Section A2 Identity of Active Substance
IUCLID: 1.1.1 A2.1 – A2.9, copper (II) oxide

Subsection (Annex Point)			Official use only
2.1	**Common name (IIA2.1)**	Cupric oxide	
2.2	**Chemical name (IIA2.2)**	Copper II oxide	
2.3	**Manufacturer´s development code number(s) (IIA2.3)**	None.	
2.4	**CAS No and EC numbers (IIA2.4)**	Non-entry field	
2.4.1	**CAS-No**	*If relevant CAS-No. for mixture of isomers* 1317-38-0	
	Isomer 1	Not applicable	
	Isomer n	Not applicable	
2.4.2	**EC-No**	*EINECS, ELINCS or No longer polymer-No.* 215-269-1	
	Isomer 1	Not applicable	
	Isomer n	Not applicable	
2.4.3	**Other**	*If possible give registration numbers of other institutions, e.g. CIPAC* The CIPAC code number for copper compounds is 45.	X
2.5	**Molecular and structural formula, molecular mass (IIA2.5)**	Non-entry field	
2.5.1	**Molecular formula**	*according to Hill or CAS system* CuO	
2.5.2	**Structural formula**	Cu=O	
2.5.3	**Molecular mass**	*Give molecular mass of a.s. in g/mol* 79.55	
2.6	**Method of manufacture of the active substance (IIA2.1)**	*Short description of the used method* [redacted]	X

Section A2 Identity of Active Substance
IUCLID: 1.1.1 A2.1 – A2.9, copper (II) oxide

[redacted]

x

≥ 780 g/kg as copper	g/l	≥ 78 % w/w as copper	% v/v

See separate standard format.

Give maximum content of active isomer and ratio isomer/diastereomers if relevant

Not applicable.

Copper is obtained from reclaimed/recycled sources, e.g. scrap metal, industrial residues containing copper, spent etchant from the electronics industry.

substance or the precursor(s) of the active substance (IIA2.9)

	Evaluation by Competent Authorities Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.1 Melting point, boiling point, relative density (IIA3.1)								
3.1.1 Melting point **IUCLID: 2.1**			**result:** 1326°C			(0) Reliability cannot be assigned because no Experimental test data has been submitted.	Lide, D.R. (2003). CRC Handbook of Chemistry and Physics. 84th Edition. CRC Press.	
3.1.2 Boiling point **IUCLID: 2.2**				Not required, as boiling point will occur at temperatures greater than 360₀C, based on melting point.(T°f =1326°C)			TNG Data Waiver A3.1.2	
3.1.3 Bulk density/ relative density **IUCLID: 2.3**			**Bulk density:** $^{14}_{4}d = 6.315$	This value has been included because the bulk density value determined on the basis of EPA Guideline 63-7 relates to an ASTM method that is not compatible with EU			The Merck Index, Thirteenth Edition. Merck Research Laboratories.	

	ASTM D1429 standard methods, 16th edition, 213E, specific gravity/density EPA Guideline 63 - 7	**purity:** [redacted] **pH:** neutral **stability:** Stable at room temperature	**bulk density:** 1.56g/cm3 test temperature: 25oC relative density: 1.018 Test temperature: 20oC	requirements.	Y	(1) valid without restriction	[redacted] (1992). Physical and chemical characteristics. Toxikon Corporation. Report No. 91-GR-0028 (unpublished).	
3.2 Vapour pressure **(IIA3.2)** **IUCLID: 2.4**				It is not possible to determine a vapour pressure due to the high melting point (and hence high boiling point)of copper oxide.			TNG Data Waiver A3.2	
3.2.1 Henry´s Law Constant **(Pt. I-A3.2)** **IUCLID: 2.4**				Henry's Law Constant is not possible to calculate without a value for vapour pressure.			TNG Data Waiver A3.2.1	

3.3 Appearance (IIA3.3) **3.3.1 Physical state** **IUCLID: 1.1.1**	A description of the physical state was performed based on visual inspection at 25oC. Conducted in accordance with: EPA Guideline 63-3 A colour analysis was performed using the Munsell colour system neutral value scale. Using this scale, black is considered 0% reflectance and white as 100% reflectance.	**purity:** [redacted] **pH:** neutral **stability:** Stable at room temperature	Copper oxide was described as a powder at 25oC		Y	(1) valid without restriction	[redacted] (1992). Physical and chemical characteristics. Toxikon Corporation. Report No. 91-GR-0028 (unpublished).	
3.3.2 Colour **IUCLID: 1.1.1**	Conducted in accordance with: EPA Guideline 63-2 The determination of odour was made at room temperature. Conducted in accordance with: EPA Guideline 63-4	**purity:** [redacted] **pH:** neutral	Copper oxide was described as: dark grey, N= 2.6 / Reflectance = 4.55%.		Y	(1) valid without restriction	[redacted] (1992). Physical and chemical characteristics. Toxikon Corporation. Report No. 91-GR-0028 (unpublished).	
3.3.3 Odour		**purity:** [redacted]	Copper oxide was described		Y	(1) valid without	[redacted] (1992).	

IUCLID: 1.1.1		**pH:** neutral **stability:** Stable at room temperature	as having no characteristic odour.			restriction	Physical and chemical characteristics. Toxikon Corporation. Report No. 91-GR-0028 (unpublished)	
3.4 Absorption spectra **(IIA3.4)** **3.4.1 UV/VIS**	OECD Guideline 101 (1981)	**purity:** [redacted] **stability:** stable at room temperature	**Molar absorption coefficient ($dm^3.mol^{-1}.cm^{-1}$):** 170 **Medium:** Acidic (pH 1.2) **Wavelength:** 242 nm	Molarity of test solutions were calculated using a molecular weight of 79.55 $g.mol^{-1}$ An acidic test medium was used due to the negligible water solubility at neutral or alkaline Ph	Y	(1) valid without restriction	[redacted] (2004) Copper Oxide: Determination of general physicochemical properties. SafePharm Laboratories. Project No: 1645/006 (unpublished)	
3.4.2 IR **IUCLID: 1.1.2**	Copper Oxide (0.0014g) was mixed with ground potassium bromide (3.0138g) and an aliquot of this mixture (0.1772g) was scanned over the range 4000 to 600 cm^{-1} using potassium bromide as a reference.	**purity:** [redacted] **stability:** stable at room temperature	Copper Oxide showed no significant absorption in the IR region.		Y	(1) valid without restriction	[redacted] (2004) Copper Oxide: Determination of general physicochemical properties. SafePharm Laboratories. Project No: 1645/006	

	IR was performed using a Perkin-Elmer 1620 Fouriertransform infrarec spectrophotometer						(unpublished)	
3.4.3 NMR **IUCLID: 1.1.2** **3.4.4 MS** **IUCLID: 1.1.2**						Determination of NMR spectra is not applicable to Simple inorganic salts, such as copper oxide, which does not contain nuclei detected by standard Commercial NMR spectrometers, and is insoluble in the required solvents. Determination of MS spectra is not applicable to metals, as MS is the molecular	TNG Data Waiver A3.4.3 [redacted] (2004) Copper Oxide: Determination of general physicochemical properties. SafePharm Laboratories. Project No: 1645/006 (unpublished) TNG Data Waiver A3.4.4	

						fragmentation at certain energy levels. On this basis, MS analysis of copper oxidecannot be provided		
Subsection (Annex Point)	**Method**	**Purity/ Specification**	**Results** Give also data on test pressure, temperature, pH and concentration range if necessary	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
3.6 Dissociation constant (-) **IUCLID: 2.12**				Based on chemical composition, it is not possible to determine a dissociation constant for copper oxide in water.			TNG Data Waiver A3.6 [redacted] (2004) Copper Oxide: Determination of general physicochemical properties. SafePharm Laboratories. Project No: 1645/006 (unpublished)	

3.7 Solubility in organic solvents, including the effect of temperature on solubility (IIIA3.1) **IUCLID: 2.6.1**	A range of concentrations of the test substance in acetone were prepared and analysed by linear regression. The concentration at the point of zero turbidity is considered the saturation or solubility concentration. EPAGuideline 63-8	**purity:** [redacted] **pH:** neutral **stability:** Stable at room temperature	**result:** 0.269 mg/l of acetone **temperature:** 20oc **Result:** Solubility of copper in monoethanolamine = 3.07×10^{5} mg/l		Yes	(1) valid without restriction (4) not assignable	[redacted](1992).Physical andchemical characteristics. Toxikon Corporation. ReportNo. 91- GR-0028 (unpublished). Anonymous (2004) In house information from protim solignum	
3.8 Stability in organic solvents used in b.p. and identity of relevant breakdown products (IIIA3.2) IUCLID: 2.14				A determination of the stability in organic solvents is unnecessary, as the products in which copper oxide will be used are exclusively aqueous in nature and will not contain organic solvents.			TNG Data Waiver A3.8	

3.9 Partition coefficient n-octanol/water (IIA3.6) **IUCLID: 2.5**	Hansch, L.A. and Elkins, C., 1971. Partition coefficients and their uses. Chem Rev. 71: 525-616		**result:** 0.00000085 **temperature:** 20oC **pH:** 1.6	It is generally considered that the determination of octanol/water partition coefficients for copper from sparingly soluble salts is impractical for technical reasons. However, given the relatively high water solubility of copper sulphate, it has been possible to determine an octanol/water partition coefficient for copper using this salt.			Pirot, F., Panisset, F., Agache, P. and Humbert, P., 1996. Simultaneous absorption of copper and zinc through human skin in vitro. Influence of counter-ion and vehicle. Skin Pharmacol. 9: 43-52.	
3.10 Thermal stability, identity of relevant breakdown products (IIA3.7) **IUCLID: 2.14**				Based on high value for melting point (T°f = 1326°C)the determination of thermal stability is not justified.			TNG Data Waiver A3.10	
3.11 Flammability, including autoflammability and identity of combustion products (IIA3.8) **IUCLID: 2.9**				Based on chemical composition, a determination of flammability was not carried out, as this test could be predicted to give a negative result.			TNG Data Waiver A3.11 [redacted] (2004) Copper Oxide: Determination of general physicochemical properties.	

							SafePharm Laboratories. Project No: 1645/006 (unpublished)	
3.12 Flash-point (IIA3.9) **IUCLID: 2.7**				A Flash-point value was not determined, as this is not relevant to solid compounds, such as copper oxide.			TNG Data Waiver A3.12	
3.13 Surface tension (IIA3.10) **IUCLID: 2.6.2**				A determination of surface tension is not applicable, as copper oxide has a very low water solubility, i.e. less than 1 mg/l.			TNG Data Waiver A3.13	
3.14 Viscosity (-) **IUCLID: 2.13**				A determination of viscosity is not applicable to a solid, such as copper oxide.			TNG Data Waiver A3.14	
3.15 Explosive properties (IIA3.11) **IUCLID: 2.10**				Based on the chemical composition and experience in use, it is considered that this test would			TNG Data Waiver A3.15	

				give a negative result for copper oxide.				
3.16 Oxidizing properties (IIA3.12) **IUCLID: 2.11**	Information on the oxidizing and reducing potential of the test substance was obtained through knowledge of the chemistry of the test substance. The method described in 44 Federal Register 162767 (March 16, 1979) was used by exposing the test substance to an oxidizing agent (potassium permanganate) and a reducing agent (iron). EPA Guideline 63-14	**purity:** [redacted] **pH:** neutral **stability:** Stable at room temperature	Copper oxide showed no oxidizing properties.		Yes	(2) valid with restrictions	[redacted] (1992). Physical and chemical characteristics. Toxikon Corporation. Report No. 91-GR-0028 (unpublished).	
3.17 Reactivity towards container material (IIA3.13) **IUCLID: 8.8**	Corrosion characteristics were made using copper, aluminium and stainless steel. The test substance was placed in contact with the test	**purity:** [redacted] **pH:** neutral **stability:** Stable at room	No significant changes in weight or appearance were noted, therefore, it can be concluded that copper oxide does not have	Observations were carried out at 23°C and not 25°C.	Yes	(1) valid without restriction	[redacted] (1992). Physical and chemical characteristics. Toxikon Corporation. Report No. 91-GR-0028 (unpublished).	

	metals and weight differentials were used to determine the amount of corrosivity (if any) over a 30 day period at 23ₒC due to the test substance. EPA Guideline 63-20	temperature	corrosive properties to commercial packaging.					

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
Date	[redacted]
Materials and methods	[redacted]
Results	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A5 IUCLID: 7.1-7.5	**Effectiveness against target organisms and intended uses**	
Subsection (Annex Point)		**Official use only**
5.1 Function (IIA5.1)	[redacted]	
5.2 Organism(s) to be controlled and products, organisms or objects to be protected (IIA5.2)	[redacted]	
5.2.1 Organism(s) to be controlled (IIA5.2)	[redacted]	

Section A5 IUCLID: 7.1-7.5	Effectiveness against target organisms and intended uses	
	[redacted]	
5.2.2 Products, organisms or objects to be protected (IIA5.2)	[redacted]	
5.3 Effects on target organisms, and likely concentration at which the active substance will be used (IIA5.3)	[redacted]	

Section A5 IUCLID: 7.1-7.5	Effectiveness against target organisms and intended uses	
	[redacted]	
5.3.1 Effects on target organisms (IIA5.3)	[redacted]	
5.3.1.1 Wood-destroying basidiomycete fungi	[redacted]	
Section A5 IUCLID: 7.1-7.5	Effectiveness against target organisms and intended uses	

	[redacted]	
5.3.1.2 Soft rotting fungi	[redacted]	
5.3.1.3 Wood destroying	[redacted]	
Section A5 **IUCLID: 7.1-7.5**	**Effectiveness against target organisms and intended uses**	
insects	[redacted]	

	[redacted]	
5.3.1.4 Termites	[redacted]	
Section A5 IUCLID: 7.1-7.5	**Effectiveness against target organisms and intended uses**	

	[redacted]
5.3.2 Likely concentrations at which the A.S. will be used (IIA5.3)	[redacted]
5.3.2.1 PT08	[redacted]
5.4 Mode of action (including time delay) (IIA5.4)	[redacted]
5.4.1 Mode of action	[redacted]
Section A5 IUCLID: 7.1-7.5	**Effectiveness against target organisms and intended uses**

	[redacted]
5.4.2 Time delay	[redacted]
5.5 Field of use envisaged (IIA5.5)	[redacted]
5.5.1 MG02: Preservatives	[redacted]
5.6 User (IIA5.6)	[redacted]
5.6.1 Industrial	[redacted]
5.6.2 Professional	[redacted]
5.6.3 General public	[redacted]
5.7 Information on the occurrence or possible occurrence of the development of resistance and	[redacted]
Section A5 IUCLID: 7.1-7.5	**Effectiveness against target organisms and intended uses**
appropriate management strategies (IIA5.7)	

5.7.1 Development of resistance	[redacted]
5.7.2 Management strategies	[redacted]
5.8 Likely tonnage to be placed on the market per year (IIA5.8)	[redacted]

Section A5 IUCLID: 7.1-7.5	Effectiveness against target organisms and intended uses	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and methods	[redacted]	

Section A5 IUCLID: 7.1-7.5	Effectiveness against target organisms and intended uses

[redacted]

Section A5 IUCLID: 7.1-7.5	Effectiveness against target organisms and intended uses	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	
emarks	[redacted]	
	COMMENTS FROM ...	
Date	*Give date of comments submitted*	
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion.* *Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Reliability	*Discuss if deviating from view of rapporteur member state*	
Acceptability	*Discuss if deviating from view of rapporteur member state*	
Remarks		

[redacted]

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Table 5_2: Summary table of experimental data on the effectiveness of the active substance against target organisms at different fields of use envisaged, where applicable

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]				
[redacted]				
[redacted]				
[redacted]				

Section A5(1) Annex Point IIA V.5.1 – V.5.1.3	Efficacy Data (against wood-destroying Basidiomycete fungi and insects)	
	1 REFERENCE	Official use only
1.1 Reference	[redacted]	
1.2 Data protection	[redacted]	
1.2.1 Data owner	[redacted]	
1.2.2		
1.2.3 Criteria for data protection	[redacted]	
1.3 Guideline study	[redacted]	
1.4 Deviations	[redacted]	
	2 CONTENTS OF THE REVIEW	
2.1 Introduction	[redacted]	
2.2 Literature data	[redacted]	
2.2.1 'Initial toxicity' to wood-destroying basidiomycete fungi	[redacted]	

Section A5(1) Annex Point IIA V.5.1 – V.5.1.3	Efficacy Data (against wood-destroying Basidiomycete fungi and insects)	
	[redacted]	
2.2.2 'Initial toxicity' to wood-destroying insects	[redacted]	
2.2.3 Permanence of toxicity	[redacted]	
2.3 Results and discussion		
2.3.1 'Initial toxicity' to wood-destroying basidiomycete fungi	[redacted]	
2.3.2 'Initial toxicity' to wood-destroying insects	[redacted]	
2.3.3 Permanence of toxicity	[redacted]	
	3 APPLICANT'S SUMMARY AND CONCLUSION	
3.1 Summary of the review	[redacted]	X1

Section A5(1) **Annex Point IIA V.5.1 – V.5.1.3**	**Efficacy Data (against wood-destroying Basidiomycete fungi and insects)**	
	[redacted]	
3.2 Conclusion	[redacted]	
3.3 Reliability	[redacted]	
3.4 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	
Remarks	[redacted]	
	COMMENTS FROM	
Date	*Give date of the comments submitted*	
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*	
Results and discussion	*Discuss if deviating from view of rapporteur member state*	

Section A5(1) **Annex Point IIA V.5.1 – V.5.1.3**	**Efficacy Data (against wood-destroying Basidiomycete fungi and insects)**	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Reliability	*Discuss if deviating from view of rapporteur member state*	
Acceptability	*Discuss if deviating from view of rapporteur member state*	

[redacted]

[redacted]	[redacted]			
	[redacted]			[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

[redacted]	[redacted]	
	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[redacted]

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Section A5(2) Annex Point IIA V.5.1 – V.5.1.3	Efficacy Data (against wood-destroying Basidiomycetes)	
	1 REFERENCE	Official use only
1.1 Reference	[redacted]	
1.2 Data protection	[redacted]	
1.2.1 Data owner	[redacted]	
1.2.2		
1.2.3 Criteria for data protection	[redacted]	
1.3 Guideline study	[redacted]	
1.4 Deviations	[redacted]	
	2 CONTENTS OF THE REPORT	
2.1 Introduction	[redacted]	
2.2 Monograph toxic limit data	[redacted]	
2.3 Results and discussion	[redacted]	x
	3 APPLICANT'S SUMMARY AND CONCLUSION	
3.1 Summary of the	[redacted]	

review.

Section A5(2) **Annex Point IIA V.5.1 – V.5.1.3**	**Efficacy Data (against wood-destroying Basidiomycetes)**	
	[redacted]	
3.2 Conclusion	[redacted]	x x
3.3 Reliability	[redacted]	
3.4 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	
Remarks		

Section A5(2) **Annex Point IIA V.5.1 – V.5.1.3**	**Efficacy Data (against wood-destroying Basidiomycetes)**	
	COMMENTS FROM	
Date	*Give date of the comments submitted*	
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*	
Results and discussion	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Reliability	*Discuss if deviating from view of rapporteur member state*	
Acceptability	*Discuss if deviating from view of rapporteur member state*	

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Section A5(3) Annex Point IIA V.5.1 – V.5.1.3	**Efficacy Data (copper tolerance in wood-destroying fungi)**	
	1 REFERENCE	Official use only
1.1 Reference	[redacted]	
1.2 Data protection	[redacted]	
1.2.1 Data owner	[redacted]	
1.2.3 Criteria for data protection	[redacted]	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	[redacted]	
2.2 GLP	[redacted]	
2.3 Deviations	[redacted]	
	3 MATERIALS AND METHODS	
3.1 Test material		
3.1.1 Fungal Isolates	[redacted]	
3.1.2 Preservative solutions	[redacted]	
3.2 Test method		
3.2.1 Copper tolerance agar screening test	[redacted]	

Section A5(3) Annex Point IIA V.5.1 – V.5.1.3	Efficacy Data (copper tolerance in wood-destroying fungi)	
	[redacted]	
3.2.2 Standard laboratory test EN 113	[redacted]	
3.2.3 Electron paramagnetic resonance spectroscopy (EPR)	[redacted]	
	4 RESULTS AND DISCUSSION	
4.1 Screening test		
4.1.1 Copper (II) sulphate	[redacted]	
4.1.2 Copper amine preservative	[redacted]	
4.1.3 Chromated copper	[redacted]	

Section A5(3) Annex Point IIA V.5.1 – V.5.1.3	Efficacy Data (copper tolerance in wood-destroying fungi)	
borate	[redacted]	
4.1.4 Potassium dichromate	[redacted]	
4.2 Standard laboratory test (EN 113)	[redacted]	
4.3 Conclusions	[redacted]	

Section A5(3) Annex Point IIA V.5.1 – V.5.1.3	Efficacy Data (copper tolerance in wood-destroying fungi)	
	[redacted]	
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and	[redacted]	

	methods		
5.2	**Results and discussion**	[redacted]	

Section A5(3) **Annex Point IIA V.5.1 – V.5.1.3**	**Efficacy Data (copper tolerance in wood-destroying fungi)**	
	[redacted]	
5.3 Conclusion	[redacted]	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

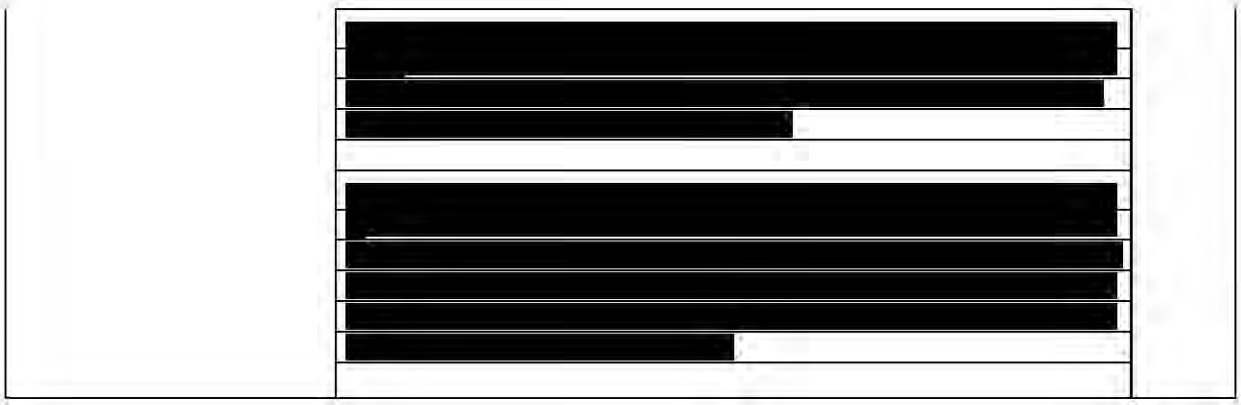
Copper carbonate

[redacted]

[redacted]

[redacted]

Section A5(4) Annex Point IIA V.5.1 – V.5.1.3	Efficacy Data (efficacy against soft rotting fungi)	
	1 REFERENCE	Official use only
1.1 Reference	[redacted]	
1.2 Data protection	[redacted]	
1.2.1 Data owner	[redacted]	
1.2.3 Criteria for data protection	[redacted]	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	[redacted]	
2.2 GLP	[redacted]	
2.3 Deviations	[redacted]	
	3 MATERIALS AND METHODS	
3.1 Test material		
3.1.1 Fungal Isolates	[redacted]	
3.1.2 Preservative solutions	[redacted]	
3.2 Test method	[redacted]	



Section A5(4) **Annex Point IIA V.5.1 – V.5.1.3**	**Efficacy Data (efficacy against soft rotting fungi)**	
	[redacted]	
	4 RESULTS AND DISCUSSION	
4.1 Screening test	[redacted]	
4.2 Conclusions	[redacted]	

Section A5(4) **Annex Point IIA V.5.1 – V.5.1.3**	**Efficacy Data (efficacy against soft rotting fungi)**	
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	[redacted]	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	

	EVALUATION BY RAPPORTEUR MEMBER STATE

Section A5(4) Annex Point IIA V.5.1 – V.5.1.3	**Efficacy Data (efficacy against soft rotting fungi)**	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	
Remarks		
	COMMENTS FROM	
Date	*Give date of the comments submitted*	
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*	
Results and discussion	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Reliability	*Discuss if deviating from view of rapporteur member state*	
Acceptability	*Discuss if deviating from view of rapporteur member state*	

Copper carbonate

[redacted]

[redacted]

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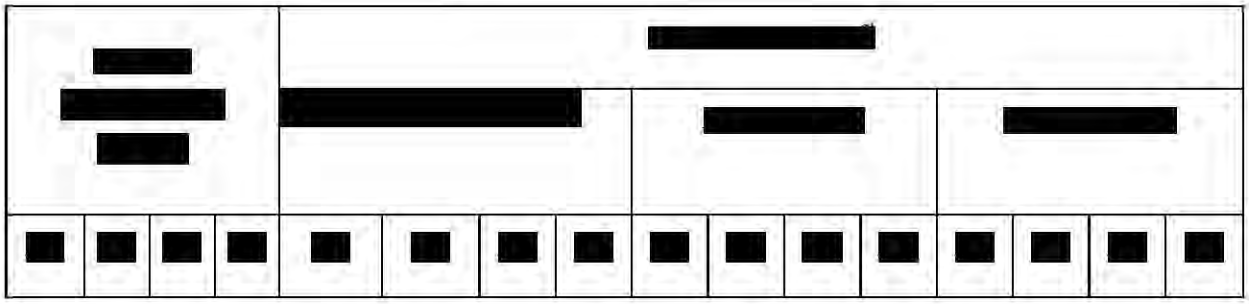
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]



[redacted]

Section A5(5) **Annex Point IIA V.5.1 – V.5.1.3**	**Efficacy Data (efficacy against soft rotting fungi)**	
	1 REFERENCE	Official use only
1.1 Reference	[redacted]	
1.2 Data protection	[redacted]	
1.2.1 Data owner	[redacted]	
1.2.3 Criteria for data protection	[redacted]	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	[redacted]	
2.2 GLP	[redacted]	
2.3 Deviations	[redacted]	
	3 MATERIALS AND METHODS	
3.1 Test materials		
3.1.1 Preservative materials	[redacted]	
3.1.2 Test organisms	[redacted]	
3.2 Test method	[redacted]	

Section A5(5) Annex Point IIA V.5.1 – V.5.1.3	Efficacy Data (efficacy against soft rotting fungi)	
	[redacted]	
	4 RESULTS AND DISCUSSION	
4.1 Surface colonisation of sawdust	[redacted]	
4.2 Quantitative decay data	[redacted]	
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and	[redacted]	

discussion	[redacted]

Section A5(5) **Annex Point IIA V.5.1 – V.5.1.3**	**Efficacy Data (efficacy against soft rotting fungi)**	
	[redacted]	
5.3 Conclusion	[redacted]	x
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	
Remarks	[redacted]	
	COMMENTS FROM	

Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers*

Section A5(5) **Annex Point IIA V.5.1 – V.5.1.3**	**Efficacy Data (efficacy against soft rotting fungi)**	
	and to applicant's summary and conclusion. *Discuss if deviating from view of rapporteur member state*	
Results and discussion	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Reliability	*Discuss if deviating from view of rapporteur member state*	
Acceptability	*Discuss if deviating from view of rapporteur member state*	

[redacted]

[redacted]	[redacted]	[redacted]			
		[redacted]			
		[redacted]	[redacted]	[redacted]	[redacted]
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	[redacted]	[redacted]			
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
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[redacted]	[redacted]	[redacted]			
		[redacted]			
		[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]			
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]				

Section A5(6) Annex Point IIA V.5.1 – V.5.1.3	Efficacy Data (efficacy against termites)	
	1 REFERENCE	Official use only
1.1 Reference	[redacted]	
1.2 Data protection	[redacted]	
1.2.1 Data owner	[redacted]	
1.2.3 Criteria for data protection	[redacted]	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	[redacted]	
2.2 GLP	[redacted]	
2.3 Deviations	[redacted]	
	3 MATERIALS AND METHODS	
3.1 Test material		
3.1.1 Preservative	[redacted]	
3.1.2 Termite test species	[redacted]	
3.1.3 Treated samples	[redacted]	

Section A5(6) Annex Point IIA V.5.1 – V.5.1.3	Efficacy Data (efficacy against termites)	
	[redacted]	
3.2 Test method	[redacted]	
	4 RESULTS AND DISCUSSION	
4.1 *Coptotermes formosanus* Tests	[redacted]	
4.1.1 Weight loss/visual rating	[redacted]	

Section A5(6) Annex Point IIA V.5.1 – V.5.1.3	Efficacy Data (efficacy against termites)	
4.1.2 Termite survival	[redacted]	
4.2 ***Reticulitermes flavipes*** **Tests**	[redacted]	
4.2.1 Weight loss/visual rating	[redacted]	
4.2.2 Termite survival	[redacted]	
4.3 Conclusions	[redacted]	
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	

Section A5(6) Annex Point IIA V.5.1 – V.5.1.3	Efficacy Data (efficacy against termites)	
	[redacted]	
5.2 Results and discussion	[redacted]	x
5.3 Conclusion	[redacted]	

Section A5(6) Annex Point IIA V.5.1 – V.5.1.3	Efficacy Data (efficacy against termites)	
	[redacted]	X x
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	
Remarks		
	COMMENTS FROM	
Date	*Give date of the comments submitted*	
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*	
Results and discussion	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	

Section A5(6) **Annex Point IIA V.5.1 – V.5.1.3**	**Efficacy Data (efficacy against termites)**	
	[redacted]	X x
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	
Remarks		
	COMMENTS FROM	
Date	*Give date of the comments submitted*	
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*	
Results and discussion	*Discuss if deviating from view of rapporteur member state*	

Conclusion	*Discuss if deviating from view of rapporteur member state*

Section A5(6) **Annex Point IIA V.5.1 – V.5.1.3**	**Efficacy Data (efficacy against termites)**	
Reliability	*Discuss if deviating from view of rapporteur member state*	
Acceptability	*Discuss if deviating from view of rapporteur member state*	

[redacted]

[redacted]

[redacted]

[redacted]

Section A5(7) Annex Point IIA V.5.1 – V.5.1.3	Efficacy Data (efficacy against wood-destroying fungi and insects)	
	1 REFERENCE	Official use only
1.1 Reference	[redacted]	
1.2 Data protection	[redacted]	
1.2.1 Data owner	[redacted]	
1.2.3 Criteria for data protection	[redacted]	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	[redacted]	X (1)
2.2 GLP	[redacted]	
2.3 Deviations	[redacted]	
	3 MATERIALS AND METHODS	
3.1 Basidiomycetes test according to EN 113	[redacted]	
3.2 Soft Rot Tests according to prENV 807	[redacted]	
3.3 Tests against *Hylotrupes bajulus*	[redacted]	

3.4 Tests against	[redacted]	
Section A5(7) **Annex Point IIA V.5.1 – V.5.1.3**	**Efficacy Data (efficacy against wood-destroying fungi and insects)**	
Termites	[redacted]	
	4 RESULTS AND DISCUSSION	
4.1 Basidiomycetes test according to EN 113	[redacted]	
4.2 Soft Rot Tests according to prENV 807	[redacted]	
4.3 Tests against *Hylotrupes bajulus*	[redacted]	
4.4 Tests against Termites	[redacted]	
4.5 Conclusions	[redacted]	
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	

Section A5(7) Annex Point IIA V.5.1 – V.5.1.3	Efficacy Data (efficacy against wood-destroying fungi and insects)	
	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	[redacted]	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	

Section A5(7) Annex Point IIA V.5.1 – V.5.1.3	**Efficacy Data (efficacy against wood-destroying fungi and insects)**	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	
Remarks	[redacted]	
	COMMENTS FROM	
Date	*Give date of the comments submitted*	
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*	
Results and discussion	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Reliability	*Discuss if deviating from view of rapporteur member state*	
Acceptability	*Discuss if deviating from view of rapporteur member state*	

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[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]

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[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]

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[redacted]	[redacted]	[redacted]			[redacted]
		[redacted]		[redacted]	
		[redacted]	[redacted]		
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]					
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Section A5.4.1 **Annex Point IIA V.5.4**	**Mode of Action (against wood-rotting fungi)**	
	1 REFERENCE	**Official use only**
1.1 Reference	[redacted]	
1.2 Data protection	[redacted]	
1.2.1 Data owner	[redacted]	
1.2.2		
1.2.3 Criteria for data protection	[redacted]	
1.3 Guideline study	[redacted]	
1.4 Deviations	[redacted]	
	2 CONTENTS OF THE REVIEW	
	[redacted]	
	3 APPLICANT'S SUMMARY AND CONCLUSION	
3.1 Summary of the review	[redacted]	
3.2 Reliability	[redacted]	
3.3 Conclusion	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	

Section A5.4.1 **Annex Point IIA V.5.4**	**Mode of Action (against wood-rotting fungi)**
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Section A5.4.1(2) Annex Point IIA V.5.4	Mode of Action (against termites)	
	1 REFERENCES	Official use only
1.1 References	[redacted]	
1.2 Data protection	[redacted]	
1.2.1 Data owner	[redacted]	
1.2.2		
1.2.3 Criteria for data protection	[redacted]	
1.3 Guideline study	[redacted]	
1.4 Deviations	[redacted]	
	2 REVIEW OF PUBLISHED LITERATURE	
	[redacted]	

Section A5.4.1(2) **Annex Point IIA V.5.4**	**Mode of Action (against termites)**	
	3 APPLICANT'S SUMMARY AND CONCLUSION	
3.1 Summary of the review	[redacted]	
3.2 Reliability	[redacted]	
3.3 Conclusion	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	
Remarks	[redacted]	
	COMMENTS FROM ... *(specij)*	
Date	*Give date of comments submitted*	
Comments	*Discuss if deviating from view of rapporteur member state*	
Summary and conclusion	*Discuss if deviating from view of rapporteur member state*	

Section A6.1.1 Acute Oral Toxicity in the Rat (LD_{50})

Annex Point IIA6.1.1	*Specify section no., heading, route and species as appropriate* *Specify type of test (Limit Test, LD_{50}, special investigation)*	
IUCLID: 5.1.1(01)	**A6.1.1(01), Acute Oral Toxicity**	
	1 REFERENCE	Official use only
1.1 Reference	*Author(s), year, title, laboratory name, laboratory report number, report date (if published, list journal name, volume: pages)* *If necessary, copy field and enter other reference(s).* [redacted] (2002) Cupric Oxide: Acute Oral Toxicity in the Rat – Acute Toxic Class Method. SafePharm Laboratories. Report No. 1645/001 (unpublished).	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* Wood Preservative Copper Taskforce	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on existing [a.s. / b.p.] for the purpose of its [entry into Annex I/IA / authorisation]	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes – the study was conducted according to the following test guideline: OECD Guidelines for the Testing of Chemicals No. 423 "Acute Oral Toxicity – Acute Toxic Class Method" (adopted 17 December 2001) *(If yes, give guidelines; if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2 GLP	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	X
2.3 Deviations	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	
	3 MATERIALS AND METHODS *In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.*	
3.1 Test material	Copper Oxide *or give name used in study report*	
3.1.1 Lot/Batch number	*List lot/batch number if available* Lot/Batch number: 02-0084	

Section A6.1.1 **Annex Point IIA6.1.1** **IUCLID: 5.1.1(01)**		**Acute Oral Toxicity in the Rat (LD_{50})** *Specify section no., heading, route and species as appropriate* *Specify type of test (Limit Test, LD_{50}, special investigation)* **A6.1.1(01), Acute Oral Toxicity**	
3.1.2	Specification	As given in section 2 *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	
3.1.2.1	Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)* Brown/black powder	
3.1.2.2	Purity	*Give purity in % of active substance* [redacted]	
3.1.2.3	Stability	*Describe stability of test material* Stable at room temperature	
3.2	**Test Animals**	*Non-entry field*	
3.2.1	Species	Rat	
3.2.2	Strain	Sprague-Dawley	X
3.2.3	Source	Charles River (UK) Ltd, Margate, Kent, UK	
3.2.4	Sex	Male	X
3.2.5	Age/weight at study initiation	Test animals were at least 200 g and were approximately 8 weeks old.	
3.2.6	Number of animals per group	*Give number* *specify, if there are differences for example for treatment and recovery groups* 3 (2 groups both dosed 2000 mg/kg bw)	
3.2.7	Control animals	No	
3.3	**Administration/ Exposure**	Oral *Fill in respective route in the following, delete other routes*	
3.3.1	Postexposure period	14 days	
		Oral	
3.3.2	Type	Gavage	
3.3.3	Concentration	Gavage	Two groups dosed at: 2000 .. mg/kg bw
3.3.4	Vehicle	Arachis oil BP	
3.3.5	Concentration in vehicle	200 mg/ml	
3.3.6	Total volume applied	10 ml/kg	
3.3.7	Controls	Not applicable – no control animals used in study	
3.4	**Examinations**	Clinical observations, mortality, bodyweights and necropsy. Observations for death or toxicity were taken 0.5, 1, 2 and 4	

hours after dosing and then once daily for fourteen days. Individual bodyweights were measured prior to dosing and seven and fourteen days after treatment. All animals were subjected to gross pathological examination after death.

3.5 Method of determination of LD_{50}

LD_{50} was determined from mortality data and not by statistical analysis.

4 RESULTS AND DISCUSSION

Describe findings. If appropriate, include table. Sample tables are given below.

4.1 Clinical signs

No effects / describe significant effects referring to data in results table

There were no signs of systemic toxicity at any observation time point in any of the treated animals.

4.2 Pathology

No effects / describe significant effects referring to data in results table

No abnormalities were noted at necropsy.

4.3 Other

Describe any other significant effects

There were no mortalities among any of the treated animals at study termination.

All animals showed expected gains in bodyweight over the study period.

4.4 LD_{50}

Give LD_{50} male, females, males + females
State if no lethal effect at maximal dose

There were no mortalities or signs of systemic toxicity among any of the animals treated with copper oxide at the test concentration of 2000 mg/kg b.w. An LD_{50} of >2500 mg/kg b.w can be estimated using the flow chart in annex 2d of OECD Guidelines for the Testing of Chemicals No. 423 "Acute Oral Toxicity – Acute Toxic Class Method" (adopted 17 December 2001).

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines

The study was performed to assess the acute oral toxicity of copper oxide following a single oral administration by gavage in the Sprague-Dawley rat. A group of three fasted male rats were treated with the test material at a dose level of 2000 mg/kg bw administered as a suspension in Arachis oil BP. This was followed by a further group of three fasted males treated with the same dose level.

The animals were observed for deaths or overt signs of

		toxicity at 0.5, 1, 2 and 4 hours after dosing and subsequently once daily for 14 days. The individual bodyweights were recorded prior to dosing, 7 and 14 days after treatment. At the end of the observation period, the animals were sacrificed and subject to gross pathological examination. The study was conducted according to OECD Guidelines for the Testing of Chemicals No. 423 "Acute Oral Toxicity – Acute Toxic Class Method" (adopted 17 December 2001). The study was also conducted according to GLP. No deviations from the test guidelines, or deficiencies in the method were reported.	X
5.2	**Results and discussion**	*Summarize relevant results; discuss dose-response relationship.* There were no mortalities or signs of systemic toxicity among any of the animals treated with copper oxide at the test concentration of 2000 mg/kg b.w. All animals showed expected gains in bodyweight over the study period and there were no abnormalities noted at necropsy. An LD_{50} of >2500 mg/kg b.w can be estimated using the flow chart in annex 2d of OECD Guidelines for the Testing of Chemicals No. 423 "Acute Oral Toxicity – Acute Toxic Class Method" (adopted 17 December 2001). The test material does not meet the criteria for classification according to EU labelling regulations Commission Directive 93/21/EEC.	
5.3	**Conclusion**	Non-entry field	
5.3.1	Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3, or 4* (1) valid without restriction	
5.3.2	Deficiencies	No *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	

Evaluation by Competent Authorities
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Section A6.1.1	**Acute Oral Toxicity in the Rat (LD_{50})**
Annex Point IIA6.1.1	*Specify section no., heading, route and species as appropriate* *Specify type of test (Limit Test, LD_{50}, special investigation)*
IUCLID: 5.1.1(01)	**A6.1.1(01), Acute Oral Toxicity**

Date	[redacted]
Materials and Methods	• [redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A6.1.1	**Acute Oral Toxicity in the Rat (LD_{50})**	
Annex Point IIA6.1.1	*Specify section no., heading, route and species as appropriate* *Specify type of test (Limit Test, LD_{50}, special investigation)*	
IUCLID: 5.1.1/02	**A6.1.1(02), Acute Oral Toxicity**	
	1 REFERENCE	**Official use only**
1.1 Reference	*Author(s), year, title, laboratory name, laboratory report number, report date (if published, list journal name, volume: pages)* *If necessary, copy field and enter other reference(s).* [redacted] (2001). Acute Oral Toxicity Study of Copper Carbonate Dry Light in Rats. Covance Laboratories, Inc. Report No. 7180-100 (unpublished).	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* Wood Preservative Copper Taskforce	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on existing [a.s. / b.p.] for the purpose of its [entry into Annex I/IA / authorisation]	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes - the study was conducted according to the following test guidelines; OECD Guidelines, No. 401. Acute Oral Toxicity (February 24, 1987) EPA. Prevention, Pesticides and Toxic Substances; OPPTS 870.1100 Acute Toxicity Testing - Background; Health Effects Test Guidelines (August 1998). *(If yes, give guidelines; if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2 GLP	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	X
2.3 Deviations	Yes At test initiation the animals were approximately 8 to 13 weeks of ages (opposed to 8 to 12 as specified in the protocol). This deviation is not considered to have had an adverse effect on the outcome. *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	
	3 MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values	

	as appropriate.	
3.1 Test material	Dry copper carbonate *or give name used in study report*	
3.1.1 Lot/Batch number	*List lot/batch number if available* Lot/batch number: No. 907	
3.1.2 Specification	As given in section 2 Deviating from specification given in section 2 as follows *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	X
3.1.2.1 Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)* Light green powder	
3.1.2.2 Purity	*Give purity in % of active substance* [redacted]	X
3.1.2.3 Stability	*Describe stability of test material* Stable at room temperature	
3.2 Test Animals	Non-entry field	
3.2.1 Species	Rat	
3.2.2 Strain	Crl:CD(SD)IGS BR	
3.2.3 Source	Charles River Laboratories, Portage, Michigan, USA	
3.2.4 Sex	Male and Female	
3.2.5 Age/weight at study initiation	Age/weight at study initiation: The animals were aged between 8 and 13 weeks old and weighed approximately 214-298 g at the start of the study.	
3.2.6 Number of animals per group	*Give number* *specify, if there are differences for example for treatment and recovery groups* 5 males and 5 females	
3.2.7 Control animals	No	
3.3 Administration/ Exposure	Oral *Fill in respective route in the following, delete other routes*	
3.3.1 Postexposure period	14 days	
	Oral	
3.3.2 Type	Gavage	
3.3.3 Vehicle	Moistened with distilled water	
3.3.4 Concentration in vehicle	500 and 2000 mg/kg bw	
3.3.5 Total volume	5 ml/kg bw	

applied	
3.3.6 Controls	Not applicable – no controls were used in the study
3.4 Examinations	Clinical observations were conducted at 1, 2.5 and 4 hours following test material administration and daily thereafter for 14 days. Mortality checks were conducted twice a day for 13 days after test material administration and again on the morning of Day 15. Bodyweights were determined before test material administration (Day 1). Additional bodyweights were determined on Day 8 and at either mortality during post-exposure period or sacrifice at test termination. All animals, whether found dead during the study, sacrificed in a moribund condition or euthanised at test termination, were subject to an abbreviated macroscopic necropsy examination. Any abnormalities were noted.
3.5 Method of determination of LD_{50}	The LD_{50} was determined from mortality data. No statistical analysis was employed.
Further remarks	Not applicable
	4 RESULTS AND DISCUSSION *describe findings. if appropriate, include table. sample tables are given below.*
4.1 Clinical signs	*No effects / describe significant effects referring to data in results table* MORTALITY: No mortality was observed at 500 mg/kg bw dose level. All 10 animals treated at 2000 mg/kg bw were either found dead (four males and five females) or sacrificed in a moribund condition (one male) within 7 days of test material administration. For further details please refer to Table A6_1-1. BODYWEIGHTS All animals surviving to the end of the observation period exhibited bodyweight gains during the study, with the exception of one female which exhibited an insignificant loss of 2 g during the second week. For further details please refer to Table A6_1-1.

X

CLINICAL SIGNS

The only clinical signs observed in animals treated at 500 mg/kg were non-formed faeces and a dark stained urogenital area. All animals at this dose level returned to a normal appearance by Day 9. Clinical signs of toxicity observed in the animals treated at the 2000 mg/kg bw dose group prior to death or moribund sacrifice included hunched posture, hypoactivity, red-stained face, green-tinted/black mucoid/non-formed faeces, few faeces, dark stained urogenital area, cold to touch, dyspnea and prostration. For further details please refer to Table A6_1-1.

4.2 Pathology *No effects / describe significant effects referring to data in results table*

The macroscopic necropsy examination conducted at termination of the animals treated at 500 mg/kg did not reveal any visible lesions. Test material related lesions observed in the 2000 mg/kg dose group pertained to abnormally coloured fluid contents in the gastrointestinal tract. All other findings were indicative of an acute death. For further details please refer to Table A6_1-1.

4.3 Other *Describe any other significant effects*

Not applicable

4.4 LD_{50} *Give LD_{50} male, females, males + females*
State if no lethal effect at maximal dose

The estimated LD_{50} values were determined to be between 500 and 2000 mg/kg bw for males, females and both sexes combined

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods *Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines*

In this study, copper carbonate dry light was evaluated for its acute oral toxicity potential in male and female rats when administered as a single gavage dose at levels of 500 and 2000 mg/kg bw. There was a 14 day post exposure period to determine clinical observations, bodyweight changes and mortality. At the end of the study the animals were sacrificed and subjected to pathological examinations.

The study was conducted according to OECD (401 – Acute Oral Toxicity) and EPA (OPPTS 870.1100 Acute Toxicity Testing) guidelines. The study was also conducted according to GLP.

At test initiation the animals were approximately 8 to 13 weeks of ages (opposed to 8 to 12 as specified in the protocol). This deviation is not considered to have had an adverse effect on the outcome.

5.2 Results and discussion *Summarize relevant results; discuss dose-response relationship*

No mortality was observed in the 500 mg/kg dose group. The only clinical signs observed were non-formed faeces and dark stained urogenital area. All animals treated at 2000 mg/kg died or were sacrificed in a moribund condition within 7 days of test material administration. Based on the mortality observed in the study, the estimated oral LD_{50} values in rats were determined to be between 500 and 2000 mg/kg for males, females and the sexes combined.

Based on the results of this study, the acute oral toxicity caused by copper carbonate was sufficient to classify the substance as 'Harmful if Swallowed' under Commission Directive 93/21/EC)

5.3 Conclusion Non-entry field

5.3.1 Reliability *Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3, or 4*

(1) valid without restriction

5.3.2 Deficiencies No

(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date [redacted]

Guidelines and quality assurance • [redacted]

Materials and Methods • [redacted]

Section A6.1.1	**Acute Oral Toxicity in the Rat (LD_{50})**
Annex Point IIA6.1.1	*Specify section no., heading, route and species as appropriate* *Specify type of test (Limit Test, LD_{50}, special investigation)*
IUCLID: 5.1.1/02	**A6.1.1(02), Acute Oral Toxicity**
	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A6_1-1. Summary of Acute Toxicity Results

Dose mg/kg	*Number of dead / number of investigated*	*Time of death (range)*	*Observations*
500 mg/kg males	0/5	-	Dark stained urogenital area was observed from Day 2 to Day 8.
500 mg/kg females	0/5	-	Dark stained urogenital area was observed from Day 3 to Day 7.
2000 mg/kg males	5/5	4-8* days	Two to three days following test substance administration clinical observations included non-formed faeces, dark stained urogenital areas, red stained face, hypoactivity, and hunched posture. All individuals exhibited a light green, granular semifluid in the gastro-intestinal tract. Other observations included dark red/brown stains in the perineum/perianal area, ocular and nasal discharge and extended lumen
2000 mg/kg females	5/5	3-7 days	Two days after test substance administration clinical signs included non-formed faeces, dark stained urogenital area, prostration, dyspnea, cold to touch, hypoactivity and a red stained face. Four individuals exhibited a light green, granular semifluid in the gastro-intestinal tract. Other observations included green stains in the perineum/perianal area along with moist material and an extended lumen.
LD_{50} value	Between 500 – 2000 mg/kg bw for males, females and both sexes combined		

Section A6.1.1	**Acute Oral Toxicity in the Rat (LD_{50})**	
Annex Point IIA6.1.1	*Specify section no., heading, route and species as appropriate* *Specify type of test (Limit Test, LD_{50}, special investigation)*	
IUCLID: 5.1.1/02	**A6.1.1(02), Acute Oral Toxicity**	
	4 REFERENCE	**Official use only**
1.1 Reference	*Author(s), year, title, laboratory name, laboratory report number, report date (if published, list journal name, volume: pages)* *If necessary, copy field and enter other reference(s).* [redacted] (2001). Acute Oral Toxicity Study of Copper Carbonate Dry Light in Rats. Covance Laboratories, Inc. Report No. 7180-100 (unpublished).	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
4.2.1 Data owner	*Give name of company* Wood Preservative Copper Taskforce	
4.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on existing [a.s. / b.p.] for the purpose of its [entry into Annex I/IA / authorisation]	
	5 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes - the study was conducted according to the following test guidelines; OECD Guidelines, No. 401. Acute Oral Toxicity (February 24, 1987) EPA. Prevention, Pesticides and Toxic Substances; OPPTS 870.1100 Acute Toxicity Testing - Background; Health Effects Test Guidelines (August 1998). *(If yes, give guidelines; if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
5.2 GLP	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	X
5.3 Deviations	Yes At test initiation the animals were approximately 8 to 13 weeks of ages (opposed to 8 to 12 as specified in the protocol). This deviation is not considered to have had an adverse effect on the outcome. *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	
	6 MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values	

	as appropriate.	
3.7 Test material	Dry copper carbonate *or give name used in study report*	
3.7.1 Lot/Batch number	*List lot/batch number if available* Lot/batch number: No. 907	
3.7.2 Specification	As given in section 2 Deviating from specification given in section 2 as follows *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	X
3.7.2.1 Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)* Light green powder	
3.7.2.2 Purity	*Give purity in % of active substance* [redacted]	X
3.7.2.3 Stability	*Describe stability of test material* Stable at room temperature	
3.8 Test Animals	Non-entry field	
3.8.1 Species	Rat	
3.8.2 Strain	Crl:CD(SD)IGS BR	
3.8.3 Source	Charles River Laboratories, Portage, Michigan, USA	
3.8.4 Sex	Male and Female	
3.8.5 Age/weight at study initiation	Age/weight at study initiation: The animals were aged between 8 and 13 weeks old and weighed approximately 214-298 g at the start of the study.	
3.8.6 Number of animals per group	*Give number* *specify, if there are differences for example for treatment and recovery groups* 5 males and 5 females	
3.8.7 Control animals	No	
3.3 Administration/ Exposure	Oral *Fill in respective route in the following, delete other routes*	
3.9.1 Postexposure period	14 days	
	Oral	
3.9.2 Type	Gavage	
3.9.3 Vehicle	Moistened with distilled water	
3.9.4 Concentration in vehicle	500 and 2000 mg/kg bw	
3.9.5 Total volume	5 ml/kg bw	

applied	
3.9.6 Controls	Not applicable – no controls were used in the study
0 3.4 Examinations	Clinical observations were conducted at 1, 2.5 and 4 hours following test material administration and daily thereafter for 14 days. Mortality checks were conducted twice a day for 13 days after test material administration and again on the morning of Day 15. Bodyweights were determined before test material administration (Day 1). Additional bodyweights were determined on Day 8 and at either mortality during post-exposure period or sacrifice at test termination. All animals, whether found dead during the study, sacrificed in a moribund condition or euthanised at test termination, were subject to an abbreviated macroscopic necropsy examination. Any abnormalities were noted.
1 3.5 Method of determination of LD_{50}	The LD_{50} was determined from mortality data. No statistical analysis was employed.
Further remarks	Not applicable

4 RESULTS AND DISCUSSION

describe findings. if appropriate, include table. sample tables are given below.

5.4 Clinical signs	*No effects / describe significant effects referring to data in results table* MORTALITY: No mortality was observed at 500 mg/kg bw dose level. All 10 animals treated at 2000 mg/kg bw were either found dead (four males and five females) or sacrificed in a moribund condition (one male) within 7 days of test material administration. For further details please refer to Table A6_1-1. BODYWEIGHTS All animals surviving to the end of the observation period exhibited bodyweight gains during the study, with the exception of one female which exhibited an insignificant loss of 2 g during the second week. For further details please refer to Table A6_1-1.

X

CLINICAL SIGNS

The only clinical signs observed in animals treated at 500 mg/kg were non-formed faeces and a dark stained urogenital area. All animals at this dose level returned to a normal appearance by Day 9. Clinical signs of toxicity observed in the animals treated at the 2000 mg/kg bw dose group prior to death or moribund sacrifice included hunched posture, hypoactivity, red-stained face, green-tinted/black mucoid/non-formed faeces, few faeces, dark stained urogenital area, cold to touch, dyspnea and prostration. For further details please refer to Table A6_1-1.

5.5 Pathology *No effects / describe significant effects referring to data in results table*

The macroscopic necropsy examination conducted at termination of the animals treated at 500 mg/kg did not reveal any visible lesions. Test material related lesions observed in the 2000 mg/kg dose group pertained to abnormally coloured fluid contents in the gastrointestinal tract. All other findings were indicative of an acute death. For further details please refer to Table A6_1-1.

5.6 Other *Describe any other significant effects*

Not applicable

5.7 LD_{50} *Give LD_{50} male, females, males + females*
State if no lethal effect at maximal dose

The estimated LD_{50} values were determined to be between 500 and 2000 mg/kg bw for males, females and both sexes combined

6 APPLICANT'S SUMMARY AND CONCLUSION

6.1 Materials and methods *Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines*

In this study, copper carbonate dry light was evaluated for its acute oral toxicity potential in male and female rats when administered as a single gavage dose at levels of 500 and 2000 mg/kg bw. There was a 14 day post exposure period to determine clinical observations, bodyweight changes and mortality. At the end of the study the animals were sacrificed and subjected to pathological examinations.

The study was conducted according to OECD (401 – Acute Oral Toxicity) and EPA (OPPTS 870.1100 Acute Toxicity Testing) guidelines. The study was also conducted according to GLP.

At test initiation the animals were approximately 8 to 13 weeks of ages (opposed to 8 to 12 as specified in the protocol). This deviation is not considered to have had an adverse effect on the outcome.

6.2 Results and discussion *Summarize relevant results; discuss dose-response relationship*

No mortality was observed in the 500 mg/kg dose group. The only clinical signs observed were non-formed faeces and dark stained urogenital area. All animals treated at 2000 mg/kg died or were sacrificed in a moribund condition within 7 days of test material administration. Based on the mortality observed in the study, the estimated oral LD_{50} values in rats were determined to be between 500 and 2000 mg/kg for males, females and the sexes combined.

Based on the results of this study, the acute oral toxicity caused by copper carbonate was sufficient to classify the substance as 'Harmful if Swallowed' under Commission Directive 93/21/EC)

6.3 Conclusion Non-entry field

6.3.1 Reliability *Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3, or 4*

(1) valid without restriction

6.3.2 Deficiencies No

(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)

Evaluation by Competent Authorities
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date [redacted]

Guidelines and quality assurance • [redacted]

Materials and Methods • [redacted]

Section A6.1.1	**Acute Oral Toxicity in the Rat (LD_{50})**
Annex Point IIA6.1.1	*Specify section no., heading, route and species as appropriate* *Specify type of test (Limit Test, LD_{50}, special investigation)*
IUCLID: 5.1.1/02	**A6.1.1(02), Acute Oral Toxicity**
	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A6_1-1. Summary of Acute Toxicity Results

Dose mg/kg	*Number of dead / number of investigated*	*Time of death (range)*	*Observations*
500 mg/kg males	0/5	-	Dark stained urogenital area was observed from Day 2 to Day 8.
500 mg/kg females	0/5	-	Dark stained urogenital area was observed from Day 3 to Day 7.
2000 mg/kg males	5/5	4-8* days	Two to three days following test substance administration clinical observations included non-formed faeces, dark stained urogenital areas, red stained face, hypoactivity, and hunched posture. All individuals exhibited a light green, granular semifluid in the gastro-intestinal tract. Other observations included dark red/brown stains in the perineum/perianal area, ocular and nasal discharge and extended lumen
2000 mg/kg females	5/5	3-7 days	Two days after test substance administration clinical signs included non-formed faeces, dark stained urogenital area, prostration, dyspnea, cold to touch, hypoactivity and a red stained face. Four individuals exhibited a light green, granular semifluid in the gastro-intestinal tract. Other observations included green stains in the perineum/perianal area along with moist material and an extended lumen.
LD_{50} value	Between 500 – 2000 mg/kg bw for males, females and both sexes combined		

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1 REFERENCE

1.1 Reference

Author(s), year, title, laboratory name, laboratory report number, report date (if published, list journal name, volume: pages) If necessary, copy field and enter other reference(s).

[redacted] (1990). Acute Oral Toxicity Test of 'Kupferkarbonat Griin Gefallt 54/56% Cu' in Rats. International Bio Research. Report No. 10-04-0714-90 (unpublished)

1.2 Data protection

Yes

(indicate if data protection is claimed)

1.2.1 Data owner

Give name of company

Wood Preservative Copper Taskforce

1.2.2 Criteria for data protection

Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:

Data submitted to the MS after 13 May 2000 on existing [a.s. / b.p.] for the purpose of its [entry into Annex I/IA / authorisation]

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study

Yes - the study was conducted to the following test guidelines:

OECD Guidelines, No. 401. Acute Oral Toxicity (February 24, 1987).

EEC Directive 84/449/EEC. (September 19, 1984).

(If yes, give guidelines; if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")

2.2 GLP

Yes

(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)

2.3 Deviations

No

(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")

3 MATERIALS AND METHODS

In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.

3.1 Test material

As given in section 2 X

or give name used in study report

3.1.1 Lot/Batch number *List lot/batch number if available*

Section A6.1.1	Acute Oral Toxicity in the Rat (LD_{50})	
Annex Point IIA6.1.1	*Specify section no., heading, route and species as appropriate* *Specify type of test (Limit Test, LD_{50}, special investigation)*	
IUCLID: 5.1.1/03	**A6.1.1(03), Acute Oral Toxicity**	
	Not reported	
3.1.2 Specification	As given in section 2	X
	(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):	
3.1.2.1 Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)*	
	Powder	
3.1.2.2 Purity	*Give purity in % of active substance*	X
	[redacted]	
3.1.2.3 Stability	*Describe stability of test material*	
	Stable at room temperature	
3.2 Test Animals	Non-entry field	
3.2.1 Species	Rat	
3.2.2 Strain	Crl.: (WI) BR - Wistar	
3.2.3 Source	Firma Charles River Wiga, Germany	
3.2.4 Sex	Male and female	
3.2.5 Age/weight at study initiation	Males weighed 220-314 g and females weighed 181-262 g.	
3.2.6 Number of animals per group	*Give number* *specify, if there are differences for example for treatment and recovery groups*	
	5 males and 5 females	
3.2.7 Control animals	No	
3.3 Administration/ Exposure	Oral *Fill in respective route in the following, delete other routes*	
3.3.1 Postexposure period	14 days	
	Oral	
3.3.2 Type	Gavage	
3.3.3 Vehicle	Carboxymethylcellulose	
3.3.4 Concentration	Following a preliminary range finding test with a dose of 2000 mg/kg the final doses were 1000, 1500 and 2000 mg/kg.	
3.3.5 Concentration in vehicle	10, 15 and 20%	X
3.3.6 Total volume applied	1.8 – 3.1 ml	
3.3.7 Controls	Not applicable	

Section A6.1.1	**Acute Oral Toxicity in the Rat (LD_{50})**
Annex Point IIA6.1.1	*Specify section no., heading, route and species as appropriate* *Specify type of test (Limit Test, LD_{50}, special investigation)*
IUCLID: 5.1.1/03	**A6.1.1(03), Acute Oral Toxicity**
3.4 Examinations	Clinical observations were recorded after 10 minutes, 1, 2, 6, 24 hours and once daily thereafter up to Day 14 following test substance administration. The bodyweights of test organisms were recorded immediately before treatment (Day 0) and surviving animals reweighed on Day 7 and Day 14 (termination). Animals found dead or killed in extremis were immediately necropsied. The surviving animals were sacrificed after 14 days and gross pathological examinations performed.
3.5 Method of determination of LD_{50}	The LD_{50} values were carried out by probit analysis.
3.6 Further remarks	Not applicable
	4 RESULTS AND DISCUSSION *Describe findings. If appropriate, include table. Sample tables are given below.*
4.1 Clinical signs	*No effects / describe significant effects referring to data in results table* Severe clinical symptoms related to CNS-symptoms, coordination, reflexes and automatic functions were observed with dose related intensity up to 9 days post administration. For further details, refer to Table A6.1.1. Weight gains were reduced in surviving animals. In the 1500 and 2000 mg/kg dose groups some weight losses were observed. For further details, refer to Table A6.1.1. X
4.2 Pathology	*No effects / describe significant effects referring to data in results table* Gross pathological examination at 14 days post administration revealed no test article dependent findings in any of the dose groups. Those macroscopic changes observed were attributable to the sacrificing procedure or to minor variations which often occur spontaneously in rats of this strain and age. In contrast, severe macroscopic changes of the gastro-intestinal tract were observed in all mid and high dose animals killed in extremis or died spontaneously. The findings are considered to be test article-related. For further details refer to Table A6.1.1
4.3 Other	*Describe any other significant effects* Not applicable

Section A6.1.1	**Acute Oral Toxicity in the Rat (LD_{50})**
Annex Point IIA6.1.1	*Specify section no., heading, route and species as appropriate* *Specify type of test (Limit Test, LD_{50}, special investigation)*
IUCLID: 5.1.1/03	**A6.1.1(03), Acute Oral Toxicity**
4.4 LD_{50}	*Give LD_{50} male, females, males + females* Males - 1434 mg/kg Females - 1291 mg/kg Male and females combined - 1385 mg/kg

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods *Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines*

The aim of this study was to determine the acute oral toxicity of copper carbonate to male and female rats. The test concentrations were 1000, 1500 and 2000 mg/kg bw. During a 14-day post exposure period the test animals were assessed for clinical observations, bodyweight change and mortality. At the end of the study all animals were sacrificed and subject to pathological examination.

The study was conducted according to GLP and the following guidelines;

OECD Guidelines, No. 401. Acute Oral Toxicity (February 24, 1987).

EEC Directive 84/449/EEC. (September 19, 1984).

5.2 Results and discussion *Summarize relevant results; discuss dose-response relationship.*

Severe clinical symptoms were observed up to 9 days post administration. There were reduced weight gains in all test animals. Gross pathological examinations at 14 days revealed no test article dependant findings in any of the dose groups. However, all mid and high dose animals killed in extremis or died spontaneously revealed characteristic gastro-intestinal alterations, which were considered to be test article related.

The resulting LD50 values were 1434, 1291 and 1385 mg/kg for males, females and both sexes combined respectively. Based on these results and according to EU directive 83/467/EEC copper carbonate should be classified as 'Harmful if Swallowed' under Commission Directive 93/21/EC)

5.3 Conclusion	Non-entry field
5.3.1 Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3, or 4* 1
5.3.2 Deficiencies	No

Section A6.1.1	**Acute Oral Toxicity in the Rat (LD_{50})**
Annex Point IIA6.1.1	*Specify section no., heading, route and species as appropriate* *Specify type of test (Limit Test, LD_{50}, special investigation)*
IUCLID: 5.1.1/03	**A6.1.1(03), Acute Oral Toxicity**

(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	• [redacted]
Results and discussion	• [redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section A6.1.1	**Acute Oral Toxicity in the Rat (LD_{50})**
Annex Point IIA6.1.1	*Specify section no., heading, route and species as appropriate* *Specify type of test (Limit Test, LD_{50}, special investigation)*
IUCLID: 5.1.1/03	**A6.1.1(03), Acute Oral Toxicity**

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A6_1-1. Summary of Findings for Acute Oral Toxicity

Dose mg/kg	*Number of dead / number of investigated*	*Time of death (range)*	*Observations*
1000 males	0/5	-	Clinical observations included reduced activity, general reactions, body tone and skin turgor. Additional signs were piloerection, diarrhoea, paleness in skin/mucous membrane and test organisms adopted a squatting position. One animal was killed in extremis and pathological investigations determined residues of the test article in the stomach and green discolouration of the intestine. After 14 days observation period, pathological findings included a white cover on the mucous membrane of the stomach in one male and one female, foamy yellow contents in the intestine, swollen liver and spleen, pale kidneys and hydrometra in the genital system of one female.
1000 females	2/5	Day 7	
1500 males	4/5	Day 2 – Day 8	Clinical observations included reduced activity and general reactions. Additional signs were pilorection, diarrhoea, paleness in skin/mucous membrane and test organisms adopted a squatting position. Pathological findings of animals killed in extremis prior to test termination included marbled lung, green discoloured and swollen mucous membrane of the stomach After 14 days, pathological findings included swollen mucous membranes in the stomach and intestine of one male and two females. One organism had an enlarged and darkened spleen.
1500 females	3/5	3 hours – Day 6	
2000 males	4/5	Day 3 – Day 9	Clinical observations included reduced activity, general reactions, body tone and skin turgor. Additional signs were pilorection, diarrhoea, paleness in skin/mucous membrane and test organisms adopted a squatting position. Pathological findings in animals killed in extremis included swollen mucous membranes, green discoloration and mucous membrane and corrosion in the stomach of 3 males and 3 females. Four males and three females had hyperaemic and green discolouration of the intestine. Other findings were reduced and discoloured spleen and abnormal coloured kidney. After 14 days two individuals had enlarged and dark discoloured spleen. Other pathological findings included a marbled liver and lung, enlarged and dark coloured spleen, marbled and discoloured kidney and inflated and green coloured intestine.
2000 females	3/5	4 hours – Day 7	
LD_{50} value	Male – 1434 mg/kg Female – 1291 mg/kg Males and Females – 1385 mg/kg		

Section A6.1.1	**Acute Oral Toxicity - LD_{50} Test in the Rat**	
Annex Point IIA6.1.1	*Specify section no., heading, route and species as appropriate* *Specify type of test (Limit Test, LD_{50}, special investigation)*	
IUCLID: 5.1.1/04	**A6.1.1(04)**	
	1 REFERENCE	Official use only
1.1 Reference	[redacted]. 1994. Test to Evaluate the Acute Toxicity Following a Single Oral Administration (LD50) in the Rat. Pharmakon Europe. Report No. 44193 (unpublished). *Author(s), year, title, laboratory name, laboratory report number, report date (if published, list journal name, volume: pages) If necessary, copy field and enter other reference(s).*	
1.2 Data protection	Yes	
1.2.1 Data owner	Wood Preservatives Copper Task Force	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on existing [a.s. / b.p.] for the purpose of its [entry into Annex I/IA / authorisation]	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes – the study was conducted according to the following test guidelines: OECD No. 401 (1987) EEC 92/69 – Annex V – Method B1 (1992) – 93/21 (1993) *(If yes, give guidelines; if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2 GLP	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3 Deviations	Yes The bodyweights of three females were noted beyond the norms (120-180 g) 117 and 119 g. It was reported that these deviations were not considered to have affected the outcome of the objectives of the study. *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	
	3 MATERIALS AND METHODS *In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.*	
3.1 Test material	As given in section 2 *or give name used in study report*	X
3.1.1 Lot/Batch number	844	

Section A6.1.1	**Acute Oral Toxicity - LD_{50} Test in the Rat**	
Annex Point IIA6.1.1	*Specify section no., heading, route and species as appropriate* *Specify type of test (Limit Test, LD_{50}, special investigation)*	
IUCLID: 5.1.1/04	**A6.1.1(04)**	
3.1.2 Specification	As given in section 2 *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	X
3.1.2.1 Description	Powder, blue crystals *If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)*	
3.1.2.2 Purity	[redacted] *Give purity in % of active substance*	
3.1.2.3 Stability	Stable at room temperature *Describe stability of test material*	
3.2 Test Animals	Non-entry field	
3.2.1 Species	Rat	
3.2.2 Strain	Sprague-Dawley	
3.2.3 Source	Iffa-Crédo, B.P. 0109 (69592 L'Arbresle Cedex, France)	
3.2.4 Sex	Males and females	
3.2.5 Age/weight at study initiation	Age: 5-7 weeks Weight of males: 130 - 230 g Weight of females: 120 – 180 g	
3.2.6 Number of animals per group	5 males and 5 females per dose group *Give number specify, if there are differences for example for treatment and recovery groups*	
3.2.7 Control animals	Yes – 5 males and 5 females	
3.3 Administration/ Exposure	Oral *Fill in respective route in the following, delete other routes*	
3.3.1 Postexposure period	14 days	
	Oral	
3.3.2 Type	Gavage	
3.3.3 Concentration	Gavage 0 (control), 447, 562, 708 and 893mg/kg bw	
3.3.4 Vehicle	Purified water	
3.3.5 Concentration in vehicle	0, 2.235, 2.810, 3.540, 4.465 % (w/v)	
3.3.6 Total volume applied	20 ml/kg	
3.3.7 Controls	Vehicle only	
3.4 Examinations	Clinical observations, mortality, bodyweights and necropsy. Animals were observed for clinical signs and mortality 15 minutes and 1, 2 and 4 hours after administration of the test material, followed by daily observations for the 14 day study period. Bodyweights were measured the day before	

		treatment, immediately before treatment, on day 8 and at death. All animals were subjected to gross pathological examination after death.
3.5	**Method of determination of LD_{50}**	Bliss, Litchfield and Wilcoxon, *or other*

4 RESULTS AND DISCUSSION

Describe findings. If appropriate, include table. Sample tables are given below.

Section A6.1.1 Annex Point IIA6.1.1 IUCLID: 5.1.1/04	**Acute Oral Toxicity - LD_{50} Test in the Rat** *Specify section no., heading, route and species as appropriate* *Specify type of test (Limit Test, LD_{50}, special investigation)* **A6.1.1(04)**
4.1 Clinical signs	The major modifications noted during clinical observations were prostration and subdued behaviour from 15 minutes after the treatment to 4 hours. Greenish diarrhoea was also observed from 1-4 hours after the treatment. Some cases of infrequent stools were noted on Day 2. No clinical signs were observed in the control group. For further details see Table A6_1-1 *No effects / describe significant effects referring to data in results table*
4.2 Pathology	There were no macroscopically detectable abnormalities detected in any of the control test organisms. There were no abnormalities detected in any of the animals sacrificed on study termination. Detected abnormalities in animals that died during the observation period included stomach distension by a greenish liquid (1 female 447 mg/kg, 1 female 562 mg/kg, 1 male 708 mg/kg), congested intestines (1 male 447 mg/kg, 2 males 893 mg/kg) and a discoloured liver (1 female 447 mg/kg). *No effects / describe significant effects referring to data in results table*
4.3 Other	Bodyweights: Body weight change in the treated animals of the 447 mg/kg dose group and the males in the 562 mg/kg dose group were similar to those in the control groups (although mean weights were statistically lower than controls in males in the 562 mg/kg dose group on day 8 only). The mortality rate observed in the other dose groups did not allow analysis of body weight changes. Mortality – see Table A6_1-1 *Describe any other significant effects*
4.4 LD_{50}	LD_{50} for males and females by the Bliss' method – 482 mg/kg (403-575 mg/kg) LD_{50} for males and females by the Litchfield & Wilcoxon method 481 mg/kg (400-580 mg/kg) *Give LD_{50} male, females, males + females* *State if no lethal effect at maximal dose*
	5 APPLICANT'S SUMMARY AND CONCLUSION
5.1 Materials and methods	An acute oral toxicity test was carried out according to OECD (No. 401) and EU (EEC 92/69 – Annex V – Method B1 (1992) – 93/21 1993) guidelines in Sprague-Dawley rats. Five males and five females were tested at each dose level

of 0 (control), 447, 562, 708 and 893 mg/kg bw. Copper sulphate was administered by gavage with purified water utilised as the vehicle.

The only protocol deviation was the bodyweights of three females which were noted to be beyond the norms (120-180 g) 117 and 119 g. This was not considered to have any affect on the outcome of the study.

Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines

5.2 Results and discussion

The oral LD_{50} of copper sulphate was determined to be 481-482 mg/kg.

There were no mortalities in the control groups. Mortality demonstrated a dose-response relationship with 2/5 test organisms dying in the 447 mg/kg group and all test organisms dying in the highest (893 mg/kg) dose group.

The major modifications noted during the clinical observations were prostration and subdued behaviour from 15 minutes after the treatment to 4 hours. Greenish diarrhoea was also observed from 1 hour to 4 hours after the treatment. Some cases of infrequent stools were noted on Day 2 (except in the 447 mg/kg dose group). No clinical signs were observed in the control groups.

Some cases of stomach distension by a greenish liquid and intestines slightly congested were observed in animals which died during the observation period. No macroscopically detectable abnormality was noted in animals sacrificed at study termination.

Body weight change in the treated animals of the 447 mg/kg dose group and the males in the 562 mg/kg dose group were similar to those in the control groups (although mean weights were statistically lower than controls in males in the 562 mg/kg dose group on day 8 only).

Summarize relevant results; discuss dose-response relationship.

5.3 Conclusion Non-entry field

5.3.1 Reliability (1) valid without restriction

Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3, or 4

5.3.2 Deficiencies No

(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

Section A6.1.1 **Acute Oral Toxicity - LD_{50} Test in the Rat**

Annex Point IIA6.1.1 *Specify section no., heading, route and species as appropriate*

IUCLID: 5.1.1/04 *Specify type of test (Limit Test, LD_{50}, special investigation)*

A6.1.1(04)

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	[redacted]
Materials and Methods	• [redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Section A6.1.1 **Acute Oral Toxicity - LD_{50} Test in the Rat**

Annex Point IIA6.1.1 *Specify section no., heading, route and species as appropriate*
Specify type of test (Limit Test, LD_{50}, special investigation)

IUCLID: 5.1.1/04 **A6.1.1(04)**

Table A6_1-1. Table for Acute Toxicity

Dose mg/kg	*Number of dead / number of investigated*	*Time of death (range)*	*Observations*
Contro l males	0/5	-	No clinical signs were observed
Control females	0/5	-	
447 males	2/5	2 hours	All animals displayed subdued behaviour 15 minutes after dosing, although this had returned to normal 2 days following treatment. Prostration was observed in one animal, 1-hour after dosing. Greenish diarrhoea was observed in 2 test organisms 2-4 hours after dosing. Infrequent stools were observed in 6 test organisms on Day 2. All surviving test organisms returned to normal from Day 3
447 females	2/5	2 hours-2 days	
562 males	2/5	2-4 hours	All animals displayed subdued behaviour 15 minutes after dosing, although this had returned to normal 2 days following treatment. Prostration was observed in three animals, 1-2 hours after dosing. Greenish diarrhoea was observed in 3 test organisms 2 hours to 2 days after dosing. Infrequent stools were observed in 3 test organisms on Day 2. All surviving test organisms returned to normal from Day 3
562 females	5/5	1 hour-2 days	
708 males	4/5	1 hour-2 days	Seven displayed subdued behaviour 15 minutes after dosing, although this had returned to normal 2 days following treatment. Prostration was observed in three animals, 15 minutes after dosing. Greenish diarrhoea was observed in 2 test organisms 2-4 hours after dosing. Infrequent stools were observed in 1 test organism on Day 2. The one surviving test organisms returned to normal from Day 3
708 females	5/5	1-4 hours	
893 males	5/5	1-2 hours	Nine animals displayed subdued behaviour 15 minutes after dosing. Prostration was observed in one animal fifteen minutes after dosing and four animals, 1-hour after dosing. Greenish diarrhoea was observed in 2 test organisms 1 hour after dosing. All animals had died 2 hours after dosing.
893 females	5/5	1-2 hours	
LD_{50} value	481-482 mg/kg		

COMMENTS FROM ...

Date *Give date of comments submitted*

Materials and Methods *Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.*
Discuss if deviating from view of rapporteur member state

Results and discussion *Discuss if deviating from view of rapporteur member state*

Section A6.1.1	**Acute Oral Toxicity - LD_{50} Test in the Rat**
Annex Point IIA6.1.1	*Specify section no., heading, route and species as appropriate* *Specify type of test (Limit Test, LD_{50}, special investigation)*
IUCLID: 5.1.1/04	**A6.1.1(04)**

Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A6_1-1. Table for Acute Toxicity

Dose mg/kg	*Number of dead / number of investigated*	*Time of death (range)*	*Observations*
Control males	0/5	-	No clinical signs were observed
Control females	0/5	-	
447 males	2/5	2 hours-2 days	All animals displayed subdued behaviour 15 minutes after dosing, although this had returned to normal 2 days following treatment. Prostration was observed in one animal, 1-hour after dosing. Greenish diarrhoea was observed in 2 test organisms 2-4 hours after dosing. Infrequent stools were observed in 6 test organisms on Day 2. All surviving test organisms returned to normal from Day 3
447 females	2/5	2 hours	
562 males	2/5	2-4 hours	All animals displayed subdued behaviour 15 minutes after dosing, although this had returned to normal 2 days following treatment. Prostration was observed in three animals, 1-2 hours after dosing. Greenish diarrhoea was observed in 3 test organisms 2 hours to 2 days after dosing. Infrequent stools were observed in 3 test organisms on Day 2. All surviving test organisms returned to normal from Day 3
562 females	5/5	1 hour-2 days	
708 males	4/5	1 hour-2 days	Seven displayed subdued behaviour 15 minutes after dosing, although this had returned to normal 2 days following treatment. Prostration was observed in three animals, 15 minutes after dosing. Greenish diarrhoea was observed in 2 test organisms 2-4 hours after dosing. Infrequent stools were observed in 1 test organism on Day 2. The one surviving test organisms returned to normal from Day 3
708 females	5/5	1-4 hours	
893 males	5/5	1-2 hours	Nine animals displayed subdued behaviour 15 minutes after dosing. Prostration was observed in one animal fifteen minutes after dosing and four animals, 1-hour after dosing. Greenish diarrhoea was observed in 2 test organisms 1 hour after dosing. All animals had died 2 hours after dosing.
893 females	5/5	1-2 hours	
LD_{50} value	481-482 mg/kg		

Section A6.1.2	**Acute Dermal Toxicity in the Rat (LD_{50})**	
Annex Point IIA6.1.2	*Specify section no., heading, route and species as appropriate* *Specify type of test (Limit Test, LD_{50}, special investigation)*	
IUCLID: 5.1.3(01)	**A6.1.2(01), Acute Dermal Toxicity**	
	1 REFERENCE	Official use only
1.1 Reference	*Author(s), year, title, laboratory name, laboratory report number, report date (if published, list journal name, volume: pages)* *If necessary, copy field and enter other reference(s).* [redacted]. (2002). Cupric Oxide: Acute Dermal Toxicity (Limit Test) in the Rat. SafePharm Laboratories Limited. Report No. 1645/002 (unpublished).	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* Wood Preservative Copper Taskforce	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on existing [a.s. / b.p.] for the purpose of its [entry into Annex I/IA / authorisation]	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes - the study was conducted according to the following test guidelines: OECD Guidelines for the Testing of Chemicals No. 402 'Acute Dermal Toxicity' (adopted 24 February 1987). Commission Directive 92/69/EEC Method B3 Acute Toxicity (Dermal). *(If yes, give guidelines; if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2 GLP	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3 Deviations	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	
	3 MATERIALS AND METHODS *In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.*	
3.1 Test material	Copper Oxide *or give name used in study report*	
3.1.1 Lot/Batch number	*List lot/batch number if available* Lot/Batch number: 02-0084	

Section A6.1.2	**Acute Dermal Toxicity in the Rat (LD_{50})**
Annex Point IIA6.1.2	*Specify section no., heading, route and species as appropriate* *Specify type of test (Limit Test, LD_{50}, special investigation)*
IUCLID: 5.1.3(01)	**A6.1.2(01), Acute Dermal Toxicity**
3.1.2 Specification	As given in section 2 *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*
3.1.2.1 Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)* Brown/black powder
3.1.2.2 Purity	*Give purity in % of active substance* [redacted]
3.1.2.3 Stability	*Describe stability of test material* Stable at room temperature
3.2 Test Animals	Non-entry field
3.2.1 Species	Rat
3.2.2 Strain	Sprague-Dawley CD (Crl:CD(SD)IGS BR)
3.2.3 Source	Charles River (UK) Ltd, Margate, Kent, UK.
3.2.4 Sex	5 males and 5 females
3.2.5 Age/weight at study initiation	At the start of the study the animals weighed at least 200 g and were approximately 8 weeks old.
3.2.6 Number of animals per group	*Give number* *specify, if there are differences for example for treatment and recovery groups* 5 male and 5 female animals per group.
3.2.7 Control animals	No
3.3 Administration/ Exposure	Dermal *Fill in respective route in the following, delete other routes*
3.3.1 Postexposure period	14 days
	Dermal
3.3.2 Area covered	10 % of body surface
3.3.3 Occlusion	semi-occluded
3.3.4 Vehicle	The test substance was moistened with distilled water.
3.3.5 Concentration	2000 mg/kg b.w.
3.3.6 Concentration in vehicle	Not reported
3.3.7 Total volume applied	Not reported

3.3.8 Duration of exposure	24 hours
3.3.9 Removal of test substance	The test site was swabbed with arachis oil BP to remove any residual material. *(give solvent, detergent)*
3.3.10 Controls	Not applicable – no control animals used in study
3.4 Examinations	Clinical observations, mortality, dermal reactions, irritation, bodyweights and necropsy. Observations for death or toxicity were taken 0.5, 1, 2 and 4 hours after dosing and then once daily for fourteen days. Dermal reactions and signs of irritation were measured after removal of the dressings and once daily for fourteen days. Individual bodyweights were measured prior to dosing and seven and fourteen days after treatment. All animals were subjected to gross pathological examination after death.
3.5 Method of determination of LD_{50}	Acute dermal median lethal dose (LD_{50}) was determined from mortality data and not by statistical analysis.
	4 RESULTS AND DISCUSSION *Describe findings. If appropriate, include table. Sample tables are given below.*
4.1 Clinical signs	*No effects / describe significant effects referring to data in results table* There were no signs of systemic toxicity at any observation time point in any of the treated animals.
4.2 Pathology	*No effects / describe significant effects referring to data in results table* No abnormalities were noted at necropsy.
4.3 Other	*Describe any other significant effects* There were no mortalities among any of the treated animals at study termination, and no signs of dermal irritation at any observation time point in any of the treated animals. All animals showed expected gains in bodyweight over the study period.
4.4 LD_{50}	*Give LD_{50} male, females, males + females* *State if no lethal effect at maximal dose* There were no mortalities or signs of systemic toxicity among any of the animals treated with copper oxide at the test concentration of 2000 mg/kg b.w. The acute median lethal dose (LD_{50}) of copper oxide in the Sprague-Dawley CD (Crl: CD (SD) IGS BR) strain of rat

was, therefore, found to be >2000 mg/kg b.w.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines

The study was performed to assess the acute dermal toxicity of copper oxide in Sprague-Dawley CD (Crl:CD (SD) IGS BR) strain rats. A group of 10 animals (five males and five females) were given a single, 24-hour semi-occluded dermal application of test material moistened with distilled water at a dose level of 2000 mg/kg bw to an area of shorn skin (approximately 10% of the total body surface area).

The animals were observed for death or overt signs of toxicity 0.5, 1, 2 and 4 hours after dosing and subsequently once daily for 14 days. Following removal of the dressing (after 24-hours exposure), the test sites were examined for evidence of primary irritation and scored according to the scale from Draize J. H. 1977.

Individual bodyweights were recorded prior to application of the test material, on Day 0, 7 and 14.

At the end of the study, animals were sacrificed and subjected to gross necropsy. The appearance of any macroscopic abnormalities was recorded.

The study was conducted according to OECD Guidelines for the Testing of Chemicals No. 402 'Acute Dermal Toxicity' (adopted 24 February 1987) and Commission Directive 92/69/EEC Method B3 Acute Toxicity (Dermal). The study was also conducted according to GLP.

No deviations from the test guidelines, or deficiencies in the method were reported.

Section A6.1.2		**Acute Dermal Toxicity in the Rat (LD_{50})**
Annex Point IIA6.1.2		*Specify section no., heading, route and species as appropriate* *Specify type of test (Limit Test, LD_{50}, special investigation)*
IUCLID: 5.1.3(01)		**A6.1.2(01), Acute Dermal Toxicity**
5.2	**Results and discussion**	*Summarize relevant results; discuss dose-response relationship.* There were no mortalities, signs of systemic toxicity, or dermal irritation among any of the animals treated with copper oxide at the test concentration of 2000 mg/kg b.w. All animals showed expected gains in bodyweight over the study period and there were no abnormalities noted at necropsy. The acute median lethal dose (LD_{50}) of copper oxide in the Sprague-Dawley CD (Crl: CD (SD) IGS BR) strain of rat was, therefore, found to be >2000 mg/kg b.w. The test material does not meet the criteria for classification and will not require labelling for dermal toxicity in accordance with EU labelling regulations Commission Directive 93/21/EEC.
5.3	**Conclusion**	Non-entry field
5.3.1	Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3, or 4* (1) valid without restriction
5.3.2	Deficiencies	No *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*

Section A6.1.2	**Acute Dermal Toxicity in the Rat (LD_{50})**
Annex Point IIA6.1.2	*Specify section no., heading, route and species as appropriate* *Specify type of test (Limit Test, LD_{50}, special investigation)*
IUCLID: 5.1.3(01)	**A6.1.2(01), Acute Dermal Toxicity**

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and	*Discuss if deviating from view of rapporteur member state*
discussion Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

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Result: Histogram Report

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Sample ID: 0420, with men \..Cr] 45 Rua Numbes: 16 Megured: Tue 13 Feb 3001 41 16844
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Range Lens: 300 mm nem Lengt b: 10,00 mm Sampler: 1+.45X14 Obscur:ilion: 16.0 %
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SZO (um)	volume In %	Mize (6n)	Volume In 9	Sire (um)	Volume In %	5124 (um)	Volume In %
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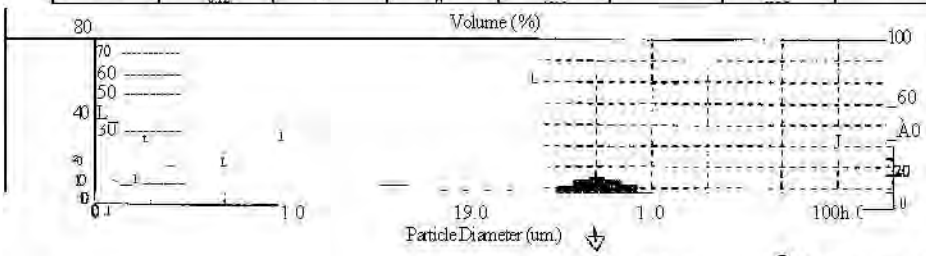
1.16	0.04		0.1	2713	1.17	1319	1.00
1.24	0.04		2	2900	220	1405	0.80
1.32	0.05		0.1	1089	2.58	149.7	0.65
1.40	0.05		3	3290	2.95	1504	052
1.49	0.05		0.1	3505	332	169.8	0.40
1.59	0.05		4	3739	3.72	1309	0,30
1.69	0.05		0.1	3976	4.09	192.6	0.23
1.80	0.05		3	4239	439	205.2	1
1.92 2	0.05		0.1	4511	462	218.6	0.17
515	0.05		6	4105	475	2328	0.12
2.16	0.06		0.1	1851.	479	248.0	0.09
2.32	0.06		7	5432	475	264.1	0.47
2.47	0.07		0.1	5807	463	281.3	0.05
2.64	0.07		8	6185	446	299.7	0.03
181			0.1	6583	425	319.2	003
2.99	0.07		9	7017	359	440.0	0-02
3.18	0.06		0.2	7474	368	362.1	0.02
3.39	0.08		0	7961	336	365.7	0.01
3.61 3.	0_0		0.2	8480	302	410.9	0.01
85	8		1	90.	264	437.6	0.01
4.10	0.09		0.2	33	232	466.1	0.51
4.37	0.09		2	9621	201	4965	000
4.65 --	0.10		0.2	1025	1.71	5211.	0.03
4.95	0.10		4	1092	1.44	8	0.00
3_28	0.11		0.2	1163	121	5633	0.00
	0.12		6				000



e.61 3 '6 I9 ws,"'7

Figure 1: Particle Size Distribution

Section A6.1.4 **Annex Point IIA6.1.4** **IUCLID : 5.2.1(01)**	**Acute Dermal Irritation in the New Zealand White Rabbit** *Specify section no., heading and species as appropriate* **A6.1.4(01), Acute Dermal Irritation**

Official use only

		1 REFERENCE
1.1	**Reference**	*Author(s), year, title, laboratory name, laboratory report number, report date (if published, list journal name, volume: pages)* *If necessary, copy field and enter other reference(s).* [redacted] (2002). Cupric Oxide: Acute Dermal Irritation in the Rabbit. SafePharm Laboratories Limited. Report No. 1654/003 (unpublished)
1.2	**Data protection**	Yes *(indicate if data protection is claimed)*
1.2.1	Data owner	*Give name of company* Wood Preservative Copper Taskforce
1.2.2	Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on existing [a.s. / b.p.] for the purpose of its [entry into Annex I/IA / authorisation]
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes - The study was conducted to the following test guidelines: OECD Guidelines for the Testing of Chemicals No. 404 'Acute Dermal Irritation/Corrosion' (adopted 17 July 1992) Commission Directive 92/69/EEC Method B4 Acute Toxicity (Skin Irritation). *(If yes, give guidelines; if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*
2.2	**GLP**	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*
2.3	**Deviations**	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*
		3 MATERIALS AND METHODS
		In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.

Section A6.1.4 **Annex Point IIA6.1.4** **IUCLID : 5.2.1(01)**	**Acute Dermal Irritation in the New Zealand White Rabbit** *Specify section no., heading and species as appropriate* **A6.1.4(01), Acute Dermal Irritation**
3.1 Test material	Copper Oxide *or give name used in study report*
3.1.1 Lot/Batch number	*List lot/batch number if available* Lot/batch number: 02-0084
3.1.2 Specification	As given in section 2 *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*
3.1.2.1 Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)* Brown/black powder
3.1.2.2 Purity	*Give purity in % active substance* [redacted]
3.1.2.3 Stability	*Describe stability of test material* Stable at room temperature
3.2 Test Animals	*Non-entry field*
3.2.1 Species	Rabbit
3.2.2 Strain	New Zealand White Rabbit
3.2.3 Source	David Percival Ltd, Moston, Sandback, Cheshire, UK.
3.2.4 Sex	Male
3.2.5 Age/weight at study initiation	At the start of the study, the mean bodyweights were reported to be 2-3.5 kg and the ages ranged from 12 - 16 weeks old.
3.2.6 Number of animals per group	*Give number* *specify, if there are differences for example for treatment and recovery groups* 3
3.2.7 Control animals	No - untreated skin areas acted as a control.
3.3 Administration/ Dermal Exposure	
3.3.1 Application	***Non entry field***
3.3.1.1 Preparation of test substance	Test substance was prepared by mixing 0.5 grams of test substance with 0.5 ml of distilled water, immediately before application.
3.3.1.2 Test site and Preparation of Test Site	*State site: dorsal area of the trunk/left/right side of the trunk* *Shaved skin or other* *State skin cleaning method and used agents* On the day before the test, the dorsal/flank area was clipped to remove all fur.
3.3.2 Occlusion	Semi-occluded

3.3.3	Vehicle	Distilled water
3.3.4	Concentration in vehicle	Not applicable.
3.3.5	Total volume applied	0.5 g of test material, moistened with distilled water, was placed under a 2.5 cm x 2.5 cm cotton gauze patch and placed on the shorn skin.
3.3.6	Removal of test substance	Any residual test material was removed with 74% Industrial Methylated Spirits. *(give solvent, detergens)*
3.3.7	Duration of exposure	4 hours
3.3.8	Postexposure period	72-hours
3.3.9	Controls	Not applicable
3.4	**Examinations**	Irritation. Test sites were examined for irritation 1 hour after removal of the patches and 24, 48 and 72 hours later.
3.4.1	Clinical signs	No clinical examinations were made
3.4.2	Dermal examination	Yes, at the time points specified below, the test sites were examined for evidence of primary irritation and scored accordingly.
3.4.2.1	scoring system	*State scoring system* Draize scoring system.
3.4.2.2	Examination time points	Approximately 1, 24, 48 and 72 hours following the removal of the patches the test sites were examined for evidence of primary irritation.
3.4.3	Other examinations	No other examinations were taken.
3.5	**Further remarks**	The pH of a 10 % w/w aqueous preparation of the test material was approximately 9.2
		4 RESULTS AND DISCUSSION *Describe findings. If appropriate, include table. Sample tables are given below.*
4.1 Average score		Non-entry field
4.1.1	Erythema	*Give average score for all animals at 24, 48, 72 h* The average score at all examination time points was 0.
4.1.2	Edema	*Give average score for all animals at 24, 48, 72 h* The average score at all examination time points was 0.
4.2 Reversibility		*Name effect and give time for reversion.* Not applicable
4.3 Other examinations		*Give results*

No other examinations were taken.

4.4 Overall result

There was no evidence of skin irritation noted during the study.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods *Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines*

This study was conducted to assess the irritancy potential of copper oxide to the skin of the New Zealand White rabbit. A group of 3 male New Zealand White rabbits were given a single, 4-hour, semi-occluded dermal application of copper oxide (0.5 g moistened with 0.5 ml of distilled water) to intact skin clipped free of fur. Irritancy was determined 1, 24, 48 and 72 hours after the test substance was removed.

The study was conducted according to OECD Guidelines for the Testing of Chemicals No. 404 'Acute Dermal Irritation/Corrosion' (adopted 17 July 1992) and Commission Directive 92/69/EEC Method B4 Acute Toxicity (Skin Irritation). The study was also conducted according to GLP.

No deviations from the test guidelines, or deficiencies in the method were reported.

5.2 Results and discussion *Summarize relevant results; discuss dose-response relationship.*

The test material produced a primary irritation index of 0.0 and was classified as NON IRRITANT to rabbit skin according to the Draize classification scheme. No corrosive effects were noted.

5.3 Conclusion

The test material did not meet the criteria for classification as irritant or corrosive to skin according to the EU labelling regulations Commission Directive 93/21/EEC.

5.3.1 Reliability

Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3, or 4

(1) valid without restriction.

5.3.2 Deficiencies

No

(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)

Section A6.1.4 **Annex Point IIA6.1.4** **IUCLID : 5.2.1(01)**	**Acute Dermal Irritation in the New Zealand White Rabbit** *Specify section no., heading and species as appropriate* **A6.1.4(01), Acute Dermal Irritation**

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 6.1.4		**Acute Eye Irritation in the New Zealand White Rabbit**	
Annex Point IIA6.1.4		*Specify section no., heading and species as appropriate*	
IUCLID : 5.2.2(01)		**A6.1.4(02), Acute Eye Irritation**	
		4 REFERENCE	Official use only
4.1	**Reference**	*Author(s), year, title, laboratory name, laboratory report number, report date (if published, list journal name, volume: pages) If necessary, copy field and enter other reference(s).* [redacted] (2002). Cupric Oxide: Acute Eye Irritation in the Rabbit. SafePharm Laboratories Limited. Report No. 1645/004 (unpublished)	X
4.2	**Data protection**	Yes *(indicate if data protection is claimed)*	
4.2.1	Data owner	*Give name of company* Wood Preservative Copper Taskforce	
4.2.2			
4.2.3	Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on existing [a.s. / b.p.] for the purpose of its [entry into Annex I/IA / authorisation]	
		5 GUIDELINES AND QUALITY ASSURANCE	
5.1	**Guideline study**	Yes – the study was conducted according to the following test guidelines: OECD Guidelines for the Testing of Chemicals No. 405 'Acute Eye Irritation/Corrosion' (adopted 24 February 1987). Commission Directive 92/69/EEC Method B5 Acute Toxicity (Eye Irritation/Corrosion). *(If yes, give guidelines; if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
5.2	**GLP**	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
5.3	**Deviations**	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	
		6 MATERIALS AND METHODS	
		In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	

Section 6.1.4	**Acute Eye Irritation in the New Zealand White Rabbit**
Annex Point IIA6.1.4	*Specify section no., heading and species as appropriate*
IUCLID : 5.2.2(01)	**A6.1.4(02), Acute Eye Irritation**

6.1 Test material	Copper Oxide *or give name used in study report*
6.1.1 Lot/Batch number	*List lot/batch number if available* Lot/batch number: 02-0084
6.1.2 Specification	As given in section 2 *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*
6.1.2.1 Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)* Brown/black powder
6.1.2.2 Purity	*Give purity in % active substance* [redacted]
6.1.2.3 Stability	*Describe stability of test material* Stable at room temperature
6.2 Test Animals	*Non-entry field*
6.2.1 Species	Rabbit
6.2.2 Strain	New Zealand White Rabbit
6.2.3 Source	David Percival Ltd, Moston, Sandbach, Cheshire, UK.
6.2.4 Sex	Male
6.2.5 Age/weight at study initiation	At the start of the study the mean bodyweights ranged from 2.0 to 3.5 kg and test animals were 12 - 16 weeks old.
6.2.6 Number of animals per group	*Give number* *specify, if there are differences for example for treatment and recovery groups* 3
6.2.7 Control animals	No - the test material was instilled into one eye, the untreated eye acted as a control.
6.3 Administration/ Exposure	
6.3.1 Preparation of test substance	Test substance was used as supplied with no additional preparation.
6.3.2 Amount of active substance instilled	0.1 ml of test material (approximately 38 mg)
6.3.3 Exposure period	72 hours
6.3.4 Postexposure period	7 days
3.3.5 Removal of test substance	The test substance was not removed from the eye. Irritancy was determined on the unrinsed eye.

Section 6.1.4	**Acute Eye Irritation in the New Zealand White Rabbit**
Annex Point IIA6.1.4	*Specify section no., heading and species as appropriate*
IUCLID : 5.2.2(01)	**A6.1.4(02), Acute Eye Irritation**

6.4 Examinations	Ocular damage/irritation. Approximately 1, 24, 48 and 72 hours after treatment, the eyes were assessed for signs of ocular damage and irritation.
6.4.1 Ophthalmoscopic examination	yes
6.4.1.1 Scoring system	*state scoring system and give time table of examinations, describe the terms slight, moderate, etc., if these terms are used* Draize scoring system and modified Kay and Calandra classification system.
6.4.1.2 Examination time points	Assessment of ocular damage/irritation was made approximately 1 hour and 24, 48 and 72 hours following treatment. An additional observation was made in one treated eye on Day 7 to assess the reversibility of the ocular effects.
6.4.2 Other investigations	*for example: effect of rinsing* Immediately after administration of the test material, an assessment of the initial pain reaction was made according to a 0 (no initial pain) to 6 (very severe initial pain) point scale. Any other ocular effects were also noted.
6.5 Further remarks	The pH of a 10 % w/v aqueous preparation of the test material was approximately 9.2.
	4 RESULTS AND DISCUSSION *Describe findings. If appropriate, include table. Sample tables are given below.*
4.1 Clinical signs	*No effects / describe significant effects referring to data in results table* Not reported
4.2 Average score	Non-entry field
4.2.1 Cornea	*Give average score for all animals at 24, 48, 72 h* See Table A_6.1.4 Acute Eye Irritation.
4.2.2 Iris	*Give average score for all animals at 24, 48, 72 h* See Table A_6.1.4 Acute Eye Irritation.
4.2.3 Conjunctiva	Non-entry field
4.2.3.1 Redness	*Give average score for all animals at 24, 48, 72 h* See Table A_6.1.4 Acute Eye Irritation.
4.2.3.2 Chemosis	*Give average score for all animals at 24, 48, 72 h* See Table A_6.1.4 Acute Eye Irritation.
4.3 Reversibility	Yes - complete reversibility was seen for all aspects of occular damage after 7 days. *Name effect and give time for reversion.*