

Summary of product characteristics for a biocidal product family

Family name: Famille de produits Acide Lactique TP3 - CEETAL

Product type(s): PT03 - Veterinary hygiene (Disinfectants)

Authorisation number: FR-2023-0056

R4BP 3 asset reference number: FR-0021556-0000

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Part I.- First information level

1. Administrative information

1.1. Family name

Famille de produits Acide Lactique TP3 - CEETAL

1.2. Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

1.3. Authorisation holder

Name and address of the authorisation holder

Name	LABORATOIRES CEETAL
Address	1 RUE DES TOURISTES - CS 10039 42001 SAINT ETIENNE CEDEX 1 France

Authorisation number

FR-2023-0056

R4BP 3 asset reference number

FR-0021556-0000

Date of the authorisation

20/09/2023

Expiry date of the authorisation

19/09/2033

1.4. Manufacturer(s) of the biocidal products

Name of the manufacturer

LABORATOIRES CEETAL

Address of the manufacturer

1 rue des Touristes - CS10039 F-42001 Saint Etienne France

Location of manufacturing sites

1 rue des Touristes - CS10039 F-42001 Saint Etienne France

Route de Cahors F-46100 Cambes France

Name of the manufacturer	Vera Chimie
Address of the manufacturer	Zone industrielle du Broteau F-69540 Irigny France
Location of manufacturing sites	Zone industrielle du Broteau F-69540 Irigny France

Name of the manufacturer	Prodhynet
Address of the manufacturer	Zone industrielle des Châtelets F-22440 Ploufragan France
Location of manufacturing sites	Zone industrielle des Châtelets F-22440 Ploufragan France

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

Active substance	1322 - L-(+)-lactic acid
Name of the manufacturer	Jungbunzlauer S.A
Address of the manufacturer	ZI Portuaire - BP 32 F-67390 Marcklosheim France
Location of manufacturing sites	Jungbunzlauer S.A - ZI Portuaire - BP 32 F-67390 Marcklosheim France
	Jungbunzlauer Ladenburg GmbH - Dr. Albert-Reimann-Strasse 18 DE-68526 Ladenburg Germany
	Jungbunzlauer Austria AG - Factory Pernhofen AT-2064 Wulzeshofen Austria

Active substance	1322 - L-(+)-lactic acid
Name of the manufacturer	Purac Bioquimica sa
Address of the manufacturer	Gran Vial 19-25 08160 MONTMELÓ Spain
Location of manufacturing sites	Gran Vial 19-25 E-08160 MONTMELÓ Spain

Active substance	1322 - L-(+)-lactic acid
Name of the manufacturer	Purac Bioquimica sa
Address of the manufacturer	Arkelsedijk 46 4200 Gorinchem Netherlands
Location of manufacturing sites	Gran Arkelsedijk 46 4206 AC Gorinchem Netherlands

2. Product family composition and formulation

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26 - 10,26

2.2. Type(s) of formulation

AL - Any other liquid

Part II.- Second information level - meta SPC(s)

1. Meta SPC administrative information

1.1. Meta SPC identifier

MetaSPC 1 - Ready-to-use LIQUID products
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1.2. Suffix to the authorisation number

1-1

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26 - 10,26

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

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Causes serious eye damage.

Contains Carvone and d-limonene. May produce an allergic reaction.

Precautionary statements

Wear protective gloves.

Wear eye protection.

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/doctor/....

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Use#1 - Teat disinfection of milkable animals: Pre- and/or post-milking teat disinfection by manual liquid dipping

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Non-medical teat disinfection pre- and/or post-milking
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage: Scientific name: Common name: Yeasts Development stage: Scientific name: Common name: Enveloped viruses Development stage: Scientific name: Common name: Bacteriophages (pre-milking only) Development stage:
Field(s) of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Method: Open system: dip treatment Detailed description: Manual liquid dipping before and after milking
Application rate(s) and frequencies	Application Rate: Cows and buffaloes: 3 to 10ml - sheep:1.5 to 5 ml - goats: 2.5 to 6 ml Dilution (%): No dilution. Ready-to-use product Number and timing of application: - cows and buffaloes: 2 to 3 times per day for pre-milking disinfection and/or 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for pre-milking disinfection and/or 1 to 2 times per day for post-milking disinfection Contact time: 1 minute for pre-milking & 5 minutes for post-milking Ambient temperature
Category(ies) of users	Professional
Pack sizes and packaging material	1L HDPE Bottle 5L HDPE Jerrican 10L HDPE Jerrican 20L HDPE Jerrican 22L HDPE Jerrican 60L HDPE Drum

220L HDPE Drum
1000L HDPE Container

4.1.1 Use-specific instructions for use

- Fill manually the clean and dry 300 ml dipping cup with the 225ml of the ready to use product.
- Squeeze three to six times the dip cup reservoir to make the liquid product rise into the 2/3 of the dipping cup reservoir.
- Apply by dipping manually on animal's teats on the full length of the teat before or after milking.
- For pre-milking application, clean carefully the teats before application of the product. Leave the product for one minute then wipe with a single use paper or a towel.
- For post-milking application, leave the product until next milking. Keep the animals standing until the product has dried (at least 5 minutes).
- Clean the application equipment regularly with water

4.1.2 Use-specific risk mitigation measures

The professional user has to wear chemical goggles and gloves during loading, application by dipping and cleaning of the equipment.

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

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

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

-

4.2 Use description

Use 2 - Use # 2 - Teat disinfection of milkable animals: Pre- and/or post-milking teat disinfection by manual dipping with foam

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Non-medical teat disinfection pre- and/or post-milking

Target organism(s) (including development stage)

Scientific name:
Common name: Bacteria
Development stage:

Scientific name:
Common name: Yeasts
Development stage:

Scientific name:
Common name: Enveloped viruses
Development stage:

Scientific name:
Common name: Bacteriophages (pre-milking only)
Development stage:

Field(s) of use

Indoor

Disinfection of teats of milk producing animals

Application method(s)

Method: Open system: dip treatment
Detailed description:
Manual dipping with foam before and after milking

Application rate(s) and frequencies

Application Rate: Cows and buffaloes: 3 to 10ml - sheep:1.5 to 5 ml - goats: 2.5 to 6 ml
Dilution (%): No dilution. Ready-to-use product
Number and timing of application:
- cows and buffaloes: 2 to 3 times per day for pre-milking disinfection and/or 2 to 3 times per day for post-milking disinfection
- sheep and goats: 1 to 2 times per day for pre-milking disinfection and/or 1 to 2 times per day for post-milking disinfection

Contact time: 1 minute for pre-milking & 5 minutes for post-milking
Ambient temperature

Category(ies) of users

Professional

Pack sizes and packaging material

1L HDPE Bottle
5L HDPE Jerrican
10L HDPE Jerrican
20L HDPE Jerrican
22L HDPE Jerrican
60L HDPE Drum
220L HDPE Drum
1000L HDPE Container

4.2.1 Use-specific instructions for use

- Connect the container to the semi-automated dipping equipment.
- Press the trigger to fill the dipping cup reservoir with the liquid product.
- Apply by dipping manually on animal's teats on the full length of the teat before or after milking.
- For pre-milking application, clean carefully the teats before application of the product. Leave the product for one minute then wipe with a single use paper or a towel.
- For post-milking application, leave the product until next milking. Keep the animals standing until the product has dried (at least 5 minutes).
- Clean the application equipment regularly with water

4.2.2 Use-specific risk mitigation measures

The professional user has to wear chemical goggles and gloves during loading, application by dipping and cleaning of the equipment.

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

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

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

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4.3 Use description

Use 3 - Use # 3 - Teat disinfection of milkable animals: Pre- and/or post-milking teat disinfection by semi-automated liquid dipping

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Non-medical teat disinfection pre- and/or post-milking

Target organism(s) (including development stage)

Scientific name:
Common name: Bacteria
Development stage:

Scientific name:
Common name: Yeasts
Development stage:

Scientific name:
Common name: Enveloped viruses
Development stage:

Scientific name:
Common name: Bacteriophages (pre-milking only)
Development stage:

Field(s) of use

Indoor

Disinfection of teats of milk producing animals

Application method(s)

Method: Open system: dip treatment
Detailed description:
Semi-automated liquid dipping before and after milking

Application rate(s) and frequencies

Application Rate: Cows and buffaloes: 3 to 10ml - sheep:1.5 to 5 ml - goats: 2.5 to 6 ml
Dilution (%): No dilution. Ready-to-use product
Number and timing of application:

Application rate:

- cows and buffaloes: 3 to 10ml
- sheep: 1.5 to 5 ml
- goats: 2.5 to 6 ml

Frequency:

- cows and buffaloes: 2 to 3 times per day for pre-milking disinfection and/or 2 to 3 times per day for post-milking disinfection
- sheep and goats: 1 to 2 times per day for pre-milking disinfection and/or 1 to 2 times per day for post-milking disinfection

Contact time: 1 minute for pre-milking & 5 minutes for post-milking
Ambient temperature

Category(ies) of users

Professional

Pack sizes and packaging material

1L HDPE Bottle
5L HDPE Jerrican
10L HDPE Jerrican
20L HDPE Jerrican
22L HDPE Jerrican
60L HDPE Drum
220L HDPE Drum
1000L HDPE Container

4.3.1 Use-specific instructions for use

- Connect the container to the semi-automated dipping equipment.
- Press the trigger to fill the dipping cup reservoir with the liquid product.
- Apply by dipping manually on animal's teats on the full length of the teat before or after milking.
- For pre-milking application, clean carefully the teats before application of the product. Leave the product for one minute then wipe with a single use paper or a towel.
- For post-milking application, leave the product until next milking. Keep the animals standing until the product has dried (at least 5 minutes).
- Clean the application equipment regularly with water

4.3.2 Use-specific risk mitigation measures

The professional user has to wear chemical goggles and gloves during loading, application by dipping and cleaning of the equipment.

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

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

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

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4.4 Use description

Use 4 - Use # 4 - Teat disinfection of milkable animals: Pre- and/or post-milking teat disinfection by semi-automated dipping with foam

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Non-medical teat disinfection

Target organism(s) (including development stage)

Scientific name:
Common name: Bacteria
Development stage:

Scientific name:
Common name: Yeasts
Development stage:

Scientific name:
Common name: Enveloped viruses
Development stage:

Scientific name:
Common name: Bacteriophages (pre-milking only)
Development stage:

Field(s) of use

Indoor

Disinfection of teats of milk producing animals

Application method(s)

Method: Open system: dip treatment
Detailed description:
Semi-automated dipping with foam before and after milking

Application rate(s) and frequencies

Application Rate: Cows and buffaloes: 3 to 10ml - sheep: 1.5 to 5 ml - goats: 2.5 to 6 ml
Dilution (%): No dilution. Ready-to-use product
Number and timing of application:

Application rate:

- cows and buffaloes: 3 to 10ml
- sheep: 1.5 to 5 ml
- goats: 2.5 to 6 ml

Frequency:

- cows and buffaloes: 2 to 3 times per day for pre-milking disinfection and/or 2 to 3 times per day for post-milking disinfection
- sheep and goats: 1 to 2 times per day for pre-milking disinfection and/or 1 to 2 times per day for post-milking disinfection

Contact time: 1 minute for pre-milking & 5 minutes for post-milking
Ambient temperature

Category(ies) of users

Professional

Pack sizes and packaging material

1L HDPE Bottle
5L HDPE Jerrican
10L HDPE Jerrican
20L HDPE Jerrican
22L HDPE Jerrican
60L HDPE Drum
220L HDPE Drum
1000L HDPE Container

4.4.1 Use-specific instructions for use

- Connect the container to the semi-automated dipping equipment.
- Press the trigger to fill the dipping cup reservoir with the foaming product.
- Apply by dipping manually on animal's teats on the full length of the teat before or after milking.
- For pre-milking application, clean carefully the teats before application of the product. Leave the product for one minute then wipe with a single use paper or a towel.
- For post-milking application, leave the product until next milking. Keep the animals standing until the product has dried (at least 5 minutes).
- Clean the application equipment regularly with water.

4.4.2 Use-specific risk mitigation measures

The professional user has to wear chemical goggles during loading, application by dipping and cleaning of the equipment.

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

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

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

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4.5 Use description

Use 5 - Use # 5 - Teat disinfection of milkable animals: Pre- and/or post-milking teat disinfection by manual spraying

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Non-medical teat disinfection
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage: Scientific name: Common name: Yeasts Development stage: Scientific name: Common name: Enveloped viruses Development stage: Scientific name: Common name: Bacteriophages (pre-milking only) Development stage:
Field(s) of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Method: Spraying Detailed description: Manual spraying before and after milking
Application rate(s) and frequencies	Application Rate: - cows and buffaloes: 6 to 20ml - sheep: 3 to 10 ml - goats: 5 to 12 ml Dilution (%): No dilution. Ready-to-use product Number and timing of application: - cows and buffaloes: 2 to 3 times per day for pre-milking disinfection and/or 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for pre-milking disinfection and/or 1 to 2 times per day for post-milking disinfection Contact time: 1 minute for pre-milking & 5 minutes for post-milking Ambient temperature
Category(ies) of users	Professional
Pack sizes and packaging material	1L HDPE Bottle 5L HDPE Jerrican 10L HDPE Jerrican 20L HDPE Jerrican 22L HDPE Jerrican 60L HDPE Drum

220L HDPE Drum
1000L HDPE Container

4.5.1 Use-specific instructions for use

- Fill manually the reservoir tank of the adapted trigger spray in good condition.
- Apply on animal's teats on the full length of the teat before or after milking by pressing the trigger spray.
- For pre-milking application, clean carefully the teats before application of the product. Leave the product for one minute then wipe with a single use paper or a towel.
- For post-milking application, leave the product until next milking. Keep the animals standing until the product has dried (at least 5 minutes).
- Clean the application equipment regularly with water

4.5.2 Use-specific risk mitigation measures

- The professional user has to wear chemical goggles and gloves during loading, application by spraying and cleaning of the equipment.
- The professional bystander has to wear the same PPE than the professional user

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

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

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

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4.6 Use description

Use 6 - Use # 6 - Teat disinfection of milkable animals: Pre- and/or post-milking teat disinfection by semi-automated spraying

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Non-medical teat disinfection
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage: Scientific name: Common name: Yeasts Development stage: Scientific name: Common name: Enveloped viruses Development stage: Scientific name: Common name: Bacteriophages (pre-milking only) Development stage:
Field(s) of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Method: Spraying Detailed description: Semi-automated spraying before and/or after milking
Application rate(s) and frequencies	Application Rate: - cows and buffaloes: 6 to 20ml - sheep: 3 to 10 ml - goats: 5 to 12 ml Dilution (%): No dilution. Ready-to-use product Number and timing of application: - cows and buffaloes: 2 to 3 times per day for pre-milking disinfection and/or 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for pre-milking disinfection and/or 1 to 2 times per day for post-milking disinfection Contact time: 1 minute for pre-milking & 5 minutes for post-milking Ambient temperature
Category(ies) of users	Professional

Pack sizes and packaging material

1L HDPE Bottle
5L HDPE Jerrican
10L HDPE Jerrican
20L HDPE Jerrican
22L HDPE Jerrican
60L HDPE Drum
220L HDPE Drum
1000L HDPE Container

4.6.1 Use-specific instructions for use

- Connect the container to the semi-automated sprayer equipment.
- Apply on animal's teats on the full length of the teat before or after milking by pressing the trigger spray.
- For pre-milking application, clean carefully the teats before application of the product. Leave the product for one minute then wipe with a single use paper or a towel.
- For post-milking application, leave the product until next milking. Keep the animals standing until the product has dried (at least 5 minutes).
- Clean the application equipment regularly with water

4.6.2 Use-specific risk mitigation measures

- The professional user has to wear chemical goggles and gloves during loading, application by spraying and cleaning of the equipment.
- The professional bystander has to wear the same PPE than the professional user

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

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

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

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4.7 Use description

Use 7 - Use # 7 - Teat disinfection of milkable animals: Pre- and/or post-milking teat disinfection by automated spraying via a spray robot

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Non-medical teat disinfection
Target organism(s) (including development stage)	<p>Scientific name: Common name: Bacteria Development stage:</p> <p>Scientific name: Common name: Yeasts Development stage:</p> <p>Scientific name: Common name: Enveloped viruses Development stage:</p> <p>Scientific name: Common name: Bacteriophages (pre-milking only) Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>Disinfection of teats of milk producing animals</p>
Application method(s)	<p>Method: Spraying Detailed description: Automated spraying via a spray robot before and/or after milking</p>
Application rate(s) and frequencies	<p>Application Rate: - cows and buffaloes: 6 to 20ml - sheep: 3 to 10 ml - goats: 5 to 12 ml Dilution (%): No dilution. Ready-to-use product Number and timing of application:</p> <p>- cows and buffaloes: 2 to 3 times per day for pre-milking disinfection and/or 2 to 3 times per day for post-milking disinfection</p>

	<p>- sheep and goats: 1 to 2 times per day for pre-milking disinfection and/or 1 to 2 times per day for post-milking disinfection Contact time: 1 minute for pre-milking & 5 minutes for post-milking Ambient temperature</p>
Category(ies) of users	Professional
Pack sizes and packaging material	1L HDPE Bottle 5L HDPE Jerrican 10L HDPE Jerrican 20L HDPE Jerrican 22L HDPE Jerrican 60L HDPE Drum 220L HDPE Drum 1000L HDPE Container

4.7.1 Use-specific instructions for use

<ul style="list-style-type: none"> • Connect the container to the spray robot equipment. • Automatic spraying of the liquid product on animal's teats on the full length of the teat before or after milking. • For pre-milking application, clean carefully the teats before application of the product. Leave the product for one minute then wipe with a single use paper or a towel. • For post-milking application, leave the product until next milking. Keep the animals standing until the product has dried (at least 5 minutes). • Clean the application equipment regularly with water.

4.7.2 Use-specific risk mitigation measures

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

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

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

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4.8 Use description

Use 8 - Use # 8 - Teat disinfection of milkable animals: Pre- and/or post-milking teat disinfection by automated spraying via a robotic milking

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Non-medical teat disinfection
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage: Scientific name: Common name: Yeasts Development stage: Scientific name: Common name: Enveloped viruses Development stage: Scientific name: Common name: Bacteriophages (pre-milking only) Development stage:
Field(s) of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Method: Spraying Detailed description: Automated spraying via a robotic milking device (milking machine) before and/or after milking
Application rate(s) and frequencies	Application Rate: - cows and buffaloes: 6 to 20ml - sheep: 3 to 10 ml - goats: 5 to 12 ml Dilution (%): No dilution. Ready-to-use product Number and timing of application: - cows and buffaloes: 2 to 3 times per day for pre-milking disinfection and/or 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for pre-milking disinfection and/or 1 to 2 times per day for post-milking disinfection

Category(ies) of users

Professional

Pack sizes and packaging material

1L HDPE Bottle
5L HDPE Jerrican
10L HDPE Jerrican
20L HDPE Jerrican
22L HDPE Jerrican
60L HDPE Drum
220L HDPE Drum
1000L HDPE Container

4.8.1 Use-specific instructions for use

- Fill the tank of the automated robotic milking device.
- Automatic spraying of the liquid product on animal's teats on the full length of the teat before or after milking.
- For pre-milking application, clean carefully the teats before application of the product. Set up the robotic milking device to wash the teats one minute after the application then wipe with a single use paper or a towel.
- For post-milking application, leave the product until next milking. Keep the animals standing until the product has dried (at least 5 minutes).
- Clean the application equipment regularly with water.

4.8.2 Use-specific risk mitigation measures

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

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

-

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

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5. General directions for use of the meta SPC

5.1. Instructions for use

- Comply with the instructions for use.
- Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.).
- Inform the registration holder if the treatment is ineffective.
- The product must be brought to a temperature above 20° before use.

5.2. Risk mitigation measures

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

- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
- 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.
- 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/ambulance for medical assistance. Information to Healthcare personnel/doctor:
 - The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH>11), amines and acids like acetic acid, formic acid or propionic acid.

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

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste in accordance with local regulations.

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

<ul style="list-style-type: none">- Do no store above 40°C.- Protect from frost. - Shelf-life : 2 years

6. Other information

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7. Third information level: individual products in the meta SPC

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

Trade name(s)	Product 1-1 - CEETAL	Market area: FR
Authorisation number <small>(R4BP 3 asset reference number - National Authorisation)</small>	FR-0021556-0001 1-1	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26

Trade name(s)

Product 1-2 - CEETAL

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0021556-0002 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26

Trade name(s)

Product 1-3 - CEETAL

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0021556-0003 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26

Trade name(s)

Product 1-4 - CEETAL

Market area: FR

DERMA GERM

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0021556-0004 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26

Trade name(s)

Product 1-5 - CEETAL

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0021556-0005 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26

Trade name(s)

Product 1-6 - CEETAL

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0021556-0006 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26

1. Meta SPC administrative information**1.1. Meta SPC identifier**

MetaSPC 2 - Ready-to-use THICK LIQUIDS

1.2. Suffix to the authorisation number

1-2

1.3 Product type(s)

2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26 - 10,26

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

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Causes serious eye damage.

Contains Carvone and d-limonene. May produce an allergic reaction.

Precautionary statements

Wear eye protection.

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 attention.

Immediately call a POISON CENTER/doctor/....

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Use # 9 - Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping with a thick liquid

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Non-medical teat disinfection.
Target organism(s) (including development stage)	<p>Scientific name: Common name: Bacteria Development stage:</p> <p>Scientific name: Common name: Yeasts Development stage:</p> <p>Scientific name: Common name: Enveloped viruses Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>Disinfection of teats of milk producing animals</p>
Application method(s)	<p>Method: Open system: dip treatment Detailed description: Manual thick liquid dipping after milking.</p>
Application rate(s) and frequencies	<p>Application Rate: - cows and buffaloes: 3 to 10ml -sheep: 1.5 to 5 ml -goats: 2.5 to 6 ml Dilution (%): No dilution. Ready-to-use product Number and timing of application:</p> <ul style="list-style-type: none"> - cows and buffaloes: 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for post-milking disinfection <p>Contact time: 5 minutes Ambient temperature</p>
Category(ies) of users	Professional
Pack sizes and packaging material	<p>1L HDPE Bottle 5L HDPE Jerrican 10L HDPE Jerrican 20L HDPE Jerrican 22L HDPE Jerrican 60L HDPE Drum 220L HDPE Drum 1000L HDPE Container</p>

4.1.1 Use-specific instructions for use

- Fill manually the clean and dry 300 ml dipping cup with the 225ml of the ready to use product.
- Squeeze three to six times the dip cup reservoir to make the thick liquid product rise into the 2/3 of the dipping cup reservoir.
- Apply by dipping manually on animal's teats on the full length of the teat after milking.
- For post-milking application, leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes). At the next milking, clean the teats with a a single use paper or a towel.
- Clean the application equipment regularly with water.

4.1.2 Use-specific risk mitigation measures

The professional user has to wear chemical goggles during loading, application by dipping and cleaning of the equipment.

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

-

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

-

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

-

4.2 Use description

Use 2 - Use # 10 - Teat disinfection of milkable animals: Post-milking teat disinfection by semi-automated dipping with a thick liquid

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Non-medical teat disinfection.

Target organism(s) (including development stage)

Scientific name:
Common name: Bacteria
Development stage:

Scientific name:
Common name: Yeasts
Development stage:

Scientific name:
Common name: Enveloped viruses
Development stage:

Field(s) of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Method: Open system: dip treatment Detailed description: Semi-automated liquid dipping after milking
Application rate(s) and frequencies	Application Rate: Cows and buffaloes: 3 to 10ml - sheep:1.5 to 5 ml - goats: 2.5 to 6 ml Dilution (%): No dilution. Ready-to-use product Number and timing of application: - cows and buffaloes: 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for post-milking disinfection Contact time: 5 minutes Ambient temperature
Category(ies) of users	Professional
Pack sizes and packaging material	1L HDPE Bottle 5L HDPE Jerrican 10L HDPE Jerrican 20L HDPE Jerrican 22L HDPE Jerrican 60L HDPE Drum 220L HDPE Drum 1000L HDPE Container

4.2.1 Use-specific instructions for use

- Connect the container to the semi-automated dipping equipment.
- Press the trigger to fill the dipping cup reservoir with the thick liquid product.
- Apply by dipping manually on animal's teats on the full length of the teat after milking.
- For post-milking application, leave the product until next milking. Keep the animals standing at least 5 minutes. At the next milking, clean the teats with a a single use paper or a towel.
- Clean the application equipment regularly with water.

4.2.2 Use-specific risk mitigation measures

The professional user has to wear chemical goggles and gloves during loading, application by dipping and cleaning of the equipment.

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

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

-

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

-

5. General directions for use of the meta SPC

5.1. Instructions for use

- Comply with the instructions for use.
- Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.).
- Inform the registration holder if the treatment is ineffective.
- The product must be brought to a temperature above 20° before use

5.2. Risk mitigation measures

-

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

- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
- 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.
- 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/ambulance for medical assistance. Information to Healthcare personnel/doctor:
- The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH>11), amines and acids like acetic acid, formic acid or propionic acid

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

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste in accordance with local regulations.

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

- Do not store above 40°C.
- After storage, shake before use.
- Shelf-life : 2 years

6. Other information

7. Third information level: individual products in the meta SPC

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

Trade name(s)

Product 2-1 - CEETAL

Market area: FR

Authorisation number

FR-0021556-0007 1-2

(R4BP 3 asset reference number - National Authorisation)

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26

Trade name(s)

Product 2-2 - CEETAL

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0021556-0008 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26

Trade name(s)

Product 2-3 - CEETAL

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0021556-0009 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26

Trade name(s)

Product 2-4 – CEETAL

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0021556-0010 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26

Trade name(s)

Product 2-5 - CEETAL

Market area: FR

DERMASHIELD EXTRA

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0021556-0011 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26

Trade name(s)

Product 2-6 - CEETAL	Market area: FR
DERMASHIELD EXTRA 2	Market area: FR
Authorisation number <small>(R4BP 3 asset reference number - National Authorisation)</small> FR-0021556-0012 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26

Trade name(s)

Product 2-7 - CEETAL	Market area: FR
Authorisation number <small>(R4BP 3 asset reference number - National Authorisation)</small> FR-0021556-0013 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26

Trade name(s)

Product 2-8 - CEETAL

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0021556-0014 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26

1. Meta SPC administrative information

1.1. Meta SPC identifier

MetaSPC 3 - Ready-to-use FILM-FORMING THICK LIQUIDS

1.2. Suffix to the authorisation number

1-3

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26 - 10,26

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

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Causes serious eye damage.
Contains Carvone and d-limonene. May produce an allergic reaction.

Precautionary statements

Wear eye protection.
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/doctor/....

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Use # 11 Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping with a film-forming property thick liquid

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Non-medical teat disinfection.
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage: Scientific name: Common name: Yeasts Development stage: Scientific name: Common name: Enveloped viruses Development stage:
Field(s) of use	Indoor Disinfection of teats of milk producing animals
Application method(s)	Method: Open system: dip treatment Detailed description: Manual film-forming property thick liquid dipping after milking
Application rate(s) and frequencies	Application Rate: Cows and buffaloes: 3 to 10ml - sheep:1.5 to 5 ml - goats: 2.5 to 6 ml Dilution (%): No dilution. Ready-to-use product Number and timing of application: - cows and buffaloes: 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for post-milking disinfection Contact time: 5 minutes Ambient temperature
Category(ies) of users	Professional
Pack sizes and packaging material	1L HDPE Bottle 5L HDPE Jerrican 10L HDPE Jerrican 20L HDPE Jerrican 22L HDPE Jerrican 60L HDPE Drum 220L HDPE Drum 1000L HDPE Container

4.1.1 Use-specific instructions for use

- Fill manually the clean and dry 300 ml dipping cup with the 225ml of the ready to use product.
- Squeeze three to six times the dip cup reservoir to make the film-forming thick liquid product rise into the 2/3 of the dipping cup reservoir.
- Apply by dipping manually on animal's teats on the full length of the teat after milking.
- For post-milking application, leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes). At the next milking, clean the teats with a single use paper or a towel.
- Clean the application equipment regularly with water.

4.1.2 Use-specific risk mitigation measures

The professional user has to wear chemical goggles during loading, application by dipping and cleaning of the equipment.

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

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

-

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

-

4.2 Use description

Use 2 - Use # 12 - Teat disinfection of milkable animals: Post-milking teat disinfection by semi-automated dipping with a film-forming property thick liquid

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Non-medical teat disinfection

Target organism(s) (including development stage)

Scientific name:
Common name: Bacteria
Development stage:

Scientific name:

	<p>Common name: Yeasts Development stage:</p> <p>Scientific name: Common name: Enveloped viruses Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>Disinfection of teats of milk producing animals</p>
Application method(s)	<p>Method: Open system: dip treatment Detailed description: Semi-automated film-forming property thick liquid dipping after milking</p>
Application rate(s) and frequencies	<p>Application Rate: Cows and buffaloes: 3 to 10ml - sheep:1.5 to 5 ml - goats: 2.5 to 6 ml Dilution (%): No dilution. Ready-to-use product Number and timing of application:</p> <ul style="list-style-type: none"> - cows and buffaloes: 2 to 3 times per day for post-milking disinfection - sheep and goats: 1 to 2 times per day for post-milking disinfection <p>Contact time: 5 minutes Ambient temperature</p>
Category(ies) of users	<p>Professional</p>
Pack sizes and packaging material	<p>1L HDPE Bottle 5L HDPE Jerrican 10L HDPE Jerrican 20L HDPE Jerrican 22L HDPE Jerrican 60L HDPE Drum 220L HDPE Drum 1000L HDPE Container</p>

4.2.1 Use-specific instructions for use

- Connect the container to the semi-automated dipping equipment.
- Press the trigger to fill the dipping cup reservoir with the film-forming thick liquid product.
- Apply by dipping manually on animal's teats on the full length of the teat after milking.
- For post-milking application, leave the product until next milking. Keep the animals standing for five minutes. At the next milking, clean the teats with a single use paper or a towel.
- Clean the application equipment regularly with water.

4.2.2 Use-specific risk mitigation measures

The professional user has to wear chemical goggles and gloves during loading, application by dipping and cleaning of the equipment.

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

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

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

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5. General directions for use of the meta SPC

5.1. Instructions for use

- Comply with the instructions for use.
- Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.).
- Inform the registration holder if the treatment is ineffective.
- The product must be brought to a temperature above 20° before use

5.2. Risk mitigation measures

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

- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
- 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.
- 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/ambulance for medical assistance. Information to Healthcare personnel/doctor:
 - The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH>11), amines and acids like acetic acid, formic acid or propionic acid

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

- []
- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
 - Dispose of unused product, its packaging and all other waste in accordance with local regulations.

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

- []
- Do not store above 40°C.
 - Protect from frost.
 - Shelf-life : 2 years

6. Other information

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7. Third information level: individual products in the meta SPC

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

Trade name(s)

Product 3-1 - CEETAL

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0021556-0015 1-3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26

Trade name(s)

Product 3-2 - CEETAL

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0021556-0016 1-3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26

Trade name(s)

Product 3-3 - CEETAL

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0021556-0017 1-3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26

Trade name(s)

Product 3-4 - CEETAL

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0021556-0018 1-3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26

Trade name(s)

Product 3-5 - CEETAL	Market area: FR
DERMASHIELD RED	Market area: FR
Authorisation number (R4BP 3 asset reference number - National Authorisation) FR-0021556-0019 1-3	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26

Trade name(s)

Product 3-6 - CEETAL	Market area: FR
DERMASHIELD RED 2	Market area: FR
Authorisation number (R4BP 3 asset reference number - National Authorisation) FR-0021556-0020 1-3	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26

Trade name(s)

Product 3-7 - CEETAL

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0021556-0021 1-3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26

Trade name(s)

Product 3-8 - CEETAL

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0021556-0022 1-3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
L-(+)-lactic acid		Active Substance	79-33-4	201-196-2	10,26
