

## II

(Non-legislative acts)

## REGULATIONS

## COMMISSION IMPLEMENTING REGULATION (EU) 2019/1844

of 22 October 2019

granting a Union authorisation for the biocidal product family 'BPF\_Iodine\_VET'

(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 <sup>(1)</sup>, and in particular the first subparagraph of Article 44(5) thereof,

Whereas:

- (1) On 7 August 2015, Applied Biocide GmbH submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named 'BPF\_Iodine\_VET' of product-type 3, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Austria had agreed to evaluate the application. The application was recorded under case number BC-XJ019074-33 in the Register for Biocidal Products.
- (2) 'BPF\_Iodine\_VET' 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 <sup>(2)</sup>, 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 22 August 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 <sup>(3)</sup>, including the draft summary of the biocidal product characteristics ('SPC') of 'BPF\_Iodine\_VET' 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 'BPF\_Iodine\_VET' 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.

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1.

<sup>(2)</sup> 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).

<sup>(3)</sup> ECHA opinion of 27 February 2019 on the Union authorisation of 'BPF\_Iodine\_VET' (ECHA/BPC/219/2019).

- (5) On 4 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 'BPF\_Iodine\_VET'.
- (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-0020540-0000 is granted to Applied Biocide GmbH for the making available on the market and use of the biocidal product family 'BPF\_Iodine\_VET', in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 25 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**

BPF\_Iodine\_VET

Product type 3 - Veterinary hygiene (Disinfectants)

Authorisation number: EU-0020540-0000

R4BP asset number: EU-0020540-0000

## PART I

**FIRST INFORMATION LEVEL**

## 1. ADMINISTRATIVE INFORMATION

1.1. **Family name**

Name	BPF_Iodine_VET
------	----------------

1.2. **Product type(s)**

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

1.3. **Authorisation holder**

Name and address of the authorisation holder	Name	Applied Biocide GmbH
	Address	Sprl 31, Rue Jules Melotte, 4350, Remicourt, Belgium
Authorisation number	EU-0020540-0000	
R4BP asset number	EU-0020540-0000	
Date of the authorisation	25 November 2019	
Expiry date of the authorisation	31 October 2029	

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

Name of manufacturer	Ewabo Chemikalien GmbH & Co KG
Address of manufacturer	Kolpingstrasse 4, 49835 Wietmarschen Germany
Location of manufacturing sites	Kolpingstrasse 4, 49835 Wietmarschen Germany
Name of manufacturer	FINK TEC GmbH
Address of manufacturer	Oberster Kamp 23, 59069 Hamm Germany
Location of manufacturing sites	Oberster Kamp 23, 59069 Hamm Germany
Name of manufacturer	IRCASERVICE

Address of manufacturer	S.S. Cremasca 591 no. 10, 24040 Fornovo S. Giovanni (BG) Italy
Location of manufacturing sites	S.S. Cremasca 591 no. 10, 24040 Fornovo S. Giovanni (BG) Italy
Name of manufacturer	Laboratorios Maymo SA
Address of manufacturer	Via Augusta, 302, 08017 Barcelona Spain
Location of manufacturing sites	Via Augusta, 302, 08017 Barcelona Spain

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

Active substance	Iodine
Name of manufacturer	Cosayach S.A. Compania de Salitre y Yodo
Address of manufacturer	Amunátegui 178, 7th Floor, 8320000 Santiago Chile
Location of manufacturing sites	S.C.M. Cosayach Cala, 1180000 Pozo Almonte Chile Chile
Active substance	Iodine
Name of manufacturer	ACF Minera S.A.
Address of manufacturer	San Martin 499, 1100000 Iquique Chile
Location of manufacturing sites	Lagunas mine, 1180000 Pozo Almonte Chile
Active substance	Iodine
Name of manufacturer	Sociedad Quimica y Minera SA
Address of manufacturer	Los Militares 4290, 7550000 Las Condes Chile
Location of manufacturing sites	Nueva Victoria, 1180000 Pozo Almonte Chile Pedro de Valdivia, 1240000 Antofagasta 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
Iodine		Active Substance	7553-56-2	231-442-4	0,1	3,0
Phosphoric Acid	Trihydroxidooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,0	10,0
Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-omega.-hydroxy-, branched	Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	0,0	31,8
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	31,8

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

Formulation(s)	meta SPC 1-5: AL — any other liquid meta SPC 6-8: SL — soluble concentrate
----------------	---

## PART II

## SECOND INFORMATION LEVEL — META SPC(S)

## META SPC 1

## 1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 1 identifier**

Identifier	Meta SPC 1
------------	------------

1.2. **Suffix to the authorisation number**

Number	1-1
--------	-----

1.3. **Product type(s)**

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

## 2. META SPC 1 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,15	0,15
Phosphoric Acid	Trihydroxidooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,0	0,0
Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-omega.-hydroxy-, branched	Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	0,0	0,0
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	0,0

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

Formulation(s)	AL — any other liquid
----------------	-----------------------

## 3. Hazard and precautionary statements of the meta SPC 1

Hazard statements	May be corrosive to metals.
Precautionary statements	Keep only in original packaging. Absorb spillage to prevent material damage. Store in corrosive resistant container with a resistant inner liner.

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

4.1. **Use description**

Table 1

**Use # 1 — Veterinary hygiene — animal husbandry — teat disinfectant — professional — indoors — spraying (post milking)**

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
Application method(s)	Open system: spray treatment Spraying: Manual and automated non-medical disinfection of teats with a ready-to-use spray (on cows, post-milking)
Application rate(s) and frequency	Application rate: 10-15 ml per cow Application frequency: During lactation period: — manual: 2 applications per day (post-milking) — automated: 3 applications per day (post-milking) During dry period: 1 application per day
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle high-density polyethylene (HDPE): 1 liter, cap is made of PP Jerry can HDPE: 5-60 liters Drum HDPE: 200 liters IBC HDPE: 600-1 000 liters

4.1.1. *Use-specific instructions for use*

—

4.1.2. *Use-specific risk mitigation measures*

—

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

—

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

—

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

—

5. GENERAL DIRECTIONS FOR USE <sup>(1)</sup> OF THE META SPC 1

#### 5.1. **Instructions for use**

Always read the label or leaflet before use and follow all the instructions provided.

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

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

Immediately after each cow has been milked, spray the entire surface of each teat with the solution. Leave the product until next milking. Do not clean the teats directly after disinfection.

Keep the cows standing until the product has dried (at least 5 minutes).

Product can be applied manually or by means of automatic teat sprayer.

Before the next milking the teats have to be cleaned, preferably with one new wet cloth per cow.

Application frequency must not exceed two applications per cow and day considering manual spraying and must not exceed three applications per cow and day considering automatic teat sprayer (post-milking).

#### 5.2. **Risk mitigation measures**

Keep out of reach of children.

Wear protective chemical resistant gloves, coated coverall and boots during product handling and application phase (material to be specified by the authorisation holder in the product information).

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**

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

After skin contact: Wash skin thoroughly.

After eye contact: Rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.

After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.

When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

<sup>(1)</sup> 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.

Environmental emergency measures:

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

#### 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.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

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

Store the product at room temperature, away from direct sunlight and in opaque containers. Protect from frost. Keep container tightly closed.

Shelf-life: 12 months in HDPE.

#### 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)	FINK — Io Spray 15 FINK — Euter-DIP PVP-S FINK Pattedyp PVP IOSpray 15 PVP
Authorisation number	EU-0020540-0001 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Sub- stance	7553-56-2	231-442-4	0,15

#### META SPC 2

#### 1. META SPC 2 ADMINISTRATIVE INFORMATION

##### 1.1. Meta SPC 2 identifier

Identifier	Meta SPC 2
------------	------------

##### 1.2. Suffix to the authorisation number

Number	1-2
--------	-----

1.3. **Product type(s)**

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

## 2. META SPC 2 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Sub-stance	7553-56-2	231-442-4	0,3	0,5
Phosphoric Acid	Trihydroxidooxido-phosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,0	0,0
Poly(oxy-1,2-ethane-diyl).alpha.-tridecyl-.omega.-hydroxy-, branched	Poly(oxy-1,2-ethane-diyl).alpha.-tridecyl-.omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	0,0	0,0
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	0,0

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	May be corrosive to metals. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep only in original packaging. Avoid release to the environment. Absorb spillage to prevent material damage. Store in corrosive resistant container with a resistant inner liner. Dispose of contents to/container in accordance with the local/national regulations.

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

4.1. **Use description**

Table 2

**Use # 1 — Veterinary hygiene — animal husbandry — teat disinfectant — professional — indoors — spraying (post milking)**

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
Application method(s)	Open system: spray treatment Spraying: Manual and automated non-medical disinfection of teats with a ready-to-use spray (on cows, post-milking)
Application rate(s) and frequency	Application rate: 10-15 ml per cow Application frequency: During lactation period: — manual: 2 applications per day (post-milking) — automated: 3 applications per day (post-milking) During dry period: 1 application per day
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle HDPE: 1 liter, cap is made of PP Jerry can HDPE: 5-60 liters Drum HDPE: 200 liters IBC HDPE: 600-1 000 liters

4.1.1. *Use-specific instructions for use*

—

4.1.2. *Use-specific risk mitigation measures*

—

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

—

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

—

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

—

5. GENERAL DIRECTIONS FOR USE <sup>(?)</sup> OF THE META SPC 2

5.1. **Instructions for use**

Always read the label or leaflet before use and follow all the instructions provided.

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

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

<sup>(?)</sup> 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.

Immediately after each cow has been milked, spray the entire surface of each teat with the solution. Leave the product until next milking. Do not clean the teats directly after disinfection.

Keep the cows standing until the product has dried (at least 5 minutes).

Product can be applied manually or by means of automatic teat sprayer.

Before the next milking the teats have to be cleaned, preferably with one new wet cloth per cow.

Application frequency must not exceed two applications per cow and day considering manual spraying and must not exceed three applications per cow and day considering automatic teat sprayer (post-milking).

## 5.2. Risk mitigation measures

Keep out of reach of children.

Wear protective chemical resistant gloves, coated coverall and boots during product handling and application phase (material to be specified by the authorisation holder in the product information).

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

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

After skin contact: Wash skin thoroughly.

After eye contact: Rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.

After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.

When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

Environmental emergency measures:

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

## 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.

European Waste Catalogue: 2001 30-detergents other than those mentioned in 20 01 29.

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

Store the product at room temperature, away from direct sunlight and in opaque containers. Protect from frost. Keep container tightly closed.

Shelf-life: 12 months in HDPE.

## 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)	Fink Io Spray - 30 ST-Io Spray DESINTEC MH Iodine S DESINTEC MH Raidip plus Iodine Spray 3000 Iodine Spray
Authorisation number	EU-0020540-0002 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Sub-stance	7553-56-2	231-442-4	0,3

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

Trade name(s)	Fink — Io Spray 50 DESINTEC MH Raidip 5000 Iodine Spray 5000
Authorisation number	EU-0020540-0003 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Sub-stance	7553-56-2	231-442-4	0,5

**META SPC 3**

## 1. META SPC 3 ADMINISTRATIVE INFORMATION

## 1.1. Meta SPC 3 identifier

Identifier	Meta SPC 3
------------	------------

## 1.2. Suffix to the authorisation number

Number	1-3
--------	-----

1.3. **Product type(s)**

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

## 2. META SPC 3 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Sub-stance	7553-56-2	231-442-4	0,5	0,5
Phosphoric Acid	Trihydroxidooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,0	0,0
Poly(oxy-1,2-ethanediy).alpha.-tridecyl-.omega.-hydroxy-, branched	Poly(oxy-1,2-ethanediy).alpha.-tridecyl-.omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	0,0	0,0
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	0,0

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	May be corrosive to metals. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep only in original packaging. Avoid release to the environment. Absorb spillage to prevent material damage. Store in corrosive resistant container with a resistant inner liner. Dispose of contents to/container in accordance with the local/national regulations.

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

4.1. **Use description**

Table 3

**Use # 1 – Veterinary hygiene - animal husbandry - teat disinfectant - professional - indoors – spraying (post milking)**

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
Application method(s)	Open system: spray treatment Spraying: Manual and automated non-medical disinfection of teats with a ready-to-use spray (on cows, post-milking)
Application rate(s) and frequency	Application rate: 10-15 ml per cow Application frequency: During lactation period: — manual: 2 applications per day (post-milking) — automated: 3 applications per day (post-milking) During dry period: 1 application per day
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle HDPE: 1 liter, cap is made of PP Jerry can HDPE: 5-60 liters Drum HDPE: 200 liters IBC HDPE: 600-1 000 liters

4.1.1. *Use-specific instructions for use*

—

4.1.2. *Use-specific risk mitigation measures*

—

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

—

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

—

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

—

5. GENERAL DIRECTIONS FOR USE <sup>(\*)</sup> OF THE META SPC 3

5.1. **Instructions for use**

Always read the label or leaflet before use and follow all the instructions provided.

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

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

Immediately after each cow has been milked, spray the entire surface of each teat with the solution. Leave the product until next milking. Do not clean the teats directly after disinfection.

Keep the cows standing until the product has dried (at least 5 minutes).

Product can be applied manually or by means of automatic teat sprayer.

(\*) 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.

Before the next milking the teats have to be cleaned, preferably with one new wet cloth per cow.

Application frequency must not exceed two applications per cow and day considering manual spraying and must not exceed three applications per cow and day considering automatic teat sprayer (post-milking).

## 5.2. Risk mitigation measures

Keep out of reach of children.

Wear protective chemical resistant gloves, coated coverall and boots during product handling and application phase (material to be specified by the authorisation holder in the product information).

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

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

After skin contact: Wash skin thoroughly.

After eye contact: Rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.

After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.

When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

Environmental emergency measures:

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

## 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.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

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

Store the product at room temperature, away from direct sunlight and in opaque containers. Protect from frost. Keep container tightly closed.

Shelf-life: 12 months in HDPE.

## 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)	Fink — Io Spray 50 (Jodophor) Fink — Io Spray 50 (Iodophor)
Authorisation number	EU-0020540-0004 1-3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,5

**META SPC 4**

## 1. META SPC 4 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 4 identifier**

Identifier	Meta SPC 4
------------	------------

1.2. **Suffix to the authorisation number**

Number	1-4
--------	-----

1.3. **Product type(s)**

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

## 2. META SPC 4 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,1	0,15
Phosphoric Acid	Trihydroxidooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,0	0,0
Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-omega.-hydroxy-, branched	Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	0,0	0,0
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	0,0

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	May be corrosive to metals.
Precautionary statements	Keep only in original packaging. Absorb spillage to prevent material damage. Store in corrosive resistant container with a resistant inner liner.

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

## 4.1. Use description

Table 4

**Use # 1 – Veterinary hygiene — animal husbandry — teat disinfectant — professional — indoors — dipping (post milking)**

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
Application method(s)	Open system: dip treatment Teat-dipping: Manual non-medical disinfection of teats with a ready-to-use liquid (on cows, post-milking)
Application rate(s) and frequency	Application rate: 5-10 ml per cow Application frequency: During lactation period: 2 applications per day (post-milking) During dry period: 1 application per day
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle HDPE: 1 liter, cap is made of PP Jerry can HDPE: 5-60 liters Drum HDPE: 200 liters IBC HDPE: 600-1 000 liters

## 4.1.1. Use-specific instructions for use

—

## 4.1.2. Use-specific risk mitigation measures

—

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

—

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

—

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

—

5. GENERAL DIRECTIONS FOR USE (\*) OF THE META SPC 4

#### 5.1. **Instructions for use**

Always read the label or leaflet before use and follow all the instructions provided.

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

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

Fill up a teat dipping cup with 2/3 of product. Immediately after each cow has been milked, dip each teat manually in the solution. Ensure that at least two thirds of the teats, preferably the entire teats, come in contact with the solution.

Do not clean the teats directly after disinfection. Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).

Refill the cup as necessary.

Teat dipping cups should be emptied after milking and washed before re-use. Before the next milking the teats have to be cleaned, preferably with one new wet cloth per cow.

Application frequency must not exceed two applications per cow and day (post-milking).

#### 5.2. **Risk mitigation measures**

Keep out of reach of children.

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

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

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

After skin contact: Wash skin thoroughly.

After eye contact: Rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.

After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.

When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

Environmental emergency measures:

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

(\*) 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.

#### 5.4. 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.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

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

Store the product at room temperature, away from direct sunlight and in opaque containers. Protect from frost. Keep container tightly closed.

Shelf-life: 12 months in HDPE.

#### 6. OTHER INFORMATION

#### 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)	FINK — Io Dip 10 IODip 10 PVP
Authorisation number	EU-0020540-0005 1-4

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Sub- stance	7553-56-2	231-442-4	0,1

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

Trade name(s)	FINK — Io Dip Protect DESINTEC MH Iodine Barrier TvP — Barrier Dip
Authorisation number	EU-0020540-0006 1-4

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Sub- stance	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
Iodine		Active Substance	7553-56-2	231-442-4	0,3	0,45
Phosphoric Acid	Trihydroxidooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,35	0,4
Poly(oxy-1,2-ethanediy).alpha.-tridecyl-omega.-hydroxy-, branched	Poly(oxy-1,2-ethanediy).alpha.-tridecyl-omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	0,0	0,0
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	0,0

## 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	May be corrosive to metals. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep only in original packaging. Avoid release to the environment. Absorb spillage to prevent material damage. Store in corrosive resistant container with a resistant inner liner. Dispose of contents to / container in accordance with the local/national regulations.

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

## 4.1. Use description

Table 5

**Use # 1 — Veterinary hygiene — animal husbandry — teat disinfectant — professional — indoors — dipping (post milking)**

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
Application method(s)	Open system: dip treatment Teat-dipping: Manual non-medical disinfection of teats with a ready-to-use liquid (on cows, post-milking)
Application rate(s) and frequency	Application rate: 5-10 ml per cow Application frequency: During lactation period: 2 applications per day (post-milking) During dry period: 1 application per day
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle HDPE: 1 liter, cap is made of PP Jerry can HDPE: 5-60 liters Drum HDPE: 200 liters IBC HDPE: 600-1 000 liters

## 4.1.1. Use-specific instructions for use

—

## 4.1.2. Use-specific risk mitigation measures

—

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

—

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

—

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

—

5. GENERAL DIRECTIONS FOR USE <sup>(\*)</sup> OF THE META SPC 5

## 5.1. Instructions for use

Always read the label or leaflet before use and follow all the instructions provided.

<sup>(\*)</sup> 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.

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

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

Fill up a teat dipping cup with 2/3 of product. Immediately after each cow has been milked, dip each teat manually in the solution. Ensure that at least two thirds of the teats, preferably the entire teats, come in contact with the solution.

Do not clean the teats directly after disinfection. Leave the product until next milking.

Keep the cows standing until the product has dried (at least 5 minutes).

Refill the cup as necessary.

Teat dipping cups should be emptied after milking and washed before re-use. Before the next milking the teats have to be cleaned, preferably with one new wet cloth per cow.

Application frequency must not exceed two applications per cow and day (post-milking).

#### 5.2. Risk mitigation measures

Keep out of reach of children.

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

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

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

After skin contact: Wash skin thoroughly.

After eye contact: Rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.

After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.

When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

Environmental emergency measures:

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

#### 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.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

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

Store the product at room temperature, away from direct sunlight and in opaque containers. Protect from frost. Keep container tightly closed.

Shelf-life: 12 months in HDPE.

## 6. OTHER INFORMATION

## 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)	Jodofilm 75/5 4 500 ppm
Authorisation number	EU-0020540-0007 1-5

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,45
Phosphoric Acid	Trihydroxidooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,4

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

Trade name(s)	Jodofilm 75/5 3 000 ppm
Authorisation number	EU-0020540-0008 1-5

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,3
Phosphoric Acid	Trihydroxidooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,35

**META SPC 6**

## 1. META SPC 6 ADMINISTRATIVE INFORMATION

## 1.1. Meta SPC 6 identifier

Identifier	Meta SPC 6
------------	------------

## 1.2. Suffix to the authorisation number

Number	1-6
--------	-----

## 1.3. Product type(s)

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

## 2. META SPC 6 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	1,75	2,4
Phosphoric Acid	Trihydroxidooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	3,0	10,0
Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-,branched	Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	0,0	25,6
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	31,8

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

Formulation(s)	SL — soluble concentrate
----------------	--------------------------

## 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 6

Hazard statements	<p>May be corrosive to metals.  Harmful if swallowed.  Causes severe skin burns and eye damage.  Causes serious eye damage.  May cause damage to thyroid gland through prolonged or repeated exposure.  Harmful to aquatic life with long lasting effects.</p>
Precautionary statements	<p>Keep only in original packaging.  Do not breathe mist.  Do not breathe spray.  Avoid release to the environment.  Wear protective gloves.  Wear protective clothing.  Wear face protection.  IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.  IF IN EYES: Rinse cautiously with water for several minutes.  Remove contact lenses, if present and easy to do. Continue rinsing.  Absorb spillage to prevent material damage.  Store locked up.  Keep out of reach of children.</p>

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

## 4.1. Use description

Table 6

**Use # 1 — Veterinary hygiene — animal husbandry — hard surface disinfectant — professional — indoors — spraying**

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts Viruses
Field(s) of use	Indoor
Application method(s)	Open system: spray treatment Disinfectant for hard surfaces in stables (excluding hatcheries). Spraying of diluted concentrate by means of a hand-held knapsack sprayer (4-7 bar)
Application rate(s) and frequency	100 ml/m <sup>2</sup> — Concentration of Iodine in application solution: 750 ppm (0,075 % w/w). Application frequency per year: Dairy cows: 1 Beef cattle: 1 Veal calves: 4 Sows, in individual pens: 5 Sows in groups: 5 Fattening pigs: 3 Laying hens in battery cages without treatment: 1 Laying hens in battery cages with aeration (belt drying): 1 Laying hens in battery cages with forced drying (deep pit, high rise): 1 Laying hens in compact battery cages: 1 Laying hens in free range with litter floor (partly litter floor, partly slatted): 1 Broilers in free range with litter floor: 7 Laying hens in free range with grating floor (aviary system): 1 Parent broilers in free range with grating floor: 1 Parent broilers in rearing with grating floor: 3 Turkeys in free range with litter floor: 2 Ducks in free range with litter floor: 13 Geese in free range with litter floor: 6
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle HDPE: 1 liter, cap is made of PP Jerry can HDPE: 5-60 liters Drum HDPE: 200 liters IBC HDPE: 600-1 000 liters

## 4.1.1. Use-specific instructions for use

Iodosan 30: Mix 29 ml product with 971 ml water to obtain 1 l application solution.

Iodosan 18: Mix 40 ml product with 960 ml water to obtain 1 l application solution.

4.1.2. *Use-specific risk mitigation measures*

—

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

—

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

—

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

—

5. GENERAL DIRECTIONS FOR USE <sup>(6)</sup> OF THE META SPC 6

5.1. **Instructions for use**

Always read the label or leaflet before use and follow all the instructions provided.

To prepare the disinfectant solution, mix the liquid product with water. Always pour in water first and then carefully stir in the product.

Use max. 100 ml application solution per m<sup>2</sup> treated area. Do not prepare more fluid than strictly necessary.

The product shall only be applied in empty (unpopulated) animal houses after surfaces have been thoroughly cleaned with a suitable cleaner.

Pre-cleaning is mandatory. Rinse or wipe the surfaces which will be treated afterwards. Leave them to dry for about 24 up to 36 h before disinfection to obtain earth-moist surfaces. Soak installations and equipment thoroughly with a thin layer of the prepared solution by spraying, using suitable devices (4 to 7 bar). During the process and for the duration of contact time (min. 30 minutes), all openings have to be closed and the ventilation has to be switched off.

5.2. **Risk mitigation measures**

Keep out of reach of children.

The form of the bottle of the product should minimise risk for splashes in order to prevent eye and skin exposure during diluting the product.

During the mixing and loading phase: The use of a face shield and protection gloves (glove material to be specified by the authorisation holder in the product information) is mandatory.

During the application phase of the in use dilution by spraying: Gloves and a protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product shall be worn (glove and coverall material to be specified by the authorisation holder in the product information). Use new gloves for each work shift.

Professionals must not carry out animal house disinfection more than 3 times per month. These professionals should not use Iodine products for additional purposes.

Only use one kind of Iodine-containing product per day.

Stable disinfection should not be carried out more than once per year or once per lifetime for calf and pigs. Feeding troughs must be covered during application.

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

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

<sup>(6)</sup> 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.

After skin contact: Immediately take off contaminated clothing and wash skin thoroughly.

After eye contact: Immediately rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.

After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.

In case of unconsciousness place patient stably in left side position for transportation. Never give anything by mouth to an unconscious individual

When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

Environmental emergency measures:

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

Methods and material for containment and cleaning up:

Stop leak if safe to do so. Absorb spillage with liquid-binding material (sand, earth, diatomite, acid binders, universal binders, sawdust) and place in container for disposal according to local / national regulations.

#### 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.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

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

Store the product away from direct sunlight and in opaque containers. Protect from frost. Keep container tightly closed.

Shelf-life: 24 months in HDPE

#### 6. OTHER INFORMATION

#### 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)	IODOSAN 30 IODOSAN IODAT DESINTEC FL-JODES ROTIE-SOL J Disinfect Jod FINK — Jodophos 15 Jod-Reiniger sauer Tankrein extra
Authorisation number	EU-0020540-0009 1-6

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	2,4
Phosphoric Acid	Trihydroxi-dooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	10,0
Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-, branched	Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	25,6

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

Trade name(s)	IODOSAN 18
Authorisation number	EU-0020540-0010 1-6

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	1,75
Phosphoric Acid	Trihydroxi-dooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	3,0
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	31,8

## META SPC 7

### 1. META SPC 7 ADMINISTRATIVE INFORMATION

#### 1.1. Meta SPC 7 identifier

Identifier	Meta SPC 7
------------	------------

#### 1.2. Suffix to the authorisation number

Number	1-7
--------	-----

#### 1.3. Product type(s)

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

## 2. META SPC 7 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	3,0	3,0
Phosphoric Acid	Trihydroxidooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	10,0	10,0
Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-,branched	Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	31,8	31,8
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	0,0

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

Formulation(s)	SL — soluble concentrate
----------------	--------------------------

## 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 7

Hazard statements	<p>May be corrosive to metals.  Harmful if swallowed.  Causes severe skin burns and eye damage.  Causes serious eye damage.  May cause damage to thyroid gland through prolonged or repeated exposure.  Toxic to aquatic life with long lasting effects.</p>
Precautionary statements	<p>Keep only in original packaging.  Do not breathe mist.  Do not breathe spray.  Avoid release to the environment.  Wear protective gloves.  Wear protective clothing.  Wear face protection.  IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.  IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  Absorb spillage to prevent material damage.  Store locked up.  Keep out of reach of children.</p>

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

## 4.1. Use description

Table 7

**Use # 1 — Veterinary hygiene — animal husbandry — hard surface disinfectant — professional — indoors — spraying**

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts Viruses
Field(s) of use	Indoor
Application method(s)	Open system: spray treatment Disinfectant for hard surfaces in stables (excluding hatcheries). Spraying of diluted concentrate by means of a hand-held knapsack sprayer (4-7 bar)
Application rate(s) and frequency	100 ml/m <sup>2</sup> - Concentration of Iodine in application solution: 750 ppm (0,075 % w/w). Application frequency per year: Dairy cows: 1 Beef cattle: 1 Veal calves: 4 Sows, in individual pens: 5 Sows in groups: 5 Fattening pigs: 3 Laying hens in battery cages without treatment: 1 Laying hens in battery cages with aeration (belt drying): 1 Laying hens in battery cages with forced drying (deep pit, high rise): 1 Laying hens in compact battery cages: 1 Laying hens in free range with litter floor (partly litter floor, partly slatted): 1 Broilers in free range with litter floor: 7 Laying hens in free range with grating floor (aviary system): 1 Parent broilers in free range with grating floor: 1 Parent broilers in rearing with grating floor: 3 Turkeys in free range with litter floor: 2 Ducks in free range with litter floor: 13 Geese in free range with litter floor: 6
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle HDPE: 1 liter, cap is made of PP Jerry can HDPE: 5-60 liters Drum HDPE: 200 liters IBC HDPE: 600-1 000 liters

## 4.1.1. Use-specific instructions for use

Iodosan 30 plus: Mix 23 ml product with 977 ml water to obtain 1 l application solution.

## 4.1.2. Use-specific risk mitigation measures

—

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

—

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

—

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

—

5. GENERAL DIRECTIONS FOR USE <sup>(7)</sup> OF THE META SPC 7

#### 5.1. **Instructions for use**

Always read the label or leaflet before use and follow all the instructions provided.

To prepare the disinfectant solution, mix the liquid product with water. Always pour in water first and then carefully stir in the product.

Use max. 100 ml application solution per m<sup>2</sup> treated area. Do not prepare more fluid than strictly necessary.

The product shall only be applied in empty (unpopulated) animal houses after surfaces have been thoroughly cleaned with a suitable cleaner.

Pre-cleaning is mandatory. Rinse or wipe the surfaces which will be treated afterwards. Leave them to dry for about 24 up to 36 h before disinfection to obtain earth-moist surfaces. Soak installations and equipment thoroughly with a thin layer of the prepared solution by spraying, using suitable devices (4 to 7 bar). During the process and for the duration of contact time (min. 30 minutes), all openings have to be closed and the ventilation has to be switched off.

#### 5.2. **Risk mitigation measures**

Keep out of reach of children.

The form of the bottle of the product should minimise risk for splashes in order to prevent eye and skin exposure during diluting the product.

During the mixing and loading phase: The use of a face shield and protection gloves (glove material to be specified by the authorisation holder in the product information) is mandatory.

During the application phase of the in use dilution by spraying: Gloves and a protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product shall be worn (glove and coverall material to be specified by the authorisation holder in the product information). Use new gloves for each work shift.

Professionals must not carry out animal house disinfection more than 3 times per month. These professionals should not use Iodine products for additional purposes.

Only use one kind of Iodine-containing product per day.

Stable disinfection should not be carried out more than once per year or once per lifetime for calf and pigs. Feeding troughs must be covered during application.

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

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

After skin contact: Immediately take off contaminated clothing and wash skin thoroughly.

<sup>(7)</sup> Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 7.

After eye contact: Immediately rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.

After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.

In case of unconsciousness place patient stably in left side position for transportation. Never give anything by mouth to an unconscious individual.

When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

Environmental emergency measures:

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

Methods and material for containment and cleaning up:

Stop leak if safe to do so. Absorb spillage with liquid-binding material (sand, earth, diatomite, acid binders, universal binders, sawdust) and place in container for disposal according to local / national regulations.

#### 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.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

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

Store the product away from direct sunlight and in opaque containers. Protect from frost. Keep container tightly closed.

Shelf-life: 24 months in HDPE

#### 6. OTHER INFORMATION

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

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

Trade name(s)	IODOSAN 30 Plus YODO CONTROL YODIVEN
Authorisation number	EU-0020540-0011 1-7

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Sub-stance	7553-56-2	231-442-4	3,0
Phosphoric Acid	Trihydroxi- doxidopho- sphorus phos- phoric acid	Non-active substance	7664-38-2	231-633-2	10,0

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-, branched	Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	31,8

**META SPC 8**

## 1. META SPC 8 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 8 identifier**

Identifier	Meta SPC 8
------------	------------

1.2. **Suffix to the authorisation number**

Number	1-8
--------	-----

1.3. **Product type(s)**

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

## 2. META SPC 8 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	1,5	1,5
Phosphoric Acid	Trihydroxidooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	3,0	3,0
Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-, branched	Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	18,0	18,0
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	0,0

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

Formulation(s)	SL - soluble concentrate
----------------	--------------------------

## 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 8

Hazard statements	<p>May be corrosive to metals.          Causes severe skin burns and eye damage.          Causes serious eye damage.          May cause damage to thyroid gland through prolonged or repeated exposure.          Harmful to aquatic life with long lasting effects.</p>
Precautionary statements	<p>Keep only in original packaging.          Do not breathe mist.          Do not breathe spray.          Avoid release to the environment.          Wear protective gloves.          Wear protective clothing.          Wear face protection.          IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.          IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.          Absorb spillage to prevent material damage.          Store locked up.          Keep out of reach of children.</p>

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

## 4.1. Use description

Table 8

**Use # 1 — Veterinary hygiene — animal husbandry — hard surface disinfectant — professional — indoors — spraying**

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts Viruses
Field(s) of use	Indoor
Application method(s)	Open system: spray treatment Disinfectant for hard surfaces in stables (excluding hatcheries). Spraying of diluted concentrate by means of a hand-held knapsack sprayer (4-7 bar)
Application rate(s) and frequency	100 ml/m <sup>2</sup> — Concentration of Iodine in application solution: 750 ppm (0,075 % w/w). Application frequency per year: Dairy cows: 1 Beef cattle: 1 Veal calves: 4 Sows, in individual pens: 5 Sows in groups: 5 Fattening pigs: 3

	Laying hens in battery cages without treatment: 1 Laying hens in battery cages with aeration (belt drying): 1 Laying hens in battery cages with forced drying (deep pit, high rise): 1 Laying hens in compact battery cages: 1 Laying hens in free range with litter floor (partly litter floor, partly slatted): 1 Broilers in free range with litter floor: 7 Laying hens in free range with grating floor (aviary system): 1 Parent broilers in free range with grating floor: 1 Parent broilers in rearing with grating floor: 3 Turkeys in free range with litter floor: 2 Ducks in free range with litter floor: 13 Geese in free range with litter floor: 6
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle HDPE: 1 liter, cap is made of PP Jerry can HDPE: 5-60 liters Drum HDPE: 200 liters IBC HDPE: 600-1 000 liters

#### 4.1.1. Use-specific instructions for use

Iodosan 15: Mix 46 ml product with 954 ml water to obtain 1 l application solution.

#### 4.1.2. Use-specific risk mitigation measures

—

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

—

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

—

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

—

### 5. GENERAL DIRECTIONS FOR USE <sup>(8)</sup> OF THE META SPC 8

#### 5.1. Instructions for use

Always read the label or leaflet before use and follow all the instructions provided.

To prepare the disinfectant solution, mix the liquid product with water. Always pour in water first and then carefully stir in the product.

Use max. 100 ml application solution per m<sup>2</sup> treated area. Do not prepare more fluid than strictly necessary.

<sup>(8)</sup> Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 8.

The product shall only be applied in empty (unpopulated) animal houses after surfaces have been thoroughly cleaned with a suitable cleaner.

Pre-cleaning is mandatory. Rinse or wipe the surfaces which will be treated afterwards. Leave them to dry for about 24 up to 36 h before disinfection to obtain earth-moist surfaces. Soak installations and equipment thoroughly with a thin layer of the prepared solution by spraying, using suitable devices (4 to 7 bar). During the process and for the duration of contact time (min. 30 minutes), all openings have to be closed and the ventilation has to be switched off.

## 5.2. Risk mitigation measures

Keep out of reach of children.

The form of the bottle of the product should minimise risk for splashes in order to prevent eye and skin exposure during diluting the product.

During the mixing and loading phase: The use of a face shield and protection gloves (glove material to be specified by the authorisation holder in the product information) is mandatory.

During the application phase of the in use dilution by spraying: Gloves and a protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product shall be worn (glove and coverall material to be specified by the authorisation holder in the product information). Use new gloves for each work shift.

Professionals must not carry out animal house disinfection more than 3 times per month. These professionals should not use Iodine products for additional purposes.

Only use one kind of Iodine-containing product per day.

Stable disinfection should not be carried out more than once per year or once per lifetime for calf and pigs. Feeding troughs must be covered during application.

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

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

After skin contact: Immediately take off contaminated clothing and wash skin thoroughly.

After eye contact: Immediately rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.

After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.

In case of unconsciousness place patient stably in left side position for transportation. Never give anything by mouth to an unconscious individual.

When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

Environmental emergency measures:

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

Methods and material for containment and cleaning up:

Stop leak if safe to do so. Absorb spillage with liquid-binding material (sand, earth, diatomite, acid binders, universal binders, sawdust) and place in container for disposal according to local / national regulations.

**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.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

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

Store the product away from direct sunlight and in opaque containers. Protect from frost. Keep container tightly closed.

Shelf-life: 24 months in HDPE.

**6. OTHER INFORMATION****7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 8****7.1. Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	IODOSAN 15
Authorisation number	EU-0020540-0012 1-8

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Sub-stance	7553-56-2	231-442-4	1,5
Phosphoric Acid	Trihydroxidooxido-phosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	3,0
Poly(oxy-1,2-ethane-diyl).alpha.-tridecyl-.omega.-hydroxy-, branched	Poly(oxy-1,2-ethane-diyl).alpha.-tridecyl-.omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	18,0