Summary of product characteristics for a biocidal product family

Family name: Famille de produits Acide Lactique TP3 - QUARON

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

Authorisation number: FR-2023-0055

R4BP 3 asset reference number: FR-0030925-0000

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Part I.- First information level

1. Administrative information

1.1. Family name

Famille de produits Acide Lactique TP3 - QUARON

1.2. Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

1.3. Authorisation holder

Name and address of the authorisation holder

Name	STOCKMEIER FRANCE SAS	
Address	3 rue de la Buhotière 35091 RENNES France	

Authorisation number

FR-2023-0055

R4BP 3 asset reference number

FR-0030925-0000

Date of the authorisation

Expiry date of the authorisation

20/09/2023

19/09/2033

1.4. Manufacturer(s) of the biocidal products

Name of the manufacturer

QUARON SAS

Address of the manufacturer

3 rue de la Buhotière – Saint-Jacques de la Lande - BP 89 152 F-35091 Rennes CEDEX 9 France

Location of manufacturing sites

3 rue de la Buhotière F-35136 Saint-Jacques de la Lande France France

Rue des Criquiers F-60220 Formerie 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	ungbunzlauer S.A - ZI Portuaire - BP 32 F-67390 Marcklosheim France		
Active substance	1322 - L-(+)-lactic acid		
Active substance	1322 - L-(+)-lactic acid		
Name of the manufacturer	rurac Bioquimica sa Gran Vial 19-25 08160 MONTMELÓ Spain		
Address of the manufacturer			
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 Gran Arkelsedijk 46 4206 AC Gorinchem Netherlands Gran Arkelsedijk 46 4206 AC Gorinchem Netherlands		
Address of the manufacturer			
Location of manufacturing sites			

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

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

Target organism(s) (including development stage)

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

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.

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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 uspackaging	se, the instructions for safe disposal of the product and its			
-				
4.1.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product torage			
-				
4.2 Use description Use 2 - Use # 2 - Teat disinfection manual dipping with foam	on of milkable animals: Pre- and/or post-milking teat disinfection by			
Product type	PT03 - Veterinary hygiene (Disinfectants)			
Where relevant, an exact description of the authorised use	Non-medical teat desinfection 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.						
.2.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid astructions and emergency measures to protect the environment						
-						
4.2.4 Where specific to the uspackaging	se, the instructions for safe disposal of the product and its					
-						
1.2.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product torage					
-						
4.3 Use description Use 3 - Use # 3 - Teat disinfections Semi-automated liquid dipping	on of milkable animals: Pre- and/or post-milking teat disinfection by					
Product type	PT03 - Veterinary hygiene (Disinfectants)					
Where relevant, an exact description of the authorised use	Non-medical teat desinfection 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 mlgoats: 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 4.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging 4.3.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 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 PT03 - Veterinary hygiene (Disinfectants) **Product type** Where relevant, an exact Non-medical teat desinfection description of the authorised Scientific name: Common name: Bacteria Development stage: Target organism(s) (including 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.

tion measures			
cal goggles during loading, application by dipping and cleaning of the equipment.			
se, the particulars of likely direct or indirect effects, first aid measures to protect the environment			
se, the instructions for safe disposal of the product and its			
se, the conditions of storage and shelf-life of the product torage			
on of milkable animals: Pre- and/or post-milking teat disinfection by			
PT03 - Veterinary hygiene (Disinfectants)			
Non-medical teat desinfection			
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 minute

- Clean the application equipment regu	ularly with water				
4.5.2 Use-specific risk mitiga	ation measures				
equipment.	 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 				
	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment				
4.5.4 Where specific to the u packaging	se, the instructions for safe disposal of the product and its				
-					
4.5.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product torage				
4.6 Use description					
Use 6 - Use # 6 - Teat disinfections semi-automated spraying	on of milkable animals: Pre- and/or post-milking teat disinfection by				
Product type	PT03 - Veterinary hygiene (Disinfectants)				
Where relevant, an exact description of the authorised use					
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 th minutes). 	ne product until next milking. Keep the animals standing until the product has dried (at least
Clean the application equipment reg	ularly with water
6.2 Use specific risk mitige	ation maggires
.6.2 Use-specific risk mitiga	ition measures
equipment.	hemical goggles and glovesduring loading, application by spraying and cleaning of the
The professional bystander has to w	vear the same PPE than the professional user
	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment
.6.4 Where specific to the us ackaging	se, the instructions for safe disposal of the product and its
6.5 Where specific to the us nder normal conditions of s	se, the conditions of storage and shelf-life of the product
Tuer Horman Conditions of 3	torage
7 Use description	
se 7 - Use # 7 - Teat disinfectio	on of milkoble enimele. Dree and/or neet milking test disinfection by
	on of milkable animals: Pre- and/or post-milking teat disinfection by robot
utomated spraying via a spray	

Where relevant, an exact description of the authorised

Target organism(s) (including development stage)

Non-medical teat disinfection

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 spray robot 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

4.7.1 Use-specific instructions for use

• 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 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 4.7.4 Where specific to the use, the instructions for safe disposal of the product and its packaging 4.7.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 4.8 Use description

Product type

PT03 - Veterinary hygiene (Disinfectants)

Use 8 - Use # 8 - Teat disinfection of milkable animals: Pre- and/or post-milking teat disinfection by

Where relevant, an exact description of the authorised use

automated spraying via a robotic milking

Non-medical teat disinfection

Scientific name:

Target organism(s) (including development stage)

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

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
-
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
-
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
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

5.2. 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.
E 4. Instructions for cofe diaposal of the product and its poskering
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 no store above 40°C. Protect from frost.
- 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

Product 1-1 - Quaron

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0030925-0001 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 - Quaron

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0030925-0002 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

Product 1-3 - Quaron

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0030925-0003 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 - Quaron

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0030925-0004 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

FESTA LACTYPUR; NET LACT; LAC DUO; LACTILAV; FOAM LACTIQUE; FOAM LACTIQUE ROBOT; LACTY F; INDAL LAC PUR G ; LACTILAV G ; FOAM LACTIQUE G; LAC G DUO ; FOAM LACTIQUE G ; INDAL LAC PUR; INDAL LAC SPRAY

Market area: FR

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0030925-0005 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)

LACTIM TEA ; LAC MOUSS TEA ; LAC RBTT; LACTY RT; INDAL LAC FOAM;

FESTA LACTYSPRAY; FESTA

LACTYFOAM; PULVE LACT; LAC MOUSS ; LACTIM; SPRAY LACTIQUE MOUSSE; SPRAY LACTIQUE M; LACTY S; INDAL ROBLACSPRAY; FESTA LACTYROBOT; SPRAY LACT R; LAC RBT;

LACTIMOUSSE; SPRAY LACTIQUE; SPRAY LACTIQUE ROBOT; LACTY R

Authorisation number

(R4BP 3 asset reference number - National

Authorisation)

FR-0030925-0006 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)

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.

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

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 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 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 goggle	es during loading, application by	/ dipping and cleaning of the e	quipment.

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 usunder normal conditions of s	se, the conditions of storage and shelf-life of the product storage
-	
4.2 Use description	
Use 2 - Use # 10 - Teat disinfect automated dipping with a thick	tion of milkable animals: Post-milking teat disinfection by semi- 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
-
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 measure:	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 no store above 40°C.
- After storage, shake before use.
- Shelf-life: 2 years

6. Other informatio	n	

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 - QUARON	Market area: FR
Authorisation number	FR-0030925-0007 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 - QUARON	Market area: FR
Authorisation number	FR-0030925-0008 1-2	
(R4BP 3 asset reference number - National Authorisation)	111-0030923-0000 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

Product 2-3 - QUARON

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0030925-0009 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 – QUARON

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0030925-0010 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

Product 2-5 - QUARON

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0030925-0011 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 - QUARON

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0030925-0012 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

INDAL LAC DIP M; FESTA M LACTY; LACTI PRO MENTHE; LACTY DIP MENTHE; INDAL NATUR A+; FESTA COSME LACTY; FESTA COSME LACT; TREMP LACT C; LAC DIP COS;

Market area: FR

LACTICOS; LACTIQUE SOFT; LACTIQUE TS; LACTY TT; INDAL LAC DIP; FESTA LACTY; TREMP LACT E; LAC DIP E; LACTIPRO; LACTIQUE EPAIS; LACTIQUE

<u>ÉTÉ ; LACTY DIP</u>

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0030925-0013 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)

LACTY TTM ; LACTIQUE TSM ; LACTICOS M ; LACTIQUE SOFT M

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0030925-0014 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: Cows and buffaloes: 3 to 10ml - sheep:1.5 to 5 ml - goats: 2.5 to 6 ml Application rate(s) and Dilution (%): No dilution. Ready-to-use product frequencies 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 Professional Category(ies) of users 1L HDPE Bottle Pack sizes and packaging 5L HDPE Jerrican material 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 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 usunder normal conditions of s	se, the conditions of storage and shelf-life of the product storage				
-					
4.2 Use description					
Use 2 - Use # 12 - Teat disinfect automated dipping with a film-f	tion of milkable animals: Post-milking teat disinfection by semi- orming 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:				
	Indoor				
Field(s) of use	Disinfection of teats of milk producing animals				
Application method(s)	Method: Open system: dip treatment Detailed description: Semi-automated 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						
4.2.1 Use-specific instruction	ns for use						
- Apply by dipping manually on anima	p reservoir with the film-forming thick liquid product. I's teats on the full length of the teat after milking. The product until next milking. Keep the animals standing for five minutes. At the next milking, or a towel.						
4.2.2 Use-specific risk mitiga	ition measures						
The professional user has to wear chemi equipment.	cal goggles and gloves during loading, application by dipping and cleaning of the						
<u>-</u>	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment						
-							
4.2.4 Where specific to the uppackaging	se, the instructions for safe disposal of the product and its						
-							

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
-
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:

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.

• 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

• Dispose of unused product, its packaging and all other waste in accordance with local regulations.

Do no store above 40°C.Protect from frost.				
- Shelf-life : 2 years				
6. Other information				
'. Third information lev	el: individual p	roducts in the m	neta SPC	
	isation number a	and specific comp	osition of each	individual
roduct	Product 3-1 - QU		Market area: FR	individual
rade name(s) Authorisation number HABP 3 asset reference number - National		JARON		individual
rade name(s) Authorisation number	Product 3-1 - QU	JARON		individual
7.1 Trade name(s), authororoduct Frade name(s) Authorisation number AUBP 3 asset reference number - National authorisation)	Product 3-1 - QU	JARON 5 1-3	Market area: FR	Content (%)

Product 3-2 - QUARON

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0030925-0016 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 - QUARON

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0030925-0017 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

Product 3-4 - QUARON

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0030925-0018 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 - QUARON

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0030925-0019 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

Product 3-6 - QUARON

Market area: FR

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0030925-0020 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)

INDAL CRYSTAL FILM; FESTA CAP

LACTY; FESTA CAP LACT; TREMP LACT FILM; LAC DIP FILM; LACTIBAR;

LACTIQUE + ; LACTIQUE H ; LACTY FILM ;

LACTY FILM GT ; LACTIBAR GT ; TREMP CITLACT FILM ; LAC CIT DIP FILM

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0030925-0021 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

LACTIQUE H BLUE ; LACTIQUE HB

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

FR-0030925-0022 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