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#### 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

(Text with EEA relevance)

(OJ L 162, 28.6.2023, p. 11)

Amended by:

►<u>B</u>

►<u>M1</u> Commission Implementing Regulation (EU) 2025/523 of 20 March L 523 1 21.3.2025

#### **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

#### (Text with EEA relevance)

### Article 1

A Union authorisation with authorisation number EU-0028957-0000 is hereby granted 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' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 18 July 2023 to 30 June 2033.

#### 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.

### ▼<u>B</u>

# 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

#### ADMINISTRATIVE INFORMATION 1.

## 1.1. Family name

Name CVAS Biocidal Product Family based on L(+) Lactic Acid	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 auth-	Name	CVAS Development GmbH
orisation 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 bv
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)
Methanesulphonic acid	Methanesulphonic 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
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### 1.2. Suffix to the authorisation number

Number	1-1
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### 1.3. Product type(s)

Product type(s)	PT03: Veterinary hygiene
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### 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 develop- ment 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

	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  $20^\circ C$  and  $30^\circ C$  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 MILCH- SÄUREMANTEL	Market area: EU
	IWETEC MILCHSÄURE DIPP	Market area: EU
	Fulldip Lacti Film	Market area: EU
	CareDip Film	Market area: EU
	Milchsäure Film	Market area: EU
	Lactoboost Film	Market area: EU
	Bonimal CARE Lac Dip	Market area: EU
	Bonimal CARE LactiVital Dip	Market area: EU
	Impos Filmdipp M	Market area: EU
	Melkpower Filmdipp M	Market area: EU

# ▼<u>M1</u>

Authorisation number		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 number		EU-0028957-0002 1-1				
Common name	IUPAC name	Function	CAS n	umber	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 Blu Film	e Kamille	Market	area: EU	
			HappyFarm Film	KamillDip	Market	area: EU	
			Lacto Film		Market	area: EU	
			MS Film		Market	area: EU	
			LA Film		Market	area: EU	
			BestFarm I Film	Blue Dip	Market	area: EU	
			Bonimal CA Dip	RE Milky	Market	area: EU	
			Bonimal CA Dip	.RE Milki	Market	area: EU	
			Bonimal CA Dip	ARE Milk	Market	area: EU	
			PQ-Blue Film		Market area: EU		
			Dipp Тор		Market area: EU		
Authorisation number			EU-0028957-0003 1-1				
Common name	IUPAC name	Fu	nction	CAS nu	mber	EC number	Content (%)
L-(+)-lactic acid		active sub	bstance 79-33-4			201-196-2	1,92 % (w/w)

Trade name(s)			Dip es prote	ct DL	Market area: EU		
			BaktoStop la	ctic H	Market	area: EU	
		Dip Agro Protect		Market area: EU			
			Kuhmilin Di	р Тор М	Market	area: EU	
		Lacti-Protect Dip		Market area: EU			
		DSR 1.5 F Ma		Market	Market area: EU		
		ProfiMix inSilk Market area: EU					
Authorisation number		EU-0028957-0004 1-1					
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

### 1. META SPC 2 ADMINISTRATIVE INFORMATION

## 1.1. Meta SPC 2 identifier

Identifier Meta SPC: mSPC2	
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### 1.2. Suffix to the authorisation number

Number	1-2
rumber	12

# 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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Hazard statements	H315: Causes skin irritation. H318: Causes serious eye damage.
Precautionary statements	<ul> <li>P264: Wash hands thoroughly after handling.</li> <li>P280: Wear protective gloves.</li> <li>P280: Wear eye protection.</li> <li>P302+P352: IF ON SKIN: Wash with plenty of water.</li> <li>P332+P313: If skin irritation occurs: Get medical advice.</li> <li>P332+P313: If skin irritation occurs: Get medical attention.</li> <li>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</li> <li>P310: Immediately call a POISON CENTER.</li> <li>P310: Immediately call a doctor.</li> <li>P501: Dispose of contents to in accordance with local regulations.</li> </ul>
	1

# 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

# 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 develop- ment 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)

▼	M1

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  $20^\circ C$  and  $30^\circ C$  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.

 $\rm EN~ISO~374$  – 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 forte Film	Amadine	Market area: EU		
Authorisation number			EU-0028957-	-0005 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)

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

Trade name(s)			Dip es lac DLX Marke		Market	et area: EU	
Authorisation number			EU-0028957-0006 1-2				
Common name	IUPAC name	Function		CAS nu	ımber	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 Film				
Authorisation number			EU-0028957-	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 protect DLX	Market area: EU
Authorisation number	EU-0028957-0008 1-2	

▼<u>M1</u>

Common name	IUPAC name	Function	CAS number	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
Identifier	Meta SPC: mSPC3

#### 1.2. Suffix to the authorisation number

Number	1 2
Nullioei	1-5

### 1.3. Product type(s)

Product type(s) PT03: Veterinary hygiene
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## 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 Any other liquid

# 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

#### Table 1

# Use # 3.1 - 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 develop- ment 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  $20^\circ C$  and  $30^\circ C$  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 Spray	Amadine	Market	area: EU	
			AGRIMARK MILCHSÄUI ENEBEL		Market	area: EU	
			IWETEC MILCHSÄUI SPRAY	RE	Market	area: EU	
			Fulldip Lacti	Spray	Market	area: EU	
			CareDip Spray N		Market area: EU		
			Milchsäure Spray		Market area: EU		
			Lactoboost Spray		Market area: EU		
			Care4cows L Spray	actic Acid	Market	area: EU	
			Bonimal CA Spray	ARE Lac	Market	area: EU	
			Bonimal CARE LactiVital Spray		Market	area: EU	
Authorisation number		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
	Lacti-Bac Spray	Market area: EU
	DS 1.0 S	Market area: EU
Authorisation number	EU-0028957-0010 1-3	

▼<u>M1</u>

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)	ade name(s)		e Kamille	Market area: EU			
			KamillDip	Market area: EU			
		Lacto Spray		Market	area: EU		
		MS Spray		Market	area: EU		
		LA Spray		Market area: EU			
			Care4Cows Lactic Mark Acid Kamille Spray		arket area: EU		
		BestFarm Blue Dip Spray		Market area: EU			
		Bonimal CARE Milky Spray		Market area: EU			
		Bonimal CARE Milki Spray		Market area: EU			
			Bonimal CARE Milk Spray		Market area: EU		
		PQ-Blue Spray		Market area: EU			
Authorisation number		EU-0028957-0011 1-3					
Common name IUPAC nam	ie Fu	nction	CAS nu	mber	EC number	Content (%)	
L-(+)-lactic acid	active sub	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 DL Spray	Market area: EU	
	Dip Agro Protect SP	Market area: EU	
	Kuhmilin Sprüh Top M	Market area: EU	
	Lacti-Protect Spray	Market area: EU	
	DSR 1.5 S	Market area: EU	
Authorisation number	EU-0028957-0012 1-3		

▼<u>M1</u>

Common name	name IUPAC name Function		CAS number 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

14
1-4

### 1.3. **Product type(s)**

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Product type(s)	PT03: Veterinary hygiene

#### 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
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# 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4

Hazard statements	H315: Causes skin irritation. H318: Causes serious eye damage.		
Precautionary statements	<ul> <li>P264: Wash hands thoroughly after handling.</li> <li>P280: Wear protective gloves.</li> <li>P280: Wear eye protection.</li> <li>P302+P352: IF ON SKIN: Wash with plenty of water.</li> <li>P332+P313: If skin irritation occurs: Get medical advice.</li> <li>P332+P313: If skin irritation occurs: Get medical attention.</li> <li>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</li> </ul>		

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

Product type	PT03: Veterinary hygiene		
Where relevant, an exact description of the authorised use	-		
Target organism(s) (including develop- ment 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		

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

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  $20^\circ C$  and  $30^\circ C$  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 forte Spray	Amadine	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	

▼<u>M1</u>

Common name	IUPAC name	Function	CAS number	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 Ma forte Spray		Market	Market area: EU	
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-0028957-0016 1-4					
Common name	IUPAC name	Fu	nction	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

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

# 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5

Hazard statements	H315: Causes skin irritation.
	H319: Causes serious eye irritation.
Precautionary statements	<ul> <li>P264: Wash hands thoroughly after handling.</li> <li>P280: Wear protective gloves.</li> <li>P280: Wear eye protection.</li> <li>P302+P352: IF ON SKIN: Wash with plenty of water.</li> </ul>
	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 develop- ment 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: Spraving				
	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 area: EU					
Authorisation number		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: mSPC	6
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#### 1.2. Suffix to the authorisation number

Number	1-6

# 1.3. Product type(s)

Product type(s) PT(	03: Veterinary hygiene
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#### 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 A	ny other liquid
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Hazard statements	H315: Causes skin irritation. H318: Causes serious eye damage.
Precautionary statements	<ul> <li>P264: Wash hands thoroughly after handling.</li> <li>P280: Wear protective gloves.</li> <li>P280: Wear eye protection.</li> <li>P302+P352: IF ON SKIN: Wash with plenty of water.</li> <li>P332+P313: If skin irritation occurs: Get medical advice.</li> <li>P332+P313: If skin irritation occurs: Get medical attention.</li> <li>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</li> <li>P310: Immediately call a POISON CENTER.</li> </ul>
	<ul><li>P310: Immediately call a doctor.</li><li>P501: Dispose of contents to in accordance with local regulations.</li><li>P501: Dispose of container to in accordance with local regulations.</li></ul>

# 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 6

# 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 develop- ment 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

▼	M1	

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  $20^\circ C$  and  $30^\circ C$  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 DLX	poly-spray	Market	area: EU		
Authorisation number		EU-0028957	-0018 1-6				
Common name	IUPAC name	Fu	nction	CAS m	ımber	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

## 1.3. **Product type(s)**

Product type(s)	PT04: Food and feed area

#### 2. META SPC 7 COMPOSITION

2.1. 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 con-	entrate
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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.		

# 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 7

# 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 develop- ment 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

▼	M1

Application method(s)	Method: Foaming Detailed description: Hard surface disinfection Manual foaming using a foam lanceAu- tomated foaming with fixed installed foaming nozzlesFoaming equip- mentSatellite 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/m<sup>2</sup>. 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		area: EU		
Authorisation number		EU-0028957-0019 1-7					
Common name	IUPAC name	Function		CAS nu	mber	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
Identifier	Meta SPC: mSPC8

#### 1.2. Suffix to the authorisation number

Number	1-8

### 1.3. Product type(s)

Product type(s)	PT04: Food and feed area

#### **META SPC 8 COMPOSITION** 2.

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

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	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

# HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 8 3.

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 al 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

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 develop- ment 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-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-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)