Section A1 Applicant

Annex Point IIA1

1.1 Applicant

Spiess-Urania Chemicals GmbH
Heidenkampsweg 77
D - 20097 Hamburg
Tel. [redacted]
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1.2 Manufacturer of Active Substance (if different)

Spiess-Urania Chemicals GmbH
Heidenkampsweg 77
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Contact person:
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Fax: [redacted]
E-mail: [redacted]@spiess-urania.com
Location of manufacturing plant:
Spiess-Urania Chemicals GmbH
[redacted]

1.3 Manufacturer of Product(s) (if different)

as above

1) Product 1

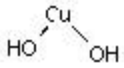
2) Product n

Section A2 Identity of Copper (II) hydroxide

Subsection (Annex Point)			Official use only
2.1	**Common name (IIA2.1)**	EINECS name: Copper dihydroxide (ISO not allocated) Synonyms: Cupric hydroxide, Funguran-OH, Cuprozin WP, Champion	X
2.2	**Chemical name (IIA2.2)**	IUPAC name: Copper(II)hydroxide, Copper-dihydroxide	
2.3	**Manufacturer´s development code number(s) (IIA2.3)**	SPU-00620-F	
2.4	**CAS No and EC numbers (IIA2.4)**		
2.4.1	**CAS-No**	20427-59-2	
	Isomer 1		
	Isomer n		
2.4.2	**EC-No**	EINECS: 243-815-9	
	Isomer 1		
	Isomer n		
2.4.3	**Other**	not stated	
2.5	**Molecular and structural formula, molecular mass (IIA2.5)**		
2.5.1	**Molecular formula**	CuH_2O_2 ; $Cu(OH)_2$	
2.5.2	**Structural formula**	not applicable	X
2.5.3	**Molecular mass**	97.54 g/mol	
2.6	**Method of manufacture of the active substance (IIA2.1)**	**CONFIDENTIAL DATA ON SECTION A2.6 ARE SUBMITTED IN A SEPARATE FILE**	
2.7	**Specification of the purity of the active substance, as appropriate (IIA2.7)**	98 % (w/w) copper hydroxide corresponding to 64 % (w/w) copper	X
2.8	**Identity of impurities and additives, as appropriate (IIA2.8)**	See separate standard format A2.8 in confidential file	
2.8.1	**Isomeric**	not applicable	

Section A2 Identity of Copper (II) hydroxide

	composition	
2.9	**The origin of the natural active substance or the precursor(s) of the active substance (IIA2.9)**	not relevant

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	April 2009, revised November 2011 (after CA meeting of September 2011)
Materials and methods	2.1 Common name Copper hydroxide, often used in the dossier, should be understood as copper (II) hydroxide. 2.5.2 Structural formula  2.7 Specification of the purity 96.5 % *(w/w) copper hydroxide, corresponding to* 62.9 % *(w/w) copper.* The results of a five-batch analysis (non-GLP) are presented in confidential part. See confidential doc IIA for more information about the specifications.
Conclusion	Adopt applicant´s version with above amendments
Reliability	Not applicable
Acceptability	Acceptable.
Remarks	The substance is manufactured as a solid salt, and is defined in this form as "active substance as manufactured" according to the REACH definition. It dissociates in solutions and releases cupric ion Cu^{2+}, e.g. in liquid biocidal products, which is the effective active substance. For these reasons, purity is specified as copper (II) hydroxide and as copper in technical grade.
	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	

Section A2.10

Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Official use only

Subsection

2.10.1 Human exposure towards active substance

2.10.1.1 Production

i) Description of process	30°C, atmospheric pressure, closed vessel, discontinuous process, batch size 6 to per batch, one batch per day (3 shifts); following precipitation the a.s. is dried and bagged
ii) Workplace description	chemical reaction and bagging (one worker per shift): enclosed building, LEV, administrative procedures: written OP's, workplace/site specific training; PPE: compulsory: helmet, goggles, gloves, voluntary: RPE
iii) Inhalation exposure	PAS, method acc. to TRGS 402 (3.5 l/min, 1.25 m/s), det. NICOSH 7029, year of measurement 2001 chemical reaction: duration of task 12 h, form during handling: suspension, 3 measurements, exposure conc. 0.13 – 1.37 mg/m³, typical case 0.2 mg/m³, reasonable worst case 1 mg/m³ bagging: duration of task 12 h, form during handling: powder, 8 measurements, exposure conc. 0.12 – 0.39 mg/m³, typical case 0.2 mg/m³, reasonable worst case 0.3 mg/m³
iv) Dermal exposure	Dermal absorption is thought not to be relevant for human exposure; there are no measures on dermal exposure available; for medical expert statement on experience with manufacturing plant personnel refer to Section A6.12.1, for information on *in vitro* percutaneous absorption of copper through human skin refer to Section A6.2/ 03.

2.10.1.2 Intended use(s)

1. Professional Users

i) Description of application process	Wood protection by pre-treatment in industrial premises (vacuum pressure impregnation and professional dipping treatment).
ii) Workplace description	Liquid wood preservative concentrate is added via automatical devices to waterfilled enclosed vessels. Mixing and loading phases are fully automated by means of double-walled premises and mechanical upstroke facilities. – After application the treated wood is transferred by means of a forklift to the transient storehouse where the wood is stocked for about 14 days during fixation time.
iii) Inhalation exposure	Inhalation exposure is not relevant as copper used as active substance in biocidal products is not volatile.
iv) Dermal exposure	Other than incidental exposure during connecting and disconnecting transfer lines is not forseeable. Incidental exposure results from contact with product inside protective gloves and from taking off protective gloves.

2. Non-professional Users including the general public

Section A2.10
Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

(i) via inhalational contact	Non-professional uses not envisaged. Exposure of the general public is not relevant because of the negligible amount of copper in in the treated wood and because copper is virtually unvolatile.
(ii) via skin contact	Non-professional uses not envisaged. Exposure of the general public negligible. Moreover, studies performed with rats have not indicated any risk after skin contact.
(iii) via drinking water	Non-professional uses not envisaged. Exposure of the general public negligible (no relevant residues found in leaching water).
(iv) via food	Non-professional uses not envisaged. Exposure of the general public negligible (wood preservative, therefore no residues in food possible).
(v) indirect via environment	No significant residues are to be expected in water and air (see above). Moreover, due to the low concentration of copper in treated wood and the low leaching rates (max. 10% over 10 years), it is not expected that significant amounts of copper will contaminate soil.

2.10.2 Environmental exposure towards active substance

2.10.2.1 Production

(i) Releases into water	Production in closed system, therefore no releases into water occur.
(ii) Releases into air	Emissions into air via filtered dust only occur in legal given frame according to German emission laws and are regularly controlled .
(iii) Waste disposal	Production in closed system, therefore no waste is produced during production cycle.

2.10.2.2 Intended use(s) *One standard format to be used for each intended use*

Affected compartment(s):	*Give a percentage distribution between the different environmental compartments estimated from the physico-chemical data or calculations with generic models (e.g. Mackay)*
water sediment air soil	In water, Copper hydroxide is not susceptible to any abiotic or biotic degradation processes, and environmental partitioning processes are not predictable by conventional models (i.e. logPow). Partitioning from water to sediment, where locally prevailing sediment sulphide concentrations will determine the degree of bioavailability, and absorption to soil are the most relevant environment distribution processes for Copper.
Predicted concentration in the affected compartment(s)	*Give an estimation of the expected concentrations of a.s. in the affected compartments from one application of a.s. using the recommended application concentrations and techniques*
water	Annual or 180 day average PEC (based on the scenario for metalworking fluids): $PEC_{surface\ water} = 1.35 \times 10^{-4}$ mg/L $PEC_{STP} = 1.98 \times 10^{-3}$ mg/L
sediment	$PEC_{sediment} = 0.02$ mg/L
air	The vapour pressure of copper hydroxide is safely assumed to be

Section A2.10 Annex Point IIA2.10	Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC
	below the level of concern at < 1.0 x 10^{-5} Pa, thus no relevant volatilisation is expected.
soil	Emissions resulting from timber treatment: $PEC_{soil, agricultural}$ = 0.04 mg/kg $PEC_{soil, grassland}$ = 0.016 mg/kg

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	15/03/2007
Materials and methods	Not applicable
Conclusion	For occupational human exposure: The data concerning production are not used because occupational human exposure during manufacture of the biocide active substance Copper hydroxide and occupational human exposure during manufacture of the biocidal product SPU 01860F are not assessed in this biocide dossier. Only occupational human exposure to Copper during the use and disposal of the biocidal product SPU 01860F is considered in this biocide dossier. The data concerning the intended use are fully reported in the document DOC IIB (CuOH)
Reliability	Not applicable
Acceptability	not acceptable
Remarks	
	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	

Section A3	Physical and Chemical Properties of Copper Hydroxide							
Subsection (Annex Point)	**Method**	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Relia-bility**	**Reference**	**Official use only**
3.1 Melting point, boiling point, relative density (IIA3.1)								
3.1.1 Melting point	--EC method A1	--Batch 23063 63% Cu	--	**No melting and boiling point determinable, since the test substance undergoes decomposition at a minimum temperature of 200°C (conducted by DSC).**	Y	1	A3.10	
3.1.2 Boiling point	---EC method A2	Batch 23063 63% Cu	--		Y	1	A3.10	
3.1.3 Bulk density/ relative density	EC method A3	-- Batch 23063 63.0 % Cu	**$\rho^{19.9}_{4.0}$ = 3.978 kg/L**	Determined with an air comparison pycnometer following DIN 55990	Y	1	A3.1.3	

Section A3	Physical and Chemical Properties of Copper Hydroxide							
Subsection (Annex Point)	**Method**	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Relia-bility**	**Reference**	**Official use only**
3.2 Vapour pressure (IIA3.2)	--	--	< 1.0 • 10^{-5} Pa	**$Cu(OH)_2$ is a crystalline, inorganic substance, which cannot exist in an unsolvated, unassociated or dissociated state, decomposes above 229°C under dehydration. The volatility of this substance type can therefore be safely assumed to be negligible , i.e. below the level of significance (1.0 • 10^{-5} Pa).**	--	--		
3.2.1 Henry´s Law Constant (Pt. I-A3.2)	--	--	no constant measured/ calculated	**The vapour pressure is not measurable.**	--	--		
3.3 Appearance (IIA3.3)		Batch 23063 63.0 % Cu			Y	1	A3.3	
3.3.1 Physical state	optical control		**powder**					
3.3.2 Colour	optical control		**light blue**					
3.3.3 Odour	smelling		**odourless**					

Section A3	Physical and Chemical Properties of Copper Hydroxide							
Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Relia-bility	Reference	Official use only
3.4 Absorption spectra (IIA3.4)								
UV/VIS	--	--	--	As an inorganic salt, $Cu(OH)_2$ does not contain UV-active chromophores.	--	--	--	
IR	--	--	--	As an inorganic salt, $Cu(OH)_2$ does not contain covalent bonds.	--	--	--	
NMR	--	--	--	Since $Cu(OH)_2$ does not contain any non acid proton or any other NMR susceptible nucleus, it cannot be measured by NMR spectroscopy.	--	--	--	
MS	--	--	--	technically not feasible (for justification refer to A3.4.4 non-sub)	--	--	--	

Section A3	Physical and Chemical Properties of Copper Hydroxide							
Subsection (Annex Point)	**Method**	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Relia-bility**	**Reference**	**Official use only**
3.5 Solubility in water (IIA3.5)		63.0 % Cu			Y	1	A3.5	X
Water solubility 1	OECD Guideline 105 EC method A.6	pure water (saturated with atmospheric carbon dioxide)	**result: 0.9318 mg/L temperature: 20°C pH: 7.0**					
Water solubility 2		pure water (free of carbon dioxide)	**result: 0.0066 mg/L temperature: 20°C pH: 8.9** **result: 0.0072 mg/L temperature: 30°C pH: 8.7**					
Water solubility 3		water, 446 mmol H_2SO_4/L	**result: 8184 mg/L temperature: 20°C pH: 4.1**					
Water solubility 4		Borate buffer, 50 mmol/L	**result: 0.0335 mg/L temperature: 20°C pH: 9.1**					
3.6 Dissociation constant (-)	--	--	--	**only required, if water solubility cannot be measured**	--	--	--	

Section A3	Physical and Chemical Properties of Copper Hydroxide							
Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Relia-bility	Reference	Official use only
3.7 Solubility in organic solvents, including the effect of temperature on solubility (IIIA3.1)	CIPAC method MT 181	Batch 23063 63.0 % Cu **Reagents:** • n-heptane • p-xylene • 1,2-dichloro-ethane • methanol • acetone • ethylacetate	**result: < 10 g/L** **temperature: 20°C** **result: < 10 g/L** **temperature: 30°C**		Y	1	A3.7	
3.8 Stability in organic solvents used in b.p. and identity of relevant breakdown products (IIIA3.2)	--	--	--	**not required since the active substance as manufactured does not contain any organic solvents and is only used in aqueous preparations**	--	--	--	
3.9 Partition coefficient n-octanol/water (IIA3.6)	--	--	--	**technically not feasible (for justification refer to A3.9 non-sub)**	--	--	--	
3.10 Thermal stability, identity of relevant breakdown products (IIA3.7)	OECD Guideline 113	Batch 23063 63.0 % Cu under nitrogen in a closed crucible	**endothermic effect in the temperature range from 130 - 200°C**	The test item did not melt, it remained in the powdery state	Y	1	A3.10	
		under air in an open crucible	**endothermic effect in the temperature range from 130 - 195°C followed by an exothermic effect at 195 – 300°C**	mass loss of 20 % (w/w)				

Section A3	Physical and Chemical Properties of Copper Hydroxide							
Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Relia-bility	Reference	Official use only
3.11 Flammability, including auto-flammability and identity of combustion products (IIA3.8)	--	--	--	**Copper hydroxide is an inorganic ionic salt in solid form, at the highest possible oxidation state (+2). Therefore it is not combustible or flammable and in addition, experience in use indicates that it is not flammable nor self-heating or auto-ignitable. (for justification refer to A3.11 non-sub)**	--	--	--	
3.12 Flash-point (IIA3.9)	--	--	--	**not required for solids (for justification refer to A3.12 non-sub)**	--	--	--	
3.13 Surface tension (IIA3.10)	OECD Guideline 115 EC method A.5	--	**result: 74.3 mN/m temperature: 20.1°C**	**Active substance not surface active**	Y	1	A3.13	
3.14 Viscosity (-)	--	--	--	**not required for solids**	--	--	--	
3.15 Explosive properties (IIA3.11)	--	--	--	**not required since no explosive groups contained**	--	--	--	
3.16 Oxidizing properties (IIA3.12)	--	--	--	**Not required since no oxidizing groups contained (for justification refer to A3.16 non-sub)**	--	--	--	

Section A3	Physical and Chemical Properties of Copper Hydroxide							
Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Relia-bility	Reference	Official use only
3.17 Reactivity towards container material (IIA3.13)	--	--	--	Storage conditions of copper hydroxide (dry solid powder) are ambient pressure and temperature.. In use are standard polylined paper bags and bigbags (PP ,PE). (see A3.17 non sub)	--	--	--	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	January 2007 and April 2009
Materials and methods	Purity : 63% copper is equivalent to 97% copper (II) hydroxide. 3.5 Water solubility Add remark: The solubilisation results from the dissociation of the salt liberating OH^- : $Cu(OH)_2 \Leftrightarrow Cu^{2+} + 2\ OH^-$. At low pH, the equilibrium is displaced with consumption of H^+ ions : $OH^- + H^+ \rightarrow H_2O$. This explains the very high solubility at low pH, compared to neutral or basic pH. Other results and remarks are acceptable.
Conclusion	Agree with applicant's version
Reliability	As in the table
Acceptability	Acceptable
Remarks	Copper hydroxide should be understood as copper (II) hydroxide)
	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	

Reference list, by section number

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A3.1.3	[redacted]	2003	Relative density of SPU-00620 (Copper hydroxide techn.). Study performed by [redacted] Doc No 20031137/01-PCRD	Y	SPU
A3.3	[redacted]	2003	Appearance, Colour and Odour of SPU-00620 (Copper hydroxide techn.). Study performed by [redacted]	Y	SPU

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			Doc No 20031137/01-PCAO		
A3.5	[redacted]	2003	Water solubility of SPU-00620. Study performed by [redacted] Doc No 20031137/01-PCSB	Y	SPU
A3.7	[redacted]	2003	Solubility of SPU-00620 (Copper hydroxide techn.) in Organic Solvents. Study performed by [redacted] Doc No 20031137/01-PSBO	Y	SPU
A3.10	[redacted]	2003	SPU-00620 - Thermal stability. Study performed by [redacted] Doc No 20030459.01	Y	SPU
A3.13	[redacted]	2003	Surface Tension of SPU-00620 (Copper hydroxide techn.). Study performed by [redacted] Doc No 20031137/01-PCST	Y	SPU

Section A3.2 Annex Point IIA3.2	Vapour pressure	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [X]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	Basic copper carbonate is a crystalline, inorganic substance, which cannot exist in an unsolvated, unassociated or dissociated state, decomposes above a minimum temperature of 240°C under dehydration. The volatility of this substance type can therefore be safely assumed to be negligible, i.e. below the level of significance ($1.0 \cdot 10^{-5}$ Pa).	

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	January 2007 amended April 2009
Evaluation of applicant's justification	Applicant's justification is about 'basic copper carbonate' whereas the active substance is here copper (II) hydroxide.
Conclusion	Applicant's justification is acceptable also for copper (II) hydroxide.
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 A3.4 Annex Point IIA3.4	Absorption spectra – UV/Vis – IR - NMR	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [] **Scientifically unjustified** [X]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	These analysis are not appropriate to the substance.	

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	15/06/2005
Evaluation of applicant's justification	
Conclusion	The justification for not conducting the test is acceptable.
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 A3.4.4 Annex Point IIA3.4	Absorption spectra – Mass Spectrum	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [X] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	The principle of mass spectrometry is the evaporation and subsequent fragmentation of a test substance in order to characterise the substance. Thus, mass spectrometry implicitly is only applicable to organic substances. Simple anorganic salts like Copper hydroxide cannot be fragmented. In addition, it has been shown that Copper hydroxide cannot be vaporised since the substance undergoes decomposition at a minimum temperature of 200°C when heated and does not reach a boiling temperature. In conclusion, a mass spectrum of Copper hydroxide cannot be provided.	

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	January 2007
Evaluation of applicant's justification	Applicant's justification is acceptable
Conclusion	Applicant's justification is acceptable
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 A3.6.	Copper hydroxide A3.6 Dissociation constant	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [X]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	Only required if water solubility cannot be measured.	

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	11/07/2005
Evaluation of applicant's justification	
Conclusion	Applicant's justification is acceptable
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 A3.8.	Copper hydroxide A3.8 Stability in organic solvents	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [X]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	The active substance Cu(OH)2 as manufactured does not include any organic solvent .	

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	11/07/2005
Evaluation of applicant's justification	
Conclusion	The justification for not conducting the test is acceptable
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 A3.9 Annex Point IIA3.6	Partition coefficient n-octanol/water	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [X] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	The octanol:water partition coefficient, P_{OW}, is defined as the ratio of the equilibrium concentrations of a dissolved substance in each of the phases in a two phase system consisting of octanol and water. It is usually expressed on a log scale. It is a key parameter in studies of the environmental fate of organic pesticides, indicating the potential for bioaccumulation and soil absorption. However, the mechanisms of absorption of Cu^{2+} into organic matter and living cells are understood to be different from those traditionally attributed to carbon-based pesticides and the parameter therefore has little relevance to ionic copper. In order to measure Log P_{OW} it is necessary to determine an absolute value for the concentration in each phase. Copper is a metallic element that can only exist in solution in a totally dissociated ionic state. Its solubility is very low in both phases, and it is not possible to determine the partition coefficient by direct measurement of the concentration in both phases. An alternative method to estimate the partition coefficient is to express the ratio of the solubilities of the pesticide in octanol and water. This method is recognised as giving a reasonable estimate of partition coefficient for organic molecules where the solubility is widely different in each solvent. In the case of inorganic copper the solubility is low in both phases. The estimate using this approach is considered unreliable. Studies on most of the forms have been conducted to confirm the solubility is low in both phases.	

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	08/12/04
Evaluation of applicant's justification	Discuss applicant's justification and, if applicable, deviating view
Conclusion	Agree with applicant's version
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 A3.11 **Annex Point A3.11**	**Copper hydroxide** **A3.11, Flammability, including auto-flammability and identity of combustion products**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible []** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	Copper hydroxide is an inorganic ionic salt in solid form. Therefore it is not combustible or flammable and in addition, experience in use indicates that it is not flammable nor self-heating or auto-ignitable.	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	21/06/05	
Evaluation of applicant's justification	In addition to the applicant's justification: Copper dihydroxide is the highest possible oxidation state (+2)	
Conclusion	The justification for not conducting the test is acceptable	
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 A3.12	**Copper hydroxide** **A3.12, Flash-point**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible []** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:		
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	22/02/05	
Evaluation of applicant's justification	In accordance with the technical guidance document in support of the directive 98/8/EC concerning the placing of biocidal products on the market, chapter 2, section A3.12 states that the flash point must be provided for liquids whose vapours can be ignited. A flash point value for Copper dihydroxide was not determined, as this test is not relevant to solid compounds.	
Conclusion	The justification for not conducting the test is acceptable.	
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 A3.14.	Copper hydroxide A3.14 Viscosity	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [X]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	Not required for solids	

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	11/07/2005
Evaluation of applicant's justification	
Conclusion	Applicant's justification is acceptable
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 A3.15 **Annex Point A3.15**	**Copper hydroxide** **A3.15, Explosive properties**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure** [ ]	**Technically not feasible** [] **Scientifically unjustified** [X] **Other justification** [ ]	
Detailed justification:	Not required since no reactive groups contained.	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	22/02/05	
Evaluation of applicant's justification	In accordance with the technical guidance document in support of the directive 98/8/EC concerning the placing of biocidal products on the market, chapter 2, section A3.15 states that a determination of the explosive properties can be exempted when available thermodynamic information (heat of formation/decomposition) or absence of certain reactive groups in the structural formula or its "oxygen balance" establishes beyond reasonable doubt that the substance is incapable of decomposing, forming gases or releasing heat very rapidly. Based on the chemical composition and experience in use, it is considered that this test would give a negative result for copper oxide.	
Conclusion	The applicant's justification is acceptable.	
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*	

Section A3.15 **Annex Point A3.15**	**Copper hydroxide** **A3.15, Explosive properties**
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A3.16 **Annex Point IIA3.12**	**Copper hydroxide** **Oxidizing properties**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible []** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	Oxidising compounds are materials that can easily transfer oxygen to other compounds. i.e. they contain weakly bound oxygen, for example NO_3 and peroxides. Bound oxygen must also become available through a low energy degradation route with a low energy of activation. The oxygen in copper hydroxide is bound up in a very stable structural grouping with strong oxygen bonds. The decomposition temperature of copper hydroxide is also high indicating a high energy of activation. Therefore it is considered inert under the conditions of oxidation. Experience in use of the copper compounds with hydroxide, oxide and sulphate over many years also indicates that they are not associated with oxidising hazards.	

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	22/02/2005
Evaluation of applicant's justification	In addition to the applicant's justification: the absence of reactive oxidizing groups in the structural formula justifies the non-realisation of the oxidizing properties test.
Conclusion	The justification for not conducting the test is acceptable. Based on the chemical composition and experience in use, it is considered that this test would give a negative result for Copper dihydroxide.
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 A3.17	Copper hydroxide Reactivity towards container material	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [X]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	Due to the non-corrosive and non-reactive properties of Copper hydroxide no special requirements are set with respect to container materials.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	16/06/2005	
Evaluation of applicant's justification		
Conclusion	The justification for not conducting the test is acceptable.	
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 A4.1

Annex Point IIA4.1

Analytical Methods for the determination of pure active substance...

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (2003): Validated method of analysis for the determination of copper in SPU-00620-F. Trial station: [redacted] Germany. Doc. no. Wa-15-07-03-00620
1.2	**Data protection**	Yes
1.2.1	Data owner	Spiess-Urania Chemicals GmbH, Hamburg
1.2.2	Companies with letter of access	--
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing active substance for the purpose of its entry into Annex I

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes Test method according to CIPAC Handbook E, page 42, total copper 44/TC/M/3.1
2.2	**GLP**	No
2.3	**Deviations**	No

3 MATERIALS AND METHODS

3.1	**Preliminary treatment**	
3.1.1	Enrichment	Digestion of 1 g copper hydroxide with boiling beads, deionized water, silicon defoamer and conc. nitric acid. After heating add again acid nitric and sulphuric acid.
3.1.2	Cleanup	Analytical round filter, rinsed with deionized water.
3.2	**Detection**	
3.2.1	Separation method	Electrolytic separation and gravimetric determination of copper.
3.2.2	Detector	Difference of weight before and after electrolysis.
3.2.3	Standard(s)	external Standard: copper(II)-oxide
3.2.4	Interfering substance(s)	not stated
3.3	**Linearity**	
3.3.1	Calibration range	not applicable
3.3.2	Number of measurements	5 single determinations
3.3.3	Linearity	not applicable

3.4	**Specifity: interfering substances**	No interfering substance was determined. The specificity was given.
3.5	**Recovery rates at different levels**	1st measurement: 16/06/2003: five determinations mean value: 63.87 (63.78 – 63.91) % Cu recovery rate: 99.95% (99.81 - 100.02%) 2nd measurement: 24/06/2003: five determinations mean value: 63.85 (63.79 – 63.90) % Cu recovery rate: 99.92% (99.83 - 100.00%)
3.5.1	Relative standard deviation	± 0.08 %
3.6	**Limit of determination**	not applicable
3.7	**Precision**	
3.7.1	Repeatability	Variation coefficient: ± 0.08 % The recommended value under condition of repeatability according to Horowitz amounts to a maximum value of 1.34 %.
3.7.2	Independent laboratory validation	not stated

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1	**Materials and methods**	1 g copper hydroxide was digested with boiling beads, deionized water, silicon defoamer and concentrated nitric acid and was then heated for approximately 30 min at 250 °C. After cooling down to room temperature acid nitric and sulphuric acid were added and heated again up to 400 °C until sulphuric acids started fuming. The remained solution was filtered at about 60 °C and washed. In the warm solution adding nitric acid and electrolysis additives an electrolysis was conducted. The copper content was calculated by the weight difference of the cathode.
4.2	**Conclusion**	No outliers according Grubbs were observed. The variation coefficient as indicator for repeatability lies inside the required limits. Therefore the method can be considered as valid..
4.2.1	Reliability	1
4.2.2	Deficiencies	No

Section A4.1

Annex Point IIA4.1

Analytical Methods for the determination of pure active substance...

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	January 2007
Materials and methods	Agree with applicant's version
Conclusion	Adopt applicant's version
Reliability	Based on the assessment of the method include appropriate reliability indicator
Acceptability	Acceptable.
Remarks	
	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	

Section A4.2

Annex Point IIA4.2

Analytical Methods for the Determination of residues in human body fluids and tissues

Official use only

1 REFERENCE

1.1	**Reference**	BURGUERA, JL ET AL, (1993): In vivo sample uptake and on-line measurements of Zinc and Copper in whole blood by microwave-assisted mineralization and flow injection AAS, Department of Chemistry, Faculty of Sciences, University of Los Andes, Merida, Venezuela, Atomic spectroscopy, Vol.14, No.4, July/August 1993. Doc.no. 00620B-IIA-42c
1.2	**Data protection**	No
1.2.1	Data owner	Not allocated
1.2.2	Companies with letter of access	No
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing active substance for the purpose of its entry into Annex I

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Not stated
2.2	**GLP**	No
2.3	**Deviations**	No

3 MATERIALS AND METHODS

3.1	**Preliminary treatment**	
3.1.1	Enrichment	The sample was withdrawn directly from a patients forearm vein to a timed injector, which was automatically controlled to bring the sample/reagents mixtures into the carrier stream.
3.1.2	Cleanup	None
3.2	**Detection**	
3.2.1	Separation method	On-line, microwave-assisted mineralisation and flow injection atomic absorption spectrometry
3.2.2	Detector	Flame atomic absorption, wavelength 324.6 nm, injector: acid mixture/EDTA/blood samples mixing ratio (3:0.5:3)
3.2.3	Standard(s)	Not stated
3.2.4	Interfering substance(s)	None
3.3	**Linearity**	
3.3.1	Calibration range	not applicable
3.3.2	Number of measurements	not applicable
3.3.3	Linearity	not applicable

Section A4.2

Annex Point IIA4.2

Analytical Methods for the Determination of residues in human body fluids and tissues

3.4	**Specificity: interfering substances**	Not applicable
3.5	**Recovery rates at different levels**	Not stated
3.5.1	Relative standard deviation	2 to 10%
3.6	**Limit of determination**	Not stated
3.7	**Precision**	
3.7.1	Repeatability	Not stated
3.7.2	Independent laboratory validation	Not required

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1	**Materials and methods**	The sample was withdrawn directly from a patients forearm vein to a timed injector, which was automatically controlled to bring the sample/reagents mixtures into the carrier stream. Determination was performed by on-line, microwave-assisted mineralization and flow injection atomic absorption spectrometry.
4.2	**Conclusion**	The method enables the specific determination of copper in blood.
4.2.1	Reliability	2
4.2.2	Deficiencies	Validation data are not given

Section A4.2

Annex Point IIA4.2

Analytical Methods for the Determination of residues in human body fluids and tissues

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	January 2007
Materials and methods	The method given here comes from literature. So even this article does not give data for validation about linearity, limit of determination….), those data can be easily determined and are not 'not applicable' as mentioned by the applicant.
Conclusion	The method enables the specific determination of copper in blood but the applicant must give validation data. Applicant's version has to be revised.
Reliability	
Acceptability	Not acceptable,- however as the active substance is not toxic, it is not relevant to require a method.
Remarks	
	COMMENTS FROM ...
Date	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A4.2

Annex Point IIA4.2

Analytical Methods including recovery rates and the limit of determination for the active substance and for residues thereof in soil

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (1989): Method Validation Report for Terrestrial Outdoor Field Dissipation. Study with Copper-Containing Pesticides. Study performed by [redacted] Study no. 88-003. 110 pages Doc. no. URA-97-08740-108
1.2	**Data protection**	Yes
1.2.1	Data owner	Spiess-Urania Chemicals GmbH, Hamburg, Germany
1.2.2	Companies with letter of access	
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing active substance for the purpose of its entry into Annex I

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Description of EPA method 7210 (Flame AA) Preparation of the soil samples according to EPA methods 3010 (extractable copper) and 3050 (total copper)
2.2	**GLP**	yes
2.3	**Deviations**	not stated

3 MATERIALS AND METHODS

3.1	**Preliminary treatment**	
3.1.1	Enrichment	Soil samples analyzed for total copper were digested according EPA method 3050 (described on page 16/17 in the study): Mixing of 0.01 g of the sample with 5 mL nitric acid. Heating the sample without boiling for about 10 to 15 minutes Heating without boiling. After cooling add 2.5 mL nitric acid and return to hot plate for 30 min. Allow the solution to evaporate. After cooling add 1 mL of deionized water and 1.5 mL of 30 % hydrogen peroxide. Return to hot plate for warming to start the peroxide reaction.
3.1.2	Cleanup	Filtering of the solution by a Whatman No 51 filter.
3.2	**Detection**	
3.2.1	Separation method	Extractable and total Copper in soil samples EPA method 7210 (described on pages 31 - 34 in the study):
3.2.2	Detector	Flame Atomic Absorption Perkin Elmer 370A with digital concentration readout. Wavelength: 324.9 nanometers slit: 0.7 nanometers

Section A4.2

Annex Point IIA4.2

Analytical Methods including recovery rates and the limit of determination for the active substance and for residues thereof in soil

		Lamp current: 15 milliamps Air Flow: 40 mL/min Acetylen Flow: 20 mL/min
3.2.3	Standard(s)	Preparation of standard curves by external standards: Extractable copper: 0.5 mg/L to 5.0 mg/L Total copper: 0.1 mg/L to 5.0 mg/L
3.2.4	Interfering substance(s)	not stated
3.3	**Linearity**	
3.3.1	Calibration range	Standard curve for total and extractable copper: 0.5 / 1.0 / 2.0 / 5.0 mg/L Repetition of the calibration, if values are not within 10 % of actual concentration
3.3.2	Number of measurements	Samples were analyzed each in 7 replicates
3.3.3	Linearity	Correlation coefficient r^2 not stated.
3.4	**Specificity: interfering substances**	Not applicable
3.5	**Recovery rates at different levels**	**Soil Core Validation (total Copper):**

(Bio. # 88-04-037-13)

Spiking level	Analyzed	Recovery rate
20 µg/g	25 ± 1.4 µg/g	84.8 %
40 µg/g	46 ± 1.4 µg/g	96.0 %
100 µg/g	100 ± 4.1 µg/g	93.3 %

85.1 - 100 %

82.2 - 109.1 %

85.5 - 114.5 %

Soil Core Validation (Extractable Copper):

(Bio. # 88-04-037-13, # 88-04-037-14, # 88-04-037-15, # 88-04-037-16)

Spiking level	Analyzed values	Rel. standard deviation	Recovery rate
25 µg/g	20 - 25 µg/g	1.9 - 4.5 µg/g	85.1 - 100 %
50 µg/g	41 - 54 µg/g	2.1 - 11 µg/g	82.2 - 109 %
75 µg/g	64 - 85 µg/g	3.7 - 7.8 µg/g	85.5 - 114 %

3.6	**Limit of determination**	Instrument detection limit: 0.03 mg/L
3.7	**Precision**	
3.7.1	Repeatability	No value given. The standard deviations of 3 measurements including 7 replicates each were in the range between 0.0079 and 0.011 mg copper/L.
3.7.2	Independent laboratory validation	not stated

Section A4.2

Annex Point IIA4.2

Analytical Methods including recovery rates and the limit of determination for the active substance and for residues thereof in soil

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1	**Materials and methods**	Extractable and total copper in soil samples may be determined by atomic absorption spectroscopy (EPA method 7210) Preparation of the samples: After extracting according to the E.A. Jenne method the samples of extractable copper are digested according to EPA method 3010. Samples where total copper has to be measured are first digested according to EPA method 3050.
4.2	**Conclusion**	The validity criteria can be considered as fulfilled The described method can be used for the determination of the total and extractable copper content in soil samples.
4.2.1	Reliability	2
4.2.2	Deficiencies	No

Section A4.2

Annex Point IIA4.2

Analytical Methods including recovery rates and the limit of determination for the active substance and for residues thereof in soil

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	January 2007
Materials and methods	Relevant discrepancies Part 3.1: it is necessary to precise how soil sample is prepared before the digestion step. In fact, drying step and grinding step at the good granulometry are very important. The copper amount will be dependant on the granulometry. Part 3.5: What does 'recovery rate' mean in this part? The found values are upper theoretical values (so, recovery rate should be > 100%) and even when found value is very close to the theory, recovery rate is different from 100%. Part 3.6: limit of determination given here is the limit of the apparatus. It is necessary to know the limit of quantification of copper by this method. This limit must be expressed in µg/g of soil and not in mg/L
Conclusion	Applicant's version has to be revised
Reliability	
Acceptability	Not acceptable.
Remarks	
	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	

Section A4.2

Annex Point IIA4.2

Analytical Methods including recovery rates and the limit of determination for the active substance and for residues thereof in water

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (1989): Method Validation Report for Terrestrial Outdoor Field Dissipation. Study with Copper-Containing Pesticides. Study performed by [redacted] Study no. 88-003. 110 pages Doc. no. URA-97-08740-108
1.2	**Data protection**	Yes
1.2.1	Data owner	Spiess-Urania Chemicals GmbH, Hamburg, Germany
1.2.2	Companies with letter of access	
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing active substance for the purpose of its entry into Annex I

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Description of EPA method 220.2 (Furnace AA) Preparation of the aqueous samples according to EPA methods 3020
2.2	**GLP**	yes
2.3	**Deviations**	not stated

3 MATERIALS AND METHODS

3.1	**Preliminary treatment**	
3.1.1	Enrichment	Metal digestion for Furnace Method (aqueous samples) according to EPA method 3020 50 mL of sample in beaker. Adding 3 mL of concentrated nitric acid and covering. Heat in order to evaporate to near dryness without boiling. After cooling add another 3 mL concentrated nitric acid and return to hot plate: Heating so that gentle reflux occurs until near dryness. After that allow to cool.
3.1.2	Cleanup	Wash down sides of beaker with deionized water. Transfer to a 50 mL volumetric flask. Fill up the flask with deionized water of rinsing and mix.
3.2	**Detection**	
3.2.1	Separation method	Total and dissolved copper in a 0.01 M calcium nitrat solution and total and dissolved copper for aqueous samples. EPA method 220.2 (described on pages 35 - 37 in the study):

Section A4.2

Annex Point IIA4.2

Analytical Methods including recovery rates and the limit of determination for the active substance and for residues thereof in water

3.2.2	Detector	Furnace Atomic Absorption Perkin Elmer Z/3030 with digital print out and auto sampler. Wavelength: 324.8 nanometers slit: 0.7 nanometers Lamp current: 15 milliamps Argon Flow: 20 mL/min
3.2.3	Standard(s)	Preparation of a standard curve by external standards with the concentrations 0.010, 0.025, 0.05 and 0.10 mg/L by diluting appropriate amounts of the copper stock standard: 1) Total and dissolved copper diluted by deionized water 2) Total and dissolved copper diluted by 0.01 M calcium nitrate solution
3.2.4	Interfering substance(s)	not stated
3.3	**Linearity**	
3.3.1	Calibration range	A standard curve of 0.10, 0.025, 0.050 and 0.10 mg/L is used as calibration check Repetition of the calibration until an acceptable response is obtained, if values are not within 10 % of actual concentration
3.3.2	Number of measurements	Samples were analyzed each in 7 replicates
3.3.3	Linearity	Correlation coefficient r^2 not stated
3.4	**Specificity: interfering substances**	Not applicable
3.5	**Recovery rates at different levels**	**Reagent Blank Validation (Furnace AA):** (Bio. # 88-003)
3.6	**Relative standard deviation**	

Spiking level [mg copper/L]	Relative standard deviation [mg copper/L]	Recovery rate
0.025	0.029 ± 0.0009	115.4 %
0.050	0.058 ± 0.0032	115.4 %
0.10	0.11 ± 0.0063	111.4 %

3.7	**Limit of determination**	Instrument detection limit: 0.002 mg/L
3.8	**Precision**	
3.8.1	Repeatability	No value given. The standard deviations of the measurements including 7 replicates each were in the range between 0.00038 and 0.00053 mg copper/L.
3.8.2	Independent laboratory validation	not stated

Section A4.2

Annex Point IIA4.2

Analytical Methods including recovery rates and the limit of determination for the active substance and for residues thereof in water

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1	**Materials and methods**	Samples are first digested according to EPA method 3020 for aqueous samples of first extracted according to the TSS method provided by Hydroqual, Inc. for composite excavate samples; then the solution is digested according to EPA method 3020. Choose the proper lamp setting and allow to warm up for 15 min. During this period enter the correct wavelength and slit width on the monochromator.
4.2	**Conclusion**	The validity criteria can be considered as fulfilled The described method can be used for the determination of the total and dissolved copper in 0.01 M calcium nitrate solution as well as for aqueous samples.
4.2.1	Reliability	2
4.2.2	Deficiencies	No

Section A4.2 Annex Point IIA4.2	Analytical Methods including recovery rates and the limit of determination for the active substance and for residues thereof in water

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	January 2007
Materials and methods	Relevant discrepancies: Part 3.3.1: the first standard solution is 0.010 mg/L, not 0.10 mg/L Parts 3.5 & 3.6: there is no recovery rate data for 0.01 mg/L. The column called 'standard deviation' is in fact the 'found/analyzed values' column. Part 3.7: limit of determination given here is the limit of the apparatus. It is necessary to know the limit of quantification of copper by this method in the water samples.
Conclusion	Applicant's version has to be revised
Reliability	
Acceptability	Not acceptable
Remarks	
	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	

Section A4.2 Annex Point IIA4.2	**Analytical Methods including recovery rates and the limit of determination for the active substance and for residues thereof in air**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	The submission of an analytical method for the active substance basic copper carbonate and for residues thereof in air is considered not to be required since copper compounds are not volatile and moreover there will be no exposition via the respiratory system when used in wood preservatives.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	January 2007 amended April 2009	
Evaluation of applicant's justification	Applicant's justification is about 'basic copper carbonate' whereas the active substance is here copper (II) hydroxide.	
Conclusion	Applicant's justification is acceptable also for copper (II) hydroxide.	
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 A4.3 Annex Point IIIA IV.1	**Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, in/on food or feedstuffs and other products where relevant**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [X]	
Detailed justification:	This additional data requirement for active substances is considered not to be relevant for wood preservatives because the active substance or the material treated with it (construction wood) is not used in a manner which may cause contact with food or feedstuffs.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	January 2007	
Evaluation of applicant's justification	Applicant's justification is applicable	
Conclusion	Applicant's justification is acceptable	
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 Effectiveness against target organisms and intended uses

Subsection (Annex Point)			Official use only
5.1	**Function (IIA5.1)**	Fungicide and insecticide	
5.2	**Organism(s) to be controlled and products, organisms or objects to be protected (IIA5.2)**		
5.2.1	**Organism(s) to be controlled (IIA5.2)**	Protective efficacy against all relevant kinds of wood destroying basidiomycetes, e.g. *Coniophora puteana*, *Gloeophyllum trabeum*, *Poria placenta* and *Coriolus versicolor*, and soft rotting micro-fungi, e.g. *Chaetomium globosum*, *Glenospora graphii*, *Humicola grisea*, *Petriella setifera*, *Lecythophora mutabilis* and *Trichurus spiralis*.	X1
		Protective efficacy against wood destroying insects, e.g. termites and larvae of house longhorn beetle (*Hylotrupes bajulus*).	X2
		Organisms to be controlled exist in all parts of the Community with the exception of termites in wide areas of middle and northern Europe.	
5.2.2	**Products, organisms or objects to be protected (IIA5.2)**	All kinds of construction wood, partical board and ply wood.	
5.3	**Effects on target organisms, and likely concentration at which the active substance will be used (IIA5.3)**		
5.3.1	**Effects on target organisms (IIA5.3)**	Copper hydroxide acts by prevention of fungal infections. Upon contact with the fungicide layer the spores passively take up copper II cations which hinder their germination. Copper II cations also act as a feeding and cell poison independent from the kind of application. The threshold concentration is about 0.1% of elemental copper. A summary on the available and relevant information on effectiveness of copper as a wood preservative is given in **Table A5- 1** to **Table A5-5**. Copper hydroxide as an active substance for wood preservatives is used solely in combination with other active substances, e.g. quaternary ammonium compounds. Therefore, efficacy data on Copper hydroxide as sole a.s. do not exist. The information presented in the current section deals with effects of copper on wood destroying organisms in combination with a variety of other compounds of both inorganic and organic nature, thus demonstrating the efficacy of copper in timber protection as a matter of principle.	
5.3.2	**Likely concentrations at which the a.s. will be used (IIA5.3)**		