

# Summary of product characteristics for a biocidal product

**Product name:** Neutral range

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

PT04 - Food and feed area (Disinfectants)

**Authorisation number:** EU-0029752-0000

**R4BP 3 asset reference number:** EU-0029752-0007

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## Administrative information

### 1.1. Trade names of the product

Nocolyse Food
Glosair 500

### 1.2. Authorisation holder

<b>Name and address of the authorisation holder</b>	Name	OXY'PHARM
	Address	rue Marcel Paul 829 94500 Champigny-sur-Marne France
<b>Authorisation number</b>	EU-0029752-0000 1-3	
<b>R4BP 3 asset reference number</b>	EU-0029752-0007	
<b>Date of the authorisation</b>	03/10/2023	
<b>Expiry date of the authorisation</b>	30/09/2032	

### 1.3. Manufacturer(s) of the biocidal products

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

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

<b>Active substance</b>	1315 - Hydrogen peroxide
<b>Name of the manufacturer</b>	Evonik Resource Efficiency GmbH
<b>Address of the manufacturer</b>	Rellinghauser Straße 1—11 45128 Essen Germany
<b>Location of manufacturing sites</b>	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	7,9
Silver		Non-active substance	7440-22-4	231-131-3	0

### 2.2. Type of formulation

AL - Any other liquid
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## 3. Hazard and precautionary statements

<b>Hazard statements</b>	Causes serious eye irritation.
<b>Precautionary statements</b>	<p>Wash hands thoroughly after handling.</p> <p>Wear eye protection.</p> <p>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>If eye irritation persists: Get medical advice.</p>

## 4. Authorised use(s)

### 4.1 Use description

#### Use 1 - Use #3.1: Hard surface disinfection by 7.9% Fogging Hydrogen Peroxide (FHP)

<b>Product type</b>	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
<b>Where relevant, an exact description of the authorised use</b>	-
<b>Target organism(s) (including development stage)</b>	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: Fungi Development stage: -
<b>Field(s) of use</b>	Indoor  Room disinfection with FHP for rooms with volumes between 4-150 m <sup>3</sup> . 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.
<b>Application method(s)</b>	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: 5 ml product/m<sup>3</sup> and 2 hours contact time. - Mycobactericidal activity (log reduction ≥ 4): 7 ml product/m<sup>3</sup> and 2 hours contact time. 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: 5 ml product/m<sup>3</sup> and 2 hours contact time.
- Mycobactericidal activity (log reduction ≥ 4): 7 ml product/m<sup>3</sup> 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

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 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

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.

### 4.2 Use description

#### Use 2 - Use #3.3: Hard surface disinfection by Fogging Hydrogen Peroxide (FHP)

##### Product type

PT04 - Food and feed area (Disinfectants)

##### Where relevant, an exact description of the authorised use

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##### 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

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<sup>3</sup>:

	<ul style="list-style-type: none"> <li>- food industries,</li> <li>- central kitchens,</li> <li>- restaurants.</li> </ul>
<b>Application method(s)</b>	<p>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.</p>
<b>Application rate(s) and frequencies</b>	<p>Application Rate: - Bactericidal, bacteriophagocidal, yeasticidal, fungicidal, sporicidal, and virucidal activity: 5 ml product/m<sup>3</sup> and 2 hours contact time. - Mycobactericidal activity (log reduction ≥ 4): 7 ml product/m<sup>3</sup> and 2 hours contact time. 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.</p>
<b>Category(ies) of users</b>	Professional
<b>Pack sizes and packaging material</b>	<ol style="list-style-type: none"> <li>1) HDPE, white (non-transparent) bottle of 1litre with a degassing screw cap.</li> <li>2) HDPE, grey (non-transparent) single-use bottle of 2 litres.</li> <li>3) HDPE, white (non-transparent) can of 5 litres (refill packaging).</li> <li>4) HDPE, white (non-transparent) can of 20 litres.</li> </ol>

#### 4.2.1 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, bacteriophagocidal, yeasticidal, fungicidal, sporicidal and virucidal activity: 5 ml product/m<sup>3</sup> and 2 hours contact time.
- Mycobactericidal activity: 7 ml product/m<sup>3</sup> 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

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

#### 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

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

#### 4.2.5 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  $\leq 0,9$  ppm (1,25 mg/m<sup>3</sup>) 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 36ppm (50 mg/m<sup>3</sup>) 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<sup>3</sup> (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