

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the single biocidal product:

WESSOCLEAN GOLD LINE

ECHA/BPC/359/2022

Adopted

28 September 2022

Opinion of the Biocidal Products Committee

on the Union authorisation of single biocidal product WESSOCLEAN GOLD LINE

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:	WESSOCLEAN GOLD LINE
Authorisation holder:	Wesso AG
Active substance common name:	Peracetic acid (CAS No 79-21-0)
Product types:	3 and 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 28 September 2017, recorded in R4BP3 under case number BC-QN034236-29, 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 9 March 2022. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-44) and its Working Groups (WG II 2022). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: Germany (DE)

The BPC opinion on the Union authorisation of the biocidal product was reached on 28 September 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 single biocidal product is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012, as defined in Article 3(1)(r).

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

The BPC agreed on the draft SPC of WESSOCLEAN GOLD LINE 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 contains the active substance peracetic acid in a concentration of 0.03 % w/w for disinfection of hatching eggs (veterinary hygiene: PT 3) and for disinfection of non-porous surfaces in the vegetable/fruit/plants packaging industry (disinfection in food and feed area: PT 4).

The biocidal product is proposed to be authorised for three uses, two in PT 3, one in PT 4, with ready-to-use liquids applied in a closed system by cold fogging by professional users only.

The following uses have been assessed:

- Use 1: Disinfection of hatching eggs at room temperature in the sluice (PT 3);
- Use 2: Disinfection of hatching eggs at 36 °C e.g. in the hatcher (PT 3);
- Use 3: Disinfection of surfaces in the vegetable/fruit/plants packaging industry by airborne diffusion (PT 4).

Identified substances of concern

The following substances of concern were identified and assessed because of their contribution to the classification of the biocidal product with Eye Irrit. 2:

- Hydrogen peroxide (CAS No 7722-84-1);
- Propan-2-ol (CAS-No 67-63-0);
- Ethanol (CAS No 64-17-5);
- Sulphuric acid (CAS No 7664-93-9).

Physico-chemical properties

The product is a clear, colourless to light yellow liquid with a characteristic (tartish, fruity) odour. The pH of the product is 3.24, a test of acidity showed 0.63 g H₂SO₄/100g solution.

The product has to be classified and labelled as Met. Corr. 1, H290.

A shelf life of 12 month can be granted.

The analytical methods provided regarding the residues of peracetic acid (and hydrogen peroxide) in water, air and blood were acceptable even if the LOQ of the methods is not sufficiently low in comparison to the current lowest limits.

Efficacy

The product demonstrated bactericidal, yeasticidal and fungicidal efficacy according to EN 1276, EN 1650 and adapted EN 17272 when applied by cold fogging for the disinfection of non-porous surfaces in the vegetable/fruit/plants packaging industry (PT 4).

The product demonstrated bactericidal, yeasticidal and fungicidal efficacy according to EN 1656, EN 1657, adapted EN 17272 and a field study in a hatchery when applied by cold fogging for the disinfection of hatching eggs (PT 3).

It can be concluded that the product is expected to be efficacious when used in accordance with the use instructions proposed in the SPC.

The development of resistance is not likely due to the unspecific mode of action of the active substance.

Human health

Classification and Labelling

According to the CLP criteria, product needs to be classified and labelled with regard to human health as follows:

- Eye Irrit. 2, H319.

A risk for professional users resulting from the use of the biocidal product for the intended uses as well as from secondary exposure ('Maintenance/repair of dosing pumps') is unlikely after a Tier 2 consideration. Risk mitigation measures have to be taken into account in order to ensure safe use of the biocidal product.

Risk mitigation measures:

For loading the product (applies to all uses):

- The use of eye protection during handling of the product is recommended.

For application of the product (applies to all uses):

- Application of the product is only permitted in closed, airtight disinfection systems. Workers must not be present during disinfection process. / No workers are allowed in the disinfection chamber during application.
- The disinfection shall only be started from outside the disinfection chamber to avoid contact with the disinfectant.

- The chamber must remain hermetically sealed during disinfection and re-entry must be prevented. It shall be indicated that a disinfection process is running.
- After application, the chamber must be completely ventilated by a technical ventilation system.
- Re-entry is only permitted once the product has dried from all surfaces and the air concentrations of peracetic acid and hydrogen peroxide have dropped below the respective reference values (AECs). To ensure sufficient ventilation, either a disinfection system with sensors indicating when the relevant concentrations have dropped below the reference values has to be used, or the required duration of the technical ventilation has to be established by measurement with suitable measurement equipment for each technical installation and after any change in relevant boundary conditions.

For repair or maintenance of dosing pumps (applies to all uses):

- Prior to intervention in the pumps, existing product residues must be largely removed by flushing the pumps.

It is unlikely that this product causes risks for consumers resulting from food or feed, as residues in food or feed are not expected from the intended uses.

Environment

The expected risks to the environment from the use of the product are considered acceptable for all uses and all relevant environmental compartments. Hence, no negative effects for the environment are to be expected due to the use of the biocidal product.

b) Presentation of the biocidal product including classification and labelling

The description of the biocidal product is available in the SPC.

The hazard and precautionary statements of the biocidal product 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 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 in accordance with Article 23 of the BPR is not required.

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

An overview of the uses to be authorised is presented below.

Uses	Application rates	Target organism	Conditions of use	Conclusions
Disinfection of hatching eggs at room temperature in the sluice	1 L undiluted product per 15 m ³ (= 0.067 L/m ³); median droplet size ≤ 15 µm	bacteria yeast fungi	Indoor	Acceptable
Disinfection of hatching eggs at 36 °C e.g. in the hatcher			Professional	Acceptable
Disinfection of surfaces in the vegetable/fruit/plants packaging industry by airborne diffusion			Closed system: cold fogging	Acceptable

The physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the intended use(s) of the biocidal product have been evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substance in the biocidal product are met.

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

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

1. the biocidal product is sufficiently effective;
2. the biocidal product 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 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 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 use(s) described in the SPC may be authorised.

2.2 BPC opinion on the Union authorisation of the biocidal product

As the conditions of Article 19(1) are met it is proposed that the single biocidal product shall be authorised¹, for the use(s) 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.