

Summary of product characteristics for a biocidal product

Product name: Javel 4.8 GP Oxena

Product type(s): 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)

Authorisation number: FR-2022-0008

R4BP 3 asset reference number: FR-0027862-0017

Table Of Contents

Administrative information	1
1.1. Trade names of the product	1
1.2. Authorisation holder	1
1.3. Manufacturer(s) of the biocidal products	2
1.4. Manufacturer(s) of the active substance(s)	2
2. Product composition and formulation	3
2.1. Qualitative and quantitative information on the composition of the biocidal product	3
2.2. Type of formulation	3
3. Hazard and precautionary statements	3
4. Authorised use(s)	4
5. General directions for use	13
5.1. Instructions for use	13
5.2. Risk mitigation measures	13
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment	13
5.4. Instructions for safe disposal of the product and its packaging	14
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage	14
6. Other information	14

Administrative information

1.1. Trade names of the product

Javel 4.8 GP Oxena
APTA JAVEL DOSE 3X250ML
NETTO JAVEL DOSE 3X250ML
ECO+ - EAU DE JAVEL 3X250 ML
BERLINGOTS JAVEL CONCENTREE 3x250ML SANS PARFUM TLJ
BERLINGOT JAVEL CONCENTREE SANS PARFUM 3x250ML LEADER PRICE
MIC
JAVEL 4,8% OXENA
JAVEL 4,8% DISTRICONCEPT
BERLINGOTS JAVEL CONCENTREE 3x250ML NON PARFUMEE TLJ
BERLINGOTS JAVEL CONCENTREE NON PARFUMEE 3x250ML LEADER PRICE
BERLINGOTS JAVEL 4,8% C.A. 3x250ML NON PARFUMEE TLJ
BERLINGOTS JAVEL 4,8% C.A. NON PARFUMEE 3x250ML LEADER PRICE
EAU DE JAVEL NON PARFUMEE ECO+ 3X250ML

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 1-5	
R4BP 3 asset reference number	FR-0027862-0017	
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			4,8
Sodium hydroxide	Sodium hydroxide	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 skin irritation.
Causes serious eye damage.
Very toxic to aquatic life with long lasting effects.
Contact with acids liberates toxic gas.
Warning! Do not use together with other products. May release dangerous gases (chlorine).

Precautionary statements

Wash thoroughly after handling.
Avoid release to the environment.
IF ON SKIN: Wash with plenty of soap and water.
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).
If skin irritation occurs: Get medical .
Take off contaminated clothing. And wash it before reuse.
Collect spillage.

Dispose of to .

If medical advice is needed, have product container or label at hand.

Keep out of reach of children.

Read carefully and follow all instructions.

4. Authorised use(s)

4.1 Use description

Use 1 - Disinfection of sanitary installations

Product type	PT02 - Disinfectants and algacides 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)	<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	<p>Indoor</p> <p>Medical sector Non medical sector</p>
Application method(s)	<p>Method: Pouring Detailed description: -</p>
Application rate(s) and frequencies	<p>Application Rate: Non medical sector: Clean conditions: Bacteria (obligatory): 413 mg/L a.c, contact time: 5 min Bacteria and yeasts (optional): 413 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 1075 mg/L a.c, contact time: 15 min Dirty conditions: Bacteria (obligatory): 1961 mg/L a.c, contact time: 5 min Bacteria and yeasts (optional): 1961 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 2270 mg/L a.c, contact time: 15 min Medical sector: Clean conditions: Contact time: 15 min Bacteria / Yeasts (obligatory): 413 mg/L a.c, Bacteria, yeasts and fungi (optional): 1135 mg/L a.c Dilution (%): 0 Number and timing of application: Non medical sector:</p> <p>Clean conditions:</p>

Bacteria (obligatory): 413 mg/L a.c, contact time: 5 min

Bacteria and yeasts (optional): 413 mg/L a.c, contact time: 15 min

Bacteria, yeasts and fungi (optional): 1075 mg/L a.c, contact time: 15 min

Dirty conditions:

Bacteria (obligatory): 1961 mg/L a.c, contact time: 5 min

Bacteria and yeasts (optional): 1961 mg/L a.c, contact time: 15 min

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

Medical sector:

Clean conditions:

Contact time: 15 min

Bacteria / Yeasts (obligatory): 413 mg/L a.c,

Bacteria, yeasts and fungi (optional): 1135 mg/L a.c

Category(ies) of users

General public (non-professional)

Pack sizes and packaging material

PVC berlingot 250 mL HDPE bottle 1 L

HDPE can 5 L, 20L

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 fro surfaces that are likely to come into contact with 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.

4.1.2 Use-specific risk mitigation measures

- Avoid any direct or indirect contact with food.

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 (non medical sector)

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: Fungi
Development stage:

Field(s) of use

Indoor
Non medical sector

Application method(s)

Method: Mopping
Detailed description:
no mechanical action

Method: Pouring
Detailed description:
no mechanical action

Method: Wiping (no mechanical action)
Detailed description:
-

Method: Scrubbing
Detailed description:
No mechanical action

Application rate(s) and frequencies

Application Rate: Clean conditions: Bacteria (obligatory): 413 mg/L a.c, contact time: 5 min Bacteria and yeasts (optional): 413 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 1135 mg/L a.c, contact time: 15 min Dirty conditions: Bacteria (obligatory): 1961 mg/L a.c, contact time: 5 min Bacteria and yeasts (optional): 1961 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): 413 mg/L a.c, contact time: 5 min

Bacteria and yeasts (optional): 413 mg/L a.c, contact time: 15 min

Bacteria, yeasts and fungi (optional): 1135 mg/L a.c, contact time: 15 min

Dirty conditions:

Bacteria (obligatory): 1961 mg/L a.c, contact time: 5 min

Bacteria and yeasts (optional): 1961 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): 413 mg/L a.c, contact time: 5 min Bacteria and yeasts (optional): 413 mg/L a.c, contact time: 15 min Bacteria, yeasts and fungi (optional): 1135 mg/L a.c, contact time: 15 min Dirty conditions: Bacteria (obligatory): 1961 mg/L a.c, contact time: 5 min Bacteria and yeasts (optional): 1961 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): 413 mg/L a.c, contact time: 5 min

Bacteria and yeasts (optional): 413 mg/L a.c, contact time: 15 min

Bacteria, yeasts and fungi (optional): 1135 mg/L a.c, contact time: 15 min

Dirty conditions:

Bacteria (obligatory): 1961 mg/L a.c, contact time: 5 min

Bacteria and yeasts (optional): 1961 mg/L a.c, contact time: 15 min

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

Application Rate: Expressed as active chlorine : Bacteria: clean conditions, contact time 5 min, 390 mg/L; Bacteria: dirty conditions, contact time 5 min, 1820 mg/L; Fungal spore: clean conditions, contact time 15 min, 1040 mg/L; Fungal spore: dirty conditions, contact time 15 min, 2080 mg/L; Yeast: clean conditions, contact time 15 min, 260 mg/L; Yeast: dirty conditions, contact time 15 min, 1040 mg/L; Virus: dirty conditions, contact time 15 min, 2080 mg/L

Dilution (%): 0

Number and timing of application:

Clean conditions:

Bacteria (obligatory): 413 mg/L a.c, contact time: 5 min

Bacteria and yeasts (optional): 413 mg/L a.c, contact time: 15 min

Bacteria, yeasts and fungi (optional): 1135 mg/L a.c, contact time: 15 min

Dirty conditions:

Bacteria (obligatory): 1961 mg/L a.c, contact time: 5 min

Bacteria and yeasts (optional): 1961 mg/L a.c, contact time: 15 min

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

Application Rate: Expressed as active chlorine : Bacteria: clean conditions, contact time 5 min, 390 mg/L; Bacteria: dirty conditions, contact time 5 min, 1820 mg/L; Fungal spore: clean conditions, contact time 15 min, 1040 mg/L; Fungal spore: dirty conditions, contact time 15 min, 2080 mg/L; Yeast: clean conditions, contact time 15 min, 260 mg/L; Yeast: dirty conditions, contact time 15 min, 1040 mg/L; Virus: dirty conditions, contact time 15 min, 2080 mg/L

Dilution (%): 0

Number and timing of application:

Clean conditions:

Bacteria (obligatory): 413 mg/L a.c, contact time: 5 min

Bacteria and yeasts (optional): 413 mg/L a.c, contact time: 15 min

Bacteria, yeasts and fungi (optional): 1135 mg/L a.c, contact time: 15 min

Dirty conditions:

Bacteria (obligatory): 1961 mg/L a.c, contact time: 5 min

Bacteria and yeasts (optional): 1961 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

General public (non-professional)

Pack sizes and packaging material

PVC berlingot 250 mL HDPE bottle 1 L

HDPE can 5 L, 20L

4.2.1 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 5 or 15 minutes (depending on the target organism), then mop/wipe scrub if required.
- Clean carefully the surfaces before application of the product for applications in clean conditions.

4.2.2 Use-specific risk mitigation measures

- Avoid any direct or indirect contact with food
- 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

4.2.3 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 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)

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: Mopping
Detailed description:
no mechanical action

Method: Pouring
Detailed description:
no mechanical action

Method: Wiping (no mechanical action)
Detailed description:
-

Method: Scrubbing
Detailed description:
no mechanical action

Application rate(s) and frequencies

Application Rate: Clean conditions: Contact time: 15 min Bacteria, yeasts (obligatory): 413 mg/L a.c Bacteria, yeasts and fungi (optional): 1135 mg/L a.c Dirty conditions: Contact time: 15 min Bacteria, yeasts (obligatory): 1961 mg/L a.c, Bacteria, yeasts and fungi (optional): 2270 mg/L a.c
Dilution (%): 0
Number and timing of application:
Clean conditions:
Contact time: 15 min
Bacteria, yeasts (obligatory): 413 mg/L a.c
Bacteria, yeasts and fungi (optional): 1135 mg/L a.c

Dirty conditions:
Contact time: 15 min
Bacteria, yeasts (obligatory): 1961 mg/L a.c,
Bacteria, yeasts and fungi (optional): 2270 mg/L a.c

Application Rate: Clean conditions: Contact time: 15 min Bacteria, yeasts (obligatory): 413 mg/L a.c Bacteria, yeasts and fungi (optional): 1135 mg/L a.c Dirty conditions: Contact time: 15 min Bacteria, yeasts (obligatory): 1961 mg/L a.c, Bacteria, yeasts and fungi (optional): 2270 mg/L a.c
Dilution (%): 0
Number and timing of application:
Clean conditions:
Contact time: 15 min
Bacteria, yeasts (obligatory): 413 mg/L a.c
Bacteria, yeasts and fungi (optional): 1135 mg/L a.c

Dirty conditions:
Contact time: 15 min
Bacteria, yeasts (obligatory): 1961 mg/L a.c,
Bacteria, yeasts and fungi (optional): 2270 mg/L a.c

Application Rate: Clean conditions: Contact time: 15 min Bacteria, yeasts (obligatory): 413 mg/L a.c Bacteria, yeasts and fungi (optional): 1135 mg/L a.c Dirty conditions: Contact time: 15 min Bacteria, yeasts (obligatory): 1961 mg/L a.c, Bacteria, yeasts and fungi (optional): 2270 mg/L a.c
Dilution (%): 0
Number and timing of application:
Clean conditions:
Contact time: 15 min
Bacteria, yeasts (obligatory): 413 mg/L a.c
Bacteria, yeasts and fungi (optional): 1135 mg/L a.c

Dirty conditions:
Contact time: 15 min
Bacteria, yeasts (obligatory): 1961 mg/L a.c,
Bacteria, yeasts and fungi (optional): 2270 mg/L a.c

Application Rate: Clean conditions: Contact time: 15 min Bacteria, yeasts (obligatory): 413 mg/L a.c Bacteria, yeasts and fungi (optional): 1135 mg/L a.c Dirty conditions: Contact time: 15 min Bacteria, yeasts (obligatory): 1961 mg/L a.c, Bacteria, yeasts and fungi (optional): 2270 mg/L a.c
 Dilution (%): 0
 Number and timing of application:

Clean conditions:
 Contact time: 15 min
 Bacteria, yeasts (obligatory): 413 mg/L a.c
 Bacteria, yeasts and fungi (optional): 1135 mg/L a.c

Dirty conditions:
 Contact time: 15 min
 Bacteria, yeasts (obligatory): 1961 mg/L a.c,
 Bacteria, yeasts and fungi (optional): 2270 mg/L a.c

Category(ies) of users

General public (non-professional)

Pack sizes and packaging material

PVC berlingot 250 mL HDPE bottle 1 L
 HDPE can 5 L, 20L

4.3.1 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.
- Clean carefully the surfaces before application of the product for applications in clean conditions.

4.3.2 Use-specific risk mitigation measures

- Rinse surfaces after treatment.
- 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.

4.3.3 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

- Washing on hands after use
- Avoid contact with eyes
- A child proof closure is required.

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

• IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTER 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.

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

• If medical advice is needed, have product container or label at hand

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: 12 months
- Protect from frost.
- Protect from direct sunlight.
- Do not store above 30°C.
- Keep out of reach of children and non-target animal/pets

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 packaging must be adapted with a child proof closure.