Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA)

Product type: 3

ECHA/BPC/243/2020

Adopted
4 March 2020

Opinion of the Biocidal Products Committee

on the application for approval of the active substance reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA) for product type 3

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 3 of the following active substance:

Common name:	**reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA)**
Chemical name:	**reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA)**
EC No.:	**201-186-8 and 450-280-7**
CAS No.:	**79-21-0 and 33734-57-5**

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 Ecolab GmbH & Co. OHG on 26 July 2007, the evaluating Competent Authority France submitted an assessment report and the conclusions of its evaluation to ECHA on 2 January 2019**.** In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-34) and its Working Groups (WG III and V 2019). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: France

The BPC opinion on the approval of the active substance reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA) in product type 3 was adopted on 4 March 2020.

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 reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA) in product type 3 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 reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA)[1] in product type 3 (veterinary hygiene biocidal products).

The active substance is not produced as such but produced directly from its starting materials (octanoic acid (OA), acetic acid (AA) and hydrogen peroxide (H2O2)) via a double equilibrium:

$$OA + H_2O_2 \leftrightarrow POOA + H_2O$$

$$AA + H_2O_2 \leftrightarrow PAA + H_2O$$

Considering that the active substance is produced in equilibria and these equilibria are reached rapidly and are stable, the reference specification is set on the double equilibrium. In consequence, the reference specification corresponds to a range of concentrations for each component of the double equilibrium where H2O2, AA and OA are considered as relevant impurities.

The physico-chemical properties of the POOA have been evaluated and are deemed acceptable for the appropriate use, storage and transportation. The physico-chemical properties of PAA are not detailed in this opinion, but are available in the assessment report of this active substance[2].

Validated analytical methods are available for determining POOA, H2O2, OA and PAA in biocidal products. They are reported in the assessment reports of these active substances.

No analytical method for the determination of POOA in the environment media was submitted. As POOA is not stable in the soil and water compartment, no data on POOA is required.

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1 POOA is included in the Review Programme in Annex II of Regulation (EU) No 1062/2014. The application was redefined according to Article 13 to “Reaction mass of POOA and PAA”. Subsequently, the Agency published an invitation to take over the role of the participant for POOA (CAS Nr. 33734-57-5) for PT 2, 3 and 4 on its web-site with a dead-line of 8 November 2020.

2 Assessment Report Peracectic acid November 2015 (PT 1-6) and August 2016 (PT11-12): http://dissemination.echa.europa.eu/Biocides/ActiveSubstances/1340-02/1340-02_Assessment_Report.pdf and https://www.echa.europa.eu/documents/10162/3e4f6b76-dace-92fa-0d84-43a61a7274b3

The degradation products of POOA in soil and water are OA and H2O2:

- Methods for monitoring in soil: because H2O2 is rapidly decomposed in soil no analytical method for H2O2 in soil is required. Furthermore, as OA metabolises and degrades easily in soil, no analytical method for determination of OA in soil is required either.
- Methods for monitoring in water: a method is available for monitoring of H2O2 in water, but no method was provided for OA. A method of determination of OA in water is required before the approval of the active substance.

Methods for monitoring in air: as POOA based products can be sprayed, a selective and validated method of determination of POOA in air is required before the approval of the active substance.

No analytical method is necessary for the determination of POOA residues in food or feedingstuffs as POOA is not stable in food and it degrades rapidly when coming into contact with organic matter. The degradation products of POOA in food and feeding stuff are OA and H2O2. OA is already naturally present in food and feeding stuff, no analytical method for determination of OA in food and feeding stuff is required. A method for the determination of H2O2 in food is available.

Analytical methods for monitoring of PAA in different media are not detailed in this opinion, but are available in the assessment report of this active substance[3].

A proposed classification and labeling according to Regulation (EC) No 1272/2008 (CLP Regulation) for POOA is:

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Pyr. Sol. 1: H250 Org. Perox. C: H242 Skin Corr. 1A: H314 Eye dam 1: H318 Aquatic Acute 1: H400 Aquatic chronic 3: H412
Labelling	
Pictogram codes	GHS02, GHS05
Signal Word	Danger
Hazard Statement Codes	H250: Catches fire spontaneously if exposed to air H242: Heating may cause a fire. H314: Causes severe skin burns and eye damage H318: Causes serious eye damage. H410: Very toxic to aquatic life with long lasting effects. EUH 071: Corrosive to the respiratory tract
Specific Concentration limits, M-Factors	Aquatic acute: M = 1

PAA 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.

3 Assessment Report Peracectic acid November 2015 (PT 1-6) and August 2016 (PT11-12): http://dissemination.echa.europa.eu/Biocides/ActiveSubstances/1340-02/1340-02_Assessment_Report.pdf and https://www.echa.europa.eu/documents/10162/3e4f6b76-dace-92fa-0d84-43a61a7274b3

The classification and labelling for PAA 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 Eye dam 1: H318 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

A proposal to amend the harmonized classification was indicated in the BPC opinion of PAA for product types 1-6.

b) Intended use, target species and effectiveness

Reaction mass of PAA and POOA is used for the disinfection in product type 3. The representative product is intended to be used for the disinfection in animal houses including disinfection of boots and animal's feet, by low pressure manual spraying and by foaming.

The claimed uses are only intended to be performed by industrial and professional users. The efficacy of reaction mass of PAA and POOA has been evaluated with different formulations for bactericidal and virucidal activities. In addition, the efficacy of POOA alone has been evaluated where basic bactericidal efficacy of POOA has been demonstrated at 680 mg/L.

The mode of action of reaction mas of POOA and PAA are based on an oxidising effect via the hydroxyl radical on organic materials. Three mechanisms have been identified that lead to killing or to permanent inactivation of microbial organisms and viruses.

As POOA is expected to degrade fast into OA, it is stated in the assessment report of OA that no resistance has been reported with regard to the use of OA as described above. However regular checks on the efficacy against the target organisms should be performed.

Though the development of resistance is unlikely, POOA applications form often part of professional hygiene programs, which also involve other biocidal substances of different chemical structures and different mode of action (alternating applications), reducing additionally the chance of any development of resistance.

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

Human health

The double equilibrium is composed of POOA and PAA and other substances (OA and H2O2 for which assessment reports are available and acetic acid, which is included in annex I of BPR).

The double equilibrium can be acute toxic by oral and inhalation route, corrosive or irritant depending on the content of the active substances and impurities. It is not genotoxic, not systemic carcinogenic and not reprotoxic. Based on the available data, a local genotoxicity cannot be excluded.

The active substance is not an ED due to the fact that only local effects are expected and there is no potential for systemic effects.

Determination of the exposure and the risk assessment was performed considering a representative product. The representative product is intended to be used for the disinfection in animal houses by low pressure manual spraying and by foaming.

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/Loading	*Primary exposure* Dermal and inhalation exposure - Dilution of concentrate for application by spraying or foaming	Professionals	Acceptable with PPE (gloves, coverall and eye/face protection) and RPE (APF40).
Application by spraying/ foaming	*Primary exposure* Dermal and inhalation exposure - Application of diluted disinfectant using low-pressure spraying or foaming for disinfection of animal housing	Professionals	Acceptable with RPE (APF40)
Presence of professional or workers during disinfection	*Secondary exposure* Inhalation exposure: - Bystander or non-user during disinfection of animal houses	By-standers (if present)	Acceptable with RPE (APF40)
Consumption of products of animal origin contaminated with active substance	*Secondary exposure* Indirect ingestion of residues of AS via food issued from animals in contact with the biocidal product	General public	Acceptable

Since the active substance is classified as corrosive, personal protective equipment (PPE) in order to prevent any spillage on skin (no splashes) have to be put in place. The results of the risk assessment demonstrated that the exposure of operators towards the representative product as a disinfectant in animal houses in product type 3 results in acceptable risks when appropriate PPE (gloves, coverall and eye/face protection) and respiratory protective equipment (RPE) (APF 40) are worn during the mixing and loading task and RPE (APF 40) is wornduring the application task.

No risk via secondary exposure is expected for consumers (no significant residues in foods are expected).

No MRL exists for POOA, PAA, H2O2 and AA and none is required as these substances are not persistent and no systemic effects are observed.

Environment

The risk assessment is performed evaluating each component of reaction mass of POOA and PAA where H2O2 and OA are considered as relevant impurities. Acetic acid is considered as a substance of no concern. Environmental hazard data were available for each component.

Peracids decompose rapidly in different environmental compartments. The reaction with organic matter is the predominant degradation pathway, leading the formation of OA, acetic acid and oxygen. Acetic acid is considered as not relevant degradation product. OA decomposes rapidly by biotic degradation and H2O2 decomposes very rapidly by biotic and abiotic degradation. To conclude: POOA, PAA, OA and H2O2 are considered as non-persistent components in environment according to the PBT assessment.

The four active components (POOA, PAA, OA and H2O2) have a low bioaccumulation potential.

According to the PBT assessment, following the provisions in Annex XIII of REACH Regulation (EC) 1907/2006, the only component considered as toxic is PAA.

Concerning the ED properties of the active substance, POOA is highly reactive when in contact with organic material. This results in the oxidation of organic material (e.g. surface of organisms) and the reduction of POOA to OA. Even if POOA was taken up into a non-target organism, the same mechanism would apply and POOA would be rapidly reduced to OA. Moreover, no effects on fish or terrestrial vertebrates have been observed. The assessment of the ecotoxicity caused by a prolonged exposure to POOA is considered not justified. Due to the expected low systemic bioavailability of POOA and its rapid degradation after contact with organic material, no effect as described in ED criteria is thus expected.

For the other substances (PAA, OA and H2O2), no evidence of endocrine disruption is presented in the assessment reports.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Disinfection of animal houses by low-pressure manual spraying by professional users	Emissions from spraying (the application rate covers also foaming) to slurry/manure. Slurry/manure will be spread on grassland or arable land and can lead to exposure of soil and groundwater and aquatic compartments (surface water and sediment). Waste water emission to STP. Emissions to surface water, soil and groundwater via STP.	Acceptable
Disinfection of animal houses by foaming by professional users		Acceptable

The risk resulting from the use for the disinfection of animal houses by low-pressure manual spraying (PT3a), and the disinfection of animal houses by foaming (PT3b) is considered acceptable for all environmental compartments.

Overall conclusion

No unacceptable risks for human health and environment are identified for the disinfection of animal houses by low-pressure manual spraying and by foaming.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria for the reaction mass of PAA and POOA

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	The reaction mass of PAA and POOA 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	The reaction mass of PAA and POOA 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)	Not T for POOA T for PAA	
Endocrine disrupting properties	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	No	POOA does not fulfil criterion (d) of Article 5(1) and criterion (e) of Article 10(1).

	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms	No	
	Article 57(f) and 59(1) of REACH	No	
	Intended mode of action that consists of controlling target organisms via their endocrine system(s).	No	
Respiratory sensitisation properties	No classification required. The reaction mass of PAA and POOA does not fulfil criterion (d) of Article 5(1).		
Concerns linked to critical effects other than those related to endocrine disrupting properties	The reaction mass of PAA and POOA does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	The active substance reaction mass of PAA and POOA is POOA in an aqueous solution containing PAA, OA, AA, H2O2 and water. In consequence, in the active substance as manufactured, the total impurities content is lower than 20% and there is no isomer. The reaction mass of POOA and PAA in aqueous solutions does not meet the conditions of the criterion (f) of Article 10(1).		

Consequently, the following is concluded:

The reaction mass of PAA and POOA does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

The reaction mass of PAA and POOA 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"[4], "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[5] and "Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment"[6] agreed at the 54th, 58th and 77th 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).

4 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).

5 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).

6 See document: Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment (https://circabc.europa.eu/sd/a/48320db7-fc33-4a91-beec-3d93044190cc/CA-March18-Doc.7.3a-final-%20EDs-%20active%20substances%20under%20assessment.docx).

2.2.2. POP criteria

The reaction mass of PAA and POOA does not fulfil criteria for being a persistent organic pollutant (POP). The reaction mass of PAA and POOA does not have potential for long-range transboundary atmospheric transport.

2.3. BPC opinion on the application for approval of the active substance reaction mass of peracetic acid and peroxyoctanoic acid in product type 3

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

1. The minimum purity of the active substance is not relevant as the active substance is a double equilibrium using hydrogen peroxide, acetic acid and octanoic acid as starting materials. The specification corresponds to a range of concentrations.

Components		Specification range content (% w/w)
active substance	peracetic acid	1.8-13.9
active substance	peroxyactanoic acid	0.15-2.42
relevant impurity	hydrogen peroxide	1.1-25.45
relevant impurity	acetic Acid	5.74-51
relevant impurity	octanoic acid	1.63-9.03

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. 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. The reaction mass of peracetic acid and peroxyoctanoic acid gives rise to concern for human health as it is classified as 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

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

    b. A qualitative risk assessment should be performed for the local effects taking into account the classification of the product and its in use dilutions.

2.5. Requirement for further information on the active substance

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of reaction mass of PAA and POOA. However, the following further data must be submitted to the evaluating Competent Authority (FR) as soon as possible but no later than 6 months before the date of approval of the active substance:

- Validated monitoring method for determination of POOA in air;
- Validated monitoring method for determination of OA in water;
- Validated monitoring method for determination of AA in the reaction mass of POOA and PAA.

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