

**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)**

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 <sup>(1)</sup>, and in particular Article 44(5), first subparagraph, thereof,

Whereas:

- (1) On 24 April 2019, CVAS Development GmbH submitted to the European Chemicals Agency ('the Agency') an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for a Union authorisation of a biocidal product family named 'CVAS Biocidal Product Family based on L (+) Lactic Acid' of product-types 3 and 4, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Slovenia had agreed to evaluate the application. The application was recorded under case number BC-XR051157-11 in the Register for Biocidal Products.
- (2) 'CVAS Biocidal Product Family based on L (+) Lactic Acid' contains L-(+)-lactic acid as the active substance, included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-types 3 and 4.
- (3) On 7 January 2022, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the Agency.
- (4) On 5 July 2022, the Agency submitted to the Commission its opinion <sup>(2)</sup>, the draft summary of the biocidal product characteristics ('SPC') of 'CVAS Biocidal Product Family based on L (+) Lactic Acid' and the final assessment report on the biocidal product family, in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that 'CVAS Biocidal Product Family based on L (+) Lactic Acid' is a biocidal product family within the meaning of Article 3(1), point (s), of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that, subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) and (6) of that Regulation.
- (6) On 20 July 2022, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for 'CVAS Biocidal Product Family based on L (+) Lactic Acid'.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1.<sup>(2)</sup> ECHA opinion of 15 June 2022 on the Union authorisation of 'CVAS Biocidal Product Family based on L (+) Lactic Acid' (ECHA/BPC/345/2022), <https://echa.europa.eu/opinions-on-union-authorisation>

HAS ADOPTED THIS REGULATION:

*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.

Done at Brussels, 27 June 2023.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX

**Summary of product characteristics for a biocidal product family**

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

Product type 3 - Veterinary hygiene (Disinfectants)

Product type 4 - Food and feed area (Disinfectants)

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 (Disinfectants) PT04 - Food and feed area (Disinfectants)
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**1.3. Authorisation holder**

Name and address of the authorisation holder	Name	CVAS Development GmbH
	Address	Am Hafen 16, 68526 Ladenburg Germany
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 biocidal products**

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

Name of manufacturer	Arthur Schopf Hygiene GmbH & Co. KG
Address of manufacturer	Pfaffensteinstraße 1, 83115 Neuubeuern Germany
Location of manufacturing sites	Pfaffensteinstraße 1, 83115 Neuubeuern 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
Location of manufacturing sites	Arkelsedijk 46, 4206AC Gorinchem Netherlands

## 2. PRODUCT FAMILY COMPOSITION AND FORMULATION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,92	17,6
Methanesulphonic acid	Methanesulphonic acid	Non-active substance	75-75-2	200-898-6	0,0	10,5
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,0	18,75
Sulphuric acid	Sulphuric acid	Non-active substance	7664-93-9	231-639-5	0,0	4,5
Isononanoic acid	Isononanoic acid	Non-active substance	3302-10-1	221-975-0	0,0	2,5

### 2.2. Type(s) of formulation

Formulation(s)	AL - Any other liquid SL - Soluble concentrate
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## PART II

### SECOND INFORMATION LEVEL - META SPC(S)

#### META SPC 1

#### 1. META SPC 1 ADMINISTRATIVE INFORMATION

##### 1.1. Meta SPC 1 identifier

Identifier	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 (Disinfectants)
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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 (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,92	1,96

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

Formulation(s)	AL - Any other liquid
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## 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	
Precautionary statements	

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

## 4.1. Use description

Table 1

## Use # 1 – Use # 1.1 - Teat-disinfection post-milking by manual or automated dipping

Product type	PT03 - Veterinary hygiene (Disinfectants)
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 Teat-disinfection post-milking
Application method(s)	Method: Dipping  Detailed description: Teat-disinfection post-milking  Manual dipping using a dip cup  Automated dipping by robot
Application rate(s) and frequency	Application Rate: Ready-To-Use (RTU) product, 1,92-1,96% L-(+)-lactic acid Dilution (%): - 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): 600-1 000 kg

4.1.1. *Use-specific instructions for use*

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 <sup>(1)</sup> 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.

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

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 MILCHSÄUREMANTEL		Market area: EU		
	IWETEC MILCHSÄURE DIPP		Market area: EU		
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

## 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 number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,92

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

Trade name(s)	calgodip Blue Kamille Film		Market area: EU		
Authorisation number	EU-0028957-0003 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

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

Trade name(s)	Dip es protect DL		Market area: EU		
	BaktoStop lactic 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				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,92

## META SPC 2

## 1. META SPC 2 ADMINISTRATIVE INFORMATION

## 1.1. Meta SPC 2 identifier

Identifier	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 (Disinfectants)
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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 (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	6,8	6,8

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

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

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

4. **AUTHORISED USE(S) OF THE META SPC 2**4.1. **Use description**

Table 2

**Use # 1 – Use # 2.1 - Teat-disinfection post-milking by manual or automated dipping**

Product type	PT03 - Veterinary hygiene (Disinfectants)
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 Teat-disinfection post-milking
Application method(s)	Method: Dipping  Detailed description: Teat-disinfection post-milking  Manual dipping using a dip cup  Automated dipping by robot

Application rate(s) and frequency	Application Rate: RTU product, 6,80% L-(+)-lactic acid Dilution (%): - 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: 600-1 000 kg

4.1.1. *Use-specific instructions for use*

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 <sup>(2)</sup> 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.

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

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

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 Amadine forte Film		Market area: EU		
Authorisation number	EU-0028957-0005 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	6,8

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

Trade name(s)	Dip es lac DLX		Market area: EU		
Authorisation number	EU-0028957-0006 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	6,8

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

Trade name(s)	calgodip Blue Kamille forte Film		Market area: EU		
Authorisation number	EU-0028957-0007 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	6,8

## 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				

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

**META SPC 3****1. META SPC 3 ADMINISTRATIVE INFORMATION****1.1. Meta SPC 3 identifier**

Identifier	mSPC3
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**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 (Disinfectants)
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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 (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,92	1,96

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

Formulation(s)	AL - Any 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 3

## 4.1. Use description

Table 3

**Use # 1 – Use # 3.1 – Teat-disinfection post-milking by manual or automated dipping or spraying**

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	<p>Scientific name: no data Common name: Bacteria Development stage: no data</p> <p>Scientific name: no data Common name: Yeasts Development stage: no data</p>
Field(s) of use	Indoor Teat-disinfection post-milking
Application method(s)	<p>Method: Dipping</p> <p>Detailed description: Teat-disinfection post-milking</p> <p>Manual dipping using a dip cup</p> <p>Automated dipping by robot</p> <p>Method: Spraying</p> <p>Detailed description: Teat-disinfection post-milking</p> <p>Manual spraying using a trigger sprayer</p> <p>Manual spraying using an electronic sprayer</p> <p>Automated spraying by robot</p>
Application rate(s) and frequency	<p>Application Rate: RTU product, 1,92-1,96% L-(+)-lactic acid</p> <p>Dilution (%): -</p> <p>Number and timing of application: 2-3 times a day (after each milking)</p>
Category(ies) of users	Professional
Pack sizes and packaging material	<p>HDPE jerrycan: 5-60 kg</p> <p>HDPE drum: 60-200 kg</p> <p>HDPE IBC: 600-1 000 kg</p>

4.1.1. *Use-specific instructions for use*

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 <sup>(\*)</sup> 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.

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(\*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 3.

**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 Amadine Spray		Market area: EU		
	AGRIMARKT MILCHSÄURENEBEL		Market area: EU		
	IWETEC MILCHSÄURE SPRAY		Market area: EU		
Authorisation number	EU-0028957-0009 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,92

**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				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,92

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

Trade name(s)	calgodip Blue Kamille Spray		Market area: EU		
Authorisation number	EU-0028957-0011 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,92

## 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				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,92

## META SPC 4

## 1. META SPC 4 ADMINISTRATIVE INFORMATION

## 1.1. Meta SPC 4 identifier

Identifier	mSPC4
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## 1.2. Suffix to the authorisation number

Number	1-4
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## 1.3. Product type(s)

Product type(s)	PT03 - Veterinary hygiene (Disinfectants)
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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 (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	6,8	6,8

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

Formulation(s)	AL - Any other liquid
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## 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4

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

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

### 4.1. Use description

Table 4

#### Use # 1 – Use # 4.1 - Teat-disinfection post-milking by manual or automated dipping or spraying

Product type	PT03 - Veterinary hygiene (Disinfectants)
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 Teat-disinfection post-milking
Application method(s)	Method: Dipping  Detailed description: Teat-disinfection post-milking  Manual dipping using a dip cup  Automated dipping by robot  Method: Spraying  Detailed description: Teat-disinfection post-milking  Manual spraying using a trigger sprayer  Manual spraying using an electronic sprayer  Automated spraying by robot
Application rate(s) and frequency	Application Rate: RTU product, 6,80% L-(+)-lactic acid  Dilution (%): -  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: 600-1 000 kg

4.1.1. *Use-specific instructions for use*

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.

Goggles, 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.

(\*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 4.

**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 number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	6,8

**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 number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	6,8

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

Trade name(s)	calgodip Blue Kamille forte Spray		Market area: EU		
Authorisation number	EU-0028957-0015 1-4				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)

L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	6,8
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#### 7.4. Trade name(s), authorisation number and specific composition of each individual product

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

### META SPC 5

#### 1. META SPC 5 ADMINISTRATIVE INFORMATION

##### 1.1. Meta SPC 5 identifier

Identifier	mSPC5
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##### 1.2. Suffix to the authorisation number

Number	1-5
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##### 1.3. Product type(s)

Product type(s)	PT03 - Veterinary hygiene (Disinfectants)
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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 (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,92	1,96

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

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

Hazard statements	Causes skin irritation. Causes serious eye irritation.
Precautionary statements	Wash hands thoroughly after handling. Wear protective gloves. Wear eye protection. IF ON SKIN:Wash with plenty of water. If skin irritation occurs:Get medical advice. If skin irritation occurs:Get medical attention. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists:Get medical advice. If eye irritation persists:Get medical attention. Dispose of container in accordance with local regulations. Dispose of contents in accordance with local regulations.

4. **AUTHORISED USE(S) OF THE META SPC 5**4.1. **Use description**

Table 5

**Use # 1 – Use # 5.1 – Teat-disinfection post-milking by manual or automated dipping or spraying**

Product type	PT03 - Veterinary hygiene (Disinfectants)
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 Teat-disinfection post-milking
Application method(s)	Method: Dipping  Detailed description:  Teat-disinfection post-milking  Manual dipping using a dip cup  Automated dipping by robot

	Method: Spraying  Detailed description: Teat-disinfection post-milking  Manual spraying using a trigger sprayer  Manual spraying using an electronic sprayer  Automated spraying by robot
Application rate(s) and frequency	Application Rate: RTU product, 1,92-1,96% L-(+)-lactic acid  Dilution (%): -  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: 600-1 000 kg

4.1.1. *Use-specific instructions for use*

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 <sup>(\*)</sup> 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.

(\*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 5.

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.

Goggles, 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.

Avoid release to an individual waste water treatment plant.

## 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 number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	1,92

**META SPC 6**1. **META SPC 6 ADMINISTRATIVE INFORMATION**1.1. **Meta SPC 6 identifier**

Identifier	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 (Disinfectants)
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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 (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	6,8	6,8

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

Formulation(s)	AL - Any other liquid
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## 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 6

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

## 4. AUTHORISED USE(S) OF THE META SPC 6

## 4.1. Use description

Table 6

**Use # 1 – Use # 6.1 - Teat-disinfection post-milking by manual or automated dipping or spraying**

Product type	PT03 - Veterinary hygiene (Disinfectants)
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 Teat-disinfection post-milking
Application method(s)	Method: Dipping  Detailed description: Teat-disinfection post-milking  Manual dipping using a dip cup  Automated dipping by robot  Method: Spraying  Detailed description: Teat-disinfection post-milking

	Manual spraying using a trigger sprayer Manual spraying using an electronic sprayer Automated spraying by robot
Application rate(s) and frequency	Application Rate: RTU product, 6,80% L-(+)-lactic acid  Dilution (%): -  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: 600-1 000 kg

4.1.1. *Use-specific instructions for use*

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 <sup>(6)</sup> 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.

<sup>(6)</sup> Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 6.

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.

Goggles, 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-spray DLX		Market area: EU		
Authorisation number	EU-0028957-0018 1-6				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	6,8

**META SPC 7**1. **META SPC 7 ADMINISTRATIVE INFORMATION**1.1. **Meta SPC 7 identifier**

Identifier	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 (Disinfectants)
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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 (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	16,0	17,6
Methanesulphonic acid	Methanesulphonic acid	Non-active substance	75-75-2	200-898-6	6,3	7,0

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

Formulation(s)	SL - Soluble concentrate
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## 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 7

Hazard statements	May be corrosive to metals. Causes severe skin burns and eye damage. Corrosive to the respiratory tract.
Precautionary statements	Do not breathe spray. Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection. IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a doctor. Immediately call a POISON CENTER. Store in corrosion resistant container with a resistant inner liner. Dispose of contents in accordance with local regulations. Dispose of container in accordance with local regulations.

## 4. AUTHORISED USE(S) OF THE META SPC 7

## 4.1. Use description

Table 7

**Use # 1 – Use # 7.1 – Hard surface disinfection by manual or automated foaming**

Product type	PT04 - Food and feed area (Disinfectants)
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 Hard surface disinfection
Application method(s)	Method: Foaming  Detailed description:  Hard surface disinfection Manual foaming using a foam lance Automated foaming with fixed installed foaming nozzles Foaming equipment

	Satellite 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  Dilution (%): 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: 600-1 000 kg

4.1.1. *Use-specific instructions for use*

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 <sup>(7)</sup> 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.

<sup>(7)</sup> Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 7.

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.

Goggles, 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.

Avoid release to an individual waste water treatment plant.

#### 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 number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	16,0
Methanesulphonic acid	Methanesulphonic acid	Non-active substance	75-75-2	200-898-6	7,0

**META SPC 8**

1. **META SPC 8 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 8 identifier**

Identifier	mSPC8
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1.2. **Suffix to the authorisation number**

Number	1-8
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1.3. **Product type(s)**

Product type(s)	PT04 - Food and feed area (Disinfectants)
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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 (%)	
					Min	Max
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	16,0	17,6

Methanesulphonic acid	Methanesulphonic acid	Non-active substance	75-75-2	200-898-6	0,0	10,5
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,0	18,75
Sulphuric acid	Sulphuric acid	Non-active substance	7664-93-9	231-639-5	4,5	4,5
Isononanoic acid	Isononanoic acid	Non-active substance	3302-10-1	221-975-0	2,25	2,5

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

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

Hazard statements	May be corrosive to metals. Causes severe skin burns and eye damage. Corrosive to the respiratory tract.
Precautionary statements	Do not breathe spray. Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection. IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER. Immediately call a doctor. Store in corrosion resistant container with a resistant inner liner. Dispose of contents in accordance with local regulations. Dispose of container in accordance with local regulations.

## 4. AUTHORISED USE(S) OF THE META SPC 8

### 4.1. Use description

Table 8

#### Use # 1 – Use # 8.1 – Hard surface disinfection by automated spraying in closed cleaning in place (CIP) system

Product type	PT04 - Food and feed area (Disinfectants)
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 Hard surface disinfection
Application method(s)	Method: Spraying  Detailed description:  Hard surface disinfection Automated dosing and spraying in closed CIP system CIP system: pipe work, fermentation and storage tanks
Application rate(s) and frequency	Application Rate: Concentrated product, 16,0-17,6% L-(+)-lactic acid  Dilution (%): 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: 600-1 000 kg

4.1.1. *Use-specific instructions for use*

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 <sup>(8)</sup> 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.

Goggles, 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.

<sup>(8)</sup> Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 8.

### 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	16,0
Methanesulphonic acid	Methanesulphonic acid	Non-active substance	75-75-2	200-898-6	10,5
Sulphuric acid	Sulphuric acid	Non-active substance	7664-93-9	231-639-5	4,5
Isononanoic acid	Isononanoic acid	Non-active substance	3302-10-1	221-975-0	2,5

#### 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	16,0

Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	18,75
Sulphuric acid	Sulphuric acid	Non-active substance	7664-93-9	231-639-5	4,5
Isononanoic acid	Isononanoic acid	Non-active substance	3302-10-1	221-975-0	2,5