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

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATION**

(submitted by the evaluating Competent Authority)



IODOL 100

Product types 3 and 4

Iodine

Case Number in R4BP: BC-UJ019574-26

Evaluating Competent Authority: France

Date: August 2018

Revised 2020

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**Note to the reader**

This PAR has been updated following mutual recognition in sequence applications and the post authorisation data assessment (highlighted in grey). It is based on the PAR of the first authorisation.

In part 2.1 of the updated PAR the “proposal for decision” corresponds to the summary of product characteristics related to the updated decision.

**History of the dossier**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **refMS** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment /renewal)** |
| NA-APP | *FR* | *BC-UJ019574-26* | 21.08.2018 | Initial assessment |
| 16.09.2019 | Post authorisation data assessment |

# CONCLUSION

The product IODOL 100 is to be used by professional users. Claimed uses are:

* the spraying for the disinfection of empty breeding buildings and equipments (PT3),
* the soaking for the disinfection of equipments (PT3),
* the filling of water and cleaning in place (CIP) for the disinfection of drinking water pipes for drinking water of animals (PT4).
* *Physico-chemical properties*

The formulation IODOL 100 is a Soluble concentrate (SL) formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

The 2 years storage study at ambient temperature in the commercial packaging should be provided in post-authorization with all requirements (appearance, AS content, packaging stability, pH, acidity/alkalinity, density and dilution stability).

According to the persistent foaming test, the volume of foam is higher than the acceptable limit. Additional data have been provided following the data requirement of ANSES indicating that the product is not a foaming product in specific conditions. However, the conditions carried out are not considered as representative of the real conditions of uses. Therefore, a report demonstrating that there is no risk for the operator when the product is diluted at the maximum concentrations of use and during the application of the biocidal product (for spraying in the livestock buildings and soaking) in the real conditions should be provided in post-authorization, within a 2 months delay.

Read across have been made for physical hazard properties with the product AQUAVIC 3%. The comparison of the composition of the product IODOL 100 and AQUAVIC 3% has been presented in the confidential annex of the PAR. The read-across is acceptable. The product is not explosive and has no oxidizing properties. The product is not considered as flammable.

The product is classified as corrosive to metal. H290 cat.1.

* **Post authorisation requirement assessment**

With regards to the long term storage study provided in 2018, the product is stable for 3 years at ambient temperature. Therefore, the 2 years shelf life is confirmed, as initially requested in post-authorization data.

The volume of persistent foaming is very high and higher than 60mL after 1 min. According to the persistent foaming test, the volume of foam is higher than the acceptable limit. Some photos and a video of the dilution of the product in real conditions and during application were provided. No formation of foam is observed at high and low concentration, demonstrated that there is no risks for the operator during dilution.

* *Efficacy assessment*

In accordance with the submitted tests and the requirements of the norm EN 14885, the product IODOL 100 is efficient against bacteria and yeasts:

* By spraying for the disinfection of empty breeding buildings and equipments (PT3),
* By soaking for the disinfection of equipments (PT3),
* By filling of water and Cleaning in Place (CIP) for the disinfection of drinking water pipes for drinking water of animals (PT4).

The authorization holder has to report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

* *Risk assessment for human health*

For PT3, the risk during spraying and soaking is acceptable for dilution at 2% when appropriate PPE are worn and RMM are put in place.

The risk is unacceptable for dilution at 3.5% as this dilution is corrosive and exposure during the spraying and soaking tasks cannot be limited even if PPE are worn.

For PT4, exposure is limited to the mixing and loading task. The risk is acceptable when PPE allowing limiting exposure are worn and RMMs are put in place.

* *Risk for consumers via residues*

Considering the intended use of IODOL 100 and based on overall available information, a risk via food cannot be excluded.

The estimation of iodine contamination in food is performed considering the worst case situation. Considering a total dietary intake of iodine in addition to exposure arising from biocidal use, a risk management decision cannot be taken in isolation with respect to the biocides use only. It would be advisable that this issue is addressed at European level in order to ensure that all relevant regulatory bodies can be involved in agreeing a way forward. So for the background levels all sources of iodine, would need to be taken into consideration. Therefore a wider approach to the consumer risk assessments encompassing different regulatory areas would need to be considered.

So, the dietary risk assessment cannot be finalised.

* *Risk assessment for environment*

The estimated exposure levels for the non-target species of aquatic, sediment and terrestrial compartments and the microorganisms in wastewater treatment plants are in the range of the natural background levels for each compartment, related to exposure to iodine and its compounds under the conditions of application specified in the SPC for IODOL 100.

The estimated groundwater concentrations associated with the use of the product IODOL 100 are in the range of environmental iodine background except in the following uses:

* disinfection with a product dilution of 3.5% v/v of livestock veal calf buildings .
* disinfection of equipment used for animals in of livestock veal calf buildings with a product dilution of 3.5% v/v.

However, the estimation of concentrations in groundwater is based on a worst case assumption taking into account the partitioning equilibrium (interstitial soil water), neglecting lateral transport or dilution in deeper soil layers as well as any uptake by plants.

**In the absence of possible refinement of this methodology the assessment of estimated concentrations in groundwater cannot be refined.**

**However, risk for groundwater is not considered as unacceptable.**

* ***Overall conclusion***

According to the assessment performed for the product IODOL 100, the following uses are proposed for authorization:

* Disinfection against bacteria of equipment for animals by spraying and soaking (2% dilution)
* Disinfection of drinking water pipes for drinking water for animals by filling (1.5%) and by cleaning in place (0.2%).

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product / product family

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| IODOL 100IODAVICAQUACEET IODE | France |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | LABORATOIRE MERIEL S.A.S |
| **Address** | 12 rue de Malacussy42100 Saint EtienneFrance |
| **Authorisation number** | **FR-2017-0071** |
| **Date of the authorisation** | **28/08/2020** |
| **Expiry date of the authorisation** | **14/10/2028** |

#### Manufacturer(s) of the products of the family

|  |  |
| --- | --- |
| **Name of manufacturer** | LABORATOIRE MERIEL S.A.S |
| **Address of manufacturer** | 12 rue de Malacussy42100 Saint Etienne France |
| **Location of manufacturing sites** | 12 rue de Malacussy42100 Saint Etienne France |

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

|  |  |
| --- | --- |
| **Active substance** | Iodine |
| **Name of manufacturer** | HYPRED  |
| **Address of manufacturer** | 57 boulevard Jules VergerBP10180 35803 Dinard CedexFrance |
| **Location of manufacturing sites** | 57 boulevard Jules VergerBP10180 35803 Dinard CedexFrance |

### Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

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 [x]

#### 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** |  |
| **Minimum purity / content** | 995g/kg |
| **Structural formula** | I - I  |
| Relevant toxicological/ecotoxicological information: | Specification according to Ph. Eur (ver. 7.0, 2010) and USP\*: 1) Bromides and chlorides (max. 0.25 g/kg) 2) Non-volatile substances (max 1 g/kg) The impurities specified are not considered relevant and as they are either below 1 g/kg (bromide and chlorides) or non-specific (non-volatiles) they should normally not be specified in the reference specification for biocidal purposes. However, in the case of iodine it is considered justified to adopt the specification according to the Ph. Eur (see further Document III-A2). It should be noted that in the case of iodine, given that it may be purchased from any manufacturer of Ph. Eur. grade active substance, it is considered acceptable that a definite list of sources or 5-batch data for all sources are not provided for a possible Annex I-listing (i.e. certificates of analysis for some of the listed sources have been provided). This is also consistent with the approach taken under the plant protection legislation, where for example it has been agreed not to require 5-batch analyses or a definite list of sources for active substances purchased as commodity chemicals (e.g. acetic acid).  |
| Original ingredient (trade name): | - |

#### Candidate(s) for substitution

Not relevant

#### Qualitative and quantitative information on the composition of the biocidal product[[1]](#footnote-2)

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Iodine | Iode | Active substance (technical) | 7553-56-2 | 231-442-4 | 1.01 |
| Orthophosphoric acid |  | Co-formulant | 7664-38-2 | 231-663-2 | 7.55 |
| Alcohols, C12-14, ethoxylated |  | surfactant | 68439-50-9 | 500-213-3 | 6.75 |

#### Information on technical equivalence

Not relevant

#### Information on the substance(s) of concern

The product is classified for skin corrosion due to its pH of 0.9 at 20°C.

Since this pH is essentially linked to the presence of orthophosphoric acid, orthophosphoric acid is considered as SOC.

According to the ECHA guidance volume III part B/C, qualitative exposure and risk assessment to determine whether P-statements normally associated with concerned H statements are sufficient.

The product contains also alcohols, C12-14, ethoxylated at a content which leads to the classification H318. In this context, alcohols, C12-14, ethoxylated is considered as SOC.

The P-statements associated to the classification H314 are sufficient for the risk assessment.

#### Assessment of endocrine disruption (ED) properties of the biocidal product / BPF

According to our assessment, none of the co-formulants contained in the products IODOL 100 are identified as endocrine disruptors.

However, one co-formulants show indications of endocrine activity (refer to confidential annex).

Based on available information, it is not possible to conclude whether this co-formulant should be considered to have ED properties or not. This should be further assessed in the frame of REACH Regulation. In case this co-formulant is finally identified as ED, the biocidal product will be considered as ED and authorisation will have to be revised accordingly.

#### Type of formulation

|  |
| --- |
| Soluble concentrate - SL |

### Hazard and precautionary statements[[2]](#footnote-3)

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

| **Classification** |
| --- |
| Hazard category | Skin Corr. 1Serious eye damage cat. 1 STOT RE. 2Metal Corr 1 Aquatic chronic 3 |
| Hazard statement | H290 cat.1: Corrosive to metalH314: Causes severe skin burns and eye damage.H318 Causes serious eye damageH373: May cause damage to organ (thyroid) through prolonged or repeated exposure. H412: Harmful to aquatic life with long lasting effects |
|  |
| **Labelling** |
| Signal words | Danger |
| Hazard statements | H290 cat.1: Corrosive to metalH314: Causes severe skin burns and eye damage.H373: May cause damage to organ (thyroid) through prolonged or repeated exposure.H412: Harmful to aquatic life with long lasting effects |
| Precautionary statements | P260: Do not breathe dust/fume/gas/mist/vapours/spray.P264: Wash … thoroughly after handling.P273: Avoid release to the environmentP280: Wear protective gloves/protective clothing/eye protection/face protection.P301+P330+P331: If SWALLOWED: Rinse mouth. Do NOT induce vomiting.P303+P361+P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated ...P363: Wash contaminated clothing before reuse.P304+P340: If INHALED : Remove person to fresh air and keep comfortable for breathingP310: Immediately call a POISON CENTER/doctor/…P321: Specific treatment (see…on this label).P305+P351+P338: IF IN EYES: Rinse cautiously with water forseveral minutes. Remove contact lenses, ifpresent and easy to do. Continue rinsing.P405: Store locked up.P501 : Dispose of contents/container to …P314: Get medical advice/attention if you feel unwell. |
|  |
| Note | EUH071: Corrosive to the respiratory tract |

### Authorised use(s)

#### Use description

Table 1. Use # 1 – Disinfection of equipment for animals by soaking

|  |  |
| --- | --- |
| **Product Type** | PT3 |
| **Where relevant, an exact description of the authorised use** | Disinfection of equipment |
| **Target organism (including development stage)** | Bacteria |
| **Field of use** | Indoor use |
| **Application method(s)** | The product is applied by soaking |
| **Application rate(s) and frequency** | 2.0% v/v dilution at 10°CContact time: 30 minutes |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | individual HDPE containers :* jerry can of 5 and 20 L and,
* drum of 60 L.
 |

##### Use-specific instructions for use

|  |
| --- |
| * Apply only on non-porous surfaces.
 |

##### Use-specific risk mitigation measures

|  |
| --- |
| * During dipping, protective chemical resistant glove (glove material to be specified by the authorisation holder within the product information) and protective coverall (at least type 6) which is coated (coverall material to be specified by the authorisation holder within the product information) shall be worn.
* Rinse materiel after treatment. The same PPE than those required during application have to be worn.
* Do not touch material until a total drying.
* If control task is needed, the same PPE as those required during the treatment have to be worn.
 |

##### 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

|  |
| --- |
| - |

#### Use description

Table 1. Intended use # 2– Disinfection of empty breeding buildings and equipment by spraying

|  |  |
| --- | --- |
| **Product Type(s)** | PT3 |
| **Where relevant, an exact description of the authorised use** | Disinfection of empty breeding buildings and equipment |
| **Target organism (including development stage)** | Bacteria |
| **Field of use** | Indoor use |
| **Application method(s)** | The product is applied by spraying  |
| **Application rate(s) and frequency** | The product IODOL 100 is a soluble concentrate to be diluted in water with caution before use (2.0% v/v dilution) at 10°CContact time: 30 minutesThe dose for spray application is 200 to 400 mL of diluted product per m². |
| **Category(ies) of user(s)** | Professional users |
| **Pack sizes and packaging material** | individual HDPE containers :* jerry can of 5 and 20 L and,
* drum of 60 L.
 |

##### Use-specific instructions for use

|  |
| --- |
| * Apply only on non-porous surfaces.
* Apply the product with a low-pressure sprayer.
 |

##### Use-specific risk mitigation measures

|  |
| --- |
| * During spraying: protective chemical resistant glove (glove material to be specified by the authorisation holder within the product information), protective coverall (at least type 4) which is impermeable (coverall material to be specified by the authorisation holder within the product information) and a mask APF 10 shall be worn.
* During the cleaning of the equipment, protective chemical resistant glove (glove material to be specified by the authorisation holder within the product information) and protective coverall (at least type 4) which is impermeable (coverall material to be specified by the authorisation holder within the product information) must be worn.
* Rinse surface or materiel after treatment. The same PPE than during application have to be worn.
* Do not authorise re-entry before total drying of surface.
* If control task is needed, the same PPE as during treatment have to be worn.
* Do not use the b.p. in animal housings where exposure to a STP cannot be prevented.
 |

##### 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

|  |
| --- |
| - |

#### Use description

Table 1. Use # 3 – Disinfection of drinking water pipes for drinking water for animals

|  |  |
| --- | --- |
| **Product Type** | PT4 |
| **Where relevant, an exact description of the authorised use** | Disinfection of drinking water pipe for drinking water for animals  |
| **Target organism (including development stage)** | BacteriaYeasts |
| **Field of use** | Indoor use |
| **Application method(s)** | The product is applied by filling and by cleaning in place |
| **Application rate(s) and frequency** | Filling the drinking water pipe * bacteria and yeasts: 1.5% v/v dilution at 20°C

Contact time : 30 minutesCleaning in place * bacteria and yeasts: 0.2% v/v dilution (residual pH 5 or 9 respectively after acidic or alkaline cleaning) at 10°C

Contact time : 60 minutes |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | individual HDPE containers :* jerry can of 5 and 20 L and,
* drum of 60 L.
 |

##### Use-specific instructions for use

|  |
| --- |
| * For the disinfection of drinking water pipes for animals by filling, a minimum temperature of 20°C has to be respected to guarantee the efficacy of the product IODOL 100
* For the disinfection of drinking water for animals by CIP applications before disinfection, residual pH of the surfaces after the cleaning (acidic or alkaline) and rinsing, has to be strictly in compliance with the conditions of uses to guarantee the efficacy of the product IODOL 100.
* Rinse drinking water pipes after treatment.
 |

##### 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

|  |
| --- |
| - |

### General directions for use

#### Instructions for use

|  |
| --- |
| * Always read the label or leaflet before use and respect follow all the instructions provided.
* Clean carefully the surfaces before application of the product.
* The diluted solution should be used immediately.
* The users should inform if the treatment is ineffective and report straightforward to the registration holder.
* Pour gradually the product into the water while stirring slowly to avoid the formation of too much foam and overflow.
 |

#### Risk mitigation measures

|  |
| --- |
| During mixing and loading exposure (corrosive product) has to be limited by use of PPE and application of technical and organisational RMM like:- Minimisation of manual phases;- Regular cleaning of equipment and work area;- Avoidance of contact with contaminated tools and objects;- Training and management of staff on good practice.**During handling of the product, the following PPE are mandatory:**, - Protective chemical resistant glove (glove material to be specified by the authorisation holder within the product information) - Protective coverall (coverall material to be specified by the authorisation holder within the product information);- Eye protection. |

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

|  |
| --- |
| Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with water. Contact poison treatment specialist if symptoms occur.Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with warm water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.Mouth contact: Wash out mouth with water. Contact poison treatment specialist immediately if symptoms occur and/or in case of mouth contact with large quantities. Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately.Inhalation: Remove victim to fresh air and keep at rest in a half-sitting position. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.Keep the container or label available. |

#### Instructions for safe disposal of the product and its packaging

|  |
| --- |
| * Dispose of unused product, its packaging and all other waste in accordance with local regulations.
* Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains.
 |

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

|  |
| --- |
| Shelf-life : 2 years |

### Other information

|  |
| --- |
|  |

### Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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)** |
| Can | 5L, 20L and 60L | HDPE | Black cap in HDPE | Professionnal | Yes |

### Documentation

#### Data submitted in relation to product application

**Identity, physico-chemical and analytical method data**

Physico-chemical properties studies and analytical methods on the biocidal product IODOL 100 were provided by Laboratoire Meriel.

**Efficacy data**

The following studies were submitted with orthophosphoric acid alone:

* Laboratory study according to EN1040 standard on bacteria
* Laboratory study according to EN 1275 standard on yeast

The following efficacy studies were submitted with the product IODOL 100:

* For bacteria :
* Laboratory study according to EN1276 standard.
* Laboratory study according to EN1656 standard.
* Laboratory study according to EN 13697 standard.
* Laboratory study according to EN14349 standard.
* For yeasts:
* Laboratory study according to EN1650 standard.
* Laboratory study according to EN1657 standard.
* Laboratory study according to EN 13697 standard.
* Laboratory study according to EN16348 standard.

#### Access to documentation

**Identity, physico-chemical and analytical method data**

Laboratoire Meriel has access to hazard physico-chemical properties and to the analytical method for the determination of iodine on the product AQUAVIC 3% thanks to a Letter of Access from QALIAN SA. Laboratoire Meriel and QALIAN are two subsidiaries of the group InVivo NSA.

Laboratoire Meriel has access to data on the active substance Iodine with a Letter of Access of HYPRED SA, one of applicants of the active substance iodine.

Data on the manufacturer and the manufacturing location of the active substance has been provided in the complementary data. The data is reported in the confidential annex.

## Assessment of the biocidal product

### Intended uses as applied for by the applicant

Table 1. Intended use # 1 – Disinfection of empty breeding buildings and equipment

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| --- | --- |
| **Product Type(s)** | Product Type 03 |
| **Where relevant, an exact description of the authorised use** | Disinfection of empty breeding buildings and equipment |
| **Target organism (including development stage)** | BacteriaYeasts |
| **Field of use** | Indoor use |
| **Application method(s)** | The product is applied by spraying or soaking (3.5% v/v or 2.0% v/v dilution). |
| **Application rate(s) and frequency** | The product IODOL 100 is a soluble concentrate to be diluted in water with caution before use. The recommended dose for spray application is 200 to 400 mL of diluted product per m². |
| **Category(ies) of user(s)** | Professional users |
| **Pack sizes and packaging material** | The product IODOL 100 is packaged in individual HDPE containers :* jerry can of 5 and 20 L and,
* drum of 60 L.
 |

Table 2. Intended use # 2 – Disinfection of drinking water pipe for drinking water of animals

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| --- | --- |
| **Product Type(s)** | Product Type 04 |
| **Where relevant, an exact description of the authorised use** | Disinfection of drinking water pipe for drinking water of animals |
| **Target organism (including development stage)** | BacteriaYeasts |
| **Field of use** | Indoor use |
| **Application method(s)** | The product is applied by filling the drinking water pipe (0.5% v/v or 2.5% v/v dilution), by cleaning in place (0.05% v/v or 0.15% v/v dilution) or by flashing effect (0.5% v/v dilution). |
| **Application rate(s) and frequency** | The product IODOL 100 is a soluble concentrate to be diluted in water with caution before use. |
| **Category(ies) of user(s)** | Professional users |
| **Pack sizes and packaging material** | The product IODOL 100 is packaged in individual HDPE containers :* jerry can of 5 and 20 L and,
* drum of 60 L.drum of 60 L.
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### Physical, chemical and technical properties

The biocidal product is not the same as the one assessed for the inclusion of the active substances in annex 1 of directive 98/8/EC. The composition of the product is confidential and is presented in a confidential annex. The product contains 1.01% of technical Iodine and 1.00% of pure Iodine.

The product does not contain PT6 preservative. It is used diluted in water (0.2%-3.5%).

Formulation type: Soluble Concentrate SL

Hydrocarbon and H304 co-formulant content: ≤10%.

The product IODOL 100 is packaged in 5L, 20L and 60L HDPE cans and hermetically closed with a HDPE cap.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR Evaluation** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual observation | Iodol 1001.08% m/mBatch 280115-1 | Liquid | Acceptable | Coffy C. 2015Etude de stabilité de IODOL 100Laboratoire Meriel |
| Colour at 20 °C and 101.3 kPa | Visual observation | Iodol 1001.08% m/mBatch 280115-1 | Brown | Acceptable | Coffy C. 2015Etude de stabilité de IODOL 100Laboratoire Meriel |
| Odour at 20 °C and 101.3 kPa |  | Iodol 1001.08% m/mBatch 280115-1 | odourless | Acceptable | Coffy C. 2015Etude de stabilité de IODOL 100Laboratoire Meriel |
| pHAcidity / alkalinity | CIPAC MT 75.3CIPAC MT 31 and MT 191 | Iodol 1001.08% m/mBatch 280115-1 | At 20°C:Pur: pH=0.91% dilution: pH=2.3Acidity: 5.98% as H2SO4 | Acceptable | Coffy C. 2015Etude de stabilité de IODOL 100Laboratoire Meriel |
| Relative density / bulk density | OECD 109 | Iodol 1001.08% m/mBatch 280115-1 | 1.058 at 20°C | Acceptable | Coffy C. 2015Etude de stabilité de IODOL 100Laboratoire MerielMarquet M. 2015Mesure de densité15-CEMR-004Laboratoire Meriel |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3Analytical method Labo1002 detailed in the analytical method part for iodine | Iodol 1001.08% m/mBatch 280115-1Packaging: HDPE, 150mL 14 days at 54°C |

|  |  |  |
| --- | --- | --- |
| Tests | T0 | T14d |
| Appearance | Brown liquid odourless |
| Iodine content | 1.08% | 1.07%(-0.9%) |
| pH | 0.9 | 0.9 |
| Acidity | 5.98% H2SO4 | 5.48% H2SO4 |
| Solution stability | No trace of sediment after 30min,homogenous after 18h | No trace of sediment after 30min,homogenous after 18h |
| packaging | No differenceNo bloating, leakage or cracking |
| m=135.262g | m=135.142g (0.1%) |

 | AcceptableThe product IODOL 100 is stable after accelerated storage stability study. | Coffy C. 2015Etude de stabilité de IODOL 100Laboratoire Meriel |
| Storage stability test – **long term storage at ambient temperature** | Analytical method Labo1002 detailed in the analytical method part for iodine | Iodol 1001.08% m/mBatch 280115-136 months at 20°C | Please refer to the table below | AcceptableThe biocidal product is stable after 36months therefore, the shelf-life of the product IODOL 100 is confirmed for 2 years, as initially requested in post-authorization data. | Coffy C. 2018Etude de stabilité après 36 mois de IODOL 100 Désinfectant pour canalisations d'eau et pour matériels et surfaces en élevageLaboratoire Mériel) |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3 | Iodol 1001.08% m/mBatch 280115-1Packaging: HDPE, 150mL7 days at 0°C | After 7 days at 0°C, the product has freezed.After come back to ambient temperature, the product is liquid again without any sediment, crystallization or separation of phases.Packaging: No bloating, leakage or cracking of the packaging after 7 days at 0°C. | Acceptable | Coffy C. 2015Etude de stabilité de IODOL 100Laboratoire Meriel |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | Not required as the commercial packaging is opaque (HDPE jerry cans and drums). See Section 12.3.  | Acceptable |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | The test item Iodol 100 was considered to be stable after 2 weeks at 54 ± 2°C (please refer to section 3.4.1.1). The test item Iodol 100 was not considered to be stable after a storage for 7 days at 0 ± 2°C. However, after an undisturbed period of few hours, the product became liquid again without crystals, deposit or phase partition (please refer to section 3.4.1.3). | Acceptable |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  |  | The commercial packaging material is HDPE. The product IODOL 100 is stable in this packaging material (see storage stability test) |  |
| Wettability |  |  | Not relevant for SL formulation |  |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not relevant for SL formulation |  |  |
| Wet sieve analysis and dry sieve test |  |  | Not relevant for SL formulation |  |  |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not relevant for SL formulation |  |  |
| Disintegration time |  |  | Not relevant for SL formulation |  |  |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | Not relevant for SL formulation |  |  |
| Persistent foaming | CIPAC MT 47.2 | Iodol 1001.08% m/mBatch 280115-1 | Concentration: 0.5 % (v/v)10s: 120 mL1min: 116 mL3min: 110 mL12min: 106 mLConcentration: 3.5% (v/v)10s: 156 mL1min: 152 mL3min: 146 mL12min: 136 mLThe foam content is higher than 60mL after 1 min. | The volume of persistent foaming is very high. The label indicates to wear the protection equipment when the product is dilute in water. According to the persistent foaming test, the volume of foam is higher than the acceptable limit. Additional data have been provided following the data requirement of ANSES indicating that the product is not a foaming product in specific conditions. However, the conditions carried out are not considered as representative of the real conditions of uses. Therefore, a report with a photo/video demonstrating that there are no risks for the operator (farmer or livestock service provider) when the product is diluted at the maximum concentrations of use in the appropriate tanks in the field and during the application (for spraying in the livestock buildings and soaking) of the biocidal product in the real conditions should be provided in post-authorization, within a 2 months delay.Data post authorisation (11/2018): Some photos and a video of the dilution of the product in real conditions and during application of the product were provided. No formation of foam is observed at high and low concentration, demonstrated that there is no risks for the operator during dilution. | Coffy C. 2015Etude de stabilité de IODOL 100Laboratoire Meriel |
| Flowability/Pourability/Dustability |  |  | Not relevant for SL formulation |  |  |
| Burning rate — smoke generators |  |  | Not relevant for SL formulation |  |  |
| Burning completeness — smoke generators |  |  | Not relevant for SL formulation |  |  |
| Composition of smoke — smoke generators |  |  | Not relevant for SL formulation |  |  |
| Spraying pattern — aerosols |  |  | Not relevant for SL formulation |  |  |
| Physical compatibility |  |  | Not relevant  |  |  |
| Chemical compatibility |  |  | Not relevant  |  |  |
| Degree of dissolution and dilution stability | CIPAC MT 41 | Iodol 1001.08% m/mBatch 280115-1 | Concentration: 3.5 % (v/v), two types of water have been tested (Hard water and Water of Saint-Etienne)No trace of sediment after 30minHomogenous solution after 18h | AcceptableThe product IODOL 100 is stable to dilution. | Coffy C. 2015Etude de stabilité de IODOL 100Laboratoire Meriel |
| Surface tension | EN 14370:2004 (ring method) | Iodol 100Batch 060416-4 | Pure product: 33.5 mN/m at 25°CDilution at 3.5%: 33.7 mN/m at 20°C | AcceptableThe product is surface active | Perin F. 2016IODOL 100 lot 060416-4 surface tensionTest report 16/000265487 |
| Viscosity | OECD 114(capillary method) | Iodol 100 (no batch number) | Kinematic viscosity at 20°C: 1.97 mm2.s-1Dynamic viscosity at 20°C: 2.07 mPa.sKinematic viscosity at 40°C: 1.83 mm2.s-1Dynamic viscosity at 40°C (calculated): 1.94 mPa.s | Acceptable | Zampieri L. 2016Validation of a method and determination of assay of iodine in Iodol 100;evaluation of stability (14 days at 54°C; 7 days at 0°C) and physical propertiesStudy N.15.531326.0002 |

**Post authorisation requirement assessment**

Results of long term storage stability after 3 years in HDPE

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Initial** | **After 1 year** | **After 2 years** | **After 3 years in HDPE** |
| Appearance | Brown liquid odourless |
| pH (neat / 1%) | 0.9 / 2.3 | - | - | 1.07 / 2.3 |
| Acidity (% H2SO4) | 5.98 | - | - | 5.73 |
| density | 1.06 |  |  | 1.06 |
| Dilution stability | No trace of sediment after 30min, homogenous after 18h | - | - | No trace of sediment after 30min, homogenous after 18h |
| Persistent foaming at 0.5% and 3.5% (mL) | >60mL | - | - | >60mL |
| Iodine content (%) | 1.08 | 1.08 | 1.05 | 1.04 (-4%) |
| Packaging stability |  | - | - | No changes after storage |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| The formulation IODOL 100 is a Soluble concentrate (SL) formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The product is a brown odourless liquid. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE packaging material (commercial packaging material). The long term storage stability study (36 months) is on-going. Intermediate results after 1 year have been provided and are acceptable. The 2 years storage study at ambient temperature in the commercial packaging should be provided in post-authorization with all requirements (appearance, AS content, packaging stability, pH, acidity/alkalinity, density and dilution stability).After 7 days at 0°C, the product is freezed however after few hours at ambient temperature the product become liquid without bloating, leakage or cracking. Its technical characteristics are acceptable for a SL formulation. The volume of persistent foaming is very high and higher than 60mL after 1 min. According to the persistent foaming test, the volume of foam is higher than the acceptable limit. Additional data have been provided following the data requirement of ANSES indicating that the product is not a foaming product in specific conditions. However, the conditions carried out are not considered as representative of the real conditions of uses. Therefore, a report demonstrating that there is no risk for the operator when the product is diluted at the maximum concentrations of use and during the application of the biocidal product (for spraying in the livestock buildings and soaking) in the real conditions should be provided in post-authorization, within a 2 months delay.* **Post authorisation requirement assessment**

The stability data indicates a shelf life of at least 3 years at ambient temperature when stored in HDPE packaging material (commercial packaging material). Therefore, the 2 years shelf-life is confirmed as initially requested in post-authorization data.The volume of persistent foaming is very high and higher than 60 mL after 1 min. According to the persistent foaming test, the volume of foam is higher than the acceptable limit. Some photos and a video of the dilution of the product in real conditions and during application were provided. No formation of foam is observed at high and low concentration, demonstrating that there is no risks for the operator during dilution. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR Evaluation** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | Statement | AQUAVIC 3% | The products Iodol 100 and Aquavic 3% have very close compositions. It was demonstrated that explosive properties can be extrapolated from studies obtained with Aquavic 3%.See details on the read-across in the confidential annex. | Read-across with AQUAVIC 3%The read-across is acceptable as the product IODOL 100 has a composition close to AQUAVIC 3% (See confidential annex)Product IODOL 100 is not expected to present a significant hazard for explosivity. | S4-1\_Aquavic 3%\_DSC:report No.15-912037-001, 2015, Demangel B., DéfitracesS4-2\_ Aquavic 3%\_Statement\_EO\_Qalian\_150727: literature review No.15/39, 2015, Detrimont H. and Ambrosi D., A.S.C. Biocides |
| Flammable gases |  |  | Not relevant as the product is liquid |  |  |
| Flammable aerosols |  |  | Not relevant as the product is liquid |  |  |
| Oxidising gases |  |  | Not relevant as the product is liquid |  |  |
| Gases under pressure |  |  | Not relevant as the product is liquid |  |  |
| Flammable liquids | Statement | IODOL 1001% iodine | The product IODOL 100 is a homogenous liquid which is not expected to present a significant hazard for flammability.Test is not required as IODOL 100 contains more than 50% w/w water and as no ingredient is considered to flammable based on available data found in literature. | AcceptableThe product IODOL 100 is not expected to have flammable properties. | Marquet M. 2015Inflammabilité et point d’éclair15-CEMR-006Laboratoire Meriel |
| Flammable solids |  |  | Not relevant as the product is liquid |  |  |
| Self-reactive substances and mixtures | Statement | AQUAVIC 3% | The products Iodol 100 and Aquavic 3% have very close compositions. It was demonstrated that self-reactive properties can be extrapolated from studies obtained with Aquavic 3%. According to Differential Scanning Calorimetry (DSC) graphs, no exothermic reaction was observed in the temperature range from 25°C to 600°C. Therefore, the test item is unlikely to be self-reactive and the test on self-reactive properties of Aquavic 3% according to UN Test series A to H described in Part II of the UN-MTC should not be performed. Therefore, Iodol 100 is not expected to present a significant hazard for self-reactive properties. | Read-across with AQUAVIC 3%The read-across is acceptable as the product IODOL 100 contains more water and other co-formulants are the same than the product AQUAVIC 3%. (See confidential annex)The product IODOL 100 is not self-reactive | S4-1\_Aquavic 3%\_DSC:report No.15-912037-001, 2015, Demangel B., DéfitracesS4-2\_ Aquavic 3%\_Statement\_EO\_Qalian\_150727: literature review No.15/39, 2015, Detrimont H. and Ambrosi D., A.S.C. Biocides |
| Pyrophoric liquids | Statement |  | Not required as Iodol 100 contains more than 50% w/w water and as experience in manufacture and handling shows that the product does not ignite spontaneously on coming into contact with air at normal temperature. | This test is required with the CLP regulation. Nevertheless, as there are no ingredients classified H250 (category 1) in the product IODOL 100, it considered acceptable. |  |
| Pyrophoric solids |  |  | Not relevant as the product is liquid |  |  |
| Self-heating substances and mixtures |  |  | No data provided | Read-across with AQUAVIC 3%According to Differential Scanning Calorimetry (DSC) graphs, no exothermic reaction was observed in the temperature range from 25°C to 600°C. Therefore, the AQUAVIC 3% is unlikely to be self-heating.The read-across is acceptable for the product IODOL 100 as it contains more water and other co-formulants are the same than the product AQUAVIC 3%.The product IODOL 100 is not self-heating. | S4-1\_Aquavic 3%\_DSC:report No.15-912037-001, 2015, Demangel B., DéfitracesS4-2\_ Aquavic 3%\_Statement\_EO\_Qalian\_150727: literature review No.15/39, 2015, Detrimont H. and Ambrosi D., A.S.C. Biocides |
| Substances and mixtures which in contact with water emit flammable gases |  |  | Not required as Iodol 100 contains more than 83% w/w water and forms a stable mixture. | Acceptable |  |
| Oxidising liquids | Statement | AQUAVIC 3% | The product Iodol 100 and Aquavic 3% have very close compositions. It was demonstrated that oxidising properties can be extrapolated from studies obtained with Aquavic 3%.See details on the read-across in the confidential annex. | Read-across with AQUAVIC 3%The read-across is acceptable as in the product IODOL 100, content of non-oxidising ingredients is the same as for AQUAVIC 3%. (See confidential annex)Product IODOL 100 is not expected to present a significant hazard for oxidising properties | S4-1\_Aquavic 3%\_DSC:report No.15-912037-001, 2015, Demangel B., DéfitracesS4-2\_ Aquavic 3%\_Statement\_EO\_Qalian\_150727: literature review No.15/39, 2015, Detrimont H. and Ambrosi D., A.S.C. Biocides |
| Oxidising solids |  |  | Not relevant as the product is liquid |  |  |
| Organic peroxides |  |  | Not relevant |  |  |
| Corrosive to metals | UN test C1 section37.4 | IODOL 100Batch number 060416-4 | Aluminum and steel plates have been tested during 7 days at 55°C

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| --- | --- | --- |
| Loss weight | 50% immersed | 100% immersed |
| Aluminum | 10.7% | 20.2% |
| Steel | 1.8% | 3.6% |

Uniform corrosion within the sample | AcceptableThe loss weight after 7 days for aluminum is higher than the limit of 13.5%, the product IODOL 100 is classified corrosive to metal H290 cat.1. | Zarpellon A., Semenzin M., 2016, Metal corrosion test for the product IODOL 100Report N 16.006357.0004Chelab |
| Auto-ignition temperatures of products (liquids and gases) | Statement |  | Not required as Iodol 100 contains more than 50% w/w water and as no ingredient is considered to be flammable or auto-flammable based on available data found in literature. | Acceptable |  |
| Relative self-ignition temperature for solids |  |  | Not relevant as the product is liquid |  |  |
| Dust explosion hazard |  |  | Not relevant as the product is liquid |  |  |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| Read across have been made for physical hazard properties with the product AQUAVIC 3%. The comparison of the composition of the product IODOL 100 and AQUAVIC 3% has been presented in the confidential annex of the PAR.The read-across is acceptable. The product is not explosive and has no oxidizing properties. The product is not considered as flammable.The product is classified as corrosive to metal. H290 cat.1.Implication concerning labelling:Classification: H290 cat.1 |

### Methods for detection and identification

#### Analytical methods for the determination of the active ingredient and impurities in the technical active ingredient

Physical and chemical properties of the active substance and analytical methods for determination of active ingredients in the technical active ingredient have already been evaluated at EU level and are presented in the CAR of the active substance iodine (2013). The notifier Laboratoire Meriel of the product IODOL 100 is not the applicant that supported the annex I inclusion dossier of the active substance (HYPRED SA) but it has a letter of access to these data.

#### Analytical method for determining the active substance and relevant component in the biocidal product

Report: Coffy, C. 2015 Description et validation de la méthode de dosage de l’iode

Document No: Labo1002

Test facilities: LABORATOIRE MERIEL S.A.S., 12 rue de Malacussy, 42100 SAINT-ETIENNE, France

Principle of the method:

Redox volumetric titration with sodium thiosulfate.

The equation is: I2 (aq) + 2 S2O32- (aq) = S4O62- (aq) + 2 I- (aq)

This analytical method for the determination of the active substance iodine was validated in the product Aquavic 3% by definition of the specificity, the linearity, the accuracy and the precision of the method. The validation of this method was considered in compliance with SANCO/3030/99 rev.4.

Validation data:

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| --- | --- |
| Specificity | To demonstrate that the quantification of iodine is not affected by other co-formulants present in the biocidal product, several preparations are dosed:* Iodine standard (known concentration)
* A blank (with phosphoric acid and water)
* A sample of known concentration of iodine (with phosphoric acid and water)

No interference was found in the blank sample. |
| Linearity | Linearity was studied by carrying out six calibration spots with single determination, over a concentration range at the “target value” ±20%. A linear regression and its correlation coefficient were calculated. |
| Compound | Linearity (working range) g of product |
| Iodine | 0.32 to 1.23 g Y = 26.085X + 0.1501R2 = 0.9999n=6 |
| Precision | Repeatability was evaluated with 5 independent determinations of the formulated product, no outlier. |
| Compound | Repeatability (RSD) |
| Iodine | RSD = 0.02% < 1.58% (RSD calculated with modified equation of Horwitz) |
| Accuracy | Accuracy was determined by analysis of 2 independent determinations in which known amounts of the reference substance were added to a blank formulation. The accuracy results are expressed as the recovery rate.  |
| Compound | Accuracy (recovery ) |
| Iodine | 101.7% |

The product IODOL 100 has a close composition to AQUAVIC 3% with the same co-formulants (see the confidential document of the PAR with the comparison of the two compositions), the iodine content in the product IODOL 100 (1%) is lower than the iodine content in the product AQUAVIC 3% (3%). The linearity of the method has been demonstrated in the range 2.4-3.6% of iodine. The linearity of the method has not been demonstrated at 1%. However the provided data are considered sufficient as it is a titration method. Therefore the provided method is considered as acceptable for the determination of iodine in the product IODOL 100.

Taking into account the conclusion of Assessment Report for iodine, Product-Type 01, 03, 04, 22 (2013/12/13):

- analytical methods for iodine residues in soil, water (including drinking water) and sediment are not required as the respective calculated PECs of each medium (water and soil) from the biocidal uses evaluated are just a fraction of natural background concentrations.

- analytical methods for iodine residues in animal and human body fluids and tissues are not required as iodine (iodide) is not classified as toxic or highly toxic.

- analytical method for iodine residues in air is available and the studies are unprotected.

Taking into account the conclusion of Assessment Report iodine, Product-Type 01, 03, 04, 22 (2013/12/13):

- analytical methods for iodine residues in food/feed of plant origin are not required as iodine-based products or materials treated with such products are not used in a manner which may cause contact with such materials.

- analytical methods for iodine residues in food/feed of animal origin are available and the studies are unprotected.

See the table below:

| **Matrix** | **Test substance** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | **Limit of quantification / detection (LOQ / LOD)** | **LOQ required** | **Acceptance** | **Reference** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Range | Mean | St. dev. |
| Soil | iodide and iodate are determined as a sum value, which is reported as iodine equivalents | ICP-MS | Not reported | 200 – 500 µg/L | Yes | Not reported | Quoted LOD = 0.01µg I /L (relates to the water extract of the soil)  | 0.05 mg/kg\* | Not acceptable as no supporitng validation data is provided. No method required due to low PECs in comparison to natural background levels  | J. Popke et al. (1997), Doc. No. 492-009; A4.2a/01P. Schramel (1997), Doc. No. 492-008; A4.2a/02 |
| iodine | Sandel-Kolthoff methodologyPhotometric determination | 5 – 1000 mg/kg moist soil / 5 replicates for natural soil, 3 replicates for artifical soil | 0.1 – 0.5 µg iodine | Yes | Natural soil: 72.9 – 100%Artificial soil: 74.5 – 93% | Natural soil: 86.3%Artificial soil: 86.2% | Natural soil:5.9 - 10.0%Artificial soil: 3.1 and 7.5%  | LOD = 5 mg /kg dry soil | 0.05 mg/kg\* | Not acceptable for monitoring due to the use of carcinogenic substance (As2O3)No method required due to low PECs in comparison to natural background levels | Knoch, E. (2009), Doc. No. 434-001, A4.2a/03 |
| iodide and iodate are determined as a sum value, which is reported as iodine | ICP-MS | 22.4-36.2 mg/kg of iodine, 2 soils 2 replicates5 replicate analyses of 4 soils with certified iodine content (1.9-19.3 mg/kg)  | 5-50 µg iodine/L (iodine/indium ratio of 0.05-0.5) | Yes | 92-105% for fortified samples. Good agreement with certified levels | - | 0-2.7% | LOD = 0.02 µg/L (refers to the water extract)LOQ at least 0.7 mg/kg | 0.05 mg/kg\* | Not fully acceptable (some missing information)No method required due to low PECs in comparison to natural background levels | H. Yamada et al (1996), Doc. No. 492-017, A4.2a/04 |
| Air | iodine | In air sampling tubes, I2 is partially but stoichiometrically converted to iodide. Iodide is determined by IC-PED. | Air at concentration of 0.05, 0.1 and 0.2 ppm and relative humidities of 25%, 50%, and 80% were sampled.6 measurements per concentration / relative humidity combination (only 5 in one case). | Calibration range: 0.1 – 5.0 µg iodide/mL | Yes | Overall62.7 – 103%25% r.H:95 – 10350% r.H:94.2 – 99.480% r.H.:62.7 – 86.8 | 90.798.297.276.5 | 12.64.22.712.4 | LOD = 0.0004 ppm (2.5 L air sample)LOQ = 0.001 ppm (2.5 L air sample) | 0.1 mg/m3\*\* | Acceptable | OSHA, (1994), Doc. No. 592-036; A4.2b/01 |
| In case of high air humidity, air sampled using impingers containing an alkaline collection solution and iodide is determined by IC-PED. The use of bubblers is expected to enhance the recovery due to increased dispersion. | Air at concentration of 0.05, 0.1 and 0.2 ppm and relative humidities of 80% were sampled.3 measurements per concentration  | See above | See above | Overall range:86.3 – 95.1% | 95.1 at 0.05 ppm94.8 at 0.1 ppm86.3 at 0.2 ppm | Range:0.002 – 0.005 | See above |  |
| Water(synthetic drinking water, industrial and domestic sewage) | iodide | Ion chromatographic separation (IC) and conductivity or UV detection | No fortification and determination of recovery rates performed. | Working range: 0.1 – 50 mg I/L | Organic acids, such as mono- and dicarboxylic acids, can interfere as well as sulphateIn case of UV-detection, organic agents may interfere. | Not reported. An interlaboratory trial was performed which proved the validity of the method (not generally required as no work up except filtering is performed)  | LOQ = 0.1 mg/L | 0.59 mg/L\*\*\* | AcceptableNo method required due to low PECs in comparison to natural background levels | DIN-ISO 10304‑3, Doc. No. 492-004; A4.2c/01 |
| Water | Reference is made to the method described for the determination of iodide in soil. This method is also applicable for the determination of iodide in water. The digestion step of the soil sample can be omitted (see above). | - | Not acceptable due to missing supporting dataNo method required due to low PECs in comparison to natural background levels | -- |
| Water | iodide | GC-ECD | For the determination of the recovery, mineral waters were fortified with with KI solutions. | Not reported | Yes | 80 – 110% | 92% | Not reported | LOQ: 2.9 µg/L to 3,6 µg/LLOD: 1,7 µg/L to 1,1 µg/L | 0.59 mg/L\*\*\* | Not acceptable for monitoring due to the use of carcinogenic substance (ethylene oxide)No method required due to low PECs in comparison to natural background levels | S. Kirchner et al. (1996); Doc. No. 492-006; A4.2c/04 |
| Water (rain water, brine solution, soil solution) | Total iodine, iodide and iodate (separately) | IC-ICP-MS | Not tested | Not reported  | Yes | - | - | - | Quoted LOD: 0.05 µg/L total iodineLOD for iodide and iodate range from 0.1 to 1 µg/L. | 0.59 mg/L\*\*\* | Not acceptable due to missing supporting dataNo method required due to low PECs in comparison to natural background levels | S. Yoshida et al (2007); Doc. No. 492-018; A4.2c/05  |
| Water (Milli Q, tap water, surface water) | Iodide and iodate (separately) | IC-ICP-MS | 5 µg/L, 5 samples | Calibration range 1-10 µg/L | Yes | Not reported | I-: 95-100%IO3-: 94-100% (for all waters) | I-: 0.9-1.8 %RSDIO3-: 1.1-1.9% RSD (for all waters) | LOQ: At least 5 µg/L (validated) Calculated: 0.77µg/L for I-, 0.48 µg/L for IO3-  | 0.59 mg/L\*\*\* | AcceptableNo method required due to low PECs in comparison to natural background levels  | Sacher et al (2005): Doc. No. 492-021; A4.2c/06  |
| Water (drinking) | Iodide and iodate (separately) | IC-ICP-MS | 6.4-17.5 µg/L (1 fortifcation level per specie, 3 samples per level and 2 different water samples) | I-: 0.06-640 µg/LIO3-: 0.09-874 µg/L | Yes | Not reported | I-: 92-95%IO3-: 94-97%  | I-: 0.5-1.4 %RSDIO3-: 0.3-0.8-% RSD  | LOQ: At least 6.4 and 8.8 µg/L for I- and IO3- respectively (validated) | 0.59 mg/L\*\*\* | AcceptableNo method required due to low PECs in comparison to natural background levels | Liu et al (2010); Doc. No. 492-022; A4.2c/07 |
| Milk and milk powder | iodide | HPLC with electrochemical detector | Accuracy/precision data generated in the approximate range 0.6-4.3 µg/g and 270-310 µg/L for milk powders and liquid milk respectively. Each sample analysed in blind duplicates over two days. 6-9 laboratories participated (interlaboratory tested). | The correlation coefficient should be > 0.99. Applicability range of method quoted as 0.03 -1 µg/g and 0.3-10.0 µg/g for whole milk and milk powders respectively (no further supporting data) | Yes | 75-106% and 87.8% for milk powders (mp) and whole milk (wm) respectively  | 90.8% (mp) 87.8% (wm) | Precision: 7-24%RSD (mp)5-12%RSD (wm) | LOQ can be taken from applicability range: 0.03 µg/g (wm) 0.3 µg/g (mp) | ≥90 µg/L (0.09 µg/g)\*\*\*\* | Acceptable (internationally agreed std method). Further data may be required pending on conclusions of a full dietary risk assessment | 1. ISO 14378, Doc. No. 492-013; A4.3/012. D. Sertl and W. Malone (1993) |
| Milk and bovine liver | Total iodine | ICP-MS of digested samples | Standard material (milk powder and bovine liver) with certified iodine content in the range 0.1-5.4 mg/kg (  | Not reported (internal standardisation with129I- enriched iodate) | Yes | Not tested (good agreement with certified content) | - | 0.8-8.8% | LOQ: At least 0.3 mg/kg (validated for milk powder)) | ≥90 µg/L (milk) \*\*\*\* | Not fully acceptable (some missing information) | Rädlinger and Heumann (1998); Doc. No. 492-019; A4.3/02 |

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| For the determination of both purity of iodine and iodine content in preparations, there exists a well-documented method (titration with sodium thiosulfate) in the European Pharmacopeia. Concerning the residue analysis in the environment, monitoring methods are only considered required for air and food of animal origin (milk) as the PECs calculated for soil and water are low compared to the natural background concentrations in these compartments and as iodine is not classified as toxic or highly toxic. However, for the environment, air is not considered a relevant compartment but a method could be considered required for the purpose of measuring worker exposure. Acceptable methods have been provided from the open literature for water (IC-ICP-MS) and air (IC-PED). Based on the limited data provided in the draft CAR for the ISO-method for iodide in food of animal origin, ISO 14378, it could not be concluded that it is acceptable. However, during the peer-review the applicant provided supporting validation data for a published interlaboratory testing of the method. The ISO-method is thus considered valid as such. Given the use in PT 3 and PT 4 for teat-dipping and milking equipment disinfection a method seems to be required for milk, based on a preliminary dietary risk assessment. Nevertheless, the final conclusion on the need for such a method and the LOQ to be required has to be referred to the product authorisation stage when the final guidance for dietary risk assessment is available. ”Final CAR of Iodine, 12/2013”Analytical methods were provided at EU level for the determination of iodine residue in animal products (milk) with a LOQ = 0.3 mg/kg.Analytical methods were provided at EU level for the determination of iodine residue in soil, water and air with respectively LOQ = 0.05 mg/kg, 0.1 mg/L and 0.1 mg/ m3.Iodine is not toxic (T) or very toxic (T+) active substance. Therefore, an analytical method in biological matrices is not required. |

### Efficacy against target organisms

#### Function and field of use

MG 01: Disinfectants

PT3: Veterinary hygiene

PT4: Food and feed area

The product IODOL 100 is a soluble concentrate to be diluted in water before use.

It is used in the veterinary and, food and feed areas. It is used for the disinfection of empty breeding buildings and equipment for domestic animals (PT3) by spraying and soaking (equipment only). It is also used for the disinfection of drinking water pipes for drinking water of animals (PT4) by filling the water and Cleaning in place (CIP).

The product is used by professional users.

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

The product IODOL 100 is used to disinfect surfaces. It irreversibly inactivates vegetative bacteria and yeasts (PT3 and PT4).

The product is used for the purpose of the protection of human and animal health.

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

The product is able to produce a reduction in the number of viable bacterial cells (bactericidal activity) and of yeast cells (yeasticidal activity) of relevant test organisms under defined conditions (following definitions in EN 14885).

#### Mode of action, including time delay

The mode of action of iodine is non-selective and is based on the following mechanisms:

* Iodine rapidly penetrates into microorganisms showing a high affinity pattern of adsorption.
* Iodine combines with protein substances in the bacterial cell; these could 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 then metabolic inhibition will result.
* Iodine reacts with key groups of proteins, in particular the free-sulphur 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.

The rapid penetration of iodine into microorganisms and its mode of action indicate that the time-delay i.e. contact time required for sufficient efficacy depends on the tolerance of the organism to iodine and the concentration of iodine used for treatment. Contact times for the different activities claimed are determined in the efficacy tests (see table below).

#### Efficacy data

The product IODOL 100 contains orthophosphoric acid which is a pH regulator in the formulation. As this ingredient was originally identified in Annex 1 of the review program (Regulation (UE) n°1451/2007) but not notified at Annex 2, phase 1 tests (EN 1040 and EN 1275 standards) were performed with orthophosphoric acid alone in order to demonstrate that, at the maximum application rate claimed of the product (3.5 % v/v for PT3 and 1.5 % for PT4), it doesn’t have any basic bactericidal and yeasticidal activities. At these in-use concentrations, orthophosphoric acid doesn’t possess any basic bactericidal and yeasticidal activities according to respectively EN 1040 and EN 1275 standards.

Laboratory studies were conducted with the product IODOL 100, according to EN 14885:2006. They are summarised in the table below.

For PT3 uses

* Bactericidal disinfection of empty breeding buildings and equipment by spraying and soaking:

Bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1656 and EN 14349), at 10°C, with a contact time of 30 minutes, in respectively low and high-level soiling conditions (3 g /L bovine albumin (BSA) and, 10 g/L yeast extract and 10 g/L BSA). As surfaces disinfected are deemed with food contact, additional strain *E.coli*, which is an obligatory bacteria for food and feed area, has been also tested in the same conditions. In low level soiling conditions, bactericidal activity is shown at the in-use concentration tested of 2 % v/v for non-porous surfaces;

* Yeasticidal disinfection of empty breeding buildings and equipment by spraying and soaking:

Yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1657 and EN 16438), at 10°C, with a contact time of 30 minutes, in respectively low and high-level soilling conditions (3 g /L bovine albumin (BSA) and, 10 g/L yeast extract and 10 g/L BSA). In low level soiling conditions, yeasticidal activity is shown at the in-use concentration tested of 3.5 % v/v for non-porous surfaces;

For PT4 uses (disinfection of drinking water pipes for drinking water of animals)

* By filling of the water:

Bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests:

* EN 1276 at 20°C, a contact time of 5 minutes with dirty conditions (3.0 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 0.5 % v/v;
* EN 13697 at 20°C, contact times of 5 and 30 minutes with clean conditions (0.3 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentrations of 3 and 1.5 % v/v respectively;

Yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, a contact time of 15 minutes, with dirty conditions (3.0 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 1.5 % v/v.

Note for the conditions of use: as no test was provided at 10°C, a minimum temperature of 20°C has to be strictly respected to guarantee the efficacy of the product IODOL 100 at claimed doses.

* By CIP:
* Bactericidal activity is demonstrated in phase 2, step 1 test (EN 1276), in obligatory conditions (20°C, contact time of 5 minutes with dirty conditions (3.0 g/L BSA)) at the in-use concentration of 0.5 % v/v. In this test, the most resistant strain is *P. aeruginosa*.
* Yeasticidal activity is demonstrated in phase 2, step 1 test (EN 1650), in obligatory conditions (20°C, contact time of 15 minutes with dirty conditions (3.0 g/L BSA)) at the in-use concentration of 0.4 % v/v).

For CIP applications, additional tests should be performed with pH 5 (acidic cleaning) and pH 9 (alkaline cleaning) buffer solutions as interfering substances, as according to European standard tests EN 1276 and 1650 for this kind of application.

As we can consider that an alkaline pH shouldn’t have any influence on the sensibility of strains to the disinfectant, it was accepted that only the strain *P. aeruginosa* was tested with pH 9 buffer solution. Then, at 10°C with a contact time of 60 minutes and pH 9 buffer solution, an activity against *P. aeruginosa* is shown at 0.15 % v/v.

At pH more acid, sensibility of strains can vary and we asked the applicant for additional test on a Gram+ bacteria to ensure that *P. aeruginosa* remains the most resistant, therefore the test was conducted on both *P. aeruginosa* (Gram-) and *S. aureus* (Gram+). At 10°C with a contact time of 60 minutes and pH 5 buffer solution, the active concentrations were respectively 0.1 and 0.05 % v/v on *P. aeruginosa* and *S. aureus*.

For the additional strain *S.* Thyphimurium, at 10°C, with a contact time of 60 minutes and, pH 5 (acidic leaning) and pH 9 (alkaline cleaning) buffer solutions, the active concentration were 0.1 and 0.2 % respectively.

The bactericidal activity including the additional strain *S.* Thyphimurium at the additional conditions (10°C, contact time of 60 minutes with buffer solutions pH 5 and 9 as an interfering substance) was 0.2 % v/v.

Yeasticidal activity is demonstrated in phase 2, step 1 test (EN 1650), in additional conditions, at 10°C, with a contact time of 60 minutes and, pH 5 (residual pH 5, after acidic cleaning) and pH 9 buffer solutions at the in-use concentration of 0.2 % v/v (residual pH 5 or 9, after respectively acidic or alkaline cleaning).

Note for the conditions of use: before application, residual pH of the surfaces after the cleaning (acidic or alkaline) and rinsing has to be strictly in compliance with the conditions of uses proposed in the tests (pH 5 and pH 9) to guarantee the efficacy of the product IODOL 100 at claimed doses.

| **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 |  | Orthophosphoric acid 75 % w/w | Bacteria*P. aeruginosa**S. aureus* | EN 1040 : 2006 | Phase 1 test (suspension test)Concentrations tested: 0.02 %, 0.1 %, 0.2 %, 0.4% and 2 %Temperature: 20°CContact time: 5 minNo interfering substancesCriteria: at least a 5 log reduction | No basic bactericidal activity demonstrated at 0.2 % v/v  | 2016-MER-005R.I: 1 |
| Bactericide | Disinfection of empty breeding buildings and equipment (PT3) | Iodol 100 | Bacteria*P. aeruginosa**S. aureus**P. vulgaris**E. hirae* | EN 1656 : 2010 | Phase 2 step 1 test (suspension test)Concentrations tested: 0.5 %, 1 % and 1.5 %Temperature: 10°CContact time: 30 minHigh level soiling conditions (10 g/L yeast extract and 10 g/L BSA)Criteria: at least a 5 log reduction | Bactericidal activity demonstrated at 1.5 % v/v | 2015-mer-023R.I: 1 |
| Bactericide | Disinfection of empty breeding buildings and equipment (PT3) | Iodol 100 | Bacteria*E. coli* | EN 1656 : 2010 | Phase 2 step 1 test (suspension test)Concentrations tested: 0.5 %, 1 % and 1.5 %Temperature: 10°CContact time: 30 minHigh level soiling conditions (10 g/L yeast extract and 10 g/L BSA)Criteria: at least a 5 log reduction | Activity against *E.coli* demonstrated at 1 % v/v | 2016-MER-008R.I: 1 |
| Bactericide | Disinfection of empty breeding buildings and equipment (PT3) | Iodol 100 | Bacteria*P. aeruginosa**S. aureus**P. vulgaris**E. hirae* | EN 14349:2008 | Phase 2 step 2 test (non-porous surface test)Concentrations tested: 0.1 %, 1 %, 1.5 %, 2 % and 2.5 %Temperature: 10°CContact time: 30 minLow level soiling conditions (3 g/L BSA)Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 2 % v/v | 011-1-REA-12 ANR.I: 1 |
| Bactericide | Disinfection of empty breeding buildings and equipment (PT3) | Iodol 100 | Bacteria*E. coli* | EN 14349:2012 | Phase 2 step 2 test (non-porous surface test)Concentrations tested: 0.01 %, 1 %, 2 % and 4 %Temperature: 10°CContact time: 30 minHigh level soiling conditions (10 g/L yeast extract and 10 g/L BSA )Criteria: at least a 4 log reduction | Activity against *E. coli* demonstrated at 1 % v/v | 2016-MER-009R.I: 1 |
| Bactericide | Disinfection of drinking water pipes for drinking water for animals (PT4) | Iodol 100 | Bacteria*P. aeruginosa**S. aureus**E. coli**E. hirae* | EN 1276:2010 | Phase 2 step 1 test (suspension test)Concentrations tested: 0.2%, 0.25 %, 0.4 %, 0.5 % and 0.6 %Temperature: 20°CContact time: 5 minDirty conditions (3 g/L BSA)Criteria: at least a 5 log reduction | Bactericidal activity demonstrated at 0.5 % v/v | 2015-MER-003R.I: 1 |
| Bactericide | Disinfection of drinking water pipes for drinking water for animals (PT4) | Iodol 100 | Bacteria*P. aeruginosa**S.* Thyphimurium | EN 1276:2010 | Phase 2 step 1 test (suspension test)Concentrations tested: 0.05 %, 0.1 %, 0.2 % and 0.5 %Additional condition:Temperature: 10°CContact time: 60 minAdditional condition: pH 5 buffer solution (acidic leaning)Criteria: at least a 5 log reduction | Activity against *P. aeruginosa* and *S.* Thyphumurium demonstrated at 0.1 % v/v | 2015-MER-021R.I: 1 |
| Bactericide | Disinfection of drinking water pipes for drinking water for animals (PT4) | Iodol 100 | Bacteria*S. aureus* | EN 1276:2010 | Phase 2 step 1 test (suspension test)Concentrations tested: 0.01 %, 0.05 %, 0.2 % and 0.5 %Additional condition:Temperature: 10°CContact time: 60 minAdditional condition: pH 5 buffer solution (acidic cleaning)Criteria: at least a 5 log reduction | Activity against *S. aureus* demonstrated at 0.05 % v/v | 2016-MER-007R.I: 1 |
| Bactericide | Disinfection of drinking water pipes for drinking water for animals (PT4) | Iodol 100 | Bacteria*P. aeruginosa*S. Thyphimurium | EN 1276:2010 | Phase 2 step 1 test (suspension test)Concentrations tested: 0.05 %, 0.1 %, 0.2 % and 0.5 %Additional condition:Temperature: 10°CContact time: 60 minAdditional condition: pH 9 buffer solution (alkaline cleaning)Criteria: at least a 5 log reduction | Activity against *P. aeruginosa* and *S.* Thyphumurium demonstrated at 0.2 % v/v | 2015-MER-022R.I: 1 |
| Bactericide | Disinfection of drinking water pipes for drinking water for animals (PT4) | Iodol 100 | Bacteria*P. aeruginosa**S. aureus**E. coli**E. hirae* | EN 13697:2015 | Phase 2 step 2 test (surface test)Concentrations tested: 0.01 %, 2.5 %, and 3 %Temperature: 20°CContact time: 5 minClean conditions (3 g/L BSA) and 8.5 g/L skimmed milk for *P. aeruginosa*Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 3 % v/v | 043-1REA15 CI ANR.I: 2 |
| Bactericide | Disinfection of drinking water pipes for drinking water for animals (PT4) | Iodol 100 | Bacteria*P. aeruginosa**S. aureus**E. coli**E. hirae* | EN 13697:2015 | Phase 2 step 2 test (surface test)Concentrations tested: 1 %, 1.5 %, and 2.5 %Temperature: 20°CContact time: 30 minClean conditions (3 g/L BSA) and 8.5 g/L skimmed milk for *P. aeruginosa*Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 1.5 % v/v | 044-1REA15 CI AN v2R.I: 2 |
| Bactericide | Disinfection of drinking water pipes for drinking water for animals (PT4) | Iodol 100 | Bacteria*P. aeruginosa* | EN 13697:2015 | Phase 2 step 2 test (surface test)Concentrations tested: 1 %, 1.5 %, and 2.5 %Additional condition:Temperature: 20°CContact time: 30 minClean conditions 8.5 g/L skimmed milk Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 1.5 % v/vAn additional test was performed as the Nts value for the active concentration on *P. aeruginosa* was less than 100 cfu/ml according to the European standard EN 13697 | RE 16074-2R.I: 1 |
| Yeasticide |  | Orthophosphoric acid 75% w/w | Yeast*C. albicans* | EN 1275 : 2006 | Phase 1 test (suspension test)Concentrations tested: 0.035 %, 0.35% and 3.5 %Temperature: 20°CContact time: 15 minNo interfering substancesCriteria: at least a 4 log reduction | No basic yeasticidal activity demonstrated at 0.035 %, 0.35% and 3.5%  | 2016-MER-006R.I: 1 |
| Yeasticide | Disinfection of empty breeding buildings and equipment (PT3) | Iodol 100 | Yeast*C. albicans* | EN 1657:2007 | Phase 2 step 1 test (suspension test)Concentrations tested: 1 %, 1.5 %, 1.75 and 2 %Temperature: 10°CContact time: 30 minDirty conditions (10 g/L yeast extract and 10 g/L BSA)Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 2.0 % v/v | 2015-MER-024R.I: 1 |
| Yeasticide | Disinfection of empty breeding buildings and equipment (PT3) | Iodol 100 | Yeast*C. albicans* | EN 16438:2014 | Phase 2 step 2 test (surface test)Concentrations tested: 2 %, 3.5 %, and 4 %Temperature: 10°CContact time: 30 minClean conditions (3 g/L BSA)Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 3.5 % v/v | 031-1-REA 15 CI ANR.I: 1 |
| Yeasticide | Disinfection of drinking water pipes for drinking water for animals (PT4) | Iodol 100 | Yeast*C. albicans* | EN 1650:2008 | Phase 2 step 1 test (suspension test)Concentrations tested: 0.2 %, 0.4 %, and 0.5 %Temperature: 20°CContact time: 15 minDirty conditions (3 g/L BSA)Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 0.4 % v/v | 2015-MER-004R.I: 1 |
| Yeasticide | Disinfection of drinking water pipes for drinking water for animals (PT4) | Iodol 100 | Yeast*C. albicans* | EN 1650:2008 | Phase 2 step 1 test (suspension test)Concentrations tested: 0.05 %, 0.2 % and 0.5 %Additional condition:Temperature: 10°CContact time: 60 minAdditional condition: pH 5 buffer solution (acidic cleaning)Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 0.2 % v/v | 2015-MER-019R.I: 1 |
| Yeasticide | Disinfection of drinking water pipes for drinking water for animals (PT4) | Iodol 100 | Yeast*C. albicans* | EN 1650:2008 | Phase 2 step 1 test (suspension test)Concentrations tested: 0.05 %, 0.2 % and 0.5 % Additional condition:Temperature: 10°CContact time: 60 minAdditional condition: pH 9 buffer solution (alkaline cleaning)Criteria: at least a 5 log reduction | Yeasticidal activity demonstrated at 0.2 % v/v | 2015-MER-020R.I: 1 |
| Yeasticide | Disinfection of drinking water pipes for drinking water for animals (PT4) | Iodol 100 | Yeast*C. albicans* | EN 13697:2015 | Phase 2 step 2 test (surface test)Concentration tested: 0.8 %, 1%, and 1.5 %Temperature: 20°CContact time: 15 minDirty conditions (3 g/L BSA)Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 1.5 % v/v | 029-1REA15R.I: 1 |

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| **Conclusion on the efficacy of the product** |
| French competent authorities (FR CA) assessed that the product IODOL 100, diluted in water has shown a sufficient efficacy, for the following uses claimed:1- Disinfection of empty breeding buildings and equipments (PT 03)* By spraying, at 2 % v/v against bacteria and 3.5 % v/v against yeasts for the disinfection of empty breeding buildings and equipments, at 10 °C, with a contact time of 30 minutes on clean non-porous surfaces.
* By soaking, at 2 % v/v against bacteria and 3.5 % v/v against yeasts for the disinfection of equipments, at 10 °C, with a contact time of 30 minutes, on clean non-porous surfaces.

2- Disinfection of drinking water pipes for drinking water for animals (PT 04)* By filling of the water at 1.5 % v/v for the disinfection (bacteria and yeasts), of clean water pipes, **at 20°C** with a contact time of 30 minutes.
* By Cleaning in Place (CIP) at 0.2 % v/v (bacteria and yeasts), for the disinfection of clean water pipes after respectively alkaline cleaning (residual pH 9) and acidic cleaning (residual pH 5), at 10°C with a contact time of 60 minutes.
 |

#### Occurrence of resistance and resistance management

No reduction in efficacy was reported in the literature for such applications indicating that no development of resistant microorganisms has occurred.

The authorization holder has to report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

#### Known limitations

There are no known limitations for the use of the product as instructed.

#### Evaluation of the label claims

French competent authorities (FR CA) assessed that the product IODOL 100, diluted in water has shown a sufficient efficacy, for the following uses claimed:

1- Disinfection of empty breeding buildings and equipments (PT 03)

* By spraying, at 2 % v/v against bacteria and at 3.5 % v/v against yeasts for the disinfection of empty breeding buildings and equipments, at 10 °C, with a contact time of 30 minutes, on clean non porous surfaces.

The product is sprayed at 200-400 mL of diluted product / m².

* By soaking, at 2 % v/v against bacteria and at 3.5 % v/v against yeasts for the disinfection of equipments, at 10 °C, with a contact time of 30 minutes, on clean non porous surfaces.

2- Disinfection of drinking water pipes for drinking water of animals (PT 04)

* By filling of the water at 1.5 % v/v for the disinfection (bacteria including the additional strain *S.* Thyphimurium, and yeasts), on clean water pipes, at 20°C with a contact time of 30 minutes.
* By Cleaning in Place (CIP) at 0.2 % v/v (residual pH 5 or 9, after respectively acidic or alkaline cleaning) for the disinfection (bacteria including the additional strain *S.* Thyphimurium, and yeasts), on clean water pipes, at 10°C with a contact time of 60 minutes.

To ensure a satisfactory level of efficacy and avoid the development of resistance in susceptible micro-organisms populations, the following recommendations have to be implemented:

* Always read the label or leaflet before use and respect follow all the instructions provided.
* For the disinfection of drinking water pipes for animals by filling, a minimum temperature of 20°C has to be respected to guarantee the efficacy of the product IODOL 100.
* Clean carefully the surfaces before application of the product.
* For the disinfection of drinking water for animals by CIP applications before disinfection, residual pH of the surfaces after the cleaning (acidic or alkaline) and rinsing, has to be strictly in compliance with the conditions of uses to guarantee the efficacy of the product IODOL 100..
* The diluted solution should be used immediately.
* For PT3 uses, apply only on non-porous surfaces.
* The users should inform if the treatment is ineffective and report straightforward to the registration holder.

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

None

### Risk assessment for human health

#### Assessment of effects on Human Health

Please refer to iodine CAR.

The following data on active substance issued from CAR will be used for human health risk assessment:

|  |  |
| --- | --- |
| **Endpoint**  | **Value** |
| AEL  | 0.01 mg/kg/d |
| AEC inhalation  | 1 mg/m3 or 0.1 ppm |
| Oral absorption  | 100% |
| P vapor | 40.7 Pa at 25°C |
| MM | 253.81 g/mol |

***Skin corrosion and irritation***

In order to avoid unnecessary animal experiment, no skin irritation / corrosion study was conducted on
this formulation. The classification for this endpoint is determined by calculation according to the CLP Regulation (Regulation (EC) No.1272/2008).

Based on the pH (0.9 at 20°C), the pure product should be classified Skin Corr. 1.

This classification will also be applied for dilution with corrosive property.

Therefore, based on the available data on active substance, formulants and product, the product should be classified Skin Corr. 1, H314, Causes severe skin burns and eye damage.

The pH of dilutions were also tested by applicant:

|  |  |
| --- | --- |
| **Dilution of product** | **pH** |
| 0.2% | 3-5.8 |
| 0.5% | 2.6-3 |
| 1% | 2.3 |
| 1.5% | 2.2-2.3 |
| 2% | 2.1-2.2 |
| 3% | 2 |
| 3.5% | 2 |
| 4% | 1.9 |

The dilutions claimed by the applicant are:

* 2% and 3.5% for disinfection by spraying and soaking of surface or equipment,
* 1.5% for disinfection of drinking water pipe by injection,
* 0.2% for disinfection of drinking water pipe by cleaning in place (CIP).

The dilution of 3.5% is clearly considered corrosive.

The dilutions 0.2, 1.5 and 2% are not considered corrosive as the pH is superior to 2, which is the threshold value.

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| --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** |
| Value/conclusion | Classified Skin Corr. 1, H314 |
| Justification for the value/conclusion | PH of pure product is 0.9 at 20°C. |
| Classification of the product according to CLP  | Skin Corr. 1, H314 |

|  |
| --- |
| **Data waiving** |
| Information requirement | In order to avoid unnecessary animal experiment, no skin irritation / corrosion study was conducted. |
| Justification | Classification for this endpoint is determined by calculation according to the CLP Regulation. |

***Eye irritation***

In order to avoid unnecessary animal experiment, no skin irritation / corrosion study was conducted on
this formulation. The classification for this endpoint is determined by calculation according to the CLP Regulation (Regulation (EC) No.1272/2008). Based on the available data on active substance, formulants and product, the product should be classified Skin Corr. 1, H314, Causes severe skin burns and eye damage, as the PH of pure product is 0.9 at 20°C.

Since the product is classified as being H314, it is also, automatically, classified as H318. This should appear in the hazard category and hazard statement.

However, it is not necessary in the labelling.

|  |
| --- |
| **Conclusion used in Risk Assessment – Eye irritation**  |
| Value/conclusion | Classified Skin Corr. 1, H314; Serious eye damage cat. 1 H318  |
| Justification for the value/conclusion | PH of pure product is 0.9 at 20°C. |
| Classification of the product according to CLP  | Skin Corr. 1, H314, Serious eye damage cat. 1 H318 |

|  |
| --- |
| **Data waiving** |
| Information requirement | In order to avoid unnecessary animal experiment, no skin irritation / corrosion study was conducted. |
| Justification | Classification for this endpoint is determined by calculation according to the CLP Regulation. |

***Respiratory tract irritation***

No study was provided. The classification for this endpoint is determined by calculation according to the CLP Regulation (Regulation (EC) No.1272/2008). Based on the available data on active substance and formulants, no classification is necessary. However, as the product is classified as corrosive, the sentence “EUH071: Corrosive to the respiratory tract” should be added.

Moreover, as iodine has irritant property on respiratory tract, a local risk assessment will be presented in the risk assessment part.

|  |
| --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** |
| Justification for the conclusion | Not classified |
| Classification of the product according to CLP  | Not classified |

|  |
| --- |
| **Data waiving** |
| Information requirement | In order to avoid unnecessary animal experiment, no irritation study was conducted. |
| Justification | Classification for this endpoint is determined by calculation according to the CLP Regulation. |

***Skin sensitization***

In order to avoid unnecessary animal experiment, no skin sensitization study was conducted on
this formulation. The classification for this endpoint is determined by calculation according to the CLP Regulation (Regulation (EC) No.1272/2008). Based on the available data on active substance and formulants, no classification is needed.

|  |
| --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** |
| Value/conclusion | Not classified |
| Justification for the value/conclusion | - |
| Classification of the product according to CLP  | Not classified |

|  |
| --- |
| **Data waiving** |
| Information requirement | In order to avoid unnecessary animal experiment, no skin sensitisation study was conducted. |
| Justification | Classification for this endpoint is determined by calculation according to the CLP Regulation. |

***Respiratory sensitization (ADS)***

In order to avoid unnecessary animal experiment, no respiratory sensitization study was conducted on
this formulation. The classification for this endpoint is determined by calculation according to the CLP Regulation (Regulation (EC) No.1272/2008). Based on the available data on active substance and formulants, no classification is needed.

|  |
| --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** |
| Value/conclusion | Not classified |
| Justification for the value/conclusion | - |
| Classification of the product according to CLP and DSD | Not classified |

|  |
| --- |
| **Data waiving** |
| Information requirement | In order to avoid unnecessary animal experiment, no respiratory sensitisation study was conducted. |
| Justification | Classification for this endpoint is determined by calculation according to the CLP Regulation. |

***Acute toxicity***

*Acute toxicity by oral route*

In order to avoid unnecessary animal experiment, no oral acute toxicity study was conducted on
this formulation. The classification for this endpoint is determined by calculation according to the CLP Regulation (Regulation (EC) No.1272/2008). Based on the available data on active substance and formulants, no classification is needed.

|  |
| --- |
| **Value used in the Risk Assessment – Acute oral toxicity** |
| Value | Not classified |
| Justification for the selected value |  |
| Classification of the product according to CLP  | Not classified |

|  |
| --- |
| **Data waiving** |
| Information requirement | In order to avoid unnecessary animal experiment, no oral acute toxicity study was conducted. |
| Justification | Classification for this endpoint is determined by calculation according to the CLP Regulation. |

*Acute toxicity by inhalation*

In order to avoid unnecessary animal experiment, no inhalation acute toxicity study was conducted on
this formulation. The classification for this endpoint is determined by calculation according to the CLP Regulation (Regulation (EC) No.1272/2008). Based on the available data on active substance and formulants, no classification is needed.

|  |
| --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** |
| Value | Not classified |
| Justification for the selected value |  |
| Classification of the product according to CLP and DSD | Not classified |

|  |
| --- |
| **Data waiving** |
| Information requirement | In order to avoid unnecessary animal experiment, no inhalation acute toxicity study was conducted. |
| Justification | Classification for this endpoint is determined by calculation according to the CLP Regulation. |

*Acute toxicity by dermal route*

In order to avoid unnecessary animal experiment, no dermal acute toxicity study was conducted on
this formulation. The classification for this endpoint is determined by calculation according to the CLP Regulation (Regulation (EC) No.1272/2008). Based on the available data on active substance and formulants, no classification is needed.

|  |
| --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** |
| Value | Not classified |
| Justification for the selected value |  |
| Classification of the product according to CLP and DSD | Not classified |

|  |
| --- |
| **Data waiving** |
| Information requirement | In order to avoid unnecessary animal experiment, no dermal acute toxicity study was conducted. |
| Justification | Classification for this endpoint is determined by calculation according to the CLP Regulation. |

Moreover, a classification STOT RE 1 H372 is proposed in the MSDS of iodine complex. Considering its content, a classification STOT RE. 2, H373: May cause damage to organ (thyroid) through prolonged or repeated exposure. is needed.

Consequently, based on the available data, IODOL 100 should be classified as follows:

* Skin Corr. 1B, H314: Causes severe skin burns and eye damage.
* STOT RE. 2, H373: May cause damage to organ (thyroid) through prolonged or repeated exposure.
* “EUH071: Corrosive to the respiratory tract” should be added.

The product is classified for skin corrosion due to its pH of 0.9 at 20°C.

Since this pH is essentially linked to the presence of orthophosphoric acid, orthophosphoric acid is considered as SOC.

According to the ECHA guidance volume III part B/C, qualitative exposure and risk assessment to determine whether P-statements normally associated with concerned H statements are sufficient.

Moreover, a local risk assessment is performed and RMM are proposed according it.

The product contains also alcohols, C12-14, ethoxylated at a content which leads to the classification H318. In this context, alcohols, C12-14, ethoxylated is considered as SOC.

The P-statements associated to the classification H314 are sufficient for the risk assessment.

***Information on dermal absorption***

No study was provided. In this context, according to the EFSA guidance on dermal absorption (2012)[[3]](#footnote-4), if a product or in use dilutions contains ≤ 5% of active substance, a default dermal absorption value of 75% should be used. Also, if oral absorption is < 75%, this can be used as a surrogate dermal absorption value.
Since the product Iodol 100 contains either 1% w/w iodine (concentrated fraction) or less of 0.035% w/w (diluted fraction), and since iodine has an oral absorption of 100%, the default dermal absorption value of the active substance in the product Iodol 100 should be 75% (for both concentrated and diluted forms).

For corrosive concentration, according to agreement of WG III 2016, a default dermal absorption of 100% should be used if risk assessment is performed.

The applicant proposed to use the dermal absorption value available in the CAR. However, the product and dilutions of IODOL 100 have corrosive or irritant properties in contrast to the representative product of the CAR. In this context, according to the EFSA guidance on dermal absorption, the read across between the products is not acceptable.

For secondary exposure to dried surface, exposure is the exposure to the active substance alone without formulant. In this context, the dermal absorption reported in the CAR of iodine will be used (12%).

|  |
| --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** |
| Substance | Iodine in formulation | Iodine (corrosive concentration) | Iodine alone |
| Value(s)\* | 75% | 100% | 12% |
| Justification for the selected value(s) | Default value | Default value | CAR value |

#### Exposure assessment

It is intended to be used by professional users in order to disinfect empty breeding buildings and equipment for domestic animals (PT03). It is also used for the disinfection of drinking water pipe for drinking water of animals (PT04).

For PT03 uses, the product is applied by spraying or soaking (2% v/v or 3.5% v/v dilution).

For PT04 uses, the product is applied by filling the drinking water pipe (1.5% v/v dilution) or by cleaning in place (0.2% v/v dilution).

The recommended dose for spray application is 200 to 400 mL of diluted product per m².

Depending on the concentrations, the product could have corrosive properties or not.

According to the agreements of WG III 2016, the use of appropriate personal protective equipment (PPE) and risk mitigation measure (RMM) will always be required for corrosive concentrations, resulting in no direct contact with the corrosive mixtures. Exposure to corrosive concentrations would thus be negligible. Therefore, in this WG it was decided not to perform systemic risk assessment for such concentrations.

In this context, two types of assessment will be presented in this dossier:

* For corrosive concentration (pure and 3.5% dilution): a qualitative local risk assessment.;
* For non-corrosive concentration (0.2, 1.5 and 2% dilution): a quantitative systemic and a local (inhalation) risk 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 | NA | YES | NA | NA | YES | NA | NA |
| Dermal | NA | YES | NA | NA | YES | NA | NA |
| Oral | NA | NO | NA | NA | NO | NA | YES |

*NA not applicable*

***List of scenarios***

| **Summary table: scenarios** |
| --- |
| **Scenario number** | **Scenario**(e.g. mixing/ loading) | **Primary or secondary exposure** **Description of scenario** | **Exposed group**(e.g. professionals, non-professionals, bystanders) |
| 1. | Disinfection of the surfaces by spraying associated with the housingof animals | Primary exposure:* (a) Mixing and loading (pure)
* (b) Spraying surface (2 to 3.5% dilution)
* (c) Cleaning spray equipment
 | Professional  |
| 2. | Disinfection of the equipment by soaking associated with the housingof animals | Primary exposure:* (a) Mixing and loading (pure)
* (b) Dipping equipment (2 to 3.5% dilution)
 | Professional |
| 3. | Disinfection of drinking water pipe by injection or cleaning in place (CIP) | Primary exposure:* Mixing and loading (pure)
 | Professional |
| 4. | Secondary exposure  | (a) inhalation of volatilised residues(b) dermal contact with treated surface  |  |

***Industrial exposure***

Not relevant

***Professional exposure***

***Scenario [1]: Disinfection of the surfaces by spraying (2-3.5% dilution)***

Three tasks are performed:

* (a) Mixing and loading of pure product at corrosive concentration
* (b) Spraying dilution:
	+ At 3.5% dilution: corrosive concentration
	+ At 2% dilution: not corrosive concentration.
* (c) Cleaning spray equipment at non-corrosive concentration

**1a. Mixing and loading of pure product**

As the pure product is corrosive, only qualitative local risk assessment according to the guidance on the BPR: Volume III HH part B is performed.

|  |  |  |
| --- | --- | --- |
| **Hazard** | **Exposure** | **Risk** |
| **HazardCategory** | **Effectsintermsof C&L** | **Additionalrelevanthazardinformation** | **PT** | **Who is exposed?** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant RMM & PPE** | **Conclusion on risk** |
| Very high hazard | Skin Corr. 1B | - | 3-4 | Professional  | Pouring and mixing pure product in receiving container | Dermal  | Application at each sanitation period. Depends on the type of breeding every 3to 7 weeks on average (farmer)1/day (disinfection professional) | Low  | RMM Technics:- Containment as appropriate;- Segregation of the emitting process;- Effective contaminant extraction;- Good standard of general ventilation;- Minimisation of manual phases;- Regular cleaning of equipment and work area;- Avoidance of contact with contaminated tools and objects;RMM Organisation:- Minimise number of staff exposed;-Management /supervision in place to checkthat the RMMs in place are being used correctly and OCs followed;- Training for staff on good practice;- Good standard of personal hygienePPE-Task appropriate gloves- Skin coverage with appropriate barrier material based on potential for contact with the chemicals- Eye protection | Exposure must be limited to brief contacts (Practically no exposure, no splashes, no hand to eye transfer, no aerosol formation). Technical RMM and PPE are requiredConsidering that these recommendations can be followed during this task, ,the risk is acceptable. |

**1b. Spraying dilution**

* Local risk assessment

For dilution with corrosive property (3.5% dilution), a local risk assessment is performed.

|  |  |  |
| --- | --- | --- |
| **Hazard** | **Exposure** | **Risk** |
| **HazardCategory** | **Effectsintermsof C&L** | **Additionalrelevanthazardinformation** | **PT** | **Who is exposed?** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant RMM & PPE** | **Conclusion on risk** |
| Very high hazard | Skin Corr. 1B | - | 3-4 | Professional  | Spraying surface | Dermal and inhalation (aerosol generation) | Application at each sanitation period. Depends on the type of breeding every 3to 7 weeks on average (farmer)1/day (disinfection professional) | Not negligible | Not proposed as the risk is unacceptable | According to the guidance for concluding qualitatively on the acceptability for professional exposure[[4]](#footnote-5), pratically no exposure and no aerosol formation should occur with substances classified Skin Corr. 1B to lead to an acceptable risk. In this context, the use for spraying surface is considering **unacceptable.** |

* Systemic risk assessment

A quantitative systemic (”classic”) risk assessment is performed for the dilution at 2%.

In this context, the assessment will be performed with a dilution at 2% of product (0.0272% of iodine)

| **Description of Scenario [1b]****Disinfection of the surfaces by spraying** |
| --- |
| According to the recommendation 6 of the Ad hoc WG on human exposure, exposure during animal house disinfection by spraying should be assessed with **Spraying model 2** considering a duration of **120 minutes**.Exposure is assessed with a dilution of product at 2% (0.0272% of iodine) and a dermal absorption value of 75%Exposure data from the model are as follows :* Hands (actual): 7.8 mg/min;
* Hands (potential): 273 mg/min;
* Body: 222 mg/min
* Inhalation: 76 mg/m3
 |
|  | **Parameters** | **Value** |
| Tier 1 | Without PPE |  |
| Tier 2a | With gloves and coated coverall | Gloves included in the model Clothing penetration: 20% |
| Tier 2b | With gloves and impermeable coverall | Gloves included in the model Clothing penetration: 5% |
| Tier 2c | With gloves, impermeable coverall and mask APF 10 | Gloves included in the model Clothing penetration: 5%Mask APF 10 |

**Calculations for Scenario [1b]**

| **Summary table: estimated exposure from professional uses** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake****(mg/kg bw/d)** | **Estimated dermal uptake****(mg/kg bw/d)** | **Estimated oral uptake****(mg/kg bw/d)** | **Estimated total uptake****(mg/kg bw/d)** |
| Scenario [1b] | Without PPE | 8.61E-04 | 2.02E-01 | nr | 2.03E-01 |
| Scenario [1b] | With gloves and coated coverall | 8.61E-04 | 2.13E-02 | nr | 2.22E-02 |
| Scenario [1b] | With gloves and impermeable coverall | 8.61E-04 | 7.71E-03 | nr | 8.57E-03 |
| Scenario [1b] | With gloves and impermeable coverall and mask APF 10 | 8.61E-05 | 7.71E-03 | nr | 7.80E-03 |

nr: not relevant

Local effect by inhalation is noted in the CAR and an AEC for inhalation route is available. In this context, the value of inhalation exposure will be compared to this value.

An indicative value of 76 mg/m3 diluted product is obtained in the spraying model 2. Considering a concentration in active substance of 0.0272%, an exposure at 0.021 mg/m3 is expected.

The applicant proposed to assess the exposure of professional during spraying with the spraying model 1. This model takes into account the mixing and loading of a liquid in a sprayer, then the application of the dilution by low-pressure spraying. The applicant proposed to harmonize the conditions of uses with this mode of application.

| **Description of Scenario [1b]****Disinfection of the surfaces by spraying** |
| --- |
| Exposure during animal house disinfection by spraying is assessed with **Spraying model 1**. A duration of **120 minutes** is considered. Exposure is assessed with a dilution of product at 2% (0.0272% of iodine) and a dermal absorption value of 75%Exposure data from the model are as follows:* Hands (actual): 10.7 mg/min;
* Hands (potential): 181 mg/min;
* Body: 92 mg/min
* Inhalation: 104 mg/m3
 |
|  | **Parameters** | **Value** |
| Tier 1 | Without PPE |  |
| Tier 2a | With gloves and coated coverall | Gloves included in the model Clothing penetration: 20% |
| Tier 2b | With gloves and impermeable coverall | Gloves included in the model Clothing penetration: 5% |
| Tier 2c | With gloves, impermeable coverall and mask APF 10 | Gloves included in the model Clothing penetration: 5%Mask APF 10 |

**Calculations for Scenario [1b]**

| **Summary table: estimated exposure from professional uses** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake****(mg/kg bw/d)** | **Estimated dermal uptake****(mg/kg bw/d)** | **Estimated oral uptake****(mg/kg bw/d)** | **Estimated total uptake****(mg/kg bw/d)** |
| **2 % dilution**  |
| Scenario [1b] | Without PPE | 1.18E-03 | 1.11E-01 | nr | 1.13E-01 |
| Scenario [1b] | With gloves and coated coverall | 1.18E-03 | 1.19E-02 | nr | 1.31E-02 |
| Scenario [1b] | With gloves and impermeable coverall | 1.18E-03 | 6.24E-03 | nr | 7.42E-03 |
| Scenario [1b] | With gloves and impermeable coverall and mask APF 10 | 1.18E-04 | 6.24E-03 | nr | 6.36E-03 |

Local effect by inhalation is noted in the CAR and an AEC for inhalation route is available. In this context, the value of inhalation exposure will be compared to this value.

An indicative value of 104 mg/m3 diluted product is obtained in the spraying model 1. Considering a concentration in active substance of 0.0272%, an exposure at 0.0282 mg/m3 is expected.

**1c. Cleaning spray equipment**

| **Description of Scenario [1c]****Cleaning spray equipment** |
| --- |
| Exposure during the cleaning of equipment is assessed with the BEAT scenario “Cleaning of the spray equipment” from TNsG second version of 2007[[5]](#footnote-6).A duration of **10 minutes** is considered.Exposure is assessed with a dilution of product at % (0.02% of iodine) and a dermal absorption value of 75%Exposure data from the model are as follows:* Hands (potential): 35.87 mg/min;
* Body: 19.28 mg/min
 |
|  | **Parameters** | **Value[[6]](#footnote-7)** |
| Tier 1 | Without PPE |  |
| Tier  | With gloves |  |

**Calculations for Scenario [1c]**

| **Summary table: estimated exposure from professional uses** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake****(mg/kg bw/d)** | **Estimated dermal uptake****(mg/kg bw/d)** | **Estimated oral uptake****(mg/kg bw/d)** | **Estimated total uptake****(mg/kg bw/d)** |
| Scenario [1c] | Without PPE | nr | 1.88E-03 | nr | 1.88E-03 |
| Scenario [1c] | With gloves | nr | 2.53E-04 | nr | 2.53E-04 |

Nr: not relevant

***Scenario [2]: Disinfection of the equipment by soaking (2-3.5% dilution)***

Two tasks are performed:

* (a) Mixing and loading of pure product at corrosive concentration
* (b) Dipping :
	+ At 3.5% dilution: corrosive concentration
	+ At 2% dilution: not corrosive concentration

**2a. Mixing and loading of pure product**

The exposure is the same that during mixing and loading of spray equipment. See scenario 1a.

**2b. Dipping**

* Local risk assessment

For dilution with corrosive property (3.5% dilution), a local risk assessment is performed.

|  |  |  |
| --- | --- | --- |
| **Hazard** | **Exposure**  | **Risk** |
| HazardCategory | Effectsintermsof C&L | Additionalrelevanthazardinformation | PT | Who is exposed? | Tasks, uses, processes | Potential exposure route  | Frequency and duration of potential exposure  | Potential degree of exposure | Relevant RMM & PPE | Conclusion on risk |
| Very high hazard | Skin Corr. 1B | - | 3-4 | Professional  | Dipping equipment | Dermal and inhalation  | 1/day  | Not negligible | Not proposed as the risk is unacceptable | According to the guidance for concluding qualitatively on the acceptability for professional exposure[[7]](#footnote-8), pratically no exposure and no splashes should occur to lead acceptable risk. Exposure would be comparable to brief contact as touching of contamined surface. Considering a dipping, splashes or exposure superior to brief contact could occur. In this context, risk is **unacceptable.** |

* Systemic risk assessment

A quantitative systemic (”classic”) risk assessment is performed for dilution 2%.

In this context, assessment will be performed with a dilution at 2% of product (0.02% of iodine)

| **Description of Scenario [2b]****Disinfection of equipment by dipping** |
| --- |
| According to the recommendation 6 of the Ad hoc WG on human exposure, dermal exposure during disinfection of equipment by dipping is assessed with **Dipping model 1**. A duration of **30 minutes** is considered.Exposure by inhalation is assessed with Consexpo ”Exposure to vapour” considering evaporation from simulate dipping tank containing 10 L of dilution at 0.0272% of iodine with a depth of 10 cm leading to a release area of 1000 cm2 in a room of 25m3 with a ventilation rate of 0.6/h.Exposure is assessed with a dilution of product at 2% (0.0272% of iodine) and a dermal absorption value of 75%Exposure data from the model are as follows:Hands (inside gloves): 25.7 mg/min;Body: 178 mg/min |
|  | **Parameters** | **Value** |
| Tier 1 | With gloves  | Included in the model  |
| Tier 2 | With gloves and coated coverall | Gloves included in the model Clothing penetration: 20% |

**Calculations for Scenario [2b]**

| **Summary table: estimated exposure from professional uses** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake****(mg/kg bw/d)** | **Estimated dermal uptake****(mg/kg bw/d)** | **Estimated oral uptake****(mg/kg bw/d)** | **Estimated total uptake****(mg/kg bw/d)** |
| Scenario [2b] | With gloves | 8.50E-04 | 2.08E-02 | nr | 2.16E-02 |
| Scenario [2b] | With gloves and coated coverall | 8.50E-04 | 6.25E-03 | nr | 7.10E-03 |
| Scenario [2b] | With gloves and impermeable coverall | 8.50E-04 | 3.53E-03 | nr | 4.38E-03 |

Nr: not relevant

Local effect by inhalation is noted in the CAR and an AEC for inhalation route is available. In this context, the value of inhalation exposure will be compared to this value.

An indicative value of 0.0816 mg/m3 of active substance is obtained in Consexpo.

**Combined scenarios**

Not relevant as no systemic risk assessment was performed for mixing and loading.

***Scenario [3]: Disinfection of drinking water pipe by injection or cleaning in place***

One task is performed:

* Mixing and loading of pure product at corrosive concentration.

The exposure is the same that during mixing and loading of spray equipment. See scenario 1a.

***Non-professional exposure***

Not relevant

***Exposure of the general public***

Adults (general public) and children are not expected to be in contact with treated areas. Therefore, no secondary risk assessment is performed for this public.

Professionals may be exposed to the product IODOL 100 via:

* (a) Inhalation route (inhalation of volatilised residues).
* (b) Dermal route by contact with treated surface.

These scenarios are not relevant for PT4 intended uses (disinfection of water pipe).

***Scenario [4a]: Inhalation of volatilised residues***

| **Description of Scenario [4a]** |
| --- |
| Exposure is assessed with a dilution of product at 2% (0.0272% of iodine) .Inhalation of volatilised residues is assessed with Consexpo ”Exposure to vapour” considering evaporation during 8h as it is a professional exposure, a dilution at 0.0272% of iodine applied on a floor of 20 m2 in a room of 25 m3 with a ventilation rate of 0.6/h.  |
|  | **Parameters** | **Value** |
| Tier 1 | Consexpo parameters see annex |  |

Remark: The day of treatment, the professional will not stay in the room for 8 hours. However, he could enter into the room for control task. In this context, the exposure to volatilised residues is also estimated for 1h of exposure.

This scenario of control task after treatment will be combined with the exposure during application and exposure during touching a treated surface.

**Calculations for Scenario [4a]**

| **Summary table: systemic exposure from non-professional uses** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake****mg/kg bw/d** | **Estimated dermal uptake****mg/kg bw/d** | **Estimated oral uptake****mg/kg bw/d** | **Estimated total uptake****mg/kg bw/d** |
| Scenario [4a] 8h0.0272% | nr | 1.36E-02 | nr | nr | 1.36E-02 |
| Scenario [4a] 1h0.0272% | nr | 1.70E-03 | nr | nr | 1.70E-03 |

Nr: not relevant

Local effect by inhalation is noted in the CAR and an AEC for inhalation route is available. In this context, the value of inhalation exposure will be compared to this value.

An indicative value of 0.0816 mg/m3 of active substance is obtained in Consexpo.

For dipping, a rinse of material after treatment is claimed. Moreover, the treated surfaces are small. Therefore, secondary exposure by inhalation to volatilised residues is considered negligible.

***Scenario [4b]: Exposure of an adult who touches a treated surface with his hands (wet and dry surface)***

| **Description of Scenario [4b]** |
| --- |
| Exposure of an adult who touches a treated surface with his hands (wet and dry surface) is assessed.The dose of application is 200 to 400 mL of diluted product per m². In this assessment the dilution of 0.0272% is used.From this surface a fraction of active substance is dislodgeable:* For wet surface, a default value of 100 % will be used.
* For dried surface, the value of 30 % proposed in TNsG for dried surface will be used.

For the exposure to wet surface, the dermal absorption value of 75 % will be used. For the exposure to dried surface, the dermal absorption value of the active substance will be used (12%). |

**Calculations for Scenario [4b]**

| **Summary table: systemic exposure from non-professional uses** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake****(mg/kg bw/d)** | **Estimated dermal uptake****(mg/kg bw/d)** | **Estimated oral uptake****(mg/kg bw/d)** | **Estimated total uptake****(mg/kg bw/d)** |
| Scenario [4b] wet surface | nr | nr | 5.58E-02 | nr | 5.58E-02 |
| Scenario [4b] dried surface | nr | nr | 2.68E-03 | nr | 2.68E-03 |

Nr: not relevant

***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****mg/kg/d** |
| 1b (spraying 2) | Professional | Without PPE | 2.03E-01 |
| 1b (spraying 2) | Professional | With gloves and coated coverall | 2.22E-02 |
| 1b (spraying 2) | Professional | With gloves and impermeable coverall | 8.57E-03 |
| 1b (spraying 2) | Professional | With gloves and impermeable coverall and mask APF 10 | 7.80E-03 |
| 1b (spraying 1) | Professional | Without PPE | 1.13E-01 |
| 1b (spraying 1) | Professional | With gloves and coated coverall | 1.31E-02 |
| 1b (spraying 1) | Professional | With gloves and impermeable coverall | 7.42E-03 |
| 1b (spraying 1) | Professional | With gloves and impermeable coverall and mask APF 10 | 6.36E-03 |
| 1c (cleaning) | Professional | Without PPE | 1.88E-03 |
| 1c (cleaning) | Professional | With gloves | 2.53E-04 |
| 2b (dipping) | Professional | With gloves | 2.16E-02 |
| 2b (dipping) | Professional | With gloves and coated coverall | 7.10E-03 |
| 2b (dipping) | Professional | With gloves and impermeable coverall | 4.38E-03 |
| 4a (residue volatile) 8h0.0272% |  |  | 1.36E-02 |
| 4a (residue volatile) 2h0.0272% |  |  | 1.70E-03 |
| 4b (hand contact) |  | Wet surface | 5.58E-02 |
| 4b (hand contact) |  | Dried surface | 2.68E-03 |

* Local inhalation risk assessment

|  |  |
| --- | --- |
| Spraying | 0.021 mg/m3 |
| Dipping | 0.0816 mg/m3 |
| Residue volatile | 0.0816 mg/m3 |

***Dietary exposure***

Considering intended uses of the product IODOL 100, livestock can be exposed to the active substance iodine. So residue of iodine can be found in food and products from animal origin. As a consequence, the human dietary assessment needs to be performed in this dossier.

**Residue definitions**

In water, iodide (I-) and iodate (IO3-) are the predominant species. In addition a natural background level of methyl iodide might also be found in water. At pH values between 4 and 9, iodide is the predominant species. In alkaline and well oxidized waters iodate is the predominant specie.

The livestock is expected to be exposed to the active substance iodine (I2), and iodide (I-). When absorbed, iodine is quickly reduced to iodide by nonenzymatic reactions. Iodide is readily and (almost) completely absorbed. The bioavailability after oral administration is > 90%.

The residue of iodine expected in food and products from animal origin is iodide (I-).

*List of scenarios*

| **Summary table of main representative dietary exposure scenarios** |
| --- |
| **Scenario number** | **Type of use** | **Description of scenario** | **Subject of exposure** |
| 1.a | Professional useVeterinary area | PT03: Disinfection of empty breedingSpraying  | Livestock |
| 1.b | Professional useVeterinary area | PT03: Disinfection of equipment Soaking | Livestock |
| 2.a | Professional useVeterinary area | PT04: Disinfection of drinking water pipe for drinking water of animals Soaking / Filling of the water pipe | Livestock |
| 2.b | Professional useVeterinary area | PT04: Disinfection of drinking water pipe for drinking water of animals Cleaning in place | Livestock |

The active substance iodine is not considered as a cumulative substance:

* no log Pow is defined,
* no data suggests a potential bioaccumulation of iodine/iodide in the body under normal circumstances,
* Iodide in excess of physiological requirement is excreted mainly via the urine, and in smaller quantities via faeces, saliva, milk, sweat, tears, bile, other secretions and exhaled air.

So no bioaccumulation of iodine is expected.

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

According to Regulation (EU) No. 2015/861, several iodine-containing compounds are authorized as feed additives, and also as antiseptics and sanitisers in veterinary medicine.

**Residue definitions**

| **Summary table of other (non-biocidal) uses** |
| --- |
|  | **Sector of use** | **Intended use** | **Reference value(s)** |
| 1. | Feed additiveIodine as - Potassium iodide, - Calcium iodate anhydrous, - Coated Granulated calcium iodate anhydrous | The recommended maximum content of total iodine in complete feed for:- equines is 3 mg/kg feed/d- dogs is 4 mg/kg feed/d- cats is 5 mg/kg feed/d- ruminants for milk production is 2 mg/kg (0.080 mg/kg bw/d)- laying hens is 3 mg/kg feed/d (0.205 mg/kg bw/d) | These values were recommended by the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel) in 2013[[8]](#footnote-9) to bring the exposure of adult consumers below the Upper Intake Level. |
| 2. | Veterinary medicineIodine and iodineinorganic compoundsincluding:- Sodium/potassium-iodide- Sodium/potassium-iodate- Iodophors including polyvinylpyrrolidoneiodine (PVP-iodine) and iodoform | All food producing species: Various iodine-containing compounds are used in veterinary medicine as antiseptics and sanitisers.Iodine compounds are used in teat dips for the prevention and control of mastitis in cattle and in topical preparations for prevention of infections in wounds. Preparations for oral and parenteral administration are also available for the treatment of iodine-deficiency. | Regulation (EU) No.37/2010 The Committee for Veterinary Medicinal Products (CVMP) decided in 1996 that it would be **inappropriate to elaborate MRLs for iodine**. Therefore, iodine was included in Annex II of Council Regulation (EEC) No. 2377/90[[9]](#footnote-10) and later, in Annex of Commission Regulation (EU) No.37/2010[[10]](#footnote-11). |

The Committee for Veterinary Medicinal Products (CVMP) has reviewed iodine for the use in veterinary medicine as antiseptic, sanitiser, teat dip for prevention and control of the mastitis, topical preparation for preventing wounds infections. CVMP reported that “only small increases in serum iodine concentration were found after teat dipping indicating that the procedure had a negligible effect on tissue iodine concentrations”, and it was concluded that no MRL is required for any food-producing species (see Commission Regulation (EU) No 37/2010).

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

***Scenario 1.a.*** PT03: Disinfection of empty breeding - *(also referred as scenario 1 for Human Health and Environment risk assessments)*

In framework of this dossier the applicant has performed livestock exposures estimation for TP03. When sufficiently relevant and in accordance with guidance documents, the calculations and arguments were considered and presented below.

Estimation of livestock exposure was performed using the ”livestock exposure calculator”. This document is a tool to facilitate the estimation of livestock exposure to biocidal active substances as described in the draft Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products (ongoing guidance, ARTFood 2016)[[11]](#footnote-12). This Calculator applies assumptions and default values as detailed below:

| **Description of Scenario 1.a** PT03: Disinfection of empty breeding |
| --- |
|  | Parameters | Value |
| Tier 1Screening step | Concentration in the concentrated product (% a.s. w/w, considering total Iode; I2 et NaI) | 1.36 (1.00%+0.36%) |
| Concentration in a 3.5% diluted solution (% a.s. v/v) | 0.047 |
| Concentration in a 3.5% diluted solution (g a.s./L)1 | 0.47 |
| Average content per unit area (mg a.s./m2) | 95-143 |
| Content per unit area for very porous surfaces (mg a.s./m2) | **190** |
| Tier 2Realistic worst case | Vapour pressure iodine at 25°C (Pa) 2 | 40.7 |
| Molecular weight iodine (g/mol) 2 | 253.81 |
| Gas constant (J/K mol) 2 | 8.31451 |
| Temperature (°K) 2 | 298.15 |
| Emission factor (fraction emitted to floor during surface treatment by spraying) 3 | 0.11 |
| Consumption of biocidal product by fly (mL/d) 3 | 0.0035 |
| Emission factor (fraction emitted to the treated surface area during surface treatment by spraying) 4 | 0.85 |
| Tier 3Refinements | Factor due to recommendation of 48 h re-entry delay 2 | 0 |
| Dermal absorption value (%)5 | 75 |
| Fraction excreted (%) 6 | 70 |
| Fraction of remained iodine in body (%) (non excreted) 6 | 30 |
| Fraction of remained iodine available for tissues (non located in thyroid) (%)7 | 40 |

1 Assuming the relative density of the diluted product is 1

2 values used to estimate inhalative exposure

3 oral exposure: default factor 0.11 used to refined feed contamination and value used to estimate exposure from dead fly ingestion

4 default factor used to refined dermal exposure (direct exposure, rubbing) and oral exposure (licking, contaminated trough)

5 default factor (EFSA 2012)

6 70% of iodine is expected to be excreted by urine (WHO, 2009), the internal dose can be estimated to be reduced to 30% (corresponding to the thyroid level)

7 60 to 90% of total iodine in the body is located in thyroid the main storage organ, the internal dose can be estimated reduced with 40% factor (EFSA, 2013)

**Calculations for estimating livestock exposure for Scenario 1.a:**

**PT03: Disinfection of empty breeding -** Tier 1 and Tier 2

As mentioned in the DRAWG guidance document, the following animal species are considered representative:

- Cattle: beef, calf and dairy cattle;

- Pigs: fattening and breeding pigs;

- Poultry: broiler, chicken and laying hens.

All these representative species are considered in this assessment.

For Tier 1 (screening step), the total exposure was estimated by the model with the following calculation:

**Exposure=AR\*Aw+f/Noanim/bw**

AR: Application rate (mg/m2)

Aw+f: wall+floor area per stable (m2)

Noanim: No. of animals per stable

bw: body weight (kg)

For Tier 2 (realistic worst case), the total exposure was estimated by the model considering the different routes of exposure (oral with licking, feed and feeding trough contamination, dead insect ingestion, dermal with rubbing behaviours, inhalative). The detail of calculation is presented in Table 1 in Annexe 3.

The table thereafter summarized results from estimation after Tier 1 and Tier 2:

| **External dose received by the animal**  |
| --- |
| livestock exposure calculator: surface treatment of animal housing (floor and wall of stable without partition) |
|  | Animal livestockGroup (worst case model)\* | Tier 1: Screening step | Tier 2: Realistic worst case |
| Livestock Total exposure(mg/kg bw/d) | Exceedance of threshold value (0.004 mg/kg bw/d) | Livestock Total exposure(mg/kg bw/d) | Exceedance of threshold value (0.004 mg/kg bw/d) |
| Scenario 1a | Beef cattle (calf) | 3.92 | Y | 523 | Y |
| Dairy cattle | 4.88 | Y | 400 | Y |
| Pig (breeding in group housing)Pig (fattening) | 6.42- | Y | -586 | Y |
| Poultry (laying hens in free range and litter floor)Broiler  | 20.30- | Y | -490 | Y |

\* the worst case model of each livestock category is selected

**Further information and considerations on scenario 1.a:**

**PT03: Disinfection of empty breeding** - Tier 3

All scenario Tiers show an exceedance of the threshold value 0.004 mg/kg bw/d for all livestock animals, and the main route of exposure is the inhalative way. So refinement can be taken into account to adjust and limit the animal exposure.

Inhalation exposure:

The biocide product is recommended to be used in empty housing. As a consequence, a re-entry delay can be set to reduce the animal exposure. Considering a re-entry delay of 48 h after housing treatment, the inhalation exposure will be negligible for all representative animal species (assumption confirmed by ConsExpo: calculations detailed in Table 2 in Annexe 3).

Dermal exposure:

The exposure via dermal route was estimated and exceeds the threshold value of 0.004 mg/kg bw/d. No residue measures on surface treated are available.

However, according to the ADME endpoints, a value of 12% is set for the active substance based on in vitro skin penetration studies through human skin with a diluted product (diluted at 0.66% iodine) and a ready-to-use product (0.26% iodine). The low dermal penetration was confirmed by the French Institut National de Recherche et de Sécurité (INRS)[[12]](#footnote-13) and the International Programme on Chemical Safety[[13]](#footnote-14), and the value was supported by information provided by US Department of Health and Human Services (US HHS)[[14]](#footnote-15) and the World Health Organization (WHO)[[15]](#footnote-16).

Nevertheless, regarding the characteristic of biocide product and its classification as irritating product, this dermal absorption factor of 12% cannot be used to refine calculation. The default factor of 75% was used in framework of this evaluation.

Internal dose: Distribution and availability of iodine in body

The metabolism of iode was largely studied and iodine metabolism in food-producing animals is well-known and has been summarised by EFSA (2005[[16]](#footnote-17)).

The information available demonstrated that:

* the thyroid gland contained 60-90 % of the body pool of the element being the tissue with the highest iodine concentration relative to its physiological function (EFSA 2013[[17]](#footnote-18))
* approximately 20 to 30% of the iodine was distributed to the thyroid whereas 30 to 60% was excreted in the urine, few hours after oral administration to human subjects (WHO 2009[[18]](#footnote-19)). This confirms the endpoint defined in the Assessment Report: “About 30% of the bioavailable iodide is removed by the thyroid for hormonal synthesis”. Therefore, 70% of the remaining substance is excreted by the kidney via urinary route.
* The content of iodine in animal tissues and products is related to the iodine intake and, thus, to the iodine concentration in the feed. In response to feed supplementation with iodine sources, the iodine level in edible tissues/products is generally found to be highest in milk and eggs, followed by kidney and liver, whereas in muscle tissue it is rather low (EFSA 2005 and 2013). This being in agreement with consumption surveys (Gireli et al., 2004; Bader et al., 2005; Hampel et al., 2009; Johner et al., 2011, 2012a,b; Soriguer et al., 2011).

As a consequence the following factors can be used to estimate the transfer to animal tissue and products, and consequently refine the consumer exposure:

* Excretion factor: 70%, as 70% of iodine is expected to be excreted by urine
* Body fraction factor : 30%, as 30% of iodine is expected to remain in the body (corresponding to the thyroid level)
* Available body fraction factor: 40%, as 40% of the remaining iodine can be considered as available for the body tissues (except thyroid) as a worst case, since thyroid is the main storage organ for iodine cumulating 60 to 90% of total iodine in the body of food-producing animals (EFSA, 2013).

As a result, it can reasonably be considered that:

* 30% \* 40% of the internal exposure value is distributed into the edible tissues,
* And until 70% of the internal exposure value is excreted into the edible products

| **Internal dose received by the animal**  |
| --- |
| Tier 3: Realistic worst case refined |
|  | Animal livestockGroup (worst case model)\* | via Inhalation exposure | via Dermal exposure | via Oral exposure | Total internal exposure | Available internal dose in tissues(total exposure\*0.3\*0.4) | Available internal dose in product(total exposure\*0.7) |
| mg/ kg bw of animal /d  | mg/ kg of tissues and products |
| Scenario 1a | Beef cattle (calf) | 0 | 0.527(0.70\*0.75) | 1.735 | 2.258 | 0.271 | - |
| Dairy cattle | 0 | 0.313(0.42\*0.75) | 1.757 | 2.066 | 0.248 | 1.446 |
| Pig (breeding in individual housing)Pig (fattening) | 0 | -0.545(0.73\*0.75) | 4.1912.156 | 4.1822.700 | 0.5020.324 | - |
| Poultry (laying hens in battery)Broiler  | 0 | - | 0.8510.0098 | 0.8510.0098 | 0.1020.001 | 0.595- |

\* the worst case model of each livestock category is selected

**Conclusion**

These results demonstrate that the exposure to iodine residues via food from animal origin is mainly expected to be related to milk and egg consumption rather than meat.

The calculations are performed considering the worst case situations, and cannot be better refined at this step without any measurements of iodine residue on surfaces, in animal tissues or in food from animal origin. As a consequence, although this assessment might overestimate the contamination of animal tissues and products, these estimations are used to estimate the human dietary exposure.

***Scenario 1.b:*** PT03: Disinfection of equipment - *(also referred as scenario 2 for Human Health and Environment risk assessments)*

In framework of this dossier the applicant has performed livestock exposures estimation for TP03. When sufficiently relevant and in accordance with guidance documents, the calculations and arguments were considered and presented below.

The scenario of disinfection of equipment in animal housing is not included in the “livestock exposure calculator”. So the estimation of livestock exposure was performed using draft guidance document available[[19]](#footnote-20).

According to the information provided by the applicant, the livestock equipment which is treated with the biocidal product by dipping only consists of small feed and drinking troughs. This equipment is made in plastic or stainless steel (non-porous surfaces).

In the case of soaking of these small troughs, the animals are only expected to be exposed to the biocidal product via oral exposure. The dermal and inhalation exposures are expected to be negligible.

| **Description of Scenario 1.b** PT03: Disinfection of equipment |
| --- |
|  |
|  | Parameters1 | Value |
| Tier 1 | Concentration in the concentrated product (% a.s. w/w, considering total Iode; I2 et NaI) | 1.36 (1.00%+0.36%) |
| Concentration in a 3.5% diluted solution (% a.s. v/v) | 0.047 |
| Concentration in a 3.5% diluted solution (g a.s./L or g a.s./dm3)1 | 0.47 |
| Average content per unit area (mg a.s./m2) | 47 |
| Animal exposed feed surface (m2)(direct treatment of troughs)2 | Dairy cattle | 6.6 |
| Calf | 2.0 |
| Fattening pig | 1.2 |
| Breeding pig | 2.8 |
| Laying hens | 0.01 |

1 Assuming that the relative density of the diluted product is 1

2 default values, Appendix I, Table 2, draft Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products (ongoing guidance, ARTFood 2016)

**Calculations for estimating livestock exposure for Scenario 1.b (PT03: Disinfection of equipment)**

All these representative species are considered in this assessment:

- Cattle: beef, calf and dairy cattle

- Pigs: fattening and breeding pigs

- Poultry: broiler, chicken and laying hens

For Tier 1, the oral exposure was estimated with the following calculation:

**Exposure=AR\* ExpoFeedSurf/bw**

AR: Application rate (mg/m2)

ExpoFeedSurf: Exposed feed surface (m2)

bw: body weight (kg)

| **External dose received by the animal** |
| --- |
| livestock exposure: surface treatment of animal housing (feeding surfaces) |
|  | Animal livestockGroup (worst case model)\* | Inhalation exposure | Dermal exposure | Oral exposure | Livestock Total exposure(mg/kg bw/d) |
| Scenario 1b | Beef cattle (calf) | - | - | 0.476 | 0.476 |
| Dairy cattle | - | - | 0.483 | 0.483 |
| Pig (fattening) | - | - | 0.571 | 0.571 |
| Poultry (laying hens) | - | - | 0.250 | 0.250 |

\* the worst case model of each livestock category is selected

**Further information and considerations on scenario 1.b (PT03: Disinfection of empty equipment)**

The scenario shows an exceedance of the threshold value 0.004 mg/kg bw/d for all livestock animals. So refinement can be taken into account to adjust and limit the animal exposure.

Internal dose: Distribution and availibality of iodine in body

The metabolism of iode was largely studied and iodine metabolism in food-producing animals is well-known and has been summarised in scenario 1a presented above.

As a result, it can reasonably be considered that:

* 30% \* 40% of the internal exposure value is distributed into the edible tissues,
* and up to 70% of the internal exposure value is excreted into the edible products.

| **Internal dose received by the animal**  |
| --- |
| Refined estimations |
|  | Animal livestockGroup (worst case model)\* | Total internal exposure | Available internal dose in tissues(total exposure\*0.3\*0.4) | Available internal dose in products(total exposure\*0.7) |
| mg/ kg bw /d of animal | mg/ kg of tissues and products |
| Scenario 1b | Beef cattle (calf) | 0.476 | 0.057 | - |
| Dairy cattle | 0.483 | 0.058 | 0.338 |
| Pig (fattening) | 0.571 | 0.068 | - |
| Poultry (laying hens) | 0.250 | 0.030 | 0.175 |

\* the worst case model of each livestock category is selected

**Conclusion**

These results demonstrate that the exposure to iodine residues via food from animal origin is mainly expected to be related to milk and egg consumption rather than meat.

The calculations are performed considering the worst case situations, and cannot be better refined at this step without any measurements of iodine residue on surfaces, in animal tissues or products. As a consequence, although this assessment might overestimate the contamination of animal tissues and products, these estimations are used to estimate the human dietary exposure.

***Scenario 2.a***. PT04: Disinfection of drinking water pipe - *(also referred as scenario 3 for Human Health and Environment risk assessments)*

In framework of this dossier the applicant has performed livestock exposures estimation for PT04. When sufficiently relevant, the arguments were considered and presented below. Without EU guidance for this senario, some default values proposed by the applicant were not considered in framework of this dossier, instead default values already used by FR are used to perform calculations.

The scenario of disinfection of equipment in animal housing is not included in the “livestock exposure calculator”. So the estimation of livestock exposure was performed using draft guidance document available[[20]](#footnote-21) and in accordance with the previous assessment for this kind of use.

In the case of soaking of pipes, the animals are only expected to be exposed to the biocidal product via oral exposure (drinking water). The dermal and inhalation exposures are expected to be negligible.

The water network system is intended to be treated 1 time per livestock batch. The following network system is considered as a worst case:

The surface of a cylinder (a pipe) of 1000 cm3 is the model used to perform the calculations: a portion of 1L (1000 cm3) of drink is in contact with treated surface (as currently agreed for residue transfer in other biocide or food contact material scenario). As a worst case the diameter of the cylinder selected as low as possible with 1 cm, which represents a cylinder surface area of 4000 cm2 /L.

| **Description of Scenario 2.a** PT04: Disinfection of drinking water pipe |
| --- |
|  | Parameters | Value |
| Tier 1 | Concentration in the concentrated product (% a.s. w/w, considering total Iode; I2 et NaI) | 1.36 (1.00+0.36) |
| Concentration in a 1.5% diluted solution (% a.s. v/v) | 0.0204 |
| Concentration in a 1.5% diluted solution (g a.s./L or g a.s./dm3 or mg a.s./cm3) | 0.20 |
| Surface of water network system (cm2/L) 1 | 4000 |
| Thickness of diluted solution absorbed on the surface of the equipment (cm) 2 | 0.010 |
| Drinking water intake (L/d) | Dairy cattle | 115 |
| Calf | 20 |
| Fattening pig | 10 |
| Breeding pig | 15 |
| Laying hens | 0.25 |
| Tier 2 | Rinsing step (L of water/dm3 treated) | 1 |
| Rinsing factor 3 | 10 |

1 As a worst case but to remain in realistic proportion, the higher ratio surface/volume for a pipe was considered with a minimal diameter of 1 cm (Radius (R) = 0.5 cm). Considering a volume of 1 L for the pipe, its corresponding calculated length (L) is: L = Volume/ πR2. According to this length, the maximal calculated surface area in contact with food follows this equation: S = 2πRx L, S = 4000 cm2

2 Default value found in Appendix I, Table 4 of the European Commission document CA-Dec10- Doc.6.2.B – “Guidance on estimating livestock exposure to active substances used in biocidal products”, and in the ECHA Guidance document “Biocides Human Health Exposure methodology”

3 HERA (Human & Environmental Risk Assessment on Ingredients of Household Cleaning Products) guidance document Methodology, February 2005

**Calculations for estimating livestock exposure for Scenario 2.a (PT04: Disinfection of of drinking water pipe)**

All these representative species are considered in this assessment:

- Cattle: beef, calf and dairy cattle;

- Pigs: fattening and breeding pigs;

- Poultry: broiler, chicken and laying hens.

For Tier 1, the oral exposure was estimated with the following calculation:

**Exposure=AR\*SurfSyst\*Film\*DWI/bw**

AR: Application rate (mg a.s./cm3)

SurfSyst: Surface of water network system (cm2/L)

Film: Thickness of diluted solution (cm)

DWI: Drinking water intake (L/d)

bw: body weight (kg)

For Tier 2, the oral exposure was estimated by the model considering one rinsing step with water. According to the applicant a rinsing step with water is intended after the treatment of piper network. The volume of water used is recommended to be related to the volume of pipe (as volume used of diluted solution = volume used to rinse). The dislogeable fraction of iodine from surface pipe is not estimated and no measurement of efficiency of the rinsing step was performed. Nevertheless, considering the solubility of iodine (0.29 g/L at 20 °C), the default rinsing factor of 10[[21]](#footnote-22) can be used.

The oral exposure was estimated with the following calculation:

Exposure= Exposure Tier1 / 10

The table thereafter summarized results of estimations after Tier 1 and Tier 2:

| **External dose received by the animal** |
| --- |
| livestock exposure: water pipe network |
|  | Animal livestockGroup (worst case model)\* | Tier 1: without rinsing step | Tier 2: with rinsing step |
| Inhalation and dermal exposures | Oral exposure(mg/kg bw/d) | Livestock Total exposure(mg/kg bw/d) | Livestock Total exposure(mg/kg bw/d) | Exceedance of threshold value (0.004 mg/kg bw/d) |
| Scenario 2a | Beef cattle (calf) | - | 0.816 | 0.816 | 0.0816 | Y |
| Dairy cattle | - | 1.444 | 1.444 | 0.1444 | Y |
| Pig (fattening) | - | 0.816 | 0.816 | 0.0816 | Y |
| Poultry (broiler)(laying hens) | - | 1.2001.073 | 1.2001.073 | 0.12000.1073 | Y |

\* the worst case model of each livestock category is selected

**Further information and considerations on scenario 2.a (PT04: Disinfection of drinking water pipe)**

Both Tiers show an exceedance of the threshold value 0.004 mg/kg bw/d for all livestock animals. So refinement can be taken into account to adjust and limit the animal exposure.

Internal dose: Distribution and availability of iodine in body

The metabolism of iode was largely studied and iodine metabolism in food-producing animals is well-known and has been summarised in scenario 1a presented above.

As a result, it can reasonably be considered that:

* 30% \* 40% of the internal exposure value is distributed into the edible tissues,
* and until 70% of the internal exposure value is excreted into the edible products

| **Internal dose received by the animal**  |
| --- |
| Refined estimations |
| 10 | Animal livestockGroup (worst case model)\* | Total internal exposure | Available internal dose in tissues(total exposure\*0.3\*0.4) | Available internal dose in products(total exposure\*0.7) |
| mg/ kg bw /d of animal | mg/ kg of tissues and products |
| Scenario 2a | Beef cattle (calf) | 0.0816 | 0.0098 | - |
| Dairy cattle | 0.1444 | 0.0173 | 0.1011 |
| Pig (fattening) | 0.0816 | 0.0098 | - |
| Poultry (broiler)(laying hens) | 0.12000.1073 | 0.01440.0129 | -0.0751 |

\* the worst case model of each livestock category is selected

**Conclusion**

These results demonstrate that the exposure to iodine residues via food from animal origin is mainly expected to be related to milk and egg consumption rather than meat.

The calculations are performed considering the worst case situations, and cannot be better refined at this step without any measurements of iodine residue on surfaces with and (without rinsing step), in animal tissues or in food from animal origin. As a consequence, although this assessment might overestimate the contamination of animal tissues and products, these estimations are used to estimate the human dietary exposure.

***Scenario 2.b.*** PT04: Disinfection of drinking water pipe (CIP) - *(also referred as scenario 3 for Human Health and Environment risk assessments)*

In framework of this dossier the applicant has performed livestock exposures estimation for TP04. When sufficiently relevant, the arguments were considered and presented below. Without EU guidance for this scenario, the default values proposed by the applicant were not considered in framework of this dossier, instead default values already used by FR are used to perform calculations.

The same approach is performed thereafter to assess the iodine exposure after Disinfection of drinking water pipe CIP. The concentration of active substance in the pipe for CIP treatment is 0.002 % w/w. This concentration is significantly lower than the concentration used in the case of soaking (0.015 % w/w).

Therefore, the soaking of pipes is considered as the worst case (see section above).

| **Description of Scenario 2.b** PT04: Disinfection of drinking water pipe |
| --- |
|  | Parameters | Value |
| Tier 1 | Concentration in the concentrated product (% a.s. w/w, considering total Iode; I2 et NaI) | 1.36 (1.00+0.36) |
| Concentration is a 0.2% diluted solution (% a.s. v/v) | 0.00272 |
| Concentration is a 0.2% diluted solution (g a.s./L or g a.s./dm3 or mg a.s./cm3)\* | 0.0272 |
| Surface of water network system (cm2/L) 1 | 4000 |
| Thickness of diluted solution absorbed on the surface of the equipment (cm) 2 | 0.010 |
| Drinking water intake (L/d) | Dairy cattle | 115 |
| Calf | 20 |
| Fattening pig | 10 |
| Breeding pig | 15 |
| Laying hens | 0.25 |
| Tier 2 | Rinsing step (L of water/dm3 treated) | 1 |
| Rinsing factor3 | 10 |

1 As a worst case but to remain in realistic proportion, the higher ratio surface/volume for a pipe was considered with a minimal diameter of 1 cm (Radius (R) = 0.5 cm). Considering a volume of 1 L for the pipe, its corresponding calculated length (L) is: L = Volume/ πR2. According to this length, the maximal calculated surface area in contact with food follows this equation: S = 2πRx L, S = 4000 cm2

2 Default value from in Appendix I, Table 4 of the European Commission document CA-Dec10- Doc.6.2.B – “Guidance on estimating livestock exposure to active substances used in biocidal products”, and in the ECHA Guidance document “Biocides Human Health Exposure methodology”

3 HERA (Human & Environmental Risk Assessment on Ingredients of Household Cleaning Products) guidance document Methodology, February 2005

**Calculations for estimating livestock exposure for Scenario 2.a (PT04: Disinfection of drinking water pipe)**

All these representative species are considered in this assessment:

- Cattle: beef, calf and dairy cattle;

- Pigs: fattening and breeding pigs;

- Poultry: broiler, chicken and laying hens.

For Tier 1, the oral exposure was estimated with the following calculation:

**Exposure=AR\*SurfSyst\*Film\*DWI/bw**

AR: Application rate (mg a.s./cm3)

SurfSyst: Surface of water network system (cm2/L)

Film: Thickness of diluted solution (cm)

DWI: Drinking water intake (L/d)

bw: body weight (kg)

For Tier 2, the oral exposure was estimated considering rinsing step with water. Without measurement of efficiency of the rinsing step and considering the solubility of iodine, the default rinsing factor of 10 is used. The oral exposure was estimated with the following calculation:

Exposure= Exposure Tier1 / 10

The table thereafter summarized results of estimations after Tier 1 and Tier 2:

| **External dose received by the animal** |
| --- |
| livestock exposure: water pipe network |
|  | Animal livestockGroup (worst case model)\* | Tier 1: without rinsing step | Tier 2: with rinsing step |
| Inhalation and dermal exposures | Oral exposure(mg/kg bw/d) | Livestock Total exposure(mg/kg bw/d) | Livestock Total exposure(mg/kg bw/d) | Exceedance of threshold value (0.004 mg/kg bw/d) |
| Scenario 2b | Beef cattle (calf) | - | 0.109 | 0.109 | 0.011 | Y |
| Dairy cattle | - | 0.193 | 0.193 | 0.019 | Y |
| Pig (fattening) | - | 0.109 | 0.109 | 0.011 | Y |
| Poultry (broiler)(laying hens) | - | 0.1600.143 | 0.1600.143 | 0.0160.014 | Y |

\* the worst case model of each livestock category is selected

**Further information and considerations on scenario 2.b (PT04: Disinfection of drinking water pipe)**

Both Tiers show an exceedance of the threshold value 0.004 mg/kg bw/d for all livestock animals. So refinement can be taken into account to adjust and limit the animal exposure.

Internal dose: Distribution and availability of iodine in body

The metabolism of iode was largely studied and iodine metabolism in food-producing animals is well-known and has been summarised in scenario 1a presented above.

As a result, it can reasonably be considered that:

* 30% \* 40% of the internal exposure value is distributed into the edible tissues,
* and until 70% of the internal exposure value is excreted into the edible products

| **Internal dose received by the animal**  |
| --- |
| Refined estimations |
|  | Animal livestock\* | Total internal exposure | Available internal dose in tissues(total exposure\*0.3\*0.4) | Available internal dose in products(total exposure\*0.7) |
| mg/ kg bw /d of animal | mg/ kg of tissues and products |
| Scenario 2b | Beef cattle (calf) | 0.011 | 0.001 | - |
| Dairy cattle | 0.019 | 0.0023 | 0.013 |
| Pig (fattening) | 0.011 | 0.001 | - |
| Poultry (broiler)(laying hens) | 0.0160.014 | 0.00190.0019 | -0.0098 |

\* the worst case model of each livestock category is selected

**Conclusion**

These results demonstrate that the exposure to iodine residues via food from animal origin is mainly expected to be related to milk and egg consumption rather than meat.

The calculations are performed considering the worst case situations, and cannot be better refined at this step without any measurements of iodine residue on surfaces with and (without rinsing step), in animal tissues or in food from animal origin. As a consequence, although this assessment might overestimate the contamination of animal tissues and products, these estimations can be used to estimate the human dietary exposure.

It is noticed that this CIP scenario is already covered by a worst case scenario 2a, and considering that these both treatments are not expected to be performed together, only the worst case scenario was used to estimate human exposure.

#### Risk characterisation for human health

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference**  | **Study** | **NOAEL (LOAEL)** | **AF1** | **Correction for oral absorption** | **Value** |
| AELshort-term | Upper intake level deduced by Scientific committee on food | 600 µg/d |  | - | 0.01 mg/kg/d |
| AELmedium-term |
| AELlong-term |
| AEC inhalation |  |  |  |  | 0.1 ppm or 1 mg/m3 |
| ARfD | Not applicable |  |  |  |  |
| ADI | Not available |  |  |  |  |

**Maximum residue limits or equivalent**

**Residue definitions:**

|  |  |  |  |
| --- | --- | --- | --- |
| **MRLs or other relevant reference values** | **Reference** | **Relevant commodities** | **Value** |
| AEL = UL(Upper Intake Level) | Iodine CAR | food | Europe: 600 μg/day(0.01 mg/kg bw/d.)USA: 1200 μg/day,0.02 mg/kg bw/d. |
| ARfD | Iodine CAR  | - | Not applicable. Substance is not acute toxic or harmful.  |
| Drinking water limit | Iodine CAR  | water | No drinking water limit is established. 30 μg/L is a threshold proposed and calculated is based on 10% Upper Intake Level and a daily intake of 2 L drinking water  |

The Scientific Committee on Food (SCF) based the iodine tolerable upper intake (UL) on studies of short term duration and in a small number of subjects (n=10-32). For iodine intakes about 1700-1800 μg/day, the studies showed an increased serum thyroid-stimulating hormone (TSH) and thyrotropin-releasing hormone (TRH), but these changes were considered marginal and not associated with any clinical adverse effects. The results were supported by a five years study where, for approximately similar iodine intakes, no clinical thyroid pathology occurred. An uncertainty factor of 3 was selected to derive the UL for adults. The ULs for toddlers and children were derived by adjustment of the adult UL on the basis of metabolic weight, since there is no evidence of increased susceptibility in children. The SCF adopted the value of 600 μg/day as a UL for adults including pregnant and lactating women (2002)[[22]](#footnote-23). The UL for toddlers was set at 200 µg/day.

Nevertheless, in the iodine CAR, it is reported that a healthy adult can tolerate iodine intake of more than 1000 µg/day without any adverse effects.

As indicated by the SCF, the tolerable upper intake levels ULs are not a safety threshold. Indeed, the SCF indicated that the UL “may be exceeded for short periods without appreciable risk to the health of the individuals concerned”.

Furthermore, besides the exposure due to the treatment the user is also exposed by dietary exposure. An assessment for dietary exposure is included. User is exposed to iodine through background in milk (due to natural sources and feed supplementation) and by other dietary sources. This exposure represents between 25% and 46% of the UL considering respectively the recommended dietary intake of iodine (approach proposed in the CAR) or the dietary intake values discussed recently for iodine union authorisations at the European level.

**As the background value has been recently discussed (between 25% or 46% of UL) in the framework of Union authorisations, both risk assessment have been performed in this report
Nevertheless, the 25% value is the one agreed in the CAR. Hence the conclusion from FRCA will be based on the agreed 25% value*.***

***Risk for industrial users***

Not relevant

***Risk for professional users***

***Scenario [1]: Disinfection of the surfaces by spraying (2-3.5% dilution)***

Three tasks are performed:

* (a) Mixing and loading of pure product at corrosive concentration
* (b) Spraying dilution
* (c) Cleaning spray equipment at non-corrosive concentration

**1a. Mixing and loading of pure product**

As the pure product is corrosive, only qualitative local risk assessment according to the guidance on the BPR: Volume III HH part B is performed.

As mentioned in the table presented in the Exposure part, the risk is considered **acceptable** when RMM are followed and PPE are worn.

**1b. Spraying dilution**

* Local risk assessment

As some dilution are corrosive, a qualitative local risk assessment according to the guidance on the BPR: Volume III HH part B is performed.

As mentioned in the table presented in the Exposure part, the risk is considered **unacceptable.**

* Systemic risk assessment (2% dilution)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/****Scenario** | **Tier** | **AEL****mg/kg bw/d** | **Estimated uptake due to biocidal use****mg/kg bw/d** | **Estimated uptake/ AEL due to biocidal use****(%)** | **Estimated uptake/ AEL due to biocidal use****+ dietary intake 46% UL (%)** | **Estimated uptake/ AEL due to biocidal use****+ dietary intake 25% UL (%)** |
| Disinfection by spraying (model 2) | Without PPE | 1.00E-02 | 2.03E-01 | **2028** | **2074** | **2053** |
| Disinfection by spraying (model 2) | With gloves and coated coverall | 1.00E-02 | 2.22E-02 | **222** | **268** | **247** |
| Disinfection by spraying (model 2) | With gloves and impermeable coverall | 1.00E-02 | 8.57E-03 | 86 | 132 | 111 |
| Disinfection by spraying (model 2) | With gloves, impermeable coverall and mask APF 10 | 1.00E-02 | 7.80E-03 | 78 | 124 | 103 |
| Disinfection by spraying (model 1) | Without PPE | 1.00E-02 | 1.13E-01 | **1126** | **1171** | **1150** |
| Disinfection by spraying (model 1) | With gloves and coated coverall | 1.00E-02 | 1.31E-02 | **131** | **177** | **156** |
| Disinfection by spraying (model 1) | With gloves and impermeable coverall | 1.00E-02 | 7.42E-03 | 74 | 120 | 99 |
| Disinfection by spraying (model 1) | With gloves, impermeable coverall and mask APF 10 | 1.00E-02 | 6.36E-03 | 64 | 110 | 89 |

*Considering the background values of 25% and 46% of UL, a risk cannot be excluded except if a low-pressure sprayer is used and a background of 25% is used.*

When the inhalation exposures of 0.021 or 0.028 mg/m3 are compared to the AEC of 1 mg/m3, the risk is also considered acceptable.

**1c. Cleaning spray equipment**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/****Scenario** | **Tier** | **AEL****mg/kg bw/d** | **Estimated uptake due to biocidal use****mg/kg bw/d** | **Estimated uptake/ AEL due to biocidal use****(%)** | **Estimated uptake/ AEL due to biocidal use****+ dietary intake 46% UL (%)** | **Estimated uptake/ AEL due to biocidal use****+ dietary intake 25% UL (%)** |
| Cleaning of spray equipment | Without PPE | 1.00E-02 | 1.88E-03 | 19 | 65 | 44 |
| Cleaning of spray equipment | Gloves | 1.00E-02 | 2.53E-04 | 3 | 49 | 28 |

*The total exposure to iodine is inferior to the upper limit intake proposed by Scientific Committee on Food of the European Commission (SCF) considering background values of 25% and 46% of UL.*

**Combined scenarios**

A combined exposure during application and cleaning spray equipment is assessed.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **AEL****mg/kg bw/d** | **Estimated uptake due to biocidal use****mg/kg bw/d** | **Estimated uptake/ AEL due to biocidal use** | **Estimated uptake/ AEL due to biocidal use****+ dietary intake 46% UL (%)** | **Estimated uptake/ AEL due to biocidal use****+ dietary intake 25% UL (%)** |
| Disinfection by spraying (With low-pressure sprayer, gloves, impermeable coverall and mask APF 10)AndCleaning of spray equipment (WithPPE) | 1.00E-02 | 6.61E-03 | 66 | 112 | 91 |

*The total exposure to iodine linked to biocidal use is inferior to the upper limit intake proposed by Scientific Committee on Food of the European Commission (SCF) when PPE are worn. Considering the background values of 46% of UL, a risk cannot be excluded even if PPE are worn.*

***Scenario [2]: Disinfection of the equipment by soaking (2-3.5% dilution)***

Two tasks are performed:

* (a) Mixing and loading of pure product at corrosive concentration
* (b) Dipping

**2a. Mixing and loading of pure product**

The exposure is the same that during mixing and loading of spray equipment. See scenario 1a.

As mentioned in the table presented in the Exposure part, the risk is considered **acceptable** when RMM are followed and PPE are worn.

**2b. Dipping**

* Local risk assessment

As some dilution are corrosive, a qualitative local risk assessment according to the guidance on the BPR: Volume III HH part B is performed.

As mentioned in the table presented in the Exposure part, the risk is considered **unacceptable.**

* Systemic risk assessment

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/****Scenario** | **Tier** | **AEL****mg/kg bw/d** | **Estimated uptake due to biocidal use****mg/kg bw/d** | **Estimated uptake/ AEL due to biocidal use** | **Estimated uptake/ AEL due to biocidal use****+ dietary intake 46% UL (%)** | **Estimated uptake/ AEL due to biocidal use****+ dietary intake 25% UL (%)** |
| Disinfection of equipment by dipping | With gloves | 1.00E-02 | 2.16E-02 | **216** | **262** | **241** |
| Disinfection of equipment by dipping | With gloves and coated coverall | 1.00E-02 | 7.10E-03 | 71 | 117 | 96 |
| Disinfection of equipment by dipping | With gloves and impermeable coverall | 1.00E-02 | 4.38E-03 | 44 | 90 | 69 |

*The total exposure to iodine is inferior to the upper limit intake proposed by Scientific Committee on Food of the European Commission (SCF) considering a background value of 25% and 46% of UL when gloves and impermeable coverall are worn.*

When the inhalation exposure of 0.0816 mg/m3 is compared to the AEC of 1 mg/m3, the risk is also considered acceptable.

**Conclusion**

* The risk during mixing and loading is acceptable when PPE are worn and RMM are followed.
* The risk during dipping is unacceptable for dilution with corrosive property (3.5% dilution).
* The risk during dipping is acceptable for the 2% dilution when gloves and impermeable coverall are worn.

***Scenario [3]: Disinfection of drinking water pipe by injection or cleaning in place***

One task is performed:

* Mixing and loading of pure product at corrosive concentration

The exposure is the same that during mixing and loading of spray equipment. See scenario 1a.

As mentioned in the table presented in the Exposure part, the risk is considered **acceptable** when RMM are followed and PPE are worn.

***Risk for non-professional users***

Not relevant

***Risk for the general public***

Professionals may be exposed to the product IODOL 100 via:

* (a) Inhalation route (inhalation of volatilised residues).
* (b) Dermal route by contact with treated surface.

***Scenario [4a]: Inhalation of volatilised residues***

* Systemic effects

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/****Scenario** | **Tier** | **AEL****mg/kg bw/d** | **Estimated uptake due to biocidal use****mg/kg bw/d** | **Estimated uptake/ AEL due to biocidal use** | **Estimated uptake/ AEL due to biocidal use****+ dietary intake 46% UL (%)** | **Estimated uptake/ AEL due to biocidal use****+ dietary intake 25% UL (%)** |
| Inhalation of volatilised residues 8h0.0272% | - | 1.00E-02 | 1.36E-02 | 136 | 182 | 161 |
| Inhalation of volatilised residues 1h0.0272% | - | 1.00E-02 | 1.70E-03 | 17 | 63 | 42 |

*The total exposure to iodine is inferior to the upper limit intake proposed by Scientific Committee on Food of the European Commission (SCF) considering a background value of 25% and 46% of UL for only 1 hour of exposure.*

When the inhalation exposure of 0.0816 mg/m3 is compared to the AEC of 1 mg/m3, the risk is also considered acceptable.

***Scenario [4b]: Exposure to an adult who touches a treated surface with its hands (wet and dry surface)***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/****Scenario** | **Tier** | **AEL****mg/kg bw/d** | **Estimated uptake due to biocidal use****mg/kg bw/d** | **Estimated uptake/ AEL due to biocidal use** | **Estimated uptake/ AEL due to biocidal use****+ dietary intake 46% UL (%)** | **Estimated uptake/ AEL due to biocidal use****+ dietary intake 25% UL (%)** |
| Exposure to an adult who touches a treated surface with its hands (wet surface) | - | 1.00E-02 | 5.58E-02 | **558** | **604** | **583** |
| Exposure to an adult who touches a treated surface with its hands (dry surface) | - | 1.00E-02 | 2.68E-03 | 27 | 73 | 52 |

*The total exposure to iodine is inferior to the upper limit intake proposed by Scientific Committee on Food of the European Commission (SCF) considering a background value of 25% and 46% of UL only when the treated surface are dried .*

In this context, a RMM is needed to exclude contact with wet surfaces: "the treated surface has not to be touched until it is totally dry”.

**Conclusion**

The risk for secondary exposure is acceptable if a RMM is applied to exclude contact with wet surface.

***Combined exposure***

A combined risk assessment is performed with a product diluted at 2% for spraying and dipping. The following conclusions are obtained:

Spraying application:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **TIER** | **Exposure** | **AEL** | **Estimated uptake/ AEL due to biocidal use** | **Estimated uptake/ AEL due to biocidal use****+ dietary intake 46% UL (%)** | **Estimated uptake/ AEL due to biocidal use****+ dietary intake 25% UL (%)** |
| Mixing and loading (spraying, soaking and injection) | Only local risk assessment: acceptable if RMM are applied and PPE are worn |  |  |  |
| Application by spraying(low pressure sprayer)(2%) | With gloves, impermeable coverall and mask APF 10 | 6.36E-03 | 1.00E-02 | 64 | 110 | 89 |
| Cleaning spray equipment | Gloves  | 2.53E-04 | 1.00E-02 | 3 | 49 | 28 |
| Inhalation of volatilised residues (1h)2% |  | 1.70E-03 | 1.00E-02 | 17 | 63 | 42 |
| Combined exposure | With gloves, impermeable coverall and mask APF 10 (application)With gloves(cleaning) | 8.31E-03 | 1.00E-02 | 83 | 129 | 108 |

*The total exposure to iodine linked to biocidal use is inferior to the upper limit intake proposed by Scientific Committee on Food of the European Commission (SCF). Considering a background value of 25% and 46% of UL even if PPE are worn during application and cleaning, the exposure to iodine is superior to upper limit intake proposed by SCF. Therefore, a RMM is needed to avoid secondary exposure to volatile residue: Rinse treated surface, aerate and wait a total drying before re-entry. During this task the same PPEs than during application have to be worn.*

**General conclusion**

**As the background value has been recently discussed (between 25% or 46% of UL) in the framework of Union authorisations, both risk assessment have been performed in this report
Nevertheless, the 25% value is the one agreed in the CAR.**

**Hence the conclusion from FRCA will be based on the agreed 25% value*.***

|  |  |
| --- | --- |
| **Uses** | **Conclusion considering background** |
| PT3 - Spraying 2% | Acceptable when gloves, impermeable coverall and mask APF 10 are worn during application with a low-pressure sprayer and gloves are worn during cleaning.Moreover, exposure to volatile residue has to be avoided. Therefore, RMM are needed:Rinse treated surface, aerate and wait a total drying before re-entry. During this task the same PPEs than during application have be worn. |
| PT3 - Soaking 2% | Acceptable when gloves and coated coverall are worn. |
| PT3 - Spraying – Soaking 3.5% | Not acceptable as the dilution is corrosive.  |
| PT4 - Disinfection water pipe (injection) 1.5% | Acceptable considering exposure only during mixing and loading |
| PT4 - Disinfection water pipe (CIP) 0.2% | Acceptable considering exposure only during mixing and loading |

***For soaking (2%),***

* During mixing and loading: PPE have to be worn and RMM to limit exposure (corrosive product) have to be followed. :

**RMM Technics:**

* Minimisation of manual phases;
* Regular cleaning of equipment and work area;
* Avoidance of contact with contaminated tools and objects.

**RMM Organisation:**

* Training and management of staff on good practice.

**PPE:**

* Task appropriate gloves
* Coated coverall with appropriate barrier material based on potential for contact with the chemicals
* Eye protection
* During dipping: gloves and coated coverall have to be worn.

***For spraying (2%),***

* During mixing and loading: PPE have to be worn and RMM to limit exposure (corrosive product) have to be followed.

**RMM Technics:**

* Minimisation of manual phases;
* Regular cleaning of equipment and work area;
* Avoidance of contact with contaminated tools and objects.

**RMM Organisation:**

* Training and management of staff on good practice.

**PPE:**

* Task appropriate gloves
* Coated coverall with appropriate barrier material based on potential for contact with the chemicals
* Eye protection
* During spraying: gloves, impermeable coverall and mask APF 10, application with a low-pressure sprayer
* During cleaning: gloves.

***For disinfection of water pipe*,** exposure is only considered during mixing and loading (PPE have to be worn and RMM to limit exposure (corrosive product) have to be followed.

Moreover, additional mitigation measures have to be put in place:

* Rinse surface or materiel after treatment. The same PPE than those required during application have to be worn.
* After rinsing, aerate
* Do not authorise re-entry before rinsing and a total drying of surface.
* Do not touch material and surface until a total drying.
* If control task is needed, the same PPE as those required during the treatment have to be worn.

***Risk for consumers via residues in food***

Actually, EMA considers only adult chronic risk assessment. Therefore, only adult chronic exposure calculations were performed in the frame of this dossier. Maximal residues estimated in animal tissues, eggs and milk were used to calculate consumer exposure.

Consumer exposure was estimated using EU consumption values for food of animal origin (Consumer standard food basket)[[23]](#footnote-24). It is assumed that the average person consumes, on a daily basis, 500 g of meat (made up of 300 g of muscle, 100 g of liver, 50 g of kidney and 50 g of fat) together with 1.5 L of milk and 100 g of eggs for an adult of 60 kg bw.

The scenario 1a for disinfection of empty breeding is considered as the use involving the major animal exposure, and therefore inducing the highest contribution to residue level. Nevertheless as the iodine can be used **simultaneously** in PT3 for disinfection of empty breeding (scenario 1a), in PT3 fordisinfection of equipment (scenario 1b) and PT4 as disinfection of drinking water pipe (scenario 2a), the residue level of iodine are cumulated in the following table.

| **Internal dose received by the animal and WCCE\*** |
| --- |
| mg/ kg of tissues and products | mg / d | mg /kg bw/d |
| Animal foodGroup (worst case model) | Scenario 1a | Scenario 1b | Scenario 2a | **Total residue levels** | **Worst case residue level** | WCCE | Adult exposure |
| Tissues bovin(calf) | 0.271 | 0.057 | 0.0098 | 0.338 | **0.567** | 0.28  | **0.053** |
| Tissues Pig (breeding in individual housing) | 0.502 | 0.054 | 0.0098 | 0.567 |
| Tissues Poultry (laying hens in battery) | 0.102 | 0.030 | 0.0129 | 0.145 |
| Milk (dairy cattle) | 1.446 | 0.338 | 0.1011 | 1.889 | **1.889** | 2.83 |
| EggsPoultry (laying hens) | 0.595 | 0.175 | 0.0751 | 0.846 | **0.846** | 0.08 |

\**Worst case consumer exposure: combined estimate of the internal dose with the standard food basket (300 g muscle, 100 g liver, 50 g fat, 50 g kidney plus 1500 g milk, 100 g eggs and 20 g honey).*

The worst case estimation of **iodine combined treatments** shows that the maximal daily intake could reach **0.053 mg/kg bw/d**, with the scenario 1a for housing disinfection being the major way of contamination, and with the residue level estimated in milk as the main contributor.

This estimation in milk is a worst case, and could be refined considering a homogeneous partition of iodine between the different excretion ways. A volume ratio between milk and urine might be estimated, milk representing only 30% of volume excreted (70% excretion via urine). So using a ratio of excretion between milk and urine to refine the expected residue level in milk, the residue level of iodine should be moderated and provided more reliable values.

| **Internal dose received by the animal and WCCE\*** |
| --- |
| mg/ kg of tissues and products | mg / d | mg /kg bw/d |
| Animal food\* | Scenario 1a | Scenario 1b | Scenario 2a | Total residue levels | Worst case residue level | WCCE | Adult exposure |
| Tissues bovin(calf) | 0.271 | 0.057 | 0.0098 | 0.338 | **0.567** | 0.28  | **0.020** |
| Tissues Pig (breeding in individual housing) | 0.502 | 0.054 | 0.0098 | 0.567 |
| Tissues Poultry (laying hens in battery) | 0.102 | 0.030 | 0.0129 | 0.145 |
| Milk refined1(dairy cattle) | **0.434** | **0.102** | **0.030** | **0.566** | **0.566** | **0.85** |
| EggsPoultry (laying hens) | 0.595 | 0.175 | 0.0751 | 0.846 | **0.846** | 0.08 |

1 using volume ratio between milk and urine: milk represents only 30% of volume excreted (70% excretion via urine)

The Upper Intake Level (UL) of 0.01 mg/kg/d is a reference value considered to compare the exposure via food estimated for the uses of IODOL 100. The UL is an indicative upper value exposure, but does not represent a threshold directly linked to a toxicological risk. In the iodine CAR, it is reported that a healthy adult can tolerate iodine intake more than 1000 μg/day (0.0167 mg/kg/d for 60 kg bw) without any adverse effects.

The exposure from the intended uses of this biocide product can also be compared to other iodine uses in biocide and veterinary or feed additive areas. Considering the recommended maximum content of total iodine in complete feed, the maximum exposure estimated for this scenario is in the same ranges as the estimations above (feed additive for dairy cattle 0.080 mg/kg bw/d, for laying hens : 0.205 mg/kg bw/d). Indeed, these other uses should be considered more critical as the treatment is directly administrated to animals, or can contaminate directly food from animal origin. So the intended uses assessed in framework of this dossier are considered to be minor contributor to the residue level expected in food from animal origin.

The worst case estimation of iodine combined treatments shows a slight exceedance of the UL of 0.01 mg/kg/d. Nevertheless, considering all the worst case assumptions taken into account, exposure via food from animal origin is expected to be below the theoretical estimation presented above.

**General conclusion**

Considering the intended use of IODOL 100 and based on overall available information, a risk via food cannot be excluded. The estimation of iodine contamination in food is performed considering the worst case situation. Considering a total dietary intake of iodine in addition to exposure arising from biocidal use, a risk management decision cannot be taken in isolation with respect to the biocides use only. It would be advisable that this issue is addressed at European level in order to ensure that all relevant regulatory bodies can be involved in agreeing a way forward. So for the background levels all sources of iodine, would need to be taken into consideration. Therefore a wider approach to the consumer risk assessments encompassing different regulatory areas would need to be considered.So the dietary risk assessment cannot be finalised.

To limit livestock exposure the following risk mitigation measures are proposed when the product is used for disinfection of breeding rooms:

* ”use only in empty building”,
* ”A livestock re-entry delay of 48h”.

### Risk assessment for animal health

As no guidance is currently available to assess the risk for animal health, the eCA did not perform risk assessment.

### Risk assessment for the environment

The risk assessment of the product IODOL 100 is based on the information provided in the CAR of Iodine (2013).

The alcohols, C12-14 ethoxylated is classified as Aquatic chronic 3, H412 but is not present at a concentration leading the product IODOL 100 to be classified for the environment. Moreover, it is not a POP, PBT or vPvB substance. In addition, the alcohols, C12-14 ethoxylated is readily biodegradable. Therefore, the applicant does not consider the component alcohols, C12-14 ethoxylated as a substance of concern.

There are no indications for synergistic effects for the active substance and the coformulants in the literature.

Conclusion: the environmental risk assessment of the product Iodol 100 is based on the active substance iodine.

#### Effects assessment on the environment

**Background levels**

Iodine and iodine compounds are ubiquitously distributed and there is a natural cycle of iodine species in the environment. Consequently, natural background levels have to be taken into account in the environmental risk assessment. Literature data were compiled in the CAR of Iodine. Environmental background values as presented in the table below:

|  |
| --- |
| **Summary table of background levels** |
| Compartment | Background level (Iodine and cover the iodine compounds) |
| Freshwater (river and lake) | 0.5 - 20 µg/L |
| Freshwater sediment | 6 mg/kg wwt |
| Soil | 0.565-22.6 mg/kg wwt with extremes up to 110.74 mg/kg wwt |
| Groundwater | < 1 - 70 µg/L |

**PNEC derivation – Active substance**

PNEC values were proposed in the CAR for iodine, iodate and iodide.

|  |
| --- |
| **Summary table on PNEC for active substance** |
| Environmental compartment | Iodine species | PNEC |
| Surface water | Iodine (I2) | 0.00059 mg/L |
| Iodate (IO3-) | 0.0585 mg/L |
| Iodide (I-) | 0.00083 mg/L |
| Freshwater sediment | - | Not used in the risk assessment according to the CAR of Iodine |
| Terrestrial | Iodine (I2) | 0.0118 mg/kgwwt |
| Iodate (IO3-) | 0.304 mg/kgwwt |
| Iodide (I-) | 0.0043 mg/kgwwt |
| STP | Iodine (I2) | 2.9 mg/L |

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

|  |
| --- |
| **Classification of the Active Substance** |
| Value/conclusion | Active substance - Iodine: H400 -Very toxic to aquatic organisms |
| Justification for the value/conclusion | Daphnia was the most sensitive aquatic organism with the lowest EC50of 0.59 mg/L derived with iodine (AR). |
| Classification of the substance according to CLP and DSD | The following classification in accordance with the criteria in Regulation (EC) No 1272/2008 is proposed in the AR:* Aquatic Acute 1; H400; M = 1
 |

|  |
| --- |
| **Classification of the Product IODOL 100** |
| Value/conclusion | Aquatic chronic 3, H412 |

***Further Ecotoxicological studies***

No data is available.

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

No data is available.

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

No data is available.

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

No data is available.

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

No data is available.

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

Please refer to section Fate and distribution in exposed environmental compartments.

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

No data is available.

***Leaching behaviour (ADS)***

No data is available.

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

No data is available.

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

No data is available.

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

No data is available.

***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)***

No data is available.

***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)***

No relevant.

#### Exposure assessment

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT 3 |
| Assessed scenarios | Scenario 1: Disinfection of livestock buildings (Sum of the floor area, the slatted area, the wall and roof areas and other areas inside) by spray application (after a 3.5% v/v dilution, a 2.0% v/v dilution in water) |
| Scenario 2: Disinfection of small equipment’s used in breeding (PT03) by soaking (dipping), followed by rinsing with drinking water (after a 3.5% v/v dilution, a 2.0% v/v dilution in water) |
| ESD(s) used | Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, 2011 |
| Approach | Scenario 1: Average consumption |
| Scenario 2: Average consumption |
| Distribution in the environment | Calculated based on ECHA Guidance on the BPR Vol IV Part B ; April 2015 |
| Groundwater simulation | No |
| Confidential Annexes | No |
| Life cycle steps assessed | Scenario 1: Application phase |
| Scenario 2: Application phase |

|  |  |
| --- | --- |
| Assessed PT | PT 4 |
| Assessed scenarios | Scenario 3: Drinking water pipe disinfection by injection (after a 1.5% v/v dilution, a 0.2% v/v dilution in a water), followed by rinsing with drinking water. |
| ESD(s) used | New scenario based on Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas, 2011 |
| Approach | Scenario 3: Average consumption |
| Distribution in the environment | Calculated based on ECHA Guidance on the BPR Vol IV Part B ; April 2015 |
| Groundwater simulation | No |
| Confidential Annexes | NO |
| Life cycle steps assessed | Scenario 3: Application phase |
| Remarks | Scenario 3 covers the two methods of application, (i) filling of the water pipe and (ii) cleaning in place. |

Following the application, a fraction of the product Iodol 100 will be transferred to the slurry/manure storage system. The agricultural soil (arable land or grassland) is then the main receiving environmental compartment following spreading of manure or slurry. The surface water and the groundwater may also be contaminated following run-off from agricultural land or leaching from the soil respectively.

In some situations (depending of the housing type), a fraction of the product may be emitted to a private on-farm wastewater treatment plant (WWTP) or to the municipal sewage treatment plant (STP). The aquatic and terrestrial compartments may also be indirectly contaminated via STP effluents or sewage sludge application respectively.

Deposition of substances to soil following release to air is negligible compared to direct application of biocide-containing manure/slurry to land and is therefore not considered.

**Fate and distribution in exposed environmental compartments**

| **Identification of relevant receiving compartments based on the exposure pathway** |
| --- |
|  | Fresh-water | sediment | STP | Air | Soil | Groundwater |
| *Via* Manure | *Via* STP | *Via* Manure | *Via* STP | *Via* Manure | *Via* STP | *Via* Manure | *Via* STP |
| **Scenario 1** | yes | yes | yes | yes | yes | no | yes | yes | yes | yes |
| **Scenario 2** | yes | yes | yes | yes | yes | no | yes | yes | yes | yes |
| **Scenario 3** | yes | yes | yes | yes | yes | no | yes | yes | yes | yes |

**Active substance: Iodine**

|  |
| --- |
| **Input parameters used in the environmental exposure assessments according to the CAR (December,2013)** |
| **Input** | **Value** |
| **Parameters for iodine** |
| Molecular weight [g.mol-1] | 253.81 |
| Vapour pressure [Pa] | 40.7 |
| Water solubility [mg.L-1] | 290 |
| Henry’s law constant [Pa.m3.mole-1] | 34.43 |
| Kpsusp [L.kg-1] | 220 |
| Ksusp-water [m3.m-3] | 55.9 |
| Kpsoi [L.kg-1] | 5.8 |
| Ksoil-water [m3.m-3] | 8.903 |
| SLUDGERATE [kg.d-1] | 790 |
| DT50 soil [d] | 1E+06 |
| DT50 leach soil [d] | 2 571 (arable land)643 (grassland) |
| **Parameters for iodide** |
| Transformation rate in surface water iodine to iodide (%) | 100 |
| Transformation rate in soil iodine to iodide via the STP (%) | 14 |
| Transformation rate in soil iodine to iodide via manure (%) | 100 |
| Molecular equivalent iodide/iodine  | 1 |
| **Parameters for iodate** |
| Transformation rate in surface water iodine to iodate (%) | 100 |
| Transformation rate in soil iodine to iodate via the STP (%) | 100 |
| Transformation rate in soil iodine to iodate via manure (%) | 100 |
| Molecular equivalent iodate/iodine  | 1.382 |

|  |
| --- |
| **Calculated fate and distribution in the STP** |
| Compartment | Percentage [%] |
| **Active substance: Iodine** |
| Water | 80% |
| Sludge | 20% |

**Emission estimation**

***Scenario [1]***

Only the worst case scenarios are developed below. For the calculated PECs when main releases are via manure/slurry application, it corresponds to the “**Veal calves**” scenario. For the calculated PECs when main releases are via the STP, it corresponds to the “**Turkey in free range – litter floor**” scenario.

Moreover for manure application, only results for **grassland** are detailed corresponding to the worst case approach compared to arable land. . The use of the product at the **dilution of 3.5% v/v** in water is considered as the worst case approach.

**Active substance: Iodine**

|  |
| --- |
| **Input parameters for calculating the local emission** |
| **Parameter** | **Nomenclature** | **Value** | **Unit** | **Origin\*** |
| **Scenario [1]**:Disinfection of livestock buildings (walls, ceilings and floor, slatted areas and other) by spray applicationAfter a **3.5% v/v dilution in water** |
| INPUTS |
| Type of housing/manure storage (for application of the notification) | cat-subcat (i1) | Turkey in free range – litter floor | Veal calves | [-] | D |
| Type of biocide | bioctype (i2) | Disinfectant | [-] | D |
| Type of application | App way (i3) | Spraying | [-] | D |
| Content of active ingredient in formulation (product diluted at 3.5% w/w) | F bioc | 0.504 | [g.L-1] | S |
| Amount of product prescribed to be used per m2 | V prod | 0.4 | [L.m-2] | S |
| Dilution factor | F dil | 1 | [-] | S |
| Fraction of active ingredient released | F slurry/manure\* | 0.3 | 0.5 | [-] | D |
| F waste water | 0.2 | 0 | [-] | D |
| Area of the housing | AREA | 8 040 | 650 | [m2] | D |
| Biocide application interval | Tbioc-int | 182 | 91 | [d] | D/O |
| Number of disinfectant applications in one year | Napp-bioc | 2 | 4 | [-] | D |
| Number of manure applications - grassland | Nlapp-grass | 4 | 4 | [-] | D |
| Manure application time interval for grassland | Tgr-int | 53 | 53 | [d] | D |
| Number of animals | Nanimal i1 | 10 000 | 80 | [-] | D |
| Amount of nitrogen per animal  | Qnitrog i1 | 0.00482 | 0.02382 | [kg.d-1] | D |
| OUTPUTS |
|  |
| ***STP*** |
| Emission from one application to sewer | E local wastewater | 3.24E-01 | NR | [kg.d-1] | O |
| ***Soil exposure*** |
| Amount of a.i. in manure after one application | Q ai manure/slurry | 4.86E-01 | 6.55E-02 | [kg] | O |
| Amount of nitrogen produced during the relevant period and application to grassland | Q nitrog grass | 2.55E+03 | 1.01E+02 | [kg] | O |

\*D: default from ESD, S: set based on product, P: pick list in ESD

NR: not relevant

‘\*. In poultry housings (i1= 8, 11, 12, 16-18), according to TAB entry ENV 168 (TAB 2.0, 2018), a combined assessment of slurry/manure+Fstp is necessary in case that relevant poultry stables are not connected to the municipal sewer system. In this situation, the worst-case animal subcategory are ducks (i1=17) and Fmanure=0.5 should be taken for calculation. After recalculation, according to the TAB 2018 and latest WG discussions, for the highest concentration of 3.5%, we obtained a PEC soil grassland veal calf = 3.59E-1 mg/kg and a PEC soil grassland ducks = 3.57E-1 mg/kg. The PEC value for the animal (sub)category i1=17 (ducks) is just below the PEC value for veal calves even in considering a cumulated fraction Fslurry/manure+Fstp for ducks. As verified, veal calf is the worst case scenario and it covers the uses in other animal housings even in considering no release to the STP.

***Scenario [2]***

According to the Technical Agreements for Biocides (TAB, 2016), for the capacity of dipping bath in PT 3 a default value of 100 L is considered as a realistic worst case for the disinfection of small items of equipment in livestock farming environment. Several smaller dipping tanks may also be used in the same location (e.g. 4 x 25 L = 100 L). For IODOL 100, the intended use is the disinfection by soaking/dipping at each disinfection phase; the biocide application intervals from the ESD have been therefore considered.

Only the worst case scenarios are developed below. For the calculated PECs when main releases are via manure/slurry application, it corresponds to the “**Veal calves**” scenario. For the calculated PECs via the STP, the calculation is independent of the type of housing/manure storage.

Moreover for manure application, only results for **grassland** are detailed corresponding to the worst case approach compared to arable land. The use of the product at the **dilution of 3.5% v/v** in water is considered as the worst case approach.

**Active substance: Iodine**

|  |
| --- |
| **Input parameters for calculating the local emission** |
| **Parameter** | **Nomenclature** | **Value** | **Unit** | **Origin\*** |
| **Scenario [2]**: Disinfection of small equipment’s used in breeding (PT03) by soaking (dipping), followed by rinsing with drinking waterAfter a **3.5% v/v dilution in water** |
| INPUTS |
| Type of housing/manure storage (for application of the notification) | cat-subcat (i1) | Veal calves | [-] | D |
| Type of biocide | bioctype (i2) | Disinfectant | [-] | D |
| Type of application | App way (i3) | Dipping | [-] | D |
| Content of active ingredient in formulation (product diluted at 3.5% w/w) | F bioc | 0.504 | [g.L-1] | S |
| Volume of the dipping bath | V bath | 100 | [L] | D |
| Dilution factor | F dil | 1 | [-] | S |
| Fraction of active ingredient released | F slurry/manure | 1 | [-] | D |
| F waste water | 1 | [-] | D |
| Biocide application interval | Tbioc-int | 91 | [d] | D/O |
| Number of disinfectant applications in one year | Napp-bioc | 4 | [-] | D |
| Number of manure applications - grassland | Nlapp-grass | 4 | [-] | D |
| Manure application time interval for grassland | Tgr-int | 53 | [d] | D |
| Number of animals | Nanimal i1 | 80 | [-] | D |
| Amount of nitrogen per animal  | Qnitrog i1 | 0.02382 | [kg.d-1] | D |
| OUTPUTS |
|  |
| ***STP*** |
| Emission from one application to sewer | E local wastewater | 5.04E-02 | [kg.d-1] | O |
| ***Soil exposure*** |
| Amount of a.i. in manure after one application | Q ai manure/slurry | 5.04E-02 | [kg] | O |
| Amount of nitrogen produced during the relevant period and application to grassland | Q nitrog grass | 1.01E+02 | [kg] | O |

\*D: default from ESD, S: set based on product, P: pick list in ESD

***Scenario [3]***

For the disinfection of drinking water pipes, a worst case value of 200 L of solution diluted at 1.5% v/v, proposed by the applicant, is used in worst case (corresponding to 0.5 L of diluted solution for 1 m of pipe (with a radius of 1.3 cm) and a pipe length of 400 m at a maximum). For Iodol 100, the intended use is the disinfection of drinking water pipes at each disinfection phase; the biocide application intervals from the ESD have been therefore considered.

Only the worst case scenarios are developed below. For the calculated PECs when main releases are via manure/slurry application, it corresponds to the “**Veal calves**” scenario. For the calculated PECs via the STP, the calculation is independent of the type of housing/manure storage.

Moreover for manure application, only results for **grassland** are detailed corresponding to the worst case approach compared to arable land. The use of the product at the **dilution of 1.5% v/v** in water is considered as the worst case approach.

**Active substance: Iodine**

|  |
| --- |
| **Input parameters for calculating the local emission** |
| **Parameter** | **Nomenclature** | **Value** | **Unit** | **Origin\*** |
| **Scenario [3]**: Drinking water pipe disinfection by injection, followed by rinsing with drinking water.After a **1.5% v/v dilution in water** |
| INPUTS |
| Type of housing/manure storage (for application of the notification) | cat-subcat (i1) | Veal calves | [-] | D |
| Type of biocide | bioctype (i2) | Disinfectant | [-] | D |
| Type of application | App way (i3) | Drinking water pipe disinfection by injection | [-] | D |
| Content of active ingredient in formulation (product diluted at 1.5% w/w) | F bioc | 0.216 | [g.L-1] | S |
| Volume of solution diluted for the pipe | V pipe | 200 | [L] | O |
| Dilution factor | F dil | 1 | [-] | S |
| Fraction of active ingredient released | F slurry/manure | 1 | [-] | D |
| F waste water | 1 | [-] | D |
| Biocide application interval | Tbioc-int | 91 | [d] | D/O |
| Number of disinfectant applications in one year | Napp-bioc | 4 | [-] | D |
| Number of manure applications - grassland | Nlapp-grass | 4 | [-] | D |
| Manure application time interval for grassland | Tgr-int | 53 | [d] | D |
| Number of animals | Nanimal i1 | 80 | [-] | D |
| Amount of nitrogen per animal  | Qnitrog i1 | 0.02382 | [kg.d-1] | D |
| OUTPUTS |
|  |
| ***STP*** |
| Emission from one application to sewer | E local wastewater | 4.32E-02 | [kg d-1] | O |
| ***Soil exposure*** |
| Amount of a.i. in manure after one application | Q ai manure/slurry | 4.32E-02 | [kg] | O |
| Amount of nitrogen produced during the relevant period and application to grassland | Q nitrog grass | 1.01E+02 | [kg] | O |

\*D: default from ESD, S: set based on product, P: pick list in ESD

**Calculated PEC values**

For the emission via the application of manure/slurry to land, according to recommendations of the BPC Ad hoc Working Group on Environmental Exposure, the revised equations to calculate PIECsoil grassland via manure application according to the Addendum to the ESD PT18 are used.

Manure and slurry applications were considered on 10 years as recently recommended for PT18. Dissipation processes (leaching) were considered over the ten years of exposure with DT50 of 643 days for grassland and 2571 days for arable land as agreed at the European level.

Finally, according to the CAR, all considered compartment with PEC/PNEC ratio above 1 will be assessed by a comparison between PEC values and background level determined for each compartment.

***Scenario [1]***

*Disinfection of livestock buildings (Sum of the floor area, the slatted area, the wall and roof areas and other areas inside) by spray application (after a 3.5% v/v dilution or a 2% v/v dilution in water).*

Only the PEC values for the worst case approach (product diluted at 3.5% v/v) are detailed below.

According to TAB entry ENV 168 (TAB 2.0) a combined assessment for manure/slurry + waste water has to be performed in case that relevant poultry stables are not connected to the municipal sewer system. In this case, Fmanure should be 0.5. It was therefore verified that environmental risk assessment for the concerned animal (sub) categories (i1=8, 11, 12, 16-18) was acceptable if we consider a release fraction in manure/slurry of 0.5. In fact, in this case, the risk is covered by the veal calves scenario.

**Active substance: Iodine**

|  |
| --- |
| **Summary table on calculated PEC and background levels (as iodine)** |
|  | **Values for Iodine** | **Values for Iodide** | **Values for Iodate** |
| **Background** | **PEC** | **PEC** | **PEC** |
| *Via* manure/slurry application – Veal calves |
| Surface water grassland (µg.L-1)1 | 0.5-20 | 10.2 | 10.2 | 14.1 |
| Soil grassland (mg.kgwwt-1) | 0.565-22.6extremes up to 110.74 | 5.33E-01 | 5.33E-01 | 7.37E-01 |
| Groundwater grassland (µg.L-1)2 | 1-70 | 102 | 102 | 141 |
| *Via* STP - Turkey in free range – litter floor |
| STP (mg/L) | - | 1.30E-01 | - | - |
| Surface water (µg/L) | 0.5-20 | 12.91 | 12.91 | 17.85 |
| Soil (mg/kgwwt) | 0.565-22.6extremes up to 110.74 | 8.02E-01 | 1.12E-01 | 1.11 |
| Groundwater(µg/L)  | 1-70 | 150 | 20.9 | 208 |

‘1 calculated from the PEC groundwater and a dilution factor of 10.

‘2 calculated from the PEC soil grassland and a K soil\_water of 8.90 m3.m-3.

***Scenario [2]***

*Disinfection of small equipment’s used in breeding (PT03) by soaking (dipping), followed by rinsing with drinking water (after a 3.5% v/v dilution or a 2% v/v dilution in water)*

Only the PEC values for the worst case approach (product diluted at 3.5% v/v) are detailed below.

**Active substance: Iodine**

|  |
| --- |
| **Summary table on calculated PEC and background levels (as iodine)** |
|  | **Values for Iodine** | **Values for Iodide** | **Values for Iodate** |
| **Background** | **PEC** | **PEC** | **PEC** |
| *Via* manure/slurry application – Veal calves |
| Surface water grassland (µg.L-1)1 | 0.5-20 | 7.84 | 7.84 | 10.83 |
| Soil grassland (mg.kgwwt-1) | 0.565-22.6extremes up to 110.74 | 4.10E-01 | 4.10E-01 | 5.67E-01 |
| Groundwater grassland (µg.L-1)2 | 1-70 | 78.37 | 78.37 | 108 |
| *Via* STP |
| STP (mg/L) | - | 2.01E-02 | - | - |
| Surface water (µg/L) | 0.5-20 | 2.01 | 2.01 | 2.77 |
| Soil (mg/kgwwt) | 0.565-22.6extremes up to 110.74 | 1.25E-01 | 1.75E-02 | 1.72E-01 |
| Groundwater(µg/L)  | 1-70 | 23.35 | 3.27 | 32.27 |

‘1 calculated from the PEC groundwater and a dilution factor of 10.

‘2 calculated from the PEC soil grassland and a K soil\_water of 8.90 m3.m-3.

***Scenario [3]***

*Scenario 3: Drinking water pipe disinfection by injection (after a 1.5% v/v dilution or a 0.2% v/v dilution, in water), followed by rinsing with drinking water.*

Only the PEC values for the worst case approach (product diluted at 1.5% v/v) are detailed below.

**Active substance: Iodine**

|  |
| --- |
| **Summary table on calculated PEC and background levels (as iodine)** |
|  | **Values for Iodine** | **Values for Iodide** | **Values for Iodate** |
| **Background** | **PEC** | **PEC** | **PEC** |
| *Via* manure/slurry application – Veal calves |
| Surface water grassland (µg.L-1)1 | 0.5-20 | 6.72 | 6.72 | 9.28 |
| Soil grassland (mg.kgwwt-1) | 0.565-22.6extremes up to 110.74 | 3.52E-01 | 3.52E-01 | 4.86E-01 |
| Groundwater grassland (µg.L-1)2 | 1-70 | 67.17 | 67.17 | 92.83 |
| *Via* STP |
| STP (mg/L) | - | 1.73E-02 | - | - |
| Surface water (µg/L) | 0.5-20 | 1.72 | 1.72 | 2.38 |
| Soil (mg/kgwwt) | 0.565-22.6extremes up to 110.74 | 1.07E-01 | 1.50E-02 | 1.48E-01 |
| Groundwater(µg/L)  | 1-70 | 20.02 | 2.81 | 27.66 |

‘1 calculated from the PEC groundwater and a dilution factor of 10.

‘2 calculated from the PEC soil grassland and a K soil\_water of 8.90 m3.m-3.

#### Risk characterisation

***Atmosphere***

Concerning emissions to air, iodine has a low vapour pressure (40.7 Pa at 25°C) and in view of the high background values of iodine in air, emission to air resulting from application of iodine as disinfectant is not considered to be relevant. This approach is in line with the one taken in the CAR. A risk assessment for the atmosphere is therefore not considered necessary.

***Sewage treatment plant (STP)***

|  |
| --- |
| **Summary table of calculated PEC/PNEC STP values** |
|  | **Dilution rate (% v/v)** | **Conclusion** |
| **1.5** | **3.5** |
| *Active substance: Iodine* |
| Scenario 1 (Turkey approach – worst case) |  | 0.045 | Acceptable |
| Scenario 2 |  | 0.007 | Acceptable |
| Scenario 3 | 0.006 |  | Acceptable |

**Conclusion**

PEC/PNEC values in STP are all below 1 which indicates acceptable risk whatever the dilution rate for the worst case scenarios.

***Aquatic compartment***

**Active substance: Iodine**

For iodine and iodide, when PEC/PNEC ratios are above 1, the risk assessment is based on the comparison of the PECs value and the range of typically background concentrations.

|  |
| --- |
| **Summary table of calculated PEC/PNEC surface water values** |
|  | **Iodine** | **Iodide** | **Iodate** | **Conclusion** |
| *Via* manure/slurry application  |
| Scenario 1 (Veal calves approach – worst case / 3.5% v/v dilution) | **17.29** | **12.89** | 0.24 | AcceptableIn the range of background concentrations for iodine |
| Scenario 2 (Veal calves approach – worst case / 3.5% v/v dilution) | **13.29** | **9.45** | 0.185 | AcceptableIn the range of background concentrations for iodine |
| Scenario 3 (Veal calves approach – worst case / 1.5% v/v dilution) | **11.39** | **8.10** | 0.159 | AcceptableIn the range of background concentrations for iodine |
| *Via* STP |
| Scenario 1 (Turkey approach – worst case / 3.5% v/v dilution) | **21.88** | **15.55** | 0.305 | AcceptableIn the range of background concentrations for iodine |
| Scenario 2 (3.5% v/v dilution) | **3.41** | **2.42** | 0.047 | AcceptableIn the range of background concentrations for iodine |
| Scenario 3 (1.5% v/v dilution) | **2.92** | **2.07** | 0.041 | AcceptableIn the range of background concentrations for iodine |

**Conclusion**

* The PEC surface water values for iodine are in the range of typically background concentrations (0.5 to 20 µg/L), indicates acceptable risk for the worst case scenarios.

***Terrestrial compartment***

For emission via manure, the PEC values were calculated only for application to grassland (worst case approach) on the nitrogen standard. It should be noted that the nitrogen standard is the most relevant in Europe notably in France.

**Active substance: Iodine**

For iodine, iodide and iodate, when PEC/PNEC ratios are above 1, the risk assessment is based on the comparison of the PECs value and the range of typically background concentrations.

|  |
| --- |
| **Summary table of calculated PEC/PNEC soil values** |
|  | **Iodine** | **Iodide** | **Iodate** | **Conclusion** |
| *Via* manure/slurry application  |
| Scenario 1 (Veal calves approach – worst case / 3.5% v/v dilution) | **45.17** | **123** | **2.42** | AcceptableIn the range of background concentrations for iodine |
| Scenario 2 (Veal calves approach – worst case / 3.5% v/v dilution) | **34.75** | **95.35** | **1.87** | Acceptable In the range of background concentrations for iodine |
| Scenario 3 (Veal calves approach – worst case / 1.5% v/v dilution) | **29.83** | **81.86** | **1.60** | Acceptable In the range of background concentrations for iodine |
| *Via* STP |
| Scenario 1 (Turkey approach – worst case / 3.5% v/v dilution) | **67.97** | **26.05** | **3.65** | Acceptable In the range of background concentrations for iodine |
| Scenario 2 (3.5% v/v dilution) | **10.59** | **4.70** | 0.57 | Acceptable In the range of background concentrations for iodine |
| Scenario 3 (1.5% v/v dilution) | **9.07** | **3.49** | 0487 | Acceptable In the range of background concentrations for iodine |

**Conclusion**

* The PEC soil values for Iodine are in the range of typically background concentrations (0.565 to 22.6 mg/kgwwt), that indicates acceptable risks for the worst case scenarios.

***Groundwater***

**Active substance: Iodine**

For groundwater, the risk assessment is based on the comparison of the PECs value for iodine and the range of typically background concentrations (70 µg/l).

|  |
| --- |
| **Concentration in Iodine (µg/l)** |
| **SCENARIO 1** | VIA MANURE | VIA STP |
| **3.5%v/v** | **2.0% v/v** | **3.5%v/v** | **2.0% v/v** |
| 1 | Dairy cow | 28.47 | 16.27 |   |   |
| 2 | Beef cattle | 14.51 | 8.29 |   |   |
| 3 | Veal calves | 101.88 | 58.22 |   |   |
| 4 | Sows, in individual pens | 61.45 | 35.12 |   |   |
| 5 | Sows in groups | 70.05 | 40.03 |   |   |
| 6 | Fattening pigs | 49.57 | 28.32 |   |   |
| 7 | Laying hens in battery cages without treatment | 25.22 | 14.41 |   |   |
| 8 | Laying hens in battery cages with aeration (belt drying) | 25.22 | 14.41 | 59.97 | 34.27 |
| 9 | Laying hens in batters cages with forced drying (deeppit, high rise) | 25.22 | 14.41 |   |   |
| 10 | Laying hens in compact battery cages | 22.60 | 12.91 |   |   |
| 11 | Laying hens in free range with litter floor (partly litter floor, partly slatted) | 48.31 | 27.61 | 86.12 | 49.21 |
| 12 | Broilers in free range - litter floor | 15.68 | 8.96 | 51.00 | 29.14 |
| 13 | Laying hens in free range - grating floor | 29.62 | 16.93 |   |   |
| 14 | Parent broilers in free range - grating floor | 18.47 | 10.55 |   |   |
| 15 | Parent broilers in rearing - grating floor | 39.73 | 22.70 |   |   |
| 16 | Turkey in free range - litter floor | 29.89 | 17.08 | 150.20 | 85.83 |
| 17 | Ducks in free range - litter floor | 60.64 | 34.65 | 91.17 | 52.09 |
| 18 | Geese in free range - litter floor | 22.53 | 12.87 | 113.21 | 64.69 |
| **SCENARIO 2** | VIA MANURE | VIA STP |
| **3.5%v/v** | **2.0%v/v** | **3.5%v/v** | **2.0%v/v** |
| 3 | Veal calves (worst case scenario) | 78.37  | 44.78 | 23.35 (all scenarios) | 13.34(all scenarios) |
| 5 | Sows in groups (2nd worst case scenario) | 15.92 | 9.10 |
| **SCENARIO 3** | **VIA MANURE** | **VIA STP** |
| **1.5%v/v** |
| 1 | Scenario 3 | 67.17 (veal calves as worst case) | 20.02 (all scenarios) |

**Conclusion**

* The PEC groundwater values for Iodine are not in the range of typically background concentrations (70 µg/l) for some of the concerned animal (sub) categories when released via Manure at 3.5% v/v dilution and via STP at 2% v/v and 3.5%v/v. That indicates acceptable risks for Manure at 2% v/v dilution and unacceptable risks for STP’s and Manure 3.5% v/v worst case scenarios.
* The estimation of concentrations in groundwater is based on a worst case assumption taking into account the partitioning equilibrium (interstitial soil water), neglecting lateral transport or dilution in deeper soil layers as well as any uptake by plants. Even when concentrations are above the trigger limit, in the absence of possible refinement of this methodology the assessment of estimated concentrations in groundwater, risks are considered acceptable for these uses.
* The following precautionary RMM should be implemented to deal with a possible risk to groundwater: “Do not use the b.p. in animal housings where exposure to a STP cannot be prevented”.

***Primary and secondary poisoning***

As iodine is an essential element for many organisms and its absorption is regulated in animals of several taxonomic groups, estimation of bioaccumulation potential for iodine is not considered relevant. In addition, as the amounts of iodine potentially released into the environment through biocidal uses are within the natural occurring background levels, there is no concern with respect to secondary poisoning. Primary poisoning is not expected for the intended use, which is taking place indoors. Hence the risk to birds and mammals is acceptable.

***Mixture toxicity***

A sum of PEC/PNEC ratio for substance of concern and Iodine and compounds is not considered as relevant because level of contamination of Iodine and compounds is compared to the background concentration.

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

|  |  |
| --- | --- |
| Scenario 1 | **Scenario 1: Disinfection of livestock buildings (Sum of the floor area, the slatted area, the wall and roof areas and other areas inside) by spray application (after a 3.5% v/v dilution, a 2.0% v/v dilution in water)** |
| 3.5% | 2.0% |
| *via* slurry/manure | *via* stp | *via* slurry/manure | *via* stp |
| STP | Acceptable |
| Surface water | Acceptable |
| Sediment | Acceptable |
| Soil | Acceptable |
| Groundwater\* | Acceptable | Acceptable | Acceptable | Acceptable |
| Scenario 2 | **Scenario 2: Disinfection of small equipment’s used in breeding (PT03) by soaking (dipping), followed by rinsing with drinking water (after a 3.5% v/v dilution, a 2.0% v/v dilution in water)** |
| 3.5% | 2.0% |
| *via* slurry/manure | *via* stp | *via* slurry/manure | *via* stp |
| STP | Acceptable |
| Surface water | Acceptable |
| Sediment | Acceptable |
| Soil | Acceptable |
| Groundwater\* | Acceptable | Acceptable | Acceptable |
| Scenario 3 | **Scenario 3: Drinking water pipe disinfection by injection (after a 1.5% v/v dilution, a 0.2% v/v dilution in a water), followed by rinsing with drinking water.** |
| 1.5% | 0.2% |
| *via* slurry/manure | *via* stp | *via* slurry/manure | *via* stp |
| STP | Acceptable |
| Surface water | Acceptable |
| Sediment | Acceptable |
| Soil | Acceptable |
| Groundwater\* | Acceptable |

\* The estimation of concentrations in groundwater is based on a worst case assumption taking into account the partitioning equilibrium (interstitial soil water), neglecting lateral transport or dilution in deeper soil layers as well as any uptake by plants. Even when concentrations are above the trigger limit, in the absence of possible refinement of this methodology the assessment of estimated concentrations in groundwater, risks are considered acceptable for these uses.The following precautionary RMM should be implemented to deal with a possible risk to groundwater: “Do not use the b.p. in animal housings where exposure to a STP cannot be prevented”. |

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

*See Summary of Product Characteristics (SPC)*

### Assessment of a combination of biocidal products

Not relevant

### Comparative assessment

Not relevant

# Annexes[[24]](#footnote-25)

## List of studies for the biocidal product

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Author(s) | Year | TitleSourceCompany Report No.GLP or GEP Status (where relevant)Published or not | Member State DataProtectionClaimed(Y/N) | **Owner** |
| Coffy C. | 2015 | Etude de stabilité de IODOL 100Désinfectant pour canalisations d’eau et pourmatériels et surfaces en élevage | Y | LABORATOIRE MERIEL S.A.S. |
| Coffy C. | 2016 | Etude intermédiaire à 1 an du dosage en iode du IODOL 100 Désinfectant pour canalisations d’eau et pour matériels et surfaces en élevage | Y | LABORATOIRE MERIEL S.A.S. |
| Coffy C. | 2015 | Etude de pH de IODOL 100Report no.15-CMER-005 | Y | LABORATOIRE MERIEL S.A.S. |
| Marquet N. | 2015 | Mesure de densité IODOL 100Report no.15-CMER-004 | Y | LABORATOIRE MERIEL S.A.S. |
| Perin F. | 2016 | surface tensionTest report 16/000265487 | Y | MERIEUXChelab |
| Zampieri L. | 2016 | Validation of a method and determination of assay of iodine in Iodol 100;evaluation of stability (14 days at 54°C; 7 days at 0°C) and physical propertiesStudy N.15.531326.0002 | Y | Chelab |
| Marquet N. | 2016 | Test de persistance de la mousse | Y | MERIEUX NutriSciences |
| Zarpellon A., Semenzin M. | 2016 | Metal corrosion test for the product IODOL 100Report N 16.006357.0004Chelab | Y | MERIEUX NutriSciences |
| Demangel B., | 2015 | Determination of exothermic reactions by DSCon AQUAVIC 3%Report no.15-912037-001 | Y | QALIAN |
| Marquet N. | 2015 | IODOL 100Inflammabilité et Point éclair Report no.15-CMER-006 | Y | LABORATOIRE MERIEL S.A.S. |
| Coffy C. | 2015 | Description et validation de la méthode de dosage de l’iode | Y | LABORATOIRE MERIEL S.A.S. |

| **Author(s)** | **Year** | **Title.Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** | **Date of first submission** |
| --- | --- | --- | --- | --- | --- |
| Marquet N | 2016 | Détermination de l’activité BACTERICIDE de base de l’acide phosphorique 75%. Méthode par dilution neutralisation. Selon la norme NF EN 1040.Laboratoire Mériel / 2016-MER-005 |  | Laboratoire Mériel |  |
| Marquet N | 2016 | Détermination de l’activité LEVURICIDE de base de l’acide phosphorique 75%. Méthode par dilution neutralisation. Selon la norme NF EN 1275 :2005.Laboratoire Mériel 2016-MER-006 |  | Laboratoire Mériel |  |
| Marquet N | 2016 | Essai selon la norme NF EN 14349.Essai quantitatif de surface pour l’évaluation de l’activité bactéricide des antiseptiques et des désinfectants chimiques utilisés dans le domaine véterinaire sur des surfaces non poreuses sans action mécanique en condition de saleté de niveau élevé. Méthode d’essai et prescription (Phase 2, étape 2).Laboratoire Mériel 2016-MER-009 |  | Laboratoire Mériel |  |
| Marquet N | 2016 | Détermination de l’activité bactéricide.Méthode par dilution neutralisationselon les conditions additionnelles de la norme NF EN 1276 :2010 pour la désinfection des matériels en place – solution tampon pH5.Laboratoire Mériel 2016-MER-007 |  | Laboratoire Mériel |  |
| Marquet N | 2016 | Détermination de l’activité bactericide des désinfectants chimiques utilisés dans le domaine vétérinaire. Méthode par dilution neutralisation. Selon la norme NF EN 1656 :2010 en conditions de saleté de niveau élevéLaboratoire Mériel 2016-MER-008  |  | Laboratoire Mériel |  |
| Benoliel C | 2016 | Essai selon la norme NF EN 13697 (juin 2015)Essai quantitatif de surface non poreuse pour l’évaluation de l’activité bactéricide des désinfectants chimiques utilisés dans le domaine de l’agroalimentaire, dans l’industrie domestiques et en collectivité.Méthode d’essai sans action mécanique et prescriptions (Phase 2, étape 2)044-1REA-15 CI v2 |  | Laboratoire Mériel |  |
| Dugué R | 2016 | Activité bactéricide selon la norme EN 13697 :2015Produit :IODOL 100- lot 010715-2Essai partiel vis-à-vis de *Pseudomonas aeruginosa*RE 16074-2 |  | Laboratoire Mériel |  |
| Marquet N | 2015 | Quantitative test for the determination of yeasticidal activity of chemical disinfectant and antiseptics used in food area according to NF EN 1650 standard general conditionsDilution-neutralization method.High level soiling conditionsProduct : IODOL 100Laboratoire Mériel /2015-MER-004 |  | Laboratoire Mériel |  |
| Marquet N | 2015 | Quantitative test for the determination of bactericidal activity of chemical disinfectant and antiseptics used in veterinary area according to NF EN 1656:2010 standard.Dilution-neutralization method.High level soiling conditionsIODOL 100Laboratoire Mériel /2015-MER-023 |  | Laboratoire Mériel |  |
| Marquet N | 2015 | Quantitative test for the determination of yeasticidal activity of chemical disinfectant and antiseptics used in veterinary area according to NF EN 1657 standard general conditions.Dilution-neutralization method.High level soiling conditionsProduct:IODOL 100Laboratoire Mériel /2015-MER-024 |  | Laboratoire Mériel |  |
| Benoliel C | 2015 | Test according to NF EN 14349 standard (April 2008)Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectant and antiseptics used in the veterinary area on non-porous surfaces without mechanical action.Test method requirements (Phase2, step 2)011-1-REA-12 AN |  | Laboratoire Mériel |  |
| Benoliel C | 2015 | Test according to the methodology of the standard NF EN 16438 (March 2014)Quantitative carrier test for evaluation of yeasticidal activity of chemical disinfectant used in veterinary area on non-porous surfaces without mechanical action.Test method requirements (phase2, step 2)031-1REA 15 CI AN |  | Laboratoire Mériel |  |
| Marquet N | 2015 | Quantitative test for the determination of bactericidal activity of chemical disinfectatnt and antiseptics used in food area according to general conditions of European standard NF EN 1276:2010. Dilution neutralization method, high level soiling conditions. Product: IODOL 100Laboratoire Mériel / 2015-MER-003 |  | Laboratoire Mériel |  |
| Marquet N | 2015 | Quantitative test for the determination of bactericidal activity of chemical disinfectant and antiseptics used in food area according to European standard NF EN 1276:2010. Dilution neutralization method, additional conditions for in place equipment disinfection. Product: IODOL 100Laboratoire Mériel / 2015-MER-021 |  | Laboratoire Mériel |  |
| Marquet N | 2015 | Quantitative test for the determination of bactericidal activity of chemical disinfectant and antiseptics used in food area according to European standard NF EN 1276:2010. Dilution neutralization method, additional conditions for in place equipment disinfection- Buffer solution pH9 Product: IODOL 100Laboratoire Mériel / 2015-MER-022 |  | Laboratoire Mériel |  |
| Marquet N | 2015 | Quantitative test for the determination of yeasticidal activity of chemical disinfectant and antiseptics used in food area according to NF EN 1650 standard. Dilution neutralization method, additional conditions for in place equipment disinfection- Buffer solution pH5 Product: IODOL 100Laboratoire Mériel / 2015-MER-019 |  | Laboratoire Mériel |  |
|  |  | Quantitative test for the determination of yeasticidal activity of chemical disinfectant and antiseptics used in food area according to NF EN 1650 standard. Dilution neutralization method, additional conditions for in place equipment disinfection- Buffer solution pH9 Product: IODOL 100Laboratoire Mériel / 2015-MER-020 |  | Laboratoire Mériel |  |
| Benoliel C | 2015 | Test according to the methodology of the standard NF EN 13697 (juin 2015)Quantitative non-porous surface test for the evaluation of bactericidal activity of chemical disinfectant and antiseptics used in the field of food processing, in industry, in domestic and institutional areas. Test method requirements (phase2, step 2)043-1REA15 CI AN |  | Laboratoire Mériel |  |
| Benoliel C | 2015 | Essai selon la norme NF EN 13697 (juin 2015)Essai quantitatif de surface non poreuse pour l’évaluation de l’activité fongicide des désinfectants chimiques utilisés dans le domaine de l’agroalimentaire, dans l’industrie, dans les domaines domestiques et en collectivité.Méthode d’essai sans action mécanique et prescriptions (Phase2, Etape 2)029-1REA15 |  | Laboratoire Mériel |  |

## Output tables from exposure assessment tools



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## New information on the active substance

## Residue behaviour

**Table 1:** PT03: Disinfection of empty breeding Tier 2: realistic worst case without refinement



**Table 2:** PT03: Disinfection of empty breeding Tier 3: realistic worst case with refinement



**Table 3: Air concentration vs time for the 6 representative animal species: Graphics extracted from Consexpo 5.0 simulations**







The UL exceedance of iodine has already been discussed at EU level for PT3 teat dip application. The uses presented in this dossier are covered largely by the assessment performed for the direct use as teat dip in PT3 (cf EU AMM on iodine). Following the WG Tox and BPC discussions, this conclusion should considered the context of the active substance iodine, and the maximalist estimation using the UL value. The iodine context for PT3 teat dip is added below:

*Following the same approach as for the other iodine UA, which has been discussed at WG and BPC, the following has been taken into consideration for the proposed decision on the authorisation of iodine teat disinfection products:*

*- The reference values for iodine of 600 µg/d for adults is not toxicological reference values but upper intake levels. These values have been derived with the aim of setting recommendations for intake and do not represent toxicological cut-off values for risk assessment. For trace elements like iodine, generally no toxicologically cut-off values are set. Therefore, it was agreed at Human Health Working Group II-2017 to use the upper intake levels as reference values. It is further noted that WHO derived a value of 1000 µg/d for adults but no value for children was set. The limit values used in this assessment as insecure, as opposed to conservative. At the moment, it is not possible to obtain a better setting of the UL due to data gaps.*

*- The estimated intakes are based on theoretical worst case levels of iodine in milk and were calculated based on a chronic exposure, which was considered to be the most appropriate based on how the UL was derived. The estimated residue levels of iodine in milk are based on a worst case assessment and the data are based on short term consumption studies.*

*- Within Europe iodine deficiency is considered a major public health problem and iodine supplementation programs are ongoing nationally and internationally to improve the iodine intake and thereby to prevent consequences for public health, e.g. by the addition of iodine in food or salt (e.g. The Netherlands) or the advice to use iodine containing dietary supplements. Other EU countries (e.g. United Kingdom, Czech Republic) regulate adequate iodine intake through addition of iodine to cattle feed. It is recognised that both insufficient and excessive iodine intakes can cause diseases.*

*- The actual amount of iodine intake in the EU is highly variable and difficult to estimate, as levels of iodine intake depend on the geographical location, the soil, people’s diet, the season, farming practices, iodine fortification of feed for dairy animals, iodine supplementation programs and other factors. From iodine supplementation programs, monitoring data on iodine nutrition will become available and a clearer picture of the iodine status across Europe will emerge. It has been discussed in the CA-meeting whether the generation of additional data on residue levels from teat disinfection in milk should be requested from applicants for post-authorisation. However, in the September 2017 CA meeting it was agreed that such a requirement cannot be imposed to the applicants for product authorisation.*

*It can be concluded that all available data have been provided to verify the outcome and conclusions, and permit authorisation of the biocidal product family. When using the products belonging to this biocidal product family according to the conditions as stated in the SPC, the products will be efficacious and will not present an unacceptable risk to human and animal health nor the environment. So it important to obtain more reliable information on iodine background levels in food items in the EU, and consequently to update the data supporting the current UL. A wider approach to the consumer risk assessments encompassing different regulatory areas would need to be considered.*

## Summaries of the efficacy studies (B.5.10.1-xx)[[25]](#footnote-26)

See IUCLID files

1. [↑](#footnote-ref-2)
2. For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work). [↑](#footnote-ref-3)
3. Guidance on Dermal Absorption, EFSA Panel on Plant Protection Products and their Residues (PPR), EFSA
Journal 2012;10(4):2665 [↑](#footnote-ref-4)
4. Guidance on the BPR: Volume III human health - part B Risk assessment [↑](#footnote-ref-5)
5. Technical Notes for Guidance Human exposure to biocidal products, january 2008 (adopted during CA meeting of 19-20 june of 2007). [↑](#footnote-ref-6)
6. HEEG opinion 9 Default protection factors for protective clothing and gloves (agreed in TM I 2010). [↑](#footnote-ref-7)
7. Guidance on the BPR: Volume III human health - part B Risk assessment [↑](#footnote-ref-8)
8. EFSA Journal 2013 ; 11(2) :3099 : Scientific opinion on the safety and efficacy of iodine compounds (E2) as feed additives for all animal species : calcium iodate anhydrous and potassium iodide, based on a dossier submitted by Ajay Europe SARL [↑](#footnote-ref-9)
9. Council Regulation (EEC) No. 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin. Official Journal of the European Communities, No L 224/1. [↑](#footnote-ref-10)
10. Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. Official Journal of the European Union, L 15/1. [↑](#footnote-ref-11)
11. ARTFood 2016, draft Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products [↑](#footnote-ref-12)
12. Fiche toxicologique Iode, FT 207, INRS (2006) [↑](#footnote-ref-13)
13. http://www.inchem.org/documents/pims/pharm/iodine.htm#SectionTitle:5.3 [↑](#footnote-ref-14)
14. Toxicological profile for Iodine, US Department of Health and Human Services (2004) [↑](#footnote-ref-15)
15. [↑](#footnote-ref-16)
16. World Health Organization (WHO) – Iodine and inorganic iodides : Human health aspects (Doc. 72) EFSA Journal 2005 ; 168, 1-42 : opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the request from the Commission on the use of iodine in feedingstuffs [↑](#footnote-ref-17)
17. EFSA Journal 2013 ; 11(2) :3099 : Scientific opinion on the safety and efficacy of iodine compounds (E2) as feed additives for all animal species : calcium iodate anhydrous and potassium iodide, based on a dossier submitted by Ajay Europe SARL [↑](#footnote-ref-18)
18. Iodine and inorganic iodides: Human health aspects, Concise international chemical assessment document 72,WHO, 2009 [↑](#footnote-ref-19)
19. ARTFood/DRAWG (2014) : Guidance on Estimating Transfer of Biocidal Active Substances into Foods – Professional Uses – 2014 - draft not yet published [↑](#footnote-ref-20)
20. ARTFood/DRAWG (2014) : Guidance on Estimating Transfer of Biocidal Active Substances into Foods – Professional Uses – 2014 – draft not yet published [↑](#footnote-ref-21)
21. Default value found in Appendix I, Table 4 of the European Commission document CA-Dec10- Doc.6.2.B – “Guidance on estimating livestock exposure to active substances used in biocidal products”, and in the ECHA Guidance document “Biocides Human Health Exposure methodology” [↑](#footnote-ref-22)
22. SCF (Scientific Committee on Food), 2002. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Iodine. 15 pp. [↑](#footnote-ref-23)
23. Volume 8: Notice to applicants and Guideline – Veterinary medicinal products : Establishment of maximum residue limits (MRLs) for residues of veterinary medicinal products in foodstuffs of animal origin [↑](#footnote-ref-24)
24. [↑](#footnote-ref-25)
25. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-26)