

Section A6.18		Summary of mammalian toxicology and conclusions	
JUSTIFICATION FOR NON-SUBMISSION OF DATA			Official use only
Other existing data	<input checked="" type="checkbox"/>	Technically not feasible	<input type="checkbox"/>
		Scientifically unjustified	<input type="checkbox"/>
Limited exposure	<input type="checkbox"/>	Other justification	<input type="checkbox"/>
Detailed justification:	The Human Health Effects Assessment for Copper hydroxide is presented in Doc.II-A. Please refer to Section 3 of Doc.II-A.		
Evaluation by Competent Authorities			
EVALUATION BY RAPPORTEUR MEMBER STATE			
Date	01/2005		
Evaluation of applicant's justification	Agree with applicant's justification.		
Conclusion	Acceptable		
Remarks			
COMMENTS FROM OTHER MEMBER STATE (specify)			
Date	<i>Give date of comments submitted</i>		
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>		
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>		
Remarks			

Section A8 Annex Point IIA8	MEASURES NECESSARY TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT	Official use only
<p>8.1 Recommended methods and precautions concerning handling, use, storage, transport or fire</p>	<p>Handling/Use:</p> <p>Avoid contact with skin and eyes. Provide sufficient air exchange and/or exhaust in work rooms. Wash hands before breaks and immediately after handling.</p> <p>Use respirator when performing operations involving potential exposure to vapor.</p> <p>Wear suitable protective clothing, rubber or plastic gloves and eye/face protection.</p> <p>Keep away from sources of ignition – No smoking. Take precautionary measures against static discharges.</p> <p>Storage:</p> <p>Product is hygroscopic. Keep container tightly closed. To maintain product quality, do not store in heat or direct sunlight. Keep in a dry, cool and well-ventilated place.</p> <p>Transport:</p> <p>The product is toxic according transportation guideline (RID/ADR). Transport packaging with UN-Certificate is required.</p> <p>Fire:</p> <p>Use dry powder, water spray or foam as extinguishing media. Water mist may be used to cool closed containers.</p> <p>Wear self-contained breathing apparatus.</p>	
<p>8.2 In case of fire, nature of reaction products, combustion gases, etc.</p>	<p>Product itself is non-combustible; adapt fire extinguishing measures to surrounding areas.</p> <p>No hazardous reactions known.</p> <p>On normal use no hazardous decomposition known.</p> <p>No thermal decomposition below <u>200 °C</u>.</p>	<p>Supprimé : 140</p>
<p>8.3 Emergency measures in case of an accident</p>	<p>Inhalation:</p> <p>Move to fresh air. Call a physician immediately. If breathing is irregular or stopped, administer artificial respiration.</p> <p>Skin contact:</p> <p>After contact with skin, wash immediately with plenty of soap and water. Take off all contaminated clothing immediately.</p> <p>Eye contact:</p> <p>Immediately flush eye(s) with plenty of water. Call a physician immediately.</p> <p>Ingestion:</p> <p>Call a physician immediately. Clean mouth with water and let the patient drink plenty of water in small gulps. Induce vomiting if patient is conscious.</p> <p>General safety and hygiene measures:</p>	

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	<p>Observe the precautions generally taken with chemicals</p> <p>Environmental precautions: Do not discharge the product into drains or the environment.</p> <p>Methods for cleaning up: Do not flush into surface water or sanitary sewer system. Sweep up or vacuum up spillage and collect in suitable container for disposal.</p>	
8.4 Possibility of destruction or decontamination following release in or on the following:	The application equipment can be cleaned by washing with water.	
a. air	No hazardous reactions known. No hazardous decomposition known Therefore, destruction in air is not a concern.	
b. water, including drinking water	The product is not readily biodegradable. The product is toxic to fish. The product is hazardous to algae and bacteria. Do not allow product to reach ground water, water course or sewage system. Disposal must be made according to official regulations.	
c. soil	Copper is strongly absorbed in the soil. It takes place a complex connection on the humus component. The decrease of the copper content in the soil takes place by plant withdrawal. In the event of a significant accidental release, contaminated soil should be disposed of according to local regulations.	
8.5 Procedures for waste management of the active substance for industry or professional users	<i>headline only</i>	
8.5.1 Possibility of re-use or recycling	<p>Uncontaminated spills can be re-used.</p> <p>Waste from residues: Must be incinerated in a suitable incineration plant holding a permit delivered by the competent authorities.</p> <p>Contaminated packaging: Where possible recycling is preferred to disposal or incineration.</p>	
8.5.2 Possibility of neutralisation of effects	Due to the characteristics of copper hydroxide a neutralization is not appropriate.	
8.5.3 Conditions for controlled discharge including leachate qualities on disposal	Do not contaminate water, foodstuff or feed by disposal. Disposal of copper and contaminated packaging should be in accordance with local or national legislation. Contaminated ground has to be taken up and carried to a suitable incineration plant. Larger amounts of contaminated ground have to be disposed in landfill according to local or national legislation.	

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8.5.4 Conditions for controlled incineration	Copper salts like Copper hydroxide, being organic salts and minerals, are not considered likely to form polyhalogenated dibenzo-p-dioxins or dibenzo-furans by hydrolysis. Being elemental, copper cannot be destroyed by controlled incineration	
8.6 Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms	Side-effects on copper hydroxide as wood preservative not known.	
8.7 Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of ground water against pollution caused by certain dangerous substances	Copper hydroxide is included in List II of the Annex to Directive 80/68/EEC.	
Evaluation by Competent Authorities		
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted		
EVALUATION BY RAPPORTEUR MEMBER STATE		
DATE MATERIALS AND METHODS RESULTS AND DISCUSSION CONCLUSION RELIABILITY ACCEPTABILITY REMARKS	14/03/2007 Not applicable Agree with applicant's version. Agree with applicant's version. Not applicable Acceptable	
COMMENTS FROM ...		
DATE MATERIALS AND METHODS RESULTS AND DISCUSSION CONCLUSION RELIABILITY ACCEPTABILITY REMARKS	<i>Give date of comments submitted</i> <i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.</i> <i>Discuss if deviating from view of rapporteur member state</i> <i>Discuss if deviating from view of rapporteur member state</i> <i>Discuss if deviating from view of rapporteur member state</i> <i>Discuss if deviating from view of rapporteur member state</i> <i>Discuss if deviating from view of rapporteur member state</i>	

Section A9 Annex Point IIA IX	CLASSIFICATION AND LABELLING	Official use only
Classification	Classification derived from calculation method of the Dangerous Preparations Directive (1999/45/EEC)	
Symbols	T; R23: Toxic by inhalation N: Dangerous to the environment	X
R-phrases	R22: Harmful if swallowed R23: Toxic by inhalation R41: Risk of serious damage to eyes R51/53: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment	
S-phrases	S22: Do not breathe dust. S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S36/37/39: Wear suitable protective clothing and eye/face protection. S45: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). S57: Use appropriate container to avoid environmentalcontamination. S63: In case of accident by inhalation: remove casualty to fresh air and keep at rest.	
Evaluation by Competent Authorities		

Section A9 Annex Point IIA IX	CLASSIFICATION AND LABELLING	Official use only
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted		
EVALUATION BY RAPPORTEUR MEMBER STATE		
DATE	November 2005	
MATERIALS AND METHODS	Not applicable.	
RESULTS AND DISCUSSION	<p>Symbols:</p> <p>T; R23: Toxic by inhalation</p> <p>N: Dangerous to the environment</p> <p>S-phrases:</p> <p>S22: Do not breathe dust.</p> <p>S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.</p> <p>S36/37/39: Wear suitable protective clothing and eye/face protection.</p> <p>S45: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).</p> <p>S57: Use appropriate container to avoid environmental contamination.</p> <p>S63: In case of accident by inhalation: remove casualty to fresh air and keep at rest.</p> <p>For environment, following S-phrases should be added:</p> <p>S60: This material and its container must be disposed of as hazardous waste.</p> <p>S61: Avoid release to the environment. Refer to special instructions/ Safety data sheets.</p>	
CONCLUSION	Agree with applicant's version with modifications	
RELIABILITY	Not applicable.	
ACCEPTABILITY	Acceptable.	
REMARKS		

Section A10	Summary and evaluation of sections 2-9.		
	JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
	<p><i>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</i></p>		
Other existing data []	Technically not feasible []	Scientifically unjustified []	
Limited exposure []	Other justification [X]		
Detailed justification:	A summary and evaluation of Sections 2-9 can be found in Document IIA.		
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			
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>			
EVALUATION BY RAPPORTEUR MEMBER STATE			
Date	October 2006		
Evaluation of applicant's justification	Agree with applicant's justification.		
Conclusion	Applicant's justification is acceptable.		
Remarks			
COMMENTS FROM OTHER MEMBER STATE (specify)			
Date	<i>Give date of comments submitted</i>		
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>		
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>		
Remarks			