COMMISSION IMPLEMENTING REGULATION (EU) 2018/1853

of 27 November 2018

granting a Union authorisation for the biocidal product family Teat disinfectants biocidal product family of CVAS

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 44(5) thereof,

Whereas:

(1) On 28 August 2015, the Scientific Consulting Company — SCC GmbH acting on behalf of CVAS Development GmbH submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named Teat disinfectants biocidal product family of CVAS ('product family') of product-type 3, as described in Annex V to that Regulation. The competent authority of Netherlands agreed to evaluate the application as referred to in Article 43(1) of Regulation (EU) No 528/2012. The application was recorded under the case number BC-WU019429-99 in the Register for Biocidal Products ('the Register').

(2) The biocidal product family contains iodine, including polyvinylpyrrolidone iodine, as the active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012. Taking into account the intrinsic properties of the active substance, and following the entry into application of the scientific criteria for the determination of endocrine-disrupting properties set out in Commission Delegated Regulation (EU) 2017/2100 ([2]), the Commission will consider the need to review the approval of iodine, including polyvinylpyrrolidone iodine, in accordance with Article 15 of Regulation (EU) No 528/2012. Depending on the outcome of that review, the Commission will then consider whether the Union authorisations for products containing the active substance have to be reviewed in accordance with Article 48 of Regulation (EU) No 528/2012.

(3) On 30 August 2017, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, the assessment report and the conclusions of its evaluation to the European Chemicals Agency ('the Agency').

(4) On 19 March 2018, the Agency submitted to the Commission an opinion ([3]), including the draft summary of the biocidal product characteristics ('SPC') of the product family and the final assessment report on the product family in accordance with Article 44(3) of Regulation (EU) No 528/2012. The opinion concludes that the product family falls within the definition of 'biocidal product family' laid down in Article 3(1)(s) of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that subject to compliance with the draft SPC, the product family meets the conditions laid down in Article 19(1) and (6) of that Regulation.

(5) On 25 April 2018, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.

(6) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for the biocidal product family.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1).

([3]) ECHA opinion of 7 March 2018 on the Union authorisation of Teat disinfectants biocidal product family of CVAS (ECHA/BPC/193/2018).

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation is granted to CVAS Development GmbH for the biocidal product family Teat disinfectants biocidal product family of CVAS with authorisation number EU-0018724-0000.

The Union authorisation is valid from 18 December 2018 until 30 November 2028.

The Union authorisation is subject to compliance with the SPC set out in the Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 27 November 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Summary of product characteristics for a biocidal product family

TEAT DISINFECTANTS BIOCIDAL PRODUCT FAMILY OF CVAS

Product type 3 — Veterinary hygiene (Disinfectants)

Authorisation number: EU-0018724-0000

R4BP 3 asset number: EU-0018724-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name	TEAT DISINFECTANTS BIOCIDAL PRODUCT FAMILY OF CVAS

1.2. Product type(s)

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

1.3. Authorisation holder

Name and address of the authorisation holder	Name	CVAS Development GmbH
	Address	Dr Albert Reimann Str. 16a, 68526 Ladenburg, Germany
Authorisation number	EU-0018724-0000	
R4BP asset number	EU-0018724-0000	
Date of the authorisation	18 December 2018	
Expiry date of the authorisation	30 November 2028	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	Calvatis GmbH
Address of manufacturer	Dr Albert Reimann Str. 16a, 68526 Ladenburg, Germany
Location of manufacturing sites	Dr Albert Reimann Str. 16a, 68526 Ladenburg, Germany

Name of manufacturer	Arthur Schopf Hygiene GmbH & Co. KG
Address of manufacturer	Pfaffensteinstr. 1, 83115 Neubeuern, Germany
Location of manufacturing sites	Pfaffensteinstr. 1, 83115 Neubeuern, Germany

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

Active substance	Iodine
Name of manufacturer	Cosayach Nitratos S.A.

Address of manufacturer	Amunategui 178 Santiago Chile
Location of manufacturing sites	S.C.M. Cosayach Cala Cala Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	ACF Minera S.A.
Address of manufacturer	San Martín No 499 Iquique Chile
Location of manufacturing sites	Lagunas mine Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	SQM S.A.
Address of manufacturer	Los Militares 4290, Piso 4 Las Condes Chile
Location of manufacturing sites	Nueva Victoria plant Pedro de Valdivia plant Chile

Active substance	Iodine
Name of manufacturer	Nihon Tennen Gas Co., Ltd/Kanto Natural Gas Development Co., Ltd
Address of manufacturer	661 Mobara 297-8550 Mobara City, Chiba Japan
Location of manufacturing sites	Chiba Plant, 2508 Minami-Hinata 299-4205 Shirako-Machi, Chosei-Gun, Chiba Japan

Active substance	Polyvinylpyrrolidone iodine
Name of manufacturer	Norkem Limited (manufacturer of PVP-iodine)
Address of manufacturer	Norkem House, Bexton Lane WA 16 9FB Knutsford, Cheshire United Kingdom
Location of manufacturing sites	Norkem House, Bexton Lane WA 16 9FB Knutsford, Cheshire United Kingdom

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 (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0	0,54
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0	4,16
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0	0,33

2.2. **Type(s) of formulation**

Formulation(s)	AL — Any other liquid

PART II

SECOND INFORMATION LEVEL — META SPC(S)

META SPC 1

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 1 identifier**

Identifier	meta SPC 1

1.2. **Suffix to the authorisation number**

Number	1-1

1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 1 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 1**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,16	1,5
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0	0

2.2. **Type(s) of formulation of the meta SPC 1**

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	
Precautionary statements	If medical advice is needed, have product container or label at hand. Keep out of reach of children.

4. AUTHORISED USE(S) OF THE META SPC 1

4.1. **Use description**

Table 1. Use # 1 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping

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

Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual dipping using a dip cup
Application rate(s) and frequency	cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

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.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the dip cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Refill the cup of the dipping unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

4.1.2. *Use-specific risk mitigation measures*

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

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*

See general directions for use.

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

See general directions for use.

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 directions for use.

4.2. **Use description**

Table 2. Use # 2 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated dipping

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

Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated dipping
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2 - 3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.2.1. *Use-specific instructions for use*

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

Open a can containing the RTU product and insert a suction tube of the automated dipping-system. Avoid discharge of surplus fluids.

After milking, the vacuum is shut off and the teat dip is injected into a manifold on the clawpiece. The teats are coated with ca. 5 mL of dip when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated dipping-system is thoroughly rinsed with water and blown out with compressed air.

In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Afterwards, the milking system is ready for the next milking event.

The whole process is automated.

4.2.2. *Use-specific risk mitigation measures*

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

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*

See general directions for use.

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

See general directions for use.

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 directions for use.

5. GENERAL DIRECTIONS FOR USE [1] OF THE META SPC 1

5.1. **Instructions for use**

See use specific instructions for use.

5.2. **Risk mitigation measures**

See use specific risk mitigation measures.

[1] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC1.

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

Mentioned in the MSDS

Description of first aid measures

After inhalation: Supply fresh air; consult doctor in case of symptoms.

After skin contact: Instantly wash with water and soap and rinse thoroughly.

After eye contact: Rinse opened eye for several minutes under running water (at least 15 minutes).

After swallowing: Rinse out mouth and then drink plenty of water. Instantly call for doctor.

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

Stability and reactivity

Reactivity: No dangerous reactions known.

Chemical stability: The product is chemically stable under normal surroundings terms (ambient temperature).

Possibility of hazardous reactions: By designated use no dangerous reactions are to be expected.

Conditions to avoid: Not determined.

Incompatible materials: Not determined.

Hazardous decomposition products: No dangerous decomposition products known.

Accidental release measures

Personal precautions, protective equipment and emergency procedures: Wear protective clothing.

Ensure adequate ventilation.

Keep ignition sources away — Do not smoke.

Environmental precautions: Do not allow to enter drainage system, surface or ground water.

Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of the material collected according to regulations.

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

Mentioned in the MSDS

Waste treatment methods: Hazardous waste (AVV). Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Must be specially treated under adherence to official regulations.

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.

Recommended cleaning agent: Water, if needed detergent

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

Shelf-life: 18 months

Products need to be protected from frost, stored at temperatures not exceeding 30 °C and away from direct sunlight.

6. OTHER INFORMATION

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7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

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

Trade name(s)	Dip es barriere Dip es barriere 1.4 Iod Dip F 14 P
Authorisation number	EU-0018724-0001 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,16
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 2 identifier**

Identifier	meta SPC 2

1.2. **Suffix to the authorisation number**

Number	1-2

1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 2 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 2**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,56	2,5
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0	0

2.2. **Type(s) of formulation of the meta SPC 2**

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

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. Avoid release to the environment. Dispose of contents to local/regional/national/international regulation. Dispose of container to local/regional/national/international regulation.

4. AUTHORISED USE(S) OF THE META SPC 2

4.1. **Use description**

Table 3. Use # 1 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual dipping using a dip cup
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

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.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the dip cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Refill the cup of the dipping unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

4.1.2. *Use-specific risk mitigation measures*

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

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*

See general directions for use.

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

See general directions for use.

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 directions for use.

4.2. **Use description**

Table 4. Use # 2 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated dipping

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated dipping
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2 - 3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.2.1. *Use-specific instructions for use*

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

Open a can containing the RTU product and insert a suction tube of the automated dipping-system. Avoid discharge of surplus fluids.

After milking, the vacuum is shut off and the teat dip is injected into a manifold on the clawpiece. The teats are coated with ca. 5 mL of dip when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated dipping-system is thoroughly rinsed with water and blown out with compressed air.

In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Afterwards, the milking system is ready for the next milking event.

The whole process is automated.

4.2.2. *Use-specific risk mitigation measures*

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

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*

See general directions for use.

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

See general directions for use.

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 directions for use.

5. GENERAL DIRECTIONS FOR USE ([1]) OF THE META SPC 2

5.1. **Instructions for use**

See use specific instructions for use.

5.2. **Risk mitigation measures**

See use specific risk mitigation measures.

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

Mentioned in the MSDS

Description of first aid measures

After inhalation: Supply fresh air; consult doctor in case of symptoms.

After skin contact: Instantly wash with water and soap and rinse thoroughly.

After eye contact: Rinse opened eye for several minutes under running water (at least 15 minutes).

After swallowing: Rinse out mouth and then drink plenty of water. Instantly call for doctor.

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

Stability and reactivity

Reactivity: No dangerous reactions known.

Chemical stability: The product is chemically stable under normal surroundings terms (ambient temperature).

Possibility of hazardous reactions: By designated use no dangerous reactions are to be expected.

Conditions to avoid: Not determined.

Incompatible materials: Not determined.

Hazardous decomposition products: No dangerous decomposition products known.

Accidental release measures

Personal precautions, protective equipment and emergency procedures: Wear protective clothing.

Ensure adequate ventilation.

Keep ignition sources away — Do not smoke.

([1]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC2.

Environmental precautions: Do not allow to enter drainage system, surface or ground water.

Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of the material collected according to regulations.

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

Mentioned in the MSDS

Waste treatment methods: Hazardous waste (AVV). Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Must be specially treated under adherence to official regulations.

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.

Recommended cleaning agent: Water, if needed detergent.

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

Shelf-life: 18 months

Products need to be protected from frost, stored at temperatures not exceeding 30 °C and away from direct sunlight.

6. OTHER INFORMATION

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7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2

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

Trade name(s)	Dip es Io-film Dip es Io-film 3.0 Iod-Dip Io-film 30				
Authorisation number	EU-0018724-0002 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		2,5
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0

META SPC 3

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 3 identifier**

Identifier	meta SPC 3

1.2. **Suffix to the authorisation number**

Number	1-3

1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 3 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 3**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,56	4,16
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0	0

2.2. **Type(s) of formulation of the meta SPC 3**

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

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. Avoid release to the environment. Dispose of contents to local/regional/national/international regulation. Dispose of container to local/regional/national/international regulation.

4. AUTHORISED USE(S) OF THE META SPC 3

4.1. **Use description**

Table 5. Use # 1 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking

Application method(s)	Manual dipping using a dip cup
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

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.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the dip cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Refill the cup of the dipping unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

4.1.2. *Use-specific risk mitigation measures*

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

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*

See general directions for use.

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

See general directions for use.

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 directions for use.

4.2. **Use description**

Table 6. Use # 2 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated dipping

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts

Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated dipping
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2 - 3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.2.1. *Use-specific instructions for use*

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

Open a can containing the RTU product and insert a suction tube of the automated dipping-system. Avoid discharge of surplus fluids.

After milking, the vacuum is shut off and the teat dip is injected into a manifold on the clawpiece. The teats are coated with ca. 5 mL of dip when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated dipping-system is thoroughly rinsed with water and blown out with compressed air.

In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Afterwards, the milking system is ready for the next milking event.

The whole process is automated.

4.2.2. *Use-specific risk mitigation measures*

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

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*

See general directions for use.

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

See general directions for use.

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 directions for use.

5. GENERAL DIRECTIONS FOR USE [1] OF THE META SPC 3

5.1. **Instructions for use**

See use specific instructions for use.

[1] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC3.

5.2. **Risk mitigation measures**

See use specific risk mitigation measures.

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

Mentioned in the MSDS

Description of first aid measures

After inhalation: Supply fresh air; consult doctor in case of symptoms.

After skin contact: Instantly wash with water and soap and rinse thoroughly.

After eye contact: Rinse opened eye for several minutes under running water (at least 15 minutes).

After swallowing: Rinse out mouth and then drink plenty of water. Instantly call for doctor.

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

Stability and reactivity

Reactivity: No dangerous reactions known.

Chemical stability: The product is chemically stable under normal surroundings terms (ambient temperature).

Possibility of hazardous reactions: By designated use no dangerous reactions are to be expected.

Conditions to avoid: Not determined.

Incompatible materials: Not determined.

Hazardous decomposition products: No dangerous decomposition products known.

Accidental release measures

Personal precautions, protective equipment and emergency procedures: Wear protective clothing.

Ensure adequate ventilation.

Keep ignition sources away — Do not smoke.

Environmental precautions: Do not allow to enter drainage system, surface or ground water.

Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of the material collected according to regulations.

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

Mentioned in the MSDS

Waste treatment methods: Hazardous waste (AVV). Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Must be specially treated under adherence to official regulations.

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.

Recommended cleaning agent: Water, if needed detergent.

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

Shelf-life: 18 months

Products need to be protected from frost, stored at temperatures not exceeding 30 °C and away from direct sunlight.

6. OTHER INFORMATION

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7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3

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

Trade name(s)	Dip es barriere S Dip es barriere 3.0 Iod-Dip F 30 P Baktostop Barier color				
Authorisation number	EU-0018724-0003 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		2,5
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0

7.2. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Dip es barriere RS Dip es barriere 5.0 Iod-Dip F 50 P BaktoStop barier				
Authorisation number	EU-0018724-0004 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		4,16
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0

META SPC 4

1. META SPC 4 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 4 identifier**

Identifier	meta SPC 4

1.2. **Suffix to the authorisation number**

Number	1-4

1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 4 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 4**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,56	2,5
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0	0

2.2. **Type(s) of formulation of the meta SPC 4**

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4

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. Avoid release to the environment. Dispose of contents to local/regional/national/international regulation. Dispose of container to local/regional/national/international regulation.

4. AUTHORISED USE(S) OF THE META SPC 4

4.1. **Use description**

Table 7. Use # 1 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking

Application method(s)	Manual dipping using a dip cup
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

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.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the dip cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Refill the cup of the dipping unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

4.1.2. *Use-specific risk mitigation measures*

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

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*

See general directions for use.

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

See general directions for use.

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 directions for use.

4.2. **Use description**

Table 8. Use # 2 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using a trigger sprayer

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts

Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual spraying using a trigger sprayer
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2 - 3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

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.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the top of the trigger sprayer on it. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, spray the disinfectant on the teats using the trigger sprayer making sure that about 3 cm of the teat around the streak canal are covered with the disinfectant.

Refill the reservoir of the trigger sprayer with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and trigger sprayer by rinsing with water.

4.2.2. *Use-specific risk mitigation measures*

Use chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during postmilking teat disinfection by manual spraying using a trigger sprayer.

Avoid working in a spray mist.

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.

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*

See general directions for use.

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

See general directions for use.

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 directions for use.

4.3. **Use description**

Table 9. Use # 3 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using an electronic sprayer

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual spraying using an electronic sprayer
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2 - 3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.3.1. *Use-specific instructions for use*

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

Open a can containing the RTU product assuming 5 mL product per cow and insert a sucking lance of the electronic sprayer. Avoid discharge of surplus fluids.

Clean carefully the teats by wiping with a single service paper towel/cloth before milking.

After milking, spray the disinfectant on the teats using the electronic sprayer making sure that about 3 cm of the teat around the streak canal are covered with the disinfectant.

Replace the empty can by a new can containing the RTU product as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, put the sucking lance system into a bucket of water and rinse the sprayer by pumping the water through the sprayer.

4.3.2. *Use-specific risk mitigation measures*

Use chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during postmilking teat disinfection by manual spraying using an electronic sprayer.

Avoid working in spray mist.

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.

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*

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.4. **Use description**

Table 10. Use # 4 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated dipping

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated dipping
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2 - 3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.4.1. *Use-specific instructions for use*

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

Open a can containing the RTU product and insert a suction tube of the automated dipping-system. Avoid discharge of surplus fluids.

After milking, the vacuum is shut off and the teat dip is injected into a manifold on the clawpiece. The teats are coated with ca. 5 mL of dip when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated dipping-system is thoroughly rinsed with water and blown out with compressed air.

In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Afterwards, the milking system is ready for the next milking event.

The whole process is automated.

4.4.2. *Use-specific risk mitigation measures*

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

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

See general directions for use.

4.4.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

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

See general directions for use.

4.5. **Use description**

Table 11. Use # 5 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated spraying by robot

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated spraying by robot
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2 - 3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.5.1. *Use-specific instructions for use*

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

Open a can containing the RTU product and insert a suction tube of the robotic milking device. Avoid discharge of surplus fluids.

The teats are cleaned by robot with automatic brushes.

After robotic milking, the disinfectant is sprayed automatically onto teats from a cluster arm.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Rinsing of the sprayer is automatic.

4.5.2. *Use-specific risk mitigation measures*

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

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

See general directions for use.

4.5.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

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

See general directions for use.

5. GENERAL DIRECTIONS FOR USE [1] OF THE META SPC 4

5.1. **Instructions for use**

See use specific instructions for use.

5.2. **Risk mitigation measures**

See use specific risk mitigation measures.

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

Mentioned in the MSDS

Description of first aid measures

After inhalation: Supply fresh air; consult doctor in case of symptoms.

After skin contact: Instantly wash with water and soap and rinse thoroughly.

After eye contact: Rinse opened eye for several minutes under running water (at least 15 minutes).

After swallowing: Rinse out mouth and then drink plenty of water. Instantly call for doctor.

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

Stability and reactivity

Reactivity: No dangerous reactions known.

Chemical stability: The product is chemically stable under normal surroundings terms (ambient temperature).

Possibility of hazardous reactions: By designated use no dangerous reactions are to be expected.

Conditions to avoid: Not determined.

Incompatible materials: Not determined.

Hazardous decomposition products: No dangerous decomposition products known.

Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Wear protective clothing.

Ensure adequate ventilation.

Keep ignition sources away — Do not smoke.

[1] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC4.

Environmental precautions: Do not allow to enter drainage system, surface or ground water.

Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of the material collected according to regulations.

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

Mentioned in the MSDS

Waste treatment methods: Hazardous waste (AVV). Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Must be specially treated under adherence to official regulations.

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.

Recommended cleaning agent: Water, if needed detergent.

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

Shelf-life: 18 months

Products need to be protected from frost, stored at temperatures not exceeding 30 °C and away from direct sunlight.

6. OTHER INFORMATION

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7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 4

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

Trade name(s)	Dip es silver				
Authorisation number	EU-0018724-0005 1-4				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		2,5
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0

META SPC 5

1. META SPC 5 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 5 identifier**

Identifier	meta SPC 5

1.2. **Suffix to the authorisation number**

Number	1-5

1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 5 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 5**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,16	1,16
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0	0

2.2. **Type(s) of formulation of the meta SPC 5**

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5

Hazard statements	
Precautionary statements	If medical advice is needed, have product container or label at hand. Keep out of reach of children.

4. AUTHORISED USE(S) OF THE META SPC 5

4.1. **Use description**

Table 12. Use # 1 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual dipping using a dip cup
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)

Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

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.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the dip cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Refill the cup of the dipping unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

4.1.2. *Use-specific risk mitigation measures*

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

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*

See general directions for use.

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

See general directions for use.

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 directions for use.

4.2. **Use description**

Table 13. Use # 2 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using a trigger sprayer

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking

Application method(s)	Manual spraying using a trigger sprayer
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2 - 3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

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.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the top of the trigger sprayer on it. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, spray the disinfectant on the teats using the trigger sprayer making sure that about 3 cm of the teat around the streak canal are covered with the disinfectant.

Refill the reservoir of the trigger sprayer with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and trigger sprayer by rinsing with water.

4.2.2. *Use-specific risk mitigation measures*

Avoid working in a spray mist.

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.

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*

See general directions for use.

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

See general directions for use.

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 directions for use.

4.3. **Use description**

Table 14. Use # 3 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using an electronic sprayer

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts

Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual spraying using an electronic sprayer
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2 - 3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.3.1. *Use-specific instructions for use*

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

Open a can containing the RTU product assuming 5 mL product per cow and insert a sucking lance of the electronic sprayer. Avoid discharge of surplus fluids.

Clean carefully the teats by wiping with a single service paper towel/cloth before milking.

After milking, spray the disinfectant on the teats using the electronic sprayer making sure that about 3 cm of the teat around the streak canal are covered with the disinfectant.

Replace the empty can by a new can containing the RTU product as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, put the sucking lance system into a bucket of water and rinse the sprayer by pumping the water through the sprayer.

4.3.2. *Use-specific risk mitigation measures*

Avoid working in a spray mist.

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.

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*

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.4. **Use description**

Table 15. Use # 4 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated dipping

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

Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated dipping
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2 - 3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.4.1. *Use-specific instructions for use*

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

Open a can containing the RTU product and insert a suction tube of the automated dipping-system. Avoid discharge of surplus fluids.

After milking, the vacuum is shut off and the teat dip is injected into a manifold on the clawpiece. The teats are coated with ca. 5 mL of dip when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated dipping-system is thoroughly rinsed with water and blown out with compressed air.

In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Afterwards, the milking system is ready for the next milking event.

The whole process is automated.

4.4.2. *Use-specific risk mitigation measures*

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

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

See general directions for use.

4.4.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

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

See general directions for use.

4.5. **Use description**

Table 16. Use # 5 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated spraying by robot

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated spraying by robot
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2 - 3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.5.1. *Use-specific instructions for use*

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

Open a can containing the RTU product and insert a suction tube of the robotic milking device. Avoid discharge of surplus fluids.

The teats are cleaned by robot with automatic brushes.

After robotic milking, the disinfectant is sprayed automatically onto teats from a cluster arm.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Rinsing of the sprayer is automatic.

4.5.2. *Use-specific risk mitigation measures*

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

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

See general directions for use.

4.5.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

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

See general directions for use.

5. GENERAL DIRECTIONS FOR USE [1] OF THE META SPC 5

5.1. **Instructions for use**

See use specific instructions for use.

5.2. **Risk mitigation measures**

See use specific risk mitigation measures.

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

Mentioned in the MSDS

Description of first aid measures

After inhalation: Supply fresh air; consult doctor in case of symptoms.

After skin contact: Instantly wash with water and soap and rinse thoroughly.

After eye contact: Rinse opened eye for several minutes under running water (at least 15 minutes).

After swallowing: Rinse out mouth and then drink plenty of water. Instantly call for doctor.

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

Stability and reactivity

Reactivity: No dangerous reactions known.

Chemical stability: The product is chemically stable under normal surroundings terms (ambient temperature).

Possibility of hazardous reactions: By designated use no dangerous reactions are to be expected.

Conditions to avoid: Not determined.

Incompatible materials: Not determined.

Hazardous decomposition products: No dangerous decomposition products known.

Accidental release measures

Personal precautions, protective equipment and emergency procedures: Wear protective clothing.

Ensure adequate ventilation.

Keep ignition sources away — Do not smoke.

Environmental precautions: Do not allow to enter drainage system, surface or ground water.

Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of the material collected according to regulations.

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

Mentioned in the MSDS

Waste treatment methods: Hazardous waste (AVV). Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Must be specially treated under adherence to official regulations.

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.

Recommended cleaning agent: Water, if needed detergent.

[1] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC5.

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

Shelf-life: 18 months

Products need to be protected from frost, stored at temperatures not exceeding 30 °C and away from direct sunlight.

6. OTHER INFORMATION

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7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 5

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

Trade name(s)	Dip es SF Dip es SF 3.0 Iod Dip S 30 P Dip es SF 1.4 Iod-Dip S 14 P EUTADIPP
Authorisation number	EU-0018724-0006 1-5

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,16
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0

META SPC 6

1. META SPC 6 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 6 identifier**

Identifier	meta SPC 6

1.2. **Suffix to the authorisation number**

Number	1-6

1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 6 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 6**

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,16	1,16
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0	0

2.2. **Type(s) of formulation of the meta SPC 6**

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 6

Hazard statements	
Precautionary statements	If medical advice is needed, have product container or label at hand. Keep out of reach of children.

4. AUTHORISED USE(S) OF THE META SPC 6

4.1. **Use description**

Table 17. Use # 1 — Teat disinfection of milkable animals: Pre-milking teat disinfection by manual foaming

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use before milking
Application method(s)	Manual foaming using a foam cup
Application rate(s) and frequency	Cows: 5 mL per treatment Pre-milking application: 2-3×/day (before each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

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.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the foam cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth before pre-milking disinfection.

Before milking, squeeze the reservoir and put the foam cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Leave the product on the teats for at least 60 seconds.

Refill the cup of the foaming unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After disinfection, empty the reservoir and clean reservoir and foam cup by rinsing with water.

4.1.2. *Use-specific risk mitigation measures*

This product can be used for pre- and post-milking disinfection in combination. However, it should not be used in combination with a different iodine-based product

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*

See general directions for use.

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

See general directions for use.

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 directions for use.

4.2. **Use description**

Table 18. Use # 2 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual foaming

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual foaming using a foam cup
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2 - 3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

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.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the foam cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, squeeze the reservoir and put the foam cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Refill the cup of the foaming unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and foam cup by rinsing with water.

4.2.2. *Use-specific risk mitigation measures*

This product can be used for pre- and post-milking disinfection in combination. However, it should not be used in combination with a different iodine-based product

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*

See general directions for use.

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

See general directions for use.

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 directions for use.

4.3. **Use description**

Table 19. Use # 3 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated foaming

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria- Yeasts-
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated foaming
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2 - 3×/day (after each milking)

Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.3.1. *Use-specific instructions for use*

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

Open a can containing the RTU product and insert a suction tube of the automated foaming-system. Avoid discharge of surplus fluids.

After milking, the vacuum is shut off and the teat disinfectant is injected into a manifold on the clawpiece. The teats are coated with ca. 5 mL of foam when the teat foam cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated foaming-system is thoroughly rinsed with water and blown out with compressed air.

In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Afterwards, the milking system is ready for the next milking event.

The whole process is automated.

4.3.2. *Use-specific risk mitigation measures*

This product can be used for pre- and post-milking disinfection in combination. However, it should not be used in combination with a different iodine-based product

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*

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.4. **Use description**

Table 20. Use # 4 — Teat disinfection of milkable animals: Pre- and post-milking teat disinfection by manual foaming

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use before and after milking
Application method(s)	Manual foaming using a foam cup

Application rate(s) and frequency	Cows: 5 mL per treatment Pre- and post-milking application: 4-6 times per day (before and after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.4.1. *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.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the foam cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth before pre-milking disinfection.

Before milking, squeeze the reservoir and put the foam cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Leave the product on the teats for at least 60 seconds.

Clean the teats carefully by wiping with a cloth immediately before milking. After milking, repeat the disinfection by foaming as described above.

Refill the cup of the foaming unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and foam cup by rinsing with water.

4.4.2. *Use-specific risk mitigation measures*

This product can be used for pre- and post-milking disinfection in combination. However, it should not be used in combination with a different iodine-based product

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

See general directions for use.

4.4.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

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

See general directions for use.

5. GENERAL DIRECTIONS FOR USE ([1]) OF THE META SPC 6

5.1. **Instructions for use**

See use specific instructions for use.

([1]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC6.

5.2. **Risk mitigation measures**

See use specific risk mitigation measures.

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

Mentioned in the MSDS

Description of first aid measures

After inhalation: Supply fresh air; consult doctor in case of symptoms.

After skin contact: Instantly wash with water and soap and rinse thoroughly.

After eye contact: Rinse opened eye for several minutes under running water (at least 15 minutes).

After swallowing: Rinse out mouth and then drink plenty of water. Instantly call for doctor.

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

Stability and reactivity

Reactivity: No dangerous reactions known.

Chemical stability: The product is chemically stable under normal surroundings terms (ambient temperature).

Possibility of hazardous reactions: By designated use no dangerous reactions are to be expected.

Conditions to avoid: Not determined.

Incompatible materials: Not determined.

Hazardous decomposition products: No dangerous decomposition products known.

Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Wear protective clothing.

Ensure adequate ventilation.

Keep ignition sources away — Do not smoke.

Environmental precautions: Do not allow to enter drainage system, surface or ground water.

Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of the material collected according to regulations.

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

Mentioned in the MSDS

Waste treatment methods: Hazardous waste (AVV). Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Must be specially treated under adherence to official regulations.

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.

Recommended cleaning agent: Water, if needed detergent.

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

Shelf-life: 18 months

Products need to be protected from frost, stored at temperatures not exceeding 30 °C and away from direct sunlight.

6. OTHER INFORMATION

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7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 6

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

Trade name(s)	Dip es Io-foam Dip es Io-foam 1.4 Iod-Dip Io-foam BaktoStop foam				
Authorisation number	EU-0018724-0007 1-6				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,16
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0

META SPC 7

1. META SPC 7 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 7 identifier**

Identifier	meta SPC 7

1.2. **Suffix to the authorisation number**

Number	1-7

1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 7 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 7**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,14	0,14
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0	0
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0,11	0,33

2.2. **Type(s) of formulation of the meta SPC 7**

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 7

Hazard statements	Harmful to aquatic life with long lasting effects.
Precautionary statements	Avoid release to the environment. Dispose of contents to local/regional/national/international regulation. Dispose of container to local/regional/national/international regulation.

4. AUTHORISED USE(S) OF THE META SPC 7

4.1. **Use description**

Table 21. Use # 1 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual dipping using a dip cup
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

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.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the dip cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Refill the cup of the dipping unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

4.1.2. *Use-specific risk mitigation measures*

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

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*

See general directions for use.

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

See general directions for use.

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 directions for use.

4.2. **Use description**

Table 22. Use # 2 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual foaming

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual foaming using a foam cup
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

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.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the foam cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, squeeze the reservoir and put the foam cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Refill the cup of the foaming unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and foam cup by rinsing with water.

4.2.2. *Use-specific risk mitigation measures*

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

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*

See general directions for use.

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

See general directions for use.

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 directions for use.

4.3. **Use description**

Table 23. Use # 3 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using a trigger sprayer

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual spraying using a trigger sprayer
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

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.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the top of the trigger sprayer on it. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, spray the disinfectant on the teats using the trigger sprayer making sure that about 3 cm of the teat around the streak canal are covered with the disinfectant.

Refill the reservoir of the trigger sprayer with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and trigger sprayer by rinsing with water.

4.3.2. *Use-specific risk mitigation measures*

Use chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during postmilking teat disinfection by manual spraying using a trigger sprayer.

Avoid working in spray mist.

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.

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*

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.4. **Use description**

Table 24. Use # 4 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using an electronic sprayer

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual spraying using an electronic sprayer
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.4.1. *Use-specific instructions for use*

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

Open a can containing the RTU product assuming 5 mL product per cow and insert a sucking lance of the electronic sprayer. Avoid discharge of surplus fluids.

Clean carefully the teats by wiping with a single service paper towel/cloth before milking.

After milking, spray the disinfectant on the teats using the electronic sprayer making sure that about 3 cm of the teat around the streak canal are covered with the disinfectant.

Replace the empty can by a new can containing the RTU product as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, put the sucking lance system into a bucket of water and rinse the sprayer by pumping the water through the sprayer.

4.4.2. *Use-specific risk mitigation measures*

Use chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during post/milking teat disinfection by manual spraying using an electronic sprayer.

Avoid working in spray mist.

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.

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

See general directions for use.

4.4.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

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

See general directions for use.

4.5. **Use description**

Table 25. Use # 5 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated dipping

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated dipping
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)

Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.5.1. *Use-specific instructions for use*

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

Open a can containing the RTU product and insert a suction tube of the automated dipping-system. Avoid discharge of surplus fluids.

After milking, the vacuum is shut off and the teat dip is injected into a manifold on the clawpiece. The teats are coated with ca. 5 mL of dip when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated dipping-system is thoroughly rinsed with water and blown out with compressed air.

In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Afterwards, the milking system is ready for the next milking event.

The whole process is automated.

4.5.2. *Use-specific risk mitigation measures*

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

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

See general directions for use.

4.5.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

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

See general directions for use.

4.6. **Use description**

Table 26. Use # 6 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated foaming

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking

Application method(s)	Automated foaming
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.6.1. *Use-specific instructions for use*

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

Open a can containing the RTU product and insert a suction tube of the automated foaming-system. Avoid discharge of surplus fluids.

After milking, the vacuum is shut off and the teat disinfectant is injected into a manifold on the clawpiece. The teats are coated with ca. 5 mL of foam when the teat foam cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated foaming-system is thoroughly rinsed with water and blown out with compressed air.

In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Afterwards, the milking system is ready for the next milking event.

The whole process is automated.

4.6.2. *Use-specific risk mitigation measures*

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

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

See general directions for use.

4.6.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

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

See general directions for use.

4.7. **Use description**

Table 27. Use # 7 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated spraying by robot

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts

Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated spraying by robot
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.7.1. *Use-specific instructions for use*

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

Open a can containing the RTU product and insert a suction tube of the robotic milking device. Avoid discharge of surplus fluids.

The teats are cleaned by robot with automatic brushes.

After robotic milking, the disinfectant is sprayed automatically onto teats from a cluster arm.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Rinsing of the sprayer is automatic.

4.7.2. *Use-specific risk mitigation measures*

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

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

See general directions for use.

4.7.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

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

See general directions for use.

5. GENERAL DIRECTIONS FOR USE [1] OF THE META SPC 7

5.1. **Instructions for use**

See use specific instructions for use.

5.2. **Risk mitigation measures**

See use specific risk mitigation measures.

[1] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC7.

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

Mentioned in the MSDS

Description of first aid measures

After inhalation: Supply fresh air; consult doctor in case of symptoms.

After skin contact: Wash with water and soap.

After eye contact: Rinse opened eye for several minutes under running water. Then consult doctor.

After swallowing: Rinse out mouth and then drink plenty of water. Seek immediate medical advice.

Stability and reactivity

Possibility of hazardous reactions: Reaction with oxidant- and reducing agent.

Conditions to avoid: No further relevant information available.

Incompatible materials: No further relevant information available.

Hazardous decomposition products: iodine (when warming up).

Accidental release measures

Personal precautions, protective equipment and emergency procedures: No special measures required.

Environmental precautions: Do not allow product to reach sewage systems or water bodies in great quantities.

Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of the material collected according to regulations.

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

Mentioned in the MSDS

Waste treatment methods

Recommendation: Must be specially treated with regard to official regulations.

Waste disposal key number: Corresponding to the regulation of the European Waste catalogue the relation of the waste key numbers has to be made specific to industry and process.

European waste catalogue: Corresponding to the regulation of the EWC the relation of the waste key numbers has to be made specific to industry and process.

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.

Recommended cleaning agent: Water, if necessary with cleaning agent.

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

Shelf-life: 24 months

Products need to be protected from frost, stored at temperatures not exceeding 30 °C and away from direct sunlight.

6. OTHER INFORMATION

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7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 7

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

Trade name(s)	calgodip D 1200 Jod-Dip S 12 Dip es SF 1200				
Authorisation number	EU-0018724-0008 1-7				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,14
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0,15

META SPC 8

1. META SPC 8 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 8 identifier**

Identifier	meta SPC 8

1.2. **Suffix to the authorisation number**

Number	1-8

1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 8 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 8**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,14	0,54
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0	0
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0,11	0,33

2.2. **Type(s) of formulation of the meta SPC 8**

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 8

Hazard statements	Harmful to aquatic life with long lasting effects.
Precautionary statements	Avoid release to the environment. Dispose of contents to local/regional/national/international regulation. Dispose of container to local/regional/national/international regulation.

4. AUTHORISED USE(S) OF THE META SPC 8

4.1. **Use description**

Table 28. Use # 1 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual dipping using a dip cup
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

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.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the dip cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Refill the cup of the dipping unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

4.1.2. *Use-specific risk mitigation measures*

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

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*

See general directions for use.

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

See general directions for use.

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 directions for use.

4.2. **Use description**

Table 29. Use # 2 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated dipping

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated dipping
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.2.1. *Use-specific instructions for use*

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

Open a can containing the RTU product and insert a suction tube of the automated dipping-system. Avoid discharge of surplus fluids.

After milking, the vacuum is shut off and the teat dip is injected into a manifold on the clawpiece. The teats are coated with ca. 5 mL of dip when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated dipping-system is thoroughly rinsed with water and blown out with compressed air.

In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Afterwards, the milking system is ready for the next milking event.

The whole process is automated.

4.2.2. *Use-specific risk mitigation measures*

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

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*

See general directions for use.

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

See general directions for use.

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 directions for use.

5. GENERAL DIRECTIONS FOR USE ([1]) OF THE META SPC 8

5.1. **Instructions for use**

See use specific instructions for use.

5.2. **Risk mitigation measures**

See use specific risk mitigation measures.

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

Mentioned in the MSDS

Description of first aid measures

After inhalation: Supply fresh air; consult doctor in case of symptoms.

After skin contact: Wash with water and soap. If skin irritation continues, consult a doctor.

After eye contact: Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor.

After swallowing: Rinse out mouth and then drink plenty of water. Seek medical treatment.

Stability and reactivity

Reactivity: No further relevant information available.

Chemical stability/thermal decomposition/conditions to be avoided: No decomposition if used according to specifications.

Possibility of hazardous reactions: No dangerous reactions known.

Conditions to avoid: No further relevant information available.

Incompatible materials: No further relevant information available.

([1]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC8.

Hazardous decomposition products: iodine (when warming up).

Accidental release measures

Personal precautions, protective equipment and emergency procedures: No special measures required.

Environmental precautions: Do not allow product to reach sewage systems or water bodies in great quantities.

Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binder). Do not use combustible material like sawdust. Dispose of the material collected according to regulations.

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

Mentioned in the MSDS

Waste treatment methods

Recommendation: Must be specially treated with regard to official regulations.

Waste disposal key number: Corresponding to the regulation of the European Waste catalogue the relation of the waste key numbers has to be made specific to industry and process.

European waste catalogue: Corresponding to the regulation of the EWC the relation of the waste key numbers has to be made specific to industry and process.

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

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

Shelf-life: 24 months

Products need to be protected from frost, stored at temperatures not exceeding 30 °C and away from direct sunlight.

6. OTHER INFORMATION

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7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 8

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

Trade name(s)	calgodip D 3000 Film Jod-Dip F 30 Jod Dipp 30 Film (Technolit) Jod 30 Film (Iwetec) Dip es barriere 3000 Lerapur Dip Jod 30 BaktoStop barrier color 3.0				
Authorisation number	EU-0018724-0009 1-8				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,34
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0,26

7.2. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	calgodip D 5000 Jod Dip F 50 Jod Dipp 50 (Iwetec) Jod-Dipp 50 (Technolit) Dip es barriere 5000 BaktoStop barrier 5.0
Authorisation number	EU-0018724-0010 1-8

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,54
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0,26

META SPC 9

1. META SPC 9 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 9 identifier**

Identifier	meta SPC 9

1.2. **Suffix to the authorisation number**

Number	1-9

1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 9 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 9**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,34	0,34
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0	0
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0,11	0,33

2.2. **Type(s) of formulation of the meta SPC 9**

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 9

Hazard statements	Harmful to aquatic life with long lasting effects.
Precautionary statements	Avoid release to the environment. Dispose of contents to local/regional/national/international regulation. Dispose of container to local/regional/national/international regulation.

4. AUTHORISED USE(S) OF THE META SPC 9

4.1. **Use description**

Table 30. Use # 1 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual dipping using a dip cup
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

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.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the dip cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking. After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Refill the cup of the dipping unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

4.1.2. *Use-specific risk mitigation measures*

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

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*

See general directions for use.

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

See general directions for use.

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 directions for use.

4.2. **Use description**

Table 31. Use # 2 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual foaming

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual foaming using a foam cup
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

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.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the foam cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, squeeze the reservoir and put the foam cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Refill the cup of the foaming unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and foam cup by rinsing with water.

4.2.2. *Use-specific risk mitigation measures*

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

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*

See general directions for use.

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

See general directions for use.

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 directions for use.

4.3. **Use description**

Table 32. Use # 3 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using a trigger sprayer

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual spraying using a trigger sprayer
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

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.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the top of the trigger sprayer on it. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, spray the disinfectant on the teats using the trigger sprayer making sure that about 3 cm of the teat around the streak canal are covered with the disinfectant.

Refill the reservoir of the trigger sprayer with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and trigger sprayer by rinsing with water.

4.3.2. *Use-specific risk mitigation measures*

Use chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), coverall and chemical resistant boots during post-milking teat disinfection by manual spraying using a trigger sprayer.

Avoid working in spray mist.

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.

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*

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.4. **Use description**

Table 33. Use # 4 — Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using an electronic sprayer

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual spraying using an electronic sprayer
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.4.1. *Use-specific instructions for use*

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

Open a can containing the RTU product assuming 5 mL product per cow and insert a sucking lance of the electronic sprayer. Avoid discharge of surplus fluids.

Clean carefully the teats by wiping with a single service paper towel/cloth before milking.

After milking, spray the disinfectant on the teats using the electronic sprayer making sure that about 3 cm of the teat around the streak canal are covered with the disinfectant.

Replace the empty can by a new can containing the RTU product as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, put the sucking lance system into a bucket of water and rinse the sprayer by pumping the water through the sprayer.

4.4.2. *Use-specific risk mitigation measures*

Use chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during post-milking teat disinfection by manual spraying using an electronic sprayer.

Avoid working in spray mist.

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.

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

See general directions for use.

4.4.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

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

See general directions for use.

4.5. **Use description**

Table 34. Use # 5 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated dipping

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated dipping
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.5.1. *Use-specific instructions for use*

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

Open a can containing the RTU product and insert a suction tube of the automated dipping-system. Avoid discharge of surplus fluids.

After milking, the vacuum is shut off and the teat dip is injected into a manifold on the clawpiece. The teats are coated with ca. 5 mL of dip when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated dipping-system is thoroughly rinsed with water and blown out with compressed air.

In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Afterwards, the milking system is ready for the next milking event.

The whole process is automated.

4.5.2. *Use-specific risk mitigation measures*

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

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

See general directions for use.

4.5.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

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

See general directions for use.

4.6. **Use description**

Table 35. Use # 6 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated foaming

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated foaming
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.6.1. *Use-specific instructions for use*

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

Open a can containing the RTU product and insert a suction tube of the automated foaming-system. Avoid discharge of surplus fluids.

After milking, the vacuum is shut off and the teat disinfectant is injected into a manifold on the clawpiece. The teats are coated with ca. 5 mL of foam when the teat foam cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated foaming-system is thoroughly rinsed with water and blown out with compressed air.

In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Afterwards, the milking system is ready for the next milking event.

The whole process is automated.

4.6.2. *Use-specific risk mitigation measures*

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

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

See general directions for use.

4.6.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

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

See general directions for use.

4.7. **Use description**

Table 36. Use # 7 — Teat disinfection of milkable animals: Post-milking teat disinfection by automated spraying by robot

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated spraying by robot
Application rate(s) and frequency	Cows: 5 mL per treatment Post-milking application: 2-3×/day (after each milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerrycan (HDPE): 5 – 60 kg Drum (HDPE): 60 – 200 kg IBC (HDPE): 600 – 1 000 kg

4.7.1. *Use-specific instructions for use*

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

Open a can containing the RTU product and insert a suction tube of the robotic milking device. Avoid discharge of surplus fluids.

The teats are cleaned by robot with automatic brushes.

After robotic milking, the disinfectant is sprayed automatically onto teats from a cluster arm.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Rinsing of the sprayer is automatic.

4.7.2. *Use-specific risk mitigation measures*

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

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

See general directions for use.

4.7.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

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

See general directions for use.

5. GENERAL DIRECTIONS FOR USE [1] OF THE META SPC 9

5.1. **Instructions for use**

See use specific instructions for use.

5.2. **Risk mitigation measures**

See use specific risk mitigation measures.

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

Mentioned in the MSDS

Description of first aid measures

After inhalation: Supply fresh air; consult doctor in case of symptoms.

After skin contact: Wash with water and soap.

After eye contact: Rinse opened eye for several minutes under running water. Then consult doctor.

After swallowing: Rinse out mouth and then drink plenty of water. Seek immediate medical advice.

Stability and reactivity

Possibility of hazardous reactions: Reaction with oxidant- and reducing agent.

Conditions to avoid: No further relevant information available.

Incompatible materials: No further relevant information available.

Hazardous decomposition products: iodine (when warming up).

[1] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC9.

Accidental release measures

Personal precautions, protective equipment and emergency procedures: No special measures required.

Environmental precautions: Do not allow product to reach sewage systems or water bodies in great quantities.

Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of the material collected according to regulations.

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

Mentioned in the MSDS

Waste treatment methods

Recommendation: Must be specially treated with regard to official regulations.

Waste disposal key number: Corresponding to the regulation of the European Waste catalogue the relation of the waste key numbers has to be made specific to industry and process.

European waste catalogue: Corresponding to the regulation of the EWC the relation of the waste key numbers has to be made specific to industry and process.

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.

Recommended cleaning agent: Water, if necessary with cleaning agent.

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

Shelf-life: 24 months

Products need to be protected from frost, stored at temperatures not exceeding 30 °C and away from direct sunlight.

6. OTHER INFORMATION

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7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 9

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

Trade name(s)	calgodip D 3000 Jod-Dip S 30 Bestfarm Dip Premium Jod 30 Universal (Iwetec) Jod-Dipp 30 (Technolit) Dip es SF 3000 Lerapur Jod SP 30				
Authorisation number	EU-0018724-0011 1-9				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,34
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0
Acetic acid	Acetic acid	Non active substance	64-19-7	200-580-7	0,26