by the RMS (LT) as a part of the data submitted in support of the cymoxanil renewal process. Furthermore, also other studies on degradation of IN-KQ960 were considered by the RMS. The valid degradation data were available for 12 soils resulting with geometric mean $DT_{50}$ of 1.55 days, which is considerably shorter than currently EU agreed $DT_{50}$ of 11.2 days derived for the single soil. As a member of the cymoxanil Task Force (CTF), the Applicant for IN002B1760 has full access to cymoxanil data considered during the renewal process.

Although the renewal process is not finalised yet, it is at the advanced stage with recent version of the DRAR issued in January 2022, after the discussion during the expert meetings, and the $DT_{50}$ of 1.55 days may be considered as already peer-reviewed. Since respective degradation data were already derived in the course of the renewal process and they include results of the studies Tan & Brands, 2009 and Hardy & Patel, 2009, additional evaluation of these studies by the zRMS is not necessary and $DT_{50}$ of 1.55 days was considered in the refined groundwater modelling for IN-KQ960.

The additional modelling at Tier 2 using FOCUS PEARL 5.5.5 and FOCUS PELMO 6.6.4 was performed by the zRMS using the same parameters as indicated in Table 8.8- 2 and $DT_{50}$ of 1.55 days for metabolite IN-KQ960. The obtained $PEC_{GW}$ values for metabolite IN-KQ960 were <0.001 µg/L in all scenarios.

During the commenting period it was correctly noticed that wrong crop interception was assumed for the early application to potatoes. Thus, additional modelling was performed using the same parameters as discussed above and correct crop interception for third application to potatoes. Obtained $PEC_{GW}$ values at Tier 2 for toxicologically relevant metabolite IN-KQ960 were still below 0.1 µg/L in all scenarios for early application in potatoes.

Overall, based on the results of the groundwater modelling performed by the Applicant and the zRMS, no unacceptable leaching of cymoxanil and its metabolites is expected when IN002B1760 is used according to the Central Zone GAP.

Please note that additional groundwater modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

## 8.9 Predicted environmental concentrations in surface water (PECsw/sed) (KCP 9.2.5)

### 8.9.1 Justification for new endpoints

Agreed EU endpoints (EFSA, 2008) were used for the PECsw/sed calculations.

~~Following the EU review, new laboratory studies have been performed (Tan & Brands, 2009, and Hardy & Patel, 2009) to generate further rate of degradation data for the IN-KQ960 metabolite, and the study is summarised in Appendix 2.~~

### 8.9.2 Active substance(s) and relevant metabolite(s) (KCP 9.2.5)

**Table 8.9-1: Inputs related to application for PECsw/sed calculations (Steps 1 and 2)**

| Use No. | 2 |
|---|---|
| Crop category | Potato |
| Application rate (g as/ha) | 148.5 |
| Number of appn. | 6 |
| Appn. interval (d) | 5 |
| Scenario (Steps 1 and 2) | N-EU/S-EU |
| Appn. window (Steps 1 and 2) | Mar-May*<br>Jun-Sep*<br>~~Oct-Feb*~~ |
| Crop cover (Steps 1 and 2) | Minimal |
| Frequency of appn. | Annual |
| Model used | Steps 1-2 in FOCUS v3.2 |

* Covers BBCH 12-95

**Table 8.9-2: Inputs related to Cymoxanil and its metabolites for PECsw/sed calculations (Steps 1 and 2)**

| Compound | Cymoxanil | IN-U3204 | IN-W3595 | IN-JX915 | Evaluated at EU level |
|---|---|---|---|---|---|
| Molar mass (g/mol) | 198.2 | 198.2 | 128.1 | 198.2 | EFSA Scientific Report (2008) |
| Water solubility (mg/L) | 783 | Parent as surrogate | Parent as surrogate | Parent as surrogate | |
| Kfoc (mL/g) | 43.6 (arithmetic mean) | 27.9 (HPLC method) | 9.2 (arithmetic mean) | 16.2 (arithmetic mean) | |
| $DT_{50}$, soil (d) | 1.2 (geomean, 20°C/$Q_{10}$ 2.58/ pF2) | 0.4 (geomean, 20°C/$Q_{10}$ 2.58/ pF2) | 2.5 (geomean, with $Q_{10}$ of 2.2)<br>2.7 (geomean, 20°C/$Q_{10}$ 2.58/ pF2) | 1.0 (geomean, 20°C/$Q_{10}$ 2.58/ pF2) | |
| $DT_{50}$, water, sediment and whole system (d) | 0.3 (geomean) | 0.4 (geomean) | 3.0 (geomean) | 1.7 (geomean) | |
| Maximum (% molar basis with respect to parent) | - | Soil: 24.7<br>Water/sed: 24.7 | Soil: 10.1<br>Water/sed: 27.5 | Soil: 10.9<br>Water/sed: 8.5 | |

| Compound | IN-KQ960 | IN-T4226 | IN-R3273 | IN-KP533 | M5 | Evaluated at EU level |
|---|---|---|---|---|---|---|
| Molar mass (g/mol) | 216.2 | 142.1 | 171.2 | 160.1 | 198.2 | EFSA Scientific Report (2008) |
| Water solubility | Parent as | Parent as | Parent as | Parent as | Parent as | |

| | | | | | | |
|---|---|---|---|---|---|---|
| (mg/L) | surrogate | surrogate | surrogate | surrogate | surrogate | |
| Kfoc (mL/g) | 21.6 (HPLC method) | 17.7 (HPLC method) | 41.9 (arithmetic mean) | 12.9 (HPLC method) | 9.2 (IN-W3595 as surrogate) | ~~For IN-KQ960 soil $DT_{50}$: Tan and Brands, 2009; Hardy and Patel, 2009~~ |
| $DT_{50}$, soil (d) | 11.2 (geomean with $Q_{10}$ of 2.2) ~~1.7 (geomean, 20°C/$Q_{10}$ 2.58/ pF2)~~ | 1000 (default) | 1000 (default) | 1000 (default) | 1000 (default) | |
| $DT_{50}$, water, sediment and whole system (d) | 47.4 (geomean) | 4.6 (geomean) | 6.3 (geomean) | 2.6 (geomean) | 1.4 (geomean) | |
| Maximum (% molar basis with respect to parent) | Soil: 6.3 Water/sed: 14.3 ~~22.9~~ | Soil: 1.7 Water/sed: 12 | Soil: 2.4 Water/sed: 5 | Soil: 2.7 Water/sed: 26 | Soil: - Water/sed: 22.9 | |

The PECsw/sed results are as follows. Values in brackets relate to a single application only.

**Table 8.9-3: PECsw/sed for Cymoxanil on potato (Steps 1 and 2) (single application in brackets)**

| FOCUS scenario | Appn. timing | Max. PECsw (µg/L) | Entry route | 21 d - PECsw,twa (µg/L) | Max. PECsed* (µg/kg) |
|---|---|---|---|---|---|
| **Use no. 2 (potato)** | | | | | |
| Step 1 | - | 48.15 | - | 1.36 | 20.40 |
| Step 2 Northern Europe | Mar-May<br>Jun-Sep<br>~~Oct-Feb~~ | 0.84 (1.37)<br>0.84 (1.37)<br>~~2.09 (1.97)~~ | Spray drift, runoff, drainage | 0.02<br>0.02<br>~~0.06~~ | 0.36<br>0.36<br>~~0.91~~ |
| Step 2 Southern Europe | Mar-May<br>Jun-Sep<br>~~Oct-Feb~~ | 1.67 (1.58)<br>1.25 (1.37)<br>~~1.67 (1.58)~~ | Spray drift, runoff, drainage | 0.05<br>0.04<br>~~0.05~~ | 0.73<br>0.55<br>~~0.73~~ |

* Provided for completeness, but not triggered since <10% AR (EFSA, 2008)

**Table 8.9-4: PECsw/sed for IN-U3204 metabolite on potato (Steps 1 and 2) (single application in brackets)**

| FOCUS scenario | Appn. timing | Max. PECsw (µg/L) | Max. PECsed* (µg/kg) |
|---|---|---|---|
| **Use no. 2 (potato)** | | | |
| Step 1 | - | 23.91 | 6.58 |
| Step 2 Northern Europe | Mar-May<br>Jun-Sep<br>~~Oct-Feb~~ | 0.21 (0.34)<br>0.21 (0.34)<br>~~0.53 (0.50)~~ | 0.06<br>0.06<br>~~0.15~~ |
| Step 2 Southern Europe | Mar-May<br>Jun-Sep<br>~~Oct-Feb~~ | 0.43 (0.40)<br>0.32 (0.34)<br>~~0.43 (0.40)~~ | 0.12<br>0.09<br>~~0.12~~ |

* Provided for completeness, but not triggered since <10% AR (EFSA, 2008)

**Table 8.9-5: PECsw/sed for IN-W3595 metabolite on potato (Steps 1 and 2) (single application in brackets)**

| FOCUS scenario | Appn. timing | Max. PECsw (µg/L) | Max. PECsed* (µg/kg) |
|---|---|---|---|
| **Use no. 2 (potato)** | | | |
| Step 1 | - | 72.76 | 6.56 |
| Step 2 Northern Europe | Mar-May<br>Jun-Sep<br>~~Oct-Feb~~ | 0.51 (0.44)<br>0.51 (0.44)<br>~~1.14 (0.95)~~ | 0.04<br>0.04<br>~~0.10~~ |
| Step 2 Southern Europe | Mar-May<br>Jun-Sep<br>~~Oct-Feb~~ | 0.93 (0.78)<br>0.72 (0.61)<br>~~0.93 (0.78)~~ | 0.08<br>0.06<br>~~0.08~~ |

* Provided for completeness, but not triggered since <10% AR (EFSA, 2008)

**Table 8.9-6: PECsw/sed for IN-JX915 metabolite on potato (Steps 1 and 2) (single application in brackets)**

| FOCUS scenario | Appn. timing | Max. PECsw (µg/L) | Max. PECsed* (µg/kg) |
|---|---|---|---|
| **Use no. 2 (potato)** | | | |
| Step 1 | - | 57.10 | 9.14 |
| Step 2<br>Northern Europe | Mar-May<br>Jun-Sep<br>~~Oct-Feb~~ | 0.15 (0.15)<br>0.15 (0.15)<br>~~0.34 (0.34)~~ | 0.02<br>0.02<br>~~0.05~~ |
| Step 2<br>Southern Europe | Mar-May<br>Jun-Sep<br>~~Oct-Feb~~ | 0.28 (0.27)<br>0.21 (0.21)<br>~~0.28 (0.27)~~ | 0.05<br>0.03<br>~~0.05~~ |

* Provided for completeness, but not triggered since <10% AR (EFSA, 2008)

**Table 8.9-7: PECsw/sed for IN-KQ960 metabolite on potato (Steps 1 and 2) (single application in brackets)**

| FOCUS scenario | Appn. timing | Max. PECsw (µg/L) | | Max. PECsed* (µg/kg) | |
|---|---|---|---|---|---|
| **Use no. 2 (potato)** | | | | | |
| Step 1 | - | 66.15 | | 14.07 | |
| Step 2<br>Northern Europe | Mar-May<br>Jun-Sep<br>~~Oct-Feb~~ | 2.11 (0.76)<br>2.11 (0.76)<br>- | ~~0.85 (0.43)~~<br>~~0.85 (0.43)~~<br>~~1.24 (0.79)~~ | 0.45 (0.16)<br>0.45 (0.16)<br>- | ~~0.18~~<br>~~0.18~~<br>~~0.26~~ |
| Step 2<br>Southern Europe | Mar-May<br>Jun-Sep<br>~~Oct-Feb~~ | 3.64 (1.33)<br>2.88 (1.05)<br>- | ~~1.11 (0.67)~~<br>~~0.98 (0.55)~~<br>~~1.11 (0.67)~~ | 0.77 (0.28)<br>0.61 (0.22)<br>- | ~~0.23~~<br>~~0.21~~<br>~~0.23~~ |

* Provided for completeness, but not triggered since <10% AR (EFSA, 2008)

**Table 8.9-8: PECsw/sed for IN-T4226 metabolite on potato (Steps 1 and 2) (single application in brackets)**

| FOCUS scenario | Appn. timing | Max. PECsw (µg/L) | Max. PECsed* (µg/kg) |
|---|---|---|---|
| **Use no. 2 (potato)** | | | |
| Step 1 | - | 29.20 | 5.04 |
| Step 2<br>Northern Europe | Mar-May<br>Jun-Sep<br>~~Oct-Feb~~ | 0.74 (0.23)<br>0.74 (0.23)<br>~~1.74 (0.49)~~ | 0.13<br>0.13<br>~~0.30~~ |
| Step 2<br>Southern Europe | Mar-May<br>Jun-Sep<br>~~Oct-Feb~~ | 1.41 (0.40)<br>1.07 (0.32)<br>~~1.41 (0.40)~~ | 0.24<br>0.19<br>~~0.24~~ |

* Provided for completeness, but not triggered since <10% AR (EFSA, 2008)

**Table 8.9-9: PECsw/sed for IN-R3273 metabolite on potato (Steps 1 and 2) (single application in brackets)**

| FOCUS scenario | Appn. timing | Max. PECsw (µg/L) | Max. PECsed* (µg/kg) |
|---|---|---|---|
| **Use no. 2 (potato)** | | | |
| Step 1 | - | 18.33 | 7.53 |
| Step 2<br>Northern Europe | Mar-May<br>Jun-Sep<br>~~Oct-Feb~~ | 1.07 (0.24)<br>1.07 (0.24)<br>~~2.59 (0.53)~~ | 0.44<br>0.44<br>~~1.08~~ |
| Step 2<br>Southern Europe | Mar-May<br>Jun-Sep<br>~~Oct-Feb~~ | 2.08 (0.43)<br>1.57 (0.33)<br>~~2.08 (0.43)~~ | 0.87<br>0.65<br>~~0.87~~ |

* Provided for completeness, but not triggered since <10% AR (EFSA, 2008)

**Table 8.9-10: PECsw/sed for IN-KP533 metabolite on potato (Steps 1 and 2) (single application in brackets)**

| FOCUS scenario | Appn. timing | Max. PECsw (µg/L) | Max. PECsed* (µg/kg) |
|---|---|---|---|
| **Use no. 2 (potato)** | | | |
| Step 1 | - | 69.41 | 8.73 |
| Step 2<br>Northern Europe | Mar-May<br>Jun-Sep<br>~~Oct-Feb~~ | 1.33 (0.45)<br>1.33 (0.45)<br>~~3.21 (0.98)~~ | 0.17<br>0.17<br>~~0.41~~ |
| Step 2<br>Southern Europe | Mar-May<br>Jun-Sep<br>~~Oct-Feb~~ | 2.58 (0.80)<br>1.96 (0.63)<br>~~2.58 (0.80)~~ | 0.33<br>0.25<br>~~0.33~~ |

* Provided for completeness, but not triggered since <10% AR (EFSA, 2008)

**Table 8.9-11: PECsw/sed for M5 metabolite on potato (Steps 1 and 2) (single application in brackets)**

| FOCUS scenario | Appn. timing | Max. PECsw (µg/L) | Max. PECsed* (µg/kg) |
|---|---|---|---|
| **Use no. 2 (potato)** | | | |
| Step 1 | - | 11.51 | 1.03 |
| Step 2<br>Northern Europe | Mar-May<br>Jun-Sep<br>~~Oct-Feb~~ | 0.23 (0.31)<br>0.23 (0.31)<br>~~0.53 (0.51)~~ | 0.02<br>0.02<br>~~0.05~~ |
| Step 2<br>Southern Europe | Mar-May<br>Jun-Sep<br>~~Oct-Feb~~ | 0.43 (0.42)<br>0.33 (0.33)<br>~~0.43 (0.42)~~ | 0.04<br>0.03<br>~~0.04~~ |

* Provided for completeness, but not triggered since <10% AR (EFSA, 2008)

**zRMS comments:**

The application pattern considered in the surface water exposure assessment presented in Table 8.9-1 is in general in line with the Central Zone GAP and is protective for intended uses of IN002B1760 in potato. It is noted that the Applicant performed additional simulations for applications time October-February, however this time of application do not cover the designated BBCH stages of 12-95. Taking this into account, the zRMS validated only the part of calculations that were performed with consideration of the application dates respective to the BBCH stages and application in Oct-Feb presented in Table 8.9-1 was struck through by the zRMS as not relevant.

The input parameters considered by the Applicant in surface water modelling for cymoxanil and its metabolites presented in Table 8.9-2 are in general in line with EU agreed endpoints reported in EFSA Scientific Report (2008) 167, 1-116 with following exceptions:

- for cymoxanil and its metabolites the geometric mean soil $DT_{50}$ values normalised with $Q_{10}$ of 2.58 were considered although the EU agreed endpoints were normalised with $Q_{10}$ of 2.2. Nevertheless, for metabolite IN-W3595 the difference between the EU agreed $DT_{50}$ (2.5 days) and this used in the modelling (2.7 days) is negligible with no expected impact on the calculated $PEC_{SW/SED}$. Taking this into account, the soil $DT_{50}$ value considered by the Applicant is agreed by the zRMS.
- for metabolite IN-KQ960 the maximum occurrence in water/sed of 22.9% was considered instead of 14.3% as reported in the LoEP and considered in the EU groundwater modelling. The respective correction were introduced in Table 8.9-2.
- for metabolite IN-KQ960 the EU agreed value of soil $DT_{50}$ is 11.2 days instead of the value used by the Applicant of 1.7 days from studies on soil degradation of IN-KQ960 in soil (Tan & Brands, 2009 and Hardy & Patel, 2009). However, as already indicated in points 8.3.1, of this document, this studies on soil degradation are considered to be the new active substance data, which may be used at the zonal level only in exceptional cases, when e.g. no safe use is identified using the EU agreed endpoints. In addition to that, the Working Document of the Central Zone in area of Section 8[1] indicates that modelling based on new/refined input parameters should be presented in addition to and not instead of simulations based on EU agreed data. Taking this into account, the information presented in Table 8.9-2 was amended accordingly.

[1] Working Document of the Central Zone in the Authorisation of Plant Protection Products, Section 8, Environmental Fate and Behaviour, Version 1, rev. 1, June 2018

The surface water modelling was independently validated by the zRMS using fully EU agreed input parameters and the same application pattern. Obtained $PEC_{SW}$ and $PEC_{SED}$ values for the cymoxanil and its metabolites: IN-U3204, IN-JX915, IN-T4226, IN-R327, IN-KP533, M5 were in good agreement with values obtained by the Applicant.
For metabolite IN-W3595 obtained results were slightly lower from values obtained by the Applicant.
For metabolite IN-KQ960 results of $PEC_{SW}$ and $PEC_{SED}$ calculated by the zRMS were higher comparing to these obtained by the Applicant, since higher soil $DT_{50}$ of 11.2 days was taken into account as it is EU agreed endpoints. Values reported in Tables 8.9-7 were thus corrected by the zRMS and may be used for purposes of the aquatic risk assessment.
$PEC_{SW}$ and $PEC_{SED}$ results that considered application time of Oct-Feb were struck through by the zRMS as this time of application do not cover the designated BBCH stages of 12-95.

Overall, surface water exposure of cymoxanil and its metabolites presented in Tables 8.9-3 to 8.9-11 may be used in the aquatic risk assessment.

Please note that additional surface water modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

### 8.9.3 Formulation (KCP 9.2.5)

The formulation spray drift PECsw was calculated using Rautmann drift for a 30 cm deep static edge-of-field water body for a field crop. Since the formulation will not remain intact in surface water after application due to breakdown of its individual components, only an initial PECsw was calculated for a single (not multiple) application and furthermore, time-aged values are not appropriate. The spray drift PECsw was based upon an application rate of 330 g FP/ha for the potato use.

**Table 8.9-12: PECsw for IN002B1760 on potato (spray drift only)**

| No-spray zone (m) | Use no. 2 |
|---|---|
| | Spray drift PECsw (µg/L) |
| | Single appn. (1 x 330 g FP/ha) |
| 1 | 3.047 |
| 5 | 0.627 |
| 10 | 0.319 |
| 15 | 0.220 |
| 20 | 0.165 |

**zRMS comments:**

The surface water exposure to formulation was validated by the zRMS using Spray Drift Calculator. Obtained $PEC_{SW}$ were in agreement with these reported in Table 8.9.12 and may be used in the aquatic risk assessment.

## 8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

**Table 8.10-1: Summary of atmospheric degradation and behaviour**

| Compound | Cymoxanil |
|---|---|
| Direct photolysis in air | Not studied – no data requested |
| Quantum yield of direct phototransformation | 0.0052 / 0.00058 (n=2) |
| Photochemical oxidative degradation in air | $DT_{50}$ of 21.3 h (Atkinson model v1.91)<br>OH (12h) concentration assumed = 1.5 x $10^{6}$ $cm^{-3}$ |
| Volatilisation | Vapour pressure (Pa): 1.5 x $10^{-4}$ Pa at 20°C<br>Henry's Law Constant ($Pa.m^3/mol^{-1}$): 3.3 x $10^{-5}$ at pH 5; 3.8 x $10^{-5}$ at pH7; no determination possible at alkaline pH due to active substance hydrolysis |
| Metabolites | Not studied – no data required |

The vapour pressure at 20°C of Cymoxanil is between $10^{-5}$ and $10^{-4}$ Pa. Hence Cymoxanil may be regarded as slightly volatile, indicating that significant losses due to volatilisation 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 x $10^6$ radicals $cm^{-3}$) indicating the small proportion of applied Cymoxanil that will volatilise 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 relevant.

**zRMS comments:**

Information regarding fate and behaviour of cymoxanil in the air presented in Table 8.10-1 is in line with EU agreed data reported in EFSA Scientific Report (2008) 167, 1-116.

Due to the vapour pressure above trigger of $10^{-5}$ Pa, cymoxanil may be considered as slightly volatile. The Henry's law constant was calculated to be 3.244 x $10^{-5}$Pa x $m^3$ x mol. In addition to that, with air $DT_{50}$ being 21.3 hours (below the trigger of 2 days), cymoxanil is not expected to be the subject to long range atmospheric transport.

Taking this into account the contamination of the atmosphere from the intended uses of IN002B1760 is considered to be negligible.

# Appendix 1 Lists of data considered in support of the evaluation

## List of data submitted by the applicant and relied on

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner | zRMS re-marks |
|---|---|---|---|---|---|---|
| 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<br>2021-E001, Expedia MRCC S.r.l.<br>Not GLP, unpublished | N | Belchim Crop Protection Indofil Industries Limited | Only calculation at Tier 1 accepted |
| ~~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~~<br>~~NOTOX B.V., ´s-Hertogenbosch, The Netherlands~~<br>~~Report No.: 487663~~<br>~~183528/A~~<br>~~GLP, unpublished~~ | ~~N~~ | ~~Belchim Crop Protection Indofil Industries Limited~~ | Studies evaluated in ongoing EU renewal process of cymoxanil |
| ~~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~~<br>~~Battelle UK Ltd., Essex, United Kingdom~~<br>~~Report No.: OZ/09/003~~<br>~~Not GLP, unpublished~~ | ~~N~~ | ~~Belchim Crop Protection Indofil Industries Limited~~ | |

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

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner | zRMS remarks |
|---|---|---|---|---|---|---|
| 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<br>NOTOX B.V., ´s-Hertogenbosch, The Netherlands<br>Report No.: 487663<br>183528/A<br>GLP, unpublished | N | Belchim Crop Protection<br>Indofil Industries Limited | Studies evaluated and agreed by the RMS (LT) in the course of evaluation of the confirmatory data for cymoxanil (DRAR Vol. 3CA and CP, B.8, January 2022) |
| 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<br>Battelle UK Ltd., Essex, United Kingdom<br>Report No.: OZ/09/003<br>Not GLP, unpublished | N | Belchim Crop Protection<br>Indofil Industries Limited | |

## List of data submitted by the applicant and not relied on

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| There were no studies submitted by the Applicant and not relied on | | | | | |

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

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| There were no studies relied on and not submitted by the Applicant. | | | | | |

# Appendix 2 Detailed evaluation of the new Annex II studies

## A 2.1 Study 1 - Determination of the Aerobic Degradation Route (in One Soil) and Rate (in Three Soils) of Cymoxanil

**and**

## A 2.2 Study 2 - Kinetic Modelling Analysis of Cymoxanil and its Metabolites from Aerobic Soil Degradation, Hydrolysis and Water/Sediment Studies

| | |
|---|---|
| Comments of zRMS: | The study has been already evaluated and agreed at the EU level by the RMS (LT) as a part of the data submitted in support of the cymoxanil renewal process. For details of the evaluation, please refer to DRAR Vol.3CA B.8, January 2022. The summary below is struck through as being not necessary.<br>For discussion on input parameters and obtained results, please refer to point 8.8 of this document. |

**Study 1**

| | |
|---|---|
| Reference: | 8.8.2 (**KCP 9.2.4.1/01**) |
| Report | 487663 |
| Guideline(s): | OECD Guideline 307: Aerobic and anaerobic transformation in soil (2002) |
| GLP: | Yes |
| Acceptability: | Yes |

**Study 2**

| | |
|---|---|
| Reference: | 8.8.2 (**KCP 9.2.4.1/02**) |
| Report | OZ/09/003 |
| Guideline(s): | FOCUS (2006): "Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration" Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference SANCO/10058/2005 version 2.0, 434 pp. |
| GLP: | Not necessary – modelling assessment |
| Acceptability: | Agreed at the EU level (see DRAR Vol.3CA B.8 of January 2022) |

~~**Materials and methods**~~

~~The radiolabelled test substance was identified as follows:~~

~~[acetyl 2-14C] labelled Cymoxanil~~
~~Batch: XVI/49~~
~~Specific radioactivity: 6.19 MBq/mg~~
~~Radiochemical purity: > 99 %~~

~~The unlabelled test substance was identified as:~~

~~Cymoxanil~~
~~Batch: 52~~
~~Purity: 99.1 %~~

~~**Test System:**~~

~~The metabolism of $^{14}C$-labelled Cymoxanil was investigated in three different soils. Soil characteristics are listed in Table 1. On the experimental start date, $^{14}C$-Cymoxanil was dissolved in acetonitrile and applied to 100 g dry weight of soil to give a nominal concentration of 0.48 mg as/kg, which is equivalent to a field rate of approximately 0.36 kg as/ha assuming an incorporation into the top 5 cm soil layer and a soil bulk density of 1.5 g/cm³. Soil samples were incubated under aerobic conditions in the dark at 20 ± 2°C. Soil moisture contents were held at about 40% of maximum water holding capacity (MWHC). The systems were continuously ventilated with moistened air and provisions were made for the trapping of organic volatiles and $^{14}CO_2$ by the installation of polyurethane foam, one trap containing ethylene glycol monoethylether followed by two traps containing 2M NaOH solution. In addition, with the test substance treated soil samples were incubated under the identical conditions but connected with another trapping system to show whether volatile activity could be lost due to the permeability of the trapping system. Samples were taken immediately after application and at 017, 0.33, 1, 2, 3, 6, 9, 15, 30, 58, 90 and 120 days after application. The samples with the modified set-up were taken at day 6 and 15.~~

~~**Table 1: Soil used to investigate the route and rate of aerobic degradation of $^{14}C$-Cymoxanil in soil**~~

| ~~Soil name~~ | ~~Cranfield 164~~ | ~~Speyer 2.3~~ | ~~Speyer 6S~~ |
|---|---|---|---|
| ~~Origin~~ | ~~Buxton, UK~~ | ~~Offenbach, Germany~~ | ~~Siebeldingen, Germany~~ |
| ~~Soil texture [USDA]~~ | ~~Silt clay loam~~ | ~~Sandy loam~~ | ~~Clay~~ |
| ~~% sand [> 50 µm]~~<br>~~% silt [< 50 – 2 µm]~~<br>~~% clay [< 2 µm]~~ | ~~20~~<br>~~52~~<br>~~28~~ | ~~60.9~~<br>~~29.8~~<br>~~9.4~~ | ~~21.9~~<br>~~36.0~~<br>~~42.1~~ |
| ~~pH value [$Ca_2Cl_2$]~~ | ~~6.0~~ | ~~6.4~~ | ~~7.2~~ |
| ~~Organic carbon [%]~~ | ~~3.7~~ | ~~0.98~~ | ~~1.75~~ |
| ~~Cation exchange capacity [meq/100 g]~~ | ~~22.8~~ | ~~8.0~~ | ~~22~~ |
| ~~MWHC [g/100g soil]~~ | ~~65.7~~ | ~~34.4~~ | ~~40.7~~ |
| ~~Microbial biomass:~~<br>~~[mg C/100 g dry soil]~~<br>~~start of study~~<br>~~day 120~~ | <br><br>~~345.1~~<br>~~386.0~~ | <br><br>~~165.8~~<br>~~119.8~~ | <br><br>~~342.4~~<br>~~393.8~~ |

~~**Analytical Method:**~~

~~Soil samples were extracted three times with 100 mL acetonitrile:acetate buffer pH 4 (80:20 v:v). Due to the relatively high amount of non-extractables after the first extraction step in Cranfield 164 soil, soil samples were further extracted using Soxhlet. Radioactivity in the extracts was quantified by LSC and analysed by HPLC. Additionally, Cymoxanil and its degradation products were confirmed by TLC and a further HPLC method. Extracted soil samples were combusted and analysed by LSC to determine the amount of non-extractable residues. Samples from day 90 and additionally from day 58 (Cranfield 164) were submitted to organic matter fractionation to determine the amount of radioactivity bound to fulvic acid and humic acid fraction. Radioactivity in the trapping solutions was determined by LSC. The presence of $^{14}CO_2$ was confirmed using barium hydroxide to produce the insoluble precipitant barium carbonate.~~

~~The data of the soil degradation study as well as the soil degradation data from the EU review were analysed in a kinetic assessment by Hardy & Patel, 2009 (KIIIA1 9.6/02, Doc. No. 782-005). All datasets were evaluated using SFO kinetics (with free optimisation of parameters) to determine a description of the kinetic behaviour of Cymoxanil and its metabolites in order to derive modelling endpoints. The kinetic assessment was performed in line with the guidance by the FOCUS workgroup on degradation kinetics (FOCUS, 2006). The model fits were evaluated using chi-square error statistics as well as visual assessment. $DT_{50}$ values from the EU review and from the study by Tan & Brands have been normalized to standard conditions of 20°C (based on the currently agreed $Q_{10}$ of 2.58) and pF2.~~

**Results and discussions:**

**Material balance** - In Cranfield 164 soil, the $^{14}C$-mass balance ranged from 73.9 to 105.5% AR (Table 2). The $^{14}C$-mass balances ranged 54.3-100.9% AR for Speyer 2.3 and from 57.4-101.6% AR for Speyer 6S soil (Tables 3 to 4). It could be shown that the lower mass balance in some samples was due to the loss of $CO_2$ in the NaOH traps.

**Extractable and non-extractable residues** - The total amount of extractable residues declined continuously in all soils. In Cranfield 164, Speyer 2.6 and Speyer 6S the extractables decreased from 90.3, 93.5 and 91.4% AR immediately after application to 1.2, 5.4 and 1.2% AR at day 120, respectively (Tables 2 to 4). The non-extractable residues increased from 5.7, 3.3 and 6.2% AR to maximum amounts of 69.8, 76.3 and 56.5% AR in the Cranfield 164, Speyer 2.6 and Speyer 6S soils. At the end of the incubation period at day 120, the non-extractables decreased accounting to 19.1, 17.2 and 17.5% AR in Cranfield 164, Speyer 2.6 and Speyer 6S soil. Low amounts of radioactivity were extracted from Cranfield 164 soil using more harsh extraction method (Soxhlet) not exceeding 2.1% AR.

**Volatile degradation products** - Volatilisation was not significant for Cymoxanil or its metabolites since no significant amount of radioactivity (<LOD) was recovered in the polyurethane foam and ethylene glycol monoethylethene traps (Tables 2 to 4). The mineralisation to $CO_2$ reached maximum values of 61.9, 52.3 and 65.9% AR in Cranfield 164; Speyer 2.6 and Speyer 6S soil.

**Principal degradation products** - Cymoxanil degraded to up to 12 different degradation products. The following three metabolites accounted at levels of >5% AR in one sample: The fraction IN-KP533, IN-R3274 and IN-W3595 accounted at a maximum of 6.9% AR in soil Speyer 2.3, IN-KQ960 at a maximum of 5.7% AR in Cranfield 164 soil and IN-T4226 at a maximum of 11.7% AR in Speyer 2.3 soil (Tables 5 to 7).

**Organic matter fractionation of non-extractable soil residues** - The fractionation of the unextracted residues into humic acid, fulvic acid and humin fraction in the samples (90 days of incubation for all soils and 58 days of incubation for Cranfield 164 soil) showed that 78-92% AR of the unextracted activity remained in the humin fraction 10-21% of the unextracted activity remained in the fulvic acid fraction and 2-7% of the unextracted activity remained in the humic acid fraction.

**$DT_{50}$ and $DT_{90}$ values** - The amount of applied Cymoxanil decreased continuously during incubation in soil samples. Cymoxanil decreased from 90.3, 93.5 and 91.4% to 2.6, 5.4 and 0.9% AR immediately after application to day 30, 120 and 58 in Cranfield 164; Speyer 2.6 and Speyer 6S soil (Tables 5 to 7). The resulting SFO $DT_{50}$ values were 1.2, 1.7 and 0.81 days and the corresponding $DT_{50}$ normalised to standard conditions of 20°C/pF2 were 1.1, 1.4 and 0.4 days in Cranfield 164; Speyer 2.6 and Speyer 6S soil, respectively (Table 8).

Due to the fact that only the half-lives for the metabolite IN-KQ960 are relevant in this context the kinetic parameters for other degradation products were not presented here. The SFO $DT_{50}$ values were 1.5, 1.6 and 0.6 days and 1.3, 1.3 and 0.3 days normalised to standard conditions for Cranfield 164; Speyer 2.6 and Speyer 6S soil, respectively. In addition, data from the EU review were re-evaluated for IN-KQ960 (Black Andosol soil) with the resulting SFO $DT_{50}$ of 7.3 days and when normalised to standard conditions gave 9.8 days (Table 9).

**Table 2:** **Recovery and extraction of radioactivity from Cranfield 164 soil treated with [14]C-Cymoxanil at a nominal 0.48 mg ai/kg and incubated at 20°C under aerobic conditions (results expressed as % AR)**

| Incubation time (d) | Extractables | Non-extractables | $^{14}CO_2$ | Organic volatiles | Total |
|---|---|---|---|---|---|
| 0 | 90.3 | 5.7 | n.a. | n.a | 96.0 |
| 0.17 | 92.7 | 8.9 | 0.0 | 0.0 | 101.6 |
| 0.33 | 87.6 | 12.4 | 0.0 | 0.0 | 100.1 |
| 1 | 71.1 | 28.0 | 1.5 | 0.0 | 100.6 |
| 2 | 42.8 | 52.7 | 1.6 | 0.0 | 97.1 |
| 3 | 22.0 | 69.8 | 0.4 | 0.0 | 92.2 |
| 6 | 6.8 | 52.0 | 14.5 | 0.0 | 80.8 |
| 6 extra[a)] | n.d. | 66.8 | 21.9 | 0.0 | 73.9 |
| 9 | 4.2 | 40.9 | 7.1 | 0.0 | 95.4 |
| 15 | 3.7 | 31.6 | 50.2 | 0.0 | 75.1 |
| 15 extra[a)] | n.d. | 45.1 | 39.8 | 0.0 | 105.6 |
| 30 | 2.5 | 33.9 | 60.4 | 0.0 | 98.0 |
| 58 | 1.9 | 26.7 | 61.6 | 0.0 | 87.6 |
| 90 | 1.4 | 27.0 | 59.1 | 0.0 | 90.3 |
| 120 | 1.2 | 19.1 | 61.9 | 0.0 | 81.1 |

n.a. not applicable; n.d. not determined; [a)] modified set up

**Table 3:** **Recovery and extraction of radioactivity from Speyer 2.3 soil treated with [14]C-Cymoxanil at a nominal 0.48 mg as/kg and incubated at 20°C under aerobic conditions (results expressed as % AR)**

| Incubation time (d) | Extractables | Non-extractables | $^{14}CO_2$ | Organic volatiles | Total |
|---|---|---|---|---|---|
| 0 | 93.5 | 3.3 | n.a. | n.a | 96.8 |
| 0.17 | 95.9 | 5.0 | 0.0 | 0.0 | 100.9 |
| 0.33 | 63.9 | 15.8 | 0.0 | 0.0 | 99.8 |
| 1 | 81.7 | 17.1 | 0.0 | 0.0 | 98.9 |
| 2 | 64.9 | 33.9 | 1.2 | 0.0 | 100.0 |
| 3 | 38.9 | 46.3 | 7.7 | 0.0 | 93.0 |
| 6 | 27.3 | 49.9 | 8.7 | 0.0 | 85.9 |
| 6 extra[a)] | n.d. | 76.3 | 15.2 | 0.0 | 91.6 |
| 9 | 15.1 | 26.0 | 30.3 | 0.0 | 71.4 |
| 15 | 14.7 | 22.0'' | 46.6 a | 0.0 | 83.3'' |
| 15 extra[a)] | n.d. | 48.2 | 52.3 | 0.0 | 100.7 |
| 30 | 11.4 | 20.4 | 45.4 | 0.0 | 77.2 d |
| 58 | 9.4 | 19.8 | 44.4 | 0.0 | 73.6 |
| 90 | 6.6 | 16.8 | 55.0 | 0.0 | 78.3 |
| 120 | 5.4 | 17.2 | 31.7 | 0.0 | 54.3 |

n.a. not applicable; n.d. not determined; [a)] including modified set up

**Table 4: Recovery and extraction of radioactivity from Speyer 6S soil treated with [14]C-Cymoxanil at a nominal 0.48 mg as/kg and incubated at 20°C under aerobic conditions (results expressed as % AR)**

| Incubation time (d) | Extractables | Non-extractables | $^{14}CO_2$ | Organic volatiles | Total |
|---|---|---|---|---|---|
| 0 | 91.4 | 6.2 | n.a. | n.a. | 97.6 |
| 0.17 | 88.8 | 12.8 | 0.0 | 0.0 | 101.6 |
| 0.33 | 84.2 | 12.9 | 0.0 | 0.0 | 97.1 |
| 1 | 62.4 | 34.0 | 1.7 | 0.0 | 98.2 |
| 2 | 19.9 | 72.2 | 5.4 | 0.0 | 97.5 |
| 3 | 9.3 | 54.9 | 1.7 | 0.0 | 65.9 |
| 6 | 5.9 | 32.4 | 19.1 | 0.0 | 57.4 |
| 6 | n.d. | 56.9 | 37.2 | 0.0 | 94.1 |
| 9 | 4.7 | 27.5 | 44.2 | 0.0 | 76.4 |
| 15 | 3.9 | 21.5 | 47.8 | 0.0 | 73.2 |
| 1 | n.d. | 35.6 | 56.3 | 0.0 | 92.0 |
| 30 | 3.2 | 21.5 | 47.1 | 0.0 | 71.9 |
| 58 | 2.0 | 15.4 | 53.9 | 0.0 | 71.3 |
| 90 | 1.8 | 16.2 | 52.7 | 0.0 | 70.7 |
| 120 | 1.2 | 17.5 | 65.9 | 0.0 | 84.7 |

n.a. not applicable; n.d. not determined

**Table 5: Characterisation of radioactivity in extracts from Cranfield 164 soil treated with [14]C-Cymoxanil at a nominal 0.48 mg as/kg (results expressed as % AR)**

| Incubation time (d) | Cymoxanil | IN-KP533, IN-R3274, IN-W3595 | IN-KQ960 | IN-T4226 |
|---|---|---|---|---|
| 0 | 90.3 | n.d. | n.d. | n.d. |
| 0.17 | 89.2 | 0.9 | n.d. | n.d. |
| 0.33 | 85.3 | n.d. | 0.7 | 1.2 |
| 1 | 64.1 | 1.0 | 2.0 | 2.8 |
| 2 | 30.3 | 1.4 | 4.6 | 4.8 |
| 3 | 11.2 | 0.5 | 5.7 | 3.8 |
| 6 | 2.9 | 2.5 | 1.5 | n.d. |
| 9 | 1.9 | 2.3 | n.d. | n.d. |
| 15 | 2.3 | 1.4 | n.d. | n.d. |
| 30 | 2.6 | n.d. | n.d. | n.d. |
| 58 | n.d. | n.d. | n.d. | n.d. |
| 90 | n.d. | n.d. | n.d. | n.d. |
| 120 | n.d. | n.d. | n.d. | n.d. |

n.d. not determined

**Table 6: Characterisation of radioactivity in extracts from Speyer 2.3 soil treated with [14]C-Cymoxanil at a nominal 0.48 mg as/kg (results expressed as % AR)**

| Incubation time (d) | Cymoxanil | IN-KP533, IN-R3274, IN-W3595 | IN-KQ960 | IN-T4226 |
|---|---|---|---|---|
| 0 | 93.5 | n.d. | n.d. | n.d. |
| 0.17 | 94.0 | 0.7 | 0.4 | 0.3 |
| 0.33 | 78.2 | 0.8 | 0.3 | 2.5 |
| 1 | 67.6 | 3.4 | 0.8 | 5.9 |
| 2 | 41.2 | 6.9 | 3.1 | 11.7 |
| 3 | 22.5 | 5.1 | 2.8 | 5.4 |
| 6 | 14.9 | 7.2 | n.d. | 1.2 |
| 9 | 10.7 | 4.4 | n.d. | n.d. |
| 15 | 10.3 | 4.4 | n.d. | n.d. |
| 30 | 11.4 | n.d. | n.d. | n.d. |
| 58 | 9.4 | n.d. | n.d. | n.d. |
| 90 | 6.6 | n.d. | n.d. | n.d. |
| 120 | 5.4 | n.d. | n.d. | n.d. |

n.d. not determined

**Table 7: Characterisation of radioactivity in extracts from Speyer 6S soil treated with [14]C-Cymoxanil at a nominal 0.48 mg as/kg (results expressed as % AR)**

| Incubation time (d) | Cymoxanil | IN-KP533, IN-R3274, IN-W3595 | IN-KQ960 | IN-T4226 |
|---|---|---|---|---|
| 0 | 91.4 | n.d. | n.d. | n.d. |
| 0.17 | 87.9 | n.d. | n.d. | n.d. |
| 0.33 | 82.7 | n.d. | 0.7 | n.d. |
| 1 | 42.4 | 2.7 | 12.0 | 3.9 |
| 2 | 9.8 | 3.4 | 4.5 | 1.6 |
| 3 | 4.6 | 2.1 | 0.9 | 0.7 |
| 6 | 2.5 | 3.4 | n.d. | n.d. |
| 9 | 2.2 | 2.5 | n.d. | n.d. |
| 15 | 1.9 | 1.3 | n.d. | n.d. |
| 30 | 1.6 | 1.1 | n.d. | n.d. |
| 58 | 0.9 | 1.1 | n.d. | n.d. |
| 90 | n.d. | n.d. | n.d. | n.d. |
| 120 | n.d. | n.d. | n.d. | n.d. |

n.d. not determined

**Table 8: Aerobic soil SFO DT$_{50}$ of Cymoxanil based on kinetics by Hardy & Patel, 2009**

| Soil name | Soil type (USDA) | SFO DT$_{50}$ (d) | $\chi^2$ error (%) | Norm. SFO DT$_{50}$ (d) |
|---|---|---|---|---|
| Cranfield 164 | Silty clay loam | 1.2 | 4.1% | 1.1 |
| Speyer 2.3 | Sandy loam | 1.7 | 5.7% | 1.4 |
| Speyer 6S | Clay | 0.8 | 2.5% | 0.4 |

~~**Table 9:** **Aerobic soil SFO $DT_{50}$ of IN-KQ960 based on kinetics by Hardy & Patel, 2009 including data from soil degradation study by Tan & Brands, 2009**~~

| ~~Soil name~~ | ~~Soil type (USDA)~~ | ~~SFO $DT_{50}$ (d)~~ | ~~$\chi^2$ error (%)~~ | ~~Norm. SFO $DT_{50}$ (d)~~ |
|---|---|---|---|---|
| ~~Black Andosol~~ | ~~Sandy clay loam~~ | ~~7.3~~ | ~~18.3%~~ | ~~9.8~~ |
| ~~Cranfield 164~~ | ~~Silty clay loam~~ | ~~1.5~~ | ~~5.5%~~ | ~~1.3~~ |
| ~~Speyer 2.3*~~ | ~~Sandy loam~~ | ~~1.6~~ | ~~21.3%~~ | ~~1.3*~~ |
| ~~Speyer 6S~~ | ~~Clay~~ | ~~0.6~~ | ~~6.0%~~ | ~~0.3~~ |

~~* $DT_{50}$ from Speyer 2.3 soil was not accepted as the fit was poor~~

~~**Conclusions:**~~

~~Cymoxanil degraded rapidly in three different soils by forming of up to 12 metabolites. Three of them reached levels >5% AR: The fraction IN-KP533, IN-R3274 and IN-W3595 accounted at a maximum of 6.9% AR, IN-KQ960 at a maximum of 5.7% AR and IN-T4226 at a maximum of 11.7% AR. The complete mineralisation (i.e. formation of $CO_2$) accounted for 65.9% AR and the level of bound residues were up to 19.1% AR after 120 days. $DT_{50}$ values for Cymoxanil ranged from 0.8 to 1.7 days and the corresponding $DT_{50}$ normalised to standard conditions (20°C/$Q_{10}$ 2.58/pF2) ranged from 0.4 to 1.4 days.~~

~~The $DT_{50}$ values for the metabolite IN-KQ960 were calculated to be 0.6 to 1.5 days and the corresponding $DT_{90}$ values were 0.3 to 1.3 days, normalised to standard conditions (20°C/$Q_{10}$ 2.58/pF2). In addition, data from the Black Andosol soil were re-evaluated from the EU review, with the resulting half-life of 7.3 days and normalised to standard conditions with 9.8 days.~~

# Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)

Enclosed to the present submission.