Summary of product characteristics for a biocidal product

Product name: GMP 42

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

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Authorisation number: 2019-07-31-B03

R4BP 3 asset reference number: MT-0013584-0009

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Administrative information

1.1. Trade names of the product

Proactive Plus		
Proactive Plus		
Proactive Plus		
Proactive Plus		

1.2. Authorisation holder

Name and address of the authorisation holder

Name	DeLaval NV
Address	Industriepark-Drongen 10 9031 Gent Belgium

Authorisation number

R4BP 3 asset reference

Date of the authorisation

Expiry date of the authorisation

number

MT-0013584-0009
02/08/2019
01/08/2029

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer

DeLaval NV

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Address of the manufacturer

Industriepark-Drongen 10 9031 Gent Belgium

Location of manufacturing sites

Industriepark-Drongen 10 9031 Gent Belgium

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

Active substance	1319 - Iodine
Name of the manufacturer	Sociedad Quimica y Minera (SQM) S.A.
Address of the manufacturer	Supplier EU: SQM Europe NV - Sint-Pietersvliet 7 bus 8 2000 Antwerpen Belgium
Location of manufacturing sites	Los Militares 4290 Piso 4 8320000 Las Condes (Santiago) Chile

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 (%)
lodine		Active Substance	7553-56-2	231-442-4	0,15
Alcohol ethoxylate		Non-active substance	68439-46-3		0
Sodium iodide		Non-active substance	7681-82-5	231-679-3	0,07

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements	Harmful to aquatic life with long lasting effects. May be corrosive to metals.
Precautionary statements	Keep out of reach of children. Avoid release to the environment.

4. Authorised use(s)

4.1 Use description

Use 1 - Teat disinfection, Ready-to-use dip products applied manually

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Teat disinfectant

Target organism(s) (including development stage)

Scientific name: Common name: Bacteria Development stage:

Scientific name: Common name: Yeasts Development stage:

Scientific name: Common name: Viruses Development stage:

Field(s) of use

Indoor

The product is intended for post-milking teat disinfection.

The product is applied directly after milking on the teats of lactating animals

Application method(s)

Method: Post-milking teat disinfection of udder teats with ready-to-use products.

Detailed description:

The product is applied manually after milking on the teats by manual dipping using a dip

cup.

Application rate(s) and frequencies

Application Rate: ca. 5 ml per cow; ca. 2.5 ml per sheep or goat

Dilution (%): 0%

Number and timing of application:

To be applied after milking, 2 times per day. The products can be used all year during

the lactation period.

Category(ies) of users

Professional

Pack sizes and packaging material

Can, Plastic: HDPE , 5L Can, Plastic: HDPE , 10L Can, Plastic: HDPE , 20L Can, Plastic: HDPE , 60L Drum, Plastic: HDPE , 200L IBC, Plastic: HDPE , 1000L

4.1.1 Use-specific instructions for use

4.1.1 Use-specific instructions for use

The product is a ready-to-use product an The product must be brought to a tempe	
Directions for use:	
It is recommended to wear gloves during manual application: use a clean dip cup.	milking and application to protect the skin and ensure hygienic milking condition. For
Ensure that teats are clean before use. A	apply the ready-to-use solution of the product on each teat immediately after milking:
DIP: dip every teat in the product. Ensure necessary;	e that the teat is covered to at least three quarters length and replenish the dip cup as
Allow teats to dry after application during	at least 5 min and keep the animals standing during this period.
4.1.2 Use-specific risk mitiga	tion measures
There are no use specific risk mitigation	measures. See 5.2 for general instructions.
-	se, the particulars of likely direct or indirect effects, first aid
There are no use specific instructions. So	measures to protect the environment ee 5.3 for general instructions.
There are no use specific instructions. So	·
There are no use specific instructions. So 4.1.4 Where specific to the u	se, the instructions for safe disposal of the product and its
There are no use specific instructions. So 4.1.4 Where specific to the upackaging There are no use specific instructions. So	se, the instructions for safe disposal of the product and its ee 5.4 for general instructions. se, the conditions of storage and shelf-life of the product
There are no use specific instructions. So 4.1.4 Where specific to the upackaging There are no use specific instructions. So 4.1.5 Where specific to the use	se, the instructions for safe disposal of the product and its ee 5.4 for general instructions. se, the conditions of storage and shelf-life of the product
There are no use specific instructions. So 4.1.4 Where specific to the upackaging There are no use specific instructions. So 4.1.5 Where specific to the use	se, the instructions for safe disposal of the product and its ee 5.4 for general instructions. se, the conditions of storage and shelf-life of the product
There are no use specific instructions. So 4.1.4 Where specific to the use packaging There are no use specific instructions. So 4.1.5 Where specific to the use under normal conditions of second conditions.	se, the instructions for safe disposal of the product and its ee 5.4 for general instructions. se, the conditions of storage and shelf-life of the product

Where relevant, an exact description of the authorised

Target organism(s) (including development stage)

Teat disinfectant

Scientific name: Common name: Bacteria Development stage:

Scientific name: Common name: Yeast Development stage:

Scientific name: Common name: Viruses Development stage:

Field(s) of use

Indoor

The product is intended for post-milking teat disinfection.

The product is applied directly after milking on the teats of lactating animals

Application method(s)

Method: post-milking teat disinfection of udder teats with ready-to-use products Detailed description:

The product is applied manually after milking on the teats by spraying using a spray

container.

Application rate(s) and frequencies

Application Rate: ca. 5 ml per cow; ca. 2.5 ml per sheep or goat

Dilution (%): 0%

Number and timing of application:

To be applied after milking, 2 times per day. The products can be used all year during the lactation period.

Category(ies) of users

Professional

Pack sizes and packaging material

Can, Plastic: HDPE, 5L Can, Plastic: HDPE, 10L Can, Plastic: HDPE, 20L Can, Plastic: HDPE, 60L Drum, Plastic: HDPE, 200L IBC, Plastic: HDPE, 1000L

4.2.1 Use-specific instructions for use

The product is a ready-to-use product and is used undiluted.

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

Directions for use:

For manual application: use a clean applicator.

Ensure that teats are clean before use. Apply the ready-to-use solution of the product on each teat immediately after milking:

1) MANUAL TRIGGER SPRAY: spray every teat 1 sec. with the product. Ensure that the teat is covered to at least three quarters length and replenish the spray container as necessary;

2) AUTOMATIC SPRAYER: spray every teat 1 sec. with the product.

Allow teats to dry after application during at least 5 min and keep the animals standing during this period.

4.2.2 Use-specific risk mitigation measures

Use chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during postmilking teat disinfection by manual spraying. See 5.2 for general instructions.

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

There are no use specific instructions. See 5.3 for general instructions.

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

There are no use specific instructions. See 5.4 for general instructions.

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

4.3 Use description

Use 3 - Teat disinfection, Ready-to-use dip or spray products applied automatically

Product type

Where relevant, an exact description of the authorised use

Target organism(s) (including development stage)

PT03 - Veterinary hygiene (Disinfectants)

Teat disinfectant

Scientific name:

Common name: Bacteria Development stage:

Scientific name: Common name: Yeasts Development stage:

Scientific name: Common name: Viruses Development stage:

Field(s) of use

Indoor

The product is intended for post-milking teat disinfection.

The product is applied directly after milking on the teats of lactating animals

Application method(s)

Method: Post-milking teat disinfection of udder teats with ready-to-use products.

Detailed description:

The product is applied automatically by milking machines after milking on the teats by integrated dipping or spraying device.

Application rate(s) and frequencies	Application Rate: ca. 5 ml per cow; ca. 2.5 ml per sheep or goat Dilution (%): 0% Number and timing of application: To be applied after milking, 3 times per day. The products can be used all year during the lactation period.
Category(ies) of users	Professional
Pack sizes and packaging material	Can, Plastic: HDPE , 5L Can, Plastic: HDPE , 10L Can, Plastic: HDPE , 20L Can, Plastic: HDPE , 60L Drum, Plastic: HDPE , 200L IBC, Plastic: HDPE , 1000L
4.3.1 Use-specific instruction	ns for use
The product is a ready-to-use product and The product must be brought to a temper	
4.3.2 Use-specific risk mitiga	tion measures
There are no use specific risk mitigation r	measures. See 5.2 for general instructions.
<u>=</u>	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment
There are no use specific instructions. Se	ee 5.3 for general instructions.
4.3.4 Where specific to the us packaging	se, the instructions for safe disposal of the product and its
There are no use specific instructions. Se	ee 5.4 for general instructions.

5. General direc	ctions for use
5.1. Instructions	for use
There are no general in	nstructions for use. See the use specific instructions for use.
5.2. Risk mitigati	on measures
In case a combination of considered for pre-milki	of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be ing disinfection.
5.3. Particulars o	f likely direct or indirect effects, first aid instructions and emergency
	tect the environment
measures to prot	tect the environment
DIRECT/INDIRECT EF According to our experi handled as specified. FIRST AID MEASURES Eye contact: Rinse thor Skin contact: Wash off	FECTS: ence and to the information provided to us, the product does not have any adverse effects if it is used and
DIRECT/INDIRECT EF According to our experinandled as specified. FIRST AID MEASURES Eye contact: Rinse thoron Skin contact: Wash offingestion: Wash out moingested. Inhalation: Move to fres EMERGENCY MEASU Prevent further leakage	FECTS: ence and to the information provided to us, the product does not have any adverse effects if it is used and S: oughly with plenty of water for at least 15 minutes. If eye irritation persists: Get medical advice/attention. immediately with soap and plenty of water removing all contaminated clothes and shoes. outh with water. Seek medical advice immediately if symptoms occur and/or large quantities have been
DIRECT/INDIRECT EF According to our experi handled as specified. FIRST AID MEASURES Eye contact: Rinse thor Skin contact: Wash off Ingestion: Wash out moingested. Inhalation: Move to fres EMERGENCY MEASU Prevent further leakage absorbent material. Preserved.	FECTS: ence and to the information provided to us, the product does not have any adverse effects if it is used and S: roughly with plenty of water for at least 15 minutes. If eye irritation persists: Get medical advice/attention. immediately with soap and plenty of water removing all contaminated clothes and shoes. Bouth with water. Seek medical advice immediately if symptoms occur and/or large quantities have been sh air. RES TO PROTECT THE ENVIRONMENT: Per or spillage if safe to do so. Methods and materials for containment and clean-up: Dam up. Soak up with iner
DIRECT/INDIRECT EF According to our experi- handled as specified. FIRST AID MEASURES Eye contact: Rinse thor- Skin contact: Wash off- Ingestion: Wash out mo- ingested. Inhalation: Move to fres EMERGENCY MEASU Prevent further leakage absorbent material. Pre-	FECTS: ence and to the information provided to us, the product does not have any adverse effects if it is used and S: oughly with plenty of water for at least 15 minutes. If eye irritation persists: Get medical advice/attention. immediately with soap and plenty of water removing all contaminated clothes and shoes. buth with water. Seek medical advice immediately if symptoms occur and/or large quantities have been sh air. RES TO PROTECT THE ENVIRONMENT: or spillage if safe to do so. Methods and materials for containment and clean-up: Dam up. Soak up with ine event product from entering drains. Keep in suitable and closed containers for disposal. for safe disposal of the product and its packaging ment, dispose unused product and the packaging in accordance with local requirements. Used product can be a sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual
DIRECT/INDIRECT EF According to our experi handled as specified. FIRST AID MEASURES Eye contact: Rinse thor Skin contact: Wash out moingested. Inhalation: Move to fres EMERGENCY MEASU Prevent further leakage absorbent material. Present further leakage absorbent material.	FECTS: ence and to the information provided to us, the product does not have any adverse effects if it is used and S: oughly with plenty of water for at least 15 minutes. If eye irritation persists: Get medical advice/attention. immediately with soap and plenty of water removing all contaminated clothes and shoes. buth with water. Seek medical advice immediately if symptoms occur and/or large quantities have been sh air. RES TO PROTECT THE ENVIRONMENT: or spillage if safe to do so. Methods and materials for containment and clean-up: Dam up. Soak up with ine event product from entering drains. Keep in suitable and closed containers for disposal. for safe disposal of the product and its packaging ment, dispose unused product and the packaging in accordance with local requirements. Used product can be a sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual