Summary of product characteristics for a biocidal product

Product name: Nocodor range

Product type(s): PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Authorisation number: EU-0029752-0000

R4BP 3 asset reference number: EU-0029752-0006

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Administrative information

1.1. Trade names of the product

Nocolyse One Shot nocodor Nocolyse + nocodor Glosair 600 nocodor

1.2. Authorisation holder

Name and address of the authorisation holder	Name	OXY'PHARM
	Address	rue Marcel Paul 829 94500 Champigny-sur-Marne France
Authorisation number	EU-0029752-0000 1-2	

R4BP 3 asset reference number	EU-0029752-0006
Date of the authorisation	03/10/2023
Expiry date of the authorisation	30/09/2032

1.3. Manufacturer(s) of the biocidal products

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

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

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	Evonik Resource Efficiency GmbH
Address of the manufacturer	Rellinghauser Straße 1—11 45128 Essen Germany
Location of manufacturing sites	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 biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	12
Silver		Non-active substance	7440-22-4	231-131-3	0,0017

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements	May intensify fire; oxidiser Causes serious eye damage. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep away from clothing and other combustible materials. Avoid release to the environment. Wear eye 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 hazardous or special waste collection point in accordance with national regulations.

Dispose of container to hazardous or special waste collection point in accordance with national regulations.

4. Authorised use(s)

4.1 Use description

Use 1 - Use #2.1: Hard surface disinfection by 12% Fogging Hydrogen Peroxide (FHP)

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)	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: Tuberculosis bacilli Development stage: - Scientific name: - Common name: Viruses Development stage: - Scientific name: - Common name: Fungi Development stage: -
Field(s) of use	Indoor Room disinfection with FHP for rooms with volumes between 4-150 m³. 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,

	- hotels, - schools, - day nurseries.
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 frequencies	Application Rate: - Bactericidal, yeasticidal, fungicidal, sporicidal and virucidal activity: 3 ml product/m³ and 2 hours contact time. Treat a second time at 3 ml product/m³ and 2 hours contact time. - Tuberculocidal activity: 5 ml product/m³ and 2 hours contact time. Treat a second time at 3 ml product/m³ and 2 hours contact time. The second treatment takes place right after the first. The two treatments can be programmed in order to be carried out sequentially. Droplet size: 1-15 µm Dilution (%): - 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 for use

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: 3 ml product/m³ and 2 hours contact time. Treat a second time at 3 ml product/m³ and 2 hours contact time. - Tuberculocidal activity: 5 ml product/m³ and 2 hours contact time. Treat a second time at 3 ml product/m³ and 2 hours contact time. The second treatment takes place right after the first. The two treatments can be programmed in order to be carried out sequentially. 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

Please refer to general directions for use of this Meta SPC.

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 112/ambulance for medical assistance.
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 INHALED: IF symptoms occur 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.

Likely direct or indirect effects
- Causes serious eye irritation

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

Please refer to general directions for use of this Meta SPC.

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

Please refer to general directions for use of this Meta SPC.

5. General directions for use

5.1. Instructions for use

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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/m³) 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/m³) 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/m³ (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

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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.

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