Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Copper, granulated

Product type: 8

ECHA/BPC/082/2015

Adopted

9 December 2015

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance copper, granulated for product type 8

In accordance with Article 90(2) 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 8 of the following active substance:

Common name:	**Copper, granulated**
Chemical name(s):	**Copper**
EC No.:	**231-159-6**
CAS No.:	**7440-50-8**
New 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 Arch Timber Protection on 30 August 2013, the evaluating Competent Authority France submitted an assessment report and the conclusions of its evaluation to the ECHA on 3 April 2015. 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: BPC member for France

The BPC opinion on the approval of the active substance copper, granulated in product type 8 was adopted on 9 December 2015.

The BPC opinion was adopted by simple majority of the members present having the right to vote. The minority position including its grounds is published on ECHA webpage:

http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that copper, granulated in product type 8 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 copper, granulated in product type 8.

The substance copper, granulated is a recycled copper in granular form. The active substance reacts as cupric ion Cu^{2+}.

Copper, granulated solubilized in the solvent monoethanolamine is the representative product.

Specifications for the reference source are established. Copper, granulated 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 and for the relevant impurities. Validated analytical method for the determination of the active substance in the reference product is not available.

No harmonised classification of the active substance is available. A CLH report was submitted to ECHA the 8 April 2015.

The proposed classification and labelling for copper, granulated according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Proposed classification according to the CLP Regulation	
Hazard Class and Category Codes	Eye Irrit. 2 / H319 Aquatic Acute 1/ H400 Aquatic Chronic 1/ H410
Labelling	
Pictograms	GHS07 GHS09
Signal Word	Warning
Hazard Statement Codes	H319 - Causes serious eye irritation H410 - Very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	M = 1 (for acute and chronic)

b) Intended use, target species and effectiveness

Copper granulated is intended to be used as a preventive wood preservative for wood in OECD Emission Scenario Document Use class 1 to 4b as defined in the EN 335[1].

The active substance is restricted to industrial use only, in timber treatment plants operated by professionals.

The function of copper, granulated is fungicide and insecticide to control fungi (wood rotting basidiomycetes and soft rot fungi) and insects (wood boring beetles and termites).

The data on copper, granulated and the representative biocidal product have demonstrated sufficient efficacy against the target species for the approval of the active substance.

There is no evidence of insects being naturally tolerant or being able to develop resistance to copper at the level of copper used for biocidal purposes in wood preservation. Nevertheless, based on literature data, there are strains of some species of wood destroying fungi that exhibit tolerance to copper. This aspect should be reviewed and updated at product authorisation stage.

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

Human health

Copper granulated is an ocular irritant. No repeated toxicity study by oral route was provided with copper granulated. However, it is considered that toxicity of copper compounds is essentially linked to Cu^{2+} 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**
Vacuum pressure application	**Primary exposure:** - the mixing and loading operations is negligible in case of automated transfer/pumping dilution; - application : three treatment cycles of 3 hours each daily; - post-application (including maintenance, recycling and disposal).	Industrial professionals	Acceptable with gloves and coated coverall
Exposure to treated wood (in-service life)			
Cutting and sanding treated timbers	**Secondary exposure:** cutting and sanding treated timbers by adults. Both acute and chronic exposures are considered.	Adults	Acceptable

[1] Since 2007 and the revision of the EN335-1, use classes has replaced hazard classes.

Chewing preserved timber off-cuts	**Secondary exposure:** toddler chewing preserved timber off-cuts.	Toddlers	Acceptable
Child playing on playground	**Secondary exposure:** children playing on preserved timber playground equipment.	Children	Acceptable
Infant playing and mouthing on treated wood	**Secondary exposure:** toddler playing on preserved timber playground equipment and mouth contacts with the treated timber surface.	Toddlers	Acceptable

With regard to human health exposure, the risk related to primary exposure is considered to be acceptable for industrial professionals when appropriate personal protection equipment (PPE) are worn.

Concerning the secondary exposure, the risk is considered to be acceptable.

Concerning secondary exposure via food contamination, inasmuch no direct interaction of treated wood with food is supported in context of this application, no dietary risk assessment (DRA) has been performed. However, at the product authorisation stage, if use of the product results in transfer of residues to food, a dietary risk assessment (DRA) will be required.

Environment

The table below summarises the exposure scenarios assessed:

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Vacuum pressure impregnation by industrial treatement		
Application	Indirect releases via the STP to surface water and sediment.	Unacceptable (no release to STP is allowed, the product should be re-cycled within the facility or collected and disposed).
	Direct release to Sewage Treatment Plant (STP).	Acceptable
	Indirect releases to terrestrial compartment via the application of STP sludge to soil.	
Storage	Direct releases to surface water, sediment.	Unacceptable (all timbers treated by industrial process should be stored on impermeable hard standing to prevent direct losses surface water and to allow losses to be collected for disposal).
	Direct releases to soil for outdoor storage	Uncceptable. Storage on bare soil is not allowed. The emissions from treated wood to soil should be substantially reduced by covering the storage area with protective roof or covering the soil with impermeable coating e.g. concrete. Leachates should be collected and treated appropriately (e.g. incineration).
In-service life		
Service life of treated wood	Noise barrier (Use Class 3) - Indirect releases via STP to surface water and sediment ; Direct releases to STP and soil	Acceptable
	Noise barrier (Use Class 3)– Indirect releases via the STP in soil	Acceptable
	House (Use Class 3) - Direct releases to soil	Acceptable
	Bridge over a pond (Use Class 3)- Direct releases to surface water and sediment	Unacceptable
	Transmission pole (Use Class 4a) - Direct releases to soil	Acceptable
	Fense post (Use Class 4a) - Direct releases to soil	Acceptable

	Jetty in a lake (Use Class 4b) - Direct releases to surface water and sediment	Unacceptable
	Sheet piling (Use Class 4b) - Direct releases to surface water and sediment	Unacceptable

Application:

With regard to environmental exposure and effects, safe uses can only be identified when there is no emission to the STP during the application.

Storage:

The environmental risk assessment indicates unacceptable risks to the aquatic and terrestrial environment during storage of freshly treated wood.

In-service:

The terrestrial risk assessment indicates acceptable risks for wood in service used in Uses Classes 3 and 4.

The aquatic risk assessment indicates acceptable risk for wood in service when a direct release to surface water is excluded. Therefore, the Uses Classes 3 and 4a can be approved when direct releases to the aquatic compartment can be prevented.

But, unacceptable risks are identified for bridge over a pond in Uses Classes 3 and Uses Classes 4b (for wood in direct contact with fresh water). All these uses cannot be allowed unless acceptable risks are demonstrated at product authorisation phase.

Overall conclusion

With regard to human health and environmental exposures and effects, a safe use of copper, granulated based products is identified if professional operators wear appropriate protective equipment and when exposures of the aquatic and terrestrial compartments during the application and the storage are limited. For the in-service life stage of treated wood, a safe use of copper, granulated based products is identified for Uses classes 1, 2, 4a and for Uses Classes 3 only when no direct releases to the aquatic compartment occur.

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	Copper, granulated 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)	Copper, granulated as inorganic metal is excluded from the P assessment taking into account the Annex XIII of Reach regulation 1272/2008.	Copper, granulated 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)	Copper, granulated not B or vB	
	Toxic (T)	Copper, granulated is T	
Respiratory sensitisation	No classification required. Copper, granulated does not fulfil criterion (b) of Article 10(1).		
Endocrine disrupting properties	Not considered to have endocrine disrupting properties. Copper, granulated does not fulfil criterion (d) of Article 5(1).		
Concerns linked to critical effects	Copper, granulated does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	Not relevant. Copper, granulated does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

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

Copper, granulated 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"[2] and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[3] 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] 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)

3 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)

2.2.2. POP criteria

The POP criteria are not relevant as copper, granulated is an inorganic compound.

2.3. BPC opinion on the application for approval of the active substance copper, granulated in product type 8

In view of the conclusions of the evaluation, it is proposed that copper, granulated 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: ≥ 99.0 % w/w. Lead, cadmium, arsenic and nickel are identified as relevant impurities with a maximum content of <0.008 mg/kg, <0.001g/kg, <0.005 g/kg and <0.01 g/kg respectively.

2. The authorisation of biocidal products is subject to the following conditions:

    a. 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.

    b. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:

        i. industrial and professional users;

        ii. surface water and sediment where there is direct release during the service life of treated wood.

    c. In view of the risks identified for surface and ground water, labels and, where provided, safety data sheets of products authorised shall indicate that industrial or professional application shall be conducted within a contained area or on impermeable hard standing with bunding, and that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.

    d. 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[4] of the European Parliament and of the Council or Regulation (EC) No 396/2005[5] of the European Parliament and of the Council shall be verified, and any appropriate risk mitigation measures shall be taken into account 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. The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:

[4] Regulation (EC) No 470/2009 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11)
[5] Regulation (EC) No 396/2005 of the European Parliament and of the Council (OJ L 70, 16.3.2005, p. 1)

a. If an unacceptable risk for industrial professionals is identified, then 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.

b. An unacceptable risk is identified for the aquatic compartments during service-life of wood used for outdoor constructions (Use Class 3 when direct releases in surface water is foreseen and Use Class 4b). If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these uses should not be authorised.

2. Treated wood with copper, granulated is not intended to be used as a food contact material. In consequence, residues in food and feed are not expected. At product authorisation level, if food contact is possible, a dietary risk assessment has to be conducted according to available guidance. In case the use leads to residues, analytical methods for food and feed must be provided.

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 copper, granulated. However, further data on the active substance are required and must be provided as soon as possible but no later than at the date of approval to the evaluating Competent Authority (FR): water solubility of copper, granulated at different pH.

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