Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Hydrogen peroxide

Product type: 6

ECHA/BPC/44/2015

Adopted

2 February 2015

Opinion of the Biocidal Products Committee

on the application for approval of the active substance hydrogen peroxide for product type 6

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 6 of the following active substance:

Common name:	**Hydrogen peroxide**
Chemical name(s):	**Hydrogen peroxide**
EC No.:	**231-765-0**
CAS No.:	**7722-84-1**

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 members of the CEFIC Peroxygens Sector Group, Subgroup Hydrogen peroxide on 26 July 2007, the evaluating Competent Authority Finland submitted an assessment report and the conclusions of its evaluation to the Commission on 2 August 2013. 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 Finland

The BPC opinion on the approval of the active substance hydrogen peroxide in product type 6 was adopted on 2 February 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 hydrogen peroxide in product type 6 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 hydrogen peroxide in product type 6. The active substance hydrogen peroxide is manufactured as its aqueous solutions containing 35 % to <70 % (by weight) hydrogen peroxide. The assessment covers risks from use of biocidal products containing hydrogen peroxide up to 49.9 %. For toxicology and ecotoxicology assessments, concentrations or amounts of hydrogen peroxide always refer to pure (100%) hydrogen peroxide unless stated otherwise.

There is no significant impurity (concentration > 0.1%) present in the substance. Impurities with a concentration of each < 1 mg/kg are lead, mercury, cadmium and arsenic. Hydrogen peroxide reacts with organic molecules, which are oxidized and even split. Target molecules include proteins, nucleic acids and lipids. Chemical reactions may lead to deactivation of critical cellular functions and cell death. Depending on the concentration hydrogen peroxide may cause local irritation or corrosion of biological tissues.

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 products.

Validated analytical methods are available for the active substance as manufactured. Analytical methods for the determination of hydrogen peroxide in food and feed stuffs are not deemed necessary. Certain analytical methods (water, air) are required as further information (See 2.5 Requirements for further information).

In 2008 hydrogen peroxide has been included in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation). The classification, as presented in the Table, is the translation of the harmonised classification made for the substance under Directive 67/548/EEC. However, the evaluating Competent Authority (Finland) is of the opinion that based on the data evaluated in the present assessment report, Aquatic Chronic 3 (H412) classification should be applied according to the 2 ATP to CLP Regulation (Regulation (EC) No 286/2011). Regarding the acute toxicity classification, the eCA is of the opinion that the acute oral toxicity can be confirmed as category 4 based on the data presented in the present assessment report. For the acute inhalation toxicity category 4 some uncertainty remains, and therefore the minimum classification as category 4 cannot be confirmed. The eCA however considers that submission of a CLH dossier to ECHA to revise the current harmonised classification is of low priority nor necessary at the moment since from the risk management point of view the changes would not substantially increase the level of safety.

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Ox. Liq. 1 H271 Acute Tox. 4 * H332 Acute Tox. 4 * H302 Skin Corr. 1A H314
Labelling	
Pictograms	GHS03, GHS05, GHS07
Signal Word	Danger
Hazard Statement Codes	H271 May cause fire or explosion; strong oxidiser. H332 Harmful if inhaled. H302 Harmful if swallowed. H314 Causes severe skin burns and eye damage.
Specific Concentration limits, M-Factors	Ox. Liq.1; H271: C ≥ 70 %**** Ox. Liq. 2; H272: 50 % ≤ C < 70 %**** Skin Corr. 1A; H314: C ≥ 70 % Skin Corr. 1B; H314: 50 % ≤ C <70 % Skin Irrit. 2; H315: 35 % ≤ C <50 % Eye Dam. 1; H318: 8 % ≤ C <50 % Eye Irrit. 2; H319:5 % ≤ C < 8 % STOT SE 3; H335: C ≥ 35 % *
Notes	B

b) Intended use, target species and effectiveness

Hydrogen peroxide is used for in-can preservation of slurries, coatings and pigments used in the paper industry.

Target organisms include bacteria, fungi and viruses. The data on hydrogen peroxide and the representative biocidal product have demonstrated sufficient efficacy against the target species.

Resistance is not observed due to the low specificity of reactions of hydrogen peroxide.

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

Human health

The adverse effects of hydrogen peroxide in humans are limited to local effects at the site of first contact with the body and to embolism in some cases. No clear systemic effects were observed which is plausible in the light of the mode of action, i.e. direct chemical reactivity leading to rapid degradation. Corrosion and/or irritation of the skin and mucous membranes are the most prominent observations in the variety of animal studies. These effects are concentration dependent with no or only minor dependence from exposure duration.
Besides the direct chemical reactivity underlying the irritation and corrosion related lesions, hydrogen peroxide causes sensory irritation.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios		
Scenario	**Primary or secondary exposure, exposed group and description of scenario**	**Acceptable or unacceptable**
Mixing and loading	Primary exposure: Professionals Connecting/disconnecting drums of concentrated hydrogen peroxide solution	Acceptable with gloves and coverall (local effects). Respiratory protection equipment (RPE) if insufficient ventilation or no local exhaust ventilation (LEV).
Application	Primary exposure to the in-can preserved paper additives: Professionals Process workers in control rooms, maintenance work in factory hall	Acceptable with gloves, coverall, goggles/face shield (local effects) and RPE in the maintenance work.

The professional use of hydrogen peroxide for in-can preservation of paper additives is acceptable. Personal protective equipment (PPE) is required in the mixing and loading scenario because of the skin and eye irritation properties of concentrated hydrogen peroxide solution. Respiratory protection equipment (RPE) is needed if there is insufficient ventilation or no local exhaust ventilation LEV. In application, process workers work in ventilated control rooms. In the maintenance and repair work there may be a need for PPE and RPE.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios	
Scenario	**Description of scenario including environmental compartments**
Preservation of paper additives (scenarios: printing and writing, tissue, newsprint)	Waste water emission to WWTP[1]. Emissions to surface water, soil and groundwater via WWTP.

[1] WWTP is an industrial waste water treatment plant with capacity to treat 5000 m^3 wastewater per day.

Hydrogen peroxide decomposes rapidly into water and oxygen in different environmental compartments, i.e. in surface water, soil, active sludge and air. In addition, hydrogen peroxide decomposes already in sewage before reaching the STP. All evaluated scenarios are identified as safe uses.

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
	Mutagenicity (M)	No classification required
	Toxic for reproduction (R)	No classification required
Respiratory sensitisation	No classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	Not P or vP
	Bioaccumulative (B) or very Bioaccumulative (vB)	Not B or vB
	Toxic (T)	Not T
Endocrine disrupting properties	Hydrogen peroxide is not considered to have endocrine disrupting properties	

Consequently, the following is concluded:

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

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

Hydrogen peroxide does not fulfil criteria for being a persistent organic pollutant (POP). Hydrogen peroxide does not have potential for long-range transboundary atmospheric transport.

2.3. BPC opinion on the application for approval of the active substance hydrogen peroxide in product type 6

In view of the conclusions of the evaluation, it is proposed that hydrogen peroxide 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: The active substance as manufactured is an aqueous solution of 350 - <700 g/kg (35 - <70 % by weight)

[1] 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)

2 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)

solution of hydrogen peroxide. The theoretical (calculated) dry weight specification: minimum purity of hydrogen peroxide is 995 g/kg (99.5% by wt).

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.

3. For 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.

Hydrogen peroxide gives rise to concern for human health as it is classified with skin corrosive of category 1A and specific target organ toxicant by single exposure mentioned in Article 28(2) of the BPR. Therefore inclusion in Annex I of Regulation (EU) 528/2012 is not acceptable.

2.4. Elements to be taken into account when authorising products

1. A qualitative risk assessment should be performed for the local effects taking into account the classification of the product and it's in use dilutions.

2. Since the assessment covers risks from use of biocidal products containing hydrogen peroxide up to 49.9 %, additional risk assessment should be performed if approvals biocidal products with concentration of 50 % or higher are applied for.

3. Regulation (EU) No 98/2013 on the marketing and use of Explosive Precursors has to be considered for applications for authorisation for non-professional use.

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 hydrogen peroxide. However, further data shall be required as detailed below:

1. A new analytical method for the determination of hydrogen peroxide in air should be submitted. Data must be provided to the evaluating Competent Authority (Finland)as soon as possible but no later than 6 months before the date of approval of the active substance.

2. A new analytical method for the determination of hydrogen peroxide in water should be submitted. Data must be provided to the evaluating Competent Authority (Finland) as soon as possible but no later than 6 months before the date of approval of the active substance.

3. Some sources could not be validated. Therefore further data will need to be submitted as specified in the confidential annex of the evaluation to the evaluating Competent Authority (Finland) as soon as possible but no later than 6 months before the date of approval of the active substance.

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