

Summary of product characteristics for a biocidal product family

Family name: Teat disinfection biocidal product family

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

Authorisation number: IE/BPA 70449

R4BP 3 asset reference number: IE-0020592-0000

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Part I.- First information level

1. Administrative information

1.1. Family name

Teat disinfection biocidal product family

1.2. Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

1.3. 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

IE/BPA 70449

R4BP 3 asset reference number

IE-0020592-0000

Date of the authorisation

16/04/2019

Expiry date of the authorisation

19/03/2029

1.4. 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

1.5. 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 family composition and formulation

2.1. Qualitative and quantitative information on the composition of the family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0.112 - 2.346
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)		157627-86-6	500-337-8	0.38 - 19.993

2.2. Type(s) of formulation

SL - Soluble concentrate AL - Any other liquid

Part II.- Second information level - meta SPC(s)

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 1

1.2. Suffix to the authorisation number

1-1

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0.112 - 0.12

Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)	157627-86-6	500-337-8	0.71 - 1.19
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2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

May be corrosive to metals.

Precautionary statements

Keep only in original packaging.
Absorb spillage to prevent material damage.
Store in container with a resistant inner liner.

4. Authorised use(s) of the meta SPC

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)

bacteria-bacteriaN/A
Yeasts-YeastsN/A

Field(s) of use

Indoor
Indoor use – Teats of lactating animals.

Application method(s)

Manual dipping/foaming -
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

Manual spraying using and electronic sprayer -
 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.

2. Manual Spraying using an Electronic Sprayer:
 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

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

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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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5. General directions for use of the meta SPC

5.1. Instructions for use

This 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.

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

1. Manual dipping/foaming
Fill teat cup 2/3 full with product. Dip the teats of each cow, making sure that the full length of the teat is immersed. Allow at least 60 seconds contact time, then using a single service paper towel, wipe and dry the teats thoroughly.
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 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.

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 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).

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(The National Poisons Information Centre, Beaumont Hospital, Dublin (01-8092166).

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.
Avoid release to the environment.

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

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)

Pre-Dip

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

IE-0020592-0001 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0.112
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)		157627-86-6	500-337-8	0.953

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 2

1.2. Suffix to the authorisation number

1-2

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0.25 - 0.33
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)		157627-86-6	500-337-8	0.38 - 0.63

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

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) of the meta SPC

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)

bacteria-bacteriaN/A

yeasts-yeastsN/A

Field(s) of use

Indoor
Indoor use – Teats of lactating animals.

Application method(s)

manual dipping -
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
cows and buffaloes: 10 ml/animal per treatment
sheep: 5 ml/animal per treatment
goats: 6 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).
Automated 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

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4.1.2 Use-specific risk mitigation measures

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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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5. General directions for use of the meta SPC

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/

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).

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(The National Poisons Information Centre, Beaumont Hospital, Dublin (01-8092166).

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 18 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

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)

PV-Pro

Authorisation number

IE-0020592-0002 1-2

(R4BP 3 asset reference number - National Authorisation)

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0.291
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)		157627-86-6	500-337-8	0.5

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 3

1.2. Suffix to the authorisation number

1-3

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0.269 - 0.5245
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)		157627-86-6	500-337-8	2.304 - 4.4702

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

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) of the meta SPC

4.1 Use description

Use 1 - Post-milking - manual dipping

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)

bacteria-bacteriaN/A

yeasts-yeastsN/A

Field(s) of use

Indoor

Indoor use – Teats of lactating animals.

Application method(s)

Manual dipping -
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.
Manual dipping
•cows and buffaloes: 10 ml/animal per treatment
•sheep: 5 ml/animal per treatment

	•goats: 6 ml/animal per treatment
Application rate(s) and frequencies	see above - - 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

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4.1.2 Use-specific risk mitigation measures

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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

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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

-

5. General directions for use of the meta SPC

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

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.

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.

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(The National Poisons Information Centre, Beaumont Hospital, Dublin (01-8092166).

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

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)

Masofilm

Authorisation number

IE-0020592-0003 1-3

(R4BP 3 asset reference number - National Authorisation)

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0.269
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)		157627-86-6	500-337-8	2.304

Trade name(s)

Visqodip

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

IE-0020592-0004 1-3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0.5245
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)		157627-86-6	500-337-8	4.4702

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta-SPC 4

1.2. Suffix to the authorisation number

1-4

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0.272 - 0.273
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)		157627-86-6	500-337-8	2.31 - 2.31

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

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) of the meta SPC

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)	bacteria-bacteriaN/A yeasts-yeastsN/A
Field(s) of use	Indoor Indoor use – Teats of lactating animals.
Application method(s)	Manual dipping/foaming - 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 Manual spraying using an electronic sprayer - 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. 2. Manual Spraying using an Electronic Sprayer: 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

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

<p>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.</p> <p>Use undiluted. Ensure udder and teats are clean and dry before using this product.</p> <p>1. <u>Manual dipping/foaming</u> Fill teat cup ¾ full with product. Dip the teats of each cow before milking, making sure that the full length of the teat is immersed. Allow at least 60 seconds contact time, then using a single service paper towel, wipe and dry the teats thoroughly. Top up with fresh solution as required. Empty and wash out cups with water after use.</p> <p>2. <u>Manual spraying using an electronic sprayer</u> 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.</p>
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4.1.2 Use-specific risk mitigation measures

<p>Keep out of reach of children.</p> <p>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.</p> <p>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).</p>

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

-

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)

bacteria-bacteriaN/A
yeasts-yeastsN/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.

	<p>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</p> <p>automated dipping - 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> <p>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</p>
<p>Application rate(s) and frequencies</p>	<p>see above - - see above</p> <p>see above - - see above</p> <p>As above - - As above</p> <p>As above - - As Above</p>
<p>Category(ies) of users</p>	<p>Trained professional</p> <p>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

4.2.1 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.

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 the 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).

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)

bacteria-bacteriaN/A
yeasts-yeastsN/A

Field(s) of use

Indoor
Indoor use – Teats of lactating animals.

Application method(s)

Manual dipping/foaming -

Pre- and Post-milking application
Apply before and after each milking every day (2-6 times a day). 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
 - 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 -

Pre- and Post-milking application
Apply before and after each milking every day (2-6 times a day). For manual application, ensure the full teat is covered with a contact time of 60 seconds for pre-

	<p>milking and ensure that the full teat is covered and the animals are left standing for 5 minutes post-milking.</p> <p>2. Manual Spraying using an electronic spray:</p> <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	<p>see above - - see above</p> <p>see above - - see above</p>
Category(ies) of users	<p>Trained professional</p> <p>Professional</p>
Pack sizes and packaging material	<p>Bottle/Pack (HDPE) 5 – 25L Drum (HDPE) 200L IBC (HDPE) 1000L</p>

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).

Use undiluted.

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

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.

Allow at least 60 seconds contact time, then using a single service paper towel, wipe and dry the teats thoroughly.

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 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 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 dipping/foaming:

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

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 overall (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 of the meta SPC

5.1. Instructions for use

See use specific instructions for use

5.2. Risk mitigation measures

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(The National Poisons Information Centre, Beaumont Hospital, Dublin (01-8092166).

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

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7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Pre-Post Gold Allantocare
Authorisation number <small>(R4BP 3 asset reference number - National Authorisation)</small>	IE-0020592-0005 1-4

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0.272
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)		157627-86-6	500-337-8	2.31

Trade name(s)	Contact
Authorisation number <small>(R4BP 3 asset reference number - National Authorisation)</small>	IE-0020592-0006 1-4

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0.273
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)		157627-86-6	500-337-8	2.31

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 5

1.2. Suffix to the authorisation number

1-5

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0.526 - 0.527
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)		157627-86-6	500-337-8	4.479 - 4.492

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

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) of the meta SPC

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)

bacteria-bacteriaN/A

yeasts-yeastsN/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).

- 3 Automated 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

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4.1.2 Use-specific risk mitigation measures

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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 of the meta SPC

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 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(The National Poisons Information Centre, Beaumont Hospital, Dublin (01-8092166).

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

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)

Masocare Extra

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

IE-0020592-0007 1-5

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

Trade name(s)

Masocare RTU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

IE-0020592-0008 1-5

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

Trade name(s)

Masodine RTU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

IE-0020592-0009 1-5

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0.527
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)		157627-86-6	500-337-8	4.492

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 6a

1.2. Suffix to the authorisation number

1-6

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0.881 - 1.191
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)		157627-86-6	500-337-8	7.448 - 10.076

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

SL - Soluble concentrate

3. Hazard and precautionary statements of the meta SPC

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) of the meta SPC

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)

bacteria-bacteriaN/A
yeasts-yeastsN/A

Field(s) of use	Indoor Indoor use – Teats of lactating animals.
Application method(s)	Manual dipping/foaming - 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 Manual spraying using an electronic sprayer - 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	see above - - see above see above - - 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 $\frac{2}{3}$ 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

-

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

-

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)

bacteria-bacteriaN/A

yeasts-yeastsN/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

	<p>automated dipping - 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> <p>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</p>
<p>Application rate(s) and frequencies</p>	<p>see above - - see above</p> <p>see above - - see above</p> <p>As above - - As above</p> <p>As above - - As Above</p>
<p>Category(ies) of users</p>	<p>Trained professional</p> <p>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

-

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 - 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)	bacteria-bacteriaN/A yeasts-yeastsN/A
Field(s) of use	Indoor Indoor use – Teats of lactating animals.
Application method(s)	Manual dipping/foaming - <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 <ul style="list-style-type: none"> • 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 Manual spraying using an electronic sprayer - <u>Pre- and Post-milking application</u> Apply before and after each milking every day (up to 5 applications per day in total). For

	<p>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.</p> <p>2. Manual Spraying using an electronic spray:</p> <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	<p>see above - - see above</p> <p>see above - - see above</p>
Category(ies) of users	<p>Trained professional</p> <p>Professional</p>
Pack sizes and packaging material	<p>Bottle/Pack (HDPE) 5 – 25L Drum (HDPE) 200L IBC (HDPE) 1000L</p>

4.3.1 Use-specific instructions for use

<p>The product must be brought to a temperature above 20°C before use.</p> <p>The use of a dosing pump for filling the product into the application equipment is recommended.</p> <p>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).</p> <p>This product requires dilution before use. Prepare a fresh solution daily.</p> <p>Containers for dilution should be clean and suitable for use.</p> <p>Ensure udder and teats are clean and dry before using this product.</p>
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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

-

4.3.5 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 of the meta SPC

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(The National Poisons Information Centre, Beaumont Hospital, Dublin (01-8092166).

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.

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)

Pro-Tec 1:3

Authorisation number

IE-0020592-0010 1-6

(R4BP 3 asset reference number - National Authorisation)

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)		157627-86-6	500-337-8	8.762

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 6b

1.2. Suffix to the authorisation number

1-7

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	1.646 - 2.228
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)		157627-86-6	500-337-8	14 - 16.51

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

SL - Soluble concentrate

3. Hazard and precautionary statements of the meta SPC

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) of the meta SPC

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)

bacteria-bacteriaN/A
yeasts-yeastsN/A

Field(s) of use

Indoor
Indoor use – Teats of lactating animals.

Application method(s)

Manual dipping/foaming -
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.

- Manual dipping/foaming:
 - Dipping
cows and buffaloes: 10 ml/animal per treatment
sheep: 5 ml/animal per treatment
goats: 6 ml/animal per treatment
 - 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 -
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.

- 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

see above - -

Application rate(s) and frequencies	see above see above - - 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 7 parts of clean water and mix well.

1. Manual dipping/foaming

Fill teat cup $\frac{2}{3}$ 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

-

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

-

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)

bacteria-bacteriaN/A

yeasts-yeastsN/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).

- Automated 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

4.2.1 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

-

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

-

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 - 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)

bacteria-bacteriaN/A

yeasts-yeastsN/A

Field(s) of use

Indoor

Indoor use – Teats of lactating animals.

Application method(s)

Manual dipping/foaming -

Pre- and Post-milking application

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

- 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 -

Pre- and Post-milking application

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:

- 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

see above - -
see above

see above - -
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.

Dilutions are different for pre and post milking, therefore separate teat cups are required. See specific instructions.

Pre-milking - Mix 1 part product with 7 parts of clean water and mix well

Post-milking - Mix 1 part product with 3 parts of clean water and mix well

1. Manual dipping/foaming

Fill teat cup $\frac{2}{3}$ 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

-

4.3.5 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 of the meta SPC

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(The National Poisons Information Centre, Beaumont Hospital, Dublin (01-8092166).

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.

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)

Masodine 1:3

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

IE-0020592-0011 1-7

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	1.937
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)		157627-86-6	500-337-8	16.51

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 7

1.2. Suffix to the authorisation number

1-8

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	2 - 2.346
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)		157627-86-6	500-337-8	18 - 19.993

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

SL - Soluble concentrate

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Causes serious eye damage.
Harmful to aquatic life with long lasting effects.
May be corrosive to metals.

Precautionary statements

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 or doctor/physician.
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) of the meta SPC

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)	bacteria-bacteriaN/A yeasts-yeastsN/A
Field(s) of use	Indoor Indoor use – Teats of lactating animals.
Application method(s)	<p>Manual dipping/foaming - 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.</p> <p>1. Manual dipping/foaming:</p> <p>a. Dipping cows and buffaloes: 10 ml/animal per treatment sheep: 5 ml/animal per treatment goats: 6 ml/animal per treatment</p> <p>b. Foaming cows and buffaloes: 5 ml/animal per treatment sheep: 2.5 ml/animal per treatment goats: 3 ml/animal per treatment</p> <p>Manual spraying using an electronic sprayer - Pre-milking application</p> <p>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.</p> <p>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</p>
Application rate(s) and frequencies	see above - - see above see above - - 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.

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

This product requires dilution before use.

Add 1 part product to 9 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.

1. Manual dipping/foaming

Fill teat cup $\frac{2}{3}$ 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 dipping/foaming :

The use of eye protection during handling of the product is mandatory.

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).

The use of eye protection during handling of the product is mandatory.

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

-

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

-

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)

bacteria-bacteriaN/A
yeasts-yeastsN/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).
 Automated 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

4.2.1 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.

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.

Add 1 part product to 4 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.

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 dipping/foaming, automated dipping and automated spraying using a robot:

The use of eye protection during handling of the product is mandatory.

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 overall (at least type 6, EN 13034) shall be worn.

The use of eye protection during handling of the product is mandatory.

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

-

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 - 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)	bacteria-bacteriaN/A yeasts-yeastsN/A
Field(s) of use	Indoor Indoor use – Teats of lactating animals.
Application method(s)	Manual dipping/foaming - <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

- 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 -

Pre- and Post-milking application

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:

- 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

see above - -
see above

see above - -
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.

Dilutions are different for pre and post milking, therefore separate teat cups are required. See specific instructions.

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.

Pre-milking - Mix 1 part product with 9 parts of clean water and mix well.

Post-Milking - Mix 1 part product with 4 parts of clean water and mix well.

1. Manual dipping/foaming

Fill teat cup $\frac{2}{3}$ 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 dipping/foaming:

The use of eye protection during handling of the product is mandatory.

For and 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

The use of eye protection during handling of the product is mandatory.

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

-

4.3.5 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 of the meta SPC

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:

- Severe irritation of the eyes or eye damage.
- 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(The National Poisons Information Centre, Beaumont Hospital, Dublin (01-8092166).

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.

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)

Masocare 1:4

Authorisation number

IE-0020592-0012 1-8

(R4BP 3 asset reference number - National
Authorisation)

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	2.346
Alcohol Ethoxylate	C13-15 Alcohol Ethoxylate (11EO)		157627-86-6	500-337-8	19.993
