

Summary of product characteristics for a biocidal product

Product name: Oxe Alca

Product type(s): PT04 - Food and feed area (Disinfectants)

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Authorisation number: FR-2022-0008

R4BP 3 asset reference number: FR-0027862-0001

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Administrative information

1.1. Trade names of the product

Oxe Alca BACTI A NON MOUSSANT

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 1-1	
R4BP 3 asset reference number	FR-0027862-0001	
Date of the authorisation	17/02/2022	
Expiry date of the authorisation	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			6,3
Sodium hydroxide	Sodium hydroxide	Non-active substance	1310-73-2	215-185-5	6,14
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 hard surfaces 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)	<p>Scientific name: Common name: Bacteria Development stage:</p> <p>Scientific name: Common name: Yeasts Development stage:</p> <p>Scientific name: Common name: Fungi Development stage:</p>
Field(s) of use	Indoor
Application method(s)	<p>Method: Spraying Detailed description: Only with trigger spray. No mechanical action</p> <p>Method: Mopping Detailed description: No mechanical action</p> <p>Method: Pouring Detailed description: No mechanical action</p> <p>Method: Wiping Detailed description: No mechanical action</p> <p>Method: Scrubbing Detailed description: -</p>
Application rate(s) and frequencies	<p>Application Rate: Bacteria, yeasts (obligatory): 573 mg/L a.c Bacteria, yeasts and fungi (optional): 2144 mg/L a.c Dirty conditions: Bacteria, yeasts (obligatory) and fungi: 4287 mg/L a.c Dilution (%): 0 Number and timing of application: Contact time: 15 min</p> <p>Bacteria, yeasts (obligatory): 573 mg/L a.c</p> <p>Bacteria, yeasts and fungi (optional): 2144 mg/L a.c</p> <p>Dirty conditions: Bacteria, yeasts (obligatory) and fungi: 4287 mg/L a.c</p>

Application Rate: Bacteria, yeasts (obligatory): 573 mg/L a.c Bacteria, yeasts and fungi (optional): 2144 mg/L a.c Dirty conditions: Bacteria, yeasts (obligatory) and fungi: 4287 mg/L a.c
Dilution (%): 0
Number and timing of application:
Contact time: 15 min

Bacteria, yeasts (obligatory): 573 mg/L a.c

Bacteria, yeasts and fungi (optional): 2144 mg/L a.c

Dirty conditions:

Bacteria, yeasts (obligatory) and fungi: 4287 mg/L a.c

Application Rate: Bacteria, yeasts (obligatory): 573 mg/L a.c Bacteria, yeasts and fungi (optional): 2144 mg/L a.c Dirty conditions: Bacteria, yeasts (obligatory) and fungi: 4287 mg/L a.c
Dilution (%): 0
Number and timing of application:
Contact time: 15 min

Bacteria, yeasts (obligatory): 573 mg/L a.c

Bacteria, yeasts and fungi (optional): 2144 mg/L a.c

Dirty conditions:

Bacteria, yeasts (obligatory) and fungi: 4287 mg/L a.c

Application Rate: Bacteria, yeasts (obligatory): 573 mg/L a.c Bacteria, yeasts and fungi (optional): 2144 mg/L a.c Dirty conditions: Bacteria, yeasts (obligatory) and fungi: 4287 mg/L a.c mg/L; Fungal spore: clean conditions, contact time 15 min, 1650 mg/L; Fungal spore: dirty conditions, contact time 15 min, 2750 mg/L; Yeast: clean conditions, contact time 15 min, 400 mg/L; Yeast: dirty conditions, contact time 15 min, 1200 mg/L;
Dilution (%): 0
Number and timing of application:
Contact time: 15 min

Bacteria, yeasts (obligatory): 573 mg/L a.c

Bacteria, yeasts and fungi (optional): 2144 mg/L a.c

Dirty conditions:

Bacteria, yeasts (obligatory) and fungi: 4287 mg/L a.c

Application Rate: Bacteria, yeasts (obligatory): 573 mg/L a.c Bacteria, yeasts and fungi (optional): 2144 mg/L a.c Dirty conditions: Bacteria, yeasts (obligatory) and fungi: 4287 mg/L a.cmg/L; Fungal spore: clean conditions, contact time 15 min, 1650 mg/L; Fungal spore: dirty conditions, contact time 15 min, 2750 mg/L; Yeast: clean conditions, contact time 15 min, 400 mg/L; Yeast: dirty conditions, contact time 15 min, 1200 mg/L; Dilution (%): 0
Number and timing of application:

Contact time: 15 min

Bacteria, yeasts (obligatory): 573 mg/L a.c

Bacteria, yeasts and fungi (optional): 2144 mg/L a.c

Dirty conditions:

Bacteria, yeasts (obligatory) and fungi: 4287 mg/L a.c

Category(ies) of users

Industrial
Professional

Pack sizes and packaging material

HDPE can 5L, 10L, 20L, 25L, 30L
HDPE barrel 5L, 10L, 20L, 30L, 60L, 200L
HDPE drum 5L, 20L
HDPE bottle 5L
HDPE keg 60L
HDPE IBC 1000L



4.1.1 Use-specific instructions for use

- 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, then mop/wipe scrub if required.

4.1.2 Use-specific risk mitigation measures

For application with a trigger spray and rinsing, 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), chemical goggles and only for application a respiratory protective equipment against aerosol.

For application by mopping/scrubbing and rinsing with a mop:

- 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
- A mop/brush with handle has to be used to apply the diluted solution to avoid exposure
- Do not immerse hands in the diluted solution.

For application by wiping and rinsing:

- 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
- pour the solution directly on the surface and wipe with a cloth.

For application by pouring and rinsing

- 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,
- avoid direct contact with the solution to be applied.

For professional bystander: Do not be present in the treatment area during disinfection process by trigger spray. If it is necessary to be present, wear same RPE and PPE as the professional user.

For general public:

- Do not be present in the treatment area during disinfection process by trigger spray.
- Do not touch the surface until it is rinsed and totally dried
- Children should not be present during disinfection and until the surface is rinsed and dry.

Animals should not be present during disinfection and until the surface is rinsed and dry.

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

Use 2 - Disinfection of hard surfaces 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)	<p>Scientific name: Common name: Bacteria Development stage:</p> <p>Scientific name: Common name: Yeasts Development stage:</p> <p>Scientific name: Common name: Fungi Development stage:</p>
Field(s) of use	Indoor
Application method(s)	<p>Method: Cleaning In Place by circulation Detailed description: -</p>
Application rate(s) and frequencies	<p>Application Rate: Clean conditions: Bacteria, yeasts (obligatory): 500 mg/L a.c Bacteria, yeasts and fungi (optional): 2144 mg/L a.c Dirty conditions (except milk and dairy production and milking parlour systems): Bacteria, yeasts (obligatory) and fungi: 3779 mg/L a.c Dilution (%): 0 Number and timing of application: Contact time: 15 min</p> <p>Clean conditions: Bacteria, yeasts (obligatory): 500 mg/L a.c Bacteria, yeasts and fungi (optional): 2144 mg/L a.c</p> <p>Dirty conditions (except milk and dairy production and milking parlour systems): Bacteria, yeasts (obligatory) and fungi: 3779 mg/L a.c</p>
Category(ies) of users	<p>Industrial</p> <p>Professional</p>

Pack sizes and packaging material

HDPE can 5L, 10L, 20L, 25L, 30L
HDPE barrel 5L, 10L, 20L, 30L, 60L, 200L
HDPE drum 5L, 20L
HDPE bottle 5L
HDPE keg 60L
HDPE IBC 1000L

4.2.1 Use-specific instructions for use

- Clean carefully the surfaces before application of the product for applications in milk and dairy production and milking parlour systems.

4.2.2 Use-specific risk mitigation measures

- For maintenance of circuit system, 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.
- For maintenance of dosing pumps, 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), chemical goggles and respiratory protective equipment against aerosols.

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

Use 3 - 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): 500 mg/L a.c, contact time: 5 min Bacteria and yeasts (optional): 500 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 2144 mg/L a.c, contact time: 15 min Dirty conditions: Bacteria (obligatory): 4287 mg/L a.c, contact time: 5 min Bacteria, yeasts and fungi (optional): 4282 mg/L a.c, contact time: 15 min
Dilution (%): 0

Number and timing of application:

Clean conditions:

Bacteria (obligatory): 500 mg/L a.c, contact time: 5 min

Bacteria and yeasts (optional): 500 mg/L a.c, contact time: 15 min

Bacteria, yeasts and fungi (optional): 2144 mg/L a.c, contact time: 15 min

Dirty conditions:

Bacteria (obligatory): 4287 mg/L a.c, contact time: 5 min

Bacteria, yeasts and fungi (optional): 4282 mg/L a.c, contact time: 15 min

Category(ies) of users

Industrial

Professional

Pack sizes and packaging material

HDPE can 5L, 10L, 20L, 25L, 30L
HDPE barrel 5L, 10L, 20L, 30L, 60L, 200L
HDPE drum 5L, 20L
HDPE bottle 5L
HDPE keg 60L
HDPE IBC 1000L

4.3.1 Use-specific instructions for use

4.3.2 Use-specific risk mitigation measures

- For maintenance of circuit system, 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) and chemical goggles
- 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.

4.3.3 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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5. General directions for use

5.1. Instructions for use

- Products should not be used in conjunction with acids or ammonia
- 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
- Rinse surfaces after treatment

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.

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

- Foaming products
- 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.