## Summary of product characteristics for a biocidal product

Product name: Javel 12.5 pro Oxena

Product type(s):

 $\mbox{\sc PT02}$  - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

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

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

PT04 - Food and feed area (Disinfectants)

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

PT04 - Food and feed area (Disinfectants)

PT04 - Food and feed area (Disinfectants)

PT04 - Food and feed area (Disinfectants)

Authorisation number: FR-2022-0008

R4BP 3 asset reference number: FR-0027862-0004

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#### **Administrative information**

#### 1.1. Trade names of the product

Javel 12.5 pro Oxena
SODICLEAN SODIF
SODICLEAN PREMIUM
EAU DE JAVEL CONCENTRE LE GLOBE

#### 1.2. Authorisation holder

Name and address of the authorisation holder

Name LABORATOIRE OXENA

Address rue Marc Seguin Zi la Motte Sud 26800 Portes les Valence France

**Authorisation number** 

FR-2022-0008 1-2

R4BP 3 asset reference number

Date of the authorisation

Expiry date of the authorisation

FR-0027862-0004
17/02/2022
16/02/2032

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

Name of the manufacturer

Laboratoire OXENA

Address of the manufacturer

ZI LA MOTTE SUD Rue Marc Seguin 26800 PORTES LES VALENCE France

Location of manufacturing sites

ZI LA MOTTE SUD Rue Marc Seguin 26800 PORTES LES VALENCE France

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

Active substance	1391 - Active chlorine released from sodium hypochlorite
Name of the manufacturer	ARKEMA
Address of the manufacturer	420 rue d'Estienne d'Orves 92705 Colombes Cedex France
Location of manufacturing sites	USINE DE JARRIE - Route Nationale 85 38560 Jarrie France
Active substance	1391 - Active chlorine released from sodium hypochlorite
Name of the manufacturer	Inovyn Chlorvinyls limited (UK)
Address of the manufacturer	South Parade WA7 4JE Runcorn United Kingdom
Location of manufacturing sites	INOVYN FRANCE SAS - 2 avenue de la république - CS 10001 39501 Tavaux Cedex France
Active substance	1391 - Active chlorine released from sodium hypochlorite
Name of the manufacturer	Kem One
Address of the manufacturer	19 rue Jacqueline Auriol - Bât A - Le Quadrille 69008 Lyon France
Location of manufacturing sites	Usine de Lavéra Écopolis Lavéra-Sud - BP 3 13117 Lavéra France
	Usine de Saint Fons 1 quai Louis Aulagne 69191 SAINT-FONS France

### 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 (%)
Active chlorine released from sodium hypochlorite		Active Substance			12,5
Sodium hydoxide	Sodium hydoxide	Non-active substance	1310-73-2	215-185-5	0
Amines, C12-14 (even numbered)- alkyldimethyl, N-oxides	Amines, C12-14 (even numbered)- alkyldimethyl, N-oxides	Non-active substance	308062-28-4	931-292-6	0

#### 2.2. Type of formulation

SL: soluble concentrate, liquid, water based

### 3. Hazard and precautionary statements

#### **Hazard statements**

May be corrosive to metals.

Causes severe skin burns and eye damage.

Very toxic to aquatic life with long lasting effects.

Contact with acids liberates toxic gas.

Corrosive to the respiratory tract.

#### **Precautionary statements**

Do not breathe .

Wash thoroughly after handling.

Avoid release to the environment.

Wear protective gloves/ protective clothing/ eye protection/ face protection.

IF SWALLOWED:Rinse mouth.Do NOT induce vomiting.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with .

IF INHALED:Remove person to fresh air and keep comfortable for breathing.

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 or doctor/physician.

Specific treatment (see on this label).

Wash contaminated clothing before reuse.

Collect spillage.

Store locked up.

Dispose of to .

### 4. Authorised use(s)

#### 4.1 Use description

#### Use 1 - Disinfection of sanitary installations

#### **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: Fungi Development stage:

#### Field(s) of use

Indoor

Medical sector Non medical sector

#### Application method(s)

Method: Pouring Detailed description:

## Application rate(s) and frequencies

Application Rate: Non medical sector: Clean conditions: Bacteria (obligatory): 562 mg/L a.c., contact time: 5 min Bacteria and yeasts (optional): 1513 mg/L a.c., contact time: 15 min Bacteria, yeasts and fungi (optional): 2270 mg/L a.c., contact time: 15 min Dirty conditions: Bacteria (obligatory): 4540 mg/L a.c., contact time: 5 min Bacteria and yeasts (optional): 4540 mg/L a.c., contact time: 15 min Bacteria, yeasts and fungi (optional): 6053 mg/L a.c., contact time: 15 min Medical sector: Clean conditions: Contact time: 15 min Bacteria / Yeasts (obligatory): 1513 mg/L a.c., Bacteria, yeasts and fungi (optional): 2270 mg/L a.c.

Dilution (%): 0

Number and timing of application:

Non medical sector:

Clean conditions:

Bacteria (obligatory): 562 mg/L a.c, contact time: 5 min

Bacteria and yeasts (optional): 1513 mg/L a.c, contact time: 15 min

Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min

Dirty conditions:

Bacteria (obligatory): 4540 mg/L a.c, contact time: 5 min

Bacteria and yeasts (optional): 4540 mg/L a.c, contact time: 15 min

Bacteria, yeasts and fungi (optional): 6053 mg/L a.c, contact time: 15 min

Medical sector:

Clean conditions:

Contact time: 15 min

Bacteria / Yeasts (obligatory): 1513 mg/L a.c,

Bacteria, yeasts and fungi (optional): 2270 mg/L a.c

#### Category(ies) of users

## Pack sizes and packaging material

Professional

HDPE bottle 250 mL

HDPE can 250mL, 5L, 10L, 20L, 30L, 200L, 1000L

HDPE barrels 5L, 10L, 20L, 30L, 60L

HDPE drum 2L, 5L, 10L, 20L, 30L

#### 4.1.1 Use-specific instructions for use

Clean carefully the surfaces before application of the product for applications in clean conditions.

For medical area, due to the contact time of 15 minutes, do not use this product for surfaces that are likely to come into contact with the patient and/or the medical staff and surfaces which are frequently touched by different people leading to the transmission of micro-organisms to the patient.

Avoid any direct or indirect contact with	th food
<u>-</u>	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment
-	
4.1.4 Where specific to the u packaging	se, the instructions for safe disposal of the product and its
-	
4.1.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product torage
-	
4.2 Use description Use 2 - Disinfection of hard sur	
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: Fungi Development stage:
	Ladaca
Field(s) of use	Indoor  Non medical sector
Application method(s)	Method: Spraying Detailed description: no mechanical action

4.1.2 Use-specific risk mitigation measures

Method: Mopping Detailed description: no mechanical action

Method: Pouring Detailed description:

no mechanical action

Method: wiping (no mechanical action)

Detailed description: no mechanical action

Method: Scrubbing Detailed description: no mechanical action

## Application rate(s) and frequencies

Application Rate: Clean conditions: Bacteria (obligatory): 562 mg/L a.c, contact time: 5 min Bacteria and yeasts (optional): 1513 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min Dirty conditions: Bacteria (obligatory): 4540 mg/L a.c, contact time: 5 min Bacteria and yeasts (optional): 4540 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 6053 mg/L a.c, contact time: 15 min

Dilution (%): 0

Number and timing of application:

Clean conditions:

Bacteria (obligatory): 562 mg/L a.c, contact time: 5 min

Bacteria and yeasts (optional): 1513 mg/L a.c, contact time: 15 min

Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min

Dirty conditions:

Bacteria (obligatory): 4540 mg/L a.c, contact time: 5 min

Bacteria and yeasts (optional): 4540 mg/L a.c, contact time: 15 min

Bacteria, yeasts and fungi (optional): 6053 mg/L a.c, contact time: 15 min

Application Rate: Clean conditions: Bacteria (obligatory): 562 mg/L a.c, contact time: 5 min Bacteria and yeasts (optional): 1513 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min Dirty conditions: Bacteria (obligatory): 4540 mg/L a.c, contact time: 5 min Bacteria and yeasts (optional): 4540 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 6053 mg/L a.c, contact time: 15 min

Dilution (%): 0

Number and timing of application:

Clean conditions:

Bacteria (obligatory): 562 mg/L a.c, contact time: 5 min

Bacteria and yeasts (optional): 1513 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min

Dirty conditions:

Bacteria (obligatory): 4540 mg/L a.c, contact time: 5 min

Bacteria and yeasts (optional): 4540 mg/L a.c, contact time: 15 min

Bacteria, yeasts and fungi (optional): 6053 mg/L a.c, contact time: 15 min

Application Rate: Clean conditions: Bacteria (obligatory): 562 mg/L a.c, contact time: 5 min Bacteria and yeasts (optional): 1513 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min Dirty conditions: Bacteria (obligatory): 4540 mg/L a.c, contact time: 5 min Bacteria and yeasts (optional): 4540 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 6053 mg/L a.c, contact time: 15 min

Dilution (%): 0

Number and timing of application:

Clean conditions:

Bacteria (obligatory): 562 mg/L a.c, contact time: 5 min

Bacteria and yeasts (optional): 1513 mg/L a.c, contact time: 15 min

Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min

Dirty conditions:

Bacteria (obligatory): 4540 mg/L a.c, contact time: 5 min

Bacteria and yeasts (optional): 4540 mg/L a.c, contact time: 15 min

Bacteria, yeasts and fungi (optional): 6053 mg/L a.c, contact time: 15 min

Application Rate: Clean conditions: Bacteria (obligatory): 562 mg/L a.c, contact time: 5 min Bacteria and yeasts (optional): 1513 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min Dirty conditions: Bacteria (obligatory): 4540 mg/L a.c, contact time: 5 min Bacteria and yeasts (optional): 4540 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 6053 mg/L a.c, contact time: 15 min

Dilution (%): 0

Number and timing of application:

Clean conditions:

Bacteria (obligatory): 562 mg/L a.c, contact time: 5 min

Bacteria and yeasts (optional): 1513 mg/L a.c, contact time: 15 min

Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min

Dirty conditions:

Bacteria (obligatory): 4540 mg/L a.c, contact time: 5 min

Bacteria and yeasts (optional): 4540 mg/L a.c, contact time: 15 min

Bacteria, yeasts and fungi (optional): 6053 mg/L a.c, contact time: 15 min

Application Rate: Clean conditions: Bacteria (obligatory): 562 mg/L a.c, contact time: 5 min Bacteria and yeasts (optional): 1513 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min Dirty conditions: Bacteria (obligatory): 4540 mg/L a.c, contact time: 5 min Bacteria and yeasts (optional): 4540 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 6053 mg/L a.c, contact time: 15 min

Dilution (%): 0

Number and timing of application:

Clean conditions:

Bacteria (obligatory): 562 mg/L a.c, contact time: 5 min

Bacteria and yeasts (optional): 1513 mg/L a.c, contact time: 15 min

Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min

Dirty conditions:

Bacteria (obligatory): 4540 mg/L a.c, contact time: 5 min

Bacteria and yeasts (optional): 4540 mg/L a.c, contact time: 15 min

Bacteria, yeasts and fungi (optional): 6053 mg/L a.c, contact time: 15 min

### Category(ies) of users

# Pack sizes and packaging material

Professional

HDPE bottle 250 mL

HDPE can 250mL, 5L, 10L, 20L, 30L, 200L, 1000L

HDPE barrels 5L, 10L, 20L, 30L, 60L

HDPE drum 2L, 5L, 10L, 20L, 30L

### 4.2.1 Use-specific instructions for use

- Apply without mechanical action on the surfaces intended to be treated and cover the entire surface.
- Clean carefully the surfaces before application of the product for application in clean conditions.
- Allow to take effect for at least 5 or 15 minutes (depending on the target organism), then mop/wipe scrub if required.

#### 4.2.2 Use-specific risk mitigation measures

- For application with a compression sprayer, wear respiratory protective equipment against aerosols at minima APF4. For professional bystander: Do not be present in the treatment area during disinfection process by compression sprayer. If it is cessary to be present, wear same RPE as the professional user.

	in the treatment area during disinfection process by compression sprayer. reatment area during disinfection process by compression sprayer.
<u>-</u>	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment
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4.2.4 Where specific to the upackaging	se, the instructions for safe disposal of the product and its
-	
4.2.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product torage
-	
4.3 Use description	
Use 3 - Disinfection of hard sur	faces (medical sector)
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: Fungi Development stage:

#### Field(s) of use

Indoor

Medical sector

#### Application method(s)

Method: Spraying Detailed description: no mechanical action

Method: Mopping Detailed description: no mechanical action

Method: Pouring Detailed description: no mechanical action

Method: Wiping (no mechanical action)

Detailed description: no mechanical action

Method: Scrubbing Detailed description: no mechanical action

## Application rate(s) and frequencies

Application Rate: Clean conditions: Bacteria (obligatory) and yeasts: 1513 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min

Dilution (%): 0

Number and timing of application:

Clean conditions:

Bacteria (obligatory) and yeasts : 1513 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min

Application Rate: Clean conditions: Bacteria (obligatory) and yeasts: 1513 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time:

15 min

Dilution (%): 0

Number and timing of application:

Clean conditions:

Bacteria (obligatory) and yeasts: 1513 mg/L a.c, contact time: 15 min

Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min

Application Rate: Clean conditions: Bacteria (obligatory) and yeasts: 1513 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min

Dilution (%): 0

Number and timing of application:

Clean conditions:

Bacteria (obligatory) and yeasts: 1513 mg/L a.c, contact time: 15 min

Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min

Application Rate: Clean conditions: Bacteria (obligatory) and yeasts: 1513 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time:

Dilution (%): 0

Number and timing of application:

Clean conditions:

Bacteria (obligatory) and yeasts: 1513 mg/L a.c., contact time: 15 min Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min

Application Rate: Clean conditions: Bacteria (obligatory) and yeasts: 1513 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time:

15 min

Dilution (%): 0

Number and timing of application:

Clean conditions:

Bacteria (obligatory) and yeasts: 1513 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min

#### Category(ies) of users

Professional

#### Pack sizes and packaging material

HDPE bottle 250 mL

HDPE can 250mL, 5L, 10L, 20L, 30L, 200L, 1000L

HDPE barrels 5L, 10L, 20L, 30L, 60L

HDPE drum 2L, 5L, 10L, 20L, 30L

#### 4.3.1 Use-specific instructions for use

- Clean carefully the surfaces before application of the product.
- Apply without mechanical action on the surfaces intended to be treated and cover the entire surface.
- Allow to take effect for at least 15 minutes (depending on the target organism), then mop/wipe scrub if required.
- For medical area, due to the contact time of 15 minutes, do not use this product for surfaces that are likely to come into contact with the patient and/or the medical staff and surfaces which are frequently touched by different people leading to the transmission of micro-organisms to the patient.

#### 4.3.2 Use-specific risk mitigation measures

- For application with a compression sprayer, wear respiratory protective equipment against aerosols at minima APF4.
- For professional bystander: Do not be present in the treatment area during disinfection process by compression sprayer. If it is necessary to be present, wear same RPE as the professional user.

	in the treatment area during disinfection process by compression sprayer. reatment area during disinfection process by compression sprayer. vith food.
=	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment
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4.3.4 Where specific to the u packaging	se, the instructions for safe disposal of the product and its
-	
4.3.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product storage
-	
4.4 Use description Use 4 - Disinfection of hard sur	faces in contact with food
Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Disinfection of hard surfaces (e.g. floors, walls, furniture, equipment)
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage:
	Scientific name: Common name: Yeasts Development stage:
	Scientific name: Common name: Fungi Development stage:
Field(s) of use	Indoor
Application method(s)	Method: Spraying Detailed description: no mechanical action
	Method: Mopping Detailed description: no mechanical action

Method: Pouring Detailed description: no mechanical action

Method: wiping Detailed description: no mechanical action

Method: Scrubbing Detailed description: no mechanical action

#### Application rate(s) and frequencies

Application Rate: Clean conditions: Bacteria, yeasts (obligatory): 1513 mg/L a.c Bacteria, yeasts and fungi (optional): 2270 mg/L a.c Dirty conditions: Bacteria, yeasts (obligatory): 4540 mg/L a.c Bacteria, yeasts and fungi (optional): 6053 mg/L a.c

Dilution (%): 0 Number and timing of application:

Contact time: 15 min

Clean conditions:

Bacteria, yeasts (obligatory): 1513 mg/L a.c Bacteria, yeasts and fungi (optional): 2270 mg/L a.c

Dirty conditions:

Bacteria, yeasts (obligatory): 4540 mg/L a.c Bacteria, yeasts and fungi (optional): 6053 mg/L a.c

Application Rate: Clean conditions: Bacteria, yeasts (obligatory): 1513 mg/L a.c Bacteria, yeasts and fungi (optional): 2270 mg/L a.c Dirty conditions: Bacteria, yeasts (obligatory): 4540 mg/L a.c Bacteria, yeasts and fungi (optional): 6053 mg/L a.c Dilution (%): 0

Number and timing of application: Contact time: 15 min

Clean conditions:

Bacteria, yeasts (obligatory): 1513 mg/L a.c Bacteria, yeasts and fungi (optional): 2270 mg/L a.c

Dirty conditions:

Bacteria, yeasts (obligatory): 4540 mg/L a.c Bacteria, yeasts and fungi (optional): 6053 mg/L a.c

Application Rate: Clean conditions: Bacteria, yeasts (obligatory): 1513 mg/L a.c Bacteria, yeasts and fungi (optional): 2270 mg/L a.c Dirty conditions: Bacteria, yeasts (obligatory): 4540 mg/L a.c Bacteria, yeasts and fungi (optional): 6053 mg/L a.c

Dilution (%): 0

Number and timing of application:

Contact time: 15 min

Clean conditions:

Bacteria, yeasts (obligatory): 1513 mg/L a.c Bacteria, yeasts and fungi (optional): 2270 mg/L a.c

Dirty conditions:

Bacteria, yeasts (obligatory): 4540 mg/L a.c Bacteria, yeasts and fungi (optional): 6053 mg/L a.c

Application Rate: Clean conditions: Bacteria, yeasts (obligatory): 1513 mg/L a.c Bacteria, yeasts and fungi (optional): 2270 mg/L a.c Dirty conditions: Bacteria, yeasts (obligatory): 4540 mg/L a.c Bacteria, yeasts and fungi (optional): 6053 mg/L a.c

Dilution (%): 0

Number and timing of application:

Contact time: 15 min

Clean conditions:

Bacteria, yeasts (obligatory): 1513 mg/L a.c Bacteria, yeasts and fungi (optional): 2270 mg/L a.c

Dirty conditions:

Bacteria, yeasts (obligatory): 4540 mg/L a.c Bacteria, yeasts and fungi (optional): 6053 mg/L a.c

Application Rate: Clean conditions: Bacteria, yeasts (obligatory): 1513 mg/L a.c Bacteria, yeasts and fungi (optional): 2270 mg/L a.c Dirty conditions: Bacteria, yeasts (obligatory): 4540 mg/L a.c Bacteria, yeasts and fungi (optional): 6053 mg/L a.c Dilution (%): 0

Number and timing of application:

Contact time: 15 min

Clean conditions:

Bacteria, yeasts (obligatory): 1513 mg/L a.c Bacteria, yeasts and fungi (optional): 2270 mg/L a.c

Dirty conditions:

Bacteria, yeasts (obligatory): 4540 mg/L a.c Bacteria, yeasts and fungi (optional): 6053 mg/L a.c

#### Category(ies) of users

Professional

## Pack sizes and packaging material

HDPE bottle 250 mL HDPE can 250mL, 5L, 10L, 20L, 30L, 200L, 1000L HDPE barrels 5L, 10L, 20L, 30L, 60L

HDPE drum 2L, 5L, 10L, 20L, 30L

#### 4.4.1 Use-specific instructions for use

- Apply without mechanical action on the surfaces intended to be treated and cover the entire surface.
- Clean carefully the surfaces before application of the product for application in clean conditions.
- Allow to take effect for at least 15 minutes, then mop/wipe scrub if required.

#### 4.4.2 Use-specific risk mitigation measures

- For application and rinsing with a compression sprayer, wear respiratory protective equipment against aerosols at minima APF4.
- For professional bystander: Do not be present in the treatment area during disinfection process by compression sprayer. If it necessary to be present, wear same RPE as the professional user.
- For general public: Do not be present in the treatment area during disinfection process by compression sprayer.
- Animals should not be present in the treatment area during disinfection by compression sprayer.
- Rinse surfaces after treatment.

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			
4.4.4 Where specific to the u packaging	se, the instructions for safe disposal of the product and its		
-			
4.4.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product storage		
-			
4.5 Use description			
Use 5 - Dinsinfection of equipm	nent/materials by immersion/soaking		
Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)		
	PT04 - Food and feed area (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: Fungi Development stage:		
Field(a) of one	Indoor		
Field(s) of use	Non medical sector (PT2) Food and feeding industry (PT4)		
Application method(s)	Method: Immersion/soaking Detailed description:		
Application rate(s) and frequencies	Application Rate: Non medical sector (PT2): Clean conditions: Bacteria (obligatory): 562 mg/L a.c, contact time: 5 min Bacteria and yeasts (optional): 1513 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min Dirty conditions: Bacteria (obligatory): 4540 mg/L a.c, contact time: 5 min Bacteria and		

yeasts (optional): 4540 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 6053 mg/L a.c, contact time: 15 min Food and feeding industry (PT 4): Clean conditions: Contact time: 15 min Bacteria / Yeasts (obligatory): 1513 mg/L a.c, Bacteria, yeasts and fungi (optional): 2270 mg/L a.c Dirty conditions: Contact time: 15 min Bacteria / Yeasts (obligatory): 4540 mg/L a.c, Bacteria, yeasts and fungi (optional): 6053 mg/L a.c

Dilution (%): 0

Number and timing of application:

Non medical sector (PT2):

Clean conditions:

Bacteria (obligatory): 562 mg/L a.c, contact time: 5 min

Bacteria and yeasts (optional): 1513 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min

Dirty conditions:

Bacteria (obligatory): 4540 mg/L a.c, contact time: 5 min

Bacteria and yeasts (optional): 4540 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 6053 mg/L a.c, contact time: 15 min

Food and feeding industry (PT 4):

Clean conditions:

Contact time: 15 min

Bacteria / Yeasts (obligatory): 1513 mg/L a.c, Bacteria, yeasts and fungi (optional): 2270 mg/L a.c

Dirty conditions: Contact time: 15 min

Bacteria / Yeasts (obligatory): 4540 mg/L a.c, Bacteria, yeasts and fungi (optional): 6053 mg/L a.c

#### Category(ies) of users

Professional

# Pack sizes and packaging material

HDPE bottle 250 mL

HDPE can 250mL, 5L, 10L, 20L, 30L, 200L, 1000L

HDPE barrels 5L, 10L, 20L, 30L, 60L HDPE drum 2L, 5L, 10L, 20L, 30L

#### 4.5.1 Use-specific instructions for use

- Clean carefully the surfaces before the application of the product for application in clean conditions.

#### 4.5.2 Use-specific risk mitigation measures

· Rinse surfaces after treatment

<u>-</u>	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment
4.5.4 Where specific to the u packaging	se, the instructions for safe disposal of the product and its
-	
4.5.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product storage
-	
4.6 Use description	
Use 6 - Disinfection of hard sur	faces in food and feed areas by cleaning-in-place (CIP)
Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Disinfection of hard surfaces (e.g. pipelines, tubes, separative membranes/ion-exchangers and tanks of filling machines or similar) in food and feed areas by circulation (CIP)
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage:
	Scientific name: Common name: Yeasts Development stage:
	Scientific name: Common name: Fungi Development stage:
Field(s) of use	Indoor
Application method(s)	Method: Cleaning In Place by circulation Detailed description: -
Application rate(s) and frequencies	Application Rate: Clean conditions: Bacteria, yeast (obligatory): 1059 mg/L a.c Bacteria, yeasts and fungi (optional): 2270 mg/L a.c Dirty conditions (except milk and dairy production and milking parlour systems): Bacteria, yeast (obligatory): 3027 mg/L a.c Bacteria, yeasts and fungi (optional): 4540 mg/L a.c Dilution (%): 0  Number and timing of application: Contact time: 15 min

	Clean conditions: Bacteria, yeast (obligatory): 1059 mg/L a.c Bacteria, yeasts and fungi (optional): 2270 mg/L a.c		
	Dirty conditions (except milk and dairy production and milking parlour systems): Bacteria, yeast (obligatory): 3027 mg/L a.c Bacteria, yeasts and fungi (optional): 4540 mg/L a.c		
Category(ies) of users	Professional		
Pack sizes and packaging material	HDPE bottle 250 mL HDPE can 250mL, 5L, 10L, 20L, 30L, 200L, 1000L HDPE barrels 5L, 10L, 20L, 30L, 60L HDPE drum 2L, 5L, 10L, 20L, 30L		
4.6.1 Use-specific instruction	ns for use		
Clean carefully the surfaces before application of the product for applications in clean conditions.			
4.6.2 Use-specific risk mitigation measures			
<ul> <li>Rinse surfaces after treatment.</li> <li>For maintenance of dosing pumps, wear gloves (gloves material to be specified by the authorisation holder within the product information), body protection (material to be specified by the authorisation holder within the product information), chemical goggles and respiratory protective equipment against aerosols.</li> </ul>			
4.6.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment			
-			
4.6.4 Where specific to the us packaging	se, the instructions for safe disposal of the product and its		
-			
4.6.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage			

SUMMARY OF PRODUCT CHARACTERISTICS

-

#### 4.7 Use description

#### Use 7 - Disinfection of inner surfaces in veterinary water systems

#### **Product type**

PT04 - Food and feed area (Disinfectants)

Where relevant, an exact description of the authorised use

Disinfection of inner surfaces in veterinary water systems

Target organism(s) (including development stage)

Scientific name: Common name: Bacteria Development stage:

Scientific name: Common name: Yeasts Development stage:

Scientific name: Common name: Fungi Development stage:

Field(s) of use

Indoor

Application method(s)

Method: Pouring Detailed description:

Application rate(s) and frequencies

Application Rate: Clean conditions: Bacteria (obligatory): 562 mg/L a.c, contact time: 5 min Bacteria and yeasts (optional): 1059 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min Dirty conditions: Bacteria (obligatory): 4540 mg/L a.c, contact time: 5 min Bacteria, Yeasts and fungi (optional): 4540 mg/L a.c, contact time: 15 min

Dilution (%): 0

Number and timing of application:

Clean conditions:

Bacteria (obligatory): 562 mg/L a.c, contact time: 5 min Bacteria and yeasts (optional): 1059 mg/L a.c, contact time: 15 min

Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min

Dirty conditions:

Bacteria (obligatory): 4540 mg/L a.c, contact time: 5 min

Bacteria, Yeasts and fungi (optional): 4540 mg/L a.c, contact time: 15 min

Category(ies) of users

Professional

Pack sizes and packaging material

HDPE bottle 250 mL

HDPE can 250mL, 5L, 10L, 20L, 30L, 200L, 1000L

HDPE barrels 5L, 10L, 20L, 30L, 60L HDPE drum 2L, 5L, 10L, 20L, 30L

<u> </u>
4.7.1 Use-specific instructions for use
Class carefully the curferes before application of the product for application in class conditions
-Clean carefully the surfaces before application of the product for application in clean conditions.
4.7.2 Use-specific risk mitigation measures
• For maintenance of dosing pumps, wear gloves (gloves material to be specified by the authorisation holder within the product information), body protection (material to be specified by the authorisation holder within the product information), chemical goggles and respiratory protective equipment against aerosols.
4.7.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment
-
4.7.4 Where specific to the use, the instructions for safe disposal of the product and its packaging
-
1.7.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage
-
5. General directions for use
5.1. Instructions for use
5.1. IIISUUCUOIIS IOI USE

Comply with the instructions for use
 Apply only on non porous surfaces

### 5.2. Risk mitigation measures

 For mixing and loading task, wear gloves (glove material to be specified by the authorisation holder within the product information), body protection (material to be specified by the authorisation holder within the product information) and chemical goggles.

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

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing.

Products should not be used in conjunction with acids or ammonia

If symptoms: Call 112/ambulance for medical assistance.

If no symptoms: Call a POISON CENTRE or a doctor.

• 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.

Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid

- 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.

#### 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

•	Shelf life: 5 months
•	Protect from frost.
•	Protect from direct sunlight.
•	Do not store above 30°C.

### 6. Other information

- The applicant should give indications of application of the product (dilution, quantity applied on surfaces, etc) on the label in order to guarantee the efficacy of the product during its application.
   The applicant should inform users of the product of the existence of MRLs for chlorates. They may be held liable if these MRLs are exceeded during controls carried out on foodstuffs that have been in contact with surfaces treated with a product from the OXENA FAMILY family.