

Summary of product characteristics for a biocidal product

Product name: GMP 34

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

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Authorisation number: 781-3

R4BP 3 asset reference number: DK-0012830-0006

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Administrative information

1.1. Trade names of the product

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1.2. Authorisation holder

Name and address of the authorisation holder

Name	DeLaval NV
Address	Industriepark-Drongen 10 9031 Gent Belgium

Authorisation number

781-3 1-3

R4BP 3 asset reference number

DK-0012830-0006

Date of the authorisation

02/08/2019

Expiry date of the authorisation

01/08/2029

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer

DeLaval NV

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 (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,15
Alcohol ethoxylate		Non-active substance	68439-46-3		1,25
Sodium iodide		Non-active substance	7681-82-5	231-679-3	0,065

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements

Precautionary statements

Keep out of reach of children.

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

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:

It is recommended to wear gloves during milking and application to protect the skin and ensure hygienic milking condition. For manual application: use a clean dip cup.

Ensure that teats are clean before use. Apply the ready-to-use solution of the product on each teat immediately after milking: DIP: dip every teat in the product. Ensure that the teat is covered to at least three quarters length and replenish the dip cup as necessary;

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 mitigation measures

There are no use specific risk mitigation measures. See 5.2 for general instructions.

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

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

4.1.4 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.

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

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4.2 Use description

Use 2 - Teat disinfection, Ready-to-use spray 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)	<p>Scientific name: Common name: Bacteria Development stage:</p> <p>Scientific name: Common name: Yeast Development stage:</p> <p>Scientific name: Common name: Viruses Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>The product is intended for post-milking teat disinfection. The product is applied directly after milking on the teats of lactating animals</p>
Application method(s)	<p>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.</p>
Application rate(s) and frequencies	<p>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.</p>
Category(ies) of users	Professional
Pack sizes and packaging material	<p>Can, Plastic: HDPE , 5L Can, Plastic: HDPE , 10L Can, Plastic: HDPE , 20L Can, Plastic: HDPE , 60L Drum, Plastic: HDPE , 200L IBC, Plastic: HDPE , 1000L</p>

4.2.1 Use-specific instructions for use

The product is a ready-to-use products 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 post-milking 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

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4.3 Use description

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

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 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 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.

4.3.2 Use-specific risk mitigation measures

There are no use specific risk mitigation measures. See 5.2 for general instructions.

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

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

4.3.4 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.

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

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5. General directions for use

5.1. Instructions for use

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

5.2. Risk mitigation measures

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

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

DIRECT/INDIRECT EFFECTS:

According to our experience and to the information provided to us, the product does not have any adverse effects if it is used and handled as specified.

FIRST AID MEASURES:

Eye contact: Rinse thoroughly with plenty of water for at least 15 minutes. If eye irritation persists: Get medical advice/attention..

Skin contact: Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.

Ingestion: Wash out mouth with water. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested.

Inhalation: Move to fresh air.

EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT:

Prevent further leakage or spillage if safe to do so. Methods and materials for containment and clean-up: Dam up. Soak up with inert absorbent material. Prevent product from entering drains. Keep in suitable and closed containers for disposal.

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

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

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

Storage: Store upright in the tightly closed original container. Protect from direct light, temperatures above 30°C and frost.
Shelf-life: 1 year.

6. Other information

Danish label

Oplysninger til etiket og brugsanvisning Delaval Iodine-based teat disinfectant family, MetaSPC "3" BPR-reg. nr. 781-3-3-x [1]
I. Etiketten skal udformes i overensstemmelse med det godkendte resumé af det biocidholdige produkts egenskaber, jf. artikel 69, stk. 1, i biocidforordningen (Forordning (EU) nr. 528/2012), og CLP-Forordningen [2].

II. Det er udelukkende ansøgers/godkendelsesindehaverens ansvar, at etiket, mærkning og pakning lever op til lovens krav, jf. biocidforordningen artikel 69. Etiket og mærkning skal være på dansk.
Nedenstående tekst i afsnit III er bidrag til overholdelsen af reglerne og således kun en del af de krav, som stilles til blandt andet etiketten.

III. Etiketten skal indeholde nedenstående oplysninger. Op-lys-ninger i citationstegn skal angives ordret:

1) I hovedfeltet:
"Veterinærhygiejne

Må kun anvendes erhvervsmæssigt til yverdesinfektion af bakterier, gær og virus på køer, får og geder efter malkning."

2) I advarselsfeltet:
"FORSIGTIG

Vask huden grundigt efter brug

Bær kemisk resistente beskyttelseshandsker ved brug af produktet"
Handskematerialet skal angives af godkendelsesindehaveren i produktdatabladet

Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

**Må kun anvendes erhvervsmæssigt til yverdesinfektion af bakterier, gær og virus på køer, får og geder efter malkning.
Må ikke anvendes mod andre skadevoldere og ikke i højere doseringer end de i brugsanvisningen nævnte.**

Opbevares utilgængeligt for børn.

Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer."

Evt. oplysninger om førstehjælp.

3) I deklarationsfeltet:

a) Teksten "Veterinærhygiejne BPR-reg. nr. 781-3-3-[x¹]. Aktivstof og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)".

b) Oplysning om præparattype: "Væske" for dette præparat.

c) Indholdet af aktivstof i vægtprocent (% w/w) og g/L ved 20 °C.

e) Udløbsdatoen skal anføres. Denne dato må højst være 1 år efter produktionsdatoen. Etikettens dato kan udformes som en hen-visning til en produktionsdato andetsteds på emballagen.

f) Batchnummer eller – betegnelse skal anføres.

g) Pakningsstørrelse i L.

h) Godkendelsesindehavers navn og adresse.

4) Brugsanvisningen:

Oplysninger om skadevoldere, anvendelsesområde og doseringer.

Følgende retningslinjer gælder i forhold til bortskaffelse.

Der skal mærkes med sikkerhedssætning P501: "Indholdet/holderen bortskaffes i overensstemmelse med kommunale regler for affaldshåndtering."

"Tom emballage og rester kan bortskaffes med dagrenovation"

[1] "X" skal erstattes med et tal som angivet i godkendelsesbrevets bilag 4.

[2] Europa-Parlamentets og Rådets forordning (EF) Nr. 1272/2008 af 16. december 2008

om

klassificering, mærkning og emballering af stoffer og blandinger og om

ændring og ophævelse af direktiv 67/548/EØF og 1999/45/EF og om ændring

af forordning (EF) nr. 1907/2006