Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Peracetic acid

Product-type: 1

ECHA/BPC/067/2015

Adopted

30 September2015

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance peracetic acid

for product-type 1

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 1 of the following active substance:

Common name:	**Peracetic acid**
Chemical name:	**Peroxyethanoic acid**
EC No.:	**201-186-8**
CAS No.:	**79-21-0**

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 Peracetic Acid Registration Group (PAR) on 23 July 2007, the evaluating Competent Authority Finland submitted an assessment report and the conclusions of its evaluation to the Commission on 16 January 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 and the Commission via the Biocides Technical Meetings (TM IV 2013). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: BPC member of Finland

The BPC opinion on the approval of the active substance peracetic acid in product-type 1 was adopted on 30 September 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 active substance peracetic acid in product type 1 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 peracetic acid in product type 1, this evaluation does not cover the active substances or biocidal products containing peracetic acid generated in situ.[1]

Pure peracetic acid does neither exist commercially nor is it an intermediate in the production of peracetic acid products: any attempt to produce pure peracetic acid would be prevented by the explosion risks of such a compound. Peracetic acid is produced by reacting hydrogen peroxide with acetic acid in an aqueous solution. In this process, peracetic acid is not obtained as a pure substance but in the form of an aqueous solution containing peracetic acid, acetic acid, hydrogen peroxide and water. The specification for the aqueous solution is based on the starting materials acetic acid and hydrogen peroxide. This evaluation covers only products containing peracetic to a concentration of 15%.

The primary mode of action of peracetic acid is oxidation. It denatures proteins, disrupts cell wall permeability, and oxidizes sulfhydral and sulfur bonds in proteins, enzymes, and other metabolites.

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.

Validated analytical methods are available for the active substance as manufactured and for the relevant and significant impurities. Validated analytical methods for residues are available for the relevant matrices air and water. For body fluids and tissues there is a method for blood. Analytical methods for the determination of peracetic acid in food and feed stuffs are not deemed necessary. Validated analytical methods are missing and required for the determination of acetic acid and stabilisers in the aqueous solution before product authorisation.

Peracetic acid is included in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) The classification, as presented in the table below, is the translation of the harmonised classification made for the substance under Directive 67/548/EEC.

The classification and labelling for peracetic acid according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

[1] See document: Management of in situ generated active substances in the context of the BPR (available from https://circabc.europa.eu/sd/a/97b0c64b-9534-49a4-ab13-fc1cbedf5d09/CA-Nov14-Doc.4.1%20-%20Substances%20generated%20in%20situ.doc) for a definition of an in-situ generated active substance.

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Flam. Liq. 3 H226 Org. Perox. D **** H242 Acute Tox. 4 * H332 Acute Tox. 4 * H312 Acute Tox. 4 * H302 Skin Corr. 1A H314 Aquatic Acute 1 H400
Labelling	
Pictograms	GHS02, GHS05, GHS07, GHS09
Signal Word	Danger
Hazard Statement Codes	H226 Flammable liquid and vapour. H242 Heating may cause a fire. H332 Harmful if inhaled. H312 Harmful in contact with skin. H302 Harmful if swallowed. H314 Causes severe skin burns and eye damage. H400 Very toxic to aquatic life.
Specific Concentration limits, M-Factors	* STOT SE 3; H335: C ≥ 1 %
Notes	B D

The evaluating Competent Authority (Finland) (eCA) is of the opinion that based on the data evaluated there is a need to update the harmonised classification. Regarding the acute toxicity the concentration limits according to the DPD (Xn; R20/21/22: C ≥ 10 %) and the presently evaluated data should be reflected in the classification. In order to derive a correct classification/ATE (Acute Toxicity Estimate) value for a mixture containing peracetic acid, a 100% substance should be classified even if the substance cannot exist in such a high concentration. Aquatic Chronic 1 (H410, M-factor 10) classification should be applied according to the 2nd ATP to CLP Regulation (Regulation (EC) No 286/2011).
A CLH dossier will be submitted by the eCA (Finland) to ECHA during 2016 at the earliest.

b) Intended use, target species and effectiveness

Peracetic acid is evaluated for topical disinfection of human skin with a general disinfecting claim. The product containing 5% peracetic acid is diluted in water to maximum of 0.2% solutions prior to application. The dilution is performed by professionals. There is also a ready-to-use product, antiseptic foam, containing 0.017% peracetic acid. The use of peracetic acid as a leave on skin disinfectant is not restricted to professionals. Hence, primary exposure for non-professionals to ready-to-use products is possible.

Target organisms include bacteria, fungi and viruses. The data on peracetic acid and the representative biocidal product have demonstrated sufficient efficacy against at least one target species (bacteria) at the lowest in-use concentration evaluated.

Peracetic acid contributes most to the biocidal efficacy of the application solutions because peracetic acid has a significantly higher biocidal activity than hydrogen peroxide, but synergistic effects cannot be excluded. Acetic acid at the concentrations present in the application solutions will not contribute to the efficacy as the pH is way above the one required for biocidal activity of an acid.

The risk of the development of resistance is regarded to be very low due to the low specificity of reactions of peracetic acid.

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

Human health

Aqueous peracetic acid is composed of peracetic acid, hydrogen peroxide, acetic acid and water. After application of peracetic acid in the intended uses, all three ingredients contribute to the human health effects and the subsequent risks, and have to be taken into account in the overall risk characterisation. The toxicity tests have been performed with the aqueous solution of peracetic acid. Hence, the results also inherently contain the effects of each ingredient. In practice, both peracetic acid and hydrogen peroxide are highly reactive and degrade rapidly at the site of first contact with organic material. Acetic acid is also metabolised relatively quickly. Based on the evaluated information, peracetic acid is the most critical ingredient of solutions with regard to possible health risks and the conclusions of the risk assessment of peracetic acid are driven by effect data on peracetic acid itself and the exposure estimates for each intended use.

The adverse effects of peracetic acid in humans are limited to local effects at the site of first contact with the body. No clear systemic effects from peracetic acid were observed which is plausible in the light of the mode of action, i.e. direct chemical reactivity leading to rapid degradation of peracetic acid. Corrosion and/or irritation of the skin and mucous membranes are the most prominent observations in the available 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, peracetic acid causes sensory irritation of the respiratory tract.

The local risk characterisation approach applies also to hydrogen peroxide, since it has been demonstrated that hydrogen peroxide exerts no systemic effects.

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. Handling concentrated peracetic acid products (5%) and diluting with water.	Acceptable with gloves, coverall and goggles/face shield (local effects). Respiratory protective equipment (RPE) if insufficient ventilation.
Application	Primary exposure: professionals. Hand disinfection, hospital use (25 applications per day) and food industry use Primary exposure: Non-professionals Hand disinfection, infrequent use.	Acceptable for in-use concentrations of ≤ 0.2 % for the short and medium term use and for in-use concentrations of ≤ 0.1 % for the long term use

The use of peracetic acid in hand disinfection is acceptable. In-use concentrations of ≤ 0.2 % are acceptable for the short and medium term use and concentrations ≤ 0.1 % for the long term use. For concentrations > 0.1% a concern was identified for long term use due to the lack of sufficient data. Personal protective equipment (PPE) is required for professionals in the mixing and loading scenario because of the corrosive properties of concentrated

peracetic acid solution. For non-professionals, use of peracetic acid ready-to-use products as skin disinfectant is acceptable.

No secondary (indirect) exposure is assumed to occur because of the rapid degradation of peracetic acid and therefore no residues appear either in food or in the environment.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Acceptable or unacceptable**
Disinfection of human skin: consumption scenario using hospitals as a representative facility.	Waste water emission to STP (sewage treatment plant). Emissions to surface water, soil and groundwater via STP.	Acceptable

Peracetic acid does not exist as a pure substance but in the form of an aqueous solution containing peracetic acid, acetic acid and hydrogen peroxide. Acetic acid and hydrogen peroxide are less toxic than the solution of peracetic acid when tested as separate substances. The hazard assessment was based on the assumption that ecotoxicity of aqueous solution was driven by peracetic acid and the predicted no effect concentrations (PNECs) were determined for peracetic acid. Acetic acid was regarded to be a substance of no concern in the risk assessment of peracetic acid, because its presence in the products does not trigger classification and labelling for the environment. Hydrogen peroxide is an active substance assessed also in the review programme. Therefore, the environmental risks of peracetic acid and hydrogen peroxide were evaluated first separately and then summed up when the risk ratios for aqueous solution of peracetic acid were determined for STP, surface water and soil. The PNECs for hydrogen peroxide were taken from the evaluation under the review programme for hydrogen peroxide. In addition, the comparison of predicted environmental concentrations in groundwater with the trigger value of 0.1 µg/l was performed separately for peracetic acid and hydrogen peroxide.

Peracetic acid and hydrogen peroxide decompose rapidly in all environmental compartments, i.e. in surface water, soil, air and active sludge. The degradation products of peracetic acid are oxygen, acetic acid and hydrogen peroxide. Acetic acid and hydrogen peroxide are further degraded to water, carbon dioxide and oxygen. In addition, peracetic acid and hydrogen peroxide decompose already in sewage before reaching the STP.

No unacceptable risks were identified for any of the scenarios.

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 properties	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)	T
Endocrine disrupting properties	Peracetic acid is not considered to have endocrine disrupting properties	
Concerns linked to critical effects	Peracetic acid does not fulfil criterion (e) of Article 10(1).	
Proportion of non-active isomers or impurities	For peracetic acid in its aqueous solutions, the starting materials, acetic acid and hydrogen peroxide, and water present in the solution manufactured are intentionally added or produced (part of water) in the reaction. In that case, they can not be considered as impurities. In consequence, in the active substance , as manufactured, the total impurities content is lower than 20% and there are no isomers. Peracetic acid in aqueous solutions does not meet the conditions of the criterion (f) of Article 10(1).	

Consequently, the following is concluded:

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

Peracetic acid 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

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

2.3. BPC opinion on the application for approval of the active substance peracetic acid in product-type 1

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

1. The active substance is peracetic acid in an aqueous solution containing acetic acid, hydrogen peroxide and water. The specification is based on the minimum purity of the starting materials hydrogen peroxide (as in Regulation (EU) 2015/1730) and acetic acid (as in Regulation (EU) No 231/2012).

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.

Peracetic acid gives rise to concern for human health as it is classified as organic peroxide, skin corrosive of category 1A, specific target organ toxicant by single exposure and toxic to aquatic life of acute category 1 mentioned in Article 28(2)(a) 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. For mixing and loading, when diluting the concentrated solutions prior to application, the need for appropriate personal protective equipment should be considered.

2. Due to the presence of hydrogen peroxide in the aqueous solution of peracetic acid, 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.

3. When authorizing products for hand disinfections with peracetic acid in-use concentrations above 0.1%, the concerns for skin irritation effects from the long-term use should be re-evaluated using more recent or formulation specific data.

4. The inhalation exposure to vapour in addition to aerosols has to be taken into account at product authorisation.

5. The hazard as well as the risk assessment is only covering products containing peracetic acid concentrations up to 15% as the exposure assessments have not been performed with higher peracetic acid concentrations. For products containing peracetic acid in concentrations > 15%, further assessment shall be required for toxicological and physico-chemical risks.

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 peracetic acid. However, further data shall be required as detailed below:

1. New analytical methods for the determination of acetic acid and stabilisers in the aqueous solution 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. Companies of the CEFIC Peracetic Acid Registration Group (PAR) for which compliance with the set specification was not demonstrated must provide quality control data to demonstrate compliance with the specification 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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