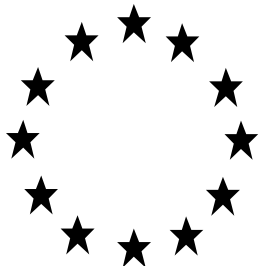
Regulation (EU) n°528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



Cu-HDO
Bis (*N*-cyclohexyl-diazenium-dioxy)-copper
Product-type 8
(wood preservatives)

13 December 2013

Austria

Bis (*N*-cyclohexyl-diazenium-dioxy)-copper (PT 8)
Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on 13 December 2013

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1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Principle of evaluation

This assessment report has been established as a result of the evaluation of bis (N-cyclohexyl-diazenium-dioxy)-copper as product-type 8 (Wood preservative), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market1, with the original view to the possible inclusion of this substance into Annex I or IA to that Directive.

The evaluation has therefore been conducted in the view to determine whether it may be expected, in light of the common principles laid down in Annex VI to Directive 98/8/EC, that there are products in product-type 8 containing bis (N-cyclohexyl-diazenium-dioxy)-copper that will fulfil the requirements laid down in Article 5(1) b), c) and d) of that Directive.

1.2. Purpose of the assessment

The aim of the assessment report is to support a decision on the approval of bis (N-cyclohexyl-diazenium-dioxy)-copper for product-type 8, and should it be approved, to facilitate the authorisation of individual biocidal products in product-type 8 that contain bis (N-cyclohexyl-diazenium-dioxy)-copper. In the evaluation of applications for product-authorisation, the provisions of Regulation (EU) No 528/2012 shall be applied, in particular the provisions of Chapter IV, as well as the common principles laid down in Annex VI.

The conclusions of this report were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix II). Extension of the use pattern beyond those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions of use will satisfy the requirements of Regulation (EU) No 528/2012.
For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Regulation (EU) No 528/2012, such conclusions may not be used to the benefit of another applicant, unless access to these data has been granted.

1.3. Procedure followed

This assessment report has been established as a result of the evaluation of bis (N-cyclohexyl-diazenium-dioxy)-copper as product-type 8 (Wood preservative), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market.
bis (N-cyclohexyl-diazenium-dioxy)-copper (CAS no. 312600-89-8) was notified as an existing active substance, by Dr. Wolman GmbH (BASF Group), hereafter referred to as the applicant, in product-type PT 8.

1 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing biocidal products on the market. OJ L 123, 24.4.98, p.1

Commission Regulation (EC) No 1451/2007 of 4 December 2007[2] lays down the detailed rules for the evaluation of dossiers and for the decision-making process in order to include or not an existing active substance into Annex I or IA to the Directive.

In accordance with the provisions of Article 7(1) of that Regulation, Austria was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for bis (N-cyclohexyl-diazenium-dioxy)-copper as an active substance in product-type 8 was 28 March 2004, in accordance with Article 9 (c) of Regulation (EC) No 1451/2007.

On 25 March 2004, Austrian competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 27 September 2004.

On 25 February 2008, the Rapporteur Member State submitted, in accordance with the provisions of Article 14(4) and (6) of Regulation (EC) No 1451/2007, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 10 March 2008. The competent authority report included a recommendation for the inclusion of bis (N-cyclohexyl-diazenium-dioxy)-copper in Annex I to the Directive for product-type 8.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on 10 March 2008. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the Commission. Revisions agreed upon were presented at technical and competent authority meetings and the competent authority report was amended accordingly.

In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 13 December 2013.

2 Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. OJ L 325, 11.12.2007, p. 3

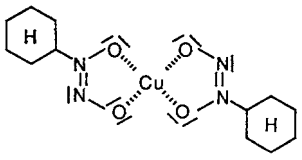
2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis

The active substance Cu-HDO with the IUPAC name "bis(*N*-cyclohexyl-diazenium-dioxy)-copper" and the synonym "copper, bis[1-cyclohexyl-1,2-di(hydroxy-κO)diazeniumato(2-)]-)" is attributed the CAS-No. 312600-89-8 (no EINECS-No. attributed). The molecular formula is $C_{12}H_{22}CuN_4O_4$, and the molecular weight is 349.9 g/mol.

Structural formula:



The structure of Cu-HDO is confirmed by all spectra (IR, ^{3}C-NMR, UV/VIS and MS).

According to the five batch analysis of solid Cu-HDO, the minimum purity of the active substance is 98.1%w/w. Apart from water, no impurities are present in quantities 1 g/kg or higher.

The physico–chemical properties are studied for the purified active substance of stated specification (min. 98.1%w/w Cu-HDO) according to the demands of the data requirements. Cu-HDO is an odourless blue violet crystalline solid (powder). It displays a melting point of 149°C. A boiling point is not detectable, since Cu-HDO decomposes at 182°C. The relative density is 1.514. The vapour pressure of Cu-HDO is below 10^{-6} hPa at 50°C and at 20°C, and the calculated Henry's law constant is below $5.7 \cdot 10^{-6}$ kPa x m^3 x mol^{-1}. The water solubility was determined by the flask method and is 34.6 mg/L at pH 4, 6.1 mg/L at pH 7 and 8.6 mg/L at pH 9. Due to this low solubility, the dissociation constant is determinable by neither conductometric method nor spectrophotometric method nor titration method. With a surface tension of 70.1 mN/m, Cu-HDO is not surface active.
Cu-HDO is soluble in n-octanol (6100 mg/L at 25°C) and in general soluble in non-polar organic solvents within a range of 1000–10 000 mg/L. The Partition coefficient octanol-water logPow is 2.6 at pH 6.1 and 25°C and 1.6 at pH 4 and 25°C.
Cu-HDO is not "highly flammable"; it has a self ignition temperature of ca. 170°C and decomposes at 182°C. Expected disintegration products are NO_x, CO_2 and H_2O. The active substance Cu-HDO is neither explosive nor oxidizing, but Cu-HDO is a flammable solid; Cat1.The identification and quantification of Cu-HDO in the manufacturing-use-product is performed by using a photometer method with UV/VIS detection. The UV/VIS has been validated. The limit of determination is 4 mg/L.

Methods for analysis of residues were validated for Cu-HDO in soil and water.
A HPLC method has been developed to analyse residues in surface water with a limit of quantification of 20 µg/L. The limit of detection was estimated to be about 3 µg/L. The submitted study is considered sufficient for surface water.
The determination of residues in soil can be performed after extraction of the soil samples according to DIN 38414 and subsequent analysis of copper by atomic absorption spectroscopy according to DIN 38406. In contrast to the analytical method for water, the method for soil is unable to analyze Cu-HDO. The method determines the overall Cu content of the soil sample. The LOQ of this method is 0.7 mg/kg Cu corresponding to 3.8 mg/kg Cu-HDO. Natural copper contens of soils may lead to an overestimation of the Cu-HDO comple. Therefore we recommend to check at product authorization stage for the availability of improved analytical methods able to measure residues of Cu-HDO in soil.
As Cu-HDO is not classified as toxic or very toxic, analytical methods for detection and identification of residues in animal and human body fluids and tissues were not assessed.

An analytical method for the determination of residues of Cu-HDO in/on food or feedstuffs is not required because the active substance is not used in a manner that may cause contact with food or feedstuffs.

2.1.2. Intended Uses and Efficacy

Cu-HDO is applied in wood preservatives for vacuum pressure treatment. The category of users is designated as industrial users. The field of use envisaged covers the preservation of structural timber for interior and exterior use, timber with ground and water contact. Scope of application is the protection of wood against wood-destroying fungi including those causing soft-rot as well as insects. The efficacy test showed the following upper threshold values for Cu-HDO: 1,5 kg/m³ for basidiomycetes on softwood, 2,1 kg/m³ for basidiomycetes on hardwood, 0,94 kg/m³ for soft rot and 0,71 kg/m³ against longhorn beetles (*Hylotrupes bajulus)*.
Concerning effectiveness against termites, the dossier does not include test results supporting the preventive activity of Cu-HDO, but tests showing effectiveness against termites are available with the biocidal product Wolmanit CX.
According to the applicant Cu-HDO is used in wood preservatives for many years. No cases of resistance have been reported for this group of fungicides so far.

The intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

2.1.3. Classification and Labelling of the active substance Cu-HDO

Bis (*N*-cyclohexyl-diazenium-dioxy)-copper is currently not classified according to Annex I of Council Directive 67/548/EEC. The manufacturing impurities are not of potentially toxicological, ecotoxicological and environmental concern and therefore do not pose a risk to humans or the environment.

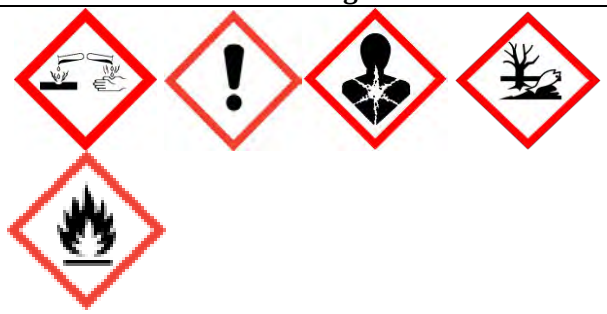
A CLH-Report was submitted by RMS AT to ECHA on 12/2010. The accordance check for CU-HDO has been received from ECHA on 14/09/2011.

The proposed classification and labelling of bis (*N*-cyclohexyl-diazenium-dioxy)-copper is presented below.

Table 2.1.3-1: Proposed classification and labelling of bis (N-cyclohexyl-diazenium-dioxy)-copper by RMS according to Reg. (EC) No 1272/2008, Annex VI, Table 3.2

Hazard symbol	
Indication of danger	E explosive O oxidising Xn harmful N dangerous for the environment
R phrases	R2: Risk of explosion by shock, friction, fire or other sources of ignition R8: Contact with combustible material may cause fire R22: Harmful if swallowed R41: Risk of severe damage to eyes R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
S phrases	S20/21: When using do not eat, drink or smoke S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice S36/37/39: Wear suitable protective clothing, gloves and eye/face protection S46: If swallowed, seek medical advice immediately and show this container or label S60: This material and its container must be disposed of as hazardous waste. S61: Avoid release to the environment. Refer to special instructions/safety data sheets.
Classification	E; R2 O; R8 Xn; R 22-41 N; R 50-53 SCL: N; R50-53 = $C_n \geq 25\%$; N; R51-53 = $2.5\% \leq C_n < 25\%$; R52-53 = $0.25\% \leq C_n < 2.5\%$;
Labelling	E; O; Xn; N; R: 2-8-22-41-50/53 S: 20/21-26-36/37/39-46-60-61

Table 2.1.3-2: Proposed classification and labelling of the active substance by RMS according to Reg. (EC) No 1272/2008[1], Annex VI, Table 3.1 and Reg. (EU) No 286/2011

		Classification and Labelling	Justification
GHS Pictograms		 GHS 02/05/07/08/09	
Signal words		Danger, Warning (classification/not labelling),	
Classification		Flam Sol 1 Acute Tox 1- H318 Acute Tox 4 – H302 STOT RE 2- H373 Aquatic Acute 1 (M=1) Aquatic Chronic 1 (M=1)	Aquatic Acute 1 (M=1): Lowest EC_{50} values for fish and algae in the range of 0.1 – 1 mg/L Aquatic Chronic 1 (M=1): not rapidly degradable and lowest chronic NOE_rC value from algae =0.056 mg/L.
Hazard statements		H228: Flammable Solid	UN-Test N.1
		H318 - Causes serious eye damage	In vivo eye irritation test
		H302 - Harmful if swallowed	Acute gavage test
		H373 – Causes damage to organs (gastrointestinal tract) through prolonged or repeated exposure	Carcinogenicity study: local effects in GI at ~ 34 mg/kg bw
		H400 - Very toxic to aquatic life (classification) H410 - Very toxic to aquatic life with long lasting effects (classification and labelling)	
Precautionary statement	**Prevention**	P210 Keep away from heat/sparks/open flames/hotsurfaces. — No smoking: P240 Ground/bond container and receiving equipment. P241 Use explosion-proof electrical/ventilating/lighting/…/equipment. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P264 - Wash thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P273 – Avoid release to the environment	
	Response	P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER or doctor/physician. P301 + P312: IF SWALLOWED: Call a POISON	

		CENTER or doctor/physician if you feel unwell. P330 Rinse mouth P391 – Collect spillage	
	Storage		
	Disposal	P501: Dispose of contents/container in accordance with local/regional/ national/international regulation (to be specified).	

2.1.4. Classification and Labelling of the biocidal product Wolmanit CX

Table 2.1.4-1: Proposed classification and labelling of the biocidal product by RMS according to Directive 1999/45/EC

	Classification and Labelling	Justification
Hazard symbol		
Indication of danger	C corrosive N dangerous for the environment	
R phrases	R20 Harmful by inhalation (product data) R22 Harmful if swallowed (product data) R34 Causes burns (product data) R 50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.	R50: Based on product data. All L(E)C_{50} values <1mg/L and >0.1 mg/L. R53: The product contains 2 relevant substances, in total 19.8%, which are classified with N; R50-53 (Cu-HDO which is not rapidly biodegradable; for the second relevant substance no specific concentration limits are given. For all other substances contained in the product no harmonised environmental C&L is needed or available. It is therefore proposed to classify and label Wolmanit CX with N; R50/53.
S phrases	S20/21 When using do not eat, drink or smoke S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S36/37/39 Wear suitable protective clothing, gloves and eye/face protection S45 In case of accident or if you feel unwell, seek medical advice immediately. (Show the label where possible.) S60 This material and its container must be disposed of as hazardous waste. S61 Avoid release to the environment. Refer to special instructions/safety data sheets.	
Classification	Xn; R20-22 C; R34 N; R50-53	
Labelling	C; N R: 20-22-34-50/53 S: 20/21-26-36/37/39-45-60-61	

Table 2.1.4-2: Proposed classification and labelling of the biocidal product by RMS according to Reg. 1272/2008/EC

GHS Pictograms		 GHS05  GHS07  GHS09	
Signal words		Danger, Warning (classification/not labelling),	
Classification		Category 1- H314 Category 4 – H302, H332 Aquatic Acute 1 Aquatic Chronic 1	Justification for Aquatic Acute 1: Based on product data. L(E)C_{50} values <1mg/L and >0.1 mg/L are available for all three trophic levels. Algae are the most sensitive species with an E_rC_{50} of 0.224 mg/L. Justification for Aquatic Chronic 1: Toxicity: A long term NOE_rC is only available for algae with 0.087 mg/L. Since algae are the most sensitive species it is justified to classify on the basis of this single long term NOEC. Degradation/Accumulation: The product contains 2 relevant substances, in total 19.8%, (Cu-HDO which is not rapidly biodegradable and classification with Aquatic Chronic 1 (M=1) is proposed; for the second relevant substance a classification with N; R50/53 is proposed in a CAR, but no SCLs or M-factors are available. For all other substances contained in the product no harmonised environmental C&L is needed or available). Therefore according to the Guidance on the application of CLP criteria (2012) it is proposed to classify the product as not rapidly biodegradable. In combination with the toxicity values this leads to a classification and labelling proposal for Wolmanit CX with Aquatic Acute 1 and Aquatic Chronic 1.
Hazard statements		H314 - Causes severe skin burns and eye damage (product data) H302 - Harmful if swallowed (product data) H332 - Harmful if inhaled (product data) EUH071 – Corrosive to the respiratory tract (product data) H400: Very toxic to aquatic life. (classification) H410: Very toxic to aquatic life with long lasting effects. (classification and labelling)	
Precautionary statement	**Prevention**	P260 - Do not breathe dust/fume/gas/mist/vapours/spray. P264 - Wash thoroughly after handling. P273 – Avoid release to the environment P280 - Wear protective gloves/protective clothing/eye protection/face protection.	
	Response	P301 + P330 + P331: IF SWALLOWED rinse mouth, do NOT induce vomiting. P303 + P361 + P353: IF ON SKIN (or hair) remove/take off immediately all con-	

		taminated clothing, rinse skin with water/shower. P304 + P340: IF INHALED remove victim to fresh air and keep at rest in a position comfortable for breathing. P310: Immediately call a POISON CENTER or doctor/physician. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P363: Wash contaminated clothing before reuse. P391 – Collect spillage
	Storage	P40: Store locked up.
	Disposal	P501: Dispose of contents/container in accordance with local/regional/ national/international regulation (to be specified).

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification

For the evaluation of Cu-HDO the following studies were submitted and evaluated: Three studies for toxicokinetics, one in vitro study for dermal absorption, three acute oral, one acute dermal and one acute inhalation study, one dermal and eye irritation study, one sensitisation study (GPMT), one sub-acute rat feeding study, two sub-chronic feeding studies (rat and dog), one chronic rat feeding study, one carcinogenicity rat feeding study, 3 genotoxicity tests with Cu-HDO (bacterial, in vitro unscheduled DNA synthesis, in vivo micronucleus), one genotoxicity test with K-HDO (in vitro mammalian gene mutation) and two developmental toxicity studies (rat and rabbit).

Cu-HDO is completely absorbed via the GI tract, excreted mainly via urine and bile and there is evidence for enterohepatic cycling. Cu-HDO might also accumulate since the terminal plasma half live is about 24 hours. One main metabolite of Cu-HDO was identified which is the glucuronide conjugate of the free HDO moiety which is only found in urine and bile. Other metabolites were below 2.5% of the applied dose and were not identified. From the repeated dose kinetic studies no enzyme induction seems evident.
From the in vitro dermal absorption study an absorption rate of 8% was deduced which accounts for the amount of substance found after 10 hours in the receptor fluid and in the skin without the superficial layers of the stratum corneum (6 tape strips. ca. 6%). The value is supported by an in vivo dermal absorption study which is not fully valid due to low recovery rates, but indicates 3% dermal absorption.

The acute toxicity studies indicate that Cu-HDO is harmful by oral exposure (LD50= 380 mg/kg bw) and causes a risk for serious damage to the eye if applied in the solid form. The acute dermal and the acute inhalation and dermal irritation and sensitisation studies do not indicate a toxicological concern.

The target organ within the sub-acute, sub-chronic, chronic and carcinogenicity studies repeated dose studies was the GI tract (irritation), furthermore some histological effects in the liver and the kidneys were observed. No carcinogenic effects are evident. Within the sub-chronic dog study the liver effects were stronger but no further target organs were identified. The systemic NOAELs of these repeated dose studies are within the same magnitude that is 47 (rat 28d), 38 (rat 90d), 26 (dog 90d), 18 rat (12m), 33 (rat 24m) mg/kg bw/day.

No neurotoxic effects were observed within the repeated dose studies and the brain was never a target organ. Furthermore within the frame of the sub-acute rat study a functional observation battery was carried out and no neurotoxic effect was detected.

No genotoxicity is evident within the three in vitro tests and within the in vivo micronucleus test and the tests are all sufficiently valid.

Based on the fact of identical target organs between the sub-chronic rat and dog studies and the comparable NOAELs and the absence of genotoxic effects and limited human exposure due to restriction to industrial application processes waving of the carcinogenicity study with the 2nd species was accepted.

Within the developmental toxicity study of the rat only maternal effects were observed that were slightly and transiently impaired food consumption and marginally impaired body weight gain in top dose dams. Within the developmental toxicity study of the rabbit a primary maternal effect on food consumption seems evident with subsequent embryo lethality and skeletal retardations. The data submitted do not indicate a concern for specific developmental toxicity. The lowest NOAEL from the developmental studies is 10 mg/kg bw/day.

Waiving of the 2-generation study was primarily accepted based on the absence of gross- and histopathological effects within the reproductive organs within the repeated dose studies and the absence of developmental effects and the requirement of neglegible exposure. The approach is supported by a probabilistic evaluation of $NOAEL_{subchr}$ /$NOAEL_{2\text{-}gen}$ ratios for about 120 substances as well as a probabilistic evaluation of classification triggers for fertility effects in repeated doses studies for more than 70 substances and consideration of product composition as skin corrosive and only industrial intended use.

2.2.1.2. Effects assessment

The short term AEL (0.1 mg/kg bw) is based on the NOAEL from the developmental rabbit study and an assessment factor of 100. This standard factor seems to be sufficiently conservative for sporadic exposure scenarios since the data package for acute and sub-acute toxicity is complete, the effect in the developmental toxicity study seems to be an unspecific maternal effect and the respective NOAEL is even below the chronic NOAEL (18 mg/kg bw/day, 12 months study).

The medium and long term AEL (0.033 mg/kg bw/day) is also based on the NOAEL from the developmental rabbit study (10 mg/kg bw day), since this NOAEL is below the systemic NOAEL of the 2-years rat study (33 mg/kg bw day). The assessment factor of 300, which should account for the waiving of the 2-generation study, results in an additional assessment factor of > 10 to the subchronic rat NOAEL of 38 mg/kg bw day. This latter assessment factor is supported by a data based probabilistic comparison of $NOAEL_{sub\text{-}chronic}$ / $NOAEL_{2\text{-}generation}$ ratios.

2.2.1.3. Exposure assessment

The human exposure assessment considers primary exposure which occurs during treatment of the wood with the representative biocidal product, as well as secondary exposure which concerns persons who come into contact with treated wood.
While industrial users are exposed to the formulated product, the general public is only exposed to the active ingredient by emissions from treated wood, e.g. dermal uptake via direct contact, and when processing, e.g. sanding wood.

Table 2.2.1.3-1: Main paths of human exposure to the active substance during manufacturing and from its use in wood preservative products

	Exposure type				
	Primary exposure: Production of a.s and b.p.	Primary exposure: Treatment of wood			Secondary exposure
Users / Route	Industrial use	Industrial use	Professional use (1)	General public (1)	General public
Inhalation(2)	yes	yes	no	no	yes
Dermal	yes	yes	no	no	yes
Oral	no	no	no	no	yes

(1) The product Wolmanit CX is intended for industrial use only.

(2) The inhalation route is considered as negligible (products are never used by manual spraying and the vapour pressure is very low). Nevertheless, it has been included in this assessment, whenever inhalation was specifically mentioned in the TNsG on human exposure for the considered application technique.

The assessment of human exposure follows the recommendations of the Technical Notes for Guidance on Human Exposure to Biocidal Products (European Commission, 2002), (TNsG on Human Exposure).
A tiered approach is followed for exposure estimation. In tier 1 the maximum theoretically possible exposure is calculated (conservative assumptions, realistic worst case), considering validated toxicological parameters (e.g. dermal absorption). If this exposure assessment produces an unacceptable outcome in risk assessment, a tier 2 assessment is performed (i.e. refinement of the exposure studies/models, considering specific data like for example time budgets, transfer factors and the effects of exposure reduction measures, e.g. personal protective equipment).

Primary exposure: Application (Vacuum pressure treatment)

Wolmanit CX is only applied by industrial user by vacuum pressure treatment. For details on the intended use please see Appendix II of this document. The assessed primary exposure scenarios include all the relevant exposure routes for industrial users (dermal and inhalation).

Assessment of inhalative exposure was done by calculating the maximum concentration of Cu-HDO in the air. Dermal exposure was measured in a vacuum pressure treatment plant in Germany under real exposure conditions (use class 4 conditions, i.e. application amounts up to max. 2.0% Wolmanit CX in water). The used PPE were nitrile gloves and protective clothing.

Exposure was modelled for the maximum application amount originally given by the applicant (i.e. 2.5% Wolmanit CX in water for use class 2 and 3; 4% Wolmanit CX in water for use class 4) for wood to be used under high hazard conditions, as no further test data were available. These values are taken forward for risk characterisation. The results for primary exposure are presented in the table below.

Table 2.2.1.3-2: Total primary human exposure (dermal and inhalation route) during application of the product (treatment of wood), modelled (Handling model 1)

Concentration	4% Wolmanit CX in water			2.5% Wolmanit CX in water		
Tiers:	Reasonable worst case	Normal use 95th%	Normal use 75th%	Reasonable worst case	Normal use 95th%	Normal use 75th%
Total systemic dermal exposure	0.097	0.033	0.010	0.061	0.021	0.006
Total systemic inhalative exposure	0.0014	0.0010	0.0003	0.0009	0.0006	0.0002
Total systemic exposure	0.099	0.034	0.010	0.062	0.021	0.006

Secondary human exposure

The assessed secondary exposure scenarios include all the relevant exposure routes (dermal, oral and inhalation) and take into account that treated wood is only used after it is completely dry.

Table 2.2.1.3-3: Routes of exposure (secondary exposure)

	Acute exposure		**Chronic exposure**			
Exposure path	Processing of treated wood (1)	Acute exposure of infant	Processing of treated wood (2)	Volatile residues indoors (3)	Child playing on playground	Infant playing on weathered structure
Inhalation	yes	n.r.	yes	yes	n.r.	n.r.
Dermal	yes	n.r.	yes	n.r.	yes	yes
Oral	n.r.	yes	n.r.	n.r.	n.r.	yes

(1) Non-professional user: Adult incidental exposed by cutting and sanding of treated wood
(2) Professional user: Adult regularly exposed by cutting and sanding of treated wood
(3) Taking into consideration inhalation by adult and infant
n r. Not relevant according to TNsG on human exposure

The scenarios to be considered for secondary exposure are described in the TNsG on Human Exposure to biocidal products, Part 3, Appendix 7.1.1, as well as in the User Guidance to the TNsG on human exposure to biocidal products (European Commission, 2002):

- acute inhalation of dust by an adult during sanding of wood
- acute dermal exposure to Cu-HDO by an adult during sanding of wood
- acute oral exposure to Cu-HDO by an infant (chewing wood off-cut)
- chronic inhalation of dust by an adult during sanding of wood
- chronic dermal exposure to Cu-HDO by an adult during sanding of wood
- chronic inhalation of volatile residues indoors by adult
- chronic inhalation of volatile residues indoors by infant
- chronic dermal exposure of child playing on playground structure outdoors
- chronic dermal and oral exposure of infant playing on and mouthing weathered structure

The results for systemic secondary exposure (considering an application amount up to max. 4% Wolmanit CX in water) are presented in the table below.

Table 2.2.1.3-4: Acute and chronic secondary exposure (oral, dermal and inhalation route)

Scenario	Time frame	Route	Systemic exposure per day [mg/kg bw/day]	
			Tier 1	Tier 2
Adult sanding / processing treated wood	acute	inhalative	3×10^{-4}	-
Adult sanding / processing treated wood	acute	dermal	0.24	1.5×10^{-4}
Ingestion by infant chewing wood chips	acute	oral	0.18	0.03
Adult sanding / processing treated wood	chronic	inhalative	1.8×10^{-3}	-
Adult sanding / processing treated wood	chronic	dermal	0.24	7×10^{-4} (Tier 2a) 1.5×10^{-4} (Tier 2b)
Adult inhaling volatilized residues indoors	chronic	inhalative	0.007	-
Infant inhaling volatilized residues indoors	chronic	inhalative	0.006	-
Child playing on playground structure outdoors	chronic	dermal	0.45	0.013 (Tier 2a) 3×10^{-4} (Tier 2b)
Infant playing on wheatered structure	chronic	dermal	0.67	0.020 (Tier 2a) 4.4×10^{-4} (Tier 2b)
Infant mouthing wheatered structure	chronic	oral	10.5 (Tier 1a) 0.25 (Tier 1b)	0.025 (Tier 2a) 0.0055 (Tier 2b)

Secondary exposure of farm animals

For farm animals, exposure calculation leads to an oral systemic exposure of 0.026 mg/kg bw/day. This scenario needs refinement, as the maximum amount of treated wood which is taken up was not substantiated by data.

Dietary risk assessment
Concerning residues in exposed farm animals, the estimated internal exposure of animals is above the actually proposed trigger value of 0.004 mg/kg bw, therefore a human dietary risk assessment for residues in food of animal origin may appear necessary (see chapter 3.3 Elements to be taken into account by Member States when authorising products of this document).

2.2.1.4. Risk characterisation for systemic effects

The manufacture of Cu-HDO and the representative product Wolmanit CX is carried out within highly automated systems resulting in very low exposure. This is also essential since the solid form of Cu-HDO as well as Wolmanit CX bear a risk of serious damage to the eye and Wolmanit CX furthermore causes burns to the skin. The risk characterisation for systemic effects due to exposure during the manufacture is based on the calculation of the saturation concentration in air an appropriate ventilation rate and the dermal exposure values from the application process as reasonable worst case assumption. The respective MOE results for the more realistic tier 2 estimates above 300.

Table 2.2.1.4-1.: Risk due to exposure to Cu-HDO during the manufacturing process of the active substance and the biocidal product

Exposure Scenario	estimated inhalation uptake [mg/kg bw day]	estimated dermal uptake [mg/kg bw]	estimated total uptake [mg/kg bw day]	toxicity reference value [mg/kg bw day]	assessment factor = reference MOE	MOE = NOAEL/exposure	exposure / AEL
Tier 1: air concentration = saturation concentration; 8% dermal absorption, 12% PPE penetration	0.0024	0.033	0.04	NOAEL chronic 10	300	282	1.06
Tier 2: air concentration = 1% of saturation concentration; 8% dermal absorption, 12% PPE penetration	0.000024	0.033	0.033	NOAEL chronic 10	300	303	0.99

Also the application of Wolmanit CX is carried out only within highly automated industrial systems (vacuum pressure method). Wolmanit CX is diluted to 0.5 to 4% which substantially reduces the risk for burns and serious damage to the eye. Therefore the risk characterisation was focused on potential systemic effects. Since no measured exposure values were submitted

for applications of Cu-HDO as aqueous 4% Wolmanit CX solution, model exposure data had to be used. Exposure to 4% Wolmanit CX is higher compared to exposure to 2.5% Wolmanit CX, thus no additional risk characterisation for the latter is carried out. The risk results acceptable with exposure values at and below the 95th percentile.

Table 2.2.1.4-2: Exposure during application of Cu-HDO as 4% Wolmanit CX by vacuum pressure method

exposure scenario		**4 % Wolmanit CX estimated total Cu-HDO uptake [mg/kg bw day]**	**toxicity reference value [mg/kg bw day]**	**assessment factor = acceptable MOE**	**4 % Wolmanit CX MOE = NOAEL/exposure**	**4 % Wolmanit CX exposure / AEL**
Exposure during application of Cu-HDO by vaccum presssure method (model values)	**Normal use 95th percentile**	0.030	NOAEL sub-acute 10	100	333	0.30
			NOAEL chronic 10	300	333	0.90
	Normal use 75th percentile	0.010	NOAEL sub-acute 10	100	1000	0.10
			NOAEL chronic 10	300	1000	0.30

Also secondary exposure was just modelled for the maximum application amount (i.e. 4% Wolmanit CX in water):

Due to the low vapour pressure of Cu-HDO the risk characterisation for chronic secondary exposure to volatilised Cu-HDO indoors results already with tier 1 estimates in a MOE above 1000 for adults and for infants.

Table 2.2.1.4-3: Risk due to secondary exposure by chronic inhalation of volatilized Cu-HDO indoors

exposure scenario		estimated total uptake [mg/kg bw day]	toxicity reference value [mg/kg bw day]	assessment factor = reference MOE	MOE = NOAEL/exposure	exposure / AEL
Chronic inhalation of volatile residues indoors by adult	Tier 1 a.s. at saturation concentration, inhalation rate = 1.25 m3/h, 24 hours exposure; 60 kg bw	0.007	NOAEL chronic 10	300	1429	0.21
Chronic inhalation of volatile residues indoors by infant	Tier 1 a.s. at saturation concentration, inhalation rate = 4m^3/day; 24 hours exposure; 10 kg bw	0.006	NOAEL chronic 10	300	1667	0.18

The exposure estimates for sanding and processing of treated wood are – for higher tier (2) estimates – based on default assumptions refined by measured wood-hand transfer values. For this higher tier estimate the risk results acceptable also without protection by gloves for sporadic and for chronic scenarios (MOEs above 1000).

Table 2.2.1.4-4: Risk due to secondary exposure during the sanding/ processing of wood

exposure scenario		estimated inhalation uptake [mg/kg bw day]	estimated dermal uptake [mg/kg bw day]	estimated total uptake [mg/kg bw day]	toxicity reference value [mg/kg bw day]	assessment factor = Reference MOE	MOE = NOAEL/exposure	exposure / AEL
Exposure during processing of wood	**tier 2** no PPE, **measured wood-hand transfer,** 8% dermal absoprtion	0.0003 (1h single exposure)	0.00015	0.0005	NOAEL sub-acute 10	100	22222	0
		0.0018 (6h daily exposure)	0.00015	0.0020	NOAEL chronic 10	300	5128	0

The risk for infants accidentally chewing treated wood seems acceptable when the default exposure assumptions are refined by considerations of water (salvia) solubility of Cu-HDO and an estimate for the potential salvia production within 5 hours (MOE >300). Nevertheless oral exposure of infants to treated wood should be avoided based on the precautionary principle.

Table 2.2.1.4-5: Risk due to acute oral ingestion by infant by chewing treated wood

exposure scenario	estimated oral uptake [mg/kg bw/day]	toxicity reference value [mg/kg bw/day]	assessment factor = reference MOE	MOE	exposure / AEL
Tier 2 extracted amount limited by solubility in water and salvia production within 5 hours	0.03	NOAEL sub-acute 10	 100	393	0.25

Also the assessment of the higher tier exposure estimates for children and infants playing on weathered playground structures indicate an acceptable risk with MOEs above 1000 to the sub-chronic and chronic NOAELs. However the higher tier estimates exclude direct mouthing of treated wood and consider oral uptake only by hand to mouth transfer.

Table 2.2.1.4-6: Child playing on treated playground structures outdoors

exposure scenario		estimated dermal uptake [mg/kg bw day]	toxicity reference value [mg/kg bw day]	assessment factor = reference MOE	MOE	exposure / AEL
Child/Infant playing on playground structure outdoors	**Tier 2** 8% dermal absorption, **measured wood-hand transfer**	0.0003	NOAEL chronic 10	300	33333	0.01

Table 2.2.1.4-7: Infant playing on weathered structure

exposure scenario	estimated total uptake [mg/kg bw/day]	toxicity reference value [mg/kg bw/day]	safety factor = acceptable MOE	MOE = NOAEL/ exposure	exposure / AEL
Tier 2b measured wood-hand transfer value; 100% oral uptake by hand-mouth transfer	0.0055	NOAEL sub-chronic and chronic 10	300	1091	0.28

Exposure of farm animals via treated wood may happen when farm animals are eating paddocks. According to the exposure estimates (see document II-B 4.5.13) in comparison with the sub-chronic NOAEL and an assessment factor of 300 the risk results only acceptable in case not more than 5g wood are taken up per day. Since this value is not substantiated by data, treated wood has to remain out of reach of livestock animals unless it can be shown (with product authorisation) that there is no risk for farm animals and no risk with human dietary exposure to food from farm animals.

Table 2.2.1.4-8: Exposure of farm animals

exposure scenario		**estimated oral uptake** [mg/kg bw/day]	**toxicity reference value** [mg/kg bw/day]	**assessment factor = reference MOE**	**MOE**	**exposure / AEL**
Ingestion of treated wood by farm animals	5g treated wood / day; 840 g a.s./m^3 wood; 400 mg/cm^3 wood density body weight 400 kg	0.026	NOAEL sub-chronic and chronic 10	300	769	0.39

In summary all the risk characterisations which are taken into consideration within this report result in an acceptable risk for exposure to Cu-HDO via Wolmanit CX and Wolmanit CX treated wood except for farm animals and respective human dietary exposure. Clearly for the risk characterisation for the exposure to Wolmanit CX and other Cu-HDO containing products the risk from aggregate exposure with the other product ingredients has to be carefully evaluated for all scenarios.

2.2.1.5. Risk characterisation for local effects

The representative product Wolmanit CX causes burns to the skin (and bears consequently also a risk for severe eye damage). A NOAEC cannot be defined for these effects.

Therefore adequate personal protective equipment has to be used in order to mitigate this risk for primary exposure situations (application of Wolmanit CX).

Secondary exposure to Wolmanit CX will appear only to the diluted product. Dilution depends on the use classes, but was limited to maximal 2% Wolmanit CX in water. This is below the classification limits for skin corrosion (5%) and eye corrosion (3%), but eventually above the classification limits for skin and eye irritation (1%).

Dermal transfer measurements from treatment plants are available providing a local exposure estimate of 0.2 mg product/cm2 (see doc IIB, 4.4.3: 0.056 mg (~2% solution of 3.5% product) * 28.6 * 50 = 80 mg/420 cm2 = 0.2 mg/cm2). In OECD TG 404 (dermal irritation test) an application rate of 83 mg/cm2 is recommended (500 mg/6 cm2). This is a factor of 400 higher than the actual dermal exposure estimate in terms of mg/cm2.

These data and further qualitative considerations may serve at product authorisation stage for a more detailed risk assessment for local effects from secondary exposure. A revision of the guidance for risk assessment for local effects is actually in progress.

Environmental Risk Assessment The applicant submitted data on Cu-HDO, but no data on copper were submitted. In TM I 11, the need of information concerning the fate and toxicity of the Cu-part of the Cu-HDO molecule was discussed (Appendix I of the R-COM-Table). So reference was made on the CAR of basic copper carbonate owned by the Wood Preservative Copper Task Force (WPCTF). Furthermore, reference to Cu-data in the VRAR-data were made in scientific discussions.For product authorization the data on copper cannot be used by the applicant or another third party without the submission of an appropriate Letter of Access from the respective data holder.

2.2.1.6. Fate and distribution in the environment

Degradation:

Cu-HDO has a water solubility of 6.1 mg/L at pH=7 and 23°C.

The substance is hydrolytically stable at pH 3 and 7 at environmentally relevant temperatures (25°C) and under alkaline conditions up to 50°C. Hydrolysis occurs only under acidic conditions at temperatures ≥35°C or at neutral pH at temperatures ≥55°C.

Cu-HDO is readily degraded by aqueous photolysis; the experimental DT_{50} of Cu-HDO was 6 hours under irradiation (test design according to SETAC[3]). The calculated DT_{50} for the top-layer of aqueous systems under Central European conditions considering the quantum yield of Cu-HDO was estimated to be less than 1 hour during the months April-August. During the 48 hours study duration cyclohexanone (45%AR) and cyclohexanone oxime (51%AR) were detected, as well as volatile degradation products (<2%AR). Because photolysis will only take place in the upper layers of the water phase the metabolites are considered of minor relevance for the environment.

The half-life of Cu-HDO when undergoing photolysis in air was estimated to be 1.87 hours and 5.6 hours (AOPWIN[4]), respectively.

Cu-HDO is neither readily nor inherently biodegradable, but in the screening tests it is well eliminated from water, mainly through adsorption processes (Zahn Wellens Test: 50% adsorption within 2 hours; 100% dissipation within 17 days, no proof for biodegradation).

In a STP simulation test Cu-HDO was eliminated from the water phase by >90% after 41 days of incubation (additional information).

In a water/sediment degradation study a DT_{50} value for degradation in the total system was calculated with 14.5 days at 25°C (41 days at 12°C). DT_{50} values for dissipation at 25°C were calculated for the water and the sediment phase with 2.4 days (6.8 days at 12°C) and 20.3 days (57 days at 12°C), respectively. The mineralization rate was determined with 13.2% after 30 days of incubation. The corresponding DT_{50} value was calculated with 89.1 days, which exceeds the limit of observation time and is therefore considered beyond the range of reliable extrapolation. The only major metabolite detected was CO_2 (13.2% TAR). Though not explicitly detected and measured in this study it is clear that copper will also add to the transformation products profile.

In an aerobic soil study Cu-HDO dissipated with a DT_{50} value of 16 days (35.6 days at 12°C). The study was not accepted as key study since important endpoints (primary and ultimate

3 SETAC Procedures for assessing the Environmental Fate and Ecotoxicity of Pesticides, SETAC Europe, Brussels, March 1995

4 http://www.epa.gov/opptintr/exposure/pubs/episuite htm

degradation, identification and quantification of metabolites, etc.) were not provided in the test report.

In a new soil simulation study (dated 2013) ^{14}C Cu-HDO is eliminated in soil based on the results of a laboratory study according to the OECD test guideline 307 with an DT_{50} value (FOMC) of 2.6 days (5.7 days at 12°C, arithmetic mean value, n=4) by formation of metabolites, NER and $^{14}CO_2$. A degradation DT_{50} (mineralization) value of 79.2 days (171.3 days at 12 °C, arithmetic mean value, n=4) was determined. The study failed to elucidate a complete degradation pathway including the quantification of respective metabolites. On day 1 the following transformation products were identified: Cyclohexene (from Cyclohexanol), Cyclohexanonoxime and Piperidine (from Caprolactam). The occurrence of metabolite $C_7H_7N_3$ (isomers possible) is nebulous, a reaction product (workup artefact) of ^{14}C Cu-HDO with the solvent acetonitrile was suggested. The applicant stated that no further clean up and analytical methods for identification and quantification for the transformation products were available. Though not explicitly detected and measured in this study it is clear that copper will also add to the transformation products profile. NER formation reached 20%AR to 40%AR in the first days of incubation and remained relatively constant or declined until study termination. No characterisation of the NER was performed.

Based on the submitted empirical evidence a substantial degradation potential of Cu-HDO is demonstrated and it can be concluded that this compound is not persistent in the terrestrial environment.

Copper has not been measured in any of the abiotic or biotc degradation studies, however it is clear, that whenever degradation occurs, copper will be part of the transformation products. Copper as an inorganic compound is not subjected to biological degradation in any environmental compartment. It is therefore not biodegradable, non-volatil and hydrolytically stable. Phototransformation is not expected. As all metals, copper becomes complexed to organic and inorganic matter in waters, soil and sediments and this affects copper speciation, bioavailability and toxicity (AR, France, 2011)[5].

Distribution:

Cu-HDO shows very high adsorption-values (geometric mean K_{Foc}=30 277.4 L/kg). Leaching to groundwater is therefore not expected.

The strong adsorbtion to organic carbon, manganese and ironoxides increases in soil with increasing pH. The most important parameters determining the distribution of copper in the aquatic and soil compartment is adsorption onto solid materials and therefore the copper partitioning coefficients (AR, France, 2011).

Accumulation:

The calculated log BCF of Cu-HDO in fish is 1.51, the resulting BCF_{fish} is 32.36 and the calculated BCF in earthworms is 5.6. According to the low BCFs there is no risk of accumulation.

5 https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp

According to the VRAR of copper (ECHA, 2008)[6] and the AR of Basic Copper (Carbonate (France, 2011) the potential for biomagnification and secondary poisoning was investigated for copper and it was concluded that, due to copper homeostasis, there was no concern for secondary poisoning.

6 http://echa.europa.eu/de/copper-voluntary-risk-assessment-reports

2.2.1.7. Effects assessment

Aquatic compartment (fish, daphnids, algae, micro-organisms):

The LC_{50}-values of Cu-HDO in fish are between 0.14 and 0.24 mg/L for rainbow trout (*Oncorhynchus mykiss*), which show high toxicity. No long term test in fish was carried out with Cu-HDO, but a fish juvenile growth test according to the OECD 215 guideline was carried out with K-HDO. The NOEC for K-HDO is 0.29 mg a.s./L. The long term $NOEC_{fish}$ based on the toxicity of Cu in Cu-HDO is 0.064 mg/L (on equimolar basis).

Cu-HDO is acutely toxic to invertebrates, as indicated by the acute EC_{50} in *Daphnia magna* of 1.1 mg/L, the chronic NOEC was determined to be 0.75 mg a.s./L.

Growth inhibition in green algae (*Scenedesmus subspicatus*) shows an EC_{50} of 0.194 mg a.s./L, the EC_{50} of the biomass inhibition is 0.079 mg a.s./L. Algae are very sensitive to Cu-HDO, as the chronic NOE_rC of the growth rate is 0.056 mg a.s./L.

Cu-HDO is moderately toxic to aquatic micro-organisms with an EC_{20} of 2.5 mg a.s./L and an EC_{50} of 9 mg a.s./L.

Air compartment:

The concentration of Cu-HDO is expected to be zero due to the low vapour pressure of the substance, thus biotic effects are not expected for the air compartment

Terrestrial compartment:

Cu-HDO exhibits low toxicity against terrestrial organisms.
The NOEC for soil micro-organisms is 28.8 mg a.s./kg soil dry weight (converted to standard soil). No EC_{50} values were determined for micro-organisms.

The LC_{50} for earthworms is 216.24 mg a.s./kg dry soil (converted to standard soil).

For plants the EC_{50} was determined with 311.0 mg a.s./kg dry soil (converted to standard soil conditions).

2.2.1.8. PBT assessment

Persistence:

Cu-HDO:

Cu-HDO is neither readily nor inherently biodegradable. In an inherent test (Zahn Wellens) it showed 100% elimination after 17 days. 50% of this elimination took place within 2 hours and was therefore attributed to adsorption. Since no abiotic control was performed there is no evidence for biodegradation.

In a **water/sediment** study (see Doc. II-A, chapter 4.1.1.1.1 Biodegradation) a DT_{50} value for degradation of Cu-HDO in the total system was calculated with 14.5 days at 25°C. CO_2 was the only major metabolite which could be detected. For the water and the sediment phase only

DT_{50} values for dissipation were calculated with 2.4 and 20.3 days at 25°C, respectively. Therefore degradation in the sediment phase was considered more relevant for the assessment of the P criterion than degradation in the water phase. The DT_{50} value (first order, dissipation) of 20.3 days for the sediment phase was used as a default value for the assessment of persistence in the sediment phase. Conversion to standard European conditions (12°C) resulted in a DT_{50} value of 57 days.

P-criterion: $T_{1/2}$ >120 days in fresh sediment – DT_{50} =57 days (12°C) => not P

^{14}C Cu-HDO is eliminated in soil based on the results of a laboratory study according to the OECD test guideline 307 with an DT_{50} value (FOMC) of 2.4 days (5.7 days at 12°C, geometric mean value, n=4) by formation of metabolites, NER and $^{14}CO_2$. The DT_{50} vlaue based on complete mineralization was 77.6 days (171.3 days at 12 °C, geomtric mean value, n=4).

P-criterion: $T_{1/2}$ >120 days in soil – DT_{50} =5.7 days (12°C) => not P

Copper:

Copper, as inorganic metal, is excluded from the P assessment taking into account the Annex XIII of Reach regulation 1272/2008. Therefore the criterion for persistence in soil is not relevant. This is line with the conclusion drawn for copper suflate pentahydrate, AR, 2013 by France.

Conclusion:

The data from the water/sediment and the soil degradation study indicate that Cu-HDO does not meet the P-criterion.

The criteria for persistence are not relevant for copper..

Bioaccumulation:

Cu-HDO:

BCF_{fish} = 32.36

Copper:

Due to the homeostatic regulation process of invertebrates and fish of copper, bioaccumulation and biomagnification of cooper are considered as not applicable for copper according to the AR on Basic Copper Carbonate (France, 2011)[7]

Conclusion:

Cu-HDO doesn't meet the B-criterion. Copper doesn't meet the B-criterion.

Toxicity:

Cu-HDO:

7 https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp

The chronic NOEC values for freshwater species are 0.064 mg/L for fish, 0.75 mg/L for invertebrates and 0.056 mg/L for algae. Cu-HDO does not meet the T-criterion.

Copper:

Considering the HC5-50 value of 7.8 µg/L for the aquatic compartment, the T criterion is fulfilled (AR, France, 2011).

Copper meets the T criterion.

Endocrine disrupting effects and CMR effects:

Cu-HDO:

No specific test for potential endocrine disruption and no 2-generation study were carried out. However within the sub-acute, sub-chronic, chronic and carcinogenicity, developmental toxicity and mutagenicity studies there is no evidence for endocrine disruption or for CMR effects.

Copper:

Concerning copper data on reproductive and developmental toxicity as well as mutagenicity and carcinogenicity and repeated dose toxicity do not indicate evidence for endocrine disruption or CMR effects (AR, France, 2011).

2.2.1.9. Exposure assessment

Wolmanit CX is only applied by industrial vacuum treatment method. For details on the intended use please see Appendix II of this document.

Production and use of Wolmanit CX may lead to the emission of Cu-HDO to the environment, during the formulation process (= production process), the treatment of the wood, the storage of the treated wood prior to shipment and from the treated wood in service. The environmental exposure assessment follows the recommendations of the Emission Scenario Document for Wood Preservative (OECD, 2003) and of the Technical Guidance Document on Risk Assessment (European Commission, 2003).
The applicability of both, the models for estimation of concentrations in ground water as well as the receiving compartment size in some models, were discussed on EU level in several Technical Meetings. As result of these discussions, a separate scenario was prepared for ground water exposure assessment. This separate scenario was summarised in the document "Groundwater exposure assessment for wood preservatives (endorsed during the 24th CA meeting)". The refined ground water assessment was performed with the model FOCUS Pearl 4.4.4. Furthermore, a decision was taken on EU level that 50 cm leaching distance (vertically and horizontally) should be used for calculation of the receiving soil compartment. These recommendations were also considered in the assessment.

No exposure assessment for copper stemming from Cu-HDO in the representative biocidal product is presented, because 94% of the total Copper in the product stems from Cu-salts and only 6% from Cu-HDO.

An exposure assessment for copper should be provided for product authorization, also with regard to the aspect that there may be products where copper stemming from Cu-HDO contributes for 100%.

The estimation of environmental exposure is made by calculating the emissions and then the concentrations for each environmental compartment on the basis of all direct and indirect emissions. Many values used in the exposure calculation are default values provided by the guidance documents on emissions and risk assessment. Some of the values are independent of substance considered. Other default values relate to the properties of Cu-HDO. Emission rates from wood were taken from field and lab studies.

Predicted environmental concentrations (PECs) are estimated for various time scales: initial (i.e. immediately after the last application e.g. at the end of the application day, no degradation processes considered), short-term (30 days) and long-term (10 years for wood in service). According to the Arona leaching workshop of 2005 (endorsed during the 19th CA Meeting in July 2005), the default service life for wood in use classes 3 and 4 for preservatives applied by vacuum pressure treatment is 20 years. However, the cumulative quantity of Cu-HDO leached out of 1 m² of treated wood over a certain time period was only available for 30 days, 35 days and 10 years. Therefore, risk assessment was based on a period covering 10 years. Already after this time period all PEC/PNEC ratios are <1. Due to the degradation behaviour of Cu-HDO the PECs after 10 years can be considered as worst case for PECs after longer assessment periods. In this case exposure assessment after 20 years is not necessary because it would not influence the outcome of the risk assessment.

In addition a tiered approach is used. In tier 1 calculations the maximum theoretically possible PECs are calculated (worst case concentrations). As realistic case approach, tier 2 estimates take into account degradation processes.

No determination of regional concentrations has been made, since the wood preservative uses outlined are not considered to be of sufficiently large scale. The exposure values relevant for risk characterisation are presented in the following chapter.

2.2.1.10. Risk characterisation

No risk assessment for copper stemming from Cu-HDO in the representative biocidal product is presented, because 94% of the total copper in the product stems from Cu-salts and only 6% from Cu-HDO. A risk assessment for copper should be provided for product authorization.

Air compartment:

The concentration of Cu-HDO in air is expected to be zero due to the low vapour pressure of the substance. Local air concentrations during the emission episode and annual average air concentrations are considered to be insignificant. Biotic effects are not expected for the air compartment. No abiotic effects which are of concern could be identified. In all, risk to atmosphere is considered to be negligible.

Aquatic compartment (including Sediment)

STP:

Sewage treatment plants are the main receiving compartment for Cu-HDO during application through vacuum-pressure treatment for UC 3 and 4 and during service life in UC 3.

Emissions during application process

During the impregnation process, including fixation period, emissions to the environment are diminished since both the impregnation plant and the freshly treated wood are placed under roof on an impervious structurally sound floor. Drips from wet wood are collected and returned to the treatment plant.

However, emission to the drain cannot be excluded. Therefore it is assumed that a certain amount of the applied active substance will enter the waste water treatment plant.

The local PECs in STP after application were calculated with 2.08×10^{-4} mg.L^{-1} for use class 3 and 3.33×10^{-4} mg.L^{-1} for use class 4 (see Doc II-B, chapter 5.2.2).

Emissions from treated wood in service

For use class 3 the local PECs in STP after leaching from a noise barrier (worst case for UC 3) were calculated with 2.64×10^{-3} mg.L^{-1} and 8.19×10^{-5} mg.L^{-1} for a 30 days and a 10 years period, respectively.

Risk characterisation

The risk characterisation for micro-organisms in STPs was done by comparing the $PECs_{STP}$ with the $PNEC_{micro\text{-}organisms}$. These aspects were already discussed in detail in document II-A and II-B, therefore only the relevant values are mentioned below.

The PNEC for STP micro-organisms was calculated to be 0.09 mg.L^{-1} (see Doc II-A, chapter 4.2.1 Aquatic compartment).

Table 2.2.2.5-1: Local PEC/PNEC ratios for STP micro-organisms

	Use Class 3		**Use Class 4**	
Exposure scenario	**PEC_{STP} (mg.L^{-1})**	**$PEC/PNEC_{STP}$**	**PEC_{STP} (mg.L^{-1})**	**$PEC/PNEC_{STP}$**
	$PNEC_{STP\ micro\text{-}organisms}$ = 0.09 mg.L^{-1}			
Application				
Vacuum pressure	2.08×10^{-4}	2.31×10^{-3}	3.33×10^{-4}	3.70×10^{-3}
Service life				
Noise barrier 30 days	2.64×10^{-3}	2.93×10^{-2}	-	-
Noise barrier 3650 days	8.19×10^{-5}	9.10×10^{-4}	-	-

Conclusion:
All relevant PEC/PNEC ratios for the STP are <1, indicating an acceptable risk for STP micro-organisms.

Surface water:
The risk characterisation for the aquatic compartment was done by comparing the PECs of the compartments with the relevant PNECs. According to the TGD no sediment assessment is triggered for substances showing a log K_{ow} <3.

Table 2.2.2.5-2: Local PEC/PNEC ratios for surface-water organisms (application, storage and treated wood in service)

	Use Class 3		**Use Class 4**	
Exposure scenario	**PEC_{water} ($mg.L^{-1}$)**	**$PEC/PNEC_{water}$**	**PEC_{water} ($mg.L^{-1}$)**	**$PEC/PNEC_{water}$**
	$PNEC_{water}$ = 0.0056 $mg.L^{-1}$			
Application and storage				
30 days	2.89×10^{-4}	5.16×10^{-2}	9.87×10^{-4}	0.176
Annual average	2.38×10^{-4}	4.25×10^{-2}	8.11×10^{-4}	0.145
Service life: Noise barrier				
Time 1: 30 days Time 2 : 3650 days	2.53×10^{-4} 7.84×10^{-6}	4.77×10^{-2} 1.4×10^{-3}	-	-
Service life: Bridge				
Time 1: 30 days Time 2 : 3650 days	2.34×10^{-4} 4.73×10^{-5}	4.18×10^{-2} 3.99×10^{-2}		
Service life: jetty				
Tier 1 Time 1 (30 days) Time 2 (3650 days)	-	-	2.5×10^{-4} 6.24×10^{-4}	4.46×10^{-2} 0.111
Tier 2 Time 1 (30 days) Time 2 (3650 days)	-	-	1.06×10^{-4} 9.94×10^{-6}	1.89×10^{-2} 1.78×10^{-3}
Service life: sheet piling				
Tier 1 Time 1 (30 days) Time 2 (3650 days)	-	-	0.114 1.78×10^{-3}	**20.355** 0.317
Tier 2 Time 1 (30 days) Time 2 (3650 days)	-	-	3.40×10^{-2} 4.37×10^{-6}	**6.07** 7.8×10^{-4}

The scenario jetty in lake gives acceptable aquatic PEC/PNEC ratios, even if no dissipation processes are considered. Calculating the PEC/PNEC ratios for the sheet piling scenario for a short time period (30 days), a slight risk would be indicated. This is the case for tier 1 calculations and for tier 2 (taking into account removal processes) as well. However, a time window of 30 days is not a representative time scale for vacuum treated wood which can be used for 10 years or more. When calculating the PEC/PNEC ratio for a time window of 10 years, the risk is reduced to acceptable levels. The long term scenario indicates that recovery is possible. So the risk of Cu-HDO used for wood preservatives in use class 3 and 4 is acceptable for aquatic organisms including sediment and STP.

Drinking water:

If surface water is intended for the abstraction of drinking water the parametric value of 0.1 $\mu g.L^{-1}$ for Cu-HDO according to Directive 98/83/EC is not met for application and storage (see PEC_{water} in table 2.2.2.5-1). Thus risk reduction measures to reduce emissions (e.g. to prevent runoff by storage under cover or collection of run-off from impermeable hard standing of storage sites) are necessary.

Concerning groundwater Cu-HDO is -under the proposed conditions- not likely to have unacceptable effects on groundwater (results of the refined groundwater assessment with the model FOCUS Pearl 4.4.4 show values <0.1 µg/L) and the requirements of 98/83/EC[8] and 2006/118/EC[9] are therefore complied with.
For Copper (100% from Cu-HDO, calculated on an equimolar basis) a comparison was done in Table 2.1.4-2 for the highest PECs in the environmental compartments to the lowest background levels reported in the AR on Basic Copper Carbonate (France 2011). The PECs groundwater were calculated for the House scenario in Use class 3, which represents the worst case situation for wood in service. As can be seen from that table the PEC for Cu-HDO as well as for Copper are both <0.001 µg/L and are therefore below the threshold value of 0.1 µg/L (according to 98/83/EC for copper the parametric value is 2 mg/L). For Cu-HDO this value has been confirmed by the FOCUS calculations. Therefore it is concluded that direct emissions of Copper to soil and subsequent to groundwater from house (worst case) are not presenting any unacceptable risk for the groundwater compartment. The risk is acceptable even considering that all copper contained in Cu-HDO (18.16%) will be leached out of the wood as Copper. This finding is in line with the conclusion of France, 2011 that indicates that no copper is expected to reach groundwater.

Sediment – risk characterisation and persistence:

According to the TGD no sediment risk assessment is triggered for substances showing a log K_{ow} <3.

In the sediment of a laboratory water/sediment system a DT_{50} value (dissipation) was calculated with 20.3 days at 25°C, corresponding to 30.3 days at 20°C, which is far below the threshold value of a DT_{50} >6 months at 20°C.

At day 0 non-extractable residues amounted to 9.3% of TAR. This value continually increased up to 44% at day 30 (end of the study). It remains unclear whether or not the threshold value of >70% non-extractable residues after 100 days would be reached.
Mineralisation was determined with 13.2% TAR after 30 days of incubation, which is far above the threshold value of <5% in 100 days.
Being an inorganic compound, the persistence criteria of DT_{50} at 20°C <6 months that are laid down in Annex VI to the Biocidal Product Directive and in the TNsG on Annex I inclusion are not applicable to copper and copper (II) oxide (AR, France, 2011).

In addition an active substance containing a metal or a semi-metal element shall not be included in annex I if the use will cause significant accumulation above the natural background levels.

8 Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption OJ L 330 , 05.12.1998, p. 3-54

9 Directive 2006/118/EC of the European Parliament and of the Council on the protection of groundwater against pollution and deterioration. OJ L 372, 27.12. 2006, p. 19-31.

According to the final AR on Basic Copper Carbonate (France, 2011) the following natural/pristine and regional background concentrations have been determined for copper:

Table 2.2.2.5-3: Background concentrations for copper (Table from AR, France, 2011)

Compartment	Natural/pristine background concentration	Regional background concentration	Unit
Surface water	0.88	2.9	[$\mu g.L^{-1}$]
Ground water	0.88	2.9	[$\mu g.L^{-1}$]
Soil	12 10.6	24.4 21.6	[$mg.kg_{dwt}^{-1}$] [$mg.kg_{wwt}^{-1}$]
Sediment	21 4.56	67.5 14.7	[$mg.kg_{dwt}^{-1}$] [$mg.kg_{wwt}^{-1}$]

Predicted environmental concentrations for copper stemming from Cu-HDO (estimation: 100%, equimolar basis) for the highest PECs in the environmental compartments were compared to these background values (cf. Table 2.2.2.5-4).

Table 2.2.2.5-4: Comparison of copper (100% from Cu-HDO) to the lowest background values:

Compartment	Use class/scenario	PEC_{Cu-HDO}	PEC_{Cu}	Natural/pristine background concentration
Surface water	UC4: Service life: sheet piling tier 2 (days 30)	0.03 $mg.L^{-1}$	6.17 $\mu g.L^{-1}$	0.88 $\mu g.L^{-1}$
	UC4: Service life: sheet piling, tier 2 (3650 days)	4.37×10^{-6} $mg.L^{-1}$	0.0008 $\mu g.L^{-1}$	
Ground water	UC3: House scenario	<0.001 $\mu g.L^{-1}$	<0.001 $\mu g.L^{-1}$	0.88 $\mu g.L^{-1}$
Soil	UC3: House scenario, tier 1, (3650 days)	1.9 mg kg_{dwt}^{-}	0.35 $mg.kg_{dwt}^{-1}$	12 mg kg_{dwt}^{-1} 10.6 mg kg_{wwt}^{-1}
Sediment	UC3, Service life; noise barrier	0.17 mg kg_{wwt}^{-1}	0.03 mg kg_{wwt}^{-1}	21 mg kg_{dwt}^{-1} 4.56 mg kg_{wwt}^{-1}

UC … use class

As it is shown in Table 2.2.2.5-4 all calculated copper concentrations except the sheet pilling scenario (30 days) are below the natural and regional copper background concentrations. However as pointed out in section 2.1.2 a time window of 30 days is not a representative time scale for vacuum treated wood which can be used for 10 years or more. When calculating the concentration for a time window of 10 years for sheet piling, the value is far below the background concentrations.
Therefore it can be concluded that Cu-HDO containing copper will not cause a significant accumulation above the natural background level for the proposed intended use in this CAR.

Conclusion:

On the basis of the available data on Cu-HDO and of the comparison of predicted worst case copper concentrations with natural background levels Cu-HDO is not persistent in sediment..

Terrestrial compartment

During application only indirect emission via sludge application on agricultural soil is considered relevant. During storage direct emission to soil due to leaching from treated wood, if stored uncovered or on permeable ground is considered.
For treated wood in service direct and indirect emission to soil is considered for UC 3 scenarios and direct emission for UC 4 scenarios.

Tier 2 calculations presented in this chapter were calculated twice using the soil DT_{50} value for degradation of 5.7 days at 12°C and the mineralization DT_{50} of 171.3 days at 12°C, because of the analytical shortcomings of the soil degradation study (**study A 7.2.2.1/02, Doc. III A7.2.2.1/02**; see Doc. A-II, chapter 4.1.1.1 Biodegradation).

The risk characterisation for the terrestrial compartment was done by comparing the local PECs with the $PNEC_{soil}$.

The PNEC for terrestrial organisms has been determined to be 0.288 $mg.kg^{-1}$ dry soil.

Table 2.2.2.5-5: Local PEC/PNEC ratios for terrestrial organisms (taking into account DT_{50} degradation of 5.7 days at 12°C)

	Use Class 3		Use Class 4	
Exposure scenario	**PEC_{soil} ($mg\ kg^{-1}_{dwt}$)**	**$PEC/PNEC_{soil}$**	**PEC_{soil} ($mg.kg^{-1}_{dwt}$)**	**$PEC/PNEC_{soil}$**
	$PNEC_{soil}$ = 0.288 $mg\ kg^{-1}_{dwt}$			
Application				
Arable agricultural soil (30 days)	1.27×10^{-5}	4.41×10^{-5}	2.03×10^{-5}	7.05×10^{-5}
Arable agricultural soil (180 days)	3.71×10^{-5}	1.29×10^{-4}	5.94×10^{-6}	2.06×10^{-5}
Grassland (180 days)	4.46×10^{-6}	1.55×10^{-5}	7.13×10^{-6}	2.47×10^{-5}
Storage				
Tier 2 (steady-state)	0.15	0.521	0.52	**1.81**
Service life: noise barrier				
Arable agricultural soil (30 days)	1.38×10^{-4}	4.79×10^{-4}	-	-
50 cm distance, tier 2 (30 days) (3650 days)	3.78×10^{-2} 1.60×10^{-3}	0.132 5.56×10^{-3}	- -	- -
Service life: house				
50 cm distance, tier 2 (30 days) (3650 days)	9.04×10^{-2} 4.48×10^{-2}	0.314 0.156	- -	- -
Service life: transmission pole				
50 cm distance, tier 2 (30 days) (3650 days)	- -	- -	3.90×10^{-2} 1.24×10^{-3}	0.135 4.31×10^{-3}
Service life: fence post				
50 cm distance, tier 2 (30 days) (3650 days)	- -	- -	1.21×10^{-2} 3.84×10^{-3}	4.20×10^{-2} 1.33×10^{-2}

If PECs are calculated on the basis of the DT_{50} degradation of 5.7 days at 12°C, all PEC/PNEC values are <1, with the exception of the PEC/PNEC ratio for use class 4, Storage, Tier 2 , which indicates a slight risk.

Table 2.2.2.5-6: Local PEC/PNEC ratios for terrestrial organisms (taking into account DT_{50} mineralization of 171.3 days at 12°C)

	Use Class 3		Use Class 4	
Exposure scenario	**PEC_{soil} (mg kg^{-1}_{dwt})**	**$PEC/PNEC_{soil}$**	**PEC_{soil} (mg.kg^{-1}_{dwt})**	**$PEC/PNEC_{soil}$**
	$PNEC_{soil}$ = 0.288 mg kg^{-1}_{dwt}			
Application				
Arable agricultural soil (30 days)	1.05×10^{-4}	3.65×10^{-4}	1.68×10^{-4}	5.83×10^{-4}
Arable agricultural soil (180 days)	9.31×10^{-5}	3.23×10^{-4}	1.49×10^{-4}	5.17×10^{-4}
Grassland (180 days)	1.26×10^{-4}	4.38×10^{-4}	2.03×10^{-4}	7.05×10^{-4}
Storage				
Tier 2 (steady-state)	4.43	**15.38**	15.6	**54.16**
Service life: noise barrier				
Arable agricultural soil (30 days)	6.29×10^{-4}	2.18×10^{-3}	-	-
50 cm distance, tier 2 (30 days) (3650 days)	0.150 7.41×10^{-2}	0.521 0.035	- -	- -
Service life: house				
50 cm distance, tier 2 (30 days) (3650 days)	0.242 0.122	0.840 0.424	- -	- -
Service life: transmission pole				
50 cm distance, tier 2 (30 days) (3650 days)	- -	- -	9.33×10^{-2} 3.47×10^{-3}	0.324 1.20×10^{-2}
Service life: fence post				
50 cm distance, tier 2 (30 days) (3650 days)	- -	- -	2.89×10^{-2} 11.0×10^{-3}	0.100 3.82×10^{-3}

If PECs are calculated on the basis of the DT_{50} mineralization of 171.3 days at 12°C, all PEC/PNEC values are <1, with the exception of the PEC/PNECs for use class 3 and 4, Storage, Tier 2 , which indicates an unacceptable risk to soil organisms under the storage area.

Conclusion:

PEC/PNEC ratios <1 were calculated for the application stage and for treated wood-in-service for use class 3 (noise barrier and house scenario), tier 2 and for use class 4 (transmission pole and fence post scenario), tier 2, indicating an acceptable risk to soil organisms.

PEC/PNEC ratios >1 were calculated for the storage of treated wood for UC 4, tier 2, if the DT_{50} of 5.7 days is taken into account and for storage, tier 2, use class 3 and 4, if the DT_{50} of 171.3 days is taken into account. The calculated risk to the local soil compartment under and around the storage areas within industrial wood treatment sites is not acceptable and emissions from the storage place to the soil compartment have to be substantially reduced.

Therefore it is proposed to reduce the risk to acceptable levels by restricting the storage of industrial treated wood to areas under roof and/or on impermeable hard standing in order to prevent direct losses to soil and allow the recovery of the losses for recycling or appropriate disposal.

Persistence in soil:

No field soil studies are available for Cu-HDO.

In a laboratory soil degradation study according to OECD test guideline 307 Cu-HDO showed a DT_{50} value for degradation of 2.4 days at 21.9°C and a DT_{90} value of 62 days at the same temperature. Conversion to standard European conditions gives a DT_{50} value of 5.7 days at 12°C. Thereby the trigger value of >6 months at 20°C is not met.

If, because of the analytical shortcomings of the soil degradation study, the DT_{50} value for mineralization of 77.6 days at 21.9°C is used to determine the persistence in soil, the trigger value of >6 months at 20°C is not met either.

The highest percentage of non-extractable residues formation starting with 40% AR after day 1 appeared in the clay loam soil. This percentage declined gradually after day 10 to around 22% AR after day120. For mineralization a mean DT_{50} of 77.6 days at 21.9°C was determined. Therefore the trigger values of non-extractable residues >70% of the initial dose after 100 days in a combination with a mineralisation rat <5% in 100 days aren't met.

The consequences or effects on non-target soil organisms have been assessed in the risk assessment above and are acceptable for all relevant scenarios. For the storage scenario the risk is reduced to acceptable values if RMM are applied.

Being an inorganic compound, the persistence criteria of DT90, field <1 year and DT50 at 20°C <6 months that are laid down in paragraph 85 of Annex VI to the Biocides Directive and in the TNsG on Annex I inclusion are not applicable to copper (II) oxide. According to the latter, the degradation triggers do not necessarily apply if the active substance is included in Annex I with regard to areas of use where a long lasting service-life of the treated material is essential and it is scientifically demonstrated that under field conditions there is no unacceptable accumulation in soil (e.g. that the PEC/PNEC <1 in soil during storage and the service-life of the treated article) (AR, France, 2011).

Similarly, an active substance containing a metal or a semi-metal element shall not be included in annex I if the use will cause significant accumulation above the natural background levels.
Reference is made to chapter "Persistence in Sediment" for the comparison of the predicted environmental concentrations for copper stemming from Cu-HDO (estimation: 100%, equimolar basis) for the highest PECs in the environmental compartments to the background values (cf. Table 2.2.2.5-4).

Conclusion:

It was shown that the use of Cu-HDO will not cause a significant accumulation of copper above the natural background levels in soils.
On the basis of the available data on Cu-HDO and of the comparison of predicted worst case copper concentrations with natural background levels Cu-HDO is not persistent in soil .

Non compartment specific effects relevant to the food chain (secondary poisoning):

There is a negligible risk of accumulation in the food chain according to the low BCF of Cu-HDO in fish and earthworms; secondary poisoning can be excluded.

According to the VRAR (ECHA, 2008)[10] the potential for secondary poisoning was investigated for copper and selected copper compounds and it was concluded that, due to copper homeostasis, there was no concern for secondary poisoning.

In line with this finding the final AR on Basic Copper Carbonate (France, 2011) concludes that copper is an essential micronutrient, well regulated in all living organisms.

In the aquatic environment, homeostatic regulation of invertebrates and fish resulted in an inverse relationship between copper BCFs and concentrations in the water. The importance of such homeostasis regulation was recognised in the regulatory framework of aquatic hazard classification (OECD, 2001 cited in AR, France, 2011). Similarly, in terrestrial plants, copper BCFs were inversely related to copper levels in soils. In higher organisms, dietary copper exposure studies in mammals and humans have shown that the intestinal adsorption / biliary excretion of copper is regulated with varying dietary intakes. Research indeed demon-strated that copper adsorption in humans can vary between 11 and 75 %, depending on the dietary intake. Similarly, mammals and birds, can rely on intestinal adsorption and biliary excretion to maintain internal copper levels with large variation in dietary intakes (AR, France, 2011)Therefore bioaccumulation and biomagnification phenomenons are considered as not applicable for copper.

2.2.2. List of endpoints

In order to facilitate the work of Member States in granting or reviewing authorisations, the most important endpoints, as identified during the evaluation process, are listed in Appendix I

3. PROPOSED DECISION

3.1. Background to the proposed Decision

The efficacy test results with the biocidal product indicate the fungicidal and insecticidal effectiveness in preventive wood preservatives. The insecticidal efficacy of the representative biocidal product is based on the combination of two copper compounds (including Cu-HDO) and a boron compound. Cu-HDO contributes to the efficacy of the representative formulation by increasing the copper content and adding the HDO specific efficacy. The biocidal product containing Cu-HDO prevents the development of wood destroying organisms by contact or ingestion with no time delay..

Regarding the physic-chemical properites Cu-HDO is oxidising and it presents a danger of explosion when submitted to the effect of flame, but not when submitted to impact of friction. The liquid wood preservative formulation has only a low Cu-HDO content and is not likely to undergo exothermic decomposition or to display significant oxidising properties. No risk was identified for the physico chemical properties of Wolmanit CX.

10 http://echa.europa.eu/de/copper-voluntary-risk-assessment-reports

On the basis of the available toxicological data severe eye damage, local gastro-intestinal effects and harmful acute toxicity are the main concern for Cu-HDO. However due to the all in one production process exposure is usually possible only via the representative product which has severe skin and respiratory tract corrosion and eye damaging propterties. Risk assessment for the intended industrial uses and secondary exposure indicates an acceptable risk for human health.
The PBT assessment, based on the available data, showed that Cu-HDO is not P, nor B and T. Therefore Cu-HDO is neither a vPvB, nor a PBT substance.
In the environmental risk assessment no risk to the air compartment, to the aquatic compartment (STP, surface water) and groundwater as well as for secondary poisoning could be determined. For the terrestrial compartment a risk was identified concerning the exposure scearnrion storage for use class 3 and 4. Therefore approprioate risk mitigation measures are mandatory as listed in the following sections. Also risk mitigation measures to reduce emissions of application and storage (for vacuum pressure treatment) are necessary if surface water is used for drinking water in the vicinity of such facilities.
Concerning copper background levels Cu-HDO containing copper will not cause a significant accumulation above the natural background level for the proposed intended use in this CAR for the aquatic and terrestrial environmental compartments.
No specific test for potential endocrine disruption and no 2-generation study were carried out. However within the sub-acute, sub-chronic, chronic and carcinogenicity, developmental toxicity and mutagenicity studies there is no evidence for endocrine disruption or for CMR effects.

3.2. Proposed decision

The overall conclusion from the evaluation of Cu-HDO for use in product type 8 (wood preservatives), is that it may be possible to issue authorisations of products containing Cu-HDO in accordance with the conditions laid down in Article 5(1) b), c) and d) of Directive 98/8/EC.

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It is therefore appropriate to approve Cu-HDO as an active substance for use in biocidal products for product-type 8 (Wood Preservative), subject to the following specific conditions:

The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

Authorisations are subject to the following conditions:

1) For industrial users, safe operational procedures and appropriate organizational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.
2) Appropriate risk mitigation measures shall be taken to protect the terrestrial compartment. Labels and, where provided, safety data sheets of products authorised shall indicate that industrial application shall be conducted within a contained area or on impermeable hard standing with bunding, that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct

losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.

3.3. Elements to be taken into account when authorising products

3.3.1. For human health and/or environmental risks

(1) No analytical methods and no toxicological risk assessment for Cu-HDO contamination in food and feeding stuff were provided. Please be aware that the use of Cu-HDO treated wood composites was only evaluated for applications that do not lead to contact with food and feeding stuff and contamination thereof.

(2) Regarding analysis of Cu-HDO in water, validation should be reported for water intended for human consumption. The submitted study is considered sufficient for surface water. However the method should be refined with respect to the parametric value of Directive 98/83/EC (EU drinking water limit).

(3) At product authorisation stage refined analytical methods have to be submitted clarifying the deficiencies and ambiguities identified during evaluation. Especially, it is recommended to check at product authorization stage for the availability of improved analytical methods able to measure residues of Cu-HDO in soil.

(4) The tanks, containers and the technical apparatuses for the production of Cu-HDO must not be cleaned, except in an automated process where rinsing water will be collected and reused in the production process. Appropriate personal protective equipment including daily new gloves should be used. The reason for this is that the risk assessment for the production of Cu-HDO considered an industrial fully automated and closed system practically excluding direct exposure to workers and the environment.

(5) The waiving of the 2-generation study was accepted based on scientific arguments that are sufficiently high margin of exposure and no critical effects with respect to fertility in the available toxicity studies.

(6) For the terrestrial environment unacceptable risk has been identified following storage of treated wood on site. Therefore the treated wood has to be stored under roof or on impermeable hard standing in order to prevent direct losses to soil and any losses may be collected for reuse or disposal. Products can't be authorized unless data is submitted to demonstrate that the risk during application can be reduced to acceptable levels. These measures are also applicable if surface water is used for drinking water in the vicinity of wood treatment facilities.

(7) Exposure of farm animals via treated wood may happen when farm animals are chewing on fenceposts around paddocks. The respective risk results only acceptable in case not more than 5 g wood is taken up per day. Since this value is not substantiated by data, treated wood has to remain out of reach of livestock animals unless it can be shown, at product authorisation stage, that there is no

risk for farm animals and no risk with human dietary exposure to food from farm animals.

(8) According to the EU waste legislation waste from wood preservative products and application solutions are considered hazardous waste. Therefore, application solutions must be collected and reused or disposed of as hazardous waste and they must not be released to soil, surface water or any kind of sewer.

(9) An exposure and risk assessment for Copper stemming from Cu-HDO was not performed, because 94% of the total Copper in the product stems from Cu-salts and only 6% from Cu-HDO. At product authorisation a respective exposure/risk assessment should be performed for the product.

(10) The representative product Wolmanit CX is corrosive on the skin and eyes, but in use solutions are just irritant on skin and eye according to calculation rules for classification. Risk assessment for local effects, for primary and secondary exposure has to be refined at product authorisation stage according to the new guidance actually in progress.

(11) If necessary further information including a risk characterisation for ecotoxicological relevant metabolites in the terrestrial compartment should be provided.

3.3.2. For efficacy reasons

(1) Member States should be aware that the efficacy at the lowest concentration values indicated for Cu-HDO application-solutions are only sufficient to wood preservatives which also include other insecticides and fungicides. If not otherwise shown, products to be authorised should contain besides Cu-HDO other insecticides and/or fungicides, as intended.

(2) The efficacy of Cu-HDO against termites is indicated by a test conducted with the representative formulation. However, to support this label claim, data on a respective product are needed.

(3) At product authorizing stage the efficacy of the product against insects has to be demonstrated specifically

3.4. Requirement for further information

It is considered that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit the proposal for the approval of bis (*N*-cyclohexyl-diazenium-dioxy)-copper.

The conditions and restrictions proposed are considered reasonable, and no further information is required. However, regarding analysis of Cu-HDO in water, validation should be reported for water intended for human consumption. The submitted study is considered sufficient for surface water. Nevertheless the method should be refined with respect to the parametric value of Directive 98/83/EC (EU drinking water limit) and preferably submitted to the RMS AT at the lasted 6 months before the approval date.

3.5. Updating this Assessment Report

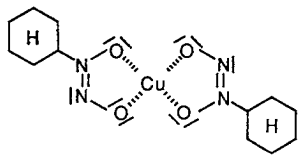
This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information submitted in relation with Regulation (EU) No 528/2012. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the approval of bis (*N*-cyclohexyl-diazenium-dioxy)-copper.

Appendix I: List of endpoints

Chapter 1: Identity, Physical and Chemical Properties, Classification and Labelling

Active substance	Cu-HDO
Product-type	PT 08 (wood preservatives)

Identity

Chemical name (IUPAC)	Bis(*N*-cyclohexyl-diazenium-dioxy)copper
Chemical name (CA)	Copper, bis[*N*-(hydroxy-κO)-*N*-(nitroso-κO)cyclohexanaminato]-
CAS No	312600-89-8
EC No	Not attributed
Other substance No.	---
Minimum purity of the active substance as manufactured (g/kg or g/l)	981 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	Confidential data and information
Molecular formula	C_{12} H_{22} Cu N_4 O_4
Molecular mass	349.9
Structural formula	

Physical and chemical properties

Melting point (state purity)	149°C
Boiling point (state purity)	Cu-HDO decomposes at 182 °C.
Temperature of decomposition	182°C
Appearance (state purity)	Blue crystalline solid, odourless
Relative density (state purity)	1.514 at 20°C
Surface tension	70.1 mN/m at 20°C
Vapour pressure (in Pa, state temperature)	< 0.000001 hPa at 20°C and at 50°C
Henry's law constant (Pa m^3 mol^{-1})	5.7 x 10^{-6} kPa m^3/mol
Solubility in water (g/l or mg/l, state temperature)	pH 4: 34.6 mg/L at 23°C
	pH 7: 6.1 mg/L at 23°C
	pH 9: 8.6 mg/L at 23°C
Solubility in organic solvents (in g/l or mg/l, state temperature)	n-octanol : 6100 mg/L at 25°C
	fat simulating medium : 4900 mg/L at 37°C

Stability in organic solvents used in biocidal products including relevant breakdown products	stable
Partition coefficient (log P_{OW}) (state temperature)	pH 6.1: log Pow = 2.6 at 25°C
Hydrolytic stability (DT_{50}) (state pH and temperature) (point VII.7.6.2.1)	pH___3___: stable at 25°C
	pH___7___: stable at 25 and 40°C
	pH___11___: stable at 40 and 50°C
Dissociation constant (not stated in Annex IIA or IIIA; additional data requirement from TNsG)	Not applicable
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	Structure is confirmed by all spectra. absorption maxima: E [1cm/1%] = 293 at 238 nm and 1.2 at 629 nm
Photostability (DT_{50}) (aqueous, sunlight, state pH) (point VII.7.6.2.2)	DT_{50} = 6 hours (aqueous, suntest CPS apparatus with Xenon lamp and UV filter to cut off wavelengths < 290 nm, pH 7)
Quantum yield of direct phototransformation in water at Σ > 290 nm (point VII.7.6.2.2)	Φ = 0.0276
Flammability	Not "highly flammable"
Explosive properties	not explosive

Classification and proposed labelling

with regard to physical/chemical data	<u>Directive 67/548/EEC</u> Classification: E; R2 O; R8 Labelling: E; O; R: 2-8 <u>Reg. 1272/2008/EC</u> Flam Sol 1 GHS 02 H228: Flammable Solid P210 Keep away from heat/sparks/open flames/hotsurfaces. — No smoking: P240 Ground/bond container and receiving equipment. P241 Use explosion-proof electrical/ventilating/lighting/…/equipment.
with regard to toxicological data	<u>Directive 67/548/EEC</u> Classification: Xn; R 22-41 Labelling: Xn; R: 22-41

	Reg. 1272/2008/EC Eye Dam 1 Acute Tox.4, STOT RE 2 H318: Causes serious eye damage H 302: Harmful if swallowed H 373 Causes damage to organs (gastrointestinal tract, liver, kidney) through prolonged or repeated exposure GHS 05/07/08 P280 - Wear protective gloves/protective clothing/eye protection/face protection. P264 - Wash thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P301 + P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. P314: Get medical advice/attention if you feel unwell. P330: Rinse mouth
with regard to fate and behaviour and ecotoxicological data	Directive 67/548/EEC N: dangerous for the environment R 50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. SCL: N; R50-53 = $C_n \geq 25\%$; N; R51-53 = $2.5\% \leq C_n < 25\%$; R52-53 = $0.25\% \leq C_n < 2.5\%$; Reg. 1272/2008/EC Aquatic Acute 1 (M=1) Aquatic Chronic 1 (M=1) H400 - Very toxic to aquatic life (classification) H410 - Very toxic to aquatic life with long lasting effects (classifica-tion and labelling) GHS 09 P273 – Avoid release to the environment P391 – Collect spillage

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method) (Annex IIA, point 4.1)	Colorimetric determination: Photometric detection at 425 nm after derivatisation with $FeCl_3$
Impurities in technical active substance (principle of method) (Annex IIA, point 4.1)	See confidential data and information of the CA-Report

Analytical methods for residues

Soil (principle of method and LOQ) (Annex IIA, point 4.2)	Digestion with aqua regia for subsequent determination of the acid soluble portion of metal according to DIN 38406 and DIN 38414 (AAS); The LOQ is 0.7 mg/kg Cu corresponding to 3.8 mg/kg Cu-HDO
Air (principle of method and LOQ) (Annex IIA, point 4.2)	Not evaluated - Not required for substances with a vapour pressure ≥0.01 Pa
Water (principle of method and LOQ) (Annex IIA, point 4.2)	RP-HPLC with UV/VIS-detection, λ = 229 nm LOD: 3 µg/L LOQ: 20 µg/L
Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2)	Not evaluated - only required where an active substance is classified as toxic or highly toxic, which isn't the case.
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not evaluated
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not evaluated

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	100% oral absorption based on urinary (78%) and bile (34%) excretion within 48 hours
Rate and extent of dermal absorption:	8% of applied dose (OECD TG 428: 9 human in vitro skin samples from 4 donors: 6.6 µg/cm^2 solution corresponding to 2% Wolmant CX solution, calculated for 10 hours, amount from 6 tape strips not included)
Distribution:	Throughout time course highest concentration in GI, liver and kidney
Potential for accumulation:	Terminal plasma half time = ca. 24 hours
Rate and extent of excretion:	Within 48 hours 78% via urine and 14% via feces, 34% in bile
Toxicologically significant metabolite(s)	Only glucuronide of free HDO was identified (58% of dose). Minor metabolites (<2.5% of dose) were not identified.

Acute toxicity

Rat LD_{50} oral	380 mg/kg
Rat LD_{50} dermal	>2500 mg/kg
Rat LC_{50} inhalation	No mortality after 8 h in a heavy dust atmosphere; limited reliability (Klimisch Code 3)
Skin irritation	Not irritating (rabbit)
Eye irritation	Severe damage to the eye (rabbit, solid Cu-HDO)
Skin sensitization (test method used and result)	Not sensitising (guinea pig maximization test)

Repeated dose toxicity

Species/ target / critical effect	Rat & dog / GI, liver, renals / irritation, cytotoxicity
Lowest relevant oral NOAEL / LOAEL	Rat, 28 days, NOAEL = 44 mg/kg bw day Rat, 3 months, NOAEL = 35 mg/kg bw day Dog, 3 months, NOAEL = 26 mg/kg mg/kg bw/day Rat, 12 months, NOAEL = 16 mg/kg bw/day
Lowest relevant dermal NOAEL / LOAEL	---
Lowest relevant inhalation NOAEL / LOAEL	---
Genotoxicity	No indications for genotoxicity: Bacterial mutation test, Unscheduled DNA synthesis with primary rat hepatocytes in vitro, Micronucleus assay in vivo

Carcinogenicity

Species/type of tumour	Rats / No oncogenic effects; NOAEL = 6 mg/kg bw/ day
lowest dose with tumours	---

Reproductive toxicity

Species/ Reproduction target / critical effect	No 2-generation study is available. The available repeated dose studies and the developmental toxicity studies do not indicate a concern for adverse effects on reproductive organs or functions.
Lowest relevant reproductive NOAEL / LOAEL	-
Species/Developmental target / critical effect	Rat: No developmental effects Rabbit: At 60 mg/kg bw increased resorption rate, increased postimplantation loss, reduced fetal body weights, increased occurrence of skeletal variations and 2 skeletal retardations (all at dose levels inducing maternally reduced food consumption and body weight gain)

Developmental toxicity	
Lowest relevant developmental NOAEL / LOAEL	Rat: Maternal NOAEL = 30 mg/kg based on transiently reduced food intake and transiently impaired body weight gain Developmental NOAEL = 100 mg/kg based on no effects up to the highest applied dose Rabbit: Maternal NOAEL = 10 mg/kg based on reduced food consumption and impaired body weight gain Developmental NOAEL = 10 mg/kg based on increased numbers of litters with skeletal variations.

Neurotoxicity / Delayed neurotoxicity

Species/ target/critical effect	Rat / Neurotoxicological investigations along a functional observation battery carried out in the scope of the subacute toxicity study in rats / No neurotoxic effects observed
Lowest relevant developmental NOAEL / LOAEL.	---

Other toxicological studies

Medical data

No poisoning incident reported

Summary (Annex IIA, point 6.10)	Value	Study	assessment factor
AEL short term	0.1 mg/kg bw/d	Rabbit developmental toxicity study	100
AEL medium term and long term	0.033 mg/kg bw/d	Rabbit developmental toxicity study	300
Drinking water limit	0.1 µg/l for Cu-HDO	98/83/EC	
Reference value for inhalation (proposed OEL)	100%		
Reference value for dermal absorption	8%		

Acceptable exposure scenarios (including method of calculation)

Professional users	
Production of active substance: Formulation of biocidal product	The risk from exposure by industrial manufacture within highly automated systems is acceptable.
Intended uses	

Secondary exposure	The risk from the following exposures is acceptable: o acute and chronic exposure by sanding and processing treated wood o acute and chronic exposure of adults and children inhaling volatilised substance from treated wood indoors o acute exposure of infant chewing treated wood chips o child playing on treated playground structure outdoors o infant playing on weathered structure No other scenarios were evaluated.
Non-professional users	Not relevant, since only industrial application
Indirect exposure as a result of use	---

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	pH 3 (25°C): stable (40°C): DT_{50} = 1087 h (55°C): DT_{50} = 305 h (70°C): DT_{50} = 60 h
	pH 7 (25°C): stable (40°C): stable (55°C): DT_{50} = 1449 h
	pH 11 (40°C): stable (50°C): stable
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	DT_{50} = 6 hours (aqueous, suntest CPS apparatus with Xenon lamp and UV filter to cut off wavelengths <290 nm, pH 7); Φ = 0.0276; Estimated photolysis rate constant k_p(1/d) = 0.1185 (pH 7); analysed metabolites: cyclohexanone and cyclohexanone oxime which further degraded to volatile degradation products of low molecular weight, e.g. carbon dioxide
Readily biodegradable (yes/no)	No; "not readily degradable"; < 10% biodegradation after 56 days; No; "not inherently biodegradable"; elimination: 100% after 17 days; 50% of this elimination took place within 2 hours (adsorption); DOC measurement; no abiotic control and therefore noevidence of biodegradation; (Modified Zahn –Wellens);
Biodegradation in a water/sediment system	DT_{50} dissipation, water phase 2.4 days (25°C); biphasic kinetic (FOMC) DT_{50} dissipation, sediment phase 20.3 days (25°C); first order kinetic (SFO) DT_{50} degradation, total system 14.5 days (25°C); first order kinetic (SFO)

	Conversion to standard conditions: DT_{50} dissipation, water phase 6.8 days (12°C) DT_{50} dissipation,sediment phase 57 days (12°C) DT_{50} degradation, total system 41 days (12°C)
Non-extractable residues	9.3%AR at day 0 and continually increase up to 44% at day 30 (end of study).
Distribution in water / sediment systems (active substance)	Water phase: 78.2%AR at day 0 5.5%AR at day 30 (end of study) Major component in the water phase was parent (75.4% TAR at day 0 and 2.8% TAR at day 30). Sediment phase: 25.9%AR at day 0 (16.6% TAR as extractable and 9.3%AR as non-extractable residues). The extractable radioactivity content in the sediment increased to 45.2% at day 10 and then decreased to 21.5% at day 30. Most of the extractable radioactivity was parent. The non-extractable residues continually increased up to 44% at day 30.
Distribution in water / sediment systems (metabolites)	A number of minor metabolites in water and in sediment; only metabolite identified is Cyclohexanone (4.3% in water and 2.2% in sediment); The only major metabolite found was CO_2 (13.2%) in the total system.

Route and rate of degradation in soil

Mineralization (aerobic)	51-61%AR after 120 days $DT_{50\ mineralization}$ (21.9°C, aerobic, days): 77.6 (geometric mean, n=4, FOMC) Converted to European standard conditions (12°C): 171.3 (geometric mean, n=4, FOMC)
Laboratory studies (range or median, with number of measurements, with regression coefficient)	$DT_{50lab\ dissipation}$ (21.9°C, aerobic, , days): 2.2 - 11 (geometric mean: 2.4, n=4, FOMC) Converted to European standard conditions (12°C, days): 5.7 (geometric mean, n=4, FOMC) For FOCUS groundwater modelling: DT50 (12°C, days): 41
	$DT_{90lab\ dissipation}$ (21.9°C, aerobic, , days): 21 - 104 (arithmetic mean: 62, n=4, FOMC)
Field studies (state location, range or median with number of measurements)	---
	---
Anaerobic degradation	---
Soil photolysis	---
Non-extractable residues	Max. 23-40%AR after 1-23 days (21.9°C, n=4)
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	Not determined Detected metabolites at day 1: Cyclohexene, Cyclohexanonoxime and Piperidine.
Soil accumulation and plateau concentration	---

Adsorption/desorption

K_{Fa} , K_{Fd} K_{Focads} , K_{Focdes}	Loamy sand: K_{Focads} = 32167 K_{Focdes} = 893081 Sand: K_{Focads} = 8739 K_{Focdes} = 33339 Loamy sand: K_{Focads} = 24884 K_{Focdes} = 133902 Sandy silt loam: K_{Focads} = 31655 K_{Focdes} = 133479 Clayey loam: K_{Focads} = 114910 Mean (geometric): K_{Focads} = 30277.4 K_{Focdes} = 151883.6

Fate and behaviour in air

Direct photolysis in air	---
Quantum yield of direct photolysis	---
Photo-oxidative degradation in air	with $c(OH)_{air}$ = 1.5 x 10^6 molecules/cm^{-3}: DT_{50} = 1.9 hours $k_{deg,\ air}$ (Cu-HDO) = 8.91 d^{-1} with $c(OH)_{air}$ = 5 x 10^5 molecules/cm^{-3}: DT_{50} = 5.6 hours $k_{deg,\ air}$ (Cu-HDO) = 2.97 d^{-1}

Volatilization	Volatilization potential is very low because of the low vapour pressure and the Henry constant

Monitoring data, if available

Soil (indicate location and type of study)	---
Surface water (indicate location and type of study)	---
Ground water (indicate location and type of study)	---
Air (indicate location and type of study)	---

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)

Species	Time-scale	Endpoint	Toxicity
Fish			
Oncorhynchus mykiss	96 h	Mortality	LC_{50} : 0.14 – 0.24 mg/L
Derived from the toxicity of Cu in the VRAR (ECHA, 2008) (on equimolar basis).			NOEC = 0.064 mg/L
Invertebrates			
Daphnia magna	48 h	Mortality	LC_{50} = 1.1 mg/L
Daphnia magna	21 days	Reproduction	NOEC = 0.75 mg/L
Algae			
Scenedesmus subspicatus	72 h	Growth rate	EC_{50} = 0.079 mg/L NOE_rC = 0.056 mg/L
Micro-organisms			
Activated sludge	180 min	Respiration inhibition	EC_{50} = 9 mg/L (nominal)
Sediment-dwelling organisms			
Chironomus riparius	—	—	—

Effects on earthworms or other soil non-target organisms

Acute toxicity to earthworms (*Eisenia fetida*)	Endpoint: mortality Duration: 14 days; NOEC: 250 mg/kg dry soil LC_{50}: 636 mg/kg dry soil Converted to standard soil: NOEC: 85 mg/kg dry soil LC_{50}: 216.24 mg/kg dry soil
Acute toxicity to plants (*Avena sativa*)	Endpoints: EC_{50} (mg/kg) NOEC (mg/kg) emergence rate >1000 ≥1000 dry matter >1000 = 250 fresh matter >1000 = 62.5 shoot length >1000 = 250 Duration: 15 days;
Acute toxicity to plants (*Brassica napus*)	Endpoints: EC_{50} (mg/kg) NOEC (mg/kg) emergence rate >1000 ≥1000 dry matter = 161 = 125 fresh matter = 202 = 62.5 shoot length = 496 = 125 Duration: 15 days;

Acute toxicity to plants (*Vicia sativa*)	Endpoints: EC_{50} (mg/kg) NOEC (mg/kg) emergence rate >1000 ≥1000 dry matter >1000 = 500 fresh matter >1000 = 125 shoot length >1000 = 125 Duration: 15 days;
Overall results for plants	NOEC: 62.5 mg/kg dry weight EC_{50}: 161 mg/kg dry weight Converted to standard soil: NOEC: 120.6 mg/kg EC_{50}: 311.0 mg/kg

Effects on soil micro-organisms

Nitrogen mineralization	NOEC ≥ 20 mg/kg dry soil (only 2 concentrations tested; 2 and 20 mg/kg dry soil); Converted to standard soil: NOEC: ≥ 28.8 mg/kg dry soil
Carbon mineralization	NOEC = 20 mg/kg dry soil (only 2 concentrations tested; 2 and 20 mg/kg dry soil); Converted to standard soil: NOEC = 28.8 mg/kg dry soil

Effects on terrestrial vertebrates

Acute toxicity to mammals	---
Acute toxicity to birds	---
Dietary toxicity to birds	---
Reproductive toxicity to birds	---

Effects on honeybees

Acute oral toxicity	---
Acute contact toxicity	---

Effects on other beneficial arthropods

Acute oral toxicity	---
Acute contact toxicity	---
Acute toxicity to	---

Bioconcentration

Bioconcentration factor (BCF)	BCF_{fish} = 32.36 L/kg_{ww}(calculated) $BCF_{earthworm}$ = 5.62 L/kg_{ww} (calculated)
Depration time (DT_{50}) (DT_{90})	---
Level of metabolites (%) in organisms accounting for >10 % of residues	---

Chapter 6: Other End Points

Appendix II: List of Intended Uses

Cu-HDO is intended to be used in the biocidal product Wolmanit CX (containing 3.5%w/w Cu-HDO) to be applied as wood preservative (product type 8) by vacuum pressure treatment. The category of users is designated as industrial users. The field of use envisaged covers the preservation of structural timber for interior and exterior use, timber with ground and water contact. Scope of application is the protection of wood against wood-destroying fungi including those causing soft-rot as well as insects, i.e. wood-boring beetles; sufficient efficacy data were provided to prove that.

Tests showing effectiveness against termites are only available with the biocidal product Wolmanit CX. For concentrations of Wolmanit CX which should be used to prevent against termites see footnote to table Appendix II-01.

In general, the test results show that lowest concentration values indicated for Cu-HDO and for treatment solutions are only sufficient to wood preservatives which also include other insecticides and fungicides.

The intended applications of the wood preservative product Wolmanit CX can be summarised as listed in table Appendix II-01.

Table Appendix II-01: Intended applications of the wood preservative product Wolmanit CX

	Formulation					Applied amount of Cu-HDO per treatment[a)]						Remarks
Use class	Type	Conc. of a.s. in product [g/kg]	Method	cycles / article	cycles / day	a.s. in application solution [g/L]		g a.s./m³ wood		g a.s./m² wood[b)]		
						Min.	Max.	Min.	Max.	Min.	Max.	
1	Water dilutable concentrate	35	Vacuum pressure	1	2	0.18	0.35	105	210	2.63	5.25	Preventive treatment
2		35		1	2	0.49	0.70	294	420	7.35	10.5	
3		35		1	2	0.49	0.70	294	420	7.35	10.5	
4		35		1	2	0.70	0.70	420	420	10.5	10.5	

a) For prevention against termites, the applied amount per treatment and the resulting retention concentrations should be raised as follows: use class 1 – 3: 1.9– 2.0 % Wolmanit CX in water (=11.4 to 12 kg Wolmanit CX /m³ wood). This corresponds to min 0.665 and max. 0.70 g a.s/L application solution; min. 400 and max. 420 g a.s./m³ wood; min. 10 and max. 10.5 g a.s./m² wood. For use class 4, the applied amount per treatment is the same as given in the table.

b) Conversion from g as/m^3 wood to g as/m^2 wood is based on the assumption that 1 m^3 wood corresponds to 40 m^2 wood.

Appendix III: List of studies

Data protection is claimed by the applicant in accordance with Article 12.1(c) (i) and (ii) of Council Directive 98/8/EC for all study reports marked "Y" in the "Data Protection Claimed" column of the table below. For studies marked Yes data protection is claimed under Article 12.1(c) (ii). These claims are based on information from the applicant. It is assumed that the relevant studies are not already protected in any other Member State of the European Union under existing national rules relating to biocidal products. It was however not possible to confirm the accuracy of this information.

List of studies for the active substance:

Section No / Reference No	Year	Title	Data Protection Claimed (Y/N)	Date of 1st submission	Owner
A 2.6	2004	Product identity and Composition of Bis- (N-Cyclohexyl-diazeniumdioxy)-copper, Dr. Wolman GmbH, BAS/04/1503, Germany, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
A 2.10.2	2005	Doc II-B 3.3.2 Predicted Environmental concentrations and environmental risk characterisation of Cu-HDO, Dr. Wolman GmbH, Wol 3101/2005, Germany, no GLP, unpublished	Y	February 2005	Dr. Wolman GmbH
A 3.1.1/01	2001	Physico-chemical properties of Bis-(N-Cyclohexyl-diazeniumdioxy)-copper, BASF AG, Germany, BASF Report 01L00056, GLP, unpublished	Y	March 2004	BASF SE
A 3.1.1/02	1999	Kalorimetrische Bestimmung der Schmelztemperatur, BASF AG, Germany, BASF Report 99 M 01618, no GLP, unpublished	Y	March 2004	BASF SE
A 3.2/01	1987	Vapor pressure of cyclohexyldiazenium oxide, BASF AG, Germany, BASF Report Bru 87.129, no GLP, unpublished	Y	March 2004	BASF SE
A 3.4/01	2002	Characterization of "Bis-(N-Cyclohexyl-diazeniumdioxy)-copper, BASF AG, Germany, BASF Report 02L00244, GLP, unpublished	Y	March 2004	BASF SE

A 3.4/02	2001	Characterization of "Bis-(N-Cyclohexyl-diazeniumdioxy)-copper before start of ecological studies, BASF AG, Germany, BASF Report 01L00055, GLP, unpublished	Y	March 2004	BASF SE
A 3.5	1992	Wasserlöslichkeit bei pH 4, pH 7 und 9 von Bis-(N-cyclohexyldiazeniumdioxy)-Kupfer, BASF AG, Germany, BASF Report 92.15.1, GLP, unpublished	Y	March 2004	BASF SE
A 3.6	1992	Dissoziationskonstante von Bis-(N-cyclohexyldiazenium-dioxy)-Kupfer, BASF AG, Germany, BASF Report 92.15.2, GLP, unpublished	Y	March 2004	BASF SE
A 3.7/01	1989	Solubility of bis-(N-Cyclohexyldiazenium-dioxy)-copper at 25°C in waterand octanol, BASF AG, Germany, BASF Report BRU 88.277, no GLP, unpublished	Y	March 2004	BASF SE
A 3.7/02	1992	Fettlöslichkeit von Bis(N-cyclohexyldiazeniumdioxy)-Kupfer bei 37°C, BASF AG, Germany, BASF Report 92.12.2, no GLP, unpublished	Y	March 2004	BASF SE
A 3.9	1989	Octanol-Wasser-Verteilungskoeffizient POW von Bis-(N-cyclohexyldiazeniumdioxy)-Kupfer bei 25 °C, BASF AG, Germany, BASF Report 88.276, no GLP, unpublished	Y	March 2004	BASF SE
A 3.11	2001	Evaluation of safety characteristics according to 92/69/EEC, annex A9-A17, BASF AG, Germany, BASF Report SIK 01/0223, GLP, unpublished	Y	March 2004	BASF SE
A 3.15	2013	Bericht über die Prüfung von “Cu-HDO” und Gutachtliche Stellungnahme Report 2.2-298/13, no GLP, unpublished	Y	October 2013	Dr. Wolman GmbH
A 4.1	2002	Validation of a Photometer method for the determination of Bis-(N-cyclohexyl-diazeniumdioxy)-copper ($Cu(HDO)_2$ in wood preservatives, Dr. Wolman GmbH, Germany, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH

A 4.2/01	2002	DIN 38414 and DIN 38406, Normausschuss Wasserwesen (NAW) im DIN Deutsches Institut für Normung e.V., 2002	N	March 2004	Publication
A 4.2/03	2004	Validation of an HPLC method for the determination of Bis-(N-Cylohexyl-diazeniumdioxy-copper) in surface water; BASF AG, GKA Analytik, Study No. 03L00272, March 18, 2004, GLP, unpublished,	Y	March 2004	BASF SE
A 5.3/01	1988	Bestimmung der Grenze der Wirksamkeit von LP 10458 gegenüber holzzerstörenden Basidiomyceten gemäß DIN EN 113 nach Auswaschbeanspruchung gemäß DIN EN 84 – BAM Berlin – 1988, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
A 5.3/02	1988	Bestimmung der Grenze der Wirksamkeit von LP 10458 gegenüber Coriolus versicolor gemäß DIN EN 113 nach Auswaschbeanspruchung gemäß DIN EN 84 – BAM Berlin – 1988, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
A 5.3/03	1988	Prüfung der moderfäulewidrigen Wirksamkeit von LP 10458. Bestimmung von Gewichtsverlusten nach Auswaschung der getränkten Kiefernsplintholz-Proben mit dem Vermiculit- und dem Erd-Eingrabe-Verfahren – BAM Berlin – 1988, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
A 5.3/04	1987	Giftwertbestimmung von Wolmanit CX gegenüber Eilarven des Hausbockkäfers gemäß DIN EN 47 nach Auswaschbeanspruchung des behandelten Holzes gemäß DIN EN 84 – BAM Berlin – 1987, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
A 5.3/05	2004	Composition of the formulation LP 10458 and Wolmanit CX used in the efficacy tests, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
A 5.3/06	1950	Wissenschaftliche Abhandlungen der deutschen Materialprüfungsanstalten, II. Folge, 1950, Heft 7, Ergebnisse einer vergleichenden Prüfung der insektentötenden Wirkung von Holzschutzmitteln. II. teil	N	March 2004	Public

A 6.1.1/01	1977	Report on the study of the acute oral toxicity of Cu-NCH in the rat, ZHT BASF AG, Germany, Report ck180681 BASF AG, department of toxicology, 1977, no GLP, un-published	Y	March 2004	BASF SE
A 6.1.1/02	1975	Report on the study of the acute oral toxicity of Cu-NCH in the rat, BASF AG, Germany, Report gl2206-1 BASF AG, no GLP, un-published	Y	March 2004	BASF SE
A 6.1.1/03	1975	Acute toxicity to rats of copper salt of NCH, Huntingdon Research Centre, division of Toxicology, BASF AG, 75/0075, no GLP; un-published	Y	March 2004	BASF SE
A 6.1.2	1975	Report on the study of the acute dermal toxicity of Cu-NCH in the rat, BASF AG, ck 180682, no GLP, unpublished	Y	March 2004	BASF SE
A 6.1.3	1975	Report on the study of the acute inhalation of Kupfer-NCH in rats (inhalation hazard test), Report 2206-5 BASF AG, Department of toxicology, no GLP, unpublished	Y	March 2004	BASF SE
A 6.1.4/01	1975	On the study of the acute dermal irritation/corrosion of Kupfer-NCH in the rabbit, Report ck220682 BASF AG, no GLP, unpublished	Y	March 2004	BASF SE
A 6.1.4/02	1975	Report on the Study of the acute eye irritation of Cu-NCH in the rabbit Report ck220681 BASF AG, no GLP; unpublished	Y	March 2004	BASF SE
A 6.1.5	1992	Report on the maximization test for the sensitising potential of Bis-(N-Cyclohexyldiazeniumdioxy)-Kupfer (Cu-HDO) in guinea pigs Report rr-gl:2566, BASF AG, GLP, unpublished	Y	March 2004	BASF SE
A 6.2/01	1993	Study on the Comparison of the adsorption and excretion of the potassium, copper and aluminium salt of 14-C-N Cyclohexyl-hydroxi-diazeniumoxide after oral, dermal and intravenous administration to Wistar rats, Report: 22B0638/896001, BASF AG, GLP, unpublished	Y	March 2004	BASF SE

A 6.2/02	2001	^{14}C-Cu-HDO Study of the Biokinetics in Rats, Report: 02B0881/006037, BASF AG, GLP, unpublished	Y	March 2004	BASF SE
A 6.2/03	2002	The Metabolism of ^{14}C-Cu-HDO in Rats, Report: 2002/1004467, BASF AG, GLP, unpublished	Y	March 2004	BASF SE
A 6.2/04	2006	^{14}C-Reg. No. 4041387 (Bis-(N-Cyclohexyldiazenium-dioxy)-copper) in Wolmanit CX (2% solution) Study of penetration through human skin in vitro, Experimental Toxicology and Ecology, BASF Aktiengesellschaft, 67056 Ludwigshafen, Germany, laboratory report number 52H0893/052242, unpublished	Y	May 2006	BASF SE
A 6.2/04-1	2004	A comparision between in vitro rat and human and in vivo rat skin absorption studies Human and Experimental Toxicology 23, 421-430	N	March 2004	published
A 6.3.1	1991a	Report on the limited study of the oral toxicity of Bis-(N-cyclohexyldiazenium-dioxy)-copper in rats after administration via the diet for 4 weeks, Report: 20C0124/88078, BASF AG, GLP, unpublished	Y	March 2004	BASF SE
A 6.4.1/01	1991b	Report on the study of the oral toxicity of Bis-(N-cyclohexyldiazeniumdioxy)-copper in rats, Report: 30C0679/89041, BASF AG, GLP, unpublished	Y	March 2004	BASF SE
A 6.4.1/02	1995	Subchronic oral toxicity study with Bis-(N-cyclohexyldiazeniumdioxy)-copper in beagle dogs, Report: 31D0141/92060, BASF AG, GLP, unpublished	Y	March 2004	BASF SE
A 6.5	1993	Report on the study of the chronic toxicity of Bis-(N-cyclohexyldiazeniumdioxy)-copper in rats, Report: 50C0679/89080, BASF AG, GLP, unpublished	Y	March 2004	BASF SE
A 6.6.1	1987	Report on the study of Cu-HDO in the AMES TEST: 40MO254/874050, BASF AG, no GLP, unpublished	Y	March 2004	BASF SE

A 6.6.3/01	1992	Rat hepatocyte DNA repair assay [UDS] in vitro: 81MO679/894495, BASF AG, GLP, unpublished	Y	March 2004	BASF SE
A 6.6.3/02	2005	Mutagenicity study of Xyligen LP 15671 in the mouse lymphoma forward mutation assay –in vitro-; Laboratory of Pharmacology and Toxicology KG, Hamburg, Germany; LPT No. 18342/04, unpublished	Y	March 2005	Dr.Wolman GmbH
A 6.6.4	1990	Micronucleus assay in bone marrow cells of the mouse with Bis-(N-Cyclohexyldiazeniumdioxy)-Kupfer: 26M0679/899010, Cytotest Cell Research GmbH, GLP, unpublished	Y	March 2004	BASF SE
A 6.7	1996	Carcinogenicity study with Bis-N-cyclohexyl-diazeniumdioxy)-copper in Wistar rats Administration in the diet for 24 months: 70C0679/89113, BASF AG, GLP, unpublished	Y	March 2004	BASF SE
A 6.8.1/01	1991	Study of the Prenatal Toxicity of BIS-(N-CYCLOHEXYL-DIAZENIUMDIOXY)-COPPER in rats after oral administration (gavage): 30R0679/89059, BASF AG, GLP, unpublished	Y	March 2004	BASF SE
A 6.8.1/02	1994	Study of the Prenatal Toxicity of BIS-(N-CYCLOHEXYL-DIAZENIUMDIOXY)-COPPER in rabbits after oral administration (gavage)administration (gavage): 40R0141/92031, BASF AG, GLP, unpublished	Y	March 2004	BASF SE
A 6.8.2/01	2007	A retrospective analysis of the added value of the rat two-generation reproductive toxicity study versus the rat subchronic toxicity study. Reproductive Toxicol 24: 103-113	N	Not applicable as no data protection claimed	published
A 6.8.2/02	2007	Strengths and limitations of using repeat-dose toxicity studies to predict effects on fertility. Reg.Tox.Pharm 48, 241-258	N	Not applicable as no data protection claimed	published
A 6.8.2/03	2003	Some aspects relating to the evaluation of the effects of chemicals on male fertility. Reg Toxicol Pharmacol 37: 356-369	N	Not applicable as no data protection claimed	published

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A 7.1.1.1.1	1993	Hydrolyse von Bis-(N-cyclohexyl-diazeniumdioxy)-Kupfer bei pH = 4, 7 und 9: Report: 92.15.3, BASF AG, GLP, unpublished	Y	March 2004	BASF SE
A 7.1.1.1.1/02	2005	Hydrolysis as a Function of pH and Temperature of Bis-(N-Cyclohexyl-diazeniumdioxy)-copper, Study No: 05L00057	Y	November 2005	BASF SE
A 7.1.1.1.2/01	1993	Thermal and photochemical degradation of wood preservatives, published in Fres. Envir. Bull., 2, (1993), 576-581	N	Not applicable as no data protection claimed	Publication
A 7.1.1.1.2/02	not indicated	Degradation of HDO in aqueous solutions exposed to UV radiation, Internal report, no GLP, unpublished	Y	March 2004	Dr.Wolman GmbH
A 7.1.1.1.2/03	2006	Aqueous photolysis of Cu-HDO [-U-14C]; BASF AG., Ludwigshafen, Germany; unpublished	Y	June 2006	BASF SE
A 7.1.1.2.1	2001	BIS-(N-CYCLOHEXYL-DIAZENIUMDIOXY)-COPPER, Determination of the Biodegradability in the Closed Bottle Test, Project No: 00/0801/23/1, BASF AG, GLP, unpublished	Y	March 2004	BASF SE
A 7.1.1.2.2	1993	Determination of the biodegradability or the Elimination of BIS-(N-CYCLOHEXYL-DIAZENIUMDIOXY)-COPPER, Cu-HDO in the Zahn-Wellens-Test: Report 92/1699/10/1, BASF AG, no GLP, unpublished	Y	March 2004	BASF SE
A 7.1.2.1.1	1980	Hydroxydiazeniumoxide (HDO) potassium salt – determination of the biological degradability in a long-term test, J-Nr: 63529, BASF Aktiengesellschaft, Ludwigshafen, no GLP, unpublished	Y	March 2004	BASF SE

A 7.1.2.2.2	2008	Aerobic aquatic metabolism of ^{14}C Cu-HDO; BASF Crop Protection, Research Triangle Park, North Carolina USA. BASF RegDoc 2008/7007202, unpublished and Addendum to Aerobic Metabolism of ^{14}C Cu-HDO (2010); Study 325744: Kinetic Evaluation - ^{14}C Formation for Cu-HDO (Aerobic Aquatic Metabolism) BASF Crop Corporation, Research Triangle Park, North Carolina RegDoc 2010/7003160	Y	August 2009	BASF SE
A 7.1.3	2006	Adsorption/desorption study with Cu-HDO according to OECD 106, Biochem agrar, Report no. 05 10 35 2028, 2006, GLP, unpublished,	Y	March 2006	Dr.Wolman GmbH
A 7.2.1	1994	Examinations concerning the degradation of HDO in soil, BASF AG, no GLP, unpublished	Y	March 2004	Dr.Wolman GmbH
A 7.2.2.1_01	1976	Verhalten von Tris-(N-nitroso-N-cyclohexyl-aminoxy)-aluminium-salz im Boden, Report 76/10021, BASF AG, Germany, no GLP, unpublished	Y	March 2004	BASF SE
A 7.2.2.1_02	2012	Transformation in Soil under aerobic conditions with radio labelled test substance. BASF SE, Germany, GLP, unpublished	Y	November 2012	BASF SE
A 7.2.2.1_02	2013	Amendment to the Report Transformation in Soil under aerobic conditions with radio labelled test substance. BASF SE, Germany, GLP, unpublished	Y	Mai 2013	BASF SE
A 7.2.3.2/01	1991	Adsorption and Desorption behaviour of Cu and HDO in three different soils, Report No: 312, no GLP, unpublished	Y	March 2004	Dr.Wolman GmbH
A 7.2.3.2/02	1992	Mobility of Active Ingredients from Wolmanit CX Pressure Treated Wood in soil – Lysimeter Test, Report No: 314, no GLP, unpublished	Y	March 2004	Dr.Wolman GmbH

A 7.4.1.1	1993	Acute toxicity study on the rainbow trout (Oncorhynchus mykiss Walbaum 1792) of Bis-(N-Cyclohexyldiazeniumdioxy)-kupfer in a static system (96 hours): Report 12 F0141/925032, BASF AG, GLP, unpublished	Y	March 2004	BASF SE
A 7.4.1.2	1992a	Determination of the acute toxicity of Bis-(N-Cyclohexyldiazeniumdioxy)-kupfer, Cu-HDO to the water flea Daphnia magna Strauss, Report 92/1699/50/1, BASF AG, GLP, unpublished	Y	March 2004	BASF SE
A 7.4.1.3	1993	Determination of the inhibitory effect of Bis-(N-Cyclohexyldiazeniumdioxy)-Kupfer, Cu-HDO on cell division of the green alga Scenedesmus subspicatus: Report 92/1699/60/1, BASF AG, GLP, unpublished	Y	March 2004	BASF SE
A 7.4.1.4	2001	Determination of the Inhibition of Oxygen Consumption by Activated Sludge in the Activated Sludge Respiration Inhibition test: Report 00/0801/08/2, BASF AG, GLP, unpublished	Y	March 2004	BASF SE
A 7.4.3.2/01	1996	Effects of water pH on copper toxicity to early life stages of the common carp (*Cyprinus carpio*). Environ Toxicol Chem, 15(3): 376-383.	N	March 2004	Public
A 7.4.3.2/02	1991	Copper toxicity to sperm, embryos and larvae of topsmelt *Atherinops affinis*, with notes on induced spawning. Mar Environ Res, 31: 17-35.	N	March 2004	Public
A 7.4.3.2/03	1977	Effect of exposure time and copper concentration on reproduction of the fathead minnow (*Pimephales promelas*). Water Res, 11: 1079-1083.	N	March 2004	Public
A 7.4.3.2/04	1988	Effects of copper on development of the fathead minnow, Pimephales promelas Rafinesque. Aquat Toxicol, 12: 107-124.	N	March 2004	Public
A 7.4.3.2/05	1968	Chronic toxicity of copper to fathead minnows (*Pimephales promelas*, Rafinesque). Water Res, 2:	N	March 2004	Public

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A 7.4.3.2/06	1969	Chronic toxicity of copper to fathead minnow *(Pimephales promelas*) in soft water. J Fish Res Board Can, 26: 2449-2457.	N	March 2004	Public
A 7.4.3.2/07	1978	Metal toxicity of embryos and larvae of eight species of freshwater fish-II: Copper. Bull Environ Contam Toxicol, 19: 608-616.	N	March 2004	Public
A 7.4.3.2/08	1979	Chronic effect of copper on the bluntnose minnow, *Pimephales notatus* (Rafinesque). Arch Environ Contam Toxicol, 8: 545-552.	N	March 2004	Public
A 7.4.3.2/09	1971	Effects of long-term exposures to copper on survival, growth, and reproduction of brook trout (*Salvelinus fontinalis*). J Fish Res Board Can, 28: 655-662.	N	March 2004	Public
A 7.4.3.2/10	1975	Chronic effects of copper on survival, growth, and reproduction of the bluegill (*Lepomis macrochirus*). Trans Am Fish Soc, 104: 353-358.	N	March 2004	Public
A 7.4.3.2/11	2005	N-Cyclohexyldiazeniumdioxy-potassium – juvenile growth test in the zebra fish (*Danio rerio*) in a flow through system (28 days), Laboratory for Wildlife and Fish Toxicology of Experimental Toxicology and Ecology, BASF AG, Germany, Report No. 44F0069/015137, unpublished	Y	November 2005	BASF SE
A 7.4.3.4	1992b	Determination of the chronic toxicity of Bis-(N-Cyclohexyldiazeniumdioxy)-Kupfer, Cu-HDO to the water flea Daphnia magna STRAUS: Report 92/1699/51/1, BASF AG, GLP, unpublished	Y	March 2004	BASF SE
A 7.5.1.1/01	2004a	Effects of Cu-HDO on the activity of soil microflora (Nitrogen transformation test), Report 04 10 35 2001 N, Biochem agrar, GLP, unpublished	Y	March 2004	Dr.Wolman GmbH
A 7.5.1.1/02	2004b	Effects of Cu-HDO on the activity of soil microflora (Carbon transformation test), Report 04 10 35 2001 C, Biochem agrar, GLP, unpublished	Y	March 2004	Dr.Wolman GmbH

A 7.5.1.2	1992	Effect of Cu-HDO on the Mortality of the Earthworm, Eisenia foetida: Report P92-E106, BASF AG, GLP, unpublished	Y	March 2004	BASF SE
A 7.5.1.3	2003	Wolmanit CX-LP 15172 - Determination of the effect on the emergence, growth and the observation of morphological changes of rice (Oryza sativa L.), Report 03/0050/65/1, Experimental Toxicology and Ecology, BASF AG, GLP, unpublished	Y	March 2004	Dr.Wolman GmbH
A 7.5.1.3/02	2006	Cu-HDO - Determination of the effect of chemicals on the emergence and growth of higher plants (oilseed rape (Brassica napus), oats (Avena sativa) and vetch (Vicia sativa)), Project No.: 65E0801/003018, Experimental Toxicology and Ecology, BASF Aktiengesellschaft, 67056 Ludwigshafen, Germany, GLP, unpublished	Y	February 2006	BASF SE

List of studies for the biocidal product

Section No / Reference No	Year	Title	Data Protection Claimed (Y/N)		Owner
B 2.2	2006	Extraction of Cu-HDO from Wolmanit CX solution with 1-Octanol	Y	March 2006	Dr. Wolman GmbH
B 3.1.1	2002	Odour, physical state and pH of Wolmanit CX-10, project No. U 8640, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 3.2	2003	Safety characteristics according to directive 92/69/EC, annex A9-A17, BASF AG, study No. SIK-Nr. 03/2303, GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 3.6	2002	Density – Wolmanit CX-10, Dr. Wolman GmbH, project No. U 8641, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 3.7/01	2003	Accelerated Storage Test by Heating – CIPAC MT 46 – Wolmanit CX-10, Dr. Wolman GmbH, Project No. UP 15467, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH

B 3.7/02	2002	Stability – Wolmanit CX-10, Dr. Wolman GmbH, Project No. U 8642, no GLP; unpublished	Y	March 2004	Dr. Wolman GmbH
B 3.8	2004	Schaumverhalten von Wolmanit CX-10 Lösungen, Dr. Wolman GmbH, Sept. 2004, no GLP, unpublished,	Y	March 2004	Dr. Wolman GmbH
B 3.10	2004	Determination of the surface tension of Wolmanit CX-10 according to EC Council Directive 92/69/EEC, A.5., Study No. 03 50 40 274, Biochem Karlsruhe, Labor für biologische und chemische Analytik GmbH, GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 3.11	2002	Viscosity – Wolmanit CX-10, Dr. Wolman GmbH, project No. U 8643, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 4.1/01	1999	Validation of an AAS method for determination of copper in wood preservatives, Dr. Wolman GmbH, 20.12.1999, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 4.1/03a	2005	Validation of an AAS method for the determination of boron in Wolmanit CX-10, Dr. Wolman GmbH, no GLP, unpublished	Y		Dr. Wolman GmbH
B 5.10.2/01	1994	Bestimmung der Grenze der Wirksamkeit von LP 11920 gegenüber holzzerstörenden Basidiomyceten gemäß DIN EN 113, Ausgabe Februar 1986, BAM Prüfungszeugnis 8.1/6170 A Ba, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 5.10.2/02	1994	Bestimmung der Grenze der Wirksamkeit von LP 11920 gegenüber holzzerstörenden Basidiomyceten gemäß DIN EN 113, Ausgabe Februar 1986 nach Auswaschbeanspruchung gemäß DIN EN 84, Ausgabe April 1990, BAM Prüfungszeugnis 8.1/6170 B Ba, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 5.10.2/03	1995	Bestimmung der Grenze der Wirksamkeit von LP 11920 gegenüber holzzerstörenden Basidiomyceten gemäß DIN EN 113, Ausgabe Februar 1986 nach Auswaschbeanspruchung gemäß DIN EN 84, Ausgabe April 1990, BAM Prüfungszeugnis 8.1/6170 E Ba, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH

B 5.10.2/04	1997	Determination of toxic values against wood-destroying fungi of Wolmanit CX-10, University of Gent, Study No. HT97-BT0320, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 5.10.2/05	1994	CIRAD, Département forestier CIRAD-Forêt, Laboratoire Préservation du Bois, Essai No. 1210, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 5.10.2/06	1997	Determination of toxic values against wood-destroying fungi of Wolmanit CX-10, University of Gent, Report No. HT97-BT0321, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 5.10.2/07	1992	Prüfung der moderfäulewidrigen Wirksamkeit von dem Produkt "LP 11920", BAM Prüfungszeugnis 8.1/6170-Mo, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 5.10.2/08	1995	Determination of toxic values against soft rotting micro-fungi and other soil inhabiting micro-organisms of Wolmanit LP 11920, University of Gent, report No. HT95-BT0510, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 5.10.2/09	1993	Giftwertbestimmung gegenüber Eilarven des Hausbockkäfers gemäß DIN EN 47, BAM Prüfungszeugnis 8.1/6170 Hb A, Bundesanstalt für Materialforschung und Prüfung, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 5.10.2/10	1993	Giftwertbestimmung gegenüber Eilarven des Hausbockkäfers gemäß DIN EN 47 nach vorausgegangener Auswaschbeanspruchung gemäß DIN EN 84, BAM Prüfungszeugnis 8.1/6170 Hb B, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 5.10.2/11	1993	Giftwertbestimmung gegenüber Eilarven des Hausbockkäfers gemäß DIN EN 47 nach Verdunstungsbeanspruchung gemäß DIN EN 73, BAM Prüfungszeugnis 8.1/6170 Hb C, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 5.10.2/12	1995	Determination du seuil d'efficacite contre reticulitermes santonensis, CTBA – Centre technique du bois et de l'ameublement, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH

B 5.10.2/13	2002	Rapport d'essai No : 01-16-EN 117, CIRAD – Forêt – Laboratoire de preservation, 30.9.2002, no GLP, unpublished,	Y	March 2004	Dr. Wolman GmbH
B 5.10.2/14	1993	Essai No. 1207 A, Laboratoire Pré-servation du Bois, no GLP, unpu-blished	Y	March 2004	Dr. Wolman GmbH
B 6.1.1	1994	Acute oral toxicity of Wolmanit CX-10" in rats, Austrian Research Centre Seibersdorf, OEFZS-A—2986, GLP, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 6.1.2	1994	Acute dermal toxicity of "Wolmanit CX-10" in rats, Research Centre Seibersdorf, Report No. OEFZS-A—2987, GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 6.1.3	2003	"Wolmanit CX-LP 15172" Acute Inhalation Toxicity in Rats, ARC Seibersdorf research GmbH, report No. Wol 66, GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 6.2/01	1994	Acute Dermal Irritation/Corrosion Study with "Wolmanit CX-10", Austrian Research Centre Seibers-dorf, report No. OEFZS-A—2988, GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 6.2/02	1994	Acute eye irritation/Corrosion study with "Wolmanit CX-10", Austrian Research Centre Seibersdorf, report No. OEFZS-A—2989, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 6.3	2004	Skin sensitisation study according to Bühler – "Wolmanit CX-LP 15172" -, BioChem, report No. 04 10 42 201, GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 6.5/01	2002	Material safety data sheet Mo-noethanolamin	Y	March 2004	Dr. Wolman GmbH
B 6.5/02	2002	Material safety data sheet Sokolan CP 10 S	Y	March 2004	Dr. Wolman GmbH
B 6.5/03	2002	Material safety data sheet Sebacic acid	Y	March 2004	Dr. Wolman GmbH
B 6.5/04	1998	Material safety data sheet Potassi-um Carbonate	Y	March 2004	Dr. Wolman GmbH
B 6.5/05	2002	Material safety data sheet Potassi-um hydroxide	Y	March 2004	Dr. Wolman GmbH
B 6.6	2006	Human exposure assessment for Cu-HDO based wood preservatives	Y		Dr. Wolman GmbH

B 6.6/01	2004	Estimation of the dermal exposure when using Wolmanit CX-10 in a vacuum-pressure treatment plant, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 6.6/02	1996	Air concentration measurements in working zones according to TRGS 402, Dr. Wolman GmbH, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 6.6/03	1991	Workplace related testing of aerial concentrations when using Wolmanit CX-S, Dr. Wolman GmbH, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 6.6/04	2002	Surface sampling and analysis for residues of Cu-HDO and copper from Wolmanit CX-10 treated wood by the wipe test, Dr. Wolman GmbH, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 6.6/05	1997	Raumluftkonzentrationsmessungen nach Anwendung von Wolmanit CX-H 200 behandelten Hölzern unter Praxisbedingungen im Innenraum, Dr. Wolman GmbH, Report No. Pm-Sz97016/scht, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 6.6/06	2005	Estimation of the dermal exposure when using Wolmanit CX-10 in a vacuum-pressure treatment plant – rest of body, unpublished, Ref. B 6.6/06	Y	November 2005	Dr. Wolman GmbH
B 7.1	2003	Leaching behaviour of Wolmanit CX treated timber, Dr. Wolman GmbH Sinzheim, Germany, Laboratory Project ID: 1410/2003, no GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 7.1/02	2005	Leaching behaviour of Wolmanit CX treated wood exposed in UC 4 and 5, Dr. Wolman GmbH, no GLP, unpublished	Y	November 2005	Dr. Wolman GmbH
B 7.1/03	2006	Predicted environmental concentrations and environmental risk characterisation of Cu-HDO	Y	December 2006	Dr. Wolman GmbH
B 7.5.1.1/01	1988a	Prüfung der biologischen Abbaubarkeit von Monoethanolamin im DOC-Abnahme (Die-Away) test, BASF AG DUU/OM-Z 570, no GLP, unpublished	Y	March 2004	BASF SE

B 7.5.1.1/02	1991	Prüfung der Atmungshemmung von Belebtschlamm von 2-Aminoethanol im Kurzzeitatmungs-test, BASF AG DUU/OM-Z 570, no GLP, unpublished,	Y	March 2004	BASF SE
B 7.5.1.1-03	1988b	Prüfung der biologischen Abbau-barkeit von Monoethanolamin im manometrischen Respirationstest, BASF AG DUU/OM-Z 570, no GLP, unpublished,	Y	March 2004	BASF SE
B 7.5.1.1-04	1988c	Prüfung der biologischen Abbau-barkeit von Monoethanolamin im CO2 Entwicklungs-test, BASF AG DUU/OM – Z 570, no GLP, unpub-lished	Y	March 2004	BASF SE
B 7.5.1.3	2003	Wolmanit CX-LP 15172-Determination of the effect on the emergence, growth and the obser-vation of morphological changes of rice (Oryza sativa L.) Report No. 03/0050/65/1, BASF, Experimental Toxicology and Ecology, GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 7.7.1.1/01	2003	Wolmanit CX-LP 15172: Acute toxicity study for Zebra fish, Report No. ARC-UL-0908, Austrian Rese-arch Centers Seibersdorf, GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 7.7.1.1/02	2003	Wolmanit CX-LP 15172: Acute Toxicity Study for Daphnia magna, Report No. ARC-UL-0909, Austri-an Research Centers Seibersdorf, GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 7.7.1.1/03	2003	Wolmanit CX-LP 15172: Alga (Selenestrum capricornutum) Growth Inhibition Test, Report No. ARC—UL-0812, GLP, unpublis-hed	Y	March 2004	Dr. Wolman GmbH
B 7.7.1.1/04	2003	Wolmanit CX-LP 15172: Activated Sludge Respiration Inhibition Test, Report No. ARC—UL-0776, GLP, unpublished,	Y	March 2004	Dr. Wolman GmbH
B 7.8.6	2003	Wolmanit CX-LP 15172-Determination of the effect on the emergence, growth and the obser-vation of morphological changes of rice (*Oryza sativa L.*) Report No. 03/0050/65/1, BASF, Experimental Toxicology and Ecology, GLP, unpublished	Y	March 2004	Dr. Wolman GmbH
B 9	2004	Safety Data Sheet of Wolmanit CX	Y	March 2004	Dr. Wolman GmbH

Appendix IV-1: Standard terms and abbreviations

Note: The technical terms “active ingredient” and “active substance” are equivalent

Stand. term / Abbreviation	**Explanation**
4’-OH	4’-hydroxybis (N-cyclohexyl-diazenium-dioxy)-copper
α-CO	2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzoate (metabolite)
ACh	acetylcholine
AChE	acetylcholinesterase
ADI	acceptable daily intake
ADME	administration distribution metabolism and excretion
ADP	adenosine diphosphate
ai	active ingredient
ALT	alanine aminotransferase (SGPT)
AOEL	acceptable operator exposure level
ANOVA	analysis of variance
approx	approximate
ARfD	acute reference dose
as	active substance
AST	aspartate aminotransferase (SGOT)
ASV	air saturation value
ATP	adenosine triphosphate
BAF	bioaccumulation factor
BCF	bioconcentration factor
BOD	biological oxygen demand
BPD	Biocidal Products Directive
BUN	blood urea nitrogen
bw	body weight

Stand. term / Abbreviation	**Explanation**
ca.	circa
CAR	Competant Authority Report
CEC	cation exchange capacity
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CL	confidence limits
cm	centimetre
COD	chemical oxygen demand
CPK	creatinine phosphatase
cv	coefficient of variation
d	day(s)
DES	diethylstilboestrol
DIS	draft international standard *(ISO)*
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic acid
DO	dissolved oxygen
DOC	dissolved organic carbon
dpi	days post inoculation
$DT_{50(lab)}$	period required for 50 percent dissipation (under laboratory conditions)
$DT_{90(lab)}$	period required for 50 percent dissipation (under laboratory conditions)
dw	dry weight
DWQG	drinking water quality guide-

Stand. term / Abbreviation	**Explanation**
c	centi- (x 10^{-2})
°C	degrees Celsius (centigrade)
E_bC_{50}	Medien affective concentration, growth rate
E_rC_{50}	Median effective concentration, biomass
EINECS	European inventory of existing commercial substances
ELINCS	European list of notified chemical substances
e-mail	electronic mail
EMDI	estimated maximum daily intake
EN	European norm
EUSES	European Union system for the evaluation of substances
F f	field female
F_0	parental generation
F_1	filial generation, first
F_2	filial generation, second
FELS	fish early-life stage
FID	flame ionisation detector
F_{mol}	fractional equivalent of the metabolite´s molecular weight compared to the active substance
FOB	functional observation battery
f_{oc}	organic carbon factor (compartment dependent)
fp	freezing point
FPD	flame photometric detector
g	gram(s)

Stand. term / Abbreviation	**Explanation**
	lines
ε	decadic molar extinction coefficient
EC_{50}	median effective concentration
FOMC	First Order Multi Compartment
GSH	glutathione
GV	granulosevirus
h	hour(s)
H	Henry's Law constant (calculated as a unitless value)
ha	hectare(s)
Hb	haemoglobin
HCG	human chorionic gonadotropin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography - mass spectrometry
HPPLC	high pressure planar liquid chromatography
HPTLC	high performance thin layer chromatography
HRGC	high resolution gas chromatography
H_S	Shannon-Weaver index
Ht	haematocrit
GEP	good experimental practice
GGT	gamma glutamyl transferase
GI	gastro-intestinal

Stand. term / Abbreviation	**Explanation**
GAP	good agricultural practice
GC	gas chromatography
GC-MS	gas chromatography-mass spectrometry
I_{50}	inhibitory dose, 50%
IC_{50}	median immobilisation concentration or median inhibitory concentration 1
ID	ionisation detector
im	intramuscular
inh	inhalation
ip	intraperitoneal
IR	infrared
ISSN	international standard serial number
IUCLID	International Uniform Chemical Information Database
iv	intravenous
k *(in combination)*	kilo
k	rate constant for degradation
K	Kelvin
Ka	acid dissociation constant
Kb	base dissociation constant
K_{ads}	adsorption constant
K_{des}	apparent desorption coefficient
kg	kilogram
K_{oc}	organic carbon adsorption coefficient
K_{om}	organic matter adsorption coefficient

Stand. term / Abbreviation	**Explanation**
GIT	gastro-intestinal tract
GLC	gas liquid chromatography
GLP	good laboratory practice
LC	liquid chromatography
LC-MS	liquid chromatography- mass spectrometry
LC_{50}	lethal concentration, median
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
ln	natural logarithm
LOAEC	lowest observable adverse effect concentration
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
log	logarithm to the base 10
LOQ	limit of quantification (determination)
LPLC	low pressure liquid chromatography
LSC	liquid scintillation counting or counter
LSD	least squared denominator multiple range test
LSS	liquid scintillation spectrometry
m	metre or male (depending on context)
m^2	square metre

Stand. term / Abbreviation	**Explanation**
K_{ow}	octanol-water partition coefficient
Kp	solid-water partition coefficient
kPa	kilopascal(s)
l, L	litre
MAC	maximum allowable concentration
MAK	maximum allowable concentration
MC	moisture content
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
MDL	method detection limit
MFO	mixed function oxidase
µg	microgram
mg	milligram
MHC	moisture holding capacity
min	minute(s)
mL	millilitre
mm	millimetre
MMAD	mass median aerodynamic diameter
MOE	margin of exposure
mol	mole(s)
MOS	margin of safety
MRE	maximum residue expected
MRL	maximum residue level or limit
mRNA	messenger ribonucleic acid
MS	mass spectrometry

Stand. term / Abbreviation	**Explanation**
m^3	cubic metre
M	molar
µm	micrometre (micron)
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOE_rC	no observed effect concentration, growth rate
NOED	no observed effect dose
NOEL	no observed effect level
NR	not reported
NTE	neurotoxic target esterase
OC	organic carbon content
OH	hydroxide
OM	organic matter content
Pa	pascal
2-PAM	2-pralidoxime
PCV	haematocrit (packed corpuscular volume)
PEC	predicted environmental concentration
PED	plasma-emissions-detector
pH	pH-value
pKa	negative logarithm (to the base 10) of the acid dissociation constant
PNEC	predicted no effect concentration (compartment to be added as subscript)
ppb	parts per billion (10^{-9})
PPE	personal protective equipment
ppm	parts per million (10^{-6})

Stand. term / Abbreviation	**Explanation**
MSDS	material safety data sheet
MW	molecular weight
n.a.	not applicable
n	number of observations
NAEL	no adverse effect level
nd	not detected
NOE_bC	No observed effect concentration, biomass
NMR	nuclear magnetic resonance
no, n°	number
r^2	coefficient of determination
RA	risk assessment
RBC	red blood cell
RfD	reference dose
RL_{50}	median residual lifetime
RNA	ribonucleic acid
RP-HPLC	reversed-phase high pressure liquid chromatography
rRNA	ribosomal ribonucleic acid
RSD	relative standard deviation
s	second
SAP	serum alkaline phosphatase
SAR	structure/activity relationship
SD	standard deviation
se	standard error
SF	safety factor
SL	Soluble concentrate
SOP	standard operating procedures
sp	species (only after a generic

Stand. term / Abbreviation	**Explanation**
PPP	plant protection product
PrT	prothrombin time
PT	product type
PTT	partial thromboplastin time
QA	quality assurance
QAU	quality assurance unit
(Q)SAR	quantitative structure-activity relationship
r	correlation coefficient
TGD	Technical guidance document
TER	toxicity exposure ratio
TER_I	toxicity exposure ratio for initial exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
tert	tertiary (in a chemical name)
TLC	thin layer chromatography
TMDI	theoretical maximum daily intake
TNsG	technical notes for guidance
TOC	total organic carbon
tRNA	transfer ribonucleic acid
TSH	thyroid stimulating hormone (thyrotropin)
TTC	2,3,5-triphenylterazoliumchloride testing method
TWA	time weighted average
UDS	unscheduled DNA synthesis
UC	Use class
UV	ultraviolet
v/v	volume ratio (volume per volume)
vis	visible
WBC	white blood cell

Stand. term / Abbreviation	**Explanation**
	name)
SPE	solid phase extraction
SPF	specific pathogen free
spp	subspecies
STP	sewage treatment plant
t	tonne(s) (metric ton)
$t_{½}$	half-life (define method of estimation)
T_3	tri-iodothyroxine
T_4	thyroxine
TG	technical guideline, technical group
VRAR	Voluntary Risk Assessment Report

Stand. term / Abbreviation	**Explanation**
wt	weight
w/v	weight per volume
ww	wet weight
w/w	weight per weight
XRFA	X-ray fluorescence analysis
yr	year
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to

Appendix IV-2: Abbreviations of organisation and publications

Abbreviation	**Explanation**
ASTM	American Society for Testing and Materials
BA	Biological Abstracts (Philadelphia)
BART	Beneficial Arthropod Registration Testing Group
BBA	German Federal Agency of Agriculture and Forestry
CA(S)	Chemical Abstracts (System)
CAS	Chemical Abstracts Service
CE	Council of Europe
CEC	Commission of the European Communities
CIPAC	Collaborative International Pesticides Analytical Council Ltd
DG	Directorate General
DIN	German Institute for Standardisation
EC	European Commission
ECB	European Chemicals Bureau
ECCO	European Commission Co-ordination
ECE	Economic Commission for Europe
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances

Abbreviation	**Explanation**
EPA	Environmental Protection Agency
EU	European Union
FAO	Food and Agriculture Organization of the UN
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GIFAP	Groupement International des Associations Nationales de
IARC	International Agency for Research on Cancer
IATS	International Academy of Toxicological Science
IMO	International Maritime Organisation
ISO	International Organization for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
OECD	Organization for Economic Co-operation and Development
OPPTS	Office of Prevention, Pesticides and Toxic Substances (US EPA)
RIVM	Netherlands National Institute of Public Health and Environmental Protection
SETAC	Society of Environmental Toxicology and Chemistry
UBA	German Environmental Protection Agency
UN	United Nations
WHO	World Health Organization