Summary of product characteristics for a biocidal product family

Family name: Eimermacher Iodine Compounds

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

Authorisation number: NL-0016702-0000

R4BP 3 asset reference number: NL-0016702-0000

Table Of Contents

Part I First information level	1
1. Administrative information	1
2. Product family composition and formulation	2
Part II Second information level - meta SPC(s)	3
1. Meta SPC administrative information - meta SPC 1: Milking cluster disinfection, ready to use	3
2. Meta SPC composition	4
3. Hazard and precautionary statements of the meta SPC	4
4. Authorised use(s) of the meta SPC	5
5. General directions for use of the meta SPC	8
6. Other information	9
7. Third information level: individual products in the meta SPC	9
1. Meta SPC administrative information - meta SPC 3: Teat disinfection (pre-/post-milking), ready to use	9
2. Meta SPC composition	10
3. Hazard and precautionary statements of the meta SPC	10
4. Authorised use(s) of the meta SPC	11
5. General directions for use of the meta SPC	19
6. Other information	20
7. Third information level: individual products in the meta SPC	20
1. Meta SPC administrative information - meta SPC 4: Teat disinfection (pre-milking), concentrates	22
2. Meta SPC composition	22
3. Hazard and precautionary statements of the meta SPC	23
4. Authorised use(s) of the meta SPC	23
5. General directions for use of the meta SPC	26
6. Other information	27
7. Third information level: individual products in the meta SPC	27
1. Meta SPC administrative information - meta SPC 5: Teat disinfection (post-milking), ready to use	28
with PVP-I 2. Meta SPC composition	20

3. Hazard and precautionary statements of the meta SPC	29
4. Authorised use(s) of the meta SPC	29
5. General directions for use of the meta SPC	34
6. Other information	35
7. Third information level: individual products in the meta SPC	36
1. Meta SPC administrative information - meta SPC 6: Teat disinfection (post-milking), ready to use with PVP-I	36
2. Meta SPC composition	37
3. Hazard and precautionary statements of the meta SPC	37
4. Authorised use(s) of the meta SPC	37
5. General directions for use of the meta SPC	40
6. Other information	41
7. Third information level: individual products in the meta SPC	41
1. Meta SPC administrative information - meta SPC 7: Teat disinfection (pre-/post-milking), ready to use	42
2. Meta SPC composition	43
3. Hazard and precautionary statements of the meta SPC	43
4. Authorised use(s) of the meta SPC	43
5. General directions for use of the meta SPC	52
6. Other information	53
7. Third information level: individual products in the meta SPC	53
1. Meta SPC administrative information - Meta SPC 8: Teat disinfection (post-milking), concentrates	53
2. Meta SPC composition	54
3. Hazard and precautionary statements of the meta SPC	54
4. Authorised use(s) of the meta SPC	55
5. General directions for use of the meta SPC	
6. Other information	60
7. Third information level: individual products in the meta SPC	61
·	61

Part I.- First information level

1. Administrative information

1.1. Family name

Eimermacher Iodine Compounds		
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1.2. Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

1.3. Authorisation holder

Name and address of the authorisation holder

Name	Ferdinand Eimermacher GmbH & Co. KG
Address	Westring 24 48356 Nordwalde Germany

Authorisation number

NL-0016702-0000

R4BP 3 asset reference number

NL-0016702-0000

Date of the authorisation

09/08/2022

Expiry date of the authorisation

05/08/2032

1.4. Manufacturer(s) of the biocidal products

Name of the manufacturer

F. Eimermacher GmbH & Co. KG

Address of the manufacturer

Westring 24 48356 Nordwalde Germany

Location of manufacturing sites

Westring 24 48356 Nordwalde Germany

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

Active substance	1319 - Iodine
Name of the manufacturer	Independent lodine Europe N.V
Address of the manufacturer	Hoogeind 43 2940 Stabroek Belgium
Location of manufacturing sites	Acf Minera SA, Chile no data Santiago Chile
Active substance	1319 - Iodine
Name of the manufacturer	SQM Europe N.V.
Address of the manufacturer	St Pietersvliet 7, bus 8 2000 Antwerpen Belgium
Location of manufacturing sites	Sociedad Quimica y Minera SA no data Santiago Chile
Active substance	1319 - Iodine
Active substance Name of the manufacturer	1319 - Iodine Norkem Limited
Name of the manufacturer	Norkem Limited
Name of the manufacturer Address of the manufacturer	Norkem Limited Bexton lane WA 16 9FB Knutsford, Cheshire United Kingdom
Name of the manufacturer Address of the manufacturer	Norkem Limited Bexton lane WA 16 9FB Knutsford, Cheshire United Kingdom
Name of the manufacturer Address of the manufacturer Location of manufacturing sites	Norkem Limited Bexton lane WA 16 9FB Knutsford, Cheshire United Kingdom Cosayach S.A. Compania de Salitre y Yodo no data Santiago Chile
Name of the manufacturer Address of the manufacturer Location of manufacturing sites Active substance	Norkem Limited Bexton lane WA 16 9FB Knutsford, Cheshire United Kingdom Cosayach S.A. Compania de Salitre y Yodo no data Santiago Chile 1349 - Polyvinylpyrrolidone iodine

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 (%)
lodine		Active Substance	7553-56-2	231-442-4	0,000001 - 1,625
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,000001 - 2,7
2-(2- butoxyethoxy)ethanol	2-(2- butoxyethoxy)ethanol	Non-active substance	112-34-5	203-961-6	0 - 6
Phosphoric acid	orthophosphoric acid	Non-active substance	7664-38-2	231-633-2	0 - 3,75
Methanol	Methan-1-ol	Non-active substance	67-56-1	200-659-6	0 - 0,15
Alcohols C9-C11, ethoylated	AlcoholsC9-C11, ethoylated	Non-active substance	68439-46-3	500-446-0	0 - 4,875
Fatty alcohol alkoxylate 4	Fattyalcohol alkoxylate 4	Non-active substance	111905-53-4		0 - 1,8

2.2. Type(s) of formulation

ΑL	_	Anv	other	liquid
,		,,	Othioi	nquiu

SL - Soluble concentrate

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

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC 1: Milking cluster disinfection, ready to use

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	0,25 - 0,25
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,000001 - 0,000001
2-(2- butoxyethoxy)ethanol	2-(2- butoxyethoxy)ethanol	Non-active substance	112-34-5	203-961-6	0 - 6
Phosphoric acid	orthophosphoric acid	Non-active substance	7664-38-2	231-633-2	3,75 - 3,75
Alcohols C9-C11, ethoylated	AlcoholsC9-C11, ethoylated	Non-active substance	68439-46-3	500-446-0	0,75 - 0,75
Fatty alcohol alkoxylate 4	Fattyalcohol alkoxylate 4	Non-active substance	111905-53-4		1,8 - 1,8

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

May be corrosive to metals.

Causes serious eye irritation.

Harmful to aquatic life with long lasting effects.

Precautionary statements

If medical advice is needed, have product container or label at hand.

Keep only in original packaging.

Wash hands thoroughly after handling.

Avoid release to the environment.

Wear eye protection.

IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists:Get medical advice.

Absorb spillage to prevent material damage.

Dispose of container to relevant legislation.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - External milking cluster disinfection

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage: Scientific name: Common name: Yeasts Development stage:
Field(s) of use	Indoor The product is ready to use and applied for surface disinfection of milking cluster

Application method(s)

Method: Spraying Detailed description:

- 1) Low to medium pressure spraying with Knapsack type sprayers.
- Triggered sprays

Application rate(s) and frequencies

Application Rate: Application rate: 400 mL product/m2

Dilution (%): 0

Number and timing of application:

application frequency: twice daily, contact time is minimal 30 minutes

Category(ies) of users

Pack sizes and packaging material

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D	rot	es	CI	Λr	12
	ıvı	CC	OI.	UI.	ıa

Plastic bottle of HDPE: 500 mL (trigger), 1000 mL J erry can of HDPE: $5\,L$, $10\,L$, $20\,L$, $25\,L$, $60\,L$

D rum of HDPE: 200 L IBC container of HDPE: 1000 L

Spraying equipment is available at the farms.

4.1.1 Use-specific instructions for use

The biocidal product is used for surface disinfection of external surface of milking clusters. It is applied twice daily by professional users. The surfaces should be cleaned before disinfection: gross dirt thoroughly removed from clusters, followed by cleaning with a lukewarm, water diluted detergent and a final rinse with water. Allow the surfaces to dry completely after which this product is used as a ready to use spray. The RTU product is directly sprayed on the surface. The product is allowed to react for minimal 30 min. Post-rinsing with potable water afterwards. The approximate application rate is 0.4 L/m ².

4.1.2 Use-specific risk mitigation measures

Keep container tightly closed. Protect against UV-radiation/sunlight and heat.

During use wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a coated coverall and eye/face protection and respiratory protection (protection factor 10). Avoid eye exposure.

In case a combination of pre- or post-milking disinfection or disinfection of milking clusters is necessary, an iodine based product can only be used for one of these uses.

Wash hands thoroughly after handling.

It is recommended to design all work processes always so that the following is excluded: Inhalation of vapours or spray/mists. Use only in well-ventilated areas.

Keep out of reach of children.

-	pecific to the use, the particulars of likely direct or indirect effects, first aid and emergency measures to protect the environment
	y direct or indirect effects: oduct is used properly according to the product label.
In case of eye conta lenses, if present ar	ns: act: After contact with skin, wash immediately with plenty of water. act: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact and easy to do. Continue rinsing. Obtain medical attention. llowed, seek medical advice immediately (call a POISON CENTER/doctor) and show this container or label.
4.1.4 Where sp packaging	pecific to the use, the instructions for safe disposal of the product and its
	eatment, dispose unused product and the packaging in accordance with local requirements. Used product can be cipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual ent plant.
-	ecific to the use, the conditions of storage and shelf-life of the product conditions of storage

5. General directions for use of the meta SPC

5.1. Instructions for use

See use-specific instructions for use of meta SPC 1. Always read the label or leaflet before use and follow all the instructions provided.
5.2. Risk mitigation measures
See use-specific risk mitigation measures for use of meta SPC 1.
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment
See specific P articulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment of meta SPC 1.
5.4. Instructions for safe disposal of the product and its packaging
See specific Instructions for safe disposal of the product and its packaging of meta SPC 1.
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage
Requirements for storage areas and containers: Keep container tightly closed in a cool place. Protect against UV-radiation/sunlight. Do not store at temperatures exceeding 40°C.
Further information on storage conditions: Do not store near food, drink and feed. The products have a shelf life of 2 years. Protect from frost

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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)	Ferdei Rox	Market area: NL
Authorisation number	NL-0016702-0001 1-1	
(R4BP 3 asset reference number - National Authorisation)		

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	0,25
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,000001
2-(2- butoxyethoxy)ethanol	2-(2- butoxyethoxy)ethanol	Non-active substance	112-34-5	203-961-6	6
Phosphoric acid	orthophosphoric acid	Non-active substance	7664-38-2	231-633-2	3,75
Alcohols C9-C11, ethoylated	AlcoholsC9-C11, ethoylated	Non-active substance	68439-46-3	500-446-0	0,75
Fatty alcohol alkoxylate 4	Fattyalcohol alkoxylate 4	Non-active substance	111905-53-4		1,8

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC 3: Teat disinfection (pre-/post-milking), ready to use

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 (%)
lodine		Active Substance	7553-56-2	231-442-4	0,25 - 0,4125
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,000001 - 0,000001

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.

Precautionary statements

If medical advice is needed, have product container or label at hand.

Keep out of reach of children.

Read carefully and follow all instructions.

Avoid release to the environment.

Dispose of container to in accordance to national legislation.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Teat disinfection (post-milking), spraying

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage:
	Scientific name: Common name: Yeasts Development stage:
	Indoor
Field(s) of use	The product is a RTU, used for teat disinfection (post-milking) of cows, sheep, goats.
Application method(s)	Method: Spraying Detailed description: (triggered) spraying
Application rate(s) and frequencies	Application Rate: spraying (per teat) 5-15 mL/cow 3-5 mL/goat 3-5 mL/sheep Dilution (%): 0 Number and timing of application: Application frequency: 2x/day (post-milking), Contact time: 5 min
Category(ies) of users	Professional
Pack sizes and packaging material	Plastic bottle of HDPE: 500 mL, 1000 mL
	'

J erry can of HDPE: 5 L, 10 L, 20 L, 25 L, 60 L

D rum of HDPE: 200 L

IBC container of HDPE: 1000 L

4.1.1 Use-specific instructions for use

Fill the spraying cup with the ready to use product.

Spray on animal's teats on the full length of the teat after milking (max. twice a day).

Use: 5-15ml per cow / 3-5 ml per goat / 3-5 ml per sheep

Keep the animals standing until the product has dried (at least 5 minutes). Leave the product until next milking.

At the next milking, wipe the teat systematically with a dry or wet cloth to remove product residues before attaching the milking cluster for the next milking event.

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

4.1.2 Use-specific risk mitigation measures

Keep container tightly closed. Protect against UV-radiation/sunlight and heat.

During use wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information). Wash hands thoroughly after handling.

It is recommended to design all work processes always so that the following is excluded: Inhalation of vapours or spray/mists Use only in well-ventilated areas.

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.

Keep out of reach of children.

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

Particulars of likely direct or indirect e Not known if the product is used properly							
First aid instructions: n case of skin contact: After contact with skin, wash immediately with plenty of water. n case of eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact enses, if present and easy to do. Continue rinsing. Obtain medical attention. f swallowed: if swallowed, seek medical advice immediately (call a POISON CENTER/doctor) and show this container or label.							
1.1.4 Where specific to the us backaging	se, the instructions for safe disposal of the product and its						
	red product and the packaging in accordance with local requirements. Used product can be ad to the manure deposit depending on local requirements. Avoid release to an individual						
.1.5 Where specific to the us inder normal conditions of s	1.5 Where specific to the use, the conditions of storage and shelf-life of the product						
See general conditions of storage and sh	<u> </u>						
1.2 Use description							
Jse 2 - Teat disinfection (post-n	nilking), dipping						
Product type	PT03 - Veterinary hygiene (Disinfectants)						
Where relevant, an exact description of the authorised use	-						
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria						

Development stage:

Scientific name: Common name: Yeasts Development stage:

Field(s) of use

Indoor

The product is a RTU, used for teat disinfection (post-milking) of cows, sheep, goats.

Application method(s)

Method: dipping Detailed description:

Application rate(s) and frequencies

Application Rate: dipping (per teat) 4-6 mL/cow 1-2 mL/goat 1-2 mL/sheep

Dilution (%): 0 Number and timing of application:

Application frequency: 2x/day (post-milking)

Contact time:

Category(ies) of users

Professional

Pack sizes and packaging material

Plastic bottle of HDPE: 500 mL, 1000 mL

J erry can of HDPE: 5 L, 10 L, 20 L, 25 L, 60 L

Drum of HDPE: 200 L

IBC container of HDPE: 1000 L

4.2.1 Use-specific instructions for use

Fill the dipping cup with the ready to use product.

Dipping on animal's teats on the full length of the teat after milking (max. twice a day).

Use: 4-6 ml per cow / 1-2 ml per goat / 1-2 ml per sheep

Keep the animals standing until the product has dried (at least 5 minutes). Leave the product until next milking.

At the next milking, wipe the teat systematically with a dry or wet cloth to remove product residues before attaching the milking cluster for the next milking event.

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

4.2.2 Use-specific risk mitigation measures

Keep container tightly closed. Protect against UV-radiation/sunlight and heat. Wash hands thoroughly after handling. It is recommended to design all work processes always so that the following is excluded: Inhalation of vapours or spray/mists Use only in well-ventilated areas.

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.

Keep out of reach of children.

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

Particulars of likely direct or indirect effects: Not known if the product is used properly according to the product label.

First aid instructions:

In case of skin contact: After contact with skin, wash immediately with plenty of water.

In case of eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

If swallowed: if swallowed, seek medical advice immediately (call a POISON CENTER/doctor) and show this container or label.

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

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

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

See general conditions of storage and shelf life of the product

4.3 Use description

Use 3 - Udder disinfection (pre-milking), wiping or dipping in foam

Product type

Where relevant, an exact description of the authorised

Target organism(s) (including development stage)

PT03 - Veterinary hygiene (Disinfectants)

Scientific name: Common name: Bacteria Development stage:

Scientific name: Common name: Yeasts Development stage:

Field(s) of use

Indoor

The product is RTU, used for udder/teat disinfection (pre-milking) of cows, sheep, goats.

Application method(s)

Method: wiping and dipping

Detailed description:

Wiping of clean udders/teats with a cloth or tissue soaked with disinfection solution or using a foam applicator on teats.

Application rate(s) and frequencies

Application Rate: Amount of product (per teat): 5-15 mL with soaked tissue/udder and teats 4-6 mL product foam / cow teat 1-2 mL product foam / goat and sheep teat Dilution (%): 0

Number and timing of application:

Application frequency: max.2x/day. Contact time 60sec.

Category(ies) of users

Professional

Pack sizes and packaging material

Plastic bottle of HDPE: 500 mL, 1000 mL

J erry can of HDPE: 5 L, 10 L, 20 L, 25 L, 60 L

Drum of HDPE: 200 L

IBC container of HDPE: 1000 L

4.3.1 Use-specific instructions for use

The product is used occasionally before milking with a soaked wet tissue on udder and teats or a foam beaker for teats. Clean the udder with a cloth, rinse with water and dry before application of the product.

<u>Wiping method</u>: For the disinfection the product is applied using a cloth which has been soaked in the application solution (5-15 ml/tissue). The product is allowed to remain on the teats and udders for 60 seconds then wiped off using a clean moist cloth before the milking equipment is attached. Residual product not completely used up for udder washing is disposed of.

<u>Foam application</u>: The teat foam product is applied via a foam beaker and pushed to form foam in the applicator. The foam is applied to every teat (4-6 ml per cow, 1-2 ml per goat and sheep teats) by dipping and allowed to remain for 60 seconds before it is removed using a water drenched towel.

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

4.3.2 Use-specific risk mitigation measures

Keep container tightly closed. Protect against UV-radiation/sunlight and heat.

During use wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information). Wash hands thoroughly after handling.

It is recommended to design all work processes always so that the following is excluded: Inhalation of vapours or spray/mists Use only in well-ventilated areas.

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.

Keep out of reach of children.

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				
	y direct or indirect effects: duct is used properly according to the product label.			
In case of eye conta	ns: act: After contact with skin, wash immediately with plenty of water. act: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact ad easy to do. Continue rinsing. Obtain medical attention.			
If swallowed: if swall	lowed, seek medical advice immediately (call a POISON CENTER/doctor) and show this container or label.			
-	ecific to the use, the instructions for safe disposal of the product and its			
oackaging	define to the dee, the mendenone for sale disposal of the product and its			
At the end of the treaflushed to the munic	atment, dispose unused product and the packaging in accordance with local requirements. Used product can be cipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual			
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flushed to the munic waste water treatment waste water treatment.	atment, dispose unused product and the packaging in accordance with local requirements. Used product can be cipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual			

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5. General directions for use of the meta SPC	
5.1. Instructions for use	
See use-specific instructions for use of meta SPC 3.	
Always read the label or leaflet before use and follow all the instructions provided	
5.2. Risk mitigation measures	
5.2. Nisk miligation measures	
See use-specific risk mitigation measures for use of meta SPC 3.	
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency	
measures to protect the environment	
See specific P articulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment of meta SI	PC 3.
5.4. Instructions for safe disposal of the product and its packaging	
See specific Instructions for safe disposal of the product and its packaging of meta SPC 3.	
See specific instructions for safe disposar of the product and its packaging of meta Si C 3.	
5.5. Conditions of storage and shelf-life of the product under normal conditions of stora	age
Requirements for storage areas and containers:	
Keep container tightly closed in a cool place. Protect against UV-radiation/sunlight. Do not store at temperatures exceeding 40)°C.

Further information on storage conditi	ons:	
Do not store near food, drink and feed.		
The products have a shelf life of 2 years. Protect from frost		
6. Other information		
7. Third information level:	individual products in the me	ta SPC
7.1 Trade name(s), authorisation	tion number and specific compos	sition of each individual
Trade name(s)	Eimü Doppeldip Iodine	Market area: NL
Authorisation number	NL-0016702-0002 1-2	
(R4BP 3 asset reference number - National Authorisation)	3310.01 0001 1	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,4
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,000001

Trade name(s)

Eimü PremaFoam Iodine

Market area: NL

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

NL-0016702-0003 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	0,25
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,000001

Trade name(s)

Eimü Doppel-Film-Dip

Market area: NL

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

NL-0016702-0004 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,4125

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,000001

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC 4: Teat disinfection (pre-milking), concentrates

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	1,625 - 1,625
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,000001 - 0,000001
Methanol	Methan-1-ol	Non-active substance	67-56-1	200-659-6	0 - 0,15

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

May be corrosive to metals.

May cause damage to organs thyroid through prolonged or repeated exposure oral.

Harmful to aquatic life with long lasting effects.

Precautionary statements

If medical advice is needed, have product container or label at hand.

Keep out of reach of children.

Read carefully and follow all instructions.

Avoid release to the environment.

Get medical advice if you feel unwell.

Absorb spillage to prevent material damage.

Dispose of container to in accordance to national legislation.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Udder disinfection (pre-milking), Foam beaker or use of soaked tissue, concentrates

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised

Target organism(s) (including development stage)

Scientific name: Common name: Bacteria Development stage:

Scientific name: Common name: Yeasts Development stage:

Field(s) of use

Indoor

The product is a concentrated, used for udder/teat disinfection (pre-milking) of cows, sheep, goats.

Application method(s)

Method: Soaked tissue and dipping

Detailed description:

Wiping of clean udders/teats with a cloth or tissue soaked with disinfection solution for udder and teats or using foam beaker on teats.

Application rate(s) and frequencies

Application Rate: Amount of diluted product (per teat): 5-15 mL on tissue per udder and teats 4-6 mL product foam / cow teat 1-2 mL product foam / goat and sheep teat Dilution (%): 2 20mL product is diluted in 1000mL water.

Number and timing of application:

Application frequency: max. 2x/day.

Contact time: 60 sec.

Category(ies) of users

Professional

Pack sizes and packaging material

Plastic bottle of HDPE: 500 mL, 1000 mL

J erry can of HDPE: 5 L, 10 L, 20 L, 25 L, 60 L

D rum of HDPE: 200 L IBC container of HDPE: 1000 L

4.1.1 Use-specific instructions for use

The product is used occasionally before milking with a soaked wet tissue on udder and teats or a foam beaker for teats. Clean the udder with a cloth, rinse with water and dry before application of the product.

The product needs to be diluted in lukewarm water (20 mL product with 1000mL water). A measuring beaker is used for weighing the amount of concentrated product. The needed amount is poured in a 10 L bucket and diluted with a calculated amount of water

according to the label instructions. The resulting blend is stirred with a stirring rod. <u>Wiping method:</u> For the disinfection the product is applied using a cloth which has been soaked in the application solution (5-15 ml/tissue). The product is allowed to remain on the teats and udders for 60 seconds then wiped off using a clean moist cloth before the milking equipment is attached. Residual product not completely used up for udder washing is disposed of. <u>Foam application:</u> The teat foam product is applied via a foam beaker and pushed to form foam in the applicator. The foam is applied to every teat (4-6 ml per cow, 1-2 ml per goat and sheep teats) by dipping and allowed to remain for 60 seconds before it is removed using a water drenched towel. The product must be brought to a temperature above 20°C before use.
1.1.2 Use-specific risk mitigation measures
Keep container tightly closed. Protect against UV-radiation/sunlight and heat. Wash hands thoroughly after handling. It is recommended to design all work processes always so that the following is excluded: Inhalation of vapours or spray/mists Use only in well-ventilated areas. 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. Keep out of reach of children.
I.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid nstructions and emergency measures to protect the environment
Particulars of likely direct or indirect effects: Not known if the product is used properly according to the product label.
First aid instructions: In case of skin contact: After contact with skin, wash immediately with plenty of water. In case of eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention. If swallowed: if swallowed, seek medical advice immediately (call a POISON CENTER/doctor) and show this container or label.

4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging
At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.
4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage
See general conditions of storage and shelf life of the product
5. General directions for use of the meta SPC
5.1. Instructions for use
See use-specific instructions for use of meta SPC 4. Always read the label or leaflet before use and follow all the instructions provided.
5.2. Risk mitigation measures
See use-specific risk mitigation measures for use of meta SPC 4.
see use specific risk militigation measures for use of meta of 0 4.
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment
See specific Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment of meta SPC 4.

See specific Instructions for safe disposa	al of the product and its packaging of meta SPC	1.				
5.5. Conditions of storage and	d shelf-life of the product under r	normal conditions of storage				
Requirements for storage areas and containers: Keep container tightly closed in a cool place. Protect against UV-radiation/sunlight. Do not store at temperatures exceeding 40°C.						
Further information on storage conditions: Do not store near food, drink and feed. The products have a shelf life of 2 years. Protect from frost.						
6. Other information						
b. Other information						
1						
7. Third information level:	individual products in the me	ta SPC				
7.1 Trade name(s), authorisa	individual products in the me					
7.1 Trade name(s), authorisa	-					
7.1 Trade name(s), authorisat product	-					
	tion number and specific compos	sition of each individual				

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	1,625
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,000001

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC 5: Teat disinfection (post-milking), ready to use with PVP-I

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 (%)
lodine		Active Substance	7553-56-2	231-442-4	0,000001 - 0,000001
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		2,7 - 2,7

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.

Precautionary statements

If medical advice is needed, have product container or label at hand.

Keep out of reach of children.

Read carefully and follow all instructions.

Avoid release to the environment.

Dispose of container to in accordance to national legislation.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Teat disinfection (post-milking), spraying, RTU

Product	type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Target organism(s) (including development stage)

Scientific name: Common name: Bacteria Development stage:

Scientific name: Common name: Yeasts Development stage:

Field(s) of use

Indoor

The product is RTU, used for teat disinfection (post-milking) of cows, sheep, goats.

Application method(s)

Method: Spraying

Detailed description: (triggered) spraying

Application rate(s) and frequencies

Application Rate: Spraying (per teat): 5-15 mL/cow 3-5 mL/goat 3-5 mL/sheep

Dilution (%): 0

Number and timing of application:

Application frequency: 2x/day (post-milking)

Contact time: 5 min.

Category(ies) of users

Professional

Pack sizes and packaging material

Plastic bottle of HDPE: 500 mL, 1000 mL

J erry can of HDPE: 5 L, 10 L, 20 L, 25 L, 60 L

D rum of HDPE: 200 L IBC container of HDPE: 1000 L

4.1.1 Use-specific instructions for use

Fill the spraying cup with the ready to use product.

Spray on animal's teats on the full length of the teat after milking (max. twice a day).

Use: 5-15ml per cow / 3-5 ml per goat / 3-5 ml per sheep

Keep the animals standing until the product has dried (at least 5 minutes). Leave the product until next milking.

At the next milking, wipe the teat systematically with a dry or wet cloth to remove product residues before attaching the milking cluster for the next milking event.

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

4.1.2 Use-specific risk mitigation measures

Keep container tightly closed. Protect against UV-radiation/sunlight and heat.

During use wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), a coated coverall and chemical resistant boots.

Wash hands thoroughly after handling.

It is recommended to design all work processes always so that the following is excluded: Inhalation of vapours or spray/mists Use only in well-ventilated areas.

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.

Keep out of reach of children.

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

Particulars of likely direct or indirect effects:

Not known if the product is used properly according to the product label.

First aid instructions:

In case of skin contact: After contact with skin, wash immediately with plenty of water.

In case of eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

If swallowed: if swallowed, seek medical advice immediately (call a POISON CENTER/doctor) and show this container or label.

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

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

4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage		
See general conditions of storage and shelf life of the product		
40 Use describetion		
4.2 Use description Use 2 - Teat disinfection (post-milking), dipping, RTU		
Use 2 - Teat disinfection (post-r	milking), dipping, RTO	
Product type	PT03 - Veterinary hygiene (Disinfectants)	
Where relevant, an exact description of the authorised use	-	
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage:	
	Scientific name: Common name: Yeasts Development stage:	
Field(s) of use	Indoor	
	The product is RTU, used for teat disinfection (post-milking) of cows, sheep, goats.	
Application method(s)	Method: dipping Detailed description:	
Application rate(s) and frequencies	Application Rate: Dipping (per teat): 4-6 mL/cow 1-2 mL/goat 1-2 mL/sheep Dilution (%): 0	

Number and timing of application:

Application frequency: 2x/day (post-milking)

Contact time:5 min.

Category(ies) of users

Professional

Pack sizes and packaging material

Plastic bottle of HDPE: 500 mL, 1000 mL

J erry can of HDPE: 5 L, 10 L, 20 L, 25 L, 60 L

Drum of HDPE: 200 L

IBC container of HDPE: 1000 L

4.2.1 Use-specific instructions for use

Fill the dipping cup with the ready to use product.

Dipping on animal's teats on the full length of the teat after milking (max. twice a day).

Use: 4-6 ml per cow / 1-2 ml per goat / 1-2 ml per sheep

Keep the animals standing until the product has dried (at least 5 minutes). Leave the product until next milking.

At the next milking, wipe the teat systematically with a dry or wet cloth to remove product residues before attaching the milking cluster for the next milking event.

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

4.2.2 Use-specific risk mitigation measures

Keep container tightly closed. Protect against UV-radiation/sunlight and heat. Wash hands thoroughly after handling. It is recommended to design all work processes always so that the following is excluded: Inhalation of vapours or spray/mists Use only in well-ventilated areas.

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.

Keep out of reach of children.

	ecific to the use, the particulars of likely direct or indirect effects, first aid demergency measures to protect the environment
	direct or indirect effects: uct is used properly according to the product label.
n case of eye contact enses, if present and	t: After contact with skin, wash immediately with plenty of water. t: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact easy to do. Continue rinsing. Obtain medical attention. wed, seek medical advice immediately (call a POISON CENTER/doctor) and show this container or label.
ackaging It the end of the treat ushed to the municip	ecific to the use, the instructions for safe disposal of the product and its ment, dispose unused product and the packaging in accordance with local requirements. Used product can hal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual
ackaging At the end of the treat	ment, dispose unused product and the packaging in accordance with local requirements. Used product can bal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individua
t the end of the treat ushed to the municip aste water treatmen	ment, dispose unused product and the packaging in accordance with local requirements. Used product can bal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individua
t the end of the treat ushed to the municip aste water treatmen 2.5 Where spe der normal co	ment, dispose unused product and the packaging in accordance with local requirements. Used product can bal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual tiplant. cific to the use, the conditions of storage and shelf-life of the product
t the end of the treat ushed to the municip vaste water treatmen 2.5 Where spe	ment, dispose unused product and the packaging in accordance with local requirements. Used product can bal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual tiplant. Cific to the use, the conditions of storage and shelf-life of the product conditions of storage
t the end of the treat ushed to the municip vaste water treatmen 2.5 Where spe	ment, dispose unused product and the packaging in accordance with local requirements. Used product can bal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual tiplant. Cific to the use, the conditions of storage and shelf-life of the product conditions of storage
ackaging It the end of the treat ushed to the municip vaste water treatmen 2.5 Where spe	ment, dispose unused product and the packaging in accordance with local requirements. Used product can bal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual tiplant. Cific to the use, the conditions of storage and shelf-life of the product conditions of storage

5.1. Instructions for use
See use-specific instructions for use of meta SPC 5. Always read the label or leaflet before use and follow all the instructions provided
5.2. Risk mitigation measures
See use-specific risk mitigation measures for use of meta SPC 5.
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment
See specific Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment of meta SPC 5.
5.4. Instructions for safe disposal of the product and its packaging
See specific Instructions for safe disposal of the product and its packaging of meta SPC 5.
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage
Requirements for storage areas and containers: Keep container tightly closed in a cool place. Protect against UV-radiation/sunlight. Do not store at temperatures exceeding 40°C.
Further information on storage conditions: Do not store near food, drink and feed. The products have a shelf life of 2 years. Protect from frost

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)	Eimü Hygiena-Dip PVP	Market area: NL
Authorisation number	NL-0016702-0006 1-4	
(R4BP 3 asset reference number - National Authorisation)		

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	0,000001
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		2,7

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC 6: Teat disinfection (post-milking), ready to use with PVP-I

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 (%)
lodine		Active Substance	7553-56-2	231-442-4	0,000001 - 0,000001
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		2,7 - 2,7
Methanol	Methan-1-ol	Non-active substance	67-56-1	200-659-6	0 - 0,12

2.2.	Type	s) o	f formulation	of t	he	meta	SP	C
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Formulation(s) AL - Any other	liquid
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3. Hazard and precautionary statements of the meta SPC

Hazard statements	Safety data sheet available on request.
Precautionary statements	

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Teat disinfection (post-milking), Foam dipping, RTU

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-

Target organism(s) (including development stage)

Scientific name: Common name: Bacteria Development stage:

Scientific name: Common name: Yeasts Development stage:

Field(s) of use

Indoor

The product is RTU, used for teat disinfection (post-milking) of cows, sheep, goats.

Application method(s)

Method: dipping Detailed description:

Application rate(s) and frequencies

Application Rate: Dipping (per teat): 15 mL/cow; 5 mL/goat; 5 mL/sheep

Dilution (%): 0

Number and timing of application:

Application frequency: 2x/day (post-milking)

Contact time: 5 min.

Category(ies) of users

Professional

Pack sizes and packaging material

Plastic bottle of HDPE: 500 mL, 1000 mL

J erry can of HDPE: 5 L, 10 L, 20 L, 25 L, 60 L

Drum of HDPE: 200 L

IBC container of HDPE: 1000 L

4.1.1 Use-specific instructions for use

Fill the foam beaker with the ready to use foam product.

Dipping on animal's teats on the full length of the teat after milking (max. twice a day).

Use: 15 ml per cow 5 ml per goat 5 ml per sheep

Keep the animals standing until the product has dried (at least 5 minutes). Leave the product until next milking. The product creates a film on the skin.

At the next milking, wipe the teat systematically with a dry or wet cloth to remove product residues before attaching the milking cluster for the next milking event.

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

4.1.2 Use-specific risk mitigation measures

Keep container tightly closed. Protect against UV-radiation/sunlight and heat.

Wash hands thoroughly after handling.

It is recommended to design all work processes always so that the following is excluded: Inhalation of vapours or spray/mists Use only in well-ventilated areas.

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.

Keep out of reach of children.

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

Particulars of likely direct or indirect effects:

Not known if the product is used properly according to the product label.

First aid instructions:

In case of skin contact: After contact with skin, wash immediately with plenty of water.

In case of eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

If swallowed: if swallowed, seek medical advice immediately (call a POISON CENTER/doctor) and show this container or label.

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

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

4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage
See general conditions of storage and shelf life of the product
5. General directions for use of the meta SPC
5.1. Instructions for use
See use-specific instructions for use of Meta SPC 6.
Always read the label or leaflet before use and follow all the instructions provided
5.2. Risk mitigation measures
Construction of the sixther than the same of the same
See use-specific risk mitigation measures for use of Meta SPC 6.
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment
See specific Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment of
meta SPC 6.
5.4. Instructions for safe disposal of the product and its packaging
See specific Instructions for safe disposal of the product and its packaging of meta SPC 6.
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage
Requirements for storage areas and containers:
Keep container tightly closed in a cool place. Protect against UV-radiation/sunlight. Do not store at temperatures exceeding 40°C.

Further information on storage condit Do not store near food, drink and feed. The products have a shelf life of 2 years					
Protect from frost					
6. Other information					
7. Third information level:7.1 Trade name(s), authorisa	•			ndividual	
product		,			
Trade name(s)	Eimü MultiCare Dip		Market area: NL		
Authorisation number (R4BP 3 asset reference number - National Authorisation)	NL-0016702-0007 1-5				
					_
Common name IUPAC name	e Function	CAS number	EC number	Content (%)	_
lodine	Active Substance	7553-56-2	231-442-4	0,000001	

Active Substance 25655-41-8

2,7

Polyvinylpyrrolidone iodine

Trade name(s)	Eimü DoppelProtect	Market area: NL
Authorisation number (R4BP 3 asset reference number - National Authorisation)	NL-0016702-0008 1-5	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	0,000001
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		2,7
Methanol	Methan-1-ol	Non-active substance	67-56-1	200-659-6	0,12

1. Meta SPC administrative information

1.1. Meta SPC identifier

meta SPC 7: Teat disinfection (pre-/post-milking), ready to use

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 (%)
lodine		Active Substance	7553-56-2	231-442-4	0,6675 - 0,6675
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,000001 - 0,000001

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.

Harmful to aquatic life with long lasting effects.

Precautionary statements

If medical advice is needed, have product container or label at hand.

Keep out of reach of children.

Read carefully and follow all instructions.

Keep only in original packaging.

Avoid release to the environment.

Absorb spillage to prevent material damage.

Dispose of container to in accordance to national legislation.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Teat disinfection (post-milking), spraying, RTU

Donalis Attack	PT03 - Veterinary hygiene (Disinfectants)
Product type	
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage:
	Scientific name: Common name: Yeasts Development stage:
Field(s) of use	Indoor
	The product is a RTU, used for teat disinfection (post-milking) of cows, sheep, goats.
Application method(s)	Method: Spraying Detailed description: (triggered) spraying
	Application Date: approximate (new teet), F. 15 ml /application Date: approximate (new teet), F. 15 ml /application Date: application Date
Application rate(s) and frequencies	Application Rate: spraying (per teat): 5-15 mL/cow; 3-5 mL/goat; 3-5 mL/sheep Dilution (%): 0 Number and timing of application:
	Application frequency: 2x/day (post-milking) Contact time: 5 min.
Category(ies) of users	Professional
Pack sizes and packaging material	Plastic bottle of HDPE: 500 mL, 1000 mL
	J erry can of HDPE: 5 L, 10 L, 20 L, 25 L, 60 L
	D rum of HDPE: 200 L IBC container of HDPE: 1000 L

I.1.1 Use-specific instruction	s for use
Use: 5-15mL per cow; 3-5 mL per goat; 3 Keep the animals standing until the produ	of the teat after milking (max. twice a day). 3-5 mL per sheep uct has dried (at least 5 minutes). Leave the product until next milking. atically with a dry or wet cloth to remove product residues before attaching the milking
I.1.2 Use-specific risk mitiga	tion measures
Keep container tightly closed. Protect aga During use wear chemical resistant glove coverall and chemical resistant boots. Wash hands thoroughly after handling.	ainst UV-radiation/sunlight and heat. s (glove material to be specified by the authorisation holder within the product information),
only in well-ventilated areas.	cesses always so that the following is excluded: Inhalation of vapours or spray/mists Use ilking disinfection is necessary, using another product not containing iodine has to be
Keep out of reach of children.	
	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment
Particulars of likely direct or indirect e Not known if the product is used properly	
First aid instructions:	

In case of skin contact: After contact with In case of eye contact: Rinse immediately lenses, if present and easy to do. Continu	skin, wash immediately with plenty of water. y with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact ue rinsing. Obtain medical attention.				
If swallowed: if swallowed, seek medical advice immediately (call a POISON CENTER/doctor) and show this container or label.					
	se, the instructions for safe disposal of the product and its				
oackaging					
	sed product and the packaging in accordance with local requirements. Used product can be ed to the manure deposit depending on local requirements. Avoid release to an individual				
	se, the conditions of storage and shelf-life of the product torage				
	torage				
ınder normal conditions of s	torage				
ınder normal conditions of s	torage				
ınder normal conditions of s	torage				
Inder normal conditions of S See general conditions of storage and sh	torage				
Inder normal conditions of s See general conditions of storage and sh 1.2 Use description	torage relf life of the product				
Inder normal conditions of s See general conditions of storage and sh 4.2 Use description Jse 2 - Teat disinfection (post-recommend)	torage relf life of the product				
Inder normal conditions of s See general conditions of storage and sh 1.2 Use description Use 2 - Teat disinfection (post-normal conditions) Product type Where relevant, an exact description of the authorised	nilking), dipping, RTU				
ınder normal conditions of s	nilking), dipping, RTU				

Field(s) of use

Indoor

The product is a RTU, used for teat disinfection (post-milking) of cows, sheep, goats.

Application method(s)

Method: dipping Detailed description:

-

Application rate(s) and frequencies

Application Rate: Dipping (per teat): 4-6 mL/cow; 1-2 mL/goat; 1-2 mL/sheep

Dilution (%): 0

Number and timing of application:

Application frequency: 2x/day (post-milking)

Contact time 5 min.

Category(ies) of users

Professional

Pack sizes and packaging material

Plastic bottle of HDPE: 500 mL, 1000 mL

J erry can of HDPE: 5 L, 10 L, 20 L, 25 L, 60 L

Drum of HDPE: 200 L

IBC container of HDPE: 1000 L

4.2.1 Use-specific instructions for use

Fill the dipping cup with the ready to use product.

Dipping on animal's teats on the full length of the teat after milking (max. twice a day).

Use: 4-6 ml per cow / 1-2 ml per goat / 1-2 ml per sheep

Keep the animals standing until the product has dried (at least 5 minutes). Leave the product until next milking.

At the next milking, wipe the teat systematically with a dry or wet cloth to remove product residues before attaching the milking cluster for the next milking event.

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

4.2.2 Use-specific risk mitigation measures

Keep container tightly closed. Protect against UV-radiation/sunlight and heat. Wash hands thoroughly after handling. Wear protective gloves/protective clothing/eye protection. It is recommended to design all work processes always so that the following is excluded: Inhalation of vapours or spray/mists Use only in well-ventilated areas. 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. Keep out of reach of children. 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 Particulars of likely direct or indirect effects: Not known if the product is used properly according to the product label. First aid instructions: In case of skin contact: After contact with skin, wash immediately with plenty of water. In case of eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention. If swallowed: if swallowed, seek medical advice immediately (call a POISON CENTER/doctor) and show this container or label. 4.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

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

See general conditions of storage and shelf life of the product	

4.3 Use description

Use 3 - Udder disinfection (pre-milking), disinfection by wiping/ dipping with foam, RTU

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Where relevant, an exact description of the authorised use

Target organism(s) (including development stage)

PT03 - Veterinary hygiene (Disinfectants)

Scientific name:

Common name: Bacteria Development stage:

Scientific name: Common name: Yeasts Development stage:

Field(s) of use

Indoor

The product is RTU, used for udder/teat disinfection (pre-milking) of cows, sheep, goats.

Application method(s)

Method: Wiping and dipping

Detailed description:

Wiping of clean udders/teats with a cloth or tissue soaked with disinfection solution or using a foam applicator on teats.

Application rate(s) and frequencies

Application Rate: Amount of product (per teat): 5–15 mL with soaked tissue/udder and teats 4-6 mL product foam / cow teat 1-2 mL product foam / goat and sheep teat Dilution (%): 0

Number and timing of application:

Application frequency: max. 2x/day. Contact time: 60 sec.

Category(ies) of users	Professional
Pack sizes and packaging material	Plastic bottle of HDPE: 500 mL, 1000 mL J erry can of HDPE: 5 L, 10 L, 20 L, 25 L, 60 L Drum of HDPE: 200 L IBC container of HDPE: 1000 L

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4.3.1 Use-specific instructions for use

The product is used occasionally before milking with a soaked wet tissue on udder and teats or a foam beaker for teats. Clean the udder with a cloth, rinse with water and dry before application of the product.

<u>Wiping method</u>: For the disinfection the product is applied using a cloth which has been soaked in the application solution (5-15 ml/tissue). The product is allowed to remain on the teats and udders for 60 seconds then wiped off using a clean moist cloth before the milking equipment is attached. Residual product not completely used up for udder washing is disposed of.

<u>Foam application:</u> The teat foam product is applied via a foam beaker and pushed to form foam in the applicator. The foam is applied to every teat (4-6 ml per cow, 1-2 ml per goat and sheep teats) by dipping and allowed to remain for 60 seconds before it is removed using a water drenched towel.

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

4.3.2 Use-specific risk mitigation measures

Keep container tightly closed. Protect against UV-radiation/sunlight and heat.

During use wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information).

Wash hands thoroughly after handling.
It is recommended to design all work processes always so that the following is excluded: Inhalation of vapours or spray/mists Use only in well-ventilated areas. 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.
Keep out of reach of children.
1.3.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid nstructions and emergency measures to protect the environment
Particulars of likely direct or indirect effects: Not known if the product is used properly according to the product label.
First aid instructions: In case of skin contact: After contact with skin, wash immediately with plenty of water. In case of eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention. If swallowed: if swallowed, seek medical advice immediately (call a POISON CENTER/doctor) and show this container or label.
1.3.4 Where specific to the use, the instructions for safe disposal of the product and its backaging
At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements . Avoid release to an individual waste water treatment plant.
.3.5 Where specific to the use, the conditions of storage and shelf-life of the product inder normal conditions of storage
See general conditions of storage and shelf life of the product

5. General directions for use of the meta SPC
5.1. Instructions for use
See use-specific instructions for use of Meta SPC 7. Always read the label or leaflet before use and follow all the instructions provided
5.2. Risk mitigation measures
See use-specific risk mitigation measures for use of Meta SPC 7.
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment
See specific Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment meta SPC 7.
5.4. Instructions for eafo disposal of the product and its packaging
5.4. Instructions for safe disposal of the product and its packaging
See specific Instructions for safe disposal of the product and its packaging of meta SPC 7.
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage
Requirements for storage areas and containers: Keep container tightly closed in a cool place. Protect against UV-radiation/sunlight. Do not store at temperatures exceeding 40°C.
Further information on storage conditions: Do not store near food, drink and feed. The products have a shelf life of 2 years.
The products have a shell life of 2 years.

Protect from frost		
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)	Eimü Defender Dip	Market area: NL
Authorisation number	NL-0016702-0009 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	0,6675
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,000001

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 8: Teat disinfection (post-milking), concentrates

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	1,562 - 1,5625
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,000001 - 0,000001
Methanol	Methan-1-ol	Non-active substance	67-56-1	200-659-6	0 - 0,15

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

May be corrosive to metals.

Causes severe skin burns and eye damage.

May cause damage to organs thyroid through prolonged or repeated exposure oral.

Harmful to aquatic life with long lasting effects.

Precautionary statements

If medical advice is needed, have product container or label at hand.

Keep out of reach of children.

Read carefully and follow all instructions.

Avoid release to the environment.

Wear protective gloves/protective clothing/eye protection/face protection...

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.

IF ON SKIN (or hair):Take off immediately all contaminated clothing.Rinse skin with shower.

Immediately call a POISON CENTER/doctor.

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/doctor.

Absorb spillage to prevent material damage.

Dispose of container to in accordance to national legislation.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Teat disinfection (post-milking), spraying

Product	type	

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Target organism(s) (including development stage)

Scientific name: Common name: Bacteria Development stage:

Scientific name: Common name: Yeasts Development stage:

Field(s) of use

Indoor

The product is a concentrate, used for teat disinfection (post-milking) of cows, sheep, noats

Application method(s)

Method: Spraying Detailed description: (triggered) spraying;

Application rate(s) and frequencies

Application Rate: Spraying (per teat): 5-15 mL/cow 3-5 mL/goat 3-5 mL/sheep

Dilution (%): 20

Number and timing of application:

Application frequency: 2x/day (post-milking)

Contact time: 5 min.

Category(ies) of users

Professional

Pack sizes and packaging material

Plastic bottle of HDPE: 500 mL, 1000 mL

J erry can of HDPE: 5 L, 10 L, 20 L, 25 L, 60 L

D rum of HDPE: 200 L

IBC container of HDPE: 1000 L

4.1.1 Use-specific instructions for use

Fill the spraying cup with the ready to use product.

Spray on animal's teats on the full length of the teat after milking (max. twice a day).

The product needs to be diluted with water (100mL product with 400mL with potable water = 20% dilution). A measuring beaker is used for weighing the amount of concentrated product. The needed amount is poured in a 10 L bucket and diluted with a calculated amount of water according to the label instructions. The resulting blend is stirred with a stirring rod and filled in the application equipment.

Use: 5-15ml per cow / 3-5 ml per goat / 3-5 ml per sheep

Keep the animals standing until the product has dried (at least 5 minutes). Leave the product until next milking.

At the next milking, wipe the teat systematically with a dry or wet cloth to remove product residues before attaching the milking cluster for the next milking event.

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

4.1.2 Use-specific risk mitigation measures

Keep container tightly closed. Protect against UV-radiation/sunlight and heat.

During use wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information). Wash hands thoroughly after handling.

It is recommended to design all work processes always so that the following is excluded: Inhalation of vapours or spray/mists Use only in well-ventilated areas.

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.

Keep out of reach of children.
4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid nstructions and emergency measures to protect the environment
Particulars of likely direct or indirect effects: Not known if the product is used properly according to the product label.
First aid instructions: In case of skin contact: After contact with skin, wash immediately with plenty of water. In case of eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.
If swallowed: if swallowed, seek medical advice immediately (call a POISON CENTER/doctor) and show this container or label.
4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.
1.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general conditions of storage and shelf life of the product
1.2 Use description
Jse 2 - Teat disinfection (post-milking), dipping
Product type Product type

Where relevant, an exact description of the authorised

Target organism(s) (including development stage)

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Scientific name: Common name: Bacteria Development stage:

Development stage:

Scientific name: Common name: Yeasts Development stage:

Field(s) of use

Indoor

The product is a concentrate, used for teat disinfection (post-milking) of cows, sheep, goats.

Application method(s)

Method: dipping Detailed description:

Application rate(s) and frequencies

Application Rate: Dipping (per teat): 4-6 mL/cow 1-2 mL/goat 1-2 mL/sheep

Dilution (%): 20 100 mL product is diluted in 400 mL water

Number and timing of application:

Application frequency: 2x/day (post-milking)

5 minutes contact time

Category(ies) of users

Professional

Pack sizes and packaging material

Plastic bottle of HDPE: 500 mL, 1000 mL

J erry can of HDPE: 5 L, 10 L, 20 L, 25 L, 60 L

Drum of HDPE: 200 L

IBC container of HDPE: 1000 L

4.2.1 Use-specific instructions for use

Fill the dipping cup with the ready to use product.

Dipping on animal's teats on the full length of the teat after milking (max. twice a day).

The product needs to be diluted with water (100mL product with 400mL lukewarm potable water = 20% dilution). A measuring beaker is used for weighing the amount of concentrated product. The needed amount is poured in a 10 L bucket and diluted with a calculated amount of water according to the label instructions. The resulting blend is stirred with a stirring rod and filled in the application equipment.

Use: 4-6 ml per cow / 1-2 ml per goat / 1-2 ml per sheep Keep the animals standing until the product has dried (at least 5 minutes). Leave the product until next milking. At the next milking, wipe the teat systematically with a dry or wet cloth to remove product residues before attaching the milking
cluster for the next milking event.
The product must be brought to a temperature above 20°C before use.
.2.2 Use-specific risk mitigation measures
Keep container tightly closed. Protect against UV-radiation/sunlight and heat. Wash hands thoroughly after handling. It is recommended to design all work processes always so that the following is excluded: Inhalation of vapours or spray/mists Use only in well-ventilated areas. 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.
Keep out of reach of children.
.2.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid
Particulars of likely direct or indirect effects: Not known if the product is used properly according to the product label.
First aid instructions: In case of skin contact: After contact with skin, wash immediately with plenty of water. In case of eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact enses, if present and easy to do. Continue rinsing. Obtain medical attention.
if swallowed: if swallowed, seek medical advice immediately (call a POISON CENTER/doctor) and show this container or label.
.2.4 Where specific to the use, the instructions for safe disposal of the product and its ackaging
At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.
2.5 Where specific to the use, the conditions of storage and shelf-life of the product nder normal conditions of storage
See general conditions of storage and shelf life of the product

5. General directions for use of the meta SP
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5.1. Instructions for use

See use-specific instructions for use of meta SPC 4.
Always read the label or leaflet before use and follow all the instructions provided.

5.2. Risk mitigation measures

See use-specific risk mitigation measures for use of meta SPC 4.

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

See specific Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment of meta SPC 4.

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

See specific Instructions for safe disposal of the product and its packaging of meta SPC 4.

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

Requirements for storage areas and containers:

Keep container tightly closed in a cool place. Protect against UV-radiation/sunlight. Do not store at temperatures exceeding 40°C.

Further information on storage conditions:

Do not store near food, drink and feed.

The products have a shelf life of 2 years.

Protect from from frost.

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)	Eimü Iodine-DES-Concentrate (Film)	Market area: NL
Authorisation number	NL-0016702-0010 1-7	
(R4BP 3 asset reference number - National Authorisation)		

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	1,5625
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,000001
Methanol	Methan-1-ol	Non-active substance	67-56-1	200-659-6	0,15

Trade name(s)	Eimü Film-Dip-Konzentrat	Market area: NL
	Stafilex-Dipspray-Konzentrat	Market area: NL

Authorisation number

NL-0016702-0011 1-7

(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	1,5625
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,000001