REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2019/423

of 13 March 2019

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

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 27 August 2015, SCC GmbH, on behalf of Novadan ApS, 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 Novadan' ('the biocidal product family') of product-type 3, as described in Annex V to that Regulation. The competent authority of Denmark 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-YV019394-00 in the Register for Biocidal Products.

(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 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 11 April 2018, 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 31 October 2018, the Agency submitted to the Commission an opinion ([3]), including the draft summary of the biocidal product characteristics ('SPC') of the biocidal product family and the final assessment report on the biocidal product family in accordance with Article 44(3) of Regulation (EU) No 528/2012. The opinion concludes that the biocidal 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 biocidal product family meets the conditions laid down in Article 19(1) and (6) of that Regulation.

(5) On 17 January 2019, 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.

([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 6 July 2018 on the Union authorisation of 'Teat disinfectants biocidal product family of Novadan' (ECHA/BPC/215/2018).

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

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation is granted to Novadan ApS for the biocidal product family 'Teat disinfectants biocidal product family of Novadan' with authorisation number EU-0019757-0000.

The Union authorisation is valid from 7 April 2019 until 31 March 2029.

The Union authorisation is subject to compliance with the summary of the biocidal product characteristics 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, 13 March 2019.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

Summary of product characteristics for a biocidal product family

Teat disinfectants biocidal product family of Novadan

Product type 3 — Veterinary hygiene (Disinfectants)

Authorisation number: EU-0019757-0000

R4BP asset number: EU-0019757-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. **Family name**

Name	Teat disinfectants biocidal product family of Novadan

1.2. **Product type(s)**

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

1.3. **Authorisation holder**

Name and address of the authorisation holder	Name	Novadan ApS
	Address	Platinvej 21, 6000 Kolding, Denmark
Authorisation number	EU-0019757-0000	
R4BP asset number	EU-0019757-0000	
Date of the authorisation	7 April 2019	
Expiry date of the authorisation	31 March 2029	

1.4. **Manufacturer(s) of the biocidal products**

Name of manufacturer	Novadan ApS
Address of manufacturer	Platinvej 21, 6000 Kolding Denmark
Location of manufacturing sites	Platinvej 21, 6000 Kolding Denmark

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

Active substance	Polyvinylpyrrolidone iodine
Name of manufacturer	Marcus Research Laboratory, Inc.
Address of manufacturer	Delmar Blvd., 63103-1789 Saint Louis, Missouri United States
Location of manufacturing sites	Delmar Blvd., 63103-1789 Saint Louis, Missouri United States

Active substance	Iodine
Name of manufacturer	Cosayach Nitratos S.A.
Address of manufacturer	Hnos Amunátegui 178, 8320000 Santiago Chile
Location of manufacturing sites	S.C.M. Cosayach Cala Cala, 1180000 Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	ACF Minera S.A.
Address of manufacturer	San Martin No 499, 11 00000 Iquique Chile
Location of manufacturing sites	Lagunas mine, 1180000 Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	Sociedad Quimica y Minera (SQM) S.A.
Address of manufacturer	Los Militares 4290, Piso 4, Las Condes, 8320000 Santiago Chile
Location of manufacturing sites	Nueva Victoria plant, 5090000 Pedro de Valdivia plant Chile

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
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,714	3,57
Iodine		Active Substance	7553-56-2	231-442-4	0,15	0,75

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

Formulation(s)	SL — Soluble concentrate AL — Any other liquid EW — Emulsion, oil in water

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
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		3,57	3,57
Iodine		Active Substance	7553-56-2	231-442-4	0,75	0,75

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

Formulation(s)	SL — Soluble concentrate

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	May be corrosive to metals. Harmful to aquatic life with long lasting effects. Safety data sheet available on request.
Precautionary statements	Keep out of reach of children. Keep only in original packaging. Avoid release to the environment. Absorb spillage to prevent material damage. Dispose of contents in accordance with local/regional/national/international regulation. Dispose of container in accordance with local/regional/national/international regulation.

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

4.1. **Use description**

Table 1. Use # 1: Post-milking manual dipping (concentrate)

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

Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Manual dipping (concentrate) Fill the reservoir with the diluted concentrate and screw the dip cup on top. 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 the full length of the teat is immersed into the disinfectant. Top up with fresh disinfectant by squeezing the reservoir as needed. After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.
Application rate(s) and frequency	Dilution: 20 % Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

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 – Post-milking, manual spraying, trigger sprayer (concentrate)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Manual spraying, trigger sprayer (concentrate) Fill the reservoir with the diluted concentrate and screw the top of the trigger sprayer on it. 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 each teat is covered with the disinfectant. Top up the reservoir with fresh disinfectant as needed. After disinfection, empty the reservoir and clean reservoir and sprayer by rinsing with water.
Application rate(s) and frequency	Dilution: 20 % Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.2.1. *Use-specific instructions for use*

See general directions for use.

4.2.2. *Use-specific risk mitigation measures*

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) when applying the product by manual spraying.

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 3. Use # 3 – Post-milking manual spraying using an electronic sprayer (concentrate)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Manual spraying, electronic sprayer (concentrate) Open a can containing the diluted concentrate and insert the suction tube of the electronic sprayer. 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 electronic sprayer making sure that each teat is covered with the disinfectant. Replace the empty can by a new can as needed. After disinfection, put the suction tube system into a bucket of water and rinse the sprayer by pumping the water through the sprayer.
Application rate(s) and frequency	Dilution: 20 % Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.3.1. *Use-specific instructions for use*

See general directions for use.

4.3.2. *Use-specific risk mitigation measures*

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) when applying the product by manual spraying.

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 4. Use # 4 – Post-milking automated dipping (concentrate)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Automated dipping (concentrate) Open a can containing the diluted concentrate and insert the suction tube of the automated dipping-system. Before milking clean teats carefully by automatic procedure or manually. After milking, the vacuum is shut off and the teat dip is injected into a manifold on the claw piece. The teats are coated with 2-4 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. Afterwards, the milking system is ready for the next milking event. The whole process is automated.
Application rate(s) and frequency	Dilution: 20 % Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.4.1. *Use-specific instructions for use*

See general directions for use.

4.4.2. *Use-specific risk mitigation measures*

See general directions for use.

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 5. Use # 5 – Post-milking automated spraying by robot (concentrate)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Automated spraying by robot (concentrate) Open a can containing the diluted concentrate and insert the suction tube of the robotic milking device. The teats are cleaned by robot with automatic brushes. After robotic milking, 2-4 ml of the disinfectant is sprayed automatically onto teats from a cluster arm. Rinsing of the sprayer is automatic.
Application rate(s) and frequency	Dilution: 20 % Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.5.1. *Use-specific instructions for use*

See general directions for use.

4.5.2. *Use-specific risk mitigation measures*

See general directions for use.

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 1

5.1. **Instructions for use**

Dilute the concentrated product by decanting or pumping. Fill the reservoir with the diluted concentrate and screw the dip cup on top. The concentrate is to be diluted 1:4 The concentrated products in meta-SPC 1 contain 0,89 % total iodine and are diluted 1:4 to an in-use solution containing 0,178 % total iodine. This corresponds to a 20 % (w/w) dilution.

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

The products must be brought to temperatures above 20 °C before use.

To ensure sufficient contact time, care should be taken that the product is not removed after application. Leave the product on the teats and keep the animals standing for at least five minutes after treatment for post-milking disinfection.

5.2. **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.

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

Description of first aid measures

General: Remove affected person from source of contamination.

After inhalation: Remove person to fresh air and keep comfortable for breathing. Get medical attention if any discomfort continues.

After skin contact: Rinse with water. Remove contaminated clothing and shoes. Seek medical advice if any skin reaction/or discomfort occurs.

After eye contact: Immediately rinse with water (at least 15 minutes). Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if any discomfort continues.

After ingestion: Contact poison treatment specialist immediately if symptoms occur and/or in case of mouth contact with large quantities. Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately.

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

Environmental emergency measures

Prevent run-off from entering drains, sewers or waterways

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air)

Dike to collect larger liquid spills

Contain and/or absorb spill with inert material, then place in closed and suitable container for disposal according to regulations

Do not place spilled materials back into the original container

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

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

Method of disposal: 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.

Empty containers are rinsed with plenty of water and disposed to normal or commercial waste.

The paper towels used for the cleaning of teats are disposed in the normal rubbish.

Product classified as hazardous waste: No

Packaging classified as hazardous waste: No

EWC waste code: EWC: 0706 wastes from the MFSU of fats, grease, soaps, detergents, disinfectants and cosmetics

Other information: When handling waste, consideration should be made to the safety precautions applying to handling of the product. Waste code applies to product remnants in pure form.

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

Mentioned in the SDS: Keep in original container. Store the product away from direct sunlight in opaque containers. Keep separate from food, feedstuffs, fertilisers and other sensitive material. Store above freezing.

Storage temperature: 0 – 30 °C

Shelf-life: 24 months.

6. OTHER INFORMATION

pH range of meta-SPC 1: 4-5

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)	Nova Dip IO Dip Udder Des 1:4 Jod Ewodip Jodopax vet Fova Dip 1:4 Tehotippi
Authorisation number	EU-0019757-0001 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		3,57
Iodine		Active Substance	7553-56-2	231-442-4	0,75

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
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,0	1,42
Iodine		Active Substance	7553-56-2	231-442-4	0,21	0,298

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

Formulation(s)	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	Harmful to aquatic life with long lasting effects. Safety data sheet available on request.
Precautionary statements	Keep out of reach of children. Avoid release to the environment. Dispose of contents in accordance with local/regional/national/international regulation. Dispose of container in accordance with local/regional/national/international regulation.

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

4.1. **Use description**

Table 6. Use # 1 – Post-milking manual dipping (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.

Application method(s)	Manual dipping (RTU) Fill the reservoir with the RTU product and screw the dip cup on top. 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 the full length of the teat is immersed into the disinfectant. Top up with fresh disinfectant by squeezing the reservoir as needed. After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

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 7. Use # 2 – Post-milking automated dipping (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.

Application method(s)	Automated dipping (RTU) Open a can containing the RTU product and insert the suction tube of the automated dipping-system. Before milking clean teats carefully by automatic procedure or manually. After milking, the vacuum is shut off and the teat dip is injected into a manifold on the claw piece. The teats are coated with 2-4 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. Afterwards, the milking system is ready for the next milking event. The whole process is automated.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.2.1. *Use-specific instructions for use*

See general directions for use.

4.2.2. *Use-specific risk mitigation measures*

See general directions for use.

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 ([2]) OF THE META SPC 2

5.1. **Instructions for use**

The products must be brought to temperatures above 20 °C before use.

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

To ensure sufficient contact time, care should be taken that the product is not removed after application. Leave the product on the teats and keep the animals standing for at least five minutes after treatment for post-milking disinfection.

([2]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 2.

5.2. **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.

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

Description of first aid measures

General: Remove affected person from source of contamination.

After inhalation: Remove person to fresh air and keep comfortable for breathing. Get medical attention if any discomfort continues.

After skin contact: Rinse with water. Remove contaminated clothing and shoes. Seek medical advice if any skin reaction/or discomfort occurs.

After eye contact: Immediately rinse with water (at least 15 minutes). Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if any discomfort continues.

After ingestion: Contact poison treatment specialist immediately if symptoms occur and/or in case of mouth contact with large quantities. Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately.

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

Environmental emergency measures

Prevent run-off from entering drains, sewers or waterways

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air)

Dike to collect larger liquid spills

Contain and/or absorb spill with inert material, then place in closed and suitable container for disposal according to regulations

Do not place spilled materials back into the original container

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

Method of disposal: 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.

Empty containers are rinsed with plenty of water and disposed to normal or commercial waste.

The paper towels used for the cleaning of teats are disposed in the normal rubbish.

Product classified as hazardous waste: No

Packaging classified as hazardous waste: No

EWC waste code: EWC: 0706 wastes from the MFSU of fats, grease, soaps, detergents, disinfectants and cosmetics

Other information: When handling waste, consideration should be made to the safety precautions applying to handling of the product. Waste code applies to product remnants in pure form.

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

Mentioned in the SDS: Keep in original container. Store the product away from direct sunlight in opaque containers. Keep separate from food, feedstuffs, fertilisers and other sensitive material. Store above freezing.

Storage temperature: 0 – 30 °C

Shelf-life: 24 months.

6. OTHER INFORMATION

pH range of meta-SPC 2: 4-5

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)	Jopo Film IO Super Dip Barrera Dip				
Authorisation number	EU-0019757-0002 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,42
Iodine		Active Substance	7553-56-2	231-442-4	0,298

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
Polyvinylpyr-rolidone iodine		Active Substance	25655-41-8		0,82	0,99
Iodine		Active Substance	7553-56-2	231-442-4	0,172	0,208

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

Formulation(s)	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

Hazard statements	Safety data sheet available on request.
Precautionary statements	Keep out of reach of children.

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

4.1. **Use description**

Table 8. Use # 1 – Post-milking manual dipping (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Manual dipping (RTU) Fill the reservoir with the RTU product and screw the dip cup on top. 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 the full length of the teat is immersed into the disinfectant. Top up with fresh disinfectant by squeezing the reservoir as needed. After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment Post-milking application 1-3 times per day (apply after every milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.1.1. *Use-specific instructions for use*

See general directions for use

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

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 9. Use # 2 – Post-milking automated dipping (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Automated dipping (RTU) Open a can containing the RTU product and insert the suction tube of the automated dipping-system. Before milking clean teats carefully by automatic procedure or manually. After milking, the vacuum is shut off and the teat dip is injected into a manifold on the claw piece. The teats are coated with 2-4 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. Afterwards, the milking system is ready for the next milking event. The whole process is automated.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment Post-milking application 1-3 times per day (apply after every milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.2.1. *Use-specific instructions for use*

See general directions for use

4.2.2. *Use-specific risk mitigation measures*

See general directions for use.

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 ([3]) OF THE META SPC 3

5.1. **Instructions for use**

Fill the reservoir with the RTU product and screw the dip cup on top.

The products must be brought to temperatures above 20 °C before use.

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

To ensure sufficient contact time, care should be taken that the product is not removed after application. Leave the product on the teats and keep the animals standing for at least five minutes after treatment for post-milking disinfection.

5.2. **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.

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

Description of first aid measures

General: Remove affected person from source of contamination.

After inhalation: Remove person to fresh air and keep comfortable for breathing. Get medical attention if any discomfort continues.

After skin contact: Rinse with water. Remove contaminated clothing and shoes. Seek medical advice if any skin reaction/or discomfort occurs.

After eye contact: Immediately rinse with water (at least 15 minutes). Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if any discomfort continues.

After ingestion: Contact poison treatment specialist immediately if symptoms occur and/or in case of mouth contact with large quantities. Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately.

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

Environmental emergency measures

Prevent run-off from entering drains, sewers or waterways

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air)

Dike to collect larger liquid spills

Contain and/or absorb spill with inert material, then place in closed and suitable container for disposal according to regulations

Do not place spilled materials back into the original container

([3]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 3.

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

Method of disposal: 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.

Empty containers are rinsed with plenty of water and disposed to normal or commercial waste.

The paper towels used for the cleaning of teats are disposed in the normal rubbish.

Product classified as hazardous waste: No

Packaging classified as hazardous waste: No

EWC waste code: EWC: 0706 wastes from the MFSU of fats, grease, soaps, detergents, disinfectants and cosmetics

Other information: When handling waste, consideration should be made to the safety precautions applying to handling of the product. Waste code applies to product remnants in pure form.

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

Mentioned in the SDS: Keep in original container. Store the product away from direct sunlight in opaque containers. Keep separate from food, feedstuffs, fertilisers and other sensitive material. Store above freezing.

Storage temperature: 0 – 30 °C

Shelf-life: 18 months.

6. OTHER INFORMATION

pH range of meta-SPC 3: 4-5

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)	Nova Dip Barriere IO Multi Dip				
Authorisation number	EU-0019757-0003 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,82
Iodine		Active Substance	7553-56-2	231-442-4	0,172

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
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,714	0,99
Iodine		Active Substance	7553-56-2	231-442-4	0,15	0,208

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

Formulation(s)	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4

Hazard statements	Safety data sheet available on request.
Precautionary statements	Keep out of reach of children.

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

4.1. **Use description**

Table 10. Use # 1 – Post-milking manual dipping (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Manual dipping (RTU) Fill the reservoir with the RTU product and screw the dip cup on top. 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 the full length of the teat is immersed into the disinfectant. Top up with fresh disinfectant by squeezing the reservoir as needed. After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

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 11. Use # 2 – Post-milking, manual spraying, trigger sprayer (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Manual spraying, trigger sprayer (RTU) Fill the reservoir with the RTU product and screw the top of the trigger sprayer on it. 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 each teat is covered with the disinfectant. Top up the reservoir with fresh disinfectant as needed. After disinfection, empty the reservoir and clean reservoir and trigger sprayer by rinsing with water.

Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.2.1. *Use-specific instructions for use*

See general directions for use.

4.2.2. *Use-specific risk mitigation measures*

Wear protective chemical resistant gloves when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information).

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

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 12. Use # 3 – Post-milking manual spraying using an electronic sprayer (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Manual spraying, electronic sprayer (RTU) Open a can containing the RTU product and insert the suction tube of the electronic sprayer. 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 electronic sprayer making sure that each teat is covered with the disinfectant. Replace the empty can by a new can as needed. After disinfection, put the suction tube system into a bucket of water and rinse the sprayer by pumping the water through the sprayer.

Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0.5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.3.1. *Use-specific instructions for use*

See general directions for use.

4.3.2. *Use-specific risk mitigation measures*

Wear protective chemical resistant gloves when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information).

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 13. Use # 4 – Post-milking automated dipping (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.

Application method(s)	Automated dipping (RTU) Open a can containing the RTU product and insert the suction tube of the automated dipping-system. Before milking clean teats carefully by automatic procedure or manually. After milking, the vacuum is shut off and the teat dip is injected into a manifold on the claw piece. The teats are coated with 2-4 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. Afterwards, the milking system is ready for the next milking event. The whole process is automated.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.4.1. *Use-specific instructions for use*

See general directions for use.

4.4.2. *Use-specific risk mitigation measures*

See general directions for use.

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 14. Use # 5 – Post-milking automated spraying by robot (RTU)

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

Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Automated spraying by robot (RTU) Open a can containing the RTU product and insert the suction tube of the robotic milking device. The teats are cleaned by robot with automatic brushes. After robotic milking, 2-4 ml of the disinfectant is sprayed automatically onto teats from a cluster arm. Rinsing of the sprayer is automatic.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.5.1. *Use-specific instructions for use*

See general directions for use.

4.5.2. *Use-specific risk mitigation measures*

See general directions for use.

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 ([4]) OF THE META SPC 4

5.1. **Instructions for use**

Fill the reservoir with the RTU product and screw the dip cup on top.

The products must be brought to temperatures above 20 °C before use.

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

To ensure sufficient contact time, care should be taken that the product is not removed after application. Leave the product on the teats and keep the animals standing for at least five minutes after treatment for post-milking disinfection.

([4]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 4.

5.2. **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.

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

Description of first aid measures

General: Remove affected person from source of contamination.

After inhalation: Remove person to fresh air and keep comfortable for breathing. Get medical attention if any discomfort continues.

After skin contact: Rinse with water. Remove contaminated clothing and shoes. Seek medical advice if any skin reaction/or discomfort occurs.

After eye contact: Immediately rinse with water (at least 15 minutes). Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if any discomfort continues.

After ingestion: Contact poison treatment specialist immediately if symptoms occur and/or in case of mouth contact with large quantities. Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately.

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

Environmental emergency measures

Prevent run-off from entering drains, sewers or waterways

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air)

Dike to collect larger liquid spills

Contain and/or absorb spill with inert material, then place in closed and suitable container for disposal according to regulations

Do not place spilled materials back into the original container

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

Method of disposal: 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.

Empty containers are rinsed with plenty of water and disposed to normal or commercial waste.

The paper towels used for the cleaning of teats are disposed in the normal rubbish.

Product classified as hazardous waste: No

Packaging classified as hazardous waste: No

EWC waste code: EWC: 0706 wastes from the MFSU of fats, grease, soaps, detergents, disinfectants and cosmetics

Other information: When handling waste, consideration should be made to the safety precautions applying to handling of the product. Waste code applies to product remnants in pure form.

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

Mentioned in the SDS: Keep in original container. Store the product away from direct sunlight in opaque containers. Keep separate from food, feedstuffs, fertilisers and other sensitive material. Store above freezing.

Storage temperature: 0 – 30 °C

Shelf-life: 24 months.

6. OTHER INFORMATION

pH range of meta-SPC 4: 4-5

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)	Jopo Spray IO Spray Barrera Spray Agro Teat Spray Nova Dip Ready for Use
Authorisation number	EU-0019757-0004 1-4

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,714
Iodine		Active Substance	7553-56-2	231-442-4	0,15

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
Polyvinylpyr-rolidone iodine		Active Substance	25655-41-8		1,0	1,46
Iodine		Active Substance	7553-56-2	231-442-4	0,21	0,307

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

Formulation(s)	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5

Hazard statements	Harmful to aquatic life with long lasting effects. Safety data sheet available on request.
Precautionary statements	Keep out of reach of children. Avoid release to the environment. Dispose of contents in accordance with local/regional/national/international regulation. Dispose of container in accordance with local/regional/national/international regulation.

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

4.1. **Use description**

Table 15. Use # 1 – Post-milking manual dipping (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Manual dipping (RTU) Fill the reservoir with the RTU product and screw the dip cup on top. 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 the full length of the teat is immersed into the disinfectant. Top up with fresh disinfectant by squeezing the reservoir as needed.. After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

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 16. Use # 2 – Post-milking, manual spraying, trigger sprayer (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Manual spraying, trigger sprayer (RTU) Fill the reservoir with the RTU product and screw the top of the trigger sprayer on it. 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 each teat is covered with the disinfectant. Top up the reservoir with fresh disinfectant as needed. After disinfection, empty the reservoir and clean reservoir and trigger sprayer by rinsing with water.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.2.1. *Use-specific instructions for use*

See general directions for use.

4.2.2. *Use-specific risk mitigation measures*

Wear protective chemical resistant gloves when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information).

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

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 17. Use # 3 – Post-milking manual spraying using an electronic sprayer (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Manual spraying, electronic sprayer (RTU) Open a can containing the RTU product and insert the suction tube of the electronic sprayer. 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 electronic sprayer making sure that each teat is covered with the disinfectant. Replace the empty can by a new can as needed. After disinfection, put the suction tube system into a bucket of water and rinse the sprayer by pumping the water through the sprayer.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.3.1. *Use-specific instructions for use*

See general directions for use.

4.3.2. *Use-specific risk mitigation measures*

Wear protective chemical resistant gloves when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information).

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 18. Use # 4 – Post-milking automated dipping (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Automated dipping (RTU) Open a can containing the RTU product and insert the suction tube of the automated dipping-system. Before milking clean teats carefully by automatic procedure or manually. After milking, the vacuum is shut off and the teat dip is injected into a manifold on the claw piece. The teats are coated with 2-4 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. Afterwards, the milking system is ready for the next milking event. The whole process is automated.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0.5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.4.1. *Use-specific instructions for use*

See general directions for use.

4.4.2. *Use-specific risk mitigation measures*

See general directions for use.

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 19. Use # 5 – Post-milking automated spraying by robot (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Automated spraying by robot (RTU) Open a can containing the RTU product and insert the suction tube of the robotic milking device. The teats are cleaned by robot with automatic brushes. After robotic milking, 2-4 ml of the disinfectant is sprayed automatically onto teats from a cluster arm. Rinsing of the sprayer is automatic.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0.5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.5.1. *Use-specific instructions for use*

See general directions for use.

4.5.2. *Use-specific risk mitigation measures*

See general directions for use.

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 ([5]) OF THE META SPC 5

5.1. **Instructions for use**

Fill the reservoir with the RTU product and screw the dip cup on top.

The products must be brought to temperatures above 20 °C before use.

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

To ensure sufficient contact time, care should be taken that the product is not removed after application. Leave the product on the teats and keep the animals standing for at least five minutes after treatment for post-milking disinfection.

5.2. **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.

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

Description of first aid measures

General: Remove affected person from source of contamination.

After inhalation: Remove person to fresh air and keep comfortable for breathing. Get medical attention if any discomfort continues.

After skin contact: Rinse with water. Remove contaminated clothing and shoes. Seek medical advice if any skin reaction/or discomfort occurs.

After eye contact: Immediately rinse with water (at least 15 minutes). Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if any discomfort continues.

After ingestion: Contact poison treatment specialist immediately if symptoms occur and/or in case of mouth contact with large quantities. Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately.

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

Environmental emergency measures

Prevent run-off from entering drains, sewers or waterways

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air)

([5]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 5.

Dike to collect larger liquid spills

Contain and/or absorb spill with inert material, then place in closed and suitable container for disposal according to regulations

Do not place spilled materials back into the original container

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

Method of disposal: 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.

Empty containers are rinsed with plenty of water and disposed to normal or commercial waste.

The paper towels used for the cleaning of teats are disposed in the normal rubbish.

Product classified as hazardous waste: No

Packaging classified as hazardous waste: No

EWC waste code: EWC: 0706 wastes from the MFSU of fats, grease, soaps, detergents, disinfectants and cosmetics

Other information: When handling waste, consideration should be made to the safety precautions applying to handling of the product. Waste code applies to product remnants in pure form.

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

Mentioned in the SDS: Keep in original container. Store the product away from direct sunlight in opaque containers. Keep separate from food, feedstuffs, fertilisers and other sensitive material. Store above freezing.

Storage temperature: 0 – 30 °C

Shelf-life: 24 months.

6. OTHER INFORMATION

pH range of meta-SPC 5: 4-5

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)	Nova Dip Spray 3000 IO Spray Plus PV-Plus 3000 Tehotippi Soft Plus F 6 Robo V
Authorisation number	EU-0019757-0005 1-5

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,46
Iodine		Active Substance	7553-56-2	231-442-4	0,307

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
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,0	1,43
Iodine		Active Substance	7553-56-2	231-442-4	0,21	0,3

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

Formulation(s)	EW — Emulsion, oil in water

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 6

Hazard statements	Harmful to aquatic life with long lasting effects. Safety data sheet available on request.
Precautionary statements	Keep out of reach of children. Avoid release to the environment. Dispose of contents in accordance with local/regional/national/international regulation. Dispose of container in accordance with local/regional/national/international regulation.

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

4.1. **Use description**

Table 20. Use # 1 – Post-milking manual dipping (RTU)

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

Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Manual dipping (RTU) Fill the reservoir with the RTU product and screw the dip cup on top. 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 the full length of the teat is immersed into the disinfectant. Top up with fresh disinfectant by squeezing the reservoir as needed. After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

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 21. Use # 2 – Post-milking, manual spraying, trigger sprayer (RTU)

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

Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Manual spraying, trigger sprayer (RTU) Fill the reservoir with the RTU product and screw the top of the trigger sprayer on it. 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 trigger sprayer making sure that each teat is covered with the disinfectant. Top up the reservoir with fresh disinfectant as needed. After disinfection, empty the reservoir and clean reservoir and trigger sprayer by rinsing with water.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.2.1. *Use-specific instructions for use*

See general directions for use.

4.2.2. *Use-specific risk mitigation measures*

Wear protective chemical resistant gloves when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information).

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

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 22. Use # 3 – Post-milking manual spraying using an electronic sprayer (RTU)

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

Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Manual spraying, electronic sprayer (RTU) Open a can containing the RTU product and insert the suction tube of the electronic sprayer. 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 each teat is covered with the disinfectant. Replace the empty can by a new can as needed. After disinfection, put the suction tube system into a bucket of water and rinse the sprayer by pumping the water through the sprayer.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.3.1. *Use-specific instructions for use*

See general directions for use.

4.3.2. *Use-specific risk mitigation measures*

Wear protective chemical resistant gloves when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information).

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 23. Use # 4 – Post-milking automated dipping (RTU)

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

Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Automated dipping (RTU) Open a can containing the RTU product and insert the suction tube of the automated dipping-system. Before milking clean teats carefully by automatic procedure or manually. After milking, the vacuum is shut off and the teat dip is injected into a manifold on the claw piece. The teats are coated with 2-4 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. Afterwards, the milking system is ready for the next milking event. The whole process is automated.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.4.1. *Use-specific instructions for use*

See general directions for use.

4.4.2. *Use-specific risk mitigation measures*

See general directions for use.

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 24. Use # 5 – Post-milking automated spraying by robot (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Automated spraying by robot (RTU) Open a can containing the RTU product and insert the suction tube of the robotic milking device. The teats are cleaned by robot with automatic brushes. After robotic milking, 2-4 ml of the disinfectant is sprayed automatically onto teats from a cluster arm. Rinsing of the sprayer is automatic.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.5.1. *Use-specific instructions for use*

See general directions for use.

4.5.2. *Use-specific risk mitigation measures*

See general directions for use.

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 ([6]) OF THE META SPC 6

5.1. **Instructions for use**

Fill the reservoir with the RTU product and screw the dip cup on top.

([6]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 6.

The products must be brought to temperatures above 20 °C before use.

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

To ensure sufficient contact time, care should be taken that the product is not removed after application. Leave the product on the teats and keep the animals standing for at least five minutes after treatment for post-milking disinfection.

5.2. **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.

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

Description of first aid measures

General: Remove affected person from source of contamination.

After inhalation: Remove person to fresh air and keep comfortable for breathing. Get medical attention if any discomfort continues.

After skin contact: Rinse with water. Remove contaminated clothing and shoes. Seek medical advice if any skin reaction/or discomfort occurs.

After eye contact: Immediately rinse with water (at least 15 minutes). Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if any discomfort continues.

After ingestion: Contact poison treatment specialist immediately if symptoms occur and/or in case of mouth contact with large quantities. Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately.

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

Environmental emergency measures

Prevent run-off from entering drains, sewers or waterways

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air)

Dike to collect larger liquid spills

Contain and/or absorb spill with inert material, then place in closed and suitable container for disposal according to regulations

Do not place spilled materials back into the original container

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

Method of disposal: 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.

Empty containers are rinsed with plenty of water and disposed to normal or commercial waste.

The paper towels used for the cleaning of teats are disposed in the normal rubbish.

Product classified as hazardous waste: No

Packaging classified as hazardous waste: No

EWC waste code: EWC: 0706 wastes from the MFSU of fats, grease, soaps, detergents, disinfectants and cosmetics

Other information: When handling waste, consideration should be made to the safety precautions applying to handling of the product. Waste code applies to product remnants in pure form.

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

Mentioned in the SDS: Keep in original container. Store the product away from direct sunlight in opaque containers. Keep separate from food, feedstuffs, fertilisers and other sensitive material. Store above freezing.

Storage temperature: 0 – 30 °C

Shelf-life: 24 months.

6. OTHER INFORMATION

pH range of meta-SPC 6: 4-5

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)	Jopo Winterspray IO Winterspray Jodopax RTU Barrera W				
Authorisation number	EU-0019757-0006 1-6				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,43
Iodine		Active Substance	7553-56-2	231-442-4	0,3