



2024/2863

13.11.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/2863

of 12 November 2024

granting a Union authorisation for the biocidal product family 'Teat disinfectants L-(+)-lactic acid based biocidal product family of Novadan' 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 ⁽¹⁾, and in particular Article 44(5), first subparagraph, thereof,

Whereas:

- (1) On 30 April 2019, ITW Novadan ApS submitted an application to the European Chemicals Agency ('the Agency') in accordance with Article 43(1) of Regulation (EU) No 528/2012 for Union authorisation of a biocidal product family named 'Teat disinfectants L-(+)-lactic acid based biocidal product family of Novadan' of product-type 3, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Denmark had agreed to evaluate the application. The application was recorded under case number BC-DB051458-55 in the Register for Biocidal Products.
- (2) 'Teat disinfectants L-(+)-lactic acid based biocidal product family of Novadan' 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-type 3.
- (3) On 30 June 2023, 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 20 March 2024, the Agency submitted to the Commission its opinion ⁽²⁾, the draft summary of the biocidal product characteristics ('SPC') of 'Teat disinfectants L-(+)-lactic acid based biocidal product family of Novadan' 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 'Teat disinfectants L-(+)-lactic acid based biocidal product family of Novadan' 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(6) of that Regulation.
- (6) On 2 April 2024, 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 the biocidal product family 'Teat disinfectants L-(+)-lactic acid based biocidal product family of Novadan'.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

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

⁽²⁾ ECHA opinion of 27 February 2024 on the Union authorisation of 'Teat disinfectants L-(+)-lactic acid based biocidal product family of Novadan' (ECHA/BPC/413/2024) (<https://echa.europa.eu/opinions-on-union-authorisation>).

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0032465-0000 is hereby granted to ITW Novadan ApS for the making available on the market and use of the biocidal product family 'Teat disinfectants L-(+)-lactic acid-based biocidal product family of Novadan' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 3 December 2024 until 30 November 2034.

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, 12 November 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT FAMILY

Teat disinfectants L-(+)-lactic acid-based biocidal product family of Novadan

Product type(s)

PT03: Veterinary hygiene

Authorisation number: EU-0032465-0000**R4BP asset number:** EU-0032465-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name	Teat disinfectants L-(+)-lactic acid-based biocidal product family of Novadan
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1.2. Product type(s)

Product type(s)	PT03: Veterinary hygiene
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1.3. Authorisation holder

Name and address of the authorisation holder	Name	ITW Novadan ApS
	Address	Platinvej 21 6000 Kolding DK
Authorisation number		EU-0032465-0000
R4BP asset number		EU-0032465-0000
Date of the authorisation		3 December 2024
Expiry date of the authorisation		30 November 2034

1.4. Manufacturer(s) of the product

Name of manufacturer	Novadan ApS
Address of manufacturer	Platinvej 21, 6000 Kolding, Denmark
Location of manufacturing sites	Novadan ApS site 1 Platinvej 21, 6000 Kolding, Denmark

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

Active substance	L-(+)-lactic acid
Name of manufacturer	Purac Bioquímica SA
Address of manufacturer	Gran Viral, 19-25, 08160 Montmelo, Spain

Location of manufacturing sites	Purac Bioquimica SA site 1 Gran Viral, 19-25, 08160 Montmelo, Spain
Active substance	L-(+)-lactic acid
Name of manufacturer	Jungbunzlauer S.A.
Address of manufacturer	Z.I. Portuaire, 67390 Marckolsheim, France
Location of manufacturing sites	Jungbunzlauer S.A. site 1 Z.I. Portuaire, 67390 Marckolsheim, France

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	4,1-4,1 % (w/w)

2.2. Type(s) of formulation

Formulation type(s)	AL Any other liquid
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PART II

SECOND INFORMATION LEVEL – META SPC(S)

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 1 identifier

Identifier	Meta SPC: meta-SPC 1
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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	4,1-4,1 % (w/w)

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

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

Hazard statements	H318: Causes serious eye damage.
Precautionary statements	P280: Wear eye protection. 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/doctor.

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1

Use #1.1: post-milking manual dipping, ready-to-use (RTU)

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	Not relevant.
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: no data Scientific name: Yeasts Common name: Yeasts Development stage: no data
Field(s) of use	indoor use Teat disinfection product for dairy animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Method: manual dipping Detailed description: Post-milking manual dipping.
Application rate(s) and frequency	Application rate: Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 2-4 ml/animal per treatment. Dilution (%): Ready-to- use (RTU) products formulated to pH = 3 ± 0,1. Not to be diluted. Number and timing of application: Post-milking application 1-3 times per day (apply after every milking). Contact time: 5 minutes.

Category(ies) of users	professional
Pack sizes and packaging material	Can, high density polyethylene (HDPE): 0,5, 5, 10, 20, 60 litres Plastic drum, HDPE: 200 litres Intermediate bulk container (IBC), HDPE: 1 000 litres Opaque containers.

4.1.1. *Use-specific instructions*

Fill the reservoir for the dip cup with the ready-to-use (RTU) product and screw the dip cup on top.

Clean the teats carefully by wiping with a single service paper towel or cloth immediately before milking.

After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that the full length of the teat is immersed into the disinfectant.

Top up with fresh disinfectant by squeezing the reservoir as needed. After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

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.

4.2. **Use description**

Table 2

Use #1.4: post-milking automated dipping, ready-to-use (RTU)

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	Not relevant.
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: no data Scientific name: Yeasts Common name: Yeasts Development stage: no data
Field(s) of use	indoor use Teat disinfection product for dairy animals (cows, buffaloes, sheep, goats) for use after milking.

Application method(s)	Method: automated dipping Detailed description: Post-milking automated dipping.
Application rate(s) and frequency	Application rate: Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 2-4 ml/animal per treatment. Dilution (%): Ready-to- use (RTU) products formulated to pH = 3 ± 0,1. Not to be diluted. Number and timing of application: Post-milking application 1-3 times per day (apply after every milking). Contact time: 5 minutes.
Category(ies) of users	professional
Pack sizes and packaging material	Can, high density polyethylene (HDPE): 0,5, 5, 10, 20, 60 litres Plastic drum, HDPE: 200 litres Intermediate bulk container (IBC), HDPE: 1 000 litres Opaque containers.

4.2.1. Use-specific instructions

Open the container with the ready-to-use (RTU) product and insert the suction tube of the automated dipping-system.

Before milking clean teats carefully by automatic procedure or manually by carefully wiping with a single service paper towel or cloth.

After milking, the vacuum is shut off and the teat dip is injected into a manifold on the claw piece. The teats are coated with 2-4 ml of dip when the teat cup is withdrawn by the Automatic Cluster Removal (ACR).

The whole process is automated.

4.2.2. Use-specific risk mitigation measures

See general directions for use.

4.2.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use.

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

See general directions for use.

4.2.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

5. GENERAL DIRECTIONS FOR USE OF THE META SPC 1

5.1. Instructions for use

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

The product must be brought to temperature above 20 °C before use.

To ensure sufficient contact time, care shall be taken that the product is not removed after application.

Leave the product until next milking. Keep the animals standing until the product has dried (at least 5 minutes).

5.2. Risk mitigation measures

The following personal protective equipment (PPE) is stipulated without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.

The use of eye protection in accordance with the European Standard EN ISO 16321 or equivalent is mandatory during mixing and loading, manual spraying, dipping and cleaning tasks.

See section 6 for the full references to legislation and EN standards.

Avoid hand to eye transfer.

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

In the case of accident: Contact a doctor or casualty department – take the label or the safety data sheet.

Contact a doctor if in doubt about the injured person's condition or if the symptoms persist.

Never give an unconscious person water or other drink.

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

If symptoms: Call 112/ambulance for medical assistance.

If no symptoms: 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: 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/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/ambulance for medical assistance.

Environmental emergency measures

Avoid discharge to lakes, streams, sewers, etc.

Contain and collect spillage with non-combustible, absorbent material e.g., sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations.

Wherever possible cleaning should be performed with normal cleaning agents. Avoid use of solvents.

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

Method of disposal:

Dispose unused product and the packaging in accordance with local requirements.

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

Avoid release to an individual waste water treatment plant.

Empty containers are rinsed with plenty of water and disposed in accordance with local requirements.

The paper towels used for the cleaning of teats are disposed as mixed municipal waste (European Waste Catalogue (EWC) code 20 03 01).

Product is not covered by regulations on dangerous waste.

Other information:

When handling waste, consideration should be made to the safety precautions applying to handling of the product.

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

Store in a dry, cool well-ventilated area.

Protect from frost.

Protect from light.

Keep in original container.

Keep out of reach of children

Shelf-life: 24 months.

6. OTHER INFORMATION

Full references of legislation and EN standards referenced in section 5.2 'Risk mitigation measures':

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).

EN ISO 16321 – Eye and face protection for occupational use

With respect to the 'Category(ies) of users' note: 'Professionals (including industrial users) means trained professionals if this is required by national legislation.'

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)		Viri Barriere Dip	Market area: EU			
		Agro White Dip	Market area: EU			
		Lacto B Dip	Market area: EU			
Authorisation number		EU-0032465-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
L-(+)-lactic acid		Active substance	79-33-4	201-196-2	4,1 % (w/w)	

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

Trade name(s)		Viri TE Dip	Market area: EU			
		Agro Lac Dip	Market area: EU			
		Lacto Extra Dip	Market area: EU			
Authorisation number		EU-0032465-0002 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
L-(+)-lactic acid		Active substance	79-33-4	201-196-2	4,1 % (w/w)	

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

Trade name(s)		Nova FD	Market area: EU			
		Agro FD	Market area: EU			
		Lacto FD	Market area: EU			
		DF CUA	Market area: EU			
		Lacto Protect Film	Market area: EU			
Authorisation number		EU-0032465-0003 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
L-(+)-lactic acid		Active substance	79-33-4	201-196-2	4,1 % (w/w)	

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

Identifier	Meta SPC: meta-SPC 2
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1.2. Suffix to the authorisation number

Number	1-2
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1.3. Product type(s)

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

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

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

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

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

Hazard statements	H318: Causes serious eye damage.
Precautionary statements	P280: Wear eye protection. 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/doctor.

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1

Use #1.1: post-milking manual dipping, ready-to-use (RTU)

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	Not relevant.
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: no data Scientific name: Yeasts Common name: Yeasts Development stage: no data

Field(s) of use	indoor use Teat disinfection product for dairy animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Method: manual dipping Detailed description: Post-milking manual dipping.
Application rate(s) and frequency	Application rate: Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 2-4 ml/animal per treatment. Dilution (%): Ready-to- use (RTU) products formulated to pH = 3 ± 0,1. Not to be diluted. Number and timing of application: Post-milking application 1-3 times per day (apply after every milking). Contact time: 5 minutes.
Category(ies) of users	professional
Pack sizes and packaging material	Can, high density polyethylene (HDPE): 0,5, 5, 10, 20, 60 litres Plastic drum, HDPE: 200 litres Intermediate bulk container (IBC), HDPE: 1 000 litres Opaque containers.

4.1.1. Use-specific instructions

Fill the reservoir for the dip cup with the ready-to-use (RTU) product and screw the dip cup on top.

Clean the teats carefully by wiping with a single service paper towel or cloth immediately before milking.

After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that the full length of the teat is immersed into the disinfectant.

Top up with fresh disinfectant by squeezing the reservoir as needed. After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

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.

4.2. Use description

Table 2

Use #1.2 post-milking, manual spraying using a trigger sprayer, ready-to-use (RTU)

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	Not relevant.

Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: no data Scientific name: Yeasts Common name: Yeasts Development stage: no data
Field(s) of use	indoor use Teat disinfection product for dairy animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Method: manual spraying, trigger sprayer Detailed description: Post-milking manual using a trigger sprayer
Application rate(s) and frequency	Application rate: Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 2-4 ml/animal per treatment. Dilution (%): Ready-to- use (RTU) products formulated to pH = 3 ± 0,1. Not to be diluted. Number and timing of application: Post-milking application 1-3 times per day (apply after every milking). Contact time: 5 minutes.
Category(ies) of users	professional
Pack sizes and packaging material	Can, high density polyethylene (HDPE): 0,5, 5, 10, 20, 60 litres Plastic drum, HDPE: 200 litres Intermediate bulk container (IBC), HDPE: 1 000 litres Opaque containers.

4.2.1. Use-specific instructions

Fill the reservoir with the ready-to-use (RTU) product and screw the top of the trigger sprayer on it.

Clean the teats carefully by wiping with a single service paper towel or cloth immediately before milking.

After milking, spray the disinfectant on the teats using the trigger sprayer making sure that each teat is covered with the disinfectant.

Top up the reservoir with fresh disinfectant as needed.

After disinfection, empty the reservoir and clean reservoir and trigger sprayer by rinsing with water.

4.2.2. Use-specific risk mitigation measures

See general directions for use.

The professional bystander must wear the same personal protective equipment (PPE) as the professional user.

4.2.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use.

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

See general directions for use.

4.2.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use.

4.3. Use description

Table 3

Use #1.3 post-milking manual spraying using an electronic sprayer, ready-to-use (RTU)

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	Not relevant.
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: no data Scientific name: Yeasts Common name: Yeasts Development stage: no data
Field(s) of use	indoor use Teat disinfection product for dairy animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Method: Manual spraying with electronic sprayer Detailed description: Post-milking manual with electronic sprayer.
Application rate(s) and frequency	Application rate: Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 2-4 ml/animal per treatment. Dilution (%): Ready-to- use (RTU) products formulated to pH = 3 ± 0,1. Not to be diluted. Number and timing of application: Post-milking application 1-3 times per day (apply after every milking). Contact time: 5 minutes.
Category(ies) of users	professional
Pack sizes and packaging material	Can, high density polyethylene (HDPE): 0,5, 5, 10, 20, 60 litres Plastic drum, HDPE: 200 litres Intermediate bulk container (IBC), HDPE: 1 000 litres Opaque containers.

4.3.1. Use-specific instructions

Open the container with the ready -to-use (RTU) product and insert the suction tube of the electronic sprayer.

Clean the teats carefully by wiping with a single service paper towel or cloth immediately before milking.

After milking, spray the disinfectant on the teats using the electronic sprayer making sure that each teat is covered with the disinfectant.

Replace the empty container by a new one as needed. After disinfection, put the suction tube system into a bucket of water and rinse the sprayer by pumping the water through the sprayer.

4.3.2. Use-specific risk mitigation measures

See general directions for use.

The professional bystander must wear the same personal protective equipment (PPE) as the professional user.

4.3.3. 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.

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

See general directions for use.

4.3.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.4. **Use description**

Table 4

Use #1.4: post-milking automated dipping, ready-to-use (RTU)

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	Not relevant.
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: no data Scientific name: Yeasts Common name: Yeasts Development stage: no data
Field(s) of use	indoor use Teat disinfection product for dairy animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Method: automated dipping Detailed description: Post-milking automated dipping.
Application rate(s) and frequency	Application rate: Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 2-4 ml/animal per treatment. Dilution (%): Ready-to- use (RTU) products formulated to pH = 3 ± 0,1. Not to be diluted. Number and timing of application: Post-milking application 1-3 times per day (apply after every milking). Contact time: 5 minutes.
Category(ies) of users	professional
Pack sizes and packaging material	Can, high density polyethylene (HDPE): 0,5, 5, 10, 20, 60 litres Plastic drum, HDPE: 200 litres Intermediate bulk container (IBC), HDPE: 1 000 litres Opaque containers.

4.4.1. *Use-specific instructions*

Open the container with the ready-to-use (RTU) product and insert the suction tube of the automated dipping-system.

Before milking clean teats carefully by automatic procedure or manually by carefully wiping with a single service paper towel or cloth.

After milking, the vacuum is shut off and the teat dip is injected into a manifold on the claw piece. The teats are coated with 2-4 ml of dip when the teat cup is withdrawn by the Automatic Cluster Removal (ACR).

The whole process is automated.

4.4.2. *Use-specific risk mitigation measures*

See general directions for use.

4.4.3. *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.

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

See general directions for use.

4.4.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.5. **Use description**

Table 5

Use # 1.5: post-milking automated spraying by robot, ready-to-use (RTU)

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	Not relevant.
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: no data Scientific name: Yeasts Common name: Yeasts Development stage: no data
Field(s) of use	indoor use Teat disinfection product for dairy animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Method: automated spraying by robot Detailed description: Post-milking automated spraying by robot.
Application rate(s) and frequency	Application rate: Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 2-4 ml/animal per treatment. Dilution (%): Ready-to- use (RTU) products formulated to pH = 3 ± 0,1. Not to be diluted. Number and timing of application: Post-milking application 1-3 times per day (apply after every milking). Contact time: 5 minutes.
Category(ies) of users	professional
Pack sizes and packaging material	Can, high density polyethylene (HDPE): 0,5, 5, 10, 20, 60 litres Plastic drum, HDPE: 200 litres Intermediate bulk container (IBC), HDPE: 1 000 litres Opaque containers.

4.5.1. *Use-specific instructions*

Open the container with the ready-to-use (RTU) product and insert the suction tube of the robotic milking device.

The teats are cleaned by robot with automatic brushes. After robotic milking, 2-4 ml of the disinfectant is sprayed automatically onto teats from a cluster arm.

Rinsing of the sprayer is automatic.

4.5.2. *Use-specific risk mitigation measures*

See general directions for use.

4.5.3. *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.

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

See general directions for use.

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

The product must be brought to temperature above 20 °C before use.

To ensure sufficient contact time, care shall be taken that the product is not removed after application.

Leave the product until next milking. Keep the animals standing until the product has dried (at least 5 minutes).

5.2. **Risk mitigation measures**

The following personal protective equipment (PPE) is stipulated without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.

The use of eye protection in accordance with the European Standard EN ISO 16321 or equivalent is mandatory during mixing and loading, manual spraying, dipping and cleaning tasks.

See section 6 for the full references to legislation and EN standards.

Avoid hand to eye transfer.

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

In the case of accident: Contact a doctor or casualty department – take the label or this safety data sheet.

Contact a doctor if in doubt about the injured person's condition or if the symptoms persist.

Never give an unconscious person water or other drink.

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

If symptoms: Call 112/ambulance for medical assistance.

If no symptoms: 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: 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/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/ambulance for medical assistance.

Environmental emergency measures

Avoid discharge to lakes, streams, sewers, etc.

Contain and collect spillage with non-combustible, absorbent material e.g., sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations.

Wherever possible cleaning should be performed with normal cleaning agents. Avoid use of solvents.

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

Dispose unused product and the packaging in accordance with local requirements.

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

Avoid release to an individual waste water treatment plant.

Empty containers are rinsed with plenty of water and disposed in accordance with local requirements.

The paper towels used for the cleaning of teats are disposed as mixed municipal waste (European Waste Catalogue (EWC) code 20 03 01).

Product is not covered by regulations on dangerous waste.

Other information:

When handling waste, consideration should be made to the safety precautions applying to handling of the product.

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

Store in a dry, cool well-ventilated area.

Protect from frost.

Protect from light.

Keep in original container.

Keep out of reach of children

Shelf-life: 24 months.

6. OTHER INFORMATION

Full references of legislation and EN standards referenced in section 5.2 'Risk mitigation measures':

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).

EN ISO 16321 – Eye and face protection for occupational use

With respect to the 'Category(ies) of users' note: 'Professionals (including industrial users) means trained professionals if this is required by national legislation.'

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)		Viri TE Spray	Market area: EU			
		Agro Lac Spray	Market area: EU			
		Lacto Extra Spray	Market area: EU			
		LactoPlus	Market area: EU			
		Teho Lacta Spray	Market area: EU			
Authorisation number		EU-0032465-0004 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
L-(+)-lactic acid		Active substance	79-33-4	201-196-2	4,1 % (w/w)	

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

Trade name(s)		Nova LA Spray	Market area: EU			
		Agro LA Spray	Market area: EU			
		Lacto LA Spray	Market area: EU			
		Lacto Max	Market area: EU			
		Lacto Protect Sprüh	Market area: EU			
Authorisation number		EU-0032465-0005 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
L-(+)-lactic acid		Active substance	79-33-4	201-196-2	4,1 % (w/w)	