Official Journal
of the European Union

EN
L series

2025/1186

18.6.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/1186

of 17 June 2025

granting a Union authorisation for the single biocidal product 'exeol air cid 01' 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 12 June 2024, SODEL submitted an application to the European Chemicals Agency ('the Agency') in accordance with Article 43(1) of Regulation (EU) No 528/2012 and Article 4 of Commission Implementing Regulation (EU) No 414/2013 ([2]) for Union authorisation of the same single biocidal product, as referred to in Article 1 of Implementing Regulation (EU) No 414/2013, named 'exeol air cid 01', of product-types 2 and 4, as described in Annex V to Regulation (EU) No 528/2012, referring to the single biocidal product with the asset number EU-0029752-0007, which is a part of the related reference biocidal product family 'Oxy'Pharm H_2O_2'. The application was recorded under case number BC-NA095946-30 in the Register for Biocidal Products. The application also indicated the authorisation number of the related reference biocidal product family 'Oxy'Pharm H_2O_2' authorised by Commission Implementing Regulation (EU) 2023/1764 ([3]), with authorisation number EU-0029752-0000.

(2) The single biocidal product 'exeol air cid 01' contains hydrogen peroxide as the active substance, 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 and 4.

(3) On 25 October 2024, the Agency submitted to the Commission its opinion ([4]) and the draft summary of the biocidal product characteristics ('SPC') of 'exeol air cid 01' in accordance with Article 6 of Implementing Regulation (EU) No 414/2013.

(4) In its opinion, the Agency concludes that the proposed differences between the single biocidal product 'exeol air cid 01' and the related single reference biocidal product with the asset number EU-0029752-0007, which is a part of the related reference biocidal product family 'Oxy'Pharm H_2O_2', are limited to information which can be the subject of an administrative change in accordance with Commission Implementing Regulation (EU) No 354/2013 ([5]), and that based on the assessment of the related reference biocidal product family 'Oxy'Pharm H_2O_2'and subject to compliance with the draft SPC, the same single biocidal product 'exeol air cid 01' meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.

([2]) Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 125, 7.5.2013, p. 4, ELI: http://data.europa.eu/eli/reg_impl/2013/414/oj).

([3]) Commission Implementing Regulation (EU) 2023/1764 of 12 September 2023 granting a Union authorisation for the biocidal product family 'Oxy'Pharm H_2O_2' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 225, 13.9.2023, p. 21, ELI: http://data.europa.eu/eli/reg_impl/2023/1764/oj).

([4]) European Chemicals Agency opinion of 25 October 2024 on the Union authorisation of the same single biocidal product 'exeol air cid 01', UBS-C-1770534-19-00/F (https://echa.europa.eu/opinions-on-union-authorisation).

([5]) Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council. (OJ L 109, 19.4.2013, p. 4, ELI: http://data.europa.eu/eli/reg_impl/2013/354/oj).

(5) On 25 October 2024, the Agency also transmitted to the Commission the draft SPC of 'exeol air cid 01' in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.

(6) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for the same single biocidal product 'exeol air cid 01'.

(7) The expiry date of the authorisation should be aligned with the expiry date of the authorisation of the related reference biocidal product family 'Oxy'Pharm H_2O_2'.

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

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0033504-0000 is hereby granted to SODEL for the making available on the market and use of the same single biocidal product 'exeol air cid 01' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 8 July 2025 until 30 September 2033.

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, 17 June 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

exeol air cid 01

Product type(s)

PT02: Disinfectants and algaecides not intended for direct application to humans or animals

PT04: Food and feed area

Authorisation number: EU-0033504-0000

R4BP asset number: EU-0033504-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	exeol air cid 01

1.2. Authorisation holder

Name and address of the authorisation holder	Name	SODEL
	Address	190 rue René Barthélémy, 14100 Lisieux, France
Authorisation number	EU-0033504-0000	
R4BP asset number	EU-0033504-0000	
Date of the authorisation	8 July 2025	
Expiry date of the authorisation	30 September 2033	

1.3. Manufacturer(s) of the product

Name of manufacturer	OXY'PHARM
Address of manufacturer	829 rue Marcel Paul, 94500 Champigny-sur-Marne, France
Location of manufacturing sites	OXY'PHARM site 1 829 rue Marcel Paul, 94500 Champigny-sur-Marne, France

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

Active substance	Hydrogen peroxide
Name of manufacturer	Evonik Resource Efficiency GmbH
Address of manufacturer	Rellinghauser Straße 1-11, 45128 Essen, Germany
Location of manufacturing sites	Evonik Resource Efficiency GmbH site 1 Evonik Industries AG/BL Active Oxygens, Untere Kanalstraße 3, 79618 Rheinfelden, Germany

2. **PRODUCT COMPOSITION AND FORMULATION**

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		active substance	7722-84-1	231-765-0	7,9 % (w/w)

2.2. **Type(s) of formulation**

AL Any other liquid

3. **HAZARD AND PRECAUTIONARY STATEMENTS**

Hazard statements	H319: Causes serious eye irritation.
Precautionary statements	P264: Wash hands thoroughly after handling. P280: Wear eye protection. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313: If eye irritation persists: Get medical advice.

4. **AUTHORISED USE(S)**

4.1. **Use description**

Table 1

Use #3.1: Hard surface disinfection by 7,9 % Fogging Hydrogen Peroxide (FHP)

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Scientific name: — Common name: Bacteria Development stage: — Scientific name: — Common name: yeasts Development stage: —

	Scientific name: — Common name: Bacterial spores Development stage: no data Scientific name: — Common name: Mycobacteria Development stage: — Scientific name: — Common name: Viruses Development stage: — Scientific name: — Common name: fungi Development stage: —
Field(s) of use	indoor use Room disinfection with FHP for rooms with volumes between 4-150 m^3. It involves disinfection of hard non-porous surfaces of equipment and material (excluding medical devices) present in the treated room: — Hospitals & clinics, — laboratories of research and analysis (including P3 laboratories and white rooms), — healthcare transport, — pharmaceutical industry, — industrial laundries, — dental surgery and implantology centres, — transport vehicles — hotels, — restaurants, — schools, — day nurseries, — veterinary clinics.
Application method(s)	Method: fogging Detailed description: The product is a ready-to-use product that is placed in a device. That device automatically fogs the biocidal product, in the closed space/room to be disinfected, without any user or bystander present.
Application rate(s) and frequency	Application rate: — Bactericidal, yeasticidal, fungicidal, sporicidal, and virucidal activity: 5 ml product/m^3 and 2 hours contact time. — Mycobactericidal activity (log reduction ≥ 4): 7 ml product/m^3 and 2 hours contact time. Droplet size: 1-15 µm Number and timing of application: Disinfect rooms and equipment as frequently as required by the hygiene protocol in place.
Category(ies) of users	professional
Pack sizes and packaging material	(1) HDPE, white (non-transparent) bottle of 1 litre with a degassing screw cap. (2) HDPE, grey (non-transparent) single-use bottle of 2 litres. (3) HDPE, white (non-transparent) can of 5 litres (refill packaging). (4) HDPE, white (non-transparent) can of 20 litres.

4.1.1. *Use-specific instructions*

Surfaces must be cleaned before disinfection. The product is ready-to-use and should be used without dilution. The product is designed for equipment such as Nocospray/Bio-sanitizer/Sanofog/Nocomax/Nocomax Easy/Glosair. Read the instructions for use before use. Use according to the following protocols:

— Bactericidal, yeasticidal, fungicidal, sporicidal, and virucidal activity: 5 ml product/m^3 and 2 hours contact time.

— Mycobactericidal activity (log reduction ≥ 4): 7 ml product/m^3 and 2 hours contact time.

Droplet size: 1-15 µm

Relative humidity: 25 %-75 %

Temperature: room temperature

Respect the contact time. The contact time starts when the required amount of product is present in the room.

The user shall always carry out a microbiological validation of the disinfection in the rooms to be disinfected (or in a suitable 'standard room', if applicable) with the devices to be used after which a protocol for disinfection of these rooms can be made and used thereafter.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

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*

First aid:

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.

IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

Likely direct or indirect effects:

— Causes severe eye irritation.

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

See general directions for use.

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

See general directions for use.

4.2. **Use description**

Table 2

Use #3.3: Hard surface disinfection by Fogging Hydrogen Peroxide (FHP)

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Scientific name: — Common name: Bacteria Development stage: — Scientific name: — Common name: Yeasts Development stage: — Scientific name: — Common name: Bacterial spores Development stage: — Scientific name: — Common name: Mycobacteria Development stage: — Scientific name: — Common name: Viruses Development stage: — Scientific name: — Common name: bacteriophages Development stage: — Scientific name: — Common name: fungi Development stage: —
Field(s) of use	indoor use Room disinfection with FHP disinfection of hard non-porous surfaces of equipment and material present in the treated room of a size between 4-150 m^3: — food industries, — central kitchens, — restaurants.
Application method(s)	Method: fogging Detailed description: The product is a ready-to-use product that is placed in a device. That device automatically fogs the biocidal product, in the closed space/room to be disinfected, without any user or bystander present.
Application rate(s) and frequency	Application rate: — Bactericidal, bacteriophagicidal, yeasticidal, fungicidal, sporicidal, and virucidal activity: 5 ml product/m^3 and 2 hours contact time. — Mycobactericidal activity (log reduction ≥ 4): 7 ml product/m^3 and 2 hours contact time. Droplet size: 1-15 µm Number and timing of application: Disinfect rooms and equipment as frequently as required by the hygiene protocol in place.

Category(ies) of users	professional
Pack sizes and packaging material	(1) HDPE, white (non-transparent) bottle of 1litre with a degassing screw cap. (2) HDPE, grey (non-transparent) single-use bottle of 2 litres. (3) HDPE, white (non-transparent) can of 5 litres (refill packaging). (4) HDPE, white (non-transparent) can of 20 litres.

4.2.1. *Use-specific instructions*

Surfaces must be cleaned before disinfection. The product is ready-to-use and should be used without dilution. The product is designed for equipment such as Nocospray/Bio-sanitizer/Sanofog/Nocomax/Nocomax Easy/Glosair. Read the instructions for use before use. Use according to the following protocols:

— Bactericidal, bacteriophagicidal, yeasticidal, fungicidal, sporicidal and virucidal activity: 5 ml product/m^3 and 2 hours contact time.

— Mycobactericidal activity: 7 ml product/m^3 and 2 hours contact time.

Droplet size: 1-15 µm

Relative humidity: 25 %-75 %

Temperature: room temperature

Respect the contact time. The contact time starts when the required amount of product is present in the room. The user shall always carry out a microbiological validation of the disinfection in the rooms to be disinfected (or in a suitable 'standard room', if applicable) with the devices to be used after which a protocol for disinfection of these rooms can be made and used thereafter.

4.2.2. *Use-specific risk mitigation measures*

See general directions for use.

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*

First aid:

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.

IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

Likely direct or indirect effects:

— Causes severe eye irritation.

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

See general directions for use.

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

See general directions for use.

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

5.1. **Instructions for use**

—

5.2. **Risk mitigation measures**

During the diffusion, keep the room closed and do not enter. Treatment must be conducted with no human or animals present.

All gaps present in the room (for example, window frames) from where fog may leak must be sealed before the diffusion.

Ensure that access to the fog-treated area is denied during the whole procedure with a warning sign.

No access to the treated area should be permitted until the concentration of hydrogen peroxide is ≤ 0,9 ppm (1,25 mg/m^3) or a lower relevant national reference value.

The professional user may enter the room only in emergency situations when the hydrogen peroxide level has dropped below 36 ppm (50 mg/m^3) and must wear the following PPE: RPE classified under EN 14387 or equivalent with APF 40 (Type of RPE to be specified by the authorisation holder within the product information) and suitable protective equipment (gloves classified under European Standard EN 374 or equivalent, eye protection consistent with European Standard EN ISO 16321 or equivalent, coverall). Gloves and coverall material to be specified by the authorisation holder within the product information. See Section 6 for the full titles of the EN standards.

A measuring device should be used to ensure that the concentration of hydrogen peroxide has decreased below 0,9 ppm or a lower relevant national reference value. Unprotected persons/animals may re-enter the treated room only after the hydrogen peroxide concentration in air decreases lower than 1,25 mg/m^3 (0,9 ppm) or a lower relevant national reference value.

Individual protective equipment:

Wear chemical resistant goggles consistent with European Standard EN ISO 16321 or equivalent as eye protection during mixing and loading of the product to the packaging that is directly used in the fogging device (such as Nocospray, Bio-sanitizer, Sanofog, Nocomax or Nocomax Easy).

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

—

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

At the end of the treatment, dispose of unused product and the packaging in accordance with local regulations. Used product can be flushed to the municipal sewer or disposed of to the manure deposit depending on local regulations. Avoid release to an individual wastewater treatment plant.

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

— Shelf life: 2 years.

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

6. **OTHER INFORMATION**

The full titles of the EN standards referenced in the 'Risk mitigation measures' sections are:

EN ISO 16321 – Eye and face protection for occupational users

EN 374 – Protective gloves against chemicals and micro-organisms

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