

## RISK MANAGEMENT OPTIONS ANALYSIS

### CONCLUSION DOCUMENT

for

**Copper II sulphate and Copper II sulphate pentahydrate**

#### EC No

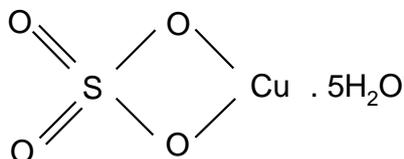
231-847-6                      Copper II sulphate

No EC number Copper II sulphate pentahydrate directly related  
to the CAS number

#### CAS No

7758-98-7                      Copper II sulphate

7758-99-8                      Copper II sulphate pentahydrate



**Member State: Denmark**

Dated: August 2014, Final version

***Disclaimer: Please note that this RMOA conclusion was compiled on the basis of available information and may change in the light of new information or further assessment.***

## 1. OVERVIEW OF OTHER REGULATORY PROCESSES / EU LEGISLATION

The RMO and the underlying surveys are a part of the review of the substances on the Danish List of undesirable substances (LOUS-review).

The Danish EPA has conducted a survey of all substances listed on the Danish "List of Undesirable Substances" (LOUS). Access to the surveys carried out so far can be found at the following link:

[http://www.mst.dk/English/Chemicals/assessment\\_of\\_chemicals/LOUS\\_2012\\_2015/](http://www.mst.dk/English/Chemicals/assessment_of_chemicals/LOUS_2012_2015/).

This survey was originally designed to cover only Copper II sulphate (CAS No. 7758-98-7). As Copper II sulphate pentahydrate is the commercially dominant form of Copper II sulphate, while the anhydrate has little commercial use, it has been specifically decided to include Copper II sulphate pentahydrate in the survey. The survey provides an overview of the use and the environmental and human health aspects of the Copper II sulphate substances. The results of the survey have been used as the main background information for this RMO.

The current status of Copper II sulphate and Copper II sulphate pentahydrate pertaining to relevant Community legislation and a Danish Statutory Order are summarised in Table 1 below.

Table 1: Relevant legislation pertaining to the manufacture and use of Copper II sulphate and Copper II sulphate pentahydrate

Legal instrument	EU/national	Status of Copper II sulphates
REACH regulation	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	Registered tonnage band by ECHA for Copper II sulphate: 10,000-100,000 tonnes per year.  Note: It is assumed that the data stated for Copper II sulphate covers all relevant Copper II sulphate compounds inclusive of the monohydrate and the pentahydrate.
CLP regulation	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures	EU harmonised classification is available for Copper II sulphate.  There is no harmonised classification for Copper II sulphate pentahydrate, but it is notified to ECHA with different suggestions for classification.  Proposal of harmonised classification for Copper II sulphate pentahydrate in a CLP report (Version number: 2), submitted by France (2013).

Directive on Chemicals Agents at Work	Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work	<p>No recommendation regarding indicative Occupational Exposure Limit (OEL) values is available.</p> <p>No SCOEL (Scientific Committee on Occupational Exposure Limits) recommendation regarding OEL values is available.</p>
Waste Framework Directive	Directive 2008/98/EC the European Parliament and of the Council of 19 November 2008 on waste	<p>Annex III of the Directive displays which properties render waste hazardous.</p> <p>If the concentration of copper compounds exceeds 25%, a given waste must be classified as hazardous.</p>
Water Framework Directive	Directive 2000/60/EC the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy.	Environmental quality standards (EQS values) have been established for copper but not for specific copper compounds.
Biocide regulation	Regulation (EU) No 528/2012 of the European Parliament and the Council of 22 May 2012 concerning the making available on the market and use of biocidal products	<p>Non-inclusion of Copper II sulphate (CAS No. 7758-98-7) in the positive list for use for the following product types:</p> <ul style="list-style-type: none"> <li>- Product type 1: "Human hygiene biocidal products" (phase-out by 1 February 2013)</li> <li>- Product type 4: "Food and feed area disinfectants" (phase-out by 1 February 2013)</li> <li>- Product type 8: "Wood preservatives" (phase-out by 1 September 2006).</li> </ul> <p>In September 2013, it was decided to include Copper II sulphate pentahydrate in the positive list for Product type 2: "Private area and public health area disinfectants and other biocidal products."</p> <p>Note: Only biocidal products containing active substances included on the positive list or in the EU review process are allowed to be use.</p>
Feed regulation	Regulation (EC) No 1334/2003 of 25 July 2003 amending the conditions for authorisation of a number of additives in feeding stuffs belonging to the group	Copper II sulphate pentahydrate had been authorized as additive under the element Copper-Cu for all animal species "Without a time limit"

	of trace elements.  Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 in additives for use in animal nutrition	(Regulation No. 1334/32003).  Following the provisions of Article 10(1) of Regulation No. 1831/2003 the compound was included in the EU Register of Feed Additives under the category "Nutritional additives" and the functional group "Compounds of trace elements".
Fertilizer regulation	Danish Statutory Order No. 862 of 27 August 2008 on fertilizers and soil improvement medias	This Statutory Order lists requirements regarding quality, content of specific compounds and packaging and labelling to be complied with by sale of fertilizers and soil improvement medias. Requirements have been established for copper oxide and copper salts. These requirements are thus valid for Copper II sulphates.

## 2. CONCLUSION OF RMOA

Conclusions	Tick box
Need for follow up regulatory action at EU level <i>[if a specific regulatory action is already identified then, please, select one or more of the specific follow up actions mentioned below]</i>	
Harmonised classification and labelling	
Identification as SVHC (authorisation)	
Restrictions	
Other EU-wide measures	
No need for regulatory follow-up action for the time being – depending on the outcome of the additional investigations and assessments of Copper II sulphates as feed additive by EFSA	X

Based on the information available, the dominant uses of Copper II sulphates in Denmark are assessed as feed additive, followed by the use in fertilizers. It should be noted that we do not have detailed information about other uses. We assume this is also the case in the EU. The use of Copper II sulphate pentahydrate as feed additive, in particular for piglets, together with other sources results in increasing content of copper in Danish agricultural soils. Also in the EU, there are indications that copper can be accumulated in soil after spreading of manure.

In general, adequate knowledge about potential impacts of present and continued supply of copper with manure from animals and other sources to agricultural soils and relevant remedial actions is lacking. At EU level, the best approach is awaiting the additional investigations and assessments of Copper II sulphates as feed additive by EFSA. Focused European-level research related to the long term effects of the repeated application of copper might be relevant after finalisation of the assessments by EFSA.

In Denmark, an investigation of the content of copper in 1) pig manure and 2)

agricultural soil being exposed to a significant amount of pig manure (the so-called "hot spot areas") is an option. As existing studies have not confirmed the hypothesis that the "Funen roe deer disease" was caused by copper supplied to agricultural soils by application of manure, the cause of this disease has to be further investigated.

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