Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Dicopper oxide

Product type: 21

ECHA/BPC/081/2015

Adopted

9 December 2015

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance dicopper oxide for product type 21

In accordance with Article 89(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 21 of the following active substance:

Common name:	**Dicopper oxide**
Chemical name(s):	**copper (I) oxide**
EC No.:	**215-270-7**
CAS No.:	**1317-39-1**

Existing active substance

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of BPC opinions

Following the submission of an application by the EU Antifouling Copper Task Force on 28 April 2006 the evaluating Competent Authority France submitted an assessment report and the conclusions of its evaluation to the ECHA on 31 October 2014. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC and its Working Groups. Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: France

The BPC opinion on the approval of the active substance dicopper oxide in product type 21 was adopted on 9 December 2015.

The BPC opinion was adopted by consensus.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the dicopper oxide in product type 21 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of dicopper oxide in product type 21.

The active substance reacts as cupric ion Cu^{2+}. The cupric ion acts to retard settlement of the microscopic larvae of fouling organisms within a microlayer of water at the paint surface via two mechanisms:

(1) the ion retards organism's vital processes by inactivating enzymes,
(2) the ion acts more directly by precipitating cytoplasmic proteins as metallic proteinates.

Specifications for the reference sources are established. Dicopper oxide as manufactured contains four relevant impurities: arsenic, cadmium, nickel and lead.

The physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal product. However, additional data are required before the approval of the active substance (see chapter 2.5).

Validated analytical methods are available for the active substance as manufactured (depending of the reference source) and for the relevant impurities. However, complete validation data for the determination of the relevant impurities, for the additives or other impurities are missing and are required (see requirements in section 2.5) for some sources.

Validated analytical method for the determination of the active substance in the reference product is not available.

Validated analytical methods are required and available for the relevant matrices (environmental matrices, body fluids and food and feed stuff matrices).

No harmonised classification according to Regulation (EC) No 1272/2008 (CLP Regulation) of active substance is available. However the RAC opinion[1] adopted in December 2014 contains the following classification:

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox 4, H302 Acute Tox 4, H332 Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic chronic 1, H410
Labelling	
Pictograms	GHS05, GHS07, GHS09
Signal Word	Danger
Hazard Statement Codes	H302 : Harmful if swallowed H332 : Harmful if inhaled. H318: Causes serious eye damage H410: very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	Aquatic Acute 1: M-factor = 100 Aquatic chronic 1: M-factor = 100

b) Intended use, target species and effectiveness

Dicopper oxide is intended to be used for the protection against fouling of both mobile (including but not limited to marine and freshwater vessels) and stationary (including but not limited to buoys, aquaculture nets, immersed structures) objects.
The antifouling product is to be used by professionals and non-professional.

With regard to efficacy, dicopper oxide representative based product at a minimum 37.5 % w/w of a.s demonstrated a sufficient activity for the approval of the active substance when considering use in European and tropical sea waters. No efficacy data has been provided neither for freshwater nor for static objects.

There has never been any recorded cases of resistance in populations of fouling organisms through the use of Copper based anti-fouling paints in the literature up to now.

However, some studies, in the literature, showed some impacts of copper pollution on marine life and indicate that some hull-fouling species have copper tolerance.

[1] Opinion proposing harmonised classification and labelling at EU level of Copper(II) oxide EC number: 215-269-1, CAS number: 1317-38-0, CLH- O-0000001412-86-45/F- Adopted 04 December 2014

c) Overall conclusion of the evaluation including need for risk management measures

The overall conclusion from the evaluation of dicopper oxide for use in product type 21 (antifouling products) is, that it may be possible for Member States to issue authorisations of products containing dicopper oxide in accordance with the conditions laid down in Regulation (EU) No 528/2012.

It should be noted that assessments carried out for human health and the environment for the limited number of substances under product type 21 (antifouling products) often indicate unacceptable risks to certain end users and/or environmental compartments exposed to these substances. These assessments also indicate the need for risk mitigation measures, such as technical controls and/or personal protective equipment (PPE), in order to protect end-users using these substances and minimise exposure of the relevant environmental compartments.

It was agreed at the 55th meeting of the representatives of Member State Competent Authorities for the implementation of the BPR to utilise generic conditions in approval regulations (as outlined in section 2.3 below) for all product type 21 substances evaluated as part of the EU Review Programme for existing active substances to reduce the risks for human health and for the environment from use of these substances[2].

Human health

Dicopper oxide is harmful by inhalation and oral route by acute administration and is irritating for eyes.
After repeated exposure by inhalation route, dicopper oxide induces essentially local effects which are reversible.
No repeated toxicity study by oral route was provided with dicopper oxide. However, it is considered that toxicity of copper compound is essentially linked to Cu2+ ion. In this context, studies on the most soluble salt (copper sulphate) were provided.
Copper is a micronutrient. It is essential for life and necessary for all living cells.
The copper transport mechanisms in the organism form part of the system of homeostasis: the body is able to maintain a balance of dietary copper intake and excretion that allows normal physiological processes to take place. When this mechanism is exceeded, after 92 days of exposure, kidney, liver and stomach are the essential target organs.

The table below summarises the exposure scenarios assessed:

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
Airless spraying			
Mixing/loading	**Primary exposure:** mixing and loading antifouling product into reservoirs for airless spraying	Professionals (potman)	Acceptable with gloves, impermeable coverall and RPE protection factor 10
Spray application	**Primary exposure:** spray application of antifouling product via airless sprayer	Professionals (sprayman)	Acceptable with impermeable coverall, gloves and RPE protection factor 40

[2] See document: Antifouling (PT21); the way forward for the management of active substances and the authorisation of biocidal products. (CA-March14-Doc.4.2 - Final).

Cleaning of spray equipment	**Primary exposure:** cleaning of spray equipment used to apply antifouling product	Professionals	Acceptable
Combined exposure: Mixing and loading and cleaning of equipment	**Primary exposure:** - mixing and loading antifouling product into reservoirs for airless spraying - cleaning of spray equipment used to apply antifouling product	Professionals (potman)	Acceptable with gloves and impermeable coverall and RPE protection factor 10 during mixing and loading and gloves when cleaning
Combined exposure: spraying phase and cleaning of equipment	**Primary exposure:** **-** spray application of antifouling product via airless sprayer - cleaning of spray equipment used to apply antifouling product	Professionals (sprayer)	Acceptable with impermeable coverall, gloves and RPE protection factor 40 during spraying and gloves when cleaning
Brush/roller application			
Application by brush/roller	**Primary exposure:** application of antifouling product by brush and roller	Professionals (including chandler)	Acceptable with gloves and coverall
Application by brush/roller	**Primary exposure:** application of antifouling product by brush and roller	non-professionals	Acceptable* with gloves
Cleaning of brushes/rollers	**Primary exposure:** cleaning of brushes/rollers used to apply antifouling product	Professionals and non-professionals	Acceptable
Combined exposure: Mixing/loading, application and cleaning of equipment	**Primary exposure:** **-** mixing, loading and application of antifouling product by brush and roller - cleaning of brushes/rollers used to apply antifouling product	Professionals	Acceptable with coverall and gloves during mixing and loading of paint into trail brushing and application
Combined exposure: Mixing/loading, application and cleaning of equipment	**Primary exposure:** **-** mixing, loading, and application of antifouling product by brush and roller - cleaning of brushes/rollers used to apply antifouling product	Non-professionals	Acceptable* with gloves during mixing and loading and application
Paint removal			
Grit filling	**Primary exposure:** filling (with sand or grit) of abrasive blasting equipment used for removal of antifouling product	Professionals (grit filler)	Acceptable with coated coverall, gloves and RPE protection factor 40

Paint removal (blasting)	**Primary exposure:** removal of antifouling product by abrasive blasting	Professionals	Acceptable with protective water-proof overalls, an airstream helmet with rubber flaps that covered a large part of their upper body, strong protective gloves and RPE protection factor 10
Paint removal (washing of abrasion)	**Primary exposure:** removal of antifouling product by high-pressure water washing or abrasion (rubbing with a wire brush)	Non-professionals	Acceptable
Secondary exposure after professional and non-professional application			
Bystanders	**Secondary exposure**: Workers at the ship yard where spray or roller/brush application of antifouling paint is used	Professionals	Acceptable with warning sign
Cleaning of work clothes	**Secondary exposure:** cleaning of work clothes contaminated from aerosol spray, brush and roller application	Non-professional	Acceptable
Toddler touching freshly-painted (wet product) surface of treated boat	**Secondary exposure:** Toddler touching a boat surface treated with antifouling product when still wet.	General public (toddler)	unacceptable
Toddler touching dry surface of treated boat	**Secondary exposure:** Toddler touching a boat surface treated with antifouling product when dry.	General public (toddler)	Acceptable
Dietary exposure from residues in fish and shellfish	**Secondary exposure:** Consumption of fish and shellfish containing residues of antifouling product	General public (toddler)	Acceptable

* Only when considering one of the two representative products.

Professionals

For professionals, the risk related to primary exposure is considered to be acceptable when appropriate personal protection equipment (PPE) (including respiratory protective equipment (RPE) for certain tasks) as reported in the table above is worn.

Principles of good working practices should be applied and label instructions and recommendations on the products respected. To protect bystanders in the ship yard the area where painting is performed should be labelled with "Unprotected persons should be kept out of treatment areas".

Non-professionals

For non-professionals, an acceptable risk is identified applying dicopper oxide in the representative product by brush and roller if appropriate gloves are worn.

An acceptable risk from combined exposure to dicopper oxide in the representative product is identified for a non-professional operator applying the representative product by brush and roller and cleaning out the paint brush/roller on the same day provided gloves are worn during the mixing and loading and application phases.

An acceptable risk was identified for an adult washing clothes contaminated with dicopper oxide following use of the representative product.

An unacceptable risk is identified (from dermal and hand-to-mouth exposure) for a toddler touching wet paint on the boat. However, the risk is acceptable for a toddler touching dry paint. Therefore, it is considered that this potential risk to children can be mitigated by suitable labelling of products containing dicopper oxide intended for non-professional use indicating that unprotected persons should be kept away from treated surfaces until they are dry.

Dietary Risk Assessment

An acceptable risk is identified for potential exposure via food contamination. This is based on available knowledge about the natural occurrence of copper, physiological needs, physico-chemical properties and regulations already in force. Exposure via food contamination may need to be reassessed when a uniform methodology to assess dietary exposure induced by an antifouling application is available.

Environment

The table below summarises the exposure scenarios assessed:

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Commercial ship		
New building – application	Direct releases to marine surface water following application by spray and brush and roller by professionals	Acceptable (wider environment of harbours only)
Maintenance and repair – application and removal of paint	Direct releases to marine surface water following spray application and high pressure washing by professionals	Acceptable (wider environment of harbours only)
In-service life stage	OECD-EU Commercial harbour OECD-EU Shipping lane	Acceptable
Aggregated exposure	Application and in-service releases were summed up. Removal and in-service releases were summed up.	Acceptable

Pleasure craft		
New building – application	Direct releases to soil and/or Sewage Treatment Plant (STP) following spray, brush and roller application by professionals. Indirect releases to marine surface water via STP by professionals.	Acceptable except for soil in case of direct releases
Maintenance and repair – application and removal of paint	Direct releases to soil (ground water) and/or STP following spray, brush and roller application by professionals; and brush and roller application by non-professionals. Direct releases to marine surface water by removal of paint by professionals and non-professionals. Indirect releases to environmental compartments via STP by professionals and non-professionals.	Acceptable (wider environment of marinas only) except for soil considering direct releases via professional activities.
In-service life stage	OECD-EU Marina	Acceptable (wider environment of marinas only)
Aggregated exposure	Removal and in-service releases were summed up	Acceptable (wider environment of marinas only)
For all scenarios evaluated the exposure is estimated within the harbour or marina as well as adjacent to the harbour and marina (defined as the wider environment). In addition, both for commercial and pleasure craft scenarios, worst case and typical case situations were evaluated.		

The marine aquatic compartment can be exposed directly or indirectly (*via* the STP) to the dicopper oxide based product during the phases of application or removal of paint and directly during the service-life of ship hulls. The proposed scenarios led to acceptable risks for commercial vessels and pleasure crafts, when the wider marine environments were considered. In fact, the risks were not deemed acceptable for the sediment inside commercial harbors and marinas, but are acceptable for the whole aquatic compartment in the adjacent areas of harbors and marinas.
It was considered that the freshwater environment (including the sediment) can also be exposed indirectly via the STP only, during the pleasure crafts application or removal phases. Whatever the scenarios, the risks were considered acceptable for the STP and the freshwater environment. Direct emissions to the freshwater environment have not been assessed due to the lack of a harmonized scenario and should be considered during product assessment, if appropriate.

The terrestrial compartment (including groundwater) can be exposed directly or indirectly via the STP during the pleasure craft application or removal of paint by professionals or non-professionals. The risks for the soil and groundwater were considered acceptable for non-professional activities (leading to direct or indirect soil emission). On the other hand, the releases during application and removal of paint by professionals working on pleasure crafts led to unacceptable risks for soil when a direct exposure of the terrestrial compartment is foreseen. In this case the risk remained acceptable for groundwater or when releases were directed to a STP. Labels and/ or safety data sheets of products authorised for professional uses shall advise users to protect the soil during application and removal to prevent direct losses to soil and water, and that any losses must be collected for disposal.

The regional copper background concentrations were added to the calculated concentrations of copper issuing from dicopper oxide antifouling paint application, for all the environmental compartments. This has been done to cover all the other possible uses of copper in the

calculation of the risk ratios, and in consequence in the assessment of the risk for environment.

Overall conclusion

With regard to human health and environmental exposures and effects, safe use of dicopper oxide antifouling based product is identified if both professional and non-professional operators wear appropriate personal protective equipment and when exposures of the aquatic and terrestrial compartments during the paint application and removal are limited.

It has to be highlighted that for environment, safe uses can only be identified for the wider aquatic environment of harbors and marinas; the risks inside the harbours and marinas are unacceptable.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

Property			Conclusions
CMR properties	Carcinogenicity (C)	no classification required	Dicopper oxide does not fulfil criterion (a), (b) and (c) of Article 5(1)
	Mutagenicity (M)	no classification required	
	Toxic for reproduction (R)	no classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	The active substance as inorganic metal is excluded from the P assessment taking into account the Annex XIII of Reach regulation 1272/2008.	Dicopper oxide does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	not B or vB	
	Toxic (T)	T	
Respiratory sensitisation	No classification required. Dicopper oxide does not fulfil criterion (b) of Article 10(1).		
Endocrine disrupting properties	Not considered to have endocrine disrupting properties Dicopper oxide does not fulfil criterion (d) of Article 5(1).		
Concerns linked to critical effects	Dicopper oxide does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	Not relevant. Dicopper oxide does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

Dicopper oxide does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

Dicopper oxide does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution.

The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR"[3] and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[4] agreed at the 54th and 58th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

2.2.2. POP criteria

The POP criteria are not relevant as dicopper oxide is an inorganic compound.

2.3. BPC opinion on the application for approval of the active substance dicopper oxide in product type 21

In view of the conclusions of the evaluation, it is proposed that dicopper oxide shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: minimum purity of the active substance evaluated: 94.2% w/w.

   Arsenic, cadmium, lead, and nickel are identified as relevant impurities with a maximum content of <0.0095g/kg, <0.04g/kg, <1.2g/kg, and <0.3g/kg respectively.

2. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

Authorisations are subjected to the following conditions:

1. For industrial or professional users, safe operational procedures and appropriate organizational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.

2. Persons making products containing dicopper oxide available on the market for non-professional users shall make sure that the products are supplied with appropriate gloves. Labels and, where provided, instructions for use shall indicate whether other personal protective equipment shall be used. Labels and, where provided, safety data sheets of products authorised shall indicate that children shall be kept away until treated surfaces are dry.

3. Labels and, where provided, safety data sheets of products authorised shall indicate that application, maintenance and repair activities shall be conducted within a contained area, on an impermeable hard standing with bunding or on soil covered with an impermeable material to prevent direct losses and minimize emissions to the

[3] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc)
4 See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc)

environment, and that any losses or waste containing dicopper oxide shall be collected for reuse or disposal.

4. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council[5] or Regulation (EC) No 396/2005 of the European Parliament and of the Council[6] shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

The active substance does not fulfil the criteria according to Article 28(2)(a) to enable inclusion in Annex I of Regulation (EU) 528/2012.

2.4. Elements to be taken into account when authorising products

1. With regard to professional operator exposure, labelling should indicate the level of personal protective equipment including respiratory protective equipment that must be worn during handling, application and removal of products containing dicopper oxide.
2. Safe uses to the aquatic environment have been identified for scenarios representative of shipping lanes, harbours and the wider environment of marinas (i.e. areas adjacent to marinas). A risk has been identified within marinas. These areas may need additional consideration at national level and the available best practices shall be applied to mitigate these risks.
3. With regard to the environment, the need to address any specific national conditions and protection goals and/or undertake regional assessments should be considered at product authorisation stage, as environmental risk assessments in this evaluation have been based on generic EU scenarios.
4. Because of deficiencies in the dermal absorption studies, new studies would be needed at product authorisation. However, for approval of the active substance, it would not be reasonable to require new dermal absorption studies before harmonised guidance for PT 21 dermal absorption studies is developed. It was agreed to set a provisional absorption value for each copper compound based on the products tested, and these values would only apply for active substance approval.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of dicopper oxide.

However, further data on the active substance are required and must be provided as soon as possible but no later than 6 months before the date of approval to the evaluating Competent Authority (FR):

1. The particle size distribution;
2. Either a scientific sound justification or a flammability test;
3. An auto-flammability test;
4. Further validation data for American Chemet and Nordox for the analytical method permitting the determination of the active substance;
5. Complete validation data for American Chemet and Nordox for the analytical method for relevant impurities and the validation data for the analysis of other impurities are required to fully validate the 5-batch analysis.

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[5] OJ L 152, 16.6.2009, p. 11.
[6] OJ L 70, 16.3.2005, p. 1