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)



HYDRACHIM IODINE FAMILY

Product types 3

Polyvinylpyrrolidone iodine

Case Number in R4BP: BC-BE019369-50

Evaluating Competent Authority: France

Date: 06 March 2019

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# CONCLUSION

* *Introduction*

The product family HYDRACHIM IODINE FAMILY is based on 1.5 to 2.9 % of polyvinylpyrrolidone iodine (PVPi) with available iodine minimum purity at 9 % of PVPi. It is an Another Liquid AL, ready-to-use formulation.

The biocidal product family is a PT3 biocidal family intended to be applied for non-medical teat disinfectants in animal houses. It is applied by professional users before or after milking by manual dipping, automatic spraying and by manual or semi-automatic spraying.

HYDRACHIM IODINE FAMILY includes several uses which were separated initially in six META-SPCs. However during the assessment, the meta SPC 2 has been withdrawn by the applicant. Therefore, the product family HYDRACHIM IODINE FAMILY contains five META-SPCs (1, 3, 4, 5 and 6).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **General application** | **Use Number** | **Use description** | **PVP Iodine concentration** |
| **Meta-SPC 1** | Pre-milking | 1 | Liquid dipping before milking | 2.9% |
| 2 | Dipping with foam before milking |
| 3 | Automated spraying before milking |
| 4 | Semi-automated or manual spraying before milking |
| **Meta-SPC 3** | Post-milking | 7 (==use 1) | Liquid dipping after milking | 1.5-2.90 |
| 8 (==use 3) | Automated spraying after milking |
| 9 (==use 4) | Semi-automated or manual spraying after milking |
| **Meta-SPC 4** | 10 (==use 1) | Thick liquid dipping after milking | 1.5-2.90 |
| **Meta-SPC 5** | 11 (==use 1) | Thick film-forming liquid dipping after milking | 1.5-2.90 |
| **Meta-SPC 6** | Pre- and post- milking | 12 (==use 3 & 8) | Automated spraying before and after milking | 2.9% |

* *Physico-chemical properties*

The product family HYDRACHIM IODINE FAMILY is an Another Liquid (AL) formulation, ready-to-use formulation. All studies submitted to support of HYDRACHIM IODINE FAMILY have been performed in accordance with the current requirements and the results are deemed to be acceptable. Products within the family are not explosive and have no oxidizing properties. The products are not considered as flammable according to CLP regulation.

According to the stability of the product family the conclusions are the following for each META-SPC:

For the META-SPC 1 and META SPC 6, the appearance of the product is that of translucent brown liquid. There is a decrease of available iodine after 18 weeks at 30°C storage. The biocidal product is not stable at 30°C. Final results of 2 years shelf life show a loss of active substance more than 10% after 24 months at 15°C when stored in HDPE. Loss of active substance is less than 10% after 12 months. Mitigation measures below are proposed.

* Protect from frost ;
* Do not store above 15°C;
* Do not store more than 12 months
* Store away from direct sunlight.

For the META-SPC 3, the appearance of the product is that of brown liquid, with no characteristic odour. There is a decrease of available iodine after 18 weeks at 30°C storage.The biocidal product is not stable at 30°C. Interim results of 2 years shelf life show that the product is stable after 24 months at 15°C when stored in HDPE. Mitigation measures below are proposed.

* Protect from frost ;
* Do not store above 15°C;
* Do not store more than 24 months
* Store away from direct sunlight.

For the META-SPC 4, the appearance of the product is that of brown liquid, with no characteristic odour. There is a decrease of available iodine after 18 weeks at 30°C storage. The biocidal product is not stable at 30°C. Final results of 2 years shelf life show a loss of active substance more than 10% after 24 months at 15°C when stored in HDPE. Loss of active substance is less than 10% after 12 months Mitigation measures below are proposed.

* Protect from frost
* Do not store above 15°C.
* Do not store more than 12 months.
* Store away from direct sunlight.

For the META-SPC 5, the appearance of the product is that of brown liquid, with no characteristic odour. There is a decrease of available iodine after 18 weeks at 30°C storage. The biocidal product is not stable at 30°C. Final results of 2 years shelf life show a loss of active substance more than 10% after 6 months at 15°C when stored in HDPE. The mitigation measures below are proposed.

* Protect from frost
* Do not store above 15°C.
* Do not store more than 3 months
* Store away from direct sunlight.

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

* *Efficacy assessment*

French competent authorities (FR CA) assessed that the products of the HYDRACHIM IODINE FAMILY, has shown a sufficient efficacy for teats disinfection as following:

* In META-SPC 1, before milking (and after cleaning), by manual dipping, manual foam dipping, automated spraying or, manual or semi-automated spraying, at with a contact time of one minute, against bacteria, yeasts and bacteriophages.
* In META-SPC 3, after milking, by manual dipping, automated spraying or, manual or semi-automated spraying, with a contact time of 5 minutes, against bacteria and yeasts.
* In META-SPC 4 after milking, by manual dipping, with a contact time of 5 minutes, against bacteria and yeasts.
* In META-SPC 5 after milking, by manual dipping, with a contact time of 5 minutes, against bacteria and yeasts. Virucidal activity against enveloped virus has not been demonstrated, as major deviation is noticed in the study (the control of efficacy for suppression of disinfectant’s activity is not validated).
* In META-SPC 6, before milking (and after cleaning), by automated spraying, with a contact time of one minute ; and after milking, by automated spraying, with a contact time of 5 minutes, against bacteria, yeasts and bacteriophages (only for pre-milking for phages).

The users should inform if the treatment is ineffective and report straightforward to the registration holder.

* *Risk assessment for human health*

Conclusion of risk assessment of the professional users is given in the Table here below

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **General application** | **Use Number** | **Use description** | **risk assessment conclusions dependiong on the background intake** |
| **Meta-SPC 1** | Pre-milking | 1 | Liquid dipping before milking | 25%: acceptable risk with PPE  46%: unacceptable risk |
| 2 | Dipping with foam before milking | 25%: acceptable risk with PPE  46%: unacceptable risk |
| 3 | Automated spraying before milking | 25%: acceptable risk without PPE  46%: acceptable risk without PPE |
| 4 | Semi-automated or manual spraying before milking | Unacceptable risk |
| **Meta-SPC 3** | Post-milking | 7 (==use 1) | Liquid dipping after milking | 25%: acceptable risk without PPE  46%: acceptable risk without PPE |
| 8 (==use 3) | Automated spraying after milking | 25%: acceptable risk without PPE  46%: acceptable risk without PPE |
| 9 (==use 4) | Semi-automated or manual spraying after milking | Unacceptable at 2.9%PVPI  2%PVPI and less :   * 25%: acceptabe risk wth PPE ( gloves and coated coverall) * 46% unacceptable risk |
| **Meta-SPC 4** | 10 (==use 1) | Thick liquid dipping after milking | 25%: acceptable risk without PPE  46%: acceptable risk without PPE |
| **Meta-SPC 5** | 11 (==use 1) | Thick film-forming liquid dipping after milking | 25%: acceptable risk without PPE  46%: acceptable risk without PPE |
| **Meta-SPC 6** | Pre- and post- milking | 12 (==use 3 & 8) | Automated spraying before and after milking | 25%: acceptable risk with PPE  46%: unacceptable risk |

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

* *Risk for consumers via residues*

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

The estimation of iodine contamination in milk has been performed considering the worst case situation. Human health risk is acceptable for all milking applications based on estimated intakes, except for toddlers, where total daily intake considerably exceeds the UL. Iodine from toddler dietary intake, arising from every other source except from iodine containing teat disinfection product residues, takes up almost the whole fraction of the UL if current EU data is used. It highlights the importance to obtain more reliable information on iodine background levels in food items in the EU, and consequently to update the data supporting the current UL.

* *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 the familly of product HYDRACHIM IODINE FAMILY.

The estimated groundwater concentrations associated with the use of the familly of product HYDRACHIM IODINE FAMILY are in the range of environmental iodine background except when pre and post milking are cumulated. For the use either in pre or post milking, the levels of iodine in groundwater are acceptable.

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, no unacceptable risk for groundwater is expected even when post and pre-mil uses are cumulated.

* ***Overall conclusions***

The biocidal product family HYDRACHIM IODINE FAMILY can be authorized under the following conditions

|  |  |  |  |
| --- | --- | --- | --- |
|  | **General application** | **Use description** | **RMM** |
| **Meta-SPC 1** | Pre-milking | Liquid dipping before milking | gloves |
| Dipping with foam before milking | gloves |
| Automated spraying before milking | - |
| **Meta-SPC 3** | Post-milking | Liquid dipping after milking | - |
| Automated spraying after milking | - |
| Semi-automated or manual spraying after milking | 2%PVPI and less  gloves and coated coverall |
| **Meta-SPC 4** | Thick liquid dipping after milking | - |
| **Meta-SPC 5** | Thick film-forming liquid dipping after milking | - |
| **Meta-SPC 6** | Pre- and post- milking | Automated spraying before and after milking | gloves |

# ASSESSMENT REPORT

## 

## Summary of the product assessment

**Part I. - First information level**

### Administrative information

#### Family name

| **Name** | HYDRACHIM IODINE FAMILY |
| --- | --- |

#### 

#### Product type(s)

| **Product type(s)** | PT 3 |
| --- | --- |

#### 

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | HYDRACHIM |
| **Address** | ZA du piquet  35370 Etrelles  France |
| **Authorisation number** | FR-2019-0061 | |
| **Date of the authorisation** | 04/07/2019 | |
| **Expiry date of the authorisation** | 03/07/2019 | |

#### 

#### . Manufacturer(s) of the biocidal products

|  |  |
| --- | --- |
| **Name of manufacturer** | HYDRACHIM |
| **Address of manufacturer** | ZA du piquet  35370 Etrelles  France |
| **Location of manufacturing sites** | HYDRACHIM  Route de Saint Poix  35370 LE PERTRE  FRANCE |
|  | HYDRACHIM  ZA La Pointe  35380 PLELAN LE GRAND  France |

#### 

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

|  |  |
| --- | --- |
| **Active substance** | 2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. with iodine |
| **Name of manufacturer** | Ashland Service BV |
| Pantheon FZE |
| BASF SE |
| **Address of manufacturer** | Ashland Service BV  Affiliate of Ashland Inc.  Pesetastraat 5  2991 XT Barendrecht  Postbus 8619  3009 Rotterdam  Netherlands |
| Pantheon FZE  (DMCC Branch)  403, Reef Tower, Jumeira Lake Tower Shaikh Zayed Road Dubai, UAE |
| BASF SE  67056 Ludwigshafen  Germany |
| **Location of manufacturing sites** | Cosayach Nitratos S.A.  Oficina Cala Cala S/N Pozo almonte Iquique  Chile  SQM  Los Militares 4290  Piso 3  Las Conde-Santiago  Chile  Algorta Norte  Ex-Oficina Ercilla s/n  Ruta B-330 Km.28,2  Comuna de Sierra Gorda  Antofagasta,  Chile  Cosayach Nitratos S.A.  Oficina Cala Cala S/N Pozo almonte  Iquique  Chile  BASF SE  67056 Ludwigshafen  Germany |

### Product family 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

* + - 1. Identity of the active substance

|  |  |
| --- | --- |
| **Premix constituent(s)** | |
| **ISO name** | 2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. with iodine |
| **IUPAC or EC name** | Polyvinylpyrrolidone iodine |
| **EC number** | Not assigned |
| **CAS number** | 25655-41-8 |
| **Index number in Annex VI of CLP** | **-** |
| **Minimum purity / content** | **Min. PVPi content: 1.5% w/w**  **Min. Iode pure content: 0.13% w/w\*** |
| **Structural formula** | **Povidone iodée** |

*\*viewing the min. purity of iodine, technical content is identical to the pure content*

|  |  |
| --- | --- |
| **Premix 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** | **995 g/kg** |
| **Structural formula** | **I - I** |

* + - 1. Candidate(s) for substitution

The active substance iodine is not candidate for substitution in accordance with Article 10 of BPR–Regulation 528/2012.

* + - 1. Qualitative and quantitative information on the composition of the family

**Please see the confidential annex for further details.**

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Polyvinylpyrrolidone iodine | 2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. with iodine | Active substance | 25655-41-8 | Not assigned | 1,5 | 2.9 |
| *Iodine* | *Iodine* | *7553-56-2* | *231-442-4* | *0.13* | *0.26* |
| *Polyvinylpyrrolidone* | *2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd* | *25655-41-8* | *Not assigned* | *1.37* | *2.74* |
| Sodium lauryl ether sulfate |  | Surfactant | 68891-38-3 |  | 0 | 0.94 |

* + - 1. Information on technical equivalence

*Not applicable*

* + - 1. Information on the substance(s) of concern

Sodium lauryl ether sulfate est considered as a SoC

* + - 1. Type(s) of formulation

| **Formulation(s)** | AL- Any other liquid |
| --- | --- |
|  |  |

**Part II. - Second information level - meta SPC 1**

**1. Meta SPC administrative information**

**1.1. Meta SPC identifier**

| **Identifier** | Meta SPC 1 |
| --- | --- |

**1.2. Suffix to the authorisation number**

|  |  |
| --- | --- |
| **Number** | - |

**1.3. Product type(s)**

| **Product type(s)** | PT 3 - Veterinary hygiene (Disinfectants) |
| --- | --- |

**2. Meta SPC composition**

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| 2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. with iodine | Polyvinylpyrrolidone iodine | Active substance | 25655-41-8 | Not assigned | 2.9 | 2.9 |
| Iodine\* | Iodine\* | 7553-56-2 | 231-442-4 | 0.26 | 0.26 |
| Sodium lauryl ether sulfate |  | Surfactant | 68891-38-3 |  | 0 | 0.94 |

**2.2. Type(s) of formulation of the meta SPC**

| **Formulation** | AL-any Other liquid |
| --- | --- |

**3. Hazard and precautionary statements of the meta SPC**

| **Classification** | |
| --- | --- |
| Hazard category | Eye Dam. Category 1  Aquatic chronic cat 3 |
| Hazard statement | H318: Causes serious eye damage.  H412: Harmful to aquatic life with long-lasting effects |
|  | |
| **Labelling** | |
| Signal words | ghs05  Danger |
| Hazard statements | H318: Causes serious eye damage.  H412: Harmful to aquatic life with long-lasting effects |
| Precautionary statements | P273 – Avoid release to the environment  P280: Wear protective gloves/protective clothing/eye protection/face protection.  P305+P351 +P338: F IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P310: . Immediately call a POISON CENTER/doctor/  P501 - Dispose of contents/container in accordance with local/ regional/national/international regulation (to be specified). |
|  | |
| Note |  |

**4. Authorised use(s) of the meta SPC 1**

**4.1. Use description - Manual disinfection by dipping (pre-milking)**

|  |  |
| --- | --- |
| **Use # 1 – Manual dipping before milking** | |
| **Product Type** | PT3- Veterinary hygiene |
| **Where relevant, an exact description of the authorised use** | Manual non-medical teat disinfection |
| **Target organism(s) (including development stage)** | Bacteria  Yeasts  Bacteriophages |
| **Field(s) of use** | disinfection of teats by manual dipping before milking |
| **Application method(s)** | Application with a dipping cup |
| **Application rate(s) and frequency** | Twice applications a day before each milking  Clean conditions  Contact time 1 min |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Polyethylene high-density (PEHD) opaque containers of 10 kg, 20 kg, 60 kg, 200 kg, 1000 kg. |

***4.1.1.* *Use-specific instructions for use***

|  |
| --- |
| * For use with a dipping cup of 300 mL. Fill a clean and dry cup to three quarters (225 ml). Exercise enough pressures (about 3 to 6) to bring the product up in the dip cup and fill it up to two thirds. Dip each teat before milking during about one minute * After the contact time, dry the teats and base of the udder with a clean cotton towel or disposable paper towel for the other modes of application. |

***4.1.2 Use-specific risk mitigation measures***

|  |
| --- |
| - Wear protective chemical resistant gloves (material to be specified by the authorisation holder within the product information) during loading and application of the products and during the wiping of the teats. |

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

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|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

**4.2. Use description - Manual disinfection by foam dipping (pre-milking)**

|  |  |
| --- | --- |
|  | |
| **Product Type** | PT3- Veterinary hygiene |
| **Where relevant, an exact description of the authorised use** | Manual non-medical teat disinfection |
| **Target organism(s) (including development stage)** | Bacteria  Yeasts  Bacteriophages |
| **Field(s) of use** | disinfection of teats by manual foam teat dipping before milking |
| **Application method(s)** | Application with a foam dipping cup |
| **Application rate(s) and frequency** | Twice application a day before each milking  Clean conditions  Contact time 1 min |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Polyethylene high-density (PEHD) opaque containers of 10 kg, 20 kg, 60 kg, 200 kg, 1000 kg. |

***4.2.1.* *Use-specific instructions for use***

|  |
| --- |
| * For use with a dipping cup of 300 mL. Fill a clean and dry cup to three quarters (225 ml). Exercise enough pressures (about 3 to 6) to bring the product up in the dip cup and fill it up to two thirds. Dip each teat before milking during about one minute. * - After the contact time, dry the teats and base of the udder with a clean cotton towel or disposable paper towel for the other modes of application. |

***4.2.2 Use-specific risk mitigation measures***

|  |
| --- |
| - Wear protective chemical resistant gloves (material to be specified by the authorisation holder within the product information) during loading and application of the products and during the wiping of the teats. |

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

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| --- |
|  |

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

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| --- |
|  |

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

|  |
| --- |
|  |

**4.3. Use description - Automatic disinfection by spraying (pre-milking)**

|  |  |
| --- | --- |
|  | |
| **Product Type** | PT3- Veterinary hygiene |
| **Where relevant, an exact description of the authorised use** | Automatic non-medical teat disinfection |
| **Target organism(s) (including development stage)** | Bacteria  Yeasts  Bacteriophages |
| **Field(s) of use** | disinfection of teats by automated spraying before milking |
| **Application method(s)** | Automatic spraying in milking machine |
| **Application rate(s) and frequency** | Twice applications a day before each milking  Clean conditions  Contact time 1 min |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Polyethylene high-density (PEHD) opaque containers of 10 kg, 20 kg, 60 kg, 200 kg, 1000 kg. |

***4.3.1.* *Use-specific instructions for use***

|  |
| --- |
| Automatic disinfection by spraying (pre-milking): For use in automatic spraying in milking machine: fill the tank and use the product according to the recommendations of the equipment manufacturer. Enable automatic spraying. Adjust the equipment to enable covering of the entire surface of the teats during one minute in order to ensure good disinfection of the skin. Adjust the settings of the equipment so that the product is removed from the teats before connecting beams. Not manual but automatic wiping. |

***4.3.2 Use-specific risk mitigation measures***

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| --- |
| - |

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

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

|  |
| --- |
| - |

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

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|  |

**5. General directions for use of the meta SPC 1**

**5.1. Instructions for use**

|  |
| --- |
| * Always read the label or leaflet before use and follow all the instructions provided. * Clean carefully the teats before application of the product for pre-milking. * No rinsing with water before connecting beams * The product must be brought to a temperature above 20°C before use.In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for post-milking disinfection |

**5.2. Risk mitigation measures**

|  |
| --- |
|  |

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

|  |
| --- |
| * 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. * Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur. * Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested. * Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled. * In case of impaired consciousness place in recovery position and seek medical advice immediately. Do not give fluids or induce vomiting. * Keep the container or label available. |

**5.4. Instructions for safe disposal of the product and its packaging**

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

**5.5. Conditions of storage and shelf-life of the product under normal conditions of storage**

|  |
| --- |
| * Keep out of reach of children * Protect from frost * Do not store above a temperature of 15°C * Do not store more than 12 months * Store away from direct sunlight |

**6. Other information**

|  |
| --- |
| * The product contains pyrrolidones derivatives. Do not use in case of known hypersensitivity. |

**7. Third information level: individual products in the meta SPC**

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **META SPC 1 – PRODUCT 1** | | | | | |
| **Trade name(s)** | IODI SPRAY  START UP IODE SPRAY  SPRAY IODINE  B'FORE MILKING SPRAY  PRE IODE FLUIDE | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Polyvinylpyrrolidone  iodine | 2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. with iodine | Active substance | 25655-41-8 | Not assigned | 2.90 |
| Iodine\* | Iodine\* |  | 7553-56-2 | 231-442-4 | 0.26 |
| sodium lauryl ether sulfate |  |  | 68891-38-3 |  | 0 |

\*Minimum content of available iodine in PVPi : 9% *(viewing the min. purity of iodine, technical content is identical to the pure content)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **META SPC 1 – PRODUCT 2** | | | | | |
| **Trade name(s)** | IODI MOUSSE  START UP IODE FOAM  IODINE FOAM  B'FORE MILKING FOAM  IO'MOUSS | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Polyvinylpyrrolidone  iodine | 2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. with iodine | Active substance | 25655-41-8 | Not assigned | 2.90 |
| Iodine\* | Iodine\* |  | 7553-56-2 | 231-442-4 | 0.26 |
| sodium lauryl ether sulfate |  |  | 68891-38-3 |  | 0.94 |

\*Minimum content of available iodine in PVPi : 9% *(viewing the min. purity of iodine, technical content is identical to the pure content)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **META SPC 1 – PRODUCT 3** | | | | | |
| **Trade name(s)** | 3 EN 1 IODINE  B'FORE MILKING 3 EN 1 | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Polyvinylpyrrolidone  iodine | 2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. with iodine | Active substance | 25655-41-8 | Not assigned | 2.90 |
| Iodine\* | Iodine\* |  | 7553-56-2 | 231-442-4 | 0.26 |
| sodium lauryl ether sulfate |  |  | 68891-38-3 |  | 0.27 |

\*Minimum content of available iodine in PVPi : 9% *(viewing the min. purity of iodine, technical content is identical to the pure content)*

**Part II. - Second information level - meta SPC 3**

**1. Meta SPC administrative information**

* 1. **Meta SPC identifier**

| **Identifier** | Meta SPC 3 |
| --- | --- |

* 1. **Suffix to the authorisation number**

|  |  |
| --- | --- |
| **Number** | - |

* 1. **Product type(s)**

| **Product type(s)** | PT 3- Veterinary hygiene |
| --- | --- |

**2. Meta SPC composition**

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Polyvinylpyrrolidone iodine | 2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. with iodine | Active substance | 25655-41-8 | Not assigned | 1.5 | 2.0 |
| Iodine\* | Iodine\* | 7553-56-2 | 231-442-4 | 0.13 | 0.18 |
| Sodium lauryl ether sulfate |  | Surfactant | 68891-38-3 |  | 0 | 0 |

\*Iodine minimum purity available in PVPi : 9%

**2.2. Type(s) of formulation of the meta SPC**

| **Formulation** | AL- Any Other liquids |
| --- | --- |

**3. Hazard and precautionary statements[[1]](#footnote-1) of the meta SPC**

|  |  |
| --- | --- |
| **Classification** | |
| Hazard category | Eye irrit. Category 2  Aquatic chronic cat 3 |
| Hazard statement | H319: Causes serious eye irritation  H412: Harmful to aquatic life with long-lasting effects |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H319: Causes serious eye irritation..  H412: Harmful to aquatic life with long-lasting effects |
| Precautionary statements | P264: Wash … thoroughly after handling  P273 – Avoid release to the environment  P280: Wear protective gloves/protective clothing/eye protection/face protection.  P305+P351 +P338: F IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P337 + P313: If eye irritation persists: Get medical advice/ attention.  P501 - Dispose of contents/container in accordance with local/ regional/national/international regulation (to be specified). |
|  | |
| Note |  |

**4. Authorised use(s) of the meta SPC**

**4.1. Use description- Manual disinfection by dipping (post-milking)**

|  |  |
| --- | --- |
|  | |
| **Product Type** | PT3- Veterinary hygiene |
| **Where relevant, an exact description of the authorised use** | Manual non-medical teat disinfection. |
| **Target organism(s) (including development stage)** | Bacteria  Yeasts |
| **Field(s) of use** | Disinfection of teats by manual dipping after milking |
| **Application method(s)** | Application with a dipping cup |
| **Application rate(s) and frequency** | Twice applications a day after each milking  Contact time 5 min |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Polyethylene high-density (PEHD) opaque containers of 10 kg, 20 kg, 60 kg, 200 kg, 1000 kg. |

***4.1.1.* *Use-specific instructions for use***

|  |
| --- |
| * For use with a dipping cup of 300 ml. Fill a clean and dry cup to three quarters (225 ml). Exercise enough pressures (about 3 to 6) to bring the product up in the dip cup and fill it up to two thirds. Dip each teat so that the teat is completely covered for 5 min |

***4.1.2 Use-specific risk mitigation measures***

|  |
| --- |
| - |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

**4.2. Use description- Automatic disinfection by spraying (post-milking)**

|  |  |
| --- | --- |
|  | |
| **Product Type** | PT3- Veterinary hygiene |
| **Where relevant, an exact description of the authorised use** | Automatic non-medical teat disinfection. |
| **Target organism(s) (including development stage)** | Bacteria  Yeasts |
| **Field(s) of use** | Disinfection of teats by automated spraying after milking |
| **Application method(s)** | Automatic spraying in milking machine |
| **Application rate(s) and frequency** | Twice applications a day after each milking  Contact time 5 min |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Polyethylene high-density (PEHD) opaque containers of 10 kg, 20 kg, 60 kg, 200 kg, 1000 kg. |

***4.2.1.* *Use-specific instructions for use***

|  |
| --- |
| For use in automatic spraying in milking machine: fill the tank and use the product according to the recommendations of the equipment manufacturer. Enable automatic spraying. Adjust the settings of the equipment so that each teat is completely covered with the product for 5 min, the time required for disinfecting action on the skin. |

***4.2.2 Use-specific risk mitigation measures***

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

**4.3. Use description- Semi-automatic or manual disinfection by spraying (post-milking)**

|  |  |
| --- | --- |
| **Use # 9 – Semi-automated or manual spraying after milking** | |
| **Product Type** | PT3- Veterinary hygiene |
| **Where relevant, an exact description of the authorised use** | Manual non-medical teat disinfection |
| **Target organism(s) (including development stage)** | Bacteria  Yeasts |
| **Field(s) of use** | Disinfection of teats by semi-automated or manual spraying after milking |
| **Application method(s)** | Semi-automated or manual spraying |
| **Application rate(s) and frequency** | Twice applications a day after each milking  Contact time 5 min |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Polyethylene high-density (PEHD) containers of 10 kg, 20 kg, 60 kg, 200 kg, 1000 kg. |

***4.3.1.* *Use-specific instructions for use***

|  |
| --- |
| For use in semi-automatic or manual spraying with suitable material in good condition. Spray the product carefully so that the entire surface of the teats is covered during 5 minutes, the time required for disinfecting action on the skin. |

***4.3.2 Use-specific risk mitigation measures***

|  |
| --- |
| - Wear protective chemical resistant gloves (material to be specified by the authorisation holder within the product information) during loading and application of the product and a protective coverall (at least category III type 6, EN13034) during application. |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

**5. General directions for use of the meta SPC**

**5.1. Instructions for use**

|  |
| --- |
| * Always read the label or leaflet before use and follow all the instructions provided. * The product must be brought to a temperature above 20°C before use. * Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes) * In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection |

**5.2. Risk mitigation measures**

|  |
| --- |
|  |

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

|  |
| --- |
| * 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. * Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur. * Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested. * Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled. * In case of impaired consciousness place in recovery position and seek medical advice immediately. Do not give fluids or induce vomiting. * Keep the container or label available. |

**5.4. Instructions for safe disposal of the product and its packaging**

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

**5.5. Conditions of storage and shelf-life of the product under normal conditions of storage**

|  |
| --- |
| * Keep out of reach of children * Protect from frost * Do not store above a temperature of 15°C * Do not store more than 24 months * Store away from direct sunlight |

**6. Other information**

|  |
| --- |
| * The product contains pyrrolidones derivatives. Do not use in case of known hypersensitivity. |

**7. Third information level: individual products in the meta SPC**

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **META SPC 3 - PRODUCT 1** | | | | | |
| **Trade name(s)** | IOSPRAY FLUIDE  LUX SPRAY 50 NV  IODE LIQUIDE  HYDRA IODE LIQUIDE  VITA IODE FLUIDE | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Polyvinylpyrrolidone  iodine | 2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. with iodine | Active substance | 25655-41-8 | Not assigned | 1.5 |
| Iodine\* | Iodine\* | 7553-56-2 | 231-442-4 | 0.13 |

\*Minimum content of available iodine in PVPi : 9% *(viewing the min. purity of iodine, technical content is identical to the pure content)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **META SPC 3 - PRODUCT 2** | | | | | |
| **Trade name(s)** | DIP SPRAY IODINE | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Polyvinylpyrrolidone  iodine | 2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. with iodine | Active substance | 25655-41-8 | Not assigned | 2 |
| Iodine\* | Iodine\* | 7553-56-2 | 231-442-4 | 0.18 |

\*Minimum content of available iodine in PVPi : 9% *(viewing the min. purity of iodine, technical content is identical to the pure content)*

**Part II. - Second information level - meta SPC 4**

**1. Meta SPC administrative information**

* 1. **Meta SPC identifier**

| **Identifier** | Meta SPC 4 |
| --- | --- |

**1.2. Suffix to the authorisation number**

|  |  |
| --- | --- |
| **Number** | - |

**1.3. Product type(s)**

| **Product type(s)** | PT 3 Veterinary hygiene |
| --- | --- |

**2. Meta SPC composition**

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Polyvinylpyrrolidone iodine | 2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. with iodine | Active substance | 25655-41-8 | Not assigned | 1,5 | 2.9 |
| Iodine\* | Iodine\* | 7553-56-2 | 231-442-4 | 0.13 | 0.26 |
| Sodium lauryl ether sulfate |  | Surfactant | 68891-38-3 |  | 0 | 0 |

\*Minimum content of available iodine in PVPi : 9% *(viewing the min. purity of iodine, technical content is identical to the pure content)*

**2.2. Type(s) of formulation of the meta SPC**

| **Formulation** | AL-any Other liquids |
| --- | --- |

**3. Hazard and precautionary statements of the meta SPC**

|  |  |
| --- | --- |
| **Classification** | |
| Hazard category | Eye irrit. Category 2  Aquatic chronic cat 3 |
| Hazard statement | H319: Causes serious eye irritation  H412: Harmful to aquatic life with long-lasting effects |
|  | |
| **Labelling** | |
| Signal words | Warning  Danger |
| Hazard statements | H319: Causes serious eye irritation.  H412: Harmful to aquatic life with long-lasting effects |
| Precautionary statements | P264: Wash … thoroughly after handling  P273 – Avoid release to the environment  P280: Wear protective gloves/protective clothing/eye protection/face protection.  P305+P351 +P338: F IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P337 + P313: If eye irritation persists: Get medical advice/ attention  P501 - Dispose of contents/container in accordance with local/ regional/national/international regulation (to be specified). |
|  | |
| Note |  |

**4. Authorised use(s) of the meta SPC**

**4.1. Use description- Manual disinfection by dipping (post-milking)**

|  |  |
| --- | --- |
|  | |
| **Product Type** | PT3- Veterinary hygiene |
| **Where relevant, an exact description of the authorised use** | Manual non-medical teat disinfection |
| **Target organism(s) (including development stage)** | Bacteria  Yeasts |
| **Field(s) of use** | Disinfection of teats by manual thick liquid teat dipping after milking |
| **Application method(s)** | Application with a dipping cup |
| **Application rate(s) and frequency** | Twice applications a day after each milking  Contact time 5 min |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Polyethylene high-density (PEHD) containers of 10 kg, 20 kg, 60kg, 200kg, 1000kg. |

***4.1.1.* *Use-specific instructions for use***

|  |
| --- |
| - For use with a dipping cup of 300 ml. Fill a clean and dry cup to three quarters (225 ml). Exercise enough pressures (about 3 to 6) to bring the product up in the dip cup and fill it up to two thirds. Dip each teat in order to have a homogeneous distribution on the udder. |

***4.1.2 Use-specific risk mitigation measures***

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

**5. General directions for use of the meta SPC**

**5.1. Instructions for use**

|  |
| --- |
| * Always read the label or leaflet before use and respect follow all the instructions provided. * Respect the conditions of use of the product (concentration, contact time, ...) * The product must be brought to a temperature above 20°C before use. * Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes) * In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection |

**5.2. Risk mitigation measures**

|  |
| --- |
|  |

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

|  |
| --- |
| * 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. * Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur. * Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested. * Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled. * In case of impaired consciousness place in recovery position and seek medical advice immediately. Do not give fluids or induce vomiting. * Keep the container or label available. |

**5.4. Instructions for safe disposal of the product and its packaging**

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

**5.5. Conditions of storage and shelf-life of the product under normal conditions of storage**

|  |
| --- |
| * Keep out of reach of children * Protect from frost * Do not store above a temperature of 15°C * Do not store more than 12 months * Store away from direct sunlight |

**6. Other information**

|  |
| --- |
| * The product contains pyrrolidones derivatives. Do not use in case of known hypersensitivity |

**7. Third information level: individual products in the meta SPC**

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

| **META SPC 4 – PRODUCT 1** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **VITA IODE EPAIS**  **IOSPRAY EPAIS**  **IODE EPAIS**  **EXPERT IODE DIP**  **TREMP IODE**  **BOVIODE**  **HYDRA IODE EPAIS** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Polyvinylpyrrolidone iodine | 2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. with iodine | Active substance | 25655-41-8 | Not assigned | 1,5 |
| Iodine\* | Iodine\* |  | 7553-56-2 | 231-442-4 | 0.13 |

\*Minimum content of available iodine in PVPi : 9% *(viewing the min. purity of iodine, technical content is identical to the pure content)*

| **META SPC 4 – PRODUCT 2** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **VISCONET HP**  **DIP CARE IODINE** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Polyvinylpyrrolidone iodine | 2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. with iodine | Active substance | 25655-41-8 | Not assigned | 2 |
| Iodine\* | Iodine\* |  | 7553-56-2 | 231-442-4 | 0.18 |

\*Minimum content of available iodine in PVPi : 9% *(viewing the min. purity of iodine, technical content is identical to the pure content)*

| **META SPC 4 – PRODUCT 3** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **DERMOPROTECT**  **DIP CARE IODINE 2900** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Polyvinylpyrrolidone iodine | 2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. with iodine | Active substance | 25655-41-8 | Not assigned | 2.90 |
| Iodine\* | Iodine\* |  | 7553-56-2 | 231-442-4 | 0.26 |

\*Minimum content of available iodine in PVPi : 9% *(viewing the min. purity of iodine, technical content is identical to the pure content)*

**Part II. - Second information level - meta SPC 5**

**1. Meta SPC administrative information**

* 1. **Meta SPC identifier**

| **Identifier** | Meta SPC 5 |
| --- | --- |

* 1. **Suffix to the authorisation number**

|  |  |
| --- | --- |
| **Number** | - |

* 1. **Product type(s)**

| **Product type(s)** | PT 3 |
| --- | --- |

**2. Meta SPC composition**

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Polyvinylpyrrolidone iodine | 2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. with iodine | Active substance | 25655-41-8 | Not assigned | 1,5 | 2.9 |
| Iodine\* | Iodine\* | 7553-56-2 | 231-442-4 | 0.13 | 0.26 |
| Sodium lauryl ether sulfate |  | Surfactant | 68891-38-3 |  | 0.94 | 0.94 |

\*Minimum content of available iodine in PVPi : 9% *(viewing the min. purity of iodine, technical content is identical to the pure content)*

**2.2. Type(s) of formulation of the meta SPC 5**

| **Formulation** | AL-Any Other liquids |
| --- | --- |

**3. Hazard and precautionary statements of the meta SPC**

| **Classification** | |
| --- | --- |
| Hazard category | Eye Dam. Category 1  Aquatic chronic cat 3 |
| Hazard statement | H318: Causes serious eye damage.  H412: Harmful to aquatic life with long-lasting effects |
|  | |
| **Labelling** | |
| Signal words | ghs05  Danger |
| Hazard statements | H318: Causes serious eye damage.  H412: Harmful to aquatic life with long-lasting effects |
| Precautionary statements | P273 – Avoid release to the environment  P280: Wear protective gloves/protective clothing/eye protection/face protection.  P305+P351 +P338: F IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P310: . Immediately call a POISON CENTER/doctor/  P501 - Dispose of contents/container in accordance with local/ regional/national/international regulation (to be specified). |
|  | |
| Note |  |

**4. Authorised use(s) of the meta SPC 5**

**4.1. Use description- Manual disinfection by dipping after milking**

|  |  |
| --- | --- |
|  | |
| **Product Type** | PT3- Veterinary hygiene |
| **Where relevant, an exact description of the authorised use** | Manual non-medical teat disinfection |
| **Target organism(s) (including development stage)** | Bacteria  Yeasts |
| **Field(s) of use** | Disinfection of teats by manual thick liquid film forming teat dipping after milking |
| **Application method(s)** | Application with a dipping cup |
| **Application rate(s) and frequency** | Twice applications a day after each milking  Contact time 5 min |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Polyethylene high-density (PEHD) containers of 10 kg, 20 kg, 60 kg, 200 kg, 1000 kg. |

***4.1.1.* *Use-specific instructions for use***

|  |
| --- |
| For use with a dipping cup of 300 ml. Fill a clean and dry cup to three quarters (225 ml). Exercise enough pressures (about 3 to 6) to bring the product up in the dip cup and fill it up to two thirds. Dip each teat in order to have a homogeneous distribution on the udder. |

***4.1.2 Use-specific risk mitigation measures***

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

**5. General directions for use of the meta SPC**

**5.1. Instructions for use6**

|  |
| --- |
| * Always read the label or leaflet before use and follow all the instructions provided. * The product must be brought to a temperature above 20°C before use. * Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes) * In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection |

**5.2. Risk mitigation measures**

|  |
| --- |
|  |

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

|  |
| --- |
| * 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. * Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur. * Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested. * Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled. * In case of impaired consciousness place in recovery position and seek medical advice immediately. Do not give fluids or induce vomiting. * Keep the container or label available. |

**5.4. Instructions for safe disposal of the product and its packaging**

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

**5.5. Conditions of storage and shelf-life of the product under normal conditions of storage**

|  |
| --- |
| * Keep out of reach of children * Protect from frost * Do not store above a temperature of 15°C * Do not store more than 3 months * Store away from direct sunlight |

**6. Other information**

|  |
| --- |
| * The product contains pyrrolidones derivatives. Do not use in case of known hypersensitivity. |

**7. Third information level: individual products in the meta SPC**

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **META SPC 5 – PRODUCT 1** | | | | | |
| **Trade name(s)** | **FILMA IODE**  **LUXDIP 50 B NB**  **FILM'PROTECT PLUS**  **CAP IODINE**  **BOVIFILM NF**  **FILM IODE PLUS** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Polyvinylpyrrolidone iodine | 2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. with iodine | Active substance | 25655-41-8 | Not assigned | 1,5 |
| Iodine\* | Iodine\* |  | 7553-56-2 | 231-442-4 | 0.13 |
| Sodium lauryl ether sulfate |  |  | 68891-38-3 |  | 0.94 |

\*Minimum content of available iodine in PVPi : 9% *(viewing the min. purity of iodine, technical content is identical to the pure content)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **META SPC 5 – PRODUCT 2** | | | | | |
| **Trade name(s)** | **IODINE GUARD**  **FILM IODE** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Polyvinylpyrrolidone iodine | 2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. with iodine | Active substance | 25655-41-8 | Not assigned | 1,5 |
| Iodine\* | Iodine\* |  | 7553-56-2 | 231-442-4 | 0.13 |
| Sodium lauryl ether sulfate |  |  | 68891-38-3 |  | 0.94 |

\*Minimum content of available iodine in PVPi : 9% *(viewing the min. purity of iodine, technical content is identical to the pure content)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **META SPC 5 – PRODUCT 3** | | | | | |
| **Trade name(s)** | CAP IODINE SPC  DIP FILM IODINE | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Polyvinylpyrrolidone iodine | 2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. with iodine | Active substance | 25655-41-8 | Not assigned | 2 |
| Iodine\* | Iodine\* |  | 7553-56-2 | 231-442-4 | 0.18 |
| Sodium lauryl ether sulfate |  |  | 68891-38-3 |  | 0.94 |

\*Minimum content of available iodine in PVPi : 9%

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **META SPC 5 – PRODUCT 4** | | | | | |
| **Trade name(s)** | **CAP IODINE FORTE** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Polyvinylpyrrolidone iodine | 2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. with iodine | Active substance | 25655-41-8 | Not assigned | 2.9 |
| Iodine\* | Iodine\* |  | 7553-56-2 | 231-442-4 | 0.26 |
| Sodium lauryl ether sulfate |  |  | 68891-38-3 |  | 0.94 |

\*Minimum content of available iodine in PVPi : 9% *(viewing the min. purity of iodine, technical content is identical to the pure content)*

**Part II. - Second information level - meta SPC 6**

**1. Meta SPC administrative information**

* 1. **Meta SPC identifier**

| **Identifier** | Meta SPC 6 |
| --- | --- |

* 1. **Suffix to the authorisation number**

|  |  |
| --- | --- |
| **Number** | - |

* 1. **Product type(s)**

| **Product type(s)** | PT 3 |
| --- | --- |

**2. Meta SPC composition**

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Polyvinylpyrrolidone iodine | 2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. with iodine | Active substance | 25655-41-8 | Not assigned | 2.9 | 2.9 |
| Iodine\* | Iodine\* | 7553-56-2 | 231-442-4 | 0.26 | 0.26 |
| Sodium lauryl ether sulfate |  | Surfactant | 68891-38-3 |  | 0 | 0 |

\*Minimum content of available iodine in PVPi : 9% *(viewing the min. purity of iodine, technical content is identical to the pure content)*

**2.2. Type(s) of formulation of the meta SPC**

| **Formulation** | AL-any other liquids |
| --- | --- |

**3. Hazard and precautionary statements of the meta SPC**

|  |  |
| --- | --- |
| **Classification** | |
| Hazard category | Eye irrit. Category 2  Aquatic chronic cat 3 |
| Hazard statement | H319: Causes serious eye irritation.  H412: Harmful to aquatic life with long-lasting effects |
|  | |
| **Labelling** | |
| Signal words | warning |
| Hazard statements | H319: Causes serious eye irritation.  H412: Harmful to aquatic life with long-lasting effects |
| Precautionary statements | P264: Wash … thoroughly after handling  P273 – Avoid release to the environment  P280: Wear protective gloves/protective clothing/eye protection/face protection.  P305+P351 +P338: F IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P337 + P313: If eye irritation persists: Get medical advice/ attention  P501 - Dispose of contents/container in accordance with local/ regional/national/international regulation (to be specified). |
|  | |
| Note |  |

**4. Authorised use(s) of the meta SPC**

**4.1. Use description- Automatic disinfection by spraying (pre-milking and post-milking)**

|  |  |
| --- | --- |
|  | |
| **Product Type** | PT3- Veterinary hygiene |
| **Where relevant, an exact description of the authorised use** | Automatic non-medical teat disinfection |
| **Target organism(s) (including development stage)** | Pre-milking : bacteria  Post milking : bacteria and yeasts |
| **Field(s) of use** | disinfection of teats by automated spraying before and after milking |
| **Application method(s)** | Automatic spraying in milking machine |
| **Application rate(s) and frequency** | Before milking: twice applications a day before each milking  Contact time: 1 min for pre milking, clean conditions  After milking: twice applications a day aftereach milking  Contact time: 5 min for post milking |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Polyethylene high-density (PEHD) containers of 10 kg, 20 kg, 60 kg, 200 kg, 1000 kg. |

***4.1.1.* *Use-specific instructions for use***

|  |
| --- |
| For use in automatic spraying in milking machine: fill the tank and use the product according to the recommendations of the equipment manufacturer. Enable automatic spraying. Adjust the equipment to enable covering of the entire surface of the teats during one minute in order to ensure good disinfection of the skin.  Before milking, adjust the settings of the equipment so that the product is removed from the teats before connecting the beams. After milking, repeat the automatic spraying operation so that the entire surface of the teats is covered during 5 minutes, the time required for isinfecting action on the skin |

***4.1.2 Use-specific risk mitigation measures***

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

**5. General directions for use of the meta SPC**

**5.1. Instructions for use**

|  |
| --- |
| * Always read the label or leaflet before use and all the instructions provided. * Clean carefully the teats before application of the product for pre-milking. * For post milking, leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes) * The product must be brought to a temperature above 20°C before use. |

**5.2. Risk mitigation measures**

|  |
| --- |
| * Wear protective chemical resistant gloves (material to be specified by the authorisation holder within the product information) during loading and application of the products and during the wiping of the teats |

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

|  |
| --- |
| * 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. * Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur. * Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested. * Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled. * In case of impaired consciousness place in recovery position and seek medical advice immediately. Do not give fluids or induce vomiting. * Keep the container or label available. |

**5.4. Instructions for safe disposal of the product and its packaging**

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

**5.5. Conditions of storage and shelf-life of the product under normal conditions of storage**

|  |
| --- |
| * Keep out of reach of children * Protect from frost * Do not storage above a temperature of 15°C * Do not stor more than 12 months * Store away from direct sunlight |

**6. Other information**

|  |
| --- |
| * The product contains pyrrolidones derivatives. Do not use in case of known hypersensitivity. |

**7. Third information level: individual products in the meta SPC**

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | | | | |
| **Trade name(s)** | **IODI FULL MILKING**  **PRE POST SPRAY IODINE**  **MULTI IODE FLUIDE** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Polyvinylpyrrolidone iodine | 2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. with iodine | Active substance | 25655-41-8 | Not assigned | 2.9 |
| Iodine\* | Iodine\* | 7553-56-2 | 231-442-4 | 0.26 |

\*Minimum content of available iodine in PVPi : 9% *(viewing the min. purity of iodine, technical content is identical to the pure content)*

### 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)** |
| Containers, barrels and tanks | 10 kg  20 kg  60 kg  200 kg  1000 kg | Opaque HDPE | Hermetically closed | 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 family HYDRACHIM Iodine Family were provided by HYDRACHIM SAS.

**Efficacy data**

**META-SPC1 and META-SPC6**: The following efficacy studies were submitted with the product META-SPC 1 AL (1.5 % or 2.9 % PVPI):

* For bacteria :
* Laboratory study according to EN 1656 standard (phase 2, step 1).
* Laboratory study according to EN 16437 standard modified on artificial skin (phase 2, step 2).
* For yeasts:
* Laboratory study according to EN 1657 standard (phase 2, step 1).
* Laboratory study according to EN 16437 standard modified on artificial skin (phase 2, step 2).
* For phages:
* Laboratory study according to EN 13610 standard (phase 2, step 1).
* Laboratory study according to EN 16437 standard modified on artificial skin (phase 2, step 2).

**META-SPC3** : The following efficacy studies were submitted with the product META-SPC 3 AL (1.5 % PVPI):

* For bacteria :
* Laboratory study according to EN 1656 standard (phase 2, step 1).
* Laboratory study according to EN 16437 standard modified on artificial skin (phase 2, step 2).
* For yeasts:
* Laboratory study according to EN 1657 standard (phase 2, step 1).
* Laboratory study according to EN 16437 standard modified on artificial skin (phase 2, step 2).

**META-SPC4** : The following efficacy studies were submitted with the product META-SPC 4 AL (1.5 % PVPI):

* For bacteria :
* Laboratory study according to EN 1656 standard (phase 2, step 1).
* Laboratory study according to EN 16437 standard modified on artificial skin (phase 2, step 2).
* For yeasts:
* Laboratory study according to EN 1657 standard (phase 2, step 1).
* Laboratory study according to EN 16437 standard modified on artificial skin (phase 2, step 2).

**META-SPC5** : The following efficacy studies were submitted with the product META-SPC 5 AL (1.5 % PVPI):

* For bacteria :
* Laboratory study according to EN 1656 standard (phase 2, step 1).
* Laboratory study according to EN 16437 standard modified on artificial skin (phase 2, step 2).
* For yeasts:
* Laboratory study according to EN 1657 standard (phase 2, step 1).
* Laboratory study according to EN 16437 standard modified on artificial skin (phase 2, step 2).
* For virus:
* Laboratory study according to EN 14675 standard (phase 2, step 1).

The following efficacy studies were submitted with the product META-SPC 5 AL (2 % PVPI):

* For bacteria (*L.monocytogenes*, *E, hirae*) :
* Laboratory study according to EN 16437 standard modified on artificial skin (phase 2, step 2).

Access to documentation

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

HYDRACHIM SAS has access to analytical methods on the active substance Iodine with a Letter of Access of SCC, secretary of IRG, applicant of the active substance iodine.

## Assessment of the biocidal product

### Intended uses as applied for by the applicant

**META- SPC 1**

**Table 1-use 1 - Manual disinfection by dipping (pre-milking)**

|  |  |
| --- | --- |
| **Use # 1 – Liquid dipping before milking** | |
| **Product Type** | PT3- Veterinary hygiene |
| **Where relevant, an exact description of the authorised use** | Manual non-medical teat disinfection |
| **Target organism(s) (including development stage)** | Bacteria (additional strains : *E cloacae, L.brevis, P.aeruginosa, P.vulgaris, S.*Typhimurium*)*  yeasts and bacteriophages |
| **Field(s) of use** | Cleaning and disinfection of teats by manual dipping before milking |
| **Application method(s)** | Application with a dipping cup |
| **Application rate(s) and frequency** | at each milking (twice a day) - ready-to-use product - |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Polyethylene high-density (PEHD) opaque containers of 10 kg, 20 kg, 60kg, 200kg, 1000kg. |

**Table 2 Use 1 - Manual disinfection by foam dipping (pre-milking)**

|  |  |
| --- | --- |
| **Use # 2 – Liquid dipping with foam before milking** | |
| **Product Type** | PT3- Veterinary hygiene |
| **Where relevant, an exact description of the authorised use** | Manual non-medical teat disinfection |
| **Target organism(s) (including development stage)** | Bacteria (additional strains : *E cloacae, L.brevis, P.aeruginosa, P.vulgaris, S.*Typhimurium*)*  yeasts and bacteriophages |
| **Field(s) of use** | Cleaning and disinfection of teats by manual foam teat dipping before milking |
| **Application method(s)** | Application with a foam dipping cup |
| **Application rate(s) and frequency** | at each milking (twice a day) - ready-to-use product - |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Polyethylene high-density (PEHD) opaque containers of 10 kg, 20 kg, 60 kg, 200 kg, 1000 kg. |

**Table 3 Use 3- Automatic disinfection by spraying (pre-milking)**

|  |  |
| --- | --- |
| **Use # 3 – Automated spraying before milking** | |
| **Product Type** | PT3- Veterinary hygiene |
| **Where relevant, an exact description of the authorised use** | Automatic non-medical teat disinfection |
| **Target organism(s) (including development stage)** | Bacteria (additional strains : *E cloacae, L.brevis, P.aeruginosa, P.vulgaris, S.*Typhimurium*)*  yeasts and bacteriophages |
| **Field(s) of use** | Cleaning and disinfection of teats by automated spraying before milking |
| **Application method(s)** | Automatic spraying in milking machine |
| **Application rate(s) and frequency** | at each milking (twice a day) - ready-to-use product - |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Polyethylene high-density (PEHD) containers of 10 kg, 20 kg, 60 kg, 200 kg, 1000 kg. |

**Table 4 Use 4 - Semi-automatic or manual disinfection by spraying (pre-milking)**

|  |  |
| --- | --- |
| **Use # 4 – Semi-automated or manual spraying before milking** | |
| **Product Type** | PT3- Veterinary hygiene |
| **Where relevant, an exact description of the authorised use** | Manual non-medical teat disinfection |
| **Target organism(s) (including development stage)** | Bacteria (additional strains : *E cloacae, L.brevis, P.aeruginosa, P.vulgaris, S.*Typhimurium*)*  yeasts and bacteriophages |
| **Field(s) of use** | Cleaning and disinfection of teats by manual spraying before milking |
| **Application method(s)** | Semi-automated or manual spraying |
| **Application rate(s) and frequency** | at each milking (twice a day) - ready-to-use product - |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Polyethylene high-density (PEHD) containers of 10 kg, 20 kg, 60kg, 200kg, 1000kg. |

**META SPC 3**

**.Table 7 Use 7- Liquid dipping after milking (1.5% PVPi)**

|  |  |
| --- | --- |
| **Use # 7 – Liquid dipping after milking** | |
| **Product Type** | PT03 - Veterinary hygiene (Disinfectants) |
| **Where relevant, an exact description of the authorised use** | Manual non-medical teat disinfection. |
| **Target organism(s) (including development stage)** | Bacteria (additional strains : *E.cloacae, E.hirae, L.brevis, L.monocytogenes, P.vulgaris, P.aeruginosa, S.agalactiae, S.*Typhimurium)  Yeasts |
| **Field(s) of use** | Indoor |
| **Application method(s)** | Open system: dip treatment |
| **Application rate(s) and frequency** | at each milking (twice a day) - ready-to-use product - |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Polyethylene high-density (PEHD) containers of 10 kg, 20 kg, 60kg, 200kg, 1000kg. |

**Tabel 8a Use 8- Automatic disinfection by spraying (post-milking)**

|  |  |
| --- | --- |
| **Use # 8 – Automated spraying after milking PVPi 1.5 %** | |
| **Product Type** | PT3- Veterinary hygiene |
| **Where relevant, an exact description of the authorised use** | Automatic non-medical teat disinfection. |
| **Target organism(s) (including development stage)** | Bacteria (additional strains : *E.cloacae, E.hirae, L.brevis, L.monocytogenes, P.vulgaris, P.aeruginosa, S.agalactiae, S.*Typhimurium)  Yeasts |
| **Field(s) of use** | Indoor |
| **Application method(s)** | Spraying |
| **Application rate(s) and frequency** | at each milking (twice a day) - ready-to-use product - |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Polyethylene high-density (PEHD) containers of 10 kg, 20 kg, 60 kg, 200 kg, 1000kg. |

**Tabel 8b Use 8- Automated disinfection by spraying (post-milking)**

|  |  |
| --- | --- |
| **Use # 8b – Automated spraying after milking PVPi 2 %** | |
| **Product Type** | PT3- Veterinary hygiene |
| **Where relevant, an exact description of the authorised use** | Automatic non-medical teat disinfection. |
| **Target organism(s) (including development stage)** | Bacteria (additional strains : *E.cloacae, E.hirae, L.brevis, L.monocytogenes, P.vulgaris, P.aeruginosa, S.agalactiae, S.*Typhimurium)  Yeasts |
| **Field(s) of use** | Indoor |
| **Application method(s)** | Spraying |
| **Application rate(s) and frequency** | at each milking (twice a day) - ready-to-use product -  at each milking (twice a day) |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Polyethylene high-density (PEHD) containers of 10 kg, 20 kg, 60 kg, 200 kg, 1000 kg. |

**Tabel 9 Use 9- Semi-automated or manual spraying (post-milking)**

|  |  |
| --- | --- |
| **Use # 9 – Semi-automated or manual spraying after milking** | |
| **Product Type** | PT3- Veterinary hygiene |
| **Where relevant, an exact description of the authorised use** | Manual non-medical teat disinfection |
| **Target organism(s) (including development stage)** | Bacteria (additional strains : *E.cloacae, E.hirae, L.brevis, L.monocytogenes, P.vulgaris, P.aeruginosa, S.agalactiae, S.*Typhimurium)  Yeasts |
| **Field(s) of use** | Indoor |
| **Application method(s)** | Semi-automated or manual spraying |
| **Application rate(s) and frequency** | at each milking (twice a day) - ready-to-use product -  ) |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Polyethylene high-density (PEHD) containers of 10 kg, 20 kg, 60 kg, 200 kg, 1000 kg. |

**META SPC 4**

**Tabel 10 Use 10- Thick liquid dipping after milking (post-milking)**

|  |  |
| --- | --- |
| **Use # 10 – Thick liquid dipping after milking** | |
| **Product Type** | PT3- Veterinary hygiene |
| **Where relevant, an exact description of the authorised use** | Manual non-medical teat disinfection |
| **Target organism(s) (including development stage)** | Bacteria (additional strains : *E.cloacae, E.hirae, L.brevis, L.monocytogenes, P.vulgaris, P.aeruginosa, S.agalactiae, S.*Typhimurium) and yeasts |
| **Field(s) of use** | Disinfection of teats by manual thick liquid teat dipping after milking |
| **Application method(s)** | Application with a dipping cup |
| **Application rate(s) and frequency** | At each milking (twice a day) |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Polyethylene high-density (PEHD) containers of 10 kg, 20 kg, 60 kg, 200 kg, 1000 kg. |

**META SPC 5**

**Table 11 a Use 11a- Manual disinfection by dipping (post-milking)**

|  |  |
| --- | --- |
| **Use # 11a – Thick film forming liquid dipping after milking (1.5 PVPi)** | |
| **Product Type** | PT3- Veterinary hygiene |
| **Where relevant, an exact description of the authorised use** | Manual non-medical teat disinfection |
| **Target organism(s) (including development stage)** | Bacteria (additional strains : *E.cloacae, E.hirae, L.brevis, L.monocytogenes, P.vulgaris, P.aeruginosa, S.agalactiae, S.*Typhimurium)  Yeasts  Envelopped virus |
| **Field(s) of use** | Disinfection of teats by manual thick liquid film forming teat dipping after milking |
| **Application method(s)** | Application with a dipping cup |
| **Application rate(s) and frequency** | at each milking (twice a day) - ready-to-use product - |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Polyethylene high-density (PEHD) containers of 10 kg, 20 kg, 60 kg, 200 kg, 1000 kg. |

**Table 11b-Use 11b: Thick film forming liquid dipping (post-milking)**

|  |  |
| --- | --- |
| **Use # 11b – Thick film forming liquid dipping after milking (2 % PVPi)** | |
| **Product Type** | PT3- Veterinary hygiene |
| **Where relevant, an exact description of the authorised use** | Manual non-medical teat disinfection |
| **Target organism(s) (including development stage)** | Bacteria (additional strains : *E.cloacae, E.hirae, L.brevis, L.monocytogenes, P.vulgaris, P.aeruginosa, S.agalactiae, S.*Typhimurium)  Yeasts  Envelopped virus |
| **Field(s) of use** | Disinfection of teats by manual thick liquid film forming teat dipping after milking |
| **Application method(s)** | Application with a dipping cup |
| **Application rate(s) and frequency** | at each milking (twice a day) - ready-to-use product - |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Polyethylene high-density (PEHD) containers of 10 kg, 20 kg, 60 kg, 200 kg, 1000 kg. |

**META-SPC 6**

**Table 12 Use 12- Automatic disinfection by spraying (pre-milking and post-milking)**

|  |  |
| --- | --- |
| **Use # 12 – Automatic spraying before and after milking** | |
| **Product Type** | PT3- Veterinary hygiene |
| **Where relevant, an exact description of the authorised use** | Automatic non-medical teat disinfection |
| **Target organism(s) (including development stage)** | Bacteria (additional strains : *E.cloacae, L.brevis, P.vulgaris, P.aeruginosa, S.*Typhimurium)  yeasts and bacteriophages |
| **Field(s) of use** | Cleaning and disinfection of teats by automated spraying before and after milking |
| **Application method(s)** | Automatic spraying in milking machine |
| **Application rate(s) and frequency** | Two applications (pre and post milking) at each milking (twice a day) - ready-to-use product |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Polyethylene high-density (PEHD) containers of 10 kg, 20 kg, 60kg, 200 kg, 1000 kg. |

### Physical, chemical and technical properties

The biocidal product family HYDRACHIM IODINE FAMILY is not the same as the one 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.

The product family contains 1.5-2.9 % of PVPI with min. 9% of available iodine. All products of the family HYDRACHIM IODINE FAMILY are ready-to-use.

META SPC 2 was no longer supported by the notifier. Therefore, it was deleted from this dossier.

The complete results are summerised below:

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Intern method | Minimal content of iodine formulation  ***FIMIN-2015-02-09-VL***  META SPC 1 AL  ***ALILAVT-2015-11-09-VL***  META SPC 3 AL  ***ALILAPT-2015-02-10-VL***  META SPC 4 AL  ***ALIEAPT-2015-02-11-VL***  META SPC 5  ***~~FIMAX-2015-02-13-VL~~***  ***FIMAX-2015-11-12-VL*** | Meta SPC1~~2~~,3,5 and 6: Translucent liquid  Meta SPC 4: Thick translucent liquid | Acceptable | SERVAJEAN E., 2015  Report No :  ~~14-99-036-ES~~  15-99-091-ES  14-99-037-ES  14-99-038-ES  ~~14-99-040-ES~~  15-99-092-ES  14-99-039-ES |
| Colour at 20 °C and 101.3 kPa | Intern method | Reddish brown for META SPC1,4,5 and 6  Brown for META SPC 3 | Acceptable |
| Odour at 20 °C and 101.3 kPa |  |  | Not required |  |  |
| Acidity / alkalinity | CIPAC method MT 75.3 | Minimal content of iodine formulation  ***FIMIN-2015-02-09-VL***  META SPC 1 AL  ***~~ALILAVT-2015-02-09-VL~~***  ***ALILAVT-2015-11-09-VL***  META SPC 3 AL  ***ALILAPT-2015-02-10-VL***  META SPC 4 AL  ***ALIEAPT-2015-02-11-VL***  META SPC 5  ***~~FIMAX-2015-02-13-VL~~***  ***FIMAX-2015-11-12-VL*** | |  |  |  | | --- | --- | --- | |  | Neat pH (at 20°C) | Dilution at 1% (at 20°C) | | Min content of iodine formulation | 4.2 | 5.3 | | Meta SPC 1 | 4.1 | 5.1 | | Meta SPC 3 | 3.2 | 5.0 | | Meta SPC 4 | 3.7 | 5.0 | | Meta SPC 5 | 4.3 | 4.9 | | Acceptable | SERVAJEAN E., 2015  Report No :  ~~14-99-036-ES~~  15-99-091-ES  14-99-037-ES  14-99-038-ES  ~~14-99-040-ES~~  15-99-092-ES  14-99-039-ES |
| Relative density / bulk density | OECD Guideline 109 | Minimal content of iodine formulation  ***FIMIN-2015-02-09-VL***  META SPC 1 AL  ***~~ALILAVT-2015-02-09-VL~~***  ***ALILAVT-2015-11-09-VL***  META SPC 3 AL  ***ALILAPT-2015-02-10-VL***  META SPC 4 AL  ***ALIEAPT-2015-02-11-VL***  META SPC 5  ***~~FIMAX-2015-02-13-VL~~***  ***FIMAX-2015-11-12-VL*** | |  |  | | --- | --- | |  | D20 | | Min content of iodine formulation | 1.001 | | Meta SPC 1 | 1.024 | | Meta SPC 3 | 1.018 | | Meta SPC 4 | 1.02 | | Meta SPC 5 | 1.039 | | Acceptable | SERVAJEAN E., 2015  Report No :  ~~14-99-036-ES~~  15-99-091-ES  14-99-037-ES  14-99-038-ES  ~~14-99-040-ES~~  15-99-092-ES  14-99-039-ES |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3  HPLC-UV method validated | META SPC 1&6 AL  ***~~ALILAVT-2015-02-09-VL~~***  ***ALILAVT-2015-11-09-VL*** | |  |  |  | | --- | --- | --- | | **META SPC 1 and META SPC 6** | | | |  | Initial | After 18 weeks at 30°C (HDPE) | | **Active subst; content** |  | | | PVPi | 28.95 g/kg | 29.67 g/kg (+1.1%) | | Total iodine | 4.94 g/kg | 4.67 g/kg (-5.5%) | | Available iodine | 3.11 g/kg | 2.62 g/kg (-15.8%) | | Appearance | Reddish brown translucent liquid | | | Packaging stability | 1L HDPE | A slight brown coloration of the initially white stopper, and of the sticker suggested iodine migration via the packaging.  No deformation of the packaging was observed. Loss of weight -0.05% | | pH (20°C) | Neat :4.1  1% : 5.1 | Neat :3.8  1% : 4.7 | | **META SPC 1&6**  Loss of available iodine content is >10%.  The iodine migration into the packaging is observed. The active substance is not stable when submitted to high temperatures.  **Note implicating labelling:**  **Do not store above 15°C.** | SERVAJEAN E., 2015  Report No :  ~~14-99-036-ES~~  15-99-091-ES |
| META SPC 3 AL  ***ALILAPT-2015-02-10-VL*** | |  |  |  | | --- | --- | --- | | **META SPC 3** | | | |  | Initial | After 18 weeks at 30°C (HDPE) | | **Active subst; content** |  | | | PVPi | 14.73 g/kg | 14.7 g/kg (-0.2%) | | Total iodine | 2.51 g/kg | 2.4 g/kg (-4.4%) | | Available iodine | 1.40 g/kg | 1.2 g/kg (-14.3%) | | Appearance | Reddish brown translucent liquid | | | Packaging stability | 1L HDPE  1074.26 g | A slight yellowish coloration of the initially white stopper, and of the sticker suggested iodine migration via the packaging.  No deformation of the packaging was observed.  1073.68 (-0.05%) | | pH (20°C) | Neat :3.2  1% : 5.0 | Neat :2.7  1% : 4.8 | | **META SPC 3**  Loss of available iodine content is >10%. The iodine migration into the packaging is observed. The active substance is not stable when submitted to high temperatures.  **Note implicating labelling:**  **Do not store above 15°C.** | SERVAJEAN E., 2015  Report No :  14-99-037-ES |
| META SPC 4 AL  ***ALIEAPT-2015-02-11-VL*** | |  |  |  | | --- | --- | --- | | **META SPC 4** | | | |  | Initial | After 18 weeks at 30°C (HDPE) | | **Active subst; content** |  | | | PVPi | 14.50 g/kg | 15.9 g/kg (+9.7%) | | Total iodine | 2.49 g/kg | 2.4 g/kg (-3.6%) | | Available iodine | 1.44 g/kg | 0.8 g/kg (-44.4%) | | Appearance | Reddish brown translucent liquid | Orange-brown translucent liquid | | Packaging stability | 1L HDPE  1014.62 g | A slight yellowish coloration of the initially white stopper, and of the sticker suggested iodine migration via the packaging.  No deformation of the packaging was observed.  1014.09 (-0.05%) | | pH (20°C) | Neat :3.7  1% : 5.0 | Neat :2.6  1% : 4.2 | | **META SPC 4**  Loss of available iodine content is important (>40%). The iodine migration into the packaging is observed. The active substance is not stable when submitted to high temperatures.  **Note implicating labelling:**  **Do not store above 15°C.** | SERVAJEAN E., 2015  Report No :  14-99-038-ES |
| META SPC 5  ***~~FIMAX-2015-02-13-VL~~***  ***FIMAX-2015-11-12-VL*** | |  |  |  | | --- | --- | --- | | **META SPC 5** | | | |  | Initial | After 18 weeks at 30°C (HDPE) | | **Active subst; content** |  | | | PVPi | 15.21 g/kg | 17.64 g/kg (+16%) | | Total iodine | 2.45 g/kg | 2.43 g/kg (-0.8%) | | Available iodine | 1.17 g/kg | 0.12 g/kg (-90%) | | Appearance | Reddish brown translucent liquid | Orange-brown translucent liquid | | Packaging stability | 1L HDPE | A slight yellowish coloration of the initially white stopper, and of the sticker suggested iodine migration via the packaging.  No deformation of the packaging was observed. Loss of weight -0.05% | | pH (20°C) | Neat :4.3  1% : 4.9 | Neat :3.3  1% : 4.0 | | Free acidity (% H2SO4 w/w) | 0.09 | 0.28 | | **META SPC 5**  Loss of available iodine content is very huge (90%). The iodine migration into the packaging is observed. The active substance is not stable when submitted to high temperatures.  **Note implicating labelling:**  **Do not store above 15°C.** | SERVAJEAN E., 2015  Report No :  ~~14-99-040-ES~~  15-99-092-ES |
| Minimal content of iodine formulation  ***FIMIN-2015-02-09-VL*** | |  |  |  | | --- | --- | --- | | **Minimal content of iodine formulation** | | | |  | Initial | After 18 weeks at 30°C (HDPE) | | **Active subst; content** |  | | | PVPi | 4.8 g/kg | 4.2 g/kg (-12.5%) | | Total iodine | 0.8 g/kg | 0.7 g/kg (-14.4%) | | Available iodine | 0.5 g/kg | 0.4 g/kg (-20.0%) | | Appearance | Brown translucent liquid | | | Packaging stability | 1L HDPE  1072.02 g | A slight yellowish coloration of the initially white stopper, and of the sticker suggested iodine migration via the packaging.  No deformation of the packaging was observed.  1071.52 (-0.05%) | | pH (20°C) | Neat :4.2  1% : 5.3 | Neat :3.6  1% : 5.4 | | **Minimal content of iodine formulation**  Loss of available iodine content is important (20%). The iodine migration into the packaging is observed. The active substance is not stable when submitted to high temperatures.  **Note implicating labelling:**  **Do not store above 15°C.** | SERVAJEAN E., 2015  Report No :  14-99-039-ES |
| Storage stability test – **long term storage at ambient temperature** | HPLC-UV method validated | META SPC 1 AL  ***ALILAVT-2015-11-09-VL*** | |  |  |  | | --- | --- | --- | | **META SPC 1&6** | | | |  | Initial | After 24 months at 15°C (HDPE) | | **Active subst; content** | | | | PVPi | 28.95 g/kg | 28.96 g/kg | | Total iodine | 4.94 g/kg | 4.91 g/kg | | Available iodine | 3.11 g/kg | 2.69 g/kg (-13.5%)  2.84 g/kg (-9%) after 12 months | | Appearence | Reddish brown translucent liquid | | | Packaging | No alteration | Coloured stopper | | pH | 4.1 (neat)  5.1 (1% dilution) | 4.0 (neat)  4.7 (1% dilution) | | Free acidity (% w/w H2SO4) | 0.12 | 0.18 | | **The final results of 2 years shelf life show that the content of available iodine is >10% after 24 months but the product is stable after 12 months at 15°C when stored in HDPE.**  The final concentration in available iodine observed, 2.69 g/kg, is greater than the minimal accepted amount of active substance upon product manufacture, which is 85% of the nominal concentration of 2.6 g/kg, i.e. 2.22 g/kg. Also, the observed contents in PVPi and total iodine during storage are stable, indicating that the measured loss in available iodine is due to transformation of iodine to iodide, and no greater risk is expected for humans or for the environment after storage than before. Finally, the physicochemical parameters of the product were shown to be stable throughout the storage period.  A shelf-life of two years is claimed by applicant.  eCA considers that the provided justification is not appropriate : even if the batch analysed is greater than the claimed concentration, it is not representative of the META SPC (as outside of the range).  Therefore, the shelf-life is fixed at 12 months. | SERVAJEAN E., 2017  Report No :  15-99-091-ES |
| META SPC 3 AL  ***ALILAPT-2015-02-10-VL*** | |  |  |  | | --- | --- | --- | | **META SPC 3** | | | |  | Initial | After 24 months at 15°C (HDPE) | | **Active subst; content** | | | | PVPi | 14.73 g/kg | 15.50 g/kg | | Total iodine | 2.51 g/kg | 2.40 g/kg | | Available iodine | 1.40 g/kg | 1.32 g/kg (-5.7%) | | Appearence | Reddish brown translucent liquid | | | Packaging | No alteration | No alteration | | pH | 3.2 (neat)  5.0 (1% dilution) | 2.7 (neat)  4.8 (1% dilution) | | Free acidity (% w/w H2SO4) | - | 0.07 | | **The final results of 2 years shelf life show that the product is stable after 24 months at 15°C when stored in HDPE. Therefore, the products of META SPC 3 are stable after 24 months at 15°C.** | SERVAJEAN E., 2017  Report No :  14-99-037-ES |
| META SPC 4 AL  ***ALIEAPT-2015-02-11-VL*** | |  |  |  | | --- | --- | --- | | **META SPC 4** | | | |  | Initial | After 24 months at 15°C (HDPE) | | **Active subst; content** | | | | PVPi | 14.50 g/kg | 15.47 g/kg | | Total iodine | 2.49 g/kg | 2.48 g/kg | | Available iodine | 1.44 g/kg | 1.12 g/kg (-22.2%)  1.31% after 12 months (-9%) | | Appearence | Reddish brown translucent liquid | | | Packaging | No alteration | | | pH | 3.7 (neat)  5.0 (1% dilution) | 3.1 (neat)  4.4 (1% dilution) | | Free acidity (% w/w H2SO4) | - | 0.06 | | **The final results of 2 years shelf life show that the content of available iodine is >10% after 24 months.**  The observed contents in PVPi and total iodine during storage are stable, indicating that the measured loss in available iodine is due to transformation of iodine to iodide, and no greater risk is expected for humans or for the environment after storage than before.  Moreover, physicochemical parameters were shown to be stable throughout the storage period.  A shelf-life of two years is thus claimed for Meta SPC 4 but only 12 months is proposed by eCA. | SERVAJEAN E., 2017  Report No :  14-99-038-ES |
| META SPC 5  ***FIMAX-2015-11-12-VL*** | |  |  |  | | --- | --- | --- | | **META SPC 5** | | | |  | Initial | After 24 months at 15°C (HDPE) | | **Active subst; content** |  | | | PVPi | 15.21 g/kg | 17.71 g/kg (+16.4%) | | Total iodine | 2.45 g/kg | 2.60 g/kg | | Available iodine | 1.17 g/kg | 0.39 g/kg (-67%)  0.60 g/kg (-49%) after 12 months  1.04 g/kg (-11%) after 3 months | | Appearence | Reddish brown translucent liquid | Orange translucent liquid | | Packaging | No alteration | | | pH | 4.3 (neat)  4.9 (1% dilution) | 3.5 (neat)  4.2 (1% dilution) | | Free acidity (% w/w H2SO4) | 0.09 | 0.049 | | The final results of 2 years shelf life show that the content of available iodine is >10% after 24 months. The product is not stable during all the long term storage.  The observed contents in PVPi and total iodine during storage are stable, indicating that the measured loss in available iodine is due to transformation of iodine to iodide, and no greater risk is expected for humans or for the environment after storage than before.  Also, efficacy studies performed on samples of the Meta SPC 5 representative product after one year of storage but this study was not assessed at this time of the dossier. Moreover, physicochemical parameters of the product did not change significantly after one year of storage.  A shelf-life of twelve months is thus claimed but only 3 months is given by eCA. | SERVAJEAN E., 2017  Report No :  15-99-092-ES |
| Minimal content of iodine formulation  ***FIMIN-2015-02-09-VL*** | |  |  |  | | --- | --- | --- | | **Minimal content of iodine formulation** | | | |  | Initial | After 24 months at 15°C (HDPE) | | **Active subst; content** |  | | | PVPi | 4.80 g/kg | 4.84 g/kg | | Total iodine | 0.82 g/kg | 0.75 g/kg | | Available iodine | 0.50 g/kg | 0.45 g/kg (-10%) | | Appearence | Reddish brown translucent liquid | Orange translucent liquid | | Packaging | No alteration |  | | pH | 4.3 (neat)  4.9 (1% dilution) | 3.5 (neat)  4.2 (1% dilution) | | Free acidity (% w/w H2SO4) | 0.09 | 0.049 | | **The product is stable after 24 months at 15°C.** | SERVAJEAN E., 2017  Report No :  14-99-039-ES |
| Storage stability test – **low temperature stability test for liquids** |  |  | All products will be labelled with the mention: “protect from frost”. | Acceptable |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | The active substance is sensitive to light effect. Nevertheless, the packagings are opaque HDPE containers. Moreover, a note on the label recommends storage away from direct sunlight. | - |  |
| 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 |  |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not relevant |  |  |
| Wet sieve analysis and dry sieve test |  |  | Not relevant |  |  |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not relevant |  |  |
| Disintegration time |  |  | Not relevant |  |  |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | Not relevant |  |  |
| Persistent foaming |  |  | Not relevant |  |  |
| Flowability/Pourability/Dustability |  |  | Not relevant |  |  |
| Burning rate — smoke generators |  |  | Not relevant |  |  |
| Burning completeness — smoke generators |  |  | Not relevant |  |  |
| Composition of smoke — smoke generators |  |  | Not relevant |  |  |
| Spraying pattern — aerosols |  |  | Not relevant |  |  |
| Physical compatibility |  |  | Not relevant |  |  |
| Chemical compatibility |  |  | Not relevant |  |  |
| Degree of dissolution and dilution stability |  |  | Not relevant |  |  |
| Surface tension | OECD Guideline 115 | Minimal content of iodine formulation  ***FIMIN-2015-02-09-VL***  META SPC 1 AL  ***~~ALILAVT-2015-02-09-VL~~***  ***ALILAVT-2015-11-09-VL***  META SPC 3 AL  ***ALILAPT-2015-02-10-VL***  META SPC 4 AL  ***ALIEAPT-2015-02-11-VL***  META SPC 5  ***~~FIMAX-2015-02-13-VL~~***  ***FIMAX-2015-11-12-VL*** | |  |  | | --- | --- | |  | Surface tension of neat products (mN/m) | | Min content of iodine formulation | 37.0 | | META SPC 1 | 32.7 | | META SPC 3 | 31.4 | | META SPC 4 | 36.8 | | META SPC 5 | 36.7 | | Acceptable  All products are surface active | SERVAJEAN E., 2015  Report No :  ~~14-99-036-ES~~  15-99-091-ES  14-99-037-ES  14-99-038-ES  ~~14-99-040-ES~~  15-99-092-ES  14-99-039-ES |
| Viscosity | OECD Guideline 114 | Minimal content of iodine formulation  ***FIMIN-2015-02-09-VL***  META SPC 1 AL  ***~~ALILAVT-2015-02-09-VL~~***  ***ALILAVT-2015-11-09-VL***  META SPC 3 AL  ***ALILAPT-2015-02-10-VL***  META SPC 4 AL  ***ALIEAPT-2015-02-11-VL***  META SPC 5  ***~~FIMAX-2015-02-13-VL~~***  ***FIMAX-2015-11-12-VL*** | |  |  | | --- | --- | |  | Kinematic Viscosity at 20°C (mm²/s) | | Min content of iodine formulation | 1.1 | | META SPC 1 | 1.8 | | META SPC 3 | 1.6 | | META SPC 4 | >20 000 | | META SPC 5 | 2366 | | Acceptable  Viscosity was tested only at 20°C.  As the products are aqueous based and therefore not classified H304 products, eCA considers that viscosity at 20°C is sufiscient and that the viscosity at 40°C will not result to a H304 hazard classement. | SERVAJEAN E., 2015  Report No :  ~~14-99-036-ES~~  15-99-091-ES  14-99-037-ES  14-99-038-ES  ~~14-99-040-ES~~  15-99-092-ES  14-99-039-ES |

|  |
| --- |
| **Conclusion on the respective characteristics of the product** |
| **META SPC1 and META SPC 6**  The products of META SPC 1 and META SPC 6 are an Another Liquid (AL) formulations, ready-to-use products. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of translucent brown liquid. The biocidal product is not stable at 30°C. The final results of 2 years shelf life show that the content of available iodine is >10% after 24 months at 15°C, whereas the product is stable after 12 months. Its technical characteristics are acceptable for an AL formulation.  **Implication concerning labelling for the META SPC 1 and 6:**   * Protect from frost * Do not store above 15°C. * Do not store more than 12 months * Store away from direct sunlight.   **META SPC3**  The products of META SPC 3 are an Another Liquid (AL) formulations, ready-to-use products. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of brown liquid, with no characteristic odour. There is a decrease of available iodine after 18 weeks at 30°C storage. The biocidal product is not stable at 30°C. The final results of 2 years shelf life show that the product is stable after 24 months at 15°C when stored in HDPE. Its technical characteristics are acceptable for an AL formulation.  **Implication concerning labelling for the META SPC:**   * Protect from frost * Do not store above 15°C. * Do not store more than 24 months * Store away from direct sunlight.   **META SPC4**  The META SPC 4 is an Another Liquid (AL) formulation, ready-to-use preparation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of brown liquid, with no characteristic odour. There is a decrease of available iodine after 18 weeks at 30°C storage. The biocidal product is not stable at 30°C. The final results of 2 years shelf life show that the content of available iodine is >10% after 24 months at 15°C whereas the product is stable after 12 months. Its other technical characteristics are acceptable for an AL formulation.  **Implication concerning labelling for the META SPC 4:**   * Protect from frost * Do not store above 15°C. * Do not store more than 12 months. * Store away from direct sunlight.   **META SPC5**  The META SPC 5 is an Another Liquid (AL) formulation, ready-to-use preparation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of brown liquid, with no characteristic odour. There is a decrease of available iodine after 18 weeks at 30°C storage. The biocidal product is not stable at 30°C. The final results of 2 years shelf life show that the content of available iodine is >10% after 6 months at 15°C**.** Its other technical characteristics are acceptable for an AL formulation.  **Implication concerning labelling for the META SPC:**   * Protect from frost * Do not store above 15°C. * Do not store more than 3 months * Store away from direct sunlight. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | Statement |  | All products in the family are water-based. No explosive compounds are used in the formulations. Moreover, the flash point for all product in the family was determined (using method EEC A9) to be >130°C. At 130 °C: boiling and denaturation of the test substance was observed without flashing | Acceptable |  |
| Flammable gases |  |  | Not relevant |  |  |
| Flammable aerosols |  |  | Not relevant |  |  |
| Oxidising gases |  |  | Not relevant |  |  |
| Gases under pressure |  |  | Not relevant |  |  |
| Flammable liquids | EEC A9 | Minimal content of iodine formulation  ***FIMIN-2015-02-09-VL***  META SPC 1 AL  ***~~ALILAVT-2015-02-09-VL~~***  ***ALILAVT-2015-11-09-VL***  META SPC 3 AL  ***ALILAPT-2015-02-10-VL***  META SPC 4 AL  ***ALIEAPT-2015-02-11-VL***  META SPC 5  ***~~FIMAX-2015-02-13-VL~~***  ***FIMAX-2015-11-12-VL*** | The flash point for all product in the family was determined (using method EEC A9) to be >130°C. At 130 °C: boiling and denaturation of the test substance was observed without flashing | Acceptable  The products are not flammable (according to CLP regulation). | SERVAJEAN E., 2015  Report No :  ~~14-99-036-ES~~  15-99-091-ES  14-99-037-ES  14-99-038-ES  ~~14-99-040-ES~~  15-99-092-ES  14-99-039-ES |
| Flammable solids |  |  | Not relevant |  |  |
| Self-reactive substances and mixtures | Statement |  | All products in the family are water-based. No self-reactive substances are used in the formulations. Moreover, the flash point for all product in the family was determined (using method EEC A9) to be >130°C. At 130 °C: boiling and denaturation of the test substance was observed without flashing. | Acceptable |  |
| Pyrophoric liquids | Statement |  | 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 |  |  | Not relevant |  |  |
| Substances and mixtures which in contact with water emit flammable gases |  |  | Not relevant |  |  |
| Oxidising liquids | Statement |  | The mixture contains no substances classified as oxidants. The CLP guidance states the following: "An inert material by definition does not contribute to the oxidising capability of the oxidising substance. Hence, the mixture can never be classified into a more severe hazard category. "(Guidance on the application of the CLP criteria, version 4.1, June 2015, p.205). | Acceptable  The products are not oxidising liquids. |  |
| Oxidising solids |  |  | Not relevant |  |  |
| Organic peroxides |  |  | Not relevant |  |  |
| Corrosive to metals | Statement |  | Only two minor components of the mixture are classified as Met. Corr. 1 (H290).  See confidential part. | Acceptable |  |
| Auto-ignition temperatures of products (liquids and gases) | Statement |  | All products in the family are water-based. No substances classified as flammable are used in the formulations. Moreover, the flash point for all product in the family was determined (using method EEC A9) to be >130°C. At 130 °C: boiling and denaturation of the test substance was observed without flashing. | Acceptable |  |
| Relative self-ignition temperature for solids |  |  | Not relevant |  |  |
| Dust explosion hazard |  |  | Not relevant |  |  |

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| --- |
| **Conclusion on the physical hazards of the product** |
| **ALL META SPC**  All products are not explosive and have no oxidizing properties. The products are not considered as flammable according to CLP regulation. |

### 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 applicant of the product family HYDRACHIM Iodine Family is not the applicant for the active substance but ta letter of access to these data has been submitted.

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

|  |  |
| --- | --- |
| **Report:** | **Servajean E., 2015** |
| Title: | Stability of ”AL iodée liquide avant traite” over accelerated storage and shelf-life determination  ~~Stability of ”SL iodée liquide avant traite” over accelerated storage and shelf-life determination~~  Stability of ”AL iodée liquide après traite” over accelerated storage and shelf-life determination  Stability of ”AL iodée épais après traite” over accelerated storage and shelf-life determination  Stability of ”formule iodée maximale” over accelerated storage and shelf-life determination  Stability of ”formule iodée minimale” over accelerated storage and shelf-life determination |
| Document No | ~~14-99-036-ES~~  15-99-091-ES  ~~14-99-035-ES~~  14-99-037-ES  14-99-038-ES  ~~14-99-040-ES~~  15-99-092-ES  14-99-039-ES |
| Test facility | PHYTOSAFE S.A.R.L.  2 rue de Marx Dormoy  64000 PAU  France |
| Guidelines: | SANCO/3030/99 rev.4 |
| GLP | Yes |

Preparation of accuracy samples:

**Determination of PVPi**

About 50 mg of test substance (PVPi) is diluted in 20 mL of water and added with an excess amount of dimethyl phenol for complexation with PVPi. The resulting PVPi-phenol complex is determined by HPLC-UV and external calibration using a certified PVPi as standard.

**Determination of total iodine**

About 50 mg of test substance (PVPi) is diluted in 20 mL of water and added with an excess amount of in Na-thiosulfate 20mM. Iodine reacts with Na-thiosulfate so that the resulting iodide ions reflects both the iodide ions initially present in the formulation, but also the free iodine in aqueous solution and the iodine involved in PVPi.

**2S2O32- + I2 🡪 2I- + S4O62-**

The resulting total iodine ions are determined by Ion Pair Chromatography using potasium iodide as standard.

**Determination of available iodine**

Iodine is exctracted with n-heptane out from an aqueous solution of the test substance. The remaning iodide ions are determined by IPC as described previously.

Available iodine is calculated as the difference between total iodine and the above remaining iodine ions. Therefore, methods for the determination of both forms of iodine should be provided in post-authorization.

Validation of the analytical method:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Specificity | To demonstrate that the quantification of iodine is not affect by other co-formulants present in the biocidal product, HPLC-UV or IPC methods were used and chromatograms were provided:  No interference was found in the blank sample or at the retention time of the active ingredients. | | | |
| Linearity | **PVPi**  Linearity was studied by carrying out 8 calibration spots between 24 – 1200 mg PVPi/L. r²>0.99.  **Iodide**  Linearity was studied by carrying out 10 calibration spots between 0.03 – 30.3 mg iodide /L. r²>0.99. | | | |
| Precision | Repeatability was evaluated with 3 independent determinations (with 6 repetitions) of the formulated product, no outlier. | | | |
| Compound | PVPi | Total Iodine | Available iodine |
| META SPC | Repeatability (RSD) | | |
| 1 | Concentration: 28.95 g/kg  RSD = 1.1% < 2.53% (RSD calculated with modified equation of Horwitz) | Concentration: 4.94 g/kg  RSD = 1.21% < 3.30% (RSD calculated with modified equation of Horwitz) | Concentration: 3.11 g/kg  RSD = 0.96% < 3.54% (RSD calculated with modified equation of Horwitz) |
| ~~2~~ | **~~RSD = 2.16% > 2.05%~~** | ~~RSD = 1.73% < 2.67%~~ | ~~RSD = 1.4% < 2.53%~~ |
| 3 | Concentration: 14.7 g/kg  RSD = 1.36% < 2.53% | Concentration: 2.5 g/kg  RSD = 0.93% < 3.30% | Concentration: 1.4 g/kg  RSD = 1.03% < 3.60% |
| 4 | Concentration: 14.7 g/kg  RSD = 1.4% < 2.53% | Concentration: 2.5 g/kg  RSD = 1.33% < 3.30% | Concentration: 1.4 g/kg  RSD = 1.1% < 3.60% |
| 5 | Concentration: 15.21 g/kg  RSD = 1.5% < 2.29% | Concentration: 2.45 g/kg  RSD = 1.9% < 3.07% | Concentration: 1.17 g/kg  RSD = 1.3% < 3.41% |
| Min content of iodine formulation | Concentration: 4.8 g/kg  RSD = 1.4% < 2.99% | Concentration: 0.8g/kg  RSD = 0.8% < 3.91% | Concentration: 0.5 g/kg  RSD = 1.0% < 4.21% |
| Accuracy | Accuracy was determined by analysis of 4 independent determinations in which known amounts of the reference substance were added to a blank formulation (concentration are the same as previously). The accuracy results are expressed as the recovery rate. | | | |
| Compound | PVPi | Total Iodine | Available iodine |
| META SPC | Accuracy (recovery) | | |
| 1 | 100.2% | 101.0% | 101.5% |
| ~~2~~ | ~~100.4%~~ | ~~99.0%~~ | ~~99.9%~~ |
| 3 | 100.4% | 99.4% | 102.3% |
| 4 | 100.6% | 98.9% | 99.5% |
| 5 | 99.7% | 100.8% | 100.0% |
| Min content of iodine formulation | 100.4% | 98.5% | 100.6% |
| LOQ |  | | | |

**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*

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| **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

HYDRACHIM IODINE FAMILY is a PT3 biocidal family for professional users intended to be applied as teats disinfectants before or after milking. The family includes several uses which were separated in meta-SPCs:

* META-SPC1 includes ready to use liquid products at 2.9 % w/w PVPi, used for teat disinfection. Before the milking and after cleaning, teats of animals are treated by manual dipping, manual foam dipping, automated spraying or, manual or semi-automated spraying, with a contact time of one minute.
* META-SPC3 includes ready to use liquid products between 1.5 % and 2.9 % w/w PVPI, used for teat disinfection. After the milking, teats of animals are treated by manual dipping, automated spraying, manual or semi-automated spraying, with a contact time of 5 minutes.
* META-SPC4 includes ready to use thick liquid products between 1.5 % and 2.9 % w/w PVPI, used for teat disinfection. After the milking, teats of animals are treated by manual dipping, with a contact time of 5 minutes.
* META-SPC5 includes ready to use thick liquid products between 1.5 % and 2.9 % w/w PVPI, used for teat disinfection. After the milking, teats of animals are treated by manual dipping, with a contact time of 5 minutes.
* META-SPC6 includes ready to use liquid products at 2.9 % w/w PVPI, used for teat disinfection. Before the milking and after cleaning, teats of animals are treated by automated spraying, with a contact time of one minute. After the milking, teats of animals are treated by automated spraying, with a contact time of 5 minutes.

META-SPC 2 has been withdrawn by the applicant during the evaluation of the dossier.

The frequency of application is twice a day (four times for META-SPC 6 as used before and after milking).

The product is used by professional users.

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

The biocidal product family is used to disinfect the teats of the udders of dairy animals, before milking and/or after milking. It irreversibly inactivates vegetative bacteria, yeasts, enveloped virus and phages.

The product is used for the purpose of the protection of human and animal health (in order to prevent the transmission of disease causing microorganisms and prevent spoilage of milk).

#### **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 viral and bacteriophage particles (virucidal and phagocidal 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**

Laboratory studies were conducted with HYDRACHIM IODINE FAMILY according to EN 14885:2006 standard and discussions/conclusions (efficacy criteria to be achieved) summarised in the minute of Efficacy WG V 2015. The results are summarized in Section 6.7 of the IUCLID file and the main points are summarized in the table below.

Efficacy tests were summarised for each META-SPC separately for more readability.

Composition of the formulations stated were included in the confidential PAR at the section 3.6.3.

Note that justifications for representative products tested and non activity of the different coformulants are included for each META-SPC below.

* **META-SPC1:**

META-SPC1 contains products at 2.9 % w/w PVPI, with range of variations for some co-formulants: ranges are presented for pH regulators (in order to achieve a pH of 4 ± 1), surfactant, moistener, solubilizer and dyes. Laboratory studies were conducted with only one representative product META-SPC1 AL (2.9 % w/w PVPI):

* Phase 2, step 1 tests have been performed for bactericidal activity (EN 1656), and phagocidal activity (EN 13610), according to the requirements of the norms for teat disinfection, at 30°C with a contact time of 60 sec and low level of soiling (3 g/L BSA), showing the efficacy of the product applied as a ready to use.

It has to be noted that yeasticidal activity (EN 1657) has been performed with the product META-SPC1 AL at 1.5 % w/w PVPI at 30°C with a contact time of 60 sec and high level of soiling (10 g/L BSA+10 g/L yeasts extracts), showing the efficacy of the product applied as a ready to use. This result can be extrapolated to the product META-SPC1 AL (2.9 % w/w PVPI).

* Phase 2, step 2 tests have been performed for bactericidal and yeasticidal activities, according to the requirements of the norm EN 16437 modified, on artificial skin by the method “drop/dip”: efficacy of the product META-SPC1 AL (2.9 % w/w PVPI) is demonstrated at 30°C with a contact time of 60 sec and low level of soiling (3 g/L BSA).

Phagocidal activity is not proven according to the criteria of the norm; nevertheless in absence of phase 2 step 2 tests validated for this activity, results from phase 2 step 1 test (EN 13610) are acceptable for the time being.

It has be noted that bactericidal activity has been also demonstrated according to EN 1656 and EN 16437 modified standards on several additional bacteria (*E.cloacae*, *L.brevis*, *P.aeruginosa, P.vulgaris* and S.Typhimurium).

Taking into account the variations of the co-formulants presented in the META-SPC1, it can be assumed that they have no impact on efficacy (pH of the formulations are targeted to 4± 1 in all cases) and the efficacy results of the representative product META-SPC1 AL cover the whole META-SPC1 claims.

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s) – META-SPC1 (and META-SPC6)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Bactericide | Teat disinfection pre-milking (PT3) | META SPC1 AL (2.9 % PVPI) | Bacteria  *E.coli*  *S.aureus*  *S.uberis* | EN 1656 : 2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 5%, 50%, 80 %  Temperature: 30°C  Contact time: 60 sec  Clean conditions (3 g/L BSA)  Criteria: at least a 5 log reduction | Bactericidal activity demonstrated at 5 % v/v | 4021-2  R.I: 1 |
| Bactericide | Teat disinfection pre-milking (PT3) | META SPC1 AL (2.9 % PVPI) | Bacteria  *P.aeruginosa*  *E.cloacae*  *P.vulgaris*  *L.brevis*  S.Typhimurium | EN 1656 : 2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 5%, 50%, 80 %  Temperature: 30°C  Contact time: 60 sec  Clean conditions (3 g/L BSA)  Criteria: at least a 5 log reduction | Bactericidal activity demonstrated at 5 % v/v | 4142-1  R.I: 1 |
| Bactericide | Teat disinfection pre-milking (PT3) | META SPC1 AL (2.9 % PVPI) | Bacteria  *E.coli*  *S.aureus*  *S.uberis* | EN 16437:2014 modified on artificial skin (drop/dip) | Phase 2 step 2 test (surface test)  Concentration tested: 1%, 50%, 100 %  Temperature: 30°C  Contact time: 60 sec  Clean conditions (3 g/L BSA)  Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 100 v/v | 3980-1  R.I: 2 |
| Bactericide | Teat disinfection pre-milking (PT3) | META SPC1 AL (2.9 % PVPI) | Bacteria  *P.aeruginosa*  *E.cloacae*  *P.vulgaris*  *L.brevis*  S.Typhimurium | EN 16437:2014 modified on artificial skin (drop/dip) | Phase 2 step 2 test (surface test)  Concentration tested: 1%, 50%, 100 %  Temperature: 30°C  Contact time: 60 sec  Clean conditions (3 g/L BSA)  Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 50 v/v | 4101-1  R.I: 2 |
| Yeasticide | Teat disinfection pre-milking (PT3) | META SPC1 AL (1.5 % PVPI) | Yeasts  *C.albicans* | EN 1657:2007 | Phase 2 step 1 test (suspension test)  Concentration tested: 1%, 50%, 100 %  Temperature: 30°C  Contact time: 30 sec and 60 sec  Dirty conditions (10 g/L BSA+10 g/L yeast extracts)  Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 50 % v/v with 30 sec contact time | L15/0122.11  R.I: 2 |
| Yeasticide | Teat disinfection pre-milking (PT3) | META SPC1 AL (2.9 % PVPI) | Yeasts  *C.albicans* | EN 16437:2014 modified on artificial skin (drop/dip) | Phase 2 step 2 test (surface test)  Concentration tested: 1%, 50%, 100 %  Temperature: 30°C  Contact time: 60 sec  Clean conditions (3 g/L BSA)  Criteria: at least a 4 log | Yeasticidal activity demonstrated at 50 % v/v with 60 sec contact time | 4027-1  R.I: 2 |
| Phagocidal activity | Teat disinfection pre-milking (PT3) | META SPC1 AL (1.5 % PVPI) | Phages  P001  P008 | EN 13610:2003 | Phase 2 step 1 test (suspension test)  Concentration tested: 1%, 50%, 100 %  Temperature: 20°C  Contact time: 30 sec  Clean conditions (3 g/L BSA)  Criteria: at least a 4 log | Phagocidal activity demonstrated at 1 % v/v | L15/0122.14  R.I: 1 |
| Phagocidal activity | Teat disinfection pre-milking (PT3) | META SPC1 AL (2.9 % PVPI) | Phages  P001  P008 | EN 16437:2014 modified on artificial skin (drop/dip) | Phase 2 step 2 test (surface test)  Concentration tested: 1%, 50%, 100 %  Temperature: 30°C  Contact time: 60 sec  Clean conditions (3 g/L BSA)  Criteria: at least a 4 log | Phagocidal activity non demonstrated at 1%, 50 % and 100 % | 4078-1  R.I: 3 |

* **META-SPC3:**

META-SPC3 contains products between 1.5 % w/w and 2.9 % w/w PVPI, with range of variations for some co-formulants: ranges are presented for pH regulators (in order to achieve a pH of 4 ± 1), surfactants, moistener, solubilizer, softener and dyes. Laboratory studies were conducted with the representative product META-SPC 3 AL (1.5 % w/w PVPI):

* Phase 2, step 1 tests have been performed for bactericidal activity (EN 1656) and yeasticidal activity (EN 1657), according to the requirements of the norms for teat disinfection, at 30°C with a contact time of 5 min and skimmed milk (1%), showing the efficacy of the product applied as a ready to use.
* Phase 2, step 2 tests have been performed for bactericidal and yeasticidal activities, according to the requirements of the norm EN 16437 modified, on artificial skin by the method “drop/dip”: efficacy of the product META-SPC3 AL (1.5 % w/w PVPI) is demonstrated at 30°C with a contact time of 5 min and skimmed milk (1 %).

It has be noted that bactericidal activity has been also demonstrated according to EN 1656 and EN 16437 modified standards on several additional bacteria (*E.cloacae*, *E.hirae*, *L.brevis*, *L.monocytogenes*, *P.aeruginosa*, *P.vulgaris*, *S.agalactiae* andS.Typhimurium).

Taking into account the variations of the co-formulants presented in the META-SPC 3, it can be assumed that they have no impact on efficacy (pH of the formulations are targeted to 4± 1 in all cases). The efficacy data generated with the representative product META-SPC 3 AL at 1.5 % w/w PVPI cover the efficacy claims for the PVPI range 1.5 % to 2.9 % w/w, as the test conditions are the same and as active substance concentration tested is the minimum.

Then the efficacy results of the representative product META-SPC 3 cover the whole META-SPC3 claims.

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| **Experimental data on the efficacy of the biocidal product against target organism(s) – META-SPC3** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Bactericide | Teat disinfection pre-milking (PT3) | META SPC3 AL (1.5 % PVPI) | Bacteria  *E.coli*  *S.aureus*  *S.uberis* | EN 1656 : 2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 1%, 50 %, 80 %  Temperature: 30°C  Contact time: 5 min  Skimmed milk 1 %  Criteria: at least a 5 log reduction | Bactericidal activity demonstrated at 50 % v/v | L15/0122-1  R.I: 1 |
| Bactericide | Teat disinfection pre-milking (PT3) | META SPC3 AL (1.5 % PVPI) | Bacteria  *E.cloacae*  *E.hirae*  *L.brevis*  *L.monocytogenes*  *P.vulgaris P.aeruginosa*  *S.agalactiae*  S.Typhimurium | EN 1656 : 2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 1 %, 50 %, 80 %  Temperature: 30°C  Contact time: 5 min  Skimmed milk 1 %  Criteria: at least a 5 log reduction | Bactericidal activity demonstrated at 50 % v/v | L15/0122-1  R.I: 1 |
| Bactericide | Teat disinfection pre-milking (PT3) | META SPC3 AL (1.5 % PVPI) | Bacteria  *E.coli*  *S.aureus*  *S.uberis* | EN 16437:2014 modified on artificial skin (drop/dip) | Phase 2 step 2 test (surface test)  Concentration tested: 1 %, 50 %, 100 %  Temperature: 30°C  Contact time: 5 min  Skimmed milk 1 %  Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 50 v/v | 3915-1  R.I: 2 |
| Bactericide | Teat disinfection pre-milking (PT3) | META SPC3 AL (1.5 % PVPI) | Bacteria  *E.cloacae*  *E.hirae*  *L.brevis*  *L.monocytogenes*  *P.vulgaris P.aeruginosa*  *S.agalactiae*  *S.*Typhimurium | EN 16437:2014 modified on artificial skin (drop/dip) | Phase 2 step 2 test (surface test)  Concentration tested: 1 %, 50 %, 100 %  Temperature: 30°C  Contact time: 5 min  Skimmed milk 1 %  Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 100 v/v | 4029-1  R.I: 2 |
| Yeasticide | Teat disinfection pre-milking (PT3) | META SPC3 AL (1.5 % PVPI) | Yeasts  *C.albicans* | EN 1657:2007 | Phase 2 step 1 test (suspension test)  Concentration tested: 1%, 50%, 80 %  Temperature: 30°C  Contact time: 5 min  Skimmed milk 1 %  Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 50 % v/v | L15/0122.7  R.I: 2 |
| Yeasticide | Teat disinfection pre-milking (PT3) | META SPC3 AL (1.5 % PVPI) | Yeasts  *C.albicans* | EN 16437:2014 modified on artificial skin (drop/dip) | Phase 2 step 2 test (surface test)  Concentration tested: 1%, 50%, 100 %  Temperature: 30°C  Contact time: 5 min  Skimmed milk 1 %  Criteria: at least a 4 log | Yeasticidal activity demonstrated at 50 % v/v | 3976-1  R.I: 2 |

* **META-SPC 4:**

META-SPC4 contains products between 1.5 % w/w and 2.9 % w/w PVPI, with range of variations for some co-formulants: ranges are presented for pH regulators (in order to achieve a pH of 4 ± 1), surfactants, moistener, thickener, solubilizer, softener and dyes. Laboratory studies were conducted with the representative product META-SPC4 AL (1.5 % w/w PVPI):

* Phase 2, step 1 tests have been performed for bactericidal activity (EN 1656) and yeasticidal activity (EN 1657), according to the requirements of the norms for teat disinfection, at 30°C with a contact time of 5 min and skimmed milk (1%), showing the efficacy of the product applied as a ready to use.
* Phase 2, step 2 tests have been performed for bactericidal and yeasticidal activities, according to the requirements of the norm EN 16437 modified, on artificial skin by the method “drop/dip”: efficacy of the product META-SPC4 AL (1.5 % w/w PVPI) is demonstrated at 30°C with a contact time of 5 min and skimmed milk (1 %).

It has be noted that bactericidal activity has been also demonstrated according to EN 1656 and EN 16437 modified standard on several additional bacteria (*E.cloacae*, *E.hirae*, *L.brevis*, *L.monocytogenes*, *P.aeruginosa*, *P.vulgaris*, *S.agaliactiae* andS.Typhimurium).

Taking into account the variations of the co-formulants presented in the META-SPC4, it can be assumed that they have no impact on efficacy (pH of the formulations are targeted to 4± 1 in all cases). The efficacy data generated with the representative product META-SPC4 AL at 1.5 % w/w PVPI cover the efficacy claims for the PVPI range 1.5 % to 2.9 % w/w, as the test conditions are the same and as active substance concentration tested is the minimum.Then the efficacy results of the representative product META-SPC4 cover the whole META-SPC4 claims.

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| **Experimental data on the efficacy of the biocidal product against target organism(s) – META-SPC4** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Bactericide | Teat disinfection post-milking (PT3) | META SPC4 AL (1.5 % PVPI) | Bacteria  *E.coli*  *S.aureus*  *S.uberis* | EN 1656 : 2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 1%, 50 %, 80 %  Temperature: 30°C  Contact time: 5 min  Skimmed milk 1 %  Criteria: at least a 5 log reduction | Bactericidal activity demonstrated at 50 % v/v | L15/0122-2  R.I: 1 |
| Bactericide | Teat disinfection post-milking (PT3) | META SPC4 AL (1.5 % PVPI) | Bacteria  *E.cloacae*  *E.hirae*  *L.brevis*  *L.monocytogenes*  *P.vulgaris P.aeruginosa*  *S.agalactiae*  *S.*Typhimurium | EN 1656 : 2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 1 %, 50 %, 80 %  Temperature: 30°C  Contact time: 5 min  Skimmed milk 1 %  Criteria: at least a 5 log reduction | Bactericidal activity demonstrated at 50 % v/v | L15/0122-2  R.I: 1 |
| Bactericide | Teat disinfection post-milking (PT3) | META SPC4 AL (1.5 % PVPI) | Bacteria  *E.coli*  *S.aureus*  *S.uberis* | EN 16437:2014 modified on artificial skin (drop/dip) | Phase 2 step 2 test (surface test)  Concentration tested: 1 %, 50 %, 100 %  Temperature: 30°C  Contact time: 5 min  Skimmed milk 1 %  Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 50 % v/v | 3977-1  R.I: 2 |
| Bactericide | Teat disinfection post-milking (PT3) | META SPC4 AL (1.5 % PVPI) | Bacteria  *E.cloacae*  *E.hirae*  *L.brevis*  *L.monocytogenes*  *P.vulgaris P.aeruginosa*  *S.agalactiae*  *S.*Typhimurium | EN 16437:2014 modified on artificial skin (drop/dip) | Phase 2 step 2 test (surface test)  Concentration tested: 1 %, 50 %, 100 %  Temperature: 30°C  Contact time: 5 min  Skimmed milk 1 %  Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 50 % v/v | 4102-1  4144-1  R.I: 2 |
| Yeasticide | Teat disinfection post-milking (PT3) | META SPC4 AL (1.5 % PVPI) | Yeasts  *C.albicans* | EN 1657:2007 | Phase 2 step 1 test (suspension test)  Concentration tested: 1%, 50%, 80 %  Temperature: 30°C  Contact time: 5 min  Skimmed milk 1 %  Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 50 % v/v | L15/0122.8  R.I: 2 |
| Yeasticide | Teat disinfection post-milking (PT3) | META SPC3 AL (1.5 % PVPI) | Yeasts  *C.albicans* | EN 16437:2014 modified on artificial skin (drop/dip) | Phase 2 step 2 test (surface test)  Concentration tested: 1%, 50%, 80 %  Temperature: 30°C  Contact time: 60 sec  Clean conditions (3 g/L BSA)  Criteria: at least a 4 log | Yeasticidal activity demonstrated at 50 % v/v | 4030-1  R.I: 2 |

* **META-SPC 5:**

META-SPC5 contains products between 1.5 % w/w and 2.9 % w/w PVPI, with range of variations for some co-formulants: ranges are presented for pH regulators (in order to achieve a pH of 4 ± 1), surfactants, moistener, thickener, solubilizer, softener, film forming and dyes. Laboratory studies were conducted with the representative product META-SPC 5 AL (1.5 % and 2 % w/w PVPI):

* Phase 2, step 1 tests have been performed for bactericidal activity (EN 1656) and yeasticidal activity (EN 1657), according to the requirements of the norms for teat disinfection, at 30°C with a contact time of 5 min and skimmed milk (1%), showing the efficacy of the product at 1.5 % w/w PVPI applied as a ready to use.
* Phase 2, step 2 tests have been performed for bactericidal and yeasticidal activities, according to the requirements of the norm EN 16437 modified, on artificial skin by the method “drop/dip”: efficacy of the product META-SPC 5 AL (1.5 % w/w PVPI) is demonstrated at 30°C with a contact time of 5 min and skimmed milk (1 %).

It has been noted that bactericidal activity has been also demonstrated according to EN 1656 and EN 16437 modified standard on several additional bacteria (*E.cloacae*, *E.hirae*, *L.brevis*, *P.aeruginosa*, *P.vulgaris*, *S.agalactiae* andS.Typhimurium) with the formulation META-SPC 5 AL at 1.5 % w/w. Efficacy against additional strains *E.hirae* and *L.monocytogenes* has been also demonstrated with the formulation META-SPC 5 AL at 2% w/w.

* Phase 2, step 1 test has been performed for an activity against enveloped virus (MVA), according to the requirements of the norm EN 14675, following conditions for teat disinfection after milking, (30°C with a contact time of 5 min and skimmed milk at 1 %). This test does not allow demonstrating the efficacy of the product because the control of efficacy for suppression of disinfectant’s activity is not validated according to the criteria of the norm.

Taking into account the variations of the co-formulants presented in the META-SPC5, it can be assumed that they have no impact on efficacy (pH of the formulations are targeted to 4± 1 in all cases). The efficacy data generated with the representative product META-SPC5 AL at 1.5 % w/w PVPI cover the efficacy claims for the PVPI concentration range 1.5 % to 2.9 % w/w, as the test conditions are the same and as active substance concentration tested is the minimum, except for additional strain *L.monocytogenes* where a minimum concentration of 2 % w/w PVPI is needed instead of 1.5 % w/w. Therefore as target organisms and conditions of use should be the same inside a META-SPC, efficacy claimed for bacteria and yeasts are validated except for additional strain *L.monocytogenes.*

Then except the additional strain *L.monocytogenes* and virucidal activity, the efficacy results of the representative product META-SPC 5 cover the whole META-SPC5 claims for products between 1.5 % et 2.9 % PVPI.

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| **Experimental data on the efficacy of the biocidal product against target organism(s) – METASPC5** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Bactericide | Teat disinfection post-milking (PT3) | META SPC5 AL (1.5 % PVPI) | Bacteria  *E.coli*  *S.aureus*  *S.uberis*  Additionnal strains*:*  *E.cloacae*  *E.hirae*  *L.brevis*  *L.monocytogenes*  *P.vulgaris P.aeruginosa*  *S.agalactiae*  S.Typhimurium | EN 1656 : 2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 1%, 50 %, 80 %  Temperature: 30°C  Contact time: 5 min  Skimmed milk 1 %  Criteria: at least a 5 log reduction | Bactericidal activity demonstrated at 50 % v/v | L16/0633-3  R.I: 1 |
| Bactericide | Teat disinfection post-milking (PT3) | META SPC5 AL (1.5 % PVPI) | Bacteria  *E.coli*  *S.aureus*  *S.uberis* | EN 16437:2014 modified on artificial skin (drop/dip) | Phase 2 step 2 test (surface test)  Concentration tested: 1 %, 50 %, 100 %  Temperature: 30°C  Contact time: 5 min  Skimmed milk 1 %  Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 50 v/v | 4001-1  R.I: 2 |
| Bactericide | Teat disinfection post-milking (PT3) | META SPC5 AL (1.5 % PVPI) | Bacteria  *E.cloacae*  *L.brevis*  *P.vulgaris P.aeruginosa*  *S.agalactiae*  *S.*Typhimurium | EN 16437:2014 modified on artificial skin (drop/dip) | Phase 2 step 2 test (surface test)  Concentration tested: 1 %, 50 %, 100 %  Temperature: 30°C  Contact time: 5 min  Skimmed milk 1 %  Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 100 v/v | 4103-1  R.I: 2 |
| Bactericide | Teat disinfection post-milking (PT3) | META SPC5 AL (2.0 % PVPI) | Bacteria  *L.monocytogenes* | EN 16437:2014 modified on artificial skin (drop/dip) | Phase 2 step 2 test (surface test)  Concentration tested: 1 %, 50 %, 100 %  Temperature: 30°C  Contact time: 5 min  Skimmed milk 1 %  Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 100 v/v | 4239-1  R.I: 2 |
| Bactericide | Teat disinfection post-milking (PT3) | FORMULE IODEE MAXIMALE (1.5 % PVPI) | Bacteria  *E.hirae* | EN 16437:2014 modified on artificial skin (drop/dip) | Phase 2 step 2 test (surface test)  Concentration tested: 1 %, 50 %, 100 %  Temperature: 30°C  Contact time: 5 min  Skimmed milk 1 %  Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 100 v/v | 4147-1  R.I: 2 |
| Bactericide | Teat disinfection post-milking (PT3) | META SPC5 AL (2.0 % PVPI) | Bacteria  *E.hirae* | EN 16437:2014 modified on artificial skin (drop/dip) | Phase 2 step 2 test (surface test)  Concentration tested: 1 %, 50 %, 100 %  Temperature: 30°C  Contact time: 5 min  Skimmed milk 1 %  Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 50 v/v | 4168-1  R.I: 2 |
| Yeasticide | Teat disinfection post-milking (PT3) | META SPC5 AL (1.5 % PVPI) | Yeasts  *C.albicans* | EN 1657:2007 | Phase 2 step 1 test (suspension test)  Concentration tested: 1%, 50%, 80 %  Temperature: 30°C  Contact time: 5 min  Skimmed milk 1 %  Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 50 % v/v | L15/0633-5  R.I: 2 |
| Yeasticide | Teat disinfection post-milking (PT3) | META SPC5 AL (1.5 % PVPI) | Yeasts  *C.albicans* | EN 16437:2014 modified on artificial skin (drop/dip) | Phase 2 step 2 test (surface test)  Concentration tested: 1%, 50%, 80 %  Temperature: 30°C  Contact time: 5 min  Skimmed milk 1 %  Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 50 % v/v | 4031-1  R.I: 2 |
| Virucide | Teat disinfection post-milking (PT3) | META SPC5 AL (1.5 % PVPI) | Enveloped virus  MVA | EN 14675:2015 | Phase 2 step 1 test (suspension test)  Concentration tested: 1%, 10%, 50%, 80 %  Contact time: 5 min  Skimmed milk 1 %  Criteria: at least a 4 log reduction | Control of efficacy for suppression of disinfectant’s activity is not validated (>0.5 log10)  Virucidal activity not demonstrated | R15L0635MV  R.I: 3 |

* **META-SPC 6:**

META-SPC6 contains products at 2.9 % w/w PVPI, with range of variations for some co-formulants: ranges are presented for pH regulators (in order to achieve a pH of 4 ± 1), surfactant, moistener, solubilizer and dyes.

For pre-milking, laboratory studies were conducted with the representative product META-SPC1 AL (2.9 % w/w PVPI). Indeed, the efficacy properties of META-SPC 6 is covered by the efficacy tests carried out with the representative formulation of META-SPC 1 (2.9 % w/w PVPI), as both formulations are identical:

* Phase 2, step 1 tests have been performed for bactericidal activity (EN 1656), and phagocidal activity (EN 13610), according to the requirements of the norms for teat disinfection, at 30°C with a contact time of 60 sec and low level of soiling (3 g/L BSA), showing the efficacy of the product applied as a ready to use.

It has to be noted that yeasticidal activity (EN 1657) has been performed with the product META-SPC1 AL at 1.5 % w/w PVPI at 30°C with a contact time of 60 sec and high level of soiling (10 g/L BSA+10 g/L yeasts extracts), showing the efficacy of the product applied as a ready to use. This result can be extrapolated to the product META-SPC 1 AL (2.9 % PVPI).

* Phase 2, step 2 tests have been performed for bactericidal and yeasticidal activities, according to the requirements of the norm EN 14347 modified, on artificial skin by the method “drop/dip”: efficacy of the product META-SPC 1 AL (2.9 % w/w PVPI) is demonstrated at 30°C with a contact time of 60 sec and low level of soiling (3 g/L BSA).

Phagocidal activity is not proven according to the criteria of the norm; nevertheless in absence of phase 2 step 2 tests validated for this activity, results from phase 2 step 1 test (EN 13610) are acceptable for the time being.

It has to be noted that bactericidal activity has also been demonstrated according to EN 1656 and EN 16437 modified standards on several additional bacteria (*E.cloacae*, *L.brevis*, *P.aeruginosa*, *P.vulgaris* and *S.Typhimurium*).

For post-milking, no tests have been provided with the representative product META-SPC1 AL (2.9 % w/w PVPI). Even if contact time is lower in pre-milking (1 min) than in post milking (5 min), as conditions of tests are different and not comparable between pre and post milking (low level of soiling with 0.3 g/l BSA in pre-milking and 1% skimmed milk in post-milking), results from pre-milking tests cannot be extrapolated for post-milking to demonstrate the efficacy of the META-SPC6 from tests performed for META-SPC1 evaluation.

Nevertheless, when comparing variations of compositions proposed on the one hand, between META-SPC 6 and META SPC 3 and, on the other hand between representative products META-SPC 6 AL and META-SPC 3 AL, FR CA assumes that range differences are slight between the coformulants, without impact on efficacy. Moreover, the active substance content for the representative product META-SPC 3 AL is lower than in the representative product META-SPC 6 AL, then efficacy of META-SPC 3 demonstrated for post-milking covers efficacy of META-SPC 6 for bacteria (and additional bacteria (*E.cloacae*, *L.brevis*, *P.aeruginosa*, *P.vulgaris*, andS.Typhimurium). and yeasts.

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| **Conclusion on the efficacy of the product** |
| French competent authorities (FR CA) assessed that the HYDRACHIM IODINE FAMILY, separated in five META-SPC has shown a sufficient efficacy for teats disinfection as following:   * In META-SPC1, including ready to use liquid products at 2.9 % w/w PVPI, before milking (and after cleaning), by manual dipping, manual foam dipping, automated spraying or, manual or semi-automated spraying, with a contact time of one minute, against bacteria (additional strains : *E.cloacae, L.brevis, , P.vulgaris, P.aeruginosa, S.*Typhimurium*)*, yeasts and phages. * In META-SPC3, including ready to use liquid products between 1.5 % et 2.9 % w/w PVPI, after milking, by manual dipping, automated spraying or, manual or semi-automated spraying, with a contact time of 5 minutes, against bacteria (additional strains : *E.cloacae, E.hirae, L.brevis, L.monocytogenes, P.vulgaris, P.aeruginosa, S.agalactiae, S.*Typhimurium*)*, and yeasts. * In META-SPC4, including ready to use thick liquid products between 1.5 % et 2.9 % w/w PVPI after milking, by manual dipping, with a contact time of 5 minutes, against bacteria (additional strains : *E.cloacae, E.hirae, L.brevis, L.monocytogenes, P.vulgaris, P.aeruginosa, S.agalactiae, S.*Typhimurium*)* and yeasts. * In META-SPC5, including ready to use thick liquid products between 1.5 % et 2.9 % w/w PVPI after milking, by manual dipping, with a contact time of 5 minutes, against bacteria (additional strains: *E.cloacae, E.hirae, L.brevis, P.vulgaris, P.aeruginosa, S.agalactiae, S.*Typhimurium*)* and yeasts. Virucidal activity against enveloped virus, and efficacy against *L.monocytogenes* have not been demonstrated. * In META-SPC6 includes ready to use liquid products at 2.9 % v/v PVPI:   before milking (and after cleaning), by automated spraying, with a contact time of one minute, against bacteria (additional strains : *E.cloacae, L.brevis, P.vulgaris, P.aeruginosa, S.*Typhimurium*)*, yeasts and phages ;  and after milking, by automated spraying, with a contact time of 5 minutes, against bacteria (additional strains : *E.cloacae, L.brevis, P.vulgaris, P.aeruginosa, S.*Typhimurium), and yeasts.  The users should inform if the treatment is ineffective and report straightforward to the registration holder. |

#### **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**

The product must be brought to a temperature above 20°C before use.

#### **Evaluation of the label claims**

French competent authorities (FR CA) assessed that the product HYDRACHIM IODINE FAMILY has demonstrated a sufficient efficacy for the following META-SPC:

* META-SPC1: Pre-milking teat disinfection against bacteria, yeasts and phages.

Dairy hygiene purpose. Clean skins.

For use with foam dipping or classic dipping (cup), automated spraying or, manual or semi-automated spraying. The entire surface of the teats must be covered during one minute in order to ensure good disinfection of the skin.

After the contact time, dry the teats and base of the udder with a clean cotton towel or disposable paper towel for all modes of application except automated and semi-automated spraying.

Additional strains : *E.cloacae, L.brevis, P.vulgaris, P.aeruginosa, S.*Typhimurium*.*

* META-SPC3: Post-milking teat disinfection.

Milking hygiene prevention of milk contaminations by bacteria and yeasts.  
Protects from bacterial and yeasticidal contaminations entering by the sphincter, until the closure of the sphincter.

For use with classic dipping (cup), manual or, semi-automatic and automatic spraying. The entire surface of the teats must be covered during 5 minutes in order to ensure good disinfection of the skin.

Additional strains : *E.cloacae, E.hirae, L.brevis, L.monocytogenes, P.vulgaris, P.aeruginosa, S.agalactiae, S.*Typhimurium

* META-SPC4: Post-milking teat disinfection.

Milking hygiene prevention of milk contaminations by bacteria and yeasts.  
Protects from bacterial and yeasticidal contaminations entering by the sphincter, until the closure of the sphincter.

For use with classic dipping (cup).

The entire surface of the teats must be covered during 5 minutes in order to ensure good disinfection of the skin.

Additional strains : *E.cloacae, E.hirae, L.brevis, L.monocytogenes, P.vulgaris, P.aeruginosa, S.agalactiae, S.*Typhimurium

* META-SPC5: Post-milking teat disinfection.

Milking hygiene prevention of milk contaminations by bacteria and yeasts.  
Protects from bacterial and yeasticidal contaminations entering by the sphincter, until the closure of the sphincter (virucidal activity against envelopped virus not demonstrated in the frame of this dossier).

For use with classic dipping (cup). The entire surface of the teats must be covered during 5 minutes in order to ensure good disinfection of the skin.

Additional strains: *E.cloacae, E.hirae, L.brevis, P.vulgaris, P.aeruginosa, S.agalactiae, S.*Typhimurium

* META-SPC6: Pre and post milking teat disinfection.

Pre-milking disinfection against bacteria, yeasts and phages: dairy hygiene purpose. Clean skins.

Post milking: protects from bacterial and yeasticidal contaminations entering by the sphincter, until the closure of the sphincter

For use automatic spraying.

The entire surface of the teats must be covered during one minute before milking and during five minutes after milking, in order to ensure good disinfection of the skin.

Additional strains (pre-milking): *E.cloacae, L.brevis, P.vulgaris, P.aeruginosa, S.*Typhimurium

Additional strains (post milking) : *E.cloacae, L.brevis, P.vulgaris, P.aeruginosa, S.*Typhimurium

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented

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

The HYDRACHIM IODINE FAMILY is not intended to be used with another biocidal product.

### Risk assessment for 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 vapour | 40.7 Pa at 25°C |
| MM | 253.81 g/mol |

#### **Assessment of effects on Human Health**

***Skin corrosion and irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Products of Meta-SPCs are not irritant |
| Justification for the value/conclusion | No studies on formulated products have been performed. Effects on skin were evaluated through the CLP calculation method based on the classifications of the active substance and other product components. |
| Classification of the product according to CLP | Based on calculation method, the following classifications are proposed for the Meta-SPCs :   * **All Meta-SPCs:** Not classified |

***Eye irritation***

| **Summary table of in vitro studies on serious eye damage and eye irritation** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Method, Guideline,**  **GLP status, Reliability** | **Test substance, Doses** | **Relevant information about the study** | **Results** | **Remarks** *(e.g. major deviations)* | **Reference** |
| Isolated chicken eye test method  OECD 438 | Formule iodée maximale- irritation Oculaire IV  30µL on 3 enucleated chicken eyes  10 seconds | Determination of corneal swelling, opacity and fluopresceine retention at 30, 75, 120, 180 and 240 min post dose. | Maximal mean score of corneal opacity: 0.8 (ICE class II)  Mean score of fluorescein retention: 3.0 (ICE class IV)  Maximal mean corneal swelling: +9%at 240 min (ICE class II) | The combination of the three endpoints was 1 \* IV and 2\*II.   * No prediction can be made | Genuer et al. 2016 |

According to the CLP calculation rules, a GCL ≥ 3 % (H318) is proposed for a mixture containing ingredients with classification as skin corrosion cat 1A, 1B or 1C, and ocular effects category 1.

Taking into account the contents of the following ingredients in products of the BPF :

* 1.5 to 2.90% of PVPi classified Eye Dam. 1 H318
* 0.04 to 0.06% of sodium hydroxide classified Skin corr. 1A H314 with a specific threshold of classification for eye irritation (Eye Dam. 1 C ≥ 2 %)
* 0 to 0.94% of sodium lauryl ether sulfate classified Eye Dam. 1 H318 in the MSDS

A concentration of 3.9% is calculated leading to a classification H318 for meta SPC where concentration of PVPi is up to 2.9% and products containing .

Considering the concentration range of PVPi and sodium lauryl ether sulfate to be authorized in each meta SPC, the following classification applies to products of the HYDRACHIM IOINE FAMILY :

* Meta SPC 1 (PVPi up to 2.9% and sodium lauryl ether sulfate up to 0.94%) : H318
* Meta SPC 3 (PVPi up to 2.0% and no sodium lauryl ether sulfate) : H319
* Meta SPC 4 (PVPi up to 2.9% and no sodium lauryl ether sulfate) : H319
* Meta SPC 5 (PVPi up to 2.9% and sodium lauryl ether sulfate up to 0.94%) : H318
* Meta SPC 6 (PVPi up to 2.9% and no sodium lauryl ether sulfate) : H319

An *in vitro* study on isolated chicken eye was provided. However, considering the combination 1 \* IV and 2\*II, no prediction can be made.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Eye damage 1 |
| Justification for the value/conclusion | Based on calculation method of CLP regulation. |
| Classification of the product according to CLP | The following classification is proposed for the Meta-SPCs:   * Meta SPC 1 and meta SPC 5: H318 * Meta SPC 3, 4 and 6 : H319 |

***Respiratory tract irritation***

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Value/conclusion | Not classified |
| Justification for the conclusion | No studies on formulated products have been performed. Effects were evaluated through the CLP calculation method based on the classifications of the active substance and other product components. |
| Classification of the product according to CLP | Based on calculation method, the following classification is proposed for the Meta-SPCs :   * **All Meta SPCs:** Not classified |

***Skin sensitization***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Not classified |
| Justification for the value/conclusion | No studies on formulated products have been performed. Effects were evaluated through the CLP calculation method based on the classifications of the active substance and other product components. |
| Classification of the product according to CLP | Based on calculation method, the following classification is proposed for the Meta-SPCs:   * **All Meta SPCs:** Not classified |

***Respiratory sensitization (ADS)***

No data available.

***Acute toxicity***

No studies on formulated products have been performed. Based on calculation method, it was established that the Meta SPCs are not classified for acute toxicity.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Not classified |
| Justification for the selected value | No studies on formulated products have been performed. Effects were evaluated through the CLP calculation method based on the classifications of the active substance and other product components. |
| Classification of the product according to CLP | Based on calculation method, the following classification is proposed for the Meta-SPCs:   * **All Meta SPCs:** Not classified |

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | Not classified |
| Justification for the selected value | No studies on formulated products have been performed. Effects were evaluated through the CLP calculation method based on the classifications of the active substance and other product components. |
| Classification of the product according to CLP | Based on calculation method, the following classification is proposed for the Meta-SPCs:   * **All Meta SPCs:** Not classified |

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | Not classified |
| Justification for the selected value | No studies on formulated products have been performed. Effects were evaluated through the CLP calculation method based on the classifications of the active substance and other product components. |
| Classification of the product according to CLP | Based on calculation method, the following classification is proposed for the Meta-SPCs:   * **All Meta SPCs:** Not classified |

***Information on dermal absorption***

|  |  |
| --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | |
| Substance | Iodine, in the PVPi formulated product |
| Value | 75% |
| Justification for the selected value(s) | The formulated product contains 0.29-0.49% iodine (I2). No dermal penetration testing has been conducted on the formulation, therefore a default skin penetration value of 75% is used for human health risk |

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

No data submitted.

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

No data submitted.

***Other***

The following information on the product is used to determine the exposure of the product:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Meta SPC 1 and Meta SPC 6 | Meta SPC 3 | Meta SPC 4 | Meta SPC 5 |
| pH | 4.1 | 3.2 | 3.7 | 4.3 |
| Density | 1.022 | 1.018 | 1.02 | 1.039 |

#### **Exposure assessment**

Hydrachim dossier is a biocidal product family containing ready-to-use products packaged in containers, barrels and tanks from 10 kg to 1000 kg.

The products are intended to be used by professionals to disinfect teats. The family includes several uses which were separated in meta-SPCs.

Table 1: Structure of the family in terms of uses

|  |  |  |  |
| --- | --- | --- | --- |
|  | **General application** | **Use Number** | **Use description** |
| **Meta-SPC 1** | Pre-milking | 1 | Liquid dipping before milking |
| 2 | Dipping with foam before milking |
| 3 | Automated spraying before milking |
| 4 | Semi-automated or manual spraying before milking |
| **Meta-SPC 3** | Post-milking | 7 (==use 1) | Liquid dipping after milking |
| 8 (==use 3) | Automated spraying after milking |
| 9 (==use 4) | Semi-automated or manual spraying after milking |
| **Meta-SPC 4** | 10 (==use 1) | Thick liquid dipping after milking |
| **Meta-SPC 5** | 11 (==use 1) | Thick film-forming liquid dipping after milking |
| **Meta-SPC 6** | Pre- and post- milking | 12 (==use 3 & 8) | Automated spraying before and after milking |

|  |
| --- |
| **Meta SPC 3 (uses 7 (==use 1), 8 (==use 3) and 9 (==use 4)) – post-milking application** |
| The exposure scenarios under Meta-SPC 3 are identical to those described for Meta-SPC1 (uses 1, 2, 3 and 4). The only difference is that treatment occurs post- rather than pre-milking. No wiping / drying of the teats is required after treatment. |
| **Meta SPC 4 (use 10 (== use1)) – post-milking application** |
| The exposure scenarios under Meta-SPC 4 are identical to those described for Meta-SPC1 (use 1: dipping). The only difference is that treatment occurs post- rather than pre-milking and the formulated product is a thick liquid. No wiping / drying of the teats is required after treatment. |
| **Meta SPC 5 (use 11 (== use 1)) – post-milking application** |
| The exposure scenarios under Meta-SPC 5 are identical to those described for Meta-SPC1 (use 1: dipping). The only difference is that treatment occurs post- rather than pre-milking and the formulated product is a tick liquid with film-forming property. No wiping / drying of the teats is required after treatment. |
| **Meta SPC 6 (use 12 (== uses 3 and 8)) – pre- and post-milking application** |
| The exposure scenarios under Meta-SPC 6 are identical to those described for Meta-SPC1 (use 3). The spraying of each teat is carried out in “closed up” circuit. No wiping /drying of the teats by professional worker. |

Table 2: Structure of the family in terms of content in active substance

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Meta SPC 1 and Meta SPC 6 | Meta SPC 3 | Meta SPC 4 | Meta SPC 5 |
| Content in PVP iodine | 2.90% | 1.5-2.90%  (1.5% -2%) | 1.5-2.90%  (1.5% -2%- 2.9%) | 1.5-2.90%  (1.5% -2%- 2.9%) |

Nominal content of total iodine (% in PVPi technical): 17%

Nominal content of available iodine (% in PVPi technical): 10%

The exposure assessment is based on use of the formulated product containing 2.9% PVPi.   
for Meta-SPCs 1, 3, 4, 5 and 6. The corresponding amount of total iodine is 0.49%.

The exposure calculations presented below are conducted with the worst-case values of  
0.49% of total iodine in first tier, since the reference values are also expressed as iodine (and not as PVPi). The assessment follows the recommendation n°13 of the BPC Ad hoc Working Group on Human Exposure (Exposure Assessment of teat disinfection products for veterinary hygiene PT3), agreed at the human Health Working group I on january 2017.

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

| **Summary table: relevant paths of human exposure** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Exposure path** | **Primary (direct) exposure** | | | **Secondary (indirect) exposure** | | | |
| **Industrial use** | **Professional use** | **Non-professional use** | **Industrial use** | **Professional use** | **General public** | **Via food** |
| Inhalation | N.A. | Yes | N.A. | N.A. | No | No | N.A. |
| Dermal | N.A. | Yes | N.A. | N.A. | Yes | No | N.A. |
| Oral | N.A. | No | N.A. | N.A. | No | No | Yes |

N.A.: not applicable

Inhalation exposure of vapour of iodine from this type of product (teat disinfectant) was a point of discussion at the WGIV, and it was concluded that *inhalation exposure to vapours could be considered as negligible for this type of formulation and therefore inhalation exposure to vapours does not need to be assessed.*

***List of scenarios***

Several mode of applications are proposed by applicant : dipping, manual spraying, semi automated spraying and fully automated spraying . Exposure is determined for each mode of application (mixing and loading + application).

For treatment before milking, a wiping of the teats is required after treatment. In this context, exposure to remaining active substance is also determined for this scenario.

**Meta SPC 1**

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario** | **Primary or secondary exposure**  **Description of scenario** | **Exposed group** |
| 1. | Mixing/loading for dipping | **Primary exposure – dermal route**  Exposure to droplets direct to the skin is considered during loading. | Professionals |
| 2. | Application by dipping (liquid/foam) | **Primary exposure – dermal route**  Worker can be exposed to some drip on the hands.  Application by dipping is covered by the mixing and loading step for dermal exposure  Remark: During the Headhoc 1 2016 meeting, it was considered that the application of a biocidal product in the form of a foam by dipping cups is deemed covered by the application of a liquid by the same product. | Professionals |
| 3. | Mixing/loading for manual/semi automated spraying | **Primary exposure – dermal route**  Exposure to droplets direct to the skin is considered during loading. | Professionals |
| 4. | Application by manual spraying | **Primary exposure – dermal route**  Worker can be exposed by dermal route during application  **Primary exposure – inhalation route**  Worker can be exposed by aerosol produced during spraying but he is also exposed to evaporation of the active substance. | Professionals |
| 5. | Mixing/loading for automated spraying | **Primary exposure – dermal route**  Exposure to droplets direct to the skin is considered during loading. | Professionals |
| 6. | Application by automated spraying | No exposure estimate required.  No wiping of the teats is required. | Professionals |
| 7. | Wipping of teats, removal of freshly applied product | **Primary exposure – dermal route**  Direct skin exposure during wiping of remaining product on teat skin. | Professionals |

For meta SPC3, 4 and 5 (post milking use) use similar to liquid dipping and spraying (manual, semi-automated and automated) are required.

As products can contain the same amount in PVP iodine (2.9%), the exposure during mixing and loading and application will be similar to the exposure determined for meta SPC 1. The only difference is that no wiping of the teats is required. Therefore, no exposure by dermal contact will occur.

For meta SPC 6, use similar to automated spraying of meta SPC 1 is required.

As products can contain the same amount of PVP iodine (2.9%), the exposure during mixing and loading will be similar to the exposure determined for meta SPC 1. However, as the treatment can be before and after milking a combined risk assessment will be performed.

##### Industrial exposure

No industrial exposure is foreseen. Therefore the assessment of industrial exposure is not relevant.

##### Professional exposure

*Scenario [1] Loading of the product in teat dip tank* *for dipping application*

| **Description of Scenario [1] – Mixing and loading - Dermal exposure** | | | |
| --- | --- | --- | --- |
| The mixing and loading model 4 as proposed in HeadHoc recommendation 13 was chosen as a reasonable worst-case scenario.  Professional worker fills teat dip cup of 300 ml with 225 ml of undiluted formulated product. Pumps three to six times the dip cup handle to make the formulated product (in liquid or foam form) rise into the application reservoir.  According to the mixing and loading model 4 (user guidance p 24/25), it is considered that professional will be exposed to 0.01 ml of product on the hands when he pours less than 1 litre of product in a receiving vessel (here = 225 mL).  Applicant does not provide the amount of product which has to be applied on teats. Therefore, the default value of 10 mL/cow/milking proposed in DRAWG draft proposal “guidance on estimating livestock exposure to active substances used in Biocidal Products” for dipping is used. | | | |
|  | Parameters | Value | Reference |
| Tier 1 | Frequency (per day) | 8 | For 82 cows, 820 mL of product is needed. Considering that 225 ml are poured, 4 phases of mixing and loading are needed (820/225 ml) per milking and two milking per day are performed. |
| Weight fraction compound (%) | 0.49% | Applicant data |
| Product amount (milligram)/event | 10.4 | Density of Hydrachim = 1.039 (worst case);  Contamination for any closure, < 1L container = 0.01 mL/operation or 0.01 g (when density 1 g/cm3). |
| Body weight (kg) | 60 | HEEG opinion No. 17, 2013 |
| Dermal absorption (%) | 75% | Default value |
| Penetration factor PPE | 100% | No PPE |
| Tier 2 | Penetration factor PPE (gloves) | 10% | HEEG opinion No. 9, 2010 |
| Other parameters | Similar to tier 1 | |

**Calculations for Scenarios [1] loading of the product in teat dip tank**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg/d)** | **Estimated dermal uptake (mg/kg/d)** | **Estimated oral uptake (mg/kg/d)** | **Estimated total uptake (mg/kg/d)** |
| Scenario [1]  Loading of the teat dip tank | 1 | n.a. | 5.1 × 10⁻3 | n.a. | 5.1 × 10⁻3 |
| Scenario [1]  Loading of the teat dip tank | 2 | n.a. | 5.1 × 10⁻4 | n.a. | 5.1 × 10⁻4 |

*Scenario [2] Application by dipping*

According to HeadHoc recommendation 13, application by dipping is covered by the mixing and loading step for the dermal exposure and by the wiping step for inhalation exposure.

As dermal and inhalation exposure are covered by other tasks no scenarios will be presented for application.

*Scenario [3] Loading of the product for spraying application*

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [3] – Mixing and loading - Dermal exposure** | | | |
| The mixing and loading model 4 as proposed in HeadHoc recommendation 13 was chosen as a reasonable worst-case scenario.  Professional worker fills teat dip cup of 300 ml with 225 ml of undiluted formulated product. Pumps three to six times the dip cup handle to make the formulated product (in liquid or foam form) rise into the application reservoir.  According to the mixing and loading model 4 (user guidance p 24/25), it is considered that professional will be exposed to 0.01 ml of product on the hands when he pours less than 1 litre of product in a receiving vessel (here = 225 mL).  Applicant does not provide the amount of product which has to be applied on teats. Therefore, the default value of 20 mL/cow/milking proposed in DRAWG draft proposal “guidance on estimating livestock exposure to active substances used in Biocidal Products” for spraying is used. | | | |
|  | Parameters | Value | Reference |
| Tier 1 | Frequency (per day) | 16 | For 82 cows, 1640 mL of product is needed. Considering that 225 ml are poured, 8 phases of mixing and loading are needed (1640/225 ml) per milking and two milking per day are performed. |
| Weight fraction compound (%) | 0.49% | Applicant data |
| Product amount (milligram)/event | 10.4 | Density of Iodiguard = 1.039 (worst case);  Contamination for any closure, < 1L container = 0.01 mL/operation or 0.01 g (when density 1 g/cm3). |
| Body weight (kg) | 60 | HEEG opinion No. 17, 2013 |
| Dermal absorption (%) | 75% | Default value |
| Penetration factor PPE | 100% | No PPE |
| Tier 2 | Penetration factor PPE (gloves) | 10% | HEEG opinion No. 9, 2010 |
| Others parameters | Similar to tier 1 | |

**Calculations for Scenarios [3] loading of the product in teat dip tank**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg/d)** | **Estimated dermal uptake (mg/kg/d)** | **Estimated oral uptake (mg/kg/d)** | **Estimated total uptake (mg/kg/d)** |
| Scenario [3]  Loading spray | 1 | n.a. | 1.0× 10⁻2 | n.a. | 1.0 × 10⁻2 |
| Scenario [3]  Loading spray | 2 | n.a. | 1.0× 10⁻3 | n.a. | 1.0 × 10⁻3 |

*Scenario [4] Application by spraying*

| **Description of Scenario [4] – Application by spraying** | | | |
| --- | --- | --- | --- |
| According to Recommendation 13 of Ad hoc WG on human exposure, exposure during application by spraying is determined by consumer product spraying and dusting model 2 - hand held sprayer.  This model determines dermal exposure: 9.7 mg/min (body) and 36.1 mg/min (hands) and inhalation (aerosol) exposure: 10.5 mg/m3. | | | |
|  | Parameters | Value | Reference |
| Tier 1 | Weight fraction compound (%) | 0.49% | Applicant data |
| Duration | 27.3 min | The spraying time per cow is 10 seconds; 82 cows are treated twice per day: 1640 seconds  HEAdhoc recommendation No. 13, 2017 |
| Body weight (kg) | 60 | HEEG opinion No. 17, 2013 |
| Dermal absorption (%) | 75% | Default value |
| Penetration factor PPE | 100% | No PPE |
| Tier 2 | Penetration factor PPE (gloves) | 10% | HEEG opinion No. 9, 2010 |
| Others parameters | Similar to tier 1 | |
| Tier 3 | Penetration factor PPE (gloves) | 10% | HEEG opinion No. 9, 2010 |
| Penetration factor PPE (coated coverall) | 10% | HEEG opinion No. 9, 2010 |
| Others parameters | Similar to tier 1 | |

**Calculations for Scenarios [4] Application by spraying**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg/d)** | **Estimated dermal uptake (mg/kg/d)** | **Estimated oral uptake (mg/kg/d)** | **Estimated total uptake (mg/kg/d)** |
| Scenario [4]  Application by spraying | 1 | 4.88 × 10⁻4 | 7.66× 10⁻2 | n.a. | 7.71× 10⁻2 |
| Scenario [4]  Application by spraying | 2 | 4.88 × 10⁻4 | 2.23× 10⁻3 | n.a. | 2.27× 10⁻2 |
| Scenario [4]  Application by spraying | 3 | 4.88 × 10⁻4 | 7.66× 10⁻3 | n.a. | 8.15× 10⁻3 |

| **Summary table: estimated concentration of iodine in air** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Mean event concentration**  **(mg/m3)** |
| Scenario [4]  Application by spraying | 1 | 5.1 × 10⁻2 |

*Scenario [5] Loading of the product for automated spraying application*

| **Description of Scenario [5] – Mixing and loading - Dermal exposure** | | | |
| --- | --- | --- | --- |
| Exposure by dermal route can occur during the connecting of lines. Estimation is performed with the indicative value of 0.92 mg/min proposed in the RISKOFDERM toolkit for connecting line according to the HEAdhoc recommendation No. 13, 2017. Inhalation exposure is not considered relevant. | | | |
|  | Parameters | Value | Reference |
| Tier 1 | Weight fraction compound (%) | 0.49% | Applicant data |
| Duration (min) | 1 | HEAdhoc recommendation No. 13, 2017 |
| Body weight (kg) | 60 | HEEG opinion No. 17, 2013 |
| Dermal absorption (%) | 75% | Default value |
| Penetration factor PPE | 100% | No PPE |

**Calculations for Scenarios [5] loading of the product**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg/d)** | **Estimated dermal uptake (mg/kg/d)** | **Estimated oral uptake (mg/kg/d)** | **Estimated total uptake (mg/kg/d)** |
| Scenario [5]  Loading automated spray | 1 | n.a. | 5.64 × 10⁻5 | n.a. | 5.64 × 10⁻5 |

*Scenario [6] Application by automated spraying*

No exposure is expected.

*Scenario [7] Wiping of teats, removal of applied product post-milking*

| **Description of Scenario [7] – Wiping of animals teats - dermal exposure** | | | |
| --- | --- | --- | --- |
| As proposed on headhoc recommendation 13 and the Disinfectant Products Fact Sheet (RIVM report 320005003/2006).  For the assessment of hand exposure, it is assumed that the surface area corresponds to the teats of the cow (44 cm2 teats and 176 cm2/cow). To calculate the amount of the biocidal product on the surface area, the layer thickness approach is considered appropriate (i.e. 44 cm2/teat x 4 teats x 0.01 cm x number of cows). As a worst-case scenario it is consider that 0.1% of the amount of biocidal product applied on animal teats will transfer on worker skin during wiping.  Dermal exposure per animal wiping is calculated according to the following formula:  Where:  AR: Application rate (mL/animal/application) = 44\*0.01\*4  C: Weight fraction substance (%)  d: Density  DA: Dermal absorption (%)  BW : body weight (kg)  The total exposure takes into account a number of 82 cows/day. | | | |
|  | Parameters | Value | Reference |
| Tier 1 | Frequency (per day) | 2 | Applicant data |
| Product amount transferred on hand during wiping (%) | 0.1% | Disinfectant Products Fact Sheet (RIVM report 320005003/2006) |
| Application rate (mL/animal/application) | 1.76 | Application rate (mL/animal/application) = 44\*0.01\*4 |
| Weight fraction substance (%) | 0.49% | Applicant data |
| Density | 1.039 | Properties of Iodiguard |
| Number of cows | 82 | HEAdhoc recommendation No. 13, 2017 |
| Body weight (kg) | 60 | HEEG opinion No. 17, 2013 |
| Product transferred to hand (g) | 0.15 | See formula above |
| Dermal absorption (%) | 75% | Properties of iodine (CAR) |
| Penetration factor PPE | 100% | No PPE |
| Tier 2 | Penetration factor PPE (gloves) | 10% | HEEG opinion No. 9, 2010 |
| Others parameters | Similar to tier 1 | |

**Calculations for Scenarios [7] wiping of animals teats**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/kg/d)** | **Estimated dermal uptake (mg/kg/d)** | **Estimated oral uptake (mg/kg/d)** | **Estimated total uptake (mg/kg/d)** |
| Scenario [7] Wiping of animals teats | 1 | n.a. | 1.8× 10⁻2 | n.a. | 1.8× 10⁻2 |
| Scenario [7] Wiping of animals teats | 2 | n.a. | 1.8× 10⁻3 | n.a. | 1.8× 10⁻3 |

##### Non-professional exposure

No non-professional exposure is foreseen.

##### Exposure of the general public

No general public exposure is foreseen.

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

Not applicable

**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** |
| Scenario [1]  Loading of the teat dip tank | Profesionnal | 1/No PPE | 5.1 × 10⁻3 |
| Scenario [1]  Loading of the teat dip tank | Profesionnal | 2/with gloves | 5.1 × 10⁻4 |
| Scenario [3]  Loading spray | Profesionnal | 1/No PPE | 1.0× 10⁻2 |
| Scenario [3]  Loading spray | Profesionnal | 2/with gloves | 1.0× 10⁻3 |
| Scenario [4]  Application by spraying | Profesionnal | 1/No PPE | 7.71× 10⁻2 |
| Scenario [4]  Application by spraying | Profesionnal | 2/with gloves | 2.27× 10⁻2 |
| Scenario [4]  Application by spraying | Profesionnal | 3/with gloves and coated coverall | 8.15× 10⁻3 |
| Scenario [5]  Loading automated spray | Profesionnal | 1/No PPE | 5.64 × 10⁻5 |
| Scenario [7] Wiping of animals teats | Profesionnal | 1/No PPE | 1.8× 10⁻2 |
| Scenario [7] Wiping of animals teats | Profesionnal | 2/with gloves | 1.8 × 10⁻3 |

| **Scenarios and values to be used in risk assessment** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Exposed group**  **(e.g. professionals, non-professionals, bystanders)** | **Tier/PPE** | **Mean event concentration**  **(mg/m3)** |
| Scenario [4]  Application by spraying | Profesionnal | 1/No PPE  2/with gloves  3/with gloves and coated coverall | 5.1 × 10⁻2 |

Combined exposure can occur. Indeed, professional will be exposed to the product during loading and application. If treatment is performed before the milking, a wiping of the teats is required and professional could be exposed. If treatment is performed after the milking, no wiping is required.

##### Dietary exposure

The product type 3 (veterinary hygiene biocidal products) was already assessed in iodine CAR as manual or automatic non-medical teat disinfection and udder washes, and as surface disinfection in animal houses.

Iodine is a natural and essential compound:

* Iodine is an essential dietary trace element for mammals. It is required for the synthesis of the thyroid hormones, which control metabolism and play an important role in reproduction, growth and development.
* Background values between 0.5 and 20 mg iodine/kg are found in soil, whereas in ground water a mean concentration of 1μg/L is reported. The background values in surface water (0.5 to 20 μg iodine/L) are considerably lower than in marine water (45 to 60 μg iodine/L). The levels in rain water (0.1 to 15 μg/L) are comparable to those of surface water (Iodine Assessment Report, SE, September 2013).

The reduction of iodine background concentrations in soil by leaching has an impact on the iodine level in crops and animals, and consequently in human food. For this reason, recommendations for the daily intake for humans were established. e.g. by the World Health Organisation (WHO) at 150 – 200 μg/day and the fortification of table salt with iodine has become a mean to prevent a deficiency for this essential dietary trace element.

*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 specie. In alkaline and well oxidized waters iodate is the predominant specie.

The livestock is expected to be exposed to the active substance iodine (I2) complexed with PVP. 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*

In place of residue data to determine residues of iodine in milk following use of the products within HYDRACHIM IODINE FAMILY, the consumer exposure followed the harmonized approach developed at EU level (WG tox II-III-IV 2017, and webex post WG tox IV 2017 meetings).

The applicant (belonging to IRG: Iodine Registration Group) has also provided dietary risk assessment in framework of this dossier: « iodine discussion paper ». Nevertheless, considering the recent EU discussions, the decisions from WG Tox and WebEx meetings have been implemented.

Based on the details below the following three theoretical intakes will be calculated and evaluated:

* Iodine intakes resulting from only the proposed teat treatment.
* Iodine intakes from milk (sum of the proposed teat treatment + background levels in milk (200 µg/L)).
* Iodine intakes from all dietary sources (sum of the proposed teat treatment + background levels in milk (200 µg/L) + mean intake associated with other dietary sources (adult = 185 µg/day, infant = 96 µg/day)).

| **Summary table of main representative dietary exposure scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Type of use** | **Description of scenario** | **Subject of exposure** |
| 1. | Professional users - indoor | non-medical teat disinfection for cows, sheep and goats.  ◦ Manual with dip treatment : metaSPC 1 / 3 / 4 / 5  used as :   * pre milking : uses 1, 2/ - / - / -   or   * post milking : uses - / 7 / 10/ 11   ◦ Automatic with spraying treatment: metaSPC 1 / 3  used as :   * pre milking : uses 3, 4/ -   or   * post milking : uses - / 8, 9   ◦ Manual with dip treatment : metaSPC 1 / 3 / 4 / 5  used as :   * pre milking : uses 1, 2/ - / - / -   or   * post milking : uses - / 7 / 10 / 11   ◦ Automatic with spraying treatment: metaSPC 6  used as pre and post milking : use 12 | Livestock (**dairy cattle**, sheep and goats)  milk from cows being the major dairy product contributor, it is the only model considered in framework of this dossier |

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.

Therefore 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[[2]](#footnote-2) 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[[3]](#footnote-3) and later, in Annex of Commission Regulation (EU) No.37/2010[[4]](#footnote-4) . |

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). Considering the EC document ”interim approach for the establishment of maximum residue limits for residues of active substances contained in biocidal products for food and feed and specific migration limits in food contact materials” adopted during Competent Authorities meetings of 17 March 2017, it was stated at the Competent Authorities meeting of 17 March and 17 May 2017, that no biocide MRL are necessary for iodine in line with CVMP assessment for iodine.

**Estimated iodine residues in milk resulting from iodine PT3 biocidal product use**

In line with the EU iodine PT3 decision, bibliographic data are used to present an approach based on linear extrapolation of iodine residues in milk from the CAR data across different in-use concentrations of iodine and numbers of product applications per day. The IRG discussion paper performs a re-assessment of two of the residues studies in milk referenced in the Iodine PT3 CAR (one study with pre-milking applications and one study with post-milking applications), as well as a more recent publication “*Iodine concentrations in milk*” (O’Brien 2013).

A comparison of the use patterns and resulting worst case iodine residues in milk considered within the CAR (studies considered sufficiently detailed and relevant by the IRG is presented in the table below) was realized. The studies summarised below are considered relevant to the proposed use patterns of iodine.

**Table 1 - Residues of iodine in milk reported in iodine PT3 CAR studies and O’Brien 2013**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| CAR Study | Iodine  (%) | Applications | Mean treated residue (µg/L) [range] | Mean control residue (µg/L) [range] | Difference (additional iodine residues in milk)  (µg/L) [mean] |
| *Falkenberg*  *2002* | 0.27 | 2x pre-milking | 243.7  [160 - 374] | 212.7  [124 - 300] | 31  (+14.6%) |
| *Iwarsson (A)*  *1974* | 0.50 | 1x post-milking  2x post-milking | 85.5  [46 - 125]  226.3  [135 - 334] | 64 [10 - 186] | 21.5  (+33.6%)  162.3 (+253.6%) |
| *Iwarsson (B)*  *1974* | 0.50 | 2x post-milking | 244  [74 - 392] | 70  [16 - 171] | 174  (+248.6 %) |
| *Iwarsson (C)*  *1974* | 0.25  0.50 | 2x post-milking | 187, 176  301, 334 | N/A - a decrease of approx. 50 % in total iodine residues was observed when halving product iodine content | |
| *O’Brien 2013†* | 0.5 | 2x post milking  2x pre- and post-milking | 475  690 | 224 | 251 (+112.1%)  467 (+208.5%) |

† These data were reported in µg/kg and have been converted to µg/L based on the density of whole milk being 1030 g/L.

So the data from *O’Brien 2013* in the table above have been used to support an approximately linear extrapolation of the iodine content in milk based on the concentration of iodine in a teat disinfectant solution, as well as for increasing numbers of applications of teat disinfectant.

These residue levels reported for a manual spraying scenario are considered to represent the worst-case in terms of current application types (i.e. dipping, spraying or foaming) and level of automation (manual, semi-automatic or automatic/robotic milking).

Milking by robots is considered to be performed on average three times per day, and manual milking two times per day. At the WebEx meeting ( October 2017) it was concluded that ‘*the expected iodine residues in milk from two milking events per day for manual milking and from three events per day for automatic milking are considered comparable*’. Looking at the applied volume of product, on a daily basis there is little difference between automatic and manual milking. Therefore for the exposure calculations, data from 2x manual application in the O’Brien 2013 study is considered appropriate to support the robotic milking uses in the Deosan Activate BPF.

HYDRACHIM IODINE FAMILY contains an in-use concentration of iodine of 0.25-0.49 %, considering 0.17% from PVPI. As the bibliographic data are based on available iodine of 0.5 % (O’Brien 2013*),* the range 0.25-0.49 % of available iodine content has been considered in the dietary risk assessment.

**Estimated iodine residues in milk considering background**

The values reported by EFSA in monitoring studies conducted within the EU indicate mean levels of iodine in milk of 100 - 200 µg/L (EFSA 2005 and EFSA 2013). The most appropriate background level to use in the risk assessment was discussed and agreed at the WebEx meeting (October 2017), where it was concluded that the value of 200 μg/L iodine in milk was appropriate as an EU harmonised value.

Based on the assumed linear relationship between iodine concentration and iodine residues in milk, and the agreed background levels in milk of 200 µg/L, the estimated residues of iodine in milk have been derived and are presented in Table 2.

**Table 2 - Estimated residues of iodine in milk based on extrapolation of O’Brien 2013 data**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Product | Iodine  (%) | Applications | Estimated mean residues of iodine in milk (µg/L) | |
| Proposed teat treatment | TOTAL milk  (+ 200) |
| *O’Brien 2013* | 0.500 | 2x pre-milking† | 215 | 415 |
| *O’Brien 2013* | 0.500 | 2x post-milking | 251 | 451 |
| *O’Brien 2013* | 0.500 | 2x pre- and 2x post-milking | 466 | 666 |
| HYDRACHIM IODINE FAMILY | 0.25-0.49 | 2x pre-milking | 107.5-211 | 307.5-411 |
| HYDRACHIM IODINE FAMILY | 0.25-0.49 | 2x post-milking | 125.5-246 | 325.5-446 |
| HYDRACHIM IODINE FAMILY | 0.25-0.49 | 2x pre-milking +  2x post-milking | 233-457 | 433-657 |

† *Pre-milking estimates calculated as; ‘pre & post milking’ – ‘post milking estimates’.*

*Calculation for 2x pre-milking:*

*For 2 milkings at 0.25-0.49 % iodine intended treatment = 215 µg/L x (0.25 to 0.49)/0.5 = 107.5-211 µg/L*

*For 2 milkings at 0.25-0.49 % iodine total = 107.5 to 211 µg/L + 200 µg/L = 307.5-411 µg/L*

*Calculation for 2x post-milking:*

*For 2 milkings at 0.25-0.49 % iodine intended treatment = 251 µg/L x (0.25 to 0.49)/0.5 = 125.5-246 µg/L*

*For 2 milkings at 0.25-0.49 % iodine total = 125.5 to 246 µg/L + 200 µg/L = 325.5-446 µg/L*

**Intake values (milk consumption) for dietary risk assessment**

There are several sources of milk consumption data available to undertake the consumer intake assessments. This point was discussed during 2017 WG tox meetings and it was concluded that the values from EFSA PRIMo rev 2 are relevant.

According to the ‘EFSA model for chronic and acute risk assessment’ (PRIMo rev.2), the consumption of milk and milk products from sheep, goats and other animals (such as buffaloes) is in the range of 0.002 - 0.12 g/kg bw/day for both adults and children leading to an uptake of milk and milk products well below 10 g/day for each of the animals. Even if the milk from these animals had considerably higher iodine residues than milk from dairy cows, these would not contribute significantly to the iodine supply. Thus, a detailed risk assessment of the residues in milk from these animals is considered to be not relevant.

As only a chronic risk assessment (see section ‘Toxicological reference values for iodine’) is being undertaken, the intake values from the EFSA PRIMo v2 **0.45 L adult and 0.46 L toddler** have been used to estimate the dietary exposure of adults and toddlers to iodine. These values have been agreed at WG Tox IV 2017. The estimated dietary exposure results are presented in Table 3.

**Table 3 – Iodine daily exposure from milk**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| HYDRACHIM IODINE FAMILY  0.25-0.49% | **Consumer group** | Estimated mean residues of iodine in milk (µg/L) | **L per day/person**  (density of whole milk 1030 g/L ) | **Daily exposure (µg/d/pers)** |
| 2x pre-milking | Adult | 307.5-411 | 0.45 | 138-185.5 |
| Toddler | 0.46 | 141.5-189 |
| 2x post-milking | Adult | 325.5-446 | 0.45 | 146.5-201 |
| Toddler | 0.46 | 150-205 |

**Intake values (from food except milk consumption) for dietary risk assessment**

Iodine dietary intake for sources other than milk was included in the third calculation.

The iodine exposure via food was measured in different dietary commodities in framework of EU countries surveys. The monitoring values are subjected to a large variability depending principally of the diets and the geographical localizations. This point was discussed during 2017 WG tox meetings and it was concluded that the values from the UK survey are adequate to represent the EU iodine dietary intake from sources other than milk: 185 µg/day for adults and 96 µg/day for toddler.

**Conclusion for dietary exposure assessment**

The dietary exposure has been discussed in various WG tox and WebEx meetings for iodine-based union authorisations. This EU iodine PT3 approach considered the following default values / decisions or the determination of the worst-case consumer exposure estimate (WCCE):

* 2 manual milkings per day where the product may be used either pre- or post milking
* total daily milk intake of 0.45 l for adults and 0.46 l for toddlers
* background iodine concentration in milk of 200 µg/l
* the intake of iodine from dietary sources other than milk is 185 µg/day for adults and 96 µg/day for toddlers

**Table 3 – Iodine daily exposure from food**

|  |  |  |
| --- | --- | --- |
|  | **Adults (0.45 L/day)** | **Toddler (0.46 L/day)** |
|  | **Estimated daily intake (µg/day)** | **Estimated daily intake (µg/day)** |
| **2x pre-milking teat disinfection (0.25-0.49% available iodine)** | | |
| Intake from milk due to teat treatment1 | 48.3-95 | 49.5-97 |
| Total milk intake2 | 138-185.5 | 141.5-189 |
| Total dietary intake3 | 315 | 229 |
| **2x post-milking teat disinfection (0.25-0.49% available iodine)** | | |
| Intake from milk due to teat treatment1 | 56.5-111 | 58-113 |
| Total milk intake2 | 146.5-201 | 150-205 |
| Total dietary intake3 | 331.5-386 | 246-301 |
| **2x pre-milking+2x post-milking teat disinfection (0.25-0.49% available iodine)** | | |
| Intake from milk due to teat treatment1 | 104.8-206 | 107.5-210 |
| Total milk intake2 | 194.8-296 | 199.5-302 |
| Total dietary intake3 | 379.5-481 | 295.5-398 |

1 Iodine intake from milk due to teat treatment is derived from BP specific residue values (based on O’Brien 2013).

2 Total milk intake is the sum of the estimated additional iodine intake resulting from the transfer into milk following teat disinfection and the iodine background in milk of 200 µg/l.

3 Total dietary intake is the sum of the estimated additional iodine intake resulting from the transfer into milk following teat disinfection, the iodine background in milk of 200 µg/l and iodine from other sources, i.e. 185 µg/day for adults or 96 µg/day for toddlers.

#### **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 bw/d |
| AELmedium-term |
| AELlong-term |
| AEC |  |  | - | - | 1 mg/m3 (0.1 ppm) |
| ARfD | n.a. | - | - | - | - |
| ADI | n.a. | - | - | - | - |

**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 for adult  (0.01 mg/kg bw/d.), 200 µg/day for infant, toddler and child (1-3 years old), 250 µg/day for child of 4-6 years old8.  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 |
| MRL | Compentent Authorities meetings of 17 March and 17 May 2017 | Food of animal origin | No MRL required. |

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)[[5]](#footnote-5). 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

**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 (%)** |
| Scenario [1]  Loading of the teat dip tank | 1 | 1 × 10⁻2 | 5.1 × 10⁻3 | 51% | **97%** | **76%** |
| Scenario [1]  Loading of the teat dip tank | 2 (gloves) | 1 × 10⁻2 | 5.1 × 10⁻4 | 5% | **51%** | **30%** |
| Scenario [3]  Loading spray | 1 | 1 × 10⁻2 | 1.0× 10⁻2 | 100% | 146% | 125% |
| Scenario [3]  Loading spray | 2 (gloves) | 1 × 10⁻2 | 1.0× 10⁻3 | 10% | **56%** | **35%** |
| Scenario [4]  Application by spraying | 1 | 1 × 10⁻2 | 7.71× 10⁻2 | 771% | 812% | 796% |
| Scenario [4]  Application by spraying | 2 (gloves) | 1 × 10⁻2 | 2.27× 10⁻2 | 227% | 273% | 252% |
| Scenario [4]  Application by spraying | 3 (gloves and coated coverall) | 1 × 10⁻2 | 8.15× 10⁻3 | 81% | **127%** | **106%** |
| Scenario [5]  Loading automated spray | 1 | 1 × 10⁻2 | 5.64 × 10⁻5 | 0.6% | **47%** | **26%** |
| Scenario [7] Wiping of animals teats | 1 | 1 × 10⁻2 | 1.8 × 10⁻2 | 180% | 226% | 205% |
| Scenario [7] Wiping of animals teats | 2 (gloves) | 1 × 10⁻2 | 1.8 × 10⁻3 | 18% | **64%** | **43%** |

**Application by dipping:**

**Combined exposure during pre-milking (liquid/foam = use 1 and 2):**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **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 (%)** |
| Scenario [1]  Loading of the teat dip tank | 2 (gloves) | 1 × 10⁻2 | 5.1 × 10⁻4 | 5% | **51%** | **30%** |
| Scenario [7] Wiping of animals teats | 2 (gloves) | 1 × 10⁻2 | 1.8 × 10⁻3 | 18% | **64%** | **43%** |
| **Combined exposure dipping** | **Gloves during wiping** | **1 × 10⁻2** | **6.9 × 10⁻3** | **69%** | **115%** | **94%** |

*The total exposure to iodine is inferior to UL considering a background value of 25% of UL if gloves are worn during the loading of the teat dip tank and wipping of teats.*

*Using a value of 46%, a risk cannot be excluded.*

**Combined exposure during post-milking (use 7,10 and 11):**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **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 (%)** |
| Scenario [1]  Loading of the teat dip tank | 1 | 1 × 10⁻2 | 5.1 × 10⁻3 | 51% | **97%** | **76%** |
| Combined exposure dipping | Without PPE | 1 × 10⁻2 | 5.1 × 10⁻3 | 51% | **97%** | **76%** |

*The total exposure to iodine is inferior to the UL considering a background value of 25% and 46% of UL.*

**Application by spraying:**

**Combined exposure during pre-milking (use 4)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **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 (%)** |
| Scenario [3]  Loading spray | 2 (gloves) | 1 × 10⁻2 | 1.0× 10⁻3 | 10% | **56%** | **35%** |
| Scenario [4]  Application by spraying | 3 (gloves and coated coverall) | 1 × 10⁻2 | 8.15× 10⁻3 | 81% | **127%** | **106%** |
| Scenario [7] Wiping of animals teats | 2 (gloves) | 1 × 10⁻2 | 1.8 × 10⁻3 | 18% |  |  |
| Combined exposure spraying | See above | 1 × 10⁻2 | 9.15× 10⁻3 | 109% | **155%** | **134%** |

*The total exposure to iodine is superior to the UL considering a background value of 25% or 46% of UL.*

**Combined exposure during post-milking (use 9) at 2.9% of PVP iodine:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **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 (%)** |
| Scenario [3]  Loading spray | 2 (gloves) | 1 × 10⁻2 | 1.0× 10⁻3 | 10% | **56%** | **35%** |
| Scenario [4]  Application by spraying | 3 (gloves and coated coverall) | 1 × 10⁻2 | 8.15× 10⁻3 | 81% | **127%** | **106%** |
| Combined exposure spraying | See above | 1 × 10⁻2 | 9.15× 10⁻3 | 91% | **137%** | **116%** |

*The total exposure to iodine is superior to the UL considering a background value of 25% or 46% of UL.*

**Combined exposure during post-milking (use 9) at 2% of PVP iodine:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **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 (%)** |
| Scenario [3]  Loading spray | 2 (gloves) | 1 × 10⁻2 | 7.1× 10⁻4 | 7% | **53%** | **32%** |
| Scenario [4]  Application by spraying | 3 (gloves and coated coverall) | 1 × 10⁻2 | 5.65× 10⁻3 | 57% | **103%** | **82%** |
| Combined exposure spraying | See above | 1 × 10⁻2 | 6.36× 10⁻3 | 64% | **110%** | **89%** |

*The total exposure to iodine is inferior to ULconsidering a background value of 25% of UL.*

*Using a value of 46%, a risk cannot be excluded.*

**Application by automated spraying (use 3 and 8):**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **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 (%)** |
| Scenario [5]  Loading automated spray | 1 | 1 × 10⁻2 | 5.64 × 10⁻5 | 0.6% | **47%** | **26%** |
| Combined exposure dipping | 1 | 1 × 10⁻2 | 5.64 × 10⁻5 | 0.6% | **47%** | **26%** |

*The total exposure to iodine is inferior to the UL considering a background value of 25% or 46% of UL.*

**Combined exposure taking in consideration a treatment by dipping before and after milking by autmated spraying (use 12).**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **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 (%)** |
| Scenario [1]  Loading of the teat dip tank (pre-milking) | 2 (gloves) | 1 × 10⁻2 | 5.1 × 10⁻4 | 5% | **51%** | **30%** |
| Scenario [1]  Loading of the teat dip tank (post milking) | 2 (gloves) | 1 × 10⁻2 | 5.1 × 10⁻4 | 5% | **51%** | **30%** |
| Scenario [7] Wiping of animals teats (pre-milking) | 2 (gloves) | 1 × 10⁻2 | 1.8 × 10⁻3 | 18% | **64%** | **43%** |
| Combined total exposure | Gloves during loading and wiping of teats | 1 × 10⁻2 | 2.82 × 10⁻3 | 28% | **73%** | **53%** |

T*he total exposure to iodine is inferior to the UL considering a background value of 25% and 46% of UL.*

A combined risk assessment, taking in consideration a treatment before and after milking, was not performed for manual spraying because the risk is already unacceptable for the treatment pre-milking.

**Local effects**

As iodine has irritant property on respiratory tract, a local risk assessment has been performed..

Local effects by inhalation are considered, taking into account the AEC of 1 mg/m3 (0.1 ppm) from the CAR.

| **Scenarios** | **Tier** | **Mean event concentration (mg/m3)** | **AEC (mg/m3)** | **Estimated uptake/ AEL (%)** | **Acceptable**  **(yes/no)** |
| --- | --- | --- | --- | --- | --- |
| Scenario [4]  Application by spraying | 1/2/3 | 5.1 × 10⁻2 | 1 | 5.1% | Yes |

The risk is acceptable.

**General conclusion**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **General application** | **Use Number** | **Use description** | **risk assessment conclusions dependiong on the background intake** |
| **Meta-SPC 1** | Pre-milking | 1 | Liquid dipping before milking | 25%: acceptable risk with PPE  46%: unacceptable risk |
| 2 | Dipping with foam before milking | 25%: acceptable risk with PPE  46%: unacceptable risk |
| 3 | Automated spraying before milking | 25%: acceptable risk without PPE  46%: acceptable risk without PPE |
| 4 | Semi-automated or manual spraying before milking | Unacceptable risk |
| **Meta-SPC 3** | Post-milking | 7 (==use 1) | Liquid dipping after milking | 25%: acceptable risk without PPE  46%: acceptable risk without PPE |
| 8 (==use 3) | Automated spraying after milking | 25%: acceptable risk without PPE  46%: acceptable risk without PPE |
| 9 (==use 4) | Semi-automated or manual spraying after milking | Unacceptable at 2.9%PVPI  2%PVPI and less :   * 25%: acceptabe risk wth PPE ( gloves and coated coverall) * 46% unacceptable risk |
| **Meta-SPC 4** | 10 (==use 1) | Thick liquid dipping after milking | 25%: acceptable risk without PPE  46%: acceptable risk without PPE |
| **Meta-SPC 5** | 11 (==use 1) | Thick film-forming liquid dipping after milking | 25%: acceptable risk without PPE  46%: acceptable risk without PPE |
| **Meta-SPC 6** | Pre- and post- milking | 12 (==use 3 & 8) | Automated spraying before and after milking | 25%: acceptable risk with PPE  46%: unacceptable risk |

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

##### Risk for non-professional users

Not relevant

##### 

##### Risk for the general public

Not relevant

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

The estimated dietary intakes of iodine have been compared to the relevant UL for adults (600 µg/d) and infants/toddlers (200 µg/d) and presented in the table below.

Considering the above mentioned hypothesis, estimated daily iodine intakes were calculated for the HYDRACHIM IODINE FAMILY biocide product (0.25-0.49% available iodine). Intakes which exceed the respective UL are highlighted in red text.

**Table 4 – Iodine Dietary risk assessment estimations**

|  |  |  |
| --- | --- | --- |
|  | **Adults (0.45 L/day)** | **Toddler (0.46 L/day)** |
|  | **Estimated daily intake (µg/day)** [% of UL] | **Estimated daily intake (µg/day)** [% of UL] |
| **2x pre-milking teat disinfection (0.25-0.49% available iodine)** | | |
| Intake from milk due to teat treatment1 | 48.3-95  [8-15.8% of UL] | 49.5-97  [24.8-48.5% of UL] |
| Total milk intake2 | 138-185.5  [23-31% of UL] | 141.5-189  [70.8-94.5% of UL] |
| Total dietary intake3 | 323-370.5  [53.8-61.8% of UL] | 237.5-285  [118.8-142.5% of UL] |
| **2x post-milking teat disinfection (0.25-0.49% available iodine)** | | |
| Intake from milk due to teat treatment1 | 56.5-111  [9.4-18.5% of UL] | 58-113  [29-56.5% of UL] |
| Total milk intake2 | 146.5-201  [24.4-33.5% of UL] | 150-205  [75-102.5% of UL] |
| Total dietary intake3 | 331.5-386  [55.3-64.3% of UL] | 246-301  [123-150.5% of UL] |
| **2x pre-milking+2x post-milking teat disinfection (0.25-0.49% available iodine)** | | |
| Intake from milk due to teat treatment1 | 104.8-206  [17.5-34.3% of UL] | 107.5-210  [53.8-105% of UL] |
| Total milk intake2 | 194.8-296  [32.5-49.3% of UL] | 199.5-302  [99.8-151% of UL] |
| Total dietary intake3 | 379.5-481  [63.3-80.2% of UL] | 295.5-398  [147.8-199% of UL] |

1 Iodine intake from milk due to teat treatment is derived from BP specific residue values (based on O’Brien 2013).

2 Total milk intake is the sum of the estimated additional iodine intake resulting from the transfer into milk following teat disinfection and the iodine background in milk of 200 µg/l.

3 Total dietary intake is the sum of the estimated additional iodine intake resulting from the transfer into milk following teat disinfection, the iodine background in milk of 200 µg/l and iodine from other sources, i.e. 185 µg/day for adults or 96 µg/day for toddlers.

*Calculation for 2x pre-milking applications:*

*Percentage UL for adult= ([48.3-95] /600) = 8-15.8 % or ([138-185.5]/600) = 23-31 % or ([323-370.5]/600) = 53.8-61.8%*

*Percentage UL for children= ([49.5-97]/200) = 24.8-48.5% or ([141.5-189]/200) = 70.8-94.5% or ([237.5-285]/200) = 118.8-142.5%*

*Calculation for 2x post-milking applications:*

*Percentage UL for adult= ([56.5-111] /600) = 9.4-18.5% or ([146.5-201]/600) = 24.4-33.5% or ([331.5-386]/600) = 55.3-64.3%*

*Percentage UL for children= ([58-113]/200) = 29-56.5% or ([150-205]/200) = 75-102.5% or ([246-301]/200) = 123-150.5%*

*Calculation for 2x pre-milking + 2x post-milking applications:*

*Percentage UL for adult= ([104.8-206] /600) = 17.5-34.3% or ([194.8-296]/600) = 32.5-49.3% or ([379.5-481]/600) = 63.3-80.2%*

*Percentage UL for children= ([107.5-210]/200) = 53.8-105% or ([199.5-302]/200) = 99.8-151% or ([295.5-398]/200) = 147.8-199%*

An exceedance of the Upper Intake Level (UL) for children cannot be excluded based on the available data. At this stage, no additional refinement can be realised without any measurements of iodine residue in milk. Indeed, considering the biocide use alone with a cumulative treatment for pre and post milking, an exceedance of UL is identified for toddler (105%). Nevertheless this case is only intended for SPC6 containing 0.49% iodine, which is only a automatic use. Considering the automatic application the iodine contamination is considered as to be overestimated. So the exposure is expected to remains below 105% of UL.

The Upper Intake Level (UL) is a reference value considered to compare the exposure via food estimated for the uses of HYDRACHIM IODINE FAMILY. As stated above, the UL is an indicative upper value exposure, but does not represent a threshold directly linked to a toxicological risk.

**Conclusion**

The estimation of iodine contamination in milk is performed considering the worst case situation. Human health risk is acceptable for all milking applications based on estimated intakes, except for toddlers, where total daily intake considerably exceeds the UL. Iodine from toddler dietary intake, arising from every other source except from iodine containing teat disinfection product residues, takes up almost the whole fraction of the UL if current EU data is used. It highlights the importance to obtain more reliable information on iodine background levels in food items in the EU, and consequently to update the data supporting the current UL.

**General conclusion for hyman health risque assessment**

Considering the intended use of HYDRACHIM IODINE FAMILY and based on overall available information, French competent authorities (FR CA) conclusions are summarized in the table below

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **General application** | **Use Number** | **Use description** | **risk assessment conclusions** |
| **Meta-SPC 1** | Pre-milking | 1 | Liquid dipping before milking | acceptable risk with PPE |
| 2 | Dipping with foam before milking | acceptable risk with gloves |
| 3 | Automated spraying before milking | acceptable risk without PPE |
| 4 | Semi-automated or manual spraying before milking | Unacceptable risk |
| **Meta-SPC 3** | Post-milking | 7 (==use 1) | Liquid dipping after milking | acceptable risk without PPE |
| 8 (==use 3) | Automated spraying after milking | acceptable risk without PPE |
| 9 (==use 4) | Semi-automated or manual spraying after milking | 2.9% PVPI : Unacceptable risk  2%PVPI and less : acceptabe risk wth PPE ( gloves and coated coverall) |
| **Meta-SPC 4** | 10 (==use 1) | Thick liquid dipping after milking | acceptable risk without PPE |
| **Meta-SPC 5** | 11 (==use 1) | Thick film-forming liquid dipping after milking | acceptable risk without PPE |
| **Meta-SPC 6** | Pre- and post- milking | 12 (==use 3 & 8) | Automated spraying before and after milking | 25%: acceptable risk with gloves |

### 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

#### Risk assessment for the environment

|  |
| --- |
| Please notice that the risk assessment for the environment (section 2.2.8) is reported as provided by the applicant. The FR CA position is presented in **green evaluation boxes.** |

The biocidal product family applied for authorization is a group of disinfectants for application in product type PT3 (Veterinary hygiene biocidal products) for professional use only. The risk assessment of this product family is based on the information provided in

the AR[[6]](#footnote-6) (formulated product based on PVPi). No new data/information on the formulated products were developed.

##### 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 should be taken into account in the environmental risk assessment. Literature data were compiled in the AR[[7]](#footnote-7). Obtained environmental background values as presented in the table below:

|  |
| --- |
| **Box 1 - FR CA position:**  We agree with the following summary of background levels. |

|  |  |
| --- | --- |
| **Summary table of background levels** | |
| **Compartment** | **Background level (as iodine)** |
| Soil | Typically 0.5 - 20 mg/kgdwt but with extremes up to 98 mg/kgdwt  Global mean value of 5 mg/kgdwt |
| Groundwater | Mean concentration: 1 µg/L  Range: < 1 - 70 µg/L with extremes up to 400 µg/L |
| Freshwater (river and lake) | 0.5 - 20 µg/L |
| Marine water | 45 - 60 µg/L |
| Rainwater | 0.1 - 15 µg/L |
| Freshwater sediment | Typically: 6 mg/kg |
| Marine sediment | Typically: 3 - 400 mg/kg |
| Air | Atmosphere: 10 - 20 ng/m3  Atmospheric concentration: over land 2 - 14 ng/m3; over ocean 17 - 52 ng/m3  Marine air contains: 100 µg/L (may refer to local inhalable air) |

***PNEC derivation:***

Based on ecotocological data presented here above, PNEC values were proposed in the AR for iodine, iodate and iodide. Resulting values are presented in the table here below :

|  |
| --- |
| **Box 2 - FR CA position:**  We agree with the following summary of PNEC values. |

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table on PNEC** | | | |
| **Environmental compartment** | | **Iodine species** | **PNEC** |
| Aquatic, freshwater | 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 |
| Aquatic, marine | Seawater | Iodine (I**2**) | 0.000059 mg/L |
| Iodate (IO**3**-) | 0.00585 mg/L |
| Iodide (I-) | 0.000083 mg/L |
| Marine sediment | - | Not used in the risk assessment |
| Terrestrial | | Iodine (I**2**) | 0.0118 mg/kg wwt |
| Iodate (IO**3**-) | 0.304 mg/kg |
| Iodide (I-) | 0.0043 mg/kg |
| 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***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Environmental Hazards** | |
| Value/conclusion | Active substance - Iodine: 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 | Based on the experience with iodine and observed aquatic toxicity, the following classification is proposed in the AR:   * **In accordance with the criteria in Directive 67/548/EEC:**   R50 - Very toxic to aquatic organisms   * **In accordance with the criteria in Regulation (EC) No 1272/2008:** Aquatic Acute 1; H400; M = 1 |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Box 3 - FR CA position:**   |  |  | | --- | --- | | **Conclusion used in Risk Assessment – Environmental Hazards** | | | Value/conclusion | Biocidal product family: Harmful to aquatic life with long-lasting effects | | Justification for the value/conclusion | - | | Classification of the product according to CLP and DSD | Based on calculation method (Guidance on the application of the CLP criteria, ECHA, version 4.1, June 2015),the following classification is proposed:   * **In accordance with the criteria in Regulation (EC) No 1272/2008:** the product is classified H412 | |

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Environmental Hazards** | |
| Value/conclusion | Biocidal product family: Harmful to aquatic life with long-lasting effects |
| Justification for the value/conclusion | - |
| Classification of the product according to CLP and DSD | Based on calculation method (Guidance on the application of the CLP criteria, ECHA, version 4.1, June 2015), the following classification is proposed:   * **In accordance with the criteria in Directive 67/548/EEC:**   R52/53 - Harmful to aquatic life with long-lasting effects   * **In accordance with the criteria in Regulation (EC) No 1272/2008:** Aquatic Chronic 3; H412 |

***Further Ecotoxicological studies***

|  |
| --- |
| **Box 4 - FR CA position:**  The following studies provided by the applicant correspond to data proposed in CAR of the active substance. These studies are not new data on the biocidal product familly. |

**Summary table - Further ecotoxicological studies**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table of effects on sewage sludge microorganisms believed to be at risk** | | | | |
| Species/  Inoculum | End point | Exposure | Results | Reference1 |
|  | Duration | EC 50 |  |
| Mixed population of activated sewage sludge micro-organisms | Respiration  inhibition | 3 h | 290 mg/L | AR, 2013 |

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment - Further ecotoxicological studies** | |
| Value/conclusion | 3 h EC50 = 290 mg/L |
| Justification for the value/conclusion | The respiration inhibition test with sewage sludge micro-organisms indicated an EC50 of 290 mg/L for iodine (AR). |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table of effects on further soil organisms believed to be** | | | | **at risk** |
| Species/ | End point | Exposure | Results | Reference1 |
| Inoculum |  | duration | EC50 (Iodine) |  |
| Soil micro-organisms | Respiration  inhibition | 28 d | 148.7 mg/kgdwt | AR |
| Soil micro-organisms | Nitrate formation | 28 d | 82.6 mg/kgdwt |  |
| *Eisenia fetida* | Acute toxicity | 14 d | >1000 mg/kg dwt >740 mg/kg wwt |  |
| *Avena sativa* | Acute toxicity | 21 d | 13.4 mg/kg dwt  11.8 mg/kg wwt |  |
| *Allium cepa* | Acute toxicity | - | 26.6 mg/kg dwt  23.4 mg/kg wwt |  |
| *Brassica napus* | Acute toxicity | - | 22.1 mg/kg dwt  19.4 mg/kg wwt |  |
| *Helianthus annuus* | Acute toxicity | - | 1. mg/kg dwt 2. mg/kg wwt |  |
| *Lycopersicon esculentum* | Acute toxicity | - | 1. mg/kg dwt 2. mg/kg wwt |  |
| *Cucumis sativa* | Acute toxicity | - | 14.2 mg/kg dwt  12.5 mg/kg wwt |  |

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment - Effects on further organisms** | |
| Value/conclusion | 21 d EC50 = 13.4 mg/kg dwt |
| Justification for the value/conclusion | Acute terrestrial toxicity tests have been submitted for earthworms, non­target plants and soil micro-organisms with non-target plants being most sensitive. In the study on terrestrial plants six different species were tested and the results were rather similar for all six, the EC50 values ranging between 13.4 and 26.6 mg/kg. The most sensitive species was Avena sativa, with an EC50 of 13.4 mg iodine/kg dry soil for the most sensitive parameter shoot fresh weight (AR). |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | - |
| Justification | No data available and no data required as intended uses and ecotoxicological data do not indicate any specific risk which would not be covers by the endpoints here above. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | - |
| Justification | No data available and no data required as the use of product will not lead to direct exposure of non-target organisms. The product is used indoor for disinfection and reaches the environment mixed with manure or wastewater. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | - |
| Justification | No data available and no data required as the use of product will not lead to direct exposure of non-target organisms. The product is used indoor for disinfection and reaches the environment mixed with manure or  wastewater. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | - |
| Justification | No data available and no data required as the product is used indoor for disinfection |

***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)

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | - |
| Justification | No data available and no data required as the product is used indoor. |

***Leaching behaviour (ADS)***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | - |
| Justification | No data available and no data required as this type of test is not relevant for PT3. |

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

*[If no data is available, delete the tables and indicate only that no data is available.]*

**Distribution**

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment - Distribution in soil** | |
| Value/conclusion | Kpsoil = 5.8 cm3/q |
| Justification for the value/conclusion | Adsorption data for iodine has been acquired from an adsorption screening test according to OECD 106 and from publicly available information. A geometrical mean Koc of 165.8 cm3/g was calculated from the OECD 106 test. However, the adsorption of iodine to soil is not only attributed to organic matter, even though this type of adsorption seems to be predominant at pH >6. A different approach is therefore applied, i.e. to use measured partitioning coefficients Kd (or KpCOmp as given in the TGD) for soil and suspended matter directly. The solids-water adsorption coefficients to be used in the environmental exposure calculations are Kpsoil = 5.8 cm3/g and Kpsusp = 2.2 x 102 cm3/g (AR). |

**Dissipation**

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment - Dissipation in soil** | |
| Value/conclusion | - |
| Justification for the value/conclusion | Whereas the term degradation is not applicable to an element, iodine may undergo different hydrolytical, photolytical and microbial transformation processes (i.e. speciation) in the different compartments. The presence of different forms of iodine is largely dependent on redox potential and pH. Iodide and iodate are the dominant iodine species in soil. Iodate is the dominant chemical form of iodine in the soil solution under non-flooded  conditions whilst under flooded conditions iodide is the dominant chemical form. Hence calculation of DT50 is not applicable (AR, 2013). |

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

**Distribution**

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment –distribution in STP** | |
| Value/conclusion | Sludge retention factor of 20% |
| Justification for the value/conclusion | When assessing the distribution of iodine species in sewage treatment plants, it was established that the Simple Treat model normally used, and that resulted in a sludge retention factor of 1.93%, was not appropriate. Molecular iodine is a chemically unstable element with oxidizing properties and it is assumed that when iodine reached the wastewater stream it will speciate into iodate and iodide. Therefore, sludge retention factors are based on literature data and laboratory and field experiments, which range between 20 and 80% retention. Considering that iodide is not highly adsorbed to sludge under typical conditions and iodate can form complexes with calcium which easily adsorb to negatively charged particle surfaces, the majority of the iodine that passes an STP will most probably not be retained in sludge and a sludge retention factor of 20% is chosen for the risk assessment (i.e. 80% of the iodine discharged to the STP remains in the effluent) (AR). |

**Distribution**

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment –Distribution in water and sediment** | |
| Value/conclusion | Kpsusp := 2.2 x 102 cm3/g |
| Justification for the value/conclusion | Please see justification for "**Distribution in soil**"  In natural water/sediment systems, iodide would be the predominant species under aerobic conditions. Iodine can enter sediments through accumulation of plant matter or fixation of iodide in water to humic substances. Weaker and reversible binding of iodide to inorganic components in sediments may also occur (Kd values ranging from -0.22 mL/g for chlorite minerals to 15.14 mL/g for iolite minerals) (AR). |

**Dissipation**

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment –Dissipation in water and sediment** | |
| Value/conclusion | - |
| Justification for the value/conclusion | Whereas the term degradation is not applicable to an element, iodine may undergo transformation processes (i.e. speciation) in the different compartments. Hence calculation of DT**50** is not applicable (AR).  Hydrolysis reaction of iodine occurs to a very small extent because iodine is sparingly soluble. Hydrolysis of iodine as the reactant is a pH-dependent dynamic equilibrium reaction with iodide (I-) and iodate (IO**3**) as products. At pH values between 4 and 9, iodide is the predominant species. In alkaline and well oxidized waters iodate is the predominant specie.  In water, iodide and iodate are the predominant species. In addition a natural background level of methyl iodide might also be found in water. Photolytic dissociation of these compounds can result in the formation of elemental iodine and inorganic iodine species (AR). |

**Bioconcentration factor**

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment –Bioconcentration factor** | |
| Value/conclusion | Not considered relevant |
| Justification for the value/conclusion | The logKow (<3) indicates that iodine has a low potential for bio­concentration and bioaccumulation. BCF factors are generally low (0.001 to 810 for freshwater and marine fish, freshwater and marine invertebrates, marine and terrestrial plants). However, these figures are not based on standard bioconcentration tests. Moreover, high intracellular iodine concentrations may have other explanations, e.g. physiological processes like active transport and intracellular enzymatic reactions.  Most importantly, estimation of bioaccumulation potential for iodine is not considered relevant as iodine is an essential element and its absorption is regulated in animals of several taxonomic groups (AR). |

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

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment –distribution and dissipation in air** | |
| Value/conclusion | - |
| Justification for the value/conclusion | The concept of degradation is not applicable as iodine is an element. However, it may undergo transformation processes (i.e. speciation) in the different compartments. Calculation of DT**50** is not applicable (AR).  Iodine is volatilised in several forms with methyl iodide (CH**3**I) probably being the most important one. Methyl iodide and molecular iodine are the predominant iodine species in air. Both iodine and methyl iodide undergo photochemical reactions to form iodine radicals, which can then go on to form a number of other iodine species through a complex series of reaction pathways. Rapid photolysis of iodine takes place in the lower atmosphere due to its strong absorption of light in the visible wavelengths (400 < À < 700 nm). Lifetime = 5-10 seconds for an overhead sun (AR). |

***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)***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | - |
| Justification | The product is used indoor for disinfection and only reaches the environment mixed with manure or wastewater. |

***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)***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | - |
| Justification | The product is used indoor for disinfection and reaches the environment mixed with manure or wastewater. |

#### **Exposure assessment**

The environmental risk assessment for the product is based on the emission scenario document for Product Type 3 (JRC Scientific and Technical Reports; 2011[[8]](#footnote-8)) as well as on the ECHA Guidance for Environmental Risk Assessment (2015[[9]](#footnote-9)).

**General information**

|  |  |  |
| --- | --- | --- |
| Assessed PT | PT 3 | |
| Assessed scenarios\* | Scenario 1 | Meta SPC1 - Pre-milking; Liquid dipping before milking |
| Scenario 2 | Meta SPC1 - Pre-milking; Liquid dipping with foam before milking |
| Scenario 3 | Meta SPC1 - Pre-milking; Automated spraying before milking |
| Scenario 4 | Meta SPC1 - Pre-milking; Semi-automated or manual spraying before milking |
| Scenario 5 | Meta SPC2 - Pre-milking; Liquid dipping to dilute before milking (liquid) |
| Scenario 6 | Meta SPC2 - Pre-milking; Liquid dipping to dilute before milking (foam) |
| Scenario 7 | Meta SPC3 - Post-milking; Liquid dipping after milking |
| Scenario 8 | Meta SPC3 - Post-milking; Automated spraying after milking |
| Scenario 9 | Meta SPC3 - Post-milking; Semi-automated or manual spraying after milking |
| Scenario 10 | Meta SPC4 - Post-milking; Thick liquid dipping after milking |
| Scenario 11 | Meta SPC5 - Post-milking; Thick film forming liquid dipping after milking |
| Scenario 12 | Meta SPC6 - Pre and Post-milking; Automatic spraying before and after milking |
| ESD(s) used | Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, 2011 | |
| Approach | Scenario 1 to 12: Average consumption | |
| Distribution in the environment | Calculated based on ECHA Guidance on the BPR; April 2015 | |
| Life cycle steps assessed | Application phase | |

\*Scenarios are numbered in agreement with numbering of uses presented in SPC

Iodine is used in veterinary hygiene biocidal products (PT3) for the purpose of manual and automatic non-medical teat disinfection. Application methods are spraying and dipping of teats, with dipping being most commonly used. In this last case, the teats are immersed before and/or after milking using a cuplike container that holds the disinfectant. At least the lower third of the teats should be immersed. Dip solution remaining in the cuplike container should be discharged. After application through spraying or dipping, the applied teat disinfectant is left to dry on the teat surface and remains there as a protective film, otherwise the worker wipes the treated teats after application.

Two emission pathways are possible: emission to waste water or to the slurry. This depends on whether the cows are milked in the stable (emission to slurry) or in a milking parlour outside the stable (emission to waste water). When the product is discharged in manure, indirect emission will occur to agricultural soil through fertilization with manure. The amount of manure to be used for fertilization is controlled by nitrogen and phosphorus emission standards. When the product is discharged to waste water, indirect emission to surface water and agricultural soil occurs (fertilization with sewage sludge).

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 AR.

The PEC and PNEC values were calculated based on the assumption that 100% iodine (I2) is transferred either to two iodide (I-) or iodate (IO3-) ions. The molecular weight of two iodide ions corresponds to the molecular weight of iodine, consequently the PECs for iodide are the same as for iodine. The molecular weight of two iodate ions is a factor of 1.382 higher than the molecular weight of iodine, therefore the PECs for iodate were calculated by multiplying the PECs of iodine by this factor. No degradation is considered for any of the PEC values. The concept of degradation is not applicable as iodine is an element.

The structure of this document does not separate emission estimation (Elocalcompartment ) and distribution in the environment (PECcompartment). This modification compared to standard template was made because the scenarios in the ESD for PT3 lead to direct calculation of PEC values in soil.

##### Emission estimation

As developed above, emissions of iodine to the environment may occur via waste water (STP) or when contaminated manure is applied onto the soil. For estimation of emission, the ESD PT 3 "Veterinary hygiene biocidal products"(2011) was used. Following product specific inputs are required: Content of active ingredient in formulation, amount of product prescribed to be used for one treatment (dipping of the four teats) of one animal, Dilution factor (for preparation of the working solution from the formulation).

For a summary of inputs values per scenario please see table here below.

Content of active ingredient (Fbioc)

The products of the family contain 2.9% PVP-iodine at their maximum range, except meta- SPC2 products which contain 6%. As proposed in the assessment report, the risk assessment is conducted on pure iodine concentration and not PVPi content. As described in the assessment report, as a worst case, the active substance contains 12% of available iodine. Thus the iodine contents of the evaluated formulations are 3.57 and 7.34 g Iodine/L respectively. A density of 1.02 kg/L was considered for all the products of the family based on the average value measured on reference products (see table here below). This approach was taken considering the low variation of density in the family.

|  |  |
| --- | --- |
| **Meta-SPC** | **Density (g/mL) (kg/L)** |
| **Minimum formulation** | **1.001** |
| 1 | **1.010** |
| 2 | **1.046** |
| 3 | **1.018** |
| 4 | **1.020** |
| 5 | **1.012** |
| **Average** | **1.018** |

*Conversion percentage to g/L :*

(% of PVPi in the product \*10)\* product density

(2.9 \*10)\*1.02 = 29.58 gPVPi/L

OR

(6 \*10)\*1.02 = 61.2 gPVPi/L

*Conversion PVPi concentration to iodine concentration:*

Concentration of PVPi \* percentage of available iodine = concentration of iodine

28.43 \* 12% = 3.57 g available iodine/L

61.2 \* 12% = 7.34 g available iodine/L

Based on these calculations, the maximum active substance contents of the products, expressed as PVPi and available iodine, are summarized in the table here below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Meta SPC** | **Theoretical maximum concentration PVPi (%)** | **Theoretical maximum content available iodine compared to PVPi (%)** | **Measured content available iodine compared to PVPi (%)\*** | **Theoretical maximum concentration available iodine (%)** |
| Minimum formulation | 0.5 | 12 | 10.4 | 0.06 |
| **Meta SPC1** | 3 | 12 | 10.7 | 3.57 |
| **Meta SPC2** | 6 | 12 | 10.6 | 7.34 |
| **Meta SPC3** | 3 | 12 | 9.5 | 3.57 |
| **Meta SPC4** | 3 | 12 | 9.9 | 3.57 |
| **Meta SPC5** | 3 | 12 | 7.7 | 3.57 |
| **Meta SPC6** | 3 | 12 | 10.7 | 3.57 |

\*Provided as supporting data to the maximum value of 12%. Data obtained from long term storage stability study, initial measurement.

Amount of product prescribed to be used for one treatment (Vprod)

The standard values proposed in DRAWG draft proposal "Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products" (Appendix I, Table 1) were used.

These values are:

• For dipping 10ml/cow/milking

• For spraying 20ml/cow/milking

• For foams 2.5 ml/cow/milking

Dilution factor (Fdil)

This factor was calculated based on recommended use of the product. No dilution are applied to the product except for Meta-SPC2. For this meta-SPC, the initial concentration is 6% and the target in-use solution is 2.9%.

The dilution factor is thus 0.49.

**Input parameters specific to each scenario**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | |
| **Scenario Name** | | **Fbioc 1)[g/L]** | **Vprod**i1,i2,i3 **2)****[L]** | **F**dil **3) [-]** |
| Scenario 1 | Meta SPC1 - Pre-milking; Liquid dipping before milking | 3.57 | 0.01 | 1 |
| Scenario 2 | Meta SPC1 - Pre-milking; Liquid dipping with foam before milking | 3.57 | 0.0025 | 1 |
| Scenario 3 | Meta SPC1 - Pre-milking; Automated spraying before milking | 3.57 | 0.02 | 1 |
| Scenario 4 | Meta SPC1 - Pre-milking; Semi-automated or manual spraying before milking | 3.57 | 0.02 | 1 |
| Scenario 5 | Meta SPC2 - Pre-milking; Liquid dipping to dilute before milking (liquid) | 7.34 | 0.01 | 0.49 |
| Scenario 6 | Meta SPC2 - Pre-milking; Liquid dipping to dilute before milking (foam) | 7.34 | 0.0025 | 0.49 |
| Scenario 7 | Meta SPC3 - Post-milking; Liquid dipping after milking | 3.57 | 0.01 | 1 |
| Scenario 8 | Meta SPC3 - Post-milking; Automated spraying after milking | 3.57 | 0.02 | 1 |
| Scenario 9 | Meta SPC3 - Post-milking; Semi-automated or manual spraying after milking | 3.57 | 0.02 | 1 |
| Scenario 10 | Meta SPC4 - Post-milking; Thick liquid dipping after milking | 3.57 | 0.01 | 1 |
| Scenario 11 | Meta SPC5 - Post-milking; Thick film forming liquid dipping after milking | 3.57 | 0.01 | 1 |
| Scenario 12 | Meta SPC6 - Pre and Post-milking; Automatic spraying before and after milking | 3.57 | 0.02 | 1 |

1) Fbioc:Content of active ingredient (iodine) in formulation (product)

2) Vprodi1,i2,i3: Amount of product prescribed to be used for one treatment (dipping of the four teats) of one animal

3) Fdil: Dilution factor (for preparation of the working solution from the formulation (product))

Based on input parameters for each specific scenario (please see table here above), the scenarios 5 and 6 (Meta-SPC 2) are found to be covered by scenarios 1 and 2. These scenarios are thus not further assessed. This same table indicates that scenario 12 is a combination of scenarios 3 and 8. Scenario 12 will thus be assessed separately as a combined scenario

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

*Fate and distribution in exposed environmental compartments via manure application*

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Fresh-water | Freshwater sediment (1) | Sea-water (2) | Seawater sediment (1) | STP | Air | Soil | Ground-water |
| Scenario 1 | *yes* | *yes* | *yes* | *yes* | *no* | *no* | *yes* | *yes* |
| Scenario 2 | *yes* | *yes* | *yes* | *yes* | *no* | *no* | *yes* | *yes* |
| Scenario 3 | *yes* | *yes* | *yes* | *yes* | *no* | *no* | *yes* | *yes* |
| Scenario 4 | *yes* | *yes* | *yes* | *yes* | *no* | *no* | *yes* | *yes* |
| Scenario 7 | *yes* | *yes* | *yes* | *yes* | *no* | *no* | *yes* | *yes* |
| Scenario 8 | *yes* | *yes* | *yes* | *yes* | *no* | *no* | *yes* | *yes* |
| Scenario 9 | *yes* | *yes* | *yes* | *yes* | *no* | *no* | *yes* | *yes* |
| Scenario 10 | *yes* | *yes* | *yes* | *yes* | *no* | *no* | *yes* | *yes* |
| Scenario 11 | *yes* | *yes* | *yes* | *yes* | *no* | *no* | *yes* | *yes* |

(1)PEC's calculated for freshwater and marine sediments are negligible compared to the natural background levels and not used in the risk assessment. Moreover, no risk assessment has been performed for sediments as both the PEC and PNEC values for sediment would have been calculated using the equilibrium partitioning method, and consequently the resulting risk quotient would be the same as described for surface/sea water

(2)PEC/PNEC ratios for seawater are not explicitly reported here since they would be the same as those for freshwater taking into account both that the PNEC values are 10 times lower and that a dilution factor of 10 is applied on the PEC.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Box 5 - FR CA position:**  We agree with the exposure assessment proposed by the applicant, but methodological changes from recommendation of the BPC Ad hoc Working Group on Environmental Exposure (agreed at the Environment Working Group V on November 26, 2015) must be taken into account in the risk assessment update.  Furthermore, the total available iodine (I2 + I-) from PVPi considered is 17%. So, the content of active substance in the in–use product for the scenarios 1 to 12 is 4.9 g/L.  As explained by the applicant, the scenario 12 is a combination of scenario 3 and 8 (combined use of pre-milking and post-milking in automated spraying). Thus, emissions calculated for scenario 12 will cover emissions of each scenario considered in the report. So, it was decided to present the environmental assessment of scenario 12 (as a worst case covering the other applications). Besides, the scenarios 3 and 8 are considered as worst case scenario for pre-milking and post-milking applications respectively. The tables below present the input parameters for the calculation of emissions to manure or STP in accordance with the characteristic of the product and the ESD for PT03[[10]](#footnote-10).   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Input parameters for emission calculations for the worst case Scenario 12** | | | | | | Parameter | Nomenclature | Value | Unit | Origin | | Type of housing/manure storage (for application of the notification) | **cat-subcat (i1)** | 1 – Dairy cows | [-] | S (ESD Appendix 1: Table 7) | | Type of biocide | **bioctype (i2)** | 1 - Disinfectant | [-] | S (ESD Appendix 1: Table 7) | | Type of application | **appway (i3)** | 1 Spraying | [-] | S (ESD Appendix 1: Table 7) | | Relevant emission stream | **stream(i4)** | 1 and 3- Manure/waste water | [-] | P (Appendix 1: Table 7) | | Content of active ingredient in formulation (product) | **Fbioc** | **4.9** | g/L | S | | Amount of product prescribed to be used for one treatment (dipping of the four teats) of one animal | **Vprodi1,i2,i3** | 0.02 | L | S | | Dilution factor (for preparation of the working solution from the formulation (product)) | **Fdil A)** | 1 | [-] | S | | Fraction of active ingredient released | **F slurry/manure or STP** | 0.5 | [-] | D | | **F air** | 0 | [-] | D | | **Fteat** | 0.5 | [-] | D | | Number of teat dipping events for one animal and one day (dipping of the four teats of one animal = one disinfectant application | **Napp-teat** | 4 (pre and post milking) | [-] | D | | Number of days of lactation period | Nday-lact | 300 | [-] | D | | Number of disinfectant applications in one year | Napp-bioc | 600 | [-] | D | | Interval between two disinfectant applications | Tbioc-int | 0.5 | [-] | D | | Number of manure applications for grassland | Napp-grass | 1 | [-] | D | | Number of manure applications for arable land | Napp-arab | 1 | [-] | D | | Manure application time interval for grassland | Tgr-int | 53 | [-] | D/S (ESD-PT3, 2011; Appendix1: Table 12) | | Manure application time interval for arable land | Tar-int | 212 | [-] | D/S (ESD-PT3, 2011; Appendix1: Table 12) | | Number of animal in housing for category/subcategory i1=1 | Nanimali1 | 100 | [-] | D/S (ESD-PT3, 2011; Appendix1: Table 8) | | Amount of nitrogen per animal for category/subcategory i1=1 | Qnitrogi1 | 0.3389 | [kg.d-1] | D (ESD-PT3, 2011; Appendix1: Table 11) | | *If nitrogen immission standards are applied:* | | | | | | Nitrogen immission standard for one year on grassland | QN,grassland | 170 | [kg.ha-1] | D (ESD-PT3, 2011; Appendix1: Table 13) | | Nitrogen immission standard for one year on arable land | QN,arable\_land | 170 | [kg.ha-1] | D (ESD-PT3, 2011; Appendix1: Table 13) | | Mixing depth with soil, grassland | DEPTHgrassland | 0.05 | [m] | D | | Mixing depth with soil, arable land | DEPTHarable \_land | 0.2 | [m] | D | | Density of wet bulk soil | RHOsoilwet | 1700 | [kg.m-3] | D |   \*D: default from ESD, S: set based on product.  The table below presents input parameters, intermediate calculations and output needed for the PEC calculations for emission via slurry and manure.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Additional Input parameters and intermediate calculations for scenario 12**  **"Input parameters for emission calculations to soil via manure application"** | | | | | | Parameter | Nomenclature | Value | Unit | Origin | | Number of biocide applications during storage period for application on grassland | Napp-manuregr | 106 | [-] | O | | Number of biocide applications during storage period for application on arable land | Napp-manurear | 424 | [-] | O | | Amount of active ingredient to be used for one application | Qai-prescri1,i2,i3 | 9.8E-05 | [kg] | O | | Amount of active ingredient in relevant stream i4 after one application for all animals | Qai i1,i2,i3,i4 | 4.9E-03 | [kg] | O | | Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to grassland | Qai-grassi1,i2,i3,i4 | 1.04 | [kg] | O | | Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to arable land | Qai-arabi1,i2,i3,i4 | 4.15 | [kg] | O | | Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to grassland | Qnitrog-grassi1,i4 | 1.80E+03 | [kg] | O | | Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to arable land | Qnitrog-arabi1,i4 | 7.18E+03 | [kg] | O | | ***OUTPUT*** | | | | | | Concentration of the biocide (active ingredient) in soil in the case of immission standard for nitrogen and land application on grassland | PIECgrs-Ni1,i2,i3,i4 | 1.06E-01 | [mg.kg-1wwt. Year-1] | O | | Concentration of the biocide (active ingredient) in soil in the case of immission standard for nitrogen and land application on arable land | PIECars-Ni1,i2,i3,i4 | 2.89E-02 | [mg.kg-1wwt. Year-1] | O | | Local emission to a standard STP or on-site waste water treatment plant | Qai-stpi1,i2,i3,i4 = Elocalwaste water | 1.61E-02 | [kg.d-1] | O |      |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Input parameters for emission calculations for the worst cases Scenario 3 or 8.** | | | | | | Parameter | Nomenclature | Value | Unit | Origin | | Type of housing/manure storage (for application of the notification) | **cat-subcat (i1)** | 1 – Dairy cows | [-] | S (ESD Appendix 1: Table 7) | | Type of biocide | **bioctype (i2)** | 1 - Disinfectant | [-] | S (ESD Appendix 1: Table 7) | | Type of application | **appway (i3)** | 1 Spraying | [-] | S (ESD Appendix 1: Table 7) | | Relevant emission stream | **stream(i4)** | 1 and 3- Manure/waste water | [-] | P (Appendix 1: Table 7) | | Content of active ingredient in formulation (product) | **Fbioc** | **4.9** | g/L | S | | Amount of product prescribed to be used for one treatment (dipping of the four teats) of one animal | **Vprodi1,i2,i3** | 0.02 | L | S | | Dilution factor (for preparation of the working solution from the formulation (product)) | **Fdil A)** | 1 | [-] | S | | Fraction of active ingredient released | **F slurry/manure or STP** | 0.5 | [-] | D | | **F air** | 0 | [-] | D | | **Fteat** | 0.5 | [-] | D | | Number of teat dipping events for one animal and one day (dipping of the four teats of one animal = one disinfectant application | **Napp-teat** | 2 (pre or post milking) | [-] | D | | Number of days of lactation period | Nday-lact | 300 | [-] | D | | Number of disinfectant applications in one year | Napp-bioc | 600 | [-] | D | | Interval between two disinfectant applications | Tbioc-int | 0.5 | [-] | D | | Number of manure applications for grassland | Napp-grass | 1 | [-] | D | | Number of manure applications for arable land | Napp-arab | 1 | [-] | D | | Manure application time interval for grassland | Tgr-int | 53 | [-] | D/S (ESD-PT3, 2011; Appendix1: Table 12) | | Manure application time interval for arable land | Tar-int | 212 | [-] | D/S (ESD-PT3, 2011; Appendix1: Table 12) | | Number of animal in housing for category/subcategory i1=1 | Nanimali1 | 100 | [-] | D/S (ESD-PT3, 2011; Appendix1: Table 8) | | Amount of nitrogen per animal for category/subcategory i1=1 | Qnitrogi1 | 0.3389 | [kg.d-1] | D (ESD-PT3, 2011; Appendix1: Table 11) | | *If nitrogen immission standards are applied:* | | | | | | Nitrogen immission standard for one year on grassland | QN,grassland | 170 | [kg.ha-1] | D (ESD-PT3, 2011; Appendix1: Table 13) | | Nitrogen immission standard for one year on arable land | QN,arable\_land | 170 | [kg.ha-1] | D (ESD-PT3, 2011; Appendix1: Table 13) | | Mixing depth with soil, grassland | DEPTHgrassland | 0.05 | [m] | D | | Mixing depth with soil, arable land | DEPTHarable \_land | 0.2 | [m] | D | | Density of wet bulk soil | RHOsoilwet | 1700 | [kg.m-3] | D |   \*D: default from ESD, S: set based on product.  The table below presents input parameters, intermediate calculations and output needed for the PEC calculations for emission via slurry and manure.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Additional Input parameters and intermediate calculations for scenarios 3&8**  **"Input parameters for emission calculations to soil via manure application"** | | | | | | Parameter | Nomenclature | Value | Unit | Origin | | Number of biocide applications during storage period for application on grassland | Napp-manuregr | 106 | [-] | O | | Number of biocide applications during storage period for application on arable land | Napp-manurear | 424 | [-] | O | | Amount of active ingredient to be used for one application | Qai-prescri1,i2,i3 | 9.8E-05 | [kg] | O | | Amount of active ingredient in relevant stream i4 after one application for all animals | Qai i1,i2,i3,i4 | 4.9E-03 | [kg] | O | | Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to grassland | Qai-grassi1,i2,i3,i4 | 5.19E-01 | [kg] | O | | Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to arable land | Qai-arabi1,i2,i3,i4 | 2.07 | [kg] | O | | Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to grassland | Qnitrog-grassi1,i4 | 1.80E+03 | [kg] | O | | Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application to arable land | Qnitrog-arabi1,i4 | 7.18E+03 | [kg] | O | | ***OUTPUT*** | | | | | | Concentration of the biocide (active ingredient) in soil in the case of immission standard for nitrogen and land application on grassland | PIECgrs-Ni1,i2,i3,i4 | 5.31E-02 | [mg.kg-1wwt. Year-1] | O | | Concentration of the biocide (active ingredient) in soil in the case of immission standard for nitrogen and land application on arable land | PIECars-Ni1,i2,i3,i4 | 1.44E-02 | [mg.kg-1wwt. Year-1] | O | | Local emission to a standard STP or on-site waste water treatment plant | Qai-stpi1,i2,i3,i4 = Elocalwaste water | 8.05E-03 | [kg.d-1] | O | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Box 6 - FR CA position:**  The table below presents the physico-chemical parameters needed for the PEC calculations.   |  |  | | --- | --- | | **Physico-chemical parameters used as inputs in the environmental exposure assessments according to the CAR (December,2013) and recommendation of the BPC (november,2015)** | | | **Parameters for iodine** | Value | | **Molecular mass (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:** Partition coefficient solid-water in suspended matter **(L/kg)** | 220 | | **Ksusp-water:** Susp-water partition coefficient **(m3/m3)** | 55.9 | | **Kpsoil:** Partition coefficient organic carbon-water **(L/kg)** | 5.8 | | **Ksoil-water:** Soil-water partition coefficient **(m3/m3)** | 8.903 | | **Fstp water:** Fraction of emission directed to water by STP released **(-)** | 0.8 | | **Fstp sludge:** Fraction of emission directed to water by STP released **(-)** | 0.2 | | **SLUDGERATE:** Rate of sewage sludge production **(kg/d)** | 790 | | **DT50 soil (days)** | 1E06 | | **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 iodide (%)** | 100 | | **Transformation rate in soil iodine to iodide via the STP (%)** | 100 | | **Transformation rate in soil iodine to iodide via manure (%)** | 100 | | **Molecular equivalent iodate/iodine** | 1.382 |   In a first time, manure and slurry applications were considered only on 1 year as proposed in the ESD for PT03. However, following the European discussions, applications on 10 years have been added taking disspation (leaching) in soil into account with DT50 of 643 days for grassland and 2571 days for arable land as agreed at the European level. The equations of the Addendum to the OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 14: Emission Scenario Document for Insecticides for Stables and Manure Storage Systems were applied.  Finally, according to the CAR, all considered compartment with PEC/PNEC ratio above 1 will be assessed by a comparison between PEC values for iodine and background level determined for each compartment. |

**PEC calculations via manure application**

Soil is the first exposed environmental compartemt when the product is discharged in manure. The predicted environmental concentration (PEC) of iodine (and the iodine species iodide and iodate) in soil has been determined using the Tier 1 procedure provided in the ESD for PT3 (JRC, 2011). Furthermore, the soil pore water concentration was used as an indicator for potential concentrations in groundwater and surface water (due to run­off from the field). These values were calculated based on the ESD Number 14 (OECD, 2006[[11]](#footnote-11)). Based on iodine's volatility characteristics and background concentrations, an estimation of atmospheric PEC is not necessary.

Using the below final equations and the default values given in the ESD PT 3 (JRC; 2011) (see table below) the concentration of iodine, iodide and iodate in soil following a single land application of manure are calculated.

**Equations if the phosphate emission standard is applicable**

Concentration of the active ingredient in soil based on the phosphate emission standard for grassland

100 x Qai-grass i1,i2,i3,i4 x QP2O5, grassland

PIECgrs- P2O5 i1,i2,i3,i4 =

Qphosph-grass i1,i4 x Nlapp-grass x DEPTH grassland x RHOsoil wet

Where:

QP2O5, grassland : Phosphate emission standard for one year on grassland

Qai-grass i1,i2,i3,i4 : Amount of active ingredient for manure or slurry after the relevant number of biocide applications for the manure application

Qphosph-grass i1,i4 : Amount of phosphate produced during the relevant period for every relevant (sub)category of animal/housing i1 and application

Concentration of the active ingredient in soil based on the phosphate emission standard for arable land

100 x Qai-arab i1,i2,i3,i4 x QP2O5, arable-land

PIECars- P2O5 i1,i2,i3,i4 =

Qphosph-arab i1,i4 x Nlapp-arab x DEPTH arable-land x RHOsoil wet

**Equations if the nitrogen emission standard is applicable**

Concentration of the active ingredient in soil based on the nitrogen emission standard for grassland

100 x Qai-grass i1,i2,i3,i4 x QN, grassland

PIECgrs- N i1,i2,i3,i4 =

Qnitro-grass i1,i4 x Nlapp-grass x DEPTH grassland x RHOsoil wet

Concentration of the active ingredient in soil based on the nitrogen emission standard for arable land

100 x Qai-arab i1,i2,i3,i4 x QN, arable-land

PIECars- Ni1,i2,i3,i4 =

Qnitro-arab i1,i4 x Nlapp-arab x DEPTH arable-land x RHOsoil wet

**Details of the environmental intermediate calculations for PECsoil via manure application**

The intermediate calculation of iodine in soil via manure application are given using the below equations.

Amount of active ingredient to be used for one application (one treatment of one animal):

Qai-presci1,i2,i3 = 10-3 x Fbioc x Vprodii,i2,i3 x Fdii

Amount of active ingredient in relevant stream i4 after one application for all animals:

Qai i1,i2,i3,i4 = F stp or slurry/manure i1,i2,i3,i4 \* Qai-prescr i1,i2,i3 \* Nanimalil

Amount of active ingredient for manure or slurry after the relevant number of biocide applications for the manure application:

* to grassland

Qai-grassi1,i2,i3,i4 = Qai i1,i2,i3,i4 \* Napp-manuregr

* to arable land

Qai-arab i1,i2,i3,i4 = Qai i1,i2,i3,i4 \* Napp-manurear

Amount of phosphate produced during the relevant period for every relevant (sub)category of animal/housing i1 and application:

* to grassland

Qphosph-grassi1,i4 = Nanimali1 \* Qphosphi1 \* Tgr-inti2

* to arable land

Qphosph-arabi1,i4 = Nanimali! \* Qphosphi! \* Tar-inti2

Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing i1 and application:

* to grassland

Qnitrog-grassi1,i4 = Nanimali1 \* Qnitrogi1 \* Tgr-inti2

* to arable land

Qnitrog-arabi1,i4 = Nanimali1 \* Qnitrogi1 \* Tar-inti2

|  |  |  |
| --- | --- | --- |
| **Additional Input parameters for intermediate calculations not listed under "Input parameters for emission calculations to soil via manure application"** | | |
| Parameter | Description | Value |
| **Napp-manure**gr | Number of biocide applications during storage period for application on grassland | 106 (D) |
| **Napp-manure**ar | Number of biocide applications during storage period for application on arable land | 424 (D) |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table on intermediate values used on the calculation of PECsoil via manure application (kg)** | | | | | | | | |
| **Scenarios** | Qai-presc  i1,i2,i3 | Qai  i1,i2,i3,i4 | Qai-grass  i1,i2,i3,i4 | Qai-arab  i1,i2,i3,i4 | Qphosph-  grassi1,i4 | Qphosph-  arabi1,i4 | Qnitrog-  grassi1,i4 | Qnitrog-  arabi1,i4 |
| **Scenario 1** | 0.000036 | 0.001785 | 0.189210 | 0.756840 | 554.70 | 2218.79 | 1796.17 | 7184.68 |
| **Scenario 2** | 0.000009 | 0.000446 | 0.047303 | 0.189210 | 554.70 | 2218.79 | 1796.17 | 7184.68 |
| **Scenario 3** | 0.000071 | 0.003570 | 0.378420 | 1.513680 | 554.70 | 2218.79 | 1796.17 | 7184.68 |
| **Scenario 4** | 0.000071 | 0.003570 | 0.378420 | 1.513680 | 554.70 | 2218.79 | 1796.17 | 7184.68 |
| **Scenario 7** | 0.000036 | 0.001785 | 0.189210 | 0.756840 | 554.70 | 2218.79 | 1796.17 | 7184.68 |
| **Scenario 8** | 0.000071 | 0.003570 | 0.378420 | 1.513680 | 554.70 | 2218.79 | 1796.17 | 7184.68 |
| **Scenario 9** | 0.000071 | 0.003570 | 0.378420 | 1.513680 | 554.70 | 2218.79 | 1796.17 | 7184.68 |
| **Scenario 10** | 0.000036 | 0.001785 | 0.189210 | 0.756840 | 554.70 | 2218.79 | 1796.17 | 7184.68 |
| **Scenario 11** | 0.000036 | 0.001785 | 0.189210 | 0.756840 | 554.70 | 2218.79 | 1796.17 | 7184.68 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for emission calculations to soil via manure application** | | | | |
| Parameter | Nomenclature | Value | Unit | Origin\* |
| Type of housing/manure storage (for application of the notification) | **cat-subcat (i1)** | 1 | [-] | S (Appendix 1: Table 7) |
| Type of biocide | **bioctype (i2)** | 1 | [-] | S (Appendix 1: Table 7) |
| Type of application | **appway (i3)** | 1 and 2 (depending on scenarios) | [-] | S (Appendix 1: Table 7) |
| Relevant emission stream | **stream(i4)** | 1 and 3 | [-] | P (Appendix 1: Table 7) |
| Content of active ingredient in formulation (product) | **Fbioc** | Parameters provided in below tables based on scenario specificities | g/L | S |
| Amount of product prescribed to be used for one treatment (dipping of the four teats) of one animal | **Vprod**i1,i2,i3 | L | S |
| Dilution factor (for preparation of the working solution from the formulation (product)) | **F**dil A) | [-] | S |
| Fraction of active ingredient released | **F** slurry/manure\_i1,i2 ,i3,i4 | 0.5 | [-] | D |
| **F** air | 0 | [-] | D |
| **F**teat | 0.5 | [-] | D |
| Number of teat dipping events for one animal and one day (dipping of the four teats of one animal = one disinfectant application | **Napp-teat** | 2 | [-] | D |
| Number of days of lactation period (corresponds to number of emission days) | **Nday-lact (= Temission)** | 300 | [-] | D |
| Number of disinfectant applications in one year (equal number of disinfectant applications in one lactation period) | **Napp-bioc** | 600 | [-] | D |
| Interval between two disinfectant applications (dipping events) | **T bioc-int** | 0.5 | d | D |
| Number of manure applications for grassland | **Nlapp-grass** | 4 | [-] | D |
| Number of manure applications for arable land | **Nlapp-arab** | 1 | [-] | D |
| Manure application time interval for grassland | **T**gr-int | 53 | d | D/S (Appendix 1: Table 12) |
| Manure application time interval for arable land | **T**ar-int | 212 | d | D/S (Appendix 1: Table 12) |
| Number of animal in housing for category/subcategory i1 = 1 | **Nanimal** i**1** | 100 | [-] | D/S (Appendix 1: Table 8) |
| Amount of phosphate per animal for category/subcategory i1 = 1 | **Qphosph**ü | 0.10466 | kg/d | D (Appendix 1: Table 11) |
| Amount of nitrogen per animal for category/subcategory i1 = 1 | **Qnitrog**ü | 0.3389 | kg/d | D (Appendix 1: Table 11) |
| If phosphate emission standards are applied: | | | | |
| Phosphate emission standard for one year on grassland | **Q**P2O5, grassland | 110 | kg/ha | D (Appendix 1: Table 13) |
| Phosphate emission standard for one year on arable land | **Q**P2O5, arable\_land | 85 | kg/ha | D (Appendix 1: Table 13) |
| If nitrogen emission standards are applied: | | | | |
| Nitrogen emission standard for one year on grassland | **Q**N,grassland | 170 | kg/ha | D (Appendix 1: Table 13) |
| Nitrogen emission standard for one year on arable land | **Q**N,arable-land | 170 | kg/ha | D (Appendix 1: Table 13) |
| Mixing depth with soil, grassland | **DEPTH**grassland | 0.05 | m | D |
| Mixing depth with soil, arable land | **DEPTH**arable\_land | 0.2 | m | D |
| Density of wet bulk soil | **RHOsoil**wet | 1700 | kg/m3 | D |

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

***Calculated PEC values***

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Box 7 - FR CA position:**  Scenario 12 as a worst case - Exposure characterization  Scenario 12 covers a combined use of pre-milking and post-milking in automated spraying. This scenario was thus assessed as a combination of scenarios 3 and 8. It should be noted that the nitrogen standard is the most relevant in Europe notably in France. Therefore, regarding emission via manure application, PEC values were calculated for application to grassland and arable land on the nitrogen standard.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Summary table on calculated PEC for scenario 12 and background levels (as iodine)** | | | | | |  | **Values for Iodine** | | **Values for Iodide** | **Values for Iodate** | | **Background** | **PEC** | **PEC** | **PEC** | | **Via manure application (10 years applications)** | | | | | | Surface water grassland (µg.L-1) | 0.5-20 | 9.09 | 9.09 | 1.26E+01 | | Surface water arable (µg.L-1) | 3.69 | 3.69 | 5.1 | | Soil grassland (mg.kgwwt ) | 0.565-22.6  extremes up to 110.74 | 4.76E-01 | 4.76E-01 | 6.58E-01 | | Soil arable (mg.kgwwt ) | 1.93E-01 | 1.93E-01 | 2.67E-01 | | Groundwater grassland (µg.L-1) | 1-70 | 9.09E+01 | 9.09E+01 | 1.26E+02 | | Groundwater arable (µg.L-1) | 3.69E+01 | 3.69E+01 | 5.10E+01 | | **Via STP** | | | | | | **Elocal** (kg/d) | 1.61E-02 | | | | | STP (mg/L) | - | 6.44E-03 | 6.44E-03 | 8.91E-03 | | Surface water (µg/L) | 0.5-20 | 6.42E-01 | 6.42E-01 | 8.88E-01 | | Soil (mg/kgwwt) | 0.565-22.6  extremes up to 110.74 | 3.99E-02 | 5.58E-03 | 5.51E-02 | | Groundwater(µg/L) | 1-70 | 7.46 | 1.04 | 1.03E+01 |   Scenario 3 or 8 as a worst case for pre-milking and post-milking application respectively - Exposure characterization  Scenario 3 and 8 cover the use of the product for pre-milking and post-milking applications. These scenarios are similar, the only difference is the timing of the application, thus the environmental assessment for the both is proposed in the following table. As explained above, the nitrogen standard is the most relevant in Europe notably in France. Therefore, regarding emission via manure application, PEC values were calculated for application to grassland and arable land on the nitrogen standard.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Summary table on calculated PEC for scenario 3 or 8 and background levels (as iodine)** | | | | | |  | **Values for Iodine** | | **Values for Iodide** | **Values for Iodate** | | **Background** | **PEC** | **PEC** | **PEC** | | **Via manure application (10 years applications)** | | | | | | Surface water grassland (µg.L-1) | 0.5-20 | 4.55 | 4.55 | 6.28 | | Surface water arable (µg.L-1) | 1.84 | 1.84 | 2.55 | | Soil grassland (mg.kgwwt ) | 0.565-22.6  extremes up to 110.74 | 2.38E-01 | 2.38E-01 | 3.29E-01 | | Soil arable (mg.kgwwt ) | 9.66E-02 | 9.66E-01 | 1.34E-01 | | Groundwater grassland (µg.L-1) | 1-70 | 4.55E+01 | 4.55E+01 | 6.28E+01 | | Groundwater arable (µg.L-1) | 1.84E+01 | 1.84E+01 | 2.55E+01 | | **Via STP** | | | | | | **Elocal** (kg/d) | 8.05E-03 | | | | | STP (mg/L) | - | 3.22E-03 | 3.22E-03 | 4.45E-03 | | Surface water (µg/L) | 0.5-20 | 3.21E-01 | 3.21E-01 | 4.44E-01 | | Soil (mg/kgwwt) | 0.565-22.6  extremes up to 110.74 | 1.99E-02 | 2.79E-03 | 2.76E-02 | | Groundwater(µg/L) | 1-70 | 3.73 | 5.22E-01 | 5.16 | |

*Calculated PECsoil values via manure application*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values for iodine, iodide and iodate** | | | | | | | | |
|  | **PECsoil Iodine and Iodide** (mg/kg wwt) | | | | **PECsoil Iodate (mg/kg wwt)** | | | |
| *Phosphate standard* | | *Nitrogen standard* | | *Phosphate standard* | | *Nitrogen standard* | |
| *Grassland* | *Arable land* | *Grassland* | *Arable land* | *Grassland* | *Arable land* | *Grassland* | *Arable land* |
| Scenario 1 | 0.011036 | 0.008528 | 0.005267 | 0.005267 | 0.015251 | 0.011786 | 0.007279 | 0.007279 |
| Scenario 2 | 0.002759 | 0.002132 | 0.001317 | 0.001317 | 0.003813 | 0.002946 | 0.001820 | 0.001820 |
| Scenario 3 | 0.022071 | 0.017055 | 0.010534 | 0.010534 | 0.030503 | 0.023570 | 0.014558 | 0.014558 |
| Scenario 4 | 0.022071 | 0.017055 | 0.010534 | 0.010534 | 0.030503 | 0.023570 | 0.014558 | 0.014558 |
| Scenario 7 | 0.011036 | 0.008528 | 0.005267 | 0.005267 | 0.015251 | 0.011786 | 0.007279 | 0.007279 |
| Scenario 8 | 0.022071 | 0.017055 | 0.010534 | 0.010534 | 0.030503 | 0.023570 | 0.014558 | 0.014558 |
| Scenario 9 | 0.022071 | 0.017055 | 0.010534 | 0.010534 | 0.030503 | 0.023570 | 0.014558 | 0.014558 |
| Scenario 10 | 0.011036 | 0.008528 | 0.005267 | 0.005267 | 0.015251 | 0.011786 | 0.007279 | 0.007279 |
| Scenario 11 | 0.011036 | 0.008528 | 0.005267 | 0.005267 | 0.015251 | 0.011786 | 0.007279 | 0.007279 |

*PEC in groundwater via manure application*

A simple Tier 1 assessment of the predicted concentration in groundwater (PECgw) has been carried out by calculating the soil porewater concentration of iodine (and the iodine species iodide and iodate) as suggested by the ESD PT18 (2006) and the ECHA Guidance for Environmental Risk Assessment (2015). The Tier 1 assessment is based on the assumption that the concentration in groundwater will not exceed the maximum soil porewater concentration.

Potential exposure to soil porewater is anticipated via application of stored manure to land and subsequent leaching to groundwater. It should be noted that this represents a very simplified worst-case approach, neglecting transformation processes and dilution in deeper soil layers. The porewater concentration of iodine (and the iodine species iodide and iodate) is calculated based on equation 67 from ECHA Guidance on the BPR:

(PEClocalsoil x RHOsoilwet)

PEC local soil, porew =

(Ksoil — water x 1000)

Where *PEClocal soil* is given by PIEC values from the phosphate or nitrogen emission standard applicable for grassland and arable land.

Where *Ksoil-water* is given by equation 24 from ECHA Guidance on the BPR.

HENRY Kpsoil

Ksoil — water = ( Fairsoil x ) + Fwatersoil + ( Fsolidsoil x x RHOsolid )

R x TEMP 1000

Using this exposure scenario and the formulae given above, the theoretical maximum concentration in groundwater is estimated in the table below:

|  |  |  |
| --- | --- | --- |
| **Input parameters for emission calculations to groundwater via manure application** | | |
| Parameter | Description | Value |
| **PEClocal soil** | Predicted environmental concentration in soil (mq/kq wwt), values for qrassland and arable land | See "calculated PECsoil  values" |
| **RHOsoil** | Bulk density of wet soil (kg/m3) | 1,700 (D) |
| **Fairsoil** | Fraction of air in soil compartment (m3/m3) | 0.2 (D) |
| **HENRY** | Henry's Law Constant (Pa m3/mol) | 34.43 (AR, 2013) |
| **R** | Gas constant (Pa m3/mol/k) | 8.314 (D) |
| **TEMP** | Temperature of the air-water interface (K) | 285 (D) |
| **Fwatersoil** | Fraction of water in soil compartment (m3/m3) | 0.2 (D) |
| **Fsolidsoil** | Fraction of solids in soil compartment (m3/m3) | 0.6 (D) |
| **Kpsoil** | Partition coefficient organic carbon-water (L/kg) | 5.8 (AR, 2013) |
| **RHOsolid** | Density of the solid phase (kg/m3) | 2,500 (D) |
| **Ksoil-water** | Soil-water partition coefficient (m3/m3) | 8.903 (intermediate calculation, see here above) |

D: default from ECHA Guidance for Environmental Risk Assessment (2015)

*Calculated PECgw values via manure application*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PECgw values for iodine, iodide and iodate** | | | | | | | | |
|  | **PECgw/PECpore-water**(mg/L) | | | | **PECgw/PECpore-water**(mg/L) | | | |
| *Phosphate standard* | | *Nitrogen standard* | | *Phosphate standard* | | *Nitrogen standard* | |
| *Grassland* | *Arable land* | *Grassland* | *Arable land* | *Grassland* | *Arable land* | *Grassland* | *Arable land* |
| Scenario 1 | 0.002107 | 0.001628 | 0.001006 | 0.001006 | 0.002912 | 0.002250 | 0.001390 | 0.001390 |
| Scenario 2 | 0.000527 | 0.000407 | 0.000251 | 0.000251 | 0.000728 | 0.000563 | 0.000347 | 0.000347 |
| Scenario 3 | 0.004214 | 0.003257 | 0.002011 | 0.002011 | 0.005824 | 0.004501 | 0.002780 | 0.002780 |
| Scenario 4 | 0.004214 | 0.003257 | 0.002011 | 0.002011 | 0.005824 | 0.004501 | 0.002780 | 0.002780 |
| Scenario 7 | 0.002107 | 0.001628 | 0.001006 | 0.001006 | 0.002912 | 0.002250 | 0.001390 | 0.001390 |
| Scenario 8 | 0.004214 | 0.003257 | 0.002011 | 0.002011 | 0.005824 | 0.004501 | 0.002780 | 0.002780 |
| Scenario 9 | 0.004214 | 0.003257 | 0.002011 | 0.002011 | 0.005824 | 0.004501 | 0.002780 | 0.002780 |
| Scenario 10 | 0.002107 | 0.001628 | 0.001006 | 0.001006 | 0.002912 | 0.002250 | 0.001390 | 0.001390 |
| Scenario 11 | 0.002107 | 0.001628 | 0.001006 | 0.001006 | 0.002912 | 0.002250 | 0.001390 | 0.001390 |

*PEC in surface water via manure application*

Use of the product is not carried out near surface water bodies. However, following use of the formulated product in animal houses and subsequent land application of manure, exposure of surface water to the active substance could potentially occur as a result of water run-off from areas treated with manure.

The predicted environmental concentration (PEC) of iodine (and the iodine species iodide and iodate) in surface water has been determined using Tier 1 procedure provided in ESD PT18 (2006). PEC surface water was calculated from the groundwater concentration assuming a dilution factor of 10.

The potential concentration of iodine (and the iodine species iodide and iodate) in surface water is given in the below equation:

PECgw

PECsw =

DILUTIONrun – off

Using this exposure scenario and the equation above, the potential concentration of iodine (and the iodine species iodide and iodate) in surface water is determined for arable land and grassland in the below table.

*Calculated PECsurface water values*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PECgw values for iodine, iodide and iodate** | | | | | | | | |
|  | **PECgw/PECpore-water**(mg/L) | | | | **PECgw/PECpore-water**(mg/L) | | | |
| *Phosphate standard* | | *Nitrogen standard* | | *Phosphate standard* | | *Nitrogen standard* | |
| *Grassland* | *Arable land* | *Grassland* | *Arable land* | *Grassland* | *Arable land* | *Grassland* | *Arable land* |
| Scenario 1 | 0.000211 | 0.000163 | 0.000101 | 0.000101 | 0.000291 | 0.000225 | 0.000139 | 0.000139 |
| Scenario 2 | 0.000053 | 0.000041 | 0.000025 | 0.000025 | 0.000073 | 0.000056 | 0.000035 | 0.000035 |
| Scenario 3 | 0.000421 | 0.000326 | 0.000201 | 0.000201 | 0.000582 | 0.000450 | 0.000278 | 0.000278 |
| Scenario 4 | 0.000421 | 0.000326 | 0.000201 | 0.000201 | 0.000582 | 0.000450 | 0.000278 | 0.000278 |
| Scenario 7 | 0.000211 | 0.000163 | 0.000101 | 0.000101 | 0.000291 | 0.000225 | 0.000139 | 0.000139 |
| Scenario 8 | 0.000421 | 0.000326 | 0.000201 | 0.000201 | 0.000582 | 0.000450 | 0.000278 | 0.000278 |
| Scenario 9 | 0.000421 | 0.000326 | 0.000201 | 0.000201 | 0.000582 | 0.000450 | 0.000278 | 0.000278 |
| Scenario 10 | 0.000211 | 0.000163 | 0.000101 | 0.000101 | 0.000291 | 0.000225 | 0.000139 | 0.000139 |
| Scenario 11 | 0.000211 | 0.000163 | 0.000101 | 0.000101 | 0.000291 | 0.000225 | 0.000139 | 0.000139 |

*Fate and distribution in exposed environmental compartments via STP*

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Fresh-water | Freshwater sediment (1) | Sea-water (2) | Seawater sediment (1) | Air | STP | Soil | Groundwater |
| Scenario 1 | *yes* | *yes* | *yes* | *yes* | *no* | *yes* | *yes* | *yes* |
| Scenario 2 | *yes* | *yes* | *yes* | *yes* | *no* | *yes* | *yes* | *yes* |
| Scenario 3 | *yes* | *yes* | *yes* | *yes* | *no* | *yes* | *yes* | *yes* |
| Scenario 4 | *yes* | *yes* | *yes* | *yes* | *no* | *yes* | *yes* | *yes* |
| Scenario 7 | *yes* | *yes* | *yes* | *yes* | *no* | *yes* | *yes* | *yes* |
| Scenario 8 | *yes* | *yes* | *yes* | *yes* | *no* | *yes* | *yes* | *yes* |
| Scenario 9 | *yes* | *yes* | *yes* | *yes* | *no* | *yes* | *yes* | *yes* |
| Scenario 10 | *yes* | *yes* | *yes* | *yes* | *no* | *yes* | *yes* | *yes* |
| Scenario 11 | *yes* | *yes* | *yes* | *yes* | *no* | *yes* | *yes* | *yes* |

(1) PEC's calculated for freshwater and marine sediments are negligible compared to the natural background levels and not used in the risk assessment. Moreover, no risk assessment has been performed for sediments as both the PEC and PNEC values for sediment would have been calculated using the equilibrium partitioning method, and consequently the resulting risk quotient would be the same as described for surface/sea water.

(2) PEC/PNEC ratios for seawater are not explicitly reported here since they would be the same as those for freshwater taking into account both that the PNEC values are 10 times lower and that a dilution factor of 10 is applied on the PEC.

**PEC calculations via STP**

The waste water treatment plant (STP) is the first exposed environmental compartment when the product is discharged in waste water. The predicted environmental concentration (PEC) of iodine (and the iodine species iodide and iodate) in STP has been determined using the Tier 1 procedure provided in the ESD PT3 and ECHA Guidance for Environmental Risk Assessment (2015).

In a second phase, STP exposure leads to emission to surface water and agricultural soil. Both PECs where calculated based on ECHA Guidance for Environmental Risk Assessment (2015) and using data from the AR on sludge retention rate. In a last phase, sludge application to soil leads to exposure of groundwater and surface water via run-off. The soil pore water concentration was used as an indicator for potential concentrations in groundwater (PECgw) and surface water (PECsw). These PECs were assessed based on the ESD Number 14 (OECD, 2006). Based on iodine's volatility characteristics and background concentrations, an estimation of atmospheric PEC is not necessary.

*PEC in STP*

The model presented in the ESD PT 3 comprises a calculation of the amount emitted to waste water. Next, ECHA Guidance for Environmental Risk Assessment (2015) was used to calculate iodine concentration in the STP influent after dilution in municipal waste water. Microorganisms of STP are considered to be exposed to iodine concentration in effluent of STP, thus to the iodine concentration after treatment of the water and elimination of the active substance to sludge.

Following the use of the product, iodine is emitted to the waste water. The resulting emitted quantity is given by the equation below (see ESD):

Qai-stp = F stp x Qai-prescr x Nanimal x Napp-teat x Temission / 365

|  |  |  |
| --- | --- | --- |
| **Input parameters for calculations of Qai-stp** | | |
| Parameter | Description | Value |
| **Fstp** | Fraction of active inqredient released | 0.5 (D) |
| **Qai-prescr** | Amount of active ingredient to be used for one application (one treatment of one animal) | See "Input parameters specific to Scenarios" |
| **Nanimal** | Number of animal in housing for category/subcategory | 100 (D) |
| **Napp-teat** | Number of teat dipping events for one animal and one day | 2 (D) |
| **Temission** | Number of days of lactation period (corresponds to number of emission days) | 300 (D) |

D: default

The quantity emitted to waste water or local emission (Qai-STP =Elocalwater) is diluted in municipal waste water. This leads to an iodine concentration in the water entering the STP (Clocalinf) calculated using following equation (equation 33 of the ECHA Guidance on the BPR):

Elocalwater x 106

……………………….Clocalinf =

EFFLUENTstp

Subsequent treatment of waste water entering the STP lead to retention of part of the iodine in sludge. Usual modelling of this process is not applicable for iodine as explained in AR and thus sludge retention rate was determined in AR based on litterature data. The parameter Clocaleff is the PECstp.

Clocaleff = Clocalinf x Fstpwater

|  |  |  |
| --- | --- | --- |
| **Input parameters for calculations of PEC STP** | | |
| Parameter | Description | Value |
| **EFFLUENTSTP** | Sewage treatment plant effluent discharge rate (L/day) | 2,000,000 (D) |
| **Fstpwater** | Fraction of emission directed to water by STP (mg/L) | 0.8 (AR) |

Using the formulae and input data given above, the resulting worst-case concentration of iodine in the effluent of the STP after treatment is calculated in the below table.

*Calculated PECSTP values*

|  |  |
| --- | --- |
| **Summary table on calculated PECSTP values for iodine** | |
|  | **PECSTP** (mg/L) |
| Scenario 1 | 0.001174 |
| Scenario 2 | 0.000293 |
| Scenario 3 | 0.002347 |
| Scenario 4 | 0.002347 |
| Scenario 7 | 0.001174 |
| Scenario 8 | 0.002347 |
| Scenario 9 | 0.002347 |
| Scenario 10 | 0.001174 |
| Scenario 11 | 0.001174 |

*PEC in surface water via STP*

The effluent of the sewage treatment plant is diluted into the surface water.

Using the following equation and the input parameters (equation 45 of the ECHA Guidance for Environmental Risk Assessment), the local concentration in surface water is calculated in the below table. This ouput corresponds to PEC surface water (PEC sw).

Clocaleff

Clocalwater =

(1 + Kpsusp x SUSPwater x 10-6) x DILUTION

|  |  |  |
| --- | --- | --- |
| **Input parameters for calculations of Clocalwater (=PEC sw)** | | |
| Parameter | Description | Value |
| **Clocaleff** | PEC for microorganisms in the STP (mg/L) | See table "Calculated  PEC**stp** values" |
| **Kpsusp** | Partition coefficient solid-water in suspended matter (L/kg) | 220 (AR, 2013) |
| **SUSPwater** | Concentration of suspended matter in the river (mg/L) | 15 (D) |
| **DILUTION** | Dilution factor (-) | 10(D) |

D: default

*Calculated PECsurface water values via STP*

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PECsurface water values for iodine, iodine and iodate** | | |
|  | **PECsurface water for** **Iodine and Iodide** (mg/L) | **PECsurface water for** **Iodate** (mg/L) |
| Scenario 1 | 0.000117 | 0.000162 |
| Scenario 2 | 0.000029 | 0.000040 |
| Scenario 3 | 0.000234 | 0.000323 |
| Scenario 4 | 0.000234 | 0.000323 |
| Scenario 7 | 0.000117 | 0.000162 |
| Scenario 8 | 0.000234 | 0.000323 |
| Scenario 9 | 0.000234 | 0.000323 |
| Scenario 10 | 0.000117 | 0.000162 | |
| Scenario 11 | 0.000117 | 0.000162 | |

*PEC in soil via sludge application*

Guidance for calculating PEClocal in soil due to application of sewage sludge in agriculture is given the the ECHA Guidance for Environmental Risk Assessment (2015).

When soil is fertilized with sludge from the STP, a concentration of iodine (and the iodine species iodide and iodate) is transferred into this compartment.

For the calculation of iodine (and the iodine species iodide and iodate) in soil via sludge application, the rate of sewage sludge production can be estimated using equation 37 of the ECHA Guidance for Environmental Risk Assessment (2015):

SLUDGERATE = 2/3 x SUSPCONCinf x EFFLUENT stp + SURPLUSsludge x CAPACITYstp

The obtained value is then used in equation 36 for the calculation of the iodine (and the iodine species iodide and iodate) concentration obtained in sewage sludge:

Fstpsludge x Elocalwater x 106

Csludge =

SLUDGERATE

The concentration in soil just after the first application can be derived with equation 60:

Csludge x APPLsludge

Csludge soil 1 (0) =

DEPTHsoil X RHOsoil

|  |  |  |
| --- | --- | --- |
| **Input parameters for calculations of PECsoil via sludge application** | | |
| Parameter | Description | Value |
| **SUSPCONCinf** | Concentration of suspended matter in STP influent (kg/m3) | 0.45 (D) |
| **EFFLUENTstp** | Effluent discharge rate of STP (m3/d) | 2,000 (D) |
| **SURPLUSsludge** | Surplus sludge per inhabitant equivalent (kg/d/eq) | 0.011 (D) |
| **CAPACITYstp** | Capacity of the STP (eq) | 10,000 (D) |
| **SLUDGERATE** | Rate of sewage sludge production (kg/d) | 710 (D) |
| **Elocalwater** | Local emission rate to water during episode (kg/d) | See "Calculated PECsw  values" |
| **Fstpsludge** | Fraction of emission directed to sludge by STP | 0.2 (AR, 2013) |
| **Csludge** | Concentration in dry sewage sludge (mg/kg) | Intermediate calculation  here above |
| **APPLsludge** | Dry sludge application rate (kg/m2/yr) | 0.5 (D) |
| **DEPTHsoil** | Mixing depth of soil (m) | 0.2 (D) |
| **RHOsoil** | Bulk density of soil (kg/m3) | 1,700 (D) |

D: default

Using the equations above and the input parameters, the concentration of iodine (and the iodine species iodide and iodate) in soil via sludge application is calculated in the table below.

*Calculated PECsoil values via sludge application*

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PECsoil values for iodine, iodine and iodate** | | |
|  | **PECsoil for** **Iodine and Iodide** (mg/kgwwt) | **PECsoil for** **Iodate** (mg/kgwwt) |
| Scenario 1 | 0.000048 | 0.000067 |
| Scenario 2 | 0.000012 | 0.000017 |
| Scenario 3 | 0.000097 | 0.000134 |
| Scenario 4 | 0.000097 | 0.000134 |
| Scenario 7 | 0.000048 | 0.000067 |
| Scenario 8 | 0.000097 | 0.000134 |
| Scenario 9 | 0.000097 | 0.000134 |
| Scenario 10 | 0.000048 | 0.000067 | |
| Scenario 11 | 0.000048 | 0.000067 | |

*PEC in groundwater via sludge application*

The predicted concentration in groundwater have been calculated according to the ECHA Guidance for Environmental Risk Assessment (2015). In a tier 1 approach, PEC groundwater is considred equivalent to PECsoil porewater.

Based on PECsoil, the porewater concentration of iodine (and the iodine species iodide and iodate) is calculated using equation 67:

(PEClocalsoil x RHOsoilwet)

PEC local soil, porew =

(Ksoil — water x 1000)

Where *Ksoil-water* is presented in equation 24:

HENRY Kpsoil

Ksoil — water = ( Fairsoil x ) + Fwatersoil + ( Fsolidsoil x x RHOsolid )

R x TEMP 1000

|  |  |  |
| --- | --- | --- |
| **Input parameters for calculations of PECsoil via sludge application** | | |
| Parameter | Description | Value |
| **PEClocal soil** | Predicted environmental concentration in soil  (mg/kg wwt) | See "calculated PECsoil values via sludqe application" |
| **RHOsoilwet** | Bulk density of wet soil (kg/m3) | 1,700 (D) |
| **Fairsoil** | Fraction of air in soil compartment (m3/m3) | 0.2 (D) |
| **HENRY** | Henry's Law Constant (Pa m3/mol) | 34.43 (AR, 2013) |
| **R** | Gas constant (Pa m3/mol/k) | 8.314 (D) |
| **TEMP** | Temperature of the air-water interface (K) | 285 (D) |
| **Fwatersoil** | Fraction of water in soil compartment (m3/m3) | 0.2 (D) |
| **Fsolidsoil** | Fraction of solids in soil compartment (m3/m3) | 0.6 (D) |
| **Kpsoil** | Partition coefficient organic carbon-water (L/kg) | 5.8 (AR, 2013) |
| **RHOsolid** | Density of the solid phase (kq/m3) | 2,500 (D) |
| **Ksoil-water** | Soil-water partition coefficient (m3/m3) | 8.903 (intermediate calculation, see here above) |

D: default

Using this exposure scenario and the formulae given above , the theoretical maximum concentration in groundwater is estimated in the table below:

*Calculated PECgroundwater values via sludge application*

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PECgroundwater values for iodine, iodine and iodate** | | |
|  | **PECgw for** **Iodine and Iodide** (mg/L) | **PECgw for** **Iodate** (mg/L) |
| Scenario 1 | 0.000009 | 0.000013 |
| Scenario 2 | 0.000002 | 0.000003 |
| Scenario 3 | 0.000019 | 0.000026 |
| Scenario 4 | 0.000019 | 0.000026 |
| Scenario 7 | 0.000009 | 0.000013 |
| Scenario 8 | 0.000019 | 0.000026 |
| Scenario 9 | 0.000019 | 0.000026 |
| Scenario 10 | 0.000009 | 0.000013 | |
| Scenario 11 | 0.000009 | 0.000013 | |

*PEC in surface water via sludge application*

The predicted environmental concentration (PEC) of iodine can be determined using Tier 1 procedure provided in ESD PT18 (2006). PEC surface water is then calculated from the groundwater concentration assuming a dilution factor of 10.

The PECs in surface water via sludge application are considered negligible compared to the calculated PECsw values estimated via manure application and via STP emission to surface water. Therefore, PEC values for surface water via sludge application are not explicitly reported here.

#### **Risk characterisation**

In addition to the classical risk assessment approach (PEC/PNEC ratios), the PEC values for iodine were compared to natural background levels to assess the environmental risk. These data were obtained from the AR and are summarized in the section "Background levels" of the effect assessment (page 5).

***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 AR. A risk assessment for the atmosphere is therefore not considered necessary.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Box 8 - FR CA position:**  Scenario 12- Cumulative risk characterization  Scenario 12 covers a combined use of pre-milking and post-milking in automated spraying. This scenario was thus assessed as a combination of scenarios 3 and 8. It should be noted that the nitrogen standard is the most relevant in Europe notably in France. So, for emission via manure, the PEC values were calculated for application to grassland and arable land on the nitrogen standard.   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | |  | **Values for Iodine** | | | **Values for Iodide** | | **Values for Iodate** | | | **Background** | **PEC** | **PEC/PNEC** | **PEC** | **PEC/PNEC** | **PEC** | **PEC/PNEC** | | **Via manure application during 10 years** | | | | | | | | | Surface water grassland (µg.L-1) | 0.5-20 | 9.09 | **1.54E+01** | 9.09 | **1.10E+01** | 1.26E+01 | 2.15E-01 | | Surface water arable (µg.L-1) | 3.69 | **6.25** | 3.69 | **4.45** | 5.1 | 8.72E-02 | | **In the background level for iodine** | | | | | | | Soil grassland (mg.kgwwt ) | 0.565-22.6  extremes up to 110.74 | 4.76E-01 | **4.04E+01** | 4.76E-01 | **1.11E+02** | 6.58E-01 | **2.16** | | Soil arable (mg.kgwwt ) | 1.93E-01 | **1.64E+01** | 1.93E-01 | **4.49E+01** | 2.67E-01 | 8.78E-01 | | **In the background level for iodine** | | | | | | | Groundwater grassland (µg.L-1) | 1-70 | **9.09E+01** | >0.1µg/L | **9.09E+01** | >0.1µg/L | **1.26E+02** | >0.1µg/L | | Groundwater arable (µg.L-1) | **3.69E+01** | >0.1µg/L | **3.69E+01** | >0.1µg/L | **5.10E+01** | >0.1µg/L | | **In or higher than the background level for iodine** | | | | | | | **Via STP** | | | | | | | | | STP (mg.L-1) | Not relevant | 6.44E-03 | 2.22E-03 | 6.44E-03 | Not relevant | 8.91E-03 | Not relevant | | Surface water (µg.L-1) | 0.5-20 | 6.42E-01 | 1.09 | 6.42E-01 | 7.74E-01 | 8.88E-01 | 1.52E-02 | | **In the background level for iodine** | | | | | | | Soil (mg.kgwwt ) | 0.565-22.6  extremes up to 110.74 | 3.99E-02 | **3.38** | 5.58E-03 | **1.30** | 5.51E-02 | 1.81E-01 | | **Lower to the background level for iodine** | | | | | | | Groundwater (µg.L-1) | 1-70 | **7.46E+00** | > 0.1 µg/L | **1.04** | > 0.1 µg/L | **1.03E+01** | > 0.1 µg/L | | **In or lower to the background level for iodine** | | | | | |   **Conclusion:**  Concerning the risk assessment via manure application after 10 years applications:  ***In surface water***  The PEC surface water values for iodine are in the range of typically background concentrations (0.5 to 20 µg/L) which indicates acceptable risks.  ***In soil***  The PEC values are below or in typically background concentrations ranging from 0.565 to 22.6 mg/kg wwt.  ***In groundwater***  In the risk assessment for groundwater, the PEC values are compared with the limit value of 0.1 µg/L provided for pesticides in the Drinking Water Directive 98/83/EC. However, as iodine and iodine compounds are not xenobiotics, this threshold value can be considered as over conservative. Calculated PECgw values for iodine are higher than the natural background concentrations of 70 µg/L. 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. However, no unacceptable risk is expected for groundwater.  Concerning the risk assessment via STP:  ***In STP***  PEC/PNEC value is below 1 which indicates acceptable risk.  ***In surface water***  PEC/PNEC values in surface water are all below 1 or in the background level for iodine in this compartment which indicates acceptable risks.  ***In soil***  PECsoil values are below or in typically background concentrations ranging from 0.565 to 22.6 mg/kg wwt for iodine.  ***In groundwater***  PECgw are below the maximum natural background concentration of 70 µg/L for iodine.  Risks are acceptable following a theoretical release to the STP. Nevertheless, according to the French legislation, the ‘green water’ coming from the milking parlour (waiting area and cleaning of the milking platforms) must be stored as slurry and manure before land application and no release to STP is authorised for this type of releases considering their high level of organic matter. Even for ‘white water’, that is the cleaning water of the milking parlour pipes and milk tank, a release to the municipal STP is not automatic and must be allowed by the local authorities. Therefore, releases to the STP from milking parlour are not considered relevant for France.  Scenario 3 or 8 as a worst case for pre-milking and post-milking application respectively - Risk characterization  Scenario 3 and 8 cover the use of the product for pre-milking and post-milking applications. These scenarios are similar, the only difference is the timing of the application, thus the environmental assessment for the both is proposed in the following table. As explained above, the nitrogen standard is the most relevant in Europe notably in France. Therefore, regarding emission via manure application, PEC values were calculated for application to grassland and arable land on the nitrogen standard.   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | |  | **Values for Iodine** | | | **Values for Iodide** | | **Values for Iodate** | | | **Background** | **PEC** | **PEC/PNEC** | **PEC** | **PEC/PNEC** | **PEC** | **PEC/PNEC** | | **Via manure application during 10 years** | | | | | | | | | Surface water grassland (µg.L-1) | 0.5-20 | 4.55 | **7.71** | 4.55 | **5.48** | 6.28 | 1.07E-01 | | Surface water arable (µg.L-1) | 1.84 | **3.13** | 1.84 | **3.13** | 2.55 | 4.36E-02 | | **In the background level for iodine** | | | | | | | Soil grassland (mg.kgwwt ) | 0.565-22.6  extremes up to 110.74 | 2.38E-01 | **2.02E+01** | 2.38E-01 | **5.54E+01** | 3.29E-01 | **1.08** | | Soil arable (mg.kgwwt ) | 9.66E-02 | **8.19** | 9.66E-01 | **2.25E+01** | 1.34E-01 | 4.39E-01 | | **Lower to the background level for iodine** | | | | | | | Groundwater grassland (µg.L-1) | 1-70 | **4.55E+01** | >0.1µg/L | **4.55E+01** | >0.1µg/L | **6.28E+01** | >0.1µg/L | | Groundwater arable (µg.L-1) | **1.84E+01** | >0.1µg/L | **1.84E+01** | >0.1µg/L | **2.55E+01** | >0.1µg/L | | **In the background level for iodine** | | | | | | | **Via STP** | | | | | | | | | STP (mg.L-1) | Not relevant | 3.22E-03 | 1.11E-03 | 3.22E-03 | Not relevant | 4.45E-03 | Not relevant | | Surface water (µg.L-1) | 0.5-20 | 3.21E-01 | 5.44E-01 | 3.21E-01 | 3.87E-01 | 4.44E-01 | 7.59E-03 | | **Lower to the background level for iodine** | | | | | | | Soil (mg.kgwwt ) | 0.565-22.6  extremes up to 110.74 | 1.99E-02 | **1.69** | 2.79E-03 | 6.49E-01 | 2.76E-02 | 9.06E-02 | | **Lower to the background level for iodine** | | | | | | | Groundwater (µg.L-1) | 1-70 | **3.73** | > 0.1 µg/L | **5.22E-01** | > 0.1 µg/L | **5.16** | > 0.1 µg/L | | **In the background level for iodine** | | | | | |   **Conclusion:**  Concerning the risk assessment via manure application after 10 years applications:  ***In surface water***  The PEC surface water values for iodine are in the range of typically background concentrations (0.5 to 20 µg/L) which indicates acceptable risks.  ***In soil***  The PEC values are below typically background concentrations ranging from 0.565 to 22.6 mg/kg wwt.  ***In groundwater***  Calculated PECgw values for iodine are lower than the natural background concentrations of 70 µg/L, which indicates acceptable risks.  Concerning the risk assessment via STP:  ***In STP***  PEC/PNEC value is below 1 which indicates acceptable risk.  ***In surface water***  PEC/PNEC values in surface water are all below 1 which indicates acceptable risks.  ***In soil***  PECsoil values are lower to the background concentrations ranging from 0.565 to 22.6 mg/kg wwt for iodine.  ***In groundwater***  PECgw are below the maximum natural background concentration of 70 µg/L for iodine. So, the risk is acceptable.  In conclusion, acceptable risks are reached for a pre-milking application or a post-milking application of products. |

##### Risk characterization via manure application

***Terrestrial compartment via manure application***

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Calculated PEC/PNEC soil values** | | | | | | | | | | | | |
|  | **Values for Iodine** | | | | **Values for Iodide** | | | | **Values for Iodate** | | | |
| **Phosphate standard** | | **Nitrogen standard** | | **Phosphate standard** | | **Nitrogen standard** | | **Phosphate**  **standard** | | **Nitrogen standard** | |
| Grass-  land | Arable land | Grass-land | Arable land | Grass-land | Arable land | Grass-land | Arable  land | Grass-  land | Arable  land | Grass-land | Arable  land |
| **Scenario 1** | 0.935254 | 0.722712 | 0.446356 | 0.446356 | **2.566512** | **1.983256** | **1.224884** | **1.224884** | 0.050168 | 0.038770 | 0.023944 | 0.023944 |
| **Scenario 2** | 0.233814 | 0.180678 | 0.111610 | 0.111610 | 0.641628 | 0.495814 | 0.306279 | 0.306279 | 0.012543 | 0.009691 | 0.005987 | 0.005987 |
| **Scenario 3** | **1.870424** | **1.445339** | 0.892712 | 0.892712 | **5.132791** | **3.966279** | **2.449767** | **2.449767** | 0.100339 | 0.077533 | 0.047888 | 0.047888 |
| **Scenario 4** | **1.870424** | **1.445339** | 0.892712 | 0.892712 | **5.132791** | **3.966279** | **2.449767** | **2.449767** | 0.100339 | 0.077533 | 0.047888 | 0.047888 |
| **Scenario 7** | 0.935254 | 0.722712 | 0.446356 | 0.446356 | **2.566512** | **1.983256** | **1.224884** | **1.224884** | 0.050168 | 0.038770 | 0.023944 | 0.023944 |
| **Scenario 8** | **1.870424** | **1.445339** | 0.892712 | 0.892712 | **5.132791** | **3.966279** | **2.449767** | **2.449767** | 0.100339 | 0.077533 | 0.047888 | 0.047888 |
| **Scenario 9** | **1.870424** | **1.445339** | 0.892712 | 0.892712 | **5.132791** | **3.966279** | **2.449767** | **2.449767** | 0.100339 | 0.077533 | 0.047888 | 0.047888 |
| **Scenario 10** | 0.935254 | 0.722712 | 0.446356 | 0.446356 | **2.566512** | **1.983256** | **1.224884** | **1.224884** | 0.050168 | 0.038770 | 0.023944 | 0.023944 |
| **Scenario 11** | 0.935254 | 0.722712 | 0.446356 | 0.446356 | **2.566512** | **1.983256** | **1.224884** | **1.224884** | 0.050168 | 0.038770 | 0.023944 | 0.023944 |

Conclusion: For iodate, PEC/PNEC values in soil are all below 1 which indicate acceptable risk. For iodine and iodide, PEC/PNEC values in soil above 1 have been identified for spreading of manure /slurry on grassland and arable land. However, the worst case PECsoil value (Scenario 3 - Phosphate standard - Grassland ) for iodine/iodide is equal to 0.022071 mg/kgwwt (i.e.. 0.024940 mg/kgdwt), which is far below typically background concentrations ranging from 0.5 to 20 mg/kgdwt (with a global mean value of 5 mg/kgdwt).

In the risk assessment of groundwater, the PECgw values are compared with the limit value of 0.1 pg/L provided for pesticides in the Drinking Water Directive 98/83/EC. However, as iodine is not a xenobiotic, this threshold value can be considered as over¬conservative. Maximum calculated PECgw values (Scenario 3 - Phosphate standard - Grassland) are 4.214 pg/L and 5.824 pg/L for iodine/iodide and iodate, respectively. Although these concentrations are above the mean natural background concentration of 1 pg/L in groundwater, they are still far below the maximum natural background concentration of 70 pg/L.

Moreover, it should be noted that the PEC values in groundwater were calculated following the ECHA Guidance for Environmental Risk Assessment (2015) using the porewater concentration in soil as indication for the groundwater concentration, not taking into account any removal processes like e.g. lateral transport or plant uptake. This leads to a large overestimation of the real concentrations in groundwater.

##### Aquatic compartment via manure application

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **PEC/PNEC surface water values** | | | | | | | | | | | | |
|  | **Values for Iodine** | | | | **Values for Iodide** | | | | **Values for Iodate** | | | |
| **Phosphate standard** | | **Nitrogen standard** | | **Phosphate standard** | | **Nitrogen standard** | | **Phosphate**  **standard** | | **Nitrogen standard** | |
| Grass-  land | Arable land | Grass-land | Arable land | Grass-land | Arable land | Grass-land | Arable  land | Grass-  land | Arable  land | Grass-land | Arable  land |
| **Scenario 1** | 0.357627 | 0.276271 | 0.171186 | 0.171186 | 0.254217 | 0.196386 | 0.121687 | 0.121687 | 0.004974 | 0.003846 | 0.002376 | 0.002376 |
| **Scenario 2** | 0.089831 | 0.069492 | 0.042373 | 0.042373 | 0.063855 | 0.049398 | 0.030120 | 0.030120 | 0.001248 | 0.000957 | 0.000598 | 0.000598 |
| **Scenario 3** | 0.713559 | 0.552542 | 0.340678 | 0.340678 | 0.507229 | 0.392771 | 0.242169 | 0.242169 | 0.009949 | 0.007692 | 0.004752 | 0.004752 |
| **Scenario 4** | 0.713559 | 0.552542 | 0.340678 | 0.340678 | 0.507229 | 0.392771 | 0.242169 | 0.242169 | 0.009949 | 0.007692 | 0.004752 | 0.004752 |
| **Scenario 7** | 0.357627 | 0.276271 | 0.171186 | 0.171186 | 0.254217 | 0.196386 | 0.121687 | 0.121687 | 0.004974 | 0.003846 | 0.002376 | 0.002376 |
| **Scenario 8** | 0.713559 | 0.552542 | 0.340678 | 0.340678 | 0.507229 | 0.392771 | 0.242169 | 0.242169 | 0.009949 | 0.007692 | 0.004752 | 0.004752 |
| **Scenario 9** | 0.713559 | 0.552542 | 0.340678 | 0.340678 | 0.507229 | 0.392771 | 0.242169 | 0.242169 | 0.009949 | 0.007692 | 0.004752 | 0.004752 |
| **Scenario 10** | 0.357627 | 0.276271 | 0.171186 | 0.171186 | 0.254217 | 0.196386 | 0.121687 | 0.121687 | 0.004974 | 0.003846 | 0.002376 | 0.002376 |
| **Scenario 11** | 0.357627 | 0.276271 | 0.171186 | 0.171186 | 0.254217 | 0.196386 | 0.121687 | 0.121687 | 0.004974 | 0.003846 | 0.002376 | 0.002376 |

Conclusion: The risk assessment for surface water via manure application resulted in PEC/PNEC ratios ranging from 5.98 x 10-4 (Scenario 2 - Nitrogen standard - Grassland and Arable-land) to 7.13 x 10-1 (Scenario 3 - Phosphate standard - Grassland) which indicate acceptable risk.

##### Risk characterization via STP

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

|  |  |
| --- | --- |
| **Summary table on calculated PEC/PNECSTP values** | |
|  | **Values for Iodine** |
| **Scenario 1** | 0.000405 |
| **Scenario 2** | 0.000101 |
| **Scenario 3** | 0.000809 |
| **Scenario 4** | 0.000809 |
| **Scenario 7** | 0.000405 |
| **Scenario 8** | 0.000809 |
| **Scenario 9** | 0.000809 |
| **Scenario 10** | 0.000405 |
| **Scenario 11** | 0.000405 |

Conclusion: The risk assessment for sewage treatment plants resulted in PEC/PNEC ratios ranging from 1.01 x 10-4 (Scenario 2) to 8.09 x 10-4 (Scenario 3) which indicate acceptable risk.

***Aquatic compartment via STP***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC surface water values** | | | |
|  | **Values for Iodine** | **Values for Iodide** | **Values for Iodate** |
| **Scenario 1** | 0.198305 | 0.140964 | 0.002769 |
| **Scenario 2** | 0.049153 | 0.034940 | 0.000684 |
| **Scenario 3** | 0.396610 | 0.281928 | 0.005521 |
| **Scenario 4** | 0.396610 | 0.281928 | 0.005521 |
| **Scenario 7** | 0.198305 | 0.140964 | 0.002769 |
| **Scenario 8** | 0.396610 | 0.281928 | 0.005521 |
| **Scenario 9** | 0.396610 | 0.281928 | 0.005521 |
| **Scenario 10** | 0.198305 | 0.140964 | 0.002769 |
| **Scenario 11** | 0.198305 | 0.140964 | 0.002769 |

Conclusion: The risk assessment for surface water via STP resulted in PEC/PNEC ratios ranging from 6.84 x 10-4 (Scenario 2) to 3.96 x 10-1 (Scenario 3) which indicate acceptable risk.

***Terrestrial compartment via sludge application***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC soil values** | | | |
|  | **Values for Iodine** | **Values for Iodide** | **Values for Iodate** |
| **Scenario 1** | 0.004068 | 0.011163 | 0.000220 |
| **Scenario 2** | 0.001017 | 0.002791 | 0.000056 |
| **Scenario 3** | 0.008220 | 0.022558 | 0.000441 |
| **Scenario 4** | 0.008220 | 0.022558 | 0.000441 |
| **Scenario 7** | 0.004068 | 0.011163 | 0.000220 |
| **Scenario 8** | 0.008220 | 0.022558 | 0.000441 |
| **Scenario 9** | 0.008220 | 0.022558 | 0.000441 |
| **Scenario 10** | 0.004068 | 0.011163 | 0.000220 |
| **Scenario 11** | 0.004068 | 0.011163 | 0.000220 |

Conclusion: The risk assessment for soil via sludge application resulted in PEC/PNEC ratios ranging from 5.6 x 10-5 (Scenario 2) to 2.25 x 10-2 (Scenario 3) which indicate acceptable risk.

***Groundwater via sludge application***

In the risk assessment of groundwater via sludge application, the PECgw values are compared with the limit value of 0.1 µg/L provided for pesticides in the Drinking Water Directive 98/83/EC. The maximum PECgw value are 0.019 µg/L and 0.026 µg/L (Scenario 3) for iodine/iodide and iodate, respectively. The above concentrations in groundwater are both below the limit value of 0.1 µg/L, which indicate acceptable risk.

Scenario 12- Cumulative risk characterization

Scenario 12 covers a combined use of pre-milking and post-milking in automated spraying. This scenario was thus assessed as a combination of scenarios 3 and 8. To this end, worst-case values (phosphate standard - Grassland values) were combined by summing PECs and thus PEC/PNEC values. Obtained results are indicated in the table here below.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Values for Iodine** | | | | **Values for Iodide** | | | **Values for Iodate** | | |
|  | **PEC** | **PNEC** | **PEC/PNEC** | **PEC** | | **PNEC** | **PEC/PNEC** | **PEC** | **PNEC** | **PEC/PNEC** |
| **Via manure application\*** | | | | | | | | | | |
| Soil (mg/kgwwt) | 0.044142 | 0.0118 | 3.740847 | 0.044142 | | 0.0043 | 10.265581 | 0.061006 | 0.304 | 0.202678 |
| Groundwater  (mg/L) | 0.008428 | - | - | 0.008428 | | - | - | 0.011648 | - | - |
| Surface water (mg/L) | 0.000842 | 0.00059 | 1.427119 | 0.000842 | | 0.00083 | 1.014458 | 0.001164 | 0.0585 | 0.019897 |
| **Via STP** | | | | | | | | | | |
| STP (mg/L) | 0.004694 | 2.9 | 0.001619 | - | | - | - | - | - | - |
| Surface water (mg/L) | 0.000468 | 0.00059 | 0.793220 | 0.000468 | | 0.00083 | 0.563856 | 0.000646 | 0.0585 | 0.011042 |
| Soil (mg/kgwwt) | 0.000194 | 0.0118 | 0.016441 | 0.000194 | | 0.0043 | 0.045116 | 0.000268 | 0.304 | 0.000882 |
| Groundwater(mg/L) | 0.000038 | - | - | 0.000038 | | - | - | 0.000052 | - | - |

\*) Use of the phosphate standard - Grassland values = worst-case values

For emission via STP, risks were acceptable for all compartments and forms of iodine (combined PEC/PNEC <1).

For emission via manure, for iodate, PEC/PNEC values in soil and surface water are all below 1 which indicate acceptable risk. PEC/PNEC values in soil and surface water are above 1. Corresponding PECsw and PECsoil are 0.842 µg/L and 0.044142 mg/kgwwt (i.e. 0.05001 mg/kgdwt), respectively. These values are far below typically concentrations ranging from 0.5 - 20 µg/L in surface water and 0.5 to 20 mg/kgdwt in soil (with a global mean value of 5 mg/kgdwt). For iodate, iodine and iodide, the PECgw values are above the limit value of 0.1 µg/L provided for pesticides in the Drinking Water Directive 98/83/EC. However, the maximum PECgw value for iodine is 8.4 µg/L, which is above the mean natural background concentration of 1 µg/L in groundwater,is still far below the maximum natural background concentration of 70

***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 product does not to pose an unacceptable risk to birds and mammals.

*Non-target arthropods (including bees)*

The risk assessment to arthropods is considered to be similar to soil organism due to their direct contact with soils.

The risk to bees is also considered acceptable, as stables or manure/sludge treated land are not considered foraging areas for bees.

***Mixture toxicity***

|  |
| --- |
| **Box 9 - FR CA position:**  One of the co-formulant, which represent about 1% of the products is classified H412.  According to the appendix 1 of the Transitional Guidance on mixture toxicity assessment for biocidal products for the environment, the calculation of the relative toxic units of compounds shows that the toxicity of product is principally linked (more than 96%) to the toxicity of iodine compounds. So, this co-formulant is not considered as substance of concern in these formulations. |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Box 10 - FR CA position:**   |  | | --- | | **Overall conclusion on the risk assessment for the environment of the product** | | |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  | **Scenario 12 (scenario 3+8)** | | | **Scenario 3 (pre-milking application)** | | | **Scenario 8 (post-milking application)** | | | | **Iodine** | **Iodide** | **Iodate** | **Iodine** | **Iodide** | **Iodate** | **Iodine** | **Iodide** | **Iodate** | | **Via manure application during 10 years** | | | | | | | | | | | Surface water grassland | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | | Surface water arable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | | Soil grassland (mg.kgwwt ) | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | | Soil arable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | | Groundwater grassland | **Unacceptable\*** | **Unacceptable\*** | **Unacceptable\*** | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | | Groundwater arable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | | **Via STP** | | | | | | | | | | | STP | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | | Surface water | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | | Soil | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | | Groundwater | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable |   \* 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. However, no unacceptable risk is exepcted for groundwater.  Risks are acceptable in all compartments except for the groundwater when the product is applied before and after the milking. | |

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| The products are emitted to wastewater or manure. Emission via waste water leads to exposure of STP and subsequently surface water and soil (including groundwater). For this emission pathway, PEC/PNEC ratios were all <1. Emission via manure leads to exposure of soil and subsequently groundwater and surface water. For this last compartment, PEC/PNEC ratios were all <1. PEC/PNEC values above 1 have been identified for the soil compartment. However, the worst case PECsoil value (Scenario 3 - Phosphate standard - Grassland ) for iodine/iodide is equal to 0.022071 mg/kgwwt (i.e. 0.024940 mg/kgdwt), which is far below typically background concentrations ranging from 0.5 to 20 mg/kgdwt (with a global mean value of 5 mg/kgdwt). In the risk assessment of groundwater, the PECgw values exceeded the limit value of 0.1 µg/L provided for pesticides in the Drinking Water Directive 98/83/EC. However the maximum PECgw values are still far below the maximum natural background concentration of 70 µg/L. It may also be noted that iodine is an essential element to both animals and plants in rather high concentrations (higher than what corresponds to a trace element). It can thus be concluded that the actual risks arising from the use of iodine-containing product should be considered acceptable. |

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

*See Summary of Product Characteristics (SPC)*

### Assessment of a combination of biocidal products

Not relevat

### 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** | **Essential for the evaluation**  **Yes/N** |
| Servajean E. | 2015  2016  &  2018 | Stability of « AL iodée liquide avant traite » over accelerated storage and shelf life determination  Phytosafe s.a.r.l  15-99-091-ES  GLP  Unpublished | Y | GFB Commission 12 | Y |
| Servajean E. | 2015 | Stability of «AL IODÉE LIQUIDE AVANT TRAITE» over accelerated storage and shelf-life determination  Phytosafe s.a.r.l  14-99-036-ES  GLP  Unpublished | Y | GFB Commission 12 | N |
| Servajean E. | 2015  &  2017 | Stability of « AL iodée liquide après traite » over accelerated storage and shelf life determination  Phytosafe s.a.r.l  14-99-037-ES  GLP  Unpublished | Y | GFB Commission 12 | Y |
| Servajean E. | 2015  &  2017 | Stability of « AL iodée épais après traite » over accelerated storage and shelf life determination  Phytosafe s.a.r.l  14-99-038-ES  GLP  Unpublished | Y | GFB Commission 12 | Y |
| Servajean E. | 2015 2016  &  2018 | Stability of « formule iodée maximale » over accelerated storage and shelf life determination  Phytosafe s.a.r.l  15-99-092-ES  GLP  Unpublished | Y | GFB Commission 12 | Y |
| Servajean E. | 2015 | Stability of «FORMULE IODÉE MAXIMALE» over accelerated storage and shelf-life determination  Phytosafe s.a.r.l  14-99-040-ES  GLP  Unpublished | Y | GFB Commission 12 | N |
| Servajean E. | 2015  &  2017 | Stability of « formule iodée minimale »  over accelerated storage and shelf life determination  Phytosafe s.a.r.l  14-99-039-ES  GLP  Unpublished | Y | GFB Commission 12 | Y |
| A. Gabillet, M. Sesques | 2016 | Test d'efficacité bactéricide selon la norme NF EN 1656 (mars 2010) - Désinfection des trayons - Formule META SPC 1 AL  LMH  4021-2  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| A. Gabillet, M. Sesques | 2016 | Test d'efficacité bactéricide selon la norme NF EN 1656 (mars 2010) (Désinfection des trayons) Formule METASPC1 AL (2,90% PVPI)  LMH  4142-1  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| A. Gabillet, M. Sesques | 2016 | Test d'efficacité pour l'activité bactéricide sur peau synthétique selon le protocole adapté de la norme NF EN 16437 en DROP/DIP - Formule META SPC1 AL  LMH  3980-1  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| A. Gabillet, M. Sesques | 2016 | Test d'efficacité pour l'activité bactéricide sur peau synthétique selon le protocole adapté de la norme NF EN 16437 en DROP/DIP - Formule META SPC 1 AL  LMH  4101-1  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| Gabriel H, Klock J-H | 2015 | Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of META SPC 1 Formule Iodée minimale in veterinary area according to DIN EN 1657:2005 (Phase 2, step 1)  Dr. Brill + Partner GmbH  L15/0122.11  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| M. Teulier, M. Sesques | 2016 | Test d'efficacité pour l'activité levuricide sur peau synthétique selon le protocole adapté de la norme NF EN 16437 en DROP/DIP - Formule META SPC 1 AL  LMH  4027-1  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| Gabriel H, Klock J-H | 2015 | Virucidal activity against bacteriophages of Meta SPC 1 AL in the quantitative suspension test according to DIN EN 13610:2002 (phase2, step 1)  Dr. Brill + Partner GmbH  L15/0122.14  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| A. Gabillet, M. Sesques | 2016 | Test d'efficacité pour l'activité virucide contre les bactériophages sur peau synthétique selon un protocole adapté de la norme NF EN 16437 en DROP/DIP - Formule META SPC1 AL  LMH  4078-1  Non-GLP  Unpublished | Y | GFB Commission 12 | N |
| Gabriel H, Klock J-H | 2015 | Bactericidal Activity of META SPC 3 AL in the quantitative suspension test according to DIN EN 1656:2009 (Phase 2, Step 1)  Dr. Brill + Partner GmbH  L15/0122.1  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| M. Teulier, M. Sesques | 2016 | Test d'efficacité pour l'activité bactéricide sur peau synthétique selon le protocole adapté de la norme NF EN 16437 en DROP/DIP - Formule Meta SPC3 AL  LMH  3915-1  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| M. Teulier, M. Sesques | 2016 | Test d'efficacité pour l'activité bactéricide sur peau synthétique selon le protocole adapté de la norme NF EN 16437 en DROP/DIP - Formule META SPC 3 AL  LMH  4029-1  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| Gabriel H, Klock J-H | 2015 | Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of META SPC 3 AL in veterinary area according to DIN EN 1657:2005 (Phase 2, step 1)  Dr. Brill + Partner GmbH  L15/0122.7  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| M. Teulier, M. Sesques | 2016 | Test d'efficacité pour l'activité levuricide sur peau synthétique selon le protocole adapté de la norme NF EN 16437 en DROP/DIP - Formule META SPC 3 AL  LMH  3976-1  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| Gabriel H, Klock J-H | 2015 | Bactericidal Activity of META SPC 4 AL in the quantitative suspension test according to DIN EN 1656:2009 (Phase 2, Step 1)  Dr. Brill + Partner GmbH  L15/0122.2  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| M. Teulier, M. Sesques | 2016 | Test d'efficacité pour l'activité bactéricide sur peau synthétique selon le protocole adapté de la norme NF EN16437 en DROP/DIP - Formule Meta SPC 4 AL  LMH  3977-1  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| A. Gabillet, M. Sesques | 2016 | Test d'efficacité pour l'activité bactéricide sur peau synthétique selon le protocole adapté de la norme NF EN 16437 en DROP/DIP - Formule META SPC 4 AL  LMH  4102-1  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| M. Teulier | 2016 | Test d’efficacité pour l’activité bactéricide sur peau synthétique selon le protocole adapté de la norme EN 16437 en drop/dip Formule META SPC 4 AL (1,50% PVPI)  LMH  4144-1  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| Gabriel H, Klock J-H | 2015 | Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of META SPC 4 AL in veterinary area according to DIN EN 1657:2005 (Phase 2, step 1)  Dr. Brill + Partner GmbH  L15/0122.8  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| A. Gabillet, M. Sesques | 2016 | Test d'efficacité pour l'activité levuricide sur peau synthétique selon le protocole adapté de la norme NF EN 16437 en DROP/DIP - Formule META SPC 4 AL  LMH  4030-1  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| F. Brill | 2016 | Bactericidal activity of MetaSPC5 1.5% in the quantitative suspension test according to DIN EN 1656:2009 (Phase 2, Step 1)  Dr Brill + Partner GmbH  L16/0633.3  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| M. Teulier, M. Sesques | 2016 | Test d'efficacité pour l'activité bactéricide sur peau synthétique selon le protocole adapté de la norme NF EN 16437 en DROP/DIP - Formule IODEE MAXIMALE  LMH  4001-1  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| M. Teulier, M. Sesques | 2016 | Test d'efficacité pour l'activité bactéricide sur peau synthétique selon le protocole adapté de la norme NF EN 16437 en DROP/DIP - Formule IODEE MAXIMALE  LMH  4103-1  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| AF. Gabillet | 2017 | Test d’efficacité pour l’activité bactéricide sur peau synthétique selon le protocole adapté de la norme EN 16437 en drop/dip Formule IODEE MAXIMALE Essai sur Listeria monocytogenes DSM 15675  LMH  4239-1  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| AF. Gabillet | 2016 | Test d'efficacité pour l'activité bactéricide sur peau synthétique selon le protocole adapté de la norme EN16437 en drop/dip - Formule iodée maximale (1.5% PVPi)  LMH  4147-1  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| M. Teulier | 2016 | Test d’efficacité pour l’activité bactéricide sur peau synthétique selon le protocole adapté de la norme EN 16437 en drop/dip Formule IODEE MAXIMALE  LMH  4168-1  Non-GLP  Unpublished | Y | GFB Commission 12 | N |
| F. Brill | 2016 | Yeasticidal activity of MetaSPC5 1.5% in the quantitative suspension test according to DIN EN 1657:2005 (Phase 2, Step 1)  Dr Brill + Partner GmbH  L15/0633.5  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| AF. Gabillet, M. Sesques | 2016 | Test d'efficacité pour l'activité levuricide sur peau synthétique selon un protocole adapté de la norme NF EN 16437 en DROP/DIP - Formule IODEE MAXIMALE  LMH  4031-1  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| J. Steinmann | 2016 | Evaluation of the effectiveness of Meta SPC5 1.5% - modified vaccinia virus Ankara (MVA)  Dr Brill + Partner GmbH  R15L0635MV  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| AF. Gabillet, M. Sesques | 2017 | Test d’efficacité bactéricide selon la norme NF EN 1656 (mars 2010) (Désinfection des trayons) META SPC 5 Formule iodée maximale après 12 mois de stockage (PHYTOSAFE study number : 15-99-092-ES)  LMH  4312-1  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| AF. Gabillet, M. Sesques | 2017 | Test d’efficacité bactéricide selon la norme NF EN 1656 (March 2010) (Désinfection des trayons) META SPC 5 Formule iodée maximale après 12 mois de stockage (PHYTOSAFE study number : 15-99-092-ES) Essai sur la souche additionnelle Enterococcus hirae  LMH  4313-1  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| AF. Gabillet, M. Sesques | 2017 | Test d’efficacité levuricide selon la norme NF EN 1657 (mai 2016) META SPC 5 Formule iodée maximale après 12 mois de stockage (PHYTOSAFE study number : 15-99-092-ES)  LMH  4314-2  Non-GLP  Unpublished | Y | GFB Commission 12 | Y |
| Gabriel H, Klock J-H | 2015 | Quantitative suspension test for the evaluation of bactericidal activity of META SPC 0 Formule Iodée Minimale in the veterinary area (DIN EN 1656:2009; Phase 2, Step 1)  Dr. Brill + Partner GmbH  L15/0122.4  Non-GLP  Unpublished | Y | GFB Commission 12 | N |
| Gabriel H, Klock J-H | 2015 | Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of META SPC 0 Formule Iodée minimale in veterinary area according to DIN EN 1657:2005 (Phase 2, step 1)  Dr. Brill + Partner GmbH  L15/0122.10  Non-GLP  Unpublished | Y | GFB Commission 12 | N |
| Gabriel H, Klock J-H | 2015 | Virucidal activity against bacteriophages of Meta SPC 0 Formule Iodée minimale in the quantitative suspension test according to DIN EN 13610:2002 (phase2, step 1)  Dr. Brill + Partner GmbH  L15/0122.13  Non-GLP  Unpublished | Y | GFB Commission 12 | N |
| Genuer C. | 2016 | Isolated chicken Eye Test method for Identifying (i) chemicals Inducing Serious Eye Damage and (ii) chemicals Not Requiring Classification for Eye irritation or Serious Eye Damage  Phycher Bio Développement  ICE-PH-15/0754  GLP  Unpublished | Y | GFB Commission 12 | N |

## Output tables from exposure assessment tools



## New information on the active substance

Not applicable

## Residue behaviour

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

- The reference values for iodine of 600 µg/d for adults and 200 µg/d for children are not toxicological reference values but upper intake levels. These values have been derived with the aim of setting recommendations for intake and do not represent toxicological cut-off values for risk assessment. For trace elements like iodine, generally no toxicologically cut-off values are set. Therefore, it was agreed at Human Health Working Group II-2017 to use the upper intake levels as reference values. It is further noted that WHO derived a value of 1000 µg/d for adults but no value for children was set. The UL for children is set by extrapolation from adults, which is not optimal considering the different hormonal status between adults and children. At the moment, it is not possible to obtain a better setting of the UL due to data gaps.

- The estimated intakes are based on theoretical worst case levels of iodine in milk and were calculated based on a chronic exposure, which was considered to be the most appropriate based on how the UL was derived. Furthermore, it is noted that the SCF (from which the UL for adult and toddler are included in the CAR for iodine) also reports adapted UL values for older children. The estimated residue levels of iodine in milk are based on a worst case assessment and the data are based on short term consumption studies.

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

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

It can be concluded that all available data have been provided to verify the outcome and conclusions, and permit authorisation of the biocidal product family. When using the products belonging to this biocidal product family according to the conditions as stated in the SPC, the products will be efficacious and will not present an unacceptable risk to human and animal health nor the environment. So it is important to obtain more reliable information on iodine background levels in food items in the EU, and consequently to update the data supporting the current UL. Iodine exposure pathways that are not a consequence of biocidal use are outside the remit of the BPC. Where unacceptable risks are identified as a result of consideration of 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, and not just those arising from teat treatments would need to be taken into consideration.Therefore a wider approach for the consumer risk assessments encompassing different regulatory areas would need to be considered.

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* EMEA/CVMP/187/00-FINAL, note for guidance on the risk analysis approach for residues of veterinary medicinal products in food of animal origin, 2001.

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

*Please see section 2.5*

## Confidential annex

*Please see the the confidential annex in the separated document*

## IUCLID filesReferences:

*Please see the UICLID File in R4BP3*

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1. According to Regulation (EC) 1272/2008, or where relevant, Directive 1999/45/EC. This section shall only include precautionary statements triggered by the CLP legislation. In accordance with paragraph 8 of document CA-May13-Doc.5.4, a precautionary statement that has been proven unnecessary in the risk assessment because of the intended use of the product should be left out of the SPC and of the label. 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)
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4. 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-4)
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7. [↑](#footnote-ref-7)
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