

**COMMISSION IMPLEMENTING REGULATION (EU) 2021/977****of 7 June 2021****amending Implementing Regulation (EU) 2019/1844 to make administrative changes to the Union authorisation of 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) and Article 50(2) thereof,

Whereas:

- (1) On 22 October 2019, Commission Implementing Regulation (EU) 2019/1844 <sup>(2)</sup> granted a Union authorisation with authorisation number EU-0020540-0000 to Applied Biocide GmbH for the making available on the market and use of the biocidal product family 'BPF\_Iodine\_VET'.
- (2) On 10 April 2020, Applied Biocide GmbH submitted a notification to the European Chemicals Agency ('the Agency'), in accordance with Article 11(1) of Commission Implementing Regulation (EU) No 354/2013 <sup>(3)</sup>, regarding administrative changes to the Union authorisation for the biocidal product family 'BPF\_Iodine\_VET' as referred to in Sections 1 and 2 of Title 1 of the Annex to that Regulation.
- (3) Applied Biocide GmbH proposed the changes in the names of the manufacturers of the biocidal products in the first information level, administrative information, the changes in the names of one product in the third information level in meta-SPC 2 and one product in meta-SPC 6 and the addition of trade names for the individual products in meta-SPCs 2 and 5, in the summary of the product characteristics for the biocidal product family 'BPF\_Iodine\_VET' as set out in the Annex to Implementing Regulation (EU) 2019/1844. The notification was recorded under the case number BC-VD058524-35 in the Register for Biocidal Products.
- (4) On 9 June 2020, the Agency submitted an opinion <sup>(4)</sup> on the proposed changes to the Commission, in accordance with Article 11(3) of Implementing Regulation (EU) No 354/2013. The opinion concludes that the amendments to the existing authorisation sought by the authorisation holder fall under Article 50(3)(a) of Regulation (EU) No 528/2012, and that after the implementation of the changes the conditions of Article 19 of that Regulation are still met. On the same date, the Agency transmitted to the Commission the revised summary of the biocidal product characteristics in all the official languages of the Union in accordance with Article 11(6) of Implementing Regulation (EU) No 354/2013.
- (5) The Commission concurs with the opinion of the Agency and therefore considers it appropriate to amend the Union authorisation of the biocidal product family 'BPF\_Iodine\_VET'.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

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

<sup>(2)</sup> Commission Implementing Regulation (EU) 2019/1844 of 22 October 2019 granting a Union authorisation for the biocidal product family BPF\_Iodine\_VET (OJ L 283, 5.11.2019, p. 1).

<sup>(3)</sup> Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p. 4).

<sup>(4)</sup> ECHA opinion of 9 June 2020 on the administrative change of the Union authorisation of the biocidal product family 'BPF\_Iodine\_VET', [https://echa.europa.eu/documents/10162/22836226/opinion\\_for\\_ua-admin\\_changes\\_bc-vd058524-35\\_en.pdf/b95474e7-89d4-a601-8d02-b42d95ccede5](https://echa.europa.eu/documents/10162/22836226/opinion_for_ua-admin_changes_bc-vd058524-35_en.pdf/b95474e7-89d4-a601-8d02-b42d95ccede5)

HAS ADOPTED THIS REGULATION:

*Article 1*

The Annex to Implementing Regulation (EU) 2019/1844 is replaced by the Annex to this Regulation.

*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, 7 June 2021.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## 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          | 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 authorisation             | 31 October 2029  |  |

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

|                                 |  |
|---------------------------------|--|
| Name of manufacturer            | THESEO Deutschland GmbH                      |
| 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            | 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 Química y Minera SA   |
| Address of manufacturer         | Los Militares 4290, 7550000 Las Condes Chile   |
| Location of manufacturing sites | Nueva Victoria, 1180000 Pozo Almonte Chile<br>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 | Trihydroxi-dooxidophosphorus 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<br>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   | Trihydroxi-dooxidophosphorus 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.<br>Absorb spillage to prevent material damage.<br>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<br>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:<br>During lactation period: <ul style="list-style-type: none"> <li>• manual: 2 applications per day (post-milking)</li> <li>• automated: 3 applications per day (post-milking)</li> </ul> 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<br>Jerry can HDPE: 5 – 60 liters<br>Drum HDPE: 200 liters<br>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 <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).

<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.

**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 1****7.1. Trade name(s), authorisation number and specific composition of each individual product**

|                      |   |                  |            |           |             |
|----------------------|---|------------------|------------|-----------|-------------|
| Trade name(s)        | FINK – Io Spray 15<br>FINK – Euter-DIP PVP-S<br>FINK Pattedyp PVP<br>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**

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

**1.3. Product type(s)**

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

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

| Common name   | IUPAC name  | Function             | CAS number | EC number | Content (%) |     |
|---|---|----------------------|------------|-----------|-------------|-----|
|   |   |                      |            |           | Min         | Max |
| Iodine  |   | Active Substance     | 7553-56-2  | 231-442-4 | 0,3         | 0,5 |
| Phosphoric Acid   | Trihydroxi-dooxidophosphorus 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 2**

|                |                       |
|----------------|-----------------------|
| Formulation(s) | AL – any other liquid |
|----------------|-----------------------|

### 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

|                          |   |
|--------------------------|---|
| Hazard statements        | May be corrosive to metals.<br>Harmful to aquatic life with long lasting effects.   |
| Precautionary statements | Keep only in original packaging.<br>Avoid release to the environment.<br>Absorb spillage to prevent material damage.<br>Store in corrosive resistant container with a resistant inner liner.<br>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<br>Yeasts  |
| Field(s) of use  | Indoor  |
| Application method(s)                                      | Open system: spray treatment<br>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<br>Application frequency:<br>During lactation period: <ul style="list-style-type: none"> <li>• manual: 2 applications per day (post-milking)</li> <li>• automated: 3 applications per day (post-milking)</li> </ul> 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<br>Jerry can HDPE: 5 – 60 liters<br>Drum HDPE: 200 liters<br>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 <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.

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.

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

#### 5.4. 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<br>ST-Io Spray<br>DESINTEC MH Iodine S<br>DESINTEC MH Raidip plus<br>Iodine Spray 3000<br>Iodine Spray<br>Io Spray 30<br>Iodine Spray 30 |                  |            |           |             |
| Authorisation number | EU-0020540-0002 1-2   |                  |            |           |             |
| Common 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<br>DESINTEC MH Raidip 5000<br>Iodine Spray 5000 |                  |            |           |             |
| Authorisation number | EU-0020540-0003 1-2  |                  |            |           |             |
| Common 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             | CAS number | EC number | Content (%) |     |
|---|---|----------------------|------------|-----------|-------------|-----|
|   |   |                      |            |           | Min         | Max |
| Iodine  |   | Active Substance     | 7553-56-2  | 231-442-4 | 0,5         | 0,5 |
| Phosphoric Acid   | Trihydroxi-dooxidophosphorus 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 3**

|                |                       |
|----------------|-----------------------|
| Formulation(s) | AL – any other liquid |
|----------------|-----------------------|

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

|                          |   |
|--------------------------|---|
| Hazard statements        | May be corrosive to metals.<br>Harmful to aquatic life with long lasting effects.   |
| Precautionary statements | Keep only in original packaging.<br>Avoid release to the environment.<br>Absorb spillage to prevent material damage.<br>Store in corrosive resistant container with a resistant inner liner.<br>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<br>Yeasts  |
| Field(s) of use  | Indoor  |
| Application method(s)                                      | Open system: spray treatment<br>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<br><br>Application frequency:<br>During lactation period: <ul style="list-style-type: none"> <li>• manual: 2 applications per day (post-milking)</li> <li>• automated: 3 applications per day (post-milking)</li> </ul> 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<br>Jerry can HDPE: 5 – 60 liters<br>Drum HDPE: 200 liters<br>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 <sup>(3)</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.

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>(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.

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 (Iodophor)<br>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   | Trihydroxi-dooxidophosphorus 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.<br>Absorb spillage to prevent material damage.<br>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<br>Yeasts   |
| Field(s) of use  | Indoor   |
| Application method(s)                                      | Open system: dip treatment<br>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<br>Application frequency:<br>During lactation period: <ul style="list-style-type: none"> <li>• 2 applications per day (post-milking)</li> </ul> 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<br>Jerry can HDPE: 5 – 60 liters<br>Drum HDPE: 200 liters<br>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 (\*) 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.

(\*) 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.

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 4

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

|                      |                                  |                  |            |           |             |
|----------------------|----------------------------------|------------------|------------|-----------|-------------|
| Trade name(s)        | FINK – Io Dip 10<br>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<br>DESINTEC MH Iodine Barrier<br>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 | 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   | Trihydroxi-dooxidophosphorus phosphoric acid                        | Non-active substance | 7664-38-2  | 231-633-2 | 0,35        | 0,4  |
| 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 5

|                |                       |
|----------------|-----------------------|
| Formulation(s) | AL – any other liquid |
|----------------|-----------------------|

## 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5

|                          |   |
|--------------------------|---|
| Hazard statements        | May be corrosive to metals.<br>Harmful to aquatic life with long lasting effects.   |
| Precautionary statements | Keep only in original packaging.<br>Avoid release to the environment.<br>Absorb spillage to prevent material damage.<br>Store in corrosive resistant container with a resistant inner liner.<br>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<br>Yeasts   |
| Field(s) of use                                  | Indoor   |
| Application method(s)                            | Open system: dip treatment<br>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<br>Application frequency:<br>During lactation period: <ul style="list-style-type: none"> <li>• 2 applications per day (post-milking)</li> </ul> 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<br>Jerry can HDPE: 5 – 60 liters<br>Drum HDPE: 200 liters<br>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 <sup>(5)</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.

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).

<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.

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 4500 ppm<br>IOFILMO SUPER<br>SUPERIO 4.5<br>PROTEGO 4500<br>TIGER 50<br>ASSOLUTO 5<br>REDFOX S<br>SUPER MANGUST<br>AUGUSTO P5<br>IO-DIN 45 |                      |            |           |             |
| 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      | Trihydroxi-dooxidophosphorus 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 3000 ppm<br>JODOFILM 75/3<br>IOFILMO<br>SUPERIO 3.0<br>PROTEGO 3000<br>TIGER 30<br>ASSOLUTO 3<br>REDFOX E<br>MANGUST<br>AUGUSTO P3<br>IO-DIN 30 |                      |            |           |             |
| 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      | Trihydroxi-dooxidophosphorus 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   | Trihydroxi-dooxidophosphorus 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.<br/> Harmful if swallowed.<br/> Causes severe skin burns and eye damage.<br/> Causes serious eye damage.<br/> May cause damage to thyroid gland through prolonged or repeated exposure.<br/> Harmful to aquatic life with long lasting effects.</p>   |
| Precautionary statements | <p>Keep only in original packaging.<br/> Do not breathe mist.<br/> Do not breathe spray.<br/> Avoid release to the environment.<br/> Wear protective gloves.<br/> Wear protective clothing.<br/> Wear face protection.<br/> IF ON SKIN (or hair): Take off immediately all contaminated clothing.<br/> Rinse skin with water.<br/> IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.<br/> Absorb spillage to prevent material damage.<br/> Store locked up.<br/> 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<br>Yeasts<br>Viruses   |
| Field(s) of use  | Indoor  |
| Application method(s)                                      | Open system: spray treatment<br>Disinfectant for hard surfaces in stables (excluding hatcheries).<br>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).<br>Application frequency per year:<br>Dairy cows: 1<br>Beef cattle: 1<br>Veal calves: 4<br>Sows, in individual pens: 5<br>Sows in groups: 5<br>Fattening pigs: 3<br>Laying hens in battery cages without treatment: 1<br>Laying hens in battery cages with aeration (belt drying): 1 |

|                                   |   |
|-----------------------------------|---|
|                                   | Laying hens in battery cages with forced drying (deep pit, high rise): 1<br>Laying hens in compact battery cages: 1<br>Laying hens in free range with litter floor (partly litter floor, partly slatted): 1<br>Broilers in free range with litter floor: 7<br>Laying hens in free range with grating floor (aviery system): 1<br>Parent broilers in free range with grating floor: 1<br>Parent broilers in rearing with grating floor: 3<br>Turkeys in free range with litter floor: 2<br>Ducks in free range with litter floor: 13<br>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<br>Jerry can HDPE: 5 – 60 liters<br>Drum HDPE: 200 liters<br>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 <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.

<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.

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.

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 6

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

|  |   |                      |            |           |             |
|--|---|----------------------|------------|-----------|-------------|
| Trade name(s)  | IODOSAN 30<br>IODOSAN<br>JODAT<br>DESINTEC FL-JODES<br>ROTIE-SOL J<br>Disinfect Jod<br>FINK – Jodophos 15<br>Jod-Reiniger sauer<br>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  | Trihydroxi-dooxidophosphorus 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.<br/> Harmful if swallowed.<br/> Causes severe skin burns and eye damage.<br/> Causes serious eye damage.<br/> May cause damage to thyroid gland through prolonged or repeated exposure.<br/> Toxic to aquatic life with long lasting effects.</p>   |
| Precautionary statements | <p>Keep only in original packaging.<br/> Do not breathe mist.<br/> Do not breathe spray.<br/> Avoid release to the environment.<br/> Wear protective gloves.<br/> Wear protective clothing.<br/> Wear face protection.<br/> IF ON SKIN (or hair): Take off immediately all contaminated clothing.<br/> Rinse skin with water.<br/> IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.<br/> Absorb spillage to prevent material damage.<br/> Store locked up.<br/> 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<br>Yeasts<br>Viruses   |
| Field(s) of use  | Indoor  |
| Application method(s)                                      | Open system: spray treatment<br>Disinfectant for hard surfaces in stables (excluding hatcheries).<br>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).<br>Application frequency per year:<br>Dairy cows: 1<br>Beef cattle: 1<br>Veal calves: 4<br>Sows, in individual pens: 5<br>Sows in groups: 5<br>Fattening pigs: 3<br>Laying hens in battery cages without treatment: 1<br>Laying hens in battery cages with aeration (belt drying): 1<br>Laying hens in battery cages with forced drying (deep pit, high rise): 1<br>Laying hens in compact battery cages: 1<br>Laying hens in free range with litter floor (partly litter floor, partly slatted): 1<br>Broilers in free range with litter floor: 7<br>Laying hens in free range with grating floor (aviary system): 1<br>Parent broilers in free range with grating floor: 1<br>Parent broilers in rearing with grating floor: 3<br>Turkeys in free range with litter floor: 2<br>Ducks in free range with litter floor: 13<br>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<br>Jerry can HDPE: 5 – 60 liters<br>Drum HDPE: 200 liters<br>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 <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 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.

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.

(7) 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.

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<br>YODO CONTROL<br>YODIVEN                          |                      |            |           |             |
| Authorisation number  | EU-0020540-0011 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-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 | 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  | Trihydroxi-dooxidophosphorus 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.</p> <p>Causes severe skin burns and eye damage.</p> <p>Causes serious eye damage.</p> <p>May cause damage to thyroid gland through prolonged or repeated exposure.</p> <p>Harmful to aquatic life with long lasting effects.</p> |
|-------------------|---|

|                          |   |
|--------------------------|---|
| Precautionary statements | <p>Keep only in original packaging.<br/>         Do not breathe mist.<br/>         Do not breathe spray.<br/>         Avoid release to the environment.<br/>         Wear protective gloves.<br/>         Wear protective clothing.<br/>         Wear face protection.<br/>         IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.<br/>         IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.<br/>         Absorb spillage to prevent material damage.<br/>         Store locked up.<br/>         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<br>Yeasts<br>Viruses  |
| Field(s) of use  | Indoor   |
| Application method(s)                                      | Open system: spray treatment<br>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                          | <p>100 mL/m<sup>2</sup> – Concentration of Iodine in application solution: 750 ppm (0,075 %w/w).<br/>         Application frequency per year:</p> <p>Dairy cows: 1<br/>         Beef cattle: 1<br/>         Veal calves: 4<br/>         Sows, in individual pens: 5<br/>         Sows in groups: 5<br/>         Fattening pigs: 3<br/>         Laying hens in battery cages without treatment: 1<br/>         Laying hens in battery cages with aeration (belt drying): 1<br/>         Laying hens in battery cages with forced drying (deep pit, high rise): 1<br/>         Laying hens in compact battery cages: 1<br/>         Laying hens in free range with litter floor (partly litter floor, partly slatted): 1</p> |

|                                   |  |
|-----------------------------------|--|
|                                   | Broilers in free range with litter floor: 7<br>Laying hens in free range with grating floor (aviery system): 1<br>Parent broilers in free range with grating floor: 1<br>Parent broilers in rearing with grating floor: 3<br>Turkeys in free range with litter floor: 2<br>Ducks in free range with litter floor: 13<br>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<br>Jerry can HDPE: 5 – 60 liters<br>Drum HDPE: 200 liters<br>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 <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.

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.

<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.

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 Substance     | 7553-56-2  | 231-442-4 | 1,5         |
| Phosphoric Acid   | Trihydroxi-dooxidophosphorus phosphoric acid                       | Non-active substance | 7664-38-2  | 231-633-2 | 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        |