

Section A6.12.8 Prognosis following poisoning

Annex Point IIA 6.9.8

The following data were already submitted in the context of an application for inclusion of the active substance in Annex I of Directive 91/414/EEC. Since these data are not considered to represent key studies, they are given below in summarised format only:

No data specifically exist on the active substance covered in this dossier. Data for copper sulphate are cited. Copper sulphate is water-soluble, unlike the five forms. However, it is reasonable to assume that if sufficient quantities of a biocidal product are consumed to overwhelm the body's homeostatic mechanisms, the resulting toxicity will present similar signs and symptoms to those of copper sulphate. The biocidal product is unlikely to cause acute toxicity except in the case of deliberate ingestion. Copper salts are emetic and highly coloured, and the patient rarely loses consciousness, so that the clinician is usually informed of the nature of the intoxicant. Analysis of the vomitus, or the gastric lavage can confirm copper intoxication, as can serum copper elevation (where present), however, there is no single diagnostic test for copper intoxication. The following represent a summary of diagnostic information from the medical literature (see also section 5.9.6, Expected effects of poisoning):

Mild cases: metallic taste in the mouth, slight pain and tenderness over the epigastric region, nausea.

Moderate cases: in addition to the above, retrosternal/epigastric burning sensation, vomiting, tachycardia, low blood pressure, tender liver, scanty urine with albumin and sometimes blood.

Severe cases: all of the above signs and symptoms, but more acute; severe tenderness, persistent tachycardia, falling blood pressure, diarrhoea, bluish/greenish loose stools often with blood, urine with blood, haemoglobinuria, haematuria, oligouria, anuria, albumin in urine and glucosuria. Jaundice, restlessness, apathy, stupor, muscular weakness, coma and death.

In moderate and severe cases, haemolysis and haemolytic anaemia, serum bilirubin slightly elevated, total protein reduced, with reversal of albumin : globulin ratio. Albumin and red blood cells present in urine, and glycosuria in the more severe cases. Port-wine urine (haematouria) observed in the most severe cases. Serum copper elevated, but not in proportion to dose. Liver enlarged and tender, and liver function test show gross derangement. Patients showing oliguria or anuria have normal blood pressure. Kidney biopsy may show swelling or necrosis of the tubular cells. Where coma occurs it is probably due to uraemia resulting from renal damage; rather than a direct effect on the brain. Deaths occurring within 24 hours were due to shock, and those occurring later appeared to be due to hepatic and/or renal complications.

Long term oral exposure to excess dietary supplement of copper (single case) was associated with malaise, jaundice and abdominal swelling, moderate ascites, splenomegaly, and with Kayser-Fleischer rings and sunflower cataracts visible on slit-lamp examination. Copper urinary excretion abnormally high, elevated enzyme levels (alkaline phosphate, aspartate amino transferase, γ -glutamyl-transpeptidase). Copper liver histopathology indistinguishable from Wilson's disease and ICC.

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	18/12/2006
Evaluation of applicant's justification	Agree with applicant's version.
Conclusion	Acceptable
Remarks	
COMMENTS FROM OTHER MEMBER STATE <i>(specify)</i>	
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 A6.13 Toxic effects on livestock and pets Annex Point IIIA VI.2		
JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data <input type="checkbox"/>	Technically not feasible <input type="checkbox"/>	Scientifically unjustified <input type="checkbox"/>
Limited exposure <input checked="" type="checkbox"/>	Other justification <input type="checkbox"/>	
Detailed justification:	Information on toxic effects on livestock and pets is considered not to be relevant since a release of the active substance from treated wood used in animal housings (indoor use) can be excluded by the application technique. Copper salts are applied to construction wood only by vacuum pressure treatment or dipping (professional application; no superficial application, e.g. via brushing or spraying, at the site of use).	
Evaluation by Competent Authorities		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date	February 2007	
Evaluation of applicant's justification	Agree with the applicant justification	
Conclusion	Applicant 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 A6.14		Other tests related to the exposure of humans	
Annex Point IIIA			
XI.2			
JUSTIFICATION FOR NON-SUBMISSION OF DATA			Official use only
Other existing data []	Technically not feasible []	Scientifically unjustified []	
Limited exposure []	Other justification [X]		
Detailed justification:	Information on further toxicity tests related to the exposure of humans is considered not to be relevant since information is required only on the toxicity of degradation products, by-products, or reaction products which are not formed by basic Copper carbonate.		
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 A6.15 Annex Point IIIA VI.4	Food and feedingstuffs Sections A6.15.1 – A6.15.6	
JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data <input type="checkbox"/>	Technically not feasible <input type="checkbox"/>	Scientifically unjustified <input type="checkbox"/>
Limited exposure <input type="checkbox"/>	Other justification <input checked="" type="checkbox"/>	
Detailed justification:	Information on the active substance basic Copper carbonate in relation to residues on food and feedingstuff is considered not to be required since additional data requirements of sections A6.15.1 – A6.15.6 do not provide for the submission of data in this context for PT08.	
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 <i>(specify)</i>		
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 A6.16 Annex Point IIIA VI.3.5		Any other tests related to the exposure of the active substance to humans, in its proposed biocidal products, that are considered necessary, may be required	
JUSTIFICATION FOR NON-SUBMISSION OF DATA			Official use only
Other existing data <input type="checkbox"/>	Technically not feasible <input type="checkbox"/>	Scientifically unjustified <input type="checkbox"/>	
Limited exposure <input type="checkbox"/>	Other justification <input checked="" type="checkbox"/>		
Detailed justification:	No information is submitted to this section point because no requirement for other tests related to the exposure of the a.s. to humans is foreseeable.		
Evaluation by Competent Authorities			
EVALUATION BY RAPPORTEUR MEMBER STATE			
Date	01/2006		
Evaluation of applicant's justification	Agree with applicant's justification.		
Conclusion	Acceptable		
Remarks			
COMMENTS FROM OTHER MEMBER STATE <i>(specify)</i>			
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 A6.17		Official use only
Annex Point IIIA		
VI.6		
If the active substance is to be used in products for action against plants ...		
JUSTIFICATION FOR NON-SUBMISSION OF DATA		
Other existing data <input type="checkbox"/>	Technically not feasible <input type="checkbox"/>	Scientifically unjustified <input type="checkbox"/>
Limited exposure <input type="checkbox"/>	Other justification <input checked="" type="checkbox"/>	
Detailed justification:	No information to this additional data requirement is considered to be relevant since no use of the active substance against plants is envisaged.	
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 <i>(specify)</i>		
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 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 basic Copper carbonate 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 <i>(specify)</i>			
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>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 an environmentally hazardous substance 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. In case of combustion evolution of dangerous gases possible.</p> <p>On normal use no hazardous decomposition known.</p> <p>No thermal decomposition below 200 °C.</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> <p>Observe the precautions generally taken with chemicals</p>	

Section A8 Annex Point IIA8	MEASURES NECESSARY TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT	Official use only
	Environmental precautions: Do not discharge the product into drains or the environment. 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.	
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 not toxic to fish and bacteria. The product is very toxic to algae and daphne magna. 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	Uncontaminated spills can be re-used. Waste from residues: Must be incinerated in a suitable incineration plant holding a permit delivered by the competent authorities. Contaminated packaging: Where possible recycling is preferred to disposal or incineration.	
8.5.2 Possibility of neutralisation of effects	Due to the characteristics of basic copper carbonate 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.	

Section A8 Annex Point IIA8	MEASURES NECESSARY TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT	Official use only
8.5.4 Conditions for controlled incineration	Copper salts like basic copper carbonate, 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 basic copper carbonate 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	Give date of comments submitted 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 Discuss if deviating from view of rapporteur member state Discuss if deviating from view of rapporteur member state Discuss if deviating from view of rapporteur member state Discuss if deviating from view of rapporteur member state	

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	Xn: Harmful N: Dangerous to the environment	
R-phrases	R20/22: Harmful by inhalation and if swallowed R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment	
S-phrases	S22: Do not breathe dust. S24/25: Avoid contact with skin and eyes S45: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). S60: This material and its container must be disposed of as hazardous waste. S61: Avoid release to the environment. Refer to special instructions/ Safety data sheets.	
Evaluation by Competent Authorities		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date	01/2005	

Section A9 Annex Point IIA IX	CLASSIFICATION AND LABELLING	Official use only
Evaluation of applicant's justification	<p>Symbols:</p> <p>Xn: Harmful</p> <p>N: Dangerous to the environment</p> <p>R-phrases:</p> <p>R20/22 Harmful by inhalation and if swallowed</p> <p>R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment</p> <p>S-phrases:</p> <p>S22: Do not breathe dust.</p> <p>S24/25: Avoid contact with skin and eyes</p> <p>S45: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).</p> <p>S36/37: Wear protective clothing and gloves</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	
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 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.</i></p> <p><i>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 []	<p><i>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.)</i></p>		
Evaluation by Competent Authorities			
<p><i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i></p>			
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			