Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

Airedale PAA product family

ECHA/BPC/347/2022

Adopted

16 June 2022

Opinion of the Biocidal Products Committee

on the Union authorisation of Airedale PAA product family

In accordance with Article 44(3) 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, the Biocidal Products Committee (BPC) has adopted this opinion on the Union authorisation of:

Name of the biocidal product family:	**Airedale PAA product family**
Authorisation holder:	**Rigest Trading (Ireland) Limited**
Active substance common name:	**Peracetic acid (CAS nr 79-21-0)**
Product types:	**2, 3, 4**

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority (eCA).

Process for the adoption of BPC opinions

Following the submission of an application on 26 September 2017, recorded in R4BP3 under case number BC-EW057176-14, the evaluating Competent Authority submitted a draft product assessment report (PAR) containing the conclusions of its evaluation and the draft Summary of Product Characteristics (SPC) to ECHA on 16 December 2021 In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-43) and its Working Groups (WG I 2022). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: Belgium

The BPC opinion on the Union authorisation of the biocidal product/biocidal product family was reached on 16 June 2022.

The BPC opinion was adopted by consensus. The opinion is published on the ECHA website.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the biocidal product family is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012 and falls within the scope of the Regulation (EU) No 528/2012 as defined in Article 3(1)(s).

The biocidal product family meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore may be authorised. The detailed grounds for the overall conclusion are described in the PAR.

The BPC agreed on the draft SPC of Airedale PAA product family referred to in Article 22(2) of Regulation (EU) No 528/2012.

2. BPC Opinion

2.1 BPC Conclusions of the evaluation

a) Summary of the evaluation and conclusions of the risk assessment

General

The Biocidal Product Family "Airedale PAA product family" contains disinfectant products divided in 3 Meta SPCs with Peracetic acid (PAA, 1.74 - 15.9 %) as active substance. Hydrogen peroxide (8.1 - 25.97 %) and acetic acid (12.22 – 24.38 %) are equilibrium partners of PAA and part of the active substance. The products of the family belong to PT 2, 3 and 4. An overview of the biocidal product family and the authorised uses is given in the following table:

AS content (%)	Substance of concern	User category	Use #	Use assessed	Use authorised
Meta SPC 1					
1.74 – 2.36	HEDP for Human health 0.99 – 1.2 % Reason: contributes to the classification of the meta-SPC as H302	Industrial and professional	#1	PT 2 ; CIP, including pharmaceutical and cosmetic industry	Yes
			#2	PT 2 ; Surface Disinfection by spraying or by pouring (followed by wiping for a homogenous distribution), including in pharmaceutical and cosmetic industries	Yes
			#3	PT 4 ; Disinfection of inner surfaces (tanks, pipes, vessels, filling machines, …) by CIP	Yes
			#4	PT 4 ; Surface Disinfection by spray or wipe (pour and wipe with cloth)	Yes

AS content (%)	Substance of concern	User category	Use #	Use assessed	Use authorised
			#5	PT 4 ; Disinfection by dipping	Yes
Meta SPC 2					
4.5 – 5.5	None	Industrial and professional	#1	PT 2 ; CIP, including in pharmaceutical and cosmetic industry	Yes
			#2	PT 2 ; Surface Disinfection by spraying or pouring (followed by wiping for a homogenous distribution), including in pharmaceutical and cosmetic industries	Yes
			#3	PT 3 ; Surface Disinfection by spraying or pouring (followed by wiping for a homogenous distribution), excluding the disinfection of animal transport vehicles	Yes
			#4	PT 3 ; Disinfection by dipping	Yes
			#5	PT 3 ; Teat disinfection (pre-milking) by dipping or spraying	No
			#6	PT 3 ; Teat disinfection (post-milking) by dipping or spraying	No
			#7	PT 4 ; Disinfection of inner surfaces (tanks, pipes, vessels, filling machines, …) by CIP	Yes
			#8	PT 4 ; Surface Disinfection by spraying or pouring or wipe (followed by wiping for a homogenous distribution)	Yes
			#9	PT 4 ; Disinfection by dipping	Yes
Meta SPC 3					
14.1 – 15.9	None	Industrial and professional	#1	PT 2 ; CIP, including in pharmaceutical and cosmetic industry	Yes
			#2	PT 2 ; Surface Disinfection by spraying or pouring (followed by wiping for a homogenous	Yes

AS content (%)	Substance of concern	User category	Use #	Use assessed	Use authorised
				distribution), including in pharmaceutical and cosmetic industries	
			#3	PT 3 ; Surface Disinfection by spraying or pouring (followed by wiping for a homogenous distribution), excluding the disinfection of animal transport vehicles	Yes
			#4	PT 3 ; Disinfection by dipping	Yes
			#5	PT 3 ; Teat disinfection (pre-milking) by dipping or spraying	No
			#6	PT 3 ; Teat disinfection (post-milking) by dipping or spraying	No
			#7	PT 4 ; Disinfection of inner surfaces (tanks, pipes, vessels, filling machines, …) by CIP	Yes
			#8	PT 4 ; Surface Disinfection by spraying or pouring or wipe (followed by wiping for a homogenous distribution)	Yes
			#9	PT 4 ; Disinfection by dipping	Yes

Physico-chemical properties

All products of this BPF are colorless, transparent, homogenous SL – soluble concentrates. pH of the neat items is around 1, and pH of the 1% dilution ranges from 2.8 to 3. The relative density varies from 1.06 to 1.16.

Since no tests on accelerated storage stability and low temperature stability have been performed, the products must be stored above 0°C and below 30°C. They must also be stored in dark conditions. The results from long term stability tests grant a shelf life of 6 months for the meta -SPC 1, and 2 and 12 months for the meta-SPC 3.

The characteristics of the products are provided by the applicant and are assessed as acceptable.

Adequate analytical methods are available to support the biocidal product family. Peracetic acid and hydrogen peroxide are analysed via titration. The rest of compounds described in the reference specification of the active substance is analysed via Ion Chromatography (IC).

The classification in relation to physical hazards is:

Meta-SPC 1: Metal Corr 1, Org Perox G, Ox Liq 2;
Meta-SPC 2: Metal Corr 1, Org Perox F;
Meta-SPC 3: Metal Corr 1, Org Perox F.

Efficacy

The target organisms for this biocidal product family include vegetative bacteria, yeasts, fungi and viruses relevant to the products' areas of use and in-use conditions.

All the effective concentrations have been based on the complete efficacy data package provided for the product PAA 5%.

Efficacy tests performed according to suspension and surface standards have been submitted: Phase 2/Step 1 efficacy tests as mandatory tests for products intended to be used for CIP with circulation procedures. Phase 2/Step 1 and Step 2 efficacy tests as mandatory tests for products intended to be used for soaking, spraying and teat disinfection procedures.

Detailed function, field of use, application rates and contact times of the products are described in the Efficacy part of the PAR and described in the section # 2.1.4." Authorized use(s)" and also summarised below:

Meta SPC-1		Validated label claims
PT2	Use #1.1 : CIP procedures with circulation (including pharmaceutical and cosmetic industry)	On hard/non-porous surfaces At room temperature, in 15 min CT • Active against bacteria and yeasts : **0.02% PAA** • Active against bacteria, yeasts and fungi : **0.1% PAA** • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA**
	Use #1.2 : Surface Disinfection by spraying or by pouring, also in pharmaceutical and cosmetic industries	On hard/non-porous surfaces At room temperature, in 15 min CT • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA**
PT4	Use #1.3 : Disinfection of inner surfaces (tanks, pipes, vessels, filling machines, …) by CIP with circulation	For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory. On hard/non-porous surfaces At room temperature, in 15 min CT • Active against bacteria and yeasts : **0.02% PAA** • Active against bacteria, yeasts and fungi : **0.1% PAA** • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA**

	Use #1.4 : Surface Disinfection by spraying or by pouring	For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory. On hard/non-porous surfaces At room temperature, in 15 min CT • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA**
	Use #1.5 : Surface Disinfection by dipping	
Meta SPC-2		**Validated label claims**
PT2	Use #2.1 : CIP procedures with circulation (including pharmaceutical and cosmetic industry)	On hard/non-porous surfaces At room temperature, in 15 min CT • Active against bacteria and yeasts **0.02% PAA** • Active against bacteria, yeasts and fungi : **0.1% PAA** • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA**
	Use #2.2 : Surface Disinfection by spraying or pouring, also in pharmaceutical and cosmetic industries	On hard/non-porous surfaces At room temperature, in 15 min CT • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA**
PT3	Use #2.3 : Surface Disinfection by spraying OR pouring (followed by wiping for a homogenous distribution)	By spraying : On hard/non-porous & porous surfaces By pouring : ONLY on hard/non-porous surfaces In 5 min contact time at +10°C <u>WITH</u> prior cleaning • Active against bacteria, yeasts and viruses **0.2% PAA**
	Use #2.4 : Surface Disinfection by dipping	
	Use #2.5 : Teat disinfection (pre-milking)	Not authorized due to unacceptable risk for animal health
	Use #2.6 : Teat disinfection (post-milking)	
PT4	Use #2.7 : Disinfection of inner surfaces (tanks, pipes, vessels, filling machines, …) by CIP with circulation	For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory. On hard/non-porous surfaces In 15 min CT, at Room Temperature • Active against bacteria and yeasts **0.02% PAA** • Active against bacteria, yeasts and fungi : **0.1% PAA** • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA**
	Use #2.8 : Surface Disinfection by spraying or pouring	For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory. On hard/non-porous surfaces In 15 min CT, at Room Temperature • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA**
	Use #2.9 : Surface Disinfection by dipping	

Meta SPC-3		Validated label claims
PT2	Use #3.1 : CIP procedures with circulation (including pharmaceutical and cosmetic industry)	On hard/non-porous surfaces In 15 min CT, at Room Temperature • Active against bacteria and yeasts **0.02% PAA** • Active against bacteria, yeasts and fungi : **0.1% PAA** • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA**
	Use #3.2 : Surface Disinfection by spraying or pouring, also in pharmaceutical and cosmetic industries	On hard/non-porous surfaces In 15 min CT, at Room Temperature • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA**
PT3	Use #3.3 : Surface Disinfection by spraying OR pouring (followed by wiping for a homogenous distribution)	By spraying : On hard/non-porous & porous surfaces By pouring : ONLY on hard/non-porous surfaces In 5 min contact time at +10°C WITH prior cleaning • Active against bacteria, yeasts and viruses : **0.2% PAA**
	Use #3.4 : Surface Disinfection by dipping	
	Use #3.5 : Teat disinfection (pre-milking)	Not authorized due to unacceptable risk for animal health
	Use #3.6 : Teat disinfection (post-milking)	
PT4	Use #3.7 : Disinfection of inner surfaces (tanks, pipes, vessels, filling machines, …) by CIP with circulation	For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory. On hard/non-porous surfaces In 15 min CT, at Room Temperature • Active against bacteria and yeasts **0.02% PAA** • Active against bacteria, yeasts and fungi : **0.1% PAA** • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA**
	Use #3.8 : Surface Disinfection by spraying or pouring	For uses in dairy industries, cleaning prior to the disinfection procedure is mandatory. On hard/non-porous surfaces In 15 min CT, at Room Temperature • Active against bacteria, yeasts, fungi and viruses : **0.15% PAA**
	Use #3.9 : Surface Disinfection by dipping	

It can be concluded that all products in the Airedale PAA product family are efficacious, when used in accordance with the use instructions as proposed in the SPC.

Human health

The information below covers the assessment of the active substance and of the substance of concern (HEDP) contained in the biocidal product family.

Professional users:

No systemic effects are observed, all the risk characterisation is based on local effects.

No oral exposure is anticipated for professional users.

The dermal exposure is acceptable for all scenarios (spraying, pouring, wiping, cleaning in place, teat disinfection and dipping) but is not acceptable for the mixing andloading. As a consequence, protective gloves, protective clothing and eye protection are required under all circumstances and are sufficient to avoid dermal contact.

Secondary exposure via treated surfaces is considered acceptable for all scenarios with no additional mitigation measures required, as the concentrations of peracetic acid and hydrogen peroxide are below the dermal limit for local effects.

Inhalation exposure is acceptable for peracetic acid for all exposure scenarios, indicating that no adverse effects will be experienced by workers.

Inhalation exposure is acceptable for hydrogen peroxide for all scenarios, excepted for spraying and pouring followed by wiping. For those uses a higher rate of ventilation or RPE are required. In case a higher ventilation rate cannot be applied, it is required to ensure an acceptable exposure via the use of RPE.

Non-professional users:

The uses of the formulated products are not intended for non-professional users.

General public:

No exposure scenarios include exposure to the general public, as all scenarios are for industrial/professional users only. Exposure via food and water are not considered relevant. The general public are not expected to be present where non-zero air concentrations may be present and are not expected to be in dermal contact with either the undiluted or diluted formulations. No secondary exposures are considered relevant for the general public.

Risk Mitigation Measure are proposed to ensure that the general public won't be exposed during or after application (see below)

Risk for consumers via residues in food:

The proposed uses are in the pharmaceutical and cosmetic industries (Uses #1.1, 1.2, 2.1, 2.2, 3.1, 3.2), for veterinary hygiene (Uses # 2.3, 2.4, 3.3, 3.4) uses would normally be relevant to exposure through food. However, the active substance is well known for its high reactivity with organic material and will rapidly degrade when in contact with food and feed.

Uses # 1.4, 2.5, 2.6, 2.8, 3.8 / 1.3, 2.7, 3.7, 3.5, 3.6 / 1.5, 2.9, 3.9 are intended for use in dairies, breweries, beverage and soft drinks industry and food processing, and therefore secondary oral and dermal exposure of consumers to residual hydrogen peroxide in food and drinking water is possible. Both peracetic acid and hydrogen peroxide are known to be highly reactive and would rapidly decompose in contact with any type of food. MRLs are not required for peracetic acid and hydrogen peroxide, and it is concluded that the risk for consumers via residues in food is negligible.

Risk for animal health:

An unacceptable risk has been identified regarding animal health for teat disinfection uses due to direct application on the animal skin and absence of suitable measures to reduce exposure, resulting in local effects. Therefore, these uses will not be authorised.

To ensure that animals will not be exposed during the application of the product for the other uses, the following risk mitigation is applied: “Animals should be removed before treatment takes place”

Classification:

The classification in relation to human health hazards is:
Meta SPC 1: Acute Tox 4 (oral), Skin Corr 1B , Eye Dam 1, STOT SE 3;
Meta SPC 2: Acute Tox 4 (oral, dermal, inhal), Skin Corr 1A, Eye Dam 1, STOT SE 3;
Meta SPC 3: Acute Tox 4 (oral), Acute Tox 3 (Dermal), Acute Tox 3 (Inhal), Skin Corr 1A, Eye Dam 1, STOT SE 3.

Risk mitigation measures:

- Wear chemical goggles consistent with EN 166 or equivalent, protective clothing chemically resistant to the biocidal product, and chemical resistant gloves classified under Standard EN374 (Protective gloves against chemicals and micro-organisms), preferably butyl rubber.

- Use with adequate ventilation. Use engineering controls to maintain airborne level below exposure limit requirements or guidelines. Atmospheric levels should be maintained below the exposure guideline. For all wiping and spraying applications, a ventilation rate of at least 10/h is required in the rooms where the application takes place.

- When respiratory protection is required (the concentration of PAA and/or H_2O_2 are above their respective AECinhal (0.5 mg/m^3 and 1.25 mg/m^3 respectively), use an approved air-purifying or positive-pressure supplied-air respirator depending on the potential airborne concentration.

- Do not use equipment/surfaces or allow animals/poultry to enter until product is completely absorbed to the surface or air dried

- Keep out of reach of children and non-target animals/pets.

- Re-entrance into treated area is only allowed once the levels of peracetic acid and hydrogen peroxide in the air are below the AECinhal (respectively 0.5 mg/m^3 for PAA and 1.25 mg/m^3 for H_2O_2).

- No bystanders are allowed in treated area during the application phase.

- Animals should be removed before treatment takes place.

Environment

Risk is acceptable for all the assessed compartments: STP, surface water and sediments following indirect exposure via STP discharge, terrestrial compartment, groundwater and air. Primary and secondary poisoning are not relevant.

When using the products of the Airedale PAA product family according to the conditions as stated in the SPC, the product will not present an unacceptable risk to the environment. No risk mitigation measures are necessary.

Classification:

The classification in relation to environmental hazards is:
Meta SPC 1: Aquatic chronic 2;
Meta SPC 2: Aquatic chronic 1;
Meta SPC 3: Aquatic chronic 1.

b) Presentation of the biocidal product family including classification and labelling

The description of the biocidal product and of the structure of the family is available in the SPC.

The hazard and precautionary statements of the biocidal product family according to the Regulation (EC) 1272/2008 is available in the SPC.

c) Description of uses proposed to be authorised

The uses claimed in the application and their assessment are described in the PAR. The description of the uses proposed to be authorised are available in the SPC.

d) Comparative assessment

The active substance peracetic acid contained in the biocidal product family does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not considered a candidate for substitution. Therefore, a comparative assessment of the biocidal product family is not necessary.

e) Overall conclusion of the evaluation of the uses proposed to be authorised

The physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the intended uses of the biocidal product/biocidal product family have been evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substance in the biocidal product family are met (technical equivalence – decision number: TAP-D-1267940-18-00/F)

The physico-chemical properties of the biocidal product family are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

For the proposed authorised uses, according to Article 19(1)(b) of the BPR, it has been concluded that:

1. the biocidal product family is sufficiently effective;

2. the biocidal product/biocidal product family has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;

3. the biocidal product family has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;

4. the biocidal product family has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:

    - the fate and distribution of the biocidal product in the environment,
    - contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
    - the impact of the biocidal product on non-target organisms,
    - the impact of the biocidal product on biodiversity and the ecosystem.

The outcome of the evaluation, as reflected in the PAR, is that the uses described in the SPC, may be authorised.

2.2 BPC opinion on the Union authorisation of the biocidal product family

As the conditions of Article 19(1) are met it is proposed that the biocidal product family shall be authorised[1], for the uses described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

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[1] This is without prejudice of any specific conditions that might apply in the territory of Member State(s) in accordance with Article 44(5) of the BPR.