

# Summary of product characteristics for a biocidal product family

**Family name:** LACTIVO 150 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-0027768-0000

**R4BP 3 asset reference number:** EU-0027768-0000

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## Part I.- First information level

### 1. Administrative information

#### 1.1. Family name

LACTIVO 150 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

<b>Name and address of the authorisation holder</b>	Name	Specialities Srl
	Address	Via Nazario Sauro, 11 24030 Berbenno Italy
<b>Authorisation number</b>	EU-0027768-0000	
<b>R4BP 3 asset reference number</b>	EU-0027768-0000	
<b>Date of the authorisation</b>	02/08/2022	
<b>Expiry date of the authorisation</b>	02/08/2032	

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

<b>Name of the manufacturer</b>	Specialities S.r.l.
<b>Address of the manufacturer</b>	Via Nazario Sauro 11 24030 Berbenno (BG) Italy
<b>Location of manufacturing sites</b>	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)

<b>Active substance</b>	1421 - Lactic acid
<b>Name of the manufacturer</b>	Jungbunzlauer S.A.
<b>Address of the manufacturer</b>	Z. I Portuaire BP 32 67390 Marckolsheim France
<b>Location of manufacturing sites</b>	Z. I Portuaire BP 32 67390 Marckolsheim France

<b>Active substance</b>	1421 - Lactic acid
<b>Name of the manufacturer</b>	Purac Biochem bv
<b>Address of the manufacturer</b>	Arkelsedijk 46 4206 AC Gorinchem Netherlands
<b>Location of manufacturing sites</b>	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	0,75 - 0,75

## 2.2. Type(s) of formulation

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 handrub)

#### 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	0,75 - 0,75

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

Formulation(s)

Ready-to-use water based liquids

## 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 - 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).

<b>Application method(s)</b>	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.
<b>Application rate(s) and frequencies</b>	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.
<b>Category(ies) of users</b>	Industrial Professional General public (non-professional)
<b>Pack sizes and packaging material</b>	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 of the meta SPC

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

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

<b>Trade name(s)</b>	LACTIVO 150 Hands	Market area: EU
	LACTIVO 150 Hands (pro and gp)	Market area: EU
<b>Authorisation number</b> <small>(R4BP 3 asset reference number - National Authorisation)</small>	EU-0027768-0001 1-1	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,75

**Trade name(s)**

LACTIVO 150 CI 02 Hands	Market area: EU
LACTIVO 150 CI 02 Hands (pro and gp)	Market area: EU

**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

EU-0027768-0002 1-1

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Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,75

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**Trade name(s)**

LACTIVO 150 CO 02 Hands	Market area: EU
LACTIVO 150 CO 02 Hands (pro and gp)	Market area: EU

**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

EU-0027768-0003 1-1

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Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,75

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**Trade name(s)**

LACTIVO 150 ML 02 Hands

Market area: EU

LACTIVO 150 ML 02 Hands (pro and gp)

Market area: EU

**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

EU-0027768-0004 1-1

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Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,75

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**Trade name(s)**

LACTIVO 150 LT 02 Hands

Market area: EU

LACTIVO 150 LT 02 Hands (pro and gp)

Market area: EU

**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

EU-0027768-0005 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,75

**Trade name(s)**

LACTIVO 150 FEE 02 Hands	Market area: EU
LACTIVO 150 FEE 02 Hands (pro and gp)	Market area: EU
<b>Authorisation number</b>  (R4BP 3 asset reference number - National Authorisation)  EU-0027768-0006 1-1	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,75

**Trade name(s)**

LACTIVO 150 CI Hands	Market area: EU
LACTIVO 150 CI Hands (pro and gp)	Market area: EU

**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

EU-0027768-0007 1-1

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Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,75

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**Trade name(s)**

LACTIVO 150 CO Hands

Market area: EU

LACTIVO 150 CO Hands (pro and gp)

Market area: EU

**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

EU-0027768-0008 1-1

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Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,75

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**Trade name(s)**

LACTIVO 150 ML Hands	Market area: EU
LACTIVO 150 ML Hands (pro and gp)	Market area: EU

**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

EU-0027768-0009 1-1

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Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,75

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**Trade name(s)**

LACTIVO 150 LT Hands	Market area: EU
LACTIVO 150 LT Hands (pro and gp)	Market area: EU

**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

EU-0027768-0010 1-1

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Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,75

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**Trade name(s)**

LACTIVO 150 FEE Hands

Market area: EU

LACTIVO 150 FEE Hands (pro and gp)

Market area: EU

**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

EU-0027768-0011 1-1

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Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,75

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**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	0,75 - 0,75

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

Formulation(s)

Ready-to-use water based liquids

## 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 - Multi surfaces disinfection (professional and non-professional)



<b>Product type</b>	<p>PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)</p> <p>PT04 - Food and feed area (Disinfectants)</p>
<b>Where relevant, an exact description of the authorised use</b>	<p>Ready-to-use disinfectants with a bactericidal, yeasticidal and virucidal efficacy only against enveloped viruses for hard surfaces in domestic, institutional and industrial area (Note: Products are not intended for use in medical area or for milk and meat industry)</p>
<b>Target organism(s) (including development stage)</b>	<p>Scientific name: Enterococcus hirae Common name: Bacteria, aerobic Gram-positive Development stage:</p> <p>Scientific name: Escherichia coli Common name: Bacteria, aerobic Gram-negative Development stage:</p> <p>Scientific name: Pseudomonas aeruginosa Common name: Bacteria, aerobic Gram-negative Development stage:</p> <p>Scientific name: Staphylococcus aureus Common name: Bacteria, aerobic Gram-positive Development stage:</p> <p>Scientific name: Candida albicans Common name: Yeasts Development stage:</p> <p>Scientific name: Vaccinia virus Ankara (MVA), ATCC VR-1508 Common name: Enveloped viruses Development stage:</p>
<b>Field(s) of use</b>	<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>
<b>Application method(s)</b>	<p>Method: Manual application: Spreading, Spraying and foam application</p> <p>Detailed description: Apply the product by fully wetting all surface (about 20 mL/m<sup>2</sup>) for 5 minutes. Rub or brush if necessary. Apply once. Repeat the application if necessary. If the product is applied on surfaces in contact with food, rinse thoroughly with drinking water. Read label before use.</p>
<b>Application rate(s) and frequencies</b>	<p>Application Rate: RTU products</p> <p>Dilution (%): 0 % (Ready to use products)</p> <p>Number and timing of application: Apply once. Repeat the application if necessary.</p>
<b>Category(ies) of users</b>	<p>Industrial</p> <p>Professional</p> <p>General public (non-professional)</p>
<b>Pack sizes and packaging material</b>	<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>

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

Apply the product by fully wetting all surface (about 20 mL/m<sup>2</sup>) 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. Read 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 of the meta SPC

### 5.1. Instructions for use

Apply the product by fully wetting all surface (about 20 mL/m<sup>2</sup>) 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. 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:

General information: No special measures required.

**-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

**- IF ON SKIN:** Wash skin with water. If symptoms occur call 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).

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

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

<b>Trade name(s)</b>	LACTIVO 150 Surfaces	Market area: EU
	LACTIVO 150 Multi Surfaces (pro and gp)	Market area: EU
<b>Authorisation number</b> <small>(R4BP 3 asset reference number - National Authorisation)</small>	EU-0027768-0012 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,75

<b>Trade name(s)</b>	LACTIVO 150 CI 02 Surfaces	Market area: EU
	LACTIVO 150 CI 02 Multi Surfaces (pro and gp)	Market area: EU
<b>Authorisation number</b>		

(R4BP 3 asset reference number - National Authorisation)

EU-0027768-0013 1-2

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Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,75

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**Trade name(s)**

LACTIVO 150 CO 02 Surfaces

Market area: EU

LACTIVO 150 CO 02 Multi Surfaces (pro and gp)

Market area: EU

**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

EU-0027768-0014 1-2

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Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,75

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**Trade name(s)**

LACTIVO 150 ML 02 Surfaces	Market area: EU
LACTIVO 150 ML 02 Multi Surfaces (pro and gp)	Market area: EU
<b>Authorisation number</b>  (R4BP 3 asset reference number - National Authorisation)  EU-0027768-0015 1-2	

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Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,75

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**Trade name(s)**

LACTIVO 150 LT 02 Surfaces	Market area: EU
LACTIVO 150 LT 02 Multi Surfaces (pro and gp)	Market area: EU
<b>Authorisation number</b>  (R4BP 3 asset reference number - National Authorisation)  EU-0027768-0016 1-2	

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Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,75

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**Trade name(s)**

LACTIVO 150 FEE 02 Surfaces

Market area: EU

LACTIVO 150 FEE 02 Multi Surfaces (pro and gp)

Market area: EU

**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

EU-0027768-0017 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,75

**Trade name(s)**

LACTIVO 150 CI Surfaces

Market area: EU

LACTIVO 150 CI Multi Surfaces (pro and gp)

Market area: EU

**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

EU-0027768-0018 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,75

**Trade name(s)**

LACTIVO 150 CO Surfaces	Market area: EU
LACTIVO 150 CO Multi Surfaces (pro and gp)	Market area: EU
<b>Authorisation number</b>  (R4BP 3 asset reference number - National Authorisation)  EU-0027768-0019 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,75

**Trade name(s)**

LACTIVO 150 ML Surfaces	Market area: EU
LACTIVO 150 ML Multi Surfaces (pro and gp)	Market area: EU

**Authorisation number**



(R4BP 3 asset reference number - National Authorisation)

EU-0027768-0020 1-2

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Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,75

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**Trade name(s)**

LACTIVO 150 LT Surfaces

Market area: EU

LACTIVO 150 LT Multi Surfaces (pro and gp)

Market area: EU

**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

EU-0027768-0021 1-2

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Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,75

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**Trade name(s)**

LACTIVO 150 FEE Surfaces	Market area: EU
LACTIVO 150 FEE Multi Surfaces (pro and gp)	Market area: EU
<b>Authorisation number</b>  (R4BP 3 asset reference number - National Authorisation)  EU-0027768-0022 1-2	

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Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid		Active Substance		200-018-0	0,75

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