This text is meant purely as a documentation tool and has no legal effect. The Union's institutions do not assume any liability for its contents. The authentic versions of the relevant acts, including their preambles, are those published in the Official Journal of the European Union and available in EUR-Lex. Those official texts are directly accessible through the links embedded in this document

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) (OJ L 283, 5.11.2019, p. 1)

Amended by:

►<u>B</u>

		Official Journal		
		No	page	date
► <u>M1</u>	Commission Implementing Regulation (EU) 2021/977 of 7 June 2021	L 216	26	18.6.2021

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)

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.

▼<u>B</u>

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 (Disin- fectants)

1.3. Authorisation holder

Name and address of the authorisation holder	Name	Applied Biocide GmbH
	Address	Siemensstraße 42, 59199 Bönen, Germany
Authorisation number	EU-0020540-0000	
R4BP asset number	EU-0020540-0000	
Date of the authorisation	25 November 2019	
Expiry date of the author- isation	31 October 2029	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	THESEO Deutschland GmbH
Address of manufacturer	Kolpingstrasse 4, 49835 Wiet- marschen Germany
Location of manufacturing sites	Kolpingstrasse 4, 49835 Wiet- marschen 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	I.R.C.A. SERVICE S.p.A.
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 Maymó S.A.

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 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 Anto- fagasta 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 (%)	
	IUFAC liame			EC number	Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,1	3,0
Phosphoric Acid	Trihydroxi- dooxidophos- phorus phos- phoric acid	Non-active substance	7664-38-2	231-633-2	0,0	10,0
Poly(oxy-1,2- ethanediyl).alpha tridecylomega hydroxy- ,branched	Poly(oxy-1,2- ethanediyl). alphatridecyl omegahydroxy- ,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

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 (%)	
				EC number	Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,15	0,15
Phosphoric Acid	Trihydroxi- dooxidophos- phorus phos- phoric acid	Non-active substance	7664-38-2	231-633-2	0,0	0,0
Poly(oxy-1,2- ethanediyl).alpha tridecylomega hydroxy- ,branched	Poly(oxy-1,2- ethanediyl).alpha. -tridecylomega. -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 - teatdisinfectant - professional - indoors - spraying (post milking)

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

▼	M1

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 – 1000 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 (1)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.

^{(&}lt;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.

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 premilking 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 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 Substance	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

-2

1.3. Product type(s)

Product type(s) PT0	3 - 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	ШРАС	E di	CAS number	EC number	Content (%)	
	Function	CAS number	EC number	Min	Max	
Iodine		Active Substance	7553-56-2	231-442-4	0,3	0,5
Phosphoric Acid	Trihydroxi- dooxidophos- phorus phos- phoric acid	Non-active substance	7664-38-2	231-633-2	0,0	0,0

Common name IUPAC name		Function	CAS number	EC number	Content (%)	
	Function	CAS number	EC number	Min	Max	
Poly(oxy-1,2- ethanediyl).alpha tridecylomega hydroxy- ,branched	Poly(oxy-1,2- ethanediyl).alpha. -tridecylomega 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 - teatdisinfectant - 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

Product-type	PT03 - Veterinary hygiene (Disinfectants)
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 – 1000 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 (²)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.

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.

^{(&}lt;sup>2</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.

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 premilking 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 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 30 Iodine Spray 30						
Authorisation number	EU-0020540-0002	EU-0020540-0002 1-2					
Common name	IUPAC name	IUPAC name Function CAS number EC number Content (%)					
Iodine		Active Substance	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	EU-0020540-0003 1-2				
Common name	IUPAC name	IUPAC name Function CAS number EC number Content (%)				
Iodine		Active Substance	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	ction CAS number EC number	EC 1	Content (%)	
Common name	IUPAC name	Function		EC number	Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,5	0,5
Phosphoric Acid	Trihydroxi- dooxidophos- phorus phos- phoric acid	Non-active substance	7664-38-2	231-633-2	0,0	0,0
Poly(oxy-1,2- ethanediyl).alpha tridecylomega hydroxy- ,branched	Poly(oxy-1,2- ethanediyl). alpha tridecylomega 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	-

▼	M1

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 – 1000 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 (3)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 $^{\circ}\mathrm{C}$ before use.

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

^{(&}lt;sup>3</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 3.

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 premilking 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

	HIDA C	Function	CAS number	EC number	Content (%)	
Common name	IUPAC name				Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,1	0,15
Phosphoric Acid	Trihydroxidooxi- dophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,0	0,0
Poly(oxy-1,2- ethanediyl).alpha tridecylomega hydroxy-,branched	Poly(oxy-1,2- ethanediyl). alphatridecyl omega hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	0,0	0,0

Common mana	HIDAC	Eurotian	CAS number	EC number	Content (%)	
Common name IUPAC name Function		CAS humber	EC number	Min	Max	
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
----------------	-----------------------

Т

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 disin- fection 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 – 1000 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 (⁴)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 reuse. 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.

^{(&}lt;sup>4</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 4.

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing Iodine has to be considered for premilking 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 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 Substance	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 Substance	7553-56-2	231-442-4	0,15

META SPC 5

1. META SPC 5 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 5 identifier

Identifier I	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

C	IUPAC name	Function	CAS number		Content (%)	
Common name	Common name IUPAC name		CAS number	EC number	Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,3	0,45
Phosphoric Acid	Trihydroxi- dooxidophos- phorus phos- phoric acid	Non-active substance	7664-38-2	231-633-2	0,35	0,4
Poly(oxy-1,2- ethanediyl).alpha tridecylomega hydroxy- ,branched	Poly(oxy-1,2- ethanediyl). alphatridecyl 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

Т

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 - teatdisinfectant - 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 disin- fection 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 – 1000 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 (⁵)OF THE META SPC 5

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 reuse. 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 premilking 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.

^{(&}lt;sup>5</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.

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 4500 ppm IOFILMO SUPER SUPERIO 4.5 PROTEGO 4500 TIGER 50 ASSOLUTO 5 REDFOX S SUPER MANGUST AUGUSTO P5 IO-DIN 45						
Authorisation number	EU-0020540-0007 1-5						
Common name	IUPAC name	IUPAC name Function CAS number EC number Content (%)					
Iodine		Active Substance	7553-56-2	231-442-4	0,45		
Phosphoric Acid	Trihydroxi- dooxidophos- phorus phos- phoric acid	Non-active substance	7664-38-2	231-633-2	0,4		

Trade name(s) Jodofilm 75/5 3000 ppm JODOFILM 75/3 IOFILMO SUPERIO 3.0 PROTEGO 3000 TIGER 30 ASSOLUTO 3 REDFOX E MANGUST AUGUSTO P3 IO-DIN 30 Authorisation EU-0020540-0008 1-5 number Common name IUPAC name Function CAS number EC number Content (%) Iodine 7553-56-2 231-442-4 0,3 Active Substance Phosphoric Acid Trihydroxidooxi-7664-38-2 231-633-2 0,35 Non-active dophosphorus substance phosphoric acid

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

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 (%)		
Common name	IUPAC name	Function	CAS number	EC number	Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	1,75	2,4
Phosphoric Acid	Trihydroxi- dooxidophos- phorus phos- phoric acid	Non-active substance	7664-38-2	231-633-2	3,0	10,0
Poly(oxy-1,2- ethanediyl).alpha tridecylomega hydroxy-,branched	Poly(oxy-1,2- ethanediyl). alphatridecyl- .omegahydroxy- ,branched	Non-active substance	69011-36-5	500-241-6	0,0	25,6

Common name IUPAC name Function		AC name	CAS number	EC number	Content (%)	
	Function	CAS number	EC number	Min	Max	
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	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.
Precautionary statements	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 immedi- ately 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.

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/m2 – 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 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 (aviery system): 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 – 1000 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 (6)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^2 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 36h 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.

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

<u>During the application phase</u> 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.

^{(&}lt;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.

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 6
- 7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	IODOSAN 30 IODOSAN JODAT DESINTEC FL-JODES ROTIE-SOL J Disinfect Jod FINK – Jodophos 15 Jod-Reiniger sauer Tankrein extra				
Authorisation number	EU-0020540-0009	9 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- dooxidophos- phorus phos- phoric acid	Non-active substance	7664-38-2	231-633-2	10,0
Poly(oxy-1,2- ethanediyl).alpha tridecylomega hydroxy-,branched	Poly(oxy-1,2- ethanediyl).alp- hatridecyl- .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	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- dooxidophos- phorus phos- phoric 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

- META SPC 7 ADMINISTRATIVE INFORMATION 1.
- 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)
-----------------	---

META SPC 7 COMPOSITION 2.

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
Common name	non name IUPAC name Fun		runction CAS number		Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	3,0	3,0
Phosphoric Acid	Trihydroxi- dooxidophos- phorus phos- phoric acid	Non-active substance	7664-38-2	231-633-2	10,0	10,0
Poly(oxy-1,2- ethanediyl).alpha tridecylomega hydroxy- ,branched	Poly(oxy-1,2- ethanediyl). alphatridecyl omegahydroxy-, 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

HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 7 3.

May be corrosive to metals. Harmful if swallowed. Causes severe skin burns and eye damage.
Causes severe skill out 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.

Precautionary statements	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 immedi- ately 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.

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/m2 – 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 (aviery 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 – 1000 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 (7)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^2 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.

^{(&}lt;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.

Pre-cleaning is mandatory. Rinse or wipe the surfaces which will be treated afterwards. Leave them to dry for about 24 up to 36h 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.

<u>During the mixing and loading phase:</u> 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 7

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

Trade name(s)	IODOSAN 30 PI Yodo contro Yodiven				
Authorisation number	EU-0020540-001	1 1-7			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	3,0
Phosphoric Acid	Trihydroxi- dooxidophos- phorus phos- phoric acid	Non-active substance	7664-38-2	231-633-2	10,0
Poly(oxy-1,2- ethanediyl).alpha tridecylomega hydroxy-,branched	Poly(oxy-1,2- ethanediyl).alp- hatridecyl- .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)

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 (%)	
Common name	IUPAC name	Function			Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	1,5	1,5
Phosphoric Acid	Trihydroxi- dooxidophos- phorus phos- phoric acid	Non-active substance	7664-38-2	231-633-2	3,0	3,0
Poly(oxy-1,2- ethanediyl).alpha tridecylomega hydroxy- ,branched	Poly(oxy-1,2- ethanediyl). alphatridecyl- .omegahydroxy- ,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	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.
Precautionary statements	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 immedi-
ately 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.

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

Т

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/m2 – 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 grating floor (aviery system): 1 Parent broilers in free range with grating floor: 1			

▼	M1

	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 – 1000 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 (8)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^2 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 36h 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.

^{(&}lt;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.

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.

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

<u>During the application phase</u> 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 Substance	7553-56-2	231-442-4	1,5		
Phosphoric Acid	Trihydroxi- dooxidophos- phorus phos- phoric acid	Non-active substance	7664-38-2	231-633-2	3,0		
Poly(oxy-1,2- ethanediyl).alpha tridecylomega hydroxy-,branched	Poly(oxy-1,2- ethanediyl).alp- hatridecyl- .omega hydroxy- ,branched	Non-active substance	69011-36-5	500-241-6	18,0		