

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the single biocidal product:

AEROCLEAN

ECHA/BPC/382/2023

Adopted

6 June 2023

Opinion of the Biocidal Products Committee

on the Union authorisation of single biocidal product AEROCLEAN

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:	AEROCLEAN
Authorisation holder:	HUVEPHARMA SA
Active substances:	L-(+)-lactic acid (CAS No.: 79-33-4) and hydrogen peroxide (CAS No.: 7722-84-1)
Product types:	2, 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 30 April 2019, recorded in R4BP3 under case number BC-ND051407-48, 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 7 December 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-47) and its Working Groups (WG I 2023). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: France

The BPC opinion on the Union authorisation of the biocidal product was reached on 6 June 2023.

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 **AEROCLEAN** 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

The sections below are a concise summary of the evaluation and conclusions of the assessment of the biocidal product AEROCLEAN.

General

The biocidal product AEROCLEAN contains L-(+)-lactic acid and hydrogen peroxide. The product is to be used by professional users for the disinfection of surfaces and equipment in PT 2, PT 3 and PT 4.

No substance of concern (SoC) is identified in the product formulation.

The following intended uses were claimed and assessed:

- Use #1 Airborne disinfection of empty greenhouses and empty shelters;
- Use #2 Airborne disinfection of eggs storage rooms (not intended for human consumption);
- Use #3 Airborne disinfection of incubators and hatcheries (including eggs);
- Use #4 Airborne disinfection of empty buildings (livestock buildings, veterinary clinic and adjoining animal rooms) and materials;
- Use #5 Airborne disinfection of breeding premises in the presence of animals;
- Use #6 Airborne disinfection of empty buildings and materials on surfaces in contact with food or feed.

Depending on the uses, the product is claimed to be applied by cold nebulisation, thermonebulisation or by evaporation.

Physico-chemical properties

Physical and chemical properties of the product AEROCLEAN have been described and are considered acceptable for a soluble concentrate for the intended uses.

A decrease of 58% of the content of L-(+)-lactic acid and 56% of the content of hydrogen peroxide are observed after 12 months of storage. An (eco)toxicological assessment of the

degradation products formed during storage and an assessment of the efficacy of the aged product have been performed. No (eco)toxicological concern was identified for the formed degradation products and the aged product after a storage period of 17 months was still efficacious. Based on that, the shelf-life of the product is set at 17 months.

The product should be protected away from direct sunlight and stored at a temperature below 25°C. It should be reported on the label "Foaming product: Do not agitate during mixing and loading to avoid foaming".

The product is neither flammable nor auto-flammable. It has no explosive, self-reactive and oxidizing properties. It is classified as corrosive to metals Cat. 1 (H290).

The analytical methods for the determination of hydrogen peroxide and L-(+)-lactic acid in the product are considered acceptable.

Efficacy

Efficacy of the product AEROCLEAN is demonstrated against:

- bacteria, yeasts, fungi, enveloped viruses for the disinfection of empty greenhouses and empty storage buildings shelters (PT 2) and for the disinfection of empty buildings and materials on surfaces in contact with food or feed (PT 4).
- bacteria, yeasts, fungi, viruses for the disinfection of eggs storage rooms, empty buildings (livestock buildings, veterinary clinic and adjoining animal rooms) and materials (PT 3),
- bacteria, yeasts, viruses for the disinfection of breeding premises (PT 3).

Efficacy is not demonstrated for:

- use #3 (PT 3 – Airborne disinfection of incubators and hatcheries (including eggs) by natural evaporation) due to an unadapted mode of application different from natural evaporation (i.e cold nebulisation) or in case where natural evaporation was used in the efficacy trial due to the absence of eggs in the test design that could impact the efficacy of the product.
- for the mode of application by thermonebulisation for the uses #1, #4 and #6 in the absence of suitable tests performed with this mode of application.

Human health

Classification is summarised in the following table:

Classification	
Skin Corr. 1C	H314
Serious eye damage cat. 1	H318

The risk is acceptable for all uses for professional users considering the risk mitigation measures (RMM) and the use of personal/respiratory protective equipment (PPE/RPE) and for general public considering the use of risk mitigation measures (RMM) listed below.

For uses of product AEROCLEAN by nebulization (uses #1, #2, #4, #5, #6), RMMs are the following:

- To apply the product, use only automated nebulizer.
- Seal the treatment enclosure (e.g. with tape) to ensure that hydrogen peroxide levels outside the enclosure are kept at acceptable levels.
- During mixing, loading and cleaning of the device, the user has to wear gloves (EN 374), coverall (at least category III type 4, EN 14605+A1) and goggles.
- In case of skin contact, wash skin exposed.
- During the nebulization (treatment time), contact time (one hour) and during ventilation time, no person (operator, by-stander etc.) is allowed to be present within the treated area.
- After nebulisation and contact time, the room must be ventilated, preferably by mechanical ventilation. The duration of the ventilation period has to be established by measurement with suitable measurement equipment. Re-entry is only permitted once the hydrogen peroxide air concentration has dropped below 0.9 ppm (1.25 mg/m³) or the corresponding national reference value.
- Use a calibrated sensor to confirm the hydrogen peroxide air concentration is ≤ 0.9 ppm (1.25 mg/m³) or below the corresponding national reference value prior to re-entry.
- The professional user may only enter the room in emergency situations or to reactivate the ventilation considering RPE with APF 40 against vapour (Type of RPE to be specified by the authorisation holder within the product information). The re-entry is therefore only possible when the hydrogen peroxide level has dropped below 36 ppm (50 mg/ m³) or below 40x the national reference value.
- Do not touch the surface until it is dried.

For use #3 (Airborne disinfection of incubators and hatcheries by evaporation), RMM are the following:

During mixing and loading, the user has to wear gloves (EN 374), coverall, goggles and a respiratory protective equipment min APF 4.

- Do not open the hatchery / incubator after treatment and contact time before a ventilation period of:
 - o 3 h 20 min at ventilation rate of 2/h,
 - o 50 min at a ventilation rate of 8/h,
 - o 23 min at a ventilation rate of 18/h.
- Do not touch the surface until it is dried.

Animal health

Regarding the disinfection of breeding premises in presence of animals, the risk for animal health is not acceptable when the animals are present in the room/buildings during

application. Therefore, the following RMM is proposed for use #5: "Only use in empty animal housing".

Moreover, for this use and for airborne disinfection of empty buildings and materials (PT 3) by cold or thermo nebulization, the risk for animal health is acceptable considering the same re-entry period for animals than for people without RPE. The following RMM is proposed: Re-entry is only permitted for animals once the hydrogen peroxide air concentration has dropped below 0.9 ppm (1.25 mg/m³) or the corresponding national reference value.

Indirect exposure via food

No specific residue data were submitted in the context of this dossier.

Regarding the intended uses of AEROCLEAN for the disinfection of empty buildings and materials on surfaces in contact with food or feed (PT 4), the disinfection of eggs storage rooms, empty buildings (livestock buildings, veterinary clinic and adjoining animal rooms) and materials and the disinfection of breeding premises (PT 3), residues in food, feed, eggs, milk or drinking water might be expected.

Nevertheless, based on the low concentration of L-(+)-lactic acid, its endogenous production, and compared to naturally occurring levels in food, significant indirect exposure via the intended uses is not expected.

Considering the properties of hydrogen peroxide, no significant exposure via food is expected.

Environment

Following the application of the product AEROCLEAN by professional users for airborne disinfection, risks are acceptable for all the environmental compartments and for all the uses presented in SPC.

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 substances L-(+)-lactic acid and hydrogen peroxide contained in the biocidal product does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and are not considered candidates for substitution. Therefore, a comparative assessment of the biocidal product is not required.

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 have been evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substances 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.

Conclusions of the assessments of each section are presented in the table below:

Uses		Conditions of use	Conclusions
1	Airborne disinfection of empty greenhouses and empty shelters – PT 2 use	Application by cold nebulization Professional users	Acceptable
		Application by thermonebulisation Professional users	Not acceptable Efficacy not demonstrated
2	Airborne disinfection of eggs storage rooms (not intended for human consumption) – PT 3 use	Application by cold nebulization Professional users	Acceptable Only in the absence of eggs during treatment
3	Airborne disinfection of incubators and hatcheries – PT 3 use	Application by professional users by evaporation	Not acceptable Efficacy not demonstrated
4	Airborne disinfection of empty buildings (livestock buildings, veterinary clinic, adjoining animal rooms) and materials – PT 3 use	Application by cold nebulization Professional users	Acceptable
		Application by thermonebulisation Professional users	Not acceptable Efficacy not demonstrated
5	Airborne disinfection of breeding premises – PT 3 use	Application by cold nebulization Professional users	Acceptable Only in the absence of animals during treatment
6	Airborne disinfection of empty buildings and materials on surfaces in contact with food or feed – PT 4 use	Application by cold nebulization Professional users	Acceptable Except for application by thermonebulisation
		Application by thermonebulisation Professional users	Not acceptable - Efficacy not demonstrated

For the proposed authorised uses, 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 uses 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 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.