

Summary of product characteristics for a biocidal product

Product name: LACTIVO 150 Hands

Product type(s): PT01 - Human hygiene (Disinfectants)

Authorisation number: EU-0027768-0000

R4BP 3 asset reference number: EU-0027768-0001

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Administrative information

1.1. Trade names of the product

LACTIVO 150 Hands
LACTIVO 150 Hands (pro and gp)

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Specialities Srl
	Address	Via Nazario Sauro, 11 24030 Berbenno Italy
Authorisation number	EU-0027768-0000 1-1	

R4BP 3 asset reference number

EU-0027768-0001

Date of the authorisation

02/08/2022

Expiry date of the authorisation

02/08/2032

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Specialities S.r.l.
Address of the manufacturer	Via Nazario Sauro 11 24030 Berbenno (BG) Italy
Location of manufacturing sites	c/o Specialities S.r.l., Via Nazario Sauro 11 24030 Berbenno (BG) Italy
	c/o Pharmac Italia S.r.l., Viale Umbria 55/57 20089 Rozzano (MI) Italy
	c/o Cosmopharmac S.r.l., Viale Umbria 102/104 20089 Rozzano (MI) Italy

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

Active substance	1421 - Lactic acid
Name of the manufacturer	Jungbunzlauer S.A.
Address of the manufacturer	Z. I Portuaire BP 32 67390 Marckolsheim France
Location of manufacturing sites	Z. I Portuaire BP 32 67390 Marckolsheim France
Active substance	1421 - Lactic acid
Name of the manufacturer	Purac Biochem bv
Address of the manufacturer	Arkelsedijk 46 4206 AC Gorinchem Netherlands
Location of manufacturing sites	Arkelsedijk 46 4206 AC Gorinchem Netherlands

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 (%)
Lactic acid		Active Substance		200-018-0	0,75

2.2. Type of formulation

Ready-to-use water based liquids

3. Hazard and precautionary statements

Hazard statements

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Precautionary statements

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4. Authorised use(s)

4.1 Use description

Use 1 - Hygienic handrub (professional and non-professional)

Product type

PT01 - Human hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Ready-to-use disinfectants for hands with a bactericidal, yeasticidal and virucidal efficacy only against enveloped virus in domestic, institutional and industrial area (Note: Products are not intended for use in medical area).

Target organism(s) (including development stage)

Scientific name: Enterococcus hirae
Common name: Bacteria, aerobic Gram-positive
Development stage:

Scientific name: Escherichia coli
Common name: Bacteria, aerobic Gram-negative
Development stage:

Scientific name: Pseudomonas aeruginosa
Common name: Bacteria, aerobic Gram-negative
Development stage:

Scientific name: Staphylococcus aureus
Common name: Bacteria, aerobic Gram-positive
Development stage:

Scientific name: Candida albicans
Common name: Yeasts
Development stage:

Scientific name: Vaccinia virus Ankara (MVA),
Common name: Enveloped viruses
Development stage:

Field(s) of use

Indoor

Outdoor

Hygienic handrub (Note: Products are not intended for use in medical area).

Application method(s)

Method: Manual application: Spreading, spraying and foam application

Detailed description:

Place 3mL on clean hands and wrists. Rub for at least 30 seconds. When the product is totally absorbed on the hands, repeat the application. Read label before use.

Application rate(s) and frequencies

Application Rate: Double application (3 mL 30 sec+when the product is totally absorbed on the hands 3 mL 30 sec)

Dilution (%): 0 % (Ready to use products)

Number and timing of application:

Apply once (double application), repeat if renewed hand disinfection is needed.

Category(ies) of users	Industrial Professional General public (non-professional)
Pack sizes and packaging material	Bag/Sack (HDPE, LDPE, PET, PE, PP): 0.05, 0.10, 0.45, 0.50, 0.75, 1 and 5 L with HDPE/PE cap Bottle (HDPE, LDPE, PET, PE, PP): 0.05, 0.075, 0.10, 0.42, 0.50, 0.75, 1 and 2 L with HDPE/PE cap. Jerry can (HDPE, LDPE): 5, 10, 11, 15 and 20 L with HPE/PE cap or tap (only industrial and professional) Drum (HDPE): 10, 20, 25, 100, 220 L with HPE/PE cap or tap (only industrial and professional) Bottle with spray/foam trigger (HDPE, LDPE, PET, PE, PP): 0.05, 0.075, 0.10, 0.42, 0.50, 0.75, 1 and 2 L with Spay and foam trigger. IBC: (HDPE): 1000 L with HPE/PE cap or tap (only industrial and professional)

4.1.1 Use-specific instructions for use

Place 3mL on clean hands and wrists. Rub for at least 30 seconds. When the product is totally absorbed on the hands, repeat the application. Apply once (double application), repeat if renewed hand disinfection is needed. Read the label before use.

4.1.2 Use-specific risk mitigation measures

Not foreseen (Simplified authorisation)

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

See general directions for use

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

See general directions for use

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

See general directions for use

5. General directions for use

5.1. Instructions for use

Place 3mL on clean hands and wrists. Rub for at least 30 seconds. When the product is totally absorbed on the hands, repeat the application. Apply once (double application), repeat if renewed hand disinfection is needed. Read label before use.

5.2. Risk mitigation measures

Additional statements:

For non-professional users: If medical advice is needed, have product container or label at hand.

For industrial and professional users only: Safety data sheet available on request.

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

First aid measures:

-IF INHALATED: If symptoms occur call POISON CENTER or a doctor

-IF SWALLOWED: If symptoms occur call POISON CENTER or a doctor

-IF IN EYE: If symptom occurs rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTER or a doctor

-Indication of any immediate medical attention and special treatment needed: If medical advice is needed, have product container or label at hand

Environmental precautions: No special measures required.

Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

5.4. Instructions for safe disposal of the product and its packaging

Do not discard the product or its packaging. Do not empty into drains. Recycle the product. When recycling is not possible, dispose through an authorized company in compliance with the local or national regulations.

Empty the containers before disposal. Do not reuse the emptied containers. Send the empty containers to recycling or to an authorized company in compliance with local and national regulations.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Protect from the frost.

Shelf-life: 24 months at room temperature (based on data obtained by accelerated stability)

Keep out of reach of children.

6. Other information

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