

Summary of product characteristics for a biocidal product

Product name: Masocare Extra

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

Authorisation number: 2019-09-24-B03

R4BP 3 asset reference number: MT-0021575-0007

Table Of Contents

Administrative information	1
1.1. Trade names of the product	1
1.2. Authorisation holder	1
1.3. Manufacturer(s) of the biocidal products	1
1.4. Manufacturer(s) of the active substance(s)	1
2. Product composition and formulation	2
2.1. Qualitative and quantitative information on the composition of the biocidal product	2
2.2. Type of formulation	3
3. Hazard and precautionary statements	3
4. Authorised use(s)	3
5. General directions for use	5
5.1. Instructions for use	6
5.2. Risk mitigation measures	6
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment	6
5.4. Instructions for safe disposal of the product and its packaging	7
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage	7
6. Other information	7

Administrative information

1.1. Trade names of the product

Masocare Extra

1.2. Authorisation holder

Name and address of the authorisation holder

Name	Evans Vanodine Europe
Address	6-9 Trinity Street D02 EY47 Dublin 2 Ireland
Authorisation number	2019-09-24-B03 1-5

R4BP 3 asset reference number

MT-0021575-0007

Date of the authorisation

24/09/2019

Expiry date of the authorisation

19/03/2029

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer

Evans Vanodine International

Address of the manufacturer

Brierley Road, Walton Summit PR5 8AH Preston, Lancashire United Kingdom

Location of manufacturing sites

Brierley Road, Walton Summit PR58AH Preston, Lancashire United Kingdom
--

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

Active substance	1319 - Iodine
Name of the manufacturer	ACF Minera S.A.
Address of the manufacturer	San Martin No. 499 Iquique Chile
Location of manufacturing sites	Lagunas Mine - Pozo Almonte Chile

Active substance	1319 - Iodine
Name of the manufacturer	Sociedad Quimica y Minera (SQM) S.A.
Address of the manufacturer	Los Militares 4290, Piso 4 Las Condes Santiago Chile
Location of manufacturing sites	Nueva Victoria Plant Pedro de Valdivia Plant Northern Chile Chile

Active substance	1319 - Iodine
Name of the manufacturer	Cosayach Nitratos S.A.
Address of the manufacturer	Hnos Amunategui 178 Santiago Chile
Location of manufacturing sites	S.C.M. Cosayach Cala Cala - Pozo Almonte Chile

Active substance	1319 - Iodine
Name of the manufacturer	ISE Chemical Corporation
Address of the manufacturer	Kitaimaizumi 3695 - Oamishirasato City Chiba Japan
Location of manufacturing sites	Shirasato Plant - - Japan

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	0,526
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)		157627-86-6	500-337-8	4,479

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

Avoid release to the environment.

Dispose of contents to in accordance with local/regional/national regulations.

Keep only in original packaging.

Absorb spillage to prevent material damage.

Store in container with a resistant inner liner.

4. Authorised use(s)

4.1 Use description

Use 1 - Post-Milking

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection products for milkable animals (cows, buffaloes, sheep, goats) for use after milking.

Target organism(s) (including development stage)

Scientific name: bacteria
Common name: bacteria
Development stage: N/A

Scientific name: yeasts

Common name: yeasts
Development stage: N/A

Field(s) of use

Indoor
Indoor use – Teats of lactating animals.

Application method(s)

Manual dipping/foaming -
Post-milking application
Apply after each milking every day (1-3 times a day). For manual application ensure full teat is covered and the animal stands for 5 minutes.

1. Manual dipping/foaming
 - a. Dipping
 - cows and buffaloes: 10 ml/animal per treatment
 - sheep: 5 ml/animal per treatment
 - goats: 6 ml/animal per treatment
 - b. Foaming
 - cows and buffaloes: 5 ml/animal per treatment
 - sheep: 2.5 ml/animal per treatment
 - goats: 3 ml/animal per treatment

Manual spraying using an electronic sprayer -
Post-milking application
Apply after each milking every day (1-3 times a day). For manual application ensure full teat is covered and the animal stands for 5 minutes.

2. Manual Spraying using an electronic spray:
 - cows and buffaloes: 10-15 ml/animal per treatment
 - sheep: 5-7.5 ml/animal per treatment
 - goats: 7-10 ml/animal per treatment

automated dipping -
Post-milking application
Apply after each milking every day (1-3 times a day).

3Automated dipping:

- cows and buffaloes: 10 ml/animal per treatment
- sheep: 5 ml/animal per treatment
- goats: 6 ml/animal per treatment

Automated spraying using a robot -
Post-milking application
Apply after each milking every day (1-3 times a day).

Automated spraying using a robot:

- cows and buffaloes: 10-15 ml/animal per treatment
- sheep: 5-7.5 ml/animal per treatment
- goats: 7-10 ml/animal per treatment

Application rate(s) and frequencies

see above - -
see above

see above - -
see above

As above - -
As above

	As above -- As Above
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Bottle/Pack (HDPE) 5 – 25L Drum (HDPE) 200L IBC (HDPE) 1000L

4.1.1 Use-specific instructions for use

-

4.1.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

5. General directions for use

5.1. Instructions for use

The product must be brought to a temperature above 20°C before use.
The use of a dosing pump for filling the product into the application equipment is recommended.

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

Use undiluted.

Ensure udder and teats are clean and dry before using this product.

1. Manual dipping/foaming

Fill teat cup $\frac{2}{3}$ full with product. Dip the teats of each cow immediately after each has been milked, making sure that the full length of the teat is immersed.

Top up with fresh solution as required.

Empty and wash out cups with water after milking.

2. Manual spraying using an electronic sprayer

Immediately after milking, spray the teats of each cow with product. Ensure the spray covers the entire surface of all teats.

3. Automated dipping

The teats are coated with product when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). The whole process is automated.

4. Automated spraying by robot

The teats are cleaned by robot with automatic brushes. After robotic milking, of the product is sprayed automatically onto teats from a cluster arm. Rinsing of the sprayer is automatic.

5.2. Risk mitigation measures

Keep out of reach of children.

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.

For manual spraying using an electronic sprayer:

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

Wear Suitable protective footwear (EN 13832) when applying this product.

A protective coverall (at least type 6, EN 13034) shall be worn.

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

Likely direct or indirect effects may include:

- Irritation of the eyes.
- General discomfort if swallowed.

First aid measures

- **Inhalation:** Unlikely route of exposure as the product does not contain volatile substances. If spray/mist has been inhaled, move affected person to fresh air and keep warm and at rest in a position comfortable for breathing.
- **Ingestion:** Do not induce vomiting. Give plenty of water to drink. Get medical attention if any discomfort continues.
- **Skin contact:** Wash with plenty of water.
- **Eye contact:** Rinse immediately with plenty of water. Get medical attention promptly if symptoms occur after washing.

NEVER LEAVE AN AFFECTED INDIVIDUAL UNATTENDED

Advice for medical and healthcare personnel:

- Provide symptomatic and supportive treatment.

WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER([INSERT LOCAL NUMBER HERE].

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

At the end of the treatment, dispose unused product, the packaging and any contaminated materials 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

Shelf-life 24 months.
Store in original sealed container and protect from extremes of temperature.
Protect from direct sunlight.
Protect from frost, if contents freeze, they must be thawed and thoroughly mixed before use.
Store in a cool, well-ventilated place.
Store below 25°C.

6. Other information