

Summary of product characteristics for a biocidal product family

Family name: LACTIVO 170 BPF

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

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

PT04 - Food and feed area (Disinfectants)

Authorisation number: EU-0030457-0000

R4BP 3 asset reference number: EU-0030457-0000

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Part I.- First information level

1. Administrative information

1.1. Family name

LACTIVO 170 BPF

1.2. Product type(s)

PT01 - Human hygiene (Disinfectants)

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

PT04 - Food and feed area (Disinfectants)

1.3. Authorisation holder

**Name and address of the
authorisation holder**

Name

Specialities Srl

Address

Via Nazario Sauro, 11 24030 Berbenno Italy

Authorisation number

EU-0030457-0000

**R4BP 3 asset reference
number**

EU-0030457-0000

Date of the authorisation

25/08/2023

**Expiry date of the
authorisation**

25/08/2033

1.4. Manufacturer(s) of the biocidal products

Name of the manufacturer	Specialities S.r.l.
Address of the manufacturer	Via Nazario Sauro 11 24030 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

1.5. 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 family composition and formulation

2.1. Qualitative and quantitative information on the composition of the family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,85 - 0,85

2.2. Type(s) of formulation

AL - Any other liquid

Ready-to-use water based liquids

Part II.- Second information level - meta SPC(s)

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC1 (Hygienic handwash)

1.2. Suffix to the authorisation number

1-1

1.3 Product type(s)

PT01 - Human hygiene (Disinfectants)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,85 - 0,85

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Precautionary statements

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Use 1 : Hygienic handwash (professional and non-professional)

Product type

PT01 - Human hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Place 4.5ml on wetted hands and wrists. Rub for at least 60 seconds, then rinse. Apply once, repeat if renewed hand disinfection is needed. Comply with the instructions for use.

Target organism(s) (including development stage)

Scientific name: Bacteria
Common name: Bacteria
Development stage:

Scientific name: Yeasts
Common name: Yeasts
Development stage:

Scientific name: Enveloped viruses
Common name: Enveloped viruses
Development stage:

Field(s) of use

Indoor

Outdoor

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

Application method(s)

Method: Manual application: Spreading, spraying and foam application.

Detailed description:

Place 4.5ml on wetted hands and wrists. Rub for at least 60 seconds, then rinse. Apply once, repeat if renewed hand disinfection is needed. Comply with the instructions for use.

Application rate(s) and frequencies

Application Rate: 4.5 ml (equivalent to three foam pumps)

	<p>Dilution (%): 0 % (Ready to use products) Number and timing of application: Apply once, repeat if renewed hand disinfection is needed.</p>
<p>Category(ies) of users</p>	<p>Industrial Professional General public (non-professional)</p>
<p>Pack sizes and packaging material</p>	<p>Bag/Sack (High-density polyethylene (HDPE), Low-density polyethylene (LDPE), Polyethylene terephthalate (PET), Polyethylene (PE), Polypropylene (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 HDPE/PE cap or tap (only industrial and professional). Drum (HDPE): 10, 20, 25, 100, 220 L with HDPE/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 Spray and foam trigger. IBC (HDPE): 1000 L with HDPE/PE cap or tap (only industrial and professional).</p>

4.1.1 Use-specific instructions for use

See section 5.1.

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 of the meta SPC

5.1. Instructions for use

Place 4.5ml on wetted hands and wrists. Rub for at least 60 seconds, then rinse. Apply once, repeat if renewed hand disinfection is needed. Comply with the instructions for use.

5.2. Risk mitigation measures

No specific risk mitigation measures

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

Description of first aid measures

- IF INHALED: If symptoms occur call POISON CENTER or a doctor
- IF SWALLOWED: If symptoms occur call POISON CENTER or a doctor
- IF IN EYE: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTER or a doctor
- IF ON SKIN: If irritation occurs wash with water and seek medical advice. In cases of unintentional skin exposure: wash with water.

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

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.

5.4. 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

Shelf-life: 24 months at room temperature. Protect from frost.

Keep out of reach of children and non-target animals/pets.

6. Other information

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7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	LACTIVO 170 Handsoap	Market area: EU
	LACTIVO 170 Handsoap (pro and gp)	Market area: EU
Authorisation number <small>(R4BP 3 asset reference number - National Authorisation)</small>	EU-0030457-0001 1-1	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,85

Trade name(s)	LACTIVO 170 CI 02 Handsoap	Market area: EU
	LACTIVO 170 CI 02 Handsoap (pro and gp)	Market area: EU
Authorisation number		

(R4BP 3 asset reference number - National
Authorisation)

EU-0030457-0002 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,85

Trade name(s)

LACTIVO 170 CI Handsoap

Market area: EU

LACTIVO 170 CI Handsoap (pro and gp)

Market area: EU

Authorisation number

(R4BP 3 asset reference number - National
Authorisation)

EU-0030457-0003 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,85

Trade name(s)

LACTIVO 170 CO 02 Handsoap	Market area: EU
LACTIVO 170 CO 02 Handsoap (pro and gp)	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0030457-0004 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,85

Trade name(s)

LACTIVO 170 CO Handsoap	Market area: EU
LACTIVO 170 CO Handsoap (pro and gp)	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0030457-0005 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,85

Trade name(s)

LACTIVO 170 FEE 02 Handsoap

Market area: EU

LACTIVO 170 FEE 02 Handsoap (pro and gp)

Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0030457-0006 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,85

Trade name(s)

LACTIVO 170 FEE Handsoap

Market area: EU

LACTIVO 170 FEE Handsoap (pro and gp)

Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0030457-0007 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,85

Trade name(s)

LACTIVO 170 LT 02 Handsoap	Market area: EU
LACTIVO 170 LT 02 Handsoap (pro and gp)	Market area: EU
Authorisation number (R4BP 3 asset reference number - National Authorisation) EU-0030457-0008 1-1	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,85

Trade name(s)

LACTIVO 170 LT Handsoap	Market area: EU
LACTIVO 170 LT Handsoap (pro and gp)	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0030457-0009 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,85

Trade name(s)

LACTIVO 170 ML 02 Handsoap

Market area: EU

LACTIVO 170 ML 02 Handsoap (pro and gp)

Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0030457-0010 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,85

Trade name(s)

LACTIVO 170 ML Handsoap	Market area: EU
LACTIVO 170 ML Handsoap (pro and gp)	Market area: EU
Authorisation number (R4BP 3 asset reference number - National Authorisation) EU-0030457-0011 1-1	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,85

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC2 (Surface disinfection)

1.2. Suffix to the authorisation number

1-2

1.3 Product type(s)

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
PT04 - Food and feed area (Disinfectants)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,85 - 0,85

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Precautionary statements

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Use 1 : Multi surfaces disinfection (professional and non-professional)

Product type

PT02 - Disinfectants and algicides 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

Apply the product by fully wetting all surface (about 20 ml/m²) for 5 minutes. Rub or brush if necessary. If the product is applied on surfaces in contact with food, rinse thoroughly with drinking water. Apply once. Repeat the application if necessary. Comply with the instructions for use.

Target organism(s) (including development stage)

Scientific name: Bacteria
Common name: Bacteria
Development stage:

	<p>Scientific name: Yeasts Common name: Yeasts Development stage:</p> <p>Scientific name: Enveloped viruses Common name: Enveloped viruses Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>Outdoor</p> <p>Multi surfaces disinfection (professional and non-professional). Note: Products are not intended for use in medical area or for milk and meat industry.</p>
Application method(s)	<p>Method: Manual application: Spreading, spraying and foam application. Detailed description: Apply the product by fully wetting all surface (about 20 ml/m²) for 5 minutes. Rub or brush if necessary. If the product is applied on surfaces in contact with food, rinse thoroughly with drinking water. Apply once. Repeat the application if necessary. Comply with the instructions for use.</p>
Application rate(s) and frequencies	<p>Application Rate: Ready-to-use products Dilution (%): 0 % (Ready to use products) Number and timing of application: Apply once. Repeat the application if necessary.</p>
Category(ies) of users	<p>Industrial</p> <p>Professional</p> <p>General public (non-professional)</p>
Pack sizes and packaging material	<p>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.</p> <p>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.</p> <p>Jerry can (HDPE, LDPE): 5, 10, 11, 15 and 20 L with HDPE/PE cap or tap (only industrial and professional).</p> <p>Drum (HDPE): 10, 20, 25, 100, 220 L with HDPE/PE cap or tap (only industrial and professional).</p> <p>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 Spray and foam trigger.</p> <p>IBC (HDPE): 1000 L with HDPE/PE cap or tap (only industrial and professional).</p>

4.1.1 Use-specific instructions for use

See section 5.1.

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 of the meta SPC

5.1. Instructions for use

Apply the product by fully wetting all surface (about 20 ml/m²) for 5 minutes. Rub or brush if necessary. If the product is applied on surfaces in contact with food, rinse thoroughly with drinking water. Apply once. Repeat the application if necessary. Comply with the instructions for use.

5.2. Risk mitigation measures

No specific risk mitigation measures.

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

Direction for the first aid:
- IF INHALED: If symptoms occur call POISON CENTER or a doctor
- IF SWALLOWED: If symptoms occur call POISON CENTER or a doctor
- IF IN EYE: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTER or a doctor

- IF ON SKIN: Wash skin with water. If symptoms occur call POISON CENTER or a doctor
Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

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.

5.4. 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.

Recommended cleansing agents: Water.

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

Shelf-life: 24 months at room temperature. Protect from frost.

Keep out of reach of children and non-target animals/pets.

6. Other information

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)

LACTIVO 170 Surfaces

Market area: EU

LACTIVO 170 Multi Surfaces (pro and gp)

Market area: EU

Authorisation number

EU-0030457-0012 1-2

(R4BP 3 asset reference number - National Authorisation)

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,85

Trade name(s)

LACTIVO 170 CI 02 Surfaces	Market area: EU
LACTIVO 170 CI 02 Multi Surfaces (pro and gp)	Market area: EU
Authorisation number (R4BP 3 asset reference number - National Authorisation) EU-0030457-0013 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,85

Trade name(s)

LACTIVO 170 CI Surfaces	Market area: EU
LACTIVO 170 CI Multi Surfaces (pro and gp)	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0030457-0014 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,85

Trade name(s)

LACTIVO 170 CO 02 Surfaces

Market area: EU

LACTIVO 170 CO 02 Multi Surfaces (pro and
gp)

Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0030457-0015 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,85

Trade name(s)

LACTIVO 170 CO Surfaces	Market area: EU
LACTIVO 170 CO Multi Surfaces (pro and gp)	Market area: EU
Authorisation number (R4BP 3 asset reference number - National Authorisation) EU-0030457-0016 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,85

Trade name(s)

LACTIVO 170 FEE 02 Surfaces	Market area: EU
LACTIVO 170 FEE 02 Multi Surfaces (pro and gp)	Market area: EU
Authorisation number (R4BP 3 asset reference number - National Authorisation) EU-0030457-0017 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,85

Trade name(s)

LACTIVO 170 FEE Surfaces

Market area: EU

LACTIVO 170 FEE Multi Surfaces (pro and gp)

Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0030457-0018 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,85

Trade name(s)

LACTIVO 170 LT 02 Surfaces

Market area: EU

LACTIVO 170 LT 02 Multi Surfaces (pro and gp)

Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0030457-0019 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,85

Trade name(s)

LACTIVO 170 LT Surfaces	Market area: EU
LACTIVO 170 LT Multi Surfaces (pro and gp)	Market area: EU
Authorisation number (R4BP 3 asset reference number - National Authorisation) EU-0030457-0020 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,85

Trade name(s)

LACTIVO 170 ML 02 Surfaces	Market area: EU
LACTIVO 170 ML 02 Multi Surfaces (pro and gp)	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0030457-0021 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,85

Trade name(s)

LACTIVO 170 ML Surfaces

Market area: EU

LACTIVO 170 ML Multi Surfaces (pro and gp)

Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

EU-0030457-0022 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,85
