

COMMISSION IMPLEMENTING REGULATION (EU) 2019/1794
of 22 October 2019
granting a Union authorisation for the biocidal product family ‘Boumatic Iodine product family’
(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 the first subparagraph of Article 44(5) thereof,

Whereas:

- (1) On 21 August 2015, Boumatic Gascoigne Melotte submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named ‘Boumatic Iodine product family’ of product-type 3, as described in Annex V to that Regulation, providing written confirmation that the competent authority of the Netherlands had agreed to evaluate the application. The application was recorded under case number BC-PG019260-52 in the Register for Biocidal Products.
- (2) The ‘Boumatic Iodine product family’ contains 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 10 April 2018, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the European Chemicals Agency (‘the Agency’).
- (4) On 4 April 2019, the Agency submitted to the Commission an opinion ⁽³⁾, including the draft summary of the biocidal product characteristics (‘SPC’) of the ‘Boumatic Iodine 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 ‘Boumatic Iodine product family’ is a biocidal product family within the meaning of 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, it meets the conditions laid down in Article 19(1) and (6) of that Regulation.
- (5) On 20 June 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 ‘Boumatic Iodine product family’.
- (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 with authorisation number EU-0020541-0000 is granted to Boumatic Gascoigne Melotte for the making available on the market and use of the biocidal product family ‘Boumatic Iodine product family’, in accordance with the summary of the biocidal product characteristics set out in the Annex.

⁽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 27 February 2019 on the Union authorisation of ‘Boumatic Iodine product family’ (ECHA/BPC/220/2019).

The Union authorisation is valid from 18 November 2019 until 31 October 2029.

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, 22 October 2019.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

Summary of product characteristics for a biocidal product family

Boumatic Iodine product family

Product type 3 — Veterinary hygiene (Disinfectants)

Authorisation number: EU-0020541-0000

R4BP asset number: EU-0020541-0000

PART I

FIRST INFORMATION LEVEL**1. ADMINISTRATIVE INFORMATION****1.1. Family name**

Name	Boumatic Iodine product family
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1.2. Product type(s)

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)
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1.3. Authorisation holder

Name and address of the authorisation holder	Name	Boumatic Gascoigne Melotte
	Address	31, Rue Jules Melotte, 4350, Remicourt, Belgium
Authorisation number	EU-0020541-0000	
R4BP asset number	EU-0020541-0000	
Date of the authorisation	18 November 2019	
Expiry date of the authorisation	31 October 2029	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	Christeyns n.v.
Address of manufacturer	Afrikalaan 182, 9000 Ghent Belgium
Location of manufacturing sites	Afrikalaan 182, 9000 Ghent Belgium

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

Active substance	Iodine
Name of manufacturer	Christeyns n.v.
Address of manufacturer	Afrikalaan 182, 9000 Ghent Belgium

Location of manufacturing sites	Cosayach Nitratos S.A, Oficina Cala Cala S/N, Pozo Almonte Iquique Chile
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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	0,26	0,5
Fatty alcohol ethoxylate		Non-active substance	69011-36-5	500-241-6	1,0	2,99

2.2. Type(s) of formulation

Formulation(s)	AL — Any other liquid
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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
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1.2. Suffix to the authorisation number

Number	1-1
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1.3. Product type(s)

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)
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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	0,44	0,5
Fatty alcohol ethoxylate		Non-active substance	69011-36-5	500-241-6	1,0	2,99

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

Formulation(s)	AL — Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	Causes serious eye irritation. Harmful to aquatic life with long lasting effects.
Precautionary statements	Wash hands thoroughly after handling. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice. Avoid release to the environment.

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

4.1. Use description

Table 1. Use # 1 – Manual dip treatment, pre- or post-milking teat disinfectants

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 disinfectants for pre- or post-milking manual dip treatment of cow teats
Application method(s)	Open system: dip treatment For pre-milking: min. 1 minute contact time For post-milking min. 5 minutes contact time
Application rate(s) and frequency	Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10 ml per treatment — Product is ready to use Use 2 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	20kg, 60kg, 200kg, 210kg high-density polyethylene (HDPE) drum and 1 000kg HDPE

4.1.1. Use-specific instructions for use

Product for disinfection of cow teat by dipping before or after milking.

Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10 ml per dip treatment.

Fill the dipping cup with indicated quantity of undiluted product straight from the original packaging. During every treatment, sufficient volume of treatment product needs to be present in the dipping cup. To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended.

4.1.2. Use-specific risk mitigation measures

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder in the product information) and eye protection.

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 of the meta SPC 1

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

See general directions for use of the meta SPC 1

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 of the meta SPC 1

4.2. Use description

Table 2. Use # 2 – Manual spraying treatment pre- or post-milking teat disinfectants

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 disinfectants for pre- or post-milking, manual spray treatment of cow teat
Application method(s)	Open system: spray treatment or pre-milking: min. 1 minute contact time or post-milking min. 5 minutes contact time
Application rate(s) and frequency	Apply an amount of product that is sufficient to cover the entire teat, at the maximum 15ml per spray — Product is ready to use Use 2 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	20kg, 60kg, 200kg, 210kg HDPE drum and 1 000kg HDPE Intermediate bulk containers (IBC)

4.2.1. Use-specific instructions for use

Product for disinfection of cow teat by spraying before or after milking.

Apply an amount of product that is sufficient to cover the entire teat at the maximum 15 ml per spray treatment.

Fill the spray flask with the indicated quantity of undiluted product straight from the original packaging. To reduce dermal exposure, use of a dosing pump for filling the product into the application equipment is recommended.

4.2.2. Use-specific risk mitigation measures

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder in the product information), protective clothing, chemical resistant boots, and eye protection.

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 of the meta SPC 1

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

See general directions for use of the meta SPC 1

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 of the meta SPC 1

4.3. Use description

Table 3. Use # 3 – Automated dip treatment, pre- or post-milking teat disinfectants

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 disinfectants for pre- or post-milking, automated dip treatment of cow teat
Application method(s)	Open system: dip treatment For pre-milking: min. 1 minute contact time For post-milking min. 5 minutes contact time
Application rate(s) and frequency	Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10 ml per dip — Product is ready to use Use 3 times per day
Category(ies) of users	Professional

Pack sizes and packaging material	20kg, 60kg, 200kg, 210kg HDPE drum and 1 000kg HDPE IBC
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4.3.1. *Use-specific instructions for use*

Product for disinfection of cow teat by dipping before or after milking.

Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10 ml per dip treatment.

Use the undiluted product straight from the original packaging. To reduce dermal exposure, use of a dosing pump for filling the product into the application equipment is recommended.

4.3.2. *Use-specific risk mitigation measures*

See general directions for use of the meta SPC 1

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 of the meta SPC 1

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

See general directions for use of the meta SPC 1

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 of the meta SPC 1

4.4. **Use description**

Table 4. Use # 4 – Automated spraying treatment, pre- or post-milking teat disinfectants

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 disinfectants for pre- or post-milking, automated spray treatment of cow teat
Application method(s)	Open system: spray treatment or pre-milking: min. 1 minute contact time or post-milking min. 5 minutes contact time
Application rate(s) and frequency	Apply an amount of product that is sufficient to cover the entire teat, at the maximum 15ml per spray — Product is ready to use Use 3 times per day
Category(ies) of users	Professional

Pack sizes and packaging material	20kg, 60kg, 200kg, 210kg HDPE drum and 1 000kg HDPE IBC
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4.4.1. *Use-specific instructions for use*

Product for disinfection of cow teat by spraying before or after milking.

Apply an amount of product that is sufficient to cover the entire teat, at the maximum of 15 ml per spray treatment.

Use the undiluted product straight from the original packaging. To reduce dermal exposure, use of a dosing pump for filling the product into the application equipment is recommended.

4.4.2. *Use-specific risk mitigation measures*

See general directions for use of the meta SPC 1

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 of the meta SPC 1

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

See general directions for use of the meta SPC 1

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 of the meta SPC 1

5. **GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 1**

5.1. **Instructions for use**

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

For pre-milking treatment: treat the entire teat with the product, let act 60 seconds and wipe teats dry using single-use towels to avoid any contamination of milk.

For post-milking treatment: The teats should be treated as soon as possible after milking in such a way that the teats are fully covered. Let the teats air dry. The cows should be kept in a standing position until the product is fully dried (at least 5 minutes).

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 either for pre- or post-milking disinfection.

Keep out of reach of children.

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

First aid: general information: immediately remove any clothing soiled by the product

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

After skin contact: Wash skin thoroughly. Generally the product does not irritate the skin.

⁽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.

After eye contact: Rinse opened eye for several minutes under running water. Remove contact lenses, if present and easy to do. Continue rinsing.

After swallowing: Rinse out mouth and then drink water. If you feel unwell, get medical advice/attention.

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

Do not allow product to enter sewers surface or ground water.

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

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

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

Protect from frost. Store in a cool, dry place, away from direct sunlight and out of reach children.

Shelf life: 2 years

6. OTHER INFORMATION

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)	Udder Dip Udder Dip Max Udder D Max Udderdine Dip Uddine Dip Udderdine DP Uddine DP Udderdine DS				
Authorisation number	EU-0020541-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,5
Fatty alcohol ethoxylate		Non-active substance	69011-36-5	500-241-6	2,99

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

Identifier	meta SPC 2
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1.2. **Suffix to the authorisation number**

Number	1-2
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1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)
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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	0,26	0,38
Fatty alcohol ethoxylate		Non-active substance	69011-36-5	500-241-6	1,0	2,99

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

Formulation(s)	AL — Any other liquid
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3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2**

Hazard statements	Causes serious eye irritation. Harmful to aquatic life with long lasting effects.
Precautionary statements	Wash hands thoroughly after handling. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice. Avoid release to the environment.

4. **AUTHORISED USE(S) OF THE META SPC 2**4.1. **Use description****Table 5. Use # 1 – Manual dip treatment, post milking teat disinfectants**

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 post –milking, manual dip treatment of cow teats
Application method(s)	Open system: dip treatment For post-milking min. 5 minutes contact time
Application rate(s) and frequency	Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10 ml per treatment — Product is ready to use Use 2 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	20kg, 60kg, 200kg, 210kg HDPE drum and 1 000kg HDPE IBC

4.1.1. Use-specific instructions for use

Product for disinfection of cow teat by dipping after milking.

Fill the dipping cup with the indicated quantity of undiluted product straight from the original packaging. During every treatment, sufficient volume of treatment product needs to be present in the dipping cup. To reduce dermal exposure, use of a dosing pump for filling the product into the application equipment is recommended.

4.1.2. Use-specific risk mitigation measures

Wear eye protection.

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 of the meta SPC 2

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

See general directions for use of the meta SPC 2

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 of the meta SPC 2

4.2. Use description

Table 6. Use # 2 – Manual spraying treatment, post milking teat disinfectants

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 post – milking, annual spray treatment of cow teats
Application method(s)	Open system: spray treatment For post-milking min. 5 minutes contact time
Application rate(s) and frequency	Apply an amount of product that is sufficient to cover the entire teat, at the maximum 15ml per spray treatment — Product is ready to use Use 2 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	20kg, 60kg, 200kg, 210kg HDPE drum and 1 000kg HDPE IBC

4.2.1. Use-specific instructions for use

Product for disinfection of cow teat by spraying after milking.

Apply an amount of product that is sufficient to cover the entire teat, at the maximum 15 ml per spray treatment.

Fill the spray flask with the indicated quantity of undiluted product straight from the original packaging. To reduce dermal exposure, use of a dosing pump for filling the product into the application equipment is recommended.

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) and eye protection.

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 of the meta SPC 2

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

See general directions for use of the meta SPC 2

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 of the meta SPC 2

4.3. Use description

Table 7. Use # 3 – Automated dip treatment, post-milking teat disinfectants

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 post – milking, utomated dip treatment of cow teats
Application method(s)	Open system: dip treatment For post-milking min. 5 minutes contact time.
Application rate(s) and frequency	Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10ml per dip treatment — Product is ready to use. Use 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	20kg, 60kg, 200kg, 210kg HDPE drum and 1 000kg HDPE IBC

4.3.1. Use-specific instructions for use

Product for disinfection of cow teat by dipping after milking.

Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10 ml per dip treatment.

Use the undiluted product straight from the original packaging. To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended.

4.3.2. Use-specific risk mitigation measures

See general directions for use of the meta SPC 2

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 of the meta SPC 2

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

See general directions for use of the meta SPC 2

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 of the meta SPC 2

4.4. Use description

Table 8. Use # 4 – Automated spraying treatment, post-milking teat disinfectants

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 postmilking, utomated spray treatment of cow teats
Application method(s)	Open system: spray treatment For post-milking min. 5 minutes contact time
Application rate(s) and frequency	Apply an amount of product that is sufficient to cover the entire teat, at the maximum 15ml per spray treatment — Product is ready to use Use 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	20kg, 60kg, 200kg, 210kg HDPE drum and 1 000kg HDPE IBC

4.4.1. *Use-specific instructions for use*

Product for disinfection of cow teat by spraying, after milking.

Apply an amount of product that is sufficient to cover the entire teat, at the maximum of 15 ml per spray treatment

Use the undiluted product straight from the original packaging. To reduce dermal exposure, use of a dosing pump for filling the product into the application equipment is recommended.

4.4.2. *Use-specific risk mitigation measures*

See general directions for use of the meta SPC 2

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 of the meta SPC 2

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

See general directions for use of the meta SPC 2

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 of the meta SPC 2

5. GENERAL DIRECTIONS FOR USE ^(?) OF THE META SPC 2

5.1. Instructions for use

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

For post-milking treatment: The teats should be treated as soon as possible after milking in such a way that the teats are fully covered. Let the teats air dry. The cows should be kept in a standing position until the product is fully dried (at least 5 minutes).

^(?) 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.

Keep out of reach of children.

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

First aid: general information: immediately remove any clothing soiled by the product

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

After skin contact: Wash skin thoroughly. Generally the product does not irritate the skin.

After eye contact: Rinse opened eye for several minutes under running water. Remove contact lenses, if present and easy to do. Continue rinsing.

After swallowing: Rinse out mouth and then drink water. If you feel unwell, get medical advice/attention.

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

Do not allow product to enter sewers surface or ground water.

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

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

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

Protect from frost. Store in a cool, dry place, away from direct sunlight and out of reach of children.

Shelf life: 1 year

6. OTHER INFORMATION

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)	Gladiator RTU Udder Max Barrier Gladiator Max Barrier Udderdine BARRIER Uddine BARRIER Udderdine RTU Uddine RTU Udderdine BR
Authorisation number	EU-0020541-0002 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,26
Fatty alcohol ethoxylate		Non-active substance	69011-36-5	500-241-6	1,2

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

Trade name(s)	Udder Star Spray Udder Spray Max Udderdine Spray Uddine Spray Udderdine SP Uddine SP				
Authorisation number	EU-0020541-0003 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,29
Fatty alcohol ethoxylate		Non-active substance	69011-36-5	500-241-6	2,99

META SPC 3

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 3 identifier

Identifier	meta SPC 3
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1.2. Suffix to the authorisation number

Number	1-3
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1.3. Product type(s)

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)
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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	0,43	0,5

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Fatty alcohol ethoxylate		Non-active substance	69011-36-5	500-241-6	1,0	2,99

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

Formulation(s)	AL — Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

Hazard statements	Causes serious eye irritation. Harmful to aquatic life with long lasting effects.
Precautionary statements	Wash hands thoroughly after handling. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice. Avoid release to the environment.

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

4.1. Use description

Table 9. Use # 1 – Manual dip treatment, post milking teat disinfectants

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 post –milking, manual dip treatment of cow teats
Application method(s)	Open system: dip treatment For post-milking min. 5 minutes contact time
Application rate(s) and frequency	Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10 ml per treatment — Product is ready to use Use 2 times per day

Category(ies) of users	Professional
Pack sizes and packaging material	20kg, 60kg, 200kg, 210kg HDPE drum and 1 000kg HDPE IBC

4.1.1. Use-specific instructions for use

Product for disinfection of cow teat by dipping after milking.

Fill the dipping cup with the indicated quantity of undiluted product straight from the original packaging. During every treatment, sufficient volume of treatment product needs to be present in the dipping cup. To reduce dermal exposure, use of a dosing pump for filling the product into the application equipment is recommended.

4.1.2. Use-specific risk mitigation measures

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder in the product information) and eye protection.

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 of the meta SPC 3

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

See general directions for use of the meta SPC 3

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 of the meta SPC 3

4.2. Use description

Table 10. Use # 2 – Manual spraying treatment, post milking teat disinfectants

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 post – milking, manual spray treatment of cow teats
Application method(s)	Open system: spray treatment For post-milking min. 5 minutes contact time
Application rate(s) and frequency	Apply an amount of product that is sufficient to cover the entire teat, at the maximum 15ml per spray treatment — Product is ready to use Use 2 times per day

Category(ies) of users	Professional
Pack sizes and packaging material	20kg, 60kg, 200kg, 210kg HDPE drum and 1 000kg HDPE IBC

4.2.1. Use-specific instructions for use

Product for disinfection of cow teat by spraying after milking.

Apply an amount of product that is sufficient to cover the entire teat, at the maximum 15 ml per spray treatment

Fill the spray flask with the indicated quantity of undiluted product straight from the original packaging. To reduce dermal exposure, use of a dosing pump for filling the product into the application equipment is recommended.

4.2.2. Use-specific risk mitigation measures

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder in the product information), protective clothing, chemical resistant boots, and eye protection.

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 of the meta SPC 3

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

See general directions for use of the meta SPC 3

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 of the meta SPC 3

4.3. Use description

Table 11. Use # 3 – Automated dip treatment, post-milking teat disinfectants

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 post – milking, automated dip treatment of cow teats
Application method(s)	Open system: dip treatment For post-milking min. 5 minutes contact time.
Application rate(s) and frequency	Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10ml per dip treatment — Product is ready to use Use 3 times per day

Category(ies) of users	Professional
Pack sizes and packaging material	20kg, 60kg, 200kg, 210kg HDPE drum and 1 000kg HDPE IBC

4.3.1. Use-specific instructions for use

Product for disinfection of cow teat by dipping after milking.

Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10 ml per dip treatment.

Use the undiluted product straight from the original packaging. To reduce dermal exposure, use of a dosing pump for filling the product into the application equipment is recommended.

4.3.2. Use-specific risk mitigation measures

See general directions for use of the meta SPC 3

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 of the meta SPC 3

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

See general directions for use of the meta SPC 3

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 of the meta SPC 3

4.4. Use description

Table 12. Use # 4 – Automated spraying treatment, post-milking teat disinfectants

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 postmilking, automated spray treatment of cow teats
Application method(s)	Open system: spray treatment For post-milking min. 5 minutes contact time
Application rate(s) and frequency	15 ml per spray treatment — Product is ready to use Use 3 times per day
Category(ies) of users	Professional

Pack sizes and packaging material	20kg, 60kg, 200kg, 210kg HDPE drum and 1 000kg HDPE IBC
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4.4.1. *Use-specific instructions for use*

Product for disinfection of cow teat by spraying after milking.

Apply an amount of product that is sufficient to cover the entire teat, at the maximum of 15 ml per spray treatment.

Use the undiluted product straight from the original packaging. To reduce dermal exposure, use of a dosing pump for filling the product into the application equipment is recommended.

4.4.2. *Use-specific risk mitigation measures*

See general directions for use of the meta SPC 3

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 of the meta SPC 3

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

See general directions for use of the meta SPC 3

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 of the meta SPC 3

5. **GENERAL DIRECTIONS FOR USE ^(?) OF THE META SPC 3**

5.1. **Instructions for use**

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

For post-milking treatment: The teats should be treated as soon as possible after milking in such a way that the teats are fully covered. Let the teats air dry. The cows should be kept in a standing position until the product is fully dried (at least 5 minutes).

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.

Keep out of reach of children.

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

First aid: general information: immediately remove any clothing soiled by the product

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

After skin contact: Wash skin thoroughly. Generally the product does not irritate the skin.

After eye contact: Rinse opened eye for several minutes under running water. Remove contact lenses, if present and easy to do. Continue rinsing.

After swallowing: Rinse out mouth and then drink water. If you feel unwell, get medical advice/attention.

^(?) 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.

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

Do not allow product to enter sewers surface or ground water.

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

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

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

Protect from frost. Store in a cool, dry place, away from direct sunlight and out of reach of children.

Shelf life: 2 years.

6. OTHER INFORMATION

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)	Udder Star Udder Star Max Udder S Max Udderdine Star Uddine Star Udderdine ST Uddine ST				
Authorisation number	EU-0020541-0004 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,5
Fatty alcohol ethoxylate		Non-active substance	69011-36-5	500-241-6	2,5