FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: FEL02

Product name(s): CUPROFIX C

Chemical active substance:

Copper (Bordeaux mixture), 200 g/kg

Cymoxanil, 40 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland

(Art. 33 new application)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: March 2023

MS Finalisation date: December 2023; January 2024; April 2024; June 2024

Version history

When	What
March 2023	Part A – version 01 of applicant
December 2023	zRMS assessment of dRR
January 2024	Consolidated zRMS version
April 2024	The final version of the RR after the commenting period
June 2024	Verification of a list of data considered for national authorization

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PART A
RISK MANAGEMENT

1 Details of the application

1.1 Application background

This dossier is intended for the application for the national authorisation of the product FEL02 according to Article 33 of Regulation (EC) No 1107/2009. The product FEL02 is based on the active substances Copper (as Bordeaux mixture), 200 g/kg, and Cymoxanil, 40 g/kg.

The active substance Copper compounds was first included in Annex I of Directive 91/414/EEC on 1 December 2009 (Commission Directive 2009/37/EC of 23 April 2009). The original rapporteur Member State France provided a Monograph in April 2007 and an Addendum in July 2008. A list of endpoints agreed at the original approval can be found in the Review Report on Copper compounds (SANCO/150/08 final 26 May 2009).

With Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011, the active substance Copper compounds was included in the list of approved active substances according to Regulation (EC) No 1107/2009.

The renewal of approval of Copper compounds (Copper hydroxide, Copper oxychloride, Copper oxide, Bordeaux mixture, tribasic Copper sulphate) according to Regulation (EC) No 1107/2009 was confirmed with Commission Implementing Regulation (EU) 2018/1981 of 13 December 2018, coming into force by 1 January 2019. The rapporteur Member State for the renewal of the EU Review, France, prepared a Renewal Assessment Report in December 2016, with updates in September and November 2017. The conclusion of the Peer Review can be found in EFSA Journal 2018;16(1):5152. The renewal the approval of Copper compounds as candidates for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009 was agreed.

The product (FEL02) was not one of the representative products of the EU Review procedure for renewal of approval of Copper compounds, however, the applicant UPL Holdings Coöperatief U.A. is a member of the European Union Copper Task Force, (EUCuTF) and was one of the notifiers of the renewal procedure. UPL Holdings Coöperatief U.A. has full access to the active substance data package submitted to the rapporteur Member State France.

The active substance Cymoxanil was first included in Annex I of Directive 91/414/EEC on 1 September 2009 (Commission Directive 2008/125/EC of 19 December 2008). The original rapporteur Member State Austria provided a Monograph in June 2007. A list of endpoints agreed at the original approval can be found in the Review Report on Cymoxanil (SANCO/179/08 final 9 July 2010).

With Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011, the active substance Cymoxanil was included in the list of approved active substances according to Regulation (EC) No 1107/2009.

Cymoxanil is in the process of renewal of approval according to Regulation (EC) No 1107/2009. The rapporteur Member State for the renewal of the EU Review, Lithuania, prepared a Renewal Assessment Report in July 2020, and the public consultation was finished in October 2020.

The product (FEL02) is not one of the representative products of the EU Review procedure for renewal of approval of cymoxanil, however, the applicant UPL Holdings Coöperatief U.A. is a member of the Cymoxanil Task Force and was one of the notifiers of the renewal procedure. UPL Holdings Coöperatief U.A. has full access to the active substance data package submitted to the rapporteur Member State Lithuania.

This application follows the data requirements for the plant protection product laid down in Regulation (EC) No 284/2013. Data submitted on the formulated product are owned by the applicant UPL Holdings Coöperatief U.A. A summary of the data is provided in dRR format. Only summaries of studies and risk assessments which have not yet been assessed in any EU Member State are included in dRR Part B.

The technical active substance Copper (Bordeaux mixture) used in FEL02 was evaluated during the EU Review for the renewal of approval of Copper compounds. Thus, an assessment of technical equivalence is not required for the current application.

For the purposes of the present submission, the risk assessment for Cymoxanil is not performed in line with the provisions of the Guideline Document SANCO/2010/13170 rev. 14 of 7 October 2016. As the expiration date of cymoxanil Annex I inclusion ~~31st of August 2023~~ 15th of August 2026 and no new end points have been agreed on EU level, please refer to the previous risk assessment performed for the formulation FEL02 as presented in the re-

spective Registration Reports following the Step 2 re-registration of FEL02. The comprehensive risk assessment for Cymoxanil has been performed of FEL02 following the renewal of the active substance Cymoxanil taking into account the current end points and guidance documents.

The EUCuTF presents several statements explaining and justifying the risk assessment approach and deviations from the EU agreed endpoints for Copper compounds in the present dossier and in line with the EU dossier submitted for the renewal. The statements are referred to in the dossier were applicable. The inappropriateness of current guidelines for the assessment of Copper compounds has been recognised among others by the EU Commission that has mandated EFSA with the development of a Copper specific guidance (Mandate No. 2019-0036).

The zonal GAP table presented in this dossier has been prepared in compliance with the renewal regulation of the active substance Copper compounds (Commission Implementing Regulation (EU) 2018/1981 of 13 December 2018) and in line with its specific provisions. The total dose for each use must not exceed 28 kg/ha of Copper metal over 7 years (4 kg/ha/year as a median). The risk assessment conducted in this dossier supports a maximum application dose of 6 kg Copper/ha independently from the number of treatments.

Applicant details

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This dossier was submitted by UPL Holdings Coöperatief U.A./UPL Europe Ltd. in March 2023 to support the application for registration of the WG formulation FEL02 containing Copper as Bordeaux mixture, 200 g/kg and Cymoxanil, 40 g/kg as active substances for use as fungicide for the control of late blight as well as bacterial diseases in potatoes and tuber vegetables. Please refer to point 2.6 for details.

1.2 Letters of Access

UPL Europe Ltd. is one of the applicants for the renewal of the active substance under review: Copper. UPL Europe Ltd has a full access to the data. A statement of membership to the Copper Renewal task force can be provided on request.

UPL Europe Ltd. is one of the applicants for the renewal of the active substance under review: Cymoxanil. UPL Europe Ltd has a full access to the data. A statement of membership to the Cymoxanil Renewal task force can be provided on request.

1.3 Justification for submission of tests and studies

Not relevant for this application.

1.4 Data protection claims

UPL Holdings Coöperatief U.A. is claiming data protection in accordance with Article 59 of Regulation (EC) No 1107/2009 for the submitted studies. Please refer to the reference list in Appendix 4 for more information.

2 Details of the authorization decision

2.1 Product identity

Product code	FEL02
Product name in MS	Not yet authorized in Central EU (MS Poland), proposed name MS Poland: Cuprofix C
Authorization number	None, see above
Function	Fungicide
Applicant	UPL Holdings Coöperatief U.A.
Active substance(s) (incl. content)	Copper (Bordeaux mixture); 200 g/kg Cymoxanil, 40 g/kg
Formulation type	WG
Packaging	Professional: 5, 10, 15 and 20 kg paper-PE bags 5, 10, 15 and 20 kg PE bags
Co-formulants of concern for national authorizations	Not applicable
Restrictions related to identity	Not applicable
Mandatory tank mixtures	Not applicable
Recommended tank mixtures	Refer to label

2.2 Conclusion

The evaluation of the application for CUPROFIX C resulted in the decision to grant the authorization.

Physical and chemical properties section:

No data gaps.

Efficacy section:

The efficacy section agrees to the registration in accordance with the approved GAP table and label.

Mammalian toxicology

Classification of CUPROFIX is: H302, H332, H319, H361fd. No risk for operator, worker using when work wear (arms, body and legs covered) or work wear and gloves (hands, arms, body and legs covered) and resident (see dRR B6).

From a toxicological point of view:

The composition of the assessed product CUPROFIX has been verified in terms of Regulation 2023/574 of March 2023 and does not contain any neutral, prohibited ingredients in plant protection products that have been identified in accordance with Annex III to Regulation (EC) No 1107/2009.

Ecotoxicology section: The use of this plant protection product according to recommendations is accepted at national level.

The evaluator also verified whether the co-formulants contained in plant protection product Cuprofix C are listed in Annex III to Regulation (EC) No 1107/2009 and/or could be considered unacceptable based on the criteria indicated in the Annex to the Commission Implementing Regulation (EU) 2023/574 of 13 March 2023.

Based on the currently available MSDSs and other information provided by applicant or manufacturer of co-formulant, the product Cuprofix C does not contain any unacceptable co-formulant/ingredient listed in the Commission Regulation (EU) 2021/383 amending Annex III to Regulation (EC) No 1107/2009.

According to the current knowledge and available information none of the co-formulants in the plant protection

product Cuprofix C meets the Annex to Regulation (EU) 2023/574 criteria for identification of co-formulants that are unacceptable for inclusion in a plant protection products. Taking this into account, none of the co-formulants/ingredients in this product is considered to be a candidate for inclusion in Annex III of Regulation (EU) 1107/2009.

Detailed assessment of co-formulants according to Article 3 of Regulation (EU)2023/574 can be found in RR Part C or annex to Part C of this submission (section 1.2.2).

Updated 04.2024r.

There are some studies formulation ATOFEL02 (Batch no:8.335.3). In our opinion - due to the same content of the active substance inside FEL02 and ATOFEL02 (cooper as Bordeaux mixture 200 g/kg and cymoxanil 40 g/kg) and the same type of formulation (water-dispersible granule - WG formulation) it could be used in risk assessment in ecotoxicology point of view. Due to the AT and CZ comments, the Applicant should provide a comparison of the formulations of ATOFEL 02 and FEL02 including Part C (considering the new more strict rules by EFSA also applied at a.s. level). This approach should be considered at MSs level.

2.3 Substances of concern for national monitoring

Not applicable.

2.4 Classification and labelling

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

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

Hazard class(es), categories:	Acute Oral Toxicity, Cat. 4 Acute Inhalation Toxicity, Cat. 4 Eye Irritant, Cat. 2 Repro. 2 Aquatic acute 1 Aquatic chronic 1

The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold:**

Hazard pictograms:	GHS07, GHS08, GHS09
Signal word:	Warning
Hazard statement(s):	H302, H319, H332, H361fd, H410: Very toxic to aquatic life with long lasting effects
Precautionary statement(s):	P201, P202, P261, P264, P270, P271, P273, P280, P301+P312, P304 + P340, P305 + P351 + P338, P308+P313, P312, P330, P337 + P313, P391, P405, P501
Additional labelling phrases:	None

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
EUH 208	Contains cymoxanil. May produce allergic reactions

See Part C for justifications of the classification and labelling proposals.

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/avoid contamination via drains from farmyards and roads).
Spe 1	To protect soil organisms do not apply this or any other product containing copper for an annual dose rate higher than 4 kg Cu/ha per year.
Spe3	**Potatoes:** To protect aquatic organisms respect an unsprayed vegetated buffer zone of 20m to surface water bodies with 90% of nozzles reduction.
Spe8	Dangerous to bees. To protect bees and other pollinating insects do not apply to crop plants when in flower. Do not use where bees are actively foraging. Do not apply when flowering weeds are present. Remove weeds before flowering. ~~Max application rate for soil organism up to 4 kg Cu/ha.~~

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

Not required.

2.5 Risk management

2.5.1 Restrictions linked to the PPP

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

Operator protection:	
-	No PPE required
Worker protection:	
-	No PPE required
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
Respective code if available	SPe3: To protect aquatic organism the 20 meter vegetative buffer zone with 90 % drift reduction nozzles should be applied to surface water bodies SPe8: Dangerous to bees. To protect bees and other pollinating insects do not apply to crop plants when in flower. Do not use where bees are actively foraging. Do not apply when flowering weeds are present. Remove weeds before flowering.

Other specific restrictions	
-	None

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

Integrated pest management (IPM)/sustainable use:	
-	None

2.5.2 Specific restrictions linked to the intended uses

No specific restrictions linked to the intended uses

2.6 Intended uses (only NATIONAL GAP)

GAP rev. , date: dd.mm.yyyy

PPP (product name/code):	**FEL02**	**Formulation type:**	**WG**
Active substance 1:	**Copper as Bordeaux mixture**	**Conc. of a.s. 1:**	**200 g/kg**
Active substance 2:	**Cymoxanil**	**Conc. of a.s. 2:**	**40 g/kg**
Safener:	**-**	**Conc. of safener:**	**-**
Synergist:	**-**	**Conc. of synergist:**	**-**
Applicant:	**UPL Holdings Coöperatief U.A.**	**Professional use:**	☒
Zone(s):	**Central Zone**	**Non professional use:**	☐
Verified by MS:	**Yes**		
Field of use:	**Fungicide**		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
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 (additionally: developmental stages of the pest or pest group)**	**Application**				**Application rate**			**PHI (days)**	**Remarks: e.g. g safener/ synergist per ha**
					Method / Kind	**Timing / Growth stage of crop & season**	**Max. number a) per use b) per crop/ season**	**Min. interval between applications (days)**	**kg product/ha a) max. rate per appl. b) max. total rate per crop/season**	**kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min/max**		
1	PL	Potatoes	F	Late blight (*Phytophthora infestans*), ~~Bacteriosis (*Pseudomonas spp.; Xanthomonas spp.)*~~*	Spraying	(BBCH 21 to 95)	6	7	a) 3.0 b) 18.0	a) 0.120 + 0.600 b) 0.720 + 3.6	100 - 1000	7	Month of application: 04 to 09

*The applicant did not submit tests regarding the control of bacterial diseases.

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(b) Catalogue of pesticide formulation types and international coding system CropLife, International Technical Monograph n°2, 6th Edition Revised May 2008

(c) g/kg or g/L

(d) Select relevant

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

(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references

2 Use official codes/nomenclatures of EU Member States

3 For, the crops EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)

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

5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.

6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

8 The maximum number of application possible under practical conditions of use must be provided.

9 Minimum interval (in days) between applications of the same product

10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.

11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).

12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.

13 PHI - minimum pre-harvest interval

14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorization decision and risk management

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

The appearance of the product is that of greyish green, free flowing micro granules. It is not explosive and has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 206°C. In aqueous solution, it has a pH value around 7.1 at 20°C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54°C, neither the active ingredient contents nor the technical properties were significantly changed. The product is found to be chemically and physically stable for at least 3 years after storage at ambient conditions in unopened commercial packaging (1-kg paper/PE bag). Its technical characteristics are acceptable for a water dispersible granule type formulation.

The intended concentration of use is 0.3% to 3.0% w/v.

No tank mixes are recommended on the label.

3.2 Efficacy (Part B, Section 3)

The Biological Assessment Dossier summarises the information related to the efficacy of the plant protection product FEL02, a water dispersible granule (WG) formulation containing two active substances: 40 g/kg of cymoxanil and 200 g/kg of copper (Bordeaux mixture).

FEL02 is a new foliar fungicide for the control of late blight (*Phytophthora infestans*) in potatoes, sweet potato and yams; for which authorization is requested via the Article 33 of Regulation (EC) No 1107/2009.

The efficacy and selectivity data presented in the Biological Assessment Dossier (BAD) fully support the application for registration of FEL02 in Member States belonging to the Central Zone in Europe, as defined in Annex I to Regulation (EC) No 1107/2009: Poland (zRMS), and Austria, Czech Republic, Germany, and Ireland (as cMS).

Products containing cymoxanil or copper (Bordeaux mixture) are already authorised for use on a range of different crops (including potato) in many EU countries, particularly in Southern Europe. In the Southern registration zone, the co-formulated product FEL02 is already authorised in Italy, Malta and Spain as the tradename CUPROFIX C DISPERSS, for use against downy mildew on grapevine, potatoes, tomatoes, cucurbits, alliums and ornamentals; comparable authorisations are also pending in Bulgaria, Greece, and Portugal. No authorisations for FEL02 exist in the Central registration zone.

A total of 29 GEP efficacy trials carried out in 2019, 2020 and 2021 in EU countries belonging to the Maritime and North-East EPPO climatic zones: 22 trials where FEL02 is applied as a standalone treatment; 7 trials where FEL02 is applied in sequence with other fungicide partners (practical use).

Data has been generated on potato (SOLTU) against *Phytophthora infestans*, but based upon the fact that sweet potato and yams are very minor crops, have a similar taxonomy, agronomy and crop development, extrapolation is requested to support the same use on sweet potato and yams, as described in EPPO standard 1/224 (2).

3.3 Efficacy data

Preliminary trials

From a total of 11 trials carried out in the Maritime EPPO climatic zone, and 2 trials carried out in the North-East EPPO climatic zone, on potato against *Phytophthora infestans*, it has been shown that the co-formulation of FEL02 applied at 3 kg/ha (120 g as/ha cymoxanil + 600 g as/ha copper) overall provides superior efficacy on both leaves and stems of potato than each solo active substance at the equivalent dose rates of each active substance. In the majority of trials, the efficacy from FEL02 is both numerically and statistically greater than from cymoxanil alone (122 g as/ha); compared to copper alone (600 g as/ha) there is less numerical and statistical difference, but still sufficient to justify the co-formulation of the two active substances.

The same trials also demonstrate that the co-formulation of FEL02 applied at 3 kg/ha (120 g as/ha cymoxanil + 600 g as/ha copper) overall provides superior numerical efficacy on both leaves and stems of potato in most trials than a tank-mixture of the two active substances at the equivalent dose rates of each active substance. A statistically significant increase was observed in some trials. In comparison to tank-mixtures with tank-mixture ratios containing either a lower rate of cymoxanil or copper, the efficacy from FEL02 is generally numerically superior to both lower ratio tank-mixtures. A statistically significant increase was observed in some trials.

Minimum effective dose tests

From a total of 15 trials carried out in the Maritime EPPO climatic zone, and 4 trials carried out in the North-East EPPO climatic zone, on potato against *Phytophthora infestans*, it has been shown that the co-formulation of FEL02 (40 g as/kg cymoxanil + 200 g as/kg copper) applied at a dose rate of 3 kg/ha (120 g as/ha cymoxanil + 600 g as/ha copper) provides superior numerical efficacy on both leaves and stems of potato than lower rates such as 2.25 kg/ha (90+450 g as/ha) and 1.5 kg/ha (60+300 g as/ha). Statistically significant differences were observed in some trials. This dose rate also provided the greatest consistent control of all relevant dose rates tested, as the range of minimum to maximum values was the smallest.

Efficacy tests

A total of 29 efficacy trials are analysed in order to demonstrate the effectiveness of the fungicide FEL02 (40 g as/ha cymoxanil + 200 g as/ha copper [Bordeaux mixture]) against *Phytophthora infestans* on potato.

The interest of the fungicide FEL02 is demonstrated for the recommended use in a stepwise approach as follows:

First, the intrinsic efficacy of FEL02 applied as a standalone treatment at the recommended rate of 3 kg/ha is studied 22 efficacy trials.

Then, the practical efficacy of FEL02 applied in sequence with other typical fungicides against *Phytophthora infestans* on potato is studied in 7 efficacy trials (practical use).

Standalone treatment

From a total of 18 trials carried out in the Maritime EPPO climatic zone, and 4 trials carried out in the North-East EPPO climatic zone, on potato against *Phytophthora infestans*, it has been shown that the co-formulation of FEL02 (40 g as/kg cymoxanil + 200 g as/kg copper) applied at a dose rate of 3 kg/ha (120 g as/ha cymoxanil + 600 g as/ha copper) provides a useful level of efficacy.

FEL02 was compared to local standard reference products containing different active substances and/or active substance combinations (cymoxanil+mancozeb or fluopicolide+propamocarb). Generally, the efficacy of FEL02 was less than from the reference products, but statistically significant differences were seldom seen, particularly compared to the cymoxanil+mancozeb reference products.

Due to the local systemic activity of cymoxanil, and the contact protectant activity of copper, it cannot be expected that FEL02 applied alone for the whole season would be sufficient to provide effective disease measurement. It is for this reason that the early and mid-season assessment timings (Assessment 1 and Assessment 2) are considered most representative of the efficacy of FEL02. At the final late season assessment (Assessment 3), there was very high disease pressure/severity in all trials (90-100%) on leaves, and it was well established in the plants; therefore, the efficacy of FEL02 and the reference products containing cymoxanil+mancozeb (contact activity and local systemic activity) was much lower than at earlier assessments.

Since the same products have been used repeatedly in the trials, it was not fully representative of a typical disease management program to control *Phytophthora infestans*, where application of products and active substances would have been better tailored to actual conditions. In common practice, FEL02 is intended to be used in sequence with other suitable fungicide products containing complementary active substances against *Phytophthora infestans* on potato. Further discussion is presented in the following section to provide an accurate representation of the practical use efficacy of FEL02.

FEL02 applied alone at the recommended rate of 3 kg/ha had a positive effect on the yield of potato in the presence of disease, with a significant increase in yield over the untreated, and similar results compared to standard reference products based upon cymoxanil+mancozeb or fluopicolide+propamocarb. Regarding tuber size grading quality, FEL02 generally increased the yield at each grade classification, and results were comparable to the reference products. No significant effects upon starch content of tubers were observed, and results were comparable to the reference product.

Given the recent non-renewal of the active substance mancozeb, and the expiry of the permitted use of all products containing mancozeb on 4th January 2022, products such as FEL02 fill an important role in the control of *Phytophthora infestans*, especially given that FEL02 contains copper, which like mancozeb has a multi-site mode of action.

Due to the similar taxonomic classification (*Solanales*) between potato and sweet potato, the identical pathogen target, and a comparable agronomy and cropping system for the three crops within the Central zone, it is considered according to EPPO Guidance PP 1/257(2) that data from potato can be extrapolated to sweet potato and yams.

Sequence use (Practical use)

From a total of 6 trials carried out in the Maritime EPPO climatic zone, FEL02 was applied at 4 applications in sequence preceeded and followed by up to 4 applications of other fungicide products and active substances, as part of a typical disease management programme for *Phytophthora infestans*. This programme was compared against an identical one, but with a product containing mancozeb in place of FEL02. In these conditions, the sequence including FEL02 applied at 3 kg/ha provided equivalent efficacy compared to the reference sequence including mancozeb instead.

FEL02 applied in sequence with other typical standard fungicide products had a positive effect on the yield of potato in the presence of disease, with a significant increase in yield over the untreated, and similar results compared to an identical programme with a mancozeb product in place of FEL02. Regarding tuber size grading quality, the FEL02 programme increased the yield at each grade classification, and results were comparable to the reference product sequence

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

Cymoxanil is an acetamide compound used as both a curative and preventive foliar fungicide. The mode of action of cymoxanil is a local systemic. It penetrates rapidly inside the plant; it cannot be washed off by rain. Copper and copper compounds (including Bordeaux mixture) are classified in FRAC Group M01 (FRAC code list, 2021). Copper is a fungicide with a multi-site contact preventative activity. Copper acts preventively with a multi-site contact activity, inhibiting the germination of spores. It is thought that Cu2+ ions formed in solution are absorbed and disrupt protein structure, enzyme function and transport systems of both fungal and bacterial phytopathogens resulting in a detrimental cumulative effect on cell function

Cymoxanil has an unknown mode of action. To date, no exact mechanism of resistance of any pathogen to cymoxanil is documented. There have been no reported cases of fungal pathogen resistance to copper and copper compounds; therefore, discussion of the mechanism of resistance is not relevant.

According to the FRAC, resistance to cymoxanil is documented in *Plasmopara viticola* with reduced sensitivity reported in different grape-growing regions. No resistance has been reported in *Phytophthora infestans* or other downy mildews. Therefore, the risk of resistance development is classified by FRAC as Low to Medium risk; and consequently, some resistance management may be required.

Both copper and copper compounds (FRAC Group M01) have been classified by FRAC as having a low risk of resistance development, as there have only been a few cases of reported resistance and these are limited to only certain phytopathogens.

When considering the combined risk of resistance based upon the inherent risk of resistance for FEL02 (cymoxanil+copper), and for medium risk pathogens such as P. infestans, the risk would be low (2).

When considering the impact of agronomic risk on the combined risk of resistance, the low overall combined pathogen risk vs. fungicide risk, and in combination with all levels of agronomic risk (0.25-1) gives an overall risk of less than 3. A score of 3 represents low overall risk, even in situations with the highest agronomic risk.

The overall risk of FEL02 is considered acceptable when used according to Good Agricultural Practices and label recommendations.

The applicant continuously monitors efficacy of its plant protection products in commercial situation at the farm level. Additionally, national official services recommending and monitoring good agricultural practices and IPM strategies also monitor the efficacy, and screen any efficacy failure event suspected to be in response to a resistance problem. In case of an efficacy shift or possibility of resistance, they are investigated and if confirmed they are reported to the registration authority and appropriate action is taken

3.3.2 Adverse effects on treated crops

Phytotoxicity

The crop safety results of 21 efficacy trials testing the new co-formulated fungicide FEL02 (40 g/kg cymoxanil + 200 g/kg copper) applied alone at the recommended rate of 3 kg/ha (120 g as/ha cymoxanil + 600 g as/ha copper) are presented. A higher dose rate of 6 kg/ha was also tested in 6 of the 21 trials. No phytotoxicity was observed in any of the trials.

The crop safety results of 7 efficacy trials testing the new co-formulated fungicide FEL02 (40 g/kg cymoxanil + 200 g/kg copper) applied at the recommended rate of 3 kg/ha (120 g as/ha cymoxanil + 600 g as/ha copper) in sequence with other fungicide product partners are presented. No phytotoxicity was observed in any of the trials.

Effects on yield and yield quality

The potential effects of FEL02 on yield and quality parameters at harvest were assessed in the majority of efficacy trials carried out on potato (26 trials). As these parameters were assessed in trials with significant levels of disease infestation, the results are considered to be part of the efficacy data, they are presented in the efficacy section. No significant negative yield or quality effects were observed.

Effects on transformation processes

The potential unintentional effects of FEL02, a water dispersible granule (WG) formulation containing two active substances: 40 g/kg cymoxanil + 200 g/kg copper, on the transformation processes of potatoes were evaluated in 4 processing studies. These potential effects were analysed regarding the culinary aptitudes of potatoes and sensory properties.

FEL02 did not have any unintentional effects upon quality parameters at harvest or processed potatoes for frying or boiling. Taint testing results indicated no effects on boiled or mashed potatoes, or on crisps after deep freezing.

Impact on treated plants or plant products used for propagation

As FEL02 shows no herbicidal or PGR activity, no dedicated crop safety trials were conducted. Additionally, FEL02 was shown to be very safe to potato. Therefore, no negative impact is expected on treated plants or plant products to be used for propagation.

Propagation

As FEL02 shows no herbicidal or PGR activity, no dedicated crop safety trials were conducted, in accordance with EPPO standard PP1/135(4) 'Phytotoxicity assessment'. Additionally, FEL02 was shown to be very safe to potato; therefore, no negative impact is expected on treated plants or plant products to be used for propagation.

The risk of negative impact of FEL02 on treated plants or plant products to be used for propagating purposes is considered as negligible when used according to proposed GAP.

3.3.3 Observations on other undesirable or unintended side-effects

No significant phytotoxic effects of FEL02 were observed to the targeted crop in the efficacy trials. In addition, both active substances: cymoxanil and copper (Bordeaux mixture), have been used for many years as fungicides on many crops without any problems, and have no herbicidal activity.

Therefore, no negative impact is expected on succeeding crops or adjacent crops, when used according to the proposed GAP.

zRMS: The Applicant conducted extensive tests regarding the efficacy of the fungicide FEL02 (Cuprofix C) in the Central Zone. They have correctly conducted and described. The received results confirm the efficacy in reducing the severity of *Phytophtora infestans* by the tested fungicide. Currently, after the preparation mancozeb has been withdrawn from use, FEL02 can fill the gap in the control of potato blight, especially in the initial period of its development. We recommend using the preparation in the Central Zone.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

A fully validated method is available for determination of both active substances in formulation. No further consideration is required. According to the Regulation (EU) 2018/1981[1] the relevant impurities to be taken into consideration for active substances copper compounds: Arsenic, Cadmium, Lead, Nickel, Cobalt, Mercury, Chromium and Antimony. Relevant impurities in the preparation result from impurities in the technical active substance. Methods

[1] COMMISSION IMPLEMENTING REGULATION (EU) 2018/1981 of 13 December 2018 renewing the approval of the active substances copper compounds, as candidates for substitution, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

for the determination of these impurities in the technical material are summarised in the RAR (2017). Other relevant impurities will not be formed during the formulation process or during storage.

However, as the lack of method in formulation has been considered as a data gap of the RAR (2017) and EFSA conclusion (2018),[2] a validation for the determination of these impurities in the formulation is included in the dossier.

3.4.2 Analytical methods for residues

Full acceptable data package for analytical methods for residues is provided with the respective ILVs where required. All the crop groups for which the authorisation is sought are properly covered, as well as all the environmental matrices. No further consideration required.

3.5 Mammalian toxicology (Part B, Section 6)

The product FEL02 was classified as Acute Tox Cat. 4, H302; Acute Tox Cat. 4, H332, Eye Irritant Cat. 2, H319 and Repr. 2, H361fd.

3.5.1 Acute toxicity

FEL02 containing 200 g/kg Copper and 40 g/kg cymoxanil has a low toxicity in respect to acute dermal toxicity, is not irritating to the rabbit skin, and not skin sensitising to guinea pigs. However, the acute oral and inhalation studies indicate that FEL02 is subject to classification as acute tox cat.4 with H302+H332 (Harmful if swallowed or inhaled) labelling. Moreover, it showed slight, reversible eye irritating characteristics in the rabbit, thus, classification as eye irritant cat. 2 and labelling with the hazard statement H319 (Causes serious eye irritation) is warranted according to Regulation (EC) No 1272/2008 and Repr.2; H361fd.

3.5.2 Operator exposure

In the risk assessments for operator, worker and bystander/resident dermal absorption values used for copper were 0.01% (concentrate) and 1.0% (dilution), and for cymoxanil were 0.42% (concentrate) and 22% (0.12 g/L dilution)

No acute operator exposure could be estimated due to no AAOEL being set.

For tractor mounted application of copper, the operator exposure estimates using a single layer of work clothing, work wear covering arms, body and legs show a safe systemic exposure of 2.9% of the AOEL.

For tractor mounted application of cymoxanil, the operator exposure estimates using a single layer of work clothing, work wear covering arms, body and legs show a safe systemic exposure of 47% of the AOEL.

Based on the first tier combined exposure calculations, the combined exposure to both active substances in FEL02 is not expected to present a risk for operators (with PPE). No further refinement of the assessment is required.

3.5.3 Worker exposure

No acute worker exposure could be estimated due to no AAOEL being set.

For copper, the potential worker exposure upon re-entry to fields after the application of FEL02 for the use in potato is safe at 39% AOEL. When work wear (arms, body and legs covered) is worn the worker exposure is further reduced to 4.4% of the AOEL.

For cymoxanil, the potential worker exposure upon re-entry to fields after the application of FEL02 for the use in potato is not safe and exceeds the limits of AOEL at 1373% AOEL. Also when work wear (arms, body and legs covered) or work wear and gloves (hands, arms, body and legs covered) are worn the worker exposure is not safe and exceeds the limits of AOEL at 154% and 137% AOEL, respectively.

For cymoxanil, higher tier exposure estimations for workers re-entering the field were also performed.

The dissipation time of cymoxanil is low. The DT_{50} value can be estimated using a residue decline study conducted on wheat and peas, a DFR study conducted in grapes, and a DFR study conducted in grapes, tomato and potato. The

[2] EFSA Journal 2018;16(1):5152.

DT_{50} found in these studies ranged from 0.42 to 1.21 days. In potato the DT_{50} was 0.95 days. Overall, it is reasonable to assume that the cymoxanil DT_{50} value of residues on the raw commodity samples would be approximately 1 day. When the DT_{50} for cymoxanil of 1 day is used, the potential exposure is not safe at 333% of the systemic AOEL. However, when work wear (arms, body and legs covered) is worn, the worker exposure is safe at 37% AOEL, and reduced to 33% AOEL when workwear and gloves are worn.

Based on the first tier combined exposure calculations, the combined exposure to both active substances in FEL02 is not expected to present a risk for workers. No further refinement of the assessment is required.

3.5.4 Bystander and resident exposure

No acute bystander exposure could be estimated due to no AAOEL being set.

For copper, the estimated exposure for both child and adult residents for the use in potato is safe at 7.7% and at 3.1% of the systemic AOEL, respectively.

For cymoxanil, the estimated exposure for both child and adult residents for the use in potato is not safe and exceeds the limits of AOEL at 209% and at 98% of the systemic AOEL, respectively. For cymoxanil, higher tier exposure estimations for child and adult residents were also performed, as this is considered necessary for the risk assessment of the combined exposure to the active substances in FEL02.

The dissipation time of cymoxanil is low. The DT50 value can be estimated using a residue decline study conducted on wheat and peas, a DFR study conducted in grapes, and a DFR study conducted in grapes, tomato and potato. The DT50 found in these studies ranged from 0.42 to 1.21 days. In potato the DT50 was 0.95 days. Overall, it is reasonable to assume that the cymoxanil DT50 value of residues on the raw commodity samples would be approximately 1 day. When the DT_{50} for cymoxanil of 1 day is used, the estimated exposure for both child and adult residents for the use in potato is safe at 86% and at 32% of the systemic AOEL, respectively.

Based on the first tier combined exposure calculations, the combined exposure to both active substances in FEL02 is not expected to present a risk for residents and bystanders. No further refinement of the assessment is required.

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

Copper (Bordeaux mixture)

Stability of Residues

No new data are submitted in the framework of this application.

Copper is an element and is inherently stable as it cannot be transformed into any other material. Therefore, under freezer storage conditions, residues of copper in crop commodities will be stable and copper is not expected to metabolise or to form degradation products.

Metabolism in plant and animal

The metabolism in plant and animal was assessed for annex 1 inclusion (approval) of the active substance and renewal procedure. The data evaluated is sufficient to support the proposed uses.

The residue definitions agreed for monitoring and risk assessment:

Total Copper (EFSA 2008, EFSA, 2018a and Reg. (EC) No 149/2008)

Copper is a monoatomic element which cannot be degraded and thus, no metabolites in animals are expected.

No further data are required.

Magnitude of residues in plants

Proposed GAP:

Max. 6 applications, BBCH 21 – 95, 0.60 kg a.s./ha, PHI: 7 (month of application: 04 to 09)

The Applicant refers to following studies:

1. A set of two at harvest supervised residue trials (2008) in the NEU zone (1 in Germany and 1 in Poland) was

performed with Copper Oxychloride 37.5 WG formulation.

Trial GAP: 4 x 1.1-1.2 kg Copper/ha, interval = 7 d, PHI = 3 d

Deviations: The trials are overdosed in relation to the application rate per treatment; Number of application are 4 instead of 6.

Studies have been already evaluated in the framework of the Review of the existing maximum residue levels for Copper compounds (EFSA Journal 2018;16(3).

The trials are considered not acceptable to support this use due to the small number of applications.

2. A set of four at harvest supervised residue trials (2006) in the NEU zone (2xAustria, 1xCzech Re-public and 1 in Slovakia) was performed with SC formulation Flowbrix (670 g/L of Copper oxychloride).

Trial GAP: 6x1 kg Copper/ha, interval 6-7 d, PHI 14 d

Deviations: PHI is 14 instead of 7

The trials are considered not acceptable to support this use due to the PHI higher than proposed.

3. A set of 12 decline supervised trials in the NEU (10x Germany; climatically different parts) was performed in 1990, 1991 and 1992 with Funguran-OH 50 WP. Trials GAP: 6 x 0.6 kg Copper/ha, PHI = 7 d.

Studies have been already evaluated in the framework of the Review of the existing maximum residue levels for Copper compounds (EFSA Journal 2018;16(3).

The trials are considered acceptable to support this application.

4. New studies on the magnitude of residue have been submitted by the applicant in the framework of this applica-tion.

A set of two supervised at harvest trials in the NEU zone (2020) was performed with BORDEAUX MIXTURE 20 % WG (FAP13) formulation.

Trial GAP: 6 x 1 kg Copper/ha, interval = 5-8 days, PHI = 7-8 days

The trials were performed at a more critical GAP than proposed and represent a worst case The higher PHI of 8 (instead of 7) in one of the trials is considered acceptable, since Copper is an element and is inherently stable.

The trials are considered acceptable to support this application.

The number of trials is sufficient to support the use of copper on potatoes according to the proposed GAP in Central Zone. The data submitted show that no exceedance of the MRL will occur.

Use is accepted.

March 2024:

AT applies for the following additional uses (see section B0): Sweet potato (0212020) and Yams (0212030). Ac-cording to EU agreed rules, an extrapolation from residues provided on potatoes is possible. In addition, MRLs for potatoes, sweet potatoes and yams are the same for copper (5 mg/kg) and Cymoxanil (0.01 mg/kg). Uses on Sweet potato (0212020) and Yams (0212030) are accepted.

Magnitude of residues in livestock

Regarding available feeding data, there is no risk for animal MRL to be exceeded. Data provided by the Applicant are accepted.

Industrial Processing and/or Household Preparation

No new data were submitted in the framework of this application.

Copper is an element and cannot be transformed into any other substance and it does not hydrolyse, therefore a con-version factor is not applicable. Consequently, the nature of the residue in all processed commodities is “Copper”.

According to the results obtained from the EFSA Primo Model for the calculation of the chronic risk assessment for Copper, the maximum percentage of contribution to the ADI of potato is negligible (highest intake: 2%, PL general).

Therefore, processing studies with potato tubers, the only edible plant part to be processed, are deemed not neces-sary.

Magnitude of residues in representative succeeding crops

EFSA Journal 2018;16(1):5152: *Based on the scientific literature, the experts agreed that plant would not absorb more than the essential nutritional amount. Therefore, field trials on rotational crops were not deemed necessary and a comprehensive survey on the copper background levels in plant commodities was used as a surrogate to assess the residue levels in all off-label crops (including rotational crops).*

No additional studies are required.

Other / special studies

Copper is non-systemic; therefore it is not likely that residues would be found in pollen or honey. Also, potatoes and also most other root and tuber vegetables have no melliferous capacity.

No further data are required.

Consumer risk assessment

Theoretical Maximum Dietary Intakes (TMDI) were estimated using the EFSA PRIMo model (revision 3.1). Calculations are acceptable.

The proposed uses of copper in the formulation FEL02 do not represent unacceptable acute and chronic risks for the consumer.

Cymoxanil

Stability of Residues

EFSA concluded (EFSA, 2008) that residues of Cymoxanil are stable under frozen condition (about -20°C and darkness) for at least 12 months in frozen potato tuber homogenates.

A new study investigating stability of residues during storage of potato samples has been submitted by the applicant in the framework of this application. Conclusion: cymoxanil residues in potato tuber homogenates are considered stable during storage at about -20°C and darkness for 12 months.

This study was submitted, by the Cymoxanil Task Force, for the first time at EU level for the purpose of the active substance renewal (on-going). The study was not considered in this assessment and not assessed by the zRMS. The stability of residues in potato for Cymoxanil was reviewed during the Annex I inclusion process and still considered adequate to address this endpoint.

No additional studies are required.

Metabolism in plant and animal

The residue definitions agreed for monitoring and risk assessment:

Plant residue definition for monitoring	Cymoxanil (Regulation (EU) No. 2018/832, Reg. (EU) 2022/1363)
Plant residue definition for risk assessment	Cymoxanil (EFSA, 2015)
Animal residue definition for monitoring	Residue definition in animal commodities is not needed but could be set as cymoxanil (for ruminant and pigs) if needed in the future EFSA Journal 2015;13(12):4355
Animal residue definition for risk assessment	Residue definition in animal commodities is not needed but could be set as cymoxanil (for ruminant and pigs) if needed in the future EFSA Journal 2015;13(12):4355

No further data are required.

Magnitude of residues in plants

Proposed GAP:

Max. 6 applications, BBCH 21 – 95, 0.12 kg a.s./ha, PHI: 7 (month of application: 04 to 09)

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

1. Submitted for the first time at EU level by the applicant for the product authorisation of FDJ03 following the first inclusion of Cymoxanil (Austria, 2013) and submitted for the active substance renewal (Lithuania, 2020).

Trials GAP: 8x 0.112-0.135 kg Cymoxanil/ha, interval= 6-8 d, PHI= 7 - 8 d

E/RA: 2x ND (< 0.002)

LOQ = 0.02 mg/kg

As no residues were detected, the overdosed trials (8 applications instead of 6 applications) can be accepted. These trials are considered relevant for this application.

2. Submitted for the purpose of the active substance renewal (Lithuania, 2020)

- Trials GAP: 6x 0.140-0.155 kg Cymoxanil/ha, interval=4-6 d, PHI=6-7 d

E/RA: 2x < LOQ (0.01)

These trials are considered relevant for this application.

- Trials GAP: 6x 0.106-0.123 kg Cymoxanil/ha, interval=3-7 d, PHI=7 d

E/RA: 4x ND (<0.003)

LOQ = 0.01 mg/kg

These trials are considered relevant for this application.

- Trials GAP: 12x 0.112-0.126 kg Cymoxanil./ha, interval= 5 d, PHI= 0 d

E/RA: 3x ND (< 0.003)

These trials are considered not relevant for this application due to PHI of 0 days. This is not consistent with what is proposed in the intended GAP.

- Trials GAP: 12 x 0.115-0.125 kg Cymoxanil./ha, interval= 5 d, PHI= 0 d

E/RA: 4x ND (< 0.003)

These trials are considered not relevant for this application due to PHI of 0 days. This is not consistent with what is proposed in the intended GAP.

The number of trials is sufficient to support the use of copper on potatoes according to the proposed GAP in Central Zone. The data submitted show that no exceedance of the MRL will occur.

Use is accepted.

AT applies for the following additional uses (see section B0): Sweet potato (0212020) and Yams (0212030). According to EU agreed rules, an extrapolation from residues provided on potatoes is possible. In addition, MRLs for potatoes, sweet potatoes and yams are the same for copper (5 mg/kg) and Cymoxanil (0.01 mg/kg). Uses on Sweet potato (0212020) and Yams (0212030) are accepted.

Magnitude of residues in livestock

No new data were submitted in the framework of this application.

EFSA conclusion, 2008: ”livestock feeding studies are regarded as not necessary, because a “non-residue” situation (<0.05 mg Cymoxanil/kg) on potato (relevant feedingstuff) is established.

Industrial Processing and/or Household Preparation

Residue trial studies showed a non-residue situation for the representative use of Cymoxanil on potato tubers, the only edible plant part to be processed; residues of Cymoxanil will not exceed the threshold of 0.01 mg/kg. Therefore, investigation of the magnitude of residues in processed potato is not required.

Magnitude of residues in representative succeeding crops

EFSA, 2015: “Studies on the nature of the residues in succeeding crops show that significant residues of Cymoxanil are not expected in rotational crops. “

Considering available data dealing with nature of residues, no study dealing with magnitude of residues in succeeding crops is needed to support the intended uses of Cymoxanil in the product FEL02 on potatoes.

Other / special studies

~~Copper is non-systemic; therefore it is not likely that residues would be found in pollen or honey. Also~~, Potatoes and

also most other root and tuber vegetables have no melliferous capacity.

No further data are required.

Consumer risk assessment

Theoretical Maximum Dietary Intakes (TMDI) were estimated using the EFSA PRIMo model (revision 3.1). Calculations are acceptable.

The proposed uses of cymoxanil in the formulation FEL02 do not represent unacceptable acute and chronic risks for the consumer.

Conclusion: proposed use is accepted.

3.6.1 Consumer exposure

Copper
As an ARfD is not deemed necessary for Copper, an acute risk assessment is not relevant.
In order to evaluate the potential chronic exposure to Copper residues through the diet, the Theoretical Maximum Dietary Intakes (TMDI/IEDI) were estimated using the EFSA PRIMo model (revision 3.1).
If all crops for which a defined MRL under 396/2005 is available are included, the diet with the highest IEDI for copper is the "NL Toddler" with 122% of ADI.

Refinements of the inputs into the PRIMo model were made to take into account data generated by background monitoring of Copper in crops throughout the UK, and also monitoring results (France, 2016). Using this refined Tier II input, the diet with the highest IEDI for copper is the "NL Toddler" with 94% of ADI. For this diet, the highest contributors were maize/corn and wheat, representing 11% of ADI, each.

Cymoxanil
A dietary risk assessment using revision 3.1 of EFSA PRIMO was performed. For the chronic consumer risk assessment, all uses of Cymoxanil at EU level were taken into consideration. For the acute consumer risk assessment only the intended use on potatoes was taken into consideration. Due to the non-residue situation for Cymoxanil in the supervised trials, the actual MRL of 0.01 mg/kg was used as input value (STMR/HR) for potatoes.

TMDI (% ADI) according to EFSA PRIMo	Not calculated
IEDI (% ADI) according to EFSA PRIMo rev.3.1	2% (based on PT general)
IESTI (% ARfD) according to EFSA PRIMo rev.3.1	Potatoes: 2% (based on children) Potatoes: 0.4% (based on adults)

The proposed uses of Cymoxanil in the formulation FEL02 on potatoes do not represent unacceptable acute and chronic risks for the consumer.

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

The formulated product FEL02 is proposed to be applied as a fungicide up to 6 times per season to potatoes with a minimum application interval of 7 days. The maximum application rates (per application) are 0.12 kg Cymoxanil/ha and 0.6 kg Copper/ha (equivalent to 3 kg product/ha). The application window is from April up to and including September.

3.7.1 Predicted environmental concentrations in soil (PECsoil)

Calculations of PECsoil were performed in accordance with the FOCUS document 'Soil persistence models and EU registration' (FOCUS, 1997) based on a simple first tier approach (Excel sheet).

A summary of the approach taken and the results for Cymoxanil (active substance 1) and its metabolites and for Copper (active substance 2) is provided in the following sections. A detailed description of PECsoil calculations,

modelling inputs and results is given in Part B, Section 8, KCP 9.1.3 of the core assessment for the central zone.

The results for PECsoil for the active substance were used for the ecotoxicological risk assessment.

3.7.1.1 Cymoxanil (active substance 1)

For Cymoxanil and the relevant soil metabolites IN-U3204, IN-W3595 and IN-JX915 calculations were performed for 6 annual applications with a 7-day interval. A crop interception of 60% was assumed for all applications in a worst case approach (early application scenario).

The endpoints used as input for the calculations were taken from the list of endpoints of the EFSA conclusion (2008) for Cymoxanil.

The PECsoil values in the upper 0-5 cm soil layer immediately after the last of 6 applications were calculated to be 0.064 mg/kg for Cymoxanil, 0.016 mg/kg for metabolite IN-U3204, 0.004 mg/kg for metabolite IN-W3595 and 0.007 mg/kg for metabolite IN-JX915. Considering that the DT90 values for Cymoxanil and its metabolites were all well below 1 year, no PECsoil,plateau concentrations were calculated

3.7.1.2 Copper (active substance 2)

For Copper calculations were performed for a single season's application (annual dose). The PEC value in soil was calculated assuming no crop interception.

The endpoints used as input for the calculations were taken from the list of endpoints of the EFSA conclusion (2018) for Copper.

The initial PECsoil value in the upper 0-5 cm soil layer immediately after a single season's application was calculated to be 4.8 mg/kg. Furthermore, considering that Copper does not degrade, a calculation of accumulated PEC in soil for an authorization period of 7 years was performed (assuming even distribution in the upper 0-20 cm soil). Furthermore, natural background levels of copper were included based on a comprehensive review of European monitoring programs and were extended with the EU LUCAS monitoring data. The overall PECsoil,accumulation values, based on 10th percentile, median and 90th percentile background values in European arable soils, were calculated to be 19.0 mg/kg, 25.4 mg/kg and 38.0 mg/kg, respectively.

3.7.2 Predicted environmental concentrations in groundwater (PECgw)

Calculations of PECgw were performed in accordance with the generic guidance for FOCUS groundwater scenarios (FOCUS, 2021) and the working document of the central zone (Anonymous, 2018). The application window is from April up to and including September. Considering the 6-month application window, two separate simulations were performed, one for early applications and one for late applications.

A summary of the approach taken and the results for Cymoxanil (active substance 1) and its metabolites and for Copper (active substance 2) is provided in the following sections. A detailed description of PECgw calculations, modelling inputs and results is given in Part B, Section 8, Point KCP 9.2.4 of the core dossier.

3.7.2.1 Cymoxanil (active substance 1)

For Cymoxanil and the metabolites IN-W3595, IN-U3204, IN-JX915 and IN-KQ960 PECgw calculations were performed using FOCUS PEARL 5.5.5 on the basis of 6 annual applications with a 7-day interval between applications. Crop interception values ranged from 60 to 85% depending on the location and the absolute application date selected.

For the parent substance and all relevant metabolites, with the exception of metabolite IN-KQ960, the endpoints used as input for the calculations were taken from the list of endpoints of the EFSA conclusion (2008) for Cymoxanil. For IN-KQ960 new information (post-approval) has become available and was used in the calculations. This new information was also used in 2013 for authorisation of the product FDJ03, which also contains Cymoxanil as active substance, and was at the time reviewed by zRMS Austria. For further detail reference is made to Part B, Section 8,

Point KCP 9.2.4 of the core dossier.

PECgw calculations for the parent substance Cymoxanil were performed based on two different DT50 values; the soil geometric mean DT50 of 1.2 days and a worst-case DT50 of 7.3 days in order to take into account the pH-dependent degradation of Cymoxanil. For the relevant metabolites, the PECgw values were calculated within the assessment for the parent compound using the transformation scheme option incorporated in the model. As the degradation rate of the parent substance will also affect the timing and magnitude of formation of metabolites, the PECgw values for the metabolites were also calculated using both the DT50 values for Cymoxanil.

For the active substance Cymoxanil and its metabolites the EU-criterion for leaching to groundwater of <0.1 µg/L was met for all scenarios. The modelling results demonstrate that there is no risk for leaching to groundwater following the use of FEL02 on potato.

3.7.1.2 Copper (active substance 2)

For Copper PECgw calculations were performed using FOCUS PEARL 4.4.4. Considering that Copper is not degraded, the application rate was entered in the model as a single season's application (annual dose). In the calculations no crop interception was assumed.

The endpoints used as input for the calculations were taken from the list of endpoints of the EFSA conclusion (2018) for Copper with the exception of the Kdoc for which a more conservative value was used. For further detail reference is made to Part B, Section 8, Point KCP 9.2.4 of the core dossier.

For the active substance Copper the EU-criterion for leaching to groundwater of <0.1 µg/L was met for all scenarios. Furthermore, the calculated PECgw values are far below the legal limit of 2 mg/L for Copper as set by the European Drinking Water Directive (98/83/EC) for groundwater. The modelling results demonstrate that there is no risk for leaching to groundwater following the use of FEL02 on potato.

3.7.3 Predicted environmental concentrations in surface water (PECsw)

Calculations of PECsw and PECsed were performed in accordance with the generic guidance for FOCUS surface water scenarios (FOCUS, 2015) and the working document of the central zone (Anonymous, 2018). Considering that the application window is from April up to and including September, the seasons Mar-May and Jun-Sep were assessed in combination with both the regions 'North Europe' and 'South Europe'.

A summary of the approach taken and the results for Cymoxanil (active substance 1) and its metabolites and for Copper (active substance 2) is provided in the following sections. A detailed description of PECsw and PECsed calculations, modelling inputs and results is given in Part B, Section 8, Point KCP 9.2.5 of the core dossier.

3.7.3.1 Cymoxanil (active substance 1)

For Cymoxanil and the metabolites IN-U3204, IN-W3595, IN-KQ960, IN-JX915, IN-T4226, IN-R3273, IN-KP533, and 'metabolite fraction M5' PECsw/sed calculations were performed on the basis of 6 annual applications with a 7-day interval between applications. For early applications (Mar-May) 'average crop cover' was selected which is associated with a crop interception of 50% for potatoes. For late applications (Jun-Sep) 'full canopy' was selected which is associated with a crop interception of 70%.

For the parent substance and all relevant metabolites, with the exception of metabolite IN-KQ960, the endpoints used as input for the calculations were taken from the list of endpoints of the EFSA conclusion (2008) for Cymoxanil. For IN-KQ960 new information (post-approval) has become available and was used in the calculations in order to be able to demonstrate safe use. This new information was also used in 2013 for authorisation of the product FDJ03, which also contains Cymoxanil as active substance, and was at the time reviewed by zRMS Austria. For further detail reference is made to Part B, Section 8, Point KCP 9.2.5 of the core dossier.

The maximum PECsw, the 21-d TWA PECsw and the maximum PECsed values for Cymoxanil and the relevant metabolites are listed in the following table.

Table Błąd! W dokumencie nie ma tekstu o podanym stylu.**-1 Summary of PECsw and PECsed values as calculated with STEPS1-2 in FOCUS**

Substance	Max. PECsw (µg/L)		21-d TWA PECsw (µg/L)		Max. PECsed (µg/kg)	
	Step 1	Step 2	Step 1	Step 2	Step 1	Step 2
Cymoxanil	38.9	1.10	1.10	0.072	16.5	0.333
IN-U3204	19.3	0.273	0.635	0.020	5.32	0.054
IN-W3595	58.8	0.398	12.0	0.082	5.30	0.035
IN-KQ960	54.6	1.70	47.0	1.46	2.86	0.089
IN-JX915	25.4	0.581	2.98	0.134	4.03	0.087
IN-T4226	23.6	0.677	7.14	0.205	4.08	0.117
IN-R3273	76.2	1.39	29.7	0.541	31.2	0.552
IN-KP533	56.1	1.24	9.99	0.221	7.06	0.157
Metabolite fraction M5	9.30	0.253	0.902	0.025	0.833	0.009

Note: Presented Step 2 values are the maximum values of all Step 2 calculations (i.e., multiple and related single applications for the different regions and seasons)

3.7.3.2 Copper (active substance 2)

For Copper PECsw calculations were performed considering all entry routes to water bodies and the single application scenario is presented as the worst-case scenario. In the calculations no crop interception was assumed.

The endpoints used as input for the calculations were taken from the list of endpoints of the EFSA conclusion (2018) for Copper. The PECsw were calculated based on total copper. For PECsw calculations no mitigation measures were considered. For further detail reference is made to Part B, Section 8, Point KCP 9.2.4 of the core dossier.

The Step 1 and Step 2 PECsw values based on total copper were calculated to be 9.85 and 5.52 µg/L, respectively (for all regions and seasons). The respective PECsw values based on dissolved copper were 3.28 and 1.84 µg/L.

3.7.4 Predicted environmental concentrations in air (PECair)

3.7.4.1 Cymoxanil (active substance 1)

Because of the vapour pressure of 1.5 x 10-4 Pa (20 °C) being > 10-5 Pa the behaviour in air has to be considered with respect to short-range and long-range transport potential and adverse effects to the environment.

Short-range transport

- Risk assessment for terrestrial organisms is covered by in-field-risk assessments.
- For risk assessment for aquatic organisms transport of Cymoxanil via volatilisation and successive deposition has only to be taken into account at FOCUS Step 4. As an acceptable risk for aquatic organisms can be demonstrated via FOCUS Step 2 PEC values, it is not necessary to consider short-range transport into surface in aquatic risk assessments.

Long-range transport potential and adverse effects to the environment:

- As the DT50 in air according to Atkinson is below the trigger of 2 days, no long-range transport potential or adverse effects to the environment are expected for Cymoxanil.

3.7.3.2 Copper (active substance 2)

Copper is not volatile at environmentally relevant temperatures and will therefore not be present in air. Furthermore, Copper cannot be transformed into related metabolites or degradation products and degradation processes likely to occur in air will have no action on Copper. Data are therefore not required.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

The Tier I acute and long-term risk assessment to birds and mammals indicated a potential risk, driven by copper. A weight of evidence paper was submitted as part of the first renewal of approval and the conclusion is that the long-term risks to birds and mammals were acceptable for application rates of up to 4 kg copper/ha (EFSA Conclusion, 2018).

3.8.2 Effects on aquatic species

In conclusion, the risk assessment for copper indicated acceptable risk to aquatic organisms from the use of FEL02.

The risk assessment for cymoxanil indicated acceptable risk to aquatic organisms from the use of FEL02.

The risk assessment for the product FEL02 (combined exposure of copper and cymoxanil) based on mixture toxicity indicated that the toxicity of FEL02 is driven by the active substance copper. The risk for the product is therefore adequately covered by the risk assessment of copper alone.

For registration in line with country specific requirements, different mitigation measures may apply.

Based on the lowest endpoint for fish agreed at EU level (EFSA Conclusion 2018) and PECsw calcula-tions agreed at Section 8, the following risk mitigation measures should be applied to surface water bodies:

- 20 meter vegetative buffer strip and 90% drift reduction nozzels for potatoes

For sediment dwelling organism the risk is not finalized in the Core Assessment.
However, there is no approved guideline for calculating PECsed values to determine protective measures for copper compounds. zRMS proposes only for Poland to apply existing default mitigation measures for PECsw for copper for aquatic organisms.

Updated 04.2024r.

The chemical analysis for the product Cuprofix C and fish, Daphnia and algae revealed, that the concentration of cymoxanil was below LOQ at the end of the test concentrations. Please noticed that in this case the calculate the endpoint with the geomean concentration for cymoxanil is probably impossible in mathemathical reason. In opur opinion no separate risk assessment for the product is considered necessary, as the risk is adequately assessed by the risk assessment of the active substance copper. The combined risk assessment confirmed that it is clear that copper drives the toxicity of the mixture for all organism groups (%TU >90%). The validity criteria for these studies were met. Apart from minor deviations from the methodology (such as the temperature range), the tests were carried out in accordance with the methodology recommendations. in this specific situation, RMS proposes due to the limita-tions of testing on vertebrates (test for fish), the validity criteria was met and the fact that the toxicity comes from 90% of the copper in the formulation, not to establish a data gap. However, this approach and the assessment of the studies for aquatic organisms for the product Cuprofix C and fish, algae and Daphnia should be considered at MSs level. In our opinion – the final conclusion for these studies in this specific situation should be considered by MSs level.

3.8.3 Effects on bees

The first-tier risk assessment of the oral acute and chronic risk to bees and bumblebees from the use of **Cuprofix C** indicates that there may be unacceptable risks. However, the higher tier risk assessment shows that the risks following exposure of **Cuprofix C** to bees are acceptable at doses of up to 2.5 kg copper/ha (proposed use of **Cuprofix C** amounts to 720 g cu/ha). ~~No higher tier data on bumblebees is available but since the risk assessment according to EFSA is only illustrative and the assessment in line with the honeybee assessment according to the SANCO/10329/2002 guidance document indicated that the risk is acceptable, no further consideration of the risk to bumblebees is required.~~

Justification: Based on the lowest LD_{50} of 12.1 µg Cu/bee value for copper high acute risk for adult bees is concluded.
It should be noted that during the renewal of the active substance – copper two studies were performed, a semi-field study and a cage test.
The results indicated that no significant effects on the numbers of dead bees or on their behavior or brood development up to concentrations of 1.25 kg Cu/ha.
Based on the available data an acceptable risk to honeybees for all intended uses with a single application rate up to 1.25kg/ha can be considered. However, the data are not considered adequate to cover multiple applications of copper. Possible adverse effects on honeybees due to multiple applications of copper are not covered by the semi-field studies. Furthermore, EFSA concluded (EFSA/2018/5152) that "*A tunnel test already considered with the confirmatory data (European Food Safety Authority, 2013a) was available where a statistically significant reduction is observed for flight intensity at the highest dose tested (2500 g Cu/ha). Data from literature provided by the applicants indicated that, chronic exposure of copper via feeding of copper solutions as an antivarroa treatment in hives did not show adverse effects on bees at dose similar to the current apiculture practices (1–2 g Cu/L preparation). Overall, with the available data, it was not possible to draw a conclusion on various aspects of the risk assessment to bees.*"
In conclusion, due to the high number of applications a long-term exposure to honeybees cannot be excluded.

Updated 04.2024
The risk assessment to bumble bees is not to be considered only illustrative, given that this is done with the more up to date scientific background document, that some MSs and the EFSA follows. Thus, the risk would remain according to in line with the EFSA guideline. However, the guideline is not yet fully implemented and therefore the final decision remains for consideration by Member states.

Final decision should be taken into account at MSs level.

Therefore, to protect bees the following restriction are proposed by zRMS-PL:
SPe 8: Dangerous to bees. To protect bees and other pollinating insects do not apply to crop plants when in flower. Do not use where bees are actively foraging. Do not apply when flowering weeds are present. Remove weeds before flowering.

Based on the low acute toxicity to bees and the rapid degradation in plants, cymoxanil is also not expected to contribute significantly to the chronic risk of Cuprofix C to bees. Therefore, the risk assessment for copper is considered to cover that for the formulation Cuprofix C as well. Combined risk assessment. Additionally, it is clear that copper drives the toxicity of the mixture for bees (%TU >90%). The risk assessment for copper alone is considered sufficient to cover the risk of exposure to the product.

The risk assessment for bees should be considered by MSs level.

3.8.4 Effects on other arthropod species other than bees

The risk to non-target arthropods from the use of copper, cymoxanil and FEL02 is acceptable.

3.8.5 Effects on soil organisms

The risks following exposure of Copper to earthworms and other non-target soil macro-organisms are considered to be acceptable at annual doses of up to 4.0 kg Cu/ha.

The risks following exposure of Copper to soil micro-organisms are acceptable at doses of up to 4.0 kg Cu/ha.

3.8.6 Effects on non-target terrestrial plants

The risk of FEL02 to non-target plants is acceptable based on the first-tier assessment. Since copper is persistent also an assessment based on literature data was performed. Based on that it can be concluded that the risks following exposure of copper to non-target plants are acceptable at annual doses of up to 6 kg Cu/ha. Since the annual dose resulting from the proposed use of FEL02 is 720 g cu/ha, no adverse effects resulting from the proposed applications are expected.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

No further testing on, or assessment of risk to, other terrestrial organisms is considered necessary as this is considered to have been addressed in the previous sections.

3.9 Relevance of metabolites (Part B, Section 10)

3.9.1 Cymoxanil (active substance 1)

None of the Cymoxanil relevant soil metabolites (IN-U3204, IN-W3595, IN-JX915 and IN-KQ960) are predicted to occur in groundwater at concentrations above 0.1 µg/L (see dRR part B section 8.8.2.1). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 – rev.10 is therefore not required.

3.9.2 Copper (active substance 2)

Copper is an element and therefore cannot be transformed into related metabolites or degradation products. Hence, it is not necessary to include further information.

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

Not required at this stage

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

Insert any data that the notifier needs to submit following authorization. As a rule, this is restricted to storage stability and monitoring data.

Insert the data that is still required for the evaluation of the product in the case where the product authorization is not granted.

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

Appendix 2 Copy of the product label

Skuteczność:

Brak uwag.

Metabolizm i pozostałości:

Brak uwag.

Toksykologia:

Korekta w części ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH.

Ekotoksykologia:

Wprowadzono zmiany w części: „Środki ostrożności związane z ochroną środowiska naturalnego”

Posiadacz zezwolenia:
UPL Holdings Coöperatief U.A., Claudius Prinsenlaan 144a, block A, 4818CP Breda, Królestwo Niderlandów, tel.: +31 85 071 23 00, e-mail: uplholdingscoop@upl-ltd.com

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:
UPL Polska Sp. z o.o., ul. Stawki 40, 01-040 Warszawa, tel.: +48 22 434 00 90, e-mail: sekretariat@upl-ltd.com

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:
……

Podmiot odpowiedzialny za końcowe etykietowanie środka ochrony roślin:
……

Cuprofix C

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:
miedź (w postaci cieczy bordoskiej) - 200 g/kg (20%)
cymoksanil (związek z grupy iminoacetylomoczników) - 40 g/kg (4%)

Zezwolenie MRiRW nr R - …./2024 z dnia .....2024 r.

Uwaga!	
H302	Działa szkodliwie po połknięciu.
H319	Działa drażniąco na oczy.
H332	Działa szkodliwie w następstwie wdychania.

H361fd	Podejrzewa się, że działa szkodliwie na płodność. Podejrzewa się, że działa szkodliwie na dziecko w łonie matki
H410	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH208	Zawiera cymoksanil. Może powodować wystąpienie reakcji alergicznej.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P201	Przed użyciem zapoznać się ze specjalnymi środkami ostrożności.
P202	Nie używać przed zapoznaniem się i zrozumieniem wszystkich środków bezpieczeństwa.
P261	Unikać wdychania rozpylonej cieczy.
P264	Dokładnie umyć ręce, przedramiona i twarz po użyciu.
P271	Stosować wyłącznie na zewnątrz lub w dobrze wentylowanym pomieszczeniu.
P280	
P301+P312	Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy.
P304+P340	W PRZYPADKU POŁKNIĘCIA: W przypadku złego samopoczucia skontaktować się z OŚRODKIEM ZATRUĆ lub z lekarzem.
P305+P351+P338	W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić mu warunki do swobodnego oddychania.
P308+P313	W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
P337+P313	W przypadku narażenia lub styczności: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
P312	W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
P330	W przypadku złego samopoczucia skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem. Wypłukać usta.
P273	Zebrać rozsypany produkt. Unikać uwolnienia do środowiska.

OPIS DZIAŁANIA

FUNGICYD w formie granul do sporządzania zawiesiny wodnej (WG) o działaniu powierzchniowym i wgłębnym do stosowania zapobiegawczego i interwencyjnego w ochronie ziemniaka przed zarazą ziemniaka. Zgodnie z klasyfikacją FRAC substancja czynna miedź zaliczona jest do grupy M01, a substancja czynna cymoksanil do grupy 27.

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnego lub ciągnikowego opryskiwacza polowego.

Ziemniak

Zaraza ziemniaka

Maksymalna / zalecana dawka dla jednorazowego zastosowania: 3,0 kg/ha

Termin stosowania środka:

Środek stosować zapobiegawczo w okresach spodziewanego zagrożenia zarazą lub zgodnie z sygnalizacją, od początku rozwoju pędów bocznych do fazy, gdy 50% liści brązowieje (BBCH 21-95), z zachowaniem okresu karencji.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 6
Odstęp między zabiegami: co najmniej 7 dni.
Zalecana ilość wody: 100-1000 l/ha
Zalecane opryskiwanie: drobnokropliste
Ilość cieczy użytkowej dostosować do zagęszczenia plantacji.

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):
Ziemniak: 7 dni

1. Podczas stosowania środka nie dopuścić do znoszenia cieczy użytkowej na sąsiednie rośliny uprawne.
2. Nie dopuścić do nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.
3. Środek zawiera substancję czynną: miedź (grupa FRAC M01) oraz cymoksanil (grupa FRAC 27). W ramach strategii przeciwdziałania odporności w populacji sprawcy choroby należy m. in. stosować środek zgodnie z zaleceniami z etykiety (dawka, termin, liczba zabiegów itp.), jedynie jako część przyjętego programu ochrony, do którego włączono inne środki grzybobójcze, zawierające substancje czynne o odmiennych mechanizmach działania (stosowanie środków sekwencyjnie lub przemiennie).

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.
Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).
Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać.
W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy:
– jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg lub
– unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin lub
– unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

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

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

Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

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

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

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

Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

Niebezpieczne dla pszczół. W celu ochrony pszczół i innych owadów zapylających nie stosować na rośliny uprawne w czasie kwitnienia. Nie używać w miejscach gdzie pszczoły mają pożytek. Nie stosować, kiedy występują kwitnące chwasty. Usuwać chwasty przed kwitnieniem.

Na danym stanowisku dawka łączna substancji czynnej miedź nie może przekroczyć w całym sezonie wegetacyjnym 4 kg/ha z uwzględnieniem wszystkich zastosowanych środków zawierających tę substancję czynną (niezależnie od jej postaci).

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 20 m od zbiorników i cieków wodnych z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%.
W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo.

Niebezpieczny dla pszczół
W celu ochrony pszczół i innych owadów zapylających nie stosować na rośliny uprawne w czasie kwitnienia. Nie używać w miejscach gdzie pszczoły mają pożytek. Nie stosować kiedy występują kwitnące chwasty. Usuwać chwasty przed kwitnieniem.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.
Środek ochrony roślin przechowywać:
– w oryginalnych opakowaniach,
– w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
– w temperaturze 0ºC - 30ºC

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

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

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

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.
W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.
W przypadku połknięcia: w przypadku złego samopoczucia skontaktować się z ośrodkiem zatruć lub z lekarzem.
Wypłukać usta.
W przypadku dostania się do dróg oddechowych: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić mu warunki do swobodnego oddychania.
W przypadku dostania się do oczu: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
W przypadku narażenia lub styczności: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
W przypadku złego samopoczucia skontaktować się z ośrodkiem zatruć/lekarzem.

Okres ważności - 3 lata
Data produkcji - .....
Zawartość netto - .....
Nr partii - .....

Appendix 3 Letter of Access

Not relevant

Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

EUCuTF = European Union Copper Task Force
UPL = UPL EU = UPL Europe Ltd
(*) UPL is a full member of the EU Copper Task Force, UPL Europe Ltd has a full access to all the studies included in the AIR dossier submitted for the EU renewal of copper compounds
UPL is a full member of the Cymoxanil AIR4 Task Force, UPL Europe Ltd has a full access to all the studies included in the AIR dossier submitted for the EU renewal of cymoxanil

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1	Noordijk, D. N. G.	2018	PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF CUPROFIX C DISPERSS (FEL02) UPL Europe Ltd., DL 18-086 Cerexagri B.V., Rotterdam, NL GLP: yes Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL Europe Ltd.
KCP 2.2.1	Noordijk, D. N. G.	2018	PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF CUPROFIX C DISPERSS (FEL02) UPL Europe Ltd., DL 18-086 Cerexagri B.V., Rotterdam, NL GLP: yes PUBLISHED: NO	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL Europe Ltd.
KCP 2.2.2	Noordijk, D. N. G.	2018	PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF CUPROFIX C DISPERSS (FEL02) UPL Europe Ltd., DL 18-086 Cerexagri B.V., Rotterdam, NL GLP: yes PUBLISHED: NO	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL Europe Ltd.
KCP 2.3.2	Noordijk, D. N. G.	2018	PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF CUPROFIX C DISPERSS (FEL02) UPL Europe Ltd., DL 18-086 Cerexagri B.V., Rotterdam, NL GLP: yes PUBLISHED: NO	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL Europe Ltd.
KCP 2.3.3/01	Noordijk, D. N. G.	2018	PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF CUPROFIX C DISPERSS (FEL02) UPL Europe Ltd., DL 18-086	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL Europe Ltd.

			Cerexagri B.V., Rotterdam, NL GLP: yes PUBLISHED: NO				
KCP 2.3.3/02	Tremain, S. P.	2018	COPPER (BB) /CYMOXANIL (200/40): CLASSIFICATION OF SELF HEATING SUBSTANCES UPL Europe Ltd., KX29DG Envigo Research Limited GLP: yes Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL Europe Ltd.
KCP 2.4.2	Noordijk, D. N. G.	2018	PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF CUPROFIX C DISPERSS (FEL02) UPL Europe Ltd., DL 18-086 Cerexagri B.V., Rotterdam, NL GLP: yes PUBLISHED: NO	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL Europe Ltd.
KCP 2.6.2	Noordijk, D. N. G.	2018	PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF CUPROFIX C DISPERSS (FEL02) UPL Europe Ltd., DL 18-086 Cerexagri B.V., Rotterdam, NL GLP: yes PUBLISHED: NO	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL Europe Ltd.
KCP 2.7.1	Noordijk, D. N. G.	2018	PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF CUPROFIX C DISPERSS (FEL02) UPL Europe Ltd., DL 18-086 Cerexagri B.V., Rotterdam, NL GLP: yes PUBLISHED: NO	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL Europe Ltd.
KCP 2.7.3	Noordijk, D. N. G.	2018	PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF CUPROFIX C DISPERSS (FEL02) UPL Europe Ltd., DL 18-086 Cerexagri B.V., Rotterdam, NL GLP: yes PUBLISHED: NO	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL Europe Ltd.

KCP 2.7.5/01	Noordijk, D. N. G.	2018	PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF CUPROFIX C DISPERSS (FEL02) UPL Europe Ltd., DL 18-086 Cerexagri B.V., Rotterdam, NL GLP: yes PUBLISHED: NO	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL Europe Ltd.
KCP 2.7.5/02	Noordijk, D. N. G.	2019	SHELF-LIFE OF CUPROFIX C DISPERSS (FEL02) FOR 2 YEARS AT AMBIENT STORAGE CONDITIONS IN 1-KG PAPER/PE BAGS UPL Europe Ltd., DL 18-087 Cerexagri B.V., Rotterdam, NL GLP: yes Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL Europe Ltd.
KCP 2.7.5/03	Suratwala, T. G.	2022	SHELF-LIFE OF CUPROFIX C DISPERSS (FEL02) FOR 3 YEARS AT AMBIENT STORAGE CONDITIONS IN 1-KG PAPER/PE BAGS UPL Europe Ltd., 237-2-11-27572 Jai Research Foundation, Gujarat, India GLP: yes Published: no	N	Y	New data for existing formulation, not previously submitted nor evaluated	UPL Europe Ltd.
KCP 2.8.1	Noordijk, D. N. G.	2018	PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF CUPROFIX C DISPERSS (FEL02) UPL Europe Ltd., DL 18-086 Cerexagri B.V., Rotterdam, NL GLP: yes PUBLISHED: NO	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL Europe Ltd.
KCP 2.8.2	Noordijk, D. N. G.	2018	PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF CUPROFIX C DISPERSS (FEL02) UPL Europe Ltd., DL 18-086 Cerexagri B.V., Rotterdam, NL GLP: yes PUBLISHED: NO	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL Europe Ltd.
KCP 2.8.3.1	Noordijk, D. N. G.	2018	PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF CUPROFIX C DISPERSS (FEL02)	N	Y	Study may have already been submitted for national authorisation, but	UPL Europe Ltd.

			UPL Europe Ltd., DL 18-086 Cerexagri B.V., Rotterdam, NL GLP: yes PUBLISHED: NO			data protection may still be active	
KCP 2.8.3.2	Noordijk, D. N. G.	2018	PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF CUPROFIX C DISPERSS (FEL02) UPL Europe Ltd., DL 18-086 Cerexagri B.V., Rotterdam, NL GLP: yes PUBLISHED: NO	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL Europe Ltd.
KCP 2.8.5.1.1 KCP 2.8.5.1.2	Noordijk, D. N. G.	2018	PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF CUPROFIX C DISPERSS (FEL02) UPL Europe Ltd., DL 18-086 Cerexagri B.V., Rotterdam, NL GLP: yes PUBLISHED: NO	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL Europe Ltd.
KCP 2.8.5.2.1 KCP 2.8.5.2.2	Noordijk, D. N. G.	2018	PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF CUPROFIX C DISPERSS (FEL02) UPL Europe Ltd., DL 18-086 Cerexagri B.V., Rotterdam, NL GLP: yes PUBLISHED: NO	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL Europe Ltd.
KCP 2.8.5.3 ~~KCP 2.8.7.1~~	Noordijk, D. N. G.	2018	PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF CUPROFIX C DISPERSS (FEL02) UPL Europe Ltd., DL 18-086 Cerexagri B.V., Rotterdam, NL GLP: yes PUBLISHED: NO	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL Europe Ltd.

KCP 2.8.7.1	Noordijk, D. N. G.	2018	PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF CUPROFIX C DISPERSS (FEL02) UPL Europe Ltd., DL 18-086 Cerexagri B.V., Rotterdam, NL GLP: yes PUBLISHED: NO	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL Europe Ltd.
KCP 2.11/01	Noordijk, D. N. G.	2018	PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF CUPROFIX C DISPERSS (FEL02) UPL Europe Ltd., DL 18-086 Cerexagri B.V., Rotterdam, NL GLP: yes PUBLISHED: NO	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL Europe Ltd.
KCP 2.11/02	Pardo Martinez, M.	2019	FEL02: VALIDATION OF THE ANALYTICAL METHOD FOR THE DETERMINATION OF THE METALLIC IMPURITIES CONTENT (ARSENIC, CADMIUM, LEAD, NICKEL, ANTIMONY, CHROMIUM, COBALT AND MERCURY) UNITED PHOSPHORUS LTD., CH - 204/2019 CHEMSERVICE S.R.L., NOVATE MILANESE , ITALY GLP: YES PUBLISHED: NO	N	Y	New data for existing formulation, not previously submitted nor evaluated	UPL Europe Ltd.
~~KCP 5.1.1/02~~	~~Heugens, R.~~	~~2003~~	~~VALIDATION OF DRAFT SOP DLA-251 VERSION 0 SOLUTION DISPERSS (ATOFDH01), DETERMINATION OF FAMOXADONE CYMOXANIL AND COPPER CONTENT~~ ~~UNITED PHOSPHORUS LTD., DL 03-034~~ ~~CEREXAGRI B.V., ROTTERDAM, NL~~ ~~GLP: YES~~ ~~PUBLISHED: NO~~	~~N~~	~~Y~~	~~Study may have already been submitted for national authorisation, but data protection may still be active~~	~~UPL Europe Ltd.~~
KCP 5.1.1/01	Diepenhorst, P. C.	2000	VALIDATION OF DRAFT SOP DLA-060 COPPER COMPOUNDS DETERMINATION OF COPPER CONTENT IN FORMULATIONS, UPL Europe Ltd., DL 99-024 Development Laboratory Elf Atochem Agri B.V., The Netherlands GLP: yes Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL Europe Ltd.

KCP 5.1.1/02	Diepenhorst, P. C.	1999	VALIDATION OF DRAFT SOP DLA-229.2 MANCOZEB/CYMOXANIL WG DETERMINATION OF ACTIVE INGREDIENTS AND SUSPENSIBILITY UPL Europe Ltd., DL 99-024 Development Laboratory Elf Atochem Agri B.V., The Netherlands GLP: yes Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL Europe Ltd.
KCP 5.1.1/03	Diepenhorst, P. C.	2010	RE-VALIDATION OF SOP DLA-249.1 VERSION 2 "COPPER-CYMOXANIL MIXED FORMULATIONS (ATOFELNN) DETERMINATION OF CONTENT OF ACTIVE INGREDIENTS", DIEPENHORST, P. C. (2010), UPL Europe Ltd.,: DL 09-102 Development Laboratory Elf Atochem Agri B.V., The Netherlands GLP: yes Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL Europe Ltd.
KCP 5.1.1/~~03~~ 04	Pardo Martinez, M.	2019	FEL02: VALIDATION OF THE ANALYTICAL METHOD FOR THE DETERMINATION OF THE METALLIC IMPURITIES CONTENT (ARSENIC, CADMIUM, LEAD, NICKEL, ANTIMONY, CHROMIUM, COBALT AND MERCURY) UNITED PHOSPHORUS LTD., CH - 204/2019 CHEMSERVICE S.R.L., NOVATE MILANESE , ITALY GLP: YES PUBLISHED: NO	N	Y	New data for existing formulation, not previously submitted nor evaluated	UPL Europe Ltd.
KCP 5.1.2/01	Maas, W.J.M., Brufau Dones, G.	2016	IN VITRO PERCUTANEOUS ABSORPTION OF COPPER, FORMULATED AS COPPER HYDROXIDE (DPX-GFJ52) 53.8WG (35% AS METALLIC COPPER), THROUGH HUMAN SKIN E.I. DU PONT DE NEMOURS AND COMPANY, DUPONT-42821 TNO TRISKELION B.V., ZEIST, THE NETHERLANDS GLP: YES PUBLISHED: NO	N	Y	New data, not previously submitted nor evaluated	E.I. du Pont de Nemours and Company

KCP 5.1.2/02	Maas, W.J.M., Bogaards, J.J.P., de Bie, A.Th.	2016	IN VIVO PERCUTANEOUS ABSORPTION OF COPPER, FORMULATED AS COPPER HYDROXIDE (DPX-GFJ52) 53.8WG (35% AS METALLIC COPPER) IN RATS E.I. DU PONT DE NEMOURS AND COMPANY, DUPONT-42648 TNO TRISKELION B.V., ZEIST, THE NETHERLANDS GLP/GEP: YES PUBLISHED: NO	Y	Y	New data, not previously submitted nor evaluated	E.I. du Pont de Nemours and Company
KCP 5.1.2/03	Falconer, D.	2019	METHOD VALIDATION FOR THE ANALYSIS OF COPPER IN EIGHT PLANT MATRICES UPL EUROPE LTD., 41027 CHARLES RIVER LABORATORIES GLP/GEP: YES PUBLISHED: NO	N	Y	New data for active ingredient, not previously submitted nor evaluated	UPL Europe Ltd.
KCP 5.1.2/04	Maccaferri, L.	2009	COPPER RESIDUES IN POTATOES AFTER FOUR APPLICATIONS OF COPPER OXYCHLORIDE 37.5 WG. TWO HARVEST TRIALS IN NORTHERN EUROPE (GERMANY AND POLAND) IN 2008, ANALYTICAL PHASE REPORT ISAGRO, RA.08.26 ISAGRO RICERCA SRL, NOVARA, ITALY GLP: YES PUBLISHED: NO	N	Y	New data for active ingredient, not previously submitted nor evaluated	UPL Europe Ltd.
KCP 5.1.2/05	Brotherhood, A.	2013	GLP VALIDATION STUDY FOR DETERMINATION OF COPPER IN FRESHWATER, ALGAE AND DAPHNIA MEDIA BY ICP-MS ASTRAZENECA UK LIMITED, 1323923 INTERTEK ASG, MANCHESTER, UK GLP: YES PUBLISHED: NO	N	Y	New data for existing formulation, not previously submitted nor evaluated	UPL Europe Ltd.
KCP 5.1.2/05	Guzman, M.H.	2011	FRESHWATER, ALGAE AND DAPHNIA COPPER ANALYSIS BY ICP-MS ASTRAZENECA UK LIMITED, TM1192-ISSUE NO. 2 INTERTEK ASG, MANCHESTER, UK GLP: YES PUBLISHED: NO	N	Y	New data for existing formulation, not previously submitted nor evaluated	UPL Europe Ltd.

KCP 5.1.2/06	Ruhland, S.	2018	CHRONIC TOXICITY OF COPPER 20% + CYMOXANIL 4% WG TO THE HONEY BEE APIS MELLIFERA L. UNDER LABORATORY CONDITIONS: VERIFICATION OF THE CONCENTRATION OF THE ACTIVE INGREDIENT IN THE TEST ITEM FEEDING SOLUTIONS UPL EUROPE LTD., 17 35 CRB 0157 BIOCHEM AGRAR, GERICHSHAIN, GERMANY GLP: YES PUBLISHED: NO	N	Y	New data for existing formulation, not previously submitted nor evaluated	UPL Europe Ltd.
KCP 5.1.2/07	Scheller, K.	2018a	COPPER 20% + CYMOXANIL 4% WG - REPEATED EXPOSURE OF HONEY BEE (APIS MELLIFERA L.) LARVAE UNDER LABORATORY CONDITIONS (IN VITRO): VERIFICATION OF THE CONCENTRATION OF THE ACTIVE INGREDIENT IN THE TEST ITEM FEEDING SOLUTIONS UPL EUROPE LTD., 17 35 CRB 0150 BIOCHEM AGRAR, GERICHSHAIN, GERMANY GLP: YES PUBLISHED: NO	N	Y	New data for existing formulation, not previously submitted nor evaluated	UPL Europe Ltd.
KCP 5.1.2/07	Scheller, K.	2018b	COPPER 20% + CYMOXANIL 4% WG – REPEATED EXPOSURE OF HONEY BEE (APIS MELLIFERA L.) LARVAE UNDER LABORATORY CONDITIONS (IN VITRO): VERIFICATION OF THE CONCENTRATION OF THE ACTIVE INGREDIENT IN THE TEST ITEM FEEDING SOLUTIONS UPL EUROPE LTD., 17 35 CRB 0149 BIOCHEM AGRAR, GERICHSHAIN, GERMANY GLP: YES PUBLISHED: NO	N	Y	New data for existing formulation, not previously submitted nor evaluated	UPL Europe Ltd.
KCP 5.1.2/08	Colli, M.	2018	CHRONIC ORAL EFFECTS OF COPPER OXYCHLORIDE 50% WP TO ADULT WORKER HONEYBEES APIS MELLIFERA L., 10-DAY FEEDING LABORATORY TEST EU COPPER TASK FORCE, BT215/17 BIOTECNOLOGIE BT SRL, TODI, ITALY GLP: YES PUBLISHED: NO	N	Y	New data for active ingredient, not previously submitted nor evaluated	EUCuTF

KCP 5.1.2/09	Richter, S.	2019	CYMOXANIL: VALIDATION OF AN ENFORCEMENT METHOD FOR VARIOUS CROP TYPES UPL EUROPE LTD., P/B 1668 G PTRL EUROPE, ULM, GERMANY GLP: YES PUBLISHED: NO	N	Y	New data for active ingredient, not previously submitted nor evaluated	UPL Europe Ltd.
KCP 5.1.2/10	Weber, H.	2008	VALIDATION OF THE ANALYTICAL METHODS FOR THE DETERMINATION OF RESIDUES OF CYMOXANIL, MANCOZEB AND ITS METABOLITE ETU IN POTATO (TUBER) BELCHIM CROP PROTECTION AND INDOFIL INDUSTRIES LIMITED, GAB-0703V EUROFINS GLP: YES PUBLISHED: NO	N	Y	New data for active ingredient, not previously submitted nor evaluated	Belchim Crop Protection and Indofil Industries Limited
KCP 5.1.2/11	Lakaschus, S.	2004	VALIDATION OF THE DFG METHOD S19 (EXTENDED AND REVISED VERSION) FOR THE DETERMINATION OF RESIDUES OF CYMOXANIL IN MATRICES WITH HIGH WATER CONTENT {MELON (PEEL AND PULP), GRAPES AND POTATOES] E.I. DU PONT DE NEMOURS AND COMPANY, DUPONT-15026 DR. SPECHT & PARTNER GLP: YES PUBLISHED: NO	N	Y	New data for active ingredient, not previously submitted nor evaluated	E.I. du Pont de Nemours and Company
KCP 5.1.2/12	Tetuan, B.	2011	DETERMINATION OF RESIDUES AT HARVEST IN POTATOES, FOLLOWING SIX BROADCAST APPLICATIONS OF HARPON WG, UNDER FIELD CONDITIONS. – NORTHERN EUROPE – SEASON 2010 GOWAN COMERCIO INTERNACIONAL & SERVICOS LTDA, 10 F PT GW P/A (PROMO/ZOX CM/10.01) PROMO-VERT GLP: YES PUBLISHED: NO	N	Y	New data for active ingredient, not previously submitted nor evaluated	Gowan Comercio Internacional & Servicos ltda

KCP 5.2/01	Riccelli, S.	2017	METHOD VALIDATION FOR THE DETERMINATION OF COPPER IN/ON DRY AND OILY MATRICES AND MATRIX EFFECT EVALUATION ON DRY, OILY, HIGH WATER AND ACID MATRICES EU COPPER TASK FORCE, RA.17.02 ISAGRO - CENTRO DI SAGGIO BPL GLP/GEP: YES PUBLISHED: NO	N	Y	New data for active ingredient, not previously submitted nor evaluated	EUCuTF
KCP 5.2/02	Pardo Martinez, M.	2018	VALIDATION OF THE ANALYTICAL METHOD FOR THE DETERMINATION OF COPPER RESIDUES IN AIR EU COPPER TASK FORCE, CH-657/2017 CHEMSERVICE S.R.L., NOVATE MILANESE, ITALY GLP/GEP: YES PUBLISHED: NO	N	Y	New data for active ingredient, not previously submitted nor evaluated	EUCuTF
KCP 5.2/03	Lakaschus, S., Gizler, A.	2013	VALIDATION OF MULTI-RESIDUE METHOD DFG S19 (LC-MS/MS MODULE) FOR THE DETERMINATION OF RESIDUES OF CYMOXANIL IN TOMATO, GRAPES, OILSEED RAPE AND WHEAT GRAIN E.I. DU PONT DE NEMOURS AND COMPANY, DUPONT-35769 EUROFINS AGROSCIENCE SERVICES CHEM GMBH GLP/GEP: YES PUBLISHED: NO	N	Y	New data for active ingredient, not previously submitted nor evaluated	E.I. du Pont de Nemours and Company
KCP 5.2/03	Seck, C., Goody, T.	2019	POSITION PAPER TO COVER THE EXTRACTION EFFICIENCY OF THE MULTI-RESIDUE METHOD DFG S19 REPORTED IN THE REPORT DUPONT-35769 CTF, NOT APPLICABLE BATTELLE UK LIMITED GLP/GEP: NO PUBLISHED: NO	N	N		CTF

KCP 5.2/04	Cermak, J.	2013a	INDEPENDENT LABORATORY VALIDATION OF MULTI-RESIDUE METHOD DFG S19 FOR THE DETERMINATION OF RESIDUES OF CYMOXANIL IN TOMATO, GRAPES, OILSEED RAPE AND WHEAT GRAIN USING LC-MS/MS E.I. DU PONT DE NEMOURS AND COMPANY, DUPONT-35770 VÝZKUMNÝ ÚSTAV ORGANICKÝCH SYNTÉZ A.S. GLP: YES PUBLISHED: NO	N	Y	New data for active ingredient, not previously submitted nor evaluated	E.I. du Pont de Nemours and Company
KCP 5.2/05	Garofani, S.	2009a	VALIDATION OF THE ANALYTICAL METHOD FOR THE DETERMINATION OF CYMOXANIL RESIDUES IN SOIL BELCHIM CROP PROTECTION AND INDOFIL INDUSTRIES LIMITED, CH-285/2008 CHEMSERVICE GLP: YES PUBLISHED: NO	N	Y	New data for active ingredient, not previously submitted nor evaluated	Belchim Crop Protection and Indofil Industries Limited
KCP 5.2/06	Garofani, S.	2013	VALIDATION OF THE ANALYTICAL METHOD FOR THE DETERMINATION OF CYMOXANIL RESIDUES IN SOIL. INTEGRATION OF THE GLP STUDY CH-285/2008 WITH LINEARITY AND RECOVERY TESTS USING PEAK AREAS OF QUALIFIER IONS BELCHIM CROP PROTECTION AND INDOFIL INDUSTRIES LIMITED, CH-377/2013 CHEMSERVICE GLP: YES PUBLISHED: NO	N	Y	New data for active ingredient, not previously submitted nor evaluated	Belchim Crop Protection and Indofil Industries Limited
KCP 5.2/07	Nichetti S.	2017a	VALIDATION OF THE ANALYTICAL METHOD FOR THE DETERMINATION OF CYMOXANIL RESIDUES IN SOIL. INTEGRATION OF THE GLP STUDY CH-285/2008 AND GLP STUDY CH-377/2013 WITH LINEARITY TEST IN A SUITABLE RANGE BELCHIM CROP PROTECTION AND INDOFIL INDUSTRIES LIMITED, CH-199/2016 CHEMSERVICE GLP: YES PUBLISHED: NO	N	Y	New data for active ingredient, not previously submitted nor evaluated	Belchim Crop Protection and Indofil Industries Limited

KCP 5.2/08	Leak, T.	2010	ANALYTICAL METHOD FOR THE DETERMINATION OF CYMOXANIL AND IN-KQ960 IN WATER (POND, STREAM, WELL, AND TAP) USING LC/MS/MS E.I. DU PONT DE NEMOURS AND COMPANY, ABC-65072 (DUPONT-27500) ABC LABORATORIES, INC. GLP: YES PUBLISHED: NO	N	Y	New data for active ingredient, not previously submitted nor evaluated	E.I. du Pont de Nemours and Company
KCP 5.2/09	Cermak, B.	2013b	INDEPENDENT LABORATORY VALIDATION FOR THE DETERMINATION OF RESIDUES OF CYMOXANIL AND IN-KQ960 IN WATER (DRINKING AND STREAM) USING LC-MS/MS E.I. DU PONT DE NEMOURS AND COMPANY, DUPONT-35792 VÝZKUMNÝ ÚSTAV ORGANICKÝCH SYNTÉZ A.S. GLP: YES PUBLISHED: NO	N	Y	New data for active ingredient, not previously submitted nor evaluated	E.I. du Pont de Nemours and Company
KCP 5.2/10	Garofani, S.	2009b	VALIDATION OF THE ANALYTICAL METHOD FOR THE DETERMINATION OF CYMOXANIL RESIDUES IN AIR BELCHIM CROP PROTECTION AND INDOFIL CHEMICALS COMPANY, CH-287/2008 CHEMSERVICE GLP/GEP: YES PUBLISHED: NO	N	Y	New data for active ingredient, not previously submitted nor evaluated	Belchim Crop Protection and Indofil Chemicals Company
KCP 5.2/11	Nichetti, S.	2017b	VALIDATION OF THE ANALYTICAL METHOD FOR THE DETERMINATION OF CYMOXANIL RESIDUES IN AIR. INTEGRATION OF THE GLP STUDY CH-287/2008 WITH LINEARITY TEST USING A SUITABLE RANGE BELCHIM CROP PROTECTION AND INDOFIL CHEMICALS COMPANY, CH-200/2016 CHEMSERVICE GLP: YES PUBLISHED: NO	N	Y	New data for active ingredient, not previously submitted nor evaluated	Belchim Crop Protection and Indofil Chemicals Company

KCP 5.2/12	Perboni, A.	2016	VALIDATION OF THE ANALYTICAL METHOD TO DETERMINE RESIDUE OF CYMOXANIL IN DIFFERENT MATRICES OF ANIMAL ORIGIN (KIDNEY, LIVER, FAT, MUSCLE, MILK AND EGGS) CTF, RAU-065-16 RESEARCH CENTER BIOSPHERES GLP: YES PUBLISHED: NO	N	Y	New data for active ingredient, not previously submitted nor evaluated	CTF
KCP 5.2/13	Fifi, A.P.	2016	INDEPENDENT LABORATORY VALIDATION OF THE ANALYTICAL METHOD TO DETERMINE RESIDUE OF CYMOXANIL IN DIFFERENT ANIMAL ORIGIN MATRICES (KIDNEY, LIVER, FAT, MUSCLE, MILK AND EGG) CTF, BT300/16 BIOTECNOLOGIE BT S.R.L. GLP: YES PUBLISHED: NO	N	Y	New data for active ingredient, not previously submitted nor evaluated	CTF
KCP 5.2/14	Andrews, G.	2019	METHOD VALIDATION - DETERMINATION OF RESIDUES OF CYMOXANIL IN BODY FLUID CTF, ZE/19/001 BATTELLE UK LIMITED GLP: YES PUBLISHED: NO	N	Y	New data for active ingredient, not previously submitted nor evaluated	CTF
KCA 6.1/01	Long, E., Weidenauer, L.	2019	CROP RESIDUE DATA AND CONSUMER RISK ASSESSMENT FOR COPPER COMPOUNDS - A CRITICAL ANALYSIS EU COPPER TASK FORCE, NOT AVAILABLE NOT AVAILABLE GLP: NO PUBLISHED: NO	N	N	-	EUCuTF(*)

KCA 6.1/02	Weber H.	2011	STORAGE STABILITY OF RESIDUES OF CYMOXANIL, MANCOZEB AND ETU IN POTATO SAMPLES. REPORT NUMBER: GAB-0704 EUROFINS – DR. SPECHT GLP GLP: YES PUBLISHED: NO	N	Y	Data/study report never submitted before to Poland	Indofil Industries Limited and Belchim Crop Protection(*)
KCA 6.3/01	Sicbaldi, F., Soddu, R., Riccelli, S.	2009	COPPER RESIDUES IN POTATO AFTER FOUR APPLICATIONS OF COPPER OXYCHLORIDE 37.5 WG. TWO HARVEST TRIALS IN NORTHERN EUROPE (GERMANY AND POLAND) IN 2008 ISAGRO S.P.A., RA.08.26 ISAGRO, RICERCA SRL GLP: YES PUBLISHED: NO	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	ISA (Isagro S.p.A)(*)
KCA 6.3/02	Klimmek, S., Gizler, A.	2007	MAGNITUDE OF RESIDUES OF COPPER IN/ON POTATO FOLLOWING SIX APPLICATIONS OF FLOWBRIX - AUSTRIA, CZECH REPUBLIC AND SLOVAKIA, SEASON 2006 KWIZDA AGRO GMBH, AUSTRIA, G06-0074, KWI-0601 EUROFINS ANALYTIK GMBH, DR. SPECHT LABORATORIEN, HAMBURG, GERMANY GLP: YES PUBLISHED: NO	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	KWI (Kwizda Agro GmbH, Austria)(*)
KCA 6.3/03	Steffen, M.	1992	APPLICATION FOR REGISTRATION OF FUNGURAN-OH 50 WP (50% COPPER AS COPPER HYDROXIDE) EU COPPER TASK FORCE, NOT STATED NOT AVAILABLE GLP: YES PUBLISHED: NO	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	EUCuTF(*)

KCA 6.3/04	Schneider, E.	2021	DETERMINATION OF COPPER RESIDUES IN POTATO RAW AGRICULTURAL COMMODITY FOLLOWING FOLIAR APPLICATIONS WITH BORDEAUX MIXTURE 20 % WG (FAP13) UNDER FIELD CONDITIONS IN NORTHERN EUROPE IN 2020, REPORT NO. R CO233 UPL EUROPE LTD., C0233 ANADIAG, FRANCE GLP: YES PUBLISHED: NO	N	Y	Data/study report never submitted before to Poland	UPL (E.I. Du Pont de Nemours and Company)(*)
KCA 6.3/05	Jonchere F.	2011b	DETERMINATION OF CYMOXANIL RESIDUES IN POTATOES FOLLOWING APPLICATIONS OF THE FORMULATED PRODUCT FAZ02 (50 G/KG CYMOXANIL + 680 G/KG MANCOZEB WG) UNDER FIELD CONDITIONS IN NORTHERN EUROPE – 2010, REPORT NO B0163 ANADIAG, FRANCE GLP: YES PUBLISHED: NO	N	Y	Data/study report never submitted before to Poland	Société Financière de Pontarlier (SFP)(*)
KCA 6.3/06	Tetuan B.	2011	DETERMINATION OF RESIDUES AT HARVEST IN POTATOES, FOLLOWING SIX BROADCAST APPLICATIONS OF HARPON WG, UNDER FIELD CONDITIONS – NORTHERN EUROPE – SEASON 2010 - REPORT NUMBER: 10 F PT GW P/A (PROMO/ZOX-CM/10.01) PROMO-VERT PROMO-VERT GLP: YES PUBLISHED: NO	N	Y	Data/study report never submitted before to Poland	Gowan Comercio Internacional & Servicos Ltda(*)
KCA 6.3/07	Semrau J.	2010a	DETERMINATION OF RESIDUES OF CYMOXANIL AND MANCOZEB AFTER SIX APPLICATIONS CYMOXANIL/MANCOZEB 4.5/68% W/W WP IN FIELD POTATOES, NORTHERN EUROPE 2007/2008. REPORT NUMBER: 20074095/E1-FPPO EUROFINS AGROSCIENCE SERVICES GLP: YES PUBLISHED: NO	N	Y	Data/study report never submitted before to Poland	Belchim Crop Protection NV and Indofil Industries Limited(*)

~~KCA 6.3/08~~	~~Old J., Hansford R.~~	~~2007~~	~~MAGNITUDE OF RESIDUES OF CYMOXANIL IN POTATOES FOLLOWING APPLICATIONS OF CYMOXANIL 60WG – NORTHERN EUROPE.~~ ~~SEASON 2006~~ ~~REPORT NUMBER: DUPONT-20033~~ ~~CHARLES RIVER LABORATORIES~~ ~~GLP: YES~~ ~~PUBLISHED: NO~~	~~N~~	~~Y~~	~~Data/study report never submitted before to Poland~~	~~E. I. du Pont de Nemours and Company(*)~~
~~KCA 6.3/09~~	~~Livingstone K., Haigh I. M.~~	~~2008~~	~~MAGNITUDE OF RESIDUES OF CYMOXANIL IN POTATOES FOLLOWING APPLICATIONS OF CYMOXANIL 60WG – NORTHERN EUROPE.~~ ~~SEASON 2007.~~ ~~REPORT NUMBER: DUPONT-22006~~ ~~CHARLES RIVER LABORATORIES~~ ~~GLP: YES~~ ~~PUBLISHED: NO~~	~~N~~	~~Y~~	~~Data/study report never submitted before to Poland~~	~~E. I. du Pont de Nemours and Company(*)~~
KCP 7.1.1/01	[redacted]	2016a	ACUTE ORAL TOXICITY STUDY OF COPPER 200 + CYMOXANIL 40 WDG IN RATS Report number 401-1-01-13507 [redacted] GLP UNPUBLISHED	Y	Y		UPL EU
KCP 7.1.2/01	Verma, R.	2016b	ACUTE DERMAL TOXICITY STUDY OF COPPER 200 + CYMOXANIL 40 WDG IN RATS Report number 403-1-01-13508 Jai Research Foundation, Department of Toxicology, Gujarat, India GLP UNPUBLISHED	Y	Y		UPL EU
KCP 7.1.3/01	Chhimwal, R.	2016a	ACUTE INHALATION STUDY OF COPPER 200 + CYMOXANIL 40 WDG IN RATS Report number 405-1-01-13509 Jai Research Foundation, Department of Toxicology, Gujarat, India GLP UNPUBLISHED	Y	Y		UPL EU

KCP 7.1.4/01	Patel, M.R.	2016a	ACUTE DERMAL IRRITATION STUDY OF COPPER 200 + CYMOXANIL WDG IN RABBITS Report number 406-1-01-13510 Jai Research Foundation, Department of Toxicology, Gujarat, India GLP UNPUBLISHED	Y	Y		UPL EU
KCP 7.1.5/01	Patel, M.R.	2016b	ACUTE EYE IRRITATION STUDY OF COPPER 200 + CYMOXANIL WDG IN RABBITS Report number 407-1-01-13511 Jai Research Foundation, Department of Toxicology, Gujarat, India GLP UNPUBLISHED	Y	Y		UPL EU
KCP 7.1.6/01	Chhimwal, R.	2016b	SKIN SENSITISATION STUDY OF COPPER 200 + CYMOXANIL 40 WDG IN GUINEA PIGS [GUINEA PIG MAXIMIZATION TEST] Report number 408-1-01-13512 Jai Research Foundation, Department of Toxicology, Gujarat, India GLP UNPUBLISHED	Y	Y		UPL EU
KCP 7.3/05	Maas, W.J.M.	2020b	The In Vitro Percutaneous Absorption of Radiolabelled Cymoxanil in a Concentrate Formulation (FEL02) and an In-Use Dilution through Human Split-Thickness Skin Report number Study No. 20220076 Charles River Loboratories Den Bosch, Hertogenbosch, The Netherlands GLP UNPUBLISHED	N	Y		UPL EU
KCP 9.2.4/01	Demetriades , A., Reimann, C., Birke M., the Eurogeosurveys Geochemistry EGG Team	2012	EUROPEAN GROUND WATER GEOCHEMISTRY USING BOTTLED WATER AS A SAMPLING MEDIUM not available, not applicable Springer Science + Business Media, Inc., 115-139 GLP/GEP: no Published: yes	N	N		Public
KCP 9.2.4.1/01	Koomen, B.	2022a	FEL02: ESTIMATIONS OF PEC_{GW} FOR THE ACTIVE SUBSTANCE CYMOXANIL AND RELEVANT SOIL METABOLITES AFTER USE ON POTATO IN THE EU (CENTRAL ZONE) UPL Europe Ltd., 1181686-CP-090204-02-SU	N	N		UPL EU

			Company Report No.: UPL/2022/21166 Source: Charles River Laboratories GLP/GEP: no Published: no				
KCP 9.2.4.1/01	Bradatsch, C.	2019	CALCULATION OF PREDICTED ENVIRONMENTAL CONCENTRATIONS IN GROUNDWATER (PEC_{GW}) FOR THE ACTIVE SUBSTANCE COPPER USING THE MODEL SOFTWARE FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3 AND FOCUS MACRO 5.5.4 - PRODUCT FEL02 - UPL Europe Ltd., 1181686-CP-090204-02-SU GAB Consulting GmbH, Stade, Germany GLP/GEP: no Published: no	N	N		UPL EU
KCP 9.2.5/01	Koomen, B.	2022b	FEL02: ESTIMATIONS OF PEC_{SW} AND PEC_{SED} FOR THE ACTIVE SUBSTANCE CYMOXANIL AND RELEVANT METABOLITES AFTER USE ON POTATO IN THE EU (CENTRAL ZONE) UPL Europe Ltd., 1181686-CP-090204-02-SU Company Report No.: UPL/2022/21297 Source: Charles River Laboratories GLP/GEP: no Published: no	N	N		UPL EU
KCP 9.2.5/01	Axmann, S.	2019	A FIELD STUDY TO DETERMINE COPPER RESIDUES IN STREAM SEDIMENTS EU Copper Task Force, S17-04438 Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH GLP: yes Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	EUCuTF(*)
KCP 10.2/01	Van Sprang, P.	2019	RESPONSE TO EFSA COMMENTS ON THE AQUATIC EFFECTS ASSESSMENT FOR CU - EXTENSION EU Copper Task Force, not available not available	N	N		EUCuTF(*)

			GLP/GEP: no Published: no				
KCP 10.2/02	Oorts, K and Verdonck, F	2019	RELEVANCE OF STANDARD ASSESSMENT FACTORS FOR RISK ASSESSMENT OF THE ESSENTIAL ELEMENT COPPER EU Copper Task Force, CuPPP20170705 not available GLP/GEP: no Published: no	N	N		EUCuTF(*)
KCP 10.2/03	[redacted]	2019	MODELLING OF THE FUNGURAN-OH EFFECTS ON ONCHORHYNCHUS MYKISS POPULATIONS EU Copper Task Force, not available not available GLP/GEP: no Published: no	N	N		EUCuTF(*)
KCP 10.2/04	Vangheluwe, M.	2019	REVISED PNEC SEDIMENT COPPER FOR THE SEDIMENT EFFECTS ASSESSMENT FOR CU : EXTENDING THE DATABASE WITH ADDITIONAL SPECIES EU Copper Task Force, not available not available GLP/GEP: no Published: no	N	N		EUCuTF(*)
KCP 10.2.1/01	[redacted]	2012a	CUPROFIX C DISPERSS (FEL02): DETERMINATION OF ACUTE TOXICITY TO RAINBOW TROUT (ONCORHYNCHUS MYKISS) United Phosphorus Ltd., BR0587/B [redacted] GLP: yes Published: no	Y	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL EU
KCP 10.2.1/02	Hutchinson, K.A., Sharpe, A.D.	2012b	CUPROFIX C DISPERSS (FEL02): DETERMINATION OF ACUTE TOXICITY TO DAPHNIA MAGNA United Phosphorus Ltd., BR0586/B Brixham Environmental Laboratory, Brixham, UK GLP: yes	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL EU

			Published: no				
KCP 10.2.1/03	Hutchinson, K.A., Sharpe, A.D.	2012c	CUPROFIX C DISPERSS (FEL02): DETERMINATION OF TOXICITY TO THE GREEN ALGA PSEUDOKIRCHNERIELLA SUBCAPITATA United Phosphorus Ltd., BR0585/B Brixham Environmental Laboratory, Brixham, UK GLP: yes Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL EU
KCP 10.3.1.1.1/01	Vinall, S.	2011	ATOFEL02 (COPPER 200 G/KG CYMOXANIL 40 G/KG WG) - LABORATORY BIOASSAYS TO DETERMINE THE ACUTE CONTACT AND ORAL TOXICITY TO THE HONEYBEE APIS MELLIFERA United Phosphorus Ltd., UP-11-13 Mambo-Tox Ltd., Southampton, UK GLP: yes Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL EU
KCP 10.3.1.1.1/02	McVean, K	2022a	COPPER (FROM BORDEAUX MIXTURE) 20 % + CYMOXANIL 4 % WG ACUTE ORAL TOXICITY TEST ON THE BUMBLEBEE *BOMBUS TERRESTRIS* UPL Europe Ltd., SO21797 NOACK LABORATORIEN GMBH GLP: yes Published: no	N	Y	New data for existing formulation, not previously submitted nor evaluated	UPL EU
KCP 10.3.1.1.2/01	McVean, K	2022b	COPPER (FROM BORDEAUX MIXTURE) 20 % + CYMOXANIL 4 % WG ACUTE CONTACT TOXICITY TEST ON THE BUMBLEBEE BOMBUS TERRESTRIS UPL Europe Ltd., SO21797 NOACK LABORATORIEN GMBH GLP: yes Published: no	N	Y	New data for existing formulation, not previously submitted nor evaluated	UPL EU
KCP 10.3.1.2/01	Ruhland, S.	2018	CHRONIC TOXICITY OF COPPER 20% + CYMOXANIL 4% WG TO THE HONEY BEE APIS MELLIFERA L. UNDER LABORATORY CONDITIONS UPL Europe Ltd., 17 48 BAC 0058 BioChem Agrar, Gerichshain, Germany GLP: yes	N	Y	New data for existing formulation, not previously submitted nor evaluated	UPL EU

			Published: no				
KCP 10.3.1.2/02	Colli, M	2018a	Chronic oral effects of copper oxychloride 50% WP to adult worker honeybees *Apis mellifera* L., 10-day feeding laboratory test BT215/17 Biotechnologie BT srl, Italy GLP: Y Published: No	N	Y	New data for existing formulation, not previously submitted nor evaluated	UPL EU
KCP 10.3.1.3/01	Scheller, K.	2018a	COPPER 20% + CYMOXANIL 4% WG - REPEATED EXPOSURE OF HONEY BEE (APIS MELLIFERA L.) LARVAE UNDER LABORATORY CONDITIONS (IN VITRO) UPL Europe Ltd., 17 48 BLA 0003 BioChem Agrar, Gerichshain, Germany GLP: yes Published: no	N	Y	New data for existing formulation, not previously submitted nor evaluated	UPL EU
KCP 10.3.1.3/02	Scheller, K.	2018b	COPPER 20% + CYMOXANIL 4% WG- REPEATED EXPOSURE OF HONEY BEE (APIS MELLIFERA L.) LARVAE UNDER LABORATORY CONDITIONS (IN VITRO) UPL Europe Ltd., 17 48 BLC 0092 BioChem Agrar, Gerichshain, Germany GLP: yes Published: no	N	Y	New data for existing formulation, not previously submitted nor evaluated	UPL EU
KCP 10.3.1.3/01	Colli, M	2018b	Effects of copper oxychloride 50% WP to honeybees *Apis mellifera* L. Larval toxicity test, repeated exposure. BT216/17 Biotechnologie BT srl, Italy GLP: Y Published: No	N	Y	New data for existing formulation, not previously submitted nor evaluated	UPL EU
KCP 10.3.2.2/01	Fallowfield, L.	2011	ATOFEL02 (CUPROFIX C DISPERSS) - A RATE-RESPONSE EXTENDED LABORATORY BIOASSAY OF THE EFFECTS OF FRESH FOLIAR RESIDUES ON THE PREDATORY MITE, TYPHLODROMUS PYRI (ACARI: PHYTOSEIIDAE) United Phosphorus Ltd., UP-11-6 Mambo-Tox Ltd., Southampton, UK GLP: yes	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL EU

			Published: no				
KCP 10.3.2.2/02	Stevens, J.	2012	ATOFEL02 (CUPROFIX C DISPERSS) - A RATE-RESPONSE EXTENDED LABORATORY BIOASSAY OF THE EFFECTS OF FRESH RESIDUES ON THE PARASITIC WASP APHIDIUS RHOPALOSIPHI (HYMENOPTERA, BRACONIDAE) United Phosphorus Ltd., UP-11-5 Mambo-Tox Ltd., Southampton, UK GLP: yes Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL EU
KCP 10.3.2.2/03	Moll, M.	2018	FEL02 (COPPER 20% + CYMOXANIL 4% WG): EFFECTS ON THE LACEWING CHRYSOPERLA CARNEA, EXTENDED LABORATORY STUDY - DOSE RESPONSE TEST - UPL Europe Ltd., 130061047 IBACON GmbH, Rossdorf Germany GLP: yes Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL EU
KCP 10.3.2.2/04	Schmitzer, St.	2018	FEL02 (COPPER 20% + CYMOXANIL 4% WG): EFFECTS ON THE REPRODUCTION OF ROVE BEETLES ALEOCHARA BILINEATA - EXTENDED LABORATORY STUDY - - DOSE RESPONSE TEST - UPL Europe Ltd., 130061071 IBACON GmbH, Rossdorf, Germany GLP: yes Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL EU
KCP 10.4.1.1/01	McCormac, A.	2012	ATOFEL 02 (COPPER 200 G/KG CYMOXANIL 40 G/KG WG) - DETERMINATION OF CHRONIC (SUB-LETHAL) TOXICITY TO THE EARTHWORM EISENIA FETIDA IN AN ARTIFICIAL SOIL SUBSTRATE United Phosphorus Ltd., UP-11-8 Mambo-Tox Ltd., Southampton, UK GLP: yes Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL EU
KCP 10.4.1/01	Oorts K. and Peeters B.	2019	DISTRIBUTION OF RAC VALUES FOR EFFECT OF CU TO SOIL INVERTEBRATES IN EUROPE. ARCHE CONSULTING, BELGIUM. RESEARCH REPORT SUBMITTED TO THE EU-	N	N		EUCuTF(*)

			ROPEAN COPPER TASK FORCE. European Union 2,4-D Task Force 2012, not available not available GLP/GEP: no Published: no				
KCP 10.4.1/02	Oorts, K.	2015	ENVIRONMENTAL HAZARD ASSESSMENT OF CU IN SOIL - EFFECTS ON EARTHWORMS ARCHE (Assessing Risks of Chemicals), CuPPP20150701 not available GLP/GEP: no Published: no	N	N		EUCuTF(*)
KCP 10.4.1.1/02	Wagenhoff, E.	2019	LABORATORY STUDY ON THE SENSITIVITY OF FIELD-CAUGHT EARTHWORMS APORRECTODEA CALIGINOSA (ANNELIDA, LUMBRIDIDAE) TO COPPER IN GRASSLAND SOILS COLLECTED AT TWO FIELD SITES IN SOUTH-WESTERN GERMANY: A CROSSOVER EXPERIMENT EU Copper Task Force, S18-00119 Eurofins Agroscience Services EcoChem GmbH GLP: yes Published: no	N	Y	New data for active ingredient, not previously submitted nor evaluated	EUCuTF(*)
KCP 10.4.1.2/01	Klein, O.	2015	A FIELD STUDY TO EVALUATE THE EFFECTS OF COPPER ON THE EARTHWORM FAUNA IN CENTRAL EUROPE European Copper Task Force, Petit-Lancy, Switzerland, 20031343/G1-NFEw Eurofins Agroscience Services EcoChem GmbH GLP: yes Published: no	N	Y	New data for active ingredient, not previously submitted nor evaluated	EUCuTF(*)
KCP 10.4.1.2/02	Klein, O.	2019	ADDENDUM TO FINAL REPORT: A FIELD STUDY TO EVALUATE THE EFFECTS OF COPPER ON THE EARTH-WORM FAUNA IN CENTRAL EUROPE - STATISTICAL ANALYSIS OF A LONG-TERM EARTHWORM FIELD STUDY EU Copper Task Force, 20031343/G1-NFEw	N	Y	New data for active ingredient, not previously submitted nor evaluated	EUCuTF(*)

			Eurofins Agroscience Services EcoChem GmbH GLP: yes Published: no				
KCP 10.4.1.2/03	Amossé, J., Bart, S., Pery, A.R.R., Pelosi, C.	2018	SHORT-TERM EFFECTS OF TWO FUNGICIDES ON ENCHYTRAEID AND EARTHWORM COMMUNITIES UNDER FIELD CONDITIONS not available, not available Ecotoxicology, 27(3), pp. 300-312 GLP/GEP: no Published: yes	N	N		Public
KCP 10.4.1.2/04	Caetano, A., L., Ribeiro Marques, C., Goncalves, F., Ferreira da Silva, E., Pereira, R.	2015	COPPER TOXICITY IN A NATURAL REFERENCE SOIL: ECOTOXICOLOGICAL DATA FOR THE DERIVATION OF PRELIMINARY SOIL SCREENING VALUES not available, not available Ecotoxicology, 25(1), pp. 163-177 GLP/GEP: no Published: yes	N	N		Public
KCP 10.4.1.2/05	de Jong, F.M.W., van Beelen, P., Smit, C.E., Monforts, M.H.M.M.	2006	A GUIDANCE DOCUMENT OF THE DUTCH PLATFORM FOR THE ASSESSMENT OF HIGHER TIER STUDIES. GUIDANCE FOR SUMMARIZING EARTHWORM FIELD STUDIES. not available, not available National Institute for Public Health and the Environment, The Netherlands, RIVM 601506006/2006, p. 47 GLP/GEP: no Published: yes	N	N		Public
KCP 10.4.1.2/06	Bouché, M.B.	1977	STRATEGIES LOMBRICIENNES. SOIL ORGANISMS AS COMPONENTS OF ECOSYSTEMS not available, not available Ecological Bulletins, 25, pp. 122-132 GLP/GEP: no	N	N		Public

			Published: yes				
KCP 10.4.1.2/07	Jones, C. G., J. H. Lawton, and M. Shachak	1997	POSITIVE AND NEGATIVE EFFECTS OF ORGANISMS AS PHYSICAL ECOSYSTEM ENGINEERS. not available, not available Ecology, 78(7), pp. 1946-1957 GLP/GEP: no Published: yes	N	N		Public
KCP 10.4.1.2/08	Menezes-Oliveira, V. B., Scott-Fordsmand, J. J., Rocco, A., Soares, A., and Amorim, M. J.B.	2011	INTERACTION BETWEEN DENSITY AND CU TOXICITY FOR ENCHYTRAEUS CRYPTICUS AND EISENIA FETIDA REFLECTING FIELD SCENARIOS. not available, not available Science of The Total Environment, 409, pp. 3370-3374 GLP/GEP: no Published: yes	N	N		Public
KCP 10.4.1.2/09	Menezes-Oliveira, V. B., Scott-Fordsmand, J. J., Soares, A. MVM, and Amorim, M. J. B.	2013	EFFECTS OF TEMPERATURE AND COPPER POLLUTION ON SOIL COMMUNITY-EXTREME TEMPERATURE EVENTS CAN LEAD TO COMMUNITY EXTINCTION. not available, not available Environmental Toxicology and Chemistry, 32, pp. 2678-2685 GLP/GEP: no Published: yes	N	N		Public
KCP 10.4.1.2/10	Van Groenigen, J. W., I. M. Lubbers, H. M. J. Vos, G. G. Brown, G. B. De Deyn, van Groenigen, K. J.	2014	EARTHWORMS INCREASE PLANT PRODUCTION: A META-ANALYSIS. not available, DOI: 10.1038/srep06365 Scientific Reports, 4, p. 6365 GLP/GEP: no Published: yes	N	N		Public
KCP 10.4.2.1/01	Lührs, U.	2018a	FEL02 (COPPER 20% + CYMOXANIL 4% WG): EFFECTS ON REPRODUCTION OF THE PREDATORY MITE HYPOASPIS ACULEIFER IN ARTIFICIAL SOIL UPL Europe Ltd., 130061089	N	Y	New data for existing formulation, not previously submitted nor evaluated	UPL EU

			IBACON GmbH, Rossdorf Germany GLP: yes Published: no				
KCP 10.4.2.1/02	Lührs, U.	2018b	FEL02 (COPPER 20% + CYMOXANIL 4% WG): EFFECTS ON REPRODUCTION OF THE COLLEMBOLA FOLSOMIA CANDIDA IN ARTIFICIAL SOIL UPL Europe Ltd., 130061016 IBACON GmbH, Rossdorf, Germany GLP: yes Published: no	N	Y	New data for existing formulation, not previously submitted nor evaluated	UPL EU
KCP 10.5/01	McVean, K	2022c	Copper (from Bordeaux Mixture) 20 % + Cymoxanil 4 % WG Soil Micro-Organisms: Nitrogen Transformation Test UPL Europe Ltd., SO21797 NOACK LABORATORIEN GMBH GLP: yes Published: no	N	Y	New data for existing formulation, not previously submitted nor evaluated	UPL EU
KCP 10.6.2/01	Friedrich, S.	2012	TERRESTRIAL (NON-TARGET) PLANT TEST WITH CUPROFIX 30 DISPERSS NC: SEEDLING EMERGENCE AND SEEDLING GROWTH TEST United Phosphorus Ltd., 12 10 48 008 P BioChem Agrar, Gerichshain, Germany GLP: yes Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL EU
KCP 10.6.2/01	Hoare, A.	2015	TOXICITY OF COPPER TO PLANTS: A LITERATURE BASED ASSESSMENT OF THE RISKS TO NON-TARGET PLANTS FROM THE USE OF COPPER FUNGICIDES EU Copper Task Force, KL/14/002/01 not available GLP/GEP: no Published: no	N	N		EUCuTF(*)
KCP 10.6.2/02	McVean, K.	2022d	Copper (from Bordeaux Mixture) 20 % + Cymoxanil 4 % WG Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test SO21795	N	Y	New data for existing formulation, not previously submitted nor evaluated	UPL

			NOACK LABORATORIEN GMBH GLP: yes Published: no				
KCP 10.6.2/03	McVean, K.	2022e	Copper (from Bordeaux Mixture) 20 % + Cymoxanil 4 % WG Terrestrial Plant Test: Vegetative Vigour Test SO21796 NOACK LABORATORIEN GMBH GLP: yes Published: no	N	Y	New data for existing formulation, not previously submitted nor evaluated	UPL

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.1/01	Diepenhorst, P.C.	2000	VALIDATION OF DRAFT SOP DLA-060 COPPER COMPOUNDS DETERMINATION OF COPPER CONTENT IN FORMULATIONS UPL Europe Ltd., DL 99-065 Development Laboratory Elf Atochem Agri B.V., The Netherlands GLP: yes Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL EU
KCP 5.1.2	Sicbaldi, F.	2002a	ANALYTICAL METHOD VALIDATION FOR THE DETERMINATION OF COPPER IN/ON GRAPES AND THEIR PROCESSED FRACTIONS EU Copper Task Force, 00123 Isagro, Ricerca Srl GLP/GEP: no Published: no	N	N		EUCuTF
KCP 5.1.2	Sicbaldi, F.	2002b	ANALYTICAL METHOD VALIDATION FOR THE DETERMINATION OF COPPER IN/ON TOMATOES, THEIR PROCESSED FRACTIONS AND LEAVES EU Copper Task Force, 00119 Isagro, Ricerca Srl GLP/GEP: no Published: no	N	N		EUCuTF
KCP 5.1.2	Sicbaldi, F., Riccelli, S.	2010	METHOD VALIDATION FOR THE REDUCTION OF THE LIMIT OF QUANTIFICATION FOR COPPER IN REPRESENTATIVE MATRICES OF PLANT ORIGIN European Copper Task Force, Petit-Lancy, Switzerland, RA.09.23 Isagro, Ricerca Srl GLP/GEP: no Published: no	N	N		EUCuTF

KCP 5.1.2	Hansford, R.J.	2008a	MAGNITUDE OF RESIDUES OF COPPER IN FIELD MELONS (CUCURBITS-INEDIBLE PEEL) FOLLOWING APPLICATIONS OF METALLIC COPPER (AS COPPEROXYCHLORIDE)/CYMOXANIL (DPX-KK807) 44WP (9.5:1)-SOUTHERN EUROPE, SEASON 2007 EU Copper Task Force, DuPont-22565 Charles River Laboratories GLP: yes PUBLISHED: NO	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	EUCuTF
KCP 5.1.2	Hansford, R.J.	2008b	MAGNITUDE OF RESIDUES OF COPPER IN PROTECTED MELONS (CURCURBITS - INEDIBLE PEEL) FOLLOWING APPLICATIONS OF METALLIC COPPER (AS COPPER OXYCHLORIDE) / CYMOXANIL (DPX-KK807) 44WP (9.5:1) - SOUTHERN EUROPE, SEASON 2007 E.I. Du Pont de Nemours and Company, 691916, DuPont-22564 Charles River Laboratories GLP: yes PUBLISHED: NO	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	DPN
KCP 5.1.2	Foster, A.C.	2006	MAGNITUDE OF RESIDUES OF COPPER AND CYMOXANIL IN FIELD MELONS (FRUITING VEGETABLES) FOLLOWING APPLICATIONS OF METALLIC COPPER (AS COPPER OXYCHLORIDE) / CYMOXANIL (DPX-KK807) 44WG (9.5:1) UNDER MAXIMUM LABEL RATES - SOUTHERN EUROPE, SEASON 2005 E.I. Du Pont de Nemours and Company, 687805, DuPont-16970 Charles River Laboratories GLP: yes PUBLISHED: NO	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	
KCP 5.1.2	Foster, A.C., Kakkonen, J.E.	2006a	MAGNITUDE OF RESIDUES OF COPPER AND CYMOXANIL IN PROTECTED MELONS (FRUITING VEGETABLES) FOLLOWING APPLICATIONS OF METALLIC COPPER (AS COPPER OXYCHLORIDE)/CYMOXANIL (DPX-KK807) 44WG (9.5:1) UNDER MAXIMUM LABEL RATES - SOUTHERN EUROPE, 2004 E.I. Du Pont de Nemours and Company, 685331, DuPont-14536 Inveresk Research International, Tranent, Scotland GLP: yes	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	DPN

			PUBLISHED: NO				
KCP 5.1.2	Foster, A.C.	2006b	MAGNITUDE OF RESIDUES OF COPPER AND CYMOXANIL IN FIELD MELONS (FRUITING VEGETABLES) FOLLOWING APPLICATIONS OF METALLIC COPPER (AS COPPER OXYCHLORIDE)/CYMOXANIL (DPX-KK807) 44WG (9.5:1) UNDER MAXIMUM LABEL RATES - SOUTHERN EUROPE, 2004 E.I. Du Pont de Nemours and Company, 685326, DuPont-14542 Inveresk Research International, Tranent, Scotland GLP: yes PUBLISHED: NO	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	DPN
KCP 5.1.2	Goebel, O.	2008a	RESIDUE DETERMINATION OF COPPER IN MELON APTER 6 APPLICATIONS OF ATOFAP02 (COPPER - 20% - WG) OR ATOFAP17NC (COPPER - 40% - WG) Cerexagri, B_06RFLME01 eurofins-GAB GmbH, Niefern-Öschelbronn, Germany GLP: yes PUBLISHED: NO	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	CEX
KCP 5.1.2	Goebel, O.	2008b	RESIDUE DETERMINATION OF COPPER IN MELON AFTER 6 APPLICATIONS OF ATOFAP02 (WG 20%) OR ATOFAP17NC (WG 40%) Cerexagri, B_05RFLME01 eurofins-GAB GmbH, Niefern-Öschelbronn, Germany GLP: yes PUBLISHED: NO	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	CEX
KCP 5.1.2	Klein, O.	2015	A FIELD STUDY TO EVALUATE THE EFFECTS OF COPPER ON THE EARTHWORM FAUNA IN CENTRAL EUROPE European Copper Task Force, Petit-Lancy, Switzerland, 20031343/G1-NFEw Eurofins Agroscience Services EcoChem GmbH GLP: yes PUBLISHED: NO	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	ECTF

KCP 5.1.2	Blust, R., Steven Joosen, S.	2016	KINETICS AND SPECIATION OF COPPER IN COPPER BASED FUNGICIDE FORMULATIONS USED IN CROP PROTECTION (UPDATE FEBRUARY 2016) European Copper Task Force, Petit-Lancy, Switzerland, F-Cu 2016-2 Department of Biology, University of Antwerp, Belgium GLP/GEP: no PUBLISHED: NO	N	N		EUCuTF
KCP 5.1.2	Schafers, C.	2000	COMMUNITY LEVEL STUDY WITH COPPER HYDROXIDE 50% WP IN AQUATIC MICROCOSMS EU Copper Task Force, URA-001/4-50 Fraunhofer Institut für Umweltchemie und Ökotoxikologie, Schmallenberg-Grafschaft, Germany GLP/GEP: no PUBLISHED: NO	N	N		ECTF
KCP 5.1.2	Shouten, A.	2016	VALIDATION OF THE DETERMINATION OF 65CU IN RECEPTOR FLUID, STRIPPED SKIN, TAPE STRIPS, RECEPTOR/DONOR WASH SOLUTION AND SKIN WASH USED IN THE IN VITRO PERCUTANEOUS ABSORPTION TEST OF COPPER THROUGH HUMAN AND RAT SKIN, USING A DOUBLE-FOCUSING HIGH RESOLUTION INDUCTIVELY COUPLED PLASMA MASS SPECTROMETER (HR-ICP-MS) EU Copper Task Force, V20801 Triskelion B.V., Zeist, The Netherlands GLP/GEP: no PUBLISHED: NO	N	N		EUCuTF
KCP 5.1.2	Maas, W.J.M.	2016	IN VITRO DERMAL ABSORPTION OF COPPER (CU) FROM 8 FORMULATIONS THROUGH HUMAN SKIN European Copper Task Force, Petit-Lancy, Switzerland, V9062 + Amendment 01 TNO GLP/GEP: no PUBLISHED: NO	N	N		ECTF
KCP 5.2.	Sicbaldi, F.	2002a	ANALYTICAL METHOD VALIDATION FOR THE DETERMINATION OF COPPER IN/ON GRAPES AND THEIR PROCESSED FRACTIONS EU Copper Task Force, 00123 Isagro, Ricerca Srl	N	N		EUCuTF

			GLP/GEP: no PUBLISHED: NO				
KCP 5.2	Sicbaldi, F.	2002b	ANALYTICAL METHOD VALIDATION FOR THE DETERMINATION OF COPPER IN/ON TOMATOES, THEIR PROCESSED FRACTIONS AND LEAVES EU Copper Task Force, 00119 Isagro, Ricerca Srl GLP/GEP: no PUBLISHED: NO	N	N		EUCuTF
KCP 5.2	Sicbaldi, F., Riccelli, S.	2010	METHOD VALIDATION FOR THE REDUCTION OF THE LIMIT OF QUANTIFICATION FOR COPPER IN REPRESENTATIVE MATRICES OF PLANT ORIGIN European Copper Task Force, Petit-Lancy, Switzerland, RA.09.23 Isagro, Ricerca Srl GLP/GEP: no PUBLISHED: NO	N	N		EUCuTF
KCP 5.2	Riccelli, S.	2016	METHOD VALIDATION FOR THE REDUCTION OF THE LIMIT OF QUANTIFICATION FOR COPPER IN REPRESENTATIVE MATRICES OF PLANT ORIGIN. EU Copper Task Force, RA.16.08 Isagro, Ricerca Srl GLP: yes Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	EUCuTF
KCP 5.2	Kiefer, R.	2003	VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF BIOAVAILABLE COPPER IN SOIL SAMPLE. EU Copper Task Force, 20031084/02-UVX GAB Biotechn. GmbH & IFU Umweltanalytik GmbH, Germany GLP: yes Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	EUCuTF
KCP 5.2	Carey, D.O.	1989	METHOD VALIDATION REPORT FOR TERRESTRIAL OUTDOOR FIELD DISSIPATION STUDY WITH COPPER CONTAINING PESTICIDES EU Copper Task Force, 88-003 Biospherics Inc., Rockville, MD, USA GLP: yes Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	EUCuTF
KCP 5.2	Kiefer, R.	2004	VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF TOTAL COPPER IN SOIL SAMPLES EU Copper Task Force, 20031084/01-UVX	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	EUCuTF

			GAB Biotechn. GmbH & IFU Umweltanalytik GmbH, Germany GLP: yes Published: no				
KCP 5.2	Heintze, A.	2001	ASSESSMENT OF SIDE EFFECTS OF URA-13900-F-0-WP ON THE LARVAE OF THE MIDGE, CHIRONOMOUS RIPARIUS WITH THE LABORATORY TEST METHOD. EU Copper Task Force, 99520/01-ASCr GAB Biotech GLP: yes Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	EUCuTF
KCP 5.2	Heintze, A.	2000	ASSESSMENT OF SIDE EFFECTS OF URA-08740-F-O-WP ON THE LARVAE OF THE MIDGE, CHIRONOMUS RIPARIUS WITH THE LABORATORY TEST METHOD EU Copper Task Force, 99507/01-ASCr GAB Biotechnologie GmbH, Niefern-Öschelbronn, Germany GLP: yes Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	EUCuTF
KCP 5.2	Anonymous	1991	GERMAN STANDARD METHODS FOR THE EXAMINATION OF WATER, WASTE WATER AND SLUDGE; CATIONS (GROUP E); DETERMINATION OF COPPER BY ATOMIC ABSORPTION SPECTROMETRY (AAS) (E 7) EU Copper Task Force, DIN 38406 Part 7 not available GLP/GEP: no Published: no	N	N	Not protected	EUCuTF
KCP 5.2	Pardo Martinez, M.	2016	VALIDATION OF THE ANALYTICAL METHOD FOR THE DETERMINATION OF COPPER RESIDUES IN SURFACE WATE EU Copper Task Force, CH - 157/2016 not available GLP: yes Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	EUCuTF
KCP 5.2	Anonymous	1999	DETERMINATION OF SUSPENDED MATTER IN AMBIENT AIR. MEASUREMENT OF THE CONCENTRATION BY MASS OF AS, BE, CD, CO, CR, CU, MN, NI, PB, SB, TL, ZN BY ATOMIC ABSORPTION SPECTROMETRY (AAS) AFTER SAMPLING ON FILTERS AND DIGESTION IN AN OXIDISING ACID MIXTURE. EUCuTF, VDI 2267, Part 1, Air Pollution,the Automobile and Public Health GLP/GEP: no Published: yes	N	N	Not protected	EUCuTF

KCP 5.2	Anonymous	1997	DETERMINATION OF SUSPENDED MATTER IN AMBIENT AIR. DETERMINATION OF THE MASS CONCENTRATION OF BE, CD, CO, CR, CU, FE, MN, NI, PB, SB, V, ZN BY OPTICAL EMISSION SPECTROMETRY (ICPOES) AFTER SAMPLING ON FILTERS AND DIGESTION IN AN OXIDISING AGENT. EUCuTF, VDI 2267, Part 5, not available GLP/GEP: no Published: no	N	N	Not protected	EUCuTF
KCP 5.2	Himmelstein, M.W.	2003	FIVE COPPER SUBSTANCES: ABSORPTION, DISTRIBUTION, AND EXCRETION IN MALE RATS. EU Copper Task Force, 11784 E.I. du Pont de Nemours GLP: yes Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	EUCuTF
KCP 5.2	Wolf, S.	2009a	INDEPENDENT LABORATORY VALIDATION (ILV) OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF CYMOXANIL IN GRAPES (RAC BUNCHES) AND POTATOES (RAC TUBERS) UPL Europe Ltd., C34136 Harlan Laboratories Ltd. GLP: yes Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL EU
KCP 5.2	Faessel, V.	2009a	VALIDATION OF THE ANALYTICAL METHOD FOR THE DETERMINATION OF CYMOXANIL RESIDUES IN WATER AND SOIL PART 1: WATER UPL EUROPE LTD., R A9161-1 ANADIAG, FRANCE GLP: YES Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL EU
KCP 5.2	Faessel, V.	2009b	VALIDATION OF THE ANALYTICAL METHOD FOR THE DETERMINATION OF CYMOXANIL RESIDUES IN WATER AND SOIL, PART 2: SOIL UPL EUROPE LTD., R A9161-2 ANADIAG, FRANCE GLP: YES Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL EU
KCP 5.2	Senciuc, M.	2009	DEVELOPMENT AND VALIDATION OF ANALYTICAL METHOD(S) FOR THE DETERMINATION OF CYMOXANIL METABOLITES (IN-U3204, IN-KQ960, INT4226 AND IN-W3595) IN WATER UPL Europe Ltd., P/B 1683 G	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL EU

			PTRL Europe, Ulm, Germany GLP: yes Published: no				
KCP 5.2	Wolf, S.	2009b	DEVELOPMENT AND VALIDATION OF A RESIDUE ANALYTICAL METHOD FOR CYMOXANIL IN AIR UPL Europe Ltd., C34147 Harlan Laboratories Ltd. GLP: yes Published: no	N	Y	Study may have already been submitted for national authorisation, but data protection may still be active	UPL EU
KCA 6.1/01	Nathan E.C.	1996	Magnitude of residues of Cymoxanil in potatoes following application of Curzate M-8 fungicide at maximum label rates and at five times maximum use rates to investigate the need for magnitude of residue data in processed fractions. Report number: AMR 3296-95 Morse Laboratories Inc. GLP: Yes Published: No	N	N		E. I. du Pont de Nemours & Co., Inc.
KCA 6.2.1/01	Li Y. and Hausmann	1996	Plant Metabolism of [2-^{14}C]Cymoxanil in Potatoes Report number: AMR 3408-95 E. I. du Pont de Nemours & Co., Inc. GLP: Yes Published: No	N	N		E. I. du Pont de Nemours & Co., Inc.
KCA 6.2.1/02	Melkebeke T., van Noorloos B.	2003	METABOLISM, DISTRIBUTION, AND EXPRESSION OF CYMOXANIL RESIDUES IN POTATOES Report number: 257772 NOTOX GLP: Yes Published: No	N	N		OXON Italia SpA
KCA 6.2.1/03	Belasco, I. J., et al	1981	Metabolism of [^{14}C] Cymoxanil in Grapes, Potatoes and Tomatoes Report number: Pestic. Sci. 1981, 12, 355-364 E. I. du Pont de Nemours & Co., Inc. GLP: No Published: Yes	N	N		N/A (Published Literature)
KCA 6.2.3/01	[redacted]	1996	The Distribution of [2-^{14}C] DPX-T3217 (Cymoxanil) in the Lactating Goat (Nature of Residue Study to EPA Guidelines) Report number: AMR 2084-91 E. I. du Pont de Nemours & Co., Inc. GLP: Yes Published: No	N	N		E. I. du Pont de Nemours & Co., Inc.
KCA 6.6.1/01	Koch Singles A., Strek H. J. &	1996	Accumulation of Residues in Confined Rotational Crops: Lettuce, Wheat, and Beets After Treatment with [^{14}C]Cymoxanil	N	N		E. I. du Pont de Nemours &

	Sheftic G. D.		Report number: AMR 3575-95 E. I. du Pont de Nemours & Co., Inc. GLP: Yes Published: No				Co., Inc.
KCP 7.1.1/02	McEwan, M.R. Donald, E.	1999a	ATO FDH01 – ACUTE ORAL TOXICITY (LIMIT) TEST IN RATS 16786 Inveresk Research Institute, Tranent, Scotland, United Kingdom GLP, Unpublished	Y	Y		UPL EU
KCP 7.1.2/02	McEwan, M.R. Donald, E.	1999b	ATO FDH01 – ACUTE DERMAL TOXICITY (LIMIT) TEST IN RATS 16634 Inveresk Research Institute, Tranent, Scotland, United Kingdom GLP, Unpublished	Y	Y		UPL EU

CP 7.1.4/02	McEwan, M.R. Donald, E.	1999c	ATO FDH01 – ACUTE DERMAL IRRITATION TEST IN RABBITS 16603 Inveresk Research Institute, Tranent, Scotland, United Kingdom GLP, Unpublished	Y	Y		UPL EU
KCP 7.1.5/02	McEwan, M.R. Donald, E.	1999d	ATO FDH01 – ACUTE EYE IRRITATION TEST IN RABBITS 16726 Inveresk Research Institute, Tranent, Scotland, United Kingdom GLP, Unpublished	Y	Y		UPL EU
KCP 7.1.6/02	Edgar, F. Donald, E.	1999	ATO FDH01 – MAGNUSSON-KLIGMAN MAXIMISATION TEST IN GUINEA PIGS 16734 Inveresk Research Institute, Tranent, Scotland, United Kingdom GLP, Unpublished	Y	Y		UPL EU
KCP 7.3/01	Maas, W.J.M., Brufau Donés, G.	2016a	*IN VITRO* PERCUTANEOUS ABSORPTION OF COPPER, FORMULATED AS COPPER HYDROXIDE (DPX-GFJ52) 53.8WG (35% AS METALLIC COPPER), THROUGH HUMAN SKIN Report number DuPont-42821 Triskelion B.V., Zeist, The Netherlands GLP Unpublished	N	Y		EU Copper Task Force(*)
KCP 7.3/02	Maas, W.J.M., Brufau Donés, G.	2016b	*IN VITRO* PERCUTANEOUS ABSORPTION OF COPPER, FORMULATED AS COPPER HYDROXIDE (DPX-GFJ52) 53.8WG (35% AS METALLIC COPPER), THROUGH RAT SKIN Triskelion B.V., Zeist, The Netherlands Report number DuPont-42649 GLP Unpublished	N	Y		EU Copper Task Force(*)
KCP 7.3/03	Maas, W.J.M., Bogaards, J.J.P., de Bie, A.Th.	2016	*IN VIVO* PERCUTANEOUS ABSORPTION OF COPPER, FORMULATED AS COPPER HYDROXIDE (DPX-GFJ52) 53.8WG (35% AS METALLIC COPPER), IN RATS Report number DuPont-42648 Triskelion B.V., Zeist, The Netherlands GLP Unpublished	N	Y		EU Copper Task Force(*)
KCP 7.3/04	Maas, W.J.M.	2020a	THE FATE OF TEST ITEM RESIDUES IN THE SKIN MEMBRANES *IN VITRO* DERMAL ABSORPTION STUDIES; IMPACT ON THE RISK ASSESSMENT OF INORGANIC COPPER SALTS Report number Not applicable Charles River Loboratories Den Bosch, Hertogenbosch, The Netherlands	N	N		EU Copper Task Force(*)

			No GLP Unpublished				

KCP 7.4.1/01	Mescalchin E., B. Agabiti, D. Bertoldi, R. Larcher, M. Gobber, A. Guerra and R. Zanzotti,	2013	CHECKING THE DISTRIBUTION QUALITY OF AGROCHEMICALS IN THE VINEYARD THROUGH THE USE OF FIELD MONITORING 1st IW on Vineyard Mechanization & Grape & Wine Quality, S. Poni, Acta Hort. 978, ISHS SATA – Studio agronomico, Italy Not stated, Yes	N	N		Public
KCP 9.2/01	Blust, R., Steven Joosen, S.	2016	KINETICS AND SPECIATION OF COPPER IN COPPER BASED FUNGICIDE FORMULATIONS USED IN CROP PROTECTION European Copper Task Force, Petit-Lancy, Switzerland, F-Cu 2016-2 Department of Biology, University of Antwerp, Belgium GLP/GEP: no Published: no	N	N		EUCuTF
KCP 9.2/02	Ma, H., Kim, S.D., Cha, D.K., Allen, H.E.	1999	EFFECT OF KINETICS OF COMPLEXATION BY HUMIC ACID ON TOXICITY OF COPPER TO CERIODAPHNIA DUBIA not available, not applicable Environmental Toxicology and Chemistry, 18(5), 828-837 GLP/GEP: no Published: yes	N	N		EUCuTF
KCP 9.2.5/01	Blust, R., Steven Joosen, S.	2016	KINETICS AND SPECIATION OF COPPER IN COPPER BASED FUNGICIDE FORMULATIONS USED IN CROP PROTECTION European Copper Task Force, Petit-Lancy, Switzerland, F-Cu 2016-2 Department of Biology, University of Antwerp, Belgium GLP/GEP: no Published: no **Submitted in: KCP 9.2/01**	N	N		EUCuTF
KCP 9.2.5/02	Ma, H., Kim, S.D., Cha, D.K., Allen, H.E.	1999	EFFECT OF KINETICS OF COMPLEXATION BY HUMIC ACID ON TOXICITY OF COPPER TO CERIODAPHNIA DUBIA	N	N		EUCuTF

			not available, not applicable Environmental Toxicology and Chemistry, 18(5), 828-837 GLP/GEP: no Published: yes **Submitted in: KCP 9.2/02**				

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	**Author(s)**	**Year**	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Verte-brate study** **Y/N**	**Data pro-tection claimed** **Y/N**	**Justification if data protection is claimed**	**Owner**
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authori-zation>	Owner

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

Data point	**Author(s)**	**Year**	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Verte-brate study** **Y/N**	**Data pro-tection claimed** **Y/N**	**Justification if data protection is claimed**	**Owner**
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authori-zation>	Owner