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)



AQUAVIC 3%

Product types 3 and 4

Iodine

Case Number in R4BP: BC-BG019597-43

Evaluating Competent Authority: France

Date: June 2018

Table of Contents

[Table of Contents 2](#_Toc523740810)

[*1* CONCLUSION 4](#_Toc523740811)

[*2* ASSESSMENT REPORT 7](#_Toc523740812)

[2.1 Summary of the product assessment 7](#_Toc523740813)

[2.1.1 Administrative information 7](#_Toc523740814)

[2.1.1.1 Identifier of the product 7](#_Toc523740815)

[2.1.1.2 Authorisation holder 7](#_Toc523740816)

[2.1.1.3 Manufacturer(s) of the product 7](#_Toc523740817)

[2.1.1.4 Manufacturer(s) of the active substance(s) 7](#_Toc523740818)

[2.1.2 Product composition and formulation 8](#_Toc523740819)

[2.1.2.1 Identity of the active substance 8](#_Toc523740820)

[2.1.2.2 Candidate(s) for substitution 8](#_Toc523740821)

[2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product 9](#_Toc523740822)

[2.1.2.4 Information on technical equivalence 9](#_Toc523740823)

[2.1.2.5 Information on the substance(s) of concern 9](#_Toc523740824)

[2.1.2.6 Type of formulation 9](#_Toc523740825)

[2.1.3 Hazard and precautionary statements 9](#_Toc523740826)

[2.1.4 Authorised use(s) 10](#_Toc523740827)

[2.1.4.1 Use description 10](#_Toc523740828)

[2.1.4.2 Use description 11](#_Toc523740829)

[2.1.5 General directions for use 12](#_Toc523740830)

[2.1.5.1 Instructions for use 12](#_Toc523740831)

[2.1.5.2 Risk mitigation measures 12](#_Toc523740832)

[2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 13](#_Toc523740833)

[2.1.5.4 Instructions for safe disposal of the product and its packaging 13](#_Toc523740834)

[2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage 13](#_Toc523740835)

[2.1.6 Other information 13](#_Toc523740836)

[2.1.7 Packaging of the biocidal product 14](#_Toc523740837)

[2.1.8 Documentation 14](#_Toc523740838)

[2.1.8.1 Data submitted in relation to product application 14](#_Toc523740839)

[2.1.8.2 Access to documentation 14](#_Toc523740840)

[2.2 Assessment of the biocidal product 15](#_Toc523740841)

[2.2.1 Intended uses as applied for by the applicant 15](#_Toc523740842)

[2.2.2 Physical, chemical and technical properties 16](#_Toc523740843)

[2.2.3 Physical hazards and respective characteristics 24](#_Toc523740844)

[2.2.4 Methods for detection and identification 27](#_Toc523740845)

[2.2.4.1 Physico-chemical properties and Analytical method for determination of active ingredient and impurities in the technical active ingredient 27](#_Toc523740846)

[2.2.4.2 Analytical method for determining the active substance and relevant component in the biocidal product 28](#_Toc523740847)

[2.2.4.3 Preparation of accuracy samples: 28](#_Toc523740848)

[2.2.4.4 Validation of the analytical method: 28](#_Toc523740849)

[2.2.4.5 Analytical methods for determining relevant components and/or residues in different matrices 29](#_Toc523740850)

[2.2.5 Efficacy against target organisms 35](#_Toc523740851)

[2.2.5.1 Function and field of use 35](#_Toc523740852)

[2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected 35](#_Toc523740853)

[2.2.5.3 Effects on target organisms, including unacceptable suffering 35](#_Toc523740854)

[2.2.5.4 Mode of action, including time delay 35](#_Toc523740855)

[2.2.5.5 Efficacy data 36](#_Toc523740856)

[2.2.5.6 Occurrence of resistance and resistance management 43](#_Toc523740857)

[2.2.5.7 Known limitations 43](#_Toc523740858)

[2.2.5.8 Evaluation of the label claims 43](#_Toc523740859)

[2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s) 44](#_Toc523740860)

[2.2.6 Risk assessment for human health 44](#_Toc523740861)

[2.2.6.1 Assessment of effects on Human Health 44](#_Toc523740862)

[2.2.6.2 Exposure assessment 48](#_Toc523740863)

[2.2.6.3 Risk characterisation for human health 79](#_Toc523740864)

[2.2.7 Risk assessment for animal health 92](#_Toc523740865)

[2.2.8 Risk assessment for the environment 92](#_Toc523740866)

[2.2.8.1 Effects assessment on the environment 93](#_Toc523740867)

[2.2.8.2 Exposure assessment 95](#_Toc523740868)

[2.2.8.3 Risk characterisation 103](#_Toc523740869)

[2.2.9 Measures to protect man, animals and the environment 114](#_Toc523740870)

[2.2.10 Assessment of a combination of biocidal products 114](#_Toc523740871)

[2.2.11 Comparative assessment 114](#_Toc523740872)

[*3* Annexes 115](#_Toc523740873)

[3.1 List of studies for the biocidal product 115](#_Toc523740874)

[3.2 Output tables from exposure assessment tools 118](#_Toc523740875)

[3.3 New information on the active substance 118](#_Toc523740876)

[3.4 Residue behaviour 119](#_Toc523740877)

[3.5 Summaries of the efficacy studies (B.5.10.1-xx) 123](#_Toc523740878)

# CONCLUSION

The product AQUAVIC 3% 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 AQUAVIC 3% 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 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.

The stability of the preparation after 2 years at ambient temperature in the commercial packaging should be required in post-authorization.

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.

Analytical method for the determination of the active substance in the biocidal product was provided and validated.

* *Efficacy assessment*

In accordance with the submitted tests and the requirements of the norm EN 14885, the product AQUAVIC 3% is efficient against bacteria, yeasts and virus:

* By spraying for the disinfection of empty breeding buildings and equipments (PT3)
* By soaking for the disinfection of equipments (PT3)

And against bacteria and yeasts

* 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 soaking is acceptable for dilution at 1% when appropriate PPE are worn. The irsk during spraying in unacceptable for dilution at 1%
* The risk during spraying and soaking is unacceptable for dilution at 1.5% even if PPE are worn.
* The risk is unacceptable for dilution at 2% as this dilution is corrosive and exposure during the spraying and soaking tasks cannot be limited.

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 AQUAVIC 3% 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.

* *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 AQUAVIC 3 %.

The estimated groundwater concentrations associated with the use of the product AQUAVIC 3% are in the range of environmental iodine background except in the following uses :

* disinfection with a product dilution of 2.0% v/v and for the following animal’s housing:
  + livestock veal calves;
  + livestock sows;
  + livestock pigs;
  + laying hens in free range with litter floor;
  + ducks in free range.
* disinfection with a product dilution of 1.5% v/v and for the following animal’s housing:
  + livestock veal calves;
  + livestock sows;
  + ducks in free range.
* disinfection with a product dilution of 1.0% v/v and for the following animal’s housing:
  + livestock veal calves.
* disinfection of equipment used for animals for a product dilution of 2.0% v/v and a dilution of 1.5% v/v used in of livestock veal calf buildings.
* drinking water pipe disinfection for a product dilution of 0.8% v/v used in of livestock veal calf buildings.

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 AQUAVIC 3%, the following uses are proposed for authorization:

* Disinfection against yeast of equipment for animals by soaking (1% dilution);
* Disinfection of drinking water pipes for drinking water for animals by filling and by cleaning in place.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

Identifier of the product

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| AQUAVIC 3% |  |
| IODISANE 3% |  |

Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | QALIAN S.A. |
| **Address** | 34, Rue Jean Monnet  ZI d'Etriché - BP 20341  49503 SEGRE  France |
| **Authorisation number** | FR-2018-0060 | |
| **Date of the authorisation** | **17/08/2018** | |
| **Expiry date of the authorisation** | **16/08/2028** | |

Manufacturer(s) of the product

|  |  |
| --- | --- |
| **Name of manufacturer** | LABORATOIRE MERIEL S.A.S |
| **Address of manufacturer** | 12 rue de Malacussy  42100 Saint Etienne  France |
| **Location of manufacturing sites** | 12 rue de Malacussy  42100 Saint Etienne  France |

Manufacturer(s) of the active substance(s)

|  |  |
| --- | --- |
| **Active substance** | Iodine |
| **Name of manufacturer** | HYPRED |
| **Address of manufacturer** | 55 boulevard Jules Verger  BP10180  35803 Dinard Cedex  France |
| **Location of manufacturing sites** | 55 boulevard Jules Verger  BP10180  35803 Dinard Cedex  France |

### 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

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Iodine | Iode | Active substance | 7553-56-2 | 231-442-4 | 3.00 |

Information on technical equivalence

Not relevant

Information on the substance(s) of concern

Not relevant

Type of formulation

|  |
| --- |
| Soluble Concentrate |

### Hazard and precautionary statements[[1]](#footnote-1)

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

|  |  |
| --- | --- |
| **Classification** | |
| Hazard category | Skin Corr. 1B  STOT RE. 2  Acute TOX 4  Metal Corr 1  Aquatic chronic 2 |
| Hazard statement | H314: Causes severe skin burns and eye damage.  H373: May cause damage to organ (thyroid) through prolonged or repeated exposure.  H302: Harmful if swallowed.  H290 cat.1: Corrosive to metal  H411: Toxic to aquatic life with long lasting effects |
|  | |
| **Labelling** | |
| Signal words | Danger |
| Hazard statements | H314: Causes severe skin burns and eye damage.  H373: May cause damage to organ (thyroid) through prolonged or repeated exposure.  H302: Harmful if swallowed.  H290 cat.1: Corrosive to metal  H411: Toxic 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 environment.  P280: 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 breathing  P310: Immediately call a POISON CENTER/doctor/…  P321: Specific treatment (see…on this label).  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P391 Collect spillage.  P405: Store locked up.  P501 : Dispose of contents/container to …  P314: Get medical advice/attention if you feel unwell.  P270: Do not eat, drink or smoke when using this product.  P301+P312: IF SWALLOWED: Call a POISON CENTER/ doctor/…/if you feel unwell.  P330: Rinse mouth. |
|  | |
| 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 for animals |
| **Target organism (including development stage)** | Yeasts |
| **Field of use** | Indoor use |
| **Application method(s)** | The product is applied by soaking |
| **Application rate(s) and frequency** | 1.0 % v/v dilution at 10°C  Contact time : 30 minutes  Clean surfaces |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | The product AQUAVIC 3% is packaged in individual HDPE containers  of 5, 20 L and 60 L. |

##### Use-specific instructions for use

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

##### Use-specific risk mitigation measures

|  |
| --- |
| * During dipping, gloves, a mask APF 10 and an impermeable coverall have to 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 2. Use # 2 – 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)** | Bacteria (including *Salmonella* Typhimurium for CIP)  Yeasts |
| **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: 0.8 % v/v dilution at 20°C * yeasts: 0.5 % v/v dilution at 20°C   Contact time : 30 minutes  Clean surfaces  Cleaning in place (bacteria including *Salmonella* Thyphimurium) and yeasts)   * 0.15% v/v dilution (residual pH 9 after alkaline cleaning) * 0.05 % v/v dilution (residual pH 5 after acidic cleaning)   Contact time : 60 minutes at 10°C  Clean surfaces |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | The product AQUAVIC 3% is packaged in individual HDPE containers of 5, 20 L and 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 AQUAVIC 3%. * 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 AQUAVIC 3 %. |

##### 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.  **PPE:**  -Task appropriate gloves;  - Impermeable coverall with appropriate barrier material based on potential for contact with the chemicals;  - 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

|  |
| --- |
| The final 2 years at ambient temperature storage study should be required in post-authorization.  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. |

### 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 | Opaque HDPE | Blue cap in HDPE | Professional | 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 AQUAVIC 3% were provided by QALIAN SA.

**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 AQUAVIC 3%:

* 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.
* For virus:
* Laboratory study according to EN 14675 standard.

Access to documentation

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

QALIAN SA has access to analytical methods on the active substance Iodine with a Letter of Access of HYPRED SA, one of applicants of the active substance iodine.

## 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

|  |  |
| --- | --- |
| **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)** | Bacteria  Yeasts  Virus |
| **Field of use** | Indoor use |
| **Application method(s)** | The product is applied by spraying or soaking (1.0, 1.5% v/v or 2.0% v/v dilution). |
| **Application rate(s) and frequency** | The product AQUAVIC 3% is a soluble concentrate to be diluted in water with caution before use.  Contact time : 30 minutes  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 AQUAVIC 3% 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

|  |  |
| --- | --- |
| **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)** | Bacteria, included *S.* Typhimurium  Yeasts |
| **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) or by cleaning in place (0.05% v/v or 0.15% v/v dilution) |
| **Application rate(s) and frequency** | The product AQUAVIC 3% is a soluble concentrate to be diluted in water with caution before use.  Contact time :   * 30 minutes by filling drinking water pipes * 60 minutes by cleaning in place |
| **Category(ies) of user(s)** | Professional users |
| **Pack sizes and packaging material** | The product AQUAVIC 3% is packaged in individual HDPE containers :   * jerry can of 5 and 20 L and, * drum of 60 L. |

### 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 3.02% of technical Iodine and 3.0% of pure Iodine.

The product does not contain PT6 preservative. It is used diluted in water (0.05%-0.8%).

Formulation type: Soluble Concentrate SL

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

The product AQUAVIC 3% 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** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual observation | AQUAVIC 3%  Batch No.: 152201  3.27% w/w of iodine | Brown liquid | Acceptable | Coffy C., 2015 |
| Colour at 20 °C and 101.3 kPa |
| Odour at 20 °C and 101.3 kPa |  | AQUAVIC 3%  Batch No.: 152201  3.27% w/w of iodine | Without characteristic odour | Acceptable | Coffy C., 2015 |
| Acidity / alkalinity | CIPAC MT75.3  CIPAC MT31 and  MT191 | AQUAVIC 3%  Batch No.: 152201  3.27% w/w of iodine | **Acidity (20°C):** 3.9% H2SO4  **pH (20°C):**  Neat: 1.1  In 1% aqueous solution: 2.5   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | |  |  |  | pH at 20°C | | | | |  | Hardness | pH water | At 1.5% | At 2.0% | At 2.5% | At 3.0% | | Distilled water | <3 | 8.4 | 2.3 | 2.0 | 1.9 | 1.9 | | Saint-Etienne water | 7 | 7.3 | 2.4 | 1.9 | 1.9 | 1.9 | | Hard water | 30 | 6.9 | 2.5 | 2.0 | 1.9 | 1.9 | | Acceptable | Coffy C., 2015 and 2017 |
| Relative density / bulk density | OECD No.109 Method (buoyancy method) | AQUAVIC 3%  Batch No.: 152201  3.27% w/w of iodine | D20=1.077 | Acceptable | Marquet N., 2015 |
| Storage stability test – **accelerated storage** | CIPAC MT75.3  CIPAC MT31 and  MT191OECD No.109 Method (buoyancy method)  CIPAC MT41 and  MT179  CIPAC MT 47.2  Method  labo1002  Method  labo1004 | AQUAVIC 3%  Batch No.: 152201  3.27% w/w of iodine | |  |  |  |  | | --- | --- | --- | --- | | Tests | Before storage | | After storage 14 days at 54°C in HDPE | | Appearance | Brown liquid without characteristic odour | | | | pH (1%, 20°C) | 2.5 | 2.5 | | | Acidity (% H2SO4) | 3.90 | 3.78 | | | Density (20°C) | 1.077 | 1.07 | | | Dilution stability (2.5%) | No sediments after 30min  Homogeneous solution after 18h | | | | Persistent foaming (after 1min) | At 0.5% (m/v): 119mL  At 2.5% (m/v): 163mL | At 0.5% (m/v): 129mL  At 2.5% (m/v): 159mL | | | Iodine content | 3.27% | 3.26%  (-0.3%) | | | Packaging stability | No bloating, leakage or cracking  m=127.983g | No bloating, leakage or cracking  m=127.870g  (-0.1%) | | | **The volume of persistent foaming is very high.**  **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.** | Coffy C., 2015  and updated 2016 |
| Storage stability test – **long term storage at ambient temperature** | Method  labo1002 | AQUAVIC 3%  Batch No.: 152201  3.27% w/w of iodine | The test is on-going (started on 01/2015 and will finish on 01/2018). Interim results after 12 months was provided:   |  |  |  | | --- | --- | --- | | Tests | Before storage | After 12 months storage at ambient temperature in HDPE | | Appearance | Brown liquid without characteristic odour | | | Iodine content | 3.27% m/m | 3.28% m/m  (+0.3%) | | **All tests required for an SL formulation (appearance, AS content, packaging stability, pH, acidity/alkalinity, density, dilution stability and persistent foaming) were not provided.**  **The 2 years storage study should be required in post-authorization with all requirements (appearance, AS content, packaging stability, pH, acidity/alkalinity, density, dilution stability and persistent foaming).** | Coffy C., 2016 |
| Storage stability test – **low temperature stability test for liquids** |  | AQUAVIC 3%  Batch No.: 152201  3.27% w/w of iodine | After 7days at 0°C, the product is frozen but after thawing, the biocidal product is homogeneous (no sediment) brown liquid. | Acceptable | Coffy C., 2015 |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | Not required |  |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | Not required |  |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  | See ”Storage stability test – **long term storage at ambient temperature”** |  |  |
| Wettability |  |  | Not relevant for a SL formulation |  |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not relevant for a SL formulation |  |  |
| Wet sieve analysis and dry sieve test |  |  | Not relevant for a SL formulation |  |  |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not relevant for a SL formulation |  |  |
| Disintegration time |  |  | Not relevant for a SL formulation |  |  |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | Not relevant for a SL formulation |  |  |
| Persistent foaming | CIPAC MT 47.2 | AQUAVIC 3%  Batch No.: 152201  3.27% w/w of iodine | |  |  |  | | --- | --- | --- | |  | Time | Volume of foam (mL) | | 0.5% (m/v) | 10s | 125 | | 1min | 119 | | 3min | 118 | | 12min | 109 | | 2.5% (m/v) | 10s | 166 | | 1min | 163 | | 3min | 156 | | 12min | 142 | | **The volume of persistent foaming is very high.**  **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.** | Coffy C., 2015 and updated 2016 |
| Flowability/Pourability/Dustability |  |  | Not relevant for a SL formulation |  |  |
| Burning rate — smoke generators |  |  | Not relevant for a SL formulation |  |  |
| Burning completeness — smoke generators |  |  | Not relevant for a SL formulation |  |  |
| Composition of smoke — smoke generators |  |  | Not relevant for a SL formulation |  |  |
| Spraying pattern — aerosols |  |  | Not relevant for a SL formulation |  |  |
| Physical compatibility |  |  | Not relevant for a SL formulation |  |  |
| Chemical compatibility |  |  | Not relevant for a SL formulation |  |  |
| Degree of dissolution and dilution stability | CIPAC MT41 | AQUAVIC 3%  Batch No.: 152201  3.27% w/w of iodine | |  |  |  | | --- | --- | --- | |  | Water of Saint-Etienne | Hard water | | Sediment after 30min | No sediment | | | Appearance after 18h | Homogeneous | | | Acceptable | Coffy C., 2015 |
| Surface tension | UNI EN 14370:2004 | AQUAVIC 3%  Batch No: 140416-1 | 33.4 mN/m at 2.5 % v/v | Acceptable  Surface active product | F. Perin, 2016 |
| Viscosity | OECD 114 | AQUAVIC 3% | Kinematic viscosity at 20°C: 20.29 mm².s-1  Kinematic viscosity at 40°C: 16.47 mm².s-1  Dynamic viscosity at 20°C: 21.81 mPa.s | Acceptable | L. Zampieri, 2016 |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives |  | AQUAVIC 3%  Batch No.: 152201  3.27% w/w of iodine | Considering the high proportion of water and of not-explosive ingredients (in total 94.00 – 96.70% w/w), the product Aquavic 3% is not expected to present a significant hazard for explosivity.  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 explosive and the test on explosive properties according to UN Test series 1 to 3 described in Part I of the UN-MTC should not be performed. | Acceptable | Demangel B., 2015  Report no.15-912037-001  Detrimont H., Ambrosi D., 2015  Report no.15/39 |
| Flammable gases |  |  | Not relevant |  |  |
| Flammable aerosols |  |  | Not relevant |  |  |
| Oxidising gases |  |  | Not relevant |  |  |
| Gases under pressure |  |  | Not relevant |  |  |
| Flammable liquids |  | AQUAVIC 3%  Batch No.: 152201  3.27% w/w of iodine | The product Aquavic 3% is not expected to present a significant hazard for flammability. Test is not required as Aquavic 3% contains more than 66% w/w water and as no ingredient is considered to flammable based on available data found in literature. | Acceptable | Marquet N., 2015 |
| Flammable solids |  |  | Not relevant |  |  |
| Self-reactive substances and mixtures |  |  | Not required |  |  |
| Pyrophoric liquids |  |  | Not required 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), it considered acceptable. |  |
| Pyrophoric solids |  |  | Not relevant |  |  |
| Self-heating substances and mixtures |  | AQUAVIC 3%  Batch No.: 152201  3.27% w/w of iodine | 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 according to UN Test series A to H described in Part II of the UN-MTC should not be performed. | Acceptable  Non self-reactive | Demangel B., 2015  Report no.15-912037-001 |
| Substances and mixtures which in contact with water emit flammable gases |  |  | Not relevant |  |  |
| Oxidising liquids |  | AQUAVIC 3%  Batch No.: 152201  3.27% w/w of iodine | Considering the high proportion of water and of not-oxidising ingredients (in total 90.50 – 92.00% w/w), the product Aquavic 3% is not expected to present a significant hazard for oxidising properties, and testing is considered as unnecessary. | Acceptable | Detrimont H., Ambrosi D., 2015  Report no.15/39 |
| Oxidising solids |  |  | Not relevant |  |  |
| Organic peroxides |  |  | Not relevant |  |  |
| Corrosive to metals | Section 37.4 of UN-MTC (UN RTDG) | AQUAVIC 3%  Batch No: 140416-1 | Aluminium plates (after 7 days immersion):  19.3% of weight loss  Steel plates (after 7 days immersion):  3.4% of weight loss | Acceptable  As the weight loss is >13.5% after 7 days for aluminium plates, the product AQUAVIC 3% is classified **H290 cat.1: corrosive to metal.** | M. Semenzin, 2016 |
| Auto-ignition temperatures of products (liquids and gases) |  |  | The product Aquavic 3% is not expected to present a significant hazard for auto-flammability. Test is not required as Aquavic 3% contains more than 66% 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 |  |  |
| Dust explosion hazard |  |  | Not relevant |  |  |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| The formulation AQUAVIC 3% 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 liquid, with no characteristic odour. It is not explosive and has no oxidizing properties. The product is not considered as flammable.There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. Its technical characteristics are acceptable for a SL formulation.  **The stability of the preparation after 2 years at ambient temperature in the commercial packaging should be required in post-authorization.**  **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.**  **Implication concerning labelling:**  **H290 cat.1. – corrosive to metal** |

### Methods for detection and identification

Physico-chemical properties and Analytical method for determination of 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 Qalian of the product AQUAVIC 3% 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** |
| Title: | Description and validation of the iodine quantification method |
| Document No | Labo1002 |
| Test facility | LABORATOIRE MERIEL S.A.S.  12 rue de Malacussy  42100 SAINT-ETIENNE  France |
| Guidelines: | - |
| GLP | - |

Preparation of accuracy samples:

Weight 0.40 ±0.04g of AQUAVIC 3% solution in a 100mL Erlenmeyer. Added 20mL of distilled water and a magnet bar.

The determination of iodine is performed by a redox titration with sodium thiosulfate. The equation is:

**I2 (aq) + 2 S2O32- (aq) = S4O62- (aq) + 2 I- (aq)**

Validation of the analytical method:

|  |  |  |
| --- | --- | --- |
| Specificity | To demonstrate that the quantification of iodine is not affected by other co-formulants presents 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 + 0.1501 R2 = 0.9999  N=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% |

Specificity, linearity, precision and accuracy were checked and are found acceptable.

Analytical methods for determining relevant components and/or residues in different matrices

| **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/01  P. Schramel (1997), Doc. No. 492-008; A4.2a/02 |
| iodine | Sandel-Kolthoff methodology  Photometric 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 replicates  5 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 | | Overall  62.7 – 103%  25% r.H:  95 – 103  50% r.H:  94.2 – 99.4  80% r.H.:  62.7 – 86.8 | 90.7  98.2  97.2   76.5 | 12.6  4.2  2.7  12.4 | 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 ppm  94.8 at 0.1 ppm  86.3 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 sulphate In 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\*\*\* | Acceptable  No 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 data  No 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/L  LOD: 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 iodine  LOD for iodide and iodate range from 0.1 to 1 µg/L. | 0.59 mg/L\*\*\* | Not acceptable due to missing supporting data  No 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 %RSD  IO3-: 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\*\*\* | Acceptable  No 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/L  IO3-: 0.09-874 µg/L | | Yes | Not reported | I-: 92-95%  IO3-: 94-97% | I-: 0.5-1.4 %RSD  IO3-: 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\*\*\* | Acceptable  No 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; A4.3/01  2. 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 |

\*: General requirement for soil according to TNsG on Analytical methods

\*\*: Based on the occupational exposure limit (OEL) / MAK value of 0.1 mg/m3 established for iodine in most European countries

\*\*\*: Lowest concentration having an effect on aquatic organisms (based on EC50 for Daphnia Magna). The general pesticide limit of 0.1 µg/L in drinking water according to Council Directive 98/83/EC does not apply to a non-xenobiotic substance like iodine

\*\*\*\*: The approximate level of natural background concentration of iodine in milk

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| **Analytical methods were provided and validated at EU level for the determination of iodine residue in animal products (milk) with a LOQ = 0.3 mg/kg.**  **Analytical methods were provided and validated at EU level for the determination of iodine residue in soil (ICP-MS), water (IC-ICP-MS) and air (ICP-PED) 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 AQUAVIC 3% is a soluble concentrate to be diluted in water before use.

It is used in the veterinary and, food and feed areas for the disinfection of empty breeding buildings and equipment for domestic animals (PT3) by spraying and soaking. 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 AQUAVIC 3% is used to disinfect surfaces. It irreversibly inactivates vegetative bacteria and yeasts (PT3 and PT4), and virus (PT3).

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), of yeast cells (yeasticidal activity), and of infectious virus particles (virucidal 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 AQUAVIC 3% 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 (2 % v/v for PT3 and 2.5 % for PT4), it doesn’t have any basic bactericidal and fungicidal 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 AQUAVIC 3%, according to EN 14885:2006. They are summarised in the table below.

For PT3 uses (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 low level soiling conditions (3.0 g/L bovine albumin (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 these conditions, bactericidal activity is shown at the in-use concentration of 1.5 % v/v for non-porous surfaces;
* 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 low level soiling conditions (3.0 g/L bovine albumin (BSA)). In these conditions, yeasticidal activity is shown at the in-use concentration of 1.0 % v/v for non-porous surfaces;
* virucidal activity is demonstrated in phase 2, step 1 test (EN 14675) - (no surface test exist until now for the veterinary area), at 10°C, with a contact time of 30 minutes, in clean conditions (3.0 g/L BSA). In these conditions, virucidal activity is shown at the in-use concentration of 2 % v/v.

For PT4 uses (disinfection of drinking water pipes by filling of the water):

* bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 5 minutes in dirty conditions (3.0 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 2.5 % v/v. An additional test according to EN 13697 has been provided demonstrating the efficacy of the product at 20°C, with a contact time of 30 minutes in clean conditions (0.3 g/L BSA or 8.5 g/L skimmed milk), at 0.8 % v/v;
* yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 18-25°C, with a contact time of 15 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 0.5 % 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 AQUAVIC 3 % at claimed doses.

For PT4 uses (disinfection of drinking water pipes 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*.

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 EN 1276 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, an activity against *P.aeruginosa* and *S.aureus* is shown at 0.05 % v/v.

These in-use concentrations were also demonstrated for S.Thyphimurium, tested as additional strain at 10°C, with a contact time of 60 minutes and, pH 5 and pH 9 buffer solutions.

* 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 0.5 % 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 EN 1650 for this kind of application. Then, at 10°C with a contact time of 60 minutes and, pH 5 and 9 buffer solutions, yeasticidal activity is shown at respectively 0.05 % (residual pH 5, after acidic cleaning) and 0.15 % v/v (residual pH 9, after 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 AQUAVIC 3 % 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)  Concentration tested: 0.02 %, 0.1 %, 0.2 %, 0.4% et 2 %  Temperature: 20°C  Contact time: 5 min  No interfering substances  Criteria: at least a 5 log reduction | No basic bactericidal activity demonstrated at 0.2 % v/v | 2016-MER-005  R.I: 1 |
| Bactericide | Disinfection of empty breeding buildings and equipment (PT3) | AQUAVIC 3% | Bacteria  *P.aeruginosa*  *S.aureus*  *P.vulgaris*  *E.hirae* | EN 1656 : 2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.25 %, 0.5 %, 0.75 %, 1 % et 2 %  Temperature: 10°C  Contact time: 30 min  Low level soiling conditions (3 g/L BSA)  Criteria: at least a 5 log reduction | Bactericidal activity demonstrated at 0.5 % v/v | 04407Q-1A  R.I: 1 |
| Bactericide | Disinfection of empty breeding buildings and equipment (PT3) | AQUAVIC 3% | Bacteria  *E.coli* | EN 1656 : 2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.01 %, 0.5 %, 1 % et 1.5 %  Temperature: 10°C  Contact time: 30 min  Low level soiling conditions (3 g/L BSA)  Criteria: at least a 5 log reduction | Activity against E.coli demonstrated at 0.5 % v/v | 2016-MER-003  R.I: 1 |
| Bactericide | Disinfection of empty breeding buildings and equipment (PT3) | AQUAVIC 3% | Bacteria  *P.aeruginosa*  *S.aureus*  *P.vulgaris*  *E.hirae* | EN 14349:2012 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 1 %, 1.5 % et 2 %  Temperature: 10°C  Contact time: 30 min  Low level soiling conditions (3 g/L BSA)  Criteria: at least a 5 log reduction | Bactericidal activity demonstrated at 1.5 % v/v | 032-1REA15  R.I: 2 |
| Bactericide | Disinfection of empty breeding buildings and equipment (PT3) | AQUAVIC 3% | Bacteria  *E.coli* | EN 14349:2012 | Phase 2 step 2 test (non-porous surface test)  Concentration tested: 0.01 %, 1 %, 1.5 % et 2 %  Temperature: 10°C  Contact time: 30 min  Low level soiling conditions (3 g/L BSA)  Criteria: at least a 4 log reduction | Activity against E.coli demonstrated at 1 % v/v | 2016-MER-004  R.I: 1 |
| Bactericide | Disinfection of drinking water pipes for drinking water for animals (PT4) | AQUAVIC 3% | Bacteria  *P.aeruginosa*  *S.aureus*  *E.coli*  *E.hirae* | EN 1276:2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.25 %, 0.5 % et 0.75 %  Temperature: 20°C  Contact time: 5 min  Dirty conditions (3 g/L BSA)  Criteria: at least a 5 log reduction | Bactericidal activity demonstrated at 0.5 % v/v | 2015-MER-001  R.I: 1 |
| Bactericide | Disinfection of drinking water pipes for drinking water for animals (PT4) | AQUAVIC 3% | Bacteria  *P.aeruginosa*  *S.*Thyphimurium | EN 1276:2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.05 %, 0.15 % et 0.4 %  Additional conditions :  Temperature: 10°C  Contact time: 60 min  Additional condition: pH 5 buffer solutions (acidic cleaning)  Criteria: at least a 5 log reduction | Activity against *P.aeruginosa* et S.Thyphumurium demonstrated at 0.05 % v/v | 2015-MER-015  R.I: 1 |
| Bactericide | Disinfection of drinking water pipes for drinking water for animals (PT4) | AQUAVIC 3% | Bacteria  *S.aureus* | EN 1276:2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.01 %, 0.05 %, 0.15 % et 0.4 %  Temperature: 10°C  Contact time: 60 min  Additional condition: pH 5 buffer solutions (acidic cleaning)  Criteria: at least a 5 log reduction | Activity against *S.aureus* demonstrated at 0.05 % v/v | 2015-MER-002  R.I: 1 |
| Bactericide | Disinfection of drinking water pipes for drinking water for animals (PT4) | AQUAVIC 3% | Bacteria  *P.aeruginosa*  *S.*Thyphimurium | EN 1276:2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.05 %, 0.15 % et 0.4 %  Temperature: 10°C  Contact time: 60 min  Additional condition: pH 9 buffer solutions (alkaline cleaning)  Criteria: at least a 5 log reduction | Activity against *P.aeruginosa* et S.Thyphumurium demonstrated at 0.15 % v/v | 2015-MER-016  R.I: 1 |
| Bactericide | Disinfection of drinking water pipes for drinking water for animals (PT4) | AQUAVIC 3% | Bacteria  *P.aeruginosa*  *S.aureus*  *E.coli*  *E.hirae* | EN 13697:2001 | Phase 2 step 2 test (surface test)  Concentration tested: 1 %, 1.5 %, 2 %, 2.5 % et 3 %  Temperature: 18-25°C  Contact time: 5 min  Dirty conditions (3 g/L BSA)  Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 2.5 % v/v | 04407Q-3A  R.I: 2 |
| Bactericide | Disinfection of drinking water pipes for drinking water for animals (PT4) | AQUAVIC 3% | Bacteria  *P.aeruginosa*  *S.aureus*  *E.coli*  *E.hirae* | EN 13697:2015 | Phase 2 step 2 test (surface test)  Concentration tested: 0.05 to 2.5 %  Temperature: 18-25°C  Contact time: 30 min  Clean conditions (0.3 g/L BSA or 8.5 g/L skimmed milk)  Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 0.8 % v/v | MIC.16/07-041B4/30QLN  R.I: 1 |
| Yeasticide | - | Orthophosphoric acid 75% w/w | Yeast  *C.albicans* | EN 1275 : 2006 | Phase 1 test (suspension test)  Concentration tested: 0.035 %, 0.35% et 3.5 %  Temperature: 20°C  Contact time: 15 min  No interfering substances  Criteria: at least a 4 log reduction | No basic yeasticidal activity demonstrated at 0.035 %, 0.35% and 3.5% | 2016-MER-006  R.I: 1 |
| Yeasticide | Disinfection of empty breeding buildings and equipment (PT3) | AQUAVIC 3% | Yeast  *C.albicans* | EN 1657:2007 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.25 %, 0.5 %, 0.75 %, 1 % et 2 %  Temperature: 10°C  Contact time: 30 min  Low level soiling conditions (3 g/L BSA)  Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 0.75 % v/v | 04407Q-4A  R.I: 1 |
| Yeasticide | Disinfection of empty breeding buildings and equipment (PT3) | AQUAVIC 3% | Yeast  *C.albicans* | EN 16438:2014 | Phase 2 step 2 test (surface test)  Concentration tested: 0.5 %, 1 %, 1.5 % et 2 %  Temperature: 10°C  Contact time: 30 min  Low level soiling conditions (3 g/L BSA)  Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 1.0 % v/v | 033-1REA 15 AN  R.I: 1 |
| Yeasticide | Disinfection of drinking water pipes for drinking water for animals (PT4) | AQUAVIC 3% | Yeast  *C.albicans* | EN 1650:2008 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.25 %, 0.5 %, et 0.75 %  Temperature: 20°C  Contact time: 15 min  Dirty conditions (3 g/L BSA)  Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 0.5 % v/v | 2015-MER-002  R.I: 1 |
| Yeasticide | Disinfection of drinking water pipes for drinking water for animals (PT4) | AQUAVIC 3% | Yeast  *C.albicans* | EN 1650:2008 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.05 %, 0.15 % et 0.4 %  Temperature: 10°C  Contact time: 60 min  Additional condition: pH 5 buffer solutions (acidic cleaning)  Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 0.05 % v/v | 2015-MER-017  R.I: 1 |
| Yeasticide | Disinfection of drinking water pipes for drinking water for animals (PT4) | AQUAVIC 3% | Yeast  *C.albicans* | EN 1650:2008 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.05 %, 0.15 % et 0.4 %  Temperature: 10°C  Contact time: 60 min  Additional condition: pH 9 buffer solutions (alkaline condition)  Criteria: at least a 5 log reduction | Yeasticidal activity demonstrated at 0.15 % v/v | 2015-MER-018  R.I: 1 |
| Yeasticide | Disinfection of drinking water pipes for drinking water for animals (PT4) | AQUAVIC 3% | Yeast  *C.albicans* | EN 13697:2015 | Phase 2 step 2 test (surface test)  Concentration tested: 0.25 %, 0.5 %, 0.75% et 1 %  Temperature: 18-25°C  Contact time: 15 min  Dirty conditions (3 g/L BSA)  Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 0.5 % v/v | MIC.16/06-231.L QLN  R.I: 1 |
| Virucidal | Disinfection of empty breeding buildings and equipment (PT3) | AQUAVIC 3% | Virus  ECBO | EN 14675:2006 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.01 %, 0.5 %, 1 %, 2 % et 3 %  Temperature: 10°C  Contact time: 30 min  Clean conditions (3 g/L BSA)  Criteria: at least a 4 log reduction | Virucidal activity at 2.0 % v/v | RE 15080-3  R.I: 1 |

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| French competent authorities (FR CA) assessed that the product AQUAVIC 3%, diluted in water has shown a sufficient efficacy, for the following uses claimed:  1- Disinfection of empty breeding buildings and equipment (PT 03)   * By spraying at 1.5 % v/v (bacteria), 1% v/v (yeasts) and 2 % v/v (virus) for the disinfection of empty breeding buildings and equipment, on clean non-porous surfaces, at 10 °C, with a contact time of 30 minutes. * By soaking at 1.5 % (bacteria), 1 % v/v (yeasts) and 2 % v/v (virus) for the disinfection of equipment used in breeding, on clean non-porous surfaces, at 10 °C, with a contact time of 30 minutes.   2- Disinfection of drinking water pipes for drinking water of animals (PT 04)   * By filling of the water at 0.8 % v/v (bacteria) and 0.5 % v/v (yeasts) for the disinfection of clean water pipes, **at 20°C** with a contact time of 30 minutes. * By Cleaning in Place (CIP), at 0.15 % v/v and 0.05 % v/v (bacteria including the additional strain *S.*Thymurium 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

None

Evaluation of the label claims

French competent authorities (FR CA) assessed that the product AQUAVIC 3%, diluted in water has shown a sufficient efficacy, for the following uses claimed:

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

* By spraying at 2 % v/v for the disinfection (bacteria, yeasts and virus) of empty breeding buildings and equipment (PT3), on clean surfaces, at 10 °C, with a contact time of 30 minutes. The product is sprayed at 200-400 mL of diluted product / m², on non-porous surfaces.
* By soaking at 2 % v/v for the disinfection (bacteria, yeasts and virus) of equipment used in breeding (PT3), on clean surfaces, at 10 °C, with a contact time of 30 minutes.

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

* By filling of the water at 0.8 % v/v for the disinfection (bacteria and yeasts) on clean water pipes, at 20°C with a contact time of 30 minutes.
* By Cleaning in Place (CIP) at 0.05 % v/v (residual pH 5 after acidic cleaning) or at 0.15 % v/v (residual pH 9 after 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 AQUAVIC 3%.
* 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 AQUAVIC 3 %.
* 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 (1.1 at 20°C), the pure product should be classified Skin Corr. 1A.

However, considering that:

* the pH is essentially linked to the presence of orthophosphoric acid and;
* this co-formulant (with a pH of 0) has an harmonised classification skin Corr. 1 B and;
* no other coformulant participates to the decrease of the pH,
* a classification skin Corr. 1B is proposed for the product.

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. 1B, H314, Causes severe skin burns and eye damage.

The pH of dilutions were also tested by applicant:

|  |  |
| --- | --- |
| **Dilution of product** | **pH** |
| 1% | 2.5 |
| 1.5% | 2.3-2.5 |
| 2% | 1.9-2 |
| 2.5% | 1.9 |
| 3% | 1.9 |

The dilutions claimed by the applicant are:

* 1%, 1.5% and 2% for disinfection by spraying and soaking of surface or equipment,
* 0.5% and 2.5% for disinfection of drinking water pipe by injection,
* 0.05% and 0.15% for disinfection of drinking water pipe by cleaning in place (CIP).

The dilution of 2% and 2.5% are clearly considered corrosive.

The dilutions 0.05%, 0.15%, and 1 and 1.5% are not considered corrosive as the pH is superior to 2, which is the threshold value.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Classified Skin Corr. 1B, H314 |
| Justification for the value/conclusion | PH of pure product is 1.1 at 20°C. |
| Classification of the product according to CLP | Skin Corr. 1B, 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. 1B, H314, Causes severe skin burns and eye damage, as the PH of pure product is 1.1 at 20°C.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Classified Skin Corr. 1B, H314 |
| Justification for the value/conclusion | PH of pure product is 1.1 at 20°C. |
| Classification of the product according to CLP | Skin Corr. 1B, 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. |

***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, a classification Acute Tox.4, H302, Harmful if swallowed is needed.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | ATE mix: 1117 mg/kg |
| Justification for the selected value |  |
| Classification of the product according to CLP | Acute Tox.4, H302, Harmful if swallowed |

|  |  |
| --- | --- |
| **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. |

Consequently, based on the available data, AQUAVIC 3% should be classified:

* 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.
* Acute Tox.4, H302: Harmful if swallowed.
* “EUH071: Corrosive to the respiratory tract” should be added.

***Information on dermal absorption***

No study was provided. In this context, according to the EFSA guidance on dermal absorption (2012)[[2]](#footnote-2), 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 AQUAVIC 3% contains either 3% w/w iodine (concentrated fraction) or less of 0.0755% w/w (diluted fraction), and considering an oral absorption of 100%, the default dermal absorption value of the active substance in the product AQUAVIC 3% should be 75% (for both concentrated and diluted fractions).

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

The applicant proposed to use the dermal absorption value available in the CAR. However, the product and dilutions of AQUAVIC 3% 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.

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

Exposure assessment

The product AQUAVIC 3% is packaged in individual HDPE containers of 5, 20 and 60 L.

It is intended to be used by professional users in order to disinfect the equipment and surfaces associated with the housing of animals (PT03) and drinking water pipe (PT04).

For PT03 uses, the product is applied by spraying or soaking (1% v/v, 1.5% v/v or 2% v/v dilution).

For PT04 uses, the product is applied by filling the drinking water pipe (0.5% v/v or 0.8% v/v dilution) or by cleaning in place (0.15% v/v or 0.05% 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 property.

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 concentrations (pure and ≥ 2% dilution): a qualitative local risk assessment;
* For non-corrosive concentration (1% and 1.5% dilution): a quantitative systemic and a local (inhalation) risk assessment;

For PT 04, only exposure during mixing and loading is expected. A qualitative risk assessment is performed, considering the manipulation of undiluted corrosive product.

**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 | NA |

*NA not applicable*

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario** | **Primary or secondary exposure**  **Description of scenario** | **Exposed group** |
| 1. | Disinfection of the surfaces by spraying associated with the housing of animals | Primary exposure:   * (a) Mixing and loading (pure) * (b) Spraying surface (1 to 2% dilution) * (c) Cleaning spray equipment | Professional |
| 2. | Disinfection of the equipment by soaking associated with the housing of animals | Primary exposure:   * (a) Mixing and loading (pure) * (b) Dipping equipment (1 to 2% 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 (1, 1.5 or 2% dilution)***

Three tasks are performed:

* (a) Mixing and loading of pure product at corrosive concentration
* (b) Spraying dilution:
  + At corrosive concentration (2% dilution)
  + At non corrosive concentration (1% and 1.5% dilution)
* (c) Cleaning spray equipment at unknown corrosive/irritant property 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** |
| **Hazard Category** | **Effects in terms of C&L** | **Additional relevant hazard information** | **PT** | **Who is exposed?** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **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 check that the RMMs in place are being used correctly and OCs followed; - Training for staff on good practice; - Good standard of personal hygiene  PPE  -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 required.  Considering that these recommendations can be followed during this task, the risk is acceptable. |

**1b Spraying dilution.**

* Local risk assessment

For dilution with corrosive property (2% dilution) a local risk assessment is performed.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | | **Exposure** | | | | | | | **Risk** |
| **Hazard Category** | **Effects in terms of C&L** | **Additional relevant hazard information** | **PT** | **Who is exposed?** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **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 ( the risk is unacceptable) | According to the guidance for concluding qualitatively on the acceptability for professional exposure[[3]](#footnote-3), practically 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 risk assessment is performed with dilutions at 1% (0.0409%) and 1.5% of product (0.06135% 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 1.5% (0.06135% of iodine) and a dermal absorption value of 75% AND  with a dilution of product at 1% (0.0409% 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)** |
| **1.5% dilution** | | | | | |
| Scenario [1b] | Without PPE | 1.94E-03 | 4.56E-01 | nr | 4.57E-01 |
| Scenario [1b] | With gloves and coated coverall | 1.94E-03 | 4.80E-02 | nr | 5.00E-02 |
| Scenario [1b] | With gloves and impermeable coverall | 1.94E-03 | 1.74E-02 | nr | 1.93E-02 |
| Scenario [1b] | With gloves and impermeable coverall and mask APF10 | 1.94E-04 | 1.74E-02 | nr | 1.76E-02 |
| **1 % dilution** | | | | | |
| Scenario [1b] | Without PPE | 1.30E-03 | 3.04E-01 | nr | 3.05E-01 |
| Scenario [1b] | With gloves and coated coverall | 1.30E-03 | 3.20E-02 | nr | 3.33E-02 |
| Scenario [1b] | With gloves and impermeable coverall | 1.30E-03 | 1.16E-02 | nr | 1.29E-02 |
| Scenario [1b] | With gloves and impermeable coverall and mask APF10 | 1.30E-04 | 1.16E-02 | nr | 1.17E-02 |

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 0.06135%, an exposure at 0.0466 mg a.s./m3 is expected without mask. Considering a concentration in active substance of 0.0409%, an exposure at 0.0311 mg a.s./m3 is expected without mask.

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 1.5% (0.06135% of iodine) and a dermal absorption value of 75% AND  with a dilution of product at 1% (0.0409% 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)** |
| **1.5% dilution** | | | | | |
| Scenario [1b] | Without PPE | 2.66E-03 | 2.51E-01 | nr | 2.54E-01 |
| Scenario [1b] | With gloves and coated coverall | 2.66E-03 | 2.68E-02 | nr | 2.94E-02 |
| Scenario [1b] | With gloves and impermeable coverall | 2.66E-03 | 1.41E-02 | nr | 1.67E-02 |
| Scenario [1b] | With gloves and impermeable coverall and mask APF 10 | 2.66E-04 | 1.41E-02 | nr | 1.43E-02 |
| **1% dilution** | | | | | |
| Scenario [1b] | Without PPE | 1.77E-03 | 1.67E-01 | nr | 1.69E-01 |
| Scenario [1b] | With gloves and coated coverall | 1.77E-03 | 1.79E-02 | nr | 1.96E-02 |
| Scenario [1b] | With gloves and impermeable coverall | 1.77E-03 | 9.39E-03 | nr | 1.12E-02 |
| Scenario [1b] | With gloves and impermeable coverall and mask APF 10 | 1.77E-04 | 9.39E-03 | nr | 9.56E-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 104 mg /m3 diluted product is obtained in the spraying model 2. Considering a concentration in active substance of 0.06135%, an exposure at 0.0638 mg/m3 is expected without mask. Considering a concentration in active substance of 0.0409%, an exposure at 0.0425 mg/m3 is expected without mask.

**1c. Cleaning spray equipment**

In order to avoid contact with corrosive dilution, a rinse of spray equipment could be recommended before cleaning. In this context, a dilution by 100 of concentration could be considered. At the maximum dilution of 2% (0.06% of iodine), a concentration of iodine of 0.0006% is thus obtained after the rinsing step. This concentration of iodine is therefore covered by the following assessments.

| **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[[4]](#footnote-4).  A duration of **10 minutes** is considered.  Exposure is assessed with a dilution of product at 1.5% (0.06135% of iodine) and a dermal absorption value of 75% AND  with a dilution of product at 1% (0.0409% 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[[5]](#footnote-5)** |
| Tier 1 | Without PPE |  |
| Tier 2 | With gloves and coated coverall | Gloves penetration:10%  Clothing penetration: 20% |

**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)** |
| 1.5% dilution | | | | | |
| Scenario [1c] | Without PPE | nr | 4.23E-03 | nr | 4.23E-03 |
| Scenario [1c] | With gloves and coated coverall | nr | 5.71E-04 | nr | 5.71E-04 |
| 1% dilution | | | | | |
| Scenario [1c] | Without PPE | nr | 2.82E-03 | nr | 2.82E-03 |
| Scenario [1c] | With gloves and coated coverall | nr | 3.81E-04 | nr | 3.81E-04 |

Nr: not relevant

***Scenario [2]:******Disinfection of the equipment by soaking (1, 1.5 or 2% dilution)***

Two tasks are performed:

* (a) Mixing and loading of pure product at corrosive concentration
* (b) Dipping :
  + In corrosive dilution (2% dilution)
  + In non-corrosive dilution (1% and 1.5% dilution)

**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 (2% dilution), a local risk assessment is performed.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | | **Exposure** | | | | | | | **Risk** |
| **Hazard Category** | **Effects in terms of C&L** | **Additional relevant hazard information** | **PT** | **Who is exposed?** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant RMM & PPE** | **Conclusion on risk** |
| Very high hazard | Skin Corr. 1B | - | 3-4 | Professional | Dipping equipment | Dermal (splashes) and inhalation | 1/day | Not negligible | Not proposed (the risk is unacceptable) | According to the guidance for concluding qualitatively on the acceptability for professional exposure[[6]](#footnote-6), 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 risk assessment is performed with dilution at 1% (0.030%) and 1.5% of product (0.045% of iodine).

| **Description of Scenario [2b]**  **Disinfection of equipment by dipping** | | |
| --- | --- | --- |
| According to the recommendantion 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 0.045% and 0.030% 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 1.5% (0.06135% of iodine) and a dermal absorption value of 75% AND  with a dilution of product at 1% (0.0409% 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 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% |

**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)** |
| **1.5% dilution** | | | | | |
| Scenario [2b] | With gloves | 1.43E-03 | 4.69E-02 | nr | 4.83E-02 |
| Scenario [2b] | With gloves and coated coverall | 1.43E-03 | 1.41E-02 | nr | 1.55E-02 |
| Scenario [2b] | With gloves and impermeable coverall | 1.43E-03 | 7.96E-03 | nr | 9.39E-03 |
| **1% dilution** | | | | | |
| Scenario [2b] | With gloves | 9.52E-04 | 3.12E-02 | nr | 3.22E-02 |
| Scenario [2b] | With gloves and coated coverall | 9.52E-04 | 9.40E-03 | nr | 1.04E-02 |
| Scenario [2b] | With gloves and impermeable coverall | 9.52E-04 | 5.31E-03 | nr | 6.26E-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 0.137 mg/m3 of active substance is obtained in Consexpo for the 1.5% dilution and 0.0.0914 mg/m3 for the 1% dilution.

**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.

Professionals may be secondary exposed to the product AQUAVIC 3% *via*:

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

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 1.5% (0.06135% of iodine) and at 1% (0.0409% 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 0.06135% or 0.0409% of iodine applied on a floor of 20 m2 in a room of 25 m3 with a ventilation rate of 0.5/h. | | |
|  | **Parameters** | **Value** |
| Tier 1 | Consexpo parameters see annex |  |

Remark: The day of treatment, the professional will not stay in the room for 8hours. However, he could enter in 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 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** |
| **1.5% dilution** | | | | | |
| Scenario [4a] 8h | nr | 3.07E-02 | nr | nr | 3.07E-02 |
| Scenario [4a] 1h | nr | 3.84E-03 | nr | nr | 3.84E-03 |
| **1% dilution** | | | | | |
| Scenario [4a] 8h | nr | 2.04E-02 | nr | nr | 2.04E-02 |
| Scenario [4a] 1h | nr | 2.56E-03 | nr | nr | 2.56E-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 0.184 mg/m3 of active substance is obtained in Consexpo for 1.5% dilution. A value of 0.123 mg/m3 is obtained for 1% dilution.

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 dilutions of 0.06135% and 0.0409% of iodine are 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 values of 75 % will be used.  For the exposure to dried surface, the dermal absorption 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)** |
| **1.5% dilution** | | | | | |
| Scenario [4b] wet surface | nr | nr | 1.26E-01 | nr | 1.26E-01 |
| Scenario [4b] dried surface | nr | nr | 6.04E-03 | nr | 6.04E-03 |
| **1% dilution** | | | | | |
| Scenario [4b] wet surface | nr | nr | 8.38E-02 | nr | 8.38E-02 |
| Scenario [4b] dried surface | nr | nr | 4.02E-03 | nr | 4.02E-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** |
| **1.5% dilution** | | | |
| 1b (spraying 2) | Professional | Without PPE | 4.57E-01 |
| 1b (spraying 2) | Professional | With gloves and coated coverall | 5.00E-02 |
| 1b (spraying 2) | Professional | With gloves and impermeable coverall | 1.93E-02 |
| 1b (spraying 2) | Professional | With gloves and impermeable coverall and mask APF 10 | 1.76E-02 |
| 1b (spraying 1) | Professional | Without PPE | 2.54E-01 |
| 1b (spraying 1) | Professional | With gloves and coated coverall | 2.94E-02 |
| 1b (spraying 1) | Professional | With gloves and impermeable coverall | 1.67E-02 |
| 1b (spraying 1) | Professional | With gloves and impermeable coverall and mask APF 10 | 1.43E-02 |
| 1c (cleaning) | Professional | Without PPE | 4.23E-03 |
| 1c (cleaning) | Professional | With gloves and coated coverall | 5.71E-04 |
| 2b (dipping) | Professional | With gloves | 4.83E-02 |
| 2b (dipping) | Professional | With gloves and coated coverall | 1.55E-02 |
| 2b (dipping) | Professional | With gloves and impermeable coverall | 9.39E-03 |
| 4a (residue volatile) 8h | Professional |  | 3.07E-02 |
| 4a (residue volatile) 1h | Professional |  | 3.84E-03 |
| 4b (hand contact) | Professional | Wet surface | 1.26E-01 |
| 4b (hand contact) | Professional | Dried surface | 6.04E-03 |
| **Dilution 1%** | | | |
| 1b (spraying 2) | Professional | Without PPE | 3.05E-01 |
| 1b (spraying 2) | Professional | With gloves and coated coverall | 3.33E-02 |
| 1b (spraying 2) | Professional | With gloves and impermeable coverall | 1.29E-02 |
| 1b (spraying 2) | Professional | With gloves and impermeable coverall and mask APF 10 | 1.17E-02 |
| 1b (spraying 1) | Professional | Without PPE | 1.69E-01 |
| 1b (spraying 1) | Professional | With gloves and coated coverall | 1.96E-02 |
| 1b (spraying 1) | Professional | With gloves and impermeable coverall | 1.12E-02 |
| 1b (spraying 1) | Professional | With gloves and impermeable coverall and mask APF 10 | 9.56E-03 |
| 1c (cleaning) | Professional | Without PPE | 2.82E-03 |
| 1c (cleaning) | Professional | With gloves and coated coverall | 3.81E-04 |
| 2b (dipping) | Professional | With gloves | 3.22E-02 |
| 2b (dipping) | Professional | With gloves and coated coverall | 1.04E-02 |
| 2b (dipping) | Professional | With gloves and impermeable coverall | 6.26E-03 |
| 4a (residue volatile) 8h | Professional |  | 2.04E-02 |
| 4a (residue volatile) 1h | Professional |  | 2.56E-03 |
| 4b (hand contact) | Professional | Wet surface | 8.38E-02 |
| 4b (hand contact) | Professional | Dried surface | 4.02E-03 |

* Local inhalation exposure assessment

|  |  |  |
| --- | --- | --- |
|  | **1.5% dilution** | **1% dilution** |
| Spraying | 0.064 mg/m3 | 0.042 mg/m3 |
| Dipping | 0.137 mg/m3 | 0.091 mg/m3 |
| Residue volatile | 0.184 mg/m3 | 0.123 mg/m3 |

***Dietary exposure***

Considering intended uses of the product AQUAVIC 3%, 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 use  Veterinary area | PT03: Disinfection of empty breeding  Spraying | Livestock |
| 1.b | Professional use  Veterinary area | PT03: Disinfection of equipment  Soaking | Livestock |
| 2.a | Professional use  Veterinary area | PT04: Disinfection of drinking water pipe for drinking water of animals  Soaking / Filling of the water pipe | Livestock |
| 2.b | Professional use  Veterinary area | PT04: Disinfection of drinking water pipe for drinking water of animals  Cleaning in place | Livestock |

1 e.g. animal husbandry, food industry, professional use, residential use.

2 e.g. chicken, milk, beer

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 additive  Iodine 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[[7]](#footnote-7) to bring the exposure of adult consumers below the Upper Intake Level. |
| 2. | Veterinary medicine  Iodine and iodine  inorganic compounds  including:  - 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[[8]](#footnote-8) and later, in Annex of Commission Regulation (EU) No.37/2010[[9]](#footnote-9) . |

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 PT03. 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)[[10]](#footnote-10). This Calculator applies assumptions and default values as detailed below:

| **Description of Scenario 1.a** PT03: Disinfection of empty breeding | | |
| --- | --- | --- |
|  | Parameters | Value |
| Tier 1  Screening step | Concentration in the concentrated product (% a.s. w/w considering total Iode; I2 et NaI) | 4.09  (3% + 1.09%) |
| Concentration in a 1-2% diluted solution (% a.s. v/v) | 0.0409-0.0818 |
| Concentration in a 1-2% diluted solution (g a.s./L)1 | 0.409-0.818 |
| Average content per unit area (mg a.s./m2) | 82-**327** |
| Tier 2  Realistic 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 3  Refinements | 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 livestock  Group (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) | 6.74 | Y | 525 | Y |
| Dairy cattle | 8.40 | Y | 401 | Y |
| Pig (breeding in group housing)  Pig (fattening) | 11.05  - | Y | -  588 | Y |
| Poultry (laying hens in free range and litter floor)  Broiler | 34.94  - | 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)[[11]](#footnote-11) and the International Programme on Chemical Safety[[12]](#footnote-12), and the value was supported by information provided by US Department of Health and Human Services (US HHS)[[13]](#footnote-13) and the World Health Organization (WHO)[[14]](#footnote-14).

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[[15]](#footnote-15)).

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[[16]](#footnote-16))
* 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[[17]](#footnote-17)). 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 livestock  Group (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 | 0.907  (1.029\*0.75) | 2.980 | 3.887 | 0.466 | - |
| Dairy cattle | 0 | 0.539  (0.719\*0.75) | 3.017 | 3.556 | 0.427 | 2.489 |
| Pig (breeding in individual housing)  Pig (fattening) | 0 | -  0.938  (1.251  \*0.75) | 7.198  3.701 | 7.198  4.640 | 0.864  0.557 | - |
| Poultry (laying hens in battery)  Broiler | 0 | - | 1.4630  0.0168 | 1.4629  0.0168 | 0.176  0.002 | 1.024  - |

\* 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 PT03. 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[[18]](#footnote-18).

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) | | 4.09  (3% + 1.09%) |
| Concentration in a 2% diluted solution  (% a.s. v/v) | | 0.0818 |
| Concentration in a 2% diluted solution  (g a.s./L or g a.s./dm3)1 | | 0.818 |
| Average content per unit area (mg a.s./m2) | | 81.8 |
| 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 livestock  Group (worst case model)\* | Inhalation exposure | Dermal exposure | Oral exposure | Livestock Total exposure  (mg/kg bw/d) |
| Scenario 1b | Beef cattle (calf) | - | - | 0.818 | 0.818 |
| Dairy cattle | - | - | 0.830 | 0.830 |
| Pig (fattening) | - | - | 0.982 | 0.982 |
| Poultry (laying hens) | - | - | 0.431 | 0.431 |

\* 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 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 up to 70% of the internal exposure value is excreted into the edible products

| **Internal dose received by the animal** | | | | |
| --- | --- | --- | --- | --- |
| Refined estimations | | | | |
|  | Animal livestock  Group (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) | 0.818 | 0.098 | - |
| Dairy cattle | 0.830 | 0.100 | 0.581 |
| Pig (fattening) | 0.982 | 0.112 | - |
| Poultry (laying hens) | 0.431 | 0.052 | 0.301 |

\* 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 scenario, 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[[19]](#footnote-19) 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) | | 4.09  (3% + 1.09%) |
| Concentration in a 0.5-0.8% diluted solution (% a.s. v/v) | | 0.0205-0.0327 |
| Concentration in a 0.5-0.8% diluted solution  (g a.s./L or g a.s./dm3 or mg a.s./cm3) | | 0.205-0.327 |
| 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[[20]](#footnote-20) 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 livestock  Group (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) | - | 1.31 | 1.31 | 0.131 | Y |
| Dairy cattle | - | 2.32 | 2.32 | 0.232 | Y |
| Pig (fattening) | - | 1.31 | 1.31 | 0.131 | Y |
| Poultry (broiler)  (laying hens) | - | 1.92  1.72 | 1.92  1.72 | 0.192  0.172 | Y |

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

**Further information and considerations on scenario 2.a (PT04: Disinfection of 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  Group (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) | 0.131 | 0.0157 | - |
| Dairy cattle | 0.232 | 0.0278 | 0.162 |
| Pig (fattening) | 0.131 | 0.0157 | - |
| Poultry  (broiler)  (laying hens) | 0.192  0.172 | 0.0230  0.0206 | -  0.120 |

\* 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 PT04. 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 0.0015-0.045 % 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 (CIP) | | | |
| --- | --- | --- | --- |
|  | Parameters | | Value |
| Tier 1 | Concentration in the concentrated product (% a.s. w/w considering total Iode; I2 et NaI) | | 4.09  (3% + 1.09%) |
| Concentration is a 0.05-0.15% diluted solution (% a.s. v/v) | | 0.002045-0.061 |
| Concentration is a 0.05-0.15% diluted solution (g a.s./L or g a.s./dm3 or mg a.s./cm3)\* | | 0.061 |
| 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 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 livestock  Group (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) | - | 0.245 | 0.245 | 0.025 | Y |
| Dairy cattle | - | 0.434 | 0.434 | 0.043 | Y |
| Pig (fattening) | - | 0.245 | 0.245 | 0.025 | Y |
| Poultry (broiler)  (laying hens) | - | 0.361  0.323 | 0.361  0.323 | 0.036  0.032 | Y |

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

**Further information and considerations on scenario 2.b (PT04: Disinfection of 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) | 0.025 | 0.0030 | - |
| Dairy cattle | 0.043 | 0.0052 | 0.030 |
| Pig (fattening) | 0.025 | 0.0030 | - |
| Poultry (broiler)  (laying hens) | 0.036  0.032 | 0.0043  0.0038 | -  0.022 |

\* 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)[[21]](#footnote-21). 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% of 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 (1, 1.5 or 2% dilution)***

Three tasks are performed:

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

**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

A qualitative local risk assessment according to the guidance on the BPR: Volume III HH part B is performed for corrosive dilution (2%).

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

* Systemic risk assessment (dilution 1 or 1.5%)

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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 (%)** |
|  | |  | | **1.5% dilution** | | | | | |
| Disinfection by spraying (model 2) | Without PPE | | 1.00E-02 | | 4.57E-01 | | 4575 | 4621 | 4600 |
| Disinfection by spraying (model 2) | With gloves and coated coverall | | 1.00E-02 | | 5.00E-02 | | 500 | 546 | 525 |
| Disinfection by spraying (model 2) | With gloves and impermeable coverall | | 1.00E-02 | | 1.93E-02 | | 193 | 239 | 218 |
| Disinfection by spraying (model 2) | With gloves and impermeable coverall and mask APF 10 | | 1.00E-02 | | 1.76E-02 | | 176 | 222 | 201 |
| Disinfection by spraying (model 1) | Without PPE | | 1.00E-02 | | 2.54E-01 | | 2539 | 2585 | 2564 |
| Disinfection by spraying (model 1) | With gloves and coated coverall | | 1.00E-02 | | 2.94E-02 | | 294 | 340 | 319 |
| Disinfection by spraying (model 1) | With gloves and impermeable coverall | | 1.00E-02 | | 1.67E-02 | | 167 | 213 | 192 |
| Disinfection by spraying (model 1) | With gloves and impermeable coverall and mask APF 10 | | 1.00E-02 | | 1.43E-02 | | 143 | 189 | 168 |
|  | |  | | **1% dilution** | | | | | |
| Disinfection by spraying (model 2) | Without PPE | | 1.00E-02 | | 3.05E-01 | 3050 | | 3096 | 3075 |
| Disinfection by spraying (model 2) | With gloves and coated coverall | | 1.00E-02 | | 3.33E-02 | 333 | | 379 | 358 |
| Disinfection by spraying (model 2) | With gloves and impermeable coverall | | 1.00E-02 | | 1.29E-02 | 129 | | 175 | 154 |
| Disinfection by spraying (model 2) | With gloves and impermeable coverall and mask APF 10 | | 1.00E-02 | | 1.17E-02 | 117 | | 163 | 142 |
| Disinfection by spraying (model 1) | Without PPE | | 1.00E-02 | | 1.69E-01 | 1693 | | 1739 | 1718 |
| Disinfection by spraying (model 1) | With gloves and coated coverall | | 1.00E-02 | | 1.96E-02 | 196 | | 242 | 221 |
| Disinfection by spraying (model 1) | With gloves and impermeable coverall | | 1.00E-02 | | 1.12E-02 | 112 | | 158 | 137 |
| Disinfection by spraying (model 1) | With gloves and impermeable coverall and mask APF 10 | | 1.00E-02 | | 9.56E-03 | 96 | | 142 | 121 |

When adding *the exposure due to the dietary intake, the total exposure to iodine is* ***superior*** *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.*

**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 (%)** |
|  | |  | | **1.5% dilution** | | | | |
| Cleaning of spray equipment | Without PPE | | 1.00E-02 | | 4.23E-03 | 42 | 88 | 67 |
| Cleaning of spray equipment | With gloves and coated coverall | | 1.00E-02 | | 5.71E-04 | 5.7 | 52 | 31 |
|  | |  | | **1% dilution** | | | | |
| Cleaning of spray equipment | Without PPE | | 1.00E-02 | | 2.82E-03 | 28 | 74 | 53 |
| Cleaning of spray equipment | With gloves and coated coverall | | 1.00E-02 | | 3.81E-04 | 3.8 | 50 | 29 |

*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% or 46% of UL.*

**Combined 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**  **+ dietary intake 46% UL (%)** | **Estimated uptake/ AEL due to biocidal use**  **+ dietary intake 25% UL (%)** |
|  | |  | | **1% dilution** | | | | |
| Disinfection by spraying (model 1) | With gloves and impermeable coverall and mask APF 10 | | 1.00E-02 | | 9.56E-03 | 96 | 142 | 121 |
| Cleaning of spray equipment | With gloves and coated coverall | | 1.00E-02 | | 3.81E-04 | 3.8 | 50 | 29 |
| Combined | | | 1.00E-02 | | 9.94E-03 | 99% | 145 | 124 |

For general sprayer, no combined risk assessment is performed since the total exposure to iodine is superior to the upper limit intake proposed by Scientific Committee on Food of the European Commission (SCF) for this use.

When adding  *the exposure due to the dietary intake, the total exposure to iodine is superior 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.*

**Considering background exposure (25% or 46% AEL): A risk cannot be excluded for spraying application of dilution 1% or 1,5% even if PPEs are worn and even if low pressure sprayer is used. .**

***Scenario [2]: Disinfection of the equipment by soaking (1, 1.5 or 2% 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.

**2b. Dipping**

* Local risk assessment

A qualitative local risk assessment according to the guidance on the BPR: Volume III HH part B is performed for corrosive dilution (2%).

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 (%)** | | |
|  | | **1.5% dilution** | | | | | |
| Disinfection of equipment by dipping | With gloves | | 1.00E-02 | 4.83E-02 | 483 | 529 | 508 | | |
| Disinfection of equipment by dipping | With gloves and coated coverall | | 1.00E-02 | 1.55E-02 | 155 | 201 | 180 | | |
| Disinfection of equipment by dipping | With gloves and impermeable coverall | | 1.00E-02 | 9.39E-03 | 94 | 140 | 119 | | |
|  | | **1% dilution** | | | | | | |
| Disinfection of equipment by dipping | With gloves | | 1.00E-02 | 3.22E-02 | 322 | 368 | 347 | | |
| Disinfection of equipment by dipping | With gloves and coated coverall | | 1.00E-02 | 1.04E-02 | 104 | 150 | 129 | | |
| Disinfection of equipment by dipping | With gloves and impermeable coverall | | 1.00E-02 | 6.26E-03 | 63 | 109 | 88 | | |

When  *adding the exposure due to the dietary intake, the total exposure to iodine is superior 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 for dilution at 1.5%.For dilution at 1%, considering the exposure due to the dietary intake, the total exposure to iodine is superior to the upper limit intake proposed by Scientific Committee on Food of the European Commission (SCF) considering a background value of 46% only.*

**Conclusion**

* **For dilution at 1.5%, even if gloves and impermeable coverall are worn, a risk cannot be excluded considering a background exposure of 25% and 46% of UL.**
* **For dilution at 1%, even if gloves and impermeable coverall are worn, a risk cannot be excluded considering a background exposure of 46% of UL.**

***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 AQUAVIC 3% via:

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

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

Inhalation of volatised residues is considered relevant for application by spraying. only 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.

* 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 (%)** |
|  | |  | | **1.5% dilution** | | | | |
| Inhalation of volatilised residues 8h | - | | 1.00E-02 | | 3.07E-02 | 370 | 416 | 395 |
| Inhalation of volatilised residues 1h | - | | 1.00E-02 | | 3.84E-03 | 38 | 84 | 63 |
|  | |  | | **1% dilution** | | | | |
| Inhalation of volatilised residues 8h | - | | 1.00E-02 | | 2.04E-02 | 204 | 250 | 229 |
| Inhalation of volatilised residues 1h | - | | 1.00E-02 | | 2.56E-03 | 26 | 72 | 51 |

*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% or 46% of UL for 1hour exposure.*

When the inhalation exposure of 0.184mg/m3 and 0.123 mg/m3 are compared to the AEC of 1 mg/m3, the risk is 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 (%)** |
|  | |  | | **1.5% dilution** | | | | |
| Exposure to an adult who touches a treated surface with its hands (wet surface) | - | | 1.00E-02 | | 1.26E-01 | 1258 | 1304 | 1283 |
| Exposure to an adult who touches a treated surface with its hands (dry surface) | - | | 1.00E-02 | | 6.04E-03 | 60 | 106 | 85 |
|  | |  | | **1% dilution** | | | | |
| Exposure to an adult who touches a treated surface with its hands (wet surface) | - | | 1.00E-02 | | 8.38E-02 | 838 | 884 | 863 |
| Exposure to an adult who touches a treated surface with its hands (dry surface) | - | | 1.00E-02 | | 4.02E-03 | 40 | 86 | 65 |

*For dilution at 1.5% and 1%, the exposure linked to biocidal use in superior to the upper limit intake proposed by SCF if the treated surface is wet. The exposure is inferior if the treated surface is* ***dried.***

*For dilution at 1.5%, in view of the addition of the exposure due to the dietary intake, 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 superior considering a value of 46% of UL*

*For dilution at 1%, considering the exposure due to the dietary intake, 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% or 46% of UL.*

***Combined exposure***

A combined risk assessment is performed considering that the same operator be exposed during the treatment, during the cleaning of the apparatus, and also secondary exposed after the treatment.

For application by spraying, only application of dilution at 1% with a low pressure sprayer leads to exposure inferior to upper limit proposed by SCF. Therefore only this scenario is considered to determine the combined exposure.. The following conclusion is obtained:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **TIER** | **Exposure** | **AEL** | **% AEL**  **Biocidal use** | **% AEL**  **Biocidal use + 46% UL** | **% AEL**  **Biocidal use + 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 material)  (1%) | With gloves and impermeable coverall and mask APF 10 | 9.56E-03 | 1.00E-02 | 96 | 142 | 121 |
| Cleaning spray equipment  (1%) | With gloves and coated coverall | 3.81E-04 | 1.00E-02 | 3.8 | 50 | 29 |
| Inhalation of volatilised residues (1h)  1% |  | 1.89E-03 | 1.00E-02 | 26 | 72 | 51 |
| Combined exposure |  | 1.18E-02 | 1.00E-02 | 118 | 164 | 143 |

Inhalation leads to unacceptable risks in case or spraying.

**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*.***

The conclusions for human health are as following:

|  |  |
| --- | --- |
| **Uses** | **Conclusion considering the background exposure.** |
| PT3 - Spraying and dipping 1% | Spraying: unacceptable  Soaking: risk acceptable with RMM. |
| PT3 - Spraying and dipping 1.5% | Unacceptable |
| PT3 - Spraying and dipping 2% | Not acceptable as the dilution is corrosive. |
| PT4 - Disinfection water pipe by injection 0.8% | Acceptable considering exposure only during mixing and loading |
| PT4 - Disinfection water pipe by injection 0.5% | Acceptable considering exposure only during mixing and loading |
| PT4 - Disinfection water pipe by CIP 0.15% | Acceptable considering exposure only during mixing and loading |
| PT4 - Disinfection water pipe by CIP 0.05% | Acceptable considering exposure only during mixing and loading |

***For dipping (1%)***

* During mixing and loading: PPE have to be worn and RMM to limit exposure (corrosive product) have to be followed.
* During dipping at 1%: gloves and impermeable coverall have to be worn.

***For disinfection of water pipe,*** exposure is considered only 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 during application have to be worn.
* Do not authorise re-entry before rinsing and total drying of surface.
* Do not touch material and surface until a total drying.
* If control task is needed, the same PPE as during 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)[[22]](#footnote-22). 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 food  Group (worst case model) | Scenario 1a | Scenario 1b | Scenario 2a | **Total residue levels** | **Worst case residue level** | WCCE | Adult exposure |
| Tissues bovin  (calf) | 0.466 | 0.098 | 0.0157 | 0.580 | **0.979** | 0.49 | **0.091** |
| Tissues  Pig (breeding in individual housing) | 0.864 | 0.099 | 0.0157 | 0.979 |
| Tissues  Poultry (laying hens in battery) | 0.176 | 0.052 | 0.0206 | 0.249 |
| Milk  (dairy cattle) | 2.489 | 0.581 | 0.162 | 3.232 | **3.232** | 4.85 |
| Eggs  Poultry (laying hens) | 1.024 | 0.301 | 0.120 | 1.445 | **1.445** | 0.14 |

\**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 **0.091 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) | 0.466 | 0.098 | 0.0157 | 0.580 | **0.979** | 0.49 | **0.034** |
| Tissues  Pig (breeding in individual housing) | 0.864 | 0.099 | 0.0157 | 0.979 |
| Tissues  Poultry (laying hens in battery) | 0.176 | 0.052 | 0.0206 | 0.249 |
| Milk refined1  (dairy cattle) | **0.855** | **0.174** | **0.048** | **0.970** | **0.970** | 1.45 |
| Eggs  Poultry (laying hens) | 1.024 | 0.301 | 0.120 | 1.445 | **1.445** | 0.14 |

1 using volume ratio between milk and urine: milk reprents only 30% of volume excreeted (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 AQUAVIC 3%. 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 AQUAVIC 3% 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 necessary for disinfection of breeding buildings:

* + ”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 AQUAVIC 3% 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 AQUAVIC 3% 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 AQUAVIC 3% 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 (I**2**) | 0.00059 mg/L |
| Iodate (IO**3**-) | 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 (I**2**) | 0.0118 mg/kgwwt |
| Iodate (IO**3**-) | 0.304 mg/kgwwt |
| Iodide (I-) | 0.0043 mg/kgwwt |
| STP | Iodine (I**2**) | 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 EC**50** of 0.59 mg/L derived with iodine (AR). |
| Classification of the product 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 AQUAVIC 3%** | |
| Value/conclusion | Aquatic chronic 2, H411 |

***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 2% v/v dilution, a 1.5% v/v dilution or a 1.0% 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 2% v/v dilution, a 1.5% v/v dilution or a 1.0% 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 | A higher tier model (FOCUS model) was performed |
| 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 0.8% v/v dilution, a 0.5% v/v dilution, a 0.15% v/v dilution or a 0.05% v/v dilution), 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 | A higher tier model (FOCUS model) was performed |
| 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 AQUAVIC 3% 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 |
| Kpsoil [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 (EUSES model 2.1.2)** | |
| 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 2% 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 application  After a **2% 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 2% w/w) | F bioc | 0.881 | | | [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 | | 5.67E-01 | NR | [kg.d-1] | O |
| ***Soil exposure*** | | | | | | |
| Amount of a.i. in manure after one application | Q ai manure/slurry | | 8.50E-01 | 1.15E-01 | [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

***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 AQUAVIC 3%, 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 2% 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 water  After a **2% 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 2% w/w) | F bioc | 0.881 | | [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 | | 8.81E-02 | [kg.d-1] | O |
| *Soil exposure* | | | | | |
| Amount of a.i. in manure after one application | Q ai manure/slurry | | 8.81E-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 0.8% 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 AQUAVIC 3%, 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 0.8% 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 **0.8% 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 0.8% w/w) | F bioc | 0.352 | | [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 | | 7.05E-02 | [mg L-1] | O |
| ***Soil exposure*** | | | | | |
| Amount of a.i. in manure after one application | Q ai manure/slurry | | 7.05E-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 equation to calculate PIECsoil grassland via manure application is provided below:

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 2% v/v dilution, a 1.5% v/v dilution or a 1.0% v/v dilution in water).*

Only the PEC values for the worst case approach (product diluted at 2% 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 | 17.8 | 17.8 | 24.6 |
| Soil grassland (mg.kgwwt-1) | 0.565-22.6  extremes up to 110.74 | 0.93 | 0.93 | 1.29 |
| Groundwater grassland (µg.L-1)2 | 1-70 | 178 | 178 | 246 |
| *Via* STP - Turkey in free range – litter floor | | | | |
| STP (mg/L) | - | 2.27E-01 | - | - |
| Surface water (µg/L) | 0.5-20 | 22.7 | 22.7 | 31.2 |
| Soil (mg/kgwwt) | 0.565-22.6  extremes up to 110.74 | 1.40E+00 | 1.95E-01 | 1.94E+00 |
| Groundwater (µg/L) | 1-70 | 263 | 36.85 | 363 |

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

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

***Scenario [2]***

*Disinfection of small equipment’s used in breeding (PT03) by soaking (dipping), followed by rinsing with drinking water (after a 2% v/v dilution, a 1.5% v/v dilution or a 1.0% v/v dilution in water)*

Only the PEC values for the worst case approach (product diluted at 2% 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 | 13.71 | 13.71 | 18.95 |
| Soil grassland (mg.kgwwt-1) | 0.565-22.6  extremes up to 110.74 | 7.18E-01 | 7.18E-01 | 9.92E-01 |
| Groundwater grassland (µg.L-1)2 | 1-70 | 137 | 137 | 189 |
| *Via* STP | | | | |
| STP (mg/L) | - | 3.52E-02 | - | - |
| Surface water (µg/L) | 0.5-20 | 3.52 | 3.52 | 4.87 |
| Soil (mg/kgwwt) | 0.565-22.6  extremes up to 110.74 | 2.18E-01 | 3.06E-02 | 3.02E-01 |
| Groundwater (µg/L) | 1-70 | 40.9 | 5.73 | 56.5 |

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

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

***Scenario [3]***

*Scenario 3: Drinking water pipe disinfection by injection (after a 0.8% v/v dilution, a 0.5% v/v dilution, a 0.15% v/v dilution or a 0.05% v/v dilution), followed by rinsing with drinking water.*

Only the PEC values for the worst case approach (product diluted at 0.8% 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 | 11 | 11 | 15.2 |
| Soil grassland (mg.kgwwt-1) | 0.565-22.6  extremes up to 110.74 | 5.74E-01 | 5.74E-01 | 7.94E-01 |
| Groundwater grassland (µg.L-1)2 | 1-70 | 110 | 110 | 152 |
| *Via* STP | | | | |
| STP (mg/L) | - | 2.82E-02 | - | - |
| Surface water (µg/L) | 0.5-20 | 2.81 | 2.81 | 3.88 |
| Soil (mg/kgwwt) | 0.565-22.6  extremes up to 110.74 | 1.75E-01 | 2.44E-02 | 2.42E-01 |
| Groundwater (µg/L) | 1-70 | 32.7 | 4.59 | 45.2 |

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

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

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** |
| **0.8** | **2** |
| *Active substance: Iodine* | | | |
| Scenario 1 (Turkey approach – worst case) |  | 0.078 | Acceptable |
| Scenario 2 |  | 0.012 | Acceptable |
| Scenario 3 | 0.009 |  | 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 / 2.0% v/v dilution) | **30.17** | **21.45** | 0.421 | Acceptable  In the range of background concentrations for iodine |
| Scenario 2 (Veal calves approach – worst case / 2.0% v/v dilution) | **23.24** | **16.52** | 0.324 | Acceptable  In the range of background concentrations for iodine |
| Scenario 3 (Veal calves approach – worst case / 0.8% v/v dilution) | **18.64** | **13.25** | 0.260 | Acceptable  In the range of background concentrations for iodine |
| *Via* STP | | | | |
| Scenario 1 (Turkey approach – worst case / 2.0% v/v dilution) | **38.47** | **27.40** | 0.533 | Unacceptable  Above the range of background concentrations for iodine |
| Scenario 2 (2.0% v/v dilution) | **5.97** | **4.24** | 0.083 | Acceptable  In the range of background concentrations for iodine |
| Scenario 3 (0.8% v/v dilution) | **4.76** | **3.39** | 0.066 | Acceptable  In 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), except to the scenario 1 (turkey approach, 2.0% v/v dilution) where the iodine concentration is slightly above the upper limit (22.7 µg.l-1). Consequently acceptable risk for the worst case scenarios are considered except for this last scenario (emission via STP, Turkey approach, 2.0% v/v dilution).

***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 / 2.0% v/v dilution) | **78.81** | **216.28** | **4.24** | Acceptable  In the range of background concentrations for iodine |
| Scenario 2 (Veal calves approach – worst case / 2.0% v/v dilution) | **60.85** | **166.98** | **3.26** | Acceptable  In the range of background concentrations for iodine |
| Scenario 3 (Veal calves approach – worst case / 0.8% v/v dilution) | **48.64** | **133.49** | **2.61** | Acceptable  In the range of background concentrations for iodine |
| *Via* STP | | | | |
| Scenario 1 (Turkey approach – worst case / 2.0% v/v dilution) | **119** | **45.3** | **6.38** | Acceptable  In the range of background concentrations for iodine |
| Scenario 2 (2.0% v/v dilution) | **18.5** | **7.12** | 0.99 | Acceptable  In the range of background concentrations for iodine |
| Scenario 3 (0.8% v/v dilution) | **14.83** | **5.67** | 0.80 | 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 | | |
| **2%v/v** | **1.5% v/v** | **1.0% v/v** | | **2%v/v** | **1.5% v/v** | **1.0% v/v** |
| 1 | Dairy cow | 49.80 | 37.35 | 24.90 | |  |  |  |
| 2 | Beef cattle | 25.38 | 19.04 | 12.69 | |  |  |  |
| 3 | Veal calves | 178.22 | 133.66 | 89.11 | |  |  |  |
| 4 | Sows, in individual pens | 107.50 | 80.63 | 53.75 | |  |  |  |
| 5 | Sows in groups | 122.54 | 91.91 | 61.27 | |  |  |  |
| 6 | Fattening pigs | 86.71 | 65.03 | 43.35 | |  |  |  |
| 7 | Laying hens in battery cages without treatment | 44.12 | 33.09 | 22.06 | |  |  |  |
| 8 | Laying hens in battery cages with aeration (belt drying) | 44.12 | 33.09 | 22.06 | | 104.90 | 78.68 | 52.45 |
| 9 | Laying hens in batters cages with forced drying (deep pit, high rise) | 44.12 | 33.09 | 22.06 | |  |  |  |
| 10 | Laying hens in compact battery cages | 39.54 | 29.65 | 19.77 | |  |  |  |
| 11 | Laying hens in free range with litter floor (partly litter floor, partly slatted) | 84.51 | 63.38 | 42.26 | | 150.66 | 112.99 | 75.33 |
| 12 | Broilers in free range - litter floor | 27.43 | 20.57 | 13.72 | | 89.22 | 66.91 | 44.61 |
| 13 | Laying hens in free range - grating floor | 51.82 | 38.87 | 25.91 | |  |  |  |
| 14 | Parent broilers in free range - grating floor | 32.31 | 24.23 | 16.16 | |  |  |  |
| 15 | Parent broilers in rearing - grating floor | 69.49 | 52.12 | 34.75 | |  |  |  |
| 16 | Turkey in free range - litter floor | 52.29 | 39.22 | 26.15 | | 262.75 | 197.06 | 131.37 |
| 17 | Ducks in free range - litter floor | 106.08 | 79.56 | 53.04 | | 159.48 | 119.61 | 79.74 |
| 18 | Geese in free range - litter floor | 39.41 | 29.56 | 19.71 | | 198.04 | 148.53 | 99.02 |
| **SCENARIO 2** | | VIA MANURE | | | | VIA STP | | |
| **2%v/v** | **1.5% v/v** | **1.0% v/v** | | **2%v/v** | **1.5% v/v** | **1.0% v/v** |
| 1 | Dairy cow | 7.71 | 5.78 | 3.85 | | 40.85 | 30.64 | 20.43 |
| 2 | Beef cattle | 7.25 | 5.44 | 3.63 | |
| 3 | Veal calves | 137.09 | 102.82 | 68.55 | |
| 4 | Sows, in individual pens | 27.85 | 20.89 | 13.93 | |
| 5 | Sows in groups | 27.85 | 20.89 | 13.93 | |
| 6 | Fattening pigs | 21.46 | 16.10 | 10.73 | |
| 7 | Laying hens in battery cages without treatment | 6.87 | 5.15 | 3.44 | |
| 8 | Laying hens in battery cages with aeration (belt drying) | 6.87 | 5.15 | 3.44 | |
| 9 | Laying hens in batters cages with forced drying (deeppit, high rise) | 6.87 | 5.15 | 3.44 | |
| 10 | Laying hens in compact battery cages | 6.16 | 4.62 | 3.08 | |
| 11 | Laying hens in free range with litter floor (partly litter floor, partly slatted) | 15.28 | 11.46 | 7.64 | |
| 12 | Broilers in free range - litter floor | 8.37 | 6.28 | 4.19 | |
| 13 | Laying hens in free range - grating floor | 7.64 | 5.73 | 3.82 | |
| 14 | Parent broilers in free range - grating floor | 12.52 | 9.39 | 6.26 | |
| 15 | Parent broilers in rearing - grating floor | 21.19 | 15.89 | 10.59 | |
| 16 | Turkey in free range - litter floor | 5.42 | 4.06 | 2.71 | |
| 17 | Ducks in free range - litter floor | 18.12 | 13.59 | 9.06 | |
| 18 | Geese in free range - litter floor | 5.42 | 4.06 | 2.71 | |
| **SCENARIO 3** | | VIA MANURE | | | | VIA STP | | |
| **0.8%v/v** | **0.5%v/v** | **0.15%v/v** | **0.05%v/v** | **0.8%v/v** | | |
| 1 | Dairy cow | 6.17 | 3.85 | 1.16 | 0.24 | 32.68 | | |
| 2 | Beef cattle | 5.80 | 3.63 | 1.09 | 0.23 |
| 3 | Veal calves | 109.67 | 68.55 | 20.56 | 4.28 |
| 4 | Sows, in individual pens | 22.28 | 13.93 | 4.18 | 0.87 |
| 5 | Sows in groups | 22.28 | 13.93 | 4.18 | 0.87 |
| 6 | Fattening pigs | 17.17 | 10.73 | 3.22 | 0.67 |
| 7 | Laying hens in battery cages without treatment | 5.50 | 3.44 | 1.03 | 0.21 |
| 8 | Laying hens in battery cages with aeration (belt drying) | 5.50 | 3.44 | 1.03 | 0.21 |
| 9 | Laying hens in batters cages with forced drying (deeppit, high rise) | 5.50 | 3.44 | 1.03 | 0.21 |
| 10 | Laying hens in compact battery cages | 4.93 | 3.08 | 0.92 | 0.19 |
| 11 | Laying hens in free range with litter floor (partly litter floor, partly slatted) | 12.22 | 7.64 | 2.29 | 0.48 |
| 12 | Broilers in free range - litter floor | 6.70 | 4.19 | 1.26 | 0.26 |
| 13 | Laying hens in free range - grating floor | 6.11 | 3.82 | 1.15 | 0.24 |
| 14 | Parent broilers in free range - grating floor | 10.02 | 6.26 | 1.88 | 0.39 |
| 15 | Parent broilers in rearing - grating floor | 16.95 | 10.59 | 3.18 | 0.66 |
| 16 | Turkey in free range - litter floor | 4.34 | 2.71 | 0.81 | 0.17 |
| 17 | Ducks in free range - litter floor | 14.49 | 9.06 | 2.72 | 0.57 |
| 18 | Geese in free range - litter floor | 4.34 | 2.71 | 0.81 | 0.17 |

***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 2% v/v dilution, a 1.5% v/v dilution or a 1.0% v/v dilution in water)** | | | | | | | | | | | | | | | | | **2.0%** | | | | | **1.5%** | | | | | | **1.0%** | | | | | | *via* slurry/manure | | *via* stp | | | *via* slurry/manure | | | *via* stp | | | *via* slurry/manure | | | *via* stp | | | STP | Acceptable | | | | | | | | | | | | | | | | | Surface water | Acceptable | | | Unacceptable\* | | | Acceptable | | | Acceptable | | | Acceptable | | Acceptable | | | Sediment | Acceptable | | | | | | | | | | | | | | | | | Soil | Acceptable | | | | | | | | | | | | | | | | | Groundwater\*\* | Acceptable  Except for disinfection of livestock veal calves, livestock sows, pigs, laying hens in free range with litter floor and ducks in free range. | | Unacceptable\* | | | Acceptable  Except for disinfection of livestock veal calves, livestock sows, and ducks in free range. | | | Unacceptable\* | | | Acceptable  Except for disinfection of livestock veal calves | | | Unacceptable\* | | | **Scenario 2** | **Scenario 2: Disinfection of small equipment’s used in breeding (PT03) by soaking (dipping), followed by rinsing with drinking water (after a 2% v/v dilution, a 1.5% v/v dilution or a 1.0% v/v dilution in water)** | | | | | | | | | | | | | | | | | **2.0%** | | | | | **1.5%** | | | | | | **1.0%** | | | | | | *via* slurry/manure | | *via* stp | | | *via* slurry/manure | | | *via* stp | | | *via* slurry/manure | | | *via* stp | | | STP | Acceptable | | | | | | | | | | | | | | | | | Surface water | Acceptable | | | | | | | | | | | | | | | | | Sediment | Acceptable | | | | | | | | | | | | | | | | | Soil | Acceptable | | | | | | | | | | | | | | | | | Groundwater\*\* | Acceptable  Except for disinfection of livestock veal calves | | Acceptable | | | Acceptable  Except for disinfection of livestock veal calves | | | Acceptable | | | Acceptable | | | Acceptable | | | **Scenario 3** | **Scenario 3: Drinking water pipe disinfection by injection (after a 0.8% v/v dilution, a 0.15% v/v dilution, a 0.5% v/v dilution or a 0.05% v/v dilution), followed by rinsing with drinking water.** | | | | | | | | | | | | | | | | | **0.8%** | | | | **0.5%** | | | | **0.15%** | | | | | **0.05%** | | | | *via* slurry/manure | *via* stp | | | *via* slurry/manure | | | *via* stp | *via* slurry/manure | | *via* stp | | | *via* slurry/manure | | *via* stp | | STP | Acceptable | | | | | | | | | | | | | | | | | Surface water | Acceptable | | | | | | | | | | | | | | | | | Sediment | Acceptable | | | | | | | | | | | | | | | | | Soil | Acceptable | | | | | | | | | | | | | | | | | Groundwater\*\* | Acceptable  Except for disinfection of livestock veal calves | Acceptable | | | Acceptable | | | Acceptable | Acceptable | | Acceptable | | | Acceptable | | Acceptable |   \* Acceptable considering the following risk mitigation measure: “Do not apply the product if releases from animal housings or manure/slurry storage areas can be directed to a sewage treatment plant.”  \*\* The estimation of concentrations in groundwater is based on a worst case assumption taking into account the partitioning equilibrium. In the absence of possible refinement of this methodology, the assessment of estimated concentrations in groundwater cannot be refined. Nevertheless, risk is not considered as unacceptable |

### 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

## List of studies for the biocidal product

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Author(s) | Year | Title Source Company Report No. GLP or GEP Status (where relevant) Published or not | Member State Data Protection Claimed (Y/N) | **Owner** |
| Coffy C. | 2015 | Etude de stabilité de l’Aquavic 3%  Désinfectant pour canalisations d’eau et pour matériels et surfaces en élevage | Y | LABORATOIRE MERIEL S.A.S. |
| Coffy C. | 2016 | Etude intermédiaire à 1 an du dosage en iode d’Aquavic 3%  Désinfectant pour canalisations d’eau et pour matériels et surfaces en élevage | Y | LABORATOIRE MERIEL S.A.S. |
| Marquet N. | 2015 | Etude de pH de AQUAVIC 3% | Y | LABORATOIRE MERIEL S.A.S. |
| Marquet N. | 2015 | Mesure de densité AQUAVIC 3% | Y | LABORATOIRE MERIEL S.A.S. |
| Demangel B.,  Report no.15-912037-001 | 2015 | Determination of exothermic reactions by DSC  on AQUAVIC 3% | Y | QALIAN |
| Detrimont H., Ambrosi D. | 2015 | Literature review on explosive and oxidizing properties of the ingredients of the product AQUAVIC 3% | Y | QALIAN |
| Marquet N. | 2015 | Rapport 15 – CMER-003  AQUAVIC 3%  Inflammabilité et Point éclair | Y | LABORATOIRE MERIEL S.A.S. |
| F. Perin | 2016 | TEST REPORT N. 16/000265479 AQUAVIC LOT: 1404161  Surface tension | Y | LABORATOIRE MERIEL S.A.S. |
| L. Zampieri | 2016 | Validation of a method and determination of assay of iodine in AQUAVIC 3% ; evluation of stability and physical properties | Y | CHELAB |
| N. Marquet | 2016 | Test de persistance de la mousse | Y | MERIEUX NutriSciences |
| M. Semenzin | 2016 | METAL CORROSION TEST FOR THE PRODUCT AQUAVIC 3% | Y | MERIEUX NutriSciences |
| 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 |  | LaboratoireMériel |  |
| 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 |  | LaboratoireMériel |  |
| Simonet A | 2012 | Essai quantitatif de suspension pour l'évaluation de l'activité bactéricide des antiseptiques et des désinfectants chimiques utilisés dans le domaine vétérinaire. Méthode d'essai et prescriptions (phase 2, étape 1). Icare / 04407Q-1A |  | Qalian |  |
| Marquet N | 2016 | Détermination de l'activité bactéricide. Méthode par dilution neutralisation. Selon la norme NF EN 1656: 2010 en conditions de saleté de niveau bas pendant 30 min à 10°C. Produit : Aquavic 3%. Laboratoire Mériel / 2016-MER-003 |  | Qalian S.A |  |
| Simonet A | 2012 | Essai quantitatif de suspension pour l'évaluation de l'activité fongicide ou levuricide des antiseptiques et des désinfectants chimiques utilisés dans le domaine vétérinaire. Méthode d'essai et prescriptions (phase 2, étape 1). Icare / 04407Q-4A |  | Qalian |  |
| Benoliel C. | 2015 | Essai selon la norme NF EN 14349 (Décembre 2012). Méthode d'essai et prescriptions (phase 2, étape 2). Scientis / 032-1REA15 |  | Qalian |  |
| Marquet N | 2016 | Essai selon la norme NF EN 14349 (décembre 2012). Méthode d’essai et prescription (Phase 2, étape2). AQUAVIC 3 % Laboratoire Mériel 2016-MER-004 |  | Qalian S.A |  |
| Benoliel C. | 2015 | Test according to the methodology of the standard NF EN 16438 (March 2014). Test method and requirements (phase 2, step 2). Scientis / 033-1REA 15 AN |  | Qalian |  |
| Dugué R. | 2015 | Virucidal activity according the EN 14675 standard against Bovine Enterovirus type 1 (ECBO). Product: Aquavic 3% (fab 22/01/2015). Laboratoire Midac / RE 15080-5 |  | Qalian |  |
| Marquet N | 2015 | European standard NF EN 1276: 2010. Dilution-neutralization method, high level soiling conditions. Product : Aquavic 3% Laboratoire Mériel / 2015-MER-001 |  | Qalian S.A |  |
| Marquet N | 2015 | European standard NF EN 1276: 2010. Additional conditions for in place equipment disinfection, buffer solution pH5. Product: Aquavic 3% Laboratoire Mériel / 2015-MER-015 |  | Qalian S.A. |  |
| Marquet N | 2016 | Détermination de l’activité BACTERICIDE. Méthode par dilution neutralisation selon les conditions additionnelles de la norme NF EN 1276 :2010 pour la désinfection des matériels en place solution tampon pH5. Produit : AQUAVIC 3%  Laboratoire Mériel 2016-MER-002 |  | Qalian S.A. |  |
| Marquet N | 2015 | European standard NF EN 1276: 2010. Additional conditions for in place equipment disinfection, buffer solution pH9. Product:Aquavic 3%  Laboratoire Mériel / 2015-MER-016 |  | Qalian S.A. |  |
| Marquet N | 2015 | Quantitative test for the determination of yeasticidal activity according to NF EN 1650 standard general conditions. Dilution neutralization method, high level soiling conditions. Product: Aquavic 3%  Laboratoire Mériel / 2015-MER-002 |  | Qalian S.A. |  |
| Marquet N | 2015 | Quantitative test for the determination of yeasticidal activity according to NF EN 1650 standard. Dilution-neutralization method, additional conditions for in place equipment disinfection, buffer solution pH5. Product: Aquavic 3%.  Laboratoire Mériel / 2015-MER-017 |  | Qalian S.A. |  |
| Marquet N | 2015 | Quantitative test for the determination of yeasticidal activity according to NF EN 1650 standard. Dilution-neutralization method, additional conditions for in place equipment disinfection, buffer solution pH9. Product: Aquavic 3%.  Laboratoire Mériel / 2015-MER-018 |  | Qalian S.A. |  |
| Poy D. | 2012 | European standard NF EN 13697. Méthode d'essai sans action mécanique et prescriptions (phase 2, étape 2).  Icare / 04407Q-3A |  | Qalian |  |
| Chiron J-P. | 2016 | AQUAVIC 3%. Essai quantitatif de surface pour l'évaluation de l'activité levuricide sur des surfaces non poreuses en condition de saleté, 15 minutes, 20°C.  A.D.R.E.M.I. -Tours / Laboratoire de Microbiologie Immunologie / MIC. 16/06-231.L QLN |  | Qalian |  |

## Output tables from exposure assessment tools

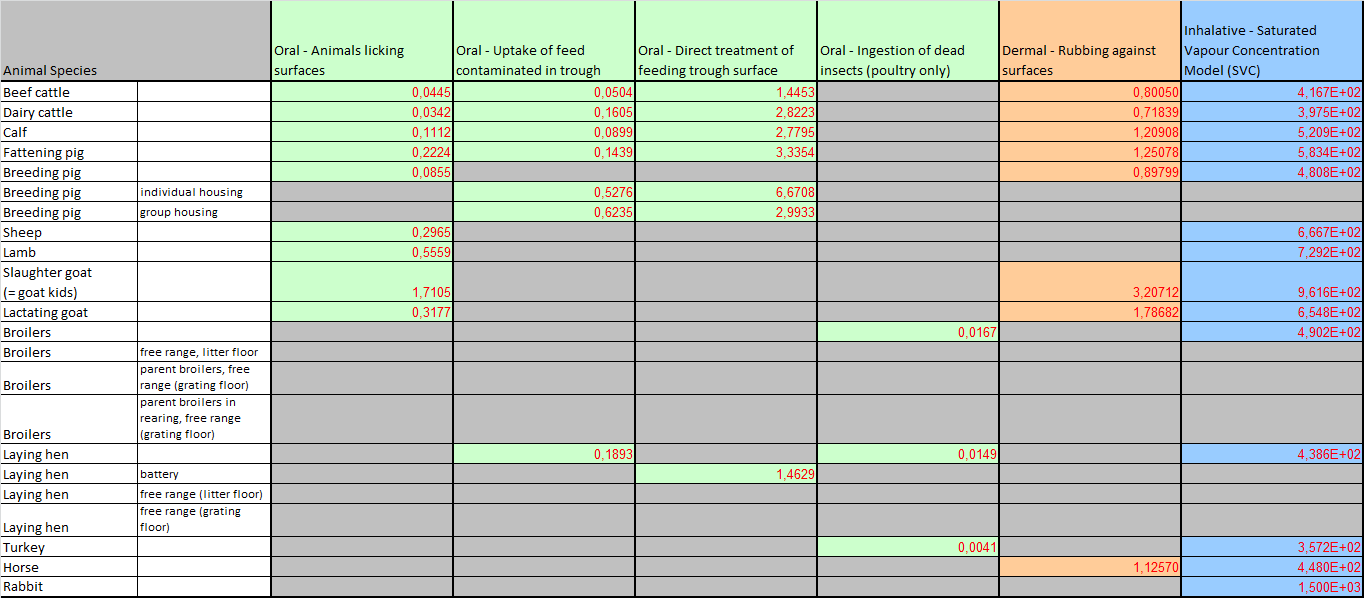
-

## New information on the active substance

-

## Residue behaviour

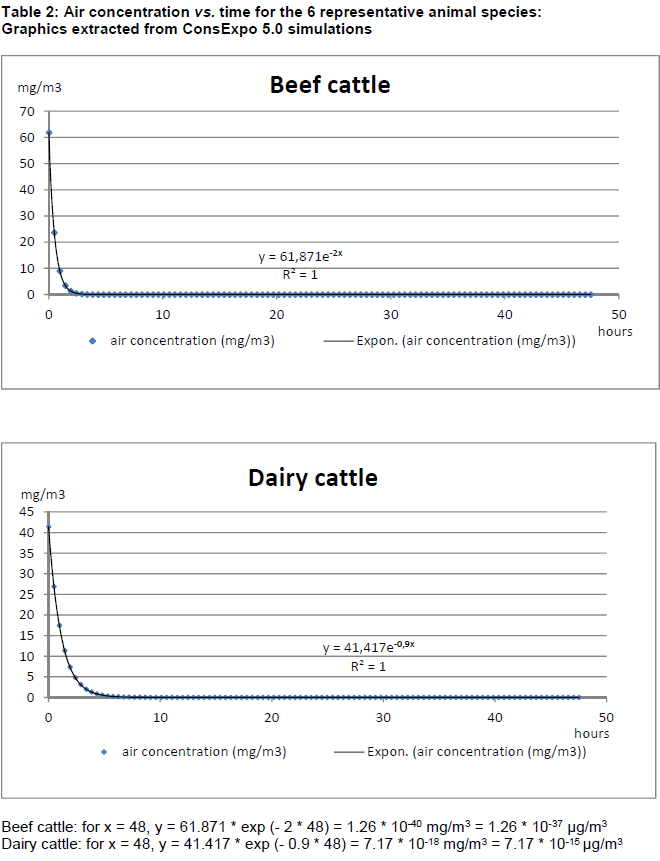
**Table 1:** PT03: Disinfection of empty breeding Tier 2: realistic worst case without refinement

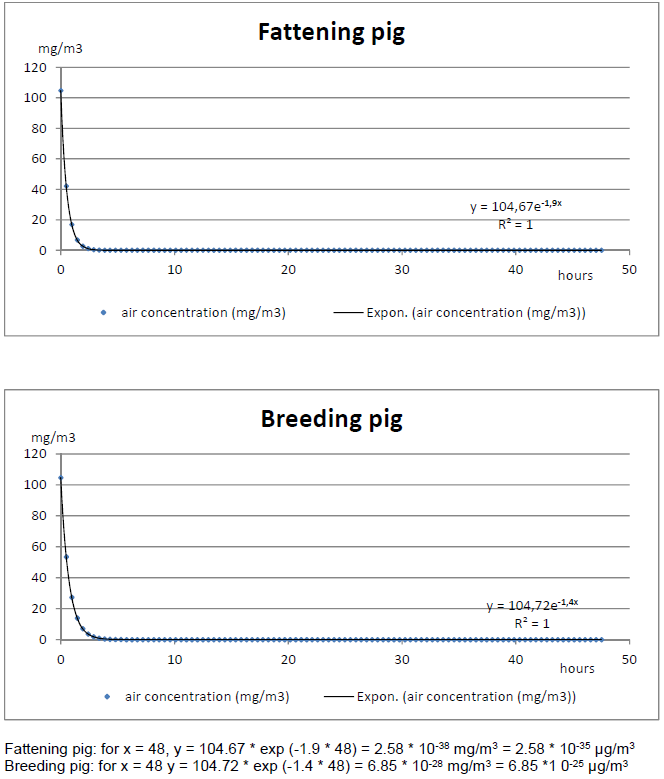


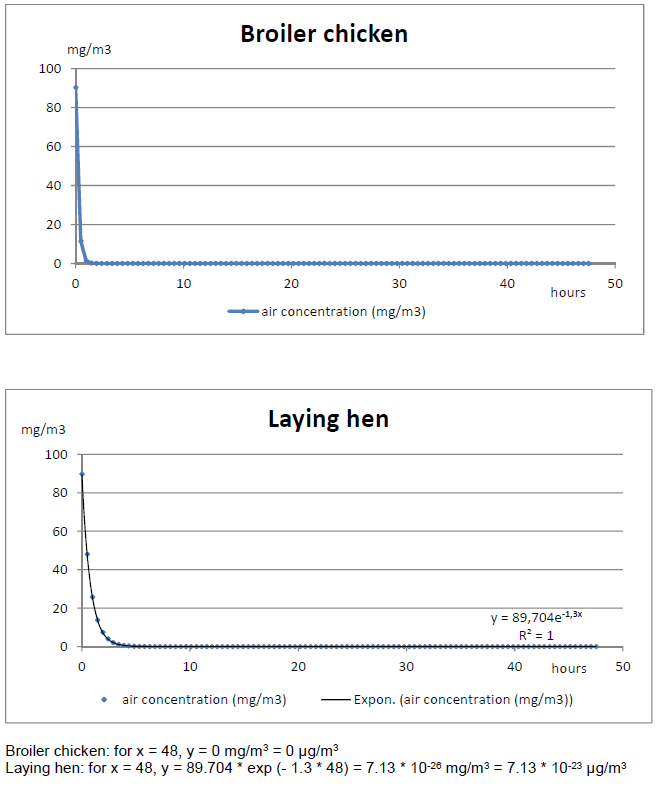
**Table 2:** PT03: Disinfection of empty breeding Tier 3: realistic worst case with refinement



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







## Summaries of the efficacy studies (B.5.10.1-xx)

See IUCLID files

1. 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-1)
2. Guidance on Dermal Absorption, EFSA Panel on Plant Protection Products and their Residues (PPR), EFSA  
   Journal 2012;10(4):2665 [↑](#footnote-ref-2)
3. Guidance on the BPR: Volume III human health - part B Risk assessment [↑](#footnote-ref-3)
4. Technical Notes for Guidance Human exposure to biocidal products, January 2008 (adopted during CA meeting of 19-20 june of 2007). [↑](#footnote-ref-4)
5. HEEG opinion 9 Default protection factors for protective clothing and gloves (agreed in TM I 2010). [↑](#footnote-ref-5)
6. Guidance on the BPR: Volume III human health - part B Risk assessment [↑](#footnote-ref-6)
7. 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-7)
8. 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-8)
9. 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-9)
10. ARTFood 2016, draft Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products [↑](#footnote-ref-10)
11. Fiche toxicologique Iode, FT 207, INRS (2006) [↑](#footnote-ref-11)
12. http://www.inchem.org/documents/pims/pharm/iodine.htm#SectionTitle:5.3 [↑](#footnote-ref-12)
13. Toxicological profile for Iodine, US Department of Health and Human Services (2004) [↑](#footnote-ref-13)
14. [↑](#footnote-ref-14)
15. 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-15)
16. 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-16)
17. Iodine and inorganic iodides: Human health aspects, Concise international chemical assessment document 72,WHO, 2009 [↑](#footnote-ref-17)
18. ARTFood/DRAWG (2014) : Guidance on Estimating Transfer of Biocidal Active Substances into Foods – Professional Uses – 2014 - draft not yet published [↑](#footnote-ref-18)
19. ARTFood/DRAWG (2014) : Guidance on Estimating Transfer of Biocidal Active Substances into Foods – Professional Uses – 2014 – draft not yet published [↑](#footnote-ref-19)
20. 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-20)
21. 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-21)
22. 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-22)