Summary of product characteristics for a biocidal product

Product name: Product 1-6 - CEETAL

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

Authorisation number: FR-2023-0056

R4BP 3 asset reference number: FR-0021556-0006

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Administrative information

1.1. Trade names of the product

Product 1-6 - CEETAL		

1.2. 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 1-1

R4BP 3 asset reference number

FR-0021556-0006

Date of the authorisation

20/09/2023

Expiry date of the authorisation

19/09/2033

1.3. 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

1.4. 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

Location of manufacturing sites

Name of the manufacturer

Address of the manufacturer

Arkelsedijk 46 4200 Gorinchem Netherlands

Purac Bioquimica sa

Gran Arkelsedijk 46 4206 AC Gorinchem Netherlands

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the biocidal product

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

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

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)

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

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.

	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment
4.1.4 Where specific to the u packaging	se, the instructions for safe disposal of the product and its
-	
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 # 2 - Teat disinfection	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(e) of year	Indoor
Field(s) of use	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, fir	st 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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12 E Whore aposific to the u	no the conditions of storage and shalf life of the product
4.2.5 where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product
-	
4.3 Use description	
Use 3 - Use # 3 - Teat disinfection	on 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	Non-medical teat desinfection pre- and/or post-milking
description of the authorised use	Non-medical teat desiniection pre- and/or post-miking
Target organism(s) (including	Scientific name: Common name: Bacteria
development stage)	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	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
frequencies	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 instruction	ns 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 mitiga	tion measures			
The professional user has to wear chemi equipment.	The professional user has to wear chemical goggles and gloves during loading, application by dipping and cleaning of the equipment.			
<u>-</u>	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment			
-				
4.3.4 Where specific to the uppackaging	se, the instructions for safe disposal of the product and its			
-				

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			
4.4 Use description			
Use 4 - Use # 4 - Teat disinfection semi-automated dipping with for	on of milkable animals: Pre- and/or post-milking teat disinfection by pam		
Product type	PT03 - Veterinary hygiene (Disinfectants)		
Where relevant, an exact description of the authorised use	Non-medical teat desinfection		
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 1L HDPE Bottle 5L HDPE Jerrican 10L HDPE Jerrican 20L HDPE Jerrican 22L HDPE Jerrican 60L HDPE Drum 220L HDPE Drum 1000L HDPE Container		
Pack sizes and packaging material			
4.4.1 Use-specific instructio	ns for use		
Apply by dipping manually on anim For pre-milking application, clean c wipe with a single use paper or a towel.	tup reservoir with the foaming product. al's teats on the full length of the teat before or after milking. arefully the teats before application of the product. Leave the product for one minute then the product until next milking. Keep the animals standing until the product has dried (at least		
4.4.2 Use-specific risk mitig	ation measures		
The professional user has to wear chemical goggles during loading, application by dipping and cleaning of the equipment.			
-	use, the particulars of likely direct or indirect effects, first aid measures to protect the environment		
-			
4.4.4 Where specific to the ι packaging	ise, the instructions for safe disposal of the product and its		

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1.4.5 Where specific to the usunder normal conditions of s	se, the conditions of storage and shelf-life of the product storage
-	
4.5 Use description	
Use 5 - Use # 5 - Teat disinfecti manual 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	Non-medical teat desinfection
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:
	Indoor
Field(s) of use	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 instruction	ons for use
Apply on animal's teats on the full For pre-milking application, clean wipe with a single use paper or a towe	the product until next milking. Keep the animals standing until the product has dried (at least
4.5.2 Use-specific risk mitiç	gation measures
equipment.	r chemical goggles and gloves during loading, application by spraying and cleaning of the wear the same PPE than the professional user
	use, the particulars of likely direct or indirect effects, first aid y measures to protect the environment
-	
4.5.4 Where specific to the packaging	use, the instructions for safe disposal of the product and its
-	

4.5.5 Where specific to the usunder normal conditions of s	se, the conditions of storage and shelf-life of the product storage
-	
4.6 Use description	
Use 6 - Use # 6 - Teat disinfection 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	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:
	Indoor
Field(s) of use	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	o the	semi-automated	spraye	er equipment.
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- 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

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 us under normal conditions of s	se, the conditions of storage and shelf-life of the product torage
-	
4.7 Use description	
Use 7 - Use # 7 - Teat disinfection automated spraying via a spray	on of milkable animals: Pre- and/or post-milking teat disinfection by 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)	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
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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
-
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

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, leave the product until next milking. Keep the animals standing until the product has dried (at least
- - 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
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 no store above 40°C Protect from frost.
- Shelf-life : 2 years
6. Other information