COMMISSION IMPLEMENTING REGULATION (EU) 2024/772

of 4 March 2024

granting a Union authorisation for the single biocidal product 'AEROCLEAN' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 44(5), first subparagraph, thereof,

Whereas:

(1) On 30 April 2019, HUVEPHARMA SA submitted to the European Chemicals Agency ('the Agency') an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for Union authorisation of a single biocidal product named 'AEROCLEAN' of product-types 2, 3 and 4 as described in Annex V to that Regulation, providing written confirmation that the competent authority of France had agreed to evaluate the application. The application was recorded under case number BC-ND051407-48 in the Register for Biocidal Products.

(2) 'AEROCLEAN' contains L-(+)-lactic acid and hydrogen peroxide as the active substances, both included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-types 2, 3 and 4.

(3) On 7 December 2022, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the Agency.

(4) On 2 August 2023, the Agency submitted to the Commission its opinion ([2]) and the draft summary of the biocidal product characteristics ('SPC') of 'AEROCLEAN' and the final assessment report on the single biocidal product, in accordance with Article 44(3) of Regulation (EU) No 528/2012.

(5) The opinion concludes that 'AEROCLEAN' is a single biocidal product within the meaning of Article 3(1), point (r), of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that, subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) of that Regulation.

(6) On 18 August 2023, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.

(7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for 'AEROCLEAN'.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) ECHA opinion of 6 June 2023 on the Union authorisation of the single biocidal product 'AEROCLEAN' (ECHA/BPC/382/2023), https://echa.europa.eu/opinions-on-union-authorisation

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0031391-0000 is granted to HUVEPHARMA SA for the making available on the market and use of the single biocidal product 'AEROCLEAN' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 25 March 2024 to 28 February 2034.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 4 March 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product

AEROCLEAN

Product type 2 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Product type 3 – Veterinary hygiene (Disinfectants)

Product type 4 – Food and feed area (Disinfectants)

Authorisation number: EU-0031391-0000

R4BP asset number: EU-0031391-0000

1. **ADMINISTRATIVE INFORMATION**

1.1. Trade name(s) of the product

Trade name(s)	AIRNAPUR EGGOA FUMICLEAN FOGAIR ASEPTOL AIR SEPTOKAIR NEBULAIR OXIR KLEANSAIR AEROCLEAN

1.2. **Authorisation holder**

Name and address of the authorisation holder	Name	HUVEPHARMA SA
	Address	34, rue Jean Monnet ZI d'Étriché – Segré, 49500 Segré-en-Anjou Bleu France
Authorisation number	EU-0031391-0000	
R4BP asset number	EU-0031391-0000	
Date of the authorisation	25 March 2024	
Expiry date of the authorisation	28 February 2034	

1.3. **Manufacturer(s) of the product**

Name of manufacturer	HUVEPHARMA SA
Address of manufacturer	12, rue de Malacussy, 42100 Saint-Etienne France
Location of manufacturing sites	12, rue de Malacussy, 42100 Saint-Etienne France

1.4. **Manufacturer(s) of the active substance(s)**

Active substance	L-(+)-lactic acid
Name of manufacturer	PURAC BIOCHEM
Address of manufacturer	Arkelseddijk 46, 4206 AC Gorinchem, P.O. Box 21, 4200 AA GORINCHEM Netherlands
Location of manufacturing sites	Arkelseddijk 46, 4206 AC Gorinchem, P.O. Box 21, 4200 AA GORINCHEM Netherlands

Active substance	L-(+)-lactic acid
Name of manufacturer	Jungbunzlauer SA
Address of manufacturer	Z.I. et Portuaire, BP 32, 67390 Mackolsheim France
Location of manufacturing sites	Z.I. et Portuaire, BP 32, 67390 Mackolsheim France

Active substance	Hydrogen peroxide
Name of manufacturer	ARKEMA France
Address of manufacturer	420 rue d'Estienne dOrves, 92705 Colombes France
Location of manufacturing sites	RN85, BP1, 38560 Jarrie France

2. **PRODUCT COMPOSITION AND FORMATION**

2.1. **Qualitative and quantitative information on the composition of the product**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	6,25
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	15,0

2.2. **Type of formulation**

SL – Soluble concentrate

3. **HAZARD AND PRECAUTIONARY STATEMENTS**

Hazard statements	Causes severe skin burns and eye damage. May be corrosive to metals. Corrosive to the respiratory tract.
Precautionary statements	Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection.

	IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER. Immediately call a doctor. Dispose of contents to in accordance with local regulation. Dispose of container to in accordance with local regulation. Do not breathe vapours. Do not breathe spray. Wash hands thoroughly after handling. IF SWALLOWED:Rinse mouth.Do NOT induce vomiting. IF ON SKIN (or hair):Take off immediately all contaminated clothing.Rinse skin with water. Specific treatment (see instructions on this label). Wash contaminated clothing before reuse. Store locked up. IF ON SKIN (or hair):Take off immediately all contaminated clothing.Rinse skin with shower. Keep only in original packaging. Immediately call a POISON CENTER. Immediately call a doctor. IF INHALED:Remove person to fresh air and keep comfortable for breathing. Absorb spillage to prevent material damage. Store in a corrosion-resistant container/container with a resistant inner liner.

4. **AUTHORISED USES(S)**

4.1. **Use description**

Table 1.

Use # 1 – Airborne disinfection of empty greenhouses and empty material shelters

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage: Common name: Enveloped viruses Development stage: Common name: Fungi Development stage:
Field(s) of use	Indoor Disinfection of non-porous surfaces of empty visibly clean greenhouses and empty material shelters.

Application method(s)	Method: Cold nebulization in large enclosures (> 4 m^3 up to 300m^3) Detailed description: Temperature: room temperature Minimum contact time: 1 hour Range of median droplet diameters: 7 to 30 µm
Application rate(s) and frequency	Application Rate: Dose of pure product to be used: • Bacteria, yeasts: 5 ml/m^3 • Enveloped viruses: 5,2 ml/m^3 • Fungi: 10 ml/m^3 Dilution (%): Before application, the product needs to be diluted in water at a concentration ranged from 25 % to 100 % v/v of pure AEROCLEAN depending on the volume to be treated. To reach the required dose (e.g. 5 ml pure product/m^3 for bacteria and yeasts), the 'application rate of the diluted product has to be adapted according to the dilution factor (e.g. for a solution of 25 %v/v AEROCLEAN, 20 ml of diluted product/m^3 have to be applied against bacteria and yeast). Biological validation shall be performed for each room to be disinfected (or in a suitable "standard" room in a facility, if applicable) with the devices to be used after which a protocol for disinfection of these rooms can be made and used thereafter. Number and timing of application: One application to be done at each sanitation period of empty buildings.
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE (High Density Polyethylene) can of 1 litre with degassing cap HDPE can of 5 litres with degassing cap HDPE can of 20 litres with degassing cap HDPE drum of 200 litres with degassing cap

4.1.1. *Use-specific instructions for use*

The product shall only be used on visually clean surfaces when applied in greenhouses.

The contact time starts when the required total volume of pure product (see application rate) is nebulized.

Apply only on non-porous surfaces.

As an example, the product has been demonstrated as efficacious against fungi (via efficacy studies performed according to the EN17272 standard) with a flow rate of 293,3 ml/minute (i.e. 17,6 litre/hour) and at 38,8 ml diluted product (at 25 % v/v) per cubic meter of room volume at room temperature.

4.1.2. *Use-specific risk mitigation measures*

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4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

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4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

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4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

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4.2. **Use description**

Table 2.

Use # 2 – Airborne disinfection of empty eggs storage rooms (not intended for human consumption)

Product type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Common name: Yeasts Development stage: Common name: Bacteria Development stage: Common name: Fungi Development stage: Common name: Viruses Development stage:
Field(s) of use	Indoor Disinfection of non-porous surfaces of empty eggs storage rooms (not intended for human consumption)
Application method(s)	Method: Cold nebulization in large enclosure (> 4 m^3 up to 150m^3) Detailed description: Minimum contact time: 1 hour Temperature: room temperature Range of median droplet diameters: 7 to 30 µm
Application rate(s) and frequency	Application Rate: Dose of pure product to be used: Bacteria, yeasts, fungi, viruses: 13,2 ml/m^3 Dilution (%): Before application, the product needs to be diluted in water at a concentration of 33 % v/v of pure AEROCLEAN in order to apply 40 ml of diluted product/m^3. Biological validation shall be performed for each room to be disinfected (or in a suitable "standard" room in a facility, if applicable) with the devices to be used after which a protocol for disinfection of these rooms can be made and used thereafter. Number and timing of application: Repeat before each new egg arrival in the room.
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE can of 1 litre with degassing cap HDPE can of 5 litres with degassing cap HDPE can of 20 litres with degassing cap HDPE drum of 200 litres with degassing cap

4.2.1. *Use-specific instructions for use*

Apply only on non-porous surfaces.

The product is not intended to disinfect eggs. Treatment only in absence of eggs.

The contact time starts when the required total volume of pure product (see application rate) is nebulized.

As an example, the product has been demonstrated as efficacious against fungi (via efficacy studies performed according to the EN17272 standard) with a flow rate of 298,8 ml/minute (i.e. 17,93 litre/hour) and at 40 ml diluted product (at 33 % v/v) per cubic meter of room volume at room temperature.

4.2.2. *Use-specific risk mitigation measures*

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4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

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4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

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4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

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4.3. **Use description**

Table 3.

Use # 3 – Airborne disinfection of empty buildings (livestock buildings, veterinary clinic and adjoining animal rooms) and materials

Product type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Common name: Yeasts Development stage: Common name: Fungi Development stage: Common name: Bacteria Development stage: Common name: Viruses Development stage:
Field(s) of use	Indoor Disinfection of non-porous surfaces of empty buildings (livestock buildings, veterinary clinic, adjoining animal rooms) and materials.
Application method(s)	Method: Cold nebulization in large enclosures (> 4 m^3 up to 300m^3) Detailed description: Minimum contact time: 1 hour Temperature: room temperature Range of median droplet diameters: 7 to 30 µm

Application rate(s) and frequency	Application Rate: Dose of pure product to be used: • Bacteria and yeasts: 5 ml/m³ • Viruses: 5,2 ml/m³ • Fungi: 10 ml/m³ Dilution (%): Before application, the product needs to be diluted in water at a concentration ranged from 25 % to 100 % v/v of pure AEROCLEAN depending on the volume to be treated. To reach the required dose (e.g. 5 ml pure product/m³ for bacteria and yeasts) the application rate of the diluted product has to be adapted according to the dilution factor (e.g. for a solution of 25 % v/v AEROCLEAN, 20 ml diluted product/m³ have to be applied against bacteria and yeast). Biological validation shall be performed for each room to be disinfected (or in a suitable "standard" room in a facility, if applicable) with the devices to be used after which a protocol for disinfection of these rooms can be made and used thereafter. Number and timing of application: One application to be done at each sanitation period of empty buildings.
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE can of 1 litre with degassing cap HDPE can of 5 litres with degassing cap HDPE can of 20 litres with degassing cap HDPE drum of 200 litres with degassing cap

4.3.1. *Use-specific instructions for use*

Apply only on non-porous surfaces.

Clean surfaces before disinfection.

The contact time starts when the required total volume of pure product (see application rate) is nebulized.

As an example, the product has been demonstrated as efficacious against fungi (via efficacy studies performed according to the EN17272 standard) with a flow rate of 293,3 ml/minute (i.e. 17,07 litre/hour) and at 40 ml diluted product (at 25 % v/v) per cubic meter of room volume at room temperature.

Treatment only use in empty animal housing.

4.3.2. *Use-specific risk mitigation measures*

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.

4.3.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

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4.3.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

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4.3.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

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4.4. **Use description**

Table 4.

Use # 4 – Airborne disinfection of empty buildings and materials on surfaces in contact with food or feed

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage: Common name: Fungi Development stage: Common name: Enveloped viruses Development stage:
Field(s) of use	Indoor Disinfection of non-porous surfaces of empty buildings and materials in feed or food industries
Application method(s)	Method: Cold nebulization in large enclosures (> 4 m^3 up to 300m^3) Detailed description: Minimum contact time: 1 hour Temperature: room temperature Range of median droplet diameters: 7 to 30 µm
Application rate(s) and frequency	Application Rate: Dose of pure product to be used: • Bacteria, yeasts: 5 ml/m^3 • Enveloped viruses: 5,2 ml/m^3 •Fungi: 10 ml/m^3 Dilution (%): Before application, the product needs to be diluted in water at a concentration ranged from 25 % to 100 % v/v of pure AEROCLEAN depending on the volume to be treated. To reach the required dose (e.g. 5 ml pure product/m^3 for bacteria and yeasts) the application rate of the diluted product has to be adapted according to the dilution factor (e.g. for a solution of 25 % v/v AEROCLEAN, 20 ml diluted product/m^3 have to be applied against bacteria and yeast). Biological validation shall be performed for each room to be disinfected (or in a suitable "standard" room in a facility, if applicable) with the devices to be used after which a protocol for disinfection of these rooms can be made and used thereafter. Number and timing of application: One application to be done at each sanitation period of empty buildings.
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE can of 1 litre with degassing cap HDPE can of 5 litres with degassing cap HDPE can of 20 litres with degassing cap HDPE drum of 200 litres with degassing cap

4.4.1. *Use-specific instructions for use*

Apply only on non-porous urfaes.

The contact time starts when the required total volume of pure product (see application rate) is nebulized.

As an example, the product has been demonstrated as efficacious against fungi (via efficacy studies performed according to the EN17272 standard) with a flow rate of 293,3 ml/minute (i.e. 17,6 litre/hour) and at 38,8 ml diluted product (at 25 % v/v) per cubic meter of room volume at room temperature.

4.4.2. *Use-specific risk mitigation measures*

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4.4.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

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4.4.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

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4.4.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

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5. **GENERAL DIRECTIONS FOR USE** ([1])

5.1. **Instructions for use**

Follow the instructions of the equipment suppliers to obtain a sufficient diffusion time.

The users shall inform and report to the authorisation holder immediately if the treatment is ineffective.

The product has been demonstrated as efficacious (via efficacy studies performed according to the EN17272 standard) with a flow rate of 268,3 to 340 ml/minute (i.e. 16,1-20,4 litre/hour).

Biological validation shall be performed for each room to be disinfected (or in a suitable "standard" room in a facility, if applicable) with the devices to be used after which a protocol for disinfection of these rooms can be made and used thereafter.

5.2. **Risk mitigation measures**

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 (below 0,9 ppm (1,25 mg/m^3) or the corresponding national reference value).

During mixing and loading and cleaning of the device, the user shall wear gloves consistent with European Standard EN ISO 374 or equivalent, coverall consistent with at least category III type 4, EN 14605 or equivalent and goggles consistent with European Standard EN ISO 16321 or equivalent.

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 shall be established by measurement with suitable measurement equipment. Re-entry is only permitted once the hydrogen peroxide air concentration has dropped below 0,9ppm (1,25 mg/m^3) or the corresponding national reference value.

([1]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

Use a calibrated sensor to confirm the hydrogen peroxide air concentration is below 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 wearing respiratory protective equipment (RPE)with assigned protection factor (APF) 40 against vapour consitent with EN 14387 or equivalent (Type of RPE to be specified by the authorisation holder within the product information). The re-entry with the RPE in emergency situations or to reactivate the ventilation is therefore only allowed when the hydrogen peroxide level has dropped below 36 ppm (50 mg/m³) or below 40 times the corresponding national reference value.

Do not touch surfaces until they are dry.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.

In case of impaired consciousness place in recovery position and seek medical advice immediately.

5.4. **Instructions for safe disposal of the product and its packaging**

Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains.

Dispose of unused product, its packaging and all other waste in accordance with local regulations.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Protect from direct sunlight

Do not store above 25 °C

Shelf life: 17 months

6. **OTHER INFORMATION**

Foaming product: Do not agitate during mixing and loading to avoid foaming.

Full titles of EN standards and legislation referred to in section 5.2:

EN ISO 374 – Protective gloves against dangerous chemicals and micro-organisms.

EN 14605 – Protective clothing against liquid chemicals – Performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])

EN ISO 16321 – Eye and face protection for occupational use

EN 14387 – Respiratory protective devices – Gas filter(s) and combined filter(s) – Requirements, testing, marking