Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Peracetic acid

Product type: 11

ECHA/BPC/106/2016

Adopted

14 June 2016

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance peracetic acid

for product type 11

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 11 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 3 October 2008, the evaluating Competent Authority Finland submitted an assessment report and the conclusions of its evaluation to ECHA on 3 July 2015. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-16) and its Working Groups (WG II 2016). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: Finland

The BPC opinion on the approval of the active substance peracetic acid in product type 11 was adopted on 14 June 2016.

The BPC opinion was adopted by consensus. The opinion is published on the ECHA webpage: http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the active substance peracetic acid in product type 11 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 11, 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. The evaluation covers only products containing peracetic acid 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. 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 the approval of the active substance.

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 preservation of cooling water in open re-circulating systems and once-through cooling systems (shock dosing). This is a professional use.

Target organisms include bacteria, fungi and algae. The data on peracetic acid and the representative biocidal product have demonstrated sufficient efficacy against the target species bacteria, specific slimicidal activity should be demonstrated at product authorisation stage.

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 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 and acetic acid. 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. 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 aqueous solutions with regard to possible health risks and the conclusions of the risk assessment of peracetic acid are driven by effect data on aqueous 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 and description of scenario**	**Exposed group**	**Conclusion**
Mixing and loading	Primary exposure: Connecting/disconnecting containers of concentrated peracetic acid product (15%).	Professionals	Acceptable with gloves, coverall and goggles/face shield and respiratory protective equipment (RPE) (local effects).
Post-application	Primary exposure: Inspection and maintenance of running cooling towers.	Professionals	Acceptable. Gloves, coverall, goggles/ face shield and respiratory protective equipment (RPE) (local effects) if exposure to concentrated product is possible.
Bystander exposure	Secondary exposure: Acute exposure during unscheduled maintenance and repair tasks	Professionals	Acceptable. Gloves, coverall, goggles/ face shield and respiratory protective equipment (RPE) (local effects) if exposure to concentrated product is possible.
	Secondary exposure: Chronic inhalation exposure to spray drift (uncontrolled windage or blowdown).	General public	Acceptable.

The professional use of peracetic acid for preservation of cooling water is acceptable. Personal protective equipment (PPE) is required in the mixing and loading scenario because of the corrosive properties of the concentrated peracetic acid solution. Respiratory protection equipment (RPE) is also needed if there is manual handling.
The in-use concentrations are below the dermal irritation values. For the post-application phase, inspection, maintenance and repair work, there is a need for PPE if exposure to concentrated product is possible. Secondary exposure to drift from cooling towers is acceptable.

Environment

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 aqueous 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. 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. In addition, peracetic acid and hydrogen peroxide decompose already in cooling systems and sewage before reaching the STP. 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 general, 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. In PTs 1-6 and PT 12, where the emissions to surface water are predominately indirect, aquatic organism are not likely to be exposed to acetic acid. The application in cooling towers in PT 11 results in direct emissions to surface water and dilution favours net reaction of peracetic acid into acetic acid and hydrogen peroxide. Therefore, the worst case risk assessment for acetic acid was performed for once-through cooling system taking into account the maximum possible theoretical total concentration of acetic acid in blown down water. No unacceptable risk was identified for acetic acid in marine water and its effect on the pH of water would be insignificant.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Once-through cooling system	Direct emission to soil from two cooling towers and subsequent emission to groundwater. Direct waste water emission to marine water.	Unacceptable for marine water, acceptable for soil and groundwater
Large open recirculating cooling system	Direct emission to soil from two cooling towers and subsequent emission to groundwater. Direct waste water emission to surface water.	Unacceptable for surface water and soil, acceptable for groundwater
Small open recirculating cooling system	Direct emission to soil from one cooling tower and subsequent emission to groundwater. Waste water emission to sewage treatment plant (STP; 2000 m^3/d). Emissions to surface water, soil and groundwater via STP.	Acceptable

Unacceptable risk to groundwater is identified from direct emission to soil in all evaluated PT 11 scenarios when calculated according to the TGD. However, the refinement of groundwater assessment with FOCUS Pearl 4.4.4 modelling using the worst case scenario (large open recirculating cooling system) revealed that there are enough acceptable groundwater scenarios for the active substance approval in all evaluated PT 11 scenarios regarding direct emissions to soil from cooling towers. The use in small open recirculating

cooling system is identified as a safe use. Unacceptable risk was identified from direct emission to marine water from once-through system. In addition, unacceptable risk from direct emissions to surface water and soil were identified from large open recirculating cooling system. The risk from direct emissions to soil could be mitigated with appropriate drift eliminators. Other refinement options for once-through cooling systems and large recirculating cooling systems will be discussed at the Ad Hoc Working Group on Environmental Exposure (AHEE). At the product authorisation stage the refinement methods agreed by the AHEE could be applied.

Overall conclusion

A safe use for human health is identified for preservation of cooling water in open re-circulating systems and once-through cooling systems (shock dosing) (industrial and professional use, provided appropriate risk mitigation measures are applied), while a safe use for environment is identified for preserving cooling water in small open re-circulating systems (shock dosing). The safe use identified for both human health and the environment is only in small open recirculating cooling systems.

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:

<table>
<tr><th colspan="2">Property</th><th colspan="2">Conclusions</th></tr>
<tr><td rowspan="3">CMR properties</td><td>Carcinogenicity (C)</td><td>No classification required</td><td rowspan="3">Peracetic acid does not fulfil criterion (a), (b) and (c) of Article 5(1)</td></tr>
<tr><td>Mutagenicity (M)</td><td>No classification required</td></tr>
<tr><td>Toxic for reproduction (R)</td><td>No classification required</td></tr>
<tr><td rowspan="3">PBT and vPvB properties</td><td>Persistent (P) or very Persistent (vP)</td><td>not P or vP</td><td rowspan="3">Peracetic acid does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)</td></tr>
<tr><td>Bioaccumulative (B) or very Bioaccumulative (vB)</td><td>not B or vB</td></tr>
<tr><td>Toxic (T)</td><td>T</td></tr>
<tr><td>Endocrine disrupting properties</td><td colspan="3">Peracetic acid is not considered to have endocrine disrupting properties</td></tr>
<tr><td>Respiratory sensitisation properties</td><td colspan="3">No classification required. Peracetic acid does not fulfil criterion (b) of Article 10(1).</td></tr>
<tr><td>Concerns linked to critical effects</td><td colspan="3">Peracetic acid does not fulfil criterion (e) of Article 10(1)</td></tr>
<tr><td>Proportion of non-active isomers or impurities</td><td colspan="3">Peracetic acid does not fulfil criterion (f) of Article 10(1)</td></tr>
</table>

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).

2.2.2. 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 11

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: Peracetic acid in an aqueous solution containing acetic acid and hydrogen peroxide. The specification is based on the starting materials hydrogen peroxide and acetic acid which are used to manufacture peracetic acid.

2. The authorisations of biocidal products are subject to the following condition(s):

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

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

        i. Industrial and professional users;

        ii. marine water for products used in once-through cooling systems;

        iii. soil and surface water for products used in large open recirculating cooling systems.

    c. Due to the presence of hydrogen peroxide, authorisations of biocidal products shall be without prejudice to Regulation (EU) No 98/2013.

[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)

The active substance does not fulfil the criteria according to Article 28(2) to enable inclusion in Annex I of Regulation (EU) 528/2012 as peracetic acid 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.

2.4. Elements to be taken into account when authorising products

The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:

a. If an unacceptable risk for industrial and professional users is identified, safe operational procedures and appropriate organizational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.

b. An unacceptable risk for marine water and surface water is identified for products used in once-through cooling systems and for large recirculating cooling systems, respectively. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these uses should not be authorised.

c. An unacceptable risk for soil is identified for products used in large open recirculating cooling systems. If the risk cannot be reduced to an acceptable level by e.g. drift eliminators, these uses should not be authorised.

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 of peracetic acid should be submitted. Data must be provided as soon as possible but no later than 6 months before the date of approval to the evaluating Competent Authority.

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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