

# DECISION

23 June 2020

## Summary

Substance	Copper powder and copper compounds
Application code	APP203732
Application type	To decide whether there are grounds for reassessment under the Hazardous Substances and New Organisms (HSNO) Act 1996 ("the Act")
Applicant	International Copper Association Southeast Asia Limited (ICA SEA)
Purpose of the application	To establish whether there are grounds for reassessment of copper powder, copper sulphate pentahydrate, copper (II) oxide, copper (I) oxide, and copper (II) oxychloride
Date application received	7 November 2018
Consideration Date	23 June 2020
Considered by	A Decision-making Committee of the Environmental Protection Authority ("EPA")
Decision	Grounds exist for the reassessment of copper powder, copper sulphate pentahydrate, copper (II) oxide, copper (I) oxide, and copper (II) oxychloride

## 1. Background

- 1.1. The hazardous substances (“the substances”) in this grounds for reassessment application were approved under the HSNO Act on 1 July 2006 via the Hazardous Substances (Chemicals) Transfer Notice 2006. Details of the chemicals, their HSNO Approval Numbers, and hazard classifications are provided in the Table below.

Substance name	CAS number	Approval number	Hazard classifications
Copper, powder	7440-50-8	HSR002948	6.1B (I), 6.1B (O), 6.4A, 6.5B, 6.6A, 6.9B (I), 6.9B (O), 9.1A (A), 9.1A (C), 9.1A (F), 9.2D, 9.3A
Copper sulphate, pentahydrate	7758-99-8	HSR003126	6.1D (O), 6.3A, 6.4A, 6.5B, 6.9B (O), 9.1A (A), 9.1A (C), 9.1A (F), 9.3C
Copper (II) oxide	1317-38-0	HSR002766	6.1D (O), 6.4A, 6.9B (O), 9.1A (C), 9.1C (F), 9.3C
Copper (I) oxide	1317-39-1	HSR002871	6.1D (I), 6.1D (O), 6.4A, 6.9B (I), 6.9B (O), 9.1A (A), 9.1A (C), 9.1A (F), 9.3B
Copper (II) oxychloride	1332-65-6	HSR003766	6.1D (O), 6.5B, 6.9B (O), 9.1A (C), 9.1D (F), 9.3C

- 1.2. The substances are chemicals that have a variety of uses. Formulated products that contain copper powder or other copper compounds are commonly used in agriculture as fungicides or bactericides. Other copper-containing products include animal nutritional supplements, veterinary medicines, anti-fouling paints, fertilisers, timber treatments and wood preservatives. Copper powder or copper compounds may also be included in minor amounts in a wide range of products for their biocidal properties. Some approved hazardous substances that contain copper powder or copper compounds are listed in the Transfer Notices while others have been approved in subsequent applications to import/manufacture hazardous substances under sections 28A and 29 of the Act.
- 1.3. A reassessment application based on this grounds for reassessment decision may include any hazardous substances that contain one or more of the copper substances listed in the Table above.
- 1.4. The applicant has applied for grounds to reassess copper powder, copper sulphate pentahydrate, copper (II) oxide, copper (I) oxide, and copper (II) oxychloride in order to revise the hazard classifications of the chemicals.
- 1.5. The purpose of this application is to decide whether there is significant new information about the effects of the substances in terms of their hazardous properties and hence grounds for the reassessment of the substances.

## 2. Application process

- 2.1. The application was formally received by the EPA on 7 November 2018 and the information supplied evaluated by EPA staff.
- 2.2. The application was considered on 23 June 2020 by a Decision-making Committee (the Committee) of the EPA.

### 3. Evaluation against the criteria in the Act

- 3.1. The Act specifies a number of factors that the EPA has to take into account when considering whether grounds exist for a reassessment. At least one of these factors must be present before the EPA can use its discretion to determine whether there are grounds for a reassessment.

#### Significant new information relating to the effects of the substance has become available (section 62(2)(a))

- 3.2. The applicant has requested that the hazard classifications of the substances are reviewed and revised based on new information included in the Organisation for Economic Co-operation and Development (OECD) Screening Information Dataset (SIDS) Initial Assessment Profile (SIAP) for copper and copper compounds dated October 2014.
- 3.3. The OECD-generated SIAP contains brief summaries of SIDS endpoints as well as the major conclusions of the hazard assessment. The SIAP for copper and various copper compounds uses a category assessment approach for this group of commonly used copper substances whose ecotoxicological and systemic human hazard profiles are related to the release of copper-ions.
- 3.4. Since filing the grounds for reassessment application, the full OECD SIDS Initial Assessment Report (SIAR) was published in December 2018 and is publicly available through the OECD Existing Chemicals Database<sup>1</sup>. The SIAR incorporates the SIAP and also contains longer discussions of the evaluated endpoints and additionally contains conclusions.
- 3.5. The toxicological hazard classification conclusions as summarised in the OECD SIAR are that copper sulphate pentahydrate, copper (I) oxide and dicopper chloride hydroxide present a hazard for human health, based notably on the release/bioaccessibility of copper ions. The human health hazards are summarised as follows:
- Copper sulphate pentahydrate: severe eye irritation and acute hazard by the oral route.
  - Copper (I) oxide: severe eye irritation, acute hazard by the oral and inhalation routes.
  - Dicopper chloride hydroxide: acute hazard by the oral and inhalation route.
- 3.6. For copper (II) oxide and copper powder, the OECD SIAR concluded that these substances do not pose a hazard to human health.
- 3.7. The ecotoxicity conclusions as summarised in the OECD SIAR are that copper and copper compounds may present a hazard for the environment based on the release/bioaccessibility of copper ions, which depends on the conditions of the receiving environment (pH, hardness, presence and type of organic matter, anions and competing cations). The report notes that the copper compounds and the fine copper powders do pose both an acute and chronic hazard to the environment, whereas coarse granules and massive copper materials release less copper ions and pose less or no acute or chronic hazard to the aquatic environment under typical environmental conditions. The OECD SIAR also refers to acute and chronic aquatic ecotoxicity data and discussions supporting the European harmonized classification of biocidal copper forms and compounds.
- 3.8. The current European harmonised classifications for the copper compounds as listed in Annex VI of Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation) are as follows:

<sup>1</sup> <https://hpvchemicals.oecd.org/ui/Search.aspx>

- Copper sulphate pentahydrate: Acute Tox. 4 (oral), Eye Dam. 1, Aquatic Acute 1, Aquatic Chronic 1
- Copper (I) oxide: Acute Tox. 4 (oral), Acute Tox. 4 (inhalation), Eye Dam. 1, Aquatic Acute 1, Aquatic Chronic 1
- Dicopper chloride hydroxide: Acute Tox. 3 (oral), Acute Tox. 4 (inhalation), Aquatic Acute 1, Aquatic Chronic 1
- Copper (II) oxide: Aquatic Acute 1, Aquatic Chronic 1
- Copper powder: not listed

- 3.9. The Committee considered that the information provided is “significant” because it provides justification for revising the hazard classifications of the substances. In particular, there are notable differences between the hazard classifications and endpoints of the current HSNO approvals for acute and chronic toxicity, skin and eye irritancy, mutagenicity, and aquatic ecotoxicity compared with those determined in the OECD report and in the European harmonised classifications.
- 3.10. The Committee also noted that the OECD SIAP was published in October 2014 and the OECD SIAR was published in December 2018. While the OECD SIAR notes that one of the limitations of its report is the small number of recent open literature data (beyond 2006), a number of significant studies reviewed in the report are dated more recently than 2006 (for example: 2009 Chung, 2010 Kirkpatrick), and the summaries of many other older studies may not have been publicly available for review by the EPA during the initial approval of the copper substances. The OECD review documents themselves also contain useful scientific opinion, justifications and conclusions which have only been available since their publication. Therefore the Committee considered this to be “new” information.

#### **A change in controls under the Health and Safety at Work Act 2015 (section 62(2)(aa))**

- 3.11. This factor is not relevant to this application.

#### **Another substance with similar or improved beneficial effects and reduced adverse effects has become available (section 62(2)(b))**

- 3.12. This factor is not relevant to this application.

#### **Information showing a significant change of use, or a significant change in the quantity manufactured, imported, or developed has become available (section 62(2)(c))**

- 3.13. This factor is not relevant to this application.

#### **Other reasons for requesting a reassessment under section 62(2)**

- 3.14. This factor is not relevant to this application.

## **4. Issues and concerns to Māori**

- 4.1. The Committee has considered Māori perspectives regarding the applicant's wish to determine whether there are grounds for the reassessment of the substance. The Committee noted that, if this application is approved and a subsequent reassessment applied for, wider public notification and/or consultation will be undertaken, including with Iwi/Māori.

- 4.2. The Committee considered that there were no issues related to the principles of the Treaty of Waitangi to be addressed in the context of this application. The Committee noted that these principles will be considered if a subsequent reassessment application is received.

## 5. International obligations

- 5.1. The Committee has considered New Zealand's international obligations regarding the applicant's wish to determine whether there are grounds for the reassessment of the substance.
- 5.2. The Committee noted that these international obligations will be considered if a subsequent reassessment application is received.

## 6. Consideration

- 6.1. The Committee considered that there is significant new information relating to the effects of the substances in view of the hazard classification study summaries, discussions and conclusions presented in both the OECD SIAP published in October 2014 and the OECD SIAR published in December 2018.
- 6.2. Taking that into account, the Committee considered that grounds exist under section 62 of the Act for the reassessment of copper powder (HSR002948), copper sulphate pentahydrate (HSR003126), copper (II) oxide (HSR002766), copper (I) oxide (HSR002871), and copper (II) oxychloride (HSR003766), and substances containing these chemicals, on the basis that significant new information about the effects of the substances has become available (section 62(2)(a)).



Signed by:

Date: 23 June 2020

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**Dr John Taylor**  
**Chair, Decision-making Committee**  
**Environmental Protection Authority**

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