Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Copper thiocyanate

Product type: 21

ECHA/BPC/079/2015

Adopted

9 December 2015

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 thiocyanate 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:	**Copper thiocyanate**
Chemical name(s):	**Copper I thiocyanate**
EC No.:	**214-183-1**
CAS No.:	**1111-67-7**

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: BPC member for France

The BPC opinion on the approval of the active substance copper thiocyanate 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 copper thiocyanate 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 copper thiocyanate 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 source are established. Copper thiocyanate as manufactured contains five relevant impurities: arsenic, cadmium, mercury, 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 section 2.5).

Validated analytical methods for the determination of relevant impurities have been provided. The analytical method for the determination of one impurity is not specific, further data should be provided. Validated analytical methods are 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	Aquatic Acute 1, H400 Aquatic chronic 1, H410
Labelling	
Pictograms	GHS09
Signal Word	Danger
Hazard Statement Codes	H410: very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	Aquatic Acute 1: M-factor = 10 Aquatic chronic 1: M-factor = 10

[1] Opinion proposing harmonised classification and labelling at EU level of Copper thiocyanate
EC number: 214-183-1, CAS number: 1111-67-7, CLH-O-0000001412-86-37/F- Adopted 04 December 2014

b) Intended use, target species and effectiveness

Copper thiocyanate 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, copper thiocyanate representative based product at 19.25 % w/w of a.s demonstrated a sufficient activity for the approval of the active substance when considering use in European sea water. 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.

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

The overall conclusion from the evaluation of copper thiocyanate for use in product type 21 (antifouling products) is, that it may be possible for Member States to issue authorisations of products containing copper thiocyanate 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

No repeated toxicity study by oral route was provided with copper thiocyanate. However, it is considered that toxicity of copper compound 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.

A toxicity of SCN anion exists and cannot be ignored. However, no robust data on toxicity is available. In this context, it is proposed to compare the exposure of thiocyanate via antifouling use to the daily exposure via diet proposed on the Addendum to the draft assessment report on potassium thiocyanate dated of September 2012.

The table below summarises the exposure scenarios assessed.

[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).

For copper compound:

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
Cleaning of spray equipment	**Primary exposure:** cleaning of spray equipment used to apply antifouling product	Professionals (potman)	Acceptable
Combined exposure: Mixing/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
Spray application	**Primary exposure:** spray application of antifouling product via airless sprayer	Professionals (sprayman)	Acceptable with coated coverall, gloves and RPE protection factor 10
Cleaning of spray equipment	**Primary exposure:** cleaning of spray equipment used to apply antifouling product	Professionals	Acceptable
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	Acceptable with coated coverall, gloves and mask APF10
Brush/roller application			
Application by brush/roller	**Primary exposure:** application of antifouling product by brush and roller	Professionals (including chandler) and non-professionals	Acceptable
Cleaning of brushes/rollers	**Primary exposure:** cleaning of brushes/rollers used to apply antifouling product	Professionals and non-professionals	Acceptable
Combined exposure: Mixing/loading and cleaning of equipment	**Primary exposure:** **-** mixing, loadind and application of antifouling product by brush and roller - cleaning of brushes/rollers used to apply antifouling product	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	Non-professionals	Acceptable

Grit filling			
Grit filling	**Primary exposure:** filling (with sand or grit) of abrasive blasting equipment used for removal of antifouling product	Professionals (grit filler)	Acceptable with gloves and RPE protection factor 10
Sand blasting			
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 and 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

For thiocyanate compound:

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, double coverall and RPE protection factor 40
Cleaning of spray equipment	**Primary exposure:** cleaning of spray equipment used to apply antifouling product	Professionals (potman)	Acceptable
Combined exposure: Mixing/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)	Unacceptable with gloves, double coverall and RPE protection factor 40 Cleaning: gloves
Spray application	**Primary exposure:** spray application of antifouling product via airless sprayer	Professionals (sprayman)	Acceptable with gloves, double coverall and RPE protection factor 40
Cleaning of spray equipment	**Primary exposure:** cleaning of spray equipment used to apply antifouling product	Professionals (sprayman)	Acceptable
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 (sprayman)	Acceptable with gloves, double coverall and RPE protection factor 40 during spraying and gloves during 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 Tyvek for professional
Application by brush/roller	**Primary exposure:** application of antifouling product by brush and roller	Non-professionals	Unacceptable (even 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 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 Tyvek coverall and gloves during M&L and brushing and no PPE during cleaning
Combined exposure: Mixing and 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	Unacceptable (even with gloves)
Grit filling			
Grit filling	**Primary exposure:** filling (with sand or grit) of abrasive blasting equipment used for removal of antifouling product	Professionals (grit filler)	Acceptable with gloves, double coverall and RPE protection factor 10
Sand blasting			
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 and 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	Not relevant as primary risk is unacceptable

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	Not relevant as primary risk is unacceptable
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	Unacceptable
Toddler touching dry surface of treated boat	**Secondary exposure**: Toddler touching a boat surface treated with antifouling product when dry.	General public	Acceptable
Dietary exposure from residues in fish and shellfish	**Secondary exposure**: Consumption of fish and shellfish containing residues of antifouling product	General public	Acceptable

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 unacceptable risk is identified applying copper thiocyanate in the representative product by brush and roller even when the wearing of gloves is considered. This is primarily due to the default dermal absorption value of 5 % used in the risk assessment for thiocyanate. However, given the matrix effect of antifouling paint, the actual dermal absorption of the thiocyanate ion is expected to be significantly lower. Consequently, it is expected that a safe use may be demonstrated at product authorisation stage if appropriate additional data are provided.

Secondary Exposure

An unacceptable risk is identified for a toddler touching wet paint on the boat. However, the risk is acceptable for an infant touching dry paint. Therefore, labels and, where provided, instructions for use shall indicate that children shall be kept away until treated surfaces are dry.

Dietary exposure

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.

Copper and thiocyanate compounds:

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
Maintenance and repair – application and removal of paint	Direct releases to marine surface water following spray application and high pressure washing by professionals	Acceptable
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 and non-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 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 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 in water and sediment for commercial vessels in harbour and wider environments. For pleasure crafts there was acceptable risk only when the wider marine environments were considered. In fact, the risks were not deemed acceptable for the sediment inside 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 only when emission on soil is indirect. The risk is unacceptable for non-professional activities with direct emission on soil. 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 and non-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 copper thiocyanate 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 copper thiocyanate antifouling based product is identified if professional operators wear appropriate personal protective equipment and when exposures of the aquatic and terrestrial compartments during the paint application and removal are limited.

For non-professional, the risk is unacceptable. This is however due to missing information on thiocyanate and it is expected that safe use may be demonstrated at product authorisation. A restriction for non-professional use is therefore not proposed.

It has to be highlighted that for environment, safe uses can only be identified for the wider aquatic environment of marinas; the risks inside the 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	Copper thiocyanate 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 cuprous ion as inorganic metal is excluded from the P assessment taking into account the Annex XIII of Reach regulation 1272/2008. Thiocyanate not P or vP	Cuprous ion does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1) Thiocyanate 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)	cuprous ion not B or vB Thiocyanate not B or vB	
	Toxic (T)	cuprous ion is T thiocyanate not T	
Respiratory sensitisation	No classification required. Copper thiocyanate does not fulfil criterion (b) of Article 10(1).		
Endocrine disrupting properties	Not considered to have endocrine disrupting properties. Copper thiocyanate does not fulfil criterion (d) of Article 5(1).		
Concerns linked to critical effects	Copper thiocyanate does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	Not relevant. Copper thiocyanate does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

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

Copper thiocyanate 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

[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)

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 copper thiocyanate is an inorganic compound.

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

In view of the conclusions of the evaluation, it is proposed that copper thiocyanate 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: 99.5% w/w which is equivalent to a copper content of 52.0%.
   Lead, cadmium, arsenic, mercury and nickel are identified as relevant impurities with a maximum content of <0.008 mg/kg, <0.05g/kg, <0.01g/kg, <0.01 g/kg, <0.01g/kg <0.05g/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 copper thiocyanate 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 environment, and that any losses or waste containing copper thiocyanate 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

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

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 coated copper flake.
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. Risk for non-professional users is identified, this is however due to missing information on thiocyanate and it is expected that safe use may be demonstrated at product authorisation stage if appropriate additional data are provided. In consequence new risk assessment taking into account these additional data should be performed at product authorisation stage.
5. 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 copper thiocyanate.

However, further data on the active substance are required and must be provided:

1. As soon as possible but no later than 6 months before the date of approval to the evaluating Competent Authority (FR):

    - A flammability and auto-flammability test on copper thiocyanate;
    - The particle size distribution;
    - Further data on linearity to fully validate the analytical method for the determination of thiocyanate in copper thiocyanate;
    - Further data or a specific analytical method for the determination of one impurity in the active substance;
    - Further validation data or a fully validated analytical method for the determination of thiocyanate in water.

2. At product authorisation stage to the reference Member State :

   - If a refinement of the risk assessment is needed, hazard information on thiocyanate will be required;

   - Considering the environmental part, no study was submitted related to the toxicity of copper thiocyanate on algae. Only an incomplete data set was submitted for the copper thiocyanate considering that the fate and effect assessment is mainly based on the fate and toxicity of the ion Cu^{2+}. However if a refinement of the risk assessment is needed, tests on algae or a demonstration of an equivalent toxicity between Cu^{2+} and copper thiocyanate for freshwater algae has to be further addressed at the product authorisation stage.

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