Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Copper pyrithione

Product type: 21

ECHA/BPC/029/2014

Adopted

3 October 2014

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

Opinion of the Biocidal Products Committee

on the application for approval of the active substance copper pyrithione 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, the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 21 of the following active substance:

Common name:	**Copper pyrithione**
Chemical name(s):	**bis(1-hydroxy-1H-pyridine-2-thionato-O,S)copper**
EC No.:	**238-984-0**
CAS No.:	**14915-37-8**
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 (AR), as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of opinions

Following the submission of an application by Arch Chemicals Inc (currently Lonza) and API Corporation (currently Mitsubishi Chemical Corporation) on 30 April 2006, the evaluating Competent Authority Sweden submitted an assessment report and the conclusions of its evaluation to the Commission in January 2011. 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 and the Commission via the Biocides Technical Meetings and the Competent Authority meeting. Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the opinion

Rapporteur: BPC member for Sweden

The BPC opinion on the approval of the active substance copper pyrithione in product-type 21 was reached on 3 October 2014.

The BPC opinion was adopted by consensus.

Detailed BPC opinion and background

1. Overall conclusion

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

2. Opinion

2.1. Conclusions of the evaluation

a) Presentation of the active substance and representative biocidal product including classification of the active substance

This evaluation covers the use of copper pyrithione in product type 21. Copper pyrithione acts as a booster biocide in the antifouling paint, by increasing the efficacy of the product in order to remove the most problematic soft fouling organisms, for example the common algae e.g. *Enteromorpha* spp. and *Amphora* spp which are tolerant of copper. Specifications for the reference source are established.

The physical-chemical properties of the active substance and the representative biocidal products have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal product.

Validated analytical methods are available for the active substance as manufactured and for the relevant and significant impurities. Validated analytical methods are available for the relevant matrices: soil; air; water; body fluids and tissues; fish and shellfish.

Copper pyrithione has no harmonized classification in accordance with Regulation (EC) No 1272/2008 (CLP Regulation) and the evaluating Competent Authority (eCA) Sweden will therefore prepare a CLH dossier that will be sent to ECHA. The proposal from the eCA is presented in the table below.

Proposed classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 2; H330 Acute Tox. 3; H301 Acute Tox. 3; H311 Eye Dam. 1; H318 STOT SE 3; H335 Repr 2; H361 STOT RE; H372 Aquatic Acute 1; H400 Aquatic Chronic 1; H410
Proposed labelling	
Pictograms	GHS06; GHS05; GHS08; GHS09
Signal Word	Danger
Hazard Statement Codes	H330 Fatal if inhaled H301 Toxic if swallowed H311 Toxic in contact with skin H318 Causes serious eye damage H335 May cause respiratory irritation H361 Suspected of damaging the unborn child H372 Causes damage to organs the nervous system through prolonged or repeated exposure H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects

Specific Concentration limits, M-Factors	M = 100 for Aquatic Acute M = 100 for Aquatic Chronic

b) Intended use, target species and effectiveness

Copper pyrithione is intended to be used as a co-biocide (booster biocide) by both professional and non-professional users in antifouling products (PT 21) against marine fouling species. A booster biocide is not the main biocide in the paint, but is meant to be effective against soft-fouling organisms, so its function is to increase the efficacy of the product in order to remove the most problematic fouling organisms, for example the common algae e.g. *Enteromorpha spp*. and *Amphora spp* which are tolerant of copper.

The intended uses differs between the six representative products (AR, appendix II), but is limited to use on pleasure crafts, use on commercial ships and use as impregnation of fishing nets. Fishing nets is only evaluated for human health since the scenario for environment is under development.

The data on copper pyrithione and the (six) representative biocidal products have demonstrated sufficient efficacy against the target species.

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

The overall conclusion from the evaluation of copper pyrithione for use in product type 21 (antifouling products) is, that it may be possible for Member States to issue authorisations of products containing copper pyrithione 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 Regulation (EU) No 528/2012 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[1].

Human health

The table below summarises the exposure scenarios assessed.

[1] 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).

Summary table: human health scenarios	
Scenario **Primary or secondary exposure: Exposed group** **Description of scenario**	**Acceptable or unacceptable**
Airless spraying Primary exposure: Professionals Spraying antifouling paint on a boat on a shipyard	Unacceptable
Painter using brush and roller Primary exposure: Professionals and non-professionals Applying antifouling paint with brush and roller either in a ship yard, a public place or in the home garden	Acceptable with personal protective equipment (PPE) for professionals and unacceptable for non-professionals
Mixing and loading (potman) Primary exposure: Professionals The potman works together with the sprayer	Unacceptable
Removal of paint Primary exposure: Professionals and non-professionals The professionals removes the paint by sand blasting whereas the non-professionals scrapes and grinds of the paint	Unacceptable for professionals but acceptable for non-professionals
Grit fillers Primary exposure: Professionals The grit filler works together with the person removing the paint by sandblasting	Unacceptable
Net coating Primary exposure: Professionals Nets are dipped into large vessels with antifouling product	Acceptable with PPE
Net deployment Primary exposure: Professionals The nets are moved and deployed at the fish farm	Acceptable with PPE
Bystanders Secondary exposure: Professionals Workers at the ship yard where spray application of antifouling paint is used	Acceptable with warning sign*
Toddler touching wet paint on a boat Secondary exposure: Children Children might touch freshly painted boats in public place or in the home garden	Unacceptable
Toddler touching wet paint on a boat and then hand to mouth contact Secondary exposure: Children Children might touch freshly painted boats in public place or in the home garden and then put their fingers in the mouth	Unacceptable
Toddler touching dry paint Secondary exposure: Children Children might touch a boat with dry antifouling paint in public places or in the home garden	Acceptable

Toddler touching dry paint on a boat and then hand to mouth contact Secondary exposure: Children Children might touch boats with dry paint in public places or in the home garden and then put their fingers in the mouth	Acceptable

*To protect bystanders in the ship yard the area where spray painting is performed should be labelled with "Unprotected people keep away from the area".

A risk is identified for non-professionals for the application phase and for children (secondary exposure) touching wet paint on a boat. A labeling provision that children must be kept away from the painted boat until the paint is dry can be considered. However, in the particular case of copper pyrithione, the risk assessment is performed using a dermal short term Acceptable Exposure Level (AEL) which is based on all available oral copper pyrithione, zinc pyrithione and sodium pyrithione subacute, subchronic, teratogenicity and 2-generation studies and an Acute Reference Dose (ARfD) which is based on neurologic effects occuring after 2.5 hours in a 90 day study in rats. Due to the acute occurrence of the effect it is considered that the label provision mentioned above is not sufficient to avoid risks. It is therefore concluded that authorisation of products for non-professional use shall not be allowed.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Result**
In-service life stage: marina	Emissions from boat hulls in contact with watergoes to water and sediment inside the marina, and adjacent to the marina (defined as the wider environment scenario).	Unacceptable risk for (pelagic and sediment living) organisms inside marina. Acceptable risk for (pelagic and sediment living) organisms in the nearby surroundings of the marina ("wider environment").
In-service life stage: commercial harbour	Emissions from boat hulls in contact with water goes to water and sediment inside the harbour, and the nearby surrounding environment.	Unacceptable risk for (pelagic and sediment living) organisms inside harbour. Acceptable risk for (pelagic and sediment living) organisms in the nearby surroundings of the harbour ("wider environment").

In-service life stage: shipping lane	Emissions from boat hulls moving in a well defined water volume goes to water and sediment.	Acceptable risk for (pelagic and sediment living) organisms inside the shipping lane.
Application, maintainance & repair: Paint particles (drops, scrapings) on soil	Emissions in the form of particles (paint droplets, scrapings, dust) from activities where boats are painted, paint layer removed, repaired. Fraction paint going to soil.	Unacceptable risk to soil living organisms.
Application, maintainance & repair: Paint particles (drops, scrapings) on soil and leaching into groundwater	TGD default scenario of porewater contamination.	Unacceptable risk to groundwater.
Application, maintainance & repair: Paint particles (drops, scrapings) to STP	Emissions in the form of particles (paint droplets, scrapings, dust) from activities where boats are painted, paint layer removed, repaired. Fraction of emission going to STP.	Risk is acceptable for the microorganisms in the sludge.
Application, maintainance & repair: STP emission to aquatic recipient (water and sediment)	TGD default scenario. Effluent water into recipient. Dilution factor 10. Release to water and sediment.	Risk is acceptable for the (pelagic and sediment living) organisms in the (fresh and marine) recipient water.
Application, maintainance & repair: STP emission to grassland and agricultural soil	TGD default scenario. Given amount STP sludge applicated onto soils yearly. Release to surface soils.	Risk is acceptable to the soil living organisms.
Aggregated exposure form in-service life (commercial harbour) and application, maintainance & repair:	Scenario according to MOTA, where land-based emissions (run-off of paint particles) are aggregated with in-service life emissions (leaching from boat hulls in contact with water). Recipient is the commercial harbour.	Unacceptable risk for (pelagic and sediment living) organisms in the recipient. Acceptable risk for (pelagic and sediment living) organisms in the nearby surroundings of the harbour ("wider environment").
Secondary poisoning	TGD default scenarios of food chain contamination.	Risk is acceptable.
Emissions to air	TGD default scenario for equilibrium concentration in air over water (STP water).	Risk is acceptable.
Impregnated fishnets	Scenario under development (WG discussions ongoing 2014)	The risk cannot be assessed because no harmonised scenario is available.

The in-service life (leaching from boat hulls on boats in traffic or in harbour) use of copper pyrithione in product type 21 results in acceptable risks to the nearby surrounding ("wider environment") marine environment (but not to the water and sediment inside the harbours). This applies for all MAMPEC-scenarios (Marina, Commercial Harbour, and Open lane).

The scenarios for application- and maintenance of PT 21 paint on ship hulls gives emissions which results in acceptable risk to the water recipient (including sediment-living organisms via suspended sediment) for professional activities on commercial ships and for non-professional activities on pleasure crafts. However, risk to soil and groundwater on ships- and boatyards are unacceptable (for professional- and non-professional activities on pleasure crafts).

For the approval of PT21 active substances it is agreed to accept unacceptable risks in the scenarios for commercial harbour and marina, as long as the risk is acceptable in the wider environment (in essence the adjacent surroundings of the harbour or marina). At product authorisation on national level, the level of protection for harbours and marinas can differ, and also the very scenarios (harbour dimensions, dilution factors etc).

Regarding the unacceptable risks which are identified to the soil and groundwater at places for application, and maintenance and repair activities with regard to emissions from paint particles (droplets, flakes and dust), risk mitigation measures are required.

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		Classification
CMR properties	Carcinogenicity (C)	no classification required
	Mutagenicity (M)	no classification required
	Toxic for reproduction (R)	Cat 2
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	not P or vP
	Bioaccumualtive (B) or very Bioaccumulative (vB)	not B or vB
	Toxic (T)	T
Endocrine disrupting properties	Guidelines are under development from the EU Commission. Therefore it is concluded that currently no firm conclusions can be drawn on the endocrine disrupting properties of copper pyrithione. The most widely agreed definition of endocrine disruptors (IPCS/WHO, 2002) requires that there is an at least plausible link between the endocrine mode of action and adverse effects in organisms and/or populations. No such plausible link has been established for copper pyrithione.	

Consequently, the following is concluded:

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

Copper pyrithione *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" agreed at the 54th meeting 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 (CA-March14-Doc.4.1 - Final - Principles for the approval of AS.doc). This implies that the assessment of the exclusion criteria is based on Article 5(1) using the temporary criteria for the determination of endocrine-disrupting properties in Article 5(3) and the assessment of substitution criteria is based on Article 10(1)(a, b and d).

POP criteria

Copper pyrithione and its organic metabolites are neither P nor B, so the substances should not be considered as POPs.

2.3. BPC opinion on the application for approval of the active substance copper pyrithione in product type *21*

In view of the conclusions of the evaluation, it is proposed that copper pyrithione 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: 95% w/w.

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

3. Products containing copper pyrithione shall not be authorised for non-professional users.

4. Authorisations are subject to the following conditions:

    a. 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.

    b. 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 and on impermeable hard standing with bunding to prevent direct losses and minimize emissions to the environment, and that any losses or waste containing copper pyrithione shall be collected for reuse or disposal.

    c. 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 or Regulation (EC) No 396/2005 of the European Parliament and of the Council shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

The active substance gives rise to some concerns according to Article 28(2) of the BPR and therefore inclusion in Annex I of Regulation (EU) No 528/2012 is not acceptable at this time.

2.4. Elements to be taken into account when authorising products

1. Whilst the efficacy data provided is sufficient to recommend approval of the substance, data demonstrating the efficacy of the product at the minimum application rate against the range of proposed target organisms using the recommended application equipment must be provided at the product authorisation stage.
2. Pyrithiones cause neurological effects in the animal studies and the most toxic exposure route seems to be through inhalation. In inhalation studies, but also in some oral studies, as well as in studies where the eyes have been exposed, sudden death among the animals has occurred and the cause of the death has not been possible to establish. The dose response curve seems to be steep for this effect. The neurological effect seems to be through effects on the Ca^{2+}-channels. Hence, at the product authorisation stage it is important to consider this information, to ensure that the total daily exposure for one worker must not exceed the AEL. In this report antifouling products have been evaluated that had a concentration of copper pyrithione between 1.5 and 4.01 % and where the dermal penetration values have been between 0.6 and 5 %. For all products it is important that all information about copper pyrithione concentration and dermal absorption is evaluated.
3. If at the product authorisation stage the spraying scenario is found to be acceptable the risk for the potman and ancillary worker has to be evaluated and it also has to be decided what type of PPE they need to use. Moreover, if the sandblasting scenario is found to be acceptable also the risk for the grit filler has to be evaluated and the need for PPE has to be decided.
4. If products are authorised for spray painting, the product should be labelled with the phrase "unprotected persons should be kept out of treatment areas".
5. For professionals the removal of paint was an unacceptable scenario. However, the calculation is made in a conservative way due to lack of more specific data. If more information is available at product authorisation level the sand blasting scenario might be acceptable.
6. For the calculations medium-term inhalation and dermal AELs have been used for copper pyrithione in Product Type 21 since exposure is expected to occur repeatedly but intermittently, according to the notifier approximately 1–2 times per month. If at the product authorisation stage any prolonged exposure would be expected, the long-term AELs have to be used.
7. The unacceptable risks which are identified to the soil and groundwater at places for maintenance and repair activities are identified with regard to emissions from paint flake and dust.
8. For the use for impregnated fishnets, the environmental risk assessment could not be finalised because of the lack of available harmonised scenarios. This should be assessed at the product authorisation stage.
9. Regarding the environmental risk assessments in product authorisations, special attention should be paid to site-specific sensitivity of ecosystems.

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 pyrithione. However, further data

shall be required as detailed below.

A new 5-batch analysis is considered required for the applicant Arch (currently Lonza) to confirm/revise their technical specification with respect to the level of impurities and should be submitted as soon as possible and at the latest 6 months before the approval date of the active substance to the evaluating Competent Authority (SE).

For the applicant API (currently Mitsubishi Chemical Corporation), access to an acceptable method for analysis of residues of copper pyrithione in sediment and water, a dermal repeated subchronic toxicity study, an *in vivo* micronucleus bone marrow study, a cancer study, and a letter of access (LoA) to a valid BCF study in fish is needed at the product authorisation stage at Member State level. Depending on whether a valid analytical method for fish and shell fish is actually considered necessary for copper pyrithione, API (currently Mitsubishi Chemical Corporation) may also need access to a method for this purpose. This should be submitted as soon as possible and at the latest 6 months before the approval date of the active substance to the evaluating Competent Authority (SE).

The applicant Arch (currently Lonza) will need access to an acceptable analytical method for monitoring in air at the product authorisation stage at Member State level. This should be submitted as soon as possible and at the latest 6 months before the approval date of the active substance to the evaluating Competent Authority (SE).

In order to address a potentially severe underestimation of the risk to sediment dwelling organisms from exposure via suspended matter, caused by the fact that sorption data (K_{OC}) has only been studied at concentrations which are not fully relevant in the marine environment, a new study on sorption at environmentally relevant conditions (concentrations µg/l to ng/l, pH ~8, DOC not too high, etc.) is to be performed before the antifouling active substances are evaluated for a potential renewal of the approval.

o0o