



Rīga

Contains a time stamp
Nr. 4-6/991

Specialities S.r.l.
fabrizio.belli@specialities.it

Via Nazario Sauro, 11, 24030
Berbenno BG, Italy

On authorisation of the biocidal product family LACTIVO 150 BPF under the simplified authorisation procedure

Latvian Environment, Geology and Meteorology Centre (LEGMC) on 10th December 2021 received application for the simplified authorisation of the **LACTIVO 150 BPF** family in accordance with Chapter V of the *Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products* (Regulation (EU) 528/2012) submitted by **Specialities S.r.l.** through Register for Biocidal Products (Case No. BC-NJ072024-43).

LEGMC as Latvian competent authority has evaluated the above mentioned application and considers that biocidal product family meets the conditions of the Article 25 of the Regulation (EU) No 528/2012:

- the active substance Lactic acid (CAS No. 50-21-5, EC No. 200-018-0) in the biocidal products appears in Annex I of the Regulation (EU) No 528/2012 and satisfy the restriction specified in that Annex;
- the biocidal products do not contain any substances of concern;
- the biocidal products do not contain nanomaterials;
- the biocidal products are effective;
- the handling of the biocidal products and those intended use do not require personal protective equipment.

Therefore, LEGMC grants authorisation for LACTIVO 150 BPF family with **Lactic acid** (CAS No. 50-21-5, EC No. 200-018-0) as active substance at the concentration **0.75% w/w** for **product type 1** (human hygiene) **as hygienic handrub, product type 2** (disinfectants and algaecides not intended for direct application to humans or animals) **and product type 4** (food and feed area) **as surface disinfectant**.

LEGMC assigns an authorisation number EU-0027768-0000 for LACTIVO 150 BPF family.

In accordance with Asset numbers in R4BP3 the authorisation numbers for biocidal products within family are following:

Trade name	Other trade name	Authorisation number
LACTIVO 150 Hands	LACTIVO 150 Hands (pro and gp)	EU-0027768-0001
LACTIVO 150 CI 02 Hands	LACTIVO 150 CI 02 Hands (pro and gp)	EU-0027768-0002
LACTIVO 150 CO 02 Hands	LACTIVO 150 CO 02 Hands (pro and gp)	EU-0027768-0003
LACTIVO 150 ML 02 Hands	LACTIVO 150 ML 02 Hands (pro and gp)	EU-0027768-0004
LACTIVO 150 LT 02 Hands	LACTIVO 150 LT 02 Hands (pro and gp)	EU-0027768-0005
LACTIVO 150 FEE 02 Hands	LACTIVO 150 FEE 02 Hands (pro and gp)	EU-0027768-0006
LACTIVO 150 CI Hands	LACTIVO 150 CI Hands (pro and gp)	EU-0027768-0007
LACTIVO 150 CO Hands	LACTIVO 150 CO Hands (pro and gp)	EU-0027768-0008
LACTIVO 150 ML Hands	LACTIVO 150 ML Hands (pro and gp)	EU-0027768-0009
LACTIVO 150 LT Hands	LACTIVO 150 LT Hands (pro and gp)	EU-0027768-0010
LACTIVO 150 FEE Hands	LACTIVO 150 FEE Hands (pro and gp)	EU-0027768-0011
LACTIVO 150 Surfaces	LACTIVO 150 Multi Surfaces (pro and gp); LACTIVO 150 General Surfaces (pro)	EU-0027768-0012
LACTIVO 150 CI 02 Surfaces	LACTIVO 150 CI 02 Multi Surfaces (pro and gp); LACTIVO 150 CI 02 General Surfaces (pro)	EU-0027768-0013
LACTIVO 150 CO 02 Surfaces	LACTIVO 150 CO 02 Multi Surfaces (pro and gp); LACTIVO 150 CO 02 General Surfaces (pro)	EU-0027768-0014
LACTIVO 150 ML 02 Surfaces	LACTIVO 150 ML 02 Multi Surfaces (pro and gp); LACTIVO 150 ML 02 General Surfaces (pro)	EU-0027768-0015
LACTIVO 150 LT 02 Surfaces	LACTIVO 150 LT 02 Multi Surfaces (pro and gp); LACTIVO 150 LT 02 General Surfaces (pro)	EU-0027768-0016
LACTIVO 150 FEE Surfaces	LACTIVO 150 FEE 02 Multi Surfaces (pro and gp); LACTIVO 150 FEE 02 General Surfaces (pro)	EU-0027768-0017
LACTIVO 150 CI Surfaces	LACTIVO 150 CI Multi Surfaces (pro and gp); LACTIVO 150 CI General Surfaces (pro)	EU-0027768-0018

Trade name	Other trade name	Authorisation number
LACTIVO 150 CO Surfaces	LACTIVO 150 CO Multi Surfaces (pro and gp); LACTIVO 150 CO General Surfaces (pro)	EU-0027768-0019
LACTIVO 150 ML Surfaces	LACTIVO 150 ML Multi Surfaces (pro and gp); LACTIVO 150 ML General Surfaces (pro)	EU-0027768-0020
LACTIVO 150 LT Surfaces	LACTIVO 150 LT Multi Surfaces (pro and gp); LACTIVO 150 LT General Surfaces (pro)	EU-0027768-0021
LACTIVO 150 FEE Surfaces	LACTIVO 150 FEE Multi Surfaces (pro and gp); LACTIVO 150 FEE General Surfaces (pro)	EU-0027768-0022

The authorisation numbers are valid until 2nd August 2032.

A person placing on the market or using the biocidal products included in the biocidal product family shall comply with the conditions for placing on the market or use of the above mentioned biocidal product family set out in Annex I - III.

The biocidal products authorised in accordance with Article 26 of the Regulation (EU) 528/2012 may be made available on the market in all Member States according to conditions laid down in Article 27 of the Regulation (EU) 528/2012.

LEGMC sets the following post-authorisation condition:

the test report on long term storage stability at ambient temperature should be submitted until 1st September 2023.

Appendix:

Annex I - General information, 1 page;

Annex II - Summary of the product characteristics for the biocidal product family, 19 pages;

Annex III – Composition of the biocidal product family (CONFIDENTIAL), 9 pages.

Head of Information Analysis Department

A. Jantone

biocides@lvgmc.lv

GENERAL INFORMATION

The following conditions apply:

1. The authorisation numbers shall be indicated on the labels of the biocidal products.
1. Specialities S.r.l. shall inform LEGMC about any changes in accordance with Commission Implementing Regulation (EU) No 354/2013 of 18th April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council.
2. The biocidal products shall not be placed on the market unless it complies with the requirements and conditions of the authorisation specified in the Summary of Product Characteristics.
3. Specialities S.r.l. is fully responsible of the composition of the biocidal product`s, labels, instructions of use and it`s safety data sheets.
4. If the authorisation holder wants to continue to make available on the market the biocidal product family beyond the 2nd August 2032, a new application for authorisation under the simplified authorisation procedure must be submitted, preferable before the 31st January 2031.

Summary of product characteristics for a biocidal product family

LACTIVO 150 BPF

Product type 1 - Human hygiene (Disinfectants)
Product type 2 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Product type 4 - Food and feed area (Disinfectants)

Authorisation number: EU-0027768-0000

R4BP asset number: EU-0027768-0000

PART I
FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name	LACTIVO 150 BPF
------	-----------------

1.2. Product type(s)

Product type(s)	PT01 - Human hygiene (Disinfectants) PT02 - Disinfectants and algacides 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 S.r.l.
	Address	Via Nazario Sauro 11, 24030 Berbenno (BG) Italy
Authorisation number	EU-0027768-0000	
<i>R4BP asset number</i>	EU-0027768-0000	
Date of the authorisation	01.08.2022.	
Expiry date of the authorisation	01.08.2032.	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	Specialities S.r.l.
Address of 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

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

Active substance	Lactic acid
Name of manufacturer	Jungbunzlauer S.A.
Address of manufacturer	Z. I Portuaire BP 32, 67390 Marckolsheim France
Location of manufacturing sites	Z. I Portuaire BP 32, 67390 Marckolsheim France
Active substance	Lactic acid
Name of manufacturer	Purac Biochem bv
Address of 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 (%)	
					Min	Max
Lactic acid	2-hydroxypropanoic acid	Active Substance	50-21-5	200-018-0	0,75	0,75

2.2. Type(s) of formulation

Formulation(s)	Ready-to-use water based liquids
----------------	----------------------------------

PART II

SECOND INFORMATION LEVEL - META SPC(S)

META SPC 1

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 1 identifier

Identifier	meta SPC1 (Hygienic handrub)
------------	------------------------------

1.2. Suffix to the authorisation number

Number	-
--------	---

1.3. Product type(s)

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

2. META SPC 1 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Lactic acid	2-hydroxypropanoic acid	Active Substance	50-21-5	200-018-0	0,75	0,75

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
	oic acid					

2.2. Type(s) of formulation of the meta SPC 1

Formulation(s)	Ready-to-use water based liquids
----------------	----------------------------------

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	-
Precautionary statements	-

4. AUTHORISED USE(S) OF THE META SPC 1

4.1. Use description

Table 1. 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)	<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), Common name: Enveloped viruses Development stage: -</p>
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 frequency	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 USE¹ OF THE META SPC 1

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)

¹ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 1.

Keep out of reach of children.

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

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

Trade name(s)	LACTIVO 150 Hands	Market area: EU			
	LACTIVO 150 Hands (pro and gp)	Market area: EU			
Authorisation number	EU-0027768-0001				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-hydroxypropanoic acid	Active Substance	50-21-5	200-018-0	0,75

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

Trade name(s)	LACTIVO 150 CI 02 Hands	Market area: EU			
	LACTIVO 150 CI 02 Hands (pro and gp)	Market area: EU			
Authorisation number	EU-0027768-0002				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-hydroxypropanoic acid	Active Substance	50-21-5	200-018-0	0,75

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

Trade name(s)	LACTIVO 150 CO 02 Hands	Market area: EU			
	LACTIVO 150 CO 02 Hands (pro and gp)	Market area: EU			
Authorisation number	EU-0027768-0003				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-hydroxypropanoic acid	Active Substance	50-21-5	200-018-0	0,75

7.4. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	LACTIVO 150 ML 02 Hands	Market area: EU			
	LACTIVO 150 ML 02 Hands (pro and gp)	Market area: EU			
Authorisation number	EU-0027768-0004				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-hydroxypropanoic acid	Active Substance	50-21-5	200-018-0	0,75

7.5. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	LACTIVO 150 LT 02 Hands	Market area: EU			
	LACTIVO 150 LT 02 Hands (pro and gp)	Market area: EU			
Authorisation number	EU-0027768-0005				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-hydroxypropanoic acid	Active Substance	50-21-5	200-018-0	0,75

7.6. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	LACTIVO 150 FEE 02 Hands	Market area: EU			
	LACTIVO 150 FEE 02 Hands (pro and gp)	Market area: EU			
Authorisation number	EU-0027768-0006				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-hydroxypropanoic acid	Active Substance	50-21-5	200-018-0	0,75

7.7. **Trade name(s), authorisation number and specific composition of each individual product**

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

Authorisation number	EU-0027768-0007				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-hydroxypropanoic acid	Active Substance	50-21-5	200-018-0	0,75

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

Trade name(s)	LACTIVO 150 CO Hands	Market area: EU			
	LACTIVO 150 CO Hands (pro and gp)	Market area: EU			
Authorisation number	EU-0027768-0008				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-hydroxypropanoic acid	Active Substance	50-21-5	200-018-0	0,75

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

Trade name(s)	LACTIVO 150 ML Hands	Market area: EU			
	LACTIVO 150 ML Hands (pro and gp)	Market area: EU			
Authorisation number	EU-0027768-0009				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-hydroxypropanoic acid	Active Substance	50-21-5	200-018-0	0,75

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

Trade name(s)	LACTIVO 150 LT Hands	Market area: EU			
	LACTIVO 150 LT Hands (pro and gp)	Market area: EU			
Authorisation number	EU-0027768-0010				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-hydroxypropanoic acid	Active Substance	50-21-5	200-018-0	0,75

7.11. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	LACTIVO 150 FEE Hands	Market area: EU			
	LACTIVO 150 FEE Hands (pro and gp)	Market area: EU			
Authorisation number	EU-0027768-0011				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2- hydroxypropan oic acid	Active Substance	50-21-5	200-018-0	0,75

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

Identifier	meta SPC2 (Surface disinfection)
------------	----------------------------------

1.2. Suffix to the authorisation number

Number	-
--------	---

1.3. Product type(s)

Product type(s)	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
-----------------	--

2. META SPC 2 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Lactic acid	2- hydroxypropan oic acid	Active Substance	50-21-5	200-018-0	0,75	0,75

2.2. Type(s) of formulation of the meta SPC 2

Formulation(s)	Ready-to-use water based liquids
----------------	----------------------------------

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	-
Precautionary statements	-

4. AUTHORISED USE(S) OF THE META SPC 2

4.1. Use description

Table 2. Use # 1 – Multi surfaces disinfection (professional and non-professional)

Product type	PT02 - Disinfectants and algacides 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	Ready-to-use disinfectants with a bactericidal and yeasticidal efficacy 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)
Target organism(s) (including development stage)	<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>
Field(s) of use	Indoor Outdoor Multi surfaces disinfection (professional and non-professional). Note: Products are not intended for use in medical area or for milk and meat industry.
Application method(s)	Method: Manual application: Spreading, Spraying and foam application Detailed description: Apply the product by fully wetting all surface (about 20 mL/m ²) 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.
Application rate(s) and frequency	Application Rate: RTU products Dilution (%): 0 % (Ready to use products) Number and timing of application: Apply once. Repeat the application if necessary.
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*

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. 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.

4.2. Use description

Table 3. Use # 2 – General surfaces disinfection (professional)

Product type	PT02 - Disinfectants and algaecides 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	Ready-to-use disinfectants with a bactericidal, yeasticidal and virucidal efficacy only against enveloped viruses for hard surfaces in institutional and industrial area (Note: Products are not intended for use in medical area or for milk and meat industry).
Target organism(s) (including development stage)	<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>
Field(s) of use	Indoor Outdoor General surfaces disinfection (professional).Note: Products are not intended for use in medical area or for milk and meat industry.
Application method(s)	Method: Manual application: Spreading, Spraying and foam application Detailed description: Apply the product by fully wetting all surface (about 20 mL/m ²) 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.
Application rate(s) and frequency	Application Rate: RTU products Dilution (%): 0 % (Ready to use products) Number and timing of application:

	Apply once. Repeat the application if necessary.
Category(ies) of users	Industrial 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)

4.2.1. *Use-specific 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. Read label before the use.

4.2.2. *Use-specific risk mitigation measures*

Not foreseen (Simplified authorisation).

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*

See general directions for use.

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.2.5. *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 USE² OF THE META SPC 2

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. Read label before use.

² Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 2.

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

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE

META SPC 2

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

Trade name(s)	LACTIVO 150 Surfaces	Market area: EU			
	LACTIVO 150 Multi Surfaces (pro and gp)	Market area: EU			
	LACTIVO 150 General Surfaces (pro)	Market area: EU			
Authorisation number	EU-0027768-0012				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-hydroxypropanoic acid	Active Substance	50-21-5	200-018-0	0,75

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

Trade name(s)	LACTIVO 150 CI 02 Surfaces	Market area: EU			
	LACTIVO 150 CI 02 Multi Surfaces (pro and gp)	Market area: EU			
	LACTIVO 150 CI 02 General Surfaces (pro)	Market area: EU			
Authorisation number	EU-0027768-0013				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-hydroxypropanoic acid	Active Substance	50-21-5	200-018-0	0,75

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

Trade name(s)	LACTIVO 150 CO 02 Surfaces	Market area: EU			
	LACTIVO 150 CO 02 Multi Surfaces (pro and gp)	Market area: EU			
	LACTIVO 150 CO 02 General Surfaces (pro)	Market area: EU			
Authorisation number	EU-0027768-0014				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-	Active	50-21-5	200-018-0	0,75

	hydroxypropanoic acid	Substance			
--	-----------------------	-----------	--	--	--

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

Trade name(s)	LACTIVO 150 ML 02 Surfaces	Market area: EU			
	LACTIVO 150 ML 02 Multi Surfaces (pro and gp)	Market area: EU			
	LACTIVO 150 ML 02 General Surfaces (pro)	Market area: EU			
Authorisation number	EU-0027768-0015				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-hydroxypropanoic acid	Active Substance	50-21-5	200-018-0	0,75

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

Trade name(s)	LACTIVO 150 LT 02 Surfaces	Market area: EU			
	LACTIVO 150 LT 02 Multi Surfaces (pro and gp)	Market area: EU			
	LACTIVO 150 LT 02 General Surfaces (pro)	Market area: EU			
Authorisation number	EU-0027768-0016				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-hydroxypropanoic acid	Active Substance	50-21-5	200-018-0	0,75

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

Trade name(s)	LACTIVO 150 FEE 02 Surfaces	Market area: EU			
	LACTIVO 150 FEE 02 Multi Surfaces (pro and gp)	Market area: EU			
	LACTIVO 150 FEE 02 General Surfaces (pro)	Market area: EU			
Authorisation number	EU-0027768-0017				

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-hydroxypropanoic acid	Active Substance	50-21-5	200-018-0	0,75

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

Trade name(s)	LACTIVO 150 CI Surfaces	Market area: EU			
	LACTIVO 150 CI Multi Surfaces (pro and gp)	Market area: EU			
	LACTIVO 150 CI General Surfaces (pro)	Market area: EU			
Authorisation number	EU-0027768-0018				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-hydroxypropanoic acid	Active Substance	50-21-5	200-018-0	0,75

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

Trade name(s)	LACTIVO 150 CO Surfaces	Market area: EU			
	LACTIVO 150 CO Multi Surfaces (pro and gp)	Market area: EU			
	LACTIVO 150 CO General Surfaces (pro)	Market area: EU			
Authorisation number	EU-0027768-0019				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-hydroxypropanoic acid	Active Substance	50-21-5	200-018-0	0,75

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

Trade name(s)	LACTIVO 150 ML Surfaces	Market area: EU			
	LACTIVO 150 ML Multi Surfaces (pro and gp)	Market area: EU			
	LACTIVO 150 ML General Surfaces (pro)	Market area: EU			
Authorisation number	EU-0027768-0020				

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-hydroxypropanoic acid	Active Substance	50-21-5	200-018-0	0,75

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

Trade name(s)	LACTIVO 150 LT Surfaces	Market area: EU			
	LACTIVO 150 LT Multi Surfaces (pro and gp)	Market area: EU			
	LACTIVO 150 LT General Surfaces (pro)	Market area: EU			
Authorisation number	EU-0027768-0021				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-hydroxypropanoic acid	Active Substance	50-21-5	200-018-0	0,75

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

Trade name(s)	LACTIVO 150 FEE Surfaces	Market area: EU			
	LACTIVO 150 FEE Multi Surfaces (pro and gp)	Market area: EU			
	LACTIVO 150 FEE General Surfaces (pro)	Market area: EU			
Authorisation number	EU-0027768-0022				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Lactic acid	2-hydroxypropanoic acid	Active Substance	50-21-5	200-018-0	0,75