21.3.2025

2025/523

COMMISSION IMPLEMENTING REGULATION (EU) 2025/523

of 20 March 2025

amending Implementing Regulation (EU) 2023/1311 as regards administrative changes to the Union authorisation for the biocidal product family 'CVAS Biocidal Product Family based on L(+) Lactic Acid'

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 (1), and in particular Article 50(2) thereof,

Whereas:

- On 27 June 2023, Commission Implementing Regulation (EU) 2023/1311 (²) granted a Union authorisation, under number EU-0028957-0000, to CVAS Development GmbH for the making available on the market and use of the biocidal product family 'CVAS Biocidal Product Family based on L(+) Lactic Acid'. The Annex to that Implementing Regulation provides the summary of product characteristics ('SPC') for that biocidal product family.
- On 12 September 2023 and 4 July 2024, CVAS Development GmbH submitted to the European Chemicals Agency (2) (the Agency'), in accordance with Article 11(1) of Commission Implementing Regulation (EU) No 354/2013 (3), notifications of administrative changes to the Union authorisation for the biocidal product family 'CVAS Biocidal Product Family based on L(+) Lactic Acid', recorded in the register for biocidal products under case numbers BC-XW088611-94 and BC-PQ098457-00. The notified proposed changes concern the addition of trade names.
- On 13 October 2023 and 2 August 2024 (4), the Agency submitted to the Commission, in accordance with Article 11(3) of Implementing Regulation (EU) No 354/2013, opinions on the notified administrative changes to the Union authorisation for the biocidal product family 'CVAS Biocidal Product Family based on L(+) Lactic Acid'. In the opinions, the Agency concludes that the proposed changes are administrative changes as referred to in Article 50(3), point (a), of Regulation (EU) No 528/2012 and as specified in Title 1, Section 1, of the Annex to Implementing Regulation (EU) No 354/2013, and that after the implementation of the changes, the conditions of Article 19 of Regulation (EU) No 528/2012 will still be met.
- (4)On 26 July 2024, the Agency transmitted to the Commission the revised summary of the biocidal product characteristics of the Union authorisation for the biocidal product family 'CVAS Biocidal Product Family based on L(+) Lactic Acid' in all official languages of the Union, covering all administrative changes applied for, in accordance with Article 11(6) of Implementing Regulation (EU) No 354/2013.
- The Commission concurs with the opinions of the Agency and therefore considers it appropriate to amend the Union authorisation for the biocidal product family 'CVAS Biocidal Product Family based on L(+) Lactic Acid' to introduce the administrative changes requested by CVAS Development GmbH.

⁽¹) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.

Commission Implementing Regulation (EU) 2023/1311 of 27 June 2023 granting a Union authorisation for the biocidal product family 'CVAS Biocidal Product Family based on L(+) Lactic Acid' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 162, 28.6.2023, p. 11, ELI: http://data.europa.eu/eli/reg_impl/2023/1311/oj).

Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p. 4, ELI: http://data.europa. eu/eli/reg_impl/2013/354/oj).

⁽⁴⁾ ECHA opinions UAD-C-1688636-18-00/F of 13 October 2023 and UAD-C-1756814-27-00/F of 2/08/2024 on administrative changes of the Union authorisation of the biocidal product family 'CVAS Biocidal Product Family based on L(+) Lactic Acid', https:// echa.europa.eu/opinions-on-union-authorisation.

(6) Except for the amendments regarding the administrative changes, all other information included in the summary of the biocidal product characteristics of 'CVAS Biocidal Product Family based on L(+) Lactic Acid' as set out in Annex to Implementing Regulation (EU) 2023/1311 remain unchanged.

- (7) In order to enhance clarity and to ease the access of users and interested parties to the consolidated version of the summary of the biocidal product characteristics which is to be published by the Agency, the Annex to Implementing Regulation (EU) 2023/1311 should be replaced in its entirety. Due to a change in the format used for the generation of the summary of biocidal product characteristics in the register for biocidal products in February 2024, the summary of biocidal product characteristics in that Annex should also include some minor editorial and layout changes.
- (8) Implementing Regulation (EU) No 2023/1311 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) 2023/1311 is replaced by the text set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 March 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product family

CVAS Biocidal Product Family based on L(+) Lactic Acid

Product type(s)

PT03: Veterinary hygiene

PT04: Food and feed area

Authorisation number EU-0028957-0000

R4BP asset number EU-0028957-0000

PART I

FIRST INFORMATION LEVEL

1. **ADMINISTRATIVE INFORMATION**

1.1. Family name

Name	CVAS Biocidal Product Family based on L(+) Lactic Acid
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1.2. **Product type(s)**

Product type(s)	PT03: Veterinary hygiene	
	PT04: Food and feed area	

1.3. Authorisation holder

Name and address of the authorisation holder	Name CVAS Development GmbH	
Name and address of the authorisation holder	Address Am Hafen 16 68526 Ladenburg DE	
Authorisation number		EU-0028957-0000
R4BP asset number		EU-0028957-0000
Date of the authorisation		18.7.2023
Expiry date of the authorisation		30.6.2033

1.4. Manufacturer(s) of the product

Name of manufacturer	Calvatis GmbH
Address of manufacturer	Am Hafen 16 68526 Ladenburg Germany
Location of manufacturing sites	Calvatis GmbH site 1 Am Hafen 16 68526 Ladenburg Germany

Name of manufacturer	Arthur Schopf Hygiene GmbH & Co. KG
Address of manufacturer	Pfaffensteinstraße 1 83115 Neubeuern Germany
Location of manufacturing sites	Arthur Schopf Hygiene GmbH & Co. KG site 1 Pfaffensteinstraße 1 83115 Neubeuern Germany

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

Active substance	L-(+)-lactic acid
Name of manufacturer	Purac Biochem by
Address of manufacturer	Arkelsedijk 46 4206AC Gorinchem Netherlands (the)
Location of manufacturing sites	Purac Biochem by site 1 Arkelsedijk 46 4206AC Gorinchem Netherlands (the)

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 (%)
L-(+)-lactic acid		active substance	79-33-4	201-196-2	1,92 - 17,6 % (w/w)
Methanesulpho- nic acid	Methanesulpho- nic acid	Non-Active substance	75-75-2	200-898-6	0 - 10,5 % (w/w)
Phosphoric acid	Phosphoric acid	Non-Active substance	7664-38-2	231-633-2	0 - 18,75 % (w/w)
Sulphuric acid	Sulphuric acid	Non-Active substance	7664-93-9	231-639-5	0 - 4,5 % (w/w)
Isononanoic acid	Isononanoic acid	Non-Active substance	3302-10-1	221-975-0	0 - 2,5 % (w/w)

2.2. Type(s) of formulation

Formulation type(s)	AL Any other liquid SL Soluble concentrate

PART II

SECOND INFORMATION LEVEL - META SPC(S)

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 1 identifier

Identifier	Meta SPC: mSPC1

1.2. Suffix to the authorisation number

Number	1-1

1.3. **Product type(s)**

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 (%)
L-(+)-lactic acid		active substance	79-33-4	201-196-2	1,92 - 1,96 % (w/w)

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

Formulation type(s)	AL Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	
Precautionary statements	

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1

Use # 1.1 – Teat-disinfection post-milking by manual or automated dipping

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts
	Development stage: no data

Field(s) of use	indoor use
	Teat-disinfection post-milking
Application method(s)	Method: Dipping
	Detailed description: Teat-disinfection post-milkingManual dipping using a dip cupAutomated dipping by robot
Application rate(s) and frequency	Application rate: Ready-To-Use (RTU) product, 1,92-1,96% L-(+)-lactic acid -
	Number and timing of application: 2-3 times a day (after each milking)
Category(ies) of users	professional
Pack sizes and packaging material	High density polyethylene (HDPE) jerrycan: 5-60 kg HDPE drum: 60-200 kg HDPE Intermediate Bulk Container (IBC): 600-1000 kg

4.1.1. Use-specific instructions

See general directions for use.

4.1.2. Use-specific risk mitigation measures

See general directions for use.

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 1

5.1. **Instructions for use**

The product must be brought to a temperature between 20°C and 30°C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill in the dosing pump reservoir with the RTU product. Avoid discharge of surplus fluids.

Apply the product by manual or automated dipping. Make sure that the teats are fully covered with disinfectant. Application volumes for cows and buffaloes - 5 ml/treatment and for sheep and goats - 3 ml/treatment.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection clean the application equipment by rinsing with water.

5.2. Risk mitigation measures

None

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

First aid instructions

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

IF ON SKIN: wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.

IF IN EYES: if symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

IF SWALLOWED: if symptoms occur call a POISON CENTRE or a doctor.

Emergency measure to protect the environment

Environmental precautions: do not allow product to reach sewage systems or water bodies.

Methods and material for containment and cleaning up: absorb with liquid-binding material (sand, diatomite, universal binder). Do not use combustible material like

sawdust. Dispose of the material collected in accordance with local regulations.

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

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements.

Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements.

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

Shelf life: 24 months

Do not store at temperatures above 40°C.

Keep away from heat and direct sunlight.

Protect from frost.

Keep container tightly closed.

6. OTHER INFORMATION

Not relevant

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)	calgodip Amadine Film	Market area: EU
	AGRIMARKT MILCHSÄUREMAN- TEL	Market area: EU
	IWETEC MILCHSÄURE DIPP	Market area: EU
	Fulldip Lacti Film	Market area: EU

		CareDip Film		Market area: EU		
ı		Milchsäure Film		Market ar	ea: EU	
		Lactoboost Film		Market ar	ea: EU	
		Bonimal CARE Lac Dip		Market area: EU		
		Bonimal CARE LactiVital Dip		Market area: EU		
		Impos Filmdipp M		Market are	ea: EU	
		Melkpower Filmdipp M		Market area: EU		
Authorisation number EU-		EU-0028957-0001 1-1				
Common name	IUPAC name	Function CAS		number	EC number	Content (%)
L-(+)-lactic acid		active substance	79-33	-4	201-196-2	1,92 % (w/w)

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

Trade name(s)	Dip es lac DL			Market area: EU		
Traylac O-F			Market area: EU			
		Baktostop Lactic		Market area: EU		
		Lacti-Bac Dip		Market area: EU		
		DS 1.0 F		Market area: EU		
Authorisation numb	er	EU-0028957-0002 1-1				
Common name	IUPAC name	Function	CAS	number	EC number	Content (%)
L-(+)-lactic acid		active substance	79-33	-4	201-196-2	1,92 % (w/w)

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

Trade name(s)	calgodip Blue Kamille Film	Market area: EU
	HappyFarm KamillDip Film	Market area: EU
	Lacto Film	Market area: EU
	MS Film	Market area: EU
	LA Film	Market area: EU
	BestFarm Blue Dip Film	Market area: EU
	Bonimal CARE Milky Dip	Market area: EU

			Bonimal CAR Dip	E Milki	Market aı	rea: EU	
			Bonimal CARE Milk Dip		Market area: EU		
			PQ-Blue Film		Market area: EU		
			Dipp Top		Market area: EU		
Authorisation 1	number	EU-0028957-0		-0003 1-1			
Commonname	IUPAC name	Function		CAS number		EC number	Content (%)
L-(+)-lactic acid		active sul	active substance			201-196-2	1,92 % (w/w)

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

Trade name(s) Dip es protect I		t DL	Market area: EU				
BaktoStop lactic		tic H	Market area: EU				
		Dip Agro Protect			Market area: EU		
			Kuhmilin Dip Top M		Market area: EU		
			Lacti-Protect Dip		Market area: EU		
			DSR 1.5 F		Market area: EU		
			ProfiMix inSilk		Market area: EU		
Authorisation	number		EU-0028957	-0004 1-1	•		
Commonname	IUPAC name	Function		CAS number		EC number	Content (%)
L-(+)-lactic acid		active sul	bstance	79-33-4		201-196-2	1,92 % (w/w)

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

identifier weta 51 C. III51 C2	Identifier	Meta SPC: mSPC2
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1.2. Suffix to the authorisation number

Number	1-2
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1.3. **Product type(s)**

Product type(s)	PT03: Veterinary hygiene
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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 (%)
L-(+)-lactic acid		active substance	79-33-4	201-196-2	6,8 - 6,8 % (w/w)

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

Formulation type(s)	AL Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	H315: Causes skin irritation.
	H318: Causes serious eye damage.
Precautionary statements	P264: Wash hands thoroughly after handling.
	P280: Wear protective gloves.
	P280: Wear eye protection.
	P302+P352: IF ON SKIN: Wash with plenty of water.
	P332+P313: If skin irritation occurs: Get medical advice.
	P332+P313: If skin irritation occurs: Get medical attention.
	P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P310: Immediately call a POISON CENTER.
	P310: Immediately call a doctor.
	P501: Dispose of contents to in accordance with local regulations.
	P501: Dispose of container to in accordance with local regulations.

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

4.1. Use description

Table 1

Use # 2.1 – Teat-disinfection post-milking by manual or automated dipping

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	-

Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data
	Scientific name: no data Common name: Yeasts Development stage: no data
Field(s) of use	indoor use
	Teat-disinfection post-milking
Application method(s)	Method: Dipping
	Detailed description: Teat-disinfection post-milkingManual dipping using a dip cupAutomated dipping by robot
Application rate(s) and frequency	Application rate: RTU product, 6,80% L-(+)-lactic acid -
	Number and timing of application: 2-3 times a day (after each milking)
Category(ies) of users	professional
Pack sizes and packaging material	HDPE jerrycan: 5-60 kg HDPE drum: 60-200 kg HDPE IBC: 600-1000 kg

4.1.1. Use-specific instructions

See general directions for use.

4.1.2. Use-specific risk mitigation measures

See general directions for use.

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 2

5.1. Instructions for use

The product must be brought to a temperature between 20°C and 30°C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill in the dosing pump reservoir with the RTU product. Avoid discharge of surplus fluids.

Apply the product by manual or automated dipping. Make sure that the teats are fully covered with disinfectant. Application volumes for cows and buffaloes - 5 ml/treatment and for sheep and goats - 3 ml/treatment.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection clean the application equipment by rinsing with water.

Keep out of reach of children.

5.2. Risk mitigation measures

Wear chemical goggles consistent with the European Standard EN ISO 16321 or equivalent, protective clothing chemically resistant to the biocidal product, chemical resistant gloves classified under the European Standard EN ISO 374 or equivalent. See section 6 for the full titles of the EN standards.

Google, gloves and coverall material to be specified by the authorisation holder within the product information.

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full reference to this act.

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

First aid instructions

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

IF ON SKIN: take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.

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 or an ambulance for medical assistance.

IF SWALLOWED: immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112 or an ambulance for medical assistance.

Emergency measure to protect the environment

Environmental precautions: do not allow product to reach sewage systems or water bodies.

Methods and material for containment and cleaning up: absorb with liquid-binding material (sand, diatomite, universal binder). Do not use combustible material like sawdust. Dispose of the material collected in accordance with local regulations.

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

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements.

Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements.

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

Shelf life: 24 months

Do not store at temperatures above 40°C.

Keep away from heat and direct sunlight.

Protect from frost.

Keep container tightly closed.

6. **OTHER INFORMATION**

The full titles of EN standards mentioned in the section 5.2 'Risk mitigation measures' are:

EN ISO 16321- Eye and face protection for occupational users.

EN ISO 374 – Protective gloves against dangerous chemicals and micro-organisms.

The full reference of the legal act mentioned in the section 5.2 'Risk mitigation measures' is:

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

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)		calgodip An Film		nadine forte	Market a	rea: EU	
Authorisation nu	ımber	EU-002895		7-0005 1-2			
Common name	IUPAC name	Function		CAS nu	mber	EC number	Content (%)
L-(+)-lactic acid		active su	bstance	79-33-4		201-196-2	6,8 % (w/w)

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

Trade name(s) Dip es lac I		LX Market area: EU					
Authorisation number EU-002		EU-002895	7-0006 1-2				
Common name	IUPAC name	Function		CAS nu	mber	EC number	Content (%)
L-(+)-lactic acid		active substance		79-33-4		201-196-2	6,8 % (w/w)

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

Trade name(s)		calgodip Blu forte Film		ıe Kamille	Market a	rea: EU	
Authorisation nu	ımber	EU-002895		7-0007 1-2			
Common name	IUPAC name	Function		CAS nu	mber	EC number	Content (%)
L-(+)-lactic acid		active substance		79-33-4		201-196-2	6,8 % (w/w)

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

Trade name(s) Dip es pr		Dip es prote	otect DLX Market area: EU				
Authorisation number EU-00289		7-0008 1-2					
Common name	IUPAC name	Function		CAS nu	mber	EC number	Content (%)
L-(+)-lactic acid		active substance		79-33-4		201-196-2	6,8 % (w/w)

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 3 identifier

Identifier	Meta SPC: mSPC3

1.2. Suffix to the authorisation number

	Number	1-3
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1.3. **Product type(s)**

Product type(s)	PT03: Veterinary hygiene

2. META SPC 3 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		active substance	79-33-4	201-196-2	1,92 - 1,96 % (w/w)

2.2. Type(s) of formulation of the meta SPC 3

Formulation type(s) AL A	ny other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

Hazard statements	
Precautionary statements	

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Use # 3.1 – Teat-disinfection post-milking by manual or automated dipping or spraying

Table 1

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data
	Common name: Yeasts Development stage: no data
Field(s) of use	indoor use
	Teat-disinfection post-milking
Application method(s)	Method: Dipping
	Detailed description: Teat-disinfection post-milkingManual dipping using a dip cupAutomated dipping by robot Method: Spraying
	Detailed description: Teat-disinfection post-milkingManual spraying using a trigger sprayerManual spraying using an electronic sprayerAutomated spraying by robot
Application rate(s) and frequency	Application rate: RTU product, 1,92-1,96% L-(+)-lactic acid -
	Number and timing of application: 2-3 times a day (after each milking)
	Application rate: RTU product, 1,92-1,96% L-(+)-lactic acid - Number and timing of application: 2-3 times a day (after each milking)
Category(ies) of users	professional
Pack sizes and packaging material	HDPE jerrycan: 5-60 kg HDPE drum: 60-200 kg HDPE IBC: 600-1000 kg

4.1.1. Use-specific instructions

See general directions for use.

4.1.2. Use-specific risk mitigation measures

See general directions for use.

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 3

5.1. Instructions for use

The product must be brought to a temperature between 20°C and 30°C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill in the dosing pump reservoir with the RTU product. Avoid discharge of surplus fluids.

Apply the product by manual or automated dipping or spraying. Make sure that the teats are fully covered with disinfectant. Application volumes for cows and buffaloes - 5 ml/treatment and for sheep and goats - 3 ml/treatment.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection clean the application equipment by rinsing with water.

5.2. Risk mitigation measures

None

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

First aid instructions

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

IF ON SKIN: wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.

IF IN EYES: if symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

IF SWALLOWED: if symptoms occur call a POISON CENTRE or a doctor.

Emergency measure to protect the environment

Environmental precautions: do not allow product to reach sewage systems or water bodies.

Methods and material for containment and cleaning up: absorb with liquid-binding material (sand, diatomite, universal binder). Do not use combustible material like sawdust. Dispose of the material collected in accordance with local regulations.

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

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements.

Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements.

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

Shelf life: 24 months

Do not store at temperatures above 40°C.

Keep away from heat and direct sunlight.

Protect from frost.

Keep container tightly closed.

6. OTHER INFORMATION

Not relevant

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3

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

Trade name(s)			calgodip An Spray	nadine	Market a	rea: EU	
		AGRIMARKT MILCHSÄURENEBEL		Market a	rea: EU		
			IWETEC MILCHSÄURE SPRAY		Market a	rea: EU	
			Fulldip Lact	i Spray	Market a	rea: EU	
			CareDip Spi	ray	Market a	rea: EU	
			Milchsäure Spray		Market a	rea: EU	
			Lactoboost Spray Care4cows Lactic Acid Spray Bonimal CARE Lac Spray		Market area: EU		
					Market a	rea: EU	
					Market a	rea: EU	
			Bonimal CA LactiVital Sp		Market a	rea: EU	
Authorisation number EU		EU-0028957-0009 1-3					
Common name	IUPAC name	Function		CAS nu	mber	EC number	Content (%)
L-(+)-lactic acid		active substance		79-33-4		201-196-2	1,92 % (w/w)

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

Trade name(s)		Dip es lac DL Spray		Market area: EU			
		Traylac O-S		Market area: EU			
	La		Lacti-Bac Spray Market an		irea: EU		
			DS 1.0 S		Market area: EU		
Authorisation number EU-00289		EU-002895	7-0010 1-3	l			
Common name	IUPAC name	Function		CAS nu	mber	EC number	Content (%)
L-(+)-lactic acid		active substance		79-33-4		201-196-2	1,92 % (w/w)

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

Trade name(s)	ame(s)			ıe Kamille	Market area: EU				
		HappyFarm KamillDip Spray				Market area: EU			
			Lacto Spray		Market a	rea: EU			
			MS Spray		Market a	rea: EU			
			LA Spray		Market a	rea: EU			
	Care4Cows Lactic Acid Kamille Spray BestFarm Blue Dip Spray		Market area: EU						
				ue Dip	Market area: EU				
			Bonimal CA Spray	ARE Milky	Market a	rea: EU			
				Bonii Spray		ARE Milki	Market area: EU		
			Bonimal CA Spray	ARE Milk	Market a	rea: EU			
	I		PQ-Blue Spi	PQ-Blue Spray		Market area: EU			
Authorisation number E		EU-0028957-0011 1-3		•					
Common name	IUPAC name	Function		CAS nu	mber	EC number	Content (%)		
L-(+)-lactic acid		active substance		79-33-4		201-196-2	1,92 % (w/w)		

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

Trade name(s)			Dip es prote	ect DL Spray	Market area: EU		
			Dip Agro Protect SP		Market area: EU		
K			Kuhmilin Sprüh Top M Market area: EU				
			Lacti-Protect Spray		Market a	rea: EU	
			DSR 1.5 S		Market a	rea: EU	
Authorisation nu	Authorisation number EU-002895		7-0012 1-3	•			
Common name	IUPAC name	Function		CAS nu	mber	EC number	Content (%)
L-(+)-lactic acid		active substance		79-33-4		201-196-2	1,92 % (w/w)

1. META SPC 4 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 4 identifier

Identifier	Meta SPC: mSPC4

1.2. Suffix to the authorisation number

Number	1-4

1.3. **Product type(s)**

Product type(s)	PT03: Veterinary hygiene
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2. META SPC 4 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 4

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		active substance	79-33-4	201-196-2	6,8 - 6,8 % (w/w)

2.2. Type(s) of formulation of the meta SPC 4

Formulation type(s)	AL Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4

Hazard statements	H315: Causes skin irritation.
	H318: Causes serious eye damage.
Precautionary statements	P264: Wash hands thoroughly after handling.
	P280: Wear protective gloves.
	P280: Wear eye protection.
	P302+P352: IF ON SKIN: Wash with plenty of water.
	P332+P313: If skin irritation occurs: Get medical advice.
	P332+P313: If skin irritation occurs: Get medical attention.
	P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P310: Immediately call a POISON CENTER.
	P310: Immediately call a doctor.
	P501: Dispose of contents to in accordance with local regulations.
	P501: Dispose of container to in accordance with local regulations.

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Use # 4.1 – Teat-disinfection post-milking by manual or automated dipping or spraying

Table 1

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data
	Scientific name: no data Common name: Yeasts Development stage: no data
Field(s) of use	indoor use Teat-disinfection post-milking

Application method(s)	Method: Dipping
	Detailed description: Teat-disinfection post-milkingManual dipping using a dip cupAutomated dipping by robot Method: Spraying
	Detailed description: Teat-disinfection post-milkingManual spraying using a trigger sprayerManual spraying using an electronic sprayerAutomated spraying by robot
Application rate(s) and frequency	Application rate: RTU product, 6,80% L-(+)-lactic acid -
	Number and timing of application: 2-3 times a day (after each milking)
	Application rate: RTU product, 6,80% L-(+)-lactic acid -
	Number and timing of application: 2-3 times a day (after each milking)
Category(ies) of users	professional
Pack sizes and packaging material	HDPE jerrycan: 5-60 kg HDPE drum: 60-200 kg HDPE IBC: 600-1000 kg

4.1.1. Use-specific instructions

See general directions for use.

4.1.2. Use-specific risk mitigation measures

See general directions for use.

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 4

5.1. **Instructions for use**

The product must be brought to a temperature between 20°C and 30°C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill in the dosing pump reservoir with the RTU product. Avoid discharge of surplus fluids.

Apply the product by manual or automated dipping or spraying. Make sure that the teats are fully covered with disinfectant. Application volumes for cows and buffaloes - 5 ml/treatment and for sheep and goats - 3 ml/treatment.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection clean the application equipment by rinsing with water.

Keep out of reach of children.

5.2. Risk mitigation measures

Wear chemical goggles consistent with the European Standard EN ISO 16321 or equivalent, protective clothing chemically resistant to the biocidal product, chemical resistant gloves classified under the European Standard EN ISO 374 or equivalent.

Google, gloves and coverall material to be specified by the authorisation holder within the product information.

This is without prejudice to the application of Directive 98/24/EC and other Union legislation in the area of health and safety at work.

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

First aid instructions

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

IF ON SKIN: take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.

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 or an ambulance for medical assistance.

IF SWALLOWED: immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112 or an ambulance for medical assistance.

Emergency measure to protect the environment

Environmental precautions: do not allow product to reach sewage systems or water bodies.

Methods and material for containment and cleaning up: absorb with liquid-binding material (sand, diatomite, universal binder). Do not use combustible material like

sawdust. Dispose of the material collected in accordance with local regulations.

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

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements.

Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements.

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

Shelf life: 24 months

Do not store at temperatures above 40°C.

Keep away from heat and direct sunlight.

Protect from frost.

Keep container tightly closed.

6. OTHER INFORMATION

Not relevant

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 4

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

Trade name(s)			calgodip Amadine forte Spray Market area: EU				
Authorisation number		EU-0028957-0013 1-4					
Common name	IUPAC name	Function		CAS nu	mber	EC number	Content (%)
L-(+)-lactic acid		active substance		79-33-4		201-196-2	6,8 % (w/w)

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

Trade name(s)			Dip es lac DLX Spray Market area: EU				
Authorisation number		EU-0028957-0014 1-4					
Common name	IUPAC name	Function		CAS nu	mber	EC number	Content (%)
L-(+)-lactic acid		active substance		79-33-4		201-196-2	6,8 % (w/w)

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

Trade name(s)			calgodip Blue Kamille Market area: EU forte Spray				
Authorisation number			EU-0028957-0015 1-4				
Common name	IUPAC name	Function		CAS nu	mber	EC number	Content (%)
L-(+)-lactic acid		active substance		79-33-4		201-196-2	6,8 % (w/w)

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

Trade name(s)		Dip es protect DLX Market area: EU Spray					
Authorisation number		EU-002895	EU-0028957-0016 1-4				
Common name	IUPAC name	Function		CAS nu	mber	EC number	Content (%)
L-(+)-lactic acid		active substance		79-33-4		201-196-2	6,8 % (w/w)

1. META SPC 5 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 5 identifier

Meta SPC: mSPC5

1.2. Suffix to the authorisation number

Number	1-5

1.3. **Product type(s)**

Product type(s)	PT03: Veterinary hygiene
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2. META SPC 5 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 5

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		active substance	79-33-4	201-196-2	1,92 - 1,96 % (w/w)

2.2. Type(s) of formulation of the meta SPC 5

Formulation type(s)	AL Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5

Hazard statements	H315: Causes skin irritation.
	H319: Causes serious eye irritation.
Precautionary statements	P264: Wash hands thoroughly after handling.
	P280: Wear protective gloves.
	P280: Wear eye protection.
	P302+P352: IF ON SKIN: Wash with plenty of water.
	P332+P313: If skin irritation occurs: Get medical advice.
	P332+P313: If skin irritation occurs: Get medical attention.
	P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P337+P313: If eye irritation persists: Get medical advice.
	P337+P313: If eye irritation persists: Get medical attention.

P501: Dispose of container to in accordance with local regulations.
P501: Dispose of contents to in accordance with local regulations.

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1

Use # 5.1 – Teat-disinfection post-milking by manual or automated dipping or spraying

Product type	PT03: Veterinary hygiene		
Where relevant, an exact description of the authorised use	-		
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data		
	Scientific name: no data Common name: Yeasts Development stage: no data		
Field(s) of use	indoor use		
	Teat-disinfection post-milking		
Application method(s)	Method: Dipping		
	Detailed description: Teat-disinfection post-milkingManual dipping using a dip cupAutomated dipping by robot Method: Spraying		
	Detailed description: Teat-disinfection post-milkingManual spraying using a trigger sprayerManual spraying using an electronic sprayerAutomated spraying by robot		
Application rate(s) and frequency	Application rate: RTU product, 1,92-1,96% L-(+)-lactic acid -		
	Number and timing of application: 2-3 times a day (after each milking)		
	Application rate: RTU product, 1,92-1,96% L-(+)-lactic acid -		
	Number and timing of application: 2-3 times a day (after each milking)		
Category(ies) of users	professional		
Pack sizes and packaging material	HDPE jerrycan: 5-60 kg HDPE drum: 60-200 kg HDPE IBC: 600-1000 kg		

4.1.1. Use-specific instructions

See general directions for use.

4.1.2. Use-specific risk mitigation measures

See general directions for use.

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

5.1. Instructions for use

The product must be brought to a temperature between 20°C and 30°C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill in the dosing pump reservoir with the RTU product. Avoid discharge of surplus fluids.

Apply the product by manual or automated dipping or spraying. Make sure that the teats are fully covered with disinfectant. Application volumes for cows and buffaloes - 5 ml/treatment and for sheep and goats - 3 ml/treatment.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection clean the application equipment by rinsing with water.

Keep out of reach of children.

5.2. Risk mitigation measures

Wear chemical goggles consistent with the European Standard EN ISO 16321 or equivalent, protective clothing chemically resistant to the biocidal product, chemical resistant gloves classified under the European Standard EN ISO 374 or equivalent.

Google, gloves and coverall material to be specified by the authorisation holder within the product information.

This is without prejudice to the application of Directive 98/24/EC and other Union legislation in the area of health and safety at work.

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

First aid instructions

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

IF ON SKIN: take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.

IF IN EYES: rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.

IF SWALLOWED: rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.

Emergency measure to protect the environment

Environmental precautions: no special environmental measures are necessary. Clean contaminated articles and floor in accordance with the environmental legislation.

Methods and material for containment: absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).

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

At the end of the application, dispose unused product and the packaging in accordance with local requirements.

Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements.

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

Shelf life: 24 months

Do not store at temperatures above 40°C.

Keep away from heat and direct sunlight.

Protect from frost.

Keep container tightly closed.

6. **OTHER INFORMATION**

Not relevant

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 5

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

Trade name(s)		Dip es poly-film Spray		Market area: EU			
		Lacti-Shield Spray		Market area: EU			
		DS 2.0 SP Market an		rea: EU			
Authorisation number		EU-002895	EU-0028957-0017 1-5				
Common name	IUPAC name	Function		CAS nu	mber	EC number	Content (%)
L-(+)-lactic acid		active substance		79-33-4		201-196-2	1,92 % (w/w)

1. META SPC 6 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 6 identifier

Identifier	Meta SPC: mSPC6
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1.2. Suffix to the authorisation number

Number	1-6
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1.3. **Product type(s)**

Product type(s)	PT03: Veterinary hygiene

2. META SPC 6 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 6

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		active substance	79-33-4	201-196-2	6,8 - 6,8 % (w/w)

2.2. Type(s) of formulation of the meta SPC 6

Formulation type(s)	AL Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 6

Hazard statements	H315: Causes skin irritation.
	H318: Causes serious eye damage.
Precautionary statements	P264: Wash hands thoroughly after handling.
	P280: Wear protective gloves.
	P280: Wear eye protection.
	P302+P352: IF ON SKIN: Wash with plenty of water.
	P332+P313: If skin irritation occurs: Get medical advice
	P332+P313: If skin irritation occurs: Get medical attention.
	P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P310: Immediately call a POISON CENTER.
	P310: Immediately call a doctor.
	P501: Dispose of contents to in accordance with local regulations.
	P501: Dispose of container to in accordance with local regulations.

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1

Use # 6.1 – Teat-disinfection post-milking by manual or automated dipping or spraying

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data
Field(s) of use	indoor use
	Teat-disinfection post-milking
Application method(s)	Method: Dipping
	Detailed description: Teat-disinfection post-milkingManual dipping using a dip cupAutomated dipping by robot Method: Spraying
	Detailed description: Teat-disinfection post-milkingManual spraying using a trigger sprayerManual spraying using an electronic sprayerAutomated spraying by robot
Application rate(s) and frequency	Application rate: RTU product, 6,80% L-(+)-lactic acid -
	Number and timing of application:
	2-3 times a day (after each milking) Application rate: RTU product, 6,80% L-(+)-lactic acid -
	Number and timing of application: 2-3 times a day (after each milking)
Category(ies) of users	professional
Pack sizes and packaging material	HDPE jerrycan: 5-60 kg HDPE drum: 60-200 kg HDPE IBC: 600-1000 kg

4.1.1. Use-specific instructions

See general directions for use.

4.1.2. Use-specific risk mitigation measures

See general directions for use.

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 6

5.1. **Instructions for use**

The product must be brought to a temperature between 20°C and 30°C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill in the dosing pump reservoir with the RTU product. Avoid discharge of surplus fluids.

Apply the product by manual or automated dipping or spraying. Make sure that the teats are fully covered with disinfectant. Application volumes for cows and buffaloes - 5 ml/treatment and for sheep and goats - 3 ml/treatment.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection clean the application equipment by rinsing with water.

Keep out of reach of children.

5.2. Risk mitigation measures

Wear chemical goggles consistent with the European Standard EN ISO 16321 or equivalent, protective clothing chemically resistant to the biocidal product, chemical resistant gloves classified under the European Standard EN ISO 374 or equivalent.

Google, gloves and coverall material to be specified by the authorisation holder within the product information.

This is without prejudice to the application of Directive 98/24/EC and other Union legislation in the area of health and safety at work.

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

First aid instructions

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

IF ON SKIN: take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.

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 or an ambulance for medical assistance.

IF SWALLOWED: immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112 or an ambulance for medical assistance.

Emergency measure to protect the environment

Environmental precautions: no special environmental measures are necessary. Clean contaminated articles and floor in accordance with the environmental legislation.

Methods and material for containment: absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).

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

At the end of the application, dispose unused product and the packaging in accordance with local requirements.

Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements.

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

Shelf life: 24 months

Do not store at temperatures above 40°C.

Keep away from heat and direct sunlight.

Protect from frost.

Keep container tightly closed.

6. **OTHER INFORMATION**

Not relevant

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 6

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

Trade name(s) Dip es poly-s		-spray DLX	Market a	rea: EU			
Authorisation number EU-00289		7-0018 1-6					
Common name	IUPAC name	Function		CAS nu	mber	EC number	Content (%)
L-(+)-lactic acid		active substance		79-33-4		201-196-2	6,8 % (w/w)

1. META SPC 7 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 7 identifier

Identifier	Meta SPC: mSPC7
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1.2. Suffix to the authorisation number

Number	1-7
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1.3. Product type(s)

Product type(s)	PT04: Food and feed area
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2. META SPC 7 COMPOSITION

$2.1. \quad \textbf{Qualitative and quantitative information on the composition of the meta SPC~7}$

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		active substance	79-33-4	201-196-2	16 - 17,6 % (w/w)
Methanesulphonic acid	Methanesulphonic acid	Non-Active substance	75-75-2	200-898-6	6,3 - 7 % (w/w)

2.2. Type(s) of formulation of the meta SPC 7

Formulation type(s)	SL Soluble concentrate

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 7

Hazard statements	H290: May be corrosive to metals.
	H314: Causes severe skin burns and eye damage.
	EUH071: Corrosive to the respiratory tract.
Precautionary statements	P260: Do not breathe spray.
	P280: Wear protective gloves.
	P280: Wear protective clothing.
	P280: Wear eye protection.
	P280: Wear face protection.
	P301+P330+P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
	P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
	P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P310: Immediately call a doctor.
	P310: Immediately call a POISON CENTER.
	P406: Store in a corrosion resistant container with a resistant inner liner.
	P501: Dispose of contents to in accordance with local regulations.
	P501: Dispose of container to in accordance with local regulations.

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1

Use # 7.1 – Hard surface disinfection by manual or automated foaming

Product type	PT04: Food and feed area	
Where relevant, an exact description of the authorised use	-	
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data	
	Scientific name: no data Common name: Yeasts Development stage: no data	
Field(s) of use	indoor use	
	Hard surface disinfection	
Application method(s)	Method: Foaming	
	Detailed description: Hard surface disinfection Manual foaming using a foam lanceAutomated foaming with fixed installed foaming nozzlesFoaming equipmentSatellite stations: fixed installations connected to jerrycans, drums or IBCs and mobile trolleys equipped with 20 litres container of concentrated product	
Application rate(s) and frequency	Application rate: Concentrated product, 16,0-17,6% L-(+)-lactic acid Bactericidal claim: 5,0% (w/w) dilution of the product, 0,80-0,88% L-(+)-lactic acid Yeasticidal claim: 5,0% (w/w) dilution of the product, 0,80-0,88% L-(+)-lactic acid	
	Number and timing of application: once a day	
Category(ies) of users	professional	
Pack sizes and packaging material	HDPE jerrycan: 5-60 kg HDPE drum: 60-200 kg HDPE IBC: 600-1000 kg	

4.1.1. Use-specific instructions

See general directions for use.

4.1.2. Use-specific risk mitigation measures

See general directions for use.

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 7

5.1. Instructions for use

For fixed installations, connect the jerrycan, drum or IBC containing the product with the dosing unit of the satellite station. For mobile versions, place a 20 litres container of the neat product on the trolley and put the suction hose in. Connect water supply to the dosing unit. Dilution is performed automatically via the dosing unit of the fixed or mobile station and monitored by conductivity measurements.

Before disinfection remove loose dirt, any further precleaning is not necessary.

Apply the foam to the hard surfaces. Application volume is 350 ml of diluted product/m². Make sure that surfaces are well covered with the disinfectant.

Minimum contact time is 5 minutes for bacteria and 15 minutes for yeasts.

After application, rinse treated surfaces and flush foaming equipment thoroughly with clean water. For flushing of mobile systems, put the suction hose into a container with clean water.

5.2. Risk mitigation measures

Wear chemical goggles consistent with the European Standard EN ISO 16321 or equivalent, protective clothing chemically resistant to the biocidal product, chemical resistant gloves classified under the European Standard EN ISO 374 or equivalent.

Google, gloves and coverall material to be specified by the authorisation holder within the product information.

Wear respiratory protection when handling the concentrated product. Respiratory protection to be specified by the authorisation holder within the product information. Avoid standing in areas with aerosol formation.

This is without prejudice to the application of Directive 98/24/EC and other Union legislation in the area of health and safety at work.

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

First aid instructions

IF INHALED: move to fresh air and keep at rest in a position comfortable for breathing.

If symptoms: call 112 or an ambulance for medical assistance.

If no symptoms: call a POISON CENTRE or a doctor.

IF ON SKIN: immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE 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 or an ambulance for medical assistance.

IF SWALLOWED: immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112 or an ambulance for medical assistance.

Emergency measure to protect the environment

Environmental precautions: do not allow product to reach sewage systems or water bodies.

Methods and material for containment and cleaning up: absorb with liquid-binding material (sand, diatomite, universal binder). Do not use combustible material like sawdust. Dispose of the material collected in accordance with local regulations. Ensure adequate ventilation.

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

At the end of the application, dispose unused product and the packaging in accordance with local requirements.

Used product can be flushed to municipal sewer depending on local requirements.

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

Shelf life: 24 months

Ensure good ventilation or exhaustion.

Do not store together with alkalis (caustic solutions).

Do not store at temperatures above 40°C.

Keep away from heat and direct sunlight.

Protect from frost.

Keep container tightly closed.

6. **OTHER INFORMATION**

Not relevant

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

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

Trade name(s)		calgonit DS 633 Market an		rea: EU			
Authorisation number EU-0		EU-002895	7-0019 1-7				
Common name	IUPAC name	Function		CAS number		EC number	Content (%)
L-(+)-lactic acid		active substance		79-33-4		201-196-2	16 % (w/w)
Methanesul- phonic acid	Methanesul- phonic acid	Non-Active substance		75-75-2		200-898-6	7 % (w/w)

1. META SPC 8 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 8 identifier

Identifier	Meta SPC: mSPC8
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1.2. Suffix to the authorisation number

Number	1-8

1.3. **Product type(s)**

Product type(s)	PT04: Food and feed area

2. META SPC 8 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 8

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
L-(+)-lactic acid		active substance	79-33-4	201-196-2	16 - 17,6 % (w/w)	
Methanesulpho- nic acid	Methanesulpho- nic acid	Non-Active substance	75-75-2	200-898-6	0 - 10,5 % (w/w)	
Phosphoric acid	Phosphoric acid	Non-Active substance	7664-38-2	231-633-2	0 - 18,75 % (w/w)	
Sulphuric acid	Sulphuric acid	Non-Active substance	7664-93-9	231-639-5	4,5 - 4,5 % (w/w)	
Isononanoic acid	Isononanoic acid	Non-Active substance	3302-10-1	221-975-0	2,25 - 2,5 % (w/w)	

2.2. Type(s) of formulation of the meta SPC 8

Formulation type(s)	SL Soluble concentrate
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 8

Hazard statements	H290: May be corrosive to metals.
	H314: Causes severe skin burns and eye damage. EUH071: Corrosive to the respiratory tract.
Precautionary statements	P260: Do not breathe spray.
	P280: Wear protective gloves.
	P280: Wear protective clothing.
	P280: Wear eye protection.
	P280: Wear face protection.
	P301+P330+P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
	P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310: Immediately call a POISON CENTER.
P310: Immediately call a doctor.
P406: Store in a corrosion resistant container with a resistant inner liner.
P501: Dispose of contents to in accordance with local regulations.
P501: Dispose of container to in accordance with local regulations.

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

 $\label{eq:Table 1} \label{eq:Table 1}$ Use # 8.1 – Hard surface disinfection by automated spraying in closed cleaning in place (CIP) system

Product type	PT04: Food and feed area			
Where relevant, an exact description of the authorised use	-			
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data			
Field(s) of use	indoor use Hard surface disinfection			
Application method(s)	Method: Spraying Detailed description: Hard surface disinfection Automated dosing and spraying in closed CIP systemCIP system: pipe work, fermentation and storage tanks			
Application rate(s) and frequency	Application rate: Concentrated product, 16,0-17,6% L-(+)-lactic acid Bactericidal claim: 2,5% (w/w) dilution of the product, 0,40-0,44% L-(+)-lactic acid Yeasticidal claim: 2% (w/w) dilution of the product, 0,32-0,35% L-(+)-lactic acid Number and timing of application: once a day			
Category(ies) of users	professional			
Pack sizes and packaging material	HDPE jerrycan: 5-60 kg HDPE drum: 60-200 kg HDPE IBC: 600-1000 kg			

4.1.1. Use-specific instructions

See general directions for use.

4.1.2. Use-specific risk mitigation measures

See general directions for use.

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 8

5.1. Instructions for use

Connect the jerrycan, drum or IBC containing the product with the dosing unit of the CIP system. Dosing and dilution are performed automatically via the dosing unit of the CIP system and monitored by conductivity measurements.

Avoid contact with aluminium, non-ferrous metals and galvanised materials.

Precleaning is not necessary.

Minimum contact time is 5 minutes for bacteria and 15 minutes for yeasts.

After application, rinse the treated system thoroughly with clean water.

5.2. Risk mitigation measures

Wear chemical goggles consistent with the European Standard EN ISO 16321 or equivalent, protective clothing chemically resistant to the biocidal product, chemical resistant gloves classified under the European Standard EN ISO 374 or equivalent.

Google, gloves and coverall material to be specified by the authorisation holder within the product information.

Wear respiratory protection when handling the concentrated product. Respiratory protection to be specified by the authorisation holder within the product information. Avoid standing in areas with aerosol formation.

This is without prejudice to the application of Directive 98/24/EC and other Union legislation in the area of health and safety at work.

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

First aid instructions

IF INHALED: move to fresh air and keep at rest in a position comfortable for breathing.

If symptoms: call 112 or an ambulance for medical assistance.

If no symptoms: call a POISON CENTRE or a doctor.

IF ON SKIN: immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE 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 or an ambulance for medical assistance.

IF SWALLOWED: immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112 or an ambulance for medical assistance.

Emergency measure to protect the environment

Environmental precautions: do not allow product to reach sewage systems or water bodies.

Methods and material for containment and cleaning up: absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of the material collected in accordance with local regulations.

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

At the end of the application, dispose unused product and the packaging in accordance with local requirements.

Used product can be flushed to municipal sewer depending on local requirements.

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

Shelf life: 24 months

Ensure good ventilation or exhaustion.

Do not store together with alkalis (caustic solutions).

Do not store at temperatures above 40°C.

Keep away from heat and direct sunlight.

Protect from frost.

Keep container tightly closed.

6. OTHER INFORMATION

Not relevant

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 8

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

Trade name(s)		calgonit Duocip		Market area: EU			
Authorisation number		EU-002895	EU-0028957-0020 1-8				
Common name	IUPAC name	Function		CAS number		EC number	Content (%)
L-(+)-lactic acid		active substance		79-33-4		201-196-2	16 % (w/w)
Methanesul- phonic acid	Methanesul- phonic acid	Non-Active substance		75-75-2		200-898-6	10,5 % (w/w)
Sulphuric acid	Sulphuric acid	Non-Active substance		7664-93-9		231-639-5	4,5 % (w/w)
Isononanoic acid	Isononanoic acid	Non-Active substance		3302-10-1		221-975-0	2,5 % (w/w)

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

Trade name(s)			calgonit Duocip P		Market area: EU			
Authorisation number			EU-002895	EU-0028957-0021 1-8				
Common name	IUPAC name	Function		CAS number		EC number	Content (%)	
L-(+)-lactic acid		active substance		79-33-4		201-196-2	16 % (w/w)	
Phosphoric acid	Phosphoric acid	Non-Active substance		7664-38-2		231-633-2	18,75 % (w/w)	
Sulphuric acid	Sulphuric acid	Non-Active substance		7664-93-9		231-639-5	4,5 % (w/w)	
Isononanoic acid	Isononanoic acid	Non-Active substance		3302-10-1		221-975-0	2,5 % (w/w)	