

Summary of product characteristics for a biocidal product

Product name: Pro-Tec 1:3

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

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Authorisation number: LV/2019/MR/016

R4BP 3 asset reference number: LV-0013292-0010

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Administrative information

1.1. Trade names of the product

Pro-Tec 1:3

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	LV/2019/MR/016 1-6

R4BP 3 asset reference number

LV-0013292-0010

Date of the authorisation

12/12/2019

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
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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	1,036
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)	Non-active substance	157627-86-6	500-337-8	8,762

2.2. Type of formulation

SL - Soluble concentrate

3. Hazard and precautionary statements

Hazard statements

Harmful to aquatic life with long lasting effects.

Precautionary statements

Avoid release to the environment.

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

4. Authorised use(s)

4.1 Use description

Use 1 - Pre-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 before 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)

Method: Manual dipping/foaming
Detailed description:
Pre-milking application
Apply before each milking every day (1-3 times a day). For manual application ensure full teat is covered for minimum contact time of 60 seconds.

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

Method: Manual spraying using an electronic sprayer
Detailed description:
Pre-milking application
Before milking, spray the teats of each cow with product. Ensure the spray covers the entire surface of all teats. Leave the product on the teats for at least 60 seconds. Then wipe and dry the teats thoroughly using a single service paper towel.

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

Application rate(s) and frequencies

Application Rate: see above
Dilution (%):
Number and timing of application:
see above

Application Rate: see above
Dilution (%):
Number and timing of application:
see 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

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

This product requires dilution before use.

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

The use of a dosing pump for filling the product into the application equipment is recommended.

Prepare a fresh solution daily.

Containers for dilution should be clean and suitable for use.

Mix 1 part product with 3 parts of clean water and mix well.

1. Manual dipping/foaming

Fill teat cup 2/3 full with diluted product.

Dip the teats of each cow before milking, making sure that the full length of the teat is immersed. Leave the product on the teats for at least 60 seconds. Then wipe and dry the teats thoroughly using a single service paper towel.

Top up with fresh solution as required.

Empty and wash out cups with water after use.

2. Manual spraying using an electronic sprayer

Before milking, spray the teats of each cow with diluted product. Ensure the spray covers the entire surface of all teats. Leave the product on the teats for at least 60 seconds. Then wipe and dry the teats thoroughly using a single service paper towel.

4.1.2 Use-specific 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 post-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).

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

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

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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 - 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)

Method: Manual dipping/foaming
Detailed description:

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

Method: Manual spraying using an electronic sprayer

Detailed description:

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

Method: automated dipping

Detailed description:

Post-milking application

Apply after each milking every day (1-3 times a day).

Automated dipping:

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

	<p>Method: Automated spraying using a robot Detailed description: 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</p>
<p>Application rate(s) and frequencies</p>	<p>Application Rate: see above Dilution (%): Number and timing of application: see above</p> <p>Application Rate: see above Dilution (%): Number and timing of application: see above</p> <p>Application Rate: As above Dilution (%): Number and timing of application: As above</p> <p>Application Rate: As above Dilution (%): Number and timing of application: As Above</p>
<p>Category(ies) of users</p>	<p>Trained professional Professional</p>
<p>Pack sizes and packaging material</p>	<p>Bottle/Pack (HDPE) 5 – 25L Drum (HDPE) 200L IBC (HDPE) 1000L</p>

4.2.1 Use-specific instructions for use

The product must be brought to a temperature above 20°C before use.
This product requires dilution before use.
Add 1 part product to 3 parts clean water and mix well.
Prepare a fresh solution daily.
Containers for dilution should be clean and suitable for use.

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

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).

1. Manual dipping/foaming

Fill teat cup $\frac{2}{3}$ full with diluted 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 diluted product.

Ensure the spray covers the entire surface of all teats.

3. Automated dipping

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

4. Automated spraying by robot

After robotic milking, the diluted product is sprayed automatically onto teats from a cluster arm. Rinsing of the sprayer is automatic.

4.2.2 Use-specific 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.

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

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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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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 - Pre- and 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 before and 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)	Method: Manual dipping/foaming Detailed description: <u>Pre- and Post-milking application</u> Apply before and after each milking every day (up to 5 applications per day in total). For manual application, ensure the full teat is covered with a contact time of 60 seconds for pre-milking and ensure that the full teat is covered and the animals are left standing for 5 minutes post-milking. 1. Manual dipping/foaming: a. Dipping <ul style="list-style-type: none">• cows and buffaloes: 10 ml/animal per treatment• sheep: 5 ml/animal per treatment• goats: 6 ml/animal per treatment b. Foaming <ul style="list-style-type: none">• cows and buffaloes: 5 ml/animal per treatment• sheep: 2.5 ml/animal per treatment• goats: 3 ml/animal per treatment Method: Manual spraying using an electronic sprayer Detailed description: <u>Pre- and Post-milking application</u> Apply before and after each milking every day (up to 5 applications per day in total). For manual application, ensure the full teat is covered with a contact time of 60 seconds for pre-milking and ensure that the full teat is covered and the animals are left standing for 5 minutes post-milking. 2. Manual Spraying using an electronic spray: <ul style="list-style-type: none">• cows and buffaloes: 10-15 ml/animal per treatment• sheep: 5-7.5 ml/animal per treatment• goats: 7- 10ml/animal per treatment

Application rate(s) and frequencies

Application Rate: see above
Dilution (%):
Number and timing of application:
see above

Application Rate: see above
Dilution (%):
Number and timing of application:
see above

Category(ies) of users

Trained professional

Professional

Pack sizes and packaging material

Bottle/Pack (HDPE) 5 – 25L
Drum (HDPE) 200L
IBC (HDPE) 1000L

4.3.1 Use-specific 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.

Post-milking: 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).

This product requires dilution before use.
Prepare a fresh solution daily.

Containers for dilution should be clean and suitable for use.

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

Mix 1 part product with 3 parts of clean water & mix well.

1. Manual dipping/foaming

Fill teat cup 2/3 full with product. Dip the teats of each cow before milking, making sure that the full length of the teat is immersed. Leave the product on the teats for at least 60 seconds. Then wipe and dry the teats thoroughly using a single service paper towel. 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 use.

2. Manual spraying using an electronic sprayer

Before milking, spray the teats of each cow with diluted product. Ensure the spray covers the entire surface of all teats. Leave the product on the teats for at least 60 seconds. Then wipe and dry the teats thoroughly using a single service paper towel. Immediately after milking, spray the teats of each cow with diluted product. Ensure the spray covers the entire surface of all teats.

4.3.2 Use-specific risk mitigation measures

Keep out of reach of children.

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.

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

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

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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

See use specific instructions for use

5.2. Risk mitigation measures

See use specific RMM

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.
Do not empty into drains.

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

Note that if any additions are made to this family Meta-SPC, the in-use concentrations must be within the range covered within the environmental risk assessments.

