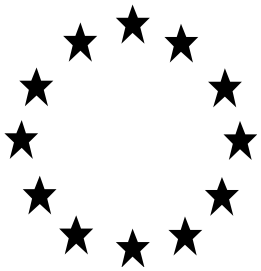
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

# PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FAMILY FOR UNION AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



Product Family "BPF_Iodine_VET"

Product type 3

Iodine as included in the Union list of approved active substances

Case Number in R4BP: BC-XJ019074-33

Evaluating Competent Authority: eCA Austria

Date: **10/05/2019** (**Final PAR, redacted**)

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# 1 CONCLUSION

## 1.1 Final

The outcome of the assessment for BPF_Iodine_VET is specified in the BPC opinion following discussions at the BPC-29 meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website.

## 1.2 Draft BPC Opinion:

*See separate document*

# 2 ASSESSMENT REPORT

## 2.1 Summary of the product assessment

### 2.1.1 Administrative information

2.1.1.1 Identifier of the product family

| **Identifier** | **Country (if relevant)** |
|---|---|
| BPF_Iodine_VET | EU |

2.1.1.2 Authorisation holder

| | | |
|---|---|---|
| **Name and address of the authorisation holder** | **Name** | Applied Biocide GmbH |
| | **Address** | Siemensstraße 42, 59199 Bönen, Germany |
| **Pre-submission phase started on** | 2015-02-18 | |
| **Pre-submission phase concluded on** | 2015-05-12 | |
| **Authorisation number** | | |
| **Date of the authorisation** | | |
| **Expiry date of the authorisation** | | |

2.1.1.3 Manufacturers of the products of the family

| | |
|---|---|
| **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** | Ewabo Chemikalien GmbH & Co KG |
| **Address of manufacturer** | Kolpingstrasse 4, 49835 Wietmarschen, Germany |
| **Location of manufacturing sites** | Kolpingstrasse 4, 49835 Wietmarschen, Germany |

| | |
|---|---|
| **Name of manufacturer** | IRCASERVICE |
| **Address of manufacturer** | S.S. Cremasca 591 no. 10, 24040 Fornovo S. Giovanni (BG), Italy |
| **Location of manufacturing sites** | S.S. Cremasca 591 no. 10, 24040 Fornovo S. Giovanni (BG), Italy |

| | |
|---|---|
| **Name of manufacturer** | Laboratorios Maymo SA |
| **Address of manufacturer** | Via Augusta, 302, 08017 Barcelona, Spain |
| **Location of manufacturing sites** | Via Augusta, 302, 08017 Barcelona, Spain |

### 2.1.1.4 Manufacturer of the active substance

All manufacturing sites for the active substance as reported in the CAR prepared by SE are located in Chile, stating only the plant's names, but no addresses of the production sites itself.

In the following the sources used by FINK TEC GmbH for purchasing Iodine are listed by the plant's names and their respective office addresses:

| | |
|---|---|
| **Active substance** | Iodine |
| **Name of manufacturer** | Cosayach S.A. Compania de Salitre y Yodo |
| **Address of manufacturer** | Amunátegui 178, 7th Floor<br>8320000 Santiago<br>Chile |
| **Location of manufacturing sites** | S.C.M. Cosayach Cala Cala<br>1180000 Pozo Almonte<br>Chile |

| | |
|---|---|
| **Active substance** | Iodine |
| **Name of manufacturer** | ACF Minera S.A. |
| **Address of manufacturer** | San Martin 499<br>1100000 Iquique<br>Chile |
| **Location of manufacturing sites** | Lagunas mine<br>1180000 Pozo Almonte<br>Chile |

| | |
|---|---|
| **Active substance** | Iodine |
| **Name of manufacturer** | Sociedad Quimica y Minera SA |
| **Address of manufacturer** | Los Militares 4290<br>7550000 Las Condes<br>Chile |
| **Location of manufacturing sites** | Nueva Victoria<br>1180000 Pozo Almonte<br>Chile<br><br>Pedro de Valdivia<br>1240000 Antofagasta<br>Chile |

### 2.1.2 Product family composition and formulation

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

#### 2.1.2.1 Identity of the active substance

| Main constituent(s) | |
|---|---|
| **ISO name** | Iodine |
| **IUPAC or EC name** | Iodine |
| **EC number** | 231-442-4 |
| **CAS number** | 7553-56-2 |
| **Index number in Annex VI of CLP** | 053-0014-00-3 |
| **Minimum purity / content** | min. 995 g/kg (manufactured to the specification of Ph. Eur) |
| **Structural formula** | I-I |

Note: Iodine is the active substance for each family member. The family includes Iodine in the form of two types of complexes (iodophores), PVP-Iodine (type 2) and surfactant stabilised Iodine (type 1).

#### 2.1.2.2 Candidate(s) for substitution

The active substance Iodine contained in the biocidal products of the family is no candidate for substitution. A comprehensive PBT assessment for the active substance Iodine is not necessary, for further details see Assessment Report for Iodine (Sweden 2013).

### 2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product family

The full composition of the biocidal product family and the individual products within the family is provided in the confidential annex.

LEVEL 1 - Biocidal product family "BPF_Iodine_VET"

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
|---|---|---|---|---|---|---|
| | | | | | **Min** | **Max** |
| Iodine | Iodine | Active substance | 7553-56-2 | 231-442-4 | 0.10 | 3.0 |
| Phosphoric acid 75% | trihydroxidooxidophosphorus phosphoric acid | pH Regulation<br><br>Substance of concern | 7664-38-2 | 231-633-2 | 0 | 10 |
| Poly(oxy-1,2-ethandiyl).alpha.-tridecyl-.omega.-hydoxy-,branched | Poly(oxy-1,2-ethandiyl).alpha.-tridecyl-.omega.-hydoxy-,branched | Solubilizing agent<br><br>Substance of concern | 69011-36-5 | 500-241-6 | 0 | 31.8 |
| Isotridecanol, ethoxylated 90%, C 9-11 Alcohol Ethoxylate | Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate | Solubilizing agent<br><br>Substance of concern | 68439-46-3 | 614-482-0 | 0 | 31.8 |

LEVEL 2 - meta SPC 1: PT03 - Veterinary hygiene / Ready-to-use teat spray

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) | |
|---|---|---|---|---|---|---|
| | | | | | Min | Max |
| Iodine | Iodine | Active substance | 7553-56-2 | 231-442-4 | 0.15 | 0.15 |

LEVEL 2 - meta SPC 2: PT03 - Veterinary hygiene / Ready-to-use teat spray

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) | |
|---|---|---|---|---|---|---|
| | | | | | Min | Max |
| Iodine | Iodine | Active substance | 7553-56-2 | 231-442-4 | 0.3 | 0.5 |

LEVEL 2 - meta SPC 3: PT03 - Veterinary hygiene / Ready-to-use teat spray

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) | |
|---|---|---|---|---|---|---|
| | | | | | Min | Max |
| Iodine | Iodine | Active substance | 7553-56-2 | 231-442-4 | 0.5 | 0.5 |

LEVEL 2 - meta SPC 4: PT03 - Veterinary hygiene / Ready-to-use teat dip

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) | |
|---|---|---|---|---|---|---|
| | | | | | Min | Max |
| Iodine | Iodine | Active substance | 7553-56-2 | 231-442-4 | 0.10 | 0.15 |

LEVEL 2 - meta SPC 5: PT03 - Veterinary hygiene / Ready-to-use teat dip

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) | |
|---|---|---|---|---|---|---|
| | | | | | Min | Max |
| Iodine | Iodine | Active substance | 7553-56-2 | 231-442-4 | 0.3 | 0.45 |
| Phosphoric acid 75% | trihydroxidooxidophosphorus<br>phosphoric acid | pH Regulation<br><br>Substance of concern | 7664-38-2 | 231-633-2 | 0.35 | 0.4 |

LEVEL 2 - meta SPC 6: PT03 - Veterinary hygiene / Surface disinfection in animal houses

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) | |
|---|---|---|---|---|---|---|
| | | | | | Min | Max |
| Iodine | Iodine | Active substance | 7553-56-2 | 231-442-4 | 1.75 | 2.4 |
| Phosphoric acid 75% | trihydroxido oxidophosphorus phosphoric acid | pH Regulation<br><br>Substance of concern | 7664-38-2 | 231-633-2 | 3 | 10 |
| Poly(oxy-1,2-ethandiyl).alpha.-tridecyl-.omega.-hydoxy-,branched | Poly(oxy-1,2-ethandiyl).alpha.-tridecyl-.omega.-hydoxy-,branched | Solubilizing agent (Substance of concern) | 69011-36-5 | 500-241-6 | Grouping concept applies. Both substances can only be used alter-natively. The content of solubilizing agents in the formulation should be in the range of<br><br>25.6 – 31.8 | |
| Isotridecanol, ethoxylated 90%, C 9-11 Alcohol Ethoxylate | Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate | Solubilizing agent (Substance of concern) | 68439-46-3 | 614-482-0 | | |

LEVEL 2 - meta SPC 7: PT03 - Veterinary hygiene / Surface disinfection in animal houses

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) | |
|---|---|---|---|---|---|---|
| | | | | | Min | Max |
| Iodine | Iodine | Active substance | 7553-56-2 | 231-442-4 | 3.0 | 3.0 |
| Phosphoric acid 75% | trihydroxidooxidophosphorus phosphoric acid | pH Regulation (Substance of concern) | 7664-38-2 | 231-633-2 | 10 | 10 |
| Poly(oxy-1,2-ethandiyl).alpha.-tridecyl-.omega.-hydoxy-,branched | Poly(oxy-1,2-ethandiyl).alpha.-tridecyl-.omega.-hydoxy-,branched | Solubilizing agent (Substance of concern) | 69011-36-5 | 500-241-6 | 31.8 | 31.8 |

LEVEL 2 - meta SPC 8: PT03 - Veterinary hygiene / Surface disinfection in animal houses

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
|---|---|---|---|---|---|---|
| | | | | | **Min** | **Max** |
| Iodine | Iodine | Active substance | 7553-56-2 | 231-442-4 | 1.5 | 1.5 |
| Phosphoric acid 75% | trihydroxidooxidophosphorus phosphoric acid | pH Regulation (Substance of concern) | 7664-38-2 | 231-633-2 | 3 | 3 |
| Poly(oxy-1,2-ethandiyl).alpha.-tridecyl-.omega.-hydoxy-,branched | Poly(oxy-1,2-ethandiyl).alpha.-tridecyl-.omega.-hydoxy-,branched | Solubilizing agent (Substance of concern) | 69011-36-5 | 500-241-6 | 18 | 18 |

### 2.1.2.4 Information on technical equivalence

The active substance supplier FINK TEC GmbH is a member of the Iodine Registration Group (IRG). [redacted]

The Iodine used for product formulation complies with the minimum purity of 995 g/kg Iodine as set by Reg. (EU) No 94/2014 approving Iodine (including PVP-Iodine) as an existing active substance. All sources applied for are approved. For details please refer to the respective paragraph on active substance manufacturers.

### 2.1.2.5 Information on the substances of concern

The biodical product family BPF_Iodine_VET does not contain any co-formulants meeting the conditions for the environment mentioned under Article 3(f) of Regulation (EU) No 528/2012, or the criteria specified under "Other grounds of concern", see ECHA, 2017c, chapter 8.
For human health, three substances of concern were identified:

- Phosphoric acid 75%,
- Poly(oxy-1,2-ethandiyl).alpha.-tridecyl-.omega.-hydoxy-,branched
- Isotridecanol, ethoxylated 90%

Please see confidential annex for further details.

### Assessment of endocrine-disrupting (ED) properties of the co-formulants in the BPF_Iodine_VET

Regarding ED indications of the co-formulants contained in the BPF_Iodine_VET they were screened for CMR and STOT properties based on data for harmonised classification in the C&L inventory and the submitted SDS by the applicant. No CMR or STOT classification was identified. Furthermore none of the substances is listed in the PACT and ED assessment list. Based on the available information none of the co-formulants are substances of concern due to an ED related issue.

### 2.1.2.6 Type of formulation

| |
|---|
| meta SPC 1-5: AL - any other liquid<br>meta SPC 6-8: SL - soluble concentrate |

### 2.1.3 Hazard and precautionary statements

**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

**LEVEL 2 - meta SPC 1: PT 3 - Veterinary hygiene / Teat spray**

| **Classification** | |
|---|---|
| Hazard category | Met. Corr. 1 |
| Hazard statement | H290: May be corrosive to metals |
| | |
| **Labelling** | |
| Signal words | Warning |
| Pictogram | - |
| Hazard statements | H290 May be corrosive to metals |
| Precautionary statements | P234 Keep only in original packaging.<br>P390 Absorb spillage to prevent material damage.<br>P406 Store in corrosive resistant container with a resistant inner liner. |
| | |
| Note | - |

**LEVEL 2 - meta SPC 2: PT 3 - Veterinary hygiene / Teat spray**

| **Classification** | |
|---|---|
| Hazard category | Met. Corr. 1<br>Aquatic Chronic 3 |
| Hazard statement | H290: May be corrosive to metals<br>H412: Harmful to aquatic life with long-lasting effects |
| | |
| **Labelling** | |
| Signal words | Warning |
| Pictogram | - |
| Hazard statements | H290 May be corrosive to metals<br>H412 Harmful to aquatic life with long-lasting effects |
| Precautionary statements | P234 Keep only in original packaging.<br>P273 Avoid release to the environment<br>P390 Absorb spillage to prevent material damage.<br>P406 Store in corrosive resistant container with a resistant inner liner.<br>P501 Dispose of contents/container in accordance to local/national regulations. |
| | |
| Note | - |

**LEVEL 2 - meta SPC 3: PT 3 - Veterinary hygiene / Teat spray**

| | |
|---|---|
| **Classification** | |
| Hazard category | Met. Corr. 1<br>Aquatic Chronic 3 |
| Hazard statement | H290: May be corrosive to metals<br>H412: Harmful to aquatic life with long-lasting effects |
| | |
| **Labelling** | |
| Signal words | Warning |
| Pictogram | - |
| Hazard statements | H290 May be corrosive to metals<br>H412 Harmful to aquatic life with long-lasting effects |
| Precautionary statements | P234 Keep only in original packaging.<br>P273 Avoid release to the environment.<br>P390 Absorb spillage to prevent material damage.<br>P406 Store in corrosive resistant container with a resistant inner liner.<br>P501 Dispose of contents/container in accordance to local/national regulations. |
| | |
| Note | - |

**LEVEL 2 - meta SPC 4: PT 3 - Veterinary hygiene / Teat dipping**

| | |
|---|---|
| **Classification** | |
| Hazard category | Met. Corr. 1 |
| Hazard statement | H290: May be corrosive to metals |
| | |
| **Labelling** | |
| Signal words | Warning |
| Pictogram | - |
| Hazard statements | H290 May be corrosive to metals |
| Precautionary statements | P234 Keep only in original packaging.<br>P390 Absorb spillage to prevent material damage.<br>P406 Store in corrosive resistant container with a resistant inner liner. |
| | |
| Note | **-** |

**LEVEL 2 - meta SPC 5: PT 3 - Veterinary hygiene / Teat dipping**

| | |
|---|---|
| **Classification** | |
| Hazard category | Met. Corr. 1<br>Aquatic Chronic 3 |
| Hazard statement | H290: May be corrosive to metals<br>H412: Harmful to aquatic life with long-lasting effects |
| | |
| **Labelling** | |
| Signal words | Warning |
| Pictogram | - |
| Hazard statements | H290 May be corrosive to metals<br>H412 Harmful to aquatic life with long-lasting effects |
| Precautionary statements | P234 Keep only in original packaging.<br>P273 Avoid release to the environment.<br>P390 Absorb spillage to prevent material damage.<br>P406 Store in corrosive resistant container with a resistant inner liner.<br>P501 Dispose of contents/container in accordance to local/national regulations. |
| | |
| Note | - |

**LEVEL 2 - meta SPC 6: PT 3 - Veterinary hygiene / Animal housing surface disinfection**

| **Classification** | |
|---|---|
| Hazard category | Met. Corr. 1<br>Acute Tox 4<br>Skin Corr. 1<br>Eye dam. 1<br>STOT RE 2<br>Aquatic Chronic 3 |
| Hazard statement | H290: May be corrosive to metals<br>H302: Harmful if swallowed<br>H314: Causes severe skin burns and eye damage<br>H318: Causes serious eye damage<br>H373: May cause damage to organs through prolonged or repeated exposure (thyroid gland)<br>H412: Harmful to aquatic life with long-lasting effects |
| | |
| **Labelling** | |
| Signal words | Danger |
| Pictogram | GHS05<br>GHS07<br>GHS08 |
| Hazard statements | H290 May be corrosive to metals<br>H302 Harmful if swallowed<br>H314 Causes severe skin burns and eye damage<br>H373 May cause damage to organs through prolonged or repeated exposure (thyroid gland)<br>H412 Harmful to aquatic life with long-lasting effects |
| Precautionary statements | P234 Keep only in original packaging.<br>P260 Do not breathe mist/spray.<br>P273 Avoid release to the environment.<br>P280 Wear protective gloves/protective clothing/face protection.<br>P303+P361+P353: IF ON SKIN (or hair) Remove / Take off immediately all contaminated clothing. Rinse skin with water.<br>P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.<br>P390 Absorb spillage to prevent material damage.<br>P405+102: Store locked up. Keep out of reach of children. |
| | |
| Note | - |

**LEVEL 2 - meta SPC 7: PT 3 - Veterinary hygiene / Animal housing surface disinfection**

| **Classification** | |
|---|---|
| Hazard category | Met. Corr. 1<br>Acute Tox 4<br>Skin Corr. 1<br>Eye dam. 1<br>STOT RE 2<br>Aquatic Chronic 2 |
| Hazard statement | H290: May be corrosive to metals<br>H302: Harmful if swallowed<br>H314: Causes severe skin burns and eye damage<br>H318: Causes serious eye damage<br>H373: May cause damage to organs through prolonged or repeated exposure (thyroid gland)<br>H411: Toxic to aquatic life with long lasting effects |
| | |
| **Labelling** | |
| Signal words | Danger |
| Pictogram | GHS05<br>GHS07<br>GHS08<br>GHS09 |
| Hazard statements | H290 May be corrosive to metals<br>H302 Harmful if swallowed<br>H314 Causes severe skin burns and eye damage<br>H373 May cause damage to organs through prolonged or repeated exposure (thyroid gland)<br>H411 Toxic to aquatic life with long lasting effects |
| Precautionary statements | P234 Keep only in original packaging.<br>P260 Do not breathe mist/spray.<br>P273 Avoid release to the environment.<br>P280 Wear protective gloves/protective clothing/face protection.<br>P303+P361+P353: IF ON SKIN (or hair) Remove / Take off immediately all contaminated clothing. Rinse skin with water.<br>P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.<br>P390 Absorb spillage to prevent material damage.<br>P405+102: Store locked up. Keep out of reach of children. |
| | |
| Note | - |

**LEVEL 2 - meta SPC 8: PT 3 - Veterinary hygiene / Animal housing surface disinfection**

| **Classification** | |
|---|---|
| Hazard category | Met. Corr. 1<br>Eye dam. 1<br>Skin corr. 1<br>STOT RE 2<br>Aquatic Chronic 3 |
| Hazard statement | H290: May be corrosive to metals<br>H314: Causes severe skin burns and eye damage<br>H318: Causes serious eye damage<br>H373: May cause damage to organs (thyroid gland) through prolonged or repeated exposure.<br>H412: Harmful to aquatic life with long-lasting effects |
| | |
| **Labelling** | |
| Signal words | Danger |
| Pictogram | GHS05<br>GHS08 |
| Hazard statements | H290 May be corrosive to metals<br>H314 Causes severe skin burns and eye damage<br>H373 May cause damage to organs (thyroid gland) through prolonged or repeated exposure<br>H412 Harmful to aquatic life with long-lasting effects |
| Precautionary statements | P234 Keep only in original packaging.<br>P260 Do not breathe mist/spray.<br>P273 Avoid release to the environment.<br>P280 Wear protective gloves/protective clothing/face protection.<br>P303+P361+P353: IF ON SKIN (or hair) Remove / Take off immediately all contaminated clothing. Rinse skin with water.<br>P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.<br>P390 Absorb spillage to prevent material damage.<br>P405+102: Store locked up. Keep out of reach of children. |
| | |
| Note | - |

## 2.1.4 Authorised uses

2.1.4.1 Meta SPC 1, Use # 1

Use description
Table 1. Use # 1: Veterinary hygiene - animal husbandry - teat disinfectant - professional - indoors – spraying (post milking)

| | |
|---|---|
| **Product Type** | 3 (Veterinary hygiene) |
| **Where relevant, an exact description of the authorised use** | --- |
| **Target organism (including development stage)** | Bacteria, yeasts |
| **Field of use** | Indoor |
| **Application method(s)** | 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 animal<br><br>Dilution: 0%<br><br>Application frequency:<br>During lactation period:<br>• manual: 2 applications per day (post-milking)<br>• automated: 3 applications per day (post-milking)<br>During dry period: 1 application per day |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Please see the relevant section. |

Use-specific instructions for use

| |
|---|
| |

Use-specific risk mitigation measures

| |
|---|
| --- |

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

| |
|---|
| --- |

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

| |
|---|
| --- |

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

| |
|---|
| --- |

2.1.4.2 Meta SPC 2, Use # 1

Use description
Table 2. Use # 1: Veterinary hygiene - animal husbandry - teat disinfectant - professional - indoors – spraying (post milking)

| | |
|---|---|
| **Product Type** | 3 (Veterinary hygiene) |
| **Where relevant, an exact description of the authorised use** | --- |
| **Target organism (including development stage)** | Bacteria, yeasts |
| **Field of use** | Indoor |
| **Application method(s)** | 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>Dilution: 0%<br><br>Application frequency:<br>During lactation period:<br>• manual: 2 applications per day (post-milking)<br>• automated: 3 applications per day (post-milking)<br>During dry period: 1 application per day |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Please see the relevant section. |

Use-specific instructions for use

| |
|---|
| --- |

Use-specific risk mitigation measures

| |
|---|
| --- |

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

| |
|---|
| --- |

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

| |
|---|
| --- |

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

| |
|---|
| --- |

2.1.4.3 Meta SPC 3, Use # 1

Use description
Table 3. Use # 1: Veterinary hygiene - animal husbandry - teat disinfectant - professional - indoors – spraying (post milking)

| | |
|---|---|
| **Product Type** | 3 (Veterinary hygiene) |
| **Where relevant, an exact description of the authorised use** | --- |
| **Target organism (including development stage)** | Bacteria, yeasts |
| **Field of use** | Indoor |
| **Application method(s)** | 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>Dilution: 0%<br><br>Application frequency:<br>During lactation period:<br>• manual: 2 applications per day (post-milking)<br>• automated: 3 applications per day (post-milking)<br>During dry period: 1 application per day |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Please see the relevant section. |

Use-specific instructions for use

---

Use-specific risk mitigation measures

---

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

---

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

---

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

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2.1.4.4 Meta SPC 4, Use # 1

Use description

Table 4. Use # 1: Veterinary hygiene - animal husbandry - teat disinfectant - professional - indoors – dipping (post milking)

| | |
|---|---|
| **Product Type** | 3 (Veterinary hygiene) |
| **Where relevant, an exact description of the authorised use** | --- |
| **Target organism (including development stage)** | Bacteria, yeasts |
| **Field of use** | Indoor |
| **Application method(s)** | 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><br>Dilution: 0%<br><br>Application frequency:<br>During lactation period:<br>• 2 applications per day (post-milking)<br>During dry period: 1 application per day |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Please see the relevant section. |

Use-specific instructions for use

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Use-specific risk mitigation measures

---

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

---

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

---

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

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2.1.4.5 Meta SPC 5, Use # 1

Use description

Table 5. Use # 1: Veterinary hygiene - animal husbandry - teat disinfectant - professional - indoors – dipping (post milking)

| | |
|---|---|
| **Product Type** | 3 (Veterinary hygiene) |
| **Where relevant, an exact description of the authorised use** | --- |
| **Target organism (including development stage)** | Bacteria, yeasts |
| **Field of use** | Indoor |
| **Application method(s)** | 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><br>Dilution: 0%<br><br>Application frequency:<br>During lactation period:<br>• 2 applications per day (post-milking)<br>During dry period: 1 application per day |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Please see the relevant section. |

Use-specific instructions for use

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Use-specific risk mitigation measures

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

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

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

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2.1.4.6 Meta SPC 6, Use # 1

Use description
Table 6. Use # 1: Veterinary hygiene - animal husbandry – hard surface disinfectant - professional - indoors - spraying

| | |
|---|---|
| **Product Type** | 3 (Veterinary hygiene) |
| **Where relevant, an exact description of the authorised use** | --- |
| **Target organism (including development stage)** | Bacteria, yeasts, viruses |
| **Field of use** | Indoor |
| **Application method(s)** | 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** | Application rate: 100 mL/$m^2$<br><br>Dilution:<br>Concentration of Iodine in application solution:<br>750 ppm (0.075%w/w).<br><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 (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** | Please see the relevant section. |

Use-specific instructions for use

| |
|---|
| Iodosan 30: Mix 29 mL product with 971 mL water to obtain 1 L application solution.<br>Iodosan 18: Mix 40 mL product with 960 mL water to obtain 1 L application solution. |

Use-specific risk mitigation measures

| |
|---|
| --- |

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

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| --- |

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

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| --- |

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

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| --- |

2.1.4.7 Meta SPC 7, Use # 1

Use description
Table 7. Use # 1: Veterinary hygiene - animal husbandry – hard surface disinfectant - professional - indoors - spraying

| | |
|---|---|
| **Product Type** | 3 (Veterinary hygiene) |
| **Where relevant, an exact description of the authorised use** | --- |
| **Target organism (including development stage)** | Bacteria, yeasts, viruses |
| **Field of use** | Indoor |
| **Application method(s)** | 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** | Application rate: 100 mL/$m^2$<br><br>Dilution:<br>Concentration of Iodine in application solution:<br>750 ppm (0.075%w/w).<br><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 (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** | Please see the relevant section. |

Use-specific instructions for use

| |
|---|
| Iodosan 30 plus: Mix 23 mL product with 977 mL water to obtain 1 L application solution. |

Use-specific risk mitigation measures

| |
|---|
| --- |

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

| |
|---|
| --- |

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

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| --- |

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

| |
|---|
| --- |

### 2.1.4.8 Meta SPC 8, Use # 1

Use description

Table 8. Use # 1: Veterinary hygiene - animal husbandry – hard surface disinfectant - professional - indoors - spraying

| | |
|---|---|
| **Product Type** | 3 (Veterinary hygiene) |
| **Where relevant, an exact description of the authorised use** | --- |
| **Target organism (including development stage)** | Bacteria, yeasts, viruses |
| **Field of use** | Indoor |
| **Application method(s)** | 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** | Application rate: 100 mL/$m^2$<br><br>Dilution:<br>Concentration of Iodine in application solution:<br>750 ppm (0.075%w/w).<br><br>Application frequency per year:<br>Dairy cows: 1<br>Beef cattle: 1 |

| | |
|---|---|
| | 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 (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** | Please see the relevant section. |

Use-specific instructions for use

| |
|---|
| Iodosan 15: Mix 46 mL product with 954 mL water to obtain 1 L application solution. |

Use-specific risk mitigation measures

| |
|---|
| --- |

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

| |
|---|
| --- |

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

| |
|---|
| --- |

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

| |
|---|
| --- |

## 2.1.5 General directions for use

2.1.5.1 Meta SPC 1 - for use # 1

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

Instructions for use

| |
|---|
| Always read the label or leaflet before use and follow all the instructions provided.<br><br>The product must be brought to a temperature above 20°C before use.<br><br>Teats should be cleaned before milking.<br><br>The use of a dosing pump for filling the product into the application equipment is recommended.<br><br>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.<br><br>Keep the cows standing until the product has dried (at least 5 minutes).<br><br>Product can be applied manually or by means of automatic teat sprayer.<br><br>Before the next milking the teats have to be cleaned, preferably with one new wet cloth per cow.<br><br>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). |

Risk mitigation measures

| |
|---|
| Keep out of reach of children.<br><br>Wear protective chemical resistant gloves, coated coverall and boots during product handling and application phase (material to be specified by the authorisation holder within the product information).<br><br>In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing Iodine has to be considered for pre-milking disinfection. |

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.<br>After skin contact: Wash skin thoroughly.<br>After eye contact: Rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.<br>After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.<br>When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here]. |

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

Instructions for 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.

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

2.1.5.2 Meta SPC 2 - for use # 1

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

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.

Teats should be cleaned before milking.

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).

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 within the product information).

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

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

After inhalation: Supply fresh air; consult doctor in case of complaints.
After skin contact: Wash skin thoroughly.
After eye contact: Rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.
After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.
When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

Environmental emergency measures: Inform the relevant authorities if the product has

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

Instructions for 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.

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

2.1.5.3 Meta SPC 3 - for use # 1

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

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.

Teats should be cleaned before milking.

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).

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 within the product information).

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

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

After inhalation: Supply fresh air; consult doctor in case of complaints.
After skin contact: Wash skin thoroughly.
After eye contact: Rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.
After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.
When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

Environmental emergency measures: Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent

malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

Instructions for 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.

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

2.1.5.4 Meta SPC 4 - for use # 1

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

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.

Teats should be cleaned before milking.

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).

Risk mitigation measures

Keep out of reach of children.

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

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

After inhalation: Supply fresh air; consult doctor in case of complaints.
After skin contact: Wash skin thoroughly.
After eye contact: Rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.
After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.
When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

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

Instructions for 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.<br>European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29. |

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.<br><br>Shelf-life: 12 months in HDPE |

2.1.5.5 Meta SPC 5 - for use # 1

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

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.

Teats should be cleaned before milking.

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).

Risk mitigation measures

Keep out of reach of children.

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

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

After inhalation: Supply fresh air; consult doctor in case of complaints.
After skin contact: Wash skin thoroughly.
After eye contact: Rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.
After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.
When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

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

Instructions for 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.<br>European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29. |

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.<br><br>Shelf-life: 12 months in HDPE |

2.1.5.6 Meta SPC 6 - for use # 1

Use # 3: Veterinary hygiene - animal husbandry – hard surface disinfectant - professional - indoors - spraying

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 m² 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.

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 within 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 within 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.

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.

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.

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

2.1.5.7 Meta SPC 7 - for use # 1

Use # 3: Veterinary hygiene - animal husbandry – hard surface disinfectant - professional - indoors - spraying

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 m² 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.

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 within 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 within 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.

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.

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.

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

2.1.5.8 Meta SPC 8 - for use # 1

Use # 3: Veterinary hygiene - animal husbandry – hard surface disinfectant - professional - indoors - spraying

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 m² 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.

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 within 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 within 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.

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.

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.

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

### 2.1.6 Other information

-

### 2.1.7 Packaging of the biocidal products

| Type of packaging | Size/volume of the packaging | Material of the packaging | Type and material of closure(s) | Intended user (e.g. professional, non-professional) | Compatibility of the product with the proposed packaging materials (Yes/No) |
|---|---|---|---|---|---|
| Bottle | 1 L | HDPE[1] | HDPE, PP[2] | professional | yes |
| Jerry can | 5 - 60 L | HDPE[1] | HDPE | professional | yes |
| Drum | 200 L | HDPE[1] | HDPE | Professional | yes |
| IBC | 600 L – 1000 L | HDPE[1] | HDPE | professional | yes |

[1]Note: All containers have to be made of opaque material because the products are sensitive to light.
[2] Cap is made of PP

### 2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new data on the active substaces and substance(s) of concern contained in the product have been submitted.

2.1.8.2 Access to documentation

Applicant is affiliate of data owner and has access to the data package on the basis of which the active substance Iodine was approved.

Applicant is data owner and has access to the data package on the basis of which the dossier for application for biocidal product family authorisation is submitted.

2.1.8.3 Similar conditions of use

The biocidal product family BPF_Iodine_VET is deemed to be eligible for Union authorisation.

(See "Outcome of the pre-submission consultation for union authorisation application under regulation (eu) no 528/2012", Helsinki, 12-05-2015, Communication number: d(2015)1854)

## 2.2 Assessment of the biocidal product (family)

### 2.2.1 Intended use(s) as applied for by the applicant

Intended use # 1 – Professional – indoors: Veterinary hygiene biocidal products – teat spray

| | |
|---|---|
| Product Type | PT03 |
| Where relevant, an exact description of the authorised use | Ready-to-use teat spray, post milking |
| Target organism (including development stage) | bactericidal, yeasticidal |
| Field of use | indoor |
| Application method(s) | Teat spraying |
| Application rate(s) and frequency | Application Concentration: 1500 - 5000 ppm Iodine<br>Lactation period: 2 application / day.<br>Dry period: 1 application / day<br>Application dose: 2 mL remaining on teats / cow; actual amount for dipping much higher (10-15 mL) |
| Category(ies) of users | professional |
| Pack sizes and packaging material | Packaging material: HDPE<br>1 L - 1000 L |

Intended use # 2 – Professional – indoors: Veterinary hygiene biocidal products – ready-to-use teat dip

| | |
|---|---|
| Product Type | PT03 |
| Where relevant, an exact description of the authorised use | Ready-to-use teat dip, post milking |
| Target organism (including development stage) | bactericidal, yeasticidal |
| Field of use | indoor |
| Application method(s) | Teat dipping |
| Application rate(s) and frequency | Application Concentration: 1000 - 5000 ppm Iodine<br>Lactation period: 2 application / day.<br>Dry period: 1 application / day<br>Application dose: 2 mL remaining on teats / cow; actual amount for dipping much higher (5-10 mL) |
| Category(ies) of users | professional |
| Pack sizes and packaging material | Packaging material: HDPE<br>1 L - 1000 L |

Intended use # 3 – Professional – indoors: Veterinary hygiene biocidal products – surface disinfection in animal houses

| | |
|---|---|
| Product Type | PT03 |
| Where relevant, an exact description of the authorised use | Concentrate.<br>Products used for the disinfection of surfaces in animal husbandry. |
| Target organism (including development stage) | bactericidal, yeasticidal, virucidal |
| Field of use | indoor |
| Application method(s) | high-pressure spraying, hand-held knapsack sprayer |
| Application rate(s) and frequency | Application concentration: 150 - 900 ppm Iodine, 100 - 400 mL/m2<br>Contact time: 2-3 hours<br>Application frequency: 2-4 applications / year (depending on animal species, in rare cases (ducks) up to 13 times/year. |
| Category(ies) of users | professional |
| Pack sizes and packaging material | Packaging material: HDPE<br>1 L - 1000 L |

### 2.2.2 Physical, chemical and technical properties

Justification for choice of biocidal products to be tested within a meta SPC:
*"The analysis of physical, chemical and technical properties has been performed with the BP within each Meta SPC with the highest content in AS since it can be expected that physical, chemical and technical properties will exhibit the most extreme values with a highly concentrated BP." (*f_OXYDE GmbH, 2016*)*

Note of the authority: The read-across was accepted as it is assumend that each product (tested for the respective meta SPC) represents the worst case with regard to the values which are relevant for risk assessment.

Further splitting of the BPF from 4 meta SPCs to 8 meta SPCs due to different hazard statements occurred during the commenting phase. Nevertheless, the studys provided in the physico-chemical section are deemed sufficient to cover the original range of the meta SPCs.

#### 2.2.2.1 Meta SPC 1-3: PT03 - Professional – indoors: Veterinary hygiene biocidal products – ready-to-use teat spray

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| **Physical state at 20°C and 101.3 kPa** | Visual assessment | FINK Io Spray 50, technical product, lot no. 28042014/37119 | liquid | [redacted] |
| **Colour at 20°C and 101.3 kPa** | Visual assessment | FINK Io Spray 50, technical product, lot no. 28042014/37119 | clear, brown | [redacted] |
| **Odour at 20°C and 101.3 kPa** | Olfactory assessment | FINK Io Spray 50, technical product, lot no. 28042014/37119 | characteristic | [redacted] |
| **Acidity / alkalinity** | OECD Guideline 122 (2013) | FINK Io Spray 50, technical product, batch number 28042014 | pH: 1.7 at 20°C<br><br>Acidity:<br>pH 7: 0.0229 mol/L corresponding to 0.108% (m/m) H2SO4<br><br>pH 4: 0.0201 mol/L | [redacted] |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| | | FINK Io Spray 50 (Iodophor), technical product, batch number 11092014 | pH: 1.9 at 20°C<br><br>Acidity:<br>pH 7: 0.0270 mol/L corresponding to 0.128% (m/m) H2SO4<br><br>pH 4: 0.0243 mol/L | [redacted] |
| | Internal method | FINK Io Spray 15, technical product, batch number 10122018 | pH: 2.4 at 20°C | [redacted] |
| | Internal method | FINK Io Spray 30, technical product, batch number 06122018 | pH: 2.0 at 20°C | [redacted] |
| | The pH values for the products in meta SPC 1-3 are in the range of 1.7 to 2.4. Read across is sought from the product with the lowest pH to the other products (see justification at the beginning of the table.) | | | |
| **Relative density / bulk density** | OECD Guideline 109 (1995) | FINK Io Spray 50, technical product, batch number 28042014 | 1.036 | [redacted] |
| | | FINK Io Spray 50 (Iodophor), technical product, batch number 11092014 | 1.031 | [redacted] |
| **Storage stability test – accelerated storage** | CIPAC MT 46.3, 14 days at 54°C | FINK IO Spray (Jodophor) (Art. No 18998), batch no. 05022015-2 | Observed decrease of active substance: 41.7%<br><br>Iodine content before storage: 0.109%(w/w)<br><br>Iodine content after storage: 0.064%(w/w) | [redacted]<br>[redacted] |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| | | | Packaging integrity: The packaging is observed to be fully resistant to the formulation. | |
| | | FINK IO Spray (PVP) (Art. No 18997), batch no. 05022015-3 | Observed decrease of active substance: 31.7%<br><br>Iodine content before storage: 0.063%(w/w)<br><br>Iodine content after storage: 0.043%(w/w)<br><br>Packaging integrity: The packaging is observed to be fully resistant to the formulation.<br><br>(accepteable efficacy study with the aged product is available, see section 2.2.5.5) | [redacted] |
| | | FINK Io Spray 50 (Iodophor) (Art. No 18207_1), batch no. 05022015-4 | Observed decrease of active substance: 22.7%<br><br>Iodine content before storage: 0.542%(w/w)<br><br>Iodine content after storage: 0.419%(w/w)<br><br>Packaging integrity: The packaging is observed to be fully resistant to the formulation. | [redacted] |
| **Storage stability test – long term storage at ambient** | Long-term storage stability (1 year at | FINK IO Spray 50, batch no. 28042014/371 19 | Observed decrease of active substance: 8.15% | [redacted] |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| **temperature** | ambient temperature ) | | Iodine content before storage: 0.552%(w/w)<br><br>Iodine content after storage: 0.507%(w/w)<br><br>Packaging integrity: The packaging is observed to be fully resistant to the formulation. | |
| | | FINK IO Spray, (Art. No 18999), batch no. 28042014 | Observed decrease of active substance: 14.5%<br><br>Iodine content before storage: 0.145%(w/w)<br><br>Iodine content after storage: 0.124%(w/w)<br><br>Packaging integrity: The packaging is observed to be fully resistant to the formulation. | [redacted] |
| | | FINK IO Spray (PVP), (Art. No 18997), batch no. 15102014 | Observed decrease of active substance: 22.81%<br><br>Iodine content before storage: 0.057%(w/w)<br><br>Iodine content after storage: 0.044%(w/w)<br><br>Packaging integrity: The packaging is observed to be fully resistant to the formulation. | [redacted] |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| | | FINK IO Spray (Jodophor), (Art. No 18998), batch no. 11092014 | Observed decrease of active substance: 36.45%<br><br>Iodine content before storage: 0.107%(w/w)<br><br>Iodine content after storage: 0.068%(w/w)<br><br>Packaging integrity: The packaging is observed to be fully resistant to the formulation.<br><br>(this product is not contained in the BPF anymore, see confidential annex) | [redacted] |
| | | FINK IO Spray 50 (Jodophor), (Art. No 18207_1), batch no. 11092014 | Observed decrease of active substance: 22.06%<br><br>Iodine content before storage: 0.562%(w/w)<br><br>Iodine content after storage: 0.438%(w/w)<br><br>Packaging integrity: The packaging is observed to be fully resistant to the formulation.<br><br>(accepteable efficacy study with the aged product is available, see section 2.2.5.5) | [redacted] |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| | | FINK IO Spray 50, batch no. 28042014/371 19 | Observed decrease of active substance during 1 year storage: 8.13%; storage conditions: mean temperature 20°C; mean humidity: 47.4 %rh; No significant deviation in pH, conductivity, density and appearance prior to and after storage. | [redacted] |
| **Storage stability test – decomposition products** | In house study | FINK Io Spray (PVP) 18999 (IOSP) Batch 26032015-1 | The study shows that degradation of $I_2$ takes place via 2 ways: A) reduction to dissolved Iodide anion, and B) release into the container headspace as elementary, gaseous Iodine.<br><br>Efficacy studies were carried out with the aged products with a degradation >10% to prove that the product is still efficacious, see section 2.2.5.<br><br>For the risk of humans and environment, it is assumed that the RA with the fresh, unaged product poses the worst case:<br>As it has been demonstrated in the storage stability tests (both at ambient temperature and accelerated) the | [redacted] |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| | | | concentration of AS (elementary Iodine) decreases significantly over shelf-life. Therefore, exposure to fresh, non-decomposed b.p. represents the worst case, both in terms of human and environmental exposure.<br>On the other hand, Iodine (in form of any inorganic species) does not „disappear" in stored Iodine BPs (except a certain degree of Iodine volatilisation in highly concentrated Iodophor Type 2 - FAE products), but will be present as Iodide and Iodate ions (formed by disproportionation of I2) as well. In this case it would not matter whether aged or fresh BP is considered for human or environmental exposure. | |
| **Storage stability test – low temperature stability test for liquids** | Justification: Label gives clear instructions that products must not be stored under conditions of ≤0°C. | | | |
| **Effects on content of the active substance and technical characteristics of the biocidal product - light** | Justification: Label gives clear instructions that products must be stored in a dark place. | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| **Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity** | Justification: Label gives clear instructions that products must be stored at room temperature. Packaging is water-impermeable. | | | |
| **Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material** | Justification: The biocidal product Io Spray 50 was stored in a representative commercial packaging (HDPE). After 1 year of storage at ambient temperature no effects of temperature and humidity were observed; pH, conductivity, density and appearance were determined to be stable.<br><br>A decrease in Iodine content of 8.1% was determined:<br>Iodine content before storage:<br>0.541%(w/w)<br>Iodine content after storage:<br>0.497%(w/w)<br><br>The packaging is observed to be fully resistant to the formulation. (Kedzierski, 2017; Benetka, 2015a) Read across to the other products within the meta SPC is accepted. | | | |
| **Wettability** | Justification: The biocidal products are not solid. | | | |
| **Suspensibility, spontaneity and dispersion stability** | Justification: The biocidal products are not forming suspensions on dilution with water. The biocidal products are neither solid, nor from the category wettable powders, suspension concentrates, water dispersible granules, aqueous capsule suspensions, dispersible concentrates, suspo-emulsions, water soluble granules and water soluble powders. | | | |
| **Wet sieve analysis and dry sieve test** | Justification: The biocidal products are not solid. | | | |
| **Emulsifiability, re-emulsifiability and emulsion stability** | Justification: Biocidal products are not mixed or diluted with lipophilc substances that may form emulsions. | | | |
| **Disintegration time** | Justification: The biocidal products are not solid or tablets. | | | |
| **Particle size distribution, content of dust/fines, attrition, friability** | Justification: The products are sold separately from the spraying cans. Furthermore, the MMAD is not an input parameter in the current human exposure assessment, and least, the MMAD is not relevant for efficacy assessment. All three arguments justify non-submission of data. | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| **Persistent foaming** | CIPAC Method 47.2 (2010) | FINK Io Spray 50, technical product, batch number 28042014<br><br>FINK Io Spray 50 (Iodophor), technical product, batch number 11092014 | Level of foam after 1 minute: 90 mL<br><br>The result is not expected to have an influence on the human RA due to use of PPE. | [redacted] |
| **Flowability/Pourability/Dustability** | Justification: The biocidal products are not solid, nor suspension concentrates, capsule suspensions or suspoemulsions. | | | |
| **Burning rate — smoke generators** | Justification: The biocidal products are not used as smoke generating biocides. | | | |
| **Burning completeness — smoke generators** | Justification: The biocidal products are not used as smoke generating biocides. | | | |
| **Composition of smoke — smoke generators** | Justification: The biocidal products are not used as smoke generating biocides. | | | |
| **Spraying pattern — aerosols** | Justification: The biocidal products are not delivered as filled aerosol packs. | | | |
| **Physical compatibility** | Justification: The biocidal products are not to be co-applied with other substances, mixtures or biocidal or non-biocidal products. | | | |
| **Chemical compatibility** | Justification: The biocidal products are not to be co-applied with other substances, mixtures or biocidal or non-biocidal products. | | | |
| **Degree of dissolution and dilution stability** | Justification: The biocidal products are not used in a water soluble bag or in form of a tablet. | | | |
| **Surface tension** | OECD Guideline 115 (1995) | FINK Io Spray 50, technical product, batch number 28042014 | 28.8 mN/m at 20°C | [redacted] |
| | | FINK Io Spray 50 (Iodophor), technical product, batch number 11092014 | 30.2 mN/m at 20°C | [redacted] |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| **Viscosity** | OECD Guideline 114 (2012) | FINK Io Spray 50, technical product, batch number 28042014 | 2.10 mPa.s (20°C)<br>1.35 mPa.s (40°C) | [redacted] |
| | | FINK Io Spray 50 (Iodophor), technical product, batch number 11092014 | 2.86 mPa.s (20°C)<br>2.50 mPa.s (40°C) | [redacted] |

### 2.2.2.2 Meta SPC 4-5: PT03 - Professional – indoors: Veterinary hygiene biocidal products – ready-to-use teat dip

Justification for choice of biocidal products to be tested within a meta SPC:
*"The analysis of physical, chemical and technical properties has been performed with the BP within each Meta SPC with the highest content in AS since it can be expected that physical, chemical and technical properties will exhibit the most extreme values with a highly concentrated BP." (*f_OXYDE GmbH, 2016*)*

Note of the authority: The read-across was accepted as it is assumend that each product (tested for the respective meta SPC) represents the worst case with regard to the values which are relevant for risk assessment.

Further splitting of the BPF from 4 meta SPCs to 8 meta SPCs due to different hazard statements occurred during the commenting phase. Nevertheless, the studys provided in the physico-chemical section are deemed sufficient to cover the original range of the meta SPCs.

Meta SPC 4-5 was tested with Fink Io Dip 50, which will not be authorised due to efficacy reasons (Please see chapter 3.6.5 for details). However, for the purpose of testing physico-chemical properties, it is acceptable to use the studies on Fink Io dip 50 as a worst case for read-across to the other products in the meta SPC 4-5 for all endpoints except storage stability.
To support read-across, the pH of additional products within meta SPC 4-5 was measured. (See table below.)

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| **Physical state at 20°C and 101.3 kPa** | Visual assessment | Fink Io Dip 50, technical product, batch no. 05022015_1 | liquid | [redacted] |
| **Colour at 20°C and 101.3 kPa** | Visual assessment | Fink Io Dip 50, technical product, batch no. 05022015_1 | dark brown | [redacted] |
| **Odour at 20°C and 101.3 kPa** | Olfactory assessment | Fink Io Dip 50 (SDS) | characteristic | [redacted] |
| **Acidity / alkalinity** | OECD Guideline 122 (2013) | Fink Io Dip 50, technical product, batch no. 05022015_1 | pH: 2.27 at 20°C<br><br>Acidity:<br>pH 7: 0.0206 mol/L<br>pH 4: 0.0154 mol/L | [redacted] |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| | Internal method | FINK - Io Dip 10, technical product, batch no. 04122018 | pH: 3.1 at 20°C | [redacted] |
| | Internal method | (Fink) Io Dip Protect, technical product, batch no. 11122018 | pH: 3.9 at 20°C | [redacted] |
| | Internal method | Jodofilm 75/5 4500 ppm, technical product, batch no. 18009 | pH: 2.1 at 20°C | [redacted] |
| | Internal method | Jodofilm 75/5 3000 ppm, technical product, batch no. 18001 | pH: 2.0 at 20°C | [redacted] |
| | The pH values for the products in meta SPC 4-5 are in the range of 2.0 to 3.9. The tested formulation Fink Io Dip 50 displays a pH of 2.27, which represents a product in the low pH-range. | | | |
| **Relative density / bulk density** | OECD Guideline 109 (1995) | Fink Io Dip 50, technical product, batch no. 05022015_1 | 1.011 | [redacted] |
| **Storage stability test – accelerated storage** | Justification: A full ambient storage study has been provided. The biocidal product must not be subject to temperatures above 30°C. Therefore, the accelerated storage study for this meta SPC is omitted. | | | |
| **Storage stability test – long term storage at ambient temperature** | Justification: in the original first dossier submission, meta SPCs 1, 2 and 3 where combined in one meta SPC, whereas due to assessment it was splitted by the authority (H/P sentences, different uses).<br>Read across is sought from the spraying products to the dipping products. The assessment of the shelf life / storage stability in meta SPC 1-3 is regarded as a worst case due to the following reasons:<br><br>1. Apart from the thickeners being present in virtually all dip products compositions are similar or even identical.<br>2. Both shelf life and impact on packaging are not related to the slightly disimilar use of the biocidal products.<br>3. The higher viscosity in the dip products (caused by the thickeners present) supposedly has a beneficial effect on storage stability due to<br>a) inhibition of Iodine vapour release into the headspace<br>b) inhibition of Iodine reducing reactions in the aqueous solution due to the reduced availability of free water molecules<br><br>To support the justification, retained product samples were analysed for their Iodine content and pH (see below). | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| | Internal method | (Fink) Io Dip Protect, technical product, batch no. 11122018 | fresh product:<br>pH: 3.9 at 20°C<br>Iodine content: 0.172%(w/w)<br><br>product aged 1 year:<br>pH: 3.8 at 20°C<br>Iodine content: 0.152%(w/w)<br><br>Observed decrease of Iodine: 11.6% | [redacted] |
| | Internal method | Jodofilm 75/5 4500 ppm, technical product, batch no. 18009 | fresh product:<br>pH: 2.1 at 20°C<br>Iodine content: 0.453%(w/w)<br>product aged 1 year:<br>pH: 1.8 at 20°C<br>Iodine content: 0.342%(w/w)<br><br>Observed decrease of Iodine: 24.5% | [redacted] |
| | Justification:<br><br>Measured pH values for all dip products are available. The pH of FINK - Io Dip 50 (2.27) is close to the mean pH of all dip products contained in the BPF (2.67). The pH range of dip products is 2.0-3.9.<br><br>Since all pH values are available no justification for read-across is deemed necessary. Furthermore, pH values for all dip products have been measured and iodine content from fresh and 12 months old QS-samples has been determined. Decomposition rates range from 3.6 to 24.5 % relative and no correlation with the measured pH values can be established. Three tested products have a decomposition rate of >10%, but these products contain significantly more active substance (1500, 3000, 4500 ppm) and there sufficient efficacy after the shelf-life is therefore covered by the test of FINK-Io Dip 10 (1000 ppm I2).<br><br>Thus, read across is justified since:<br>1. no correlation between the pH values and the decomposition rate could be identified.<br>2. BPs covering storage stability in meta SPC 1 show a relative decrease in iodine content between 8.1 and 36.1% which is similar, in actual fact slightly higher than for the tested (QS-samples) dip products (range 3.6-24.5%). | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| | Consequently, shelf life read-across from meta SPC 1 to meta SPC 3 is considered to be feasible. | | | |
| **Storage stability test – low temperature stability test for liquids** | Justification: Label gives clear instructions that products must not be stored under conditions of ≤0°C. | | | |
| **Effects on content of the active substance and technical characteristics of the biocidal product - light** | Justification: Label gives clear instructions that products must be stored in a dark place. | | | |
| **Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity** | Justification: Label gives clear instructions that products must be stored at room temperature. Packaging is water-impermeable. | | | |
| **Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material** | See justification on long term storage. Acceptable container material: HDPE. | | | |
| **Wettability** | Justification: The biocidal products are not solid. | | | |
| **Suspensibility, spontaneity and dispersion stability** | Justification: The biocidal products are not forming suspensions on dilution with water. The biocidal products are neither solid, nor from the category wettable powders, suspension concentrates, water dispersible granules, aqueous capsule suspensions, dispersible concentrates, suspo-emulsions, water soluble granules and water soluble powders. | | | |
| **Wet sieve analysis and dry sieve test** | Justification: The biocidal products are not solid. | | | |
| **Emulsifiability, re-emulsifiability and emulsion stability** | Justification: Biocidal products are not mixed or diluted with lipophilc substances that may form emulsions. | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| **Disintegration time** | Justification: The biocidal products are not solid or tablets. | | | |
| **Particle size distribution, content of dust/fines, attrition, friability** | Justification: The biocidal products are not solid. | | | |
| **Persistent foaming** | CIPAC Method 47.2 (2010) | Fink Io Dip 50, technical product, batch no. 05022015_1 | Level of foam after 1 minute: <10 mL | [redacted] |
| **Flowability/Pourability/Dustability** | Justification: The biocidal products are not solid, nor suspension concentrates, capsule suspensions or suspoemulsions. | | | |
| **Burning rate — smoke generators** | Justification: The biocidal products are not used as smoke generating biocides. | | | |
| **Burning completeness — smoke generators** | Justification: The biocidal products are not used as smoke generating biocides. | | | |
| **Composition of smoke — smoke generators** | Justification: The biocidal products are not used as smoke generating biocides. | | | |
| **Spraying pattern — aerosols** | Justification: The biocidal products in this meta SPC are not intended to be sprayed. | | | |
| **Physical compatibility** | Justification: The biocidal products are not to be co-applied with other substances, mixtures or biocidal or non-biocidal products. | | | |
| **Chemical compatibility** | Justification: The biocidal products are not to be co-applied with other substances, mixtures or biocidal or non-biocidal products. | | | |
| **Degree of dissolution and dilution stability** | Justification: The biocidal products are not used in a water soluble bag or in form of a tablet. | | | |
| **Surface tension** | OECD Guideline 115 (1995) | Fink Io Dip 50, technical product, batch no. 05022015_1 | 30.6 mN/m at 20°C | [redacted] |
| **Viscosity** | OECD Guideline 114 (2012) | Fink Io Dip 50, technical product, batch no. 05022015_1 | 1340 mPa.s (sp3/20rpm, 20°C)<br>693 mPa.s (sp3/50rpm, 20°C)<br>1148 mPa.s (sp3/20rpm, | [redacted] |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| | | | 40°C) 595 mPa.s (sp3/50rpm, 40°C) | |

### 2.2.2.3 Meta SPC 6-8: PT03 - Professional – indoors: Veterinary hygiene biocidal products – surface disinfection in animal houses

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| **Physical state at 20°C and 101.3 kPa** | Visual assessment | Iodosan 30 plus, technical product, batch no. E11813 | liquid | [redacted] |
| **Colour at 20°C and 101.3 kPa** | Visual assessment | Iodosan 30 plus, technical product, batch no. E11813 | clear, dark brown | [redacted] |
| **Odour at 20°C and 101.3 kPa** | Olfactory assessment | Iodosan 30 plus, technical product, batch no. E11813 | characteristic | [redacted] |
| **Acidity / alkalinity** | OECD Guideline 122 (2013) | Iodosan 30 plus, technical product, batch no. E11813 | pH (undiluted): 0.76 at 20°C<br><br>pH (1% dilution) 2.36 at 20°C<br><br>Acidity:<br>pH 7: 1.334 mol/L<br>pH 4: 0.840 mol/L | [redacted] |
| **Relative density / bulk density** | OECD Guideline 109 (1995) | Iodosan 30 plus, technical product, batch no. E11813 | 1.084 | [redacted] |
| **Storage stability test – accelerated storage** | CIPAC MT46.3, 2 weeks at 54°C | Iodosan 15, batch number E11811 | Observed decrease in active substance: 8.8%<br><br>Iodine content before storage: 1.81%(w/w)<br><br>Iodine content after storage: 1.65%(w/w)<br><br>Packaging integrity: The packaging is observed to be fully resistant to the formulation. | [redacted] |
| | | Iodosan 30 plus, batch number E11813 | Observed decrease in active substance: 3.9%<br><br>Iodine content before storage: 3.59%(w/w)<br><br>Iodine content after | [redacted] |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| | | | storage: 3.45%(w/w)<br><br>Packaging integrity: The packaging is observed to be fully resistant to the formulation.<br><br>(accepteable efficacy study with the aged product is available, see section 2.2.5.5) | |
| **Storage stability test – long term storage at ambient temperature** | Long-term storage stability (2 years at ambient temperature) | Iodosan 15, batch number E11811 | Observed decrease in active substance: 4.42%<br><br>Iodine content before storage: 1.81%(w/w)<br><br>Iodine content after storage: 1.73%(w/w)<br><br>Packaging integrity: The packaging is observed to be fully resistant to the formulation. | [redacted] |
| | | Iodosan 30 plus, batch number E11813 | Observed decrease in active substance: 0.56%<br><br>Iodine content before storage: 3.59%(w/w)<br><br>Iodine content after storage: 3.57%(w/w)<br><br>Packaging integrity: The packaging is observed to be fully resistant to the formulation. | [redacted] |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| | | Iodosan 30 plus, batch number E11813 | Observed decrease of active substance during 2 years: 0.58%;<br><br>Iodine content before storage: 3.45%(w/w)<br><br>Iodine content after storage: 3.43%(w/w)<br><br>Storage conditions: mean temperature 19.3°C; mean humidity: 46.8%rh; No significant deviation in pH, conductivity, density and appearance prior to and after storage. | [redacted] |
| **Storage stability test – decomposition products** | In house study | EWABO Iodosan 30 plus (IO30+), Batch E 11819 | The study shows that degradation of $I_2$ takes place via 2 ways: A) reduction to dissolved Iodide anion, and B) release into the container headspace as elementary, gaseous Iodine.<br><br>Efficacy studies were carried out with the aged products with a degradation >10% to prove that the product is still efficacious, see section 2.2.5.<br><br>For the risk of humans and environment, it is assumed that the RA with the fresh, | [redacted] |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| | | | unaged product poses the worst case. | |
| **Storage stability test – low temperature stability test for liquids** | Justification: Label gives clear instructions that products must not be stored under conditions of ≤0°C. | | | |
| **Effects on content of the active substance and technical characteristics of the biocidal product - light** | Justification: Label gives clear instructions that products must be stored in a dark place. | | | |
| **Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity** | Justification: Label gives clear instructions that products must be stored at room temperature. Packaging is water-impermeable. | | | |
| **Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material** | Justification: The biocidal product Iodosan 30 plus was stored in a representative commercial packaging (**HDPE**). After 2 years of storage at ambient temperature no effects of temperature and humidity were observed; pH, conductivity, density and appearance were determined to be stable, a decrease in Iodine content of 0.58% was determined. The packaging is observed to be fully resistant to the formulation. (Kedzierski, 2017; Benetka, 2017b) Read across to the other products within the meta SPC is accepted. | | | |
| **Wettability** | Justification: The biocidal products are not solid. | | | |
| **Suspensibility, spontaneity and dispersion stability** | Justification: The biocidal products are not forming suspensions on dilution with water. The biocidal products are neither solid, nor from the category wettable powders, suspension concentrates, water dispersible granules, aqueous capsule suspensions, dispersible concentrates, suspo-emulsions, water soluble granules and water soluble powders. | | | |
| **Wet sieve analysis and dry sieve test** | Justification: The biocidal products are not solid. | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| **Emulsifiability, re-emulsifiability and emulsion stability** | Justification: Biocidal products are not mixed or diluted with lipophilc substances that may form emulsions. | | | |
| **Disintegration time** | Justification: The biocidal products are not solid or tablets. | | | |
| **Particle size distribution, content of dust/fines, attrition, friability** | Justification: The biocidal products are not solid. | | | |
| **Persistent foaming** | CIPAC Method 47.2 (2010) | Iodosan 30 plus, technical product, batch no. E11813 | Level of foam after 1 minute: >90 mL For 1% and 0.5% dilutions (Note: The dilutions for the application solution will be higher; end-concentration of Iodine: 750 ppm) The result is not expected to have an influence on the human RA due to use of PPE. | [redacted] |
| **Flowability/Pourability/Dustability** | Justification: The biocidal products are not solid, nor suspension concentrates, capsule suspensions or suspoemulsions. | | | |
| **Burning rate — smoke generators** | Justification: The biocidal products are not used as smoke generating biocides. | | | |
| **Burning completeness — smoke generators** | Justification: The biocidal products are not used as smoke generating biocides. | | | |
| **Composition of smoke — smoke generators** | Justification: The biocidal products are not used as smoke generating biocides. | | | |
| **Spraying pattern — aerosols** | Justification: The biocidal products are not delivered as filled aerosol packs. | | | |
| **Physical compatibility** | Justification: The biocidal products are not to be co-applied with other substances, mixtures or biocidal or non-biocidal products. | | | |
| **Chemical** | Justification: The biocidal products are not to be co-applied with other | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| **compatibility** | substances, mixtures or biocidal or non-biocidal products. | | | |
| **Degree of dissolution and dilution stability** | Justification: Degree of dissolution: The biocidal products are not used in a water soluble bag or in form of a tablet.<br>Dilution stability: Not relevant for meta SPC 1-5.<br>Meta SPC 6-8: Due to the nature of the ingredients contained in these products, dilutions are deemed to be stable (cf. to chapter 3.6.1, meta SPC 6-8). | | | |
| **Surface tension** | OECD Guideline 115 (1995) | 1%w/w solution of Iodosan 30 plus, technical product, batch no. E11813 | 27.4 mN/m at 20°C | [redacted] |
| **Viscosity** | OECD Guideline 114 (2012) | Iodosan 30 plus, technical product, batch no. E11813 | 218 mPa.s (sp2/20rpm, 20°C)<br>214 mPa.s (sp2/50rpm, 20°C)<br>56 mPa.s (sp1/20rpm, 40°C)<br>66 mPa.s (sp1/50rpm, 40°C) | [redacted] |

**Conclusion on the physical, chemical and technical properties of the BPF**

**LEVEL 2 information - meta SPC 1-3: PT03 - Veterinary hygiene / Ready-to-use teat spray disinfection**

The biocidal products in meta SPC 1-3 (teat spraying) are dark brown, clear liquids with charcteristic odour, an acidity range at pH 7 from 0.0229 to 0.0270 mol/L, at pH 4 from 0.0201 to 0.0243 mol/L. The pH of the formulated products is determined to be 1.7 – 2.4, relative density from 1.031 to 1.036 and surface tension from 28.8 to 30.2 mN/m. The persistant foam is observed to be 90 mL after 1 min, which is however not expected to pose an unacceptable risk to operators. The viscosity for spray biocidal products ranges from 2.1 to 2.86 mPa*s (20°C). A decrease in a.s. content of up to 36.45% Iodine was determined in biocidal products after 1 year of storage at ambient temperature. No biocidal product within meta SPC 1-3 is physically hazardous. The packaging (HDPE) is stable for the required shelf life (1 year). The biocidal products are not intended for use in conjunction with any other products.

**LEVEL 2 information - meta SPC 4-5: PT03 - Veterinary hygiene / Ready-to-use teat dip disinfection**

The biocidal products in meta SPC 4-5 (teat dipping) are dark brown, clear liquids with charcteristic odour. The acidity of the biocidal product with the highest content in active substance representative for the meta SPCs was determined to be 0.0206 mol/L at pH 7 and 0.0154 mol/L at pH 4, the pH of the formulated products is determined to be 2.0 – 3.9, the relative density is observed to be 1.011 and surface tension is down to 30.6 mN/m at 20°C. <10 mL of persistent foam were observed after 1 min. The viscosity of dip biocidal products was determined to be up to 1340 mPa*s at 20 rpm and 693 mPa*s at 50 rpm (20°C). The fact that the viscosities analysed are different at two different rotation speeds indicates the presence of a non - Newton liquid. For storage stability, read across to meta SPC 1-3 is sought, which is backed by analysis of retained product samples.. No biocidal product within meta SPC 4-5 is physically hazardous. The packaging (HDPE) is stable for the required shelf life (1 year). The biocidal products are not intended for use in conjunction with any other products.

**LEVEL 2 information - meta SPC 6-8: PT03 - Veterinary hygiene / Surface disinfection in animal houses**

The biocidal products in meta SPC 6-8 (animal housing disinfection) are dark brown clear liquids with characteristic odour. The acidity of the biocidal product with the highest content in active substance representative for the meta SPCs was determined to be 1.334 mol/L at pH 7 and 0.840 mol/L at pH 4, the pH of the undiluted BP is 0.76 and 2.36 in a 1% solution, the relative denisty is observed to be 1.084 at 20°C and surface tension in a 1% solution is down to 27.4 mN/m at 20°C. Viscosity was dermined to be up to 218 mPa*s (20°C). In a 1% solution >90 mL foam were observed after 1 min, which is however not expected to pose an unacceptable risk to operators. A decrease in a.s. content of up to 4.49% Iodine was determined in biocidal products after 2 years of storage at ambient temperature. No biocidal product within meta SPC 6-8 is physically hazardous. The packaging (HDPE) is stable for the required shelf life (2 years). The biocidal products are not intended for use in conjunction with any other products.

### 2.2.3 Physical hazards and respective characteristics

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| **Explosives** | Justification: None of the ingredients present in the biocidal products is classified as explosive according to the classifications provided by companies to ECHA. Moreover, there are no chemical groups associated with explosive properties present in the molecules of the ingredients;<br>Conclusion: None of the products in the biocidal product family is classified as explosive according to the CLP Regulation 1272/2008. | | | |
| **Flammable gases** | Justification: The biocidal products are not a gas or gas mixture. | | | |
| **Flammable aerosols** | Justification: The biocidal products are sprayed with low pressure spraying devices that will not generate aerosols. The spraying devices do not contain a gas compressed, liquefied or dissolved under pressure. | | | |
| **Oxidising gases** | Justification: The biocidal products are not a gas or gas mixture. | | | |
| **Gases under pressure** | Justification: The biocidal products are not gases under pressure. | | | |
| **Flammable liquids** | Justification: None of the ingredients present in the biocidal products is classified as flammable according to the ECHA C&L inventory. Moreover, the by far largest part of components is water (meta SPC 1-5: >81%w/w; meta SPC 6-8: >55%w/w).<br>Conclusion: None of the products in the Biocidal product family is classified as flammable according to the CLP Regulation 1272/2008. | | | |
| **Flammable solids** | Justification: The biocidal products are not solid. | | | |
| **Self-reactive substances and mixtures** | Justification: None of the biocidal products contains aliphatic azo compounds, organic azides, N-nitroso compounds, or aromatic sulfohydrazides. The storage stability tests show that the products decompose at slow rates that will not result in any significant exothermic behaviour. | | | |
| **Pyrophoric liquids** | Justification: None of the actives or non actives present in the biocidal products is classified as being pyrophoric. The biocidal products do not contain anyr organo-metals, organo-metalloids or organo-phosphines. Moreover, the by far largest part of components in the products is water. | | | |
| **Pyrophoric solids** | Justification: The biocidal products are not solid. | | | |
| **Self-heating substances and mixtures** | Justification: In general, the phenomenon of self-heating applies only to solids. Furthermore, the liquid biocidal products will not be adsorbed on a large surface. Moreover, the by far largest part of components in the products is water. | | | |
| **Substances and mixtures which in contact with water emit flammable gases** | Justification: The biocidal products are already an aqueous solution and none of the gases that may develop over long time storage (Iodine vapor and oxygen) are flammable. The biocidal products are neither gases nor pyrophoric liquids nor pyrophoric solids. | | | |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| **Oxidising liquids** | Justification: For organic substances or mixtures the classification procedure for this hazard class need not to be applied if:<br>a. the substance or mixture does not contain oxygen, fluorine or chlorine; or<br>b. the substance or mixture contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen.<br>This is the case for all ingredients of the biocidal products of this BPF.<br>The only oxidiser present is the active substance Iodine which is the weakest oxidiser of all halogens. Iodine is present up to 3% in an aqueous solution. Therefore a behaviour aqueous biocidal product as an oxidising liquid can be ruled out. This corresponds to classification of the mixture acc. To CLP 1272/2008. | | | |
| **Oxidising solids** | Justification: The biocidal products are not solid. | | | |
| **Organic peroxides** | Justification: The biocidal products do not contain any organic peroxides. | | | |
| **Corrosive to metals**<br><br>meta SPC 1&2 | Modified UN Test C.1 as described in Section 37.4 of the UN-MTC | FINK – Io Spray 50,<br>charge 18207 / 7401 / 180919-1 | Corrosive<br><br>(criterion max. intrusion depth > 120µm after 7 days is met)<br><br>( Klimisch 2) | [redacted] |
| | UN Test C.1 as described in Section 37.4 of the UN-MTC | FINK – Io Spray 50,<br>batch no. 250418-1 | "Not applicable as the product is instable under the conditions of the UN.C1 test, degradation occurs."<br><br>(Klimisch 3) | [redacted] |
| **Corrosive to metals**<br><br>meta SPC 3 | Modified UN Test C.1 as described in Section 37.4 of the UN-MTC | FINK- Io Spray 50 (Jodophor), charge 18997 / 7401 / 180919-2 | Corrosive<br><br>(criterion max. intrusion depth >120µm after 7 days is met)<br><br>(Klimisch 2) | [redacted] |
| | UN Test C.1 as described in Section 37.4 of the UN-MTC | FINK – Io Spray 50 (Jodophor),<br>batch no. 250418-2 | "Not applicable as the product is instable under the conditions of the UN.C1 test, degradation occurs." | [redacted] |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| | | | ( Klimisch 3) | |
| **Corrosive to metals**<br><br>meta SPC 4&5 | Modified UN Test C.1 as described in Section 37.4 of the UN-MTC | Jodofilm 75/5 4500ppm, charge 18006 07/2018 | Corrosive<br><br>(criterion max. intrusion depth >120µm after 7 days is met)<br><br>(Klimisch 2) | [redacted] |
| | UN Test C.1 as described in Section 37.4 of the UN-MTC | Jodofilm 75/5 4500ppm, batch no. 250418-3 | "Not applicable as the product is instable under the conditions of the UN.C1 test, degradation occurs."<br><br>Note: Klimisch 3 | [redacted] |
| **Corrosive to metals**<br><br>meta SPC 6-9 | UN Test C.1 as described in Section 37.4 of the UN-MTC | Iodosan 30 plus, batch no. 250418-5 | Uniform corrosion attack (fully submerged):<br>Mass loss in aluminium after 7 days: 60%<br>Mass loss in steel after 7 days: 8.3%<br>(Criterion for mass loss: 13.5%)<br><br>Localised corrosion attack (fully submerged):<br>No intrusion after 7 days (steel and aluminium) | [redacted] |
| | UN Test C.1 as described in Section 37.4 of the UN-MTC | Iodosan 30 plus, batch no. 250418-5, 2% solution | "Not applicable as the product is instable under the conditions of the UN.C1 test, degradation | [redacted] |

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| | | | occurs." | |
| **Corrosive to metals**<br><br>all meta SPCs | Valid modified UN_Tests for "corrosivity to metals" have been provided for three individual products covering on dip product (Jodofilm 75/5 4500 ppm) on spray product with PVP as complexing agent (FINK - Io Spray 50) and one spray product with FAC as solubilizer (FINK - Io Spray 50 (Jodophor)). All these products showed clear corrosivity to both types of metals tested.<br>Considering the relatively low pH values of these iodine products it can be assumed that corrosivity is driven by product acidity, supported by the presence of the oxidizer Iodine. Therefore, the basic composition of all teat disinfectants in the BPF is considered similar and consequently the three corrosivity tests are representative for all meta SPCs containing teat disinfection products. All products within the family are consequently classified corrosive. | | | |
| **Auto-ignition temperatures of products (liquids and gases)** | Justification: None of the actives or non actives present in the biocidal products is classified as being flammable according to the classifications provided by companies to ECHA and therefore no auto-ignition can take place. Moreover, the by far largest part of components is water. | | | |
| **Relative self-ignition temperature for solids** | Justification: The biocidal products are not solid. | | | |
| **Dust explosion hazard** | Justification: The biocidal products are not solids that can form dust. | | | |

| **Conclusion on the physical hazards and respective characteristics of the product** |
|---|
| All products in the Biocidal product family are classified as "corrosive to metals" with regard to physical hazards according to the CLP Regulation 1272/2008. |

### 2.2.4 Methods for detection and identification

| Analytical methods for the analysis of the product as such including the active substance, impurities and residues | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| | | | | | Range | Mean | RSD | | |
| $I_2$ | Titration with Sodium Thiosulfate; Amperometric detection (Platinum electrode). | Measurements of aliquots of the test formulation in the range of 2, 4, 6, 8 and 10 mL.<br>Each concentration level was repeated six times.<br>1 mL of the test formulation equals to 1.2 mg $I_2$ | The function was linear from the detection limit up to the highest sample aliquot. | The specificity was proven by decolouration of Iodine during the titration process. | Assumed to be always 100% due to the kind of method used | | | LOQ at Signal/ratio 1:10: 0.13 mg $I_2$<br>validated range:<br>0.2 – 14.6 mg $I_2$<br>It is possible to analyse samples<br>with higher contents applying a proper dilution with distilled water or taking smaller sample aliquots. | [redacted] |

For the validation of the method (Benetka, 2015h) a test formulation containing 0.12%(w/w) of $I_2$ has been used which equals the formulations given for meta SPC 1-2. The test formulation has initially been submitted as a member of the biocidal product family, but deleted by the applicant at a later stage during evaluation. For detailed composition please refer to Confidential Annex, section 3.6.2.

For analysis aliqutos of the test sample have been diluted with 60 mL distilled water and 10 mL 0.25 M sulphuric acid. To avoid degradation of Iodine in the acidic solution or by light the resulting solution immediately was titrated with 0.1 M sodium thiosulphate solution until the equivalence point. The titrations were carried out six times for each aliquot. No blank formulation has been measured.

The method has been proven to be linear resulting in the following equation:
Y = 7.64 * X + 1.56

X = mg $I_2$
Y = µmol demand on thiosulphate solution

With regard to concentration range it is possible to analyse samples with higher contents applying a proper dilution with distilled water or taking smaller sample aliquots. So it is simply a matter of sample size and dilution to stay within the validated range of 0.2 – 14.6 mg $I_2$.

Precision of the method is reported as +/- 0.04 mg $I_2$ which equals to 0.46%.

Regarding specifity, please note:
1. The sensor electrode used for validation and determinations (indicated simply as „Pt" in the report) was a platinum ring vs. Ag/AgCl type („Redox-electrode"), and not a double-Pt amperometric sensor.
2. The EC voltage and potential curve are determined by the redox-pair I2 / I- (iodine / iodide), and the presence of elementary Iodine can be ruled out in distilled water.
3. It is technically impossible to judge the blank concentration of Iodine in water by the absolute EC voltage of the acidified sample, only the logarithmic voltage step at the end-point can be used as analytical signal.
4. Consequently, the extrapolated blank signal can only be read from the calibration curve provided.

Based on the type of analytical method used (volumetric determination of Iodine by means of reduction with sodium thiosulfat) any concentration of Iodine can be determined quantitatively and without the need for calibration by selecting the appropriate dilution and thereby the correct absolute mass of analyte can be determined within the given validation range. Due to the kind of analytical method (redox titration) no interferences from any of the co-formulants present in the total BPF are expected. Therefore recovery is always expected to amount to 100%.

The method is expected to be suitable for the products within the family. None of the co-formulants are expected to interfere with the titration method.

| Analytical methods for monitoring | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| | | | | | Range | Mean | RSD | | |
| Analytical methods for the determination of Iodine are presented in the Iodine CAR (Sweden 2013), Doc III A4.2 and A4.3 | | | | | | | | | |

| Analytical methods for soil | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| | | | | | Range | Mean | RSD | | |
| Analytical methods for the determination of Iodine in soil are presented in the Iodine CAR (Sweden 2013), Doc III A4.2 | | | | | | | | | |

| Analytical methods for air | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| | | | | | Range | Mean | RSD | | |
| Analytical methods for the determination of Iodine in air are presented in the Iodine CAR (Sweden 2013), Doc III A4.2 | | | | | | | | | |

| Analytical methods for water | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| | | | | | Range | Mean | RSD | | |
| Analytical methods for the determination of Iodine in water are presented in the Iodine CAR (Sweden 2013), Doc III A4.2 | | | | | | | | | |

| Analytical methods for animal and human body fluids and tisues | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| | | | | | Range | Mean | RSD | | |
| Not relevant, as the active substance Iodine is not classified as toxic or very toxic. | | | | | | | | | |

| Analytical methods for monitoring of active substances and residues in food and feeding stuff | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| | | | | | Range | Mean | RSD | | |
| Analytical methods for the determination of Iodine in soil are presented in the Iodine CAR (Sweden 2013), Doc III A4.3 | | | | | | | | | |

**Conclusion on the methods for detection and identification of the product**

The validation and method establishment for the quantitative determination of the active substance has been performed using a test formulation equal to teat disinfectant spray products as presented in meta SPC 1 with a nominal Iodine content of 1200 ppm (= 0.12%(w/w)). This concentration is close to the lowest a.s. concentration in the BPF which amounts to 0.1%(w/w) Iodine.

It has been concluded, that the method for the determination of Iodine is applicable for aqueous formulations within the validated range (0.2 – 14.6 mg $I_2$) with a suitable precision. It is possible to analyse samples with higher $I_2$ contents applying a proper dilution with distilled water or taking smaller sample aliquots. None of the co-formulants are expected to interfere with the titration method.

## 2.2.5 Efficacy against target organisms

### 2.2.5.1 Function and field of use

*Function:*

The Iodine product family "BPF_Iodine_VET" comprises in total 8 meta SPCs, which include ready-to-use (RTU) teat dip or spraying products for veterinary hygiene with an active substance content between 0.1%(w/w) Iodine and 0.5%(w/w) Iodine (meta SPC 1 - 5) and products for surface disinfection in animal houses with an active substance content between 1.5%(w/w) and 3%(w/w) Iodine (meta SPC 6 - 8).

All RTU post-milking teat disinfection products in the family have bactericidal and yeasticidal effects. Products for surface disinfection in animal houses have bactericidal, yeasticidal and virucidal effects.

*Field of use:*

The products for the veterinary hygiene (PT3) are ready-to-use teat spraying (meta SPC 1 - 3) or teat dipping biocidal products (meta SPC 4 - 5). The products are intended only for the purpose of non-medical teat spray disinfection by manual and automated disinfection and non-medical teat dip disinfection by manual disinfection of dairy cows. Application of the biocidal product for PT3 is only intended after milking (post-milking). Products in meta SPC 1 – 5 are not allowed to be used before milking.

Products in meta SPC 6 – 8 are intended for animal housing surface disinfection. The biocidal products are concentrated products, which are diluted and sprayed on hard surface. Hard surfaces have to be cleaned before application of the biocidal products.

All products of the "BPF_Iodine_VET" are restricted to professionals only. The intended use is indoors.

### 2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

The ready-to-use biocidal products are non-medical teat disinfectants, which display a bactericidal and yeasticidal activity (meta SPC 1 - 5) for post-milking use. For animal housing surface disinfection bactericidal, yeasticidal and virucidal activity is shown (meta SPC 6 – 8).

### 2.2.5.3 Effects on target organisms, including unacceptable suffering

The effect of the active substance on target organisms is a killing effect.

This is in detail:

Bacteria: kills vegetative bacteria under defined conditions
Yeast: product that kills yeast under defined conditions
Virus: product that inactivates viruses under defined conditions

Teat disinfectants (sprays, dips) have a bactericidal and yeasticidal activity, after post-milking, and surface disinfectants of animal housing show an additional virucidal activity.

### 2.2.5.4 Mode of action, including time delay

Several mechanisms of action contribute to the high reactivity and non-selective action of Iodine against different microorganisms (cf. Sweden 2013):

- *Iodine rapidly penetrates into microorganisms showing a high affinity pattern of adsorption.*
- *Iodine combines with protein substances in the bacterial cell; these can be peptidoglycans in the cell walls or enzymes in the cytoplasm. This results in irreversible coagulation of the protein and consequent loss of function.*
- *Iodine is known to act on thiol groups in the cell; if a thiol enzyme is part of a metabolic chain, metabolic inhibition will result.*
- *Iodine reacts with key groups of proteins, in particular the free-sulfur amino acids cysteine and methionine, nucleotides and fatty acids.*
- *Iodine interferes at the level of the respiratory chain of the aerobic microorganisms by blocking the transport of electrons through electrophilic reactions with the enzymes of the respiratory chain.*

Time delay:

The products used after milking are efficacious in 5 minutes. For surface disinfection of animal housing a contact time of 30 min shall be ensured.

### 2.2.5.5 Efficacy data

Iodine is the active substance for each family member. The family includes Iodine in the form of two types of complexes (iodophores), PVP-Iodine (type 2) and surfactant stabilised Iodine (type 1).

**Meta SPC 1-2: PT03 - Professional – indoors: Veterinary hygiene biocidal products – ready-to-use teat spray**

The originally submitted meta SPC 1 from the applicant was divided by the eCA Austria into meta SPC 1 and meta SPC 2 due to different complexing agents used in the individual formulations. Grouping for this kind of co-formulants was not possible because of different classifications of the substances, resulting in different classification of the individual formulations. After discussion at the WG HH and ENVII-2018, the splitting of the meta SPCs 1 into meta SPC 1 and 2 was made, because due to changes in classification for human health and environmental hazards.

Data requirements:

Following efficacy data are required according to the Guidance (ECHA, 2017f) for teat disinfection:

Bacteria and Yeast (post-milking):

- a quantitative suspension test (phase 2/step1: EN 1656 + EN1657, contact time 5 min; clean/dirty soiling conditions, bacteria: lg 4 reduction; yeast: lg 3 reduction) and

- a quantitative carrier test (phase 2/step2): no validated tests are available for yeast, and for bacteria no European standard phase 2, step 2 test is available for teat disinfection

Both tests are simulating the intended use conditions (temperature, soiling, and contact time). Phase 3 tests, field tests are optional.

The eCA Austria agreed with the applicant to perform phase 2, step 2 efficacy tests for bactericidal activity on a porous surface (VITRO SKIN®, synthetic skin) according to a protocol adapted from the EN 16437 standard conducting the drop/drop method to simulate the spraying application. According to discussions in the WG efficacy the modified EN16437 can be performed with *S. aureus* only, as worst-case test organism.

Biocidal products in meta SPC 1 and meta SPC 2:

Meta SPC 1 includes ready-to-use products to disinfect the teats after milking. Products are sprayed on teats with an active substance content between 0.15%(w/w) and 0.5%(w/w) Iodine. Meta SPC 2 includes ready-to-use spray products to disinfect the teats after milking with an active substance content of 0.3%(w/w) Iodine. Polyvinylpyrrolidone (PVP) is added as complexing/solubilising agent. The composition of the biocidal products is available in the confidential Annex (ref. to Chapter 3.6 Confidential annex – 3.6.1 Product family composition and formulation). During evaluation phase the applicant withdrew several products, cf. to chapter 3.6.6. Tested products have an active substance content beween 0.05%(w/w) - 0.15%(w/w) Iodine.

Conclusion on the efficacy:

Bactericidal efficacy:

Phase 2/step 1 tests:

Before storage:
The bactericidal efficacy was tested with the fresh product containing 0.05%(w/w) Iodine according the international standards EN 1656 against *Staphylococcus aureus*, *E.coli* and *Streptococcus uberis* under test conditions (temperature: 30°C, contact time: 5 min, soiling: 10 g/L skimmed milk) defined for teat disinfectants (post-milking). The required log reduction of lg 4 was accomplished when diluted ≥ 30% after 5 min contact time ([redacted]).

After storage:
The bactericidal efficacy was tested after accelerated storage (2 weeks, 54°C) with biocidal products containing 0.05%(w/w) Iodine according to the international standards EN 1656 against *Staphylococcus aureus*, *E.coli* and *Streptococcus uberis* under test conditions (temperature: 30°C, contact time: 5 min, soiling: 10 g/L skimmed milk) defined for teat disinfectants (post-milking). The required log reduction of lg 4 was accomplished when diluted ≥ 30% after 5 min contact time ([redacted]).

The bactericidal efficacy was tested after 1 year storage with biocidal products containing 0.05%(w/w) Iodine according the international standards EN 1656 against *Enterococcus hirae, Proteus hauseri, Pseudomonas aeroginosa, Staphylococcus aureus,* and *Streptococcus uberis* under test conditions (temperature: 30°C, contact time: 5 min, soiling: 10 g/L skimmed milk) defined for teat disinfectants (post-milking). The required log reduction of lg4 was accomplished when diluted ≥ 30% after 5 min contact time

([redacted]). 1-year storage and conditions (25°C) was confirmed by the applicant (ref. to R4BP Communication number: UAP-C-1276112-32-00/F).

Phase 2/step 2 tests:
No tests are available with biocidal products containing 0.3 or 0.5%(w/w) Iodine. Instead, a modified EN16437 test using Vitroskin® (drop/drop) towards *S. aureus* DSM 799 has been conducted with biocidal products containing the lowest Iodine content within this meta SPC ([redacted]). The biocidal product containing 0.15%(w/w) Iodine has been tested before storage at 100%, 80% and 67%. 1% skimmed milk has been used as interfering substance; the contact time was 5 min at 30°C. A lg reduction ≥ 4 has been achieved at 100%(v/v) concentration of the tested product.

Yeasticidal efficacy:

Phase 2/step 1 tests:

After storage:
The yeasticidal efficacy was tested after accelerated storage (2 weeks, 54°C) with a biocidal product containing 0.05%(w/w) Iodine according the international standards EN 1657 against *Candida albicans* under test conditions (30°C, contact time: 5 min, soiling: 10 g/L skimmed milk) defined for teat disinfection (post-milking). The biocidal product shows after 14 days storage at 54°C at a contact time of 5 min in a concentration of 30% an effect against *C. albicans* ([redacted]).

The yeasticidal efficacy was tested after 1 year storage at with a biocidal product containing 0.05%(w/w) Iodine according the international standards preEN 1657 against *Candida albicans* under test conditions (30°C, contact time: 5 min, soiling: 10 g/L skimmed milk) defined for teat disinfection (post-milking). The biocidal product shows after storage at a contact time of 5 min in a concentration of 30% (v/v) an ≥ 4 lg reduction against *C. albicans* ([redacted]). 1-year storage and conditions (25°C) of the test item used in [redacted] was confirmed by the applicant (ref. to R4BP Communication number: UAP-C-1276112-32-00/F).

Storage stability:

FINK Io Spray (PVP):
Under accelerated storage conditions a decrease in Iodine content of 32.3% was determined in FINK Io Spray (PVP) ([redacted]). Under long term storage conditions (1 year, at ambient temperature) conditions a decrease in Iodine content of 23.21% was determined in FINK IO Spray (PVP), batch no. 15102014 ([redacted]).

FINK IO Spray 50:
Under long term storage conditions (1 year, at ambient temperature) conditions a decrease in Iodine content of 8.13% was determined in FINK IO Spray 50, batch no. 28042014/37119 ([redacted]).

For IO Spray 15 PVP (0.15%(w/w) Iodine) no storage stability test is available.

Conclusion meta SPC 1 and meta SPC 2: PT03 - Professional – indoors: Veterinary hygiene biocidal products – ready-to-use teat spray

Meta SPC 1 and 2 include ready-to-use products to disinfect the teats after milking. Products are sprayed on teats with an active substance content between 0.15%(w/w) and 0.5%(w/w) Iodine. Phase 2/step 2 tests on efficacy towards *S. aureus* have been conducted with products containing the lowest Iodine content of this meta SPC (0.15%(w/w) Iodine) and this has been found to fulfil the suggested requirements of the Vitroskin® test using the suggested test protocols (drop/drop) from the IRG ring trial. A lg reduction ≥ 4 has been achieved at 100%(v/v) concentration of the tested product. The product contained the lowest Iodine concentration and is representative for the worst case product for meta SPC 1 - 2. No efficacy test is available with the aged product containing the 0.15%(w/w) Iodine. However, Phase 2/step 1 tests on bactericidal and yeasticidal efficacy with biocidal products starting with 0.05%(w/w) Iodine, which are lower than for the given meta SPC 1 and 2 have been conducted. To cover the range of meta SPC 1 and 2, bactericidal and yeasticidal activity prior to and after accerlerated and 1 year storage was determined. Efficacy test with this product showed a bactericidal and yeasticidal efficacy prior to and after storage. Therefore, the eCA Austria concludes that products in meta SPC 1 and 2 are efficacious.

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| bactericide | teat disinfection | Io Spray (PVP) 18997<br><br>Prior to storage | *E. coli, S. aureus, S. uberis* | EN 1656 | T: 30°C ± 1°C<br><br>conditions: 10.0 g/L skim milk (organic load for teat disinfectants)<br><br>exposure time: 5 min<br><br>conc.: 80%, 60%, 40%, 30% (v/v) | BP dilution ≥30% (v/v): bactericidal activity (≥5 lg reduction) in 5 min | [redacted] |
| bactericide | teat disinfection | Io Spray (PVP) 18997<br><br>After storage (2 weeks, 54°C) | *E. coli, S. aureus, S. uberis* | EN 1656 | T: 30°C<br><br>conditions: 10.0 g/L skim milk (organic load for teat disinfectants)<br><br>exposure time: 5 min<br><br>conc.: 80%, 60%, 40%, | BP dilution ≥30% (v/v): bactericidal activity (≥5 lg reduction) | [redacted] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | 30% (v/v) | | |
| bactericide | teat disinfection | FINK Io Spray - PVP 500 ppm 18997 After storage (1 year, 25°C) | *E. hirae* *P. hauseri* *P. aeruginosa* *S. aureus,* *S. uberis* | EN 1656 | T: 30°C<br><br>conditions: 10.0 g/L skim milk (organic load for teat disinfectants)<br><br>exposure time: 5 min<br><br>conc.: 80%, 60%, 40%, 30% (v/v)<br><br>Storage was confirmed by the applicant (ref. to R4BP Communication number: UAP-C-1276112 | BP dilution ≥30% (v/v): bactericidal activity (≥5 lg reduction) | [redacted] |
| yeasticide | teat disinfection | FINK Io Spray (PVP) 18997<br><br>After storage (2 weeks, 54°C) | *C. albicans* | EN 1657 | T: 30°C<br><br>conditions: 10.0 g/L skim milk (organic load for teat disinfectants)<br><br>exposure time: 5 min<br><br>conc.: 80%, 60%, 40%, 30% (v/v) | BP dilution ≥30% (v/v): yeasticidal activity (≥4 lg reduction) | [redacted] |
| yeasticide | teat disinfection | FINK Io Spray - PVP 500 ppm 18997<br><br>After storage (1 year, 25°C) | *C. albicans* | EN 1657 | T: 30°C<br><br>conditions: 10.0 g/L skim milk (organic load for teat disinfectants)<br><br>exposure time: 5 min<br><br>conc.: 80%, 60%, 40%, 30% (v/v)<br><br>Storage was | BP dilution ≥30% (v/v): yeasticidal activity (≥4 lg reduction) | [redacted] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | confirmed by the applicant (ref. to R4BP Communication number: UAP-C-1276112 | | |
| bactericide | teat disinfection | IOSpray 15 PVP | S. aureus | EN 16437 drop/drop | T: 30°C<br><br>conditions: 1 % skimmed milk<br><br>exposure time: 5 min<br><br>conc.: 100%, 80%, 67%,(v/v) | BP dilution ≥100% (v/v): bactericidal activity (≥4 lg reduction) | [redacted] |

## Meta SPC 3: PT03 - Professional – indoors: Veterinary hygiene biocidal products – ready-to-use teat spray

The submitted meta SPC 1 from the applicant was divided by the eCA Austria into meta SPC 1 and meta SPC 2 due to different complexing agents used in the individual formulations. Grouping for this kind of co-formulants was not possible because of different classifications of the substances, resulting in different classification of the individual formulations, which would not fulfil the requirement that in each meta SPC the same H and P sentences are prevalent. Due to changes in classification for human health and environmental hazards meta SPC were split, meta SPC2 was re-named to meta SPC 3.

Data requirements: for teat disinfection are included under Meta SPC 1 – 2.

Biocidal products in meta SPC 3:

Meta SPC 3 includes a ready-to-use product, which is sprayed on teats with an active substance content of 0.5%(w/w) Iodine. Fatty alcohol ethoxylates (FAE) are added as complexing/solubilising agent.

Tested product: Fink Io Spray 50 (Jodophore).

Conclusion on the efficacy:

Bactericidal efficacy:

Phase 2/step 1 tests:
The bactericidal efficacy was tested with biocidal product containing 0.5%(w/w) Iodine according the international standards EN 1656 against *Enterococcus hirae, Proteus hauseri, Pseudomonas aeruginosa, Staphylococcus aureus, and Streptococcus uberis* ([redacted]) under test conditions (temperature: 30°C, contact time: 5 min, soiling: 10 g/L skimmed milk) defined for teat disinfectants after 1 year storage (post-milking). Appropriate storage condition and period was confirmed by the applicant ([redacted]). The required log reduction of lg4 was accomplished when diluted at 80%, 60%, 40% and 30% after 5 min contact time. The biocidal product containing 0.5%(w/w) Iodine has been tested after 2 weeks stored at 54°C ([redacted]) and has shown in a concentration ≥30%(v/v) at 30°C under soiling with skimmed milk a bactericidal effect within 5 min for *S. aureus, E. coli,* and *Streptococcus uberis*.

Phase 2/step 2 tests:
No tests are available with the biocidal product containing 0.5%(w/w) Iodine. Instead, a modified EN16437 test using Vitroskin® (drop/drop) towards *S. aureus* DSM 799 has been conducted with a biocidal product containing 0.15%(w/w) Iodine (tested at 100%, 80% and 67%). 1% skimmed milk was used as interfering substance, the contact time was 5 min. A lg reduction ≥ 4 was achieved at 100%(v/v) and 80%(v/v) concentration of the tested product ([redacted]).

Yeasticidal efficacy:

Phase 2/step 1 tests:
The yeasticidal efficacy of the biocidal product containing 0.5%(w/w) Iodine was tested after one year storage (25°C) according to the international standards pre EN 1657 (2014) against *Candida albicans* under test conditions (30°C, contact time: 5 min, soiling: 10 g/L skimmed milk) defined for teat disinfection (post-milking). The biocidal product shows at a contact time of 5 min in a concentration of 30% an effect against *C. albicans* ([redacted]).

The yeasticidal efficacy of the biocidal product containing 0.5%(w/w) Iodine was tested after accelerated storage (2 weeks, 54°C) according to the international standards EN 1657 against *Candida albicans* under test conditions (30°C, contact time: 5 min, soiling: 10 g/L skimmed milk) defined for teat disinfection (post-milking). The biocidal product shows after 14 days storage at 54°C at a contact time of 5 min in a concentration of 30% an effect against *C. albicans* ([redacted]).

Storage stability:
The biocidal product containing 0.15%(w/w) Iodine and FAE was deleted from the BPF by the eCA Austria based on the missing long-term storage stability. Read across to other products from products with higher Iodine content to products with lower Iodine content is not possible. The only product which is also stabilised with FAE, and for which accelerated storage and long term storage stability studies are available, is FINK Io Spray 50 (Jodophor). Iodine decreases in an accelerated storage (2 weeks, 54°C) to 22.7% ([redacted]). Long term storage at ambient temperature shows a decrease of a.s. of 21.92% ([redacted]).

Conclusion meta SPC 3: PT03 - Professional – indoors: Veterinary hygiene biocidal products – ready-to-use teat spray

Meta SPC 3 includes a ready-to-use product, which is sprayed on teats with an active substance content of 0.5%(w/w) Iodine. Fatty alcohol ethoxylates (FAE) are added as complexing/solubilising agent. In phase 2/step 1 tests bactericidal and yeasticidal efficacy was shown after 1 year storage. Phase 2/step 2 tests on efficacy towards *S. aureus* have been conducted with a product containing only 0.15%(w/w) Iodine, which is lower than the Iodine content of the meta SPC 3 and this has been found to fulfil the suggested requirements of the Vitroskin® test using the suggested test protocols (drop/drop) from the IRG ring trial. A lg reduction ≥ 4 has been achieved at 100%(v/v) and 80%(v/v) concentration of the tested product. Therefore it is assumed by the eCA that a product with a higher Iodine content with the sme stabilizer wil pass the phase 2, step 2 test as well. However, this product has been deleted by the eCA based on missing long-term storage stability. A worst case decrease (accelerated storage) of Iodine using biocidal product containing 0.5%(w/w) Iodine stabilized with FAE shows a decrease of 22.7% a.s, which would theoretically result in a Iodine concentration of 0.38%, which is higher then the concentration in the phase 2/step2 tests. Therefore, the eCA Austria concludes that the product in meta SPC 3 is efficacious.

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| bactericide | teat disinfection | FINK Io Spray 50 Jodophor (18207_1)<br><br>After storage (2 weeks, 54°C | *E. coli, S. aureus, S. uberis* | EN 1656 | T: 30°C<br><br>conditions: 10.0 g/L skim milk (organic load for teat disinfectants<br><br>exposure time:<br>5 min<br><br>conc.: 80%, 60%, 40%, 30%(v/v) | BP dilution ≥30% (v/v): bactericidal activity (≥5 lg reduction) | [redacted] |
| bactericide | teat disinfection | FINK Io Spray 50 Jodophor (18207_1)<br><br>After storage (1 year, 25°C | *E. hirae*<br>*P. hauseri*<br>*P. aeruginosa*<br>*S. aureus,*<br>*S. uberis* | EN 1656 | T: 30°C<br><br>conditions: 10.0 g/L skim milk (organic load for teat disinfectants<br><br>exposure time:<br>5 min | BP dilution ≥30% (v/v): bactericidal activity (≥5 lg reduction) | [redacted] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | | conc.: 80%, 60%, 40%, 30% (v/v) | | |
| yeasticide | teat disinfection | FINK Io Spray 50 Jodophor (18207_1)<br><br>After storage (2 weeks, 54°C | *C. albicans* | EN 1657 | T: 30°C<br><br>conditions: 10.0 g/L skim milk (organic load for teat disinfectants)<br><br>exposure time:<br>5 min<br><br>conc.: 80%, 60%, 40%, 30% (v/v) | BP dilution ≥30% (v/v): yeasticidal activity (≥4 lg reduction) | [redacted] |
| yeasticide | teat disinfection | FINK Io Spray 50 Jodophor (18207_1)<br><br>After storage (1 year, 25°C | *C. albicans* | EN 1657 | T: 30°C<br><br>conditions: 10.0 g/L skim milk (organic load for teat disinfectants)<br><br>exposure time:<br>5 min<br><br>conc.: 80%, 60%, 40%, 30% (v/v)<br><br>eCA Austria: In the report it is not mentioned that the product was stored for 1 year, letter from the applicant was requested to confirm the storage period and conditions, ref. to [redacted]) | BP dilution ≥30% (v/v): yeasticidal activity (≥4 lg reduction) | [redacted] |
| bactericid | teat | IOSpray | *S. aureus* | EN 16437 | T: 30°C | BP dilution | [redacted] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| e | disinfection | 15 Type I | | drop/drop | conditions: 1 % skimmed milk<br><br>exposure time:<br>5 min<br><br>conc.: 100%, 80%, 67%(v/v) | ≥80% (v/v): bactericidal activity (≥4 lg reduction) | [redacted] |
| bactericide | teat disinfection | Fink Io Spray 50 18207<br><br>After storage (1year, 25°C) | E. coli, S. aureus, S. uberis | EN 1656 | T: 30°C<br><br>conditions: 10.0 g/L skim milk (organic load for teat disinfectants)<br><br>exposure time:<br>5 min<br><br>conc.: 80%, 60%, 40%, 30%(v/v) | BP dilution ≥30% (v/v): bactericidal activity (≥5 lg reduction) | [redacted] |
| yeasticide | teat disinfection | Fink Io Spray 50 18207<br><br>After storage (1year, 25°C) | A read across to a study for the same biocidal product with the only change being a different type of Iodophore (surfactant instead of PVP) is considered to be sufficient. The following reasons can be given to justify the read across:<br>1. identical use pattern and formulation apart from the different Iodophore<br>2. identical concentration in a.s. as formulated<br>3. since surfactant - iodophor products have the tendency to decompose slightly quicker upon storage than the corresponding PVP products, tests with products containing surfactants as iodophors at the end of the shelf life testing period can be considered as worst case for efficacy assessment. | | | | |
| bactericide | teat disinfection | FINK Io Spray 50 Jodophor (18207_1)<br><br>After storage (2 weeks, 54°C | *E. coli, S. aureus, S. uberis* | EN 1656 | T: 30°C<br><br>conditions: 10.0 g/L skim milk (organic load for teat disinfectants<br><br>exposure time:<br>5 min<br><br>conc.: 80%, 60%, 40%, 30% (v/v) | BP dilution ≥30% (v/v): bactericidal activity (≥5 lg reduction) | [redacted] |
| bactericide | teat disinfectio | FINK Io Spray 50 | *E. hirae*<br>*P. hauseri* | EN 1656 | T: 30°C | BP dilution | [redacted] |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | n | Jodophor (18207_1)<br><br>After storage (1 year, 25°C | *P. aeruginosa S. aureus, S. uberis* | | conditions: 10.0 g/L skim milk (organic load for teat disinfectants<br><br>exposure time: 5 min<br><br>conc.: 80%, 60%, 40%, 30% (v/v) | ≥30% (v/v): bactericidal activity (≥5 lg reduction) | |
| yeasticide | teat disinfection | FINK Io Spray 50 Jodophor (18207_1)<br><br>After storage (2 weeks, 54°C | *C. albicans* | EN 1657 | T: 30°C<br><br>conditions: 10.0 g/L skim milk (organic load for teat disinfectants)<br><br>exposure time: 5 min<br><br>conc.: 80%, 60%, 40%, 30% (v/v) | BP dilution ≥30% (v/v): yeasticidal activity (≥4 lg reduction) | [redacted] |
| yeasticide | teat disinfection | FINK Io Spray 50 Jodophor (18207_1)<br><br>After storage (1 year, 25°C | *C. albicans* | EN 1657 | T: 30°C<br><br>conditions: 10.0 g/L skim milk (organic load for teat disinfectants)<br><br>exposure time: 5 min<br><br>conc.: 80%, 60%, 40%, 30% (v/v) | BP dilution ≥30% (v/v): yeasticidal activity (≥4 lg reduction) | [redacted] |

## Meta SPC 4 - 5: PT03 - Professional – indoors: Veterinary hygiene biocidal products – ready-to-use teat dip

Data requirements: for teat disinfection are included under Meta SPC 1 – 2.

Biocidal products in meta SPC 4 - 5:
The splitting of the meta SPCs 1, 3 and 4 was made, due to changes in classification for human health and environmental hazards.

Individual products in meta SPC 3 are: FINK Io Dip 10 (=IoDip 10 PVP); Fink Io Dip Protect; Iodofilm 75/5 4500 ppm; Iodofilm 75/5 3000 ppm

Meta SPC 3 includes ready-to-use teat dip products with an active substance content of 0.1 – 0.45%(w/w) Iodine. Polyvinylpyrrolidone (PVP) is added as complexing/solubilising agent.

Tested product: FINK Io Dip 10 (=IoDip 10 PVP)

Phase 2/step 1 tests:
The lack of phase 2, step 1 experimental efficacy data for teat dip disinfectants is caused by the splitting of the teat disinfection meta SPCs. However, applicant has decided to provide phase 2, step 2 tests with teat dip products in order to prove their efficacy. Moreover, it is highly unlikely that there will be pronounced differences between very similar (apart from the thickener) biocidal products in phase 2 step 1 suspension testing towards bacteria and yeast. Therefore, to fill the data gap a read-across with FINK Io Spray PVP 500 (18997) containing 0.05%(w/w) Iodine and a lower PVP content compared to biocidal products in meta SPC 3 is accepted. Phase 2/step 1 tests on bactericidal and yeasticidal efficacy with biocidal products starting with 0.05%(w/w) Iodine have been conducted. Bactericidal and yeasticidal activity prior to and after accelerated and 1 year storage was determined. Efficacy test with this product showed a bactericidal and yeasticidal efficacy prior to and after storage.

Phase 2/step 2 tests:
A modified EN16437 test using Vitroskin (drop/dip) towards *S. aureus* DSM 799 has been conducted with 0.1%(w/w) Iodine (IODip 10 PVP) tested at 100%, 80% and 60%). 1% skimmed milk was used as interfering substance; the contact time was 5 min. A lg reduction ≥ 4 was achieved at 100%(v/v) concentration of the tested product.

Regarding, the influence of thickeners in efficacy testing: in the opinion of the eCA thickeners have not a significant influence on the results of phase 2, step 1 (suspension) tests, since both formulations, with or without thickener, are homogenous aqueous solutions and act as such on organism suspension. In addition, surface tests or real – life conditions should be considered worst case when thickeners are absent (spray products), resulting in quicker and more comprehensive "drip-loss" and thereby in a reduced amount of disinfectant / active substance at the target site.

Conclusion meta SPC 4 - 5: PT03 - Professional – indoors: Veterinary hygiene biocidal products – ready-to-use teat dip

Meta SPC 4 and 5 include ready-to-use teat dip products with an active substance content of 0.1 – 0.45%(w/w) Iodine. Polyvinylpyrrolidone (PVP) is added as complexing/solubilising agent. Phase 2/step 2 tests on efficacy towards *S. aureus* have been conducted with a product containing only 0.1%(w/w) Iodine and PVP and this has been found to fulfil the suggested requirements of the Vitroskin® test using the suggested test protocols

(drop/drop) from the IRG ring trial. A lg reduction ≥ 4 has been achieved at 100%(v/v) concentration of the tested product. For Phase 2/step 1 tests a read across with a FINK Io Spray PVP 500 (18997) containing 0.05%(w/w) Iodine and lower PVP content is performed. Efficacy test with this product showed a bactericidal and yeasticidal efficacy prior to and after storage. Read Across is accepted by the eCA Austria.

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| bactericide | teat disinfection | IODip 10 PVP | *S. aureus* | EN 16437 drop/dip | T: 30°C<br><br>conditions: 1 % skimmed milk<br><br>exposure time: 5 min<br><br>conc.: 100%, 80%, 60%,(v/v) | BP dilution ≥100% (v/v): bactericidal activity (≥4 lg reduction) | [redacted] |

## Meta SPC 6 - 8: PT03 - Professional – indoors: Veterinary hygiene biocidal products – surface disinfection in animal houses

The splitting of the former meta SPC 4 into meta SPC 6 – 8 was made, due to changes in classification for human health and environmental hazards.

Following efficacy data are required according to the Guidance (ECHA, 2017f) for hard surfaces:

- a quantitative suspension test (2,1 test: EN 1656 + EN1657, contact time normally 5 min up to maximum of 30 min; 10°C, clean/dirty, bacteria: lg 5 reduction; yeast: lg 4 reduction) and
- a quantitative surface test (2,2 test: EN 14349/EN 16437 and EN 16438),

Both are stimulating the intended use conditions (temperature, soiling, porous and non-porous surfaces and contact time). Phase 3 tests are optional.

Products for veterinary hygiene / surface disinfection in animal houses contain active substance between 1.5 and 3%(w/w) Iodine (meta SPC 6 - 8). The product with the lowest content of Iodine is Iodosan 15, which contains 1.5%(w/w) Iodine. All biocidal products within these meta SPCs are concentrated products, which are diluted. The higher concentrated products are used at higher dilution rates. The final concentration sprayed on the surfaces is the same for all products (end-use Iodine concentration 0.06%(w/w)).

Meta SPC 6 - 8: PT03 - Professional – indoors: Veterinary hygiene biocidal products – surface disinfection in animal houses

Bactericidal efficacy:
Phase 2/step 1 and Phase 2/step 2 tests on bactericidal efficacy have been conducted prior to and after accelerated storage (2 weeks, 54°C) with biocidal products with minimum (1.5%(w/w) Iodine) and maximum (3%(w/w) Iodine) a.s. concentration.

Phase 2/step 1 tests:
The bactericidal efficacy of the Iodine product family of "BPF_Iodine_VET" was tested according the international standards EN 1656 against *S. aureus, E. hirae, P. aeruginosa, E.coli, Proteus vulgaris* under test conditions (temperature: 10°C, contact time: 30 min, soiling: 3 g/L bovine albumin) defined for hard surfaces prior and after accelerated storage. Only low level soiling conditions were used in the tests.

The biocidal product with the lowest Iodine concentration of 1.5%(w/w) (Iodosan 15, batch E11811) has been tested at 1.5%, 2%, 4% and 5%(v/v) prior to storage and after storage (2 weeks, 54°C). Prior to storage and after storage, Iodosan 15 (and all products with same formulation) was efficacious against bacteria at a concentration of ≥ 1.5 %(v/v) at 10°C and at low level soiling (3 g BSA/L) conditions within 30 minutes ([redacted]).

The biocidal product with the highest Iodine concentration (Iodosan 30 plus) has been tested according the international standards EN 1656 under test conditions (temperature: 10°C, contact time: 30 min, low level soiling: 3 g/L bovine albumin) and shows in a concentration of 0.3%(w/w) an effect against *S. aureus, E. hirae, P. aeruginosa, E.coli, Proteus vulgaris* after 14 days storage at 54°C ([redacted]).

Phase 2/step 2 tests:
The bactericidal efficacy of the Iodine product family of "BPF_Iodine_VET" was tested according the international standards EN 14349 against *S. aureus, E. hirae, P. aeruginosa, E.coli, Proteus vulgaris* under test conditions (temperature: 10°C, contact time: 30 min, soiling: 3 g/L bovine albumin) defined for hard surfaces prior and after accelerated storage. Only low-level soiling conditions were used in the tests ([redacted]).

The BP with the lowest Iodine concentration of 1.5%(w/w) (Iodosan 15, batch E11811) has been tested at 1.5%, 2%, 4% and 5%(v/v) prior to storage and after storage (2 weeks, 54°C). Prior to storage and after storage, Iodosan 15 (and all products with same formulation) has been efficacious against bacteria at a concentration of ≥1.5%(v/v) at 10°C and at low level soiling (3 g BSA/L) conditions within 30 minutes ([redacted]).

The biocidal product with the highest Iodine concentration (Iodosan 30 plus) has been tested according the international standards EN 14349 under test conditions (temperature: 10°C, contact time: 30 min, low level soiling: 3 g/L bovine albumin) and shows in a concentration of 1% an effect against *S. aureus, E. hirae, P. aeruginosa, E.coli, Proteus vulgaris* after 14 days storage at 54°C ([redacted]).

Yeasticidal efficacy:
Phase 2/step 1 and Phase 2/step 2 tests on yeasticidal efficacy have been conducted prior to and after accelerated storage (2 weeks, 54°C) with biocidal products with minimum (1.5%(w/w) Iodine) and maximum (3%(w/w) Iodine) a.s. concentration.

Phase 2/step 1 tests:
The yeasticidal efficacy of the Iodine product family of "BPF_Iodine_VET" was tested according the international standards EN 1657 against *Candida albicans* under test conditions (10°C, contact time: 30 min, soiling: 3 g/L bovine albumin) defined for hard surfaces. Only low level soiling conditions were used in the tests.

The biocidal product with the lowest Iodine concentration of 1.5% (Iodosan 15, batch E11811) was tested at 1.5%, 2%, 4% and 5%(v/v) prior to storage and after storage (2 weeks, 54°C). Prior and after storage to storage, Iodosan 15 (and all products with same formulation) was efficacious against yeast at a concentration of ≥1.5%(v/v) at 10°C and at low level soiling (3 g BSA/L) conditions within 30 minutes ([redacted]).

The biocidal product with the highest Iodine concentration (Iodosan 30 plus) was tested according the international standards EN 1657 under test conditions (temperature: 10°C, contact time: 30 min, low level soiling: 3 g/L bovine albumin) and shows in a concentration of 0.3% an effect against *C. albicans* after 14 days storage at 54°C ([redacted]).

Phase 2/step 2 tests:
The yeasticidal efficacy of the Iodine product family of "BPF_Iodine_VET" was tested according the international standards EN 16438 against *Candida albicans* under test conditions (10°C, contact time: 30 min, soiling: 3 g/L bovine albumin) defined for hard surfaces. Only low level soiling conditions were used in the tests.

The BP with the lowest Iodine concentration of 1.5%(w/w) (Iodosan 15, batch E11811) was tested at 1.5%, 2%, 4% and 5%(v/v) prior to storage and after storage (2 weeks, 54°C). Prior and after storage, Iodosan 15 (and all products with same formulation) was efficacious against yeast at a concentration of ≥1.5 %(v/v) at 10°C and at low level soiling (3 g BSA/L) conditions within 30 minutes ([redacted]).

The biocidal product with the highest Iodine concentration (Iodosan 30 plus) was tested according the international standards EN 16438 under test conditions (temperature: 10°C, contact time: 30 min, low level soiling: 3 g/L bovine albumin) and shows in a concentration of 0.5% an effect against *C. albicans* after 14 days storage at 54°C (Sorger, 2015f).

Virucidal efficacy:
Virucidal quantitative suspension test against *Bovine Enterovirus Type* 1 VR-248 according to EN 14675 was conducted with the biocidal product with the lowest Iodine concentration of 1.5%(w/w) (Iodosan 15, batch E11811) at 2%, 5% and 6%(v/v) concentration prior to and after accelerated storage (2 weeks, 54°C). After an exposure time of 30 min at 10°C with 5% Iodosan 15 under clean conditions prior and after accelerated aging, no replication of *Bovine Enterovirus Type* 1 could be detected in cultures of PT-cells. The required titer reduction of 4 lg10 could be demonstrated ([redacted]).

Virucidal quantitative suspension test against *Bovine Enterovirus Type* 1 VR-248 according to EN 14675 was conducted the biocidal product with the highest Iodine concentration of 3%(w/w) (Iodosan 30 plus, batch E11813) at 0.5%, 1%, 1.5%, 2%, and 2.5%(v/v) concentration prior to and after accelerated storage (2 weeks, 54°C). After an exposure time of 30 min at 10°C with 2% Iodosan 30 plus under clean conditions prior and after accelerated aging, no replication of *Bovine Enterovirus Type* 1 could be detected in cultures of PT-cells. The required titer reduction of 4 lg10 could be demonstrated ([redacted]).

Conclusion meta SPC 6 - 8: PT03 - Professional – indoors: Veterinary hygiene biocidal products – surface disinfection in animal houses

Bacterial, yeasticidal and virucidal efficacy was shown within 30 minutes exposure for the biocidal products with minimum (1.5%(w/w)) and maximum (3%(w/w)) Iodine content prior and after accelerated storage under low level soiling (3 g BSA/L) conditions at 10°C. The efficacious dilutions of all biocidal products within this meta SPCs are discussed under the Chapter Label claims.

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| bactericide | surface disinfection n animal housing | Iodosan 15<br><br>Prior to storage | *S. aureus, E. hirae, P. aeruginosa, E. coli, P. vulgaris* | EN 1656 | T: 10°C<br><br>conditions: 3.0 g/L bovine albumin)<br><br>exposure time: 30 min<br><br>conc: 5%, 4%, 2%, 1.5% (v/v) | BP dilution ≥1.5% (v/v): bactericidal activity (≥5 lg reduction) | [redacted] |

| Experimental data on the efficacy of the biocidal product against target organism(s) | | | | | | | |
|---|---|---|---|---|---|---|---|
| bactericide | surface disinfection animal housing | Iodosan 15<br><br>After storage (2 weeks, 54°C | *S. aureus, E. hirae, P. aeruginosa, E. coli, P. vulgaris* | EN 1656 | T: 10°C<br><br>conditions: 3.0 g/L bovine albumin)<br><br>exposure time: 30 min<br><br>conc: 5%, 4%, 2%, 1.5% (v/v) | BP dilution ≥1.5% (v/v): bactericidal activity (≥5 lg reduction) | [redacted] |
| bactericide | surface disinfection animal housing | Iodosan 15<br><br>Prior to storage | *S. aureus, E. hirae, P. aeruginosa, E. coli, P. vulgaris* | EN 14349 | T: 10 ± 1°C<br><br>conditions: 3.0 g/L bovine albumin)<br><br>exposure time: 30 min<br><br>conc: 5%, 4%, 2%, 1.5% (v/v) | BP dilution ≥1.5% (v/v): bactericidal activity (≥4 lg reduction) | [redacted] |
| bactericide | surface disinfection animal housing | Iodosan 15<br><br>After storage (2 weeks, 54°C | *S. aureus, E. hirae, P. aeruginosa, E. coli, P. vulgaris* | EN 14349 | T: 10 ± 1°C<br><br>conditions: 3.0 g/L bovine albumin)<br><br>exposure time: 30 min<br><br>conc: 5%, 4%, 2%, 1.5% (v/v) | BP dilution ≥1.5% (v/v): bactericidal activity (≥4 lg reduction) | [redacted] |
| yeasticide | surface disinfection animal housing | Iodosan 15<br><br>Prior to storage | *C. albicans* | EN 1657 | T: 10°C<br><br>conditions: 3.0 g/L bovine albumin)<br><br>exposure time: 30 min<br><br>conc: 5%, 4%, 2%, 1.5% (v/v) | BP dilution ≥1.5% (v/v): yeasticidal activity (≥4 lg reduction) | [redacted] |

| Experimental data on the efficacy of the biocidal product against target organism(s) | | | | | | | |
|---|---|---|---|---|---|---|---|
| yeasticide | surface disinfection animal housing | Iodosan 15<br><br>After storage (2 weeks, 54°C | *C. albicans* | EN 1657 | T: 10°C<br><br>conditions: 3.0 g/L bovine albumin)<br><br>exposure time: 30 min<br><br>conc: 5%, 4%, 2%, 1.5% (v/v) | BP dilution ≥1.5% (v/v): yeasticidal activity (≥4 lg reduction) | [redacted] |
| yeasticide | surface disinfection animal housing | Iodosan 15<br><br>Prior to storage | *C. albicans* | EN 16438 | T: 10 ± 1°C<br><br>conditions: 3.0 g/L bovine albumin)<br><br>exposure time: 30 min<br><br>conc: 5%, 4%, 2%, 1.5% (v/v) | BP dilution ≥1.5% (v/v): yeasticidal activity (≥3 lg reduction) | [redacted] |
| yeasticide | surface disinfection animal housing | Iodosan 15<br><br>After storage (2 weeks, 54°C | *C. albicans* | EN 16438 | T: 10 ± 1°C<br><br>conditions: 3.0 g/L bovine albumin)<br><br>exposure time: 30 min<br><br>conc: 5%, 4%, 2%, 1.5% v/v | BP dilution ≥1.5% (v/v): yeasticidal activity (≥3 lg reduction) | [redacted] |
| virucide | surface disinfection animal housing | Iodosan 15<br><br>Prior to storage | *Bovine Enterovirus* Type 1 VR-248 | EN 14675 | T: 10°C ± 0.5°C<br><br>conditions: 3.0 3.0 g BSA/L<br><br>exposure time: 30 min<br><br>conc 2%, 3%, 4%, 5%, 6% (v/v) | BP dilution ≥5% (v/v): virucidal activity (≥4 lg reduction) | [redacted] |

| Experimental data on the efficacy of the biocidal product against target organism(s) | | | | | | | |
|---|---|---|---|---|---|---|---|
| virucide | surface disinfection animal housing | Iodosan 15<br><br>After storage (2 weeks, 54°C | *Bovine Enterovirus* Type 1 VR-248 | EN 14675 | T: 10°C ± 0.5°C<br><br>conditions: 3.0 3.0 g BSA/L<br><br>exposure time: 30 min<br><br>conc 2%, 5%, 6% (v/v) | BP dilution ≥5% (v/v): virucidal activity (≥4 lg reduction) | [redacted] |
| bactericide | surface disinfection animal housing | Iodosan 30 plus<br><br>After storage (2 weeks, 54°C | *S. aureus, E. hirae, P. aeruginosa, E. coli, P. vulgaris* | EN 1656 | T: 10°C<br><br>conditions: 3.0 g/L bovine albumin)<br><br>exposure time: 30 min<br><br>conc: 1.5%, 1%, 0.5%, 0.3% (v/v) | BP dilution ≥0.3% (v/v): bactericidal activity (≥5 lg reduction) | [redacted] |
| bactericide | surface disinfection animal housing | Iodosan 30 plus<br><br>After storage (2 weeks, 54°C | *S. aureus, E. hirae, P. aeruginosa, E. coli, P. vulgaris* | EN 14349 | T: 10°C<br><br>conditions: 3.0 g/L bovine albumin)<br><br>exposure time: 30 min<br><br>conc: 1.5%, 1%, 0.5%, 0.3% (v/v) | BP dilution ≥1% (v/v): bactericidal activity (≥4 lg reduction) | [redacted] |
| yeasticide | surface disinfection animal housing | Iodosan 30 plus<br><br>After storage (2 weeks, 54°C | *C. albicans* | EN 1657 | T: 10°C<br><br>conditions: 3.0 g/L bovine albumin)<br><br>exposure time: 30 min<br><br>conc: 1.5%, 1%, 0.5%, 0.3% (v/v) | BP dilution ≥0.3% (v/v): yeasticidal activity (≥4 lg reduction) | [redacted] |

| Experimental data on the efficacy of the biocidal product against target organism(s) | | | | | | | |
|---|---|---|---|---|---|---|---|
| yeasticide | surface disinfection animal housing | Iodosan 30 plus<br><br>After storage (2 weeks, 54°C | *C. albicans* | EN 16438 | T: 10°C<br><br>conditions: 3.0 g/L bovine albumin)<br><br>exposure time: 30 min<br><br>conc: 1.5%, 1%, 0.5%, 0.3% (v/v) | BP dilution ≥0.5% (v/v): yeasticidal activity (≥3 lg reduction) | [redacted] |
| virucide | surface disinfection animal housing | Iodosan 30 plus<br><br>After storage (2 weeks, 54°C | *Bovine Enterovirus* Type 1 VR-248 | EN 14675 | T: 10°C ± 0.5°C<br><br>conditions: 3.0 3.0 g BSA/L<br><br>exposure time: 30 min<br><br>0.5%, 1.0%, 1.5%, 2.0%, 2.5% v/v | BP dilution ≥2% (v/v): virucidal activity (≥4 lg reduction) | [redacted] |
| virucide | surface disinfection animal housing | Iodosan 30 plus<br><br>After storage (2 weeks, 54°C | *Bovine Enterovirus* Type 1 VR-248 | EN 14675 | T: 10°C ± 0.5°C<br><br>conditions: 3.0 3.0 g BSA/L<br><br>exposure time: 30 min<br><br>conc 0.5%, 2.0%, 2.5% (v/v) | BP dilution ≥2% (v/v): virucidal activity (≥4 lg reduction) | [redacted] |

**Conclusion on the efficacy of the product**

meta SPC 1 - 2: PT03 - Professional – indoors: Veterinary hygiene biocidal products – ready-to-use teat spray

Meta SPC 1 and 2 includes ready-to-use products to disinfect the teats after milking. Products are sprayed on teats with an active substance content between 0.15%(w/w) and 0.5%(w/w) Iodine. Polyvinylpyrrolidone (PVP) is added as complexing/solubilising agent. Phase 2/step 2 tests on efficacy towards *S. aureus* have been conducted with products containing the lowest Iodine content of this meta SPC (0.15%(w/w) Iodine) and this has been found to fulfil the suggested requirements of the Vitroskin® test using the test protocols (drop/drop) from the IRG ring trial. A lg reduction ≥ 4 has been achieved at 100%(v/v) concentration of the tested product. No efficacy test is available with the aged product containing the 0.15%(w/w) Iodine. However, Phase 2/step 1 tests on bactericidal and yeasticidal efficacy with biocidal products starting with 0.05%(w/w) Iodine have been conducted. To cover the range of meta SPC 1, bactericidal and yeasticidal activity prior to and after accelerated and 1 year storage was determined. Efficacy test with this product showed a bactericidal and yeasticidal efficacy prior to and after storage.

meta SPC 3: PT03 - Professional – indoors: Veterinary hygiene biocidal products – ready-to-use teat spray

Meta SPC 3 includes a ready-to-use product, which is sprayed on teats with an active substance content of 0.5%(w/w) Iodine. Fatty alcohol ethoxylates (FAE) are added as complexing/solubilising agent. Phase 2/step 1 tests on bactericidal and yeasticidal efficacy was shown after 1 year storage. Phase 2/step 2 tests on efficacy towards *S. aureus* have been conducted with a product containing only 0.15%(w/w) Iodine and this has been found to fulfil the suggested requirements of the Vitroskin® test using the suggested test protocols (drop/drop) from the IRG ring trial. A lg reduction ≥ 4 has been achieved at 100%(v/v) and 80%(v/v) concentration of the tested product. However, this product has been deleted by the eCA from the family based on missing long-term storage stability. A worst case decrease (accelerated storage) of Iodine using FINK Io Spray 50 (Jodophore) shows a decrease of 22.7%(w/w) a.s, which would theoretically result in a Iodine concentration of 0.38%(w/w), which is higher then the concentration in the phase 2/step2 tests. Therefore, the eCA Austria concludes that the products in meta SPC 3 are efficacious.

meta SPC 4 - 5: PT03 - Professional – indoors: Veterinary hygiene biocidal products – ready-to-use teat dip

Meta SPC 4 and 5 include ready-to-use teat dip products with an active substance content of 0.1 – 0.45%(w/w) Iodine. Polyvinylpyrrolidone (PVP) is added as complexing/solubilising agent. Phase 2/step 2 tests on efficacy towards *S. aureus* have been conducted with a product containing only 0.1%(w/w) Iodine and PVP as complexing/solubilizing agent; this has been found to fulfil the suggested requirements of the Vitroskin® test using the suggested test protocols (drop/drop) from the IRG ring trial. A lg reduction ≥ 4 has been achieved at 100%(v/v) concentration of the tested product. For Phase 2/step 1 tests a read across with a FINK Io Spray PVP 500 (18997) containing 0.05%(w/w) Iodine and PVP is performed. Efficacy test with this product showed a bactericidal and yeasticidal efficacy prior to and after storage.

Meta SPC 6 - 8: PT03 - Professional – indoors: Veterinary hygiene biocidal products – surface disinfection in animal houses

Products for veterinary hygiene / surface disinfection in animal houses contain an active substance content between 1.5 and 3%(w/w) Iodine (meta SPC 4). The product with the lowest content of Iodine is Iodosan 15, which contains 1.5%(w/w) Iodine. All biocidal products within this meta SPC are concentrated products, which are diluted. Bacterial, yeasticidal and virucidal efficacy was shown within 30 minutes exposure for the biocidal product with minimum (1.5%(w/w)) and maximum (3%(w/w)) Iodine content prior and after accelerated storage under low level soiling (3 g BSA/L) conditions at 10°C.

### 2.2.5.6 Occurrence of resistance and resistance management

eCA Austria accepted the statement of the applicant, that if one takes into account the mode of action of Iodine which is non-selective, the development of resistant microorganisms and viruses against Iodine is unlikely. Iodine / Iodophors have been used for a very long period of time; no reduction in efficacy was reported to the producers of Iodine/iodophor-based products for such applications indicating that no development of resistant microorganisms or viruses has occurred.

Development of resistance

According to the CAR of Iodine (Sweden 2013), in general intrinsic resistance is regarded as unlikely and further that no management strategies have been developed and no occurrence of resistance has been observed. In addition, Iodine-based products are exclusively applied by professional users, in most cases as part of professional hygiene programs, which also involve other biocidal substances of different chemical structure and different mode of action (alternating applications).

### 2.2.5.7 Known limitations

Teats should be cleaned before disinfection. For disinfection of animal housings it shall be ensured that the surfaces are cleaned mechanically before disinfection, and that also residues of cleaning solutions are removed by rinsing with water or wiping.

### 2.2.5.8 Evaluation of the label claims

For each meta SPC the target organisms, minimum efficacious concentration, contact time, and instructions for the user are described.

To cover each concentration range of the four meta SPCs, different products have been tested with regard to their bactericidal, yeasticidal and in meta SPC 6 -8 in addition the virucidal activity.

Detailed description of relationships between individual biocidal products in each meta SPC and an assessment of the maximum risk and minimum efficacy products that cover the endpoint can be found in IUCLID Section 13.

To guarantee sufficient efficacy, during the process all openings have to be closed and the ventilation has to be switched off.

Meta SPC 1 - 2: PT03 - Professional – indoors: Veterinary hygiene biocidal products – ready-to-use teat spray

Meta SPC 1 and 2 include ready-to-use products to disinfect the teats after milking. Products are sprayed on teats with an active substance content between 0.15%(w/w) and 0.5%(w/w) Iodine. Polyvinylpyrrolidone (PVP) is added as complexing/solubilising agent.

**Target organisms:** The products are efficacious against bacteria, yeasts.

| | **Minimum efficacious a.s. concentration EN 1656 (bacteria)** | **Minimum efficacious a.s. concentration EN 1657 (yeast)** | **Minimum efficacious a.s. concentration phase 2, step 2 (bacteria)** | **Overall minimum efficacious a.s. concentration** |
|---|---|---|---|---|
| **b.p.** | FINK Io Spray – PVP 500 ppm 18997, prior & after storage | FINK Io Spray – PVP 500 ppm 18997, after storage | FINK Io Spray 15, prior to storage | |
| **Conc.** | **500 ppm (0.05%)** a.s. nominal conc. | **500 ppm** a.s. nominal conc. | **1500 ppm** a.s. nominal conc. | **1500 ppm** |

For phase 2, step 1 tests (bacteria, yeast) the required lg reduction was achieved when the product was diluted to ≥30%. Phase 2, step 2 tests were provided or FINK Io Spray 15, which was tested prior to storage and it was shown that the biocidal product was efficacious against *S. aureus* at a biocidal product concentration of 100%. Each product with same or higher a.s. concentration and at least same content of complexing/solubilizing agent has to be considered as sufficiently effective, independent from product name or availability at the time of dossier submission.

**Dilutions of BPs**: 0

**Contact time:** Efficacy was shown after 5 min. at 30°C.

**Instruction to the User:**

- 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.
- No dilution of the product necessary.
- Teats should be cleaned before to disinfection, preferably with one new, wet cloth per cow.
- The use of a dosing pump for filling the product into the application equipment is recommended.
- Product can be applied manually or by means of automatic teat sprayer on animal's teats on the full length of the teat (post-milking).
- Application rate: 10-15 mL per cow
- Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes). Do not clean the teats directly after disinfection.
- Application frequency must not exceed two applications per cow and day considering manual application and must not exceed three applications per cow and day considering automatic teat sprayer (post-milking).

Meta SPC 3: PT03 - Professional – indoors: Veterinary hygiene biocidal products – ready-to-use teat spray

Meta SPC 3 includes a ready-to-use product, which is sprayed on teats with an active substance content of 0.5%(w/w) Iodine. Fatty alcohol ethoxylates (FAE) are added as complexing/solubilising agent.

**Target organisms:** The products are efficacious against bacteria, yeasts.

| | **Minimum efficacious a.s. concentration EN 1656 (bacteria)** | **Minimum efficacious a.s. concentration EN 1657 (yeast)** | **Minimum efficacious a.s. concentration phase 2, step 2 (bacteria)** | **Overall minimum efficacious a.s. concentration** |
|---|---|---|---|---|
| **b.p.** | FINK Io Spray 50 after storage | FINK Io Spray 50 after storage | FINK Io Spray 15 (Jodophor) – prior to storage | |
| **Conc.** | **1500 ppm** a.s. nominal conc. | **1500 ppm** a.s. nominal conc. | **1500 ppm** a.s. nominal conc. | **1500 ppm** |

For phase 2, step 1 efficacy tests (bacteria) the required lg reduction was achieved when the 5000 ppm product was diluted to ≥30% v/v (= 1500 ppm) after 1 year storage. Phase 2, step 2 tests were provided for fresh FINK Io Spray 15 (Jodophore), which was tested prior to storage and it was shown that the biocidal product was efficacious against *S. aureus* at a b.p. concentration of 80% and 100%. The b.p. contains 0.15%(w/w) Iodine and 0.32%(w/w) FAE, however neither a long-term stability studies nor a no valid read across to another product was submitted by the applicant. Only biocidal products with higher Iodine concentrations are present, therefore no valid read across can be performed by the eCA Austria. Based on this reason FINK Io Spray 15 (Jodophor) is not authorised.

**Dilutions of BPs**: 0

**Contact time:** Efficacy was shown after 5 min. at 30°C.

**Instruction to the User:**

- 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.
- No dilution of the product necessary.
- Teats should be cleaned before to disinfection, preferably with one new, wet cloth per cow.
- The use of a dosing pump for filling the product into the application equipment is recommended.
- Product can be applied manually or by means of automatic teat sprayer on animal's teats on the full length of the teat (post-milking).
- Application rate: 10-15 mL per cow
- Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes). Do not clean the teats directly after disinfection.
- Application frequency must not exceed two applications per cow and day considering manual application and must not exceed three applications per cow and day considering automatic teat sprayer (post-milking).

Meta SPC 4 - 5: PT03 - Professional – indoors: Veterinary hygiene biocidal products – ready-to-use teat dip

Meta SPC 4 -5 include ready-to-use teat dip products with an active substance content of 0.1 – 0.45%(w/w) Iodine. Polyvinylpyrrolidone (PVP) is added as complexing/solubilising agent.

**Target organisms:** The products are efficacious against bacteria, yeasts.

| | **Minimum efficacious a.s. concentration EN 1656 (bacteria)** | **Minimum efficacious a.s. concentration EN 1657 (yeast)** | **Minimum efficacious a.s. concentration phase 2 step 2 (bacteria)** | **Overall minimum efficacious concentration** |
|---|---|---|---|---|
| **b.p.** | FINK Io Spray – PVP 500 ppm 18997 - prior & after storage | FINK Io Spray – PVP 500 ppm 18997 - prior & after storage | IoDip 10 PVP | |
| **Dip*** | **500 ppm** a.s. nominal conc. | **500 ppm** a.s. nominal conc. | **1000 ppm** a.s. nominal conc. | **1000 ppm** |

The lack of phase 2, step 1 experimental efficacy data for teat dip disinfectants is caused by the splitting of the teat disinfection meta SPCs. However, applicant has decided to provide phase 2, step 2 tests with teat dip products in order to prove their efficacy. Moreover, it is highly unlikely that there will be pronounced differences between very similar (apart from the thickener) BPs in phase 2 step 1 suspension testing towards bacteria and yeast.

For phase 2, step 1 tests (bacteria, yeast) the required lg reduction was achieved when the product was diluted to ≥30%. Phase 2, step 2 tests were provided with IoDip 10 PVP, which was tested prior to storage and it was shown that the BP was efficacious against *S. aureus* at BP concentration of 100%. Each product with same or higher a.s. concentration and at least same content of complexing/solubilizing agent has to be considered as sufficiently effective, independent from product name or availability at the time of dossier submission.

**Dilutions of BPs**: 0

**Contact time:** Efficacy was shown after 5 min. at 30°C.

**Instruction to the User:**

- 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.
- No dilution of the product necessary.
- Teats should be cleaned before to disinfection.
- Fill the dipping cup manually with with 2/3 of product the ready-to-use product. Apply by dipping manually after each cow has been milked.
- Application rate: 5-10 mL per animal

- Ensure that at least two thirds of the teats, preferably the entire teats, come in contact with the solution.

- Application frequency must not exceed two applications per cow and day (post-milking).
- Re-fill the cup as necessary.

Meta SPC 6 - 8: PT03 - Professional – indoors: Veterinary hygiene biocidal products – surface disinfection in animal houses

Products with the maximum and the minimum a.s. concentration have been tested with regard to their bactericidal, yeasticidal and virucidal activity. Efficacy of other products within the Meta SPC is extrapolated based on these results.

**Target organisms:** The products are efficacious against bacteria, yeasts and viruses.

BPs are claimed to be efficacious depending on Iodine concentration - see examples in the table below:

| **Product name** | **[%(w/w)] I2 specified** | **lowest bactericidal concentration [%(v/v)]** | **lowest yeasticidal concentration [%(v/v)]** | **lowest virucidal concentration [%(v/v)]** |
|---|---|---|---|---|
| Iodosan 15 | 1.5 | 1.5 | 1.5 | 5 |
| Iodosan 18 | 1.75 | 1.4 | 1.3 | 4.5 |
| Iodosan 30 | 2.4 | 1.2 | 0.9 | 3.2 |
| Iodosan 30 plus | 3.0 | 1 | 0.5 | 2 |

The results from the efficacy tests were used to calculate the min. efficacious a.s. in-use concentration (see Table below, [redacted]).

| | **Min. efficacious a.s. in-use concentration** | | | | | |
|---|---|---|---|---|---|---|
| | **EN 1656 (bacteria)** | **EN 14349 (bacteria)** | **EN 1657 (yeast)** | **EN 16438 (yeast)** | **EN 14675 (Bovine Enterovirus Type 1 VR-248)** | **Overall** |
| **b.p.** | Iodosan 15 – prior & after storage (2 weeks, 54°C) | Iodosan 15 – prior & after storage (2 weeks, 54°C) | Iodosan 30 plus - after storage (2 weeks, 54°C) | Iodosan 30 plus - after storage (2 weeks, 54°C) | Iodosan 30 plus – after storage (2 weeks, 54°C) | |
| **Conc.** | **225 ppm a.s.** nominal conc. | **225 ppm a.s.** nominal conc. | **90 ppm a.s.** nominal conc. | **150 ppm a.s.** nominal conc. | **750 ppm a.s.** nominal conc. | bactericidal/ yeasticidal **225 ppm**<br>virucidal **750 ppm** |

Further, the efficacy of Iodosan 30 and Iodosan 18 within the meta SPC 6 - 8 were extrapolated by the applicant based on these results of Iodosan 15 and Iodosan 30 plus ([redacted]), results and dilutions of BPs can be seen below:

Iodosan 15 (and all products with same formulation):
bactericidal ≥1.5%(v/v), yeasticidal ≥1.5%(v/v), virucidal ≥5%(v/v)

Iodosan 18 (and all products with same formulation):

bactericidal ≥1.4%(v/v), yeasticidal ≥1.3%(v/v), virucidal ≥4.5%(v/v)

Iodosan 30 (and all products with same formulation):
bactericidal ≥1.2%(v/v), yeasticidal ≥0.9%(v/v), virucidal ≥3.2%(v/v)

Iodosan 30 plus (and all products with same formulation):
bactericidal ≥1%(v/v), yeasticidal ≥ 0.5%(v/v), virucidal ≥2%(v/v).

**Contact time:** Efficacy of biocidal products was shown after 30 min.

**Instruction to the User:**

- 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.
- During the treatment time, the surfaces have to remain moist.
- Dilute the concentrate to obtain a minimum efficacious Iodine concertation of 750 ppm.
- Use max. 100 mL application solution per m² treated area. Do not prepare more fluid than strictly necessary.
- Ensure a minimum contact time of 30 min.

### 2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

Biocidal products are not intended to be authorised for the use with other biocidal products.

## 2.2.6 Risk assessment for human health

### 2.2.6.1 Assessment of effects on Human Health

***Skin corrosion and irritation***

| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
|---|---|
| Value/conclusion | A desktop based assessment of each component and the maximum risk products of all meta SPCs was conducted.<br><br>The available data allow the drawing of reliable conclusions on the skin irritating potential of all components of the biocidal product family BPF_Iodine_VET, under the definitions of the EU CLP regulation. Iodine is classified as Skin Irrit. 2; phosphoric acid triggers classification as Skin Irrit. 2 at concentrations ≥10%, and as Skin Corrosive 1 at concentrations ≥25%. All the other ingredients are either not classified or present in concentrations below the generic cut-off value of 1% (CLP Regulation, Annex I table 1.1.) in which case they would not be considered for classification. In accordance with guidance on the BPR, further testing need not be conducted. |
| Justification for the value/conclusion | **meta SPC 1,2,3:**<br>Biocidal products contain only one component classified as skin irritant (i.e. the a.s. Iodine) and only at a concentration below 1% (the generic cut-off limit). Therefore the b.p. do not require classification for skin irritation.<br><br>**meta SPC 4,5:**<br>Biocidal products contain potentially skin irritating components below a concentration of 1% (the generic cut-off limit), i.e. Iodine with 0.45%, two alternative wetting agents with 0.9% and phosphoric acid with 0.4%. To all of them a concentration limit of 10% applies (GCL for Iodine and the wetting agents, SPC for phosphoric acid). Therefore these components do not trigger a mixture classification for skin irritation.<br><br>**meta SPC 6,7,8:**<br>The sum of Iodine (3%) and phosphoric acid (10%), both classified as Skin Irrit. 2 with a concentration limit of 10% (GCL for Iodine, SPC for phosphoric acid) trigger a mixture classification for skin irritation category 2. No other components classified for skin corrosion are present in the product. However due to the presence of the surfactants Poly(oxy-1,2-ethandiyl).alpha.-tridecyl-.omega.-hydoxy-,branched and Isotridecanol, ethoxylated 90%, the skin corrosion SPC of phosphoric acid (skin corr 1B C ≥25%) is not considered as reliable for product classification. Therefore classification of the Meta SPC 6,7,8 for skin corrosion is based on low pH, which is due to phosphoric acid content. |

| Conclusion used in Risk Assessment – Skin corrosion and irritation - continued | |
|---|---|
| | The applicant does not consider the teat disinfectant products to be skin irritant even if the pH is slightly below 2 because:<br>1. the measured pH is between 1.7 and 1.9 for the spray products and 2.3 for the dipping products and therefore does not undercut the limit of 2 significantly.<br>2. in order to ensure skin compatibility, teat disinfectant products as in the present BPF contain emollients both for ensuring sufficient moisture as well as for adding a lipophilic layer to the treated skin. These effects will easily compensate the influence from the relatively low pH.<br>3. biocidal products as in the present BPF have been used since decades without any known reports regarding skin irritation from animals.<br>The pH of the the animal house disinfection products is 0.76 (and the pH of the 1% dilution is about 2.36). As explained above the products for meta SPC 6,7,8 need to be classified for skin corrosion. |
| Classification of the products according to CLP and DSD | meta SPC 1,2,3,4,5: no classification for skin irritation or skin corrosion<br>meta SPC 6,7,8: Skin Corr. 1 |

### *Eye irritation*

| Conclusion used in Risk Assessment – Eye irritation | |
|---|---|
| Value/conclusion | A desktop based assessment of each component and the maximum risk products of all meta SPCs was conducted.<br><br>The available data allow drawing of reliable conclusions on the potential eye irritancy of all components of the biocidal product family, under the definitions of the EU CLP regulation. Phosphoric acid triggers classification as Eye Irrit. 2 at concentrations ≥10% in the mixture, while concentrations ≥25% are covered by the existing classification as Skin Corrosive 1.<br>Two complexing or solubilizing agents for the meta SPCs 6,7,8 are classified for eye damage category 1 (Poly(oxy-1,2-ethandiyl).alpha.-tridecyl-.omega.-hydoxy-,branched and Isotridecanol, ethoxylated 90%, C 9-11 Alcohol Ethoxylate) and they present at concentrations above 3% in these products.<br>Moreover, due to the presence of these two surfactants, the skin corrosion SCL for phosphoric acid (25%) is considered as not reliable. Therefore the low pH in the products for meta SPC 6,7,8 triggers classification for skin corrosion, and the respective H-phrase also includes serious eye damage.<br>Other ingredients classified for eye damage category 1 are present only in concentrations below the generic cut-off value of 1% and therefore should not contribute to the classification of the products. In accordance with guidance on the BPR, further testing need not be conducted. |

| | |
|---|---|
| Justification for the value/conclusion | **meta SPC 1,2,3,4,5:**<br>b.p. do not contain components classified for eye dam. 1 or eye irrit. 2. at concentrations above the generic cut-off value of 1%. Therefore the products do not require classification for eye irritation.<br><br>**meta SPC 6,7,8:**<br>b.p. contain components classified for eye dam. 1 at concentrations above the generic concentration limit of 3%. Moreover the skin corrosion SCL of phosphoric acid (25%) is not reliable due to the presence of these two surfactants. Therefore the low pH in the products for meta SPC 6,7,8 triggers classification for skin corrosion, and the respective H-phrase also includes serious eye damage. Consequently, the products from these meta SPCs require classification for eye corrosion. |

| **Conclusion used in Risk Assessment – Eye irritation continued** | |
|---|---|
| | The applicant does not consider the **teat disinfectant products** from **meta SPC 1, 2, 3, 4, 5** to be eye irritant even if the pH is slightly below 2 because:<br>1. the measured pH is between 1.7 and 2.3 and therefore does not undercut the limit of 2 significantly<br>2. in order to ensure skin compatibility, teat disinfectant products as in the present BPF contain emollients both for ensuring sufficient moisture as well as for adding a lipophilic layer to the treated skin. These effects will easily compensate the influence from the relatively low pH, even if accidental eye contact happens.<br>3. biocidal products as in the present BPF have been used since decades without any known reports regarding skin or eye irritation from animals.<br><br>The **animal house disinfection products** from **meta SPC 6,7,8** need to be classified with Eye Damage 1 (see explanation above). |
| Classification of the products according to CLP | meta SPC 1, 2, 3, 4, 5: no classification or eye irritation<br>meta SPC 6,7,8: eye damage category 1 |

### *Respiratory tract irritation*

| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
|---|---|
| Justification for the conclusion | As none of the components are classified, classification of the product formulations is not required. |
| Classification of the products according to CLP | No classification |

### *Skin sensitisation*

| **Conclusion used in Risk Assessment – Skin sensitisation** | |
|---|---|
| Value/conclusion | A desktop based assessment of each component and the maximum risk products of all meta SPCs was conducted.<br><br>None of the components of the biocidal product family are classified as skin sensitisers under the definitions of the EU CLP regulation. The data is robust and therefore, in accordance with guidance on the BPR, further testing need not be conducted. |
| **Conclusion used in Risk Assessment – Skin sensitisation continued** | |
| Justification for the value/conclusion | Since none of the components are classified no classification is required for any of products within the meta SPCs. |
| Classification of the products according to CLP | No classification |

### *Respiratory sensitization (ADS)*

| **Conclusion used in Risk Assessment – Respiratory sensitisation** | |
|---|---|
| Value/conclusion | None of the components of the products within the biocidal family are classified for skin or respiratory sensitization. Therefore the risk is low that the product would cause respiratory sensitisation.<br>In accordance with guidance on the BPR, further testing need not be conducted. |
| Justification for the value/conclusion | Since none of the components are classified no classification is required for any product within the meta SPCs. |
| Classification of the products according to CLP | No classification |

### *Acute toxicity*

*Acute toxicity by oral route*

| **Value used in the Risk Assessment – Acute oral toxicity** | |
|---|---|
| Value | meta SPC 1,2,3,4,5: $ATE_{mix}$ >2000 mg/kg bw<br>meta SPC 6: $ATE_{mix}$ ≥ 1490 mg/kg bw<br>meta SPC 7: $ATE_{mix}$ = 1515 mg/kg bw<br>meta SPC 8: $ATE_{mix}$ >2000 mg/kg bw |

| **Value used in the Risk Assessment – Acute oral toxicity** | |
|---|---|
| Justification for the selected value | A desktop based assessment of each component and the maximum risk products of all meta SPCs was conducted.<br>Oral $LD_{50}$ values were identified for all components of the product family BPF_Iodine_VET and these were considered robust as the basis for classification for their acute oral toxicity under the definitions of the EU CLP regulation. Each ingredient is either not classified for acute oral toxicity or is classified as Acute Tox. 4. Thus, in accordance with guidance on the BPR, further testing does need not be conducted.<br><br>When the $LD_{50}$ ATE values are known for all components, the ATE of the mixture is estimated using<br>$$\frac{100}{ATE_{mix}} = \sum_{n} \frac{C_i}{ATE_i}$$<br>where: $ATE_{mix}$ is the ATE of the mixture;<br>$C_i$ is the concentration of ingredient i (%w/w or %v/v);<br>i is the individual ingredient from 1 to n;<br>n is the number of ingredients; and<br>$ATE_i$ is the ATE of ingredient i. |
| Classification of the products according to CLP | meta SPC 1, 2, 3,4, 5: no classification<br>meta SPC 8: no classification<br>meta SPC 6,7: Acute Tox 4 (harmful if swallowed) |

*Acute toxicity by inhalation*

| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
|---|---|
| Value | meta SPC 1,2,3,4,5,6,7,8: $ATE_{mix}$ >20 mg/L (vapour) |
| Justification for the selected value | A desktop based assessment of each component and the maximum risk products of all meta SPCs was conducted.<br><br>Indications of acute inhalation toxicity robust enough to support classification (either quantitative $LC_{50}$ values or weight of evidence) were identified for all components of the biocidal product family. Iodine itself is classified as Acute Tox. 4. All the other ingredients are not classified. In accordance with guidance on the BPR, further testing need not be conducted.<br><br>When the $LD_{50}$ ATE values are known for all components, the ATE of the mixture is estimated using<br>$$\frac{100}{ATE_{mix}} = \sum_{n} \frac{C_i}{ATE_i}$$<br>where: $ATE_{mix}$ is the ATE of the mixture;<br>$C_i$ is the concentration of ingredient i (%w/w or %v/v);<br>i is the individual ingredient from 1 to n;<br>n is the number of ingredients; and<br>$ATE_i$ is the ATE of ingredient i. |
| Classification of the products according to CLP | No classification |

*Acute toxicity by dermal route*

| **Value used in the Risk Assessment – Acute dermal toxicity** | |
|---|---|
| Value | meta SPC 1,2,3,4,5,6,7,8: $ATE_{mix}$ >2000 mg/kg bw |
| Justification for the selected value | A desktop based assessment of each component and the maximum risk products of all meta SPCs was conducted.<br><br>Dermal $LD_{50}$ values, or reliable studies demonstrating a lack of acute dermal toxicity, were identified for all components of the biocidal product family. These were considered robust enough to propose a classification for their acute dermal toxicity under the definitions of the EU CLP regulation. Iodine is classified as Acute Tox. 4. All the other ingredients are not classified. In accordance with guidance on the BPR, further testing need not be conducted.<br><br>When the $LD_{50}$ ATE values are known for all components, the ATE of the mixture is estimated using<br><br>$$\frac{100}{ATE_{mix}} = \sum_{n} \frac{C_i}{ATE_i}$$<br>where: $ATE_{mix}$ is the ATE of the mixture;<br>$C_i$ is the concentration of ingredient i (% w/w or % v/v);<br>i is the individual ingredient from 1 to n;<br>n is the number of ingredients; and<br>$ATE_i$ is the ATE of ingredient i. |
| Classification of the products according to CLP | No classification |

### *Information on dermal absorption*

| Summary table of in vitro studies on dermal absorption | | | | |
|---|---|---|---|---|
| **Method, Guideline, GLP status, Reliability** | **Species, Number of skin samples tested per dose, Other relevant information about the study** | **Test substance, Doses** | **Absorption data for each compartment and final absorption value** | **Reference** |
| OECD 428, GLP: yes, Reliability: 1 | Human skin membranes (split-thickness), 9 skin membranes from three donors<br><br>8h exposure, 16h post-exposure | Biocide 1006 (2.63%w/w Iodine diluted to 0.66% Iodine), PE 305-1 (0.26% w/w Iodine) | The mean total absorption, defined as the amount of total Iodine present in the receptor fluid, the receptor compartment wash and the skin membranes (excluding tape strips) was 6.9% (Biocide 1006) and 6.8% (PE 305-1) of the dose applied. When additionally including the amounts found in tape strips 3-15, the mean total absorption was 11.3% for Biocide 1006 and 12.0% for PE 305-1 of the dose applied, respectively. The mean maximal flux was 0.128 µg/cm$^2$/h and 0.02 µg/cm$^2$/h for the biocidal formulations containing 0.66% and 0.26% total Iodine, respectively. The results further demonstrated that in the concentration range tested, the dermal penetration of total Iodine was independent of the concentration of Iodine in the biocidal formulations. Based on these results, a dermal penetration rate of 12% was used for the human health exposure assessment and the subsequent risk characterisation. | [redacted] (See Sweden 2013) |

| **Value(s) used in the Risk Assessment – Dermal absorption** | | |
|---|---|---|
| Substance | Iodine | |
| Value(s) | Tier 1: 75% | Tier 2: 12% |
| Justification for the selected value(s) | No data are available regarding the dermal absorption of Iodine in the proposed family of products. *In vitro* studies using human skin, analysed the dermal absorption of Iodine from two formulations, Biocide 1006, and PE 305-1, at two dilutions (Iodine concentrations of 0.66%w/w and 0.26%w/w), and were considered for the Annex I inclusion of Iodine. From these data, dermal absorption values of 11.3% and 12.0% were derived for Biocide 1006 and PE 305-1, respectively.<br><br>Considering the differences in the compositions and/or natures of the formulations used in the CAR and the current family of products, comparison of dermal absorption values cannot be made directly on the basis of any similarity of formulations as set out in the EFSA (2012) guidance on dermal absorption. However the composition of the products Iodine Biocide 1006 and PE305-1 from Sweden, 2013 (for which which human in vitro dermal absorption test data were generated) can be compared to composition of BPF_Iodine_VET: Considering the components of the products from the CAR in terms of their function, the composition of Biocide 1006 and PE305-1 may be considered comparable to the composition of BPF_Iodine_VET. Also the in use concentrations in terms of Iodine% are comparable or higher in BPF_Iodine_VET (see embedded excel in the confidential section).<br><br>However in the absence of product specific data, a Tier 1 assessment using the default dermal absorption values set out in the current guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873)[1] might be used (50% for in use dilution of water based products, 10% for water based concentrates).<br><br>However, it was concluded in the Iodine CAR (RMS Sweden) that a dermal penetration rate of 12% would be acceptable for use in the human health exposure assessment and the subsequent risk characterization. This dermal penetration rate of 12% was used in the Iodine CAR for the assessment of products ranging from concentrations of 0.02-2.8% irrespective of co-formulants or dilution rates. In light of this it is considered adequate to use the Iodine CAR dermal absorption values for each product in the current family of Iodine products, within this dilution range.<br><br>The applicant provided further arguments for this as follows:<br>The approach presented above can be further supported using extrapolation as proposed in the EFSA guidance on dermal absorption. The EFSA guidance states: '*Pro rata* correction assuming a linear response is considered to be a conservative but appropriate approach in the absence of data'. Therefore, the AR dilution values for each product might be extrapolated to the family of Iodine products as follows, whilst also taking in to account differences in the concentrations of the in-use dilutions: | |

1 Guidance on dermal absorption, doi: 10.2903/j.efsa.2017.4873

| Value(s) used in the Risk Assessment – Dermal absorption continued | |
|---|---|
| | For the representative products in the CAR, dermal absorption was 11.3% at 6.6 g/L (Biocide 1006) and 12% at 2.6 g/L. Using this data, interpolation can be made to 5 g/L the maximum concentration for in-use teat disinfection (both teat dip and teat spray). The equation derived is:<br><br>*% dermal absorption = –0.175* x *concentration (g/L) + 12.455*<br>(cf. appendix 3.3).<br><br>Hence, where the concentration is 5 g/L, dermal absorption is 12% (rounded from 11.6%). Similarly, extrapolation can be made to 0.2 g/L for in-use spray dilutions used in animal house treatments. The equation derived is:<br><br>*% dermal absorption = –0.175* x *concentration (g/L) + 12.455*<br>(cf. appendix 3.3).<br><br>Hence, where the concentration is 0.2 g/L, dermal absorption is 12% (rounded from 12.4%).<br><br>Therefore, a rounded value of 12% may still be adopted for Iodine for both the ready-to-use products and the in-use dilution for animal house disinfectant treatments, and may also be used as a conservative estimate for the animal house disinfectant concentrate (18–35 g/L). |

## *Specific target organ toxicity, repeated exposure (STOT RE)*

| Value used in the Risk Assessment – STOT RE | |
|---|---|
| Justification | A desktop based assessment of each component and the maximum risk products of all meta SPCs were conducted. Only for Iodine a concern for specific target organ toxicity was identified.<br><br>The Iodine REACH consortium has proposed a classification for Iodine with STOT RE (thyroid gland), category 1. In line with other biocides dossier evaluations this classification and the general concentration limit for mixture classification for STOT RE 2, i.e. 1%, is taken into account for the BPF Iodine VET. |
| Classification of the products according to CLP | meta SPC 1, 2, 3,4, 5: no classification<br>meta SPC 6,7,8: STOT RE 2, H373: May cause damage to organs (thyroid gland) through prolonged or repeated exposure. |

### *Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)*

A desktop based assessment of each component and the maximum risk products of all meta SPCs was conducted.

Biocidal products from meta SPC 6,7,8 contain substances of concern (SoCs), that lead to classification for skin corrosion, eye damage and acute oral toxicity (for explanation see section 1.2, heading "Substances of concern").

These classifications are within bands A and B (according to Annex A in BPC Guidance Volume III Human Health - Assessment & Evaluation, Parts B+C). These bands require the application of the standard P and H-statements (Band A: acute tox 4) or a qualitative exposure/risk assessment (Band B: eye dam 1, skin corr 1).
A qualitative exposure/risk assessment for local effects is provided for the animal house disinfection products of meta SPCs 6,7,8.

### *Available toxicological data relating to a mixture*

No experimental hazard data for mixtures of the product with other products or in use solutions are available. Risk assessment is based on the hazard information of the individual compontents as far as relevant.

### *Other: Potential for dndocrine disruption*

The current assessment report for Iodine (2015) concludes: "*Iodine is an essential element and has a physiological function in thyroid hormone synthesis (i.e. intentionally interacts with the endocrine system). This means that both Iodine deficiency as well as excess Iodine can impair thyroid homeostasis/thyroid hormone levels. This is to be considered as an endocrine effect. However, it would not be justified to conclude from this that Iodine should be considered to be an endocrine disruptor. In contrast to typical xenobiotic substances, which are not needed at all for the functioning of the human body, and which normally only have negative effects on man, Iodine is a physiologically essential element. Consequently, the concept of endocrine disruption is not meaningful for essential elements such as Iodine since it neglects that they are needed for maintaining hormone homeostasis…".*
For the co-formulants no concern for endocrine disrupting properties is apparent. The harmonized C&L within the ECHA inventory and/or the SDSs submitted by the applicant were screened for CMR and STOT classification. Furthermore, the substances were be screened if they were listed in the PACT and ED assessment list.

### 2.2.6.2 Exposure assessment

**Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product**

| Summary table: relevant paths of human exposure | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Exposure path** | **Primary (direct) exposure** | | | **Secondary (indirect) exposure** | | | |
| | **Industrial use** | **Professional use** | **Non-professional use** | **Industrial use** | **Professional use** | **General public** | **Via food** |
| Inhalation | n.a. | Yes[1] | n.a. | n.a. | n.a. | n.a. | No |
| Dermal | n.a. | Yes | n.a. | n.a. | n.a. | n.a. | No |
| Oral | n.a. | No | n.a. | n.a. | n.a. | n.a. | Yes (via milk) |

[1] Inhalation exposure is only assessed for aerosol formation, as Iodine is formulated in a complex with PVP, or emulsified with other co-formulants and therefore stalilised by a polymeric matrix and/or micelles. Due to the characteristics of the formulation, the ability of Iodine to evaporate from the aqueous dispersion is reduced significantly. Moreover, in aqueous solutions, Iodine disproportionates into different ionic species, e.g. Iodide ($I^-$), Iodate ($IO^{3-}$), tri-Iodide ($I^{3-}$). These ions are highly soluble and do not tend to evaporate. Moreover Iodine in aqueous biocidal products is bound in complexes surfactants or PVP. The complex bound ionic Iodine species are not considered to evaporate easily.
Concerning dried solutions, exposure is considered negligible as in stables the ventilation rate is usually high. In addition, it was noted that when the formulation is dried, Iodine is even more captured in the structure of the carrier and less Iodine is available.

### *List of scenarios*

| Summary table: scenarios | | | |
|---|---|---|---|
| **Scenario number** | **Scenario** | **Primary or secondary exposure Description of scenario** | **Exposed group** |
| [1] | RTU teat spray treatment (meta SPC 1-3) | Primary exposure; Worker disinfects teats after milking by spraying | Professionals |
| [2] | RTU teat dip treatment (meta SPC 4-5) | Primary exposure; Worker disinfects teats after milking by dipping | Professionals |
| [3] | Animal house treatment by spraying (meta SPC 6-8) | Primary exposure; Worker disinfects animal housing by spraying | Professionals |
| [4] | Cleaning of equipment | Primary exposure; Worker cleans equipment (dipping cup, spraying nozzle et.) after application | Professionals |
| [5] | RTU teat spray treatment – animal exposure (meta SPC 1-3) | Primary animal exposure from teat treatment. | Animals |
| [6] | RTU teat dip treatment – animal exposure (meta SPC 4-5) | Primary animal exposure from teat treatment. | Animals |
| [7] | Animal house treatment by spraying – animal exposure (meta SPC 6-8) | Secondary animal exposure due to residues from spraying of animal houses. | Animals |
| [8] | Human dietary exposure | Secondary human exposure due to uptake of Iodine residues in milk and other food sources. | General public |

### *Industrial exposure*

Not applicable.

## *Professional exposure*

*Scenario [1]*

| **Description of Scenario [1]** |
|---|
| In this scenario, teat disinfection is performed via ready-to-use spray treatment. It is considered that the disinfection is carried out by one worker.<br><br>**Scenario 1A: Decanting**<br>Mixing and loading comprises pouring the ready-to-use (RTU) - solution into the spray bottle. According to ECHA 2017b, mixing and loading model 4 applies (ECHA 2015, page 272).<br>The max. Iodine concentration in the product is 0.5%. Hand contamination of 0.2 mL is assumed for the individual performing pouring operations with a container of unspecified design (5L) to fill the smaller container. The indicative exposure value covers the total amount of applied solution per day.<br><br>**Scenario 1B: Application**<br><br>According to ECHA 2017b, the hand-held trigger spray model (Consumer product spraying and dusting model 2, ECHA 2015, page 344) should be used for calculation. The model covers both manual trigger spraying and electronic spraying. (Application by robots doesn't lead to human exposure during application.) For post-milking disinfection, the application duration per day is 27 min (82 cows x 10 seconds/cow x 2 times/day; ECHA 2017b).<br><br>**Scenario 1C: Post-Application**<br>After disinfection, the formulation is not removed but stays on the teats until the next milking process.<br>According to ECHA 2017b, for cleaning of teats as well as for removal of dried residues post-milking, exposure can be considered limited, and no exposure calculation is required. Therefore, no calculations are performed for scenario 1C.<br>(Note: Cleaning of equipment is considered within scenario 4.)<br><br>The relevant exposure parameters are reported as follows. |

| | **Parameters** | **Value** |
|---|---|---|
| [1A]<br>Tier 1<br>Decanting | Indicative dermal exposure value per operation[1] | 0.2 mL b.p./day |
| | Density[2] | 1.034 g/mL |
| | Concentration of a.s. in b.p. (RTU)[3] | 0.5%w/w |
| | Dermal absorption[4] | 12% |
| | Body weight adult[5] | 60 kg |
| [1A]<br>Tier 2<br>Decanting | PPE penetration<br>(gloves, 90% protection)[6] | 10% |

| | | |
|---|---|---|
| [1B]<br>Tier 1<br>APPL | Indicative actual dermal exposure value, hand and forearm (75th %)[7] | 36.1 mg b.p./min |
| | Indicative actual dermal exposure value, legs, feet & face (75th %)[7] | 9.7 mg b.p./min |
| | Indicative inhalative exposure value, aerosol (75th %)[7] | 10.5 mg b.p./m³ |
| | Concentration of a.s. in b.p. (RTU)[3] | 0.5% |
| | Application duration per day[8] | 27 min/day |
| | Inhalation rate[9] | 0.021 m³/min |
| | Dermal absorption[4] | 12% (measured value) |
| | Inhalative absorption[4] | 100% |
| | Body weight, adult[5] | 60 kg |
| [1B]<br>Tier 2<br>APPL | Penetration<br>(chemical resistant coverall; gloves; chemical resistant boots;<br>90% protection)[6] | 10% |

[1] ECHA 2015, page 272

[2] See chapter 2.2.2 of this document

[3] See chapter 2.1.2 of this document

[4] See chapter 2.2.6.1 of this document

[5] ECHA 2015, page 15, table 1

[6] ECHA 2015, page 156f, table B

[7] ECHA 2015, page 344

[8] ECHA 2017b, page 6 (10 s per cow, 82 lactating cows, 2 applications per day)

[9] ECHA 2015, page 16, table 2

### *Calculations for Scenario [1]*

See Appendix 3.2.

| Summary table: estimated exposure from professional uses (values expressed as µg a.s./kg bw/day) | | | | | |
|---|---|---|---|---|---|
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [1A] | Tier 1 / no PPE | n.r. | 2.07 | n.r. | 2.07 |
| | Tier 2 / PPE: gloves | n.r. | 0.21 | n.r. | 0.21 |
| Scenario [1B] | Tier 1 / no PPE | 0.50 | 12.52 | n.r. | 13.02 |
| | Tier 2a / PPE: gloves | 0.50 | 3.64 | n.r. | 4.14 |
| | Tier 2b / PPE: gloves, chemical resistant coated coverall and boots | 0.50 | 1.25 | n.r. | 1.75 |
| **Scenario [1], total** | Tier 1 / no PPE | 0.50 | 14.59 | n.r. | 15.09 |
| | Tier 2a / PPE: gloves | 0.50 | 3.85 | n.r. | 4.35 |
| | Tier 2b / PPE: gloves, chemical resistant coated coverall and boots | 0.50 | 1.46 | n.r. | 1.96 |

### *Further information and considerations on scenario [1]*

None.

*Scenario [2]*

**Description of Scenario [2]**

In this scenario, teat disinfection is performed via ready-to-use teat dip treatment. It is considered that the disinfection is carried out by one worker.

**Scenario 2A: Decanting**
The exposure scenario considers the use of Iodine as a post-milking disinfectant teat dip. Exposure is expected to occur primarily through the loading/pouring of the product into a small container (with screw top and/or a squeeze top dispenser).

This is reflected in the mixing and loading model 4 (ECHA 2015, page 272; ECHA 2017b). The mixing and loading scenario considers the process of decanting the ready-to-use product from a larger container to a small container (i.e. teat dip cup, see Fig. 1).

a. 

b. 

**Figure 1: a. a squeeze-to-fill container used to measure a volume of liquid. b. a squeeze top dispenser used for teat disinfectant applications.**

Generally, the larger containers are opened manually and connected to a nozzle or a dispenser to fill the smaller container. However, for the purpose of assessing exposure to Iodine in teat dip products it has conservatively been assumed the product is lifted and manually poured in to the smaller container. The teat dip cups are filled about two thirds with the post-dip formulation.
Both the loading and dipping scenario involve a RTU product containing max. 0.45% Iodine. Hand contamination of 0.2 mL is assumed for the individual performing pouring operations with a container of unspecified design (5L) to fill the smaller container. The indicative exposure value covers the total amount of applied solution per day.

**Scenario 2B: Application**
The teats are disinfected by dipping them individually into the open reservoir of solution which is in held in the top part of the teat dip cup. The cup system is topped up with dip if necessary. According to ECHA 2017b, dermal exposure is already covered by the mixing and loading step, whereas inhalation exposure is covered by the cleaning phase. Therefore, no calculations are performed for scenario 2B.

**Scenario 2C: Post-Application**
According to ECHA 2017b, for cleaning of teats as well as for removal of dried residues post-milking, exposure can be considered limited, and no exposure calculation is required. Therefore, no calculations are performed for scenario 2C.
(Note: cleaning of equipment is considered within scenario 4.)

The relevant exposure parameters are reported below.

| | Parameters | Value |
|---|---|---|
| [2A] Tier 1 Decanting | Indicative dermal exposure value per operation[1] | 0.2 mL b.p./day |
| | Relative density[2] | 1.011 |
| | Concentration of a.s. in b.p. (RTU)[3] | 0.45 % |
| | Dermal absorption[4] | 12% |
| | Body weight adult[5] | 60 kg |
| [2A] Tier 2 Decanting | PPE (gloves, 90% protection): penetration[6] | 10% |

[1] ECHA 2015, Mixing and loading model 4, page 272
[2] See chapter 2.2.2
[3] See chapter 2.1.2
[4] See chapter 2.2.6.1
[5] ECHA 2015, page 15, table 1
[6] ECHA 2015, page 156f, table B

### *Calculations for Scenario [2]*

See Appendix 3.2.

| Summary table: estimated exposure from professional uses (values expressed as µg a.s./kg bw/day) | | | | | |
|---|---|---|---|---|---|
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [2] | Tier 1 / no PPE | n.r. | 1.82 | n.r. | 1.82 |
| Scenario [2] | Tier 2 / PPE: gloves | n.r. | 0.18 | n.r. | 0.18 |

### *Further information and considerations on scenario [2]*

Assessment of SoC Phosphoric acid:

| **Summary table: estimated exposure from professional uses to Phosphoric acid (values expressed as mg/m³)** | | | | | |
|---|---|---|---|---|---|
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [2] | Tier 1 / no PPE | 0.27 | n.r. | n.r. | 0.27 |

Calculations: See Appendix 3.2.

*Scenario [3]*

| **Description of Scenario [3]** | | |
|---|---|---|
| In this scenario, animal houses are treated by spraying. The product is diluted prior to use. The worst case for meta SPC 6-8 is represented by an in-use concentration of Iodine of 0.075%.<br><br>ECHA 2017a recommends Spraying model 2 (ECHA 2015, page 284 f.) to assess disinfection of animal houses. Spraying model 2 predicts exposure for operators using medium pressure (4 to 7 bar) hand-held sprayers. The model represents the data arising from 50 separate studies of operators using remedial biocides. The results apply to both powder and liquid spraying, indoors and outdoors, whether in an overhead or downward direction, and include a contribution to exposure from mixing and loading operations.<br>(Note: cleaning of equipment is considered within scenario 4.)<br><br>The relevant exposure parameters are reported below. | | |
| | **Parameters** | **Value** |
| Tier 1 | Indicative value for potential dermal exposure (body)[1] | 222 mg b.p./min |
| | Indicative value for potential dermal exposure (hands)[1] | 273 mg b.p./min |
| | Indicative value for inhalation exposure[1] | 76 mg b.p./m³ |
| | Concentration of a.s.[2] | 0.075% |
| | Exposure duration[3] | 120 min/day (2 h/day) |
| | Body weight, adult[4] | 60 kg |
| | Inhalation rate, adult[5] | 1.25 m³/h |
| | Dermal absorption[6] | 12% |
| | Inhalative absorption[6] | 100% |

| | | |
|---|---|---|
| Tier 2a<br>PPE: gloves | Indicative value for actual dermal exposure (hands)[1] | 7.8 mg b.p./min |
| Tier 2b<br>PPE: gloves, chemical resistant coated coverall and boots | Impermeable coverall (chemical resistant, 95% protection) penetration[7] | 5% |

[1] ECHA 2015, page 284f.

[2] See chapter 2.1.5 of this document

[3] ECHA 2017a

[4] ECHA 2015, page 15, table 1

[5] ECHA 2015, page 16, table 2

[6] See chapter 2.2.6.1 of this document

[7] ECHA 2015, page 156f, table B

### *Calculations for Scenario [3]*

See Appendix 3.2.

| **Summary table: estimated exposure from professional uses (values expressed as µg a.s./kg bw/day)** | | | | | |
|---|---|---|---|---|---|
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [3] | Tier 1 / no PPE | 2.38 | 89.10 | n.r. | 91.48 |
| Scenario [3] | Tier 2a / PPE: gloves | 2.38 | 41.36 | n.r. | 43.74 |
| Scenario [3] | Tier 2b / PPE: gloves, coverall | 2.38 | 3.40 | n.r. | 5.78 |

### *Further information and considerations on scenario [3]*

Assessment of SoC Phosphoric acid (75%):

| Summary table: estimated exposure from professional uses to Phosphoric acid (values expressed as mg/m³) | | | | | |
|---|---|---|---|---|---|
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [2] | Tier 1 / no PPE | 0.23 | n.r. | n.r. | 0.23 |

Calculations: See Appendix 3.2.

*Scenario [4]*

| **Description of Scenario 4** | | |
|---|---|---|
| Cleaning of equipment: This task is undertaken by the operator, who typically wears a coverall and suitable protective gloves.<br>According to ECHA 2017b, only hands will be exposed. The indicative value of "Riskofderm 'loading liquid, automated or semi-automated' for the cleaning phase of different equipment (dipping cup, spraying nozzle etc.) is 0.92 mg/min, and the duration is 5 minutes.<br><br>The relevant exposure parameters are reported below. | | |
| | **Parameters** | **Value** |
| Tier 1 | Indicative value for potential dermal exposure (hands)[1] | 0.92 mg/min |
| | Concentration of a.s.[2] | 0.5 % |
| | Dermal exposure duration[1] | 5 min/day |
| | Body weight, adult[3] | 60 kg |
| | Dermal absorption[4] | 12% |
| | Mean event concentration of Iodine in air[5] | 0.0003 mg/m³ |
| | Inhalative exposure duration[1] | 3 h/day |
| | Inhalation rate[6] | 1.25 m³/h |
| Tier 2 | Protective gloves (90% protection) penetration[7] | 10% |

[1] ECHA 2017b

[2] See chapter 2.1.2 of this document

[3] ECHA 2015, page 15, table 1

[4] See chapter 2.2.6.1 of this document

[5] calculated with CONSEXPO

[6] ECHA 2015, page 16, table 2

[7] ECHA 2015, page 156f, table B

### *Calculations for Scenario [4]*

See Appendix 3.2.

| Summary table: estimated exposure from professional uses (values expressed as µg a.s./kg bw/day) | | | | | |
|---|---|---|---|---|---|
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [4] | Tier 1 / no PPE | 0.02 | 0.05 | n.r. | 0.07 |
| Scenario [4] | Tier 2 / PPE: gloves | 0.02 | 0.0046 | n.r. | 0.02 |

### *Further information and considerations on scenario [4]*

Assessment of SoC Phosphoric acid:

| Summary table: estimated exposure from professional uses to Phosphoric acid (values expressed as mg/m³) | | | | | |
|---|---|---|---|---|---|
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [4] | Tier 1 / no PPE | 0.27 | n.r. | n.r. | 0.27 |

Calculations: See Appendix 3.2.

*Combined scenarios*

| Summary table: combined systemic exposure from professional uses (values expressed as µg a.s./kg bw/day) | | | | |
|---|---|---|---|---|
| **Scenarios combined** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenarios [1,4]; Tier 2b (gloves) | 0.52 | 3.85 | n.r. | 4.37 |
| Scenarios [1,4]; Tier 2b (gloves, chemical resistant coated coverall and boots) | 0.52 | 1.46 | n.r. | 1.98 |
| Scenarios [2,4]; Tier 2 (gloves) | 0.02 | 0.18 | n.r. | 0.2 |
| Scenarios [3,4]; Tier 2a (gloves) | 2.40 | 41.41 | n.r. | 43.81 |
| Scenarios [3,4]; Tier 2b (gloves, chemical resistant coated coverall and boots) | 2.40 | 3.40 | n.r. | 5.8 |

The combinations comprise teat spraying plus cleaning of equipment; teat dipping plus cleaning of equipment; disinfection of animal houses plus cleaning of equipment.
It is assumed that teat dipping and spraying are not carried out simultaneously by the same worker, but that this is an either-or choice.

### *Non-professional exposure*

The BPs in the present BPF will not be used by non-professionals. Therefore exposure of other groups of population than professionals is not considered.

### *Exposure of the general public*

The general public is not expected to be present during the application of the biocidal products of BPF_Iodine_VET. Access to the milking parlour is restricted.

### *Monitoring data*

In the Assessment Report on Iodine (Sweden 2013) and Reg. (EU) No 94/2014 approving Iodine for use in PT3, it was stated that the "need to set new or to amend existing maximum residue levels (MRLs) in accordance with Reg. (EC) No 470/2009 and of Reg. (EC) No 396/2005 shall be verified…."

However, based on the following information, re-assessment of MRLs for Iodine would not be needed:

- Monitoring data for Iodine levels in bulk milk samples of various European studies were recently reported to be in the range of 100 to 200 µg/L milk (EFSA, 2013), which indicates no concerns for the safety of the consumers.
- no MRLs are required for Iodine and Iodine inorganic compounds such as iodophors (including polyvinylpyrrolidone-Iodine) for all food producing species and all target tissues according to Reg. (EC) No 470/2009 and Commission Regulation (EU) No 37/2010. Note eCA: This based on veterinary use of teat disinfection. Veterinary medicinal products with Iodine as active substance can be different from similar biocidal products with respect to application rate and duration.
- According to the working document CA-Dec13-Doc.5.1.e on the *Establishment of maximum residue levels for residues of active substances contained in biocidal products* duplication of work for biocidal active substances for which MRLs already exist due to uses in other areas should as far as possible be avoided. It is further stated in the working document that MRLs for pharmacologically active substances in animals set in Reg. (EU) No 37/2010 should in most cases be applicable, as long as the concerned species are covered. According to the first bullet point, MRLs have not been established for any food producing species.
- The May 2017 CA meeting agreed that in line with the agreed interim approach on MRLs, the current entry in the Commission Regulation (EU) No 37/2010 "No MRL required" should be sufficient for biocidal use.

## ***Estimating Livestock Exposure to Active Substances used in Biocidal Products***

*List of scenarios*

| Summary table of scenarios related to livestock exposure assessment | | | |
|---|---|---|---|
| **Scenario number** | **Type of use** | **Description of scenario** | **Subject of exposure** |
| [5] | RTU teat spray treatment– animal exposure (meta SPC 1,2,3) | Teat disinfection of dairy cows used for milk production by spraying | Livestock animals (dairy cows) |
| [6] | RTU teat dip treatment – animal exposure (meta SPC 4,5) | Teat disinfection of dairy cows used for milk production by dipping | Livestock animals (dairy cows) |
| [7] | Animal house treatment by spraying – animal exposure (meta SPC 6,7,8) | Disinfection of unpopulated animal housing after pre-cleaning, 1-13 times a year, depending on species | Livestock animals |

**Scenario [5]: RTU teat spray treatment– animal exposure (meta SPC 1,2 -3)**

| **Description of Scenario [5]** | | |
|---|---|---|
| Assumption of two milkings a day, post-milking only. Treated animal: dairy cow. Application rate from [redacted] on dairy cows; drip-off during first 60 seconds post application from [redacted] taken into account. | | |
| | Parameters | Value |
| Tier 1 | Frequency[1] | 2 applications/day |
| | max. Iodine concentration | 5 mg/mL |
| | Application rate[2] | 2 mL |
| | Amount remaining on teats after 60 seconds drip off phase[2] | 1.2 mL |
| | Application type | spraying |
| | Iodine uptake via feed<br>feed consumption[3] * 5 mg Iodine/kg feed[4] / bw of animal[5] | [mg/kg bw day]<br>dairy cattle =0.19<br>sheep = 0.20<br>lacting goat=0.20<br>buffalo=0.20 |
| Tier 2 | dermal absorption rate from human study introduced to calculate transfer of disinfectant into animals body | 12% |

[1] Default according to ECHA 2012, DRAWG Draft Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products (CA-Dec10-Doc.6.2.b) =2/day; in BPC WG HH webex meeting at October 3, 2017 it was rewiewed and agreed that manual milking leads to higher residues compared to automatic milking; therefore 2 manual milkings per day would lead to similar residues compared to 3 automatic milkings per day.

[2] according to [redacted], 2 mL are remaining on the teats immediately after dipping; 1.2 mL are remaining on the teats after 60 seconds drip off. This is a worst case estimate for the smaller animals sheep, goat, buffalo.

[3] from draft DRAWG guidance: dairy cow = 26 kg/day, sheep 3 kg/day, lacting goat 2.8 kg/day, buffalo 20 kg/day

[4] EFSA Journal 2013;11(2):3101: The FEEDAP Panel recommends that the maximum Iodine contents in complete feed be reduced as follows: dairy cows: 2 mg/Iodine / kg feed. However the BPC WG VII 2018 concluded that the current maximum value of 5 mg/Iodine /kg feed is used for this estimate.

[5] from draft DRAWG guidance: dairy cow = 650 kg, sheep 75kg, lacting goat 70 kg, buffalo 500 kg.

**Scenario [6]: RTU teat spray treatment– animal exposure (meta SPC 4,5)**

| **Description of Scenario [6]** | | |
|---|---|---|
| Same assumptions and parameters as in scenario [5], except: | | |
| Tier 1 | Parameter | Value |
| | Application type | dipping |
| | max. Iodine concentration | 4.5 mg/mL |

**Scenario [7]: Animal house treatment by spraying – animal exposure (meta SPC 6,7,8)**

| **Description of Scenario [7]** | | |
|---|---|---|
| Animal house treatment by spraying – animal exposure (see DRAWG guidance for exposure model[1]).<br>Scenario 7a: calf<br>Scenario 7b: laying hen<br>Scenario 7c: dairy cattle[7]<br>Scenario 7d: pig | | |
| | Parameters | Value |
| Tier 1 | Iodine concentration in application solution | 0.75 mg/mL |
| | Iodine application rate | 400 mL/m$^2$ |
| | Application frequency[2] | usually once per year and stable , i.e. once per life time for calf, pig, laying hen |
| | Application type | spraying |
| | Iodine uptake via feed<br>feed consumption[3] * mg Iodine/kg feed[4] / bw of animal[5] | calf and dairy cattle: 0.20 mg/kg bw<br>laying hen: 0.34 mg/kg bw<br>pig: 0.15 mg/kg bw day |
| Tier 2[6] | Dermal absorption rate from human study introduced to calculate transfer of disinfectant into animals body[8] | 12% |
| | Cleaning efficiency | not considered |

[1] ECHA 2012, DRAWG: Draft Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products (CA-Dec10-Doc.6.2.b)

[2] according to general directions for use

[3] from draft DRAWG guidance: calf = 8 kg/d; laying hen = 0.13 kg/d; dairy cow = 26 kg/d

[4] EFSA Journal 2013;11(2):3101: The FEEDAP Panel recommends that the maximum Iodine contents in complete feed be reduced as follows: dairy cows and minor dairy ruminants= 2 mg Iodine / kg feed; laying hen = 3 mg Iodine /kg feed. However within the BPC WG VII 2018 it was concluded that the currently allowed maximum amount of 5mg/kg feed is used as a conservative estimate.

[5] from draft DRAWG guidance: calf =200kg bw; laying hen = 1.9 kg bw; dairy cattle= 650 kg bw, fattening pig = 100 kg

[6] Only include the parameters changed with respect to the previous Tier.

[7] surface and food exposure same emission factors were used as for calf (which is not explicit in the draft DRAWG)

[8] It is noted that, within in vitro methods for dermal absorption, pig-skin was often used as a replacement of human skin, due to similarity. However, in general animal skin is often considered more permeable than human skin due to the higher density of hair follicles. Yet this is considered when using dermal absorption studies with shaved animals to estimate human dermal absorption. Here the assessment-aim is a different one: Dermal absorption for non-shaved animals (including the passage through fur or feathers). For this case, it may be assumed that larger proportions of the substance adhere to the fur or feathers and do not pass on to the skin and consequently dermal absorption will at least not be higher compared to nude human in vitro skin.
The 12% value was estimated based on two in vitro studies performed with two different formulations that differed both in terms of Iodine concentration and co-formulants (see section on human hazard assessment).

## Calculations for estimating livestock exposure for Scenario [5], [6] and [7]

**Scenario [5]: RTU teat spray treatment– animal exposure (meta SPC 1, 2, 3)**

| Internal dose received by the animal | | | |
|---|---|---|---|
| Scenario [5] | Iodine uptake via teat disinfection | Iodine uptake via Iodine supplemented feed | Total exposure |
| | mg/kg bw/day | mg/kg bw/day | mg/kg bw/day |
| Tier 1 | | | |
| dairy cow | 0.018 | 0.19 | 0.21 |
| sheep | 0.16 | 0.2 | 0.36 |
| lacting goat | 0.171 | 0.2 | 0.37 |
| buffalo | 0.024 | 0.2 | 0.22 |
| Tier 2* | | | |
| dairy cow | 0.002 | 0.19 | 0.19 |
| sheep | 0.019 | 0.2 | 0.22 |
| lacting goat | 0.021 | 0.2 | 0.22 |
| buffalo | 0.003 | 0.2 | 0.2 |

***12% dermal absorption considered***

**Scenario [6]: RTU teat dip treatment (scenario 6) – animal exposure (meta SPC 4, 5)**

See RTU teat spray treatment– animal exposure (meta SPC 1, 2, 3): Exposure calculation is identical, maximum concentration in meta SPC 1,2,3 is 5 mg/mL, in meta SPC 4, 5 is 0.45 mg/mL. Therefore, scenario 5 covers scenario 6 as a worst case. No additional calculations are needed.

**Scenario [7]: Animal house treatment by spraying – animal exposure (meta SPC 6,7,8)**

| Internal dose received by the animal | | | |
|---|---|---|---|
| | via animal house spraying [mg/kg bw day] | via supplemented feed [mg/kg bw day] | total exposure [mg/kg bw day] |
| **Tier 1** | | | |
| Scenario 7a calf | 1.29 | 0.20 | 1.49 |
| Scenario 7b: laying hen | 0.264 | 0.34 | 0.61 |
| Scenario 7c: dairy cattle | 0.154 | 0.19 | 0.35 |
| Scenario 7d: pig | 1.484 | 0.15 | 1.63 |
| **Tier 2*** | | | |
| Scenario 7a calf | 0.318 | 0.20 | 0.52 |
| Scenario 7b: laying hen | 0.209 | 0.34 | 0.55 |
| Scenario 7c: dairy cattle | 0.148 | 0.19 | 0.34 |
| Scenario 7d: pig | 0.474 | 0.15 | 0.62 |

***12% dermal absorption considered***

### *Human dietary exposure [scenario 8]*

| **Description of Scenario and result [8] -** Human dietary exposure to Iodine via teat treatment related residues in milk, animal house disinfection related residues in milk and other animal derived products and other background exposure. | |
|---|---|
| The assessment includes exposure to Iodine coming from several sources:<br>1) teat treatment<br>2) background from milk (due to Iodine sources other than from treat treatment, including residues from animal house desinfection)<br>3) dietary intake from non dairy sources (including animal derived products with Iodine residues from animal house disinfection) | |
| Parameters | Value |
| Teat treatment: since only post-milking treatment: transfer from systemic body exposure to milk[1] | 252 ug/L |
| Background from milk[2] | 200 µg/L |
| Daily milk consumption[3] | 0.45 L/day for adults<br>0.46 L/day for toddlers |
| Dietary intake from other sources[4] | 185 µg/day for adults<br>96 µg/day for toddlers |
| Total exposure | 388 µg/day for adults<br>304 µg/day for toddlers |
| % of total exposure from teat treatment | 29% for adults<br>38% for toddlers |

[1] as agreed at BPC WG V 2017: value taken from O´Brien 2013 from post-milking application with a product containing 0.5% Iodine. It represents an additional Iodine residue value (difference to non-Iodine teat-desinfection control group). (See also document 8.02. for this submission). 244 mg/kg milk = 252 mg/L milk, considering milk density of 1.03.

[2] as agreed at BPC WG V 2017: The range of 100 to 200 µg/L of average Iodine values from milk bulk sample analysis of various EU studies is reported in the EFSA FEEDAP Scientific Opinion 2013 (EFSA Journal 2013;11(2):3101). It was noted that these Iodine values represent the overall Iodine exposure coming from several sources, not allowing discriminating the contribution of teat disinfection and diet supplementation from the other sources; therefore it may be an overestimation for the Iodine background level in milk. In the BPC WG VII 2018 it was agreed that this value is considered to include also Iodine residues in milk from animal house disinfection.

[3] As agreed at BPC WG V 2017: It was agreed that the daily milk consumption for adult and toddler should be calculated using the following parameters: values from EFSA PRIMo (Version 2) from highest mean intake (g/kg bw/day) for Dutch population for adult and for French population for toddlers; the body weight (70 kg adult, 12 kg toddler) and the milk density (‡ Density of whole milk 1030 g/L). The corresponding daily milk consumptions are: 0.45 L/day for adult and 0.46 L/day for toddler.

[4] as agreed at BPC WG V 2017: Within an UK survey (Retail survey of Iodine in UK produced dairy foods, FSIS 02/08, 16 June 2008) the Iodine dietary intake for dietary sources other than milk was estimated. At October 3, 2017 within a TC of a subgroup of the BPC WG HH it was agreed to use the following rounded values: 185 µg/day for adults and 96 µg/day for toddlers. In the BPC WG VII 2018 it was agreed that this value is considered to include also Iodine residues in non-dairy food stemming from animal house disinfection.

*Information of non-biocidal use of the active substance*

| Summary table of other (non-biocidal) uses | | | |
|---|---|---|---|
| | **Sector of use** | **Intended use** | **Reference value(s)** |
| 1. | VMP | Wound disinfection and mastitis treatment | "no MRL required" for all target tissues according to Commission Regulation (EU) No 37/2010 of 22 Dec. 2009. [Based on an evaluation of the committee for veterinary medicinal products were it was agreed that it would be inappropriate to elaborate MRLs for Iodine. |
| 2. | Food additives | Fortification of food (iodised salt) | 10-75 mg/kg salt (majority of values in the range of 15-30 mg/kg) according to EFSA NDA Panel, 2014, Scientific Opinion on Dietary Reference Values for Iodine, EFSA Journal 2014; 12(5);3660 (doi:10.2903/j.efsa.2014.3660) |
| 3. | Feed additive | Iodine supplement to e.g. dairy cows[1] | 2-5 mg/kg dry feed added |
| 4. | Pharmaceutical product | Wound disinfection, regulated by EMA | n.a. |

[1] EFSA Journal 2013;11(2):3101: The FEEDAP Panel recommends that the maximum Iodine contents in complete feed be reduced as follows: dairy cows and minor dairy ruminants, 2 mg I/kg; laying hens, 3 mg I/kg; horses, 3 mg I/kg; dogs, 4 mg I/kg; cats, 5 mg I/kg.

*Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)*

No direct contamination of milk due to teat-dip disinfection is expected due to post-milking application only (Scenario 5, 6).

No direct contamination of milk due to animal-house disinfection is expected due to usual hygienic measures (Scenario 7).

*Estimating transfer of biocidal active substances into foods as a result of non-professional use*

Not foreseen.

### *Exposure associated with production, formulation and disposal of the biocidal product*

Occupational exposure during production and formulation of the biocidal product is not assessed under the requirements of the BPR. It is assumed that the production is performed in conformity with national and European occupational safety and health regulations.
In addition, production or formulation of biocidal products are already covered by REACH legislation, where the registrants (manufacturers/importers) of substances are obliged to consider human hazard and exposure and to provide RMMs/exposure scenarios for ensuring safe use (e.g. via SDS in the supply chain). Moreover, it is assumed that industrial production sites are subject to permit for installation. Therefore, it is not considered relevant to perform an additional exposure assessment under the biocide regime.

Moreover, the applicant provided the following information:

*Production and formulation is addressed under other EU legislation (e.g. Directive 98/24/EC) and not repeated under Regulation 528/2012 (this principle was agreed at Biocides Technical Meeting TMI06).*

*Waste must be disposed of according to the applicable regulations. As much as possible of the content should be used because only empty containers should be added to the general waste collection. Exposure during the disposal of biocidal product containers is expected to be negligible.*

### *Aggregated exposure*

To be added once the methodology has been developed.

### *Summary of exposure assessment*

| **Scenarios and values to be used in risk assessment** | | | |
|---|---|---|---|
| **Scenario number** | **Exposed group (e.g. professionals, non-professionals, bystanders)** | **Tier/PPE** | **Estimated total uptake [µg a.s./kg bw/day]** |
| [1] | professionals | Tier 2 | 5.46 |
| [2] | professionals | Tier 2 | 0.27 |
| [3] | professionals | Tier 2b | 5.5 |
| [4] | professionals | Tier 2 | 0.10 |
| [1]&[4] | professionals | Tier 2 | 7.87 |
| [2]&[4] | professionals | Tier 2 | 0.40 |
| [3]&[4] | professionals | Tier 2b | 5.6 |

## 2.2.6.3 Risk characterisation for human health

### 2.2.6.3.1 Risk for local effects

The meta SPC 1-5, products are not classified for local effects. Therefore no risk assessment for local effects is necessary for these products.

The meta SPC 6,7,8 products for animal house disinfection use are classified for eye damage category 1 and skin corrosion category 1. The in-use dilution contains maximally 2% of the product. Considering the components classified for skin irritation (Iodine 3% and phosphoric acid 10%) and eye damage ([redacted] surfactants 31.8%) the components within in-use solution would not meet the classification limits for skin irritation or eye irritation. The pH of a 1% solution is reported as 2.36. Consequently a risk assessment for local effects is just required for the step of mixing and diluting the product to the in use dilution.

Table – Risk assessment for local effects of the products from meta SPC 6,7,8

| Hazard | | | Exposure | | | | | | | Risk |
|---|---|---|---|---|---|---|---|---|---|---|
| Hazard Category | effects in terms of C&L | additional relevant hazard information | PT | Who is exposed? | Tasks, uses, processes | Potential exposure route | frequency and duration of potential exposure | Rough degree of exposure | Relevant RMM & PPE | Conclusion on risk |
| high | H318: eye dam.<br>H314: skin corr. | - | 3 | professional | Manual addition of up to 3 liters of the product to 97 liter of water and stirring | Skin<br>Eye | up to 15 minutes per task, usually 2 to 4 times per year; for ducks up to 13 times per year | n.r. | Package design minimising risk for splashes/eye and skin exposure<br>Face shield or goggles<br>Protection gloves | Acceptable:<br>+ professionals using appropriate PPE<br>+ used for short duration<br>+ used with low frequency |

The task of diluting the meta SPC 6,7,8 products to the in-use solutions is carried out for few minutes per day, usually not more than 1 time per stable and year and rarely (for ducks) up to 13 times per stable and year. Professional workers from service companies may also be exposed more frequently (up to 3 times per month due to RMM constrains from systemic exposure estimates). However, appropriate RMM and PPE are used by professionals and specific training and experience may be expected for frequent professional use. The risk for local effects is considered acceptable.

### 2.2.6.3.2 Risk for systemic effects

**Reference values to be used in Risk Characterisation**

| Reference | Source | Reference values |
|---|---|---|
| Lowest effect level in humans | Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Iodine, SCF/CS/NUT/UPPLEV/26 Final 7 October 2002 | 1700-1800 µg Iodine/day[1] |
| $UL_{human}$ = tolerable upper intake (for all time frames)[2] | CAR for Iodine 2013, RMS SE<br>(in line with Scientific Opinion on Dietary Reference Values for Iodine, EFSA Journal 2014;12(5):3660) | 600 µg Iodine/day for adults (60 kg bw)[4]<br>250 µg/day for a 6-year old child (19 kg bw)<br>200 µg/day for toddlers (1-3 years, 12 kg bq)<br>10 µg/ kg bw day (adults) |
| OEL | Based on human data, reference value in most European countries, see e.g. See e.g. http://limitvalue.ifa.dguv.de/WebForm_ueliste2.aspx (in line with CAR for Iodine 2013) | 0.1 ppm (1 mg/m$^3$) |
| AI: adequate daily intake of Iodine as essential nutrient | Scientific Opinion on Dietary Reference Values for Iodine, EFSA Journal 2014;12(5):3660 | pregnancy, lactation: 200 µg/day<br>≥ 18 years: 150 µg/day<br>11-18 years: 120-150 µg/day<br>1-10 years: 90 µg/day<br>7-11 months: 70 µg/day |
| Drinking water limit[3] | CAR for Iodine | 30 g/L |

[1] **Effects observed with high dose exposure:** Chronic excessive Iodine supply can also lead to goitre, as has, for example, been observed following chronic excessive Iodine intakes through water in China (Zhao et al., 2000). Long-term follow-up suggests that chronic excessive Iodine intakes may accelerate the development of sub-clinical thyroid disorders to overt hypothyroidism or hyperthyroidism, increase the incidence of autoimmune thyroiditis and increase the risk of thyroid cancer (Laurberg et al., 1998; Teng et al., 2006). The SCF (2002) adopted the value of 600 µg/day as a Tolerable Upper Intake Level (UL) for adults including pregnant and lactating women (i.e. approximately half of the value of 1 100 µg/day adopted by IOM (2001)), on the basis of dose-response studies of short duration (two weeks) and in a small number of subjects (n = 10–32). For Iodine intakes of about **1700–1800 µg/day, the studies showed an increased response of thyroid-stimulating hormone (TSH) concentrations to thyrotropin-releasing hormone (TRH) provided intravenously (Gardner et al., 1988; Paul et al., 1988), but these changes were considered marginal and not associated with any clinical adverse effects.** A study by Stockton and Thomas (1978) covering a five-year exposure to approximately similar Iodine intakes in which no clinical thyroid pathology occurred was also considered, and an uncertainty factor of 3 was selected to derive the UL for adults. The ULs for children were derived by adjustment of the adult UL on the basis of metabolic weight (body weight 0.75).

[2] Minutes from BPC WG II 2017: The UL will be used as toxicological reference value. The uncertainty related to the derivation of the UL should be taken into account in the risk assessment. The lowest effect level of 1700-1800 µg/day in humans should be included when concluding on the risk.

[3] No drinking water limit is established. Calculation is based on 10% Upper Intake Level and a daily intake of 2 L drinking water.

[4] EFSA has used 70 kg bw for adults as a default value.

#### 2.2.6.3.2.1 Risk for industrial users

No industrial use is foreseen. The risk associated with production, formulation and disposal of the biocidal product is not assessed.

#### 2.2.6.3.2.2 Risk for professional users

Risk from individual scenarios

| Task/ Scenario | Tier | UL mg/kg bw/d | Estimated uptake mg/kg bw/d | Estimated uptake/ UL (%) |
|---|---|---|---|---|
| Scenario 1: mixing and loading and application to teats by trigger spray | Tier 1 | 0.01 | 0.0151 | 150 |
| | Tier 2a: gloves | 0.01 | 0.0043 | 43 |
| | Tier 2b: including 90% protection factor by gloves, chemical resistant coated coverall and boots | 0.01 | 0.0019 | 20 |
| Scenario 2: mixing and loading and application to teats by dip treatment | Tier 1 | 0.01 | 0.0182 | 18 |
| | Tier 2: including 90% protection factor for gloves | 0.01 | 0.00018 | 2 |
| Scenario 3: animal house spraying | Tier 1 | 0.01 | 0.0915 | 915 |
| | Tier 2a: gloves | 0.01 | 0.0437 | 437 |
| | Tier 2b: gloves and 95% protection factor by impermeable coverall, chemical resistant | 0.01 | 0.0058 | 58 |
| Scenario 4: cleaning of equipment | Tier 1 | 0.01 | 0.000065 | 1 |
| | Tier 2: including 90% protection factor for gloves | 0.01 | 0.000023 | <1% |

**Conclusion**

As summarised in the table "Risk from individual scenarios", the exposure for the use of the Iodine products for teat spraying (Scenario 1, maximal content of Iodine = 0.5%) is slightly above 100% of the UL for tier 2a (i.e. use of gloves) and 85% of the UL for tier 2b, (i.e. with the use of coated coverall, gloves and boots). The exposure for the use of Iodine products for teat dipping (Scenario 2, maximal content 0.45%) is below 100% of UL also without personal protective equipment.
For the animal house spraying (scenario 3, 0.075% Iodine) within tier 2b (including impermeable coverall and gloves) an exposure value of 58% of the UL is estimated. Using just gloves as PPE (tier 2a) would result in 437% of the UL. The exposure for cleaning of equipment is calculated for the dipping product (Scenario 4, maximal content 0.45%) and results with tier 2 estimates including protection gloves as less than 1% of the UL. This means, it does not significantly contribute to the overall exposure.

However, it was agreed within the BPC WG that professional exposure estimates for Iodine products use should be combined with expected dietary Iodine exposure. The potential risk from combined professional with dietary exposure is provided in section 2.2.6.3.2.5.

#### 2.2.6.3.2.3 Risk for non-professional users and general public

The biocidal products in the present BPF will not be used by non-professionals. Occasional secondary human exposure via contact with freshly treated surfaces may be relevant on farms. The tier 1 exposure calculations for cleaning of equipment (scenario 4) may be considered as a rough worst case estimate. This results in a potential uptake of 1% of the UL. Such occasional exposure would is equivalent to a very minor fraction to the total dietary intake. Therefore, exposure of other groups of population than professionals is not considered Therefore exposure of other groups of population than professionals is not considered.

#### 2.2.6.3.2.4 Risk for consumers via residues in food

*Risk from human dietary exposure to Iodine via teat treatment related residues in milk,* animal house disinfection related residues in milk and other animal derived products *and other background exposure*

| Scenario 8 | UL [mg/day] | Exposure [mg/day] | % UL | Acceptable (yes/no) |
|---|---|---|---|---|
| adults | 600 | 388 | 65 | yes |
| toddlers | 200 | 304 | 152 | Yes (see arguments below) |

| | |
|---|---|
| % of UL of adults from teat treatment | 19 |
| % of UL of toddlers from teat treatment | 58 |
| % of UL of adults from background in milk | 15 |
| % of UL of toddlers from background in milk | 46 |
| % of UL of adults from other sources | 31 |
| % of UL of toddlers from other sources | 48 |

The risk assessment for residues in food includes exposure estimates from the sources 1) teat treatment, 2) background from milk (due to Iodine sources other than from teat treatment, including residues from animal house disinfection) and 3) dietary intake from non-dairy sources (including animal derived products with Iodine residues from animal house disinfection). The exposure values considered for this estimate are explained in the exposure section (see "Description of Scenario and result [8] - Human dietary exposure"). As summarised in the table above the corresponding dietary risk appears acceptable for adults.

For toddlers the risk appears borderline to acceptable. However,

- the toddler's dietary Iodine intake from milk due to the teat disinfection procedure represents just approximately 58% of the UL (i.e. 38% of the total toddler´s dietary Iodine exposure). The rest stems from background exposure in milk and from other sources of human dietary exposure (including residues from animal house disinfection).
- The last two aspects may be very variable throughout Europe. Reducing the dietary exposure estimate by about 30% would result in a total exposure value of 100% of the UL also for the toddler.
- In spite of slightly exceeding the UL value for toddlers (300 instead of 200 µg/day), there is still a high margin to doses where marginal and not clinically adverse effects were observed in adult humans (1700-1800 µg/day for adults).

Therefore, and in line with earlier BPC WG agreements for other Iodine products for teat disinfection the risk is considered acceptable also for the dietary exposure of toddler.

#### 2.2.6.3.2.5 Risk from combined professional exposure and human dietary exposure

Risk from combined professional exposure and human dietary exposure

| Scenarios combined professional and human dietary exposure | Tiers | Professional exposure [1] [% of UL] | Dietary exposure [% of UL][2] | Total exposure [% of UL] | UL adult [mg/day] | exposure [mg/day] | Acceptable (yes/no) |
|---|---|---|---|---|---|---|---|
| 1+4+8 | Tier 1 | 151 | 65 | 215 | 600 | 1292 | no |
| | Tier 2a (gloves) | 43 | | 108 | | 646 | borderline |
| | Tier 2b (gloves, chemical resistant coated coverall and boots) | 19 | | 84 | | 504 | yes |
| 2+4+8 | Tier 1 | 19 | 65 | 83 | 600 | 500 | yes |
| | Tier 2 (gloves) | 2 | | 67 | | 401 | yes |
| 3+4+8 | Tier 1 | 915 | 65 | 980 | 600 | 6992 | no |
| | Tier 2a (gloves) | 437 | | 502 | | 3010 | no |
| | Tier 2b (gloves and chemical resistant coated coverall) | 58 | | 123 | | 737 | borderline |

[1] see chapter 2.2.6.3.2.2
[2] see chapter 2.2.6.3.2.4.

As indicated in the table above professional exposure from teat spray disinfection (1) and cleaning of equipment (4) combined with potential dietary exposure (8) represents an borderline to acceptable risk (108% of UL) for tier 2a estimates, i.e. if just gloves are used as personal protective equipment. With the tier 2b estimate, i.e. use of chemical resistant coated coverall, gloves and chemical resistant boots, the risk would be clearly acceptable (85% of UL). Therefore, for teat spray disinfection, gloves, protective coverall and boots are obligatory.

Professional exposure from teat dipping disinfection (2) and cleaning of equipment (4) combined with potential dietary exposure (8) represents an acceptable risk also with tier 1 estimates, i.e. without PPM.

In contrast, professional exposure from animal house disinfection with just gloves as PPE would as such already result in 437% of the UL and this would represent an unacceptable risk. However if a chemical resistant impermeable coverall is used (tier 2b, 95% protection factor) and this is even combined with the dietary exposure estimate, the exposure estimate is just 123% of the UL. This exceedance of the UL would normally not be acceptable. However, the following arguments support to accept this exceedance in the specific case:

- Exposure from animal house disinfection should not be carried out at high frequency, i.e. not more than 3 times per month
- The animal house disinfection as such results in just 58% of the UL, the rough dietary exposure estimate adds the higher amount of 65%.
- In spite of slightly exceeding the UL value, there are still high margins to doses where marginal and not clinically adverse effects were observed in adult humans (1700-1800 µg Iodine/day for adults, see footnote 1 to table underneath section heading 2.2.6.3.2.2.).
- A face shield and protective gloves are obligatory for mixing and loading.

Consequently, the risk for these professional and dietary combined exposures is considered acceptable, in case frequency of application in animal housing spraying is low, not more than 3 times per month.

At the BPC WG VII 2018 it was decided that combined scenarios over more than one meta SPC are not assessed, but a precautionary RMM is applied, i.e. a label indicating: Only use one kind of Iodine-containing product per day.
This RMM is in line with previous Union authorisations for products with Iodine as active substance. (e.g. In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing Iodine has to be considered for pre-milking disinfection.)

#### 2.2.6.3.2.6 Risk characterisation for substances of concern

**Phosphoric acid is a substance of concern**, since it contributes to the classification for skin corrosion of the animal house disinfection products (meta SPC 6,7,8). A qualitiative risk assessment for these local effects is provided in section 2.2.6.3.1. and this risk is considered as acceptable.

Moreover, for Phosphoric acid a harmonised respiratory SCOEL value of 1 mg/m$^3$ air is available. Consequently also a quantitative risk assessment is provided for the professional exposure from the use products which contain phosphoric acid: The teat disinfection spraying products (meta SPC 4,5) and the animal house disinfection products (meta SPC 6,7,8).

| Task/ Scenario | Tier | AEC mg/m³ | Estimated uptake mg/m³ | Estimated uptake/ AEC (%) |
|---|---|---|---|---|
| Scenario 2: mixing and loading and application to teats by dip treatment | Tier 1 | 1 | 0.27 | 27 |
| Scenario 3: animal house spraying | Tier 1 | 1 | 0.23 | 23 |
| Scenario 4: cleaning of equipment | Tier 1 | 1 | 0.27 | 27 |

As indicated in the table above the risk from respiratory exposure to Phosphoric acid appears acceptable for all relevant scenarios within tier 1 estimates.

Since the limit value is expressed, as an AEC and the scenarios would –if at all- be carried out sequentially, a risk estimate for the combination of the scenarios is not relevant.

#### 2.2.6.3.2.7 Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

Not relevant.

## 2.2.7 **Risk assessment for animal health**

**Reference values to be used in Risk Characterisation**

| | | |
|---|---|---|
| $UL_{farm\text{-}animals}$ = tolerable upper intake (for all time frames)[1] | Scientific Opinion on the safety and efficacy of Iodine compounds (E2) as feed additives for all species; EFSA Journal 2013;11(2):3101 | 10 mg/kg feed =<br><br>0.3 mg/kg bw day for pig<br>0.4 mg/kg bw day for cattle, calf, sheep, goat<br>0.7 mg/kg bw day for laying hen |
| Dermal absorption rate | Based on in vitro studies and conclusion for human dermal absorption.[2] | 12% |

[1] EFSA Journal 2013;11(2):3101 reviewed available data for animal health and concluded (see section 3.1.2) that currently established maximum Iodine content in feed (10 mg/kg) coincides with the upper tolerated level in chickens, pigs as well as dairy cows. The eCA considered this value indicative also for sheep and goats. Furthermore, the EFSA reference includes a reference to Meyer et al 2008 (Livestock Science, 115, 219–225), a study with fattening 34 growing fattening bulls of the "German Holstein" breed, in the range from 223 to 550 kg body weight, so this includes calf to youg adult exposure. Dry matter intake and daily weight gain were not significantly influenced by Iodine concentration of 8 mg/kg dry weight feed. Though the thyroid weight was significantly increased at this top concentration level, the eCA considered this concentration level useful as an indicative limit value for the single calf exposure expected from animal house disinfection (the calfs grow to adult before potential next stable disinfections). Considering the feed consumption (26kg for dairy cow, 8 kg calf, 3 kg for sheep, 3 kg for pig, 2.8 kg for lacting goat, 0.13 kg laying hen) and an UL of 10 mg Iodine/kg food and the body weight of these animals (650 kg for dairy cow, 200 kg for calf, 100 kg for pig, 75 kg for sheep, 70 kg for lacting goat, 1.9 kg for laying hen) this results in an UL of 0.3 mg/kg bw day for pig, 0.4 mg/kg bw day for cow, calf, sheep, goat and 0.7 mg/kg bw day for laying hen.

[2] see section on animal exposure.

***Teat-disinfection***

| Scenario [5] | Iodine uptake via teat disinfection | Iodine uptake via Iodine supplemented feed | Total exposure | UL farm- animals | % of UL farm- animals | **Acceptable (yes/no)** |
|---|---|---|---|---|---|---|
| | mg/kg bw/day | mg/kg bw/day | mg/kg bw/day | mg/kg bw day | % | |
| Tier 1 | | | | | | |
| dairy cow | 0.018 | 0.19 | 0.21 | 0.4 | 55 | yes |
| sheep | 0.16 | 0.2 | 0.36 | 0.4 | 90 | yes |
| lacting goat | 0.171 | 0.2 | 0.37 | 0.4 | 93 | yes |
| buffalo | 0.024 | 0.2 | 0.22 | 0.4 | 56 | yes |
| Tier 2* | | | | | | |
| dairy cow | 0.002 | 0.19 | 0.19 | 0.4 | 51 | yes |
| sheep | 0.019 | 0.2 | 0.22 | 0.4 | 55 | yes |
| lacting goat | 0.021 | 0.2 | 0.22 | 0.4 | 55 | yes |
| buffalo | 0.003 | 0.2 | 0.2 | 0.4 | 51 | yes |

*dermal absorption rate of 12% assumed as for human

**Conclusion**

The exposure assessment according to the DRAWG draft guidance for biocides was carried out for the post milking spray application (meta SPC 1,2,3 maximal Iodine concentation 0.5%) and this is representative also for the post milking dipping application (meta SPC 4, 5, see exposure section).

The resulting total exposure estimates for dairy cows, sheep, lacting goat and buffalo are beyond the human UL in terms of mg/kg bw day but below the UL for farm animals as derived from the EFSA 2013 opinion on the safety and efficacy of Iodine compounds (E2) as feed additives (see table above "Reference values to be used in Risk Characterisation" in section 2.2.7 Risk Assessment for animal health).

Within this opinion it was also concluded that the Iodine level in edible tissues/products is generally found to be highest in milk and not in meat. In line with this also EMEA (European Agency for the Evaluation of Medicinal Products) concluded within their summary report on Iodine-containing products used for veterinary medicine, that only small increases in serum Iodine concentration have been found after teat dipping indicating that the procedure has a negligible effect on tissue Iodine concentrations. In addition, Iodine-based teat-disinfection products have a long history as safe veterinary hygiene and medicinal products.

Consequently, the risk from post-milking teat disinfection within meta SPC 1, 2, 3, 4 and 5 is considered acceptable also with regard to animal health protection.

***Animal house spraying***

| | via animal house spraying [mg/kg bw day] | via supplemented feed [mg/kg bw day] | total exposure [mg/kg bw day] | UL farm-animal [mg/kg bw day] | % UL | **Acceptable (yes/no)** |
|---|---|---|---|---|---|---|
| **Tier 1** | | | | | | |
| Scenario 7a calf | 1.29 | 0.20 | 1.49 | 0.4 | 374 | no |
| Scenario 7b: laying hen | 0.264 | 0.34 | 0.61 | 0.7 | 89 | yes |
| Scenario 7c: dairy cattle | 0.154 | 0.19 | 0.35 | 0.4 | 90 | yes |
| Scenario 7d: pig | 1.484 | 0.15 | 1.63 | 0.3 | 545 | no |
| **Tier 2*** | | | | | | |
| Scenario 7a calf | 0.318 | 0.20 | 0.52 | 0.4 | 129 | Yes (see arguments below) |
| Scenario 7b: laying hen | 0.209 | 0.34 | 0.55 | 0.7 | 81 | yes |
| Scenario 7c: dairy cattle | 0.148 | 0.19 | 0.34 | 0.4 | 89 | yes |
| Scenario 7d: pig | 0.474 | 0.15 | 0.62 | 0.3 | 208 | Yes (see arguments below) |

*dermal absorption rate of 12% assumed as for human

**Conclusion**

The exposure assessment for animal house spraying application according to the DRAWG draft guidance for biocides was corrected within tier 2 for a dermal absorption rate of 12% as for humans. The exposure-estimate for laying hen [7b] appears to be 81% of the respective upper limit of 7 mg/kg bw/day and may therefore be considered acceptable. The exposure-estimate for dairy cattle [7c] appears to be 89% of the respective upper limit of 4 mg/kg bw day and may therefore be also considered acceptable. The exposure estimate for calf appears to be 129% of the respective upper limit of 0.4 mg/kg bw/day and the exposure estimate for pigs appears to be 208% of the respective upper limit of 0.3 mg/kg bw day. However, the risk for calfs and pigs from animal house disinfection residues is nevertheless considered acceptable, since

- The animal specific limit values were derived from maximum content of iodine in feed allowed for animal health protection. However the calfes and pigs would experience the exceedance only once in their life-time.
- The exposure estimate is quite conservative. After disinfection, the stables are kept empty for usually 14 days for drying and heating. Within that time, a very considerable amount of iodine will evaporate. This aspect was not considerd in the exposure estimate.

Therefore the risk for animal health from exposure due to animal house spraying application appears acceptable for laying hen, dairy cattle, calf and pig.

***Potential risk for pets***

The risk for pets is concluded as acceptable, based on the following considerations:

- Animal house disinfection must only be carried out in empty (unpopulated) animal houses.
- Risk from post-treatment exposure for small farm animals, i.e. laying hen and calf was considered acceptable
- Therefore also occasional secondary pet exposure via contact with freshly treated surfaces is likely to result in an acceptable risk.

Consequently no separate exposure assessment for pets is provided.

## 2.2.8 Risk assessment for the environment

### 2.2.8.1 Effects assessment on the environment

***Information relating to the ecotoxicity of the biocidal product family which is sufficient to enable a decision to be made concerning the classification of the product family is required***

Valid data concerning the ecotoxicological effects of the components in the biocidal product family are available. Ecotoxicological effects of the mixtures are solely based on the active substance Iodine. Further effects from other components, including synergistic effects are not expected.
Acute and/or chronic aquatic toxicity studies with members of the BPF_Iodine_VET have not been conducted.
According to Reg. (EC) No 1272/2008 (0.ATP) the harmonised classification of Iodine for its environmental effects is Aquatic Acute 1, H400 Very toxic to aquatic life (M=1). At the WG ENVII-2018 it was decided to classify Iodine as Aquatic Chronic 1, H410 Very toxic to aquatic life with long lasting effects. Based on the content of Iodine in the single members of the biocidal product family (0.1-3% (w/w)) products containing iodine concentrations ≤0.25% are not classified for the environment, ≥0.25% – <2.5% classified as Aquatic Chronic 3, H412, Harmful to aquatic life with long lasting effects and ≥2.5% as Aquatic Chronic 2 H411, Toxic to aquatic life with long lasting effects.

***Further Ecotoxicological studies***

No further data was submitted for the active substance or for any biocidal product of the biocidal family.

***Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)***

No further data was submitted for the active substance or for any biocidal product of the biocidal family.

***Supervised trials to assess risks to non-target organisms under field conditions***

No further data was submitted for the active substance or for any biocidal product of the biocidal family.

***Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk***

No further data was submitted for the active substance or for any biocidal product of the biocidal family. Furthermore such tests are not required since the biocidal products are not in the form of bait or as granules.

***Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)***

Such tests are only triggered in case when a habitat such as a water body, wetland, forest or field is treated. Any such treatment is not intended for the products: the products are only used for indoor application in stables. Consequently, no testing of secondary ecological effect is needed.

### *Foreseeable routes of entry into the environment on the basis of the use envisaged*

meta SPC 1, 2, 3, 4 and 5:
The products are intended for use as teat-disinfectants for dairy cows. They are used in animal houses (in-door use) and are applied by dipping or spraying to the teats of the animals after milking. Exposure to the environment is always secondary, via liquid manure and STP. Exposure to air is not relevant due to the low vapour pressure of the active substance. The main route of exposure to the environment is via liquid manure to arable land and grassland. When applying the products to the animal teats by spraying, spray may not reach the animal teats or part of the product applied to the teats may be lost by drip formation. Drip formation may also occur when the products are applied by dipping. In both cases the losses go into the liquid manure. When applied post-milking, the products will only partly remain on the animal teats between two milking events. The part which simply falls off or is lost due to contact with the surfaces (e.g. when the cows lie down for rest) will finally end up in the liquid manure. The part remaining on the teats will be removed before the next milking by wiping with a dry or wet tissue. If disposable tissues are used, the product will end up in the waste bin; if reusable cloths are used (which is not recommended), the removed product will end up in the drain when the cloth are cleaned / washed after the milking.

meta SPC 6, 7 and 8:
According to the ESD for PT3 (EU 2011) the disinfection of animal houses is carried out as follows: upon removal of all animals, the stable is thoroughly cleaned. Once the areas have dried, the disinfectant is applied by spraying surfaces using medium pressure (4 to 7 bar) equipment. The main emission paths are into the slurry/manure system and into the air. However, exposure to air is not relevant in the case of Iodine due to the low vapour pressure of the active substance. Furthermore, the fraction of active substance released to air is assumed to be zero according to the ESD for PT3 (EU 2011). The emissions to slurry/manure depend on the different animal categories and the respective data on housing sizes, animal numbers, slurry/manure production and the default values for the number of disinfection events for the different animal categories. In the case of some housing types, emission to waste water can take place.

### *Further studies on fate and behaviour in the environment (ADS)*

No further data was submitted for the active substance or for any biocidal product of the biocidal family. The prodcuts are used indoor (in animal housings) only.

### *Leaching behaviour (ADS)*

Not applicable for the uses assessed.

### *Testing for distribution and dissipation in soil (ADS)*

No further data was submitted for the active substance or for any biocidal product of the biocidal family.

### *Testing for distribution and dissipation in water and sediment (ADS)*

No further data was submitted for the active substance or for any biocidal product of the biocidal family.

### *Testing for distribution and dissipation in air (ADS)*

No further data was submitted for the active substance or for any biocidal product of the biocidal family.

### *If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)*

The products are not intended to be sprayed near to surface water. The spraying application gets applied indoor only. Therefore no overspray study is needed to assess risks to aquatic organisms or plant under field conditions.

### *If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)*

The biocidal products can be sprayed, but only indoor and on small scale. Therefore, the performance of an overspray study is not triggered.

### 2.2.8.2 Exposure assessment

**General information**

| | |
|---|---|
| Assessed PT | PT3 – Veterinary hygiene (Disinfectants) |
| Assessed scenarios | **Scenario [1]**: RTU teat spray treatment, manual/automated, post milking (meta SPC 1, 2 and 3)<br>**Scenario [2]**: RTU teat dip treatment, manual, post milking (meta SPC 4 and 5)<br>**Scenario [3a]**: Animal house treatment by spraying - veal calves (meta SPC 6, 7 and 8)<br>**Scenario [3b]**: Animal house treatment by spraying - ducks (meta SPC 6, 7 and 8)<br>**Scenario [3c]**: Animal house treatment by spraying - turkey (meta SPC 6, 7 and 8) |
| ESD(s) used | Emission Scenario Document for Product Type 3:<br>Veterinary hygiene biocidal products, JRC Scientific and Technical Reports, Report nr. EUR 25116 EN, Publications Office of the European Union, Luxembourg, 2011 |
| Approach | Average consumption<br>Scenario [1] & [2]:<br>The products can either be dipped (maximum product volume of 10 mL/cow/milking, application concentration of 4.5 mg/mL, 2 applications per day) or be sprayed (maximum product volume of 15 mL/cow/milking, application concentration of 5 mg/mL, 3 applications per day considering automatic spraying, 2 applications per day considering manual spraying). Since spraying results in a higher application rate per day than dipping due to higher applied product volume, higher application concentration and higher application frequency due to automatic spraying is considered, spraying is assessed as worst resulting in the highest emission to the environment. Consequently, the dipping application is covered by the spraying scenario. In case of robotic milking product is only applied by automated spraying. However, there is no difference concerning environmental release between robotic spraying and manual spraying. Therefore, robotic milking is also covered by the spraying scenario.<br>Scenario [3a] & [3b] & [3c]:<br>In these scenarios, animal housings are treated by spraying. The product is diluted prior to use. The worst case for meta SPC 6, 7 and 8 is represented by an in-use concentration of Iodine of approximately 0.075%(w/w). |
| Distribution in the environment | Scenario [1] & [2] & [3a] & [3b] & [3c]:<br>Two emission pathways are considered: On one hand residues are released to the manure/slurry. Soils are indirect exposed when manure/slurry is applied as a soil fertiliser. Subsequently, the active substance may be transported to groundwater due to leaching from the top soil layer or enters the aquatic compartment due to runoff. On the other hand emission to the sewage treatment plant and subsequently to surface water and sediment is relevant for those farms connected to the municipal sewer. |
| Groundwater simulation | No. The calculation of the concentration in groundwater was performed according to the approach described in ECHA (2017c) where the concentration in porewater of agricultural soil is used as a first indication for groundwater concentrations. As Focus PEARL is |

| | |
|---|---|
| | designed for organic substances, emission to groundwater for the nine EU-scenarios was not performed. Note that the limit value for pesticides of 0.1 µg/L specified in the Reg. (EC) No 98/83 is not applicable for Iodine and its Iodine species since the definition of pesticides in Reg. (EC) No 98/83 is limited to organic substances. At the BPC ENV WG-III-2017 it was agreed to take the natural background concentration of 70 µg/L as reference value to compare the PECgw with. |
| Confidential Annexes | No confidential annex relevant for the environmental risk assessment. |
| Life cycle steps assessed | Use and disposal, according to the requirements of the BPR<br>Scenario [1] & [2] & [3a] & [3b] & [3c]:<br>Production: No (outside the EU)<br>Formulation: No (cf. to chapter 2.2.6.2, section "Exposure associated with production, formulation and disposal of the biocidal product")<br>Use: Yes<br>Service life: No (no service life after application) |
| Remarks | Emission to air is not considered as it may be expected that Iodine and their relevant species (Iodide and Iodate) are not volatile. |

## *Emission estimation*

Scenario [1] & [2] (meta SPC 1, 2, 3, 4 and 5)

Teat disinfections are applied by manual dipping, manual spraying or automated spraying. The latter applies when the cows are milked by a robot.
Since spraying results in a higher application rate per day than dipping due to higher applied product volume und higher application concentration, spraying is assessed as worst resulting in the highest emission to the environment. Consequently, the dipping application is covered by the spraying scenario. In case of robotic milking, product is only applied by automated spraying. However, there is no difference concerning environmental release between robotic spraying (3 applications per day) and manual spraying (2 applications per day), aside from the number of applications per day. Therefore, robotic milking is also covered by the spraying scenario and the worst case of application of the biocidal product is 3 times a day based on robotic spraying.

Scenario [3a] & [3b] & [3c] (meta SPC 6, 7 and 8)

The products are used as disinfectant for hard surfaces in stables (excluding hatcheries) by spraying of diluted concentrate by means of a hand-held knapsack sprayer.
The environmental exposure assessment is based on default values stated in the ESD for PT3 (EU 2011) regarding the different animal categories and the respective data on housing sizes, animal numbers and manure/slurry production.

Relating to scenarios [1] & [2] & [3a] & [3b] & [3c]

The environmental risk assessment was performed for the active substance Iodine ($I_2$) and its different ionic species only, e.g. Iodide ($I^-$) and Iodate ($IO_3^-$) as no other environmentally relevant substance or substance of concern was identified.

The route of exposure of Iodine to the environment is either via application of manure/ slurry to soil or by release from the facility drain to an STP and subsequent compartments.

- Pathway 1 - emissions to slurry/manure: although no direct treatment of the manure/slurry is performed, it is assumed that the remaining dipping solution could come into contact with manure/slurry which is subsequently collected, stored and applied to agricultural soil and grassland.
- Pathway 2 - emissions to wastewater: wastewater will be released to a municipal STP and results in subsequent emissions to surface water, sediment and soil via sewage sludge application.

The amount of biocide applied in the manure to soil correlates with the nitrogen content in manure and the nitrogen immission standards. However, in various countries there may be an immission standard for $P_2O_5$ instead. It is even possible that there are standards for both $P_2O_5$ and nitrogen. Information for different countries on tolerated N values for use of manure are taken from Defra (2005) and adapted to the decisions made of the member states at Technical Meeting I/08. According to the Technical Agreements for Biocides (ECHA 2017d) it is sufficient to provide a risk assessment only based on nitrogen imission standards. Therefore, PEC values based on nitrogen imission standards are presented only.

**Scenario [1] – RTU teat spray treatment, manual/automated, post milking (meta SPC 1, 2 and 3; covering meta SPC 4 and 5)**

Teat disinfections are applied by manual dipping, manual spraying or automated spraying. The latter applies when the cows are milked by a robot.
In the case of robotic milking, individual cows may be milked up to five times per day; however the average milking frequency per herd is always below three milking events per day (experience from a test house specialised in veterinary farm research). Thus, milking by robots is considered to be performed on average three times per day, and manual milking two times per day. Therefore, consens in recent Union Authorisations was that in case of robotic milking, three milking events per day are more appropriate.
Since spraying results in a higher application rate per day (15 mL/cow and milking) than dipping (10 mL/cow and milking), spraying is assessed as worst case. Consequently, the dipping application is covered by the spraying scenario assuming 3 applications per day.

The emission estimation is based on input parameter given in the ESD for PT3 (EU 2011), the Addendum to OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 14 (ECHA 2014; agreed at the BPC WG-V-2015) and are in accordance with the Technical Agreements for Biocides (ECHA 2017d).

| **Input parameters for calculating the local emission**<br>**RTU teat spray treatment, manual/automated, post milking: scenario [1] – meta SPC 1, 2 and 3; covering meta SPC 4 and 5** | | | | |
|---|---|---|---|---|
| **Input** | | **Value** | **Unit** | **S/D/O/R***<br>**Origin** |
| **Scenario [1]: RTU teat spray treatment, manual/automated, post milking (meta SPC 1 and 2)** | | | | |
| Application rate of biocidal product: Amount of product prescribed to be used for one treatment (spraying of the four teats) of one animal | Vprodi1,i2,i3 | 0.015 | [L/cow/treatment] | S<br>for the application method spraying (manual / automated) |
| Time of application | - | Post-milking | [-] | S |

| **Input parameters for calculating the local emission**<br>**RTU teat spray treatment, manual/automated, post milking: scenario [1] – meta SPC 1, 2 and 3; covering meta SPC 4 and 5** | | | | |
|---|---|---|---|---|
| **Input** | | **Value** | **Unit** | **S/D/O/R*** **Origin** |
| Number of teat dipping events for one animal and one day | Napp-teat | 3 | [$d^{-1}$] | S |
| Resulting product volume for spraying for all treatments per cow per day | $Vprodi_{1,i2,i3\text{-}total}$ | 0.045 | [L/cow/day] | S |
| Concentration of active substance in the product | $F_{bioc}$ | 5 | [g/L] | S |
| Type of housing/manure storage (for application of the notification) | $cat_{\text{-subcat (i1)}}$ | i1=1 (dairy cows) | [-] | P (ESD, Appendix1: Table 7) |
| Type of biocide | bioctype $_{(i2)}$ | iI2=3 (disinfectant) | [-] | D (ESD Appendix1: Table 7) |
| Type of application | appway (i3)** | i3=2 | [-] | D (ESD Appendix1: Table 7) |
| Relevant emission stream | stream (i4)*** | 1.manure/slurry<br>2.wastewater | [-] | P (ESD Appendix1: Table 7) |
| Dilution factor (for preparation of the working solution from the formulation (product)) | $F_{dil}$ | 1 | [-] | S |
| Fraction of active ingredient released | ($F_{stp}$ = $F_{ww}$)<br>$F_{stp\_i1,i2,i3,i4}$ | 0 | [-] | D (ESD, Appendix1: Table 10) |
| | $F_{slurry/manure\_i1,i2,i3,i4F}$) | 0.5 (1- $F_{teat}$) | [-] | D (ESD, Appendix1: Table 10) |
| | $F_{air}$ | 0 | [-] | D (ESD, Appendix1: Table 10) |
| | $F_{teat}$ | 0.5 | [-] | D (ESD, Appendix1: Table 10) |
| Number of days of lactation period | Nday-lact | 300 | [-] | D |
| Number of disinfectant applications in one year (equals number of disinfectant applications in one lactation period) | Napp-bioc | 900 | [-] | S |
| Interval between two disinfectant applications (dipping events) | Tbioc-int | 0.33 | [d] | D |
| Number of manure applications for grassland | Nlapp-grass | 4 | [-] | D |
| Number of manure applications for arable land | Nlapp-arab | 1 | [-] | D |
| Land application interval for grassland | $T_{gr\text{-}int}$ | 53 | [d ] | according to ECHA, 2014 |
| Manure storage time arable land | $Tmanure\text{-}int_{ar2}$ | 212 | [d ] | according to ECHA, 2014 |
| Number of animals in housing for category/subcategory *i1* =1 | Nanimal | 100 **** | [-] | P |

| Input parameters for calculating the local emission<br>RTU teat spray treatment, manual/automated, post milking: scenario [1] – meta SPC 1, 2 and 3; covering meta SPC 4 and 5 | | | | |
|---|---|---|---|---|
| **Input** | | **Value** | **Unit** | **S/D/O/R* Origin** |
| Amount of nitrogen per animal for category/subcategory *i1* =1 | Qnitrog | 0.3389 | [kg/d] | P |
| **If nitrogen emission standards are applied** | | | | |
| Nitrogen immission standard for one year on grassland | $Q_{N,grassland}$ | 170 | [kg/ha] | D |
| Nitrogen immission standard for one year on arable land | $Q_{N,arable\_land}$ | 170 | [kg/ha] | D |
| **Soil default values** | | | | |
| Mixing depth with soil, grassland | $DEPTH_{grassland}$ | 0.05 | [m] | D |
| Mixing depth with soil, arable land | $DEPTH_{arable\_land}$ | 0.2 | [m] | D |
| Density of wet bulk soil | RHOsoil | 1700 | [kg/m³] | D |

*Set, Default, Output, Refined
** spraying, dipping

*** Release to the environment is either via application of manure/slurry to soil or by release from the facility drain to an STP.

**** The default value for a dairy cow herd size is 100 animals. The lactation period for dairy cows is normally 270 to 300 days, as two months before calving, dairy cows do not produce milk. Considering a lactating period of 300 days, 82 milk producing cows (100*300/365=82) are milked per day, from a herd of 100 dairy cows (ECHA 2017b).

**Scenario [2] - RTU teat dip treatment, manual, post milking (meta SPC 4 and 5)**

The dipping scenario is covered by the spraying scenario, since spraying results in a higher application rate per day than dipping due to higher applied product volume und higher application concentration, spraying is assessed as worst case resulting in the highest emission to the environment.

**Scenario [3a] - Animal house treatment by spraying - veal cattle**
**Scenario [3b] - Animal house treatment by spraying - ducks**
**Scenario [3c] - Animal house treatment by spraying - turkey**
**(meta SPC 6, 7 and 8)**

According to the ESD for PT3 (EU, 2011) and based on the intended use, the biocidal product is used for the disinfection of stables in animal husbandry. Upon removal of all animals, the stable is thoroughly cleaned and dryed before disinfection to obtain earth-moist surfaces. The disinfectant is then applied by spraying.
The product is diluted prior to use. The in-use Iodine concentration regarding all products in meta SPC 6, 7 and 8 is 0.075%(w/w).

The emission estimation is based on input parameter given in the ESD for PT3 (EU 2011), the Addendum to OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 14 (ECHA 2014; agreed at the BPC WG-V-2015) and are in accordance with the Technical Agreements

for Biocides (TAB, ECHA 2017d). Accordingly to TAB (2017, ENV #45) all surfaces of the respective animal housing, provided in Table 8 of the ESD for PT 3 (EU 2011; page 51) are incorporated.

The concentrations in soil based on the immission standard for nitrogen for grassland and arable land (PECgr_N and PECar_N: taking degradation and leaching into deeper soil layers into account) and emissions to STP were calculated for all categories of animal stables given in the ESD for PT3 (EU 2011) and are presented in the Annex of this document (see chapter 3.2.2. Environmental Exposure).

The following worst case scenarios were defined:

- **concentration in grassland after manure/slurry application (PECgr_N):** veal calves (cat. 3)
- **concentration in arable land after manure/slurry application (PECar_N):** ducks in free range with litter floor (cat. 17)
- **emission to sewer system: Elocalwaste water (STP):** turkeys in free range with litter floor (cat. 16)

**Scenario [3a] - Animal house treatment by spraying - veal calves (meta SPC 6, 7 and 8)**

| Parameters | Symbol | Veal calves | Unit | S/D/O/R* |
|---|---|---|---|---|
| Type of housing/manure storage (for application of the notification) | cat-subcat (i1) | i1=3 | [-] | D (Appendix1: Table 7) |
| Type of biocide | bioctype (i2) | iI2=3 (disinfectant) | [-] | D (Appendix1: Table 7) |
| Type of application | appway (i3)** | i3=1 | [-] | D (Appendix1: Table 7) |
| Relevant emission stream | stream (i4)*** | manure/slurry | [-] | D (Appendix1: Table 7) |
| Content of active ingredient in formulation (product) | Fbioc | 0.75 | [g/L] | S |
| Amount of product prescribed to be used for one treatment | $V_{product}$ | 0.1 | [L/m²] | S |
| Dilution factor (for preparation of the working solution from the formulation (product)) | $F_{dil}$ | 1 | [-] | S |
| Area of housing treated [2] | AREAi | 650 | [$m^2$] | D |
| Fraction of active ingredient released | $F_{stp} = F_{ww}$ | 0 | [-] | D (Appendix1: Table 10) |
| | $F_{slurry/manure}$ | 0.5 | [-] | |
| | $F_{air}$ | 0 | [-] | |
| Total fraction of active ingredient released | $F_{released}$ | | [-] | D |
| Number of disinfectant applications in one year (equals number of disinfectant applications in one lactation period) | $N_{app\text{-}bioc}$ | 4 | [-] | D |
| Interval between two disinfectant applications (dipping events) | $T_{bioc\text{-}int}$ | 91 | [-] | D |
| Number of manure applications for Grassland (worst case) | $N_{lapp\text{-}grass}$ | 4 | [-] | D |
| Number of manure applications for arable land | $N_{lapp\text{-}arab}$ | 1 | [-] | D |
| Land application interval for grassland | $T_{gr\text{-}int}$ | 53 | [d ] | according to |

[2] All surfaces in the respective animal housing, provided in Table 8 of the ESD for PT 3 (page 51) are considered.

| | | | | |
|---|---|---|---|---|
| | | | | ECHA, 2014 |
| Manure storage time arable land | $Tmanure\text{-}int_{ar2}$ | 212 | [d ] | according to ECHA, 2014 |
| Number of animals in housing for category/subcategory i1 =3 | $N_{anima1}$ | 80 | [-] | D (Appendix 1: Table 8) |
| Amount of nitrogen per animal for category/subcategory i1 =3 | $Q_{nitrog}$ | 0.02382 | [kg/d] | D (Appendix 1: Table 11) |
| Number of disinfectant applications in one year (equals number of disinfectant applications in one lactation period) | $N_{app\text{-}bioc}$ | 4 | [-] | D |
| Interval between two disinfectant applications (dipping events) | $T_{bioc\text{-}int}$ | 91 | [-] | D |
| Number of manure applications for Grassland (worst case) | $N_{lapp\text{-}grass}$ | 4 | [-] | D |
| **If nitrogen emission standards are applied** | | | | |
| Nitrogen emission standard for one year on grassland | $QN_{,grassland}$ | 170 | [kg/ha] | D (Appendix 1: Table 13) |
| Nitrogen emission standard for one year on arable land | $QN_{,arable\_land}$ | 170 | [kg/ha] | D (Appendix 1: Table 13) |
| **Soil default values** | | | | |
| Mixing depth with soil, grassland | $DEPTH_{grassland}$ | 0.05 | [m] | D |
| Mixing depth with soil, arable land | $DEPTH_{arable\ land}$ | 0.20 | [m] | D |
| Density of wet bulk soil | $RHO_{soilwet}$ | 1700 | [kg/m$^3$] | D |
| *Set, Default, Output, Refined<br>** spraying<br>*** Release to the environment via application of manure/slurry to soil only. | | | | |

**Scenario [3b] - Animal house treatment by spraying - ducks (meta SPC 6, 7 and 8)**

| Parameters | Symbol | Ducks | Unit | S/D/O/R* |
|---|---|---|---|---|
| Type of housing/manure storage (for application of the notification) | cat-subcat (i1) | i1=17 | [-] | D (Appendix1: Table 7) |
| Type of biocide | bioctype (i2) | iI2=3 (disinfectant) | [-] | D (Appendix1: Table 7) |
| Type of application | $app_{way}$ (i3)** | i3=1 | [-] | D (Appendix1: Table 7) |
| Relevant emission stream | stream (i4)*** | 1.manure/slurry<br>2.wastewater | [-] | D (Appendix1: Table 7) |
| Content of active ingredient in formulation (product) | Fbioc | 0.75 | [g/L] | S |
| Amount of product prescribed to be used for one treatment | $V_{product}$ | 0.1 | [L/m²] | S |
| Dilution factor (for preparation of the working solution from the formulation (product)) | $F_{dil}$ | 1 | [-] | S |
| Area of housing treated [3] | AREAi | 4880 | [m$^2$] | D |
| Fraction of active ingredient released | $F_{stp} = F_{ww}$ | 0.2 | [-] | D (Appendix1: Table 10) |
| | $F_{slurry/manure}$ | 0.3 | [-] | |
| | $F_{air}$ | 0 | [-] | |
| Total fraction of active ingredient released | $F_{released}$ | 0.5 | [-] | D |
| Number of disinfectant applications in one year (equals number of disinfectant applications in one lactation period) | $N_{app\text{-}bioc}$ | 13 | [-] | D |

[3] All surfaces in the respective animal housing, provided in Table 8 of the ESD for PT 3 (page 51) are considered.

| Parameters | Symbol | Ducks | Unit | S/D/O/R* |
|---|---|---|---|---|
| Interval between two disinfectant applications (dipping events) | $T_{bioc-int}$ | 28 | [-] | D |
| Number of manure applications for Grassland (worst case) | $N_{lapp-grass}$ | 4 | [-] | D |
| Number of manure applications for arable land | $N_{lapp-arab}$ | 1 | [-] | D |
| Land application interval for grassland | $T_{gr-int}$ | 53 | [d] | according to ECHA, 2014 |
| Manure storage time arable land | $Tmanure\text{-}int_{ar2}$ | 212 | [d] | according to ECHA, 2014 |
| Number of animals in housing for category/subcategory i1 =17 | $N_{anima1}$ | 10000 | [-] | D (Appendix 1: Table 8) |
| Amount of nitrogen per animal for category/subcategory i1 =17 | $Q_{nitrog}$ | 0.00274 | [kg/d] | D (Appendix 1: Table 11) |
| **If nitrogen emission standards are applied** | | | | |
| Nitrogen emission standard for one year on grassland | $QN_{,grassland}$ | 170 | [kg/ha] | D (Appendix 1: Table 13) |
| Nitrogen emission standard for one year on arable land | $QN_{,arable\_land}$ | 170 | [kg/ha] | D (Appendix 1: Table 13) |
| **Soil default values** | | | | |
| Mixing depth with soil, grassland | $DEPTH_{grassland}$ | 0.05 | [m] | D |
| Mixing depth with soil, arable land | $DEPTH_{arable\_land}$ | 0.20 | [m] | D |
| Density of wet bulk soil | $RHO_{soilwet}$ | 1700 | [kg/m$^3$] | D |
| *Set, Default, Output, Refined<br>** spraying<br>*** Release to the environment is either via application of manure/slurry to soil or by release from the facility drain to an STP | | | | |

**Scenario [3c] - Animal house treatment by spraying - turkey (meta SPC 6, 7 and 8)**

| Parameters | Symbol | Turkey | Unit | S/D/O/R* |
|---|---|---|---|---|
| Type of housing/manure storage (for application of the notification) | cat-subcat (i1) | i1=16 | [-] | D (Appendix1: Table 7) |
| Type of biocide | bioctype (i2) | iI2=3 (disinfectant) | [-] | D (Appendix1: Table 7) |
| Type of application | $app_{way}$ (i3) | i3=1 | [-] | D (Appendix1: Table 7) |
| Relevant emission stream | stream (i4)** | 1.manure/slurry<br>2.wastewater | [-] | D (Appendix1: Table 7) |
| Content of active ingredient in formulation (product) | Fbioc | 0.75 | [g/L] | S |
| Amount of product prescribed to be used for one treatment | $V_{product}$ | 0.4 | [L] | S |
| Dilution factor (for preparation of the working solution from the formulation (product)) | $F_{dil}$ | 1 | [-] | S |
| Area of housing treated [4] | AREAi | 8040 | [m$^2$] | D |
| Fraction of active ingredient released | $F_{stp} = F_{ww}$ | 0.2 | [-] | D (Appendix1: Table 10) |
| | $F_{slurry/manure}$ | 0.3 | [-] | |
| | $F_{air}$ | 0 | [-] | |
| Number of disinfectant applications in one year (equals number of disinfectant applications in one lactation period) | $N_{app-bioc}$ | 2 | [-] | D |

[4] All surfaces in the respective animal housing, provided in Table 8 of the ESD for PT 3 (page 51) are considered.

| Parameters | Symbol | Turkey | Unit | S/D/O/R* |
|---|---|---|---|---|
| Interval between two disinfectant applications (dipping events) | $T_{bioc-int}$ | 182 | [-] | D |
| Number of manure applications for Grassland (worst case) | $N_{lapp-grass}$ | 4 | [-] | D |
| Number of manure applications for arable land | $N_{lapp-arab}$ | 1 | [-] | D |
| Land application interval for grassland | $T_{gr-int}$ | 53 | [d] | according to ECHA, 2014 |
| Manure storage time arable land | $Tmanure\text{-}int_{ar2}$ | 212 | [d] | according to ECHA, 2014 |
| Number of animals in housing for category/subcategory i1 =16 | $N_{anima1}$ | 10000 | [-] | D (Appendix 1: Table 8) |
| Amount of nitrogen per animal for category/subcategory i1 =16 | $Q_{nitrog}$ | 0.00482 | [kg/d] | D (Appendix 1: Table 11) |
| Number of disinfectant applications in one year (equals number of disinfectant applications in one lactation period) | $N_{app-bioc}$ | 2 | [-] | D |
| **If nitrogen emission standards are applied** | | | | |
| Nitrogen emission standard for one year on grassland | $QN_{,grassland}$ | 170 | [kg/ha] | D (Appendix 1: Table 13) |
| Nitrogen emission standard for one year on arable land | $QN_{,arable\_land}$ | 170 | [kg/ha] | D (Appendix 1: Table 13) |
| **Soil default values** | | | | |
| Mixing depth with soil, grassland | $DEPTH_{grassland}$ | 0.05 | [m] | D |
| Mixing depth with soil, arable land | $DEPTH_{arable\_land}$ | 0.20 | [m] | D |
| Density of wet bulk soil | $RHO_{soilwet}$ | 1700 | [$kg/m^3$] | D |
| *Set, Default, Output, Refined (referring to ESD for PT3 (EU 2011)) | | | | |
| ** Release to the environment is either via application of manure/slurry to soil or by release from the facility drain to an STP | | | | |

## Calculations for Scenario [1]

The resulting local emissions to relevant environmental compartments for the assessed scenarios are reported in the following tables.

### Scenario [1]: RTU teat spray treatment, manual/automated spraying, post milking (meta SPC 1, 2 and 3; covering meta SPC 4 and 5)

| Resulting local emission to relevant environmental compartments<br>Scenario [1] - teat disinfection dairy cows (spraying) | | | | |
|---|---|---|---|---|
| **Parameters** | | **Value** | **Unit** | **S/D/ O/R*** |
| **Iodine (=Iodide)** | | | | |
| **via STP** | | | | |
| Daily emission to the sewer system | $Elocal_{waste\ water}$ | 9.25E-03 | [kg/d] | O |
| **Based on nitrogen immission standard** | | | | |
| Amount of active ingredient in manure or slurry at the end of the storage period (53 days, one manure application). Grasslands are fertilised four times annually ** | Qai_grass | 4.90E-01 | [kg] | O |
| Amount of active ingredient in manure or slurry at the end of the storage period (212 days) | Qai-ar | 1.96 | [kg] | O |
| **Iodate** | | | | |
| **Based on nitrogen immission standard** | | | | |
| Amount of active ingredient in manure or slurry at the end of the storage period (53 days, one manure application). Note that grasslands are fertilised four times annually ** | Qai_grass | 6.75E-01 | [kg] | O |
| Amount of active ingredient in manure or slurry at the end of the storage period (212 days) | Qai-ar | 2.70 | [kg] | O |
| *Set, Default, Output, Refined<br>**In the ESD it is assumed that 4 applications of manure per year are made to grassland. The formula of the ESD calculates the Elocalsoil for the first application only. The resulting value is multiplied with 4 to obtain the total yearly emission to soil, which is the basis for the ERA. | | | | |

## Calculations for Scenario [2]

### Scenario [2] - RTU teat dip treatment, manual, post milking (meta SPC 4 and 5)

The dipping scenario is covered by the spraying scenario, since spraying results in a higher application rate per day than dipping due to higher applied product volume und higher application concentration, spraying is assessed as worst case resulting in the highest emission to the environment. Therefore, no calculations are provided regarding the teat dipping scenario.

## Calculations for Scenario [3a]

### Scenario [3a]: Animal house treatment by spraying - veal calves (meta SPC 6, 7 and 8)

| Resulting local emission to relevant environmental compartments<br>Scenario [3a] - Animal house treatment by spraying - veal calves | | | | |
|---|---|---|---|---|
| **Parameters** | | **Value** | **Unit** | **S/D/ O/R*** |
| **Iodine (=Iodide)** | | | | |
| | | | | |
| Daily emission to the sewer system | $Elocal_{waste\ water}$ | 0 | [kg/d] | O |
| **Based on nitrogen immission standard** | | | | |
| Amount of active ingredient in manure or slurry at the end of the storage period (53 days, one manure application). Note that grasslands are fertilised four times annually ** | Qai_grass | 2.44E-02 | [kg] | O |
| Amount of active ingredient in manure or slurry at the end of the storage period (212 days) | Qai-ar | 4.88E-02 | [kg] | O |
| **Iodate** | | | | |
| **Based on nitrogen immission standard** | | | | |
| Amount of active ingredient in manure or slurry at the end of the storage period (53 days, one manure application). Note that grasslands are fertilised four times annually ** | Qai_grass | 3.36E-02 | [kg] | O |
| Amount of active ingredient in manure or slurry at the end of the storage period (212 days) | Qai-ar | 6.73E-02 | [kg] | O |
| *Set, Default, Output, Refined<br>**In the ESD it is assumed that 4 applications of manure per year are made to grassland. The formula of the ESD calculates the $Elocal_{soil}$ for the first application only. The resulting value is multiplied with 4 to obtain the total yearly emission to soil, which is the basis for the ERA. | | | | |

## Calculations for Scenario [3b]

### Scenario [3b] - Animal house treatment by spraying - ducks (meta SPC 6, 7 and 8)

| Resulting local emission to relevant environmental compartments<br>Scenario [3b] - Animal house treatment by spraying - ducks | | | | |
|---|---|---|---|---|
| **Parameters** | | **Value** | **Unit** | **S/D/ O/R*** |
| **Iodine (=Iodide)** | | | | |
| **via STP** | | | | |
| Daily emission to the sewer system | $Elocal_{waste\ water}$ | 7.32E-02 | [kg/d] | O |
| **Based on nitrogen immission standard** | | | | |
| Amount of active ingredient in manure or slurry at the end of the storage period (53 days, one manure application). Note that grasslands are fertilised four times annually ** | Qai_grass | 2.20E-01 | [kg] | O |
| Amount of active ingredient in manure or slurry at the end of the storage period (212 days) | Qai-ar | 8.78E-01 | [kg] | O |
| **Iodate** | | | | |
| **Based on nitrogen immission standard** | | | | |
| Amount of active ingredient in manure or slurry at the end of the storage period (53 days, one manure application). Note that grasslands are fertilised four times annually ** | Qai_grass | 3.03E-01 | [kg] | O |
| Amount of active ingredient in manure or slurry at the end of the storage period (212 days) | Qai-ar | 1.21 | [kg] | O |
| *Set, Default, Output, Refined<br>**In the ESD it is assumed that 4 applications of manure per year are made to grassland. The formula of the ESD calculates the Elocalsoil for the first application only. The resulting value is multiplied with 4 to obtain the total yearly emission to soil, which is the basis for the ERA. | | | | |

## Calculations for Scenario [3c]

### Scenario [3c] - Animal house treatment by spraying - turkey (meta SPC 6, 7 and 8)

| Resulting local emission to relevant environmental compartments<br>Animal house treatment by spraying: scenario [3c] - turkeys | | | | |
|---|---|---|---|---|
| **Parameters** | | **Value** | **Unit** | **S/D/ O/R*** |
| **Iodine (=Iodide)** | | | | |
| **Via STP** | | | | |
| Daily emission to the sewer system | $Elocal_{waste\ water}$ | 1.21E-01 | [kg/d] | O |
| **Via manure/slurry** | | | | |
| **Nitrogen:** | | | | |
| Amount of active ingredient in manure or slurry at the end of the storage period (53 days, one manure application). Note that grasslands are fertilised four times annually ** | Qai_grass | 1.81E-01 | [kg] | O |

| Resulting local emission to relevant environmental compartments<br>Animal house treatment by spraying: scenario [3c] - turkeys | | | | |
|---|---|---|---|---|
| **Parameters** | | **Value** | **Unit** | **S/D/ O/R*** |
| Amount of active ingredient in manure or slurry at the end of the storage period (212 days) | Qai-ar | 1.81E-01 | [kg] | O |
| **Iodate** | | | | |
| **Via manure/slurry** | | | | |
| **Nitrogen:** | | | | |
| Amount of active ingredient in manure or slurry at the end of the storage period (53 days, one manure application). Note that grasslands are fertilised four times annually ** | Qai_grass | 2.49E-01 | [kg] | O |
| Amount of active ingredient in manure or slurry at the end of the storage period (212 days) | Qai-ar | 2.49E-01 | [kg] | O |
| *Set, Default, Output, Refined | | | | |

## No connection to local drainage system (STP) is assumed

Accordingly to TAB (2017) ENV #131, animal housing sub-categories 8, 11, 12, 16, 17 and 18 give rise to a discharge fraction in manure, which will ultimately reach the soil compartment via manure deposition on agricultural land. Furthermore, for these housing sub-categories a discharge fraction to waste water should be considered, which could either reach the local STP or must be added to the discharge fraction in manure and increase this fraction reaching soil in cases where no connection to local drainage system is assumed.

| | | **Iodine** | |
|---|---|---|---|
| | | **Spreading of manure Elocal [kg]** | |
| | | **GRASSLAND** | **ARABLE LAND** |
| **Category** | **Animal group** | Amount of active ingredient in manure or slurry at the end of the storage period (53 days, one manure application). Note that grasslands are fertilised four times annually * | Amount of active ingredient in manure or slurry at the end of the storage period (212 days) |
| 8 | laying hens in battery cages with aeration (belt drying) | 0.6615 | 0.6615 |
| 11 | Laying hens in free range with litter floor (partly litter floor, partly slatted) | 0.6915 | 0.6915 |
| 12 | Broilers in free range with litter floor | 0.4095 | 1.638 |
| 16 | turkeys in free range with litter floor | 1.206 | 1.206 |
| 17 | ducks in free range with litter floor | 1.464 | 5.856 |
| 18 | geese in free range with litter floor | 0.909 | 2.727 |

* In the ESD it is assumed that 4 applications of manure per year are made to grassland. The formula of the ESD calculates the Elocalsoil for the first application only. The resulting value is multiplied with 4 to obtain the total yearly emission to soil, which is the basis for the ERA.

### *Fate and distribution in exposed environmental compartments*

As discussed in the AR, Iodine ($I_2$) and Iodine compounds are ubiquitously distributed in the environment and natural background concentrations for different environmental compartments such as soil, groundwater and freshwater were presented. In soil the typical background concentration measured was between 0.4-18 mg/$kg_{wwt}$ (global mean values: 4 mg/$kg_{wwt}$, but with max. values of 87 mg/$kg_{wwt}$) and for groundwater the natural background levels of Iodine are reported as 1-70 µg/L (mean concentration of 1 µg/L), with some extreme levels of 400 µg/L being noted. For freshwater (rivers and lakes) the concentration range was between 0.5-20 µg/L and for freshwater sediment a typical concentration of 6 mg/kg was observed. The natural background levels in seawater are in a range of 40-65 µg/L and for marine sediments the natural background levels are in a range of 3-400 mg/kg. The atmospheric average background level of Iodine was stated to be between 10 and 20 ng/$m^3$ in air.
Because Iodine is a natural occurring compounds and many uncertainties exist in the applied methodology as appropriate models for runoff to surface water and leaching to groundwater are not available for inorganic substances like Iodine, background concentrations has been accepted as a substitute for the PNEC.
As Iodine is an element, degradation is not applicable, however it is reported that Iodine may undergo speciation by hydrolysis, photolysis and microbial transformation processes and be converted into Iodide ($I^-$) or Iodate ($IO_3^-$). The formation fraction of the different species e.g. Iodine into Iodide or Iodate largely depends on redox potential and pH.
Iodide ($I^-$) and Iodate ($IO_3^-$) are the dominant chemical forms of Iodine in soil. Iodate ($IO_3^-$) is the dominant chemical form under aerobic, non-flooded conditions whilst under flooded conditions Iodide ($I^-$) is the dominant chemical form. In water, the prevalent Iodine forms are Iodide and Iodate. For the exposure scenarios, it was assumed that Iodine is transformed to Iodide in the alkaline anaerobic conditions in the manure, whilst when it is spread and mixed into the top layer of agricultural soil it will predominantly be transformed into Iodate. In the case of release via STP Iodine will be transformed into Iodide and Iodate, depending on the redox conditions. In the AR of Iodine (Sweden 2013) for the purpose of exposure modelling it was assumed that 100% of Iodine transforms into Iodate and, in soil only, 14% into Iodide (if released via STP)[5]. PEC-values are therefore reported as Iodine, Iodide and Iodate.

For further information regarding the distribution of Iodine and the formation of Iodide and Iodate in the different environmental compartments considering the emission pathway via sewage treatment plant and the emission pathway to soil via manure/slurry application in detail, please see AR of Iodine (Sweden 2013).

5 The conversion is based on information from open literature (Yuita 1994), which was presented in the AR of Iodine (Sweden 2013).

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Fresh-water | Fresh-water sediment | Sea-water | Seawater sediment | STP | Air | Soil | Ground-water | Other |
| <u>via STP</u><br>Scenario [1]&[2]&[3b]&[3c] | Yes<br>+ | Yes<br>+ | Yes<br>+ | yes<br>+ | Yes<br>+ | n.r.<br>(+) | Yes<br>+ | Yes<br>+ | no |
| <u>via slurry/ manure</u><br>Scenario [1]&[2]&[3a]&[3b]&[3c] | Yes<br>+ | yes<br>+ | no | no | no | n.r.<br>(+) | Yes<br>+ | Yes<br>+ | no |

++ Compartment directly exposed, + Compartment indirectly exposed, (+) Compartment potentially exposed (but unlikely significant concern due to minimal scale of exposure),; n.r. not relevant.

Regarding the adsorption behaviour, a geometric mean $K_{oc}$ of 165.8 L/kg was reported in the AR of Iodine (Sweden 2013), however some uncertainties regarding organic matter and pH dependence were discussed and therefore as presented in the AR of Iodine (Sweden 2013) the partition coefficients in soil ($Kp_{,soil}$) and the partition coefficient in suspended matter ($Kp_{susp}$) were modified to 5.8 L/kg and 220 L/kg, respectively.

| Input parameters (only set values) for calculating the fate and distribution in the environment | | | |
|---|---|---|---|
| Input | Value | Unit | Remarks |
| Molecular weight | 253.81 | [g/mol] | AR (Sweden 2013), molweight for Iodine ($I_2$) |
| Melting point | 113.7 | [°C] | AR (Sweden 2013) |
| Boiling point | 184.5 | [°C] | AR (Sweden 2013) |
| Vapour pressure (at 25°C) | 1.00E-06 | [Pa] | AR (Sweden 2013): Although Iodide ($I_2$) may evaporate as the vapour pressure is 40.7 Pa, it cannot be expected that ionised Iodine species are volatile. Therefore, emission to air was not considered. |
| Water solubility (at 25°C) | 1.00E+05 | [mg/L] | AR (Sweden 2013) |
| Henry's law constant (at 12°) | 4.05E-07 | [Pa m³/mol] | Calculated |
| Log Octanol/water partition coefficient | - | [-] | inorganic substance |
| Organic carbon/water partition coefficient (Koc) | 165.83 | [L/kg] | not applied in the risk assessment. Overruled by $K_d$ and $K_p$ |
| Solids-water partition coefficient in soil ($K_{p, soil}$) | 5.8 | [L/kg] | AR (Sweden 2013) |
| Solids-water partition coefficient in sediment ($K_{p, sed}$) | 200 | [L/kg] | AR (Sweden 2013) |
| Solids-water partition coefficient in suspended matter ($K_{p, susp}$) | 220 | [L/kg] | AR (Sweden 2013) |
| Biodegradability | Not biode-gradable | [-] | Inorganic substance[6] |

### *Pathway 1 - emission to soil via manure/slurry application*

According to the ESD of PT3 (EU 2011), manure is applied to arable soil (1 application/year) and to grassland (4 applications/year) and the applications are controlled according to EU standards for phosphate and nitrogen emissions. However, potential concentrations of Iodine are estimated for the soil compartment (arable land and grassland) based on nitrogen standard application rates only.

Concentratios in soils after ten years were calculated according to the Addendum for PT18 (ECHA 2014), although the no-manure time was increased from 206 to 365 days. This approach has been accepted by the BPC working group (WG-I-2018).

The emission to soil from the application of slurry/manure has been determined based upon the nitrogen immission standard for grassland, four applications per year and 10

[6] Iodine is an inorganic substance, which cannot biodegrade. Depending on whether aerobic or anaerobic conditions prevail, Iodine is present in the environment either as Iodide or Iodate (see AR of Iodine, Sweden 2013).

consecutive years loading taking degradation and leaching to deeper soil layersinto account for a period of 10 years (agreed at BPC WG-IV-2017). This has been calculated in accordance with the Technical Agreements for Biocides (ECHA 2017d, ENV#125), with the additional amendment that the *T*gr-int$_{no_manure}$ value for application to grassland has been amended to 365 days as agreed at WG-I-2018.

It is assumed that 100% Iodine is transferred either to 2 Iodide or Iodate ions. The molecular weight of 2 Iodide ions corresponds to the molecular weight of Iodine, consequently the PECs for Iodide are the same as for Iodine. The molecular weight of 2 Iodate ions is a factor of 1.3782 higher than the molecular weight of Iodine, therefore, the PECs for Iodate were calculated by multiplying the PECs of Iodine by this factor.

The calculations regarding all scenarios are reported in Annex 3 under chapter 3.3.2 Environmental Exposure.

### *Pathway 2 - emission to wastewater/STP*

The distribution of Iodine species in the environment after release to the sewer system was calculated using EUSES 2.1.2. The calculated daily local emission to the STP was used as input parameter (set value) for Elocal$_{wastewater}$ in EUSES 2.1.2.

EUSES Output reports concerning the release pathway via STP are reported in Annex 3 under chapter 3.3.2 Environmental Exposure.

In the AR of Iodine (Sweden 2013) it is mentioned that Iodine will not be highly adsorbed by sludge and the majority of the Iodine that passes through a STP will most probably not be retained in sludge. Distribution in the sewage treatment plants was not calculated according SimpleTreat, but based on laboratory and field tests.
A sludge retention factor of 20% was chosen for the risk assessment (i.e. 80% of the Iodine discharged to the STP remains in the effluent). Exposure to air was not considered as Iodide and Iodate are assumed not to be volatile. In accordance with the AR of Iodine (Sweden 2013), the STP distribution for the model Simple Treat (incorporated in EUSES 2.1.2) is presented below.

| **Calculated fate and distribution in the STP** | | |
|---|---|---|
| Compartment | Percentage [%] | Remarks |
| | Scenario [1]&[2]&[3b]&[3c] | |
| Air | 0 | AR of Iodine (Sweden 2013) based on laboratory and field experiments |
| Water | 80 | |
| Sludge | 20 | |
| Degraded in STP | 0 | |

For the exposure route via STP it is assumed that the total Iodine concentration in soil by sewage sludge application is transformed into Iodate (100%), but only 14% in Iodide (see Sweden 2013). In contrast, for the direct release into the environment through applied via slurry/manure), it is assumed that Iodine is transformed into Iodate (100%) or Iodide (100%) in agricultural soil.

## *Calculated PEC values*

PEC values are announced as Iodine, Iodide and Iodate, due to the transformation of Iodine to Iodide in the alkaline anaerobic conditions in the manure on one hand and on the other hand the predominante transformation to Iodate when it is spread and mixed into the top layer of agricultural soil and grassland as a soil fertiliser. In the case of release via STP Iodine will be transformed into Iodide and Iodate, depending on the redox conditions. PECsoil, PECgw and PECsw values were calculated for application to grassland and arable land, each based on phosphate and nitrogen standards. It should be noted that the nitrogen standard is the most relevant in Europe and the focus during the evaluation of Iodine species is put on the nitrogen standard (e.g. the PEC-values listed below are based on the nitrogen standard only, according to TAB (ECHA 2017d)).

**PEC in soil and groundwater**

At BPC ENV WG-IV-2017 the Member States agreed to use $k_{leach}$ to derive $k_{total}$, which is relevant for the groundwater assessment:

$k_{total} = k_{degradation} + k_{leach}$

The corresponding half-lives for leaching from the topsoil layer are 2567 d in arable land (20 cm) and 642 d in grassland (5 cm). Due to the value for $k_{leach}$ is derived from the soil depth, this value is different for arable and grass land.
PECs in groundwater (PECgw) were calculated according to equations (67) and (68) of ECHA (2017c) using $PECsoil_{10years}$ values considering degradation and leaching to deeper soil layers. This approach was agreed at BPC ENV WG-IV-2017. As an indication for potential groundwater levels, the concentration in porewater of agricultural soil is taken. According to the AR of Iodine (Sweden 2013) the solid-water partition coefficient Ksoil-water is equal to 8.90 $m^3/m^3$ and the soil density (RHOsoil) is assumed to be 1700 $kg/m^3$ as default regarding to ECHA (2017c). PECgw values have been calculated for Iodine, Iodide and Iodate.
The limit of 0.1 µg/L in ground water and FOCUS groundwater models are not relevant for inorganic substance like Iodine. At the BPC ENV WG-III-2017 it was agreed to take the natural background concentration of 70 µg/L as reference value to compare the PECgw with, to be in line with the AR for the active substance Iodine (Sweden 2013)

**PEC in surface water and sediment (fresh water/seawater)**

In case of application of manure/slurry to arable land or grassland, exposure of the active substance to surface water could potentially occur as a result of run-off from areas (arable lands and grassland) treated with manure, according to the ESD for PT3 (EU 2011) and ESD for PT18. The surface water concentration is calculated from the pore water concentration according to the method of Montforts (1999). The concentrations were additionally corrected for sorption onto suspended matter. PECs where therefore calculated according to equation (48) of ECHA (2015c) by using an experimentally derived solids-water partition coefficient in suspended matter (Kp, susp) of 220 L/kg and a dilution of ten. Therefore, PEC in surface water ($PEC_{sw}$) is estimated based on the following adapted equation:

$PEC_{sw} = PEC_{local\ soil,porew}/((1+ K_{p,\ susp} \times SUSP_{water} \times 10^{-6}) \times DILUTION_{run\text{-}off})$

Although this approach may largely overestimate the concentration in surface water, no additional calculations using e.g. SWASH were performed as the available models were considered inaccurate for inorganic compounds such as Iodine.

PECs in sediment have been calculated based on the estimated $PEC_{sw}$ values according to equation (53) of ECHA (2017c) using a suspended matter-water partitioning coefficient Ksusp_water of 55.90 m³/m³.

PECs in sediments were calculated, although as no predicted no effect concentrations (PNECs) are available. However, background concentrations in the sediment are available and therefore, PECs in sediment are compareable to the background concentration.

In the following tables the calculated PEC-values for all relevant environmental compartments are reported for all assessed scenarios:

**Scenario [1] - RTU teat spray treatment, manual/automated, post milking (meta SPC 1, 2 and 3; covering meta SPC 4 and 5)**

| **Summary table on calculated PEC values for Iodine and Iodide[1]: scenario [1]** | | | | | | |
|---|---|---|---|---|---|---|
| | **$PEC_{STP}$** | **$PEC_{freshwater}$** | **$PEC_{fresh\ water\ sed}$** | **$PEC_{soil}$** | **$PEC_{GW}$** | **$PEC_{air}$** |
| | [mg/L] | [mg/L] | [$mg/kg_{wwt}$] | [$mg/kg_{wwt}$] | [µg/L] | [$mg/m^3$] |
| **via STP** | | | | | | |
| | 3.70E-03 | 3.69E-04 | 1.79E-02 | Iodine: 2.29E-02 Iodide: [2] 3.21E-03 | Iodine: 4.29 Iodide: [2] 6.01E-01 | -- |
| **via slurry/manure – concentrations after ten years** degradation and leaching from the top soil layer between two applications is considered | | | | | | |
| grass-land | -- | 2.83E-03 | 1.38E-01 | 1.49E-01 | 28.4 | -- |
| arable land | -- | 1.73E-03 | 8.39E-02 | 9.07E-02 | 17.3 | -- |

1 Assuming 100% transformation into Iodide when applied via slurry/manure.
2 For the exposure route via STP it is assumed that the total Iodine concentration in soil is transformed into Iodate (100%), but only 14% in Iodide according to AR for Iodine (Sweden 2013).

| **Summary table on calculated PEC values for Iodate[1]: scenario [1]** | | | | | | |
|---|---|---|---|---|---|---|
| | **$PEC_{STP}$** | **$PEC_{freshwater}$** | **$PEC_{fresh\ water\ sed}$** | **$PEC_{soil}$** | **$PEC_{GW}$[1]** | **$PEC_{air}$** |
| | [mg/L] | [mg/L] | [$mg/kg_{wwt}$] | [$mg/kg_{wwt}$] | [µg/L] | [$mg/m^3$] |
| **via STP** | | | | | | |
| | 5.10E-03 | 5.09E-04 | 2.47E-02 | 3.16E-02 | 5.91 | -- |
| **via slurry/manure – concentrations after ten years** degradation and leaching from the top soil layer between two applications is considered | | | | | | |
| grass-land | -- | 3.90E-03 | 1.90E-01 | 2.05E-01 | 39.1 | -- |
| arable land | -- | 2.38E-03 | 1.16E-01 | 1.25E-01 | 23.8 | -- |

1 Assuming 100% transformation into Iodate, i.e. under aerobic and non-flooded conditions.

**Scenario [2] - RTU teat dip treatment, manual - post milking (meta SPC 4 and 5)**

The dipping scenario is covered by the spraying scenario, since spraying results in a higher application rate per day than dipping due to higher applied product volume und higher application concentration, spraying is assessed as worst case resulting in the highest emission to the environment. Therefore, no PEC calculations are provided regarding the teat dipping scenario.

**Scenario [3a]: Animal house treatment by spraying - veal calves (meta SPC 6, 7 and 8)**

**Worst case scenario regarding PECsoil grass land**

| **Summary table on calculated PEC values for Iodine and Iodide[1]: scenario [3a] – veal calves** | | | | | | |
|---|---|---|---|---|---|---|
| | **$PEC_{STP}$** | **$PEC_{freshwater}$** | **$PEC_{fresh\ water\ sed}$** | **$PEC_{soil}$** | **$PEC_{GW}$** | **$PEC_{air}$** |
| | [mg/L] | [mg/L] | [mg/$kg_{wwt}$] | [mg/$kg_{wwt}$] | [µg/L] | [mg/$m^3$] |
| **via STP** | | | | | | |
| | -- | -- | -- | -- | -- | -- |
| **via slurry/manure – concentrations after ten years** degradation and leaching from the top soil layer between two applications are considered | | | | | | |
| grass-land | -- | 2.50E-03 | 1.22E-01 | 1.34E-01 | 25.1 | -- |
| arable land | -- | 7.64E-04 | 3.71E-02 | 4.03E-02 | 7.66 | -- |

1 Assuming 100% transformation into Iodide when applied via slurry/manure.
2 For the exposure route via STP it is assumed that the total Iodine concentration in soil is transformed into Iodate (100%), but only 14% in Iodide according to AR for Iodine (Sweden 2013).

| **Summary table on calculated PEC values for Iodate[1]: scenario [3a] – veal calves** | | | | | | |
|---|---|---|---|---|---|---|
| | **$PEC_{STP}$** | **$PEC_{freshwater}$** | **$PEC_{fresh\ water\ sed}$** | **$PEC_{soil}$** | **$PEC_{GW}$[1]** | **$PEC_{air}$** |
| | [mg/L] | [mg/L] | [mg/$kg_{wwt}$] | [mg/$kg_{wwt}$] | [µg/L] | [mg/$m^3$] |
| **via STP** | | | | | | |
| | -- | -- | -- | -- | -- | -- |
| **via slurry/manure – concentrations after ten years** degradation and leaching from the top soil layer between two applications are considered | | | | | | |
| grass-land | -- | 3.45E-03 | 1.68E-01 | 1.84E-01 | 34.6 | -- |
| arable land | -- | 1.05E-03 | 5.12E-02 | 5.55E-02 | 10.6 | -- |

1 Assuming 100% transformation into Iodate, i.e. under aerobic and non-flooded conditions.

**Scenario [3b] - Animal house treatment by spraying - ducks (meta SPC 6, 7 and 8)**

**Worst case scenario regarding PECsoil arable land**

| **Summary table on calculated PEC values for Iodine and Iodide[1]: scenario [3b] - ducks** | | | | | | |
|---|---|---|---|---|---|---|
| | **$PEC_{STP}$** | **$PEC_{freshwater}$** | **$PEC_{fresh\ water\ sed}$** | **$PEC_{soil}$** | **$PEC_{GW}$** | **$PEC_{air}$** |
| | [mg/L] | [mg/L] | [$mg/kg_{wwt}$] | [$mg/kg_{wwt}$] | [µg/L] | [$mg/m^3$] |
| **via STP** | | | | | | |
| | 3.22E-02 | 3.22E-03 | 1.57E-01 | Iodine: 2.00E-01 Iodide: [2] 2.80E-02 | Iodine: 37.5 Iodide: [2] 5.25 | -- |
| **via slurry/manure – concentrations after ten years** degradation and leaching from the top soil layer between two applications are considered | | | | | | |
| grass-land | -- | 1.74E-03 | 8.41E-02 | 9.23E-02 | 17.4 | -- |
| arable land | -- | 1.05E-03 | 5.13E-02 | 5.57E-02 | 10.6 | -- |

1 Assuming 100% transformation into Iodide when applied via slurry/manure.
2 For the exposure route via STP it is assumed that the total Iodine concentration in soil is transformed into Iodate (100%), but only 14% in Iodide according to CAR for Iodine (Sweden 2013).

| **Summary table on calculated PEC values for Iodate[1]: scenario [3b] - ducks** | | | | | | |
|---|---|---|---|---|---|---|
| | **$PEC_{STP}$** | **$PEC_{freshwater}$** | **$PEC_{fresh\ water\ sed}$** | **$PEC_{soil}$** | **$PEC_{GW}$[1]** | **$PEC_{air}$** |
| | [mg/L] | [mg/L] | [$mg/kg_{wwt}$] | [$mg/kg_{wwt}$] | [µg/L] | [$mg/m^3$] |
| **via STP** | | | | | | |
| | 4.44E-02 | 4.44E-03 | 2.17E-01 | 2.75E-01 | 51.7 | -- |
| **via slurry/manure – concentrations after ten years** degradation and leaching from the top soil layer between two applications are considered | | | | | | |
| grass-land | -- | 2.39E-03 | 1.16E-01 | 1.27E-01 | 23.9 | -- |
| arable land | -- | 1.45E-03 | 7.07E-02 | 7.67E-02 | 14.6 | -- |

1 Assuming 100% transformation into Iodide when applied via slurry/manure.

**Scenario [3c] - Animal house treatment by spraying - turkey (meta SPC 6, 7 and 8)**

**Worst case scenario regarding emissions to STP**

| Summary table on calculated PEC values for Iodine and Iodide[1]: scenario [3c] - turkeys | | | | | | |
|---|---|---|---|---|---|---|
| | **$PEC_{STP}$** | **$PEC_{freshwater}$** | **$PEC_{fresh\ water\ sed}$** | **$PEC_{soil}$** | **$PEC_{GW}$** | **$PEC_{air}$** |
| | [mg/L] | [mg/L] | [$mg/kg_{wwt}$] | [$mg/kg_{wwt}$] | [µg/L] | [$mg/m^3$] |
| **via STP** | | | | | | |
| | 4.83E-02 | 4.81E-03 | 2.34E-01 | Iodine: 2.99E-01 Iodide: [2] 4.19E-02 | Iodine: 55.88 Iodide: [2] 7.83 | -- |
| **via slurry/manure – concentrations after ten years** degradation and leaching from the top soil layer between two applications are considered | | | | | | |
| grass-land | -- | 7.35E-04 | 3.58E-02 | 3.93E-02 | 7.38 | -- |
| arable land | -- | 1.12E-04 | 5.45E-03 | 5.91E-03 | 1.12 | -- |

1 Assuming 100% transformation into Iodide when applied via slurry/manure.
2 For the exposure route via STP it is assumed that the total Iodine concentration in soil is transformed into Iodate (100%), but only 14% in Iodide according to AR for Iodine (Sweden 2013).

| Summary table on calculated PEC values for Iodate[1]: scenario [3c] - turkeys | | | | | | |
|---|---|---|---|---|---|---|
| | **$PEC_{STP}$** | **$PEC_{freshwater}$** | **$PEC_{fresh\ water\ sed}$** | **$PEC_{soil}$** | **$PEC_{GW}$[1]** | **$PEC_{air}$** |
| | [mg/L] | [mg/L] | [$mg/kg_{wwt}$] | [$mg/kg_{wwt}$] | [µg/L] | [$mg/m^3$] |
| **via STP** | | | | | | |
| | 6.65E-02 | 6.63E-03 | 3.22E-01 | 4.12E-01 | 77.0 | -- |
| **via slurry/manure – concentrations after ten years** degradation and leaching from the top soil layer between two applications are considered | | | | | | |
| grass-land | -- | 1.01E-03 | 4.93E-02 | 5.41E-02 | 10.2 | -- |
| arable land | -- | 1.54E-04 | 7.51E-03 | 8.15E-03 | 1.55 | -- |

1 Assuming 100% transformation into Iodate, i.e. under aerobic and non-flooded conditions.

**No connection to local drainage system (STP) is assumed**

| **Summary table on calculated PEC values for Iodine and Iodide ducks (worst case regarding no connection to STP is assumed)** | | | | | | |
|---|---|---|---|---|---|---|
| | **$PEC_{STP}$** | **$PEC_{freshwater}$** | **$PEC_{fresh\ water\ sed}$** | **$PEC_{soil}$** | **$PEC_{GW}$** | **$PEC_{air}$** |
| | [mg/L] | [mg/L] | [$mg/kg_{wwt}$] | [$mg/kg_{wwt}$] | [µg/L] | [$mg/m^3$] |
| **via STP** | | | | | | |
| | -- | -- | -- | -- | -- | -- |
| **via slurry/manure – concentrations after ten years** degradation and leaching from the top soil layer between two applications are considered | | | | | | |
| grass-land | -- | 2.61E-03 | 1.28E-01 | 1.40E-01 | 26.3 | -- |
| arable land | -- | 1.60E-03 | 7.75E-02 | 8.41E-02 | 16.0 | -- |

| **Summary table on calculated PEC values for Iodate ducks (worst case regarding no connection to STP is assumed)** | | | | | | |
|---|---|---|---|---|---|---|
| | **$PEC_{STP}$** | **$PEC_{freshwater}$** | **$PEC_{fresh\ water\ sed}$** | **$PEC_{soil}$** | **$PEC_{GW}$[1]** | **$PEC_{air}$** |
| | [mg/L] | [mg/L] | [$mg/kg_{wwt}$] | [$mg/kg_{wwt}$] | [µg/L] | [$mg/m^3$] |
| **via STP** | | | | | | |
| | -- | -- | -- | -- | -- | -- |
| **via slurry/manure – concentrations after ten years** degradation and leaching from the top soil layer between two applications are considered | | | | | | |
| grass-land | -- | 3.60E-03 | 1.76E-01 | 1.93E-01 | 36.2 | -- |
| arable land | -- | 2.20E-03 | 1.07E-01 | 1.16E-01 | 22.1 | -- |

### *Primary and secondary poisoning*

The product is used indoor therefore a direct uptake by non-target organisms is not expected.
Moreover, according to the AR for Iodine (Sweden 2013) the bioaccumulation potential for an inorganic substance, as Iodine, is not considered relevant. Furthermore, it was concluded that there was no concern regarding primary and secondary poisoning through the use of Iodine in disinfectants, as the amounts which were released were considered to be negligible compared to the natural occurring background concentrations and the fact that Iodine is an essential element (e.g. for the functioning of the thyroid hormone synthesis). This argumentation can also be followed for the BPF_Iodine_VET.

### 2.2.8.3 Risk characterisation

In the following chapter, PEC/PNEC ratios are presented for the application of Iodine as teat disinfection or as surface disinfection in animal housings. Although only three animal categories are presented, they represent the worst-case scenarios and it can be ensured that these senarios cover the other uses and animals sufficiently.

**PNECs on Iodine species as presented in the AR for Iodine (Sweden 2013)**

| **Environmental compartment** | | **Iodine species** | **PNEC** |
|---|---|---|---|
| ***Aquatic. freshwater*** | Surface water | Iodine ($I_2$) | 5.90E-04 mg/L |
| | | Iodate($IO_3^-$) | 5.85E-02 mg/L |
| | | Iodide($I^-$) | 8.30E-04 mg/L |
| | Freshwater sediment | - | not used in the risk assessment |
| ***Terrestrial*** | | Iodine ($I_2$) | 1.18E-02 mg/$kg_{wwt}$ |
| | | Iodate($IO_3^-$) | 3.04E-01 mg/kg |
| | | Iodide($I^-$) | 4.30E-03 mg/kg |
| ***STP*** | | Iodine ($I_2$) | 2.9 mg/L |

The environmental risk assessment was performed for the active substance Iodine ($I_2$) and its ionic species Iodide ($I^-$) and Iodate ($IO_3^-$) as no other environmentally relevant substance or Substance of Concern was identified.

If calculated PEC/PNEC values are >1, the PEC values are compared to the natural background levels in the concerned compartments, which is acceptable according to the AR of Iodine (Sweden 2013) was agreed in the BPC ENV WG-IV-17 (WGIV-2017 ENV 7-2a and 7-2b).

**Natural background concentrations on Iodine as presented in the AR for Iodine (Sweden 2013)**

| **Background concentration of Iodine in the environment** | |
|---|---|
| **Compartment** | **natural background concentration** |
| Air | - |
| STP | - |
| Surface water | 5.00E-04 – 2.00E-02 mg Iodine/L |
| Freshwater sediment | typically 6 mg Iodine/kg |
| Seawater | 4.50E-02 – 6.00E-02 mg Iodine/L |
| Marine sediment | 3 - 400 mg Iodine/kg |
| Soil | 5.00E-01 – 20 mg Iodine/$kg_{dwt}$<br>with extremes up to 90 mg/$kg_{dwt}$ (corresponding to 4.00E-01 - 18 mg Iodine/$kg_{wwt}$ with extremes up to 86 mg Iodine /$kg_{wwt}$) |
| Groundwater | <1-70 µg Iodine/L<br>(with extremes up to 400 µg/L) |

### *Atmosphere*

According to the AR for Iodine (Sweden 2013), emissions to air are not considered relevant in this risk assessment compared to the natural background concentration of Iodine in air (10-20 ng/$m^3$). Iodine or other organic-bounded Iodine is not listed as so called "controlled substances" in the Annex I of Regulation (EC) No 1005/2009. There is no evidence that Iodine contributes to a depletion of the ozone layer. Hence the risk for the air compartment is negliable.

### *Sewage treatment plant (STP)*

As described above, emissions to wastewater would lead to emissions to the sewage treatment plant and thereof further to freshwater, freshwater sediment and soil. For Iodide and Iodate no PEC/PNEC-values were calculated, since no data on STP micro-organisms are available. However, Iodide and Iodate are less toxic than Iodine in the aquatic compartment.

| **Calculated PEC/PNEC$_{STP}$ values for Iodine, Iodide and Iodate** | | |
|---|---|---|
| | **PEC$_{STP}$ [mg/L]** | **PEC/PNEC$_{STP}$** |
| **Scenario [1] teat disinfection by spraying – dairy cows (meta SPC 1 - 3)** | | |
| Iodine | 3.70E-03 | 1.28E-03 |
| Iodide | 3.70E-03 | not relevant |
| Iodate | 5.10E-03 | not relevant |
| **Scenario [2] meta SPC 4-5; covered by scenario [1]** | | |
| **Scenario [3a] veal calves – worst case scenario regarding PECsoil grass land (meta SPC 6 - 8)** | | |
| Iodine | no emission via STP | -- |
| Iodide | no emission via STP | -- |
| Iodate | no emission via STP | -- |
| **Scenario [3b] ducks - worst case scenario regarding PECsoil arable land (meta SPC 6 - 8)** | | |
| Iodine | 2.93E-02 | 1.01E-02 |
| Iodide | 2.93E-02 | not relevant |
| Iodate | 4.03E-02 | not relevant |

| Calculated PEC/PNECSTP values for Iodine. Iodide and Iodate - continued | | |
|---|---|---|
| | **$PEC_{STP}$ [mg/L]** | **$PEC/PNEC_{STP}$** |
| **Scenario [3c] turkeys - worst case scenario regarding emissions to STP (meta SPC 6 - 8)** | | |
| Iodine | 4.83E-02 | 1.66E-02 |
| Iodide | 4.83E-02 | not relevant |
| Iodate | 6.65E-02 | not relevant |

**Conclusion**

All calculated PEC/PNEC ratios are <1. Therefore the use of Iodine for teat disinfection and animal housing disinfection does not pose an unacceptable risk to microorganisms in the STP.

### *Aquatic compartment*

The PEC/PNEC values are presented for all calculated scenarios and both relevant emission pathways. The PECs and the PNECs for the sediment compartment (freshwater) were calculated with the equilibrium partitonating method based on the PECs and PNECs for freshwater. Hence, the PEC/PNEC ratios for the sediment compartments are identical to the PEC/PNEC ratios for the aquatic compartments.

**Scenario [1] - RTU teat spray treatment, manual/automated, post milking (meta SPC 1, 2 and 3; covering meta SPC 4 and 5)**

| Summary table on calculated $PEC/PNEC_{aquatic.\ freshwater}$ values for Iodine, Iodide and Iodate | | | | |
|---|---|---|---|---|
| | **$PEC_{freshwater}$ [mg/L]** | **$PEC/PNEC_{freshwater}$** | **$PEC_{freshwater\ sed}$ [mg/L]** | **$PEC/PNEC_{freshwater\ sed}$** |
| **Scenario [1] teat disinfection by spraying – dairy cows** | | | | |
| **via STP** | | | | |
| Iodine | 3.69E-04 | 6.25E-01 | 1.79E-02 | 6.25E-01 |
| Iodide | 3.69E-04 | 4.45E-01 | 1.79E-02 | 4.45E-01 |
| Iodate | 5.09E-04 | 8.70E-03 | 2.47E-02 | 8.70E-03 |
| **via slurry/manure (via run-off from treated areas) – concentrations <u>after ten years</u>** degradation and leaching from the top soil layer between two applications is considered | | | | |
| **grassland** | | | | |
| Iodine | 2.83E-03 | 4.80 | 1.38E-01 | 4.80 |
| Iodide | 2.83E-03 | 3.41 | 1.38E-01 | 3.41 |
| Iodate | 3.90E-03 | 6.67E-02 | 1.90E-01 | 6.67E-02 |
| **arable land** | | | | |
| Iodine | 1.73E-03 | 2.93 | 8.39E-02 | 2.93 |
| Iodide | 1.73E-03 | 2.08 | 8.39E-02 | 2.08 |
| Iodate | 2.38E-03 | 4.07E-02 | 1.16E-01 | 4.07E-02 |

**Conclusion**

For the teat disinfection (scenario [1]) PEC/PNEC ratios are below the trigger value of 1 for Iodine, Iodide and Iodate for the indirect exposure via STP.

The calculated PEC/PNEC ratios for Iodate regarding the indirect exposure to fresh water and sediment after slurry/manure application on grassland and arable land are below the trigger value of 1 as well.

The calculated PEC/PNEC ratios for Iodine and Iodide regarding the indirect exposure to fresh water and sediment after slurry/manure application on grassland and arable land are above the trigger value of 1. For these PEC/PNEC ratios the natural background concentration for freshwater (range of 5.00E-04 – 2.00E-02 mg Iodine/L) and for freshwater sediment (typically 6 mg Iodine/kg) were compared to the PEC values. The PECs for freshwater are within the range and for sediment they are below the typical natural background concentration, indicating that no unacceptable risk for the aquatic and sediment compartment is to be expected.

**Scenario [2] - RTU teat dipping treatment. post milking (meta SPC 4 and 5)**

Covered by scenario [1].

**Scenario [3a]: Animal house treatment by spraying - veal calves (meta SPC 6, 7 and 8) - worst case scenario regarding PECsoil grass land**

| **Summary table on calculated PEC/PNEC$_{aquatic}$ values for Iodine, Iodide and Iodate** | | | | |
|---|---|---|---|---|
| | **PEC$_{freshwater}$ [mg/L]** | **PEC/PNEC $_{freshwater}$** | **PEC$_{freshwater\ sed}$ [mg/L]** | **PEC/PNEC$_{freshwater\ sed}$** |
| **Scenario [3a] veal calves – worst case scenario regarding PECsoil grass land** | | | | |
| **via STP** | | | | |
| Iodine | no emission via STP | | | |
| Iodide | no emission via STP | | | |
| Iodate | no emission via STP | | | |
| **via slurry/manure (via run-off from treated areas) – concentrations <u>after ten years</u>** degradation and leaching from the top soil layer between two applications is considered | | | | |
| **grassland** | | | | |
| Iodine | 8.39E-02 | 2.93 | 8.39E-02 | 2.93 |
| Iodide | 8.39E-02 | 2.08 | 8.39E-02 | 2.08 |
| Iodate | 8.39E-02 | 2.93 | 8.39E-02 | 2.93 |
| **arable land** | | | | |
| Iodine | 7.64E-04 | 1.30 | 3.71E-02 | 1.30 |
| Iodide | 7.64E-04 | 9.20E-01 | 3.71E-02 | 9.20E-01 |
| Iodate | 1.05E-03 | 1.80E-02 | 5.11E-02 | 1.80E-02 |

**Conclusion**

For the animal housing disinfection scenario (veal calves [3a]) PEC/PNEC ratios are below the trigger value of 1 for Iodide and Iodate for the indirect exposure via run-off from treated areas after slurry/manure application on arable land (concerning freshwater and freshwater sediment) and above the trigger value of 1 after slurry/manure application on grass land.

The calculated PEC/PNEC ratios for Iodine for indirect exposure via run-off from treated areas after slurry/manure application on grassland and arable land are above the trigger value of 1 (concerning freshwater and freshwater sediment). Therefore, the natural background concentration for freshwater (range of 5.00E-04 – 2.00E-02 mg Iodine/L) and for freshwater sediment (typically 6 mg Iodine/kg) were compared to the PEC values. All PECs are within the range of the background concentration for freshwater and well below the typical background concentration for sediment, indicating that no unacceptable risk for the aquatic and sediment compartment is to be expected.

**Scenario [3b]: Animal house treatment by spraying – ducks**
**(meta SPC 6, 7 and 8) - worst case scenario regarding PECsoil arable land**

| **Summary table on calculated PEC/PNEC$_{aquatic}$ values for Iodine, Iodide and Iodate** | | | | |
|---|---|---|---|---|
| | **PEC$_{freshwater}$ [mg/L]** | **PEC/PNEC $_{freshwater}$** | **PEC$_{freshwater\ sed}$ [mg/L]** | **PEC/PNEC$_{freshwater\ sed}$** |
| **Scenario [3b] ducks – worst case scenario regarding PECsoil arable land** | | | | |
| **via wastewater/STP** | | | | |
| Iodine | 2.93E-03 | 4.96 | 1.43E-01 | 4.96 |
| Iodide | 2.93E-03 | 3.53 | 1.43E-01 | 3.53 |
| Iodate | 4.03E-03 | 6.88E-02 | 1.96E-01 | 6.88E-02 |
| **via slurry/manure (via run-off from treated areas) – concentrations <u>after ten years</u>** degradation and leaching from the top soil layer between two applications is considered | | | | |
| **grassland** | | | | |
| Iodine | 1.58E-03 | 2.68 | 7.63E-02 | 2.68 |
| Iodide | 1.58E-03 | 1.90 | 7.63E-02 | 1.90 |
| Iodate | 2.18E-03 | 3.71E-02 | 1.05E-01 | 3.71E-02 |
| **arable land** | | | | |
| Iodine | 9.56E-04 | 1.63 | 4.65E-02 | 1.63 |
| Iodide | 9.56E-04 | 1.15 | 4.65E-02 | 1.15 |
| Iodate | 1.31E-03 | 2.24E-02 | 6.41E-02 | 2.24E-02 |

**Conclusion**

For the animal housing disinfection scenario (ducks [3b]) PEC/PNEC ratios are below the trigger value of 1 for Iodate for indirect exposure via STP as well as for the indirect exposure after slurry/manure application on grassland and arable land due to run-off from treated areas.

The calculated PEC/PNEC values for Iodine and Iodide for the indirect exposure via STP and via run-off from treated areas after slurry/manure application on grassland and arable land are above the trigger value of 1. For these PEC/PNEC ratios the natural background concentration for freshwater (range of 5.00E-04 – 2.00E-02 mg Iodine/L) and for freshwater sediment (typically 6 mg Iodine/kg) were compared to the PEC values. The PECs of the freshwater are within the range of the background concentrations, the PECs of the freshwater sediment are below the typical natural background concentration. This indicates that no unacceptable risk for the aquatic and sediment compartment is to be expected.

**Scenario [3c]: Animal house treatment by spraying – turkey**

**(meta SPC 6, 7 and 8) - worst case scenario regarding emission to STP**

| **Summary table on calculated PEC/PNEC$_{aquatic}$ values for Iodine, Iodide and Iodate** | | | | |
|---|---|---|---|---|
| | **PEC$_{freshwater}$ [mg/L]** | **PEC/PNEC $_{freshwater}$** | **PEC$_{freshwater\ sed}$ [mg/L]** | **PEC/PNEC$_{freshwater\ sed}$** |
| **Scenario [3c] turkeys - worst case scenario regarding emission to STP** | | | | |
| **via STP** | | | | |
| Iodine | 4.81E-03 | 8.16 | 2.34E-01 | 8.16 |
| Iodide | 4.81E-03 | 5.80 | 2.34E-01 | 5.80 |
| Iodate | 6.65E-03 | 1.14E-01 | 3.23E-01 | 1.14E-01 |
| **via slurry/manure – concentrations <u>after ten years</u>** degradation and leaching from the top soil layer between two applications is considered | | | | |
| **grassland** | | | | |
| Iodine | 7.35E-04 | 1.25 | 3.58E-02 | 1.25 |
| Iodide | 7.35E-04 | 8.85E-01 | 3.58E-02 | 8.85E-01 |
| Iodate | 1.01E-03 | 1.73E-02 | 4.93E-02 | 1.73E-02 |
| **arable land** | | | | |
| Iodine | 1.12E-04 | 1.90E-01 | 5.45E-03 | 1.90E-01 |
| Iodide | 1.12E-04 | 1.35E-01 | 5.45E-03 | 1.35E-01 |
| Iodate | 1.54E-04 | 2.63E-03 | 7.51E-03 | 2.63E-03 |

**Conclusion**

For the animal housing disinfection scenario (turkey [3c]) PEC/PNEC ratios are below the trigger value of 1 for Iodate for indirect exposure via STP (concerning freshwater and freshwater sediment), as well as for the indirect exposure via run-off from treated areas after slurry/manure application on grassland and arable land (concerning freshwater and freshwater sediment). PEC/PNEC ratios were also below the trigger value of 1 for Iodine and Iodide for indirect exposure via run-off from treated areas after slurry/manure application on arable land (concerning freshwater and freshwater sediment).

The calculated PEC/PNEC values for Iodine and Iodide for the indirect exposure via STP and via run-off from treated areas after slurry/manure application on grassland are above the trigger value of 1 (concerning freshwater and freshwater sediment). For these PEC/PNEC ratios the natural background concentration for freshwater (range of 5.00E-04 – 2.00E-02 mg Iodine/L) and for the freshwater sediment (typically 6 mg Iodine/kg) were compared to the PEC values. All PECs are within the range for the freshwater and below the typical natural background concentration of the freshwater sediment indicating that no unacceptable risk for the aquatic and sediment compartment is to be expected.

**No connection to local drainage system (STP) is assumed**
**(meta SPC 6, 7 and 8)**

| **Summary table on calculated PEC/PNEC$_{aquatic}$ values for Iodine, Iodide and Iodate** | | | | |
|---|---|---|---|---|
| | **PEC$_{freshwater}$ [mg/L]** | **PEC/PNEC $_{freshwater}$** | **PEC$_{freshwater\ sed}$ [mg/L]** | **PEC/PNEC$_{freshwater\ sed}$** |
| **ducks (worst case regarding no connection to sewer system is assumed)** | | | | |
| **via slurry/manure – concentrations after ten years**<br>degradation and leaching from the top soil layer between two applications is considered | | | | |
| **grassland** | | | | |
| Iodine | 2.61E-03 | 4.43 | 1.28E-01 | 4.43 |
| Iodide | 2.61E-03 | 3.15 | 1.28E-01 | 3.15 |
| Iodate | 3.60E-03 | 6.15E-02 | 1.76E-01 | 6.15E-02 |
| **arable land** | | | | |
| Iodine | 1.60E-03 | 2.71 | 7.75E-02 | 2.71 |
| Iodide | 1.60E-03 | 1.93 | 7.75E-02 | 1.93 |
| Iodate | 2.20E-03 | 3.76E-02 | 1.07E-01 | 3.76E-02 |

**Conclusion**

For the animal housing disinfection scenario for ducks, which represent the worst case if no connection to the sewer system is assumed, PEC/PNEC ratios are below the trigger value of 1 for Iodate for the indirect exposure via run-off from treated areas after slurry/manure application on grassland and arable land (concerning freshwater and freshwater sediment).

The calculated PEC/PNEC ratios for Iodine and Iodide based on run-off from treated areas after slurry/manure application on grassland and arable land are above the trigger value of 1 (concerning freshwater and freshwater sediment). For these PEC/PNEC ratios the natural

background concentration for freshwater (range of 5.00E-04 – 2.00E-02 mg Iodine/L) and for the freshwater sediment (typically 6 mg Iodine/kg) were compared to the PEC values. All PECs are within the range for the freshwater and below the typical natural background concentration of the freshwater sediment indicating that no unacceptable risk for the aquatic and sediment compartment is to be expected in case of no connection to a sewer system is assumed.

### *Terrestrial compartment*

**Scenario [1] - RTU teat spray treatment - manual/automated - post milking (meta SPC 1, 2 and 3; covering meta SPC 4 and 5)**

| **Calculated PEC/PNEC$_{soil}$ values for Iodine, Iodide and Iodate** | | |
|---|---|---|
| | **PEC$_{soil}$ [**mg/kg$_{wwt}$] | **PEC/PNEC$_{soil}$** |
| **Scenario [1] teat disinfection by spraying – dairy cows** | | |
| ***via STP*** | | |
| Iodine | 2.29E-02 | 1.94 |
| Iodide | 3.21E-03 | 7.47E-01 |
| Iodate | 3.16E-02 | 1.04E-01 |
| ***via slurry/manure*** | | |
| **grassland** | | |
| Iodine | 1.49E-01 | 12.6 |
| Iodide | 1.49E-01 | 34.7 |
| Iodate | 2.05E-01 | 6.74E-01 |
| **arable land** | | |
| Iodine | 9.07E-02 | 7.69 |
| Iodide | 9.07E-02 | 21.1 |
| Iodate | 1.25E-01 | 4.11E-01 |

**Scenario [2] - RTU teat dipping treatment - post milking (meta SPC 4 and 5)**

Covered by scenario [1].

**Conclusion**

For the teat disinfection (scenario [1]) PEC/PNEC ratios are below the trigger value of 1 for Iodide and Iodate for indirect exposure of soil via sludge application as well as for Iodate after slurry/manure application after 10 years on arable land taking degradation and leaching to deeper soil layers into account.

All other calculated PEC/PNEC ratios are above the trigger value of 1. For these PEC/PNEC ratios the natural background concentration for soil (0.4 - 18 mg Iodine/kg$_{wwt}$) was compared to the PEC values. All PECs are below the lower limit of the background concentrations for soil indicating that no unacceptable risk is to be expected.

**Scenario [3a]: Animal house treatment by spraying - veal calves (meta SPC 6, 7 and 8) - worst case scenario regarding PECsoil grass land**

| **Calculated PEC/PNEC$_{soil}$ values for Iodine, Iodide and Iodate** | | |
|---|---|---|
| | **PEC$_{soil}$ [**mg/kg$_{wwt}$] | **PEC/PNEC$_{soil}$** |
| **Scenario [3a] veal calves – worst case scenario regarding PECsoil grass land** | | |
| ***via STP*** | no emission to STP | |
| ***via slurry/manure*** | | |
| **grassland** | | |
| Iodine | 1.34E-01 | 11.3 |
| Iodide | 1.34E-01 | 31.1 |
| Iodate | 1.84E-01 | 6.05E-01 |
| **arable land** | | |
| Iodine | 4.03E-02 | 3.41 |
| Iodide | 4.03E-02 | 9.36 |
| Iodate | 5.55E-02 | 1.83E-01 |

**Conclusion**

For the animal housing disinfection scenario (veal calves [3a]) PEC/PNEC ratios are below the trigger value of 1 for Iodate for indirect exposure of soil via slurry/manure application on grassland and on arable land after 10 years taking degradation and leaching to deeper soil layers into account.

All calculated PEC/PNEC ratios for Iodine and Iodide are above the trigger value of 1. For these PEC/PNEC ratios the natural background (0.4 - 18 mg Iodine/kg$_{wwt}$) was compared to the PEC values. All PECs are below the lower limit of the background concentrations for soil indicating that no unacceptable risk is to be expected.

**Scenario [3b]: Animal house treatment by spraying – ducks**
**(meta SPC 6, 7 and 8) - worst case scenario regarding PECsoil arable land**

| Calculated PEC/PNEC$_{soil}$ values for Iodine, Iodide and Iodate | | |
|---|---|---|
| | **PEC$_{soil}$ [mg/kg$_{wwt}$]** | **PEC/PNEC$_{soil}$** |
| **Scenario [3b] ducks - worst case scenario regarding PECsoil arable land** | | |
| ***via STP*** | | |
| Iodine | 1.81E-01 | 15.4 |
| Iodide | 2.54E-02 | 5.90 |
| Iodate | 2.50E-01 | 8.23E-01 |
| ***via slurry/manure*** | | |
| **grassland** | | |
| Iodine | 8.38E-02 | 7.10 |
| Iodide | 8.38E-02 | 19.5 |
| Iodate | 1.15E-01 | 3.80E-01 |
| **arable land** | | |
| Iodine | 5.05E-02 | 4.28 |
| Iodide | 5.05E-02 | 11.8 |
| Iodate | 6.96E-02 | 2.29E-01 |

**Conclusion**

For the animal housing disinfection scenario (ducks [3b]) PEC/PNEC ratios are below the trigger value of 1 for Iodate for indirect exposure of soil via slurry/manure application on grassland and on arable land after 10 years taking degradation and leaching to deeper soil layers into account and via sludge application.

The PEC/PNEC ratios for Iodine and Iodide are above the trigger value of 1 for indirect exposure of soil via slurry/manure application on grassland and on arable land after 10 years taking degradation and leaching to deeper soil layers into account and for exposure via sludge application. For these PEC/PNEC ratios the natural background concentration for soil (0.4 - 18 mg Iodine/kg$_{wwt}$) was compared to the PEC values. All PECs are below the lower limit of the background concentrations for soil. These results indicate that no unacceptable risk to soil organisms is to be expected.

**Scenario [3c]: Animal house treatment by spraying – turkeys**
**(meta SPC 6, 7 and 8) - worst case scenario regarding emissions to STP**

| Calculated PEC/PNEC$_{soil}$ values for Iodine, Iodide and Iodate | | |
|---|---|---|
| | PEC$_{soil}$ [mg/kg$_{wwt}$] | PEC/PNEC$_{soil}$ |
| **Scenario [3c] turkeys - worst case scenario regarding emissions to STP** | | |
| ***via STP*** | | |
| Iodine | 2.99E-01 | 25.4 |
| Iodide | 4.19E-02 | 9.74 |
| Iodate | 4.11E-01 | 1.35 |
| ***via slurry/manure*** | | |
| **grassland** | | |
| Iodine | 3.93E-02 | 3.33 |
| Iodide | 3.93E-02 | 9.13 |
| Iodate | 5.41E-02 | 1.78E-01 |
| **arable land** | | |
| Iodine | 5.91E-03 | 5.01E-01 |
| Iodide | 5.91E-03 | 1.38 |
| Iodate | 8.15E-03 | 2.68E-02 |

**Conclusion**

For the animal housing disinfection scenario (turkeys [3c]) PEC/PNEC ratios are below the trigger value of 1 Iodate for indirect exposure of soil via slurry/manure application on grassland and for Iodine and Iodate on arable land after 10 years taking degradation and leaching to deeper soil layers into account and via sludge application.

All other calculated PEC/PNEC ratios are above the trigger value of 1. For these PEC/PNEC ratios the natural background concentration for soil (0.4 – 18 mg Iodine/kg$_{wwt}$) was compared to the PEC values. All PECs are below the lower limit of the background concentrations for soil. These results indicating that no unacceptable risk to soil organisms is to be expected.

**<u>No connection to local drainage system (STP) is assumed</u>**
**(meta SPC 6, 7 and 8)**

| Calculated PEC/PNEC$_{soil}$ values for Iodine, Iodide and Iodate | | |
|---|---|---|
| | **PEC$_{soil}$ [mg/kg$_{wwt}$]** | **PEC/PNEC$_{soil}$** |
| **ducks (worst case regarding no connection to sewer system)** | | |
| ***via slurry/manure*** | | |
| **grassland** | | |
| Iodine | 1.40E-01 | 11.9 |
| Iodide | 1.40E-01 | 32.5 |
| Iodate | 1.93E-01 | 6.34E-01 |
| **arable land** | | |
| Iodine | 8.41E-02 | 7.13 |
| Iodide | 8.41E-02 | 19.6 |
| Iodate | 1.16E-01 | 3.81E-01 |

**Conclusion**

For the animal housing disinfection scenario for ducks, which represents the worst case if no connection to the sewer system is assumed, PEC/PNEC ratios are below the trigger value of 1 regarding Iodate for indirect exposure of soil via slurry/manure application on grassland and on arable land after 10 years taking degradation and leaching to deeper soil layers into account and via sludge application.

The calculated PEC/PNEC ratios regarding Iodine and Iodide are above the trigger value of 1. For these PEC/PNEC ratios the natural background concentration for soil (0.4 – 18 mg Iodine/kg$_{wwt}$) was compared to the PEC values. All PECs are below the lower limit of the background concentrations for soil. These results indicating that no unacceptable risk to soil organisms is to be expected in case of no connection to a sewer system is assumed.

## *Groundwater*

Predicted environmental concentrations in groundwater are conducted from concentrations in pore water of agricultural soil (ECHA 2017c).
In the AR for Iodine (Sweden 2013) it was pointed out that the groundwater threshold of 0.1 µg/L specified in the Drinking Water Directive 98/83/EC is not considered applicable for Iodine as it is an inorganic element. The calculated concentrations in groundwater (porewater) are in a range within 4.29 µg/L (scenario [1]) and 55.9 µg/L (scenario [3c]) regarding Iodine and Iodide and 5.91 µg/L (scenario [1]) and 77.2 µg/L (scenario [3c]) regarding Iodate. The calculated groundwater concentrations regarding Iodine are within the range of the natural background concentration of 1-70 µg/L. The calculated groundwater concentrations regarding Iodate exceed the natural background concentration of 70 µg/L slightly (worst case scenario for emission pathway via STP - application of sewage sludge).
The PEC values in groundwater were calculated following the approach described in the Guidance on the BPR Volume IV (ECHA 2017c) using the porewater concentration in soil as indication for the groundwater level i.e. the calculation assumes all the active substance and its metabolites in the soil porewater is carried through to groundwater and no removal, dilution or transformation processes like e.g. lateral transport or plant uptake are taken into

account. Therefore, the calculated concentration is an overestimate of the likely concentrations in groundwater.
In addition the AR for Iodine (Sweden 2013) states that data for soil indicates the general tendency that iodate is strongly adsorbed to soil and it is therefore assumed that Iodate will not reach deeper soil layers and the groundwater level, respectively.

**Conclusion**

All calculated $PEC_{GW}$ values regarding Iodine are well above the 0.1 µg/L threshold and acceptable human intake limits but below or within the range of the natural background concentrations. The groundwater concentrations regarding Iodate exceed the natural background concentration of 70 µg/L slightly. However, the ground water calculations according to Guidance on the BPR (ECHA 2017c) represents the factual situation of leaching to groundwater level only in a very simplified way, not taking into account removal, dilution or transformation processes. Therefore, overestimations of the likely concentrations in groundwater are expected and further on no unacceptable risks for groundwater are assumed.

## *Primary and secondary poisoning*

The product is used indoors only; therefore a direct uptake by non-target organisms is not expected.

Moreover, according to the AR for Iodine (Sweden 2013) the bioaccumulation potential for an inorganic substance, as Iodine, is not considered relevant. Furthermore, it was concluded that there was no concern regarding primary and secondary poisoning through the use of Iodine in disinfectants, as the amounts which are released to the environment were considered to be negligible compared to the natural occurring background concentrations and the fact that Iodine is an essential element (e.g. for the functioning of the thyroid hormone synthesis). This argumentation can also be followed for the BPF_Iodine_VET.

## *Mixture toxicity*

*Screening step*

Screening Step 1: Identification of the concerned environmental compartments

Concerned environmental compartments (likely to be at risk): STP (direct), freshwater and freshwater (indirect), soil (indirect) and groundwater (indirect);

Screening Step 2: Identification of relevant substances

Apart from the a.s. Iodine, no Substances of Concern are present in the BPF.

Screening Step 3: Screen on synergistic interactions

There are no indications on synergistic interactions.

| **Screening step** | | |
|---|---|---|
| 1 | Significant exposure of environmental compartments? | **Yes** |
| 2 | Number of relevant substances >1? | **No** |
| 3 | Indication for synergistic effects for the product or its constituents in the literature? | **No** |

**Conclusion**
No assessment of mixture toxicity needed according to the criteria defined in ECHA (2017c, chapter 10: Tiered Approach for biocidal products).

## *Aggregated exposure (combined for relevant emmission sources)*

The combined emissions for teat disinfection and stable disinfection (dairy cows only) should be addressed. Nevertheless, as teats are disinfected daily and stables are disinfected once annually, aggregated exposure will have negligible effects on the calculated PECs. Therefore, a quantitative assessment is acceptable.

**Aggregated exposure: Teat dipping scenario and animal housing disinfection (dairy cows)**

| **Summary table on calculated PEC values for Iodine aggregated exposure: Teat dipping scenario and animal housing disinfection (dairy cows)** | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | **$PEC_{STP}$** | **$PEC_{fresh\ -water}$** | **$PEC_{fresh\ water\ sed}$** | **$PEC_{soil}$** | **PEC GW** | **$PEC_{air}$** |
| | | [mg/L] | [mg/L] | [$mg/kg_{wwt}$] | [$mg/kg_{wwt}$] | [µg/L] | [$mg/m^3$] |
| **via STP** | | | | | | | |
| Teat spray treatment | | 3.70E-03 | 3.69E-04 | 1.79E-02 | 2.29E-02 | 4.29E-03 | -- |
| Animal housing disinfection (dairy cows) | | -- | -- | -- | -- | -- | -- |
| Summary | | 3.70E-03 | 3.69E-04 | 1.79E-02 | 2.29E-02 | 4.29E-03 | -- |
| Background concentrations Iodine | | | 5.00E-04 – 2.00E-02 mg Iodine/L | 6 mg Iodine/kg | 4.00E-01 - 18 mg Iodine/ kgwwt | <1-70 µg Iodine/L | -- |
| **via slurry/manure – concentrations after ten years degradation and leaching to deeper soil layers between two applications are considered** | | | | | | | |
| Teat spray treatment | grassland | -- | 2.83E-03 | 1.38E-01 | 1.49E-01 | 2.84E-02 | -- |
| | arable land | -- | 1.73E-03 | 8.39E-02 | 9.07E-02 | 1.73E-02 | -- |
| Animal housing disinfection (dairy cows) | grassland | -- | 7.00E-04 | 3.40E-02 | 3.74E-02 | 7.03 | -- |
| | arable land | -- | 1.07E-04 | 5.19E-03 | 5.63E-03 | 1.07 | -- |
| Summary | grassland | -- | 3.53E-03 | 1.72E-01 | 1.86E-01 | 7.05 | -- |
| | arable land | -- | 1.84E-03 | 8.91E-02 | 9.63E-02 | 1.09 | -- |
| Background concentrations Iodine | | -- | 5.00E-04 – 2.00E-02 mg Iodine/L | 6 mg Iodine/kg | 4.00E-01 - 18 mg Iodine/kgw wt | <1-70 µg Iodine/L | -- |

**Conclusion**

The PEC values of the aggregated risk assessment (considering the PEC values of the teat disinfection scenario summed up with the PEC values of the dairy cows housing disinfection scenario) are below the lower limit of the background concentrations for all environmental compartments. These results indicate that no unacceptable risk to any environmental compartmentis is expected.

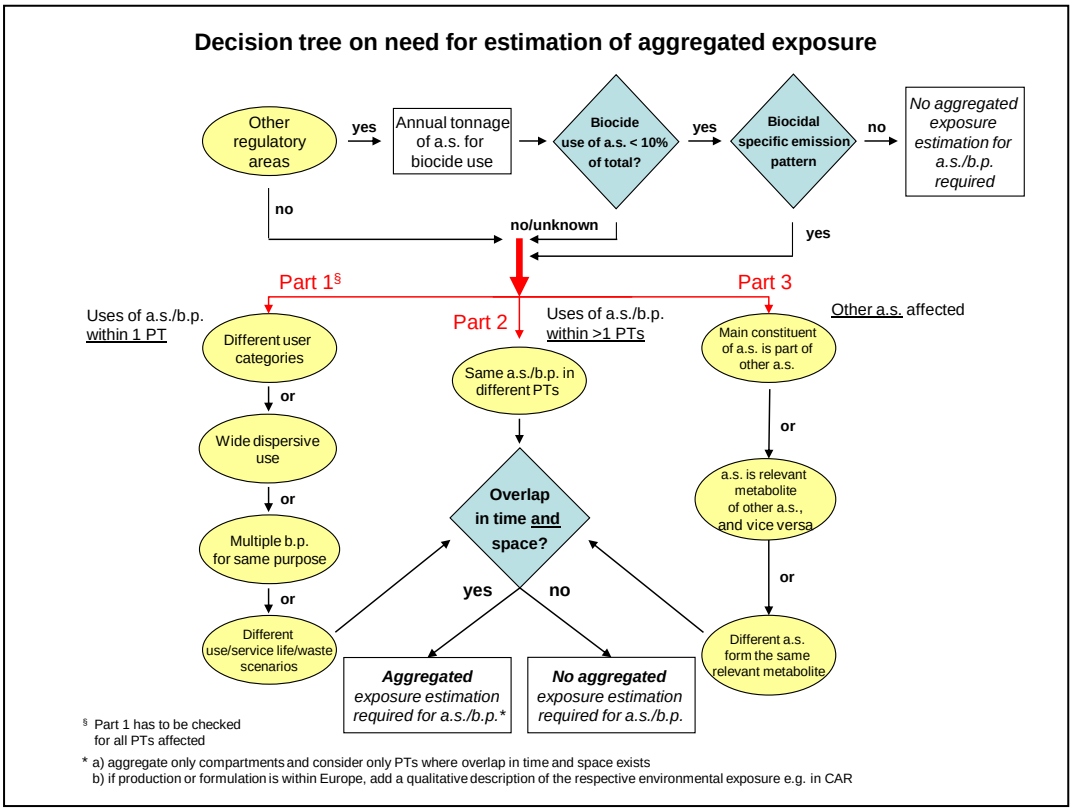


*Figure 1: Decision tree on the need for estimation of aggregated exposure*

**Overall conclusion on the risk assessment for the environment of the product**

**Meta SPC 1, 2, 3, 4 and 5: teat treatment - spraying and dipping**

When the product is released to the sewer no unacceptable risk is expected for micro-organisms in the municipal sewage treatment plant, for aquatic organisms in freshwater and freshwater sediment and for terrestrial organisms in soil. PEC/PNEC ratios are either <1, or if >1, the concerned PEC values are well below or within the natural background concentration (ranges).

PECs in groundwater are well above the threshold of 0.1 µg/L and acceptable human intake limits. The limit value for pesticides of 0.1 µg/L specified in the Drinking Water Directive 98/83/EC is not applicable for Iodine and its Iodine species since the definition for pesticides is limited to organic substances. However, the calculated Iodine concentrations are within the natural background concentration range of 1-70 µg/L. The groundwater concentrations regarding Iodate exceed the natural background concentration of 70 µg/L slightly. However, due to the fact that leaching to groundwater level does not taking into account removal, dilution or transformation processes, overestimations of the likely Iodate concentrations in groundwater are expected and further on no unacceptable risks for groundwater are assumed.

Regarding indirect exposure of Iodine via run-off from treated areas after slurry/manure application on grassland and arable land, the PECs for freshwater are within the range and for sediment they are below the typical natural background concentration, indicating that no unacceptable risk for the aquatic and sediment compartment is to be expected. Furthermore, no unacceptable risks to soil organisms are to be expected. All calculated $PEC_{GW}$ values after slurry/manure application on grassland and arable land regarding Iodine are well above the 0.1 µg/L threshold and acceptable human intake limits but below or within the range of the natural background concentrations. Furthermore, it was concluded that there was no concern regarding primary and secondary poisoning through the use of Iodine in disinfectants.

**Meta SPC 6, 7 and 8: Animal housing surface disinfection**

No unacceptable risk is expected for micro-organisms in the municipal sewage treatment plant, for aquatic organisms in freshwater and freshwater sediment and for terrestrial organisms in soil as PEC/PNEC ratios are either <1, or if >1, the concerned PEC values are well below or within the natural background concentration (ranges).

PECs in groundwater are well above the threshold of 0.1 µg/L and acceptable human intake limits. The limit value for pesticides of 0.1 µg/L specified in the Drinking Water Directive 98/83/EC is not applicable for Iodine and its Iodine species since the definition for pesticides is limited to organic substances. However, the calculated concentrations are within the natural background concentration range of 1-70 µg/L.

### 2.2.9 Measures to protect man, animals and the environment

**Recommended methods and precautions concerning handling, use, storage, disposal, transport or fire:**

Please see chapter 2.1.5 General directions for use. No special meaures concerning fire are recommended.

**Identity of relevant combustion products in cases of fire:**

Combustion products: the following gases may be formed: carbon dioxide, carbon monoxide, nitrous gases, cyanides.

**Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available; emergency measures to protect the environment**

Please see chapter 2.1.5 General directions for use.

**Possibility of destruction or decontamination following release in or on the following: Air, Water, Soil**

Please see chapter 2.1.5 General directions for use. No special decontamination measures needed.

**Procedures for waste management of the biocidal product and its packaging for industrial use. use by trained professionals. professional users and non-professional users (e.g. possibility of reuse or recycling, neutralisation, conditions for controlled discharge and incineration)**

Please see chapter 2.1.5 General directions for use.

**Procedures for cleaning application equipment where relevant**

Please see chapter 2.1.5 General directions for use. Equipment may be cleaned with water.

**Specify any repellents or poison control measures included in the product that are present to prevent action against non-target organisms**

Not relevant.

### 2.2.10 Assessment of a combination of biocidal products

Biocidal products are not intended to be authorised for the use with other biocidal products.

### 2.2.11 Comparative assessment

The active substance Iodine contained in the biocidal product family does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not considered a candidate for substitution. The current assessment report for Iodine (2015) concludes, that the concept of endocrine disruption is not meaningful for essential elements such as Iodine. Therefore, currently a comparative assessment of the biocidal product family in accordance with Article 23 of the BPR was not carried out but may become relevant after early review of ED criteria (cf. to CA-September18.Doc.7.5.a-final).

# 3 Annexes

## 3.1 List of studies for the biocidal product (family)

| BPR datapoint | Author(s) | Year | Title | Testing Company | Report No. | GLP Study (Yes/No) | Data Owner |
|---|---|---|---|---|---|---|---|
| 3 (general) | [redacted] | 2016 | EVALUATION ON MAXIMUM RISK AND MINIMUM EFFICACY PRODUCTS WITHIN THE BIOCIDAL PRODUCT FAMILIY „BPF_IODINE_VET" | [redacted] | No report number provided | N | Applied Biocide GmbH |
| 3.1<br>3.4.1 | [redacted] | 2015a | Determination of Iodine in the product "FINK IO SPRAY 50" (18207) - storage stability study (one year) | [redacted] | LC 1324/15 | N | Applied Biocide GmbH |
| 3.1<br>3.2<br>3.3<br>3.5<br>3.8<br>3.9 | [redacted] | 2015a | FINK - Io Dip 50 (pH. Persitent Foam. Relative Density. Surface Tension. Alkalinity/Acidity. Viscosity) | [redacted] | 13/2015. 5 | N | Applied Biocide GmbH |
| 3.1 | [redacted] | 2015 | Safety data sheet according to 1907/2006/EC. Article 31. FINK - Io Dip 50 | [redacted] | No report number provided | N | Applied Biocide GmbH |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 3.1<br>3.4.1 | [redacted] | 2015b | Determination of Iodine in the product "Iodosan 30 plus" - accelerated storage stability study according to CIPAC MT46.3 | [redacted] | LC 0517/15 | N | Applied Biocide GmbH |
| 3.2<br>3.3<br>3.5<br>3.8<br>3.9 | [redacted] | 2015b | FINK - Io Spray 50 (pH. Persitent Foam. Relative Density. Surface Tension. Alkalinity/Acidity. Viscosity) | [redacted] | 47/14. 25 | N | Applied Biocide GmbH |
| 3.2<br>3.3<br>3.5<br>3.8<br>3.9 | [redacted] | 2015c | FINK - Io Spray 50 (Iodophor) (pH. Persitent Foam. Relative Density. Surface Tension. Alkalinity/Acidity. Viscosity) | [redacted] | 88/14. 30 | N | Applied Biocide GmbH |
| 3.2<br>3.3<br>3.5<br>3.8<br>3.9 | [redacted] | 2015d | Iodosan 30 plus (pH. Persitent Foam. Relative Density. Surface Tension. Alkalinity/Acidity. Viscosity) | [redacted] | 12/2015. 5 | N | Applied Biocide GmbH |
| 3.2 | [redacted] | 2018a | Determination of pH in the test item "Io Spray 15" | [redacted] | LC 6548/18-6 | N | Applied Biocide GmbH |
| 3.2 | [redacted] | 2018b | Determination of pH in the test item "Io Spray 30" | [redacted] | LC 6548/18-7 | N | Applied Biocide GmbH |
| 3.2 | [redacted] | 2018c | Determination of Iodine and pH in the test item "Io Dip 10" | [redacted] | LC 6548/18-1 | N | Applied Biocide GmbH |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 3.2 | [redacted] | 2018d | Determination of Iodine and pH in the test item "Io Dip Protect" | [redacted] | LC 6548/18-2 | N | Applied Biocide GmbH |
| 3.2 | [redacted] | 2018e | Determination of Iodine and pH in the test item "JODOFILM 75/5 4500" | [redacted] | LC 6548/18-4 | N | Applied Biocide GmbH |
| 3.2 | [redacted] | 2019a | Determination of Iodine and pH in the test item "JODOFILM 75/5 3000" | [redacted] | LC 6548/18-3 | N | Applied Biocide GmbH |
| 3.4.1 | [redacted] | 2015c | Determination of Iodine in the product "IO Spray" (Art. No 18999) - storage stability study (one year) | [redacted] | LC 1110/14 | N | Applied Biocide GmbH |
| 3.4.1 | [redacted] | 2016a | Determination of Iodine in the product "FINK-IO Spray (PVP)" (Art. No 18997) - storage stability study over a period of 12 months | [redacted] | LC 3376/15 | N | Applied Biocide GmbH |
| 3.4.1 | [redacted] | 2016b | Determination of Iodine in the product - "FINK-IO Spray (Jodophor)" (Art. No 18998) - storage stability study over a period of 12 months | [redacted] | LC 3377/15 | N | Applied Biocide GmbH |
| 3.4.1 | [redacted] | 2016c | Determination of Iodine in the product - "FINK-IO Spray 50 (Jodophor)" (Art. No 18207_1) - storage stability study over a period of 12 months | [redacted] | LC 3378/15 | N | Applied Biocide GmbH |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 3.4.1 | [redacted] | 2017a | Determination of Iodine in the product "Iodosan 15" - long term storage stability study | [redacted] | LC 1391/17-1 | N | Applied Biocide GmbH |
| 3.4.1 | [redacted] | 2017b | Determination of Iodine in the product "Iodosan 30 plus" - long term stability study | [redacted] | LC 1391/17-2 | N | Applied Biocide GmbH |
| 3.4.1 | [redacted] | 2015d | Determination of Iodine in the product "IO Spray (Jodophor)" (Art. No 18998) - accelerated storage stability study according to CIPAC MT46.3 | [redacted] | LC 0515/15 | N | Applied Biocide GmbH |
| 3.4.1 | [redacted] | 2015e | Determination of Iodine in the product "IO Spray (PVP)" (Art. No 18997) - accelerated storage stability study according to CIPAC MT46.3 | [redacted] | LC 0512/15 | N | Applied Biocide GmbH |
| 3.4.1 | [redacted] | 2015f | Determination of Iodine in the product "IO Spray 50 (Jodophor)" (Art. No 18207_1) - accelerated storage stability study according to CIPAC MT46.3 | [redacted] | LC 0514/15 | N | Applied Biocide GmbH |
| 3.4.1 | [redacted] | 2015g | Determination of Iodine in the product "Iodosan 15" - accelerated storage stability study according to CIPAC MT46.3 | [redacted] | LC 0516/15 | N | Applied Biocide GmbH |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 3.4.1 | [redacted] | 2017 | Effects on characteristics and stability of packaging of biocidal products - Biocidal Product Family "BPF_Iodine_ VET" | [redacted] | 0501/2015 | N | Applied Biocide GmbH |
| 3.4.1 | [redacted] | 2015d | Decomposition products from biocidal active substance elementary Iodine. experimental data from storage stability testing and electrochemical evaluation of Iodine / water redox-system | [redacted] | 0701/2015 | N | Applied Biocide GmbH |
| 4.16 | [redacted] | 2018a | "Test Report of the determination of the corrosion of metal; FINK – Io Spray 50" | [redacted] | 36/18. 31 | N | Applied Biocide GmbH |
| 4.16 | [redacted] | 2018b | "Test Report of the determination of the corrosion of metal; FINK – Io Spray 50 (Jodophor)" | [redacted] | 35/18. 30 | N | Applied Biocide GmbH |
| 4.16 | [redacted] | 2018c | "Test Report of the determination of the corrosion of metal; Iodofilm 75/5 4500ppm" | [redacted] | 37/18. 32 | N | Applied Biocide GmbH |
| 4.16 | [redacted] | 2018d | "Test Report of the determination of the corrosion of metal; Iodosan 30 plus" | [redacted] | 38/18. 36 | N | Applied Biocide GmbH |

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|---|---|---|---|---|---|---|---|
| 4.16 | [redacted] | 2018e | "Test Report of the determination of the corrosion of metal; Iodosan 30 plus 2%" | [redacted] | 39/18. 37 | N | Applied Biocide GmbH |
| 4.16 | [redacted] | 2019a | "Test Report of the determination of the corrosion of metal FINK- Io Spray 50" | [redacted] | 162/18 | N | Applied Biocide GmbH |
| 4.16 | [redacted] | 2019b | "Test Report of the determination of the corrosion of metal FINK- Io Spray 50 Jodophor" | [redacted] | 163/18 | N | Applied Biocide GmbH |
| 4.16 | [redacted] | 2019c | "Test Report of the determination of the corrosion of metal Jodofilm 75/5 4500ppm" | [redacted] | 164/18 | N | Applied Biocide GmbH |
| 5.1 | [redacted] | 2015h | "Io Spray (Art. Nr. 18999)": Method validation. | [redacted] | SL-LC007/15 | Y | Applied Biocide GmbH |
| 6.7 | [redacted] | 2014 | Prüfbericht / test report B 19179a | [redacted] | B 19179a | N | Applied Biocide GmbH |
| 6.7 | [redacted] | 2015a | Fink Io Spray 50 - 18207 - EN 1656 and EN 1657 | [redacted] | 15107922 | N | Applied Biocide GmbH |
| 6.7 | [redacted] | 2015b | FINK Io Spray PVP (18997) | [redacted] | 15063523 | N | Applied Biocide GmbH |
| 6.7 | [redacted] | 2015c | Fink Io Spray 50 Jodophor (18207_1) | [redacted] | 15063323 | N | Applied Biocide GmbH |
| 6.7 | [redacted] | 2016e | Prüfbericht / test report B 20068a | [redacted] | B 20068a | N | Applied Biocide GmbH |

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|---|---|---|---|---|---|---|---|
| 6.7 | [redacted] | 2016a | Prüfbericht / test report B 20068b | [redacted] | B 20068b | N | Applied Biocide GmbH |
| 6.7 | [redacted] | 2016b | Prüfbericht / test report B 20070a | [redacted] | B 20070a | N | Applied Biocide GmbH |
| 6.7 | [redacted] | 2016c | Prüfbericht / test report B 20070b | [redacted] | B 20070b | N | Applied Biocide GmbH |
| 6.7 | [redacted] | 2015d | Iodosan 15 - test before storage | [redacted] | 15063621 | N | Applied Biocide GmbH |
| 6.7 | [redacted] | 2015e | Iodosan 15 after 14 day storage at 54°C | [redacted] | 15063622 | N | Applied Biocide GmbH |
| 6.7 | [redacted] | 2015a | Virucidal quantitative suspension test according to EN 14675 | [redacted] | SN 18540a | N | Applied Biocide GmbH |
| 6.7 | [redacted] | 2015b | Virucidal quantitative suspension test according to EN 14675 | [redacted] | SN 18540b | N | Applied Biocide GmbH |
| 6.7 | [redacted] | 2015f | Iodosan 30 plus after 14 day storage at 54°C | [redacted] | 15063721 | N | Applied Biocide GmbH |
| 6.7 | [redacted] | 2015c | Virucidal quantitative suspension test according to EN 14675 | [redacted] | 18541a | N | Applied Biocide GmbH |
| 6.7 | [redacted] | 2015d | Virucidal quantitative suspension test according to EN 14675 | [redacted] | 18541b | N | Applied Biocide GmbH |

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|---|---|---|---|---|---|---|---|
| 6.7 | [redacted] | 2016a | Efficacy test for bactericidal activity on a porous surface (VITRO SKIN® synthetic skin) according to a protocol adapted from the EN 16437 standard in drop/drop IOSpray 15 PVP | [redacted] | 4184-1 | N | Applied Biocide GmbH |
| 6.7 | [redacted] | 2016 | Efficacy test for bactericidal activity on a porous surface (VITRO SKIN® synthetic skin) according to a protocol adapted from the EN 16437 standard in drop/drop IOSpray 15 Type I | [redacted] | 4183-1 | N | Applied Biocide GmbH |
| 6.7 | [redacted] | 2016b | Efficacy test for bactericidal activity on a porous surface (VITRO SKIN® synthetic skin) according to a protocol adapted from the EN 16437 standard in drop/dip IODip 10 PVP | [redacted] | 4188-1 | N | Applied Biocide GmbH |
| 6.7 | [redacted] | 2017 | MIN effictive dose calculations (based on test results after storage) | [redacted] | 6.7._23_min_effective_dose | N | Applied Biocide GmbH |
| 6.7 | [redacted] | 2015c | calculated concentrations for not-tested BPs | [redacted] | 6.7._22_calculated_appl_conc | N | Applied Biocide GmbH |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 8.6 | [redacted] | 2009 | In vitro percutaneous absorption of total Iodine from two biocide formulations through huan skin membranes | [redacted] | V8124 | Y | IRG Iodine Registration Group |
| 8.8 | [redacted] | 2015b | Dietary Risk Assessment | [redacted] | 0703/2015 | Y | Applied Biocide GmbH |
| 8.8 | [redacted] | 2015 | Iodine residues in milk due to Iodine-based teat-disinfection: Assessment of consumer safety | [redacted] | BC124-00002 | Y | IRG Iodine Registration Group |
| 8.8 | [redacted] | 2015 | Livestock exposure assessment | [redacted] | 0704/2015 | Y | Applied Biocide GmbH |
| 8.8 | [redacted] | 2015a | Study report: Iodine teat disinfectants – actual application rates and related drip-off from cow´s udder | [redacted] | 0702/2015 | y | Applied Biocide GmbH |

## 3.2 Output tables from exposure assessment tools

### 3.2.1 Human and Animal Exposure

Scenarios 1 to 4:

Human Expo Scenarios 1-4.xlsx

| **SCENARIO [5] post-milking teat disinfection by spraying (Iodine = 5 mg/mL)** representative also for **SCENARIO [6]** post-milking teat disinfection by dipping (Iodine = 4.5 mg/mL) | | |
|---|---|---|
| **Parameters** | **Value** | **Unit** |
| Iodine concentration | 5 | mg/mL |
| remaining amount on teat | 1.2 | mL |
| frequency of milking | 2 | per day |
| milk/milking event | 20 | L |
| dermal absorption rate | 12 | % |
| body weight dairy cow | 650 | kg |
| body weight sheep | 75 | kg |
| body weight lacting goat | 70 | kg |
| body weight buffalo | 500 | kg |
| Total exposure. Tier 2. internal – dairy cattle | 0.0022 | mg a.s./kg bw/day |
| Total exposure. Tier 2. internal – sheep | 0.0192 | mg a.s./kg bw/day |
| Total exposure. Tier 2. internal – lacting goat | 0.0206 | mg a.s./kg bw/day |
| Total exposure. Tier 2. internal – buffalo | 0.0029 | mg a.s./kg bw/day |

| SCENARIO [7a] animal house spraying: calf | | |
|---|---|---|
| **Parameters** | **Value** | **Unit** |
| Iodine concentration in product | 30 | mg/mL |
| Iodine concentration within in use solution | 0.75 | mg/mL |
| Application rate for product | 400 | mL/$m^2$ |
| cleaning efficiency after disinfection | Not considered | % |
| fraction emitted to the treated surface (relevant for exposure via licking of surfaces) during surface treatment by spraying | 0.85 | |
| tongue surface area | 0.008 | $m^2$ |
| licks per day | 10 | |
| fraction emitted to the floor (relevant for exposure via feed) during surface treatment by spraying | 0.11 | |
| exposed feed surface | 0.5 | $m^2$ |
| fraction emitted to the treated surface (relevant for exposur e via rubbing against surfaces) during surface treatment by spraying | 0.85 | |
| body surface area in contact with surface | 0.87 | $m^2$ |
| dermal absorption | 12 | % |
| worst case estimate for animal exposure via respiration taken from human exposure estimate during spraying task | 76 | mg b.p./$m^3$ |
| Respiratory exposure reduction factor due to ventilation and sedimentation of aerosols (3 hours ventilation with 1 Vol/h)[1] | 0.05 | |
| Alveolar ventilation rate | 25 | $m^3$/day |
| body weight calf | 200 | kg |
| Total exposure, Tier 2, internal – calf | 0.318 | mg a.s./kg bw/day |

[1] 1 Vol/h represents the minimal ventilation rate for stables according to the draft DRWAG Annex

| SCENARIO [7b] animal house spraying: laying hen | | |
|---|---|---|
| **Parameters** | **Value** | **Unit** |
| Iodine concentration in biocidal product | 30 | mg Iodine/mL b.p. |
| Iodine concentration within in use solution | 0.75 | mg Iodine/mL b.p. |
| Iodine concentration within in use solution | 0.0006 | mg Iodine/mg b.p. |
| application rate for biocidal product | 400 | mL/m2 |
| cleaning efficiency after disinfection | Not considered | % |
| fly consumption | 10 | flies/ day |
| consumption of biocidal product via flies (spray deposite/fly) | 3.5 | mg bp/fly |
| fraction emitted to the floor (relevant for exposure via feed) during surface treatment by spraying | 0.11 | |
| exposed feed surface | 0.01 | $m^2$ |
| fraction of spray hitting hens (relevant for dermal exposure) = fraction emitted to floor during surface treatment (0.11) x 50% (assuming that 50% of the floor is covered by hens) | 0.055 | |
| Treated area = wall area | 600 | $m^2$ |
| dermal absorption | 12 | % |
| Number of animals | 10000 | |
| worst case estimate for animal exposure via respiration taken from human exposure estimate during spraying task | 76 | mg b.p./$m^3$ |
| Respiratory exposure reduction factor due to ventilation and sedimentation of aerosols (3 hours ventilation with 1 Vol/h1) | 0.05 | |
| Alveolar ventilation rate | 0.2 | $m^3$/day |
| body weight hen | 1.9 | kg |
| Total exposure, Tier 2, internal – laying hen | 0.209 | mg a.s./kg bw/day |

[1] 1 Vol/h represents the minimal ventilation rate for stables according to the draft DRWAG Annex

| SCENARIO [7c] animal house spraying: dairy cattle | | |
|---|---|---|
| **Parameters** | **Value** | **Unit** |
| Iodine concentration in product | 30 | mg/mL |
| Iodine concentration within in use solution | 0.75 | mg/mL |
| Application rate for product | 400 | mL/$m^2$ |
| cleaning efficiency after disinfection | Not considered | % |
| fraction emitted to the floor (relevant for exposure via feed) during surface treatment by spraying | 0.11 | |
| exposed feed surface | 2.9 | $m^2$ |
| fraction emitted to the treated surface (relevant for exposur e via rubbing against surfaces) during surface treatment by spraying | 0.85 | |
| body surface area in contact with surface | 1.68 | $m^2$ |
| dermal absorption | 12 | % |
| worst case estimate for animal exposure via respiration taken from human exposure estimate during spraying task | 76 | mg b.p./$m^3$ |
| Respiratory exposure reduction factor due to ventilation and sedimentation of aerosols (3 hours ventilation with 1 Vol/h)[1] | 0.05 | |
| Alveolar ventilation rate | 25 | $m^3$/day |
| body weight dairy cattle | 650 | kg |
| Total exposure, Tier 2, internal – dairy cattle | 0.148 | mg a.s./kg bw/day |

[1] 1 Vol/h represents the minimal ventilation rate for stables according to the draft DRWAG Annex

| SCENARIO [7d] animal house spraying: fattening pig | | |
|---|---|---|
| **Parameters** | **Value** | **Unit** |
| Iodine concentration in product | 30 | mg/mL |
| Iodine concentration within in use solution | 0.75 | mg/mL |
| Application rate for product | 400 | mL/$m^2$ |
| cleaning efficiency after disinfection | Not considered | % |
| fraction emitted to the treated surface (relevant for exposure via licking of surfaces) during surface treatment by spraying | 0.85 | |
| tongue surface area | 0.008 | $m^2$ |
| licks per day | 10 | |
| fraction emitted to the floor (relevant for exposure via feed) during surface treatment by spraying | 0.11 | |
| exposed feed surface | 0.4 | $m^2$ |
| fraction emitted to the treated surface (relevant for exposur e via rubbing against surfaces) during surface treatment by spraying | 0.45 | |
| body surface area in contact with surface | 0.87 | $m^2$ |
| dermal absorption | 12 | % |
| worst case estimate for animal exposure via respiration taken from human exposure estimate during spraying task | 76 | mg b.p./$m^3$ |
| Respiratory exposure reduction factor due to ventilation and sedimentation of aerosols (3 hours ventilation with 1 Vol/h)[1] | 0.05 | |
| Alveolar ventilation rate | 14 | $m^3$/day |
| body weight calf | 100 | kg |
| Total exposure, Tier 2, internal – calf | 0.474 | mg a.s./kg bw/day |

[1] 1 Vol/h represents the minimal ventilation rate for stables according to the draft DRWAG Annex

| Animal exposure to Idoine via feed additives | | |
|---|---|---|
| **Parameters** | **Value** | **Unit** |
| Feed consumption: dairy cow | 25 | kg |
| Feed consumption: sheep | 3 | kg |
| Feed consumption: lacting goat | 2.8 | kg |
| Feed consumption: buffalo | 20 | kg |
| Feed consumption: calf | 8 | kg |
| Feed consumption: fattening pig | 3 | kg |
| Feed consumption: laying hen | 0.13 | kg |
| Iodine content in feed: dairy cows and minor dairy ruminants | 5 | mg /kg food |
| Iodine content in feed: laying hen | 5 | mg /kg food |
| body weight: dairy cattle | 650 | kg |
| body weight: sheep | 75 | kg |
| body weight: lacting goat | 70 | kg |
| body weight: buffalo = beef | 500 | kg |
| body weight: calf | 200 | kg |
| body weight: fattening pig | 100 | kg |
| body weight: laying hen | 1.9 | kg |
| Total exposure: dairy cattle | 0.19 | mg/kg bw day |
| Total exposure: sheep | 0.20 | mg/kg bw day |
| Total exposure: lacting goat | 0.20 | mg/kg bw day |
| Total exposure: buffalo = beef | 0.20 | mg/kg bw day |
| Total exposure: calf | 0.20 | mg/kg bw day |
| Total exposure: pig | 0.15 | mg/kg bw day |
| Total exposure: laying hen | 0.34 | mg/kg bw day |

### 3.2.2 Environmental Exposure

The calculations of PEC-values and the intermediate calculations for all scenarios are reported in this chapter.

## Pathway 1 - emission to soil via manure/slurry application

Input parameters for the $PECsoil_{10years}$ calculations considering degradation and leaching to deeper soil layers are listed in the table below:

| Parameters | Symbol | Value | Unit | S/D/O/R |
|---|---|---|---|---|
| Fraction of rain water that infiltrates into soil | Finf_soil | 0.25 | - | ECHA, 2017c: formula (58) |
| Rate of wet precitipation (700 mm/year) | RAINrate | 1.92E-03 | m/d | ECHA, 2017c: formula (58) |
| First-order rate constant for leaching from soil layer (grassland) | kleach_gr | 1.08E-03 | $d^{-1}$ | ECHA, 2017c: formula (58) |
| Half-life for leaching from soils (grassland) | DT50soil_gr | 642.71 | d | |
| First-order rate constant for leaching from soil layer (arable land) | kleach_ar | 2.70E-04 | $d^{-1}$ | ECHA, 2017c: formula (58) |
| Half-life for leaching from soils (arable land) | DT50soil_ar | 2570.82 | d | |
| First-order rate constant for removal from top soil layer (grassland) | ktot_gr | 1.08E-03 | $d^{-1}$ | ECHA, 2017c: formula (56) |
| First-order rate constant for removal from top soil layer (arable land) | ktot_ar | 2.70E-04 | $d^{-1}$ | ECHA, 2017c: formula (56) |

**Scenario [1]: RTU teat spray treatment - manual/automated - post milking**

**meta SPC 1, 2 and 3, covering meta SPC 4 and 5**

The relevant input parameters for the emission estimation according to the ESD for PT3 (EU 2011) for scenario [1] are presented in the table below.

| **Input parameters for calculating the local emissionscenario [1] – meta SPC 1, 2 and 3** | | | | |
|---|---|---|---|---|
| **Input** | | **Value** | **Unit** | **S/D/O/R* Origin** |
| **Scenario [1]: RTU teat spray treatment - manual/automated - post milking (mSPC 1 and 2)** | | | | |
| Application rate of biocidal product: Amount of product prescribed to be used for one treatment (spraying of the four teats) of one animal | Vprodi1,i2,i3 | 0.015 | L/cow/treatment | S for the application method spraying (manual / automated) |
| Time of application | - | Post-milking | - | S |
| Number of teat dipping events for one animal and one day | Napp-teat | 3 | $d^{-1}$ | S |
| Resulting product volume for spraying for all treatments per cow per day | $Vprodi_{1.i2.i3\text{-}total}$ | 0.045 | L/cow/day | S |
| Concentration of active substance in the product | $F_{bioc}$ | 5 | g/L | S |

| **Input parameters for calculating the local emissionscenario [1] – meta SPC 1, 2 and 3** | | | | |
|---|---|---|---|---|
| **Input** | | **Value** | **Unit** | **S/D/O/R* Origin** |
| Type of housing/manure storage (for application of the notification) | $cat_{-subcat\ (i1)}$ | i1=1 (dairy cows) | - | P (ESD. Appendix1: Table 7) |
| Type of biocide | bioctype $_{(i2)}$ | iI2=3 (disinfectant) | - | D (ESD Appendix1: Table 7) |
| Type of application | appway (i3)** | i3=2 | - | D (ESD Appendix1: Table 7) |
| Relevant emission stream | stream (i4)*** | 1.manure/slurry 2.wastewater | - | P (ESD Appendix1: Table 7) |
| Dilution factor (for preparation of the working solution from the formulation (product)) | $F_{dil}$ | 1 | - | S |
| Fraction of active ingredient released | ($F_{stp}$ = $F_{ww}$) $F_{stp\_i1.i2.i3.i4}$ | 0 | - | D (ESD. Appendix1: Table 10) |
| | $F_{slurry/manure\_i1.i2.i3.i4F}$) | 0.5 (1- $F_{teat}$) | - | D (ESD. Appendix1: Table 10) |
| | $F_{air}$ | 0 | - | D (ESD. Appendix1: Table 10) |
| | $F_{teat}$ | 0.5 | - | D (ESD. Appendix1: Table 10) |
| Number of days of lactation period | Nday-lact | 300 | - | D |
| Number of disinfectant applications in one year (equals number of disinfectant applications in one lactation period) | Napp-bioc | 900 | - | D |
| Interval between two disinfectant applications (dipping events) | Tbioc-int | 0.33 | d | D |
| Number of manure applications for grassland | Nlapp-grass | 4 | - | D |
| Number of manure applications for arable land | Nlapp-arab | 1 | - | D |
| Land application interval for grassland | $T_{gr-int}$ | 53 | d | according to ECHA, 2014 |
| Manure storage time arable land | $Tmanure\text{-}int_{ar2}$ | 212 | d | according to ECHA, 2014 |
| Number of animals in housing for category/subcategory *i1* =1 | Nanimal | 100 **** | - | D |
| Amount of phosphate per animal for category/subcategory *i1* =1 | Qphosph | 0.10466 | kg/d | D |
| Amount of nitrogen per animal for category/subcategory *i1* =1 | Qnitrog | 0.3389 | kg/d | D |
| **If phosphate emission standards are applied** | | | | |
| Phosphate immission standard for | $Q_{P2O5.grassland}$ | 110 | kg/ha | D |

| Input parameters for calculating the local emissionscenario [1] – meta SPC 1, 2 and 3 | | | | |
|---|---|---|---|---|
| **Input** | | **Value** | **Unit** | **S/D/O/R* Origin** |
| one year on grassland | | | | |
| Phosphate immission standard for one year on arable land | $Q_{P2O5.arable\_land}$ | 85 | kg/ha | D |
| **If nitrogen emission standards are applied** | | | | |
| Nitrogen immission standard for one year on grassland | $Q_{N.grassland}$ | 170 | kg/ha | D |
| Nitrogen immission standard for one year on arable land | $Q_{N.arable\_land}$ | 170 | kg/ha | D |
| **Soil default values** | | | | |
| Mixing depth with soil. grassland | $DEPTH_{grassland}$ | 0.05 | m | D |
| Mixing depth with soil. arable land | $DEPTH_{arable\_land}$ | 0.2 | m | D |
| Density of wet bulk soil | RHOsoil | 1700 | kg/m³ | D |
| * Set, Default, Output, Refined<br>** Spraying, dipping and/or bath (same category in ESD, no difference in release estimation)<br>*** Release to the environment is either via application of manure/slurry to soil or by release from the facility drain to an STP.<br>**** The default value for a dairy cow herd size is 100 animals. The lactation period for dairy cows is normally 270 to 300 days, as two months before calving dairy cows do not produce milk. Considering a lactating period of 300 days. 82 milk producing cows (100*300/365=82) are milked per day, from a herd of 100 dairy cows (ECHA 2017b). | | | | |

The intermediate calculations and output parameters for the emission estimation according to the ESD for PT3 (EU 2011) for scenario [1] are presented in the table below.

**Intermediate Calculations: Scenario [1] – <u>RTU teat spray treatment - manual/automated - post milking</u> – dairy cows**

**meta SPC 1, 2 and 3; covering meta SPC 4 and 5**

| **Parameters** | | **Value (dairy cows)** | **Unit** | **S/D/O/R*** |
|---|---|---|---|---|
| Number of biocide applications during storage period for application on grassland | $N_{app\text{-}manure\ gr}$ | 159** | - | O |
| Number of biocide applications during storage period for application on arable land | $N_{app\text{-}manure\ ar}$ | 636** | - | O |
| Qai-prescri1.i2.i3 = $10^{-3}$ x Fbioc x Vprodi1.i2.i3 x Fdil | | | | |
| Amount of active ingredient to be used for one application (one treatment of one animal) | $Q_{ai\text{-}prescri1.i2.i3}$ | 7.50E-05 | kg | O |
| Qai i1.i2.i3.i4 = Fstp or slurry/manure i1.i2.i3.i4 x Qai-prescr i1.i2.i3 x Nanimali1 x Nday_lact/365 | | | | |
| Amount of active ingredient in relevant stream i4 after two applications for all animals | $Q_{ai\ i1.i2.i3.i4}$ | 3.08E-03 | kg | O |
| Qai-grassi1.i2.i3.i4 = Qai i1.i2.i3.i4 x Napp-manuregr | | | | |
| Amount of active ingredient in manure or | $Q_{ai\text{-}grassi1.i2.i3.i4}$ | 4.90E-01 | kg | O |

| | | | | |
|---|---|---|---|---|
| slurry after the relevant number of biocide applications for the manure application to grassland | | | | |
| Qai-arabi1.i2.i3.i4 = Qaii i1.i2.i3.i4 x Napp-manurear | | | | |
| Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to arable land | $Q_{ai\text{-}arabi1.i2.i3.i4}$ | 1.96 | kg | O |
| Qnitrog-grassi1.i4 = Nanimali1 x Qnitrogi1 x Tgr-inti2 | | | | |
| Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to grassland | $Q_{nitroggrassi1.i4}$ | 1796.17 | kg | O |
| Qnitrog-arabi1.i4 = Nanimali1 x Qnitrogi1 x Tar-inti2 | | | | |
| Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to arable land | $Q_{nitrog\text{-}arabi1.i4}$ | 7184.68 | kg | O |
| *Set, Default, Output, Refined (referring to ESD for PT3 (EU 2011))<br>** For arable land:<br>If Tbioc-int ≥a) Tmanure-intar2, then Napp-biomanure_ar2 = 1.<br>If Tbioc-int < Tmanure-intar2, then Napp-biomanure_ar2 = ROUND (z,[n])b) (Tmanure-intar2/Tbioc-int), with n=1.<br>If Napp-biomanure_ar2 > Napp-bioc. then Napp-biomanure_ar2 = Napp-bioc<br>** For grass land:<br>If Tbioc-int ≥a) Tgr-intb, then<br>Napp-manuregr = 1<br>If Tbioc-int < Tgr-int, then<br>Napp-manuregr = ROUND (z,[n])c) (Tgr-int/Tbioc-int), with n=1.<br>If Napp-manuregr > Napp-prescr, then<br>Napp-manuregr = Napp-prescr<br>(according to ECHA 2014) | | | | |

**Scenario [3]: Animal house disinfection by spraying**
**meta SPC 6, 7 and 8**

Comparison of emission estimations of the different animal categories:

| | | **Iodine** | | |
|---|---|---|---|---|
| | | **Spreading of manure Elocal [kg]** | | **Release to STP [kg/d]** |
| | | **GRASSLAND** | **ARABLE LAND** | **$Elocal_{waste\ water}$** |
| **Category** | **Animal group** | Amount of active ingredient in manure or slurry at the end of the storage period (53 days. one manure application). Note that grasslands are fertilised four times annually * | Amount of active ingredient in manure or slurry at the end of the storage period (212 days) | Amount of active ingredient in untreated waste water |
| 1 | Dairy cows | 0.1211 | 0.1211 | 0 |
| 2 | beef cattle | 0.0656 | 0.0656 | 0 |
| 3 | veal calves | 0.0244 | 0.0488 | 0 |
| 4 | Sows, in individual pens | 0.0724 | 0.2171 | 0 |

| | | Iodine | | |
|---|---|---|---|---|
| | | Spreading of manure Elocal [kg] | | Release to STP [kg/d] |
| | | GRASSLAND | ARABLE LAND | $Elocal_{waste\ water}$ |
| 5 | sows in groups | 0.0825 | 0.2475 | 0 |
| 6 | fattening pigs | 0.0758 | 0.1515 | 0 |
| 7 | laying hens in battery cages without treatment | 0.1654 | 0.1654 | 0 |
| 8 | laying hens in battery cages with aeration (belt drying) | 0.0993 | 0.0993 | 0.0663 |
| 9 | laying hens in battery cages with forced drying (deep pit, high rise) | 0.1429 | 0.1429 | 0 |
| 10 | laying hens in compact battery cages | 0.1316 | 0.1316 | 0 |
| 11 | Laying hens in free range with litter floor (partly litter floor, partly slatted) | 0.1038 | 0.1038 | 0.0691 |
| 12 | Broilers in free range with litter floor | 0.0614 | 0.2458 | 0.0410 |
| 13 | laying hens in free range with grating floor (aviery system) | 0.1273 | 0.1273 | 0 |
| 14 | parent broilers in free range with grating floor | 0.0484 | 0.0484 | 0 |
| 15 | parent broilers in rearing with grating floor | 0.0615 | 0.1230 | 0 |
| 16 | turkeys in free range with litter floor | 0.1809 | 0.1809 | 0.1206 |
| 17 | ducks in free range with litter floor | 0.2196 | 0.8784 | 0.0731 |
| 18 | geese in free range with litter floor | 0.1364 | 0.1364 | 0.0910 |

* In the ESD it is assumed that 4 applications of manure per year are made to grassland. The formula of the ESD calculates the Elocalsoil for the first application only. The resulting value is multiplied with 4 to obtain the total yearly emission to soil, which is the basis for the ERA.

**TAB (2017, ENV #131, page 49):** Animal housing sub-categories 8, 11, 12, 16, 17 and 18 give rise to a discharge fraction in manure, which will ultimately reach the soil compartment via manure deposition on agricultural land. Furthermore, for these housing sub-categories a discharge fraction to waste water should be considered, which could either reach the local STP or must be added to the discharge fraction in manure and increase this fraction reaching soil in cases where no connection to local drainage system is assumed. The worst case for this approach is the scenario "ducks in free range with litter floor" (cat. 17).

| Discharge to manure/slurry only | | | |
|---|---|---|---|
| | | Iodine | |
| | | Spreading of manure Elocal [kg] | |
| | | GRASSLAND | ARABLE LAND |
| **Category** | **Animal group** | Amount of active ingredient in manure or slurry at the end of the storage period (53 days. one manure application). Note that grasslands are fertilised four times annually * **Qai_grass** | Amount of active ingredient in manure or slurry at the end of the storage period (212 days) **Qai_ar** |
| 8 | laying hens in battery cages with aeration (belt drying) | 0.6615 | 0.6615 |
| 11 | Laying hens in free range with litter floor (partly litter floor, partly slatted) | 0.6915 | 0.6915 |
| 12 | Broilers in free range with litter floor | 0.4095 | 16380 |
| 16 | turkeys in free range with litter floor | 1.206 | 1.206 |
| 17 | ducks in free range with litter floor | **1.464** | **5.856** |
| 18 | geese in free range with litter floor | 0.909 | 2.727 |

* In the ESD it is assumed that 4 applications of manure per year are made to grassland. The formula of the ESD calculates the Elocalsoil for the first application only. The resulting value is multiplied with 4 to obtain the total yearly emission to soil, which is the basis for the ERA.

Comparision of the concentrations in soil after manure/slurry application and emission to untreated waste water in order to identify the worst case scenarios:

| **Concentration in soil in the case of an immission standard for nitrogen and emission to STP of Iodine** | | | | |
|---|---|---|---|---|
| | | **Spreading of manure $PEC_{soil}$ [mg/kg]** | | **Release to STP [kg/d]** |
| | | **GRASSLAND PECgr_N** | **ARABLE LAND PECar_N** | **$Elocal_{waste\ water}$** |
| | | Concentration in soil in the case of an immission standard for nitrogen and land application on grassland (four manure applications)<br><br>(taking degradation and leaching into deeper soil leyers into account) | Concentration in soil in the case of an immission standard for nitrogen and land application on arable land<br><br>(taking degradation and leaching into deeper soil leyers into account) | |
| **Category** | **Animal group** | | | |
| 1 | Dairy cows | 0.0489 | 0.0034 | 0 |
| 2 | beef cattle | 0.0249 | 0.0017 | 0 |
| 3 | veal calves | **0.1750** | 0.0240 | 0 |
| 4 | Sows, in individual pens | 0.1054 | 0.0218 | 0 |
| 5 | sows in groups | 0.1201 | 0.0248 | 0 |
| 6 | fattening pigs | 0.0850 | 0.0117 | 0 |
| 7 | laying hens in battery cages without treatment | 0.0594 | 0.0041 | 0 |
| 8 | laying hens in battery cages with aeration (belt drying) | 0.0356 | 0.0025 | 0.2650 |
| 9 | laying hens in battery cages with forced drying (deep pit. high rise) | 0.0514 | 0.0035 | 0 |
| 10 | laying hens in compact battery cages | 0.0424 | 0.0029 | 0 |
| 11 | Laying hens in free range with litter floor (partly litter floor. partly slatted) | 0.0829 | 0.0057 | 0.2763 |
| 12 | Broilers in free range with litter floor | 0.0269 | 0.0074 | 0.1638 |
| 13 | laying hens in free range with grating floor (aviery system) | 0.0508 | 0.0035 | 0 |
| 14 | parent broilers in free range with grating floor | 0.0316 | 0.0022 | 0 |
| 15 | parent broilers in rearing with grating floor | 0.0681 | 0.0094 | 0 |
| 16 | turkeys in free range with litter floor | 0.0513 | 0.0035 | **0.4825** |

| Concentration in soil in the case of an immission standard for nitrogen and emission to STP of Iodine | | | | |
|---|---|---|---|---|
| 17 | ducks in free range with litter floor | 0.1095 | **0.0301** | 0.2925 |
| 18 | geese in free range with litter floor | 0.0386 | 0.0080 | 0.3638 |

Worst case scenarios
**PECgr_N:** veal calves (cat. 3)
**PECar_N:** ducks in free range with litter floor (cat. 17)
**Elocalwaste water (STP)**: turkeys in free range with litter floor (cat. 16)

**Scenario [3a]: Animal house disinfection by spraying - veal calves**
**meta SPC 6, 7 and 8**

The relevant input parameters according to the ESD for PT3 (EU 2011) for the emission estimation for scenario [3a] are presented in the tables below.

| Parameters | | veal calves | Unit | S/D/O/R* |
|---|---|---|---|---|
| Type of housing/manure storage (for application of the notification) | cat-subcat (i1) | i1=3 | - | D (Appendix1: Table 7) |
| Type of biocide | bioctype (i2) | iI2=3 (disinfectant) | - | D (Appendix1: Table 7) |
| Type of application | appway (i3) | i3=1 | - | D (Appendix1: Table 7) |
| Relevant emission stream | stream (i4)** | 1.manure/slurry 2.wastewater | - | D (Appendix1: Table 7) |
| Content of active ingredient in formulation (product) | Fbioc | 0.75 | g/L | S |
| Amount of product prescribed to be used for one treatment | $V_{product}$ | 0.1 | L/m² | S |
| Dilution factor (for preparation of the working solution from the formulation (product)) | $F_{dil}$ | 1 | - | S |
| Area of housing treated [7] | AREAi | 650 | $m^2$ | D |
| Fraction of active ingredient released | $F_{stp} = F_{ww}$ | 0 | - | D (Appendix1: Table 10) |
| | $F_{slurry/manure}$ | 0.5 | - | |
| | $F_{air}$ | 0 | - | |
| Total fraction of active ingredient released | $F_{released}$ | 0.5 | - | D |

*Set, Default, Output, Refined

** Release to the environment is either via application of manure/slurry to soil or by release from the facility drain to an STP

[7] All surfaces in the respective animal housing, provided in Table 8 of the ESD for PT 3 (page 51) are considered.

| Parameters | | Veal calves | Unit | S/D/O/R* |
|---|---|---|---|---|
| Number of disinfectant applications in one year (equals number of disinfectant applications in one lactation period) | $N_{app\text{-}bioc}$ | 4 | - | D |
| Interval between two disinfectant applications (dipping events) | $T_{bioc\text{-}int}$ | 91 | - | D |
| Number of manure applications for Grassland (worst case) | $N_{lapp\text{-}grass}$ | 4 | - | D |
| Number of manure applications for arable land | $N_{lapp\text{-}arab}$ | 1 | - | D |
| Land application interval for grassland | $T_{gr\text{-}int}$ | 53 | d | according to ECHA. 2014 |
| Manure storage time arable land | $Tmanure\text{-}int_{ar2}$ | 212 | d | according to ECHA. 2014 |
| Number of animals in housing for category/subcategory i1 =3 | $N_{anima1}$ | 80 | - | D (Appendix 1: Table 8) |
| Amount of nitrogen per animal for category/subcategory i1 =3 | $Q_{nitrog}$ | 0.02382 | kg/d | D (Appendix 1: Table 11) |
| **If nitrogen emission standards are applied** | | | | |
| Nitrogen emission standard for one year on grassland | $QN._{grassland}$ | 170 | kg/ha | D (Appendix 1: Table 13) |
| Nitrogen emission standard for one year on arable land | $QN._{arable\_land}$ | 170 | kg/ha | D (Appendix 1: Table 13) |
| **Soil default values** | | | | |
| Mixing depth with soil. grassland | $DEPTH_{grassland}$ | 0.05 | m | D |
| Mixing depth with soil. arable land | $DEPTH_{arable\ land}$ | 0.20 | m | D |
| Density of wet bulk soil | $RHO_{soilwet}$ | 1700 | $kg/m^3$ | D |
| *Set, Default, Output, Refined | | | | |

The intermediate calculations and output parameters for the emission estimation according to the ESD for PT3 (EU 2011) for scenario [3a] are presented in the table below.

**Intermediate Calculations: Scenario [3a] - Animal house treatment by spraying – veal calves**

**meta SPC 6, 7 and 8**

| **Parameters** | | **Veal calves** | **Unit** | **S/D/O/R*** |
|---|---|---|---|---|
| Number of biocide applications during storage period for application on grassland | $N_{app\text{-}manure\ gr}$ | 1 ** | - | O |
| Number of biocide applications during storage period for application on arable land | $N_{app\text{-}manure\ ar}$ | 2 ** | - | O |
| Amount of active ingredient to be used for one application (one treatment of one animal) | $Q_{ai\text{-}prescri1.i2.i3}$ | 0.0488 | kg | O |
| Amount of active ingredient in relevant stream i4 after one application for all animals | $Q_{ai\ i1.i2.i3.i4}$ (slurry/manure) | 0.0244 | kg | O |
| Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to grassland | $Q_{ai\text{-}grassi1.i2.i3.i4}$ | 0.0244 | kg | O |
| Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to arable land | $Q_{ai\text{-}arabi1.i2.i3.i4}$ | 0.0488 | kg | O |
| Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to grassland | $Q_{nitroggrassi1.i4}$ | 126.2460 | kg | O |
| Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to arable land | $Q_{nitrog\text{-}arabi1.i4}$ | 504.9840 | kg | O |

*Set, Default, Output, Refined (referring to ESD for PT3 (EU, 2011))

<u>** For arable land:</u>
If Tbioc-int ≥a) Tmanure-intar2, then Napp-biomanure_ar2 = 1.
If Tbioc-int < Tmanure-intar2, then Napp-biomanure_ar2 = ROUND (z,[n])b) (Tmanure-intar2/Tbioc-int), with n=1.
If Napp-biomanure_ar2 > Napp-bioc. then Napp-biomanure_ar2 = Napp-bioc
<u>** For grass land:</u>
If Tbioc-int ≥a) Tgr-intb, then
Napp-manuregr = 1
If Tbioc-int < Tgr-int, then
Napp-manuregr = ROUND (z,[n])c) (Tgr-int/Tbioc-int), with n=1.
If Napp-manuregr > Napp-prescr, then
Napp-manuregr = Napp-prescr
(according to ECHA 2014)

**Scenario [3b] - Animal house disinfectiont by spraying – ducks**
**meta SPC 6, 7 and 8**

The relevant input parameters according to the ESD for PT3 (EU 2011) for the emission estimation for scenario [3b] are presented in the tables below.

| **Parameters** | | **ducks** | **Unit** | **S/D/O/R*** |
|---|---|---|---|---|
| Type of housing/manure storage (for application of the notification) | cat-subcat (i1) | i1=17 | - | D (Appendix1: Table 7) |
| Type of biocide | bioctype (i2) | iI2=3 (disinfectant) | - | D (Appendix1: Table 7) |
| Type of application | $app_{way}$ (i3) | i3=1 | - | D (Appendix1: Table 7) |
| Relevant emission stream | stream (i4)** | 1.manure/slurry 2.wastewater | - | D (Appendix1: Table 7) |
| Content of active ingredient in formulation (product) | Fbioc | 0.75 | g/L | S |
| Amount of product prescribed to be used for one treatment | $V_{product}$ | 0.1 | L/m² | S |
| Dilution factor (for preparation of the working solution from the formulation (product)) | $F_{dil}$ | 1 | - | S |
| Area of housing treated [8] | AREAi | 4880 | $m^2$ | D |
| Fraction of active ingredient released | $F_{stp} = F_{ww}$ | 0.2 | - | D (Appendix1: Table 10) |
| | $F_{slurry/manure}$ | 0.3 | - | |
| | $F_{air}$ | 0 | - | |
| Total fraction of active ingredient released | $F_{released}$ | 0.5 | - | D |
| *Set, Default, Output, Refined<br>** Release to the environment is either via application of manure/slurry to soil or by release from the facility drain to an STP | | | | |

| **Parameters** | | **ducks** | **Unit** | **S/D/O/R*** |
|---|---|---|---|---|
| Number of disinfectant applications in one year (equals number of disinfectant applications in one lactation period) | $N_{app\text{-}bioc}$ | 13 | - | D |
| Interval between two disinfectant applications (dipping events) | $T_{bioc\text{-}int}$ | 28 | - | D |
| Number of manure applications for Grassland (worst case) | $N_{lapp\text{-}grass}$ | 4 | - | D |
| Number of manure applications for arable land | $N_{lapp\text{-}arab}$ | 1 | - | D |
| Land application interval for grassland | $T_{gr\text{-}int}$ | 53 | d | according to ECHA. 2014 |
| Manure storage time arable land | $Tmanure\text{-}int_{ar2}$ | 212 | d | according to ECHA. 2014 |
| Number of animals in housing for category/subcategory i1 =17 | $N_{anima1}$ | 10000 | - | D (Appendix 1: Table 8) |
| Amount of nitrogen per animal for category/subcategory i1 =17 | $Q_{nitrog}$ | 0.00274 | kg/d | D (Appendix 1: Table 11) |
| **If nitrogen emission standards are applied** | | | | |

[8] All surfaces in the respective animal housing, provided in Table 8 of the ESD for PT 3 (page 51) are considered.

| | | | | |
|---|---|---|---|---|
| Nitrogen emission standard for one year on grassland | $QN_{.grassland}$ | 170 | kg/ha | D (Appendix 1: Table 13) |
| Nitrogen emission standard for one year on arable land | $QN_{.arable\_land}$ | 170 | kg/ha | D (Appendix 1: Table 13) |
| **Soil default values** | | | | |
| Mixing depth with soil, grassland | $DEPTH_{grassland}$ | 0.05 | m | D |
| Mixing depth with soil, arable land | $DEPTH_{arable\_land}$ | 0.20 | m | D |
| Density of wet bulk soil | $RHO_{soilwet}$ | 1700 | $kg/m^3$ | D |
| *Set, Default, Output, Refined | | | | |

The intermediate calculations and output parameters for the emission estimation according to the ESD for PT3 (EU 2011) for scenario [3b] are presented in the table below.

**Intermediate Calculations: Scenario [3b] - Animal house disinfection by spraying - ducks meta SPC 6, 7 and 8**

| **Parameters** | | **ducks** | **Unit** | **S/D/ O/R*** |
|---|---|---|---|---|
| Number of biocide applications during storage period for application on grassland | $N_{app\text{-}manure\ gr}$ | 2 ** | - | O |
| Number of biocide applications during storage period for application on arable land | $N_{app\text{-}manure\ ar}$ | 8 ** | - | O |
| Amount of active ingredient to be used for one application (one treatment of one animal) | $Q_{ai\text{-}prescri1.i2.i3}$ | 0.3660 | kg | O |
| Amount of active ingredient in relevant stream i4 after one application for all animals | $Q_{ai\ i1.i2.i3.i4}$ slurry/manure | 0.1098 | kg | O |
| | $Q_{ai\ i1.i2.i3.i4}$ STP | 0.0733 | kg | O |
| Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to grassland | $Q_{ai\text{-}grassi1.i2.i3.i4}$ | 0.2200 | kg | O |
| Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to arable land | $Q_{ai\text{-}arabi1.i2.i3.i4}$ | 0.8788 | kg | O |
| Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to grassland | $Q_{nitroggrassi1.i4}$ | 1815.25 | kg | O |
| Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to arable land | $Q_{nitrog\text{-}arabi1.i4}$ | 7261.0 | kg | O |

*Set, Default, Output, Refined (referring to ESD for PT3 (EU, 2011))

** <u>For arable land:</u>
If Tbioc-int ≥a) Tmanure-intar2, then Napp-biomanure_ar2 = 1.
If Tbioc-int < Tmanure-intar2, then Napp-biomanure_ar2 = ROUND (z,[n])b) (Tmanure-intar2/Tbioc-int), with n=1.
If Napp-biomanure_ar2 > Napp-bioc. then Napp-biomanure_ar2 = Napp-bioc
** <u>For grass land:</u>
If Tbioc-int ≥a) Tgr-intb, then
Napp-manuregr = 1
If Tbioc-int < Tgr-int, then
Napp-manuregr = ROUND (z,[n])c) (Tgr-int/Tbioc-int), with n=1.
If Napp-manuregr > Napp-prescr, then
Napp-manuregr = Napp-prescr
(according to ECHA 2014)

**Scenario [3c] - Animal house treatment by spraying – turkeys**
**meta SPC 6, 7 and 8**

The relevant input parameters according to the ESD for PT3 (EU 2011) for the emission estimation for scenario [3c] are presented in the tables below.

| Parameters | | turkey | Unit | S/D/O/R* |
|---|---|---|---|---|
| Type of housing/manure storage (for application of the notification) | cat-subcat (i1) | i1=16 | - | D (Appendix1: Table 7) |
| Type of biocide | bioctype (i2) | iI2=3 (disinfectant) | - | D (Appendix1: Table 7) |
| Type of application | $app_{way}$ (i3) | i3=1 | - | D (Appendix1: Table 7) |
| Relevant emission stream | stream (i4)** | 1.manure/slurry 2.wastewater | - | D (Appendix1: Table 7) |
| Content of active ingredient in formulation (product) | Fbioc | 0.75 | g/L | S |
| Amount of product prescribed to be used for one treatment | $V_{product}$ | 0.1 | L/m² | S |
| Dilution factor (for preparation of the working solution from the formulation (product)) | $F_{dil}$ | 1 | - | S |
| Area of housing treated [9] | AREAi | 8040 | $m^2$ | D |
| Fraction of active ingredient released | $F_{stp} = F_{ww}$ | 0.2 | - | D (Appendix1: Table 10) |
| | $F_{slurry/manure}$ | 0.3 | - | |
| | $F_{air}$ | 0 | - | |
| Total fraction of active ingredient released | $F_{released}$ | 0.5 | - | D |
| *Set, Default, Output, Refined (referring to ESD for PT3 (EU 2011)) ** Release to the environment is either via application of manure/slurry to soil or by release from the facility drain to an STP | | | | |

The intermediate calculations and output parameters for the emission estimation according to the ESD for PT3 (EU, 2011) for scenario [3c] are presented in the table below.

**Intermediate Calculations: Scenario [3c] - Animal house disinfection by spraying - turkeys**
**meta SPC 6, 7 and 8**

| Parameters | | turkeys | Unit | S/D/O/R* |
|---|---|---|---|---|
| Number of disinfectant applications in one year (equals number of disinfectant applications in one lactation period) | $N_{app\text{-}bioc}$ | 2 | - | D |
| Interval between two disinfectant applications (dipping events) | $T_{bioc\text{-}int}$ | 182 | - | D |
| Number of manure applications for Grassland (worst case) | $N_{lapp\text{-}grass}$ | 4 | - | D |
| Number of manure applications for arable land | $N_{lapp\text{-}arab}$ | 1 | - | D |
| Land application interval for grassland | $T_{gr\text{-}int}$ | 53 | d | according to ECHA, 2014 |
| Manure storage time arable land | $Tmanure\text{-}int_{ar2}$ | 212 | d | according to ECHA, 2014 |
| Number of animals in housing for category/subcategory i1 =16 | $N_{anima1}$ | 10000 | - | D (Appendix 1: Table 8) |

[9] All surfaces in the respective animal housing, provided in Table 8 of the ESD for PT 3 (page 51) are considered.

| | | | | |
|---|---|---|---|---|
| Amount of nitrogen per animal for category/subcategory i1 =16 | $Q_{nitrog}$ | 0.00482 | kg/d | D (Appendix 1: Table 11) |
| **If nitrogen emission standards are applied** | | | | |
| Nitrogen emission standard for one year on grassland | $QN_{.grassland}$ | 170 | kg/ha | D (Appendix 1: Table 13) |
| Nitrogen emission standard for one year on arable land | $QN_{.arable\_land}$ | 170 | kg/ha | D (Appendix 1: Table 13) |
| **Soil default values** | | | | |
| Mixing depth with soil. grassland | $DEPTH_{grassland}$ | 0.05 | m | D |
| Mixing depth with soil. arable land | $DEPTH_{arable\_land}$ | 0.20 | m | D |
| Density of wet bulk soil | $RHO_{soilwet}$ | 1700 | $kg/m^3$ | D |
| *Set, Default, Output, Refined (referring to ESD for PT3 (EU 2011)) | | | | |

**Intermediate Calculations: Scenario [3c] - Animal house treatment by spraying - turkeys meta SPC 6, 7 and 8**

| **Parameters** | | **turkeys** | **Unit** | **S/D/ O/R*** |
|---|---|---|---|---|
| Number of biocide applications during storage period for application on grassland | $N_{app\text{-}manure\ gr}$ | 1 ** | - | O |
| Number of biocide applications during storage period for application on arable land | $N_{app\text{-}manure\ ar}$ | 1 ** | - | O |
| Amount of active ingredient to be used for one application (one treatment of one animal) | $Q_{ai\text{-}prescri1.i2.i3}$ | 0.6030 | kg | O |
| Amount of active ingredient in relevant stream i4 after one application for all animals | $Q_{ai\ i1.i2.i3.i4}$ Slurry/manure | 0.1809 | kg | O |
| | $Q_{ai\ i1.i2.i3.i4}$ STP | 0.1206 | kg | O |
| Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to grassland | $Q_{ai\text{-}grassi1.i2.i3.i4}$ | 0.1809 | kg | O |
| Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to arable land | $Q_{ai\text{-}arabi1.i2.i3.i4}$ | 0.1809 | kg | O |
| Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to grassland | $Q_{nitroggrassi1.i4}$ | 3193.25 | kg | O |
| Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to arable land | $Q_{nitrog\text{-}arabi1.i4}$ | 12773.0 | kg | O |

*Set, Default, Output, Refined (referring to ESD for PT3 (EU 2011))

** <u>For arable land:</u>
If Tbioc-int ≥a) Tmanure-intar2, then Napp-biomanure_ar2 = 1.
If Tbioc-int < Tmanure-intar2, then Napp-biomanure_ar2 = ROUND (z,[n])b) (Tmanure-intar2/Tbioc-int), with n=1.
If Napp-biomanure_ar2 > Napp-bioc. then Napp-biomanure_ar2 = Napp-bioc
<u>** For grass land:</u>
If Tbioc-int ≥a) Tgr-intb, then
Napp-manuregr = 1
If Tbioc-int < Tgr-int, then
Napp-manuregr = ROUND (z,[n])c) (Tgr-int/Tbioc-int), with n=1.
If Napp-manuregr > Napp-prescr, then
Napp-manuregr = Napp-prescr
(according to ECHA 2014)

## Emission to STP and soil via manure/slurry application

### Scenario [1]: teat disinfection - dairy cows

| Resulting local emission to relevant environmental compartments | | | |
|---|---|---|---|
| **Compartment** | **Local emission ($Elocal_{compartment}$)** | **Unit** | **Remarks** |
| STP | 9.25-03 | kg/d | daily emission to the STP |
| $Soil_{grassland}$ | 4.90E-01 | kg | amount of Iodine collected over 53 days |
| $Soil_{arable\ land}$ | 1.96 | kg | amount of Iodine collected over 212 days |

The table below shows the resulting local emission to relevant environmental compartments regarding teat disinfection dairy cows.

| Resulting local emission to relevant environmental compartments<br>teat disinfection dairy cows<br>Pathway 1 - via manure/slurry | | | | |
|---|---|---|---|---|
| **Parameters** | | **Value** | **Unit** | **S/D/ O/R*** |
| **Iodine (=Iodide)** | | | | |
| **Nitrogen:** | | | | |
| Concentration of the active ingredient in soil based on the **nitrogen** emission standard for **grassland** (four maure applications) | $PIEC_{grs}$- $N_{i1.i2.i3.i4}$ | 5.46E-02 | $mg/kg_{wwt}$ | O |
| Concentration of the active ingredient in soil based on the **nitrogen** emission standard for **arable land** (one manure application) | $PIEC_{ars}$- $N_{i1.i2.i3.i4}$ | 1.36E-02 | $mg/kg_{wwt}$ | O |
| **Iodate** | | | | |
| **Nitrogen:** | | | | |
| Concentration of the active ingredient in soil based on the **nitrogen** emission standard for **grassland** | $PIEC_{grs}$- $N_{i1.i2.i3.i4}$ | 7.52E-02 | $mg/kg_{wwt}$ | O |
| Concentration of the active ingredient in soil based on the **nitrogen** emission standard for **arable land** | $PIEC_{ars}$- $N_{i1.i2.i3.i4}$ | 1.87E-02 | $mg/kg_{wwt}$ | O |
| *Set, Default, Output, Refined | | | | |

**Scenario [3a] Animal house disinfection by spraying - veal calves (worst case for PECsoil grass land)**
**meta SPC 6, 7 and 8**

| Resulting local emission to relevant environmental compartments | | | |
|---|---|---|---|
| **Compartment** | **Local emission ($Elocal_{compartment}$)** | **Unit** | **Remarks** |
| STP | 0 | kg/d | daily emission to the STP |
| $Soil_{grassland}$ | 0.02438 | kg | amount of Iodine collected over 53 days |
| $Soil_{arable\ land}$ | 0.04875 | kg | amount of Iodine collected over 212 days |

The table below shows the resulting local emission to relevant environmental compartments regarding animal house treatment by spraying - veal calves.

| Resulting local emission to relevant environmental compartments<br>Animal house treatment by spraying: scenario [3a] - veal calves | | | | |
|---|---|---|---|---|
| **Parameters** | | **Value** | **Unit** | **S/D/ O/R*** |
| **Iodine (=Iodide)** | | | | |
| **Via STP** | | | | |
| Emission to the sewer system | $Elocal_{waste\ water}$ | 0 | kg/d | O |
| **Via manure/slurry (degradation and leaching to deeper soil layers considered)** | | | | |
| **Nitrogen:** | | | | |
| Concentration of the active ingredient in soil based on the **nitrogen** emission standard for **grassland** (four maure applications) | $PIEC_{grs}$- $N_{i1.i2.i3.i4}$ | 0.175 | $mg/kg_{wwt}$ | O |
| Concentration of the active ingredient in soil based on the **nitrogen** emission standard for **arable land** (one manure application) | $PIEC_{ars}$- $N_{i1.i2.i3.i4}$ | 0.024 | $mg/kg_{wwt}$ | O |
| **Iodate** | | | | |
| **Via STP** | | | | |
| Daily emission to the sewer system | $Elocal_{waste\ water}$ | 0 | kg/d | O |
| **Via manure/slurry** | | | | |
| **Nitrogen:** | | | | |
| Concentration of the active ingredient in soil based on the **nitrogen** emission standard for **grassland** | $PIEC_{grs}$- $N_{i1.i2.i3.i4}$ | 0.24113 | $mg/kg_{wwt}$ | O |
| Concentration of the active ingredient in soil based on the **nitrogen** emission standard for **arable land** | $PIEC_{ars}$- $N_{i1.i2.i3.i4}$ | 0.03313 | $mg/kg_{wwt}$ | O |
| *Set. Default. Output. Refined | | | | |

**Scenario [3b] Animal house treatment by spraying - ducks (worst case for PECsoil arable land)**
**meta SPC 6, 7 and 8**

| Resulting local emission to relevant environmental compartments | | | |
|---|---|---|---|
| **Compartment** | **Local emission ($Elocal_{compartment}$)** | **Unit** | **Remarks** |
| STP | 7.33E-02 | kg/d | daily emission to the STP |
| $Soil_{grassland}$ | 2.20E-01 | kg | amount of Iodine collected over 53 days |
| $Soil_{arable\ land}$ | 8.78E-01 | kg | amount of Iodine collected over 212 days |

The table below shows the resulting local emission to relevant environmental compartments regarding animal house treatment by spraying - ducks.

| Resulting local emission to relevant environmental compartments<br>Animal house treatment by spraying: scenario [3b] - ducks | | | | |
|---|---|---|---|---|
| **Parameters** | | **Value** | **Unit** | **S/D/ O/R*** |
| **Iodine (=Iodide)** | | | | |
| **Via STP** | | | | |
| Emission to the sewer system | $Elocal_{waste\ water}$ | 7.33E-02 | kg/d | O |
| **Via manure/slurry (degradation and leaching to deeper soil layers considered)** | | | | |
| **Nitrogen:** | | | | |
| Concentration of the active ingredient in soil based on the **nitrogen** emission standard for **grassland** (four maure applications) | $PIEC_{grs}$- $N_{i1.i2.i3.i4}$ | 0.1095 | $mg/kg_{wwt}$ | O |
| Concentration of the active ingredient in soil based on the **nitrogen** emission standard for **arable land** (one manure application) | $PIEC_{ars}$- $N_{i1.i2.i3.i4}$ | 0.0301 | $mg/kg_{wwt}$ | O |
| **Iodate** | | | | |
| **Via STP** | | | | |
| Daily emission to the sewer system | $Elocal_{waste\ water}$ | 0.4031 | kg/d | O |
| **Via manure/slurry** | | | | |
| **Nitrogen:** | | | | |
| Concentration of the active ingredient in soil based on the **nitrogen** emission standard for **grassland** | $PIEC_{grs}$- $N_{i1.i2.i3.i4}$ | 0.1509 | $mg/kg_{wwt}$ | O |
| Concentration of the active ingredient in soil based on the **nitrogen** emission standard for **arable land** | $PIEC_{ars}$- $N_{i1.i2.i3.i4}$ | 0.0415 | $mg/kg_{wwt}$ | O |
| *Set, Default, Output, Refined | | | | |

**Scenario [3c] Animal house disinfection by spraying – turkeys (worst case for emission to STP)**
**meta SPC 6, 7 and 8**

| Resulting local emission to relevant environmental compartments | | | |
|---|---|---|---|
| **Compartment** | **Local emission ($Elocal_{compartment}$)** | **Unit** | **Remarks** |
| STP | 0.1206 | kg/d | daily emission to the STP |
| $Soil_{grassland}$ | 0.1809 | kg | amount of Iodine collected over 53 days |
| $Soil_{arable\ land}$ | 0.1809 | kg | amount of Iodine collected over 212 days |

The table below shows the resulting local emission to relevant environmental compartments regarding animal house treatment by spraying - turkeys.

| Resulting local emission to relevant environmental compartments<br>Animal house treatment by spraying: scenario [3c] - turkeys | | | | |
|---|---|---|---|---|
| **Parameters** | | **Value** | **Unit** | **S/D/ O/R*** |
| **Iodine (=Iodide)** | | | | |
| **Via STP** | | | | |
| Emission to the sewer system | $Elocal_{waste\ water}$ | 0.1206 | kg/d | O |
| **Via manure/slurry (degradation and leaching to deeper soil layers considered)** | | | | |
| **Nitrogen:** | | | | |
| Concentration of the active ingredient in soil based on the **nitrogen** emission standard for **grassland** (four maure applications) | $PIEC_{grs}$- $N_{i1.i2.i3.i4}$ | 0.0141 | $mg/kg_{wwt}$ | O |
| Concentration of the active ingredient in soil based on the **nitrogen** emission standard for **arable land** (one manure application) | $PIEC_{ars}$- $N_{i1.i2.i3.i4}$ | 0.0009 | $mg/kg_{wwt}$ | O |
| **Iodate** | | | | |
| **Via STP** | | | | |
| Daily emission to the sewer system | $Elocal_{waste\ water}$ | 0.1663 | kg/d | O |
| **Via manure/slurry** | | | | |
| **Nitrogen:** | | | | |
| Concentration of the active ingredient in soil based on the **nitrogen** emission standard for **grassland** | $PIEC_{grs}$- $N_{i1.i2.i3.i4}$ | 0.0195 | $mg/kg_{wwt}$ | O |
| Concentration of the active ingredient in soil based on the **nitrogen** emission standard for **arable land** | $PIEC_{ars}$- $N_{i1.i2.i3.i4}$ | 0.0012 | $mg/kg_{wwt}$ | O |
| *Set. Default. Output. Refined | | | | |

## Pathway 2 - emission to wastewater/STP

| Resulting local emission to relevant environmental compartments – Pathway 2 via STP | | | | |
|---|---|---|---|---|
| **Parameters** | | **Value** | **Unit** | **S/D/O/R*** |
| **Qai_presc =0.001 x Fbioc x Vprod x Fdil<br>Elocalwaste water =Fstp x Qai_prescr x Nanimal x Napp_teat x Nday_lact/365** | | | | |
| **Scenario [1]: RTU teat spray treatment, manual/automated, post milking (meta SPC 1, 2 and 3)** | | | | |
| Local emission to a standard STP or an on-site waste water treatment plant** | $Q_{ai\text{-}stpi1.i2.i3.i4}$ = $Elocal_{waster\ water}$ | 9.25E-03 | kg/d | O |
| **Scenario [2]: RTU teat dip treatment, manual, post milking (meta SPC 4 and 5)** | | | | |
| Local emission to a standard STP or an on-site waste water treatment plant** | $Q_{ai\text{-}stpi1.i2.i3.i4}$ = $Elocal_{waster\ water}$ | covered by scenario [1] | | |
| **Qai_presc = 0.001 x Fbioc x Vprod x Fdil x AREA<br>$Elocal_{waste\ water}$ =Fstp x Qai_prescr** | | | | |
| **Scenario [3a]: Animal house treatment by spraying - veal calves (meta SPC 6, 7 and 8)** | | | | |
| Local emission to a standard STP or an on-site waste water treatment plant** | $Q_{ai\text{-}stpi1.i2.i3.i4}$ = $Elocal_{waster\ water}$ | 0 | kg/d | O |
| **Scenario [3b] - Animal house treatment by spraying - ducks (meta SPC 6, 7 and 8)** | | | | |
| Local emission to a standard STP or an on-site waste water treatment plant** | $Q_{ai\text{-}stpi1.i2.i3.i4}$ = $Elocal_{waster\ water}$ | 7.33E-02 | kg/d | O |
| **Scenario [3c] - Animal house treatment by spraying - turkey (meta SPC 6, 7 and 8)** | | | | |
| Local emission to a standard STP or an on-site waste water treatment plant** | $Q_{ai\text{-}stpi1.i2.i3.i4}$ = $Elocal_{waster\ water}$ | 1.21E-01 | kg/d | O |
| *Set, Default, Output, Refined<br>** Value inserted in EUSES 2.1.2 to calculate PECvalues | | | | |

# Calculated PEC values (EUSES 2.1.2)

## Scenario [1] – teat disinfection (dairy cows): EUSES 2.1.2 output file Emissions via STP

| | | | |
|---|---|---|---|
| **USE PATTERN** | | | |
| Industry category | 15/0 Others | | D |
| Use category | 39 Biocides. non-agricultural | | S |
| Extra details on use category | No extra details necessary | | D |
| Extra details on use category | No extra details necessary | | D |
| Scenario choice for biocides | (1) Human Hygiene | | S |
| **INDUSTRIAL USE** | | | |
| Use specific emission scenario | No | | D |
| Emission scenario | no special scenario selected/available | | S |
| Main category industrial use | III Non-dispersive use | | S |
| **TONNAGE** | | | |
| Fraction of tonnage for application | 1 | [-] | O |
| Fraction of chemical in formulation | 1 | [-] | D |
| Tonnage of formulated product | 0 | [tonnes.yr-1] | O |
| Relevant tonnage for application | 0 | [tonnes.yr-1] | O |
| Regional tonnage of substance | 0 | [tonnes.yr-1] | O |
| Tonnage of formulated product | 0 | [tonnes.yr-1] | O |
| Regional tonnage of substance (private use step) | 0 | [tonnes.yr-1] | O |
| Continental tonnage of substance (private use step) | 0 | [tonnes.yr-1] | O |
| Total of fractions for all applications | 1 | [-] | O |
| **INTERMEDIATE RESULTS** | | | |
| **INTERMEDIATE** | | | |
| **RELEASE FRACTIONS AND EMISSION DAYS** | | | |
| **INDUSTRIAL USE** | | | |
| Emission tables | A3.16 (general table). B3.14 (general table) | | S |
| **RELEASE FRACTIONS** | | | |
| Fraction of tonnage released to air | 1E-05 | [-] | O |
| Fraction of tonnage released to wastewater | 0.75 | [-] | O |
| Fraction of tonnage released to surface water | 0 | [-] | O |
| Fraction of tonnage released to industrial soil | 1E-03 | [-] | O |
| Fraction of tonnage released to agricultural soil | 0 | [-] | O |
| Emission fractions determined by special scenario | No | | O |
| **EMISSION DAYS** | | | |
| Fraction of the main local source | 1 | [-] | O |
| Number of emission days per year | 300 | [-] | S |
| Release to wastewater only | No | | D |
| Emission days determined by special scenario | No | | O |
| **LOCAL** | | | |
| **[INDUSTRIAL USE]** | | | |
| Local emission to air during episode | 0 | [kg.d-1] | O |
| Emission to air calculated by special scenario | No | | O |
| Local emission to wastewater during episode | 9.25E-03 | [kg.d-1] | S |
| Emission to water calculated by special scenario | No | | O |
| Specific biocides scenario available | Yes | | D |
| Show this step in further calculations | Yes | | O |
| Intermittent release | No | | S |
| **DISTRIBUTION** | | | |
| **SEWAGE TREATMENT** | | | |
| **CONTINENTAL** | | | |
| Fraction of emission directed to air | 0 | [%] | O |
| Fraction of emission directed to water | 80 | [%] | S |
| Fraction of emission directed to sludge | 20 | [%] | S |
| Fraction of the emission degraded | 0 | [%] | O |
| Total of fractions | 100 | [%] | O |
| Indirect emission to air | 0 | [kg.d-1] | O |
| Indirect emission to surface water | 0 | [kg.d-1] | O |
| Indirect emission to agricultural soil | 0 | [kg.d-1] | O |

**REGIONAL**

| | | | |
|---|---|---|---|
| Fraction of emission directed to air | 0 | [%] | O |
| Fraction of emission directed to water | 80 | [%] | S |
| Fraction of emission directed to sludge | 20 | [%] | S |
| Fraction of the emission degraded | 0 | [%] | O |
| Total of fractions | 100 | [%] | O |
| Indirect emission to air | 0 | [kg.d-1] | O |
| Indirect emission to surface water | 0 | [kg.d-1] | O |
| Indirect emission to agricultural soil | 0 | [kg.d-1] | O |

**LOCAL**
**[INDUSTRIAL USE]**
**INPUT AND CONFIGURATION [INDUSTRIAL USE]**
**INPUT**

| | | | |
|---|---|---|---|
| Use or bypass STP (local freshwater assessment) | Use STP | | D |
| Use or bypass STP (local marine assessment) | Bypass STP | | D |
| Local emission to wastewater during episode | 9.25E-03 | [kg.d-1] | S |
| Concentration in untreated wastewater | 4.63E-03 | [mg.l-1] | O |
| Local emission entering the STP | 9.25E-03 | [kg.d-1] | O |

**CONFIGURATION**

| | | | |
|---|---|---|---|
| Type of local STP | With primary settler (9-box) | | D |
| Number of inhabitants feeding this STP | 1E+04 | [eq] | O |
| Effluent discharge rate of this STP | 2E+06 | [l.d-1] | O |
| Calculate dilution from river flow rate | No | | O |
| Flow rate of the river | 1.8E+04 | [m3.d-1] | O |
| Dilution factor (rivers) | 10 | [-] | O |
| Dilution factor (coastal areas) | 100 | [-] | O |

**OUTPUT [INDUSTRIAL USE]**

| | | | |
|---|---|---|---|
| Fraction of emission directed to air by STP | 0 | [%] | S |
| Fraction of emission directed to water by STP | 80 | [%] | S |
| Fraction of emission directed to sludge by STP | 20 | [%] | S |
| Fraction of the emission degraded in STP | 0 | [%] | O |
| Total of fractions | 100 | [%] | O |
| Local indirect emission to air from STP during episode | 0 | [kg.d-1] | O |
| Concentration in untreated wastewater | 4.63E-03 | [mg.l-1] | O |
| Concentration of chemical (total) in the STP-effluent | 3.7E-03 | [mg.l-1] | O |
| Concentration in effluent exceeds solubility | No | | O |
| Concentration in dry sewage sludge | 2.34 | [mg.kg-1] | O |
| PEC for micro-organisms in the STP | 3.7E-03 | [mg.l-1] | O |

**LOCAL**
**[INDUSTRIAL USE]**
**LOCAL CONCENTRATIONS AND DEPOSITIONS [INDUSTRIAL USE]**
**AIR**

| | | | |
|---|---|---|---|
| Concentration in air during emission episode | 0 | [mg.m-3] | O |
| Annual average concentration in air. 100 m from point source | 0 | [mg.m-3] | O |
| Total deposition flux during emission episode | 0 | [mg.m-2.d-1] | O |
| Annual average total deposition flux | 0 | [mg.m-2.d-1] | O |

**WATER. SEDIMENT**

| | | | |
|---|---|---|---|
| Concentration in surface water during emission episode (dissolved) | 3.69E-04 | [mg.l-1] | O |
| Concentration in surface water exceeds solubility | No | | O |
| Annual average concentration in surface water (dissolved) | 3.03E-04 | [mg.l-1] | O |
| Concentration in seawater during emission episode (dissolved) | 4.61E-05 | [mg.l-1] | O |
| Annual average concentration in seawater (dissolved) | 3.79E-05 | [mg.l-1] | O |

**SOIL. GROUNDWATER**

| | | | |
|---|---|---|---|
| Concentration in agric. soil averaged over 30 days | 0.0229 | [mg.kgwwt-1] | O |
| Concentration in agric. soil averaged over 180 days | 0.0224 | [mg.kgwwt-1] | O |
| Concentration in grassland averaged over 180 days | 6.32E-03 | [mg.kgwwt-1] | O |
| Fraction of steady-state (agricultural soil) | 0.627 | [-] | O |
| Fraction of steady-state (grassland soil) | 0.86 | [-] | O |

**LOCAL PECS [INDUSTRIAL USE]**
**AIR**

| | | | |
|---|---|---|---|
| Annual average local PEC in air (total) | 0 | [mg.m-3] | O |

**WATER. SEDIMENT**

| | | | |
|---|---|---|---|
| Local PEC in surface water during emission episode (dissolved) | 3.69E-04 | [mg.l-1] | O |
| Qualitative assessment might be needed (TGD Part II. 5.6) | No | | O |
| Annual average local PEC in surface water (dissolved) | 3.03E-04 | [mg.l-1] | O |
| Local PEC in fresh-water sediment during emission episode | 0.0179 | [mg.kgwwt-1] | O |
| Local PEC in seawater during emission episode (dissolved) | 4.61E-05 | [mg.l-1] | O |
| Qualitative assessment might be needed (TGD Part II. 5.6) | No | | O |
| Annual average local PEC in seawater (dissolved) | 3.79E-05 | [mg.l-1] | O |
| Local PEC in marine sediment during emission episode | 2.24E-03 | [mg.kgwwt-1] | O |

**SOIL. GROUNDWATER**

| | | | |
|---|---|---|---|
| Local PEC in agric. soil (total) averaged over 30 days | 0.0229 | [mg.kgwwt-1] | O |
| Local PEC in agric. soil (total) averaged over 180 days | 0.0224 | [mg.kgwwt-1] | O |
| Local PEC in grassland (total) averaged over 180 days | 6.32E-03 | [mg.kgwwt-1] | O |
| Local PEC in pore water of agricultural soil | 4.29E-03 | [mg.l-1] | O |
| Local PEC in pore water of grassland | 1.21E-03 | [mg.l-1] | O |
| Local PEC in groundwater under agricultural soil | 4.29E-03 | [mg.l-1] | O |

## Scenario [3b] – animal house disinfection (ducks): EUSES 2.1.2 output file Worst case scenario for PECsoil arable land

**DEFAULTS**
**DEFAULT IDENTIFICATION**

| | | |
|---|---|---|
| General name | Standard Euses 2.1 | D |
| Description | According to TGDs | D |

**CHARACTERISTICS OF COMPARTMENTS**
**GENERAL**

| | | | |
|---|---|---|---|
| Density of solid phase | 2.5 | [kg.l-1] | D |
| Density of water phase | 1 | [kg.l-1] | D |
| Density of air phase | 1.3E-03 | [kg.l-1] | D |
| Environmental temperature | 12 | [oC] | D |
| Standard temperature for Vp and Sol | 25 | [oC] | D |
| Temperature correction method | Temperature correction for local distribution | | D |
| Constant of Junge equation | 0.01 | [Pa.m] | D |
| Surface area of aerosol particles | 0.01 | [m2.m-3] | D |
| Gas constant (8.314) | 8.314 | [Pa.m3.mol-1.K-1] | D |

**SUSPENDED MATTER**

| | | | |
|---|---|---|---|
| Volume fraction solids in suspended matter | 0.1 | [m3.m-3] | D |
| Volume fraction water in suspended matter | 0.9 | [m3.m-3] | D |
| Weight fraction of organic carbon in suspended matter | 0.1 | [kg.kg-1] | |
| Bulk density of suspended matter | 1.15E+03 | [kgwwt.m-3] | |
| Conversion factor wet-dry suspened matter | 4.6 [kgwwt.kgdwt-1] | | O |

**SEDIMENT**

| | | | |
|---|---|---|---|
| Volume fraction solids in sediment | 0.2 | [m3.m-3] | D |
| Volume fraction water in sediment | 0.8 | [m3.m-3] | D |
| Weight fraction of organic carbon in sediment | 0.05 | [kg.kg-1] | D |

**SOIL**

| | | | |
|---|---|---|---|
| Volume fraction solids in soil | 0.6 | [m3.m-3] | D |
| Volume fraction water in soil | 0.2 | [m3.m-3] | D |
| Volume fraction air in soil | 0.2 | [m3.m-3] | D |
| Weight fraction of organic carbon in soil | 0.02 | [kg.kg-1] | D |
| Weight fraction of organic matter in soil | 0.034 | [kg.kg-1] | O |
| Bulk density of soil | 1.7E+03 | [kgwwt.m-3] | |
| Conversion factor wet-dry soil | 1.13 [kgwwt.kgdwt-1] | | O |

**STP SLUDGE**

| | | | |
|---|---|---|---|
| Fraction of organic carbon in raw sewage sludge | 0.3 | [kg.kg-1] | D |
| Fraction of organic carbon in settled sewage sludge | 0.3 | [kg.kg-1] | D |
| Fraction of organic carbon in activated sewage sludge | 0.37 | [kg.kg-1] | D |
| Fraction of organic carbon in effluent sewage sludge | 0.37 | [kg.kg-1] | D |

| | | | |
|---|---|---|---|
| **DEGRADATION AND TRANSFORMATION RATES** | | | |
| Rate constant for abiotic degradation in STP | 0 | [d-1] | D |
| Rate constant for abiotic degradation in bulk sediment | 0 | [d-1] (12[oC]) | |
| Rate constant for anaerobic biodegradation in sediment | 0 | [d-1] (12[oC]) | |
| Fraction of sediment compartment that is aerated | 0.1 | [m3.m-3] | D |
| Concentration of OH-radicals in atmosphere | 5E+05 | [molec.cm-3] | |
| Rate constant for abiotic degradation in bulk soil | 0 | [d-1] (12[oC]) | |
| **RELEASE ESTIMATION** | | | |
| Fraction of EU production volume for region | 100 | [%] | D |
| Fraction of EU tonnage for region (private use) | 10 | [%] | D |
| Fraction connected to sewer systems | 80 | [%] | D |
| **SEWAGE TREATMENT** | | | |
| **GENERAL** | | | |
| Number of inhabitants feeding one STP | 1E+04 | [eq] | D |
| Sewage flow | 200 | [l.eq-1.d-1] | D |
| Effluent discharge rate of local STP | 2E+06 | [l.d-1] | O |
| Temperature correction for STP degradation | No | | D |
| Temperature of air above aeration tank | 15 | [oC] | D |
| Temperature of water in aeration tank | 15 | [oC] | D |
| Height of air column above STP | 10 | [m] | D |
| Number of inhabitants of region | 2E+07 | [eq] | D |
| Number of inhabitants of continental system | 3.5E+08 | [eq] | O |
| Windspeed in the system | 3 | [m.s-1] | D |
| **RAW SEWAGE** | | | |
| Mass of O2 binding material per person per day | 54 | [g.eq-1.d-1] | |
| Dry weight solids produced per person per day | 0.09 | [kg.eq-1.d-1] | |
| Density solids in raw sewage | 1.5 | [kg.l-1] | D |
| Fraction of organic carbon in raw sewage sludge | 0.3 | [kg.kg-1] | D |
| **PRIMARY SETTLER** | | | |
| Depth of primary settler | 4 | [m] | D |
| Hydraulic retention time of primary settler | 2 | [hr] | D |
| Density suspended and settled solids in primary settler | 1.5 | [kg.l-1] | D |
| Fraction of organic carbon in settled sewage sludge | 0.3 | [kg.kg-1] | D |
| **ACTIVATED SLUDGE TANK** | | | |
| Depth of aeration tank | 3 | [m] | D |
| Density solids of activated sludge | 1.3 | [kg.l-1] | D |
| Concentration solids of activated sludge | 4 | [kg.m-3] | D |
| Steady state O2 concentration in activated sludge | 2E-03 | [kg.m-3] | D |
| Mode of aeration | Surface | | |
| Aeration rate of bubble aeration | 1.31E-05 | [m3.s-1.eq-1] | |
| Fraction of organic carbon in activated sewage sludge | 0.37 | [kg.kg-1] | D |
| Sludge loading rate | 0.15 | [kg.kg-1.d-1] | |
| Hydraulic retention time in aerator (9-box STP) | 6.9 | [hr] | O |
| Hydraulic retention time in aerator (6-box STP) | 10.8 | [hr] | O |
| Sludge retention time of aeration tank | 9.2 | [d] | O |
| **SOLIDS-LIQUIDS SEPARATOR** | | | |
| Depth of solids-liquid separator | 3 | [m] | D |
| Density suspended and settled solids in solids-liquid separator | 1.3 | [kg.l-1] | D |
| Concentration solids in effluent | 30 | [mg.l-1] | D |
| Hydraulic retention time of solids-liquid separator | 6 | [hr] | D |
| Fraction of organic carbon in effluent sewage sludge | 0.37 | [kg.kg-1] | D |
| **LOCAL DISTRIBUTION** | | | |
| **AIR AND SURFACE WATER** | | | |
| Concentration in air at source strength 1 [kg.d-1] | 2.78E-04 | [mg.m-3] | D |
| Standard deposition flux of aerosol-bound compounds | 0.01 | [mg.m-2.d-1] | |
| Standard deposition flux of gaseous compounds | 5E-04 | [mg.m-2.d-1] | |
| Suspended solids concentration in STP effluent water | 15 | [mg.l-1] | D |
| Dilution factor (rivers) | 10 | [-] | D |
| Flow rate of the river | 1.8E+04 | [m3.d-1] | D |
| Calculate dilution from river flow rate | No | | D |
| Dilution factor (coastal areas) | 100 | [-] | D |

| | | | |
|---|---|---|---|
| **SOIL** | | | |
| Mixing depth of grassland soil | 0.1 | [m] | D |
| Dry sludge application rate on agricultural soil | 5E+03 | [kg.ha-1.yr-1] | |
| Dry sludge application rate on grassland | 1000 | [kg.ha-1.yr-1] | |
| Averaging time soil (for terrestrial ecosystem) | 30 | [d] | D |
| Averaging time agricultural soil | 180 | [d] | D |
| Averaging time grassland | 180 | [d] | D |
| PMTC, air side of air-soil interface | 1.05E-03 | [m.s-1] | O |
| Soil-air PMTC (air-soil interface) | 5.56E-06 | [m.s-1] | D |
| Soil-water film PMTC (air-soil interface) | 5.56E-10 | [m.s-1] | D |
| Mixing depth agricultural soil | 0.2 | [m] | D |
| Fraction of rain water infiltrating soil | 0.25 | [-] | D |
| Average annual precipitation | 700 | [mm.yr-1] | D |
| **REGIONAL AND CONTINENTAL DISTRIBUTION CONFIGURATION** | | | |
| Fraction of direct regional emissions to seawater | 1 | [%] | D |
| Fraction of direct continental emissions to seawater | 0 | [%] | D |
| Fraction of regional STP effluent to seawater | 0 | [%] | D |
| Fraction of continental STP effluent to seawater | 0 | [%] | D |
| Fraction of flow from continental rivers to regional rivers | 0.034 | [-] | D |
| Fraction of flow from continental rivers to regional sea | 0 | [-] | D |
| Fraction of flow from continental rivers to continental sea | 0.966 | [-] | O |
| Number of inhabitants of region | 2E+07 | [eq] | D |
| Number of inhabitants in the EU | 3.7E+08 | [eq] | D |
| Number of inhabitants of continental system | 3.5E+08 | [eq] | O |
| **AREAS** | | | |
| **REGIONAL** | | | |
| Area (land+rivers) of regional system | 4E+04 | [km2] | D |
| Area fraction of freshwater, region (excl. sea) | 0.03 | [-] | D |
| Area fraction of natural soil, region (excl. sea) | 0.27 | [-] | D |
| Area fraction of agricultural soil, region (excl. sea) | 0.6 | [-] | D |
| Area fraction of industrial/urban soil, region (excl. sea) | 0.1 | [-] | D |
| Length of regional seawater | 40 | [km] | D |
| Width of regional seawater | 10 | [km] | D |
| Area of regional seawater | 400 | [km2] | O |
| Area (land+rivers+sea) of regional system | 4.04E+04 | [km2] | O |
| Area fraction of freshwater, region (total) | 0.0297 | [-] | O |
| Area fraction of seawater, region (total) | 9.9E-03 | [-] | O |
| Area fraction of natural soil, region (total) | 0.267 | [-] | O |
| Area fraction of agricultural soil, region (total) | 0.594 | [-] | O |
| Area fraction of industrial/urban soil, region (total) | 0.099 | [-] | O |
| **CONTINENTAL** | | | |
| Total area of EU (continent+region, incl. sea) | 7.04E+06 | [km2] | D |
| Area (land+rivers+sea) of continental system | 7E+06 | [km2] | O |
| Area (land+rivers) of continental system | 3.5E+06 | [km2] | O |
| Area fraction of freshwater, continent (excl. sea) | 0.03 | [-] | D |
| Area fraction of natural soil, continent (excl. sea) | 0.27 | [-] | D |
| Area fraction of agricultural soil, continent (excl. sea) | 0.6 | [-] | D |
| Area fraction of industrial/urban soil, continent (excl. sea) | 0.1 | [-] | D |
| Area fraction of freshwater, continent (total) | 0.015 | [-] | O |
| Area fraction of seawater, continent (total) | 0.5 | [-] | D |
| Area fraction of natural soil, continent (total) | 0.135 | [-] | O |
| Area fraction of agricultural soil, continent (total) | 0.3 | [-] | O |
| Area fraction of industrial/urban soil, continent (total) | 0.05 | [-] | O |
| **MODERATE** | | | |
| Area of moderate system (incl.continent,region) | 8.5E+07 | [km2] | D |
| Area of moderate system (excl.continent, region) | 7.8E+07 | [km2] | O |
| Area fraction of water, moderate system | 0.5 | [-] | D |
| **ARCTIC** | | | |
| Area of arctic system | 4.25E+07 | [km2] | D |
| Area fraction of water, arctic system | 0.6 | [-] | D |
| **TROPIC** | | | |
| Area of tropic system | 1.275E+08 | [km2] | D |
| Area fraction of water, tropic system | 0.7 | [-] | D |

| | | | |
|---|---|---|---|
| **TEMPERATURE** | | | |
| Environmental temperature, regional scale | 12 | [oC] | D |
| Environmental temperature, continental scale | 12 | [oC] | D |
| Environmental temperature, moderate scale | 12 | [oC] | D |
| Environmental temperature, arctic scale | -10 | [oC] | D |
| Environmental temperature, tropic scale | 25 | [oC] | D |
| Enthalpy of vaporisation | 50 | [kJ.mol-1] | D |
| Enthalpy of solution | 10 | [kJ.mol-1] | D |
| **MASS TRANSFER** | | | |
| Air-film PMTC (air-water interface) | 3.71E-03 | [m.s-1] | O |
| Water-film PMTC (air-water interface) | 4.53E-06 | [m.s-1] | O |
| PMTC, air side of air-soil interface | 1.05E-03 | [m.s-1] | O |
| PMTC, soil side of air-soil interface | 6.34E-10 | [m.s-1] | O |
| Soil-air PMTC (air-soil interface) | 5.56E-06 | [m.s-1] | D |
| Soil-water film PMTC (air-soil interface) | 5.56E-10 | [m.s-1] | D |
| Water-film PMTC (sediment-water interface) | 2.78E-06 | [m.s-1] | D |
| Pore water PMTC (sediment-water interface) | 2.78E-08 | [m.s-1] | D |
| **AIR** | | | |
| **GENERAL** | | | |
| Atmospheric mixing height | 1000 | [m] | D |
| Windspeed in the system | 3 | [m.s-1] | D |
| Aerosol deposition velocity | 1E-03 | [m.s-1] | D |
| Aerosol collection efficiency | 2E+05 | [-] | D |
| **RAIN** | | | |
| Average precipitation, regional system | 700 | [mm.yr-1] | D |
| Average precipitation, continental system | 700 | [mm.yr-1] | D |
| Average precipitation, moderate system | 700 | [mm.yr-1] | D |
| Average precipitation, arctic system | 250 | [mm.yr-1] | D |
| Average precipitation, tropic system | 1.3E+03 | [mm.yr-1] | D |
| **RESIDENCE TIMES** | | | |
| Residence time of air, regional | 0.687 | [d] | O |
| Residence time of air, continental | 9.05 | [d] | O |
| Residence time of air, moderate | 30.2 | [d] | O |
| Residence time of air, arctic | 22.3 | [d] | O |
| Residence time of air, tropic | 38.6 | [d] | O |
| **WATER** | | | |
| **DEPTH** | | | |
| Water depth of freshwater, regional system | 3 | [m] | D |
| Water depth of seawater, regional system | 10 | [m] | D |
| Water depth of freshwater, continental system | 3 | [m] | D |
| Water depth of seawater, continental system | 200 | [m] | D |
| Water depth, moderate system | 1000 | [m] | D |
| Water depth, arctic system | 1000 | [m] | D |
| Water depth, tropic system | 1000 | [m] | D |
| **SUSPENDED SOLIDS** | | | |
| Suspended solids conc. freshwater, regional | 15 | [mg.l-1] | D |
| Suspended solids conc. seawater, regional | 5 | [mg.l-1] | D |
| Suspended solids conc. freshwater, continental | 15 | [mg.l-1] | D |
| Suspended solids conc. seawater, continental | 5 | [mg.l-1] | D |
| Suspended solids conc. seawater, moderate | 5 | [mg.l-1] | D |
| Suspended solids conc. seawater, arctic | 5 | [mg.l-1] | D |
| Suspended solids conc. seawater, tropic | 5 | [mg.l-1] | D |
| Concentration solids in effluent, regional | 30 | [mg.l-1] | D |
| Concentration solids in effluent, continental | 30 | [mg.l-1] | D |
| Concentration biota | 1 | [mgwwt.l-1] | |
| **RESIDENCE TIMES** | | | |
| Residence time of freshwater, regional | 43.3 | [d] | O |
| Residence time of seawater, regional | 4.64 | [d] | O |
| Residence time of freshwater, continental | 172 | [d] | O |
| Residence time of seawater, continental | 365 | [d] | O |
| Residence time of water, moderate | 2.69E+03 | [d] | O |
| Residence time of water, arctic | 5.84E+03 | [d] | O |
| Residence time of water, tropic | 1.09E+04 | [d] | O |
| **SEDIMENT** | | | |
| **DEPTH** | | | |
| Sediment mixing depth | 0.03 | [m] | D |

| | | | |
|---|---|---|---|
| **SUSPENDED SOLIDS** | | | |
| (Biogenic) prod. susp. solids in freshwater, reg | 10 | [g.m-2.yr-1] | |
| (Biogenic) prod. susp. solids in seawater, reg | 10 | [g.m-2.yr-1] | |
| (Biogenic) prod. susp. solids in freshwater, cont | 10 | [g.m-2.yr-1] | |
| (Biogenic) prod. susp. solids in seawater, cont | 5 | [g.m-2.yr-1] | |
| (Biogenic) prod. susp. solids in water, moderate | 1 | [g.m-2.yr-1] | |
| (Biogenic) prod. susp. solids in water, arctic | 1 | [g.m-2.yr-1] | |
| (Biogenic) prod. susp. solids in water, tropic | 1 | [g.m-2.yr-1] | |
| **SEDIMENTATION RATES** | | | |
| Settling velocity of suspended solids | 2.5 | [m.d-1] | D |
| Net sedimentation rate, freshwater, regional | 2.8 | [mm.yr-1] | O |
| Net sedimentation rate, seawater, regional | 1.53 | [mm.yr-1] | O |
| Net sedimentation rate, freshwater, continental | 2.75 | [mm.yr-1] | O |
| Net sedimentation rate, seawater, continental | 6.69E-03 | [mm.yr-1] | O |
| Net sedimentation rate, moderate | 2.8E-03 | [mm.yr-1] | O |
| Net sedimentation rate, arctic | 2E-03 | [mm.yr-1] | O |
| Net sedimentation rate, tropic | 2E-03 | [mm.yr-1] | O |
| **SOIL** | | | |
| **GENERAL** | | | |
| Fraction of rain water infiltrating soil | 0.25 | [-] | D |
| Fraction of rain water running off soil | 0.25 | [-] | D |
| **DEPTH** | | | |
| Chemical-dependent soil depth | No | | D |
| Mixing depth natural soil | 0.05 | [m] | D |
| Mixing depth agricultural soil | 0.2 | [m] | D |
| Mixing depth industrial/urban soil | 0.05 | [m] | D |
| Mixing depth of soil, moderate system | 0.05 | [m] | D |
| Mixing depth of soil, arctic system | 0.05 | [m] | D |
| Mixing depth of soil, tropic system | 0.05 | [m] | D |
| **EROSION** | | | |
| Soil erosion rate, regional system | 0.03 | [mm.yr-1] | D |
| Soil erosion rate, continental system | 0.03 | [mm.yr-1] | D |
| Soil erosion rate, moderate system | 0.03 | [mm.yr-1] | D |
| Soil erosion rate, arctic system | 0.03 | [mm.yr-1] | D |
| Soil erosion rate, tropic system | 0.03 | [mm.yr-1] | D |
| **CHARACTERISTICS OF PLANTS, WORMS AND CATTLE** | | | |
| **PLANTS** | | | |
| Volume fraction of water in plant tissue | 0.65 | [m3.m-3] | D |
| Volume fraction of lipids in plant tissue | 0.01 | [m3.m-3] | D |
| Volume fraction of air in plant tissue | 0.3 | [m3.m-3] | D |
| Correction for differences between plant lipids and octanol | 0.95 | [-] | D |
| Bulk density of plant tissue (wet weight) | 0.7 | [kg.l-1] | D |
| Rate constant for metabolism in plants | 0 | [d-1] | D |
| Rate constant for photolysis in plants | 0 | [d-1] | D |
| Leaf surface area | 5 | [m2] | D |
| Conductance | 1E-03 | [m.s-1] | D |
| Shoot volume | 2 | [l] | D |
| Rate constant for dilution by growth | 0.035 | [d-1] | D |
| Transpiration stream | 1 | [l.d-1] | D |
| **WORMS** | | | |
| Volume fraction of water inside a worm | 0.84 | [m3.m-3] | D |
| Volume fraction of lipids inside a worm | 0.012 | [m3.m-3] | D |
| Density of earthworms | 1 | [kgwwt.l-1] | D |
| Fraction of gut loading in worm | 0.1 | [kg.kg-1] | D |
| **CATTLE** | | | |
| Daily intake for cattle of grass (dryweight) | 16.9 | [kg.d-1] | D |
| Conversion factor grass from dryweight to wetweight | 4 | [kg.kg-1] | D |
| Daily intake of soil (dryweight) | 0.41 | [kg.d-1] | D |
| Daily inhalation rate for cattle | 122 | [m3.d-1] | D |
| Daily intake of drinking water for cattle | 55 | [l.d-1] | D |
| **SUBSTANCE** | | | |
| **SUBSTANCE IDENTIFICATION** | | | |
| General name | BPF_Iodine_VET_17_ducks_refine_0.07 | | |
| 5% | S | | |
| Description | BPF_Iodine_VET_17_ducks_refine_0.07 | | |

| | | | |
|---|---|---|---|
| 5% | S | | |
| CAS-No | | | D |
| EC-notification no. | | | D |
| EINECS no. | | | D |
| **PHYSICO-CHEMICAL PROPERTIES** | | | |
| Molecular weight | 253.81 | [g.mol-1] | S |
| Melting point | 113.7 | [oC] | S |
| Boiling point | 184.5 | [oC] | S |
| Vapour pressure at test temperature | 1E-06 | [Pa] | S |
| Temperature at which vapour pressure was measured | 25 | [oC] | D |
| Vapour pressure at 25 [oC] | 1E-06 | [Pa] | O |
| Octanol-water partition coefficient | 2.49 | [log10] | S |
| Water solubility at test temperature | 1E+05 | [mg.l-1] | S |
| Temperature at which solubility was measured | 25 | [oC] | D |
| Water solubility at 25 [oC] | 1E+05 | [mg.l-1] | O |
| **PARTITION COEFFICIENTS AND BIOCONCENTRATION FACTORS** | | | |
| **SOLIDS-WATER** | | | |
| Chemical class for Koc-QSAR | Non-hydrophobics (default QSAR) | | D |
| Organic carbon-water partition coefficient | 206 | [l.kg-1] | O |
| Solids-water partition coefficient in soil | 5.8 | [l.kg-1] | S |
| Solids-water partition coefficient in sediment | 200 | [l.kg-1] | S |
| Solids-water partition coefficient suspended matter | 220 | [l.kg-1] | S |
| Solids-water partition coefficient in raw sewage sludge | 61.9 | [l.kg-1] | O |
| Solids-water partition coefficient in settled sewage sludge | 61.9 | [l.kg-1] | O |
| Solids-water partition coefficient in activated sewage sludge | 76.4 | [l.kg-1] | O |
| Solids-water partition coefficient in effluent sewage sludge | 76.4 | [l.kg-1] | O |
| Soil-water partition coefficient | 8.9 | [m3.m-3] | O |
| Suspended matter-water partition coefficient | 55.9 | [m3.m-3] | O |
| Sediment-water partition coefficient | 101 | [m3.m-3] | O |
| **AIR-WATER** | | | |
| Environmental temperature | 12 | [oC] | D |
| Water solubility at environmental temperature | 8.32E+04 | [mg.l-1] | O |
| Vapour pressure at environmental temperature | 3.98E-07 | [Pa] | O |
| Sub-cooled liquid vapour pressure | 4.49E-06 | [Pa] | O |
| Fraction of chemical associated with aerosol particles | 0.957 | [-] | O |
| Henry's law constant at test temparature | ?? | [Pa.m3.mol-1] | D |
| Temperature at which Henry's law constant was measured | 25 | [oC] | D |
| Henry's law constant at 25 [oC] | 2.54E-09 | [Pa.m3.mol-1] | O |
| Henry's law constant at enviromental temparature | 1.22E-09 | [Pa.m3.mol-1] | O |
| Air-water partitioning coefficient | 5.13E-13 | [m3.m-3] | O |
| **BIOCONCENTRATION FACTORS** | | | |
| **PREDATOR EXPOSURE** | | | |
| Bioconcentration factor for earthworms | 4.55 | [l.kgwwt-1] | O |
| **HUMAN AND PREDATOR EXPOSURE** | | | |
| Bioconcentration factor for fish | 26.1 | [l.kgwwt-1] | O |
| QSAR valid for calculation of BCF-Fish | Yes | | O |
| Biomagnification factor in fish | 1 | [-] | O |
| Biomagnification factor in predator | 1 | [-] | O |
| **HUMAN EXPOSURE** | | | |
| Partition coefficient between leaves and air | 5.79E+12 | [m3.m-3] | O |
| Partition coefficient between plant tissue and water | 2.97 | [m3.m-3] | O |
| Transpiration-stream concentration factor | 0.638 | [-] | O |
| Bioaccumulation factor for meat | 7.76E-06 | [d.kg-1] | O |
| Bioaccumulation factor for milk | 7.94E-06 | [d.kg-1] | O |
| Purification factor for surface water | 1 | [-] | O |
| **DEGRADATION AND TRANSFORMATION RATES** | | | |
| **CHARACTARIZATION** | | | |
| Characterization of biodegradability | Not biodegradable | | D |

| | | | |
|---|---|---|---|
| **STP** | | | |
| Degradation calculation method in STP | First order, standard OECD/EU tests | | D |
| Rate constant for biodegradation in STP | 0 | [d-1] | O |
| Total rate constant for degradation in STP | 0 | [d-1] | O |
| Maximum growth rate of specific microorganisms | 2 | [d-1] | D |
| Half saturation concentration | 0.5 | [g.m-3] | D |
| **WATER/SEDIMENT** | | | |
| **WATER** | | | |
| Rate constant for hydrolysis in surface water | 6.93E-07 | [d-1] (12[oC]) | |
| Rate constant for photolysis in surface water | 6.93E-07 | [d-1] | O |
| Rate constant for biodegradation in surface water | 0 | [d-1] (12[oC]) | |
| Total rate constant for degradation in bulk surface water | 1.39E-06 | [d-1] (12[oC]) | |
| Rate constant for biodegradation in saltwater | 0 | [d-1] (12[oC]) | |
| Total rate constant for degradation in bulk saltwater | 1.39E-06 | [d-1] (12[oC]) | |
| **SEDIMENT** | | | |
| Rate constant for biodegradation in aerated sediment | 6.93E-07 | [d-1] (12[oC]) | |
| Total rate constant for degradation in bulk sediment | 6.93E-08 | [d-1] (12[oC]) | |
| **AIR** | | | |
| Specific degradation rate constant with OH-radicals | 0 | [cm3.molec-1.s-1] | D |
| Rate constant for degradation in air | 0 | [d-1] | O |
| **SOIL** | | | |
| Rate constant for biodegradation in bulk soil | 6.93E-07 | [d-1] (12[oC]) | |
| Total rate constant for degradation in bulk soil | 6.93E-07 | [d-1] (12[oC]) | |
| **REMOVAL RATE CONSTANTS SOIL** | | | |
| Total rate constant for degradation in bulk soil | 6.93E-07 | [d-1] (12[oC]) | |
| Rate constant for volatilisation from agricultural soil | 2.61E-11 | [d-1] | O |
| Rate constant for leaching from agricultural soil | 2.69E-04 | [d-1] | O |
| Total rate constant for removal from agricultural top soil | 2.7E-04 | [d-1] | O |
| Rate constant for volatilisation from grassland soil | 5.22E-11 | [d-1] | O |
| Rate constant for leaching from grassland soil | 5.39E-04 | [d-1] | O |
| Total rate constant for removal from grassland top soil | 5.39E-04 | [d-1] | O |
| Rate constant for volatilisation from industrial soil | 1.04E-10 | [d-1] | O |
| Rate constant for leaching from industrial soil | 1.08E-03 | [d-1] | O |
| Total rate constant for removal from industrial soil | 1.08E-03 | [d-1] | O |
| **RELEASE ESTIMATION** | | | |
| **BIOCIDE SCENARIO INPUT DATA** | | | |
| Usage/production title | | | D |
| Scenario choice for biocides | (1) Human Hygiene | | S |
| **INDUSTRIAL USE** | | | |
| Emission scenario | Local wastewater emission | | |
| (ELocalWater) | S | | |
| **INTERMEDIATE RESULTS** | | | |
| **RELEASE FRACTIONS AND EMISSION DAYS** | | | |
| **INDUSTRIAL USE** | | | |
| **APPLICATION** | | | |
| Use tonnage or application data | Application data | | S |
| Tonnage of substance in Europe | 0 | [tonnes.yr-1] | |
| Regional tonnage of substance | 0 | [tonnes.yr-1] | |
| Type of industrial human hygiene product | Others | | D |
| Consumption of active ingredient per bed | 0.038 | [g.d-1] | O |
| Consumption of active ingredient per occupied bed | 0.0507 | [g.d-1] | O |
| Number of emission days per year | 300 | [-] | S |
| Local emission to wastewater during episode | 0.0732 | [kg.d-1] | S |
| **DEFAULTS** | | | |
| Fraction of EU production volume for region | 10 | [%] | D |
| Fraction of the local main source | 7E-03 | [-] | D |
| Fraction released to wastewater | 1 | [-] | D |
| Number of emission days, industrial use | 365 | [d] | D |
| Number of beds in model hospital | 400 | [-] | D |
| Occupancy rate | 0.75 | [-] | D |
| Number of occupied beds in model hospital | 300 | [-] | O |

**LOCAL**
**[INDUSTRIAL USE]**

| | | | |
|---|---|---|---|
| Local emission to air during episode | 0 | [kg.d-1] | O |
| Emission to air calculated by special scenario | Yes | | O |
| Local emission to wastewater during episode | 0.0732 | [kg.d-1] | S |
| Emission to water calculated by special scenario | Yes | | O |
| Specific biocides scenario available | Yes | | D |
| Show this step in further calculations | Yes | | O |
| Intermittent release | No | | S |

**DISTRIBUTION**
**SEWAGE TREATMENT**
**CONTINENTAL**

| | | | |
|---|---|---|---|
| Fraction of emission directed to air | 0 | [%] | O |
| Fraction of emission directed to water | 80 | [%] | S |
| Fraction of emission directed to sludge | 20 | [%] | S |
| Fraction of the emission degraded | 0 | [%] | O |
| Total of fractions | 100 | [%] | O |
| Indirect emission to air | 0 | [kg.d-1] | O |
| Indirect emission to surface water | 0 | [kg.d-1] | O |
| Indirect emission to agricultural soil | 0 | [kg.d-1] | O |

**REGIONAL**

| | | | |
|---|---|---|---|
| Fraction of emission directed to air | 0 | [%] | O |
| Fraction of emission directed to water | 80 | [%] | S |
| Fraction of emission directed to sludge | 20 | [%] | S |
| Fraction of the emission degraded | 0 | [%] | O |
| Total of fractions | 100 | [%] | O |
| Indirect emission to air | 0 | [kg.d-1] | O |
| Indirect emission to surface water | 0 | [kg.d-1] | O |
| Indirect emission to agricultural soil | 0 | [kg.d-1] | O |

**[INDUSTRIAL USE]**
**INPUT AND CONFIGURATION [INDUSTRIAL USE]**
**INPUT**

| | | | |
|---|---|---|---|
| Use or bypass STP (local freshwater assessment) | Use STP | | D |
| Use or bypass STP (local marine assessment) | Bypass STP | | D |
| Local emission to wastewater during episode | 0.0732 | [kg.d-1] | S |
| Concentration in untreated wastewater | 0.0366 | [mg.l-1] | O |
| Local emission entering the STP | 0.0732 | [kg.d-1] | O |

**CONFIGURATION**

| | | | |
|---|---|---|---|
| Type of local STP | With primary settler (9-box) | | D |
| Number of inhabitants feeding this STP | 1E+04 | [eq] | O |
| Effluent discharge rate of this STP | 2E+06 | [l.d-1] | O |
| Calculate dilution from river flow rate | No | | O |
| Flow rate of the river | 1.8E+04 | [m3.d-1] | O |
| Dilution factor (rivers) | 10 | [-] | O |
| Dilution factor (coastal areas) | 100 | [-] | O |

**OUTPUT [INDUSTRIAL USE]**

| | | | |
|---|---|---|---|
| Fraction of emission directed to air by STP | 0 | [%] | S |
| Fraction of emission directed to water by STP | 80 | [%] | S |
| Fraction of emission directed to sludge by STP | 20 | [%] | S |
| Fraction of the emission degraded in STP | 0 | [%] | O |
| Total of fractions | 100 | [%] | O |
| Local indirect emission to air from STP during episode | 0 | [kg.d-1] | O |
| Concentration in untreated wastewater | 0.0366 | [mg.l-1] | O |
| Concentration of chemical (total) in the STP-effluent | 0.0293 | [mg.l-1] | O |
| Concentration in effluent exceeds solubility | No | | O |
| Concentration in dry sewage sludge | 18.5 | [mg.kg-1] | O |
| PEC for micro-organisms in the STP | 0.0293 | [mg.l-1] | O |

**LIFE CYCLE STEPS**
**[INDUSTRIAL USE]**
**LOCAL CONCENTRATIONS AND DEPOSITIONS [INDUSTRIAL USE]**
**AIR**

| | | | |
|---|---|---|---|
| Concentration in air during emission episode | 0 | [mg.m-3] | O |
| Annual average concentration in air, 100 m from point source | 0 | [mg.m-3] | |
| Total deposition flux during emission episode | 0 | [mg.m-2.d-1] | |
| Annual average total deposition flux | 0 | [mg.m-2.d-1] | |

| | | | |
|---|---|---|---|
| **WATER, SEDIMENT** | | | |
| Concentration in surface water during emission episode (dissolved) | 2.92E-03 | [mg.l-1] | O |
| Concentration in surface water exceeds solubility | No | | O |
| Annual average concentration in surface water (dissolved) | 2.4E-03 | [mg.l-1] | O |
| Concentration in seawater during emission episode (dissolved) | 3.65E-04 | [mg.l-1] | O |
| Annual average concentration in seawater (dissolved) | 3E-04 | [mg.l-1] | O |
| **SOIL, GROUNDWATER** | | | |
| Concentration in agric. soil averaged over 30 days | 0.181 | [mg.kgwwt-1] | |
| Concentration in agric. soil averaged over 180 days | 0.178 | [mg.kgwwt-1] | |
| Concentration in grassland averaged over 180 days | 0.05 | [mg.kgwwt-1] | |
| Fraction of steady-state (agricultural soil) | 0.627 | [-] | O |
| Fraction of steady-state (grassland soil) | 0.86 | [-] | O |
| **LOCAL PECS [INDUSTRIAL USE]** | | | |
| **AIR** | | | |
| Annual average local PEC in air (total) | 0 | [mg.m-3] | O |
| **WATER, SEDIMENT** | | | |
| Local PEC in surface water during emission episode (dissolved) | 2.92E-03 | [mg.l-1] | O |
| Qualitative assessment might be needed (TGD Part II, 5.6) | No | | O |
| Annual average local PEC in surface water (dissolved) | 2.4E-03 | [mg.l-1] | O |
| Local PEC in fresh-water sediment during emission episode | 0.142 | [mg.kgwwt-1] | |
| Local PEC in seawater during emission episode (dissolved) | 3.65E-04 | [mg.l-1] | O |
| Qualitative assessment might be needed (TGD Part II, 5.6) | No | | O |
| Annual average local PEC in seawater (dissolved) | 3E-04 | [mg.l-1] | O |
| Local PEC in marine sediment during emission episode | 0.0177 | [mg.kgwwt-1] | |
| **SOIL, GROUNDWATER** | | | |
| Local PEC in agric. soil (total) averaged over 30 days | 0.181 | [mg.kgwwt-1] | |
| Local PEC in agric. soil (total) averaged over 180 days | 0.178 | [mg.kgwwt-1] | |
| Local PEC in grassland (total) averaged over 180 days | 0.05 | [mg.kgwwt-1] | |
| Local PEC in pore water of agricultural soil | 0.0339 | [mg.l-1] | O |
| Local PEC in pore water of grassland | 9.55E-03 | [mg.l-1] | O |
| Local PEC in groundwater under agricultural soil | 0.0339 | [mg.l-1] | O |

## Scenario [3c] – animal house disinfection (turkey): EUSES 2.1.2 output file Worst case scenario for concentration in untreated waste water ($Elocal_{waste\ water}$)

| | | | |
|---|---|---|---|
| **RELEASE ESTIMATION** | | | |
| **BIOCIDE SCENARIO INPUT DATA** | | | |
| Usage/production title | | | D |
| Scenario choice for biocides | (1) Human Hygiene | | S |
| **INDUSTRIAL USE** | | | |
| Emission scenario | Local wastewater emission | | |
| (ELocalWater) | S | | |
| **INTERMEDIATE RESULTS** | | | |
| **RELEASE FRACTIONS AND EMISSION DAYS** | | | |
| **INDUSTRIAL USE** | | | |
| **APPLICATION** | | | |
| Use tonnage or application data | Application data | | S |
| Tonnage of substance in Europe | 0 | [tonnes.yr-1] | |
| Regional tonnage of substance | 0 | [tonnes.yr-1] | |
| Type of industrial human hygiene product | Others | | D |
| Consumption of active ingredient per bed | 0.038 | [g.d-1] | O |
| Consumption of active ingredient per occupied bed | 0.0507 | [g.d-1] | O |
| Number of emission days per year | 300 | [-] | S |
| Local emission to wastewater during episode | 0.121 | [kg.d-1] | S |
| **DEFAULTS** | | | |
| Fraction of EU production volume for region | 10 | [%] | D |
| Fraction of the local main source | 7E-03 | [-] | D |
| Fraction released to wastewater | 1 | [-] | D |
| Number of emission days, industrial use | 365 | [d] | D |
| Number of beds in model hospital | 400 | [-] | D |
| Occupancy rate | 0.75 | [-] | D |
| Number of occupied beds in model hospital | 300 | [-] | O |

**LOCAL**
**[INDUSTRIAL USE]**

| | | | |
|---|---|---|---|
| Local emission to air during episode | 0 | [kg.d-1] | O |
| Emission to air calculated by special scenario | Yes | | O |
| Local emission to wastewater during episode | 0.121 | [kg.d-1] | S |
| Emission to water calculated by special scenario | Yes | | O |
| Specific biocides scenario available | Yes | | D |
| Show this step in further calculations | Yes | | O |
| Intermittent release | No | | S |

**[INDUSTRIAL USE]**
**INPUT AND CONFIGURATION [INDUSTRIAL USE]**
**INPUT**

| | | | |
|---|---|---|---|
| Use or bypass STP (local freshwater assessment) | Use STP | | D |
| Use or bypass STP (local marine assessment) | Bypass STP | | D |
| Local emission to wastewater during episode | 0.121 | [kg.d-1] | S |
| Concentration in untreated wastewater | 0.0605 | [mg.l-1] | O |
| Local emission entering the STP | 0.121 | [kg.d-1] | O |

**CONFIGURATION**

| | | | |
|---|---|---|---|
| Type of local STP | With primary settler (9-box) | | D |
| Number of inhabitants feeding this STP | 1E+04 | [eq] | O |
| Effluent discharge rate of this STP | 2E+06 | [l.d-1] | O |
| Calculate dilution from river flow rate | No | | O |
| Flow rate of the river | 1.8E+04 | [m3.d-1] | O |
| Dilution factor (rivers) | 10 | [-] | O |
| Dilution factor (coastal areas) | 100 | [-] | O |

**OUTPUT [INDUSTRIAL USE]**

| | | | |
|---|---|---|---|
| Fraction of emission directed to air by STP | 0 | [%] | S |
| Fraction of emission directed to water by STP | 80 | [%] | S |
| Fraction of emission directed to sludge by STP | 20 | [%] | S |
| Fraction of the emission degraded in STP | 0 | [%] | O |
| Total of fractions | 100 | [%] | O |
| Local indirect emission to air from STP during episode | 0 | [kg.d-1] | O |
| Concentration in untreated wastewater | 0.0605 | [mg.l-1] | O |
| Concentration of chemical (total) in the STP-effluent | 0.0484 | [mg.l-1] | O |
| Concentration in effluent exceeds solubility | No | | O |
| Concentration in dry sewage sludge | 30.6 | [mg.kg-1] | O |
| PEC for micro-organisms in the STP | 0.0484 | [mg.l-1] | O |

**LIFE CYCLE STEPS**
**[INDUSTRIAL USE]**
**LOCAL CONCENTRATIONS AND DEPOSITIONS [INDUSTRIAL USE]**
**AIR**

| | | | |
|---|---|---|---|
| Concentration in air during emission episode | 0 | [mg.m-3] | O |
| Annual average concentration in air, 100 m from point source | 0 | [mg.m-3] | O |
| Total deposition flux during emission episode | 0 | [mg.m-2.d-1] | |
| Annual average total deposition flux | 0 | [mg.m-2.d-1] | |

**WATER, SEDIMENT**

| | | | |
|---|---|---|---|
| Concentration in surface water during emission episode (dissolved) | 4.82E-03 | [mg.l-1] | O |
| Concentration in surface water exceeds solubility | No | | O |
| Annual average concentration in surface water (dissolved) | 3.96E-03 | [mg.l-1] | O |
| Concentration in seawater during emission episode (dissolved) | 6.03E-04 | [mg.l-1] | O |
| Annual average concentration in seawater (dissolved) | 4.96E-04 | [mg.l-1] | O |

**SOIL, GROUNDWATE**

| | | | |
|---|---|---|---|
| Concentration in agric. soil averaged over 30 days | 0.3 | [mg.kgwwt-1] | |
| Concentration in agric. soil averaged over 180 days | 0.294 | [mg.kgwwt-1] | |
| Concentration in grassland averaged over 180 days | 0.0827 | [mg.kgwwt-1] | |
| Fraction of steady-state (agricultural soil) | 0.627 | [-] | O |
| Fraction of steady-state (grassland soil) | 0.86 | [-] | O |

**LOCAL PECS [INDUSTRIAL USE]**
**AIR**

| | | | |
|---|---|---|---|
| Annual average local PEC in air (total) | 0 | [mg.m-3] | O |

**WATER, SEDIMENT**

| | | |
|---|---|---|
| Local PEC in surface water during emission episode (dissolved) | 4.82E-03 | [mg.l-1] O |
| Qualitative assessment might be needed (TGD Part II, 5.6) | No | O |
| Annual average local PEC in surface water (dissolved) | 3.96E-03 | [mg.l-1] O |
| Local PEC in fresh-water sediment during emission episode | 0.234 | [mg.kgwwt-1] |
| Local PEC in seawater during emission episode (dissolved) | 6.03E-04 | [mg.l-1] O |
| Qualitative assessment might be needed (TGD Part II, 5.6) | No | O |
| Annual average local PEC in seawater (dissolved) | 4.96E-04 | [mg.l-1] O |
| Local PEC in marine sediment during emission episode | 0.0293 | [mg.kgwwt-1] |

**SOIL, GROUNDWATE**

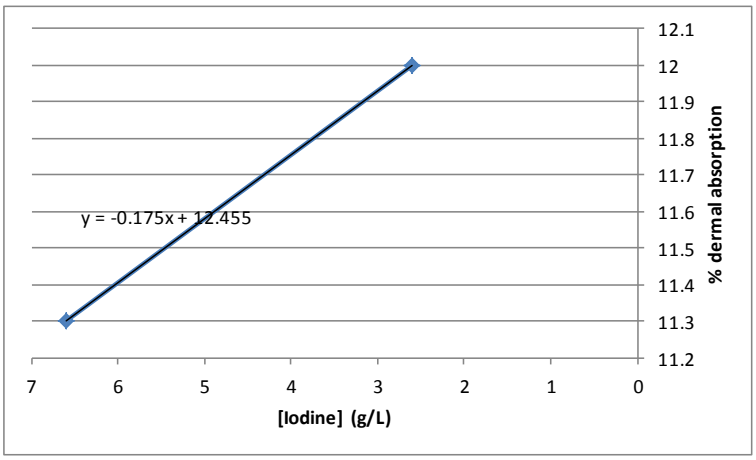
| | | |
|---|---|---|
| Local PEC in agric. soil (total) averaged over 30 days | 0.3 | [mg.kgwwt-1] |
| Local PEC in agric. soil (total) averaged over 180 days | 0.294 | [mg.kgwwt-1] |
| Local PEC in grassland (total) averaged over 180 days | 0.0827 | [mg.kgwwt-1] |
| Local PEC in pore water of agricultural soil | 0.0561 | [mg.l-1] O |
| Local PEC in pore water of grassland | 0.0158 | [mg.l-1] O |
| Local PEC in groundwater under agricultural soil | 0.0561 | [mg.l-1] O |

## 3.3 New information on the active substance

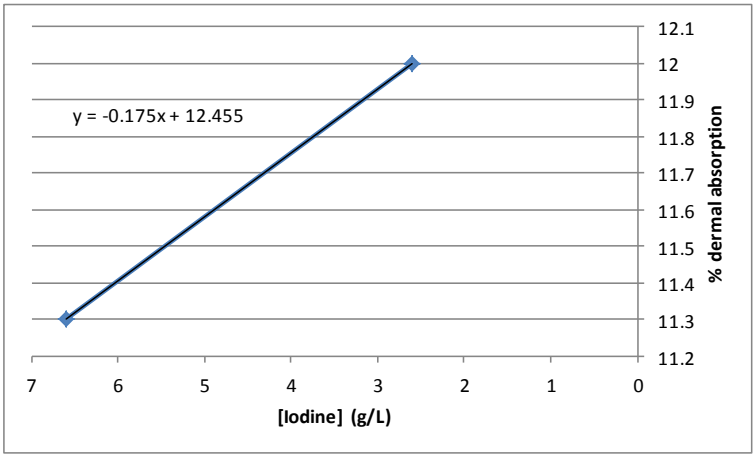
**Linear extrapolations of dermal absorption for Iodine based on CAR data.**

Extrapolations were performed using the Add Trend line function in Microsoft Excel.

| g/L | %DA |
|---|---|
| 6.6 | 11.3 |
| 2.6 | 12 |
| 5 | 11.6 |




| g/L | %DA |
|---|---|
| 6.6 | 11.3 |
| 2.6 | 12 |
| 0.2 | 12.4 |




## 3.4 Residue behaviour

Residues in food for human consumption have been adressed in the risk assessment section. Residues in environmental compartments are highly unlikely due to the physico-chemical nature of the a.s.

## 3.5 Summaries of the efficacy studies (B.5.10.1-xx)

Please see the relevant IUCLID section.

## 3.6 Confidential annex

Please see separate document.

## 3.7 Other

### *3.7.1* Reference list (excluding list of studies. cf. to chapter 3.1)

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EC 2012, DRAWG: Technical Notes for Guidance: Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products (CA-Dec10-Doc.6.2.b)

EC 2017, An interim approach for the establishment of maximum residue limits for residues of active substances contained in biocidal products for food and feed and specific migration limits in food contact materials( CA-March17-Doc.7.6.c-final)

ECHA 2014, Addendum to OECD SERIES ON EMISSION SCENARIO DOCUMENTS. Number 14: Emission Scenario Document for Insecticides for Stables and Manure Storage Systems. ENV/JM/MONO(2006)4. Outcome of the ECHA BPC Ad hoc EE WG consultation "PT 18 - Ad hoc EE WG consultation on the exposure assessment for manure application". launched at September 29. 2014. Agreed at the Environment Working Group V on November 26. 2015.

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ECHA 2017c, Guidance on the Biocidal Products Regulation. Volume IV Environment - Assessment and Evaluation (Parts B + C), Version 2.0, ECHA October 2017. Reference: ECHA-17-G-23-EN. Available at: https://echa.europa.eu/documents/10162/23036412/bpr_guidance_ra_vol_iv_part_b-c_en.pdf/e2622aea-0b93-493f-85a3-f9cb42be16ae. 2018-22-01

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ECHA 2017e. Guidance on the Biocidal Products Regulation. Volume III Human Health-Assessment & Evaluation (Parts B+D), draft version 3, section 5 only: Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses

ECHA 2017f, Guidance on the BPR: Volume II Efficacy. Assessment + Evaluation (Parts B+C). available at: https://echa.europa.eu/documents/10162/23036412/bpr_guidance_assessment_evaluation_part_vol_ii_part_bc_en.pdf/950efefa-f2bf-0b4a-a3fd-41c86daae468

ECHA 2017g, Guidance on the Application of CLP criteria. available at: https://echa.europa.eu/guidance-documents/guidance-on-clp

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EU 2011, Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products. JRC Scientific and Technical Reports. Report nr. EUR 25116 EN. Publications Office of the European Union. Luxembourg, 2011. Available at: https://echa.europa.eu/documents/10162/16908203/pt3_veterinary_hygiene_en.pdf/949c57b2-a511-48bb-acf3-72cf58c526de. 2018-22-01

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