

REGISTRATION REPORT

Part A

Risk Management

Product code: **Nordox 75 WG**

Chemical active substance(s):

Copper (I) oxide (Cu₂O), 750 g/kg

NATIONAL ASSESSMENT

Poland

(Authorization in accordance to Art. 43)

Applicant: Nordox AS

Submission date: 31/01/2022

Evaluation date: December 2022

MS Finalisation date: Marzec 2023

Revision date: June 2023

Version history

When	What
31/01/2022	Original version from the applicant Nordox AS for Art. 43 submission. All new data and information are marked in yellow.
12/2022	Version evaluated by PL zRMS
03/2023	Version amended by PL zRMS after comments. No significant changes.
06/2023	Version amended by PL zRMS after additional comments. New mitigation measures were proposed.

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Submission and Evaluation of Copper compounds under Art.43 of 1107/2009

General observation: Deviation from standard Guidance Documents and EFSA conclusion is necessary and unavoidable for Copper.

The RMS and EFSA are held to assess plant protection products according to the existing methodology described in a series of guidance documents (GDs). Those have been developed for synthetic, organic molecules, and are in most cases not applicable to minerals and Copper. This has led to an EFSA conclusion that indicated a number of critical concerns, or assessments that could not be finalized, which do not reflect any realistic risk, but rather illustrate the inappropriateness of the current GDs for the assessment of Copper. This can easily be seen in a number of endpoints that suggest a high risk exists at concentrations below natural background of this essential micronutrient. **This has been recognized by EFSA, the RMS and several MS (see comments from DE and IT in the Peer review Report), and the EU Commission has mandated EFSA with the development with a Copper specific guidance (Mandate No. 2019-0036).**

Art.43 submissions and their evaluation by MS are unfortunately due before this GD will be available. The current EFSA conclusion and list of endpoints could at best be considered as a first tier, and applicants as well as MS are required to deviate from the standard procedures described in the GD for the following reasons:

- The current GD do not consider bio-availability; for an essential, ubiquitous micronutrient that is a metal it is indispensable to provide assessment methodologies that consider the bioavailability and the potentially toxic fraction in each real-world exposure scenario. Total concentrations do not result in any meaningful outcome.
- Data normalisation to enable comparison of toxicological lab and field data as well as data obtained with different bioavailable fractions is a pre-requisite to allow a realistic assessment of potential risk. Simplistic worst-case scenarios will always indicate a high risk already at naturally occurring concentrations.
- For a homeostatically tight controlled essential element the application of assessment factors is meaningless. The question whether an excess exposure or deficiency leads to an adverse disruption of the homeostatic control cannot be approached in this way. Further, the exceptional data richness of the Copper dossier and more than 100 years of experience with the use as fungicide make safety factors unnecessary.

These unique features of Copper are already considered in the assessment of Copper under separate legislation (REACH, BPD). While COM directed EFSA in their mandate to take advantage of those methodologies, TF members have to anticipate their use and in their proposed assessments of the critical areas of concern identified in the EFSA conclusion. This should be reviewed once the new GD is available and no use should be cancelled until then.

Submission and Evaluation of Copper compounds under Art.43 of 1107/2009

General observation: Copper compounds should not be considered as Candidate for Substitution (CfS).

The implementing Regulation (EU) 2018/1981 is renewing the approval of the active substance Copper compounds as candidate for substitution (CfS), in accordance with Regulation (EC) 1107/2009. Whereas (12) considers that Copper compounds are persistent and toxic in accordance with points 3.7.2.1 and 3.7.2.3 of Annex II to Regulation (EC) 1107/2009 (PBT assessment), and fulfil the condition set in the second indent of point 4 of Annex II to Regulation (EC) 1107/2009.

The EUCuTF disagrees with the approval as CfS. The conditions in Annex to Regulation (EC) 1107/2009 lack the exemption of inorganic compounds like Copper minerals from the PBT assessment as it has been established under other chemical legislations like REACH and BPD. As laid down in those legislations, the term persistence is meaningless for an element or mineral, due to its natural occurrence. Persistence per se is therefore not a relevant parameter and consequently a PBT assessment is not carried out for inorganic compounds under REACH and BPD. The recent mandate from COM to EFSA directs the development of a guidance towards methods and procedures available under those legislations better adapted for the assessment of inorganic compounds, where the relevant parameter is their bioavailability. This should include an exempt statement regarding the PBT assessment to harmonize the assessment of the same compounds under different legislations.

It should be noted that persistence of minerals is considered not relevant for being categorized as low-risk active substance according to Regulation (EU) 2017/1432. This is clearly not compatible with the same parameter leading to a classification as CfS under the same Regulation (EC) 1107/2009.

The EUCuTF is of the opinion that Copper compounds should not be considered CfS, and have lodged an action for annulment against Regulation (EU) 2018/1981 and renewing the approval of the active substance Copper compounds as candidate for substitution (case number T-153/19 European Union Task Force v. European Commission).

PART A

RISK MANAGEMENT

This document describes the acceptable use conditions required for the registration of Nordox 75 WG containing the active substance Copper (I) oxide in Poland.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-10 and Part C. The information, data and assessments provided in Registration Report, Part B includes assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to Nordox 75 WG where that data has not been considered in the EU review. Otherwise assessments for the safe use of Nordox 75 WG have been made using endpoints agreed in the EU review of Copper (EFSA Journal 2018;16(1):5152).

1 Details of the application

1.1 Application background

This application was submitted by Nordox AS.

The application was for approval of Nordox 75 WG, an WG formulation type (Water dispersible granule) containing 750 g/kg Copper (I) oxide for use as a fungicide and bactericide.

1.2 Letters of Access

The Copper Task Force, grants the right to refer to the Copper Annex II data package to the applicant.

For efficacy trials a letter of access is available from Certis Europe B.V. and Masso S.A.

For the Letter of Access, please refer to Appendix 3.

1.3 Justification for submission of tests and studies

All tests and studies were prepared and submitted in support of the assessment as required according to 284/2013 EU.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

2 Details of the authorization decision

2.1 Product identity

Product code	Nordox 75 WG
Product name in MS	Nordox 75 WG
Authorization number	R-173/2015
Function	Fungicide and bactericide
Applicant	Nordox AS
Active substance(s) (incl. content)	750 g/kg Copper (I) oxide
Formulation type	Water dispersible granule [Code: WG]
Packaging	Paper lined multi-layer sacks for 1 10, 25 kg bags
Co-formulants of concern for national authorizations	--
Restrictions related to identity	--
Mandatory tank mixtures	--
Recommended tank mixtures	--

2.2 Conclusion

The evaluation of the application for Nordox 75 WG resulted in the decision to grant the authorization for the intended **field uses: apples, pears, quinces, cucumber, courgettes, grapes, strawberries, shallots, onion, and garlic** consistently with the GAP table (2.6) - section 7.

2.3 Substances of concern for national monitoring

Not relevant.

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:

Pictograms: GHS09

Signal word: Warning

Hazard statement: H400 - Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements: P273 - Avoid release to the environment.

P391 - Collect spillage.

P501 - Dispose of contents/container to a hazardous or special waste collection point

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

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

Please refer to point 2.4.1.

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

Not relevant.

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:	
--	--
Worker protection:	
Orchards (use 1,2):	Work wear
Vine (use 3):	Work wear
Strawberry (use 4):	None
Fruiting vegetables (use 5, 8, 9):	None
Bulb vegetables (use 6):	None
Leaf vegetables (lettuce, scarole/ use 7):	None
Ornamentals (use 10):	Work wear
Integrated pest management (IPM)/sustainable use:	
--	--
Environmental protection	
Aquatic	20 m spray drift buffer zone + 90 % runoff mitigation
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
Other specific restrictions	
--	Max. 28 kg a.s./ha in 7 years Max. 5 kg a.s./ha from February -October (bird breeding season)

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

Integrated pest management (IPM)/sustainable use:	
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2.5.2 Specific restrictions linked to the intended uses

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

Integrated pest management (IPM)/sustainable use:	Relevant
--	-----------------

			for use no.
Respective code if available	--		--
Environmental protection:			Relevant for use no.
Non-target plants - apple	10 m buffer strip without drift reduction or 50 % drift reduction		1
Non-target plants - pear, quince	5 m buffer strip without drift reduction or 50 % drift reduction		2
Arable fields	5 m NSS + 20 m VFS	5 m NSS + 90% DRT + 20 m VFS 10 m NSS + 75% DRT + 20 m VFS 30 m NSS + 20 m VFS	5 – 9
Vineyards “Vines, late applications”	5 m NSS + 90% DRT + 20 m VFS 10 m + 50% DRT + 20 m VFS 20 m NSS + 20 m VFS	20 m NSS + 90% DRT + 20 m VFS 30 m NSS + 75% DRT + 20 m VFS 40 m NSS + 50% DRT + 20 m VFS 60 m NSS + 20 m VFS	3
Vineyards “Vines, early applications”	5 m + 50% DRT + 20 m VFS 10 m NSS + 20 m VFS	10 m NSS + 75% DRT + 20 m VFS 20 m NSS + 50% DRT + 20 m VFS 30 m NSS + 20 m VFS	3
Pome fruit “Early applications”	20 m NSS + 90% DRT + 20 m VFS 30 m + 50% DRT + 20 m VFS 40 m NSS + 20 m VFS	40 m NSS + 90% DRT + 20 m VFS 60 m NSS + 75% DRT + 20 m VFS 70 m NSS + 50% DRT + 20 m VFS 90 m NSS + 20 m VFS	1
Pome fruit “Late applications”	10 m NSS + 90% DRT + 20 m VFS 20 m + 50% DRT + 20 m VFS 30 m NSS + 20 m VFS	30 m NSS + 90% DRT + 20 m VFS 40 m NSS + 75% DRT + 20 m VFS 60 m NSS + 50% DRT + 20 m VFS 90 m NSS + 20 m VFS	2
Ornamentals h < 50 cm	5 m NSS + 20 m VFS	5 m NSS + 90% DRT + 20 m VFS 10 m NSS + 75% DRT + 20 m VFS 30 m NSS	10
Ornamentals h > 50 cm	20 m NSS + 90% DRT + 20 m VFS 30 m + 50% DRT + 20 m VFS 40 m NSS + 20 m VFS	40 m NSS + 90% DRT + 20 m VFS 60 m NSS + 75% DRT + 20 m VFS 70 m NSS + 50% DRT + 20 m VFS 90 m NSS + 20 m VFS	10

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code): Nordox 75 WG
Active substance 1: Copper (I) oxide
Safener: safener
Synergist: synergist
Applicant: Nordox AS
Zone(s): Southern
Verified by MS: yes

GAP rev. 01, date:
Formulation type: WG
Conc. of as 1: 750 ^(c)
Conc. of safener: conc. ^(c)
Conc. of synergist: conc. ^(c)
Professional use:
Non professional use:

Field of use: Fungicide and bactericide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. ^(e)	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. safener/synergist per ha ^(f)
					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.i./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL	Apple	F	<i>Venturia inaequalis</i>	Foliar spray	BBCH 03- BBCH 53	a) 2 b) 2	14	a) 1.0 b) 2.0	a) 0.75 b) 1.50	500-750	144	
2	PL	Pear, quince	F	<i>Venturia pyrina</i> <i>Venturia inaequalis</i> Bacteriosis: <i>Pseudomonas syringae</i> <i>Ervinia amylovora</i> <i>Nectria galligena</i>	Foliar spay	From the beginning of dormancy period (autumn) - BBCH99 and before BBCH 54(spring)	a) 2 b) 2	14	a) 1.67 b) 3.34	a) 1.25 b) 2.50	500-1000	144	

3	PL	Vine	F	<i>Plasmopara viticola</i>	Foliar spray	BBCH 15- BBCH 81 & BBCH 91	a) 2 b) 2	7	a) 1.60 b) 3.20	a) 1.20 b) 2.40	200-400	21	
4	PL	Strawberry	F/G	<i>Marssonina fragariae</i> , <i>Zythia fragariae</i> <i>Mycosphaerella</i> , bacterial disease, <i>Colletotrichum sp.</i>	Foliar spray	BBCH 13 - BBCH 85	a) 3 b) 3	7	a) 1.33 b) 3.99	a) 1.0 b) 3.0	200 - 800	3	
5	PL	Tomato Eggplant Pepper	F/G	<i>Phytophthora spp.</i> , <i>Alternaria</i> , <i>Colletotrichum</i> , <i>Bacterial dis-</i> <i>ease (Pseudomonas spp., Xan-</i> <i>thomonas spp.)</i>	Foliar spray	BBCH 15 - BBCH 51	a) 3 b) 3	7	a) 1.33 b) 3.99	a) 1.0 b) 3.0	200-1000	10	
6	PL	Shallots Onion Garlic	F	<i>Alternaria</i> , <i>Antracnosis</i> , <i>Bacterial disease</i> , <i>Peronospora</i> <i>destructor</i> , <i>Stemphyllum</i>	Foliar spray	BBCH 14 - BBCH 47	a) 3 b) 3	7	a) 1.33 b) 3.99	a) 1.0 b) 3.0	200-1000	3	
7	PL	Lettuce Scarole	F/G	<i>Alternaria</i> , <i>Bremia lactucae</i> <i>Bacterial disease</i> : <i>Erwinia spp.</i> , <i>Pseudomonas spp.</i> , <i>Xanthomonas spp.</i>	Foliar spray	BBCH12- BBCH49	a) 3 b) 3	7	a) 1.33 b) 3.99	a) 1.0 b) 3.0	300-1000	3	
8	PL	Cucumber	F/ G	<i>Alternaria</i> , <i>Antracnosis</i> , <i>Phytophthora spp.</i> ,	Foliar spray	BBCH 15 - BBCH 89	a) 3 b) 3	7	a) 1.33 b) 3.99	a) 1.0 b) 3.0	200-1000	3	
9	PL	Pumpkin, Courgettes Melon	F	<i>Alternaria</i> , <i>Antracnosis</i> , <i>Phytophthora spp.</i> ,	Foliar spray	BBCH 15 - BBCH 89	a) 3 b) 3	7	a) 1.33 b) 3.99	a) 1.0 b) 3.0	200-1000	3	

10	PL	Ornamental plants	F	<i>Alternaria</i> , <i>Antracnosis</i> , <i>Phytophthora spp.</i> ,	Foliar spray	Spring - until the beginning of flowering	a) 3 b) 3	7	a) 1.33 b) 3.99	a) 1.0 b) 3.0	200-1000	-	
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Remarks table heading:

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

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

Remarks columns:

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

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

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	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
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	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	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	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.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high-volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipment (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	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)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a red-brown free flowing granule free from foreign matter with a vanilla odour. It is not explosive and has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 234 °C. In aqueous solution, it has a pH value around 7.1 at 21°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 content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in aluminium laminate sachets. Its technical characteristics are acceptable for a Water dispersible granule (WG) formulation.

Nature and characteristics of the packaging: Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

3.2 Efficacy (Part B, Section 3)

The present Part A is submitted in the framework of the authorization in accordance to Art. 43 with no GAP changes. For the efficacy please refer to the original registration.

3.3 Efficacy data

The dossier has been submitted to support the renewal of NORDOX 75WG in Poland (PL) which belongs to the North-East Eppo Climatic Zone and Hungary (HU) and Slovenia (SI) which belongs to the South-East Eppo Climatic Zone, according to Art. 43 of Regulation (EC) No. 1107/2009, following the renewal of Copper compounds (Copper oxide) as active substances under Regulation (EC) No. 1107/2009.

This core assessment concerns the renewal of authorization of the uses of the protectant fungicide/bactericide, which is currently authorized under product names NORDOX 75WG in Poland (PL) which belongs to the North-East Eppo Climatic Zone and Hungary (HU) and Slovenia (SI) which belongs to the South-East Eppo Climatic Zone. NORDOX 75WG is formulated as a Wettable Granule (WG) and contains 86.2% of copper oxide i.e 750 g/kg of copper (as metal). The product is currently authorised for use as protectant fungicide/bactericide which prevents infection on plants, being active against a broad spectrum of plant pathogenic fungi.

The basis for renewal is an unchanged product (the formulation of the product remains the same) and an unchanged GAP and national label. The applicant provided a statement that this is the case for all CMS's. However, only an in-depth check has been performed for the PL uses in the GAP and the Polish label. Based on this check zRMS confirms that the PL-GAP has remained unchanged indeed. For all other CMS, it is left up to check and confirm if the submitted GAP and national label have remained unchanged indeed. In the case the GAP of an individual CMS has been changed, it is left up to the particular CMS to confirm zRMS conclusions on a national level.

The evaluation for renewal focuses on the resistance section. For evaluation of efficacy, reference can be made to evaluation and experience with the product in the past. Therefore efficacy does not need to be evaluated again. If no resistance has developed, it can be expected that the efficacy of the product is unchanged.

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

3.3.2 Adverse effects on treated crops

3.3.3 Observations on other undesirable or unintended side-effects

3.4 Methods of analysis (Part B, Section 5)

Analytical methods for determination of Copper, impurities and relevance of CIPAC methods in Nordox 75 WG were evaluated in Part B, Section 5.

3.4.1 Analytical method for the formulation

CIPAC methods are available for the determination of total Copper in formulations:

- CIPAC method 44/WP/M/ (Copper in wettable powder formulation)
- CIPAC method 44/DP/M/ (Copper in dustable powder formulation)

3.4.2 Analytical methods for residues

All information and validation data were provided in the EU review of Copper compounds and were considered adequate.

3.5 Mammalian toxicology (Part B, Section 6)

3.5.1 Acute toxicity

The acute toxicity tests were performed on Nordox 75 WG, one of the representative formulations in the EU review of Copper compounds. The acute toxicity studies for Nordox 75 WG were evaluated during the review and were considered adequate.

Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for Nordox 75 WG

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat	3165 mg/kg bw	Yes	None	xxx (2000)

(OECD 401)				EU agreed dRAR, Vol.3, B6 (2016)
LD ₅₀ dermal, rat (OECD 402)	> 2000 mg/kg bw	Yes	None	xxx (2000) EU agreed dRAR, Vol.3, B6 (2016)
LC ₅₀ inhalation, rat (OECD 403)	> 5 mg/L air	Yes	None	xxx (2000) EU agreed dRAR, Vol.3, B6 (2016)
Skin irritation, rabbit (OECD 404)	Non-irritant	Yes	None	xxx (2000) EU agreed dRAR, Vol.3, B6 (2016)
Eye irritation, rabbits (US EPA equivalent to EC method B5)	Non-irritant	Yes	None	xxx (1999) EU agreed dRAR, Vol.3, B6 (2016)
Skin sensitisation, guinea pig (OECD 406, M&K)	Non-sensitising	Yes	None	xxx (2000) EU agreed dRAR, Vol.3, B6 (2016)
Supplementary studies for combinations of plant protection products	No data – not required			

3.5.2 Operator exposure

For Copper, an AOEL of 0.08 mg/kg bw/d was set.

An AAOEL was not allocated during the peer review for the renewal of approval of Copper. Therefore, estimates of the acute exposure to operators has not been conducted.

The proposed dermal absorption rates for Copper of 0.1 % for the concentrate and 1.0 % for the dilution are based on dermal absorption studies on a formulation containing Copper hydroxide. It has already been established during the EU peer review that, given the nature of the active sub-stance (Cu²⁺), dermal penetration factors for both concentrate and in-use spray dilutions from these studies are justifiably relevant to all forms of Copper (oxide, hydroxide, oxychloride, tribasic sulphate and Bordeaux Mixture) and all formulation types (WP, WG, and SC).

The risk assessment was performed with the EFSA AOEM model according to the Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874.

The risks posed to operators from the application of Nordox 75 WG are considered to be acceptable.

Implications for the labelling: None.

zRMS:

Dermal absorption of copper (as copper (I) oxide) from a product Nordox 75 WG determined in this registration report according to the Triple pack' approach based on acceptable studies and interpreted in line with current EU guidelines to be used for risk assessment are: 0.1% for the concentrate and 1% for the

dilution. This approach is considered valid for determination of dermal absorption in case of this application of Nordox 75 WG therefore these endpoints are used for exposure estimation

Taking into account dermal absorption 0.1% for concentrate and 1% for dilution the potential exposure to copper (as copper (I) oxide), estimated with EFSA AOEM model, of operator applying Nordox 75 WG in vehicle-mounted sprayer on pome fruits at application rate of 1.25 kg a.s./ha, upward spraying, on grapes at application rate of 1.20 kg a.s./ha, upward spraying, on strawberry, leaf, bulb and fruiting vegetables at rate 1.0 kg a.s./ha, downward spraying and on ornamentals at application rate 1.0 kg a.s./ha, upward spraying are all below AOEL, thus these applications do not cause unacceptable risk for operator not wearing any PPE.

In case the higher dermal absorption of 1% from concentrate and 9% from the dilution (9%) is assumed then the exposure of operator is below AOEL for all these applications foreseen in GAP when operator is wearing work wear covering arms, body and legs during mixing/loading and application and protective gloves during mixing/loading.

3.5.3 Worker exposure

The risk assessment was performed with the EFSA AOEM model according to the Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874.

The risks posed to workers re-entering areas treated with Nordox 75 WG are considered to be acceptable providing normal work-wear is worn.

Implications for the labelling:

<u>Pome fruit (use 1,2)</u>	Work wear
<u>Vine (use 3):</u>	Work wear
<u>Strawberry (use 4):</u>	None
<u>Fruiting vegetables (use 5, 8, 9):</u>	None
<u>Bulb vegetables (use 6):</u>	None
<u>Leaf vegetables (use 7):</u>	None
<u>Ornamentals (use 8):</u>	Work wear

zRMS:

Taking into account the dermal absorption 0.1% for concentrate and 1% for dilution the exposure of worker wearing work wear covering arms, body and legs estimated with EFSA AOEM model to copper (as copper (I) oxide), who enters for 8 hour for various tasks a field of all crops foreseen in GAP to be treated with Nordox 75 WG (pome fruits at application rate of 1.25 kg a.s./ha, grapes at application rate of 1.20 kg a.s./ha, strawberry, leaf, bulb and fruiting vegetables at rate 1.0 kg a.s./ha and ornamentals at application rate 1.0 kg a.s./ha) are all below AOEL, thus these applications do not cause unacceptable risk for worker wearing appropriate work wear.

In case the higher dermal absorption of 1% from concentrate and 9% from the dilution (9%) is assumed then the exposure of worker, estimated with EFSA AOEM model, to copper (as copper (I) oxide) is only below AOEL when worker is wearing a work wear covering arms, body and legs and protective gloves and is entering a fields of low berries, fruiting vegetables, bulb vegetables and leaf vegetables, treated with Nordox 75 WG at application rate 3 x 1.0 kg a.s./ha. The exposure of worker wearing a work wear covering arms, body and legs and protective gloves and entering for 8 hours a field of pome fruits treated with Nordox WG 75 at application rate of 2 x 1.25 kg a.s./ha, or vineyards treated at a rate of 2 x 1.20 kg a.s./ha or ornamentals treated at a rate 3 x 1.0 kg a.s./ha is above the AOEL, thus it is not acceptable.

3.5.4 Bystander and resident exposure

The risk assessment was performed with the EFSA AOEM model according to the Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874.

The risks posed to bystander and residents treated with Nordox 75 WG are considered to be acceptable.

Implications for the labelling: None.

zRMS:

Taking into account the dermal absorption 0.1% for concentrate and 1% for dilution, the exposure of child and adult residents to copper (as copper (I) oxide), which was estimated with EFSA AOEM model, due to application of a product Nordox WG 75 according to GAP on pome fruits at application rate of 1.25 kg a.s./ha, on grapes at application rate of 1.20 kg a.s./ha, on strawberry and leaf, bulb and fruiting vegetables at rate 1.0 kg a.s./ha, and on ornamentals at application rate 1.0 kg a.s./ha are all well below AOEL, thus these applications do not cause unacceptable risk for child and adult residents

In case the higher dermal absorption of 1% from concentrate and 9% from the dilution (9%) is assumed then the exposure of child and adult residents to copper (as copper (I) oxide), which was estimated with EFSA AOEM model, due to application of a product Nordox WG 75 according to GAP on pome fruits at application rate of 1.25 kg a.s./ha, on grapes at application rate of 1.20 kg a.s./ha, on strawberry and leaf, bulb and fruiting vegetables at rate 1.0 kg a.s./ha, and on ornamentals at application rate 1.0 kg a.s./ha are all below AOEL, thus these applications do not cause unacceptable risk for child and adult residents

No bystander acute exposure estimation for Nordox WG 75 is required since no acute acceptable operator exposure value (AAOEL) has been set for copper (as copper (I) oxide), an active substance of Nordox WG 75. Therefore, as indicated in the EU guidance (SANTE-10832-2015 rev. 1.7; 24 January 2017), no unacceptable risk is expected for bystanders due to short-term single exposure to copper as a result of application of Nordox WG 75 with accordance with intended use within good agricultural practice.

Summing up application of a product Nordox WG 75 in line with GAP does not pose an unacceptable health risk for residents and bystanders.

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

The existing relevant residue data for extrapolation of cucumber and courgettes are unprotected as submitted in EU in 2011 on the renewal and available then in the RAR (see Kreke, N. (2009, 2010). For pome fruits is enough submitted NEU data for permissible extrapolation. For grapes, strawberries, shallots, onion, and garlic the residue data are consistent with the requirements. Thus, the approval for these uses can be granted.

For tomatoes (eggplants) (DAR 2007) and peppers are not enough NEU data for registration. For field lettuce, scarole, pumpkin and melon no NEU data at all.

An exceedance of the current MRLs of Copper as laid down in Reg. (EU) 396/2005 for the intended uses for which the approval can be done is not expected.

The data available are considered sufficient for risk assessment.

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

As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended **field uses: apples, pears, quinces, cucumber, courgettes, grapes, strawberries, shallots, onion, and garlic.**

Ornamentals are not the subject of the evaluation. The use is accepted.

According to available data, no specific mitigation measures should apply. No data gaps are noticed.

3.6.1 Residues

Since Copper does not degrade in plants and since transportation and distribution of Copper in plants following application as a plant protection product is limited compared to the Copper already present in the plant arising from uptake from the soil, specific studies to evaluate the metabolism, distribution and expression of the residue in plants following application as a plant protection product have not been conducted and are not required. The critical issue is the magnitude of residues of Copper in the edible portions of grapes following applications of Copper as a plant protection product.

The metabolism of Copper in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.

Since Copper is known to be inherently stable and cannot degrade into any other material and since the analytical techniques measure total Copper content irrespective of form, studies to measure the effects of industrial processing or household preparation on the nature of the residue are not required.

Copper is an element and will not be metabolized. The chemical fate of Copper in mammals is well documented and no new information will be produced by conducting metabolism studies in livestock, consequently none have been conducted.

Studies on the magnitude of residues in plants has been submitted and are partly already EU evaluated. New pre-flowering studies for cherry, walnut and olive have been submitted in the framework of this application.

According to the available data, the intended uses are considered acceptable. However, not for every crop a whole data set for the southern zone is available and for some crops the calculated MRLs exceed their current MRLs.

Only the uses compliant with the relevant MRLs can be approved.

Crop	Sufficient residue trials?	MRL compliance
Pome fruits (apples, pear, quince) – Pre-flowering	Yes (7x NEU & 12x SEU on apple, plum, cherry, pear)	Yes
Grapes	Yes (15x table grapes (N/SEU), 15x wine grapes (N/SEU))	No** Yes
Strawberry	Yes (8x Indoor, 8x NEU)	No** Yes
Bulb vegetables (onion garlic, shallots)	Yes* (8x NEU)	Yes
Tomato, eggplants	Yes* (4 indoor, 9x NEU)	No**
Pepper	Yes (4x NEU 8x SEU)	No**
Cucurbits edible peel (cucumber)	Yes (8 x SEU & 8 x indoor)	Yes
Cucurbits inedible peel (melon, pumpkin)	Yes (8x EUS + 6 indoor)	No**
Lettuce and similar	Yes* (7x lettuce (SEU)+8x indoor)	No*

*Because of identical GAPs and comparable results for indoor, north and south trials overall calculations and conclusion were done and used for consumer risk assessments.

**During the EFSA MRL review (Art. 12, EFSA 2018) new tentative MRLs were proposed. All calculated MRLs are below the new tentative proposed MRLs by EFSA, except potatoes.

For pepper, Lettuce, cucubits (edible & inedible peel), trials are missing for a complete northern data set.

3.6.2 Consumer exposure

Copper is used as feed additive for all livestock species. Therefore, dietary burden calculations were performed.

But it can be concluded that the livestock dietary burden calculation based on the method in Animal Burden Calculation according to OECD 505 is not suitable for the risk assessment of a micronutrient like Copper. Nevertheless, the use of Copper as a plant protection product can be considered acceptable.

The TMDI estimates for the various diets were found 93 – 6 % of ADI (Tier II). The highest TMDI was calculated for the “NL Toddler”. For this diet, maize and wheat were the highest contributors to the residue intake, representing 11 % of ADI for both. It should be noted that the biggest contributors (cereal) are not supported uses for Copper compounds.

The NESTI was not calculated as no ARfD was set.

TMDI (% ADI) according to EFSA PRIMo	93 % (NL Toddler Diet)
IEDI (% ADI) according to EFSA PRIMo	Not calculated, not necessary
NEDI (% ADI)**	--
IESTI (% ARfD) according to EFSA PRIMo*	Not calculated
NESTI (% ARfD) **	--

* include raw and processed commodities if both values are required for PRIMo

** if national model is available

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

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

Concentrations of Nordox 75 WG in various environmental compartments are predicted following the proposed use pattern. The predicted environmental concentrations (PEC values) in soil, surface water, sediment groundwater and air are provided. The long-term concentrations are based on results obtained for the active substance contained in the formulation.

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

PEC_{soil} values were calculated for the active substance Copper following a single season’s application according to FOCUS and considering a soil depth of 5 cm. For Copper, the estimation of PEC_{soil} has assumed that there is no crop interception.

The resulting PEC_{soil} values were added to the natural background concentrations reported from the LUCAS data.

Details are given in Part B, core assessment, Section 8, chapter 8.7.

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

The PEC_{gw} calculations are performed for the FOCUS crop scenario pome fruit, vine and tomato with the respective yearly application rate. It should be noted that the FOCUS modelling is not designed or validated to predict the behaviour of metals in the environment, and thus is not suitable for Copper predictions and was only carried out for completeness.

The results of the PEC_{gw} calculations, based on these worst-case assumptions, lead to PEC_{gw} values $< 0.001 \mu\text{g/L}$. No unacceptable contamination is to be expected.

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

The applicant would like to reiterate that FOCUS modelling is not designed or validated to predict the behaviour of metals in the environment, and thus is not suitable for Copper predictions and was only carried out for completeness. The applicant would like to request that more suitable assessment protocols are used for minerals such as Copper.

However, standard FOCUS Step 1 and 2 PEC_{sw} values as described below were calculated:

A) Via spray drift / runoff / drainage – without mitigation

FOCUS Step 1 and 2 PEC_{sw} values (FOCUS Steps 1 and 2, version 3.2) were calculated considering all entry routes to water bodies with an interception of 0 % (no cover crop) selected as a worst-case scenario.

B) Via runoff / drainage only – with runoff mitigation

FOCUS Step 1 and 2 values were firstly calculated with the no spray drift option to derive the PEC from runoff and drainage only. As these results showed that mitigation measures were required the FOCUS landscape mitigation document (FOCUS 2007) states that the maximum possible reductions in exposure via runoff should not exceed 90 % (e.g. 20 m vegetated buffer) a percentage of 90 % run-off mitigation was therefore carried out.

C) Via spray drift only – with spray drift mitigation

FOCUS Step 1 and 2 values were then calculated using the no drainage and runoff option with spray drift values for a single application. These values were then factored down based on different spray drift mitigation values taken for different distances from the FOCUS spray drift calculator (version 1.1) in the SWASH shell, not going beyond 95 % mitigation [$PEC_{Step 2} / (\% \text{ drift for Step 2} / \% \text{ drift for the buffer})$]. These values were then added to the values estimated from the runoff and drainage calculation. These results were based on the highest acceptable mitigation for all entry routes to water bodies (95% limit on spray drift mitigation and 90 % limit on runoff mitigation). These values were then added to the values estimated from the runoff and drainage calculation in FOCUS Step 2.

The applicants would like to point out that on page 15 of the EFSA conclusion that they are pleased to see that EFSA recognises that due to the very rapid dissipation of Copper (Cu^{2+} ions) from surface waters to

sediment, *it was considered that the single application scenario represents the worst-case for the exposure assessment.* As a result of this statement the notifier would like the PEC surface water modelling results for multiple applications from Appendix A (LoEP) to be considered as irrelevant, as they ignore any dissipation from the water phase.

As described above, the spray drift scenario starts with a non-equilibrium phase during which total Copper dissipates with a DT_{50} of < 1 day (Blust and Joosen 2016). Any free Copper ions also dissipate with < 1 day (Ma 2008). The system will reach an equilibrium stage within ca. 24 hours, and the resulting dissolved copper concentration will be a function of the water chemistry (pH, DOC, hardness, etc.).

Therefore, a DT_{50} of < 1 day is appropriate and the single application scenario shall be presented as the worst-case scenario in Art.43 evaluations.

Under the spray drift scenario, the particulate, barely water-soluble Copper compound that hits the surface water will start dissolving while complexation to DOC and sedimentation remove copper from the dissolved fraction. The results from the Blust and Joosen 2016 study (CP-9.2.3/01) have demonstrated that in a realistic water/sediment scenario the total Copper declines very rapidly in the water phase while dissolved Copper was at least a factor of 10 lower. This study describes best the speciation and kinetic behaviour of Copper in an aquatic environment following a spray drift event. Despite, the EUCuTF has proposed a more conservative total/dissolved value of 3 for use in the risk assessment, based on the measurements in the mesocosm study.

The EFSA evaluation used a total/dissolved ratio of 1, which suggests that all Copper is dissolved. This is against all observations in the monitoring studies and studies from the dossier cited above. The Art.43 evaluation should apply a total to dissolved copper ratio of at least 3.

~~The notifier would like to reiterate that all interested parties had previously agreed that the FOCUS models are not appropriate for predicting the behaviour of metals such as copper. In the FOCUS models substance sorption to soil or sediment is described solely by interaction with organic material and thus are not suitable to predict the behaviour of Copper reaching surface water bodies from run-off and drainage. The adsorption properties of the Cu^{2+} ion is not limited to organic carbon binding and other significant processes occur, many of which are effectively irreversible. Many of the Copper species formed are only sparingly soluble. Furthermore, important binding processes for the Cu^{2+} ion, such as adsorption to clay and mineral oxides can occur in soil and sediment. The IDMM model has been considered by EFSA in the authorisation process for use of manure containing Copper. If MS continue to refuse evaluating this model and reject it an appropriate model should be recommended to the applicants for their Art.43 submissions.~~

Details are given in Part B Section 8, chapter 8.9.

The results for PEC_{sw} and PEC_{sed} for the active substance were used for the eco-toxicological risk assessment.

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

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.

3.8 Ecotoxicology (Part B, Section 9)

A full risk assessment according to Uniform Principles for the plant protection product Nordox 75 WG in its intended uses is documented in detail in the core assessment.

3.8.1 Effects on terrestrial vertebrates

The risk assessment for birds and other terrestrial vertebrates for the application of Nordox 75 WG is based on the latest Guidance of EFSA on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12):1438). The first tier acute and long-term risk assessment to birds and mammals indicated a potential risk. A weight of evidence paper was submitted as part of the renewal of approval and the conclusion is that the long-term risks to birds and mammals were acceptable for application rates of up to 5 kg Cu/ha (EFSA, 2018). Since the form of Copper applied does not affect overall risks this conclusion is relevant to Nordox 75 WG.

3.8.2 Effects on aquatic species

The BLM-normalised SSD-RAC_{sw,ch} value of 7.9 µg/L for fish is significantly higher than the aquatic invertebrate and algae ETO-RAC_{sw,ch} of 4.8 µg/L thereby confirming that fish are not the most sensitive species. The ETO-RAC_{sw,ch} of 4.8 µg/L is therefore considered by the applicants as sufficiently protective of all aquatic organisms and hence is used as the critical endpoint for the aquatic risk assessment for all aquatic organisms. Looking on the monitoring data and natural Copper contents in surface water, this seems to be a sufficiently conservative value, still significantly lower as those derived under REACH and BPR.

During the review of the renewal of approval of Copper the EUCuTF made the claim that the standard models used to predict the PEC of Copper in surface water are not relevant to metals such as Copper. The Commission has agreed with this premise and in their Renewal Report (SAN-TE/10506/2018) called for more relevant models to be developed.

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the “Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009”, as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

The calculations demonstrate that no significant risk to aquatic organisms can be discerned for the intended GAP uses of Nordox 75 WG when applying the following mitigation measurements depending on crops:

Crop	Mitigation-measures	
	Non-sprayed-buffe	Vegetated-buffe
Arable fields “Planting vegetables”	5-m NSS	20-m VPS
Vineyards “Vines, late applications”	5-m NSS +90% DRT 10-m +50% DRT 20-m NSS	20-m VPS
Vineyards “Vines, early applications”	5-m +50% DRT 10-m NSS	20-m VPS
Pome fruit “Early applications”	20-m NSS +90% DRT 30-m +50% DRT 10-m NSS	20-m VPS

Pome fruit "Late applications"	10 m NSS +90% DRT 20 m NSS +50% DRT 30 m NSS	20 m VFS
Ornamentals h < 50 cm	5 m NSS	20 m VFS
Ornamentals h > 50 cm	20 m NSS +90% DRT 30 m NSS +50% DRT 40 m NSS	20 m VFS

Crop	Mitigation measures	
	Non- sprayed buffer	Vegetated buffer
Arable fields "Fruiting vegetables"	5 m NSS + 90% DRT 10 m NSS +75% DRT 30 m NSS	20 m VFS
Vineyards "Vines, early applications"	10 m NSS +75% DRT 20 m NSS +50% DRT 30 m NSS	20 m VFS
Vineyards "Vines, late applications"	20 m NSS +90% DRT 30 m NSS +75% DRT 40 m NSS +50% DRT 60 m NSS	20 m VFS
Pome fruit "Early applications"	40 m NSS +90% DRT 60 m NSS +75% DRT 70 m NSS +50% DRT 90 m NSS	20 m VFS
Pome fruit "Late applications"	30 m NSS +90% DRT 40 m NSS +75% DRT 60 m NSS +50% DRT 90 m NSS	20 m VFS
Ornamentals h < 50 cm	5 m NSS + +90% DRT 10 m NSS + +75% DRT 30 m NSS	20 m VFS
Ornamentals h > 50 cm	40 m NSS +90% DRT 60 m NSS +75% DRT 70 m NSS +50% DRT 90 m NSS	20 m VFS

20 m spray drift buffer zone combined with 90 % runoff mitigation

3.8.3 Effects on bees

The evaluation of the risk for bees was performed in accordance with the new Bee Guidance Document EFSA (2013). The refined risk assessment of the effects of Copper oxide indicates no unacceptable risk to bees after exposure to Nordox 75 WG. No risk mitigation measures are required.

3.8.4 Effects on other arthropod species other than bees

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

First tier risk assessment demonstrated a low in-field and off-field risk for non-target arthropods other than bees when the product is applied according to GAP.

3.8.5 Effects on soil organisms

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002). For non-target soil meso- and macrofauna a higher tier risk assessment was presented, demonstrating an acceptable risk for application rates of up to 8 kg Cu/ha/year. Thus, there is no unacceptable risk for non-target soil meso- and macrofauna after exposure to Nordox 75 WG when applied according to GAP. Additionally, based on laboratory and field data it was concluded that an annual application of 3.00 kg Cu/ha, in the form of Nordox 75 WG is not expected to cause adverse effects on soil microbial function and so the risks following the proposed use of Nordox 75 WG are acceptable.

3.8.6 Effects on non-target terrestrial plants

The evaluation of the risk is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002).

There is no unacceptable risk for non-target terrestrial plants after exposure to Nordox 75 WG, when applying the following mitigation measurements:

Crop	Use no.	Mitigation measurement
Apple	1	10 m buffer strip without drift reduction or 50 % drift reduction
Pear, quince	2	5 m buffer strip without drift reduction or 50 % drift reduction
Vine	3	None
Vegetable, ornamentals, small fruits < 50 cm	4, 6, 7, 10	None
Vegetable, ornamentals > 50 cm	5, 8, 9, 10	None

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Not relevant.

3.9 Relevance of metabolites (Part B, Section 10)

An estimation of the concentration of metabolites in groundwater is not required because, as an element, Copper cannot be transformed into metabolites or degradation products.

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

Not relevant.

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

Not relevant.

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

The product label will be provided separately by the applicant.

Appendix 3 Letter of Access

Studies owned by the Copper Task Force

xxx

Efficacy trials owned by Certis

xxx

Efficacy trials owned by Masso

xxx

Appendix 4 Lists of data considered for national authorization

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.10/03	Brereton, R.	2003	Copper: Residue levels in pome fruit from trials conducted in France, Spain and Italy during 2001/2002 Company Report No: AF/6150/CU Agrisearch UK GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EuCu Task Force
KCA 6.3.10/04	Brereton, R.	2004	Copper: Residue levels in pome fruit from trials conducted in the UK, France and Germany du ring 2001 /2002 Company Report No: AF-6151-CU Agrisearch UK GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EuCu Task Force
KCA 6.3.11/08	Grall, E.	2011	Bordoflow New, Copper oxychloride 50 WP (SU), Copper hydroxide 25% DF, Nordox 75 WG, Cuproxat flüssig, Bordeaux Mixture 20% WG, Copper Oxychloride 37.5 NC WG, CA2111 (CHAMP DP), ATOFAP17: Determination of residues of Copper in stone fruit (RAC fruit) following three treatments with different Copper formulations under open field conditions in northern and southern Europe in 2010 Company Report No: C48222 Harlan Laboratories Ltd., Itingen, Switzerland GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EuCu Task Force

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.11/09	North, L.	2021	Determination of residues of copper after one application of copper in cherry (outdoor) at 1 site in Southern Europe 2020 Company Report No: S20-01045 Eurofins AgroScience, Germany GLP Unpublished <i>Also submitted under KCP 5.1.2/02</i>	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nordox AS
KCA 6.3.12/01	Grall, E.	2011	Nordox 75 WG , Copper Oxychloride 37.5 NC WG, Flowbrix SC, Copper hydroxide 40% WG, Copper hydroxide 25% DF, Bordoflow New Determination of residues of Copper in strawberry (RAC fruit) following four treatments with different Copper formulations under open field conditions in northern and southern Europe in 2009 Company Report No: C48301 Harlan Laboratories Ltd., Itingen, Switzerland GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EuCu Task Force
KCA 6.3.12/02	Grall, E.	2011	Flowbrix SC (Copper oxychloride SC), Copper hydroxide 40% WG, Bordeaux Mixture RSR Disperss, Nordox 75 WG, Copper Oxychloride 50% WP, Copper oxychloride 50 WP (SU), Cuproxat flüssig, Copper hydroxide 25% DF: Determination of residues of Copper in strawberry (RAC fruit) following four treatments with different Copper formulations under open field conditions in northern and southern Europe in 2010 Company Report No: C91308 Harlan Laboratories Ltd., Itingen, Switzerland GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EuCu Task Force

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.18/01	Kreke, N.	2011	Nordox 75 WG, Bordeaux Mixture 20 NC WG, Funguran-OH 50 WP. Determination of residues of Copper in onion (RAC bulb) following four treatments with different Copper formulations under open field conditions in northern Europe in 2010 Company Report No: C91073 Harlan Laboratories Ltd. Itingen, Switzerland GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EuCu Task Force
KCA 6.3.18/02	Kreke, N.	2011	Bordeaux Mixture 20 NC WG, Nordox 75 WG, Copper oxychloride 37.5 NC WG, COC 35 DF, CA2111 (Champ DP), Copper oxychloride 50 WP (SU), Funguran-OH 50 WP, ATOFAP17, Bordeaux Mixture 20% WG, Flowbrix SC (Copper oxychloride SC). Determination of residues of Copper in onion (RAC bulb) following four treatments with different Copper formulations under open field conditions in northern and southern Europe in 2009 Company Report No: C48110 Harlan Laboratories Ltd. Itingen, Switzerland GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EuCu Task Force
KCA 6.3.19/01	Kreke, N.	2011	Bordeaux Mixture 20 NC WG, Flowbrix SC (Copper oxychloride SC), Funguran-OH 50 WP, Nordox 75 WG, Cuproxat flüssig, Bordeaux Mixture RSR Disperss, Copper Oxychloride 50% WP, Copper hydroxide 25% DF Determination of residues of Copper in peppers (RAC fruit) following four treatments with different Copper formulations under open field conditions in northern and southern Europe in 2009 Company Report No: C48108 Harlan Laboratories Ltd. Itingen, Switzerland GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EuCu Task Force

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KCA 6.3.19/02	Kreke, N.	2011	Copper oxychloride 50 WP (SU), CA2112 (CHAMP FLO), Flowbrix SC (Copper oxychloride SC), Bordoflow New, ATOFAP17: Determination of residues of Copper in peppers (RAC fruit) following four treatments with different Copper formulations under open field conditions in northern and southern Europe in 2010 Company Report No: C91062 Harlan Laboratories Ltd. Itingen, Switzerland GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EuCu Task Force
KCA 6.3.21/01	Kreke, N.	2011	ATOFAP17, CA2112 (CHAMP FLO), Copper oxychloride 50 WP (SU), Bordoflow New Determination of residues of Copper in lettuce (RAC whole plant without roots) following four treatments with different Copper formulations under open field conditions in southern Europe in 2009 Company Report No: C48064 Harlan Laboratories Ltd. Itingen, Switzerland GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EuCu Task Force
KCA 6.3.21/02	Kreke, N.	2012	Bordeaux Mixture 20 NC WG, Copper hydroxide 25% DF, Flowbrix SC (Copper oxychloride SC), Copper hydroxide 40% WG; Determination of residues of Copper in lettuce (RAC whole plant without roots) following four treatments with different Copper formulations under open field conditions in southern Europe in 2010 Company Report No: C91040 Harlan Laboratories Ltd. Itingen, Switzerland GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EuCu Task Force

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.21/03	Sicbaldi, F.	2005	Copper residue levels on lettuce (open field) after four applications of copper oxychloride 37.5 WG. A decline study in Northern Italy in 2005 Company Report No: RA.05.14 GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EuCu Task Force
KCA 6.3.21/04	Sicbaldi, F.	2005	Copper residue levels on lettuce (open field) after four applications of copper oxychloride 37.5 WG. A decline study in Southern Italy in 2005 Company Report No: RA.05.15 GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EuCu Task Force

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 1.2/01	Mercedes, P. M.	2021	CONFIDENTIAL INFORMATION please refer to Part C				
KCP 1.2/02	Mercedes, P. M.	2021	CONFIDENTIAL INFORMATION please refer to Part C				
KCP 1.4.2/01	Anonymous	2018	Safety Data Sheet. Nordox 75 WG Version 1.0 Revision 05.10.2018 No GLP, published	N	N	--	--
KCP 1.4.3/01-03			CONFIDENTIAL INFORMATION please refer to Part C				
KCP 2.3.3/01	Baker, D.	2003	Regulatory testing on a sample of Cuprous Oxide Technical Report No. 14603 revision 1 GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nordox AS
KCP 2.7.1/01	Seaman, G. D.	2012	Physical and Chemical Properties of Nordox 75 WG: Storage Stability for up to 2 weeks at 54°C. Report No. XN/12/001/1 GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nordox AS
KCP 2.7.5/01	Seaman, G. D.	2014	Physical and Chemical Properties of Nordox 75 WG: Storage Stability for up to 104 weeks at 20°C. Report No. XN/12/001/2 GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nordox AS
KCP 5.1.1/01	Pardo Martinez, M.	2021	Nordox Agro Grade: Validation of the Analytical Method for the Determination of the Copper Active Ingredient Content Company Report No.: 0093/2021 ChemService S.r.l. Controlli e Ricerche, Italy GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nordox AS

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 5.1.1/02	Pardo Martinez, M.	2021	Nordox Agro Grade: Validation of the Analytical Method for the Determination of the Sulphate and Chloride Significant Impurities Content Company Report No.: 0094/2021 ChemService S.r.l. Controlli e Ricerche, Italy GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nordox AS
KCP 5.1.1/03	Pardo Martinez, M.	2021	Nordox Agro Grade: Validation of the Analytical Method for the Determination of the Metallic Impurities Content (Arsenic, Cadmium, Lead, Nickel, Chromium, Cobalt, Antimony and Mercury) Company Report No.: 0095/2021 ChemService S.r.l. Controlli e Ricerche, Italy GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nordox AS
KCP 5.1.2/01 <i>Submitted under KCA 6.3.9/03</i>	North, L.	2020	Determination of residues of copper after one application of copper in walnuts (outdoor) at 2 sites in Southern Europe 2019 Company Report No.: S19-03752 Eurofins AgroScience Service, Germany GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nordox AS
KCP 5.1.2/02 <i>Submitted under KCA 6.3.11/09</i>	North, L.	2021	Determination of residues of copper after one application of copper in cherry (outdoor) at 1 site in Southern Europe 2020 Company Report No: S20-01045 Eurofins AgroScience, Germany GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nordox AS

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KCP 5.1.2/03 Submitted under KCA 6.3.14/07	North, L.	2020	Determination of residues of copper after three applications of copper in olive (outdoor) at 4 sites in Southern Europe 2019 Company Report No: S19-03751 Eurofins AgroScience, Germany GLP Unpublished	N		Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	Nordox AS
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 Company Report No RA.17.02 Isagro – Centro di Saggio BPL GLP Published	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF
KCP 5.2/02	Pardo Martinez M.	2018	Validation of the Analytical Method for the determination of Copper residues in Air Company Report No: CH-657/2017 ChemService GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF
KCP 7.3/01	xxx	2016	<i>In vitro</i> percutaneous absorption of copper, formulated as Copper Hydroxide (DPX-GFJ52) 53.8WG (35% as metallic copper), through human skin Du-Pont-42821 xxx, The Netherlands GLP: Y Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF

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 7.3/02	xxx	2016	<i>In vitro</i> percutaneous absorption of copper, formulated as Copper Hydroxide (DPX-GFJ52) 53.8WG (35% as metallic copper), through rat skin Du-Pont-42649 xxx, The Netherlands GLP: Y Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF
KCP 7.3/03	xxx	2016	<i>In vivo</i> percutaneous absorption of copper, formulated as Copper Hydroxide (DPX-GFJ52) 53.8WG (35% as metallic copper), in rats Du-Pont-42648 xxx, The Netherlands GLP: Y Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF
KCP 7.3/04	xxx	2020	The fate of test item residues in the skin membranes in <i>in vitro</i> dermal absorption studies; impact on the risk assessment of inorganic copper salts n.a. xxx GLP: N Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF
KCP 9.2.4/01	Demetriades, A. et al	2012	Title European Ground Water Geochemistry Using Bottled Water as a Sampling Medium Company Report No Source Clean Soil and Safe Water Non GLP Published	N	N	--	Literature Paper

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KCP 9.2.5/01	Axmann, S	2015	Title A field study to determine copper residues in stream sediments Company Report No S17-04438 Source N/A GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF
KCP 9.2.5/02	Lofts, S	2015	Title Prediction of soil, surface water and sediment concentrations of copper resulting from use of fungicide copper in agricultural catchments Company Report No NEC05505/1 Source N/A GLP Unpublished	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF
KCP 10.2/01	Van Sprang, P.	2019	Response to EFSA comments on the aquatic effects assessment for Cu—extension GLP: N Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF
KCP 10.2/02	Oorts, K. and Verdonck, F.	2019	Relevance of Standard Assessment Factors for Risk Assessment of the Essential Element Copper CuPPP20170705 GLP: N Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF
KCP 10.2/03	Janssen, S.D., Viaene, K., Van Sprang, P., Deschamphelaere, K.	2019	Modelling of the Funguran-OH Effects on <i>Onchorhynchus mykiss</i> Populations GLP: N Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	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 GLP: N Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.1.2/01	Colli, M.	2018	Chronic oral effects of Copper oxychloride 50% WP to adult worker honeybees <i>Apis mellifera</i> L., 10-day feeding laboratory test BT215/17 Biotechnologie BT srl, Italy GLP: Y Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF
KCP 10.3.1.2/02	Colli, M.	2017	Effects of Copper oxychloride 50% WP to honeybees <i>Apis mellifera</i> L. Larval toxicity test, repeated exposure. BT216/17 Biotechnologie BT srl, Italy GLP: Y Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF
KCP-10.4/01	Wagenhoff, E.	2018	Laboratory Study on the Sensitivity of Field-Caught Earthworms <i>Aporrectodea caliginosa</i> (Annelida: Lumbricidae) to Copper in Grassland Soils Collected at five Field Sites in South-Western Germany: a Crossover Experiment Report no.: S18-00419 GLP: N Published: No	Y	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF
KCP-10.4/02	Klein, O.	2010	Addendum to Final Report: A Field Study to Evaluate the Effects of Copper on the Earthworm Fauna in Central Europe: Statistical Analysis of a long-term earthworm field study 20031343/G4-NPEW Eurofins Agroscience Services Ecotox GmbH, Niefern-Öschelbronn, Germany GLP: N Published: No	Y	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.4/03	Arsoese et al.	2013	Short-term effects of two fungicides on enchytraeid and earthworm communities under field conditions. Ecotoxicology GLP: N Published: Yes. DOI https://doi.org/10.1007/s10646-013-1895-7	Y	Y		Literature Paper
KCP 10.4/04	Exelans et al.	2013	Copper toxicity in a natural reference soil - ecotoxicological data for the derivation of preliminary soil screening values. Ecotoxicology GLP: N Published: Yes. DOI https://doi.org/10.1007/s10646-013-1577-7	Y	Y		Literature Paper
KCP 10.4/05	Oorts K. and Peeters B.	2019	Distribution of RAC values for effect of Cu to soil invertebrates in Eu-rope. ARCHE Consulting, Belgium. Research report submitted to the European Copper Task Force. GLP: N Published: No	N	Y	Article 59(1) & (2) of Regulation (EC) 1107/2009 applies	EUCuTF