

Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Peracetic acid generated from tetraacetythylenediamine and sodium percarbonate

Product type: 4

ECHA/BPC/126/2016

Adopted

13 December 2016

Opinion of the Biocidal Products Committee

on the application for approval of the active substance peracetic acid generated from tetraacetythylenediamine and sodium percarbonate for product type 4

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 4 of the following active substance:

| | |
|----------------------------------|---------------------------------------------------------------------------------------|
| Common name: | Peracetic acid generated from tetraacetythylenediamine and sodium percarbonate |
| Chemical name: | - |
| EC No.: | - |
| CAS No.: | - |
| 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 (BPC-18) and its Working Groups (WG V 2014, WG V 2015, WG IV 2016) 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: Finland

The BPC opinion on the approval of the active substance peracetic acid generated from tetraacetylenediamine and sodium percarbonate in product type 4 was adopted on 13 December 2016.

The BPC opinion was adopted by consensus. The opinion is published on the ECHA webpage at: <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 generated from tetraacetylenediamine and sodium percarbonate in product type 4 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 generated from tetraacetylenediamine and sodium percarbonate in product type 4. The active substance peracetic acid is generated *in situ* from the biocidal product containing the precursors tetraacetylenediamine (TAED) and sodium percarbonate. When the solid product gets into contact with water (e.g. in mixing of the disinfection solution), sodium percarbonate dissociates to sodium carbonate and hydrogen peroxide. In the presence of hydrogen peroxide, TAED rapidly undergoes perhydrolysis to form DAED (diacetylenediamine) and the active substance peracetic acid.

The specification for peracetic acid generated *in situ* is based on the precursors tetraacetylenediamine and sodium percarbonate.

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

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

Methods for the determination of peracetic acid in air and water are available. Methods for the determination of peracetic acid in food and feed stuffs are not deemed necessary.

The classification of the active substance peracetic acid is presented here as it was for peracetic acid in aqueous solution (PT 1-6, 11, 12). No separate classification for the active substance generated *in situ* is needed. In the context of *in situ* generation, precursors generating the active substance are considered as the biocidal product.

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:

| 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 \geq 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 \geq 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 2017 at the earliest.

According to the ECHA Classification and Labelling Inventory the precursor TAED is not classified, while sodium percarbonate is classified as Ox. Sol. 2; H272 (May intensify fire; oxidiser), Acute Tox. 4; H302 (Harmful if swallowed), Eye Dam. 1; H318 (Causes serious eye damage) (Specific Concentration limits: Eye Dam. 1: C \geq 25%, Eye Irrit. 2: 7.5% \leq C < 25%).

b) Intended use, target species and effectiveness

Peracetic acid generated from tetraacetylenediamine and sodium percarbonate (in-situ PAA) is evaluated for disinfection of surfaces and equipment in food and beverage industry in professional use.

Target organisms include bacteria, spores of bacteria, yeasts and viruses. The data on representative in-situ peracetic acid products have demonstrated sufficient efficacy against the target organisms. However, products referred to in the evaluation are theoretical products and hence efficacy data on real products appropriately simulating in-use conditions have to be submitted at product authorisation phase.

Peracetic acid solutions generated *in situ* from tetraacetylenediamine and sodium percarbonate contain also hydrogen peroxide. Peracetic acid has a significantly higher biocidal activity than hydrogen peroxide, but synergistic effects of peracetic acid and hydrogen peroxide in the in-situ PAA products cannot be excluded.

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

The active substance peracetic acid is formed when the solid biocidal product containing the precursors TAED and sodium percarbonate is diluted with water (e.g. in mixing of the disinfection solution). Sodium percarbonate dissociates to sodium carbonate and hydrogen peroxide. In the presence of hydrogen peroxide, TAED rapidly undergoes perhydrolysis to form DAED (diacetylenediamine) and the active substance peracetic acid. All these ingredients contribute to the human health effects and the subsequent risks, and have to be taken into account in the overall risk characterisation. No toxicity tests for the substance generated *in situ* is available, and therefore the respective data on peracetic acid in aqueous solution (containing also hydrogen peroxide and acetic acid) was used for the toxicology part regarding peracetic acid in the in-use solution. For the precursors and DAED limited toxicological data was available to derive the reference values.

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 PAA 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 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, peracetic acid causes sensory irritation to 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.

For TAED and DAED a quantitative risk assessment based on the systemic effects was performed. For the precursor sodium percarbonate risk characterization for local effects was performed.

The exposure and risks were assessed for the precursors TAED and sodium percarbonate in the mixing and loading scenario. Since sodium percarbonate is dissociated in contact with water liberating hydrogen peroxide, the exposure and risk assessments for application of the in use solution are performed for hydrogen peroxide. Further for the application the exposure and risks to peracetic acid, TAED and its degradation product DAED were separately assessed including primary and secondary exposure.

The inhalation exposure to vapour of peracetic acid in addition to aerosols during use of solutions (e.g. wiping, dipping, spraying) has to be calculated and taken into account at product authorisation.

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 |
| Disinfection of surfaces in food & beverage industries by wiping and mopping | | | |
| Mixing and loading | Primary exposure: Preparation of disinfection solution by dilution | Professionals | Acceptable with goggles (local effects). |
| Application | Primary exposure: Cleaning surfaces by wiping and mopping (0.25% PAA). | Professionals | Acceptable with gloves (local effects). |
| Post-application | Primary exposure: Draining of cleaning solutions and handling of empty containers. | Professionals | Acceptable with gloves (local effects). |
| Disinfection of equipment by dipping | | | |
| Mixing and loading | Primary exposure: Preparation of disinfection solution | Professionals | Acceptable with goggles (local effects). |
| Application by dipping | Primary exposure: Placing and removal of equipment in the dipping bath (0.25%). | Professionals | Acceptable with gloves (local effects). |
| Post-application | Primary exposure: Water rinse of equipment Draining of cleaning solutions. | Professionals | Acceptable with gloves (local effects). |
| Disinfection of surfaces and equipment by low-pressure manual spraying | | | |
| Mixing and loading | Primary exposure: Preparation of disinfection solution | Professionals | Acceptable with goggles (local effects). |
| Application by spraying | Primary exposure: Disinfection of surfaces and equipment by spraying (0.25%). | Professionals | Acceptable with gloves, coverall and RPE (local effects). |
| Post-application | Primary exposure: Water rinse of treated surfaces, Handling of empty containers | Professionals | Acceptable |
| Indirect exposure | Secondary exposure: Inhalation exposure during spraying. | Professionals/ general public | Acceptable with RPE (local effects). No-entry for non-professionals. |
| Indirect exposure | Secondary exposure: Dermal <i>via</i> disinfected surfaces/objects. | Professionals/ general public | Acceptable |

The professional use of peracetic acid generated *in situ* for disinfection of surfaces in food & beverage industries by wiping is acceptable. No PPE is needed based on the risk assessment for systemic effects of TAED and DAED. Based on the classification of the precursor sodium

percarbonate, the theoretical biocidal product is classified with Eye Dam. 1 indicating a need for eye protection in mixing and loading. However, the likelihood of eye exposure to sodium percarbonate is considered low as the product typically is a non-dusty powder with inert coating, and it is loaded with a dosing cup with no direct hand contact. Gloves are needed in application against local effects of peracetic acid.

The professional use of disinfection of surfaces and equipment by spraying is acceptable. Eye protection is needed in mixing and loading. During application by spraying skin and eye protection, including RPE, is needed against local effects. The disinfected premises have to be well-ventilated before re-entry.

The professional use for disinfection of equipment by dipping is acceptable. Eye protection is needed in mixing and loading and gloves in dipping against local effects.

No secondary (indirect) dermal exposure is assumed because of the rapid degradation of peracetic acid and therefore no residuals appear either in food or in the environment. Additionally, the treated surfaces and equipment are rinsed with water after a contact time of 30 min.

Secondary inhalation exposure is considered acceptable during application and also secondary dermal exposure after the application regarding the systemic exposure to TAED and DAED.

Indirect exposure via food

No MRL setting is required as peracetic acid is not persistent, no systemic effects are observed and because of its high reactivity. No information related to the residues on precursors is available.

Environment

The hazard assessment of peracetic acid generated from tetra-acetylenediamine (TAED) and sodium percarbonate was based on the respective assessment on aqueous peracetic acid described in the evaluations for PT 1-6 and PT 11-12. For hydrogen peroxide the hazard assessment is described in the evaluation of hydrogen peroxide for PT 1-6, while for the TAED and its degradation product diacetylenediamine (DAED) fate and ecotoxicological data available in the report of HERA (A voluntary industry programme to carry out Human and Environmental Risk Assessments on ingredients of household cleaning products) were used.

In the exposure assessment the predicted environmental concentrations (PEC values) were calculated separately for peracetic acid, hydrogen peroxide, TAED and DAED. Upon contact with water, sodium percarbonate dissociates to sodium, carbonate and hydrogen peroxide. Therefore the assessment considers hydrogen peroxide but not sodium percarbonate. The dissociation products sodium and carbonate are not considered in release estimations and risk assessments because of their ubiquitous presence in the environment. It was assumed that the discharge of sodium and carbonate *via* disinfection products is much lower than the background concentration in the environment and the discharge *via* other anthropogenic activities. Third dissociation product of sodium percarbonate, hydrogen peroxide, was taken into account in the environmental exposure and the risk assessment, but only the remaining amount of hydrogen peroxide which was not consumed in reaction with TAED.

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 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 the risk characterisation the risk ratios (PEC/PNEC) of peracetic acid and hydrogen peroxide were summed up whereas the risk ratios of TAED and DAED were considered separately. 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, hydrogen peroxide, TAED and DAED.

The table below summarises the exposure scenarios assessed.

| Summary table: environment scenarios | | |
|------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|-------------------|
| Scenario | Description of scenario including environmental compartments | Conclusion |
| Disinfection of surfaces in small-scale businesses of food and beverage industries | Waste water emission to STP (sewage treatment plant). Emissions to surface water, soil and groundwater <i>via</i> STP. | Acceptable |
| Disinfection of equipment in small-scale businesses of food and beverage industries by dipping | Waste water emission to STP. Emissions to surface water, soil and groundwater <i>via</i> STP. | Acceptable |

No unacceptable risks were identified for any of the scenarios.

Overall conclusion

A safe use for human health and environment is identified for disinfection of surfaces and equipment in food and beverage industry in professional use.

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 | Peracetic acid 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) | not P or vP | Peracetic acid 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) | not B or vB | |
| | Toxic (T) | T | |
| Endocrine disrupting properties | Peracetic acid is not considered to have endocrine disrupting properties | | |
| Respiratory sensitisation properties | No classification required. Peracetic acid does not fulfil criterion (b) of Article 10(1). | | |
| Concerns linked to critical effects | Peracetic acid does not fulfil criterion (e) of Article 10(1) | | |
| Proportion of non-active isomers or impurities | Peracetic acid does not fulfil 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"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

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 generated from tetraacetylenediamine and sodium percarbonate in product-type 4

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

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](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))

1. The active substance: the specification for peracetic acid generated *in situ* is based on the precursors tetraacetythylenediamine and sodium percarbonate. The minimum purity of tetraacetythylenediamine is 99.0% and the minimum purity of the sodium percarbonate is 85.1%.
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.

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. The inhalation exposure to vapour in addition to aerosols has to be taken into account at product authorisation.
- c. Label and, where provided, instructions for use should contain information that disinfected premises have to be well-ventilated before re-entry. Practical instructions should be given at product authorization stage to assure that concentrations in the air in the disinfected premises are sufficiently low before re-entry.
- d. An assessment of the risk in food and feed areas may be required at product authorisation where use of the product may lead to contamination of food and feeding stuffs.
- e. Guidance on the evaluation of in-situ generated active substances is under development. Where relevant, this guidance will have to be considered at product authorisation.

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 generated from tetraacetythylenediamine (TAED) and sodium percarbonate. However, further data shall be required as detailed below:

Companies of the CEFIC Peracetic Acid Registration Group (PAR) for which compliance with the set specification was not demonstrated must provide quality control data (sodium percarbonate) and 5-BA-data (tetraacetylenediamine) 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.

o0o