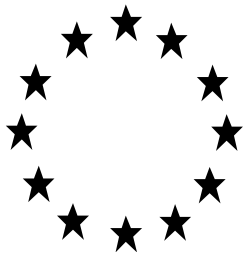
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

DRAFT RISK ASSESSMENT OF A BIOCIDAL PRODUCT FAMILY FOR UNION AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



Iodine product family Boumatic

Product type PT3

Iodine as included in the Union list of approved active substances

Case Number in R4BP: BC-PG019260-52

Evaluating Competent Authority: the Netherlands

Date: 25-03-2019

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1 CONCLUSION

The outcome of the assessment of the 'Iodine product family Boumatic' is specified in the BPC opinion following discussions at the BPC-29 meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website.

2 ASSESSMENT REPORT

2.1 SUMMARY

2.1.1 Presentation of the biocidal product family

A. IDENTITY OF THE ACTIVE SUBSTANCE

Main constituent(s)	
ISO name	Iodine
IUPAC or EC name	Iodine
EC number	231-442-4
CAS number	7553-56-2
Index number in Annex VI of CLP	053-001-00-3
Minimum purity / content	995 g/kg
Structural formula	I-I

B. 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.

Qualitative and quantitative information on the composition of the family

Overall family composition (level 1)

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
Iodine	Iodine	Active substance	7553-56-2	231-442-4	0.26	0.5
Fatty alcohol ethoxylated	Isotridecanol, ethoxylated	Substance of concern.	69011-36-5	500-241-6	1	2.99

For further details, please refer to the confidential annex

Information on the structure of the family

The family contains 3 *meta* SPC's. *Meta* SPC 1 contains 1 product (Udder dip), *meta* SPC 2 contains 2 products (Gladiator RTU, Udder Star Spray) and *meta* SPC 3 contains 1 product (Udder Star). The **composition** of the 4 products is regarded as similar.
The **use** of the products is regarded as similar. The products Gladiator RTU, Udder Star Spray and Udder star are used as teat disinfectants for post-milking dip or spray treatment. The product Udder dip is used as pre- or post-milking dip or spray treatment. In section C, both dip and spray treatment are described, the treatments are regarded as similar as both result in the liquid product adsorbed to the cow teat.
The **classification and labelling** for all 4 products is the same, as all products are classified as eye irritation cat. 2 (H319), & aq. chronic cat. 3 (H412) and have the corresponding P-phrases (section 2.2.4).
The **instructions of first aid, disposal and storage** (see section 2.2.5) are also the same for all products.
Conclusion: One *meta* SPC (*meta* SPC 1) is for pre- or post-milking spray or dip treatment, with iodine levels between 0.44 and 0.50 %. A second *meta* SPC (*meta* SPC 2) is for products used as post-milking spray or dip treatment, with iodine levels between 0.26 and 0.38 % (note eCA: based on the risk assessment, the max iodine level is reduced to 0.36). The third *meta* SPC (*meta* SPC 3) is for products used as post-milking spray or dip treatment, with iodine levels between 0.43-0.5%.

Information on the substance(s) of concern
More detailed information is provided in the confidential annex

C. AUTHORISED USE(S)

Meta SPC 1
Table 1: Use # 1.1– Manual dip treatment, pre- or post-milking teat disinfectants

Product Type(s)	PT03
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor Teat disinfectants for pre- or post-milking manual dip treatment of cow teats
Application method(s)	Manual dip treatment
Application rate(s) and frequency	Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10 ml per dip treatment; 2 times per day for pre-milking: min. 1 minute contact time for post-milking min 5 minutes contact time. Product is ready to use.
Category(ies) of user(s)	professionals
Pack sizes and packaging	20 kg, 60 kg, 200 kg, 210 kg HDPE drum and 1000 kg HDPE

material	IBC

Use 1.1 Use-specific instructions for use

Ready to use product for disinfection of cow teat by dipping treatment, before or after milking. Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10 ml per dip treatment.Fill the dipping cup with the indicated quantity of undiluted product straight from the original packaging. With every treatment, care should be taken to the volume of treatment product in the dipping cup. To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended.

 # Use 1.1 Use-specific risk mitigation measures

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and eye protection.

 # Use 1.1 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use of the meta SPC 1

 # Use 1.1 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use of the meta SPC 1

 # Use 1.1 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use of the meta SPC 1

Table 2: Use # 1.2 – Manual spraying treatment, pre- or post-milking teat disinfectants

Product Type(s)	PT03
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor Teat disinfectants for pre- or post-milking manual spray treatment of cow teat
Application method(s)	Manual spray treatment
Application rate(s) and frequency	Apply an amount of product that is sufficient to cover the entire teat , at the maximum 15 ml per spray treatment; 2 times per day

	for pre-milking: min. 1 minute contact time, for post-milking min. 5 minutes contact time. Product is ready to use.
Category(ies) of user(s)	professionals
Pack sizes and packaging material	20 kg, 60 kg, 200 kg, 210 kg HDPE drum and 1000 kg HDPE IBC

 # Use 1.2 Use-specific instructions for use

Ready to use product for disinfection of cow teat by spraying, before or after milking Apply an amount of product that is sufficient to cover the entire teat at the maximum 15 ml per spray treatment. Fill the spray flask with the indicated quantity of undiluted product straight from the original packaging. To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended.

 # Use 1.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), protective clothing, chemical resistant boots, and eye protection.

 # Use 1.2 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use of the meta SPC 1

 # Use 1.2 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use of the meta SPC 1

 # Use 1.2 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use of the meta SPC 1

Use # 1.3– Automated dip/spray treatment, pre- or post milking teat disinfectants

Product Type	PT3
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor Teat disinfectants for pre- or post-milking, dip/spray treatment of cow teat

Application method(s)	Automated dip/spray treatment
Application rate(s) and frequency	Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10 ml per dip treatment; 3 times per day, 15 ml per spray treatment; 3 times per day, pre-milking: min. 1 minute contact time, post-milking: min. 5 minutes contact time. Product is ready to use.
Category(ies) of users	professionals
Pack sizes and packaging material	20 kg, 60 kg, 200kg, 210 kg and 1000 kg HDPE

 # Use 1.3 Use-specific instructions for use

Ready to use product for disinfection of cow teat by spraying, before or after milking Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10 ml per dip treatment or at the maximum of 15 ml per spray treatment. Use the undiluted product straight from the original packaging. To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended.

 # Use 1.3 Use-specific risk mitigation measures

See general directions for use of the meta SPC 1

 # Use 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

See general directions for use of the meta SPC 1

 # Use 1.3 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use of the meta SPC 1

 # Use 1.3 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use of the meta SPC 1

General directions for use of the meta SPC 1

Instructions for use

See use specific instructions for each use. The products must be brought to temperatures above 20°C before use. For pre-milking treatment: treat the entire teat with the product, let act 60 seconds and wipe teats dry using single-use towels to avoid any contamination of milk. For the post-milking treatment: The teats should be treated as soon as possible after milking in such a way that the teats are fully covered. Let the teats air dry. The cows should be kept in a standing position until the product is fully dried (at least 5 minutes).

Risk mitigation measures

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered either for pre- or post-milking disinfection. Keep out of reach of children.

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

First aid: general information: immediately remove any clothing soiled by the product After inhalation: Supply fresh air; consult doctor in case of complaints. After skin contact: Wash skin thoroughly. Generally the product does not irritate the skin. After eye contact: Rinse opened eye for several minutes under running water. Remove contact lenses, if present and easy to do. Continue rinsing. After swallowing: Rinse out mouth and then drink water. If you feel unwell, get medicinal advise/attention. If medical advice is needed, have product container or label at hand.

Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

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

Protect from frost. Store in a cool, dry place, away from direct sunlight and out of reach from children. Shelf life: 2 years.

Meta SPC 2

Table 3 Use # 2.1 – Manual dip treatment, post milking teat disinfectants

Product Type	PT3
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria Yeasts
Field of use	indoor Teat disinfection for post –milking, manual dip treatment of cow teats
Application method(s)	Manual dip treatment
Application rate(s) and frequency	Apply an amount of product that is sufficient to cover the entire teat, a the maximum 10 ml per dip treatment; 2 times per day. For post-milking min. 5 minutes contact time

	Product is ready to use.
Category(ies) of users	professionals
Pack sizes and packaging material	20 kg, 60 kg, 200 kg, 210 kg HDPE drum and 1000 kg HDPE IBC

 # Use 2.1 Use-specific instructions for use

Ready to use product for disinfection of cow teat by dipping treatment, after milking.

Apply an amount of product that is sufficient to cover the entire teat, a the maximum 10 ml per dip treatment.Fill the dipping cup with the indicated quantity of undiluted product straight from the original packaging. With every treatment, care should be taken to the volume of treatment product in the dipping cup. To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended.

 # Use 2.1 Use-specific risk mitigation measures

Wear eye protection.

 # Use 2.1 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use of the meta SPC 2

 # Use 2.1 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use of the meta SPC 2

 # Use 2.1 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use of the meta SPC 2

Table 41. Use # 2.2 – Manual spraying treatment, post milking teat disinfectants

Product Type	PT3
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor Teat disinfection for post – milking, manual spray treatment of cow teats
Application method(s)	Manual spray treatment
Application rate(s) and frequency	Apply an amount of product that is sufficient to cover the entire teat, a the maximum 15 ml per spray treatment; 2 times per day

	For post-milking min. 5 minutes contact time Product is ready to use.
Category(ies) of users	professionals
Pack sizes and packaging material	20 kg, 60 kg, 200 kg, 210 kg HDPE drum and 1000 kg HDPE IBC

 # Use 2.2 Use-specific instructions for use

Ready to use product for disinfection of cow teat by spraying, after milking. Apply an amount of product that is sufficient to cover the entire teat, a the maximum 15 ml per spray treatment.Fill the spray flask with the indicated quantity of undiluted product straight from the original packaging. To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended.

 # Use 2.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and eye protection.

 # Use 2.2 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use of the meta SPC 2

 # Use 2.2 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use of the meta SPC 2

 # Use 2.2 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use of the meta SPC 2

Use # 2.3– Automated dip/spray treatment, pre- or post milking teat disinfectants

Product Type	PT3
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor Teat disinfectants for post-milking, dip/spray treatment of cow teat
Application method(s)	Automated dip/spray treatment

Application rate(s) and frequency	Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10 ml per dip treatment; 3 times per day, or 15 ml per spray treatment; 3 times per day, post-milking: min. 5 minutes contact time. Product is ready to use.
Category(ies) of users	professionals
Pack sizes and packaging material	20 kg, 60 kg, 200kg, 210 kg and 1000 kg HDPE

 # Use 2.3 Use-specific instructions for use

Ready to use product for disinfection of cow teat by spraying, before or after milking
Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10 ml per dip treatment or at the maximum of15 ml per spray treatment;
Use the undiluted product straight from the original packaging. To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended.

 # Use 2.3 Use-specific risk mitigation measures

See general directions for use of the meta SPC 2

 # Use 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

See general directions for use of the meta SPC 2

 # Use 2.3 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use of the meta SPC 2

 # Use 2.3 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use of the meta SPC 2

General directions for use of the meta SPC 2

Instructions for use

See use specific instructions for each use.
The products must be brought to temperatures above 20°C before use.

For the post-milking treatment: The teats should be treated as soon as possible after milking in such a way that the teats are fully covered. Let the teats air dry. The cows should be kept in a standing position until the product is fully dried (at least 5 minutes).

Risk mitigation measures

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

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

First aid: general information: immediately remove any clothing soiled by the product After inhalation: Supply fresh air; consult doctor in case of complaints. After skin contact: Wash skin thoroughly. Generally the product does not irritate the skin. After eye contact: Rinse opened eye for several minutes under running water. Remove contact lenses, if present and easy to do. Continue rinsing. After swallowing: Rinse out mouth and then drink water. If you feel unwell, get medical advice/attention. If medical advice is needed, have product container or label at hand.

Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

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

Protect from frost. Store in a cool, dry place, away from direct sunlight and out of reach from children. Shelf life: 1 year.

Meta SPC 3

Table 5 Use # 3.1 – Manual dip treatment, post milking teat disinfectants

Product Type	PT3
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria Yeasts
Field of use	indoor Teat disinfection for post –milking, manual dip treatment of cow teats
Application method(s)	Manual dip treatment
Application rate(s) and frequency	Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10 ml per dip treatment; 2 times per day. For post-milking min. 5 minutes contact time Product is ready to use.

Category(ies) of users	professionals
Pack sizes and packaging material	20 kg, 60 kg, 200 kg, 210 kg HDPE drum and 1000 kg HDPE IBC

 # Use 3.1 Use-specific instructions for use

Ready to use product for disinfection of cow teat by dipping treatment, after milking

Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10 ml per dip treatment. Fill the dipping cup with the indicated quantity of undiluted product straight from the original packaging. With every treatment, care should be taken to the volume of treatment product in the dipping cup. To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended.

 # Use 3.1 Use-specific risk mitigation measures

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and eye protection.

 # Use 3.1 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use of the meta SPC 3

 # Use 3.1 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use of the meta SPC 3

 # Use 3.1 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use of the meta SPC 3

Table 62. Use # 3.2 – Manual spraying treatment, post milking teat disinfectants

Product Type	PT3
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor Teat disinfection for post – milking, spray treatment of cow teats
Application method(s)	Manual spray treatment
Application rate(s) and frequency	Apply an amount of product that is sufficient to cover the entire teat, at the maximum 15 ml per spray treatment; 2 times per day for manual spraying with trigger sprayer or electronic sprayer. For post-milking min. 5 minutes contact time

	Product is ready to use.
Category(ies) of users	professionals
Pack sizes and packaging material	20 kg, 60 kg, 200 kg, 210 kg HDPE drum and 1000 kg HDPE IBC

 # Use 3.2 Use-specific instructions for use

Ready to use product for disinfection of cow teat by spraying, after milking. Apply an amount of product that is sufficient to cover the entire teat, at the maximum 15 ml per spray treatment Fill the spray flask with the indicated quantity of undiluted product straight from the original packaging. To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended.

 # Use 3.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), protective clothing, chemical resistant boots, and eye protection.

 # Use 3.2 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use of the meta SPC 3

 # Use 3.2 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use of the meta SPC 3

 # Use 3.2 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use of the meta SPC 3

Use # 1.3– Automated dip/spray treatment, pre- or post milking teat disinfectants

Product Type	PT3
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor Teat disinfectants for pre- or post-milking, dip/spray treatment of cow teat
Application method(s)	Automated dip/spray treatment
Application rate(s) and	Apply an amount of product that is sufficient to cover the entire

frequency	teat, at the maximum 10 ml per dip treatment; 3 times per day, 15 ml per spray treatment; 3 times per day, pre-milking: min. 1 minute contact time, post-milking: min. 5 minutes contact time. Product is ready to use.
Category(ies) of users	professionals
Pack sizes and packaging material	20 kg, 60 kg, 200kg, 210 kg and 1000 kg HDPE

 # Use 3.3 Use-specific instructions for use

Ready to use product for disinfection of cow teat by spraying, before or after milking
Apply an amount of product that is sufficient to cover the entire teat, at the maximum 10 ml per dip treatment or at the maximum of 15 ml per spray treatment.
Use the undiluted product straight from the original packaging. To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended.

 # Use 3.3 Use-specific risk mitigation measures

See general directions for use of the meta SPC 3

 # Use 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

See general directions for use of the meta SPC 3

 # Use 3.3 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use of the meta SPC3

 # Use 3.3 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use of the meta SPC 3

General directions for use of the meta SPC 3

Instructions for use

See use specific instructions for each use.
The products must be brought to temperatures above 20°C before use.

For the post-milking treatment: The teats should be treated as soon as possible after milking in such a way that the teats are fully covered. Let the teats air dry. The cows should be kept in a standing position until the product is fully dried (at least 5 minutes).

Risk mitigation measures

See use specific risk mitigation measures.

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

Keep out of reach of children.

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

First aid: general information: immediately remove any clothing soiled by the product
After inhalation: Supply fresh air; consult doctor in case of complaints.
After skin contact: Wash skin thoroughly. Generally the product does not irritate the skin.
After eye contact: Rinse opened eye for several minutes under running water. Remove contact lenses, if present and easy to do. Continue rinsing.
After swallowing: If medical advice is needed, have product container or label at hand.

Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

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

Protect from frost. Store in a cool, dry place, away from direct sunlight and out of reach from children.
Shelf life: 2 years.

D. HAZARD AND PRECAUTIONARY STATEMENTS

Classification and Labelling according to Regulation (EC) No 1272/2008:

Classification	
Hazard category	Eye irritation Aquatic Chronic 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 hands thoroughly after handling P280 - Wear eye protection P305 + P351 + P338 - IF 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. P273 -Avoid release to the environment P501 – Dispose content/container to hazardous waste collection point in accordance with all regulations
Note	

E. 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)**
drum	20 kg	HDPE	HDPE Screw cap	professional	Yes
drum	60 kg	HDPE	HDPE Screw cap	professional	Yes
drum	200 kg or 210 kg	HDPE	HDPE Screw cap	professional	Yes
IBC	1000 kg	HDPE	HDPE Screw cap	professional	Yes

2.1.2 Summary of the physical, chemical and technical properties

Products are all (yellow to) brown liquids, with a characteristic iodine odour.
Products in this family are not classified for any of physical hazards.
pH will be within a range of 4 and 6 for all *meta* SPC's.
All products in *meta* SPC's 1 and 3 are stable at ambient temperature for a shelf life of 24 months. Products in *meta* SPC 2 have a shelf life of 12 months.
No reactivity against container material was observed.

2.1.3 Summary of the Human Health Risk Assessment

The product family represented in this risk assessment dossier contains four iodine-based products.

The risk calculations are performed using HEAdhoc recommendation no. 13 and taking into account the outcome of various working group meetings concerning the evaluation of iodine based teat disinfection.

Professional exposure

Conclusions pre-milking application:

metaSPC1
For manual dipping applications, chemical resistant gloves are needed for safe use.
For manual spraying application using a trigger sprayer, chemical resistant gloves, protective clothing and chemical resistant boots are needed for safe use.

Conclusions post-milking application:

metaSPC1
For manual dipping applications, chemical resistant gloves are needed for safe use.
For manual spraying application using a trigger sprayer, chemical resistant gloves, protective clothing and chemical resistant boots are needed for safe use.

metaSPC2
For manual dipping no PPE is necessary for safe use.
For manual spraying applications using a trigger sprayer, chemical resistant gloves are needed for safe use.

metaSPC3
For manual dipping applications, chemical resistant gloves are needed for safe use.
For manual spraying application using a trigger sprayer, chemical resistant gloves, protective clothing and chemical resistant boots are needed for safe use.

Exposure to residues

Conclusion
Although the intended use includes either pre- or post-milking, products could be combined and therefore this is assessed. Based on combined pre- **and** post-milking teat disinfection results in 107% UL for toddlers by exposure to residues due to treatment. Therefore, the combination of pre- and post-milking is considered not safe. The following risk mitigation measure needs to be included in paragraph 5.2 of the SPC: In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre- **or** post-milking disinfection.

For all metaSPCs the UL for toddlers is exceeded when taken into account teat disinfection and dietary intake.

NL decision
Based on the estimated total intakes for adults, the human health risk is acceptable in all milking applications. In contrast, the estimated total daily intake for toddlers exceeds the UL in all scenarios when taking into account either pre- or post-milking and the worst case exposure conditions (i.e. 0.5% iodine, and 149-157% of UL or 1.49-1.57 fold exceedance). It is noted that for toddlers, exceedance of the UL is reported from dietary intakes arising from iodine background levels (milk from untreated teats and diet). Furthermore, it is generally reported that the main contributor for iodine levels in milk is animal feed (natural sources and

supplementations). Ideally, further work should be performed to obtain more reliable information on iodine background levels in food items in the EU. Moreover, it should be mentioned that by using the agreed upon values for background in milk and other dietary sources lead to 94% of UL for toddlers.

For the eCA proposal for a risk management decision we refer to the general conclusions in chapter 1 of this PAR

2.1.4 Summary of the Environmental Risk Assessment

PEC:PNEC for STP is well below 1. However, a precautionary measure stating that residues must be discharged to the (liquid) manure depot or municipal sewer will be added to the SPC as dairy farms are not necessarily connected to the municipal sewer. Domestic waste water may be purified on-site by individual sewage treatment plants. Considering that these systems are small (a few cubic meters), high loads of iodine may kill the microbial population therein instantly, resulting in malfunctioning of the plant.

For the emission pathway via STP, the PEC/PNEC values for iodine, iodide and iodate in the aquatic compartment (surface water incl. sediment, marine water incl. sediment) are below the 1. Therefore, unacceptable risk for the aquatic environment cannot expected.

Although iodate is the dominant iodine specie in soils under aerobic conditions, it may be transformed to iodide once entering the aquatic environment depending on the acidity and redox potential (oxygen concentrations). Unacceptable risks may be expected in surface water low in oxygen. Iodine is however a natural occurring compound for which aquatic background levels are reported between 0.5 and 20 µg/L. The expected slight exceedance of the PNEC is consequently considered acceptable.

Once released to soils, iodine will be transformed into iodide or iodate depending on the redox conditions. Unacceptable risks are calculated for iodide in both arable and grassland after one year, i.e. after one or four manure applications respectively, while the PECs remain below the PNEC in case of iodate. These risks are nevertheless hypothetical as iodide only occurs in anaerobic i.e. flooded soils which may happen only incidentally. As the ecological impact of long-term flooding is more disastrous compared to the risks related to anthropogenic elevated iodine concentrations, the estimated PEC:PNEC ratios are considered unrealistic for agricultural soils for cattle and crops.

Iodine and iodide species occur naturally in the terrestrial environment for which the natural global mean background concentration is 5 mg/kg dwt and varies with geographical locations and local geology. Emission from teat disinfectants can significantly enlarge natural deposition, especially where background levels are low. Nevertheless, the accompanied risks are acceptable as the PEC:PNEC ratios for the dominant iodine specie in soils (iodate) remains below one. Despite an increase of background concentrations unacceptable risks in soils are not expected.

Although concentrations in groundwater exceed the threshold limit value of 0.1 µg/L, the 0.1 µg/L limit is set for organic chemicals and is not feasible for iodine. Iodine is a natural occurring compound occurring in groundwater for which the concentration ranges from 1 to 70 µg/L. Considering that the PECs are within these natural background ranges, emission to groundwater is considered acceptable.
Conclusively, application of the current biocidal product family as non-medical teat disinfectants does not results in unacceptable risks for the environment. Risk mitigation measures are not necessary, but a precautionary measure to protect individual waste water treatment plants will be added to the SPC.

2.2 GENERAL INFORMATION ABOUT THE PRODUCT APPLICATION

2.2.1 Administrative information

A. TRADE NAME(S) OF THE PRODUCTS OF THE FAMILY

Trade name[1]	**Country (if relevant)**
Udder Dip (Udder Dip Max, Udder D Max, Udderdine Dip, Uddine Dip, Udderdine DP, Uddine DP, Udderdine DS)	EU
Udder Star (Udder Star Max, Udder S Max, Udderdine Star, Uddine Star, Udderdine ST, Uddine ST)	EU
Udder Star Spray (Udder Spray Max, Udderdine Spray, Uddine Spray, Udderdine SP, Uddine SP)	EU
Gladiator RTU (Udder Max Barrier, Gladiator Max Barrier, Udderdine BARRIER, Uddine BARRIER, Udderdine RTU, Uddine RTU, Udderdine BR)	EU

B. AUTHORISATION HOLDER

Name and address of the authorisation holder	Name	Boumatic Gascoigne Melotte
	Address	Rue Jules Mélotte 31 4350 Remicourt Belgium
Telephone:	+32 19 54 42 66	
Fax:		
E-mail address:	info@boumatic.com	
Pre-submission phase started on:	23/02/2015	
Pre-submission phase concluded on:	12/05/2015	
Case number in R4BP3:	BC-PG019260-52	

[1] In case the product would have more than one name, all names can be provided in this field, if the other elements of the SPC are identical. Otherwise additional SPCs would have to be provided (one SPC per name).

C. APPLICANT (IF DIFFERENT FROM AUTHORISATION HOLDER)

Same as authorisation holder

D. PERSON AUTHORISED FOR COMMUNICATION ON BEHALF OF THE APPLICANT

Contact person 1	
Name:	Christophe Ribes
Function:	Product Manager
E-mail address:	cribes@boumatic.com
Telephone:	+33 677 322 459 (mobile)
Contact person 2	
Name:	Romain Wolfer
Function:	Dairy Hygiene Regulatory Manager
E-mail address:	rwolfer@boumatic.com
Telephone:	+32 4 70 86 20 05(mobile), +32 19 54 99 19(office)
Address:	Rue Jules Melotte, 31
City:	Remicourt
Postal Code:	4350
Country:	Belgium

E. MANUFACTURER OF THE PRODUCTS OF THE FAMILY

Name of manufacturer	Christeyns n.v.
Address of manufacturer	Afrikalaan 182, 9000 Ghent, Belgium
Location of manufacturing sites	Afrikalaan 182, 9000 Ghent, Belgium

MANUFACTURER(S) OF THE ACTIVE SUBSTANCE(S)

Active substance	Iodine
Name of manufacturer	Christeyns n.v.
Address of manufacturer	Afrikalaan 182, 9000 Ghent, Belgium
Location of manufacturing sites	Cosayach Nitratos S.A Oficina Cala Cala S/N Pozo Almonte, Iquique Chile

F. CANDIDATE(S) FOR SUBSTITUTION

Not applicable.

2.2.2 Product (family) composition and formulation

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

Yes ☐
No ☒

A. IDENTITY OF THE ACTIVE SUBSTANCE

Main constituent(s)	
ISO name	Iodine
IUPAC or EC name	Iodine
EC number	231-442-4
CAS number	7553-56-2
Index number in Annex VI of CLP	053-001-00-3
Minimum purity / content	Purity: 998 g/kg
Structural formula	I-I

B. QUALITATIVE AND QUANTITATIVE INFORMATION ON THE COMPOSITION OF THE BIOCIDAL PRODUCT (FAMILY)

Please see the confidential annex for further details.

BPF:

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
Iodine	Iodine	Active substance	7553-56-2	231-442-4	0.26	0.5
Fatty alcohol ethoxylated	Isotridecanol, ethoxylated	Substance of concern	69011-36-5	500-241-6	1	2.99

Meta SPC 1

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
Iodine	Iodine	Active substance	7553-56-2	231-442-4	0.44	0.5

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
Fatty alcohol ethoxylated	Isotridecanol, ethoxylated	Substance of concern	69011-36-5	500-241-6	1	2.99

Meta SPC 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine	Iodine	Active substance	7553-56-2	231-442-4	0.26	0.38
Fatty alcohol ethoxylated	Isotridecanol, ethoxylated	Substance of concern	69011-36-5	500-241-6	1	2.99

Meta SPC 3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine	Iodine	Active substance	7553-56-2	231-442-4	0.43	0.5
Fatty alcohol ethoxylated	Isotridecanol, ethoxylated	Substance of concern	69011-36-5	500-241-6	1	2.99

C. INFORMATION ON TECHNICAL EQUIVALENCE

Information on the manufacturing location is more detailed than the information included in the CAR. Therefore, full comparison was not possible. Based of the available information it was assumed that the manufacturing site has been assessed in the CAR.

D. INFORMATION ON THE SUBSTANCE(S) OF CONCERN

Please see the confidential annex for further details.

SoC 1

Concentration	1.2-2.99 %
Classification and Labelling according to Regulation (EC) No 1272/2008:	Eye damage. Cat 1 H318, acute tox. Cat 4 H302
Relevant toxicological/ecotoxicological information	-

E. TYPE OF FORMULATION

Any other liquid (AL)/ Ready-to-use liquid

2.2.3 Intended use(s)as applied for by the applicant

The uses below are the ones applied for by the applicant, without any changes by the e-CA. These uses are assessed in the following chapters.
See 2.1.1 C for the authorised uses, after assessment of the dossier.

Table 1: Use # 1.1 – dip treatment- pre- or post-milking teat disinfectants

Product Type	PT3
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria Yeasts
Field of use	indoor Teat disinfectants for pre- or post-milking, dip treatment of cow teat
Application method(s)	Dip treatment
Application rate(s) and frequency	10 ml per dip treatment; 2 times per day, pre-milking: min. 1 minute contact time, post-milking: min.5 minutes contact time. Product is ready to use.
Category(ies) of users	professionals
Pack sizes and packaging material	20 kg, 60 kg, 200 kg, 210 kg and 1000 kg HDPE

Table 2: Use # 1.2 – spraying treatment - pre- or post-milking teat disinfectants

Product Type	PT3
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor Teat disinfectants for pre- or post-milking, spray treatment of

	cow teat
Application method(s)	spray treatment
Application rate(s) and frequency	15 ml per spray treatment; 2 times per day, pre-milking: min. 1 minute contact time, post-milking: min.5 minutes contact time. Product is ready to use.
Category(ies) of users	professionals
Pack sizes and packaging material	20 kg, 60 kg, 200kg, 210 kg and 1000 kg HDPE

Table 3. Use # 2.1 and #3.1– dip treatment, post milking teat disinfectants

Product Type	PT3
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria Yeasts
Field of use	indoor Teat disinfection for post –milking, dip treatment of cow teats
Application method(s)	Dip treatment
Application rate(s) and frequency	10 ml per dip treatment; 2 times per day. For post-milking min. 5 minutes contact time Product is ready to use.
Category(ies) of users	professionals
Pack sizes and packaging material	20 kg, 60 kg, 200 kg, 210 kg and 1000 kg HDPE

Table 4. Use # 2.2 and #3.2 – spraying treatment, post milking teat disinfectants

Product Type	PT3
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor Teat disinfection for post – milking, spray treatment of cow teats
Application method(s)	Spray treatment
Application rate(s) and frequency	15 ml per spray treatment; 2 times per day For post-milking min. 5 minutes contact time

	Product is ready to use.
Category(ies) of users	professionals
Pack sizes and packaging material	20 kg, 60 kg, 200 kg, 210 kg and 1000 kg HDPE

2.2.4 Hazard and precautionary statements

A. PROPOSED CLASSIFICATION AND LABELLING OF THE BIOCIDAL PRODUCT

Classification and Labelling according to Regulation (EC) No 1272/2008:

Classification	
Hazard category	Eye Irrit 2 Aquatic Chronic 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 hands thoroughly after handling P273 -Avoid release to the environment P280 – Wear eye protection P305 + P351 + P338 - IF 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. P501 – Dispose content/container to hazardous waste collection point in accordance with all regulations
Note	

B. 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)
drum	20 kg	HDPE	HDPE screw cap	professional	Yes
drum	60 kg	HDPE	HDPE screw cap	professional	Yes
drum	200 kg or 210 kg	HDPE	HDPE screw cap	professional	Yes
IBC	1000 kg	HDPE	HDPE screw cap	professional	Yes

Directions for use

A. INSTRUCTIONS FOR USE

Use # 1.1 – dip treatment, pre- or post-milking teat disinfectants

Ready to use product for disinfection of cow teat by dipping treatment, before or after milking

Fill the dipping cup with the indicated quantity of undiluted product straight from the original packaging. With every treatment, care should be taken to the volume of treatment product in the dipping cup. To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended.

The products must be brought to temperatures above 20°C before use.
For pre-milking treatment: treat the entire teat with the product, let act 60 seconds and wipe teats dry using single-use towels to avoid any contamination of milk.
For the post-milking treatment: The teats should be sprayed as soon as possible after milking in such a way that the teats are fully covered. Let the teats air dry. The cows should be kept in a standing position until the product is fully dried (at least 5 minutes).

Use # 1.2 – spray treatment, pre- or post-milking teat disinfectants

Ready to use product for disinfection of cow teat by spraying, before or after milking

Fill the spray flask with the indicated quantity of undiluted product straight from the original packaging. To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended.

The products must be brought to temperatures above 20°C before use.
For pre-milking treatment: treat the entire teat with the product, let act 60 seconds and wipe teats dry using single-use towels to avoid any contamination of milk.
For the post-milking treatment: The teats should be sprayed as soon as possible after milking in such a way that the teats are fully covered. Let the teats air dry. The cows should be kept in a standing position until the product is fully dried (at least 5 minutes).

Use # 2.1 & 3.1 – dip treatment, post-milking teat disinfectants

Ready to use product for disinfection of cow teat by dipping treatment, after milking

Fill the dipping cup with the indicated quantity of undiluted product straight from the original packaging. With every treatment, care should be taken to the volume of treatment product in the dipping cup. To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended.

The products must be brought to temperatures above 20°C before use.

For the post-milking treatment: The teats should be dipped as soon as possible after milking in such a way that the teats are fully covered. Let the teats air dry. The cows should be kept in a standing position until the product is fully dried (at least 5 minutes).

Use # 2.2 & 3.2 – spray treatment, post-milking teat disinfectants

Ready to use product for disinfection of cow teat by spraying, after milking Fill the spray flask with the indicated quantity of undiluted product straight from the original packaging. To reduce dermal exposure, the use of a dosing pump for filling the product into the application equipment is recommended. The products must be brought to temperatures above 20°C before use. For the post-milking treatment: The teats should be dipped as soon as possible after milking in such a way that the teats are fully covered. Let the teats air dry. The cows should be kept in a standing position until the product is fully dried (at least 5 minutes).

Use Restrictions:	In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for either pre- or post-milking disinfection. Keep out of reach of children.

B. PARTICULARS OF LIKELY DIRECT OR INDIRECT EFFECTS, FIRST AID INSTRUCTIONS AND EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT

First aid: general information: immediately remove any clothing soiled by the product After inhalation: Supply fresh air; consult doctor in case of complaints. After skin contact: Wash skin thoroughly. Generally the product does not irritate the skin. After eye contact: Rinse opened eye for several minutes under running water. Remove contact lenses, if present and easy to do. Continue rinsing. After swallowing: Rinse out mouth and then drink water. If you feel unwell, get medical advice/attention. If medical advice is needed, have product container or label at hand.

C. INSTRUCTIONS FOR SAFE DISPOSAL OF THE PRODUCT AND ITS PACKAGING

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water

treatment plant.

D. CONDITIONS OF STORAGE AND SHELF-LIFE OF THE PRODUCT UNDER NORMAL CONDITIONS OF STORAGE

Protect from frost. Store in a cool, dry place, away from direct sunlight and out of reach from children. Shelf life: 2 years for *meta* SPC 1 and 3; 1 year for *meta* SPC 2

2.2.5 Documentation

A. DATA SUBMITTED IN RELATION TO PRODUCT APPLICATION

No new human health or ecotoxicological studies have been performed on product level.

B. ACCESS TO DOCUMENTATION

Letter of access to the original dossier of the active substance.

C. SIMILAR CONDITIONS OF USE

The biocidal product family Boumatic Iodine product family is deemed to be eligible
For Union authorization, based on the outcome of the pre-submission consultation:

'Based on the information provided by the applicant, it appears that the application could meet the basic requirements of Article 42(1) of the Biocidal Products Regulation. No objections were raised from either the Commission or the Member States Competent Authorities (MSCA5) as regards the eligibility of the prospective application for Union authorisation on the grounds that the biocidal product family Boumatic Iodine product family falls outside of the scope of the Biocidal Products Regulation, or had been attributed the wrong product type, or that it would have non-similar conditions of use across the Union (see Annex).'

2.2.6 Other information

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2.3 ASSESSMENT OF THE BIOCIDAL PRODUCT FAMILY

2.3.1 Physical, chemical and technical properties

Tested trade names	*meta* SPC
Udder Dip	1
Udder Star Spray Gladiator RTU	2
Udder Star	3

Property	**Guideline and Method**	**Purity of the test substance (% w/w)**	**Results**	**Reference**
Physical state at 20 °C and 101.3 kPa	EPA OPPTS 830.6303	Pure product tested	Liquid (all products)	'report 202245-495769', Brekelmans, 2013 'report 202245-495768', Brekelmans, 2013 'report S15-04600' Birnschein, 2017 'report S15-04608' Birnschein, 2017
Colour at 20 °C and 101.3 kPa	EPA OPPTS 803.6302	Pure product tested	Brown (all products)	'report 202245-495769', Brekelmans, 2013 'report 202245-495768', Brekelmans, 2013 'report S15-04600' Birnschein, 2017 'report S15-04608' Birnschein, 2017
Odour at 20 °C and 101.3 kPa	EPA OPPTS 803.6304	Pure product tested	No characteristic odour (all products)	'report 202245-495769', Brekelmans, 2013 'report 202245-495768', Brekelmans, 2013 'report S15-04600' Birnschein, 2017 'report S15-04608' Birnschein, 2017
Acidity / alkalinity	CIPAC MT 75.3	Pure product tested	Acidity/alkalinity test not required, pH is between range 4-10 -Udder Dip: 5.2 (1% solution), 4.9 (100% solution) -Udder Star: 4.8 (1% solution), 4.4 (100% solution)	'report 202245-495769', Brekelmans, 2013 'report 202245-495768', Brekelmans, 2013 'report S15-04600' Birnschein, 2017 'report S15-04608' Birnschein, 2017

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
			Udder star spray: 4.69 (1% solution) Gladiator RTU: 5.68 (1% solution)	
Relative density / bulk density	OECD 109	Pure product tested	Udder dip: 1.03 Udder star: 1.04 Udder star spray: 1.06 Gladiator RTU: 1.02	'report 202245-495769', Brekelmans, 2013 'report 202245-495768', Brekelmans, 2013 'report S15-04600' Birnschein, 2017 'report S15-04608' Birnschein, 2017
Storage stability test – **accelerated storage**	CIPAC MT46.3 (NOTOX/WIL test)	Pure product tested	Udder Dip: Stable after 14 days storage at 54°C Udder Dip tested during 2 weeks at 54°C in glass. Tested parameters: iodine content, appearance, pH and density. **Before storage:** *Iodine content:* 0.552% w/w *Appearance:* Brown liquid with no characteristic odour. *pH 1%:* 4.9 *pH pure:* 4.7 *Density:* 1.03 **After storage:** *Iodine content:* 0.502% w/w *Appearance:* Brown liquid with no characteristic odour. *pH 1%:* 4.7 *pH pure:* 4.4 *Density:* 1.03 *Active substance decrease: 9.06% w/w*	'report 493616',Brekelmans, 2010
Storage stability test – **long term storage at ambient temperature**	pH: CIPAC MT 75.3 Density: EC	Pure product tested	Udder Dip tested during 24 months at ambient in HDPE. Tested parameters:	'report 202245-495769', Brekelmans, 2013 'report 202245-495768', Brekelmans, 2013

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
	A.3, OECD 109 Iodine determination: Titration with sodium thiosulphate (validated)		iodine content, appearance, pH and density. **Before storage:** *Iodine content:* 0.525% w/w *Appearance:* Brown liquid with no characteristic odour. *pH 1%:* 5.2 *pH pure:* 4.9 *Density:* 1.03 **After storage:** *Iodine content:* 0.508% w/w *Appearance:* Brown liquid with no characteristic odour. *pH 1%:* 5.1 *pH pure:* 4.8 *Density:* 1.03 *Active substance decrease: 3.24% w/w* Udder Star tested during 24 months at ambient in HDPE. Tested parameters: iodine content, appearance, pH and density. **Before storage:** *Iodine content:* 0.535% w/w *Appearance:* Brown liquid with no characteristic odour. *pH 1%:* 4.8 *pH pure:* 4.4 *Density:* 1.04 **After storage:** *Iodine content:* 0.515% w/w *Appearance:* Brown liquid with	'S15-04600_Final Report_PCTY_Udder Star Spray' 'S15-04608_Final Report_PCTY_Gladiator RTU'

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
			no characteristic odour. *pH 1%:* 4.6 *pH pure:* 4.3 *Density:* 1.04 *Active substance decrease:* *3.74% w/w* Gladiator RTU tested during 12 months at ambient in HDPE. Tested parameters: iodine content, appearance, pH. **Before storage:** *Iodine content:* 2.18 g/L *Appearance:* Brown liquid with no characteristic odour. *pH 1%:* 5.68 **After storage:** *Iodine content:* 2.05 g/L *Appearance:* Brown liquid with no characteristic odour. *pH 1%:* 5.52 *Active substance decrease:* *5.96% w/w* Udder Star Spray tested during 12 months at ambient in HDPE. Tested parameters: iodine content, appearance, pH. **Before storage:** *Iodine content:* 2.84 g/L *Appearance:* Brown liquid with no characteristic odour.	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
			pH 1%: 4.69 **After storage:** *Iodine content:* 2.61 g/L *Appearance:* Brown liquid with no characteristic odour. *pH 1%:* 4.75 *Active substance decrease:* *8.10% w/w*	
Storage stability test – **low temperature stability test for liquids**			Not required: label mentions "protect from frost" (all products)	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			Not required: label mentions "protect from direct sunlight"; the packaging is not transparent (all products)	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			Label mentions "store in a cool, dry place" (all products)	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	EPA OPPTS 803.6320	Pure product tested	No reactivity towards packaging material observed during shelf life study Udder Dip: No significant change during 24 months Udder Star: No significant change during 24 months Gladiator RTU: No significant change in weight (≤ 0.09%) found after 12 months Udder Star Spray:	'report 202245-495769', Brekelmans, 2013 'report 202245-495768', Brekelmans, 2013 'report S15-04600' Birnschein, 2017 'report S15-04608' Birnschein, 2017

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
			No significant change in weight (≤ 0.09%) found after 12 months	
Wettability			Test not required: product is a liquid (all products)	
Suspensibility, spontaneity and dispersion stability			Test not required: product is RTU (all products)	
Wet sieve analysis and dry sieve test			Test not required: product is a liquid (all products)	
Emulsifiability, re-emulsifiability and emulsion stability			Test not required: product is not an emulsion (all products)	
Disintegration time			Test not required: product is a liquid (all products)	
Particle size distribution, content of dust/fines, attrition, friability			Test not required: 1. Although some of the products may be used in spray applications, the products are not sold in or together with spraying equipment. 2. The MMAD is not required as an input parameter for the human exposure assessment. The risk assessment is based on the assumption that there will be only large droplets present upon use and information on particle size is not needed to complete the risk assessment. 3. The MMAD is not relevant to demonstrate efficacy.	
Persistent foaming			Test not required: product is a RTU liquid and does not need to be diluted (all products)	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Flowability/Pourability/Dustability			Test not required: product is a liquid (all products)	
Burning rate — smoke generators			Test not required: product is not a smoke generator (all products)	
Burning completeness — smoke generators			Test not required: product is not a smoke generator (all products)	
Composition of smoke — smoke generators			Test not required: product is not a smoke genrator (all products)	
Spraying pattern — aerosols			The product is not an aerosol and is not sold in spray packaging (all products)	
Physical compatibility			Not applicable, product not to be mixed with other products (all products)	
Chemical compatibility			Not applicable, product not to be mixed with other products (all products)	
Degree of dissolution and dilution stability			Not required: RTU liquid product (all products)	
Surface tension	OECD 115	Pure product tested	Gladiator RTU: 34.6 Nm/m at 25°C Udder Dip: 29.3 Nm/m at 25°C	'report S15-04533' Koch, 2015 'report S15-04505' Koch, 2015
Viscosity	CIPAC MT 192, OECD 114	Pure product tested	Udder star spray: 3.55 mPas at 20°C / 3.17 mPa at 40°C , (at shear rate 5-100 s^{-1}) test item is considered a Newtonian liquid. Gladiator RTU: 2147.74 mPas (at 5 s^{-1} shear rate) – 181.96 mPas (at 100 s^{-1} shear rate) at	'report S15-04504' Birnschein, 2016 'report S15-04505', Birnschein, 2016

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
			20°C 1626.53 mPas (at 5 s^{-1} shear rate) – 154.29 mPas (at 100 s^{-1} shear rate) at 40°C test item is considered non-Newtonian liquid	

2.3.2 Physical hazards and respective characteristics

Property	Guideline and Method	Results	Reference
Explosives	-	Product does not contain substances with chemicals groups associated with explosive properties and is therefore not considered explosive.	-
Flammable gases	-	Not applicable, product is a liquid	-
Flammable aerosols	-	Not applicable, product is not an aerosol	-
Oxidising gases	-	Not applicable, product is a liquid	-
Gases under pressure	-	Not applicable, not under pressure	-
Flammable liquids	-	Not applicable. As the safety data sheets show no classification as flammable, flashpoints should at least be >60°C and the biocidal product family only contains non-flammable components.	-
Flammable solids	-	Not applicable, product is a liquid	-
Self-reactive substances and mixtures	-	Not self-reactive, product contains no self-reacting substances	-
Pyrophoric liquids	-	No pyrophoric substances present, not applicable	-
Pyrophoric solids	-	Not applicable, product is a liquid	-
Self-heating substances and mixtures	-	No self-heating compounds present	-
Substances and mixtures which in contact with water emit flammable gases	-	Not applicable, product is a stable aqueous solution, by which no flammable gas is emitted	-
Oxidising liquids	-	No substances with oxidizing properties in the product: in organic compounds oxygen is only bound to carbon or hydrogen, iodine is not classified as oxidizing. Therefore, the product is not considered as oxidizing	-
Oxidising solids	-	Not applicable, product is liquid	-
Organic peroxides	-	Not applicable, no compounds present with	-

Property	Guideline and Method	Results	Reference
		bivalent O-O structure present	
Corrosive to metals	UN manual of tests and criteria Part III, 37.4 (test C.1)	Not classified as corrosive to metals. A worst case representative mixture was tested on metal corrosion classification. The mixture shows a negative result for corrosion to metal. The results are valid for the entire family. After 28 days of testing: Aluminium: 10.659% weight loss Steel: 10.173% weight loss The weight loss is well below the threshold of 51.5%. Due to the uniform nature of the corrosion only mass loss is reported. Intrusion depth is not relevant in this case.	'report 3202214', A. Beaumont, 2018
eCA remark: The worst case representative mixture is a modified version of Udder Dip containing the highest concentration of iodine in the biocidal product family. For the composition of Udder Dip Modified and a justification for the worst case choice see confidential annex.			
Auto-ignition temperatures of products (liquids and gases)	-	The products are known to be stable at room temperature and do not ignite spontaneously. The product is not considered to be auto-ignitable.	-
Relative self-ignition temperature for solids	-	Not applicable	-
Dust explosion hazard	-	Not applicable	-

All products are ready to use (yellow to) brown liquids, with a characteristic iodine odour. They are not classified based on physical and chemical properties. Products in meta-SPC 1 and 3 are stable at ambient temperature during 24 months in HDPE. The shelf life for products in meta-SPC 2 is 12 months in HDPE. No reactivity against container material was observed.
pH-measurements on all 4 products were performed. Given the ranges of ingredient concentrations in the meta SPC's, the pH level will remain between 4 and 6. Values between these limits will not require any additional considerations.
The information provided in the table above is considered representative for all products in the family.

2.3.3 Methods for detection and identification

	Analytical methods for the analysis of the product as such including the active substance, impurities and residues								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Iodine (Udder Dip)	Titration with sodium thiosulfate using starch solution as indicator	n=5 1 g/L	N/A	Specific, no interferences	100%	100 %	Precision: % RSD = 0.39 %RSD r = 3.0	-	Brekelmans, 2013 (WIL Research, project 495769)
Iodine (Udder Star)	Titration with sodium thiosulfate using starch solution as indicator	n=5 1 g/L	N/A	Specific, no interferences	99 %	99%	Precision: % RSD = 0.44 %RSD r = 2.9	-	Brekelmans, 2013 (WIL Research, project 495768)
Iodine	Titration with sodium thiosulfate using starch solution as indicator		-						CAR iodine, 2013
Impurities in technical active substance	Determination/Quantification of bromides and chlorides by opalescence. Determination/Quantification of non-volatile substances after sublimation		-						CAR iodine, 2013

Principle of the method and sample preparation

Accurately weighed samples of approximately 20g were taken from the test substance and transferred into a beaker of 250 ml. After addition of 100 g water, the solution was titrated with sodium thiosulphate solution 0.1N until the colour turned from brown to colourless. Thereafter, 5 ml 20% sulphuric acid in water was added but titration had not to be continued since the solution remained colourless.

Conclusion on analytical methods

The method of detection for iodine in the product was a titration method with sodium thiosulfate as titrant. The validation of the method was compliant with the requirements and the provided data are considered representative for the biocidal product family.
The validation of the analytical method was performed on product Udder Star and Udder Dip.
More information on read-across is provided in the confidential annex.

Analytical methods for soil	
No fully acceptable method available – not required as the calculated PECs from the biocidal product uses evaluated are just a fraction of natural background concentrations	CAR iodine, 2013

Analytical methods for air	
In air sampling tubes, I_2 is partially but stoichiometrically converted to iodide. Iodide is determined by IC-PED. In case of high relative humidity, the use of impingers or bubblers for air sampling is recommended. LOQ = 0.001 ppm; LOD = 0.0004 ppm	CAR iodine, 2013

Analytical methods for water	
Acceptable methods are available: Synthetic drinking water, industrial and domestic sewage water (iodide): Ion chromatographic separation (IC) and conductivity or UV detection: LOQ = 0.1 mg/L Tap water and surface water (iodide and iodate separately): Ion chromatographic separation and inductively coupled plasma mass spectrographic detection (IC-ICP-MS): LOQ: At least 5 µg/L Drinking water (iodide and iodate separately): IC-ICP-MS LOQ: at least 6.4 and 8.8 µg/L for I^- and IO_3^- respectively	CAR iodine, 2013
No method required as the calculated PECs from the biocidal product use evaluated are just a fraction of natural background concentrations	CAR iodine, 2013

Analytical methods for animal and human body fluids and tisues	
Not necessary, because iodine (iodide) is not classified as toxic or highly toxic.	CAR iodine, 2013

Analytical methods for monitoring of active substances and residues in food and feeding stuff		
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Reference**
Iodide	Determination of iodide in milk and milk powder: HPLC with electrochemical detection (ISO 14378), Applicability range in whole milk: 0.03 µg/g to 1 µg/g Applicability range in dried skimmed milk: 0.3 µg/g to 10.0 µg/g	CAR iodine, 2013

2.3.4 Efficacy against target organisms

A. FUNCTION AND FIELD OF USE

The three *meta* SPC's in this iodine product family contain four biocidal products which are ready-to-use liquid solutions for the disinfection of cow teats that claim bactericidal and yeasticidal activity.

The products are suitable for indoor pre- or post-milking treatments by dip or spray application by professional users.

The dip and the spray treatment respectively require 10ml and 15ml of product. The product can be applied two times per day, and has a contact time of 60 seconds (pre-milking) or 5 minutes (post-milking).

B. ORGANISMS TO BE CONTROLLED AND PRODUCTS, ORGANISMS OR OBJECTS TO BE PROTECTED

The products of this family are intended for PT3 use, veterinary hygiene, more specifically teat disinfection. They function as a bactericide and yeasticidal, the target organisms are bacteria and yeasts. The organisms to be protected are cows.

C. EFFECTS ON TARGET ORGANISMS, INCLUDING UNACCEPTABLE SUFFERING

The effects on target organisms are lethal. The products kill yeast and bacteria on the teats of dairy cows. No unacceptable suffering is induced.

D. MODE OF ACTION, INCLUDING TIME DELAY

The active substance iodine works in a non-selective way against microorganisms by rapidly penetrating into the cells and by interfering with several processes. Iodine combines with proteins which can lead to loss of function and metabolic inhibition. It interferes with the respiratory chain of aerobic microorganisms by blocking the transport of electrons.

The required time delay for sufficient efficacy depends on the tolerance of the microorganism to iodine and the concentration of iodine in the used product. Iodine works more effective at higher temperatures.

E. EFFICACY DATA

The efficacy tests were split up in 2: for pre-milking and for post-milking treatments. More information on the potential effect of co-formulants on the efficacy is provided in the confidential annex.

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organ-ism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
bactericide	*pre-milking, clean conditions*	**Udder Dip** 0.5% iodine (*meta* SPC 1)	*E. coli, S. uberis, S. aureus*	EN 1656	30°C, **30s**, 3 g/L bovine albumin, 80% concentration	Log R>5 for all 3 test organisms	*'report S-2015-01936'*
bactericide	*pre-milking, clean conditions*	**Udder Dip** 0.5% iodine (*meta* SPC	*E. coli, S. uberis, S. aureus*	EN 1656	30°C, **60s**, 3 g/L bovine albumin, 10% concentration	Log R>5 for all 3 test	*'report S-2015-01936'*

		1)				organisms	
bacteri cide	*pre-milking, dirty conditions*	**Udder Dip** 0.5% iodine (*meta* SPC 1)	*E. coli, S. uberis, S. aureus*	EN 1656	30°C, **30s**, 10 g/L bovine albumin + 10 g/L yeast, 80% concentration	Log R**<5** for all 3 test organisms	*'report S-2015-01937'*
bacteri cide	*pre-milking, dirty conditions*	**Udder Dip** 0.5% iodine (*meta* SPC 1)	*E. coli, S. uberis, S. aureus*	EN 1656	30°C, **60s**, 10 g/L bovine albumin + 10 g/L yeast, 80% concentration	Log R>5 for all 3 test organisms	*'report S-2015-01937'*
yeastici de	*pre-milking, clean conditions*	**Udder Dip** 0.5% iodine (*meta* SPC 1)	*C. Albicans*	EN 1657	30°C, **30s**, 3 g/L bovine albumin, 10% concentration	Log R>4	*'report S-2015-01939'*
yeastici de	*pre-milking, clean conditions*	**Udder Dip** 0.5% iodine (*meta* SPC 1)	*C. Albicans*	EN 1657	30°C, **60s**, 3 g/L bovine albumin, 5% concentration	Log R>4	*'report S-2015-01939'*
yeastici de	*pre-milking, dirty conditions*	**Udder Dip** 0.5% iodine (*meta* SPC 1)	*C. Albicans*	EN 1657	30°C, 30s, 10 g/L bovine albumin + 10 g/L yeast, 20 % concentration	Log R> 4	
bacteri cide	*post-milking*	**Gladiator RTU** 0.26% iodine (*meta* SPC 2)	*E. coli, S. uberis, S. aureus*	EN 1656	30°C, 5 min, 10 g/L reconstituted milk, 20% concentration	Log R>5 for all 3 test organisms	MIDAC test report no 13 504-1.
yeastici de	*post-milking*	**Gladiator RTU** 0.26% iodine (*meta* SPC 2)	*C. Albicans*	EN 1657	30°C, 5 min, 10 g/L reconstituted milk, 10% concentration	Log R>4	*'report S-2015-01941'*
bacteri cide	*Pre-milking*	**Udder Dip** 0.50% iodine (*meta* SPC 1)	*E. coli,* ,	prEN1643 7 (with in Vitro Skin Carrier)	30°C, 60 sec, 10 g/L bovine albumin + 10 g/L yeast, 50% and 100% concentration	*E.coli* Log R 100% >6.4 50% >6	*'report S-2016-00148'*
			S. uberis			*S. uberis* Log R 100% >6.7 50% >6	
			S. aureus			*S. aureus* Log R 100%: 3.38 50%:2.95	
bacteri cide	*Post-milking*	**Udder Star** 0.5% iodine (*meta* SPC 3)	*E. coli,*	prEN1643 7 (with in Vitro Skin Carrier)	30°C, 5min, 10 g/L reconstituted milk, 50% and 100% concentration	*E.coli* Log R 100%:2.9 50%: 1.9	*'report S-2016-00149'*
			S. uberis,			*S. uberis* Log R 100%:4.3 50%: 1.5	

			S. aureus			*S. aureus* Log R 100%:3.9 50%: 2.3	
bactericide	*Post-milking*	**Udder Star** 0.5% iodine (*meta* SPC 3)	*E. coli, S. uberis, S. aureus*	EN 13697	30°C, 5min, 10 g/L reconstituted milk, 50% concentration	Log >4	*'report RE16329-1'*

Conclusion on the efficacy of the product

The four biocidal products with bactericidal and yeasticidal efficacy in this iodine product family are ready-to-use liquid solutions for the disinfection of cow teats.
The family consists of three *meta* SPC's, one for pre- or post-milking and two for post-milking.

Meta SPC 1 contains one product, Udder Dip (0.5% iodine) for pre- and post-milking teat disinfection. 80% concentration passes phase 2 step 1 efficacy tests for both pre- and post-milking, therefore 0.4% iodine is set as the minimum required concentration for efficacy in *meta* SPC 1.

Due to the toxicology evaluation the original *meta* SPC 2 (0.26-0.5 % iodine) was split into 2 *meta* SPC's: *meta* SPC 2 (0.26-0.38 % iodine, products with 0.26 and 0.29%) and *meta* SPC 3 (0.43 and 0.5% iodine, product with 0.5%). The efficacy evaluation is done for both *meta* SPC's together, since the worst case product for *meta* SPC 2 is also worst case for *meta* SPC 3.
Meta SPC 2 contains two products and *meta* SPC 3 one product, all for post milking teat disinfection. For these *meta* SPC's Gladiator RTU (0.26% iodine) is the worst case product but contains two co-formulants which have not the lowest concentration of *meta* SPC's. The applicant provided enough evidence that these co-formulants do not influence the efficacy of the product (see confidential annex). Alternatively, Udder Star (*meta* SPC 3, 0.5% iodine) can be tested at 50% (=0.25% iodine) which is also worst case for these *meta* SPC's.

Phase 2 step 1and step 2 efficacy testing for pre-milking applications have been done under high soiling conditions. The pre-milking product of *meta* SPC 1 , therefore, can be applied without any pre-cleaning of the teats.
The post-milking products of *meta* SPC 1, 2 and 3 were tested with milk soiling, as required for this use. These products can also be applied without any pre-cleaning of the teats.

Results of phase 2, step 2 tests are not considered to be fully reliable: for example, the least susceptible test species is not the same for pre- and post-milking conditions.

The pre-milking phase 2, step 2 meets the requirement for 2 out of 3 test species at the highest contact time at both tested concentration. For *S. aureus* the log reduction is still > 3 at 100% concentration (0.5% iodine) and just below 3 at 50% concentration (log R 2.95).

The post-milking phase 2, step 2 test at the highest contact time with undiluted concentration meets the requirements for *S. uberis* and is also considered to be efficacious against *S. aureus* as this log R is only just below the requirement (log R 3.9). The result for *E. coli* is not considered to be reliable, as this value is not in line with the results from phase 2, step 1 tests,

nor with the results from pre-milking phase 2, step 2 test. 50% dilution does not show sufficient efficacy at post-milk conditions.

To provide further evidence that the products in this family are efficacious under in-use conditions (e.g. dried organisms), an additional hard surface phase 2, step 2 EN13697 test was performed on Udder Star (0.5% iodine) for post-milking conditions to prove that the product can meet the requirements. Results of this test show a sufficient log reduction for both 100% and 50%-dilutions (log R>4, 0.25% iodine). It is hereby demonstrated that the test-results for phase 2, step 2 on the in vitro skin carrier are not fully reliable and the insufficient log reduction is not caused by product failure, but is more related to the preliminary nature of the in vitro skin carrier-test itself. The tests do demonstrate that the products are active on skin.

A similar rationale can be applied for pre-milking efficacy. Based on the results of the phase 2, step 1 test for pre-milking and provided that also results of the in vitro skin carrier phase 2, step 2 test are not fully reliable (but already provide higher log reductions than for post-milking conditions in the same in vitro skin carrier test) the conclusion for pre-milking efficacy is that at 100% the products containing 0.5% iodine provide sufficient log reduction at a contact time of 60 seconds.

The RTU-products of *meta* SPC 1 are effective in 60 seconds for pre-milking application and in 5 minutes for post milking disinfection.
The RTU-products of *meta* SPC 2 are effective for post milking disinfection with a contact time of 5 min.
The RTU-products of *meta* SPC 3 are effective for post milking disinfection with a contact time of 5 min.

F. OCCURRENCE OF RESISTANCE AND RESISTANCE MANAGEMENT

No development of resistance or reduction in efficacy has been reported up to now, iodine products have already been used for over 170 years. Since iodine acts against micro-organisms in a non-selective way, the development of resistance is unlikely.

G. KNOWN LIMITATIONS

No known limitations.

H. EVALUATION OF THE LABEL CLAIMS

The use of the biocidal products only intend the general claims made in PT3 teat disinfection.
The efficacy test results are given in section E. Efficacy data.
The authorised claims can be found in 2.1. C and SPC.

I. RELEVANT INFORMATION IF THE PRODUCT IS INTENDED TO BE AUTHORISED FOR USE WITH OTHER BIOCIDAL PRODUCT(S)

The products are not intended to be used with any other products.

2.3.5 Comparative assessment

Not applicable: iodine is not a candidate for substitution.

Risk assessment for human health

A. ASSESSMENT OF EFFECTS ON HUMAN HEALTH

No toxicological test data are available on the products in the BPF, effects on human health are derived from information on all components present in the 3 *meta* SPCs.

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not classified as skin irritant
Justification for the value/conclusion	The products are not classified and only contain iodine classified as Skin Irrit. 2 but below the generic cut-off limit for classification. No other components classified as irritant or corrosive are present. The products do not have extreme pH values.
Classification of the product according to CLP	The products/*meta* SPCs are not classified for skin corrosion and irritation according to CLP regulation (Regulation 1272/2008/EC).

Data waiving	
Information requirement	Skin corrosion and irritation: reference is made to information available on individual substances.
Justification	Classification of the products is based upon CLP mixture rules.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The products/*meta* SPCs are classified as Eye Irrit. 2 H319
Justification for the value/conclusion	Classification as Eye Irrit. 2 is based upon CLP mixture rules
Classification of the product according to CLP	The products/*meta* SPCs are classified as Eye Irrit. 2. H319

Data waiving	
Information requirement	Eye irritation: reference is made to information available on individual substances.
Justification	Classification of the products is based upon CLP mixture rules (Regulation 1272/2008/EC).

Respiratory tract irritation

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not classified for respiratory tract irritation.
Justification for the value/conclusion	Classification is based upon CLP mixture rules. None of the co-formulants are classified for respiratory tract irritation.
Classification of the product according to CLP	No classification for this endpoint.

Data waiving	
Information requirement	Respiratory tract irritation: reference is made to information available on individual substances.
Justification	Classification of the products is based upon CLP mixture rules (Regulation 1272/2008/EC).

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitization	
Value/conclusion	Not classified for skin sensitization.
Justification for the value/conclusion	Classification is based upon CLP mixture rules None of the co-formulants are classified for skin sensitization.
Classification of the product according to CLP	Products/*meta* SPCs are not classified for skin sensitization

Data waiving	
Information requirement	Skin sensitization: reference is made to information available on individual substances.
Justification	Classification of the products is based upon CLP-mixture rules (Regulation 1272/2008/EC).

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – respiratory sensitization	
Value/conclusion	Not classified for respiratory sensitization.
Justification for the value/conclusion	Classification is based upon CLP mixture rules. None of the co-formulants are classified for respiratory sensitization.
Classification of the product according to CLP	None of the products/*meta* SPCs are classified for respiratory sensitization.

Data waiving	
Information requirement	Respiratory sensitisation: reference is made to information available on individual substances

Justification	Classification of the products is based upon CLP mixture rules (Regulation 1272/2008/EC).

Acute toxicity

Acute toxicity by oral route / inhalation / dermal route

Conclusion used in Risk Assessment – Acute tox	
Value/conclusion	Not classified for acute toxicity.
Justification for the value/conclusion	Classification is based upon CLP mixture rules does not lead to classification.
Classification of the product according to CLP	None of the products/*meta* SPCs are classified for acute toxicity.

Data waiving	
Information requirement	Acute toxicity: reference is made to information available on individual substances
Justification	Classification of the products is based upon CLP mixture rules. There are currently no testing requirements on mixtures regarding this endpoint.

Information on dermal absorption

Data waiving	
Information requirement	Dermal absorption of iodine is 12% according to the CAR of iodine.
Justification	'The dermal absorption percentage of 12% was based on an in vitro skin penetration study, in which two biocide formulations (Biocide 1006 and PE 305-1) were tested. Biocide 1006 is a formulation, which contains 2.63% total iodine. This formulation was diluted 4 times giving a final iodine concentration of 0.66%. The PE 305-1 is a ready-to-use formulation containing PVP-iodine, which contained 0.26% total iodine. The results for both formulations were similar: 11.3% for Biocide 1006 and 12.0% for PE 305-1. The concentration level of iodine for products in the current biocidal product family is within the same range as iodine concentration of the products used in the in vitro skin penetration study. In addition, the products in this family are not classified for skin effects which could influence the absorption potential, Use of 12% as dermal absorption percentage is considered sufficiently justified. eCA comment: An overview of BPF/metaSPCs and tested formulations as included in the CAR for iodine is prepared by the eCA. This will be made available to the MS only, as the composition of the tested formulations in the CAR may not be revealed to the applicant/consultant without permission of the study owners. In the provided document justification in accordance to EFSA 2012 guidance is provided. Based on this evaluation

	it is concluded that a dermal absorption of 12 % can be used for the risk assessment of the BGM/ARCHE biocidal product family.

Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)
Based on the SoC guidance included in the BPR guidance, Fatty alcohol ethoxylated is identified as a SoC, as this substance adds to the BPF classification. A risk assessment is included in the confidential annex.

Available toxicological data relating to a mixture
There are no toxicological test data available on the mixtures.
None of the co-formulants are classified for other endpoints than already discussed above.

Assessment for endocrine disrupting properties
According to the ED (endocrine disruptor) criteria with respect to humans established in the Commission Delgated Regulation (EU) 2017/2100, a substance shall be considered as having endocrine disrupting properties if it meets all of the following criteria:

a) it shows an adverse effect in [an intact organism or its progeny]/[non-target organisms], which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;
b) it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;
c) the adverse effect is a consequence of the endocrine mode of action.

To examine if any of the other co-formulants contained in the product may possess ED properties, a screening was performed by examining the co-formulants are

- Classified as CMR or PBT;
- Identified as ED in the DG Santé's Impact Assessment study on Screening of available evidence on chemical substances for the identification of endocrine disruptors;
- Identified as ED in the EU list of potential endocrine disruptors; or
- Listed in CoRAP linked to ED concerns.

None of the co-formulants triggered an alert for ED property. See assessment included in the confidential annex.

Subsequently, it was examined if there are any concerns for adverse effect to meet the criteria a) as described above using ECHA REACH database. This examination did not result in alerts, and therefore no further ED assessment was required

B. EXPOSURE ASSESSMENT

The products are only provided to **professional** users, and are used in two different teat disinfection treatment applications*:*

- Dip treatment: 10 ml of product in a dipping cup

- Spray treatment: 15 ml of product in a spray flask

Identification of main paths of human exposure towards active substances and substances of concern from its use in biocidal product

Following the CAR of the active substance, relevant routes of primary exposure are dermal contact and inhalation. Oral exposure is deemed not to be relevant since the users are professionals.

Secondary oral exposure is possible via the consumption of milk with residues from teat disinfectants. Secondary dermal exposure during cleaning of the teats (dried fluid) or by a drop falling from the teat on the hand. Secondary exposure by inhalation is considered to be negligible.

Regarding inhalation exposure, only exposure towards aerosol was assessed for relevant scenarios as in the teat disinfection products the iodine is present as ionic and/or complex-bound species which are not prone to evaporation. A detailed justification as to why inhalation exposure towards vapour is negligible is provided in Annex 3.2.

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.	n.a.	n.a.	n.a.
Dermal	n.a.	**Yes**	n.a.	n.a.	**Yes**	n.a.	n.a.
Oral	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	**Yes**

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure** **Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Mixing/loading	Loading of the product in the teat dipping cups or sprayers	professionals
2.1	Application	Teat dipping	professionals
2.2	Application	Teat spraying	professionals
2.3	Application	Application of teat disinfectant by robot with automatic dipping/sprayer	professionals
3.1	Primary exposure	Cleaning of teats by wiping with cloth: removal of freshly applied product	professionals
3.2	Primary exposure	Cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment	professionals
3.3	Primary exposure	Cleaning of teats by robot	professionals
4.1	Primary exposure	Cleaning of equipment such as dip cups and trigger sprayer after use	professionals
4.2	Primary exposure	Cleaning of automated dipping/spraying system	professionals

Professional exposure

Scenario [1] – Mixing and loading

Description of Scenario [1]

The packaging of the product is opened and undiluted liquid is poured into the teat dipping cup or the sprayer (manual or automatic). The cup or the sprayer is closed.

In line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017), for mixing and loading of concentrated product for dermal exposure, mixing and loading model 4 is used.

For the dermal exposure, the total amount of the required solution that is needed per day is of importance. Manually, cows are milked twice a day, treated either pre- **or** post-milking as the dietary risk assessment shows that pre- **and** post-milking would result in exceeding the UL for toddlers, due to use of the product (see conclusion dietary risk assessment).
Automatically, cows are miked three times a day (i.e. manually cows are milked twice a day) , therefore for the worst case the amount needed for one day is:15ml product x 3 times a day = 60 ml.
Considering 82 cows, this results in a total amount of product per day of 60 ml x 82 cows = 5 L product/day.
For mixing and loading model 4, the indicative hand exposure for handling 5 L is 0.2 ml/treatment is used.

As iodine is the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed.

This M/L step is considered to also cover exposure from refilling of dipping/foaming cups or sprayer. Furthermore, this step also covers loading of an electronic sprayer or robotic milking device (for automated spraying).

	Parameters	Value
Tier 1	Total iodine concentration	0.5%
	Dermal penetration	12%
	Body weight	60 kg
	indicative dermal exposure value (mixing and loading model 4)	0.2 ml/event
	No PPE	
Tier 2	Gloves	90% protection

Calculations for Scenario [1] – mixing and loading of RTU for dip or trigger sprayer, electronic sprayer or automated milking device

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier**	**Estimated inhalation uptake** (µg/kg bw/day)	**Estimated dermal uptake** (mg/kg bw/day)	**Estimated oral uptake**	**Estimated total uptake** (mg/kg bw/day)
Scenario [1.1] – M/L model 4 – 0.5% total iodine	1	-	2.00E-03	n.r.	2.00E-03
	2	-	2.00E-04	n.r.	2.008E-04

The calculation sheets are provided in Annex 3.2.

Scenario [2.1] – Application: teat dipping

Description of Scenario [2.1]
A professional user dips the cows teat in such a way that the teat are fully covered with the product. Dipping model 4, which was used in the CAR for calculating exposure from dipping, is not considered relevant for estimating this exposure scenario in HEAdhoc recommendation 6, as this model is derived from "semiautomatic dipping in open vats (fishing nets)". This task cannot really be compared to manual disinfection of cow teats with a dipping cup (HEAdhoc recommendation 6, note 17) In line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017), for application by dipping indicate the exposure during the use of dipping cups is covered by the dermal exposure as calculated by the scenario of mixing and loading. Furthermore, it is assumed that dipping cups are designed specifically for this task. This cup has an upper compartment as reservoir for the dipping solution. During the application the worker holds the cup at the lower compartment, so direct hand exposure to the biocidal product or treated teat is avoided. Additionally, as iodine is the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed.

Scenario [2.2] – Application: teat spraying

Description of Scenario [2.2]		
A professional user sprays the cows teat in such a way that the teats are fully covered with the product. In line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017), for application by spraying (both manual trigger spraying and electronic spraying (not with robot)) Hand-held trigger spray model (consumer product spraying and dusting model 2, Biocides Human Health Exposure Methodology) is used. The following assumptions are considered in the calculations: - The farmer milks 82 cows twice a day - The spraying time per cow/event is 10 seconds - Results in (10 seconds x82 cows)/60 = 13.7 min exposure time This application step is considered to also cover exposure from spraying with an electronic sprayer.		
	Parameters	Value
Tier 1	Iodine concentration	0.5%
	Dermal penetration	12%
	Body weight	60 kg
	Inhalation rate (short- and long-term; acc. to HEEG opinion "Default human factor values for use in exposure assessments for biocidal products", 2013)	1.25 m³/h (0.021 m³/min)
	Exposure duration	13.7 min
	No PPE	
Tier 2	Default protection factor for gloves Default protection factor for protective clothing and chemical resistant boots	90 % 90%

Calculations for Scenario [2.2] - Application of teat disinfectant by spraying using a trigger sprayer

Estimated uptake values for iodine were calculated using consumer spraying and dusting model 2; hand-held trigger spray, twice a day.
The output tables are included in Annex 3.2.

Summary table: estimated exposure from professional uses

Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated oral uptake (mg/kg bw/d)	Estimated total uptake (mg/kg bw/d)
Iodine	1	4.98E-04	1.25E-02	-	1.30E-02
	2/PPE (gloves, protective clothing and chemical resistant boots)	4.98E-04	1.25E-03	-	1.75E-03

Further information and considerations on scenario [2.2] - Application of teat disinfectant by spraying using a trigger sprayer: Local exposure concentration of iodine in air

Summary table: estimated exposure from professional uses	
Exposure scenario	**Iodine in air inhaled (mg/m³)**
Scenario [2.2] – Consumer spraying and dusting model 2, Hand-held trigger spray	5.25E-02

The calculation sheets are provided in Appendix 3.2.

Scenario [2.3]: Application of teat disinfectant by robot with automatic dipping/sprayer

Scenario [2.3]
After robotic milking, the disinfectant is either dipped automatically or sprayed automatically onto teats from a cluster arm. No exposure of professionals occurs, therefore no exposure calculations need to be conducted. This scenario was not considered in the CAR.

Scenario [3.1] – Primary exposure: teat cleaning by wiping with cloth: removal of freshly applied product

Description of Scenario [3.1]		
The teats which have been treated with a disinfectant shortly before are carefully cleaned by wiping with a dry cloth immediately before milking. In the CAR, the TNsG 2002 model "surface disinfection model 2" was used for assessing the cleaning of teats during pre-milking disinfection. It is indicated by the applicant that this model does not adequately describe the task "cleaning of teats", since it refers to "washing and wiping floors with mob, bucket and wringer". Furthermore, the model does not provide any indicative value for inhalation exposure nor for dermal exposure to hands. In addition, the indicative value for the body provided in the model is not relevant at all for the cleaning of teats with cloth. As alternative approach, the applicant proposed to assess the dermal exposure assuming a worst-case exposure estimate of 0.1% of the amount on the surface area (here the teats and a part of the udder with 44 cm^2/teat and 176 cm^2/cow) contacts the palm of the hands based on the Disinfectant Products Fact Sheet (RIVM report 320005003/2006), which is in line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017) for this exposure scenario. To calculate the amount of the RTU on the surface area, the layer thickness approach is considered appropriate, i.e. 44 cm^2/teat x 4 teats x 0.01 cm x number of cows. Additionally, as iodine is the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed.		
	Parameters	Value
Tier 1	Concentration iodine	0.5%
	Dermal penetration	12%
	Body weight	60 kg
	Use frequency	2/day
	No PPE	
Tier 2	Gloves	90% protection

Calculations for Scenario [3.1]- *teat cleaning by wiping with cloth: removal of freshly applied product*

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**

Iodine	1	-	2.89E-03	-	2.89E-03
Iodine	2	-	2.89E-04	-	2.89E-04

The calculation sheets are provided in Appendix 3.2.

Scenario [3.2] – Primary exposure: teat cleaning by wiping with cloth: removal of dried residues from post-milking treatment

Description of Scenario [3.2]
Cleaning of teats by wiping with a dry cloth before milking is only relevant if the cows have received a pre-milking treatment. The disinfectant is expected to have completely dried up and either fallen off or rubbed off during the time span between treatment and cleaning. Therefore, any exposure to remains of the disinfectant on the teats is considered to be negligible. Generally dry disposable paper tissues are used. Since the residues (if any) are dry and the tissue is dry as well and disposed after each animal, there is definitely no relevant exposure. This conclusion is in line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017) for this exposure scenario.

Scenario [3.3]: Teat cleaning by robot

Scenario [3.3]
No exposure of professionals occurs during teat cleaning by robot, therefore no exposure calculations need to be conducted. This scenario was not considered in the CAR.

Scenario [4] - Cleaning of equipment such as dip cups and trigger sprayer after use

Description of Scenario [4]

In the CAR the model for washing and wiping floors with mob, bucket and wringer was used. As this does not reflect the exposure for "cleaning equipment', the applicant proposed an alternative approach to the CAR, using the RISKOFDERM toolkit. The indicative values for dermal and inhalation exposure, as derived from the RISKOFDERM toolkit, were taken from the HEEG 2008 opinion on alternatives to M/L model 7. However, within this HEEG opinion it is indicated that the RISKOFDERM toolkit is a semi-quantitative model, and needs to be avoided.

In line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017), for cleaning of equipment, RISKOFDERM 'Loading liquid, automated or semi-automated' for the cleaning phase of different equipment (dipping cup, spraying nozzle etc.) is used. The indicative value is 0.92 mg/min and a duration of is 5 minutes is considered.

Additionally, as iodine is the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed.

	Parameters	Value
Tier 1	Concentration iodine	0.5%
	Dermal penetration	12%
	Body weight	60 kg
	indicative value of RISKOFDERM 'Loading liquid, automated or semi-automated'	0.92 mg/min
	Use frequency	5 min/day
	No PPE	
Tier 2	Gloves	90% protection

Calculations for Scenario [4]- *Cleaning of equipment such as dip cups and trigger sprayer after use*

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Iodine	1	-	4.6E-05*	-	4.6E -05
Iodine	2	-	4.6E -06	-	4.6E -05

*(0.92 mg/min x 5 min x 0.5% iodine equivalents in product x 12% dermal absorption)/60 kg = 4.6E -05

Scenario [4.2]: Cleaning of automated dipping/spraying-system

Scenario [4.2]
No exposure of professionals occurs during cleaning of the automated dipping/spraying system, therefore no exposure calculations need to be conducted. This scenario was not considered in the CAR.

Non-professional exposure
The products are intended for professional use only.

Exposure of the general public
Indirect respiratory exposure to iodine as a result of use of the teat disinfectants cannot be excluded. However, worker and bystander exposure is considered to be a fraction for professional exposure during application. Since no health risks are anticipated for the professional user after respiratory exposure to iodine, no risk is anticipated for re-entry workers or bystanders.

Monitoring data
There are no monitoring data available for this product. Iodine is not classified as toxic or highly toxic.

Dietary exposure
Teat dipping may increase the iodine content in milk. However, ATSDR (Agency for Toxic Substances and Disease Registry) concluded that the major contributor to iodine content in milk is feed supplementation rather than the use of iodine teat dip/spray.

Several publications are available concerning effects on iodine levels in milk via teat disinfection. Data presented by Falchowsky et al (2013) showed that use of iodine based teat disinfectant before and after milking leads to increase in iodine levels in milk. Solutions with an iodine concentration between 2.5 and 5 g/L lead to iodine levels in milk varying between 7 and 120 µg/L, on average a value around 50 to 60 µg/L was found for dipping treatment. A spraying treatment generally leads to higher increase in iodine residue.
Similar values are cited in the CAR of iodine (i.e. increase of iodine levels 50 – 174 µg/L in milk). A recent study by French et al (2016) also concluded that use of iodine teat disinfectants at 0.25% & 0.5% iodine concentration, applied by dip or spray treatment, can increase the level of iodine in milk. However, **increase of iodine levels in milk by teat disinfection is considered acceptable (within 100 µg/L) if cows are fed with recommended levels of iodine in their diet and care is taken following proper procedure for milking process.**
Both pre-milking and post-milking treatment are considered for the products in this family, although treatments are never applied both at the same time. Therefore, combination of both

pre- and post-milking treatments should not be taken into account. Use of the products is also limited to 2 treatments per day (i.e.) at each milking event.

The EFSA FEEDAP report on iodine compounds in feed additives (2014) concluded that adult's & children's main intake source of iodine is milk. The FEEDAP report also refers to the EFSA food consumption database, which provides conservative intake value of 1.05L of milk per day for a toddler and 1.50L of milk for adults. Considering that the Upper Intake Level of iodine for toddlers is 200-250 µg/day, it is unlikely this limit will exceeded on a long term base by iodine residue in milk originating from teat disinfectants alone. General recommendations on intake of iodine for diet of cows should be set to maintain acceptable levels of iodine in milk.

In addition , in 2000 the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (UK) published a report on iodine in cows' milk and concluded:

"We consider that there is a paucity of data which might allow the accurate determination of the daily intake of iodine that can be safely ingested by infants and children over long periods. We encourage research to address this point. Nevertheless we take reassurance from a study in which ***1-11 year old children were given doses of iodide up to 1000 microgram/day over a period of four months without signs of toxicity.*** *Since this dose corresponds to 59-94 microgram/kg b.w./day in children aged 1½ to 4½, over three times the JECFA Provisional Maximum Tolerable Daily Intake, we consider that the intake of iodine (23 microgram/kg b.w./day in winter, 11 microgram/kg b.w./day in summer) at the concentrations that have been found in cows' milk is unlikely to pose a risk to health.*

Please note that this committee also has published a review on iodine in 2017 which can be found here: https://cot.food.gov.uk/sites/default/files/statementiodine0to5.pdf.

Furthermore, following MRL evaluation, it was concluded by the European Medicines Agency that it was not necessary to establish a MRL value for iodine; it is included in Annex II of Council Regulation (EEC) 2377/90. At the 72th CA-meeting in was agreed that the current entry in the Commission Regulation (EU) No 37/2010 "No MRL required" should be sufficient for biocidal use, which is in line with the interim approach on MRLs.

Note eCA: dietary exposure is discussed in various human health working group meetings and WebEx meetings for eCA evaluating iodine based union authorisations application. For the exposure to residues, the O'Brien study can be used. The assumptions that could be considered for the exposure to residues via milk were that needs to be considered are included below:

- Exposure in accordance to intended use (WGIII 2017). Therefore, the indicated worst case scenarios are taken into account, based on 0.5% available iodine.
- For exposure to residues the following was concluded by eCAs from iodine based union authorisation applications (Secure Webex meeting (3-10-2017)): "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". However, this

is not accepted as it was not in line with the intended use (BPC29 2019).Therefore, the exposure calculations using information of the O'Brien study which considers 2x manual application, is adapted to 3x application to also cover the automatic use. Taking into account a density of 1.03 kg/L for whole milk (Ullmanns's Food and Feed, 3 Volume set. (Elvers, B. (2017). 1st ed. Weinhem, Germany: Wiley-VCH, page 344).

- 50% reduction due to bulking of milk is not allowed (WGII 2017).
- 27% reduction due to pasteurisation of the milk is not allowed. (WGII 2017)
- At WGIV 2017 it was agreed that for daily milk consumption to use 0.45 L/day for adults (EFSA PRIMo version 2, based on highest mean for Dutch populations) and 0.46 L/day for infant/toddlers (EFSA PRIMo version 2, based on highest mean for French population).
- For the calculations information from the O'Brien study was used. The O'Brien study assessed the effect of a teat disinfection product is used, based on 0.5% available iodine on the total iodine content in milk. Therefore, the measured residues in milk are from the O'Brien study does not need to be corrected for the BPF of BGM/ARCHE as the maximum concentration in the BPF is equal to the O'Brien study. Furthermore, as products can be used for pre- and/or post-application or pre-and post-application , these are included in the table below. Consumers are exposed to residues of iodine due to various sources. The inclusion from other sources in the consumer risk assessment was discussed at WGIV, and the following was concluded:
  Iodine exposure from all sources will be included in the assessment.
  The assessment will include exposure to iodine coming from:
  1. Teat treatment
  2. Teat treatment + background from milk (= total milk intake)
  3. Teat treatment + background from milk + dietary intake from other sources (= total dietary intake)
- Background in milk is variable due to differences in iodine concentrations in natural sources (drinking water and grass) and due to feed (supplemented with various amounts of iodine). The background was discussed in the Secure Webex meeting (3-10-2017), in which was concluded by eCAs from iodine based union authorisation applications: "General support was given to the derivation of an EU harmonised value. The value of 200 µg/L iodine in milk was considered appropriate as an EU harmonised value, based on the monitoring data from EFSA 2013 (EFSA Journal 2013;11(2):3101) and the O'Brien study."
- Iodine dietary intake from other sources than milk was also discussed in the Secure WebEx meeting (3-10-2017), in which was concluded by eCAs from iodine based union authorisation applications: "The values from the UK survey were considered adequate to represent the EU iodine dietary intake from sources other than milk. Rounding of the values to 185 µg/day for adults and 96 µg/day for toddler was agreed." It should be noted that these values excluded iodine intake from milk. Furthermore, within this UK study (UK retail survey of iodine in UK produced dairy foods, FSIS 02/08, 16 June 2008) 350 samples of dairy and seaweed products were purchased from eight areas of the UK. Levels of iodine found were generally in similar ranges to those reported from previous surveys (MAFF iodine in milk), Furthermore the reported values are in agreement with an EFSA scientific opinion on the use of iodine in feeding stuffs. It is noted that in the UK study report for the calculations for body weights 76 for adults and 14.5 kg for infants are considered,

whereas 70 kg and 12 kg are used in the consumption calculations. Moreover, during the discussion at the Secure WebEx meeting it was noted that comparable values could be obtained from French and German monitoring studies.

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 depicted in the table below. Intakes which exceed the respective UL are highlighted in red in the table below. Calculations are included in annex 3.2 (BGM ARCHE residues).

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.

Comparison of estimated daily iodine intakes compared to upper limit of pre- and/or post-milking teat-disinfection by manual dipping/spraying, based on 0.5% available iodine. Intakes which exceed the UL are highlighted in red in the table below.

	Adults (0.45 L/day)	**Toddlers (0.46 L/day)**
	Estimated daily intake (µg/day) [% of UL]	**Estimated daily intake (µg/day) [% of UL]**
3x post-milking		
Intake from milk due to teat treatment	170 [28]	173 [87]
Total milk intake*	260 [43]	265 [133]
Total dietary intake**	445 [74]	361 [181]
3x pre-milking		
Intake from milk due to teat treatment	145 [24]	149 [74]
Total milk intake*	235 [39]	241 [120]
Total dietary intake**	420 [70]	337 [168]
3x pre- and post-milking (when combining using products intended for either pre- or post-milking teat-disinfection)		
Intake from milk due to teat treatment	315 [52]	322 [161]
Total milk intake*	405 [67]	414 [212]
Total dietary intake**	601 [98]	510 [255]

* Total milk intake is the sum of the estimated additional intake resulting from the transfer into milk following teat disinfection (based on O'Brien) and the background milk value of 200 µg/L (EFSA 2013)

** Total dietary intake is the sum of the estimated additional intake resulting from the transfer into milk following teat disinfection (based on O'Brien), the background milk value of 200 µg/L (EFSA 2013) and 185 µg/d for adult or 96 µg/d for infant based on UK data (2008).

Conclusion: Pre- or post-milking teat-disinfection

Considering the exposure in the intended, three worst case scenarios are identified:

1. post-milking teat-disinfection
2. pre-milking teat-disinfection
3. pre-and post-milking teat-disinfection (when combining using products intended for either pre- or post-milking teat-disinfection)

Post-milking teat-disinfection

For adults, the estimated daily intake of iodine resulting from biocidal product use is maximally 28% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 43% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 74% of the UL.

For toddlers, the estimated daily intake of iodine resulting from biocidal product use is maximally 87% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 133% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 181% of the UL.

Pre-milking teat-disinfection

For adults, the estimated daily intake of iodine resulting from biocidal product use is maximally 24% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 39% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 70% of the UL.

For toddlers, the estimated daily intake of iodine resulting from biocidal product use is maximally 74% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 120% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 168% of the UL.

Pre- and post-milking teat-disinfection

For adults, the estimated daily intake of iodine resulting from biocidal product use is maximally 52% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 67% of the UL. Finally, a total dietary intake of

iodine resulting from milk consumption and from other dietary sources lead to maximally 98% of the UL.

For infants, the estimated daily intake of iodine resulting from biocidal product use is maximally 161% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 207% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 255% of the UL.

Conclusion

Although the intended use includes either pre- or post-milking, products could be combined and therefore this is assessed. Based on combined pre- **and** post-milking teat disinfection results in 161% UL for toddlers by exposure to residues due to treatment. Therefore, the combination of pre- and post-milking is considered not safe. The following risk mitigation measure needs to be included in paragraph 5.2 of the SPC: In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre- **or** post-milking disinfection.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake [mg/kg bw/day]**
[1.1] Mixing and loading of RTU	professionals	1/none	2.00-03
		2/Gloves	2.00-03
[2.1] Application of teat disinfectant by manual dipping	Exposure is considered covered by the mixing and loading scenario.		
[2.2] Application of teat disinfectant by manual spraying - using a trigger sprayer or electronic sprayer RTU	professionals	1/none	1.30E-02
		2/Gloves, protective clothing and chemical resistant boots	1.75E-03
[2.3] – Application of teat disinfectant by robot with automatic dipping/sprayer	No exposure of professionals occurs during automated dipping or spraying.		
[3.1] / Cleaning of teats by wiping with cloth (removal of freshly applied product) - RTU	professionals	1/none	2.89E-03
		2/ gloves	2.89E-04
[3.2] / Cleaning of teats by wiping with cloth (removal of dried product)	Exposure of professionals considered to be negligible during cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment.		
[3.3] - Cleaning of teats by robot	No exposure of professionals occurs during cleaning of teats by robot.		
[4.1] / Cleaning of equipment - RTU	professionals	1/none	4.60E-05
		2/ Gloves	4.60E-06
[4.2] - Cleaning of automated dipping/spraying system	No exposure of professionals occurs during rinsing of automated dipping/spraying-system.		

C. RISK CHARACTERISATION FOR HUMAN HEALTH

Risk for professional users

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
$AEL_{short-term}$	Not derived in the CAR and not relevant for HHRA.				
$AEL_{medium-term}$	Not derived in the CAR and not relevant for HHRA.				
$AEL_{long-term}$ = Upper Intake Level (UL)	Human data				600 µg/day (0.01 mg/kg bw/d) Toddler: 200 µg/day
ARfD	According to CAR, not applicable. Substance is not acute toxic or harmful.				
ADI	Not derived in the CAR and not relevant for HHRA. Instead of an ADI, a Recommended daily intake of 150-200 µg/day is given in the CAR.				
AEC = OEL (Occupational exposure limit)	Human data				0.1 ppm / 1 mg/m3

Residue definitions

In the Assessment Report on iodine and Commission Implementing Regulation (EU) n° 94/2014 approving iodine for use in PT3, it was stated that the "need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council or Regulation (EC) No 396/2005 of the European Parliament and of the Council shall be verified…."

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

- no MRLs are required for iodine and iodine inorganic compounds such as iodophors (including polyvinylpyrrolidone-iodine) for all food producing species and all target tissues according to Regulation (EC) No 470/2009 of the European Parliament and of the Council and Commission Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. Note eCA: This based on veterinary use of teat disinfection. Veterinary medicinal products with iodine as active substance can be different from similar biocidal products with respect to application rate and duration.

- According to the working document CA-Dec13-Doc.5.1.e on the Establishment of maximum residue levels for residues of active substances contained in biocidal products duplication of work for biocidal active substances for which MRLs already exist due to uses in other areas should as far as possible be avoided. It is further stated in the working document that MRLs for pharmacologically active substances in animals set in Regulation No 37/2010 should in most cases be applicable, as long as

the concerned species are covered. According to the first bullet point, MRLs have not been established for any food producing species.

- Monitoring data for iodine levels in bulk milk samples of various European studies were recently reported to be in the range of 100 to 200 µg/L milk (EFSA, 2013), which indicates no concerns for the safety of the consumers.

Risk for industrial users

Industrial exposure is not relevant.

Risk for professional users

Intakes which exceed the respective UL are highlighted in red in the table below.

Systemic effects

As a worst-case, the estimated daily iodine intakes post-milking (0.5% available iodine) have been added to the individual tasks/scenarios.

Task/ Scenario	Tier/ PPE	Estimated uptake mg/kg bw/d	% UL (0.01 mg/kg bw/day) due to biocidal use	% UL (0.01 mg/kg bw/day) due to biocidal use + iodine from milk due to teat treatment[1]	% UL (0.01 mg/kg bw/day) due to biocidal use + total milk intake[2]	% UL (0.01 mg/kg bw/day) due to biocidal use + total dietary intake[3]
[1.1] – M/L of concentrate for dip cup or trigger sprayer	1/ none	2.00E-04	20	48	63	94
	2/ Gloves	2.00E-05	2	30	45	76
[2.1] – Application of teat disinfectant by manual dipping	Exposure is considered covered by the mixing and loading scenario.					
[2.2] – Application of teat disinfectant by manual spraying **using a trigger sprayer or electronic sprayer**	1/ none	1.30E-02	130	158	173	204
	2/ Gloves, protective clothing and chemical resistant boots	1.75E-03	17	45	60	91
[2.3] – Application of teat disinfectant by robot with	No exposure of professionals occurs during automated dipping or spraying.					

Task/ Scenario	Tier/ PPE	Estimated uptake mg/kg bw/d	% UL (0.01 mg/kg bw/day) due to biocidal use	% UL (0.01 mg/kg bw/day) due to biocidal use + iodine from milk due to teat treatment[1]	% UL (0.01 mg/kg bw/day) due to biocidal use + total milk intake[2]	% UL (0.01 mg/kg bw/day) due to biocidal use + total dietary intake[3]
automatic dipping/sprayer						
[3.1] – Cleaning of teats with cloth: removal of freshly applied product)	1/ none	2.89E-03	29	53	68	99
	2/Gloves	2.89E-04	3	27	42	73
[3.2] - Cleaning of teats by wiping with cloth (removal of dried residues from post-milking treatment	Exposure of professionals considered to be negligible during cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment.					
[3.3] - Cleaning of teats by robot	No exposure of professionals occurs during cleaning of teats by robot.					
[4.1] - Cleaning of equipment such as dip cups, trigger sprayer after use	1/ none	4.60E-05	0	28	43	74
	2/Gloves	4.60E-06	0	28	43	74
[4.2] - Cleaning of automated dipping/spraying system	No exposure of professionals occurs during rinsing of automated dipping/spraying-system.					

[1] as worst case, values derived from post-application use are included. However, the outcome would be comparable when values derived from pre-application use would be included.

[2] Total milk intake is the sum of the estimated additional intake resulting from the transfer into milk following teat disinfection (based on O'Brien) and the background milk value of 200 µg/L (EFSA 2013)

[3] Total dietary intake is the sum of the estimated additional intake resulting from the transfer into milk following teat disinfection (based on O'Brien), the background milk value of 200 µg/L (EFSA 2013) and 185 µg/d for adult or 96 µg/d for infant based on UK data (2008).

Calculation sheet is included in annex 3.2.

Local effects

The local exposure concentration is provided in the following table for the worst-case concentrations of the individual tasks.

Task/ Scenario	substance in air inhaled (mg/m³)	% OEL	Acceptable (yes/no)
[2.2] – Application of teat disinfectant by manual spraying –**iodine**	5.25E-02	5.25	yes

Furthermore, all products included in the BPF are classified for eye irritation (H319: Causes serious eye irritation), Therefore an evaluation in accordance to BPF guidances for local effects is included below.

Summary table: estimated local exposure from professional uses							
Hazard category	**Effects in terms of C&L**	**Who is exposed**	**Taskes, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Relevant RMMM & PPE**	**Conclusion on risk**
Low	Eye Irr. H319	Professional	Loading the product in dipping cups or spraying devise, application by dipping or spraying the product, cleaning of dipping cups and spray equipment	Skin Eye (splashes, hand to eye transfer)	Minutes during mixing and loading, and cleaning of spray equipment For application, an hour per day	P280 Wear eye protection is assigned in case of splashes into the eyes of the user, he should rinse his eyes with water. This is clearly indicated on the label, covered by the phrases P305+P351+P338.	Acceptable

Combined scenarios: Pre- milking disinfection of 82 animals twice a day

- RTU: 0.5% total iodine
- Intakes which exceed the UL are highlighted in red in the table below.

Task/ Scenario	Tier/ PPE	Estimated uptake mg/kg bw/d	% UL (0.01 mg/kg bw/day) due to biocidal use	% UL (0.01 mg/kg bw/day) due to biocidal use + iodine from milk due to teat treatment[1]	% UL (0.01 mg/kg bw/day) due to biocidal use + total milk intake[2]	% UL (0.01 mg/kg bw/day) due to biocidal use + total dietary intake[3]
Manual dipping - Scenarios [1.1; 2.1; 3.1; 4.1]	1/ none	4.94E-03	49	73	88	119
	2/ Gloves	4.94E-04	5	29	4	75
Manual spraying using a trigger sprayer or electronic sprayer -	1/ none	1.30E-02	150	174	189	220
	2/	1.75E-03	20	44	59	90

Task/ Scenario	Tier/ PPE	Estimated uptake mg/kg bw/d	% UL (0.01 mg/kg bw/day) due to biocidal use	% UL (0.01 mg/kg bw/day) due to biocidal use + iodine from milk due to teat treatment[1]	% UL (0.01 mg/kg bw/day) due to biocidal use + total milk intake[2]	% UL (0.01 mg/kg bw/day) due to biocidal use + total dietary intake[3]
Scenarios [1.1; 2.2; 3.1; 4.1]	Gloves, protective clothing and chemical resistant boots					
Automated dipping/spraying Scenarios [1.1; 2,3; 3.3; 4.2]	1/ none	2.00E-04	20	44	59	90
	2/ Gloves	2.00E-05	2	26	41	72

[1] Values derived from pre-application use are included.

[2] Total milk intake is the sum of the estimated additional intake resulting from the transfer into milk following teat disinfection (based on O'Brien) and the background milk value of 200 µg/L (EFSA 2013)

[3] Total dietary intake is the sum of the estimated additional intake resulting from the transfer into milk following teat disinfection (based on O'Brien), the background milk value of 200 µg/L (EFSA 2013) and 185 µg/d for adult or 96 µg/d for infant based on UK data (2008).

Calculation sheet is included in annex 3.2.

Conclusion: Pre-milking disinfection *of 82 animals twice a day*

Tier 1: When using the RTU product (0.5% total iodine), **exposure from biocidal use** without considering PPE (Tier 1) results in 49% of the UL for manual dipping, 150% of the UL for manual spraying using a trigger sprayer or electronic sprayer, and 20% of the UL for automated dipping/spraying.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 1) results in 73% for manual dipping, 174% of the UL for manual spraying using a trigger sprayer or electronic sprayer, and 44% of the UL for automated dipping/spraying.
Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 1) results in 88% for manual dipping, 189% of the UL for manual spraying using a trigger sprayer or electronic sprayer, and 59% of the UL for automated dipping/spraying.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 119% for manual dipping, 220% of the UL for manual spraying using a trigger sprayer or electronic sprayer, and 90% of the UL for automated dipping/spraying.

Tier 2: When using the RTU product (0.5% total iodine), **exposure from biocidal use** considering PPE (Tier 2) results in 5% of the UL for manual dipping, 20% of the UL for manual spraying using a trigger sprayer or electronic sprayer, and 2% of the UL for automated dipping/spraying.

Exposure from biocidal use, including iodine from milk consumption due to teat treatment, considering PPE (Tier 2) results in 29% for manual dipping, 44% of the UL for manual spraying using a trigger sprayer or electronic sprayer, and 44% of the UL for automated dipping/spraying.
Exposure from biocidal use, including iodine from milk consumption, considering PPE (Tier 2) results in 44% for manual dipping, 59% of the UL for manual spraying using a trigger sprayer or electronic sprayer, and 41% of the UL for automated dipping/spraying.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, considering PPE (Tier 2) results in 75% for manual dipping, 90% of the UL for manual spraying using a trigger sprayer or electronic sprayer, and 72% of the UL for automated dipping/spraying.

Conclusions pre-milking application:

metaSPC1
For manual dipping applications, chemical resistant gloves are needed for safe use.
For manual spraying application using a trigger sprayer or electronic sprayer , chemical resistant gloves, protective clothing and chemical resistant boots are needed for safe use.
For automated dipping/spraying applications, no PPE is are needed for safe use.

Refinement of worst case calculations
Conclusions are based on worst case calculations, taking into account 0.5% total iodine. However, as prescribing PPE should be included as a last resort, re-calculations are performed for the exposure scenarios for which PPE was concluded above to obtain the total iodine concentration that would result in safe use without, for example gloves.

When using RTU product (0.5% total iodine), exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 119% of the UL for manual dipping. **The total iodine concentration for manually dipping by pre-milking application, that would lead to safe use without gloves < 0.42 % total iodine.**

Only metaSPC1 includes the use pre-milking application. This metaSPC includes a range of 0.44-0.5% total iodine, and only 1 product containing 0.5% total iodine is included. Therefore, taking into account the lowest value of the range of metaSPC1 would lead to the same RMM as when considering the worst case calculations, i.e. chemical resistant gloves, protective clothing and chemical resistant boots are needed for safe use.

Combined scenarios: Post- milking disinfection of 82 animals twice a day

- RTU: 0.5% total iodine
- Intakes which exceed the UL are highlighted in red in the table below.

Task/ Scenario	Tier/ PPE	Estimated uptake mg/kg bw/d	% UL (0.01 mg/kg bw/day) due to biocidal use	% UL (0.01 mg/kg bw/day) due to biocidal use + iodine from milk due to teat treatment[1]	% UL (0.01 mg/kg bw/day) due to biocidal use + total milk intake[2]	% UL (0.01 mg/kg bw/day) due to biocidal use + total dietary intake[3]
Manual dipping - Scenarios [1.1; 2.1; 3.2; 4.1]	1/ none	4.94E-03	49	77	92	123
	2/ Gloves	4.94E-04	5	33	48	79
Manual spraying using a trigger sprayer or electronic sprayer - Scenarios [1.1; 2.2; 3.2; 4.1]	1/ none	1.50E-02	150	178	193	224
	2/ Gloves, protective clothing and chemical resistant boots	1.95E-03	20	48	63	94
Automated dipping/spraying Scenarios [1.1; 2,3; 3.3; 4.2]	1/ none	2.00E-04	20	48	63	94
	2/ Gloves	2.00E-05	2	30	45	76

[1] Values derived from post-application use are included.

[2] Total milk intake is the sum of the estimated additional intake resulting from the transfer into milk following teat disinfection (based on O'Brien) and the background milk value of 200 µg/L (EFSA 2013)

[3] Total dietary intake is the sum of the estimated additional intake resulting from the transfer into milk following teat disinfection (based on O'Brien), the background milk value of 200 µg/L (EFSA 2013) and 185 µg/d for adult or 96 µg/d for infant based on UK data (2008).

Calculation sheet is included in annex 3.2.

Conclusion: Post-milking disinfection *of 82 animals twice a day*

Tier 1: When using the RTU product (0.5% total iodine), **exposure from biocidal use** without considering PPE (Tier 1) results in 49% of the UL for manual dipping, 150% of the UL for manual spraying using a trigger sprayer or electronic sprayer, and 20% of the UL for automated dipping/spraying.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 1) results in 77% for manual dipping, 178% of the UL for manual spraying using a trigger sprayer or electronic sprayer, and 48% of the UL for automated dipping/spraying.
Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 1) results in 92% for manual dipping, 193% of the UL for manual spraying using a trigger sprayer or electronic sprayer, and 63% of the UL for automated dipping/spraying.

Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 123% for manual dipping, 224% of the UL for manual spraying using a trigger sprayer or electronic sprayer, and 94% of the UL for automated dipping/spraying.

Tier 2: When using the RTU product (0.5% total iodine), **exposure from biocidal use** considering PPE (Tier 2) results in 5% of the UL for manual dipping, 20% of the UL for manual spraying using a trigger sprayer or electronic sprayer, and 2% of the UL for automated dipping/spraying.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, considering PPE (Tier 2) results in 33% for manual dipping, 48% of the UL for manual spraying using a trigger sprayer or electronic sprayer, and 30% of the UL for automated dipping/spraying.
Exposure from biocidal use, including iodine from milk consumption, considering PPE (Tier 2) results in 48% for manual dipping, 63% of the UL for manual spraying using a trigger sprayer or electronic sprayer, and 45% of the UL for automated dipping/spraying.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, considering PPE (Tier 2) results in 79% for manual dipping, 94% of the UL for manual spraying using a trigger sprayer or electronic sprayer, and 76% of the UL for automated dipping/spraying.

Conclusions post-milking application:

For manual dipping applications, chemical resistant gloves are needed for safe use.
For manual spraying application using a trigger sprayer or electronic sprayer, chemical resistant gloves, protective clothing and chemical resistant boots are needed for safe use.
For automated dipping/spraying applications, no PPE is are needed for safe use.

Refinement of worst case calculations
Conclusions are based on worst case calculations, taking into account 0.5% total iodine. However, as prescribing PPE should be included as a last resort, re-calculations are performed for the exposure scenarios for which PPE was concluded above to obtain the total iodine concentration that would result in safe use without, for example gloves.

When using RTU product (0.5% total iodine), exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 123% of the UL for manual dipping. **The total iodine concentration for manually dipping by post-milking application, that would lead to safe use without gloves < 0.41 % total iodine.**

metaSPC1 includes a range of 0.44-0.5% total iodine, and only 1 product containing 0.5% total iodine is included. Therefore, taking into account the lowest value of the range of metaSPC1 would lead to the same RMM as when considering the worst case calculations, i.e. chemical resistant glovesare necessary for safe use for manual dipping.

metaSPC2 includes a range of 0.26-0.38% total iodine, therefore for this metaSPC safe use without the use of PPE is identified for post-milking use by manual dipping.

metaSPC3 includes a range of 0.43-0.5% total iodine, and only 1 product containing 0.5% total iodine is included. Therefore, taking into account the lowest value of the range of metaSPC3 would lead to the same RMM as when considering the worst case calculations, i.e. chemical resistant gloves are necessary for safe use for manual dipping.

When using RTU product (0.5% total iodine), exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 224% of the UL for manual spraying by trigger spray or electronic sprayer. **The total iodine concentration for manually spraying by post-milking application, that would lead to safe use without gloves < 0.22 % total iodine.**

As the lower range of the BPF is 0.26, therefore PPE is necessary for safe use by manual spraying using a trigger sprayer or electronic sprayer.

However, metaSPC2 includes range of 0.26-0.38% total iodine. A refinement calculations is performed, taking into account a product containing 0.38% total iodine (calculation sheet is included in annex 3.2).

Task/ Scenario	Tier/ PPE	Estimated uptake mg/kg bw/d	% UL (0.01 mg/kg bw/day) due to biocidal use	% UL (0.01 mg/kg bw/day) due to biocidal use + iodine from milk due to teat treatment[1]	% UL (0.01 mg/kg bw/day) due to biocidal use + total milk intake[2]	% UL (0.01 mg/kg bw/day) due to biocidal use + total dietary intake[3]
Manual spraying using a trigger sprayer or electronic sprayer – 0.38% total iodine Scenarios [1.1; 2.2; 3.1; 4.1]	1/ none	1.11E-02	111	139	154	185
	2/ Gloves	3.26E-03	33	61	76	107

[1] Values derived from post-application use are included, corrected for 0.38% available iodine.

[2] Total milk intake is the sum of the estimated additional intake resulting from the transfer into milk following teat disinfection (based on O'Brien) and the background milk value of 200 µg/L (EFSA 2013)

[3] Total dietary intake is the sum of the estimated additional intake resulting from the transfer into milk following teat disinfection (based on O'Brien), the background milk value of 200 µg/L (EFSA 2013) and 185 µg/d for adult or 96 µg/d for infant based on UK data (2008).

When using RTU product (0.38% total iodine), exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering chemical resistant gloves (Tier 2) results in 107% of the UL for manual spraying by trigger sprayer or electronic sprayer. The total iodine concentration for manually spraying by post-milking application, that would lead to safe use with gloves and not exceeding the UL is 0.36 % total iodine. Two products are included in metaSPC containing 0.26% and 0.29 % total iodine. As concentration more than 0.36% would result in exceeding the UL, the maximum concentration of total iodine included metaSPC2 will be reduced to 0.36% ensuring the same PPE for all products included in metaSPC2.

metaSPC1 includes a range of 0.44-0.5% total iodine, and only 1 product containing 0.5% total iodine is included. Furthermore, metaSPC3 includes a range of 0.44-0.5% total iodine, and only 1 product containing 0.5% total iodine is included. Therefore, taking into account the lowest value of the range of metaSPC 1 and 3 would lead to the same RMM as when considering the worst case calculations, i.e. chemical resistant gloves, protective clothing and chemical resistant boots are needed for safe use.

Calculation sheet is included in annex 3.2

Conclusions post-milking application:

metaSPC1
For manual dipping applications, chemical resistant gloves are needed for safe use.
For manual spraying applications using a trigger sprayer or electronic sprayer, chemical resistant gloves , protective clothing and chemical resistant boots are needed for safe use.
For automated dipping/spraying applications, no PPE is are needed for safe use.

metaSPC2
For manual dipping no PPE is necessary for safe use.
For manual spraying applications using a trigger sprayer or electronic sprayer, chemical resistant gloves are needed for safe use.
For automated dipping/spraying applications, no PPE is are needed for safe use.

To ensure that the same PPE is assigned for all products included in metaSPC2, the maximum concentration of total iodine in metaSPC2 will be reduced to 0.36% .

metaSPC3
For manual dipping applications, chemical resistant gloves are needed for safe use.
For manual spraying application using a trigger sprayer or electronic sprayer, chemical resistant gloves, protective clothing and chemical resistant boots are needed for safe use.
For automated dipping/spraying applications, no PPE is are needed for safe use.

Risk for the general public

No health risks are anticipated for the professional user after respiratory exposure to iodine, and as workers or by-standers have the same or lower exposure than the professional user, no risk is anticipated for re-entry workers or for bystanders.

Risk for consumers via residues in food

Note eCA: dietary exposure is discussed in various human health working group meetings and WebEx meetings for eCA evaluating iodine based union authorisations application. For the exposure to residues, the O'Brien study can be used. The assumptions that could be considered for the exposure to residues via milk were that needs to be considered are included below:

- Exposure in accordance to intended use (WGIII 2017). Therefore, the indicated worst case scenarios are taken into account, based on 0.5% available iodine.

- For exposure to residues the following was concluded by eCAs from iodine based union authorisation applications (Secure Webex meeting (3-10-2017)): "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". However, this is not accepted as it was not in line with the intended use (BPC29 2019). Therefore, the exposure calculations using information of the O'Brien study, which considers 2x manual application, is adapted to 3x application to also cover the automatic use. Taking into account a density of 1.03 kg/L for whole milk (Ullmanns's Food and Feed, 3 Volume set. (Elvers, B. (2017). 1st ed. Weinhem, Germany: Wiley-VCH, page 344).
- 50% reduction due to bulking of milk is not allowed (WGII 2017).
- 27% reduction due to pasteurisation of the milk is not allowed. (WGII 2017)
- At WGIV 2017 it was agreed that for daily milk consumption to use 0.45 L/day for adults (EFSA PRIMo version 2, based on highest mean for Dutch populations) and 0.46 L/day for infant/toddlers (EFSA PRIMo version 2, based on highest mean for French population).
- For the calculations information from the O'Brien study was used. The O'Brien study assessed the effect of a teat disinfection product is used, based on 0.5% available iodine on the total iodine content in milk. Therefore, the measured residues in milk are from the O'Brien study does not need to be corrected for the BPF of BGM/ARCHE as the maximum concentration in the BPF is equal to the O'Brien study. Furthermore, as products can be used for pre- and/or post-application or pre-and post-application , these are included in the table below. Consumers are exposed to residues of iodine due to various sources. The inclusion from other sources in the consumer risk assessment was discussed at WGIV, and the following was concluded:
  Iodine exposure from all sources will be included in the assessment.
  The assessment will include exposure to iodine coming from:
  1. Teat treatment
  2. Teat treatment + background from milk (= total milk intake)
  3. Teat treatment + background from milk + dietary intake from other sources (= total dietary intake)
- **Background in milk is variable due to differences in iodine concentrations in natural sources (drinking water and grass) and due to feed (supplemented with various amounts of iodine).** The background was discussed in the Secure Webex meeting (3-10-2017), in which was concluded by eCAs from iodine based union authorisation applications: "General support was given to the derivation of an EU harmonised value. The value of 200 µg/L iodine in milk was considered appropriate as an EU harmonised value, based on the monitoring data from EFSA 2013 (EFSA Journal 2013;11(2):3101) and the O'Brien study."
- Iodine dietary intake from other sources than milk was also discussed in the Secure WebEx meeting (3-10-2017), in which was concluded by eCAs from iodine based union authorisation applications: "The values from the UK survey were considered adequate to represent the EU iodine dietary intake from sources other than milk. Rounding of the values to 185 µg/day for adults and 96 µg/day for toddler was agreed." It should be noted that these values excluded iodine intake from milk. Furthermore, within this UK study (UK retail survey of iodine in UK produced dairy foods, FSIS 02/08, 16 June 2008) 350 samples of dairy and seaweed products were

purchased from eight areas of the UK. Levels of iodine found were generally in similar ranges to those reported from previous surveys (MAFF iodine in milk), Furthermore the reported values are in agreement with an EFSA scientific opinion on the use of iodine in feeding stuffs. It is noted that in the UK study report for the calculations for body weights 76 for adults and 14.5 kg for infants are considered, whereas 70 kg and 12 kg are used in the consumption calculations. Moreover, during the discussion at the Secure WebEx meeting it was noted that comparable values could be obtained from French and German monitoring studies.

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 depicted in the table below. Intakes which exceed the respective UL are highlighted in red in the table below. Calculations are included in annex 3.2 (BGM ARCHE residues).

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.

Comparison of estimated daily iodine intakes compared to upper limit of pre- and/or post-milking teat-disinfection by manual dipping/spraying, based on 0.5% available iodine. Intakes which exceed the UL are highlighted in red in the table below.

	Adults (0.45 L/day)	**Toddlers (0.46 L/day)**
	Estimated daily intake (µg/day) [% of UL]	**Estimated daily intake (µg/day) [% of UL]**
3x post-milking		
Intake from milk due to teat treatment	170 [28]	173 [87]
Total milk intake*	260 [43]	265 [133]
Total dietary intake**	456 [74]	361 [181]
3x pre-milking		
Intake from milk due to teat treatment	145 [24]	149 [74]
Total milk intake*	235 [39]	241 [120]
Total dietary intake**	420 [70]	337 [168]
2x pre- and post-milking (when combining using products intended for either pre- or post-milking teat-disinfection)		
Intake from milk due to	315	322

teat treatment	[52]	[161]
Total milk intake*	405 [67]	414 [207]
Total dietary intake**	590 [98]	510 [255]

* Total milk intake is the sum of the estimated additional intake resulting from the transfer into milk following teat disinfection (based on O'Brien) and the background milk value of 200 µg/L (EFSA 2013)

** Total dietary intake is the sum of the estimated additional intake resulting from the transfer into milk following teat disinfection (based on O'Brien), the background milk value of 200 µg/L (EFSA 2013) and 185 µg/d for adult or 96 µg/d for infant based on UK data (2008).

Conclusion: Pre- or post-milking teat-disinfection

Considering the exposure in the intended, three worst case scenarios are identified:

1. post-milking teat-disinfection
2. pre-milking teat-disinfection
3. pre-and post-milking teat-disinfection (when combining using products intended for either pre- or post-milking teat-disinfection)

Post-milking teat-disinfection

For adults, the estimated daily intake of iodine resulting from biocidal product use is maximally 28% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 43% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 74% of the UL.

For toddlers, the estimated daily intake of iodine resulting from biocidal product use is maximally 87% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 133% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 181% of the UL.

Pre-milking teat-disinfection

For adults, the estimated daily intake of iodine resulting from biocidal product use is maximally 24% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 39% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 70% of the UL.

For toddlers, the estimated daily intake of iodine resulting from biocidal product use is maximally 74% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 120% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 168% of the UL.

Pre- and post-milking teat-disinfection (when combining using products intended for either pre- or post-milking teat-disinfection)
For adults, the estimated daily intake of iodine resulting from biocidal product use is maximally 52% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 67% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 98% of the UL.

For infants, the estimated daily intake of iodine resulting from biocidal product use is maximally 161% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 207% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 255% of the UL.

Conclusion
Although the intended use includes either pre- or post-milking, products could be combined and therefore this is assessed. Based on combined pre- and post-milking teat disinfection results in 161% UL for toddlers by exposure to residues due to treatment. Therefore, the combination of pre- **and** post-milking is considered not safe. The following risk mitigation measure needs to be included in paragraph 5.2 of the SPC: In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre- or post-milking disinfection.

For all metaSPCs the UL for toddlers is exceeded when taken into account teat disinfection and dietary intake.

Exposure to iodine via drinking water was not taken into account in the risk assessment. The use of the iodine teat treatments could potentially contribute to the levels found in groundwater. As part of the environmental risk assessment PEC have been estimated. However, the main issue with these estimated PEC is that they are significant overestimates as they are done as a porewater calculation so do not account for any means of dissipation at all i.e. binding to organic matter, plant uptake, lateral transfer. In addition, assuming that 100 % drinking water comes from groundwater could be an overestimate; the proportion of drinking water that is sourced from groundwater sources varies from region to region.
With no agreed background levels of iodine in water, no agreed proportion of water sourced as groundwater and with significantly overestimated PEC values for the iodine teat treatment uses then at this time a consumer risk assessment including water would be subject to a high level of uncertainty. However, this issue should be a part of the consideration by MS/ECHA/EFSA in obtaining more reliable information on the sources of iodine in the diet.

The consumer exposure evaluation shows exceedance of the UL for toddlers, however this is not a new issue. The ‘UK retail survey of iodine in UK product dairy foods’ (please note that this reference is also used for total dietary intake calculations) noted exceedances of the PMTDI (Provisional Maximum Tolerable Daily Intake = 0.017 mg/kg bodyweight/day). It was however noted that these exceedances result from worst case exposure scenarios and the occasional exceedance of the PMTDI would not be of concern.

Another notable example of exceedance of the UL was reported in an EFSA scientific opinion of the safety and efficacy of iodine compounds (2013). Please note that this report included the reference used for the background value for milk used in the residue calculations. In this paper it was stated that: 'The iodine content of food of animal origin, if produced from animals receiving the currently authorised maximum contents of total iodine in complete feed for dairy cows and laying hens (5 mg/kg), would represent a substantial risk to consumers, mainly for high-consuming (95th percentile) adults and toddlers. The risk would originate primarily from the consumption of milk and, to some extent, from consumption of eggs. The ULs would for adults be exceeded by a factor of 2 (1230 vs. 600 µg I/day), and for toddlers by a factor of 4 (840 vs. 200 µg I/day).' As a result of these exceedances the FEEDAP Panel recommended a reduction in the currently authorised maximum iodine contents in complete feed. The recommended reduced supplementation of 2 mg/kg would still result in an exceedance for the toddler (336 vs. 200 µg I/day).

Iodine can be consumed from many different sources, however in many countries, also the Netherlands, the natural iodine levels in the diet are insufficient to meet the requirements. Therefore, international and national legislation and guidelines exist to improve the iodine intake by e.g. addition of iodine to food or salt (e.g. the Netherlands) or advice to use iodine containing dietary supplements. Other EU countries (e.g. UK, Czech Republic) regulate adequate iodine intake through addition of iodine to cattle feed, which subsequently leads to increased iodine levels in milk, eggs and animal tissues (meat, fat, edible offal). Although it is recognised that both insufficient and excessive iodine intakes can cause diseases, **it is generally considered that the benefits of the prevention of diseases from iodine deficiency far outweighs possible side-effects of oversupply.**

Relevant sources of iodine outside the scope of the BPR are:

1. Feed supplementation
2. Food and salt supplementation
3. Dietary supplements

The risk assessment performed could be considered worst case/conservative, based on the following

1. For the assessment the O`Brien study (2013) study has been used. This study was considered reliable, and therefore could be used for the assessment. This study has information on background levels in milk (based on untreated cows), and therefore the contributions on total iodine in milk due to the teat disinfection could be assessed. However, looking at reported total levels in milk from monitoring data (100-200 µg/L, EFSA 2013) which is based on all sources (natural, feed supplementation, teat disinfection) and total measured iodine in milk from the O`Brien study, based on background and teat disinfection which was much higher (e.g. 461 µg/kg for 2-times post milking applications, equal to 475 µg/L assuming a milk density of 1.03), one could consider the O`Brien study worst case.

   Several studies have been conducted to experimentally determine the contribution to iodine levels in milk from use of iodine containing teat dips [Conrad & Hemken, 1978; Hemken, 1980; Sheldrake et al. 1980; Hemken et al, 1981; Galton et al., 1984; Berg & Padgitt, 1985; Van Ryssen et al, 1985; Galton et al., 1986; Aumont, 1987; Bruhn et al, 1987; Swanson et al., 1990; Rasmussen et al., 1991; Ingawa et al., 1992;

Serieys & Poutrel, 1996]. Interpretation of these experiments is hampered by the fact that total iodine levels in milk fluctuate considerably between and within cows because of differences and changes of iodine levels in feed during the course of the study. Furthermore, iodine levels in milk fluctuate because total iodine levels in milk derived from teat dips decrease with milk yield and because some analytical methods are not able to detect iodine from iodophors.

However, the studies tend to indicate that absorption of iodine from teat dips is possible, but it is generally only described for cows that are iodine deficient (below 0.025 mg/L iodine in milk) [Conrad & Hemken, 1978]. For cows that receive adequate iodine through feed or feed supplementation, the iodine levels derived from pre-and post-milking teat dips tend to depend on the effort that is taken to remove the iodine just before milking and on the dryness of the teats at the time of milking. Milk iodine levels derived from teat dips could range between 0-0.3 mg/L or 0-300 µg/L iodine in milk for pre- and/or post-milking teat dips containing 0.5% available iodine [Sheldrake et al., 1980, Galton et al., 1984, Galton et al., 1986, Rasmussen et al, 1991, Ingawa et al, 1992]. Good agriculture practice would be to apply only a post-milking teat dip and clean the teats for at least 20 sec with a disposable paper towel or moist cotton cloth just before the next milking [Rasmussen et al, 1991]. Such a treatment could possibly increase iodine levels in milk with 0.05-0.08 mg/L for a teat dip with 0.5% available iodine [Sheldrake et al., 1980; Galton et al, 1984, Galton et al, 1986]. These levels may increase to 0.3 mg/L or 300 µg/L total iodine in milk when the teat dips are just left to dry [Sheldrake et al, 1980]. Again, when compared to the results of the O`Brien study (addition in milk due to teat disinfection is 215 µg/L for 2-times post milking 251 µg/L for 2-times post milking applications, and 467 µg/L for 2x pre- and post-application assuming a milk density of 1.03) tend to be on the high site of reported range and therefore is considered worst case.

2. For background in milk we have used a value of 200 µg/L based reported total levels in milk from monitoring data (100-200 µg/L, EFSA 2013). Using the higher value, consider to take into account the EU variation. However, as the higher value is used, and this value also take into account the effect of teat disinfection, the resulting milk intake from the assessment is considered worst case, as for the assessment the additional milk intake due to teat disinfection is also taken into account separately.

3. The UL used is based on the limit values in the CAR were taken from/in line with the report of The Scientific Committee on Food (SCF). SCF based the iodine tolerable upper intake (UL) on studies in humans (male/female). The studies showed an increased serum thyroid-stimulating hormone (TSH) level in response to iodine intake and an enhanced response of TSH concentrations to thyrotropin-releasing hormone (TRH) at 1700-1800 µg/day. However, these changes were considered marginal and not associated with any clinical adverse effects. An uncertainty factor of 3 was selected to derive the UL for adults. For nutrients, an UF of 3 is a relatively high uncertainty factor, and therefore the derived UL is considered conservative. An additional factor of 3 was used to derive an UL for toddlers of 200 µg/day, which is standard approach to compensate differences between adults and children. Exceedance of the UL was discussed in various WG meetings. It was acknowledged that the value itself could be considered conservative, taken in mind that the value

based on marginal effects and taken in mind that WHO derived a value of 1000 µg/day. However, no agreement was reached what would be considered acceptable for exceedance, and also there was no support to change the limit value at this stage. Therefore, the limit value should be considered during active substance renewal.

4. Furthermore, it is noted that the estimated intakes are based on worst case theoretical levels of iodine in milk from a short term study. The intakes are compared to the UL, which is derived for chronic exposure. Furthermore, it is noted that SCF (from which the UL for adult and toddler are included in the CAR for iodine) also reports adapted UL values for older children. Taken this in consideration, as the estimated residue levels of iodine in milk are based on worst case assessments and the data are based on short term consumption studies, the intakes seen in reality may not be of concern if the lifelong exposures of varying sources of food and levels were considered.

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 cattle, iodine supplementation programs and other factors. **The iodine intake that can be attributed to the use of iodine-containing teat disinfectants is only a minor part of the total iodine intake**. Exceedances of the UL are reported when worst case consumption values are used in the human health risk assessment, but these **exceedances can, for the larger part, be attributed to the iodine intakes arising from background levels.** The additional burden arising from teat disinfection is considered of no significant impact. To ensure that the population's needs are met and not exceeded, a wider approach encompassing different regulatory regimes would need to be considered. Such a task can't be handled in the context of the Biocidal Product Regulation alone, but requires an integrated concept.

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

Not relevant, since only one active substances is included in the BPF for which a systemic risk assessment needs to be performed. Furthermore, local effects for iodine, inhalation exposure, and the SoC Fatty alcohol ethoxylated, as it adds to the BPF classification, are taken into account.
A risk assessment for the SoC is included in the confidential annex.

2.3.6 Risk assessment for animal health

All products are classified for eye irritation. There is in principle no exposure to the eyes of treated cows, therefore local effects on eyes are not considered relevant here. As the products are not classified for skin irritation, local effects after teat disinfection are not expected.
According to the EMEA (European Agency for the Evaluation of Medicinal Products) summary report on iodine-containing products used for veterinary medicine, only small increases in serum iodine concentration have been found after teat dipping indicating that the procedure has a negligible effect on tissue iodine concentrations. These results suggest limited livestock exposure and no-detailed risk assessment was therefore performed for animal health. This is supported by the EFSA 2013 opinion on the safety and efficacy of iodine compounds (E2) as feed additives, in which it was concluded that the iodine level in

edible tissues/products is generally found to be highest in milk and not in meat. In addition, iodine-based teat-disinfection products have a long history as safe veterinary hygiene and medicinal products.

2.3.7 Risk assessment for the environment

A. EFFECTS ASSESSMENT ON THE ENVIRONMENT

As regards the classification of the products in this BPF, CLP mixture rules were used but no ecotoxicological studies were conducted on the products. There has been a slight composition change for 2 of the products, more info is provided in the annex.

The products contain only one substance that needs to be considered for environmental risk assessment: the active substance iodine. All other ingredients in the product family do not pose an environmental risk as these are not classified regarding the environment. Therefore, these co-formulants cannot be regarded as substances of concern and do not need to be assessed. Note that classification was based on the total iodine contents in the products including iodine from possible other sources. Also note that iodine is currently classified as H400 (harmonised classification according to ATP00), but data provided in the assessment report also justify H410 based on a NOEC of 0.25 mg/L (*Daphnia magna*). The available NOEC was also considered for classification.

Environmental compartment		**Iodine species**	**PNEC**
Aquatic, freshwater	Surface water	Iodine (I_2)	0.59 µg/L
		Iodate (IO_3^-)	58.5 µg/L
		Iodide (I^-)	0.83 µg/L
	Freshwater sediment	-	not used in 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

Iodine is a natural occurring substances for which background values are available. These will be considered as well. The background levels are summarised below.

Background concentration of iodine in the environment (CAR, 2011 on iodine)	
Compartment	**natural background concentration**
Air	-
STP	-
Surface water	0.5 – 20 µg iodine/L
Fresh water sediment	typically 6 mg iodine/kg
Sea water	45 - 60 µg iodine/L

Marine sediment	3 - 400 mg iodine/kg
Soil	0.5 – 20 mg/kg_{dwt} with extremes up to 98 mg/kg_{dwt} (corresponding to 0.4 - 18 mg iodine/kg_{wwt} with extremes up to 86 mg/kg_{wwt}) depending on soil types and locations. Highest concentrations are found in peaty soils (18.7-98.2 mg/kg dwt). Concentrations in sandy and clayey soils are respectively 1.7-5.4 mg/kg dwt and 2.1-8.9 mg/kg dwt (source DOCIIIA, 7.2.1/01-03 and references therein).
Groundwater	mean concentration: 1 µg/L < 1-70 µg iodine/L (with extremes up to 400 µg/L) depending on geographical location and local geology. Higher concentrations can be found in saline waters such as coastal and arid areas (source DOCIIIA, 7.2.3.2 and references therein).

Further Ecotoxicological studies

No data available

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

No data available, but may be required at the renewal stage due to the conclusions of the current risk assessment.

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

No data available, but may be required at the renewal stage due to the conclusions of the current risk assessment.

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

No data available.

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

Not relevant

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

The products are intended for use as teat-disinfectants for dairy cows. They are applied by dipping or spraying to the teats of the animals before or after milking. Exposure to the environment is predominantly secondary, i.e. via liquid manure to soils or to surface water via the municipal sewer. Exposure to air during application is not relevant due to the low vapour pressure of the active substance.

When applying the products to the animal teats by spraying, spray may not reach the animal teats or part of the product applied to the teats may be lost by drip formation. Drip formation may also occur when the products are applied by dipping. In both cases losses are possible into the liquid manure (release pathway via manure spreading on grassland or arable land) or the sewer system (release pathway via STP). If applied post-milking, the products will only partly remain on the animal teats between two milking events. The part which simply falls off or is lost due to contact with the surfaces (e.g. when the cows lie down for rest) will finally end up in the liquid manure. The part remaining on the teats will be removed before the next milking by wiping with a dry cloth or a single paper towel. If disposable tissues are used, the product will end up in the waste bin. Residues are also released to the environment during cleaning of the applied equipment such as milking cups and reusable milking cloths. Considering that most farms are not connected to the municipal sewer, waste water is often released to the manure depot instead. If present, residues may be released to individual sewage treatment plants as well when equipment is for instance rinsed above sinks. In all other cases release to the municipal sewer and subsequently to a sewage treatment plant (STP) is likely.

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

No data available

Leaching behaviour (ADS)

No data available

Testing for distribution and dissipation in soil (ADS)

No data available

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

Data reported in the CAR is sufficient for the risk assessment. However, environmental standards were exceeded for one or more compartments. Additional data at the renewal stage may be required.

Testing for distribution and dissipation in air (ADS)

No data available

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

Not relevant for the use of the product family.

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)

Not relevant for the use.

B. EXPOSURE ASSESSMENT

General information

The product family represented in this risk assessment dossier contains four iodine-based products from which two are authorised (2012) in The Netherlands (Udder Dip and Udder Star). The products contain only iodine as active substance and no other substances that are classified for environmental hazard (H400-H413). Therefore, the product does not contain substances of concern.

Predicted Environmental Concentrations (PECs) were calculated according to the exposure scenario document (ESDs, release to the environment) for veterinary health products (PT03), the guidance on biocide legislation, Part B, volume IV, version 1.0 (distribution in the environment), and the model SimpleTreat (version 3.1, concentrations for micro-organisms in a STP and the STP's effluent) by using the default values for parameters, unless otherwise noted. The assessment was made for the highest dose from both *meta* SPC's. The general approach is summarised below.

Assessed PT	PT 3
Assessed scenarios	Disinfection of teats of dairy cows
ESD(s) used	Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, JRC Scientific and Technical Reports, Report nr. EUR 25116 EN, Publications Office of the European Union, Luxembourg, 2011
Approach	Average consumption The products can either be applied by dipping (product volume of 10 ml/cow/milking) or spraying (product volume of 15 ml/cow/milking). The products are applied two or three times daily.
Distribution in the environment	Emission to manure and subsequently to soils and surface water; Emission to the public sewer, STP, and surface water
Groundwater simulation	Concentrations in groundwater were calculated according to the guidance (equilibrium partitioning) as a first indication for emission to groundwater.
Confidential Annexes	No
Life cycle steps assessed	Production of active substance iodine: not assessed; the production takes place outside the EU. Formulation: assessed (statement) Use: assessed Service life: not applicable
Remarks	Only the highest dose from all *meta* SPC's was assessed (worst-case approach), which is use #1.3 (0.5% max, 15 mL/treatment, thrice daily, and pre and post milking applications).

Emission estimation

Formulation and disposal of the biocidal product
The products are formulated and disposed in accordance to local and national safety and environmental regulations. Emission during formulation is therefore negligible.

Disinfection of teats of dairy cows
The table below summarises the iodine concentrations and iodine consumption for each product family

iodine concentrations and consumption							
Meta SPC	**use**	**iodine in product (g/L)**	**application**	**volume (ml/cow/event)**	**daily applications**	**pre/post milking**	**daily iodine consumption (mg/animal)**
1	1.1	4.4-5.0	dip	10	2	pre or post	88-100
	1.2		spray	15			122-300
	1.3		automated dip/spray	15*	3		183-450
2	2.1	2.6-3.8	dip	10	2	post	52-76
	2.2		spray	6.5			78-115
	2.3		automated dip/spray	15*	3		117-172.5
3	3.1	4.3-5.0	dip	10	2	post	86-100
	3.2		spray	15			129-150

* highest application volume corresponding to spray treatment taken as a worst-case

Maximum iodine concentrations in the products and dosages are similar for both product families. Because spraying consumes more product, predicted environmental concentrations (PECs) were calculated for automated spraying representing the worst-case. Emission to the STP, grassland, and arable land was calculated according to the ESD by applying the default parameters and the following input variables marked as 'user' (S) in the ESD:

- Content of active ingredient in formulation (F_{bioc}) 5 g/L
- Amount of product prescribed to be used for one treatment (V_{proc}) 15 mL
- Number of daily applications 3
- Dilution factor (F_{dil}) 1

The applied values results in the following iodine releases to the environment.

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$)**	**Remarks**
STP	9.24E-03 kg/d	daily emission to the STP

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$)**	**Remarks**
$Soil_{grassland}$	0.597 kg	amount of iodine collected over 53 days
$Soil_{arable\ land}$	2.39 kg	amount of iodine collected over 212 days

According to the ESD for PT3, the deposition of active substances onto agricultural land (grassland) by manure/ slurry is estimated on the basis of emission standards for nitrogen or phosphor. Depending on the amount of nitrogen or phosphor in manure and the type of soil to which it is applied, these emission standards define the maximum amount of manure/slurry that can be applied per hectare and per year. The concentration in soil after manure/slurry application at maximum permissible rate (170 kg N/ha for both grassland and arable land and 110 kg P/ha for grassland and 85 kg P/ha for arable land) is calculated using the equations as proposed in the ESD for PT3. Note that dairy cows produce three times more nitrogen than phosphor (0.3389 vs. 0.1047 kg/animal/d), while the nitrogen emission standards are about a factor of two higher. Consequently, the phosphate emission standards combined with the dairy's cows phosphate production allows more manure per hectare and therefore higher PECs. Although the PECs based on the phosphate emission standards are worst-case, one should realise that the nitrogen emission standards are already exceeded. In other words, the nitrogen emission standards limit the emission to the environment for dairy cows. Therefore, only the predicted environmental concentrations (PECs) based on the nitrogen emission standards are presented in the current PAR.

According to the assessment report for iodine (I_2), iodate (IO_3^-) may be considered to be the dominant chemical form of iodine in the soil solution under aerobic non-flooded soil conditions, while iodide (I^-) appears mainly under anaerobic conditions. In surface water, however, both species may appear depending on the acidity (pH) and oxygen concentrations (redox) of the receiving fresh water body. In general iodate is the dominant species in oxygen rich water, while iodide is present in water low in oxygen contents. Predicted environmental concentrations were therefore calculated assuming no transformation (100% iodine) and 100% transformation into iodide or iodate. Limited information on the behaviour of iodate and iodide in environmental compartments is available. Therefore, the physical-chemical properties for iodine were applied to these two transformation products as well. PECs for iodate were derived by multiplying those for iodine with 1.382 (differences in molar weight).

The PEC's as calculated with the ESD represent the concentration after one manure application on arable land and one on grassland (Predicted Initial Environmental Concentrations, PIEC). However, agricultural soils are fertilised repeatedly and iodine may consequently accumulate in soils after successive years of manure applications. Therefore, the concentrations presented in the current assessment report are the concentrations after ten years, i.e. ten manure applications on arable land and forty on grassland. Concentrations in soils after ten years were calculated according to the addendum for PT18 (insecticide in stables), although the no-manure time was increased from 206 to 365 days. This approach has been meanwhile accepted by the BPC working group (WG-I-2018).

Although iodine being an element does not degrade, it disappears from soils between two subsequent manure events due to leaching. The leaching rate constants and resulting PECs

were calculated according to the guidance by applying an experimentally-derived solid-water partitioning coefficient for soils of 5.8 L/kg and the active substance's physical-chemical parameters as presented elsewhere. The corresponding half-lives for leaching from the topsoil layer are 2571 d in arable land (20 cm) and 643 d in grassland (5 cm).

PECs in adjacent surface water due to runoff was derived from the concentration in the soil's pore water according to the principles described in the ESD for PT18, but concentrations were additionally corrected for sorption onto suspended matter. PECs where therefore calculated according to formula 45 of the guidance by using an experimentally derived solids-water partition coefficient in suspended matter ($K_{p,\ susp}$) of 220 L/kg and a dilution of ten. Although this approach may largely overestimate the concentration in surface water, higher tier models such as SWASH were not applied as these were considered inaccurate for inorganic compounds such as iodine. PECs for sediments were not calculated as no predicted no effect concentrations (PNECs) are available. Although PNECs may be calculated using equilibrium partitioning, the same formulas are applied to derive $PEC_{sediment}$. Therefore, the PEC:PNEC ratios and risk for sediment is similar to that for water.

Fate and distribution in exposed environmental compartments

Two different emission pathways are described in the ESD for PT3 (2011):

- Release via sewage treatment plant (STP) or
- Release into slurry/manure

The receiving compartments for these scenarios are different (see the following table).

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
via STP	yes	yes	yes	yes	yes	no	yes	yes	no
via slurry/ manure	yes	yes	yes	yes	no	no	yes	yes	no

The active substance's properties applied for the risk assessment are summarised below.

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	253.81	g/mol	Source: ECHA[a], mol. weight for iodine (I_2)
Melting point	113.7	°C	Source: ECHA
Boiling point	184.5	°C	Source: ECHA
Vapour pressure (at 25°C)	1×10^{-6}	Pa	Source: ECHA Although iodide (I_2) may evaporate as the vapour pressure is 40.7 Pa, it cannot be expected that ionised iodine species are volatile. Therefore, emission to air was not considered.
Water solubility (at 25°C)	300	g/L	Source: ECHA

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Henry's law constant (12°)	4.05E-07	Pa m³/mol	Calculated
Log Octanol/water partition coefficient	-	-	inorganic substance
Organic carbon/water partition coefficient (Koc)	165.83	L/kg	not applied in the risk assessment. Overruled by K_d.
Solids-water partition coefficient in soil (K_d)	5.8	L/kg	Source: ECHA
Solids-water partition coefficient in sediment (Kp_{sed})	200	L/kg	Source: ECHA
Solids-water partition coefficient in suspended matter (Kp_{susp})	220	L/kg	Source: ECHA
Biodegradability	Not biode-gradable		Inorganic substance[b]

[a] Regulation (EU) n°528/2012 concerning the making available on the market and use of biocidal products. Evaluation of active substances. Assessment Report for Iodine (including PVP-iodine) product types 1, 3, 4, and 22. 13 December 2013,

[b] Iodine is an inorganic substance, which is not biodegradable. Depending on whether aerobic or anaerobic conditions prevail, iodine is present in the environment either as iodide or iodate (CAR (2013) on iodine).

Distribution in the sewage treatment plants was not calculated according SimpleTreat, but based on laboratory and field tests. The values applied in the risks assessment are summarised below.

Calculated fate and distribution in the STP		
Compartment	**Percentage [%]**	**Remarks**
Air	negligible	Source: ECHA[a], based on laboratory and field experiments
Water	80	
Sludge	20	
Degraded in STP	0	

[a] Regulation (EU) n°528/2012 concerning the making available on the market and use of biocidal products. Evaluation of active substances. Assessment Report for Iodine (including PVP-iodine) product types 1, 3, 4, and 22. 13 December 2013,

PEC values

The PECs resulting from disinfection of cow's teats are presented below. Concentrations are calculated after ten years of successive manure and sewage applications. Emission via manure is based on nitrogen emission standards.

Summary table on calculated PEC values for iodine and iodide						
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[µg/l]	[µg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
via STP						
	3.71	0.38	0.03	0.23	4.41	--
via slurry/manure – concentrations after ten years. Leaching from the top soil layer between two applications is considered.						
grassland	--	3.45	0.17	0.18	34.58	--
arable land	--	2.10	0.10	0.11	21.11	--

Summary table on calculated PEC values for iodate						
	PEC_{STP}	PEC_{water}	PEC_{sed}	PEC_{soil}	PEC_{GW}	PEC_{air}
	[µg/l]	[µg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
via STP						
	5.13	0.51	0.02	0.03	6.06	--
via slurry/manure – concentrations after ten years. Leaching from the top soil layer between two applications is considered.						
grassland	--	4.79	0.23	0.26	47.82	--
arable land	--	2.91	0.14	0.15	29.15	--

Primary and secondary poisoning

Direct exposure of birds or mammals other than the treated animal is considered negligible as there is no direct release of the product in the environment. In addition, iodine is an essential nutrient and therefore organisms may able to regulate internal concentrations within small boundaries by passive uptake or elimination.

C. RISK CHARACTERISATION

Atmosphere

Exposure to air is not considered as iodine is assumed to speciate into non-volatile iodide and iodate in the different compartments to which it is eventually released. It cannot be expected that airborne iodine will significantly increase the already high background values in air (1.10E-2 to 2.10E-2 µg/m³, according to the CAR on iodine). There are no indications that iodine contributes to depletion of the ozone layer as iodine or organic-bound iodine are not listed as 'controlled substance' in Annex I of Regulation (EC) No 1005/2009 of the European Parliament. Therefore, the risks for the air compartment are considered acceptable.

Sewage treatment plant (STP)

The risk ratio for the STP in case iodine is released to the municipal sewer is presented below. Because no PNECs are available for iodide and iodate, it may be expected that the risk assessment for iodine is protective enough.

Summary table on calculated PEC/PNEC values - Iodine	
	$PEC/PNEC_{STP}$
Disinfection of teats (PT03)	
	<0.001

As the PEC is well below the PNEC, it cannot be expected that release of iodine to the municipal sewer affects micro-organisms in the STP. However, dairy farms are not necessarily connected to the municipal sewer and domestic waste water may be purified on-site by individual sewage treatment plants. Considering that these systems are small (a few cubic meters), high loads of iodine may kill the microbial population therein instantly, resulting in malfunctioning of the plant. Therefore, a precautionary measure stating that residues must be discharged to the (liquid) manure depot or municipal sewer will be added to the SPC.

Aquatic compartment

The risk evaluation (PEC:PNEC ratios) for the aquatic compartment when residues are released to the STP or due to runoff from fertilised agricultural land is presented below. The risk ratios for sediment are not presented in the PAR. Because both PEC and PNEC are derived from the aqueous concentrations, risks ratios for sediment will be similar to water. The PECs in sediment will be therefore only compared to the background values.

Summary table on calculated PEC/PNEC values for iodine and their transformation products						
	$PEC/PNEC_{water}$					
via STP						
	iodine		iodide		iodate	
Dairy cattle	0.62		0.44		0.01	
via slurry/manure – PEC:PNEC ratios after ten years. Leaching from the top soil layer between two applications is considered.						
	grassland			arable land		
	iodine	iodide	iodate	iodine	iodide	iodate
Dairy cattle	**5.85**	**4.16**	0.08	**3.57**	**2.54**	0.05

For the emission pathway via STP, the PEC/PNEC values for iodine, iodide and iodate in the aquatic compartment (surface water incl. sediment, marine water incl. sediment) are below the trigger value of 1 (max. 0.62). Therefore, unacceptable risk for the aquatic environment cannot be expected.

Although iodate is the dominant iodine specie in soils under aerobic conditions, it may be transformed to iodide once entering the aquatic environment depending on the acidity and redox potential (oxygen concentrations). The maximum PEC/PNEC value for iodide is 4.16 after ten years of successive manure applications, while iodate results in a PEC:PNEC ratio of 0.08. Unacceptable risks may be expected in surface water low in oxygen. Iodine is however a natural occurring compound for which aquatic background levels are reported between 0.5 and 20 µg/L. Moreover, many uncertainties exist as currently available higher tier modelling (FOCUS PEARL, SWASH) are not suitable for inorganic substances such as iodine. It was therefore agreed that the natural background concentration replaces the PNEC as environmental standard. The PECs in sediment are well below the typical natural background concentration of 6 mg/kg. The accompanied risks are consequently considered acceptable.

Terrestrial compartment

The risk evaluation (PEC:PNEC ratios) for the soil compartment when residues are released to the STP or due to runoff from fertilised agricultural land is presented below.

Summary table on calculated PEC/PNEC values for iodine and their transformation products						
	$PEC/PNEC_{soil}$					
via STP						
	iodine		iodide		iodate	
Dairy cattle	**4.50**		**12.36**		0.11	
via slurry/manure – PEC:PNEC ratios after ten years. Leaching from the top soil layer between two applications is considered.						
	grassland			arable land		
	iodine	iodide	iodate	iodine	iodide	iodate
Dairy cattle	**15.60**	**42.80**	0.84	**9.39**	**25.79**	0.51

Once released to soils, iodine will be transformed into iodide or iodate depending on the redox conditions. Iodine is therefore not relevant for the soil compartment. Unacceptable risks are expected for iodide in both arable and grassland after one year, i.e. after one or four manure applications respectively, while the PECs remain below the PNEC in case of iodate. The highest risks are expected for the most toxic specie iodide. These risks are nevertheless hypothetical as iodide only occurs in anaerobic i.e. flooded soils which may happen only incidentally. The ecological impact of long-term flooding is more disastrous compared to the risks related to anthropogenic elevated iodine concentrations. Moreover, the PECs are based on 100% transformation into iodide, while 14% transformation was reported in the assessment report for iodine. Therefore, the estimated PEC:PNEC ratios are considered unrealistic for agricultural soils for cattle and crops.
Iodine and iodide species occur naturally in the terrestrial environment for which the natural global mean background concentration is 5 mg/kg dwt and varies with geographical locations and local geology. The background concentrations in sandy and clayey soils vary between 1.7-5.4 and 2.1-8.9 mg/kg dwt, respectively, while peaty soils may contain 18.7-98.2 mg/kg dwt. The expected PECs after ten years (0.18 mg iodine/kg wwt in grassland and 0.11 mg iodine/kg wwt in arable land) are in the lower range and therefore a significant increase of the background concentration cannot be expected, although it should be realised that atmospheric deposition is double as anthropogenic imission to soils due to teat disinfection is 16.3 g/ha/y[2]

[2] 1.590 kg iodine is release to the manure intended for grassland or arable land (ESD outcome). Cows produce 7185 kg nitrogen annually (ESD default) which requires 42.3 ha

and natural atmospheric deposition 25.6 g/ha/y[3]. However, naturally occurring iodine may be less bioavailable due to strong sorption on organic material or complexation with e.g. metals. Unacceptable risks in soils are conclusively not expected.

Groundwater

The concentrations in groundwater for the different intended uses are summarised below.

Concentrations in pore water (µg/L)				
	via STP		via slurry/manure	
	iodine/iodide	iodate	iodine/iodide	iodate
Disinfection of teats				
	4.41	**6.06**	**21.00-34.50**	**29.15-47.82**

Concentrations in groundwater exceed the threshold limit value of 0.1 µg/L. However, it should be noted that the 0.1 µg/L limit is set for organic chemicals and therefore not feasible for iodine. Therefore, the predicted concentrations were compared to natural background concentrations.

Iodine is a natural occurring compound occurring in groundwater for which the concentration ranges from 1 to 70 µg/L (the latter are found in coastal and arid areas). Anthropogenic emission may therefore increase the natural background concentrations multiple times in case groundwater is low in iodine, but the expected concentrations are still within the natural background concentrations. The calculated exceeding of the PNEC is therefore considered acceptable.

Primary and secondary poisoning

Because the product is mainly applied indoors and not released to the environment directly, direct uptake by non-target organisms is not expected. Moreover, because iodine is an essential nutrient and its hydrophobicity does not exceed the trigger value for bioaccumulation, excessive passive uptake is not expected. Therefore, the PEC will not exceed the oral PNEC. No risks from primary and secondary poisoning are expected.

agricultural land considering a nitrogen emission standards of 170 kg/ha for both arable land and grassland.

3 Johanson, K.J. Iodine in soils, Technical Report TR-00-21, Svensk Kärnbränslehantering AB, Stockholm, Sweden.

Mixture toxicity

Not relevant for this product family as the product only contains one active substance and no substances of concern.

Aggregated exposure (combined for relevant emmission sources)

Although iodine is released from multiple sources, aggregated exposure assessment is not deemed necessary as there is no overlap in space and time. Iodine as a teat disinfectant is predominantly released to agricultural soils and therefore not mixed with iodine from other anthropogenic sources. See the decision tree in Figure 1 for details.

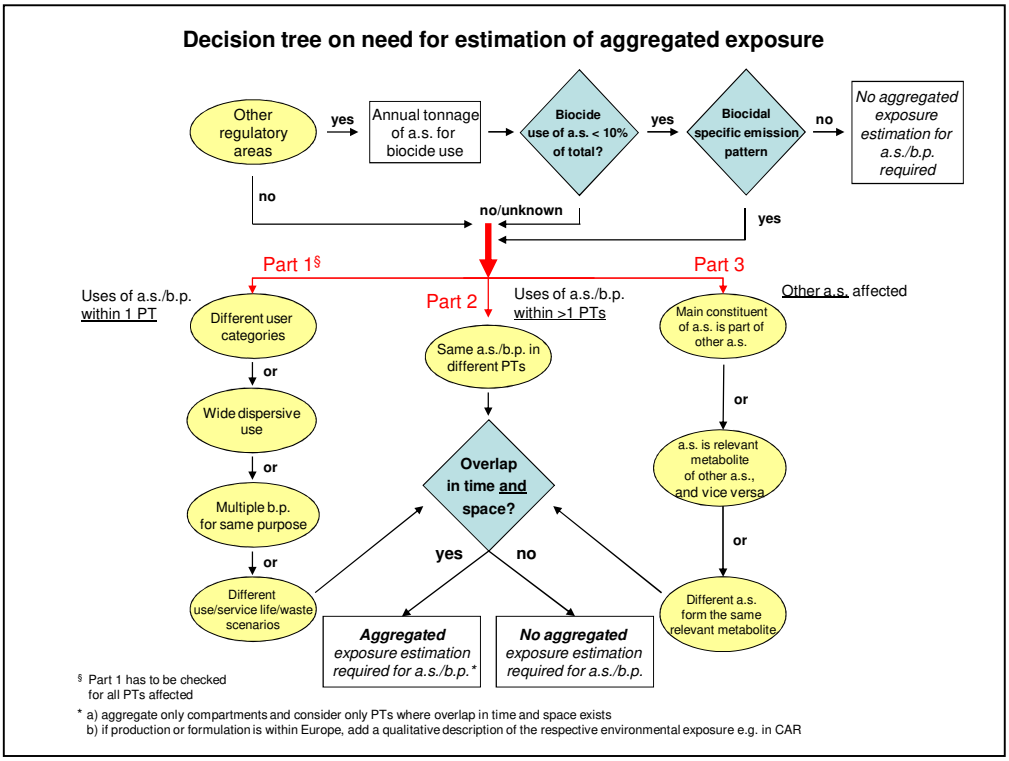


Figure 1: Decision tree on the need for estimation of aggregated exposure

Overall conclusion on the risk assessment for the environment of the product
When residues are released to the sewer, no unacceptable risks are expected for micro-organisms in the sewage treatment plant, and aquatic organisms in surface water and sediment as all predicted environmental concentrations (PECs) are well below the predicted no-effect concentrations (PNECs). Distribution of sewage sludge on agricultural land does not result in unacceptable risks either considering that all iodine is transformed into iodate as soils are aerobic. Release via manure results in a PEC:PNEC ration >1 for surface water adjacent agricultural soils due to runoff and concentrations in groundwater >0.1 µg/L due to leaching. The expected concentrations are however within the natural background range. The accompanied risks are therefore considered acceptable.

2.3.8 Measures to protect man, animals and the environment

A. RECOMMENDED METHODS AND PRECAUTIONS

Wear eye protection.
Wash hands thoroughly after handling.
Avoid release to an individual waste water treatment plant.

B. IDENTITY OF RELEVANT COMBUSTION PRODUCTS IN CASES OF FIRE

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

C. SPECIFIC TREATMENT IN CASE OF AN ACCIDENT

First aid measures
After inhalation: Supply fresh air; consult a doctor in case of complaints.
After skin contact: Generally the product does not irritate the skin.
After eye contact: Rinse opened eye for several minutes under running water.
After swallowing: Rinse mouth. Do not induce vomiting and seek medical advice immediately and show this container or label.

D. POSSIBILITY OF DESTRUCTION OR DECONTAMINATION FOLLOWING RELEASE

Accidental release measures
Dilute with plenty of water
Do not allow to enter sewers/surface or ground water
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust)

E. PROCEDURES FOR WASTE MANAGEMENT OF THE BIOCIDAL PRODUCT AND ITS PACKAGING

Must not be disposed together with household garbage. Do not allow product to reach sewage system. Packaging disposal must be made according to official regulations.

F. PROCEDURES FOR CLEANING APPLICATION EQUIPMENT WHERE RELEVANT

No specific procedure required

G. SPECIFY ANY REPELLENTS OR POISON CONTROL MEASURES INCLUDED IN THE PRODUCT

Not applicable

2.3.9 Assessment of a combination of biocidal products

Not relevant, the biocidal products are not intended to be used with other biocidal products.

2.3.10 Comparative assessment

Not applicable: active substance is not a candidate for substitution.

3 ANNEXES

3.1 LIST OF STUDIES FOR THE BIOCIDAL PRODUCT FAMILY

Document III-A: Study summaries - Active substance. Main data have been taken from the Assessment report of iodine finalized in 2013. Refer to the study summaries of this document for further information.

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
						Yes	No
all	-	RMS Sweden	2013	Assessment Report - Iodine	RMS Sweden		N

Document III-B: Study summaries - Biocidal products.

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
						Yes	No
3.1	495769	M.J.C. Brekelmans	2010	Determination of the stability of Udder dip, active substance: iodine during storage for 3,6,12 months at ambient temperature	Boumatic		X
3.1	495768	M.J.C. Brekelmans	2012	Determination of the stability of Udder star, active substance: iodine during storage for 3,6,12 months at ambient temperature	Boumatic		X
3.2	495769	M.J.C. Brekelmans	2010	Determination of the stability of Udder dip, active substance: iodine during storage for 3,6,12 months at ambient temperature	Boumatic		X
3.2	495768	M.J.C. Brekelmans	2012	Determination of the stability of Udder star, active substance: iodine during storage for 3,6,12 months at ambient temperature	Boumatic		X
3.3	495769	M.J.C. Brekelmans	2010	Determination of the stability of Udder dip, active substance: iodine during storage for 3,6,12 months at ambient temperature	Boumatic		X
3.3	495768	M.J.C. Brekelmans	2012	Determination of the stability of Udder star, active substance: iodine during storage for 3,6,12 months at ambient temperature	Boumatic		X
3.3	S15-04538	Dr. André Koch	2015	Relative Density of Udder Star Spray	Boumatic		X
3.4.1	495769	M.J.C. Brekelmans	2010	Determination of the stability of Udder dip, active substance: iodine during storage for 3,6,12 months at ambient temperature	Boumatic		X

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
3.4.1	495768	M.J.C. Brekelmans	2012	Determination of the stability of Udder star, active substance: iodine during storage for 3,6,12 months at ambient temperature	Boumatic		X
3.4.1	493616	Brekelmans M.J.C	2010	Determination of the accelerated storage stability of Udder dip, active substance: iodine by heating	Boumatic		X
3.4.1	S15-04608	Kai Birnschein	2017	Physico-chemical Properties of Gladiator RTU over 1 year at 20°C	Boumatic		X
3.4.1	S15-04600	Kai Birnschein	2017	Physico-chemical Properties of Udder Star Spray over 1 year at 20°C	Boumatic		X
3.4.2.1	495769	M.J.C. Brekelmans	2010	Determination of the stability of Udder dip, active substance: iodine during storage for 3,6,12 months at ambient temperature	Boumatic		X
3.4.2.1	495768	M.J.C. Brekelmans	2012	Determination of the stability of Udder star, active substance: iodine during storage for 3,6,12 months at ambient temperature	Boumatic		X
3.8	S15-04536	Dr. André Koch	2015	Surface Tension of Udder Dip	Boumatic		X
3.8	S15-04533	Dr. André Koch	2015	Surface Tension of Gladiator RTU	Boumatic		X
3.9	S15-04504	Kai Birnschein	2016	Viscosity of Udder Star Spray	Boumatic		X
3.9	S15-04505	Kai Birnschein	2016	Viscosity of Gladiator RTU	Boumatic		X
4.16	3202214	A. Beaumont	2018	Non-GLP Corrosivity Testng	Boumatic		X
5	495769	M.J.C. Brekelmans	2010	Determination of the stability of Udder dip, active substance: iodine during storage for 3,6,12 months at ambient temperature	Boumatic		X
5	495768	M.J.C. Brekelmans	2012	Determination of the stability of Udder star, active substance: iodine during storage for 3,6,12 months at ambient temperature	Boumatic		X
6.7	S-2015-01936	Laura Brambilla	2015	Suspension bactericidal effectiveness simulating low-level soiling for veterinary field on udder dip	Boumatic		X
6.7	S-2015-01937	Laura Brambilla	2015	Suspension bactericidal effectiveness simulating high-level soiling for veterinary field on udder dip	Boumatic		X

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
6.7	S-2015-01939	Laura Brambilla	2015	Suspension yeasticidal effectiveness simulating low-level soiling for veterinary field on udder dip	Boumatic		X
6.7	S-2015-01944	Laura Brambilla	2015	Suspension yeasticidal effectiveness simulating low-level soiling for veterinary field on udder dip without trisodium citrate	Boumatic		X
6.7	S-2015-01945	Laura Brambilla	2015	Suspension yeasticidal effectiveness simulating high-level soiling for veterinary field on udder dip without trisodium citrate	Boumatic		X
6.7	S-2015-01940	Laura Brambilla	2015	Suspension yeasticidal effectiveness simulating high-level soiling for veterinary field on udder dip	Boumatic		X
6.7	S-2016-00145	Camilla Carloni	2016	Udder dip without sodium citrate EN1657	Boumatic		X
6.7	S-2016-00148	Camilla Carloni	2016	Udder dip EN 16437	Boumatic		X
6.7	13 504-1	Mélinda Maux	2013	Quantative suspension test for the evaluation of bactericidal activity according to NF EN 1656:2010	Boumatic		X
6.7	S-2016-00147	Camilla Carloni	2016	Udder dip without sodium citrate EN1656	Boumatic		X
6.7	S-2015-01941	Laura Brambilla	2015	Suspencial yeasticidal effectiveness with skim milk for veterinary field on Gladiator RTU	Boumatic		X
6.7	S-2015-01947	Laura Brambilla	2015	Suspencial yeasticidal effectiveness with skim milk for veterinary field on Gladiator RTU without sodium citrate	Boumatic		X
6.7	S-2016-00149	Camilla Carloni	2016	Udder star EN16437	Boumatic		X
6.7	16329-1	Raphaël Dugué	2016	Bactericidal activity according to the NF EN 13697:2015 standard – Product: Udder Star – Batch SO16/261	Boumatic		X

3.2 OUTPUT TABLES FROM EXPOSURE ASSESSMENT TOOLS

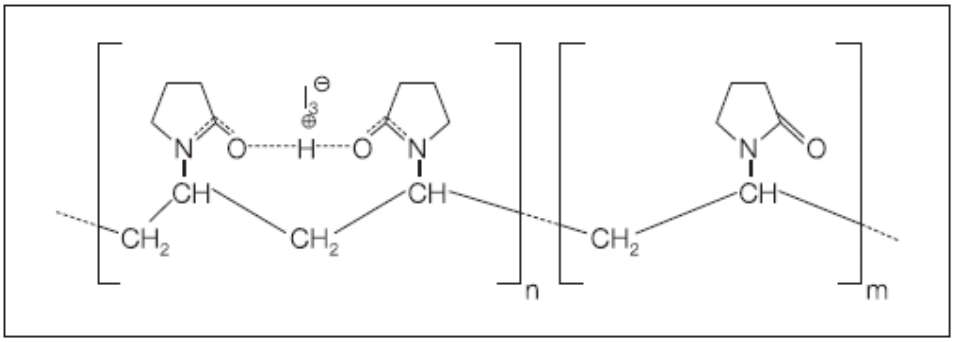
Human health risk assessment

Justification regarding inhalation exposure towards vapour
Background
Inhalation exposure towards vapours of iodine was a point of discussion at TOX WG-IV-2017 for two Union Authorisation dossiers (eCA NL). The issue was further discussed in an *ad hoc* follow-up meeting (secure WebEx discussion on 25 October 2017). In preparation of the discussion, one applicant submitted a detailed justification as to why inhalation exposure towards iodine vapour is negligible for biocidal products based on either iodophor type 1 (iodine complexed with surfactants) or iodophor type 2 (PVP-iodine).
The TOX working group followed the argumentation of the applicant and the issue was closed. As eCA NL and UK considered the argumentation relevant for all iodine dossiers, it was proposed to share the argumentation within the IRG PT3 sub-group.
The argumentation discussed and agreed in the *ad hoc* follow-up meeting of October 2017 is provided in the following. It may be used by applicants who are members of the IRG PT3 sub-group to support their conclusions regarding negligible vapours of iodine in the human health exposure and risk assessments.

Considerations regarding evaporation of iodine from iodine-based biocidal products
In the iodine Assessment Report for PTs, 1, 3, 4 and 22 (Sweden 2013) it is clearly detailed in the identity chapter 2.1.1, that "In the case of iodophor 1 (iodine complexed with surfactants) […] iodine can be regarded as the active substance […] present in stabilized (complexed) form." Analogously, iodophor 2 (PVP-iodine) is described as a complex between iodine and PVP. In summary, both iodophors are regarded as carriers which are capable of complexing iodine in their scaffolds.
As the iodine dossier has been approved by all EU member states, it can be concluded that there is a common understanding about the fact that iodine used in PT 3 is complex-bound either to surfactants (in the case of iodophor 1) or PVP (in the case of PVP-iodine, i.e. iodophor 2).
Despite the clear description in the iodine dossier, more details on the structure of iodophors and the release of complex-bound iodine from these iodophors are included below.

In the following, PVP-iodine (iodophor type 2) is taken as an example iodophor. However, the considerations are expected to also apply to other types of iodophors such as iodophor type 1 (iodine complexed with surfactants).

The predicted structure of solid PVP-iodine as provided in the iodine dossier and e.g. Ref [1] is given in the following. Instead of polyvinyl pyrrolidone (PVP), the backbone of the iodophor can also consist of other neutral polymers such as alcohol ethoxylates (surfactants) as described in Ref [2].



As can be seen from the figure, iodine is complex-bound to the carrier in the form of I_3^-, which is an ionic species resulting from the reaction of molecular iodine (I_2) and iodide (I^-). Of note, it is not bound as molecular iodine I_2, reason why solid PVP-iodine does not smell of iodine and also indicating a tight bound of I_3^- to the carrier molecule.

When discussing iodophor structures and release of complex-bound iodine out of it, the following terms are important to explain first (see Ref [1]):

Available iodine (available I_2) = *iodine that can be titrated with sodium thiosulphate; also the complex bound iodine fraction can be determined*

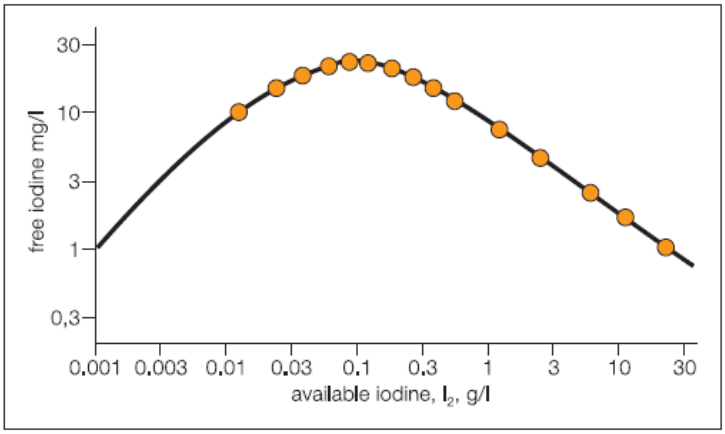
Iodide (I^-) = *reaction partner of available iodine in the iodophor*

Triiodide (I_3^-) = *iodine species bound in iodophor-complex, reaction product of I_2 and I^-*

Total iodine = *sum of available iodine + iodide content*

Free iodine (free I_2) = *non-complexed iodine that can be determined via dialysis or in an electrochemical model, microbial activity is proportional to the free iodine content*

In aqueous solutions of iodophors, an equilibrium is formed between I_2, I^- and I_3^-. However, according to Ref [1] and [2], the concentration of free iodine in solutions is extremely low. Of note, the free iodine content is inversely proportional to the concentration of available iodine. The relationship between available iodine and free iodine can be described as follows (Ref [1]):


30
10
3
1
0,3
free iodine mg/l
0.001 0.003 0.01 0.03 0.1 0.3 1 3 10 30
available iodine, I_2, g/l

At a typical concentration of 0.5% available iodine (5 g/L), only about 0.0005% free iodine (5 mg/L) are present in solution. Only this minor fraction may contribute to vapour above the solution.

The content of free iodine (I_2) in solid iodophor complexes is predicted to be zero based on the inverse relationship between available iodine and free iodine. Consequently, no iodine is expected to evaporate from dried residues. In other words: no secondary exposure of the professional user towards iodine vapour is possible when all the water has been evaporated.

Finally, in the iodine dossier (document "Iodine Final Doc II-B2 PT3.docx") the following is mentioned in chapter 8.3.3.2 Uptake via inhalation (p. 58): *"The evaporation of iodine from water-based products is assumed to be very low. Iodine is supposed to react immediately with organic matter (microorganisms, protein substances etc.), also by formation of different iodine species (iodide etc.). For these reasons and with respect of the natural background values in the air (ambient air: 10 to 20 ng/m^3. marine air: 100 µg/m^3), iodine evaporation and – consequently - contamination of the air is regarded as negligible due to teat disinfection."*

Consequently, the argument that inhalation exposure towards iodine vapour is negligible in practice is also supported by the mode of action of iodine.

Conclusion
Iodine used for teat disinfection in PT3 is complex-bound to iodophors in the form of triiodide (I_3^-).

In aqueous solutions, the bound triiodide releases only minute fractions of free (molecular) iodine (I_2).

Free iodine (I_2) immediately reacts with organic matter and forms ionic iodine species such as iodide (I^-) which do not tend to evaporate.

Residual free iodine (I_2) in aqueous solutions, if at all present, is considered to lead to negligible exposure towards iodine vapour.

References

Ref [1]

Technical Information PVP-Iodine grades, BASF group, August 2010

TDS_BASF_PVP-Iodine-grades.pdf

Ref [2]

Tatsuo Kaiho, 2015, Iodine Chemistry and Applications, Wiley, p. 387

20.3.2.1 Iodophors

An iodophor is a complex of iodine with a carrier that has at least three functions: (i) to increase the solubility of iodine, (ii) to provide a sustained-release reservoir of the halogen, and (ii) to reduce the equilibrium concentration of free molecular iodine. The carriers are neutral polymers, such as polyvinyl pyrrolidinone, polyether glycols, polyvinyl alcohols, polyacrylic acid, polyamides, polyoxyalkylenes, and polysaccharides.

In the solid state iodophors form crystalline powders of a deep brown to black color that usually do not smell of iodine, indicating a tight bonding with the carrier molecules. Their solubility in water is good but depends on the chain length of the polymeric molecules and varies in the case of povidone–iodine between 5% (type 90/04, average molecular weight near 1,000,000) and more than 20% (type 17/12, average molecular weight near 10,000). The best-known iodophor is povidone–iodine, a compound of 1-vinyl-2-pyrrolidinone polymer with iodine, which according to USP XXIII contains not less than 9.0% and not more than 12.0% available iodine. On the basis of spectroscopic investigations [44], it was found that povidone–iodine (in the solid state) is an adduct not with molecular iodine (I_2) but with hydrotriiodic acid (HI_3), where the proton is fixed via a short hydrogen bond between two carbonyl groups of two pyrrolidinone rings and the triiodide anion is bound ionically to this cation.

A completely different situation occurs in solution where this structure no longer exists and equilibria between I_2, I^-, I_3^-, and the polymeric organic molecules are established (Eqs. 20.11–20.13). The high amount of carrier molecules (~90 g l^{-1}) results in the content of free molecular iodine being greatly reduced in such preparations (10% aqueous solution of povidone–iodine: $c(I_2) \approx c(I^-) \approx 0.04\,M\,l^{-1}$), $[I_2] \approx 1 \times 10^{-5}\,M\,l^{-1}$ or 2.54 ppm), in comparison with pure aqueous solutions with the same total iodine and total iodide content (aqueous iodine solution: $c(I_2) = c(I^-) = 0.04\,M\,l^{-1}$, pH 5: $[I_2] = 5.77 \times 10^{-3}\,M\,l^{-1}$ or 1466 ppm[3]). The high content of free iodide (which varies between 10^{-3} and $10^{-1}\,M\,l^{-1}$, according to the preparation) also means that HOI can be disregarded, and only I_2 is responsible for disinfection (see earlier).

Calculations for Scenario [1] – mixing and loading of RTU for dip or trigger sprayer

Mixing and loading of RTU for dip/foam cup or trigger sprayer - 1x/day (for pre- or post-milking)			
Dermal exposure: Mixing/Loading model 4 - Professional pouring liquid (TNsG, 2002); model covers all relevant M/L tasks performed on an 8-hour working day Inhalation exposure: not relevant Acc. to HEAdhoc Recommendation no. 13 (Jan. 2017)			
		Tier 1	**Tier 2 gloves**
Product	**Units**		
Density	g/ml	1	1
Active substance	% w/w	0,5	0,5
Body weight	kg	60	60
Dermal penetration rate	%	12	12
Dermal exposure			
Indicative value (hands)	ml/treatment	0,20[1]	0,20[1]
Duration	min	n.r.	n.r.
Potential hand deposit [product]	mg	200,0	200,0
penetration through gloves	%	100	10
Actual dermal deposit [product]	mg	200,0	20,0
Total dermal exposure			
Total dermal deposit [a.s.]	mg	1,000	0,100
Penetration through skin [a.s.]	mg	0,120	0,012
Number of applications/day	counts	1	1
Systemic exposure via dermal route	**mg/kg bw/day**	**2,00E-03**	**2,00E-04**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**20,00**	**2,00**
Exposure by inhalation			
not relevant			
Total systemic exposure	**mg/kg bw/day**	**2,00E-03**	**2,00E-04**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**20,00**	**2,00**

[1] For the dermal exposure , the total amount of the required solution that is needed per day is of importance. Based on the dietary risk assessment only pre- **or** post-milking is allowed. Automatically, cows are miked three times a day (i.e. manually cows are milked twice a day) , therefore for the worst case the amount needed for one day is:15ml product x 3 times a day = 60 ml.

Considering 82 cows, this results in a total amount of product per day of 60 ml x 82 cows = 5 L product/day.
For mixing and loading model 4, the indicative hand exposure for handling 5 L is 0.2 ml/treatment is used.

Calculations for Scenario [2.2] - Application of teat disinfectant by spraying using a trigger sprayer: iodine

Consumer spraying and dusting model 2 Hand-held trigger spray		Tier 1	Tier 2
Product			
active substance	% w/w	0,5	0,5
body weight	kg	60	60
dermal absorption	%	12	12
Dermal exposure			
Potential hand/forearm exposure			
indicative value	mg/min	36,1	36,1
duration	min	13,7	13,7
potential hand deposit	mg	493,37	493,37
penetration through gloves	%	100	10
actual hand deposit	mg	493,37	49,34
Potential legs, feet and face exposure			
indicative value	mg/min	9,7	9,7
duration	min	13,7	13,7
potential legs, feet and face deposit	mg	132,5667	132,5667
penetration through clothing	%	100	10
actual legs, feet and face deposit	mg	132,57	13,26
Total dermal dermal exposure			
total dermal deposit (a.s.)	mg	3,13	0,31
penetration through skin (a.s.)	mg	0,38	0,04
number of applications	counts	2,00	2,00
systemic exposure via dermal route	**mg/kg bw/d**	**1,25E-02**	**1,25E-03**
% Upper intake level	**%**	**125,19**	**12,52**
Inhalation exposure			
indicative value	mg/m3	10,5	10,5
duration	min	13,7	13,7
inhalation rate	m3/min	0,02	0,02
inhaled volume	m3	0,28	0,28
inhaled product	mg	2,99	2,99
inhaled a.s.	mg	0,01	0,01
inhaled a.s.	m/m3	0,05	0,05
number of applications	counts	2,00	2,00
systemic exposure via inhalation route	**mg/kg bw/d**	**4,98E-04**	**4,98E-04**
% Upper intake level	**%**	**4,98**	**4,98**
active substance	**mg/m3**	**5,25E-02**	**5,25E-02**
OEL	**mg/m3**	**1**	**1**
% OEL	**%**	**5,25**	**5,25**
Total systemic exposure	**mg/kg bw/d**	**1,30E-02**	**1,75E-03**
% Upper intake level	**%**	**130,17**	**17,50**

Calculations for Scenario [3.1]-_teat cleaning by wiping with cloth: removal of freshly applied product

Cleaning of teats by wiping with cloth - removal of freshly applied product 2x/day (pre-milking)

Dermal exposure: generic approach, worst case estimate: 0.1% of the amount on the surface area contacts the palm of the hands. Application of layer thickness (44 cm2/teat x 4 teats x 0.01 cm = 1.76 g), assuming 82 cows
Inhalation exposure: not relevant
Acc. to HEAdhoc Recommendation no. 13 (Jan. 2017)

		Tier 1	Tier 2 gloves
Product	**Units**		
Density	g/ml	1	1
Active substance	% w/w	0,5	0,5
Body weight	kg	60	60
Dermal penetration rate	%	12	12
Dermal exposure			
Product amount (film thickness approach, 0.44 g/teat)	mg/cow	1760,00	1760,00
Number of cows	counts	82	82
Product amount	mg	144320,0	144320,0
Product amount with contact to hand (0.1%)	mg	144,3	144,3
Penetration through gloves	%	100	10
Actual dermal deposit [product]	mg	144,3	14,4
Total dermal exposure			
Total dermal deposit [a.s.]	mg	0,722	0,072
Penetration through skin [a.s.]	mg	0,087	0,009
Number of applications/day	counts	2	2
Systemic exposure via dermal route	**mg/kg bw/day**	**2,89E-03**	**2,89E-04**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**28,86**	**2,89**
Exposure by inhalation			
not relevant			
Total systemic exposure	**mg/kg bw/day**	**2,89E-03**	**2,89E-04**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**28,86**	**2,89**

Combined exposure assessment professional uses including residues (see Appendix 1)

BGM ARCHE combined prof exposı

Consumer exposure: Dietary exposure to iodine residues (See appendix 2)

BGM_ARCHE residues.xlsx

3.3 RESIDUE BEHAVIOUR

According to the Iodine assessment report, it was concluded

1. For food & feedstuff residues, in respect of teat dip application, that:
   (1) Compared to samples of control days, the residues in milk sampled on experimental days were 15 – 20 % higher. However, the overall variation in the iodine content of milk by far exceeds the increase noted in this study.
   (2) The average increase of milk iodine content in the publications was about 50 – 174 µg/L, i.e. within the natural variation of the iodine content of milk noted in untreated animals.
   (3) Iodine content in milk may contribute to the compensation of iodine deficiency in food. If the daily dietary intake of iodine exceeds the daily requirements up to 1000 µg/day, it is eliminated without signs of toxicity. Consequently, even very high levels of iodine in milk are of no concern for children.
2. For environmental rout and rate of degradation:
   Non-extractable residues are not applicable, because iodine is an inorganic element
   The level of metabolites in organisms that account for >10% of residues is also not applicable for elements

According to the European Agency for the Evaluation of Medicinal Products, it was agreed that it would be inappropriate to elaborate MRLs for iodine.

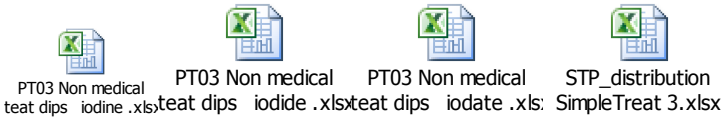
- Iodine is an essential micronutrient for all animal species. Iodine containing salts are also permitted for inclusion in animal feedingstuffs, in accordance with the provisions of Council Directive 70/524/EEC.
- Most iodine compounds are of fairly low acute toxicity and the iodophors, the inorganic iodide and iodates were of considerably lower acute toxicity than iodine itself. JECFA set a provisional maximum tolerable daily intake of 1.0 mg iodine/day (0,017 mg/kg bw)
- Small increases in serum iodine concentration were found after teat dipping, indicating that the procedure had a negligible effect on tissue iodine concentrations.

3.4 SUMMARIES OF THE EFFICACY STUDIES (B.5.10.1-XX)

See 2.3.4 E and IUCLID 6.7

3.5 ENVIRONMENTAL RISK ASSESSMENT

Input parameters, intermediate outcomes, and final results are summarised in the attached Excel documents.



(see Appendices 3-6)

3.6 CONFIDENTIAL ANNEX

See separate document

3.7 OTHER

Not applicable

Appendix 1: Combined exposure assessment professional uses including residues

Active substance	iodine
Formulation	BGM ARCHE

Consumer spraying and dusting model 2 **Hand-held trigger spray**			
		Tier 1	**Tier 2**
Product			
active substance	% w/w	0,38	0,38
body weight	kg	60	60
dermal absorption	%	12	12
Dermal exposure			
Potential hand/forearm exposure			
indicative value	mg/min	36,1	36,1
duration	min	13,7	13,7
potential hand deposit	mg	493,37	493,37
penetration through gloves	%	100	10
actual hand deposit	mg	493,37	49,34
Potential legs, feet and face exposure			
indicative value	mg/min	9,7	9,7
duration	min	13,7	13,7
potential legs, feet and face deposit	mg	132,5667	132,5667
penetration through clothing	%	100	100
actual legs, feet and face deposit	mg	132,57	132,57
Total dermal dermal exposure			
total dermal deposit (a.s.)	mg	2,38	0,69
penetration through skin (a.s.)	mg	0,29	0,08
number of applications	counts	2,00	2,00
systemic exposure via dermal route	**mg/kg bw/d**	**9,51E-03**	**2,76E-03**
% Upper intake level	**%**	**95,14**	**27,65**
Inhalation exposure			
indicative value	mg/m3	10,5	10,5
duration	min	13,7	13,7
inhalation rate	m3/min	0,02	0,02
inhaled volume	m3	0,28	0,28
inhaled product	mg	2,99	2,99
inhaled a.s.	mg	0,01	0,01
inhaled a.s.	m/m3	0,04	0,04
number of applications	counts	2,00	2,00
systemic exposure via inhalation route	**mg/kg bw/d**	**3,79E-04**	**3,79E-04**
% Upper intake level	**%**	**3,79**	**3,79**
active substance	**mg/m3**	**3,99E-02**	**3,99E-02**
OEL	**mg/m3**	**1**	**1**
% OEL	**%**	**3,99**	**3,99**
Total systemic exposure	**mg/kg bw/d**	**9,89E-03**	**3,14E-03**
% Upper intake level	**%**	**98,93**	**31,44**

UL adult	**600 ug/d**	
	0,6 mg/d	
	0,01	mg/kg bw/d

combined systemic exposure from prof uses (post-milking) & residues post-milking

	Tier/PPE	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	total	% UL due to biocidal use	% UL due to biocidal use + iodine from milk due to teat treatment	% UL due to biocidal use + iodine from milk due to teat treatment + iodine from milk background	% UL due to biocidal use + iodine from milk due to teat treatment + iodine from milk background + iodine from other dietary
Manual spraying using a trigger sprayer - RTU (0.38% total iodine)								
Scenarios [1.1; 2.2; 3.2; 4.1]	1	3,79E-04	1,07E-02	1,11E-02	111	139	154	185
	2	3,79E-04	2,88E-03	3,26E-03	33	61	76	107

	Tier/PPE	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	total
Manual spraying using a trigger sprayer - RTU (0.38% total iodine)				
scenario 2.2	1	3,79E-04	9,51E-03	9,89E-03
	2	3,79E-04	2,76E-03	3,14E-03

combined systemic exposure from prof uses (post-milking) & residues post-milking

	Tier/PPE	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	total	% UL due to biocidal use	% UL due to biocidal use + iodine from milk due to teat treatment	% UL due to biocidal use + iodine from milk due to teat treatment + iodine from milk background	% UL due to biocidal use + iodine from milk due to teat treatment + iodine from
Manual dipping - RTU								
Scenarios [1.1; 2.1; 3.2; 4.1]	1	0,00E+00	4,94E-03	4,94E-03	49	77	92	123
	2	0,00E+00	4,94E-04	4,94E-04	5	33	48	79
Manual spraying using a trigger sprayer or electronic sprayer- RTU								
Scenarios [1.1; 2.2; 3.2; 4.1]	1	4,98E-04	1,45E-02	1,50E-02	150	178	193	224
	2	4,98E-04	1,45E-03	1,95E-03	20	48	63	94
Automated dipping/spraying - RTU								
Scenarios [1.1; 2,3; 3.3; 4.2]	1	0,00E+00	2,00E-03	2,00E-03	20	48	63	94
	2	0,00E+00	2,00E-04	2,00E-04	2	30	45	76

combined systemic exposure from prof uses (pre-milking) & residues pre-milking

	Tier/PPE	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	total	% UL due to biocidal use	% UL due to biocidal use + iodine from milk due to teat treatment	% UL due to biocidal use + iodine from milk due to teat treatment + iodine from milk background	% UL due to biocidal use + iodine from milk due to teat treatment + iodine from milk background + iodine from other dietary
Manual dipping - RTU								
Scenarios [1.1; 2.1; 3.1; 4.1]	1	0,00E+00	4,94E-03	4,94E-03	49	73	88	119
	2	0,00E+00	4,94E-04	4,94E-04	5	29	44	75
Manual spraying using a trigger sprayer or electronic sprayer- RTU								
Scenarios [1.1; 2.2; 3.1; 4.1]	1	4,98E-04	1,45E-02	1,50E-02	150	174	189	220
	2	4,98E-04	1,45E-03	1,95E-03	20	44	59	90
Automated dipping/spraying - RTU								
Scenarios [1.1; 2,3; 3.3; 4.2]	1	0,00E+00	2,00E-03	2,00E-03	20	44	59	90
	2	0,00E+00	2,00E-04	2,00E-04	2	26	41	72

summary & residues post-milking

	tier	inhal	dermal	total	% UL due to biocidal use	% UL due to biocidal use + iodine from milke due to teat treatment	% UL due to biocidal use + iodine from milke due to teat treatment + iodine from milk background	% UL due to biocidal use + iodine from milke due to teat treatment + iodine from milk background + iodine from other dietary sources
scenario 1,1								
0,5% total iodine	1		2,00E-03	2,00E-03	20	48	63	94
	2		2,00E-04	2,00E-04	2	30	45	76
scenario 2,1								
Exposure is considered covered by the mixing and loading scenario.								
scenario 2,2								
0,5% total iodine	1	4,98E-04	1,25E-02	1,30E-02	130	158	173	204
	2	4,98E-04	1,25E-03	1,75E-03	17	45	60	91
scenario 2,3								
No exposure of professionals occurs during automated dipping or spraying								
scenario 3,2								
Exposure of professionals considered to be negligible during cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatmen								
scenario 3,3								
No exposure of professionals occurs during cleaning of teats by robot.								
scenario 4,1								
0,5% total iodine	1		4,60E-05	4,60E-05	0	28	43	74
	2		4,60E-06	4,60E-06	0	28	43	74
scenario 4,2								
No exposure of professionals occurs during rinsing of automated dipping/spraying-system								

	adult (0,45 L) estimated daily intake (µg/day)
3x post-milking, 0.5%	
treatment	170
	28
total milk intake	260
	43
total dietary intake	445
	74

summary & residues pre-milking

	tier	inhal	dermal	total	% UL due to biocidal use	% UL due to biocidal use + iodine from milke due to teat treatment	% UL due to biocidal use + iodine from milke due to teat treatment + iodine from milk background	% UL due to biocidal use + iodine from milke due to teat treatment + iodine from milk background + iodine from other dietary sources
scenario 1,1								
0,5% total iodine	1		2,00E-03	2,00E-03	20	44	59	90
	2		2,00E-04	2,00E-04	2	26	41	72
scenario 2,1								
Exposure is considered covered by the mixing and loading scenario.								
scenario 2,2								
0,5% total iodine	1	4,98E-04	1,25E-02	1,30E-02	130	154	169	200
	2	4,98E-04	1,25E-03	1,75E-03	17	41	56	87
scenario 2,3								
No exposure of professionals occurs during automated dipping or spraying								
scenario 3,1								
0,5% total iodine	1		2,89E-03	2,89E-03	29	53	68	99
	2		2,89E-04	2,89E-04	3	27	42	73
scenario 3,3								
No exposure of professionals occurs during cleaning of teats by robot.								
scenario 4,1								
0,5% total iodine	1		4,60E-05	4,60E-05	0	24	39	70
	2		4,60E-06	4,60E-06	0	24	39	70
scenario 4,2								
No exposure of professionals occurs during rinsing of automated dipping/spraying-system								

	adult (0,45 L) estimated daily intake (µg/day)
3x pre-milking, 0.5%	
treatment	145
	24
total milk intake	235
	39
total dietary intake	420
	70

Appendix 2: Combined exposure: Dietary exposure to iodine residues

	% iodine	application	mean residue (mg/kg)	mean treated residue (µg/kg)	mean control residue (µg/kg)	density milk (kg/L)	mean treated residue (µg/L)	mean control residue (µg/L)	mean control residue (µg/L)
O'Brien	0,5	2x post milking	461	244	217	1,03	251	224	259
		2x pre- milking	426	209			215		
		2x pre-and post milking	670	453			467		

Background in milk (Secure Webex meeting, okt 2017) 200

			mean treated residue (µg/L)	mean treated residue (µg/L) + background milk
BGM/ARCI	0,5	3x post milking	377	577
		3x pre- milking	323	523
		3x pre-and post milking	700	900

	milk intak (L/day)
adult	0,45
infant	0,46

other dietary intake
discussed in WebExmeeting 3-10-2017
concluded - 185 µg/d for adult, 96 µg/d for infant based on UK data

BGM/ARCHE		**adult (0,45 L)** estimated daily intake (µg/day)	**infant (0,46 L)** estimated daily intake (µg/day)
	3x post milking		
	treatment	170	173
		28	87
	total milk intake	260	265
		43	133
	total dietary intake	445	361
		74	181
	3x pre- milking		
	treatment	145	149
		24	74
	total milk intake	235	241
		39	120
	total dietary intake	420	337
		70	168
	3x pre-and post milking		
	treatment	315	322
		52	161
	total milk intake	405	414
		67	207
	total dietary intake	590	510
		98	255

Appendix 3: PT03 Non medical teat dips iodine

ctgb Board for the Authorisation of Plant Protection Products and Biocides

Sewage Treatment Plant - 9-box

Product	**Boumatic Iodine product family**
Active substance	**Iodine incl metabolites**
Application number	**20150623**

system characteristics

Variable	Value	Unit	Origin
general			
Height air column	10	m	D
Area of the plant	0,04	m²/PE	D
raw sewage			
Input solids in raw sewage	0,09	kg dwt/PE/d	D
Density solids raw sewage	1,5	kg dwt/L	D
C susp solids raw sewage	0,45	kg dwt/m³	O
Fraction oc raw sewage	0,3	-	D
BOD in raw sewage	54	g BOD/PE/d	D
primary sedimentation			
Depth PS	4	m	D
HRTPS	2	h	D
Volume PS	0,016666667	m³/PE	O
Area PS	0,004166667	m²/PE	O
C susp solids PS	0,15	kg dwt/m³	O
Fraction oc solids PS	0,3	-	D
Density solids PS	1,5	kg dwt/L	D
aerator			
Depth aerator	3	m	D
HRT	6,9	h	O
Volume aerator	0,0575	m³/PE	O
Area	0,019166667	m²/PE	O
Oxygen requirement	0,1725	kg BOD/m³	O
Oxygen concentration	0,002	kg O_{2wf}	D
Aeration rate	0,0000131	m³/s/PE	D
C activated sludge	4	kg dwt/m³	D
Fraction oc activated sludge	0,37		D
Density solids activated sludge	1,3	kg dwt/L	D
solids liquid separation			
Depth SLS	3	m	D
HRTSLS	6	h	D
Volume SLS	0,05	m³/PE	O
Area SLS	0,016666667	m²/PE	O
C susp solids SLS	0,03	kg dwt/m³	D
Fraction oc solids SLS	0,37		D
Density solids SLS	1,3	kg dwt/L	D
sludge loading characteristics			
F BOD removal	0,898058463	-	O
Y BOD	0,806802833	kg dwt/kg BOD	O
Surplus sludge	0,018997186	kg dwt/PE/d	O
Emitted solids in effluent	0,006	kg dwt/PE/d	O
SRT	9,201035712	d	O
Sludge loading rate	0,15	kg BOD/kg dwt/d	O
Advective transport from i to j: ADV(i,j)			
ADV(0,1)	600	m³/s	O
ADV(1,0)	600	m³/s	O
ADV(0,2)	0,023148148	m³/s	O
ADV(2,5)	0,023148148	m³/s	O
ADV(0,3)	6,94444E-06	m³/s	O
ADV(3,4)	4,62963E-06	m³/s	O
ADV(3,6)	2,31481E-06	m³/s	O
ADV(4,0)	4,62963E-06	m³/s	O
ADV(5,7)	0,023148148	m³/s	O
ADV(6,8)	7,12251E-05	m³/s	O
ADV(7,0)	0,023148148	m³/s	O
ADV(8,0)	5,34188E-07	m³/s	O
ADV(8,9)	7,06909E-05	m³/s	O
ADV(9,6)	6,89995E-05	m³/s	O
ADV(9,0)	1,69134E-06	m³/s	O
7,13144E-05	= aer in	7,12251E-05	= aer out
volume(i) of box i			
V(1)	4000	m³	O
V(2)	166,6666667	m³	O
V(3)	0,016666667	m³	O
V(4)	4,166666667	m³	O
V(5)	575	m³	O
V(6)	1,769230769	m³	O
V(7)	500	m³	O
V(8)	0,011538462	m³	O
V(9)	16,66666667	m³	O
external concentration chemical C(0,i) in medium i			
C(0,2)	0,001305768	g/m³	O
C(0,3)	0,097440957	g/m³	O

interaction between chemical and system

Variable	Value	Unit	Origin
physico-chemical characteristics			
pKw	14,36173	-	D
pH	7	-	D
partition coefficients			
Kp raw sewage	49,749	L/kg dwt	O
Kp PS	49,749	L/kg dwt	O
Kp aerator	61,3571	L/kg dwt	O
Kp SLS	61,3571	L/kg dwt	O
Kair_water_STP	1,69183E-10	-	O
Sablic1	0,81		D
Sablic2	0,1		D
fugacity capacity Z(i) in box i			
Z(1)	0,000417636	mol/m³/Pa	O
Z(2)	2468542,147	mol/m³/Pa	O
Z(3)	184211254,9	mol/m³/Pa	O
Z(4)	184211254,9	mol/m³/Pa	O
Z(5)	2468542,147	mol/m³/Pa	O
Z(6)	196901363,5	mol/m³/Pa	O
Z(7)	2468542,147	mol/m³/Pa	O
Z(8)	196901363,5	mol/m³/Pa	O
Z(9)	196901363,5	mol/m³/Pa	O

exchange rate parameters

Variable	Value	Unit	Origin
air-water in non-aerated basins			
Mackay et al. (1985):			
K airM	0,00278	m/s	D
K waterM	0,0000278	m/s	D
K pore waterM	0,00000278	m/s	D
Liss & Slater (1974):			
K airL&S	0,002219221	m/s	O
K waterL&S	2,31313E-05	m/s	O
Schwarzenbach et al. (1993):			
K airS	0,003708928	m/s	O
K waterS	4,21208E-06	m/s	O
K air	0,00278	m/s	O
K water	0,0000278	m/s	O
air-water in aerated basins			
Psi	0,6	-	D
kGa/kLa	40	-	D
DO2	0,007	kg O_2/m³	O
gas phase correction	6,76732E-09	-	O
ksurf	4,02817E-12	/s	O
1) Factor Blackburn et al. (1984)	0,000504	-	D
2) Factor Hsieh et al. (1993b)	0,00089	-	D
kbubble1)	2,39847E-14	/s	O
kbubble2)	4,55885E-14	/s	O
kbubble	4,55885E-14	/s	O
kstrip	4,02817E-12	/s	O
kvolatilization	0,000278	/s	O
k aerator	0,000278	/s	O
solids-water half-lives for uptake & clearance			
t1/2 PS	3600	s	D
t1/2 aeration	360	s	D
t1/2 SLS	3600	s	D
Interphase transfer coefficients			
D(1,2) D(2,1)	4,83761E-05	mol/Pa/s	O
D(1,7) D(7,1)	0,000193504	mol/Pa/s	O
D(1,5) D(5,1)	0,00022253	mol/Pa/s	O
D(2,3) D(3,2)	586,7580355	mol/Pa/s	O
D(5,6) D(6,5)	538564,1028	mol/Pa/s	O
D(7,8) D(8,7)	436,6373816	mol/Pa/s	O

degradation rate parameters

Variable	Value	Unit	Origin
Monod kinetics			
Ctotal in settled sewage	0,001315512	mg/L	O
K decay	0,054341708	/d	O
SRT critical	50	d	O
mact	0,163025125	/d	O
Cout	0,001315512	mg/L	O
kmonod	0	/h	O
k biodeg in aqueous phase	0	/h	O
k biodeg in solids	0	/h	O
first order biodegradation rate constant in box i			
k (5)	0	/s	O
k (6)	0	/s	O
Diffusive transport from i to j: XCH(i,j)			
XCH(1,2)	0,115833331	m³/s	O
XCH(2,1)	1,9597E-11	m³/s	O
XCH(1,5)	0,532833332	m³/s	O
XCH(5,1)	9,01464E-11	m³/s	O
XCH(1,7)	0,463333325	m³/s	O
XCH(7,1)	7,83882E-11	m³/s	O
XCH(2,3)	0,000237694	m³/s	O
XCH(3,2)	3,18525E-06	m³/s	O
XCH(5,6)	0,218170917	m³/s	O
XCH(6,5)	0,002735197	m³/s	O
XCH(7,8)	0,000176881	m³/s	O
XCH(8,7)	2,21754E-06	m³/s	O
XCH(2,4)		m³/s	O
XCH(4,2)		m³/s	O
XCH(7,9)		m³/s	O
XCH(9,7)		m³/s	O

mass balance computation (9 boxes)

coef_9box_	1	2	3	4	5	6	7	8	9	constant
box 1	601,112	-1,96E-11	0	0	-9,01E-11	0	-7,84E-11	0	0	0
box 2	-0,115833	0,0233858	-3,19E-06	0	0	0	0	0	0	3,02261E-05
box 3	0	-0,000238	1,013E-05	0	0	0	0	0	0	6,76673E-07
box 4	0	0	-4,63E-06	4,63E-06	0	0	0	0	0	0
box 5	-0,532833	-0,023148	0	0	0,2413191	-0,002735	0	0	0	0
box 6	0	0	-2,31E-06	0	-0,218171	0,0028064	0	0	-6,9E-05	0
box 7	-0,463333	0	0	0	-0,023148	0	0,023325	-2,22E-06	0	0
box 8	0	0	0	0	0	-7,12E-05	-0,000177	7,344E-05	0	0
box 9	0	0	0	0	0	0	0	-7,07E-05	7,069E-05	0

coef_1_9box_	1	2	3	4	5	6	7	8	9	concentration	
box 1	0,0016636	1,336E-11	6,945E-12	0	1,202E-11	1,201E-11	5,678E-12	1,145E-11	1,172E-11	9boxC 1	4,08595E-16	g/m³
box 2	0,0082664	42,898018	13,489131	0	5,973E-11	5,966E-11	2,821E-11	5,69E-11	5,823E-11	9boxC 2	0,001305768	g/m³
box 3	0,1939714	1006,6062	99036,23	0	1,402E-09	1,4E-09	6,62E-10	1,335E-09	1,366E-09	9boxC 3	0,097440957	g/m³
box 4	0,1939714	1006,6062	99036,23	216000	1,402E-09	1,4E-09	6,62E-10	1,335E-09	1,366E-09	9boxC 4	0,097440957	g/m³
box 5	0,04646	42,671793	23,199598	0	42,871741	42,804549	0,3050321	40,224201	41,78041	9boxC 5	0,001305501	g/m³
box 6	3,7050014	3401,7682	1932,6784	0	3416,8534	3776,5295	26,91216	3548,8724	3686,1725	9boxC 6	0,104129992	g/m³
box 7	0,0795132	42,671617	23,207177	0	42,871485	42,837957	43,18749	41,550391	41,813019	9boxC 7	0,0013055	g/m³
box 8	3,784633	3401,8256	1930,2153	0	3416,9366	3765,6718	130,11319	17157,861	3675,5746	9boxC 8	0,10413006	g/m³
box 9	3,784633	3401,8256	1930,2153	0	3416,9366	3765,6718	130,11319	17157,861	17821,67	9boxC 9	0,10413006	g/m³

9boxin	3,09E-05	g/s	0,00267	kg/d
9boxout	3,09E-05	g/s	0,00267	kg/d
D	6,099E-20	g/s	5,269E-18	kg/d

Appendix 4: PT03 Non medical teat dips iodide

ctgb Board for the Authorisation of Plant Protection Products and Biocides

Non-medical teat dips (PT03)

Legend and explanation

Colour	Symbol	Explanation
	S	Required input
	S	Optional input
	D	Default value
	P	Default value from pickup-list
	O	Intermediate results
	O	Final results

Worksheet	Explanation
Input	Add all the necessary input data here
Defaults	Scenario-related default values
Fate	Defaults and intermidiate calculation regarding distribution in the environment
PECs	Predicted environmental concentrations after one year
PEcs10Years	Predicted environmental concentrations after ten year
Other	Additional outcomes such as pore water concentrations and PEARL dosages
Summary	Ready to copy table with final results

Reference

Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, JRC Scientific and Technical Reports, Report nr. EUR 25116 EN, Publications Office of the European Union, Luxembourg, 2011

Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B: Risk Assessment (Active Substances). European Chemicals Agency, Report no. ECHA-15-G-01-EN, Helsinki, Finland

Notes

Emission to soil and groundwater after the spreading of manure on land from indoor use of teat dips. In line with the current national assessment of plant protection products, run off and drain surface water of treated manure spread on grassland or arable land is not taken into account in the risk assessment. Direct emission to surface water after spreading manure on land is not expe agricultural practice includes incorporation of manure. The relevant environmental compartments therefore are soil and groundwater.

Emission of diluted liquid waste stream from cleaning activities. As a matter of fact most indoor surfaces will be cleaned. The cleaning step will lead to releases either to wastes (manure storage waste water (STP). Therefore, in the ESD for teat dips the sewage treatment plant (STP) is considered as “receiving compartment”. Release to and exposure of the STP is not considered relevant cattle farms. Discharge of manure on the sewage system or on surface water is not permitted. Manure and liquid manure waste streams are collected and spread on land.

Versions

Version	Date	Details
V1.1	24-08-2011	- All input paramters are transfered to the input-tab. - Degradation between two manure events on grassland is now included. Final concentrations are time-weighed averaged over 30 days.
V2.0	20-02-2014	- The sheet now calculates the concentration after one year, i.e. one manure application on grassland and four manure applications on arable land. PECgrassland is deriv PECarableland by using a correction factor representing the differences in mixing depth. Because, based on nitrogen imission standards, the annual amount of manure a arable land and grassland is equal and both receives the same amount of biocide annually, the amount that is mixed into the soil is equal as well. However, manure is m the top 5-10 cm in grassland, but until 20 cm in arable land, the concentrations in grassland is always 2 (manure is injected) to 4 (manure is distributed) times higher. Th factors are 2.58 and 5.16 for injection and distribution, respectively, in case of phosphate standards. Degradation between two manure events is included. Here, PECgra divided by the number of manure applications holding biocides (four in case of teat dips) and calculate the remaining concentration after the fourth manure application - the ROUND command is removed to calculate the number of biocide applications directed to the manure. - layout adjustments
V3.0	10-07-2015	Major lay-out update; Sheet now calculates concentrations in pore water, concentrations after 10 years, and dosage to be entered in PEARL; Leaching from soils is now included; Kp soil is added as an optional input parameter; Sheet is now applicable for both fertilisation by injection and spreading; An option is added for three milkings per day (robots) as well as pre- and postdipping
V3.1	12-01-2016	PECs for arable land are no longer calculated from the concentration in arable land using a correction factor.
V3.11	16-03-2016	Some typos were corrected
V3.2	07-04-2016	PECs for soils were not adjusted for >2 biocide application per day. This is now corrected.
V3.3	24-06-2016	- First tier assessment for adjacent surface water is added; - PECs after ten years and PECs for surface water are added to the summary tables - lay-out updates
V3.31	05-07-2016	- some typos were corrected; - layout improvements
V3.40	30-03-2017	- volume per treatment is added as an optional input parameter; - it is now possible to choose between initial and time-weighed average PNECs for soils depending on how PNECs were derived. - layout improvements

ctgb Board for the Authorisation of Plant Protection Products and Biocides

Non-medical teat dips (PT03)

Product	Boumatic Iodine product family
Compound	iodide (I-)
Application number	20150623

Environmental Emission

Parameter	Symbol	Value	Unit	Origin	Remarks
Content of active ingredient in formulation (product)	Fbioc	5	g/L	S	
Dilution factor (for preparation of the working solution from the formulation (product))	Fdil	1	-	S	
Volume applied per cow and treatment	Vprod_usr	6,5	mL	S	If left empty, the default value (10 mL for dipping) is applied instead. Note that actual consumption should be substantiated experimentally.
Manure distribution on grassland	Manure_application	Spreading	-	S	This parameters determines the mixing depth for grassland: - **Spreading**: mixing depth is 5 cm. Use this value for BPR; - **Injection:** mixing depth is 10 cm (manure is injected).
Applied in milking robots?	Robot	No	-	S	Choose 'Yes' if the product is applied in milking robots. This increases the number of daily teat dipping events from two to three as cowms are milked up to three times daily in milking robots.
Applied pre- and post milking?	Milking	No	-	S	Choose 'Yes' if teats are disinfected both prior and after milking.
PEC based on initial or time-weighed average (TWA) concentrations?	PECtype	Initial	-	S	- **Initial:** PNECsoil is based on nominal concentrations. PECs are therefore based on nominal concentrations (PIECs) as well, but disappearance between two manure applications is still considered; - **TWA:** PNECsoil is based on mean measured exposure concentrations, time-weighed average concentrations, or similar. PECs are therefore calculated as time-weighed average concentrations over 30 days after the peak.

Predicted No Effect Concentrations (PNECs)

Parameter	Symbol	Value	Unit	Origin	Remarks
PNEC for surface water (fresh)	PNECwater	0,00083	mg/kg wwt	S	Only relevant for active substances that are mobile in soils
PNEC for sediment (freshwater)	PNECsed		mg/kg wwt	S	
PNEC for terrestrial invertebrates	PNECsoil	0,0043	mg/kg wwt	S	

Environmental Fate and Behaviour

Parameter	Symbol	Value	Unit	Origin	Remarks
Molecular weight	molw	253,8	g/mol	S	
Experimental vapour pressure at test temperature	VP_exp	4,07E+01	Pa	S	
Temperature at which vapour pressures is determined	VP_exp_temp	25	°C	S	
Experimental solubility at test temperature	SOL_exp	300	mg/L	S	
Test temperature at which solybility is determined	SOL_exp_temp	25	°C	S	
Experimental Henry's law constant	HENRY_exp		$Pa/m^3/mol$	S	Leave blank if no experimental Henry's constant is available.
Temperature at which Henry's law constant is determined	HENRY_exp_temp		°C	S	
Organic carbon-water partitioning coefficient (K_{oc})	Koc		L/kg	S	
Experimentally derived solid-water partition coefficient in soil	Kp_soil_exp	5,8	L/kg	S	Leave blank if no experimentalvalues are available.
Experimentally derived solid-water partition coefficient in suspended matter	Kp_susp_exp	220	L/kg	S	Leave blank if no experimentalvalues are available.
Half-life for biodegradation in soil	DT50deg_soil	1,00E+06	day	S	Leave empty when biodegradation is not relevant or no data available.

ctgb Board for the Authorisation of Plant Protection Products and Biocides

Non-medical teat dips (PT03)

Product	Boumatic Iodine product family
Compound	iodide (I-)
Application number	20150623

Parameter	Symbol	Value	Unit	Origin	Remarks
Amount of product prescribed to be used for one treatment (dipping of the four teats) of one animal	Vprod	0,007	L	S	Default value is 10 mL/cow/treatment for dipping as agreed at WGV-2016. Will be replaced by an experimental-derived value (e.g. field tests) when available.
Fraction of active ingredient released	($F_{stp} = F_{ww}$) F_{stp}	0,5	-	D	
	$F_{slurry/manure}$	0,5	-	D	
	F_{air}	0	-	D	
	F_{teat}	0,5	-	D	
Number of daily milking events	milking_day	2	-	O	The ESD assummes two milking per day. However, cows are milked three times a day in milking robots
Number of teat dippings per milking	teat_milking	1	-	O	The ESD assumes teat dipping prior OR after milking. However, some products are applied both pre- AND post milking
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	-	O	
Number of days of lactation period	Nday-lact	300	-	D	
Number of disinfectant applications in one year (equals number of disinfectant applications in one lactation period)	Napp-bioc	600	-	D	
Interval between two disinfectant applications (dipping events)	Tbioc-int	0,50	d	D	The ESD assumes only pre- or post milking applications twice a day and therefore Tbioc-int is 0.5 d by default. For pre- and post milking, as well as application in milking robots (three times a day), the interval between two events must be adjusted accordingly. Note that PECsoil is not directly calculated from Napp-teat, but from Tbioc-int. Although a value of e.g. 0.25 suggest that the interval between two applications is 6 hrs, emission is still based on four daily applications.
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	Tgr-int	53	d	D	
Manure application time interval for arable land	Tar-int	212	d	D	
Number of animals in housing for category/subcategory *i1* =1	Nanimal	100	-	P	
Amount of phosphate per animal for category/subcategory *i1* =1	Qphosph	0,10466	kg/d	P	
Amount of nitrogen per animal for category/subcategory *i1* =1	Qnitrog	0,3389	kg/d	P	
Phosphate immission standard for one year on grassland	$Q_{P2O5,grassland}$	110	kg/ha	D	
Phosphate immission standard for one year on arable land	$Q_{P2O5,arable\_land}$	85	kg/ha	D	
Nitrogen immission standard for one year on grassland	$Q_{N,grassland}$	170	kg/ha	D	
Nitrogen immission standard for one year on arable land	$Q_{N,arable\_land}$	170	kg/ha	D	
Mixing depth with soil, grassland	$DEPTH_{grassland}$	0,05	m	D	
Mixing depth with soil, arable land	$DEPTH_{arable\_land}$	0,2	m	D	
Density of wet bulk soil	RHOsoil	1700	kg/m³	D	
Averaging time	T	30	d	D	

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Non-medical teat dips (PT03)

Product	Boumatic Iodine product family
Compound	iodide (I-)
Application number	20150623

Degradation

Parameter	Symbol	Value	Unit	Origin	Remarks
First order rate constant for degradation in bull	kbio_soil	6,93E-07	/day	o	

Correction of vapour pressure, solubility, and Henry's constant for 12°C

Parameter	Symbol	Value	Unit	Origin	Remarks
Environmental temperature	TEMP_env	285	K	D	
Enthalpy of vapourisation	H0_VP	50000	J/mol	D	
Enthalpy of solution	H0_SOL	10000	J/mol	D	
Gas constant	R_	8,314	Pa m³/mol/K	D	
Vapour pressure at the environmental temperature	VP	16,2	Pa	O	
Solubility at the environmental temperature	SOL	249,6	mg/L	O	
Henry's constant at the environmental temperature	HENRY	16,5	Pa m³/mol	O	

Soil partitioning coefficients

Parameter	Symbol	Value	Unit	Origin	Remarks
Air-water partition coefficient	Kair_water	6,96E-03	-	O	TGD formula 22
Density of the solid phase	RHOsolid	2,50E+03	-	O	TGD formula 24
Volume fraction of water in soils	Fwater_soil	0,2	-	D	TGD default (table 5)
Volume fraction of solids in soils	Fsolid_soil	0,6	-	D	TGD default (table 5)
Volume fraction of air in soils	Fair_soil	0,2	-	D	TGD default (table 5)
Weight fraction of organic carbon in soils	Foc_soil	0,02	-	D	TGD default (table 5)
Partition coefficient solid-water in soils	Kp_soil	5,80	-	O	TGD formula 23
Soil-water partitioning coefficient	Ksoil_water	8,90	-	O	TGD formula 24

Leaching from soils

Parameter	Symbol	Value	Unit	Origin	Remarks
Fraction of rain water that infiltrates into soil	Finf_soil	0,25	-	D	TGD formula 58
Rate of wet precitipation (700 mm/year)	RAINrate	1,92E-03	m/d	D	TGD formula 58
First-order rate constant for leaching from soil layer (grassland)	kleach_gr	1,08E-03	/d	O	TGD formula 58
Half-life for leaching from soils (grassland)		642,71	d	O	
First-order rate constant for leaching from soil layer (arable land)	kleach_ar	2,70E-04	/d	O	TGD formula 58
Half-life for leaching from soils (arable land)		2570,82	d	O	
First-order rate constant for removal from top soil layer (grassland)	ktot_gr	1,08E-03	/d	O	TGD formula 56
First-order rate constant for removal from top soil layer (arable land)	k_ar	2,70E-04	/d	O	TGD formula 56

Suspended matter partitioning coefficients

Parameter	Symbol	Value	Unit	Origin	Remarks
Effluent dillution factor (fresh water)	dilution	10	-	D	
Concentration of suspended matter in the river	SUSPwater	15	-	D	TGD default (Table 5)
Weight fraction of organic carbon in suspended matter	Foc_susp	0,1	-	D	TGD default (Table 5)
Solid-water partition coefficient in suspended matter	Kp_susp	220,00	-	D	TGD formula 23
Fraction water in suspended matter	Fwater_susp	0,9	-	D	TGD default (Table 5)
Fraction solids in suspended matter	Fsolid_susp	0,1	-	D	TGD default (Table 5)
Suspended matter-water partitioning coefficient	Ksusp_water	55,90	-	O	TGD formula 24
Density of suspended matter	RHOsusp	1150	kg wwt/m³	D	TGD formula 18

ctgb Board for the Authorisation of Plant Protection Products and Biocides

Non-medical teat dips (PT03)

Product	Boumatic Iodine product family
Compound	iodide (I-)
Application number	20150623

Intermediate Calculations

Parameter	Symbol	Value	Unit	Origin	Remarks
Number of biocide applications during storage period for application on grassland	Napp_manure_gr	106	-	O	
Number of biocide applications during storage period for application on arable land	Napp_manure_ar	424	-	O	
Amount of active ingredient to be used for one application (one treatment of one animal)	Qai_prescr	0,0000325	kg	O	
Amount of active ingredient in relevant stream *i4* after one application for all animals	Qai	0,001625	kg	O	
Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to grassland	Qai_grass	0,17225	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-ar	0,689	kg	O	
Amount of phosphate produced during the relevant period for every relevant (sub)category of animal/housing *i1* and application to grassland	Qphosph_grass	554,698	kg	O	
Amount of phosphate produced during the relevant period for every relevant (sub)category of animal/housing *i1* and application to arable land	Qphosph_ar	2218,792	kg	O	
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing *i1* and application to grassland	Qnitrog_grass	1796,17	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_ar	7184,68	kg	O	

Predicted enviromental concentrations

	Symbol	PEC (mg/kg wwt)			Remarks
		no degradation	degradation	leach	
Concentration in soil in the case of an immission standard for **phosphate** and land application on **grassland** (four manure applications)	PECgr_Q	4,02E-02	4,02E-02	3,70E-02	If the PNEC is based on initial concentrations, the PEC is expressed as the concentration during the last manure application. In case of PNEC that are based on actual measured concentration during the soil tests, the PEC is averaged over 30 days after the last manure application. Disappearance between two applications due to degradation and leaching to deeper soil layers is still considered. Concentration in pore water are, however, always based on time-weighed average concentrations as they are not compared with a PNEC, but with the 0.1 µg/L standard. Moreover, when emission to groundwater is assessed using PEARL (tier 2), final concentrations are averaged anyway. Therefore, concentration in pore water based on initial concentrations in soils may results in unnecessary PEARL simulations.
PEC:PNEC		9,35	9,35	8,59	
Concentration in soil in the case of an immission standard for **phosphate** and land application on **arable land**	PECar_Q	7,76E-03	7,76E-03	7,76E-03	
PEC:PNEC		1,81	1,81	1,81	
Concentration in soil in the case of an immission standard for **nitrogen** and land application on **grassland** (four manure applications)	PECgr_N	1,92E-02	1,92E-02	1,76E-02	
PEC:PNEC		4,46	4,46	4,10	
Concentration in soil in the case of an immission standard for **nitrogen** and land application on **arable land**	PECar_N	4,79E-03	4,79E-03	4,79E-03	
PEC:PNEC		1,12	1,12	1,12	

Intermediate calculations for PECs after four manure applications - Phosphate imission standards

Parameter	Symbol	Days since manure application	Concentration (mg/kg wwt)		Remarks
			degradation	leach	
concentration of biocide at fourth manure application:					
initial concentration after one manure application			1,00E-02		
from first manure application		159	1,00E-02	8,46E-03	
from second manure application		106	1,00E-02	8,96E-03	
from third manure application		53	1,00E-02	9,49E-03	
from fourth manure application		0	1,00E-02	1,00E-02	
total concentration in soil directly after fourth manure application	PEC_Nlapp_4_P		4,02E-02	3,70E-02	

Intermediate calculations for PECs after four manure applications - Nitrogen imission standards

Parameter	Symbol	Days since manure application	Concentration (mg/kg wwt)		Remarks
			degradation	leach	
concentration of biocide at fourth manure application:					
initial concentration after one manure application			4,79E-03		
from first manure application		159	4,79E-03	4,04E-03	
from second manure application		106	4,79E-03	4,28E-03	
from third manure application		53	4,79E-03	4,53E-03	
from fourth manure application		0	4,79E-03	4,79E-03	
total concentration in soil directly after fourth manure application	PEC_Nlapp_4_N		1,92E-02	1,76E-02	

Sewage Treatment Plant

Parameter	Symbol	Value	Unit	Origin	Remarks
Local emission to a standard STP or an on-site waste water treatment plant	$Qai\text{-}stp_{i1,i2,i3,i4} = Elocal_{waste\ water}$	2,67E-03	kg/d	O	

ctgb Board for the Authorisation of Plant Protection Products and Biocides

Non-medical teat dips (PT03)

Product	Boumatic Iodine product family
Compound	iodide (I-)
Application number	20150623

Grassland

Manure event	Days since manure application	Concentration (mg/kg wwt)			
		degradation		degradation and leaching	
		phosphate	nitrogen	phosphate	nitrogen
PEC after one emanure event		1,00E-02	4,79E-03	1,00E-02	4,79E-03
1	3444	1,00E-02	4,78E-03	2,44E-04	1,17E-04
2	3391	1,00E-02	4,78E-03	2,59E-04	1,23E-04
3	3338	1,00E-02	4,78E-03	2,74E-04	1,31E-04
4	**3285**	1,00E-02	4,78E-03	2,90E-04	1,38E-04
5	3079	1,00E-02	4,78E-03	3,62E-04	1,73E-04
6	3026	1,00E-02	4,78E-03	3,84E-04	1,83E-04
7	2973	1,00E-02	4,79E-03	4,06E-04	1,94E-04
8	**2920**	1,00E-02	4,79E-03	4,30E-04	2,05E-04
9	2714	1,00E-02	4,79E-03	5,37E-04	2,56E-04
10	2661	1,00E-02	4,79E-03	5,69E-04	2,71E-04
11	2608	1,00E-02	4,79E-03	6,02E-04	2,87E-04
12	**2555**	1,00E-02	4,79E-03	6,38E-04	3,04E-04
13	2349	1,00E-02	4,79E-03	7,96E-04	3,80E-04
14	2296	1,00E-02	4,79E-03	8,43E-04	4,02E-04
15	2243	1,00E-02	4,79E-03	8,93E-04	4,26E-04
16	**2190**	1,00E-02	4,79E-03	9,45E-04	4,51E-04
17	1984	1,00E-02	4,79E-03	1,18E-03	5,64E-04
18	1931	1,00E-02	4,79E-03	1,25E-03	5,97E-04
19	1878	1,00E-02	4,79E-03	1,32E-03	6,32E-04
20	**1825**	1,00E-02	4,79E-03	1,40E-03	6,69E-04
21	1619	1,00E-02	4,79E-03	1,75E-03	8,36E-04
22	1566	1,00E-02	4,79E-03	1,85E-03	8,85E-04
23	1513	1,00E-02	4,79E-03	1,96E-03	9,37E-04
24	**1460**	1,00E-02	4,79E-03	2,08E-03	9,92E-04
25	1254	1,00E-02	4,79E-03	2,60E-03	1,24E-03
26	1201	1,00E-02	4,79E-03	2,75E-03	1,31E-03
27	1148	1,00E-02	4,79E-03	2,91E-03	1,39E-03
28	**1095**	1,00E-02	4,79E-03	3,08E-03	1,47E-03
29	889	1,00E-02	4,79E-03	3,85E-03	1,84E-03
30	836	1,00E-02	4,79E-03	4,08E-03	1,95E-03
31	783	1,00E-02	4,79E-03	4,32E-03	2,06E-03
32	**730**	1,00E-02	4,79E-03	4,57E-03	2,18E-03
33	524	1,00E-02	4,79E-03	5,71E-03	2,72E-03
34	471	1,00E-02	4,79E-03	6,04E-03	2,88E-03
35	418	1,00E-02	4,79E-03	6,40E-03	3,05E-03
36	**365**	1,00E-02	4,79E-03	6,78E-03	3,23E-03
37	159	1,00E-02	4,79E-03	8,46E-03	4,04E-03
38	106	1,00E-02	4,79E-03	8,96E-03	4,28E-03
39	53	1,00E-02	4,79E-03	9,49E-03	4,53E-03
40	0	1,00E-02	4,79E-03	1,00E-02	4,79E-03
PEC based on initial concentrations (mg/kg wwt)		4,01E-01	1,92E-01	1,11E-01	5,31E-02
PEC:PNEC		93,34	44,55	25,88	12,35

Arable land

Manure event	Days since manure application	Concentration (mg/kg wwt)			
		degradation		degradation and leaching	
		phosphate	nitrogen	phosphate	nitrogen
PEC after on emanure event		7,76E-03	4,79E-03	7,76E-03	4,79E-03
1	3285	7,75E-03	4,78E-03	3,19E-03	1,97E-03
2	2920	7,75E-03	4,79E-03	3,53E-03	2,18E-03
3	2555	7,75E-03	4,79E-03	3,89E-03	2,40E-03
4	2190	7,75E-03	4,79E-03	4,29E-03	2,65E-03
5	1825	7,75E-03	4,79E-03	4,74E-03	2,93E-03
6	1460	7,76E-03	4,79E-03	5,23E-03	3,23E-03
7	1095	7,76E-03	4,79E-03	5,77E-03	3,57E-03
8	730	7,76E-03	4,79E-03	6,37E-03	3,94E-03
9	365	7,76E-03	4,79E-03	7,03E-03	4,34E-03
10	0	7,76E-03	4,79E-03	7,76E-03	4,79E-03
PEC based on initial concentrations (mg/kg wwt)		7,75E-02	4,79E-02	5,18E-02	3,20E-02
PEC:PNEC		18,03	11,14	12,05	7,44

ctgb Board for the Authorisation of Plant Protection Products and Biocides

Non-medical teat dips (PT03)

Product	Boumatic Iodine product family
Compound	iodide (I-)
Application number	20150623

Phosphate imission standards - Concentrations in groundwater and PEARL input values

	concentration in pore water (µg/L)		dose to be entered in PEARL (kg/ha/year)	
	grassland	arable land	grassland	arable land
concentration after four manure application on grassland or one application on arable land				
degradation not considered	7,67E+00	1,48E+00	8,54E-03	2,64E-02
degradation considered	7,67E+00	1,48E+00		
degradation and leaching considered	6,95E+00	1,48E+00		
concentrations after ten years of successive manure applications				
degradation considered	7,67E+01	1,48E+01		
degradation and leaching considered	2,09E+01	9,86E+00		

Phosphate imission standards - Concentrations in surface water and sediment adjacents of grassland

	surface water		sediment		
	PEC (mg/L)	PEC:PNEC	PEC (mg/kg wwt)	PEC:PNEC	
concentration after four manure application on grassland					
degradation not considered	7,65E-04	9,22E-01	3,72E-02	#DEEL/0!	Concentrations are derived from those in pore water by using the default dilition factor (10) and corrected for sorption onto suspended matter.
degradation considered	7,65E-04	9,22E-01	3,72E-02	#DEEL/0!	
degradation and leaching considered	6,92E-04	8,34E-01	3,36E-02	#DEEL/0!	
concentrations after ten years of successive manure applications					
degradation considered	7,64E-03	9,21E+00	3,71E-01	#DEEL/0!	
degradation and leaching considered	2,08E-03	2,51E+00	1,01E-01	#DEEL/0!	

Phosphate imission standards - Concentrations in surface water and sediment adjacents of arable land

	surface water		sediment		
	PEC (mg/L)	PEC:PNEC	PEC (mg/kg wwt)	PEC:PNEC	
concentration after four manure application on arable land					
degradation not considered	1,48E-04	1,78E-01	7,18E-03	#DEEL/0!	Concentrations are derived from those in pore water by using the default dilition factor (10) and corrected for sorption onto suspended matter.
degradation considered	1,48E-04	1,78E-01	7,18E-03	#DEEL/0!	
degradation and leaching considered	1,47E-04	1,77E-01	7,15E-03	#DEEL/0!	
concentrations after ten years of successive manure applications					
degradation considered	1,48E-03	1,78E+00	7,17E-02	#DEEL/0!	
degradation and leaching considered	9,82E-04	1,18E+00	4,78E-02	#DEEL/0!	

Nitrate imission standards - Concentrations in groundwater and PEARL input values

	concentration in pore water (µg/L)		dose to be entered in PEARL (kg/ha)	
	grassland	arable land	grassland	arable land
concentration after four manure application on grassland or one application on arable land				
degradation not considered	3,66E+00	9,16E-01	4,08E-03	1,63E-02
degradation considered	3,66E+00	9,16E-01		
degradation and leaching considered	3,31E+00	9,12E-01		
concentrations after ten years of successive manure applications				
degradation considered	3,66E+01	9,15E+00		
degradation and leaching considered	9,98E+00	6,09E+00		

Nitrate imission standards - Concentrations in surface water and sediment adjacents of grassland

	surface water		sediment		
	PEC (mg/L)	PEC:PNEC	PEC (mg/kg wwt)	PEC:PNEC	
concentration after four manure application on grassland					
degradation not considered	3,65E-04	4,40E-01	1,77E-02	#DEEL/0!	Concentrations are derived from those in pore water by using the default dilition factor (10) and corrected for sorption onto suspended matter.
degradation considered	3,65E-04	4,40E-01	1,77E-02	#DEEL/0!	
degradation and leaching considered	3,30E-04	3,98E-01	1,61E-02	#DEEL/0!	
concentrations after ten years of successive manure applications					
degradation considered	3,65E-03	4,39E+00	1,77E-01	#DEEL/0!	
degradation and leaching considered	9,95E-04	1,20E+00	4,84E-02	#DEEL/0!	

Nitrate imission standards - Concentrations in surface water and sediment adjacents of arable land

	surface water		sediment		
	PEC (mg/L)	PEC:PNEC	PEC (mg/kg wwt)	PEC:PNEC	
concentration after four manure application on arable land					
degradation not considered	9,13E-05	1,10E-01	4,44E-03	#DEEL/0!	Concentrations are derived from those in pore water by using the default dilition factor (10) and corrected for sorption onto suspended matter.
degradation considered	9,13E-05	1,10E-01	4,44E-03	#DEEL/0!	
degradation and leaching considered	9,09E-05	1,10E-01	4,42E-03	#DEEL/0!	
concentrations after ten years of successive manure applications					
degradation considered	9,12E-04	1,10E+00	4,43E-02	#DEEL/0!	
degradation and leaching considered	6,07E-04	7,31E-01	2,95E-02	#DEEL/0!	

ctgb Board for the Authorisation of Plant Protection Products and Biocides

Non-medical teat dips (PT03)

Product	Boumatic Iodine product family
Compound	iodide (I-)
Application number	20150623

Predicted environmental concentrations after four manure applications on grassland and one manure application on arable land resulting from disinfection of cow teats. PECs are based on nitrogen imission standards

	Grassland		Arable land	
	PEC (mg/kg wwt)	PEC:PNEC	PEC (mg/kg wwt)	PEC:PNEC
Without degradation in soils	1,92E-02	**4,46**	4,79E-03	**1,12**
With degradation in soils	1,92E-02	**4,46**	4,79E-03	**1,12**
With degradation in and leaching from soils	1,76E-02	**4,1**	4,79E-03	**1,12**

Predicted environmental concentrations after ten years of successive manure applications resulting from disinfection of cow teats. PECs are based on nitrogen imission standards

	Grassland		Arable land	
	PEC (mg/kg wwt)	PEC:PNEC	PEC (mg/kg wwt)	PEC:PNEC
With degradation in soils	1,92E-01	**44,6**	4,79E-02	**11,1**
With degradation in and leaching from soils	5,31E-02	**12,4**	3,20E-02	**7,44**

Predicted environmental concentrations in water and sediment adjacent of grassland resulting from disinfection of cow teats. PECs are based on nitrogen imission standards

	surface water		sediment	
	PEC (mg/L)	PEC:PNEC	PEC (mg/kg wwt)	PEC:PNEC
concentration after four manure application on grassland				
degradation not considered	3,65E-04	0,44	1,77E-02	#DEEL/0!
degradation considered	3,65E-04	0,44	1,77E-02	#DEEL/0!
degradation and leaching considered	3,30E-04	0,398	1,61E-02	#DEEL/0!
concentrations after ten years of successive manure applications				
degradation considered	3,65E-03	**4,39**	1,77E-01	#DEEL/0!
degradation and leaching considered	9,95E-04	**1,2**	4,84E-02	#DEEL/0!

Predicted environmental concentrations in water and sediment adjacent of arable land resulting from disinfection of cow teats. PECs are based on nitrogen imission standards

	surface water		sediment	
	PEC (mg/L)	PEC:PNEC	PEC (mg/kg wwt)	PEC:PNEC
concentration after one manure application on arable land				
degradation not considered	9,13E-05	0,11	4,44E-03	#DEEL/0!
degradation considered	9,13E-05	0,11	4,44E-03	#DEEL/0!
degradation and leaching considered	9,09E-05	0,11	4,42E-03	#DEEL/0!
concentrations after ten years of successive manure applications				
degradation considered	9,12E-04	**1,1**	4,43E-02	#DEEL/0!
degradation and leaching considered	6,07E-04	0,731	2,95E-02	#DEEL/0!

ctgb Board for the Authorisation of Plant Protection Products and Biocides

Non-medical teat dips (PT03)

Product	Boumatic Iodine product family
Compound	iodide (I-)
Application number	20150623

Predicted environmental concentrations after four manure applications on grassland and one manure application on arable land resulting from disinfection of cow teats. PECs are based on phosphate imission standards

	Grassland		Arable land	
	PEC (mg/kg wwt)	PEC:PNEC	PEC (mg/kg wwt)	PEC:PNEC
Without degradation in soils	4,02E-02	**9,35**	7,76E-03	**1,81**
With degradation in soils	4,02E-02	**9,35**	7,76E-03	**1,81**
With degradation in and leaching from soils	3,70E-02	**8,59**	7,76E-03	**1,81**

Predicted environmental concentrations after ten years of successive manure applications resulting from disinfection of cow teats. PECs are based on phosphate imission standards

	Grassland		Arable land	
	PEC (mg/kg wwt)	PEC:PNEC	PEC (mg/kg wwt)	PEC:PNEC
With degradation in soils	4,01E-01	**93,3**	7,75E-02	**18**
With degradation in and leaching from soils	1,11E-01	**44,6**	5,18E-02	**11,1**

Predicted environmental concentrations in water and sediment adjacent of grassland resulting from disinfection of cow teats. PECs are based on phosphate imission standards

	surface water		sediment	
	PEC (mg/L)	PEC:PNEC	PEC (mg/kg wwt)	PEC:PNEC
concentration after four manure application on grassland				
degradation not considered	7,65E-04	0,922	3,72E-02	#DEEL/0!
degradation considered	7,65E-04	0,922	3,72E-02	#DEEL/0!
degradation and leaching considered	6,92E-04	0,834	3,36E-02	#DEEL/0!
concentrations after ten years of successive manure applications				
degradation considered	7,64E-03	**9,21**	3,71E-01	#DEEL/0!
degradation and leaching considered	2,08E-03	**2,51**	1,01E-01	#DEEL/0!

Predicted environmental concentrations in water and sediment adjacent of arable land resulting from disinfection of cow teats. PECs are based on phosphate imission standards

	surface water		sediment	
	PEC (mg/L)	PEC:PNEC	PEC (mg/kg wwt)	PEC:PNEC
concentration after one manure application on arable land				
degradation not considered	1,48E-04	0,178	7,18E-03	#DEEL/0!
degradation considered	1,48E-04	0,178	7,18E-03	#DEEL/0!
degradation and leaching considered	1,47E-04	0,177	7,15E-03	#DEEL/0!
concentrations after ten years of successive manure applications				
degradation considered	1,48E-03	**1,78**	7,17E-02	#DEEL/0!
degradation and leaching considered	9,82E-04	**1,18**	4,78E-02	#DEEL/0!

Appendix 5: PT03 Non medical teat dips iodate

ctgb Board for the Authorisation of Plant Protection Products and Biocides

Non-medical teat dips (PT03)

Legend and explanation

Colour	Symbol	Explanation
	S	Required input
	S	Optional input
	D	Default value
	P	Default value from pickup-list
	O	Intermediate results
	O	Final results

Worksheet	Explanation
Input	Add all the necessary input data here
Defaults	Scenario-related default values
Fate	Defaults and intermidiate calculation regarding distribution in the environment
PECs	Predicted environmental concentrations after one year
PEcs10Years	Predicted environmental concentrations after ten year
Other	Additional outcomes such as pore water concentrations and PEARL dosages
Summary	Ready to copy table with final results

Reference

Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, JRC Scientific and Technical Reports, Report nr. EUR 25116 EN, Publications Office of the European Union, Luxembourg, 2011

Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B: Risk Assessment (Active Substances). European Chemicals Agency, Report no. ECHA-15-G-01-EN, Helsinki, Finland

Notes

Emission to soil and groundwater after the spreading of manure on land from indoor use of teat dips. In line with the current national assessment of plant protection products, run off and drain surface water of treated manure spread on grassland or arable land is not taken into account in the risk assessment. Direct emission to surface water after spreading manure on land is not expe agricultural practice includes incorporation of manure. The relevant environmental compartments therefore are soil and groundwater.

Emission of diluted liquid waste stream from cleaning activities. As a matter of fact most indoor surfaces will be cleaned. The cleaning step will lead to releases either to wastes (manure storage waste water (STP). Therefore, in the ESD for teat dips the sewage treatment plant (STP) is considered as “receiving compartment”. Release to and exposure of the STP is not considered relevant cattle farms. Discharge of manure on the sewage system or on surface water is not permitted. Manure and liquid manure waste streams are collected and spread on land.

Versions

Version	Date	Details
V1.1	24-08-2011	- All input paramters are transfered to the input-tab. - Degradation between two manure events on grassland is now included. Final concentrations are time-weighed averaged over 30 days.
V2.0	20-02-2014	- The sheet now calculates the concentration after one year, i.e. one manure application on grassland and four manure applications on arable land. PECgrassland is deriv PECarableland by using a correction factor representing the differences in mixing depth. Because, based on nitrogen imission standards, the annual amount of manure a arable land and grassland is equal and both receives the same amount of biocide annually, the amount that is mixed into the soil is equal as well. However, manure is m the top 5-10 cm in grassland, but until 20 cm in arable land, the concentrations in grassland is always 2 (manure is injected) to 4 (manure is distributed) times higher. Th factors are 2.58 and 5.16 for injection and distribution, respectively, in case of phosphate standards. Degradation between two manure events is included. Here, PECgra divided by the number of manure applications holding biocides (four in case of teat dips) and calculate the remaining concentration after the fourth manure application - the ROUND command is removed to calculate the number of biocide applications directed to the manure. - layout adjustments
V3.0	10-07-2015	Major lay-out update; Sheet now calculates concentrations in pore water, concentrations after 10 years, and dosage to be entered in PEARL; Leaching from soils is now included; Kp soil is added as an optional input parameter; Sheet is now applicable for both fertilisation by injection and spreading; An option is added for three milkings per day (robots) as well as pre- and postdipping
V3.1	12-01-2016	PECs for arable land are no longer calculated from the concentration in arable land using a correction factor.
V3.11	16-03-2016	Some typos were corrected
V3.2	07-04-2016	PECs for soils were not adjusted for >2 biocide application per day. This is now corrected.
V3.3	24-06-2016	- First tier assessment for adjacent surface water is added; - PECs after ten years and PECs for surface water are added to the summary tables - lay-out updates
V3.31	05-07-2016	- some typos were corrected; - layout improvements
V3.40	30-03-2017	- volume per treatment is added as an optional input parameter; - it is now possible to choose between initial and time-weighed average PNECs for soils depending on how PNECs were derived. - layout improvements

ctgb Board for the Authorisation of Plant Protection Products and Biocides

Non-medical teat dips (PT03)

Product	Boumatic Iodine product family
Compound	iodate (IO3-)
Application number	20150623

Environmental Emission

Parameter	Symbol	Value	Unit	Origin	Remarks
Content of active ingredient in formulation (product)	Fbioc	6,91	g/L	S	
Dilution factor (for preparation of the working solution from the formulation (product))	Fdil	1	-	S	
Volume applied per cow and treatment	Vprod_usr	6,5	mL	S	If left empty, the default value (10 mL for dipping) is applied instead. Note that actual consumption should be substantiated experimentally.
Manure distribution on grassland	Manure_application	Spreading	-	S	This parameters determines the mixing depth for grassland: - **Spreading**: mixing depth is 5 cm. Use this value for BPR; - **Injection:** mixing depth is 10 cm (manure is injected).
Applied in milking robots?	Robot	No	-	S	Choose 'Yes' if the product is applied in milking robots. This increases the number of daily teat dipping events from two to three as cowms are milked up to three times daily in milking robots.
Applied pre- and post milking?	Milking	No	-	S	Choose 'Yes' if teats are disinfected both prior and after milking.
PEC based on initial or time-weighed average (TWA) concentrations?	PECtype	Initial	-	S	- **Initial:** PNECsoil is based on nominal concentrations. PECs are therefore based on nominal concentrations (PIECs) as well, but disappearance between two manure applications is still considered; - **TWA:** PNECsoil is based on mean measured exposure concentrations, time-weighed average concentrations, or similar. PECs are therefore calculated as time-weighed average concentrations over 30 days after the peak.

Predicted No Effect Concentrations (PNECs)

Parameter	Symbol	Value	Unit	Origin	Remarks
PNEC for surface water (fresh)	PNECwater	0,0585	mg/kg wwt	S	Only relevant for active substances that are mobile in soils
PNEC for sediment (freshwater)	PNECsed		mg/kg wwt	S	
PNEC for terrestrial invertebrates	PNECsoil	0,304	mg/kg wwt	S	

Environmental Fate and Behaviour

Parameter	Symbol	Value	Unit	Origin	Remarks
Molecular weight	molw	253,8	g/mol	S	
Experimental vapour pressure at test temperature	VP_exp	4,07E+01	Pa	S	
Temperature at which vapour pressures is determined	VP_exp_temp	25	°C	S	
Experimental solubility at test temperature	SOL_exp	300	mg/L	S	
Test temperature at which solybility is determined	SOL_exp_temp	25	°C	S	
Experimental Henry's law constant	HENRY_exp		$Pa/m^3/mol$	S	Leave blank if no experimental Henry's constant is available.
Temperature at which Henry's law constant is determined	HENRY_exp_temp		°C	S	
Organic carbon-water partitioning coefficient (K_{oc})	Koc		L/kg	S	
Experimentally derived solid-water partition coefficient in soil	Kp_soil_exp	5,8	L/kg	S	Leave blank if no experimentalvalues are available.
Experimentally derived solid-water partition coefficient in suspended matter	Kp_susp_exp	220	L/kg	S	Leave blank if no experimentalvalues are available.
Half-life for biodegradation in soil	DT50deg_soil	1,00E+06	day	S	Leave empty when biodegradation is not relevant or no data available.

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Non-medical teat dips (PT03)

Product	Boumatic Iodine product family
Compound	iodate (IO3-)
Application number	20150623

Parameter	Symbol	Value	Unit	Origin	Remarks
Amount of product prescribed to be used for one treatment (dipping of the four teats) of one animal	Vprod	0,007	L	S	Default value is 10 mL/cow/treatment for dipping as agreed at WGV-2016. Will be replaced by an experimental-derived value (e.g. field tests) when available.
Fraction of active ingredient released	($F_{stp} = F_{ww}$) F_{stp}	0,5	-	D	
	$F_{slurry/manure}$	0,5	-	D	
	F_{air}	0	-	D	
	F_{teat}	0,5	-	D	
Number of daily milking events	milking_day	2	-	O	The ESD assummes two milking per day. However, cows are milked three times a day in milking robots
Number of teat dippings per milking	teat_milking	1	-	O	The ESD assumes teat dipping prior OR after milking. However, some products are applied both pre- AND post milking
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	-	O	
Number of days of lactation period	Nday-lact	300	-	D	
Number of disinfectant applications in one year (equals number of disinfectant applications in one lactation period)	Napp-bioc	600	-	D	
Interval between two disinfectant applications (dipping events)	Tbioc-int	0,50	d	D	The ESD assumes only pre- or post milking applications twice a day and therefore Tbioc-int is 0.5 d by default. For pre- and post milking, as well as application in milking robots (three times a day), the interval between two events must be adjusted accordingly. Note that PECsoil is not directly calculated from Napp-teat, but from Tbioc-int. Although a value of e.g. 0.25 suggest that the interval between two applications is 6 hrs, emission is still based on four daily applications.
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	Tgr-int	53	d	D	
Manure application time interval for arable land	Tar-int	212	d	D	
Number of animals in housing for category/subcategory *i1* =1	Nanimal	100	-	P	
Amount of phosphate per animal for category/subcategory *i1* =1	Qphosph	0,10466	kg/d	P	
Amount of nitrogen per animal for category/subcategory *i1* =1	Qnitrog	0,3389	kg/d	P	
Phosphate immission standard for one year on grassland	$Q_{P2O5,grassland}$	110	kg/ha	D	
Phosphate immission standard for one year on arable land	$Q_{P2O5,arable\_land}$	85	kg/ha	D	
Nitrogen immission standard for one year on grassland	$Q_{N,grassland}$	170	kg/ha	D	
Nitrogen immission standard for one year on arable land	$Q_{N,arable\_land}$	170	kg/ha	D	
Mixing depth with soil, grassland	$DEPTH_{grassland}$	0,05	m	D	
Mixing depth with soil, arable land	$DEPTH_{arable\_land}$	0,2	m	D	
Density of wet bulk soil	RHOsoil	1700	kg/m³	D	
Averaging time	T	30	d	D	

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Non-medical teat dips (PT03)

Product	Boumatic Iodine product family
Compound	iodate (IO3-)
Application number	20150623

Degradation

Parameter	Symbol	Value	Unit	Origin	Remarks
First order rate constant for degradation in bull	kbio_soil	6,93E-07	/day	o	

Correction of vapour pressure, solubility, and Henry's constant for 12°C

Parameter	Symbol	Value	Unit	Origin	Remarks
Environmental temperature	TEMP_env	285	K	D	
Enthalpy of vapourisation	H0_VP	50000	J/mol	D	
Enthalpy of solution	H0_SOL	10000	J/mol	D	
Gas constant	R_	8,314	Pa m³/mol/K	D	
Vapour pressure at the environmental temperature	VP	16,2	Pa	O	
Solubility at the environmental temperature	SOL	249,6	mg/L	O	
Henry's constant at the environmental temperature	HENRY	16,5	Pa m³/mol	O	

Soil partitioning coefficients

Parameter	Symbol	Value	Unit	Origin	Remarks
Air-water partition coefficient	Kair_water	6,96E-03	-	O	TGD formula 22
Density of the solid phase	RHOsolid	2,50E+03	-	O	TGD formula 24
Volume fraction of water in soils	Fwater_soil	0,2	-	D	TGD default (table 5)
Volume fraction of solids in soils	Fsolid_soil	0,6	-	D	TGD default (table 5)
Volume fraction of air in soils	Fair_soil	0,2	-	D	TGD default (table 5)
Weight fraction of organic carbon in soils	Foc_soil	0,02	-	D	TGD default (table 5)
Partition coefficient solid-water in soils	Kp_soil	5,80	-	O	TGD formula 23
Soil-water partitioning coefficient	Ksoil_water	8,90	-	O	TGD formula 24

Leaching from soils

Parameter	Symbol	Value	Unit	Origin	Remarks
Fraction of rain water that infiltrates into soil	Finf_soil	0,25	-	D	TGD formula 58
Rate of wet precitipation (700 mm/year)	RAINrate	1,92E-03	m/d	D	TGD formula 58
First-order rate constant for leaching from soil layer (grassland)	kleach_gr	1,08E-03	/d	O	TGD formula 58
Half-life for leaching from soils (grassland)		642,71	d	O	
First-order rate constant for leaching from soil layer (arable land)	kleach_ar	2,70E-04	/d	O	TGD formula 58
Half-life for leaching from soils (arable land)		2570,82	d	O	
First-order rate constant for removal from top soil layer (grassland)	ktot_gr	1,08E-03	/d	O	TGD formula 56
First-order rate constant for removal from top soil layer (arable land)	k_ar	2,70E-04	/d	O	TGD formula 56

Suspended matter partitioning coefficients

Parameter	Symbol	Value	Unit	Origin	Remarks
Effluent dillution factor (fresh water)	dilution	10	-	D	
Concentration of suspended matter in the river	SUSPwater	15	-	D	TGD default (Table 5)
Weight fraction of organic carbon in suspended matter	Foc_susp	0,1	-	D	TGD default (Table 5)
Solid-water partition coefficient in suspended matter	Kp_susp	220,00	-	D	TGD formula 23
Fraction water in suspended matter	Fwater_susp	0,9	-	D	TGD default (Table 5)
Fraction solids in suspended matter	Fsolid_susp	0,1	-	D	TGD default (Table 5)
Suspended matter-water partitioning coefficient	Ksusp_water	55,90	-	O	TGD formula 24
Density of suspended matter	RHOsusp	1150	kg wwt/m³	D	TGD formula 18

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Non-medical teat dips (PT03)

Product	Boumatic Iodine product family
Compound	iodate (IO3-)
Application number	20150623

Intermediate Calculations

Parameter	Symbol	Value	Unit	Origin	Remarks
Number of biocide applications during storage period for application on grassland	Napp_manure_gr	106	-	O	
Number of biocide applications during storage period for application on arable land	Napp_manure_ar	424	-	O	
Amount of active ingredient to be used for one application (one treatment of one animal)	Qai_prescr	0,000044915	kg	O	
Amount of active ingredient in relevant stream *i4* after one application for all animals	Qai	0,00224575	kg	O	
Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to grassland	Qai_grass	0,2380495	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-ar	0,952198	kg	O	
Amount of phosphate produced during the relevant period for every relevant (sub)category of animal/housing *i1* and application to grassland	Qphosph_grass	554,698	kg	O	
Amount of phosphate produced during the relevant period for every relevant (sub)category of animal/housing *i1* and application to arable land	Qphosph_ar	2218,792	kg	O	
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing *i1* and application to grassland	Qnitrog_grass	1796,17	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_ar	7184,68	kg	O	

Predicted enviromental concentrations

	Symbol	PEC (mg/kg wwt)			Remarks
		no degradation	degradation	leach	
Concentration in soil in the case of an immission standard for **phosphate** and land application on **grassland** (four manure applications)	PECgr_Q	5,55E-02	5,55E-02	5,11E-02	If the PNEC is based on initial concentrations, the PEC is expressed as the concentration during the last manure application. In case of PNEC that are based on actual measured concentration during the soil tests, the PEC is averaged over 30 days after the last manure application. Disappearance between two applications due to degradation and leaching to deeper soil layers is still considered. Concentration in pore water are, however, always based on time-weighed average concentrations as they are not compared with a PNEC, but with the 0.1 µg/L standard. Moreover, when emission to groundwater is assessed using PEARL (tier 2), final concentrations are averaged anyway. Therefore, concentration in pore water based on initial concentrations in soils may results in unnecessary PEARL simulations.
PEC:PNEC		0,18	0,18	0,17	
Concentration in soil in the case of an immission standard for **phosphate** and land application on **arable land**	PECar_Q	1,07E-02	1,07E-02	1,07E-02	
PEC:PNEC		0,04	0,04	0,04	
Concentration in soil in the case of an immission standard for **nitrogen** and land application on **grassland** (four manure applications)	PECgr_N	2,65E-02	2,65E-02	2,44E-02	
PEC:PNEC		0,09	0,09	0,08	
Concentration in soil in the case of an immission standard for **nitrogen** and land application on **arable land**	PECar_N	6,63E-03	6,63E-03	6,63E-03	
PEC:PNEC		0,02	0,02	0,02	

Intermediate calculations for PECs after four manure applications - Phosphate imission standards

Parameter	Symbol	Days since manure application	Concentration (mg/kg wwt)		Remarks
			degradation	leach	
concentration of biocide at fourth manure application:					
initial concentration after one manure application			1,39E-02		
from first manure application		159	1,39E-02	1,17E-02	
from second manure application		106	1,39E-02	1,24E-02	
from third manure application		53	1,39E-02	1,31E-02	
from fourth manure application		0	1,39E-02	1,39E-02	
total concentration in soil directly after fourth manure application	PEC_Nlapp_4_P		5,55E-02	5,11E-02	

Intermediate calculations for PECs after four manure applications - Nitrogen imission standards

Parameter	Symbol	Days since manure application	Concentration (mg/kg wwt)		Remarks
			degradation	leach	
concentration of biocide at fourth manure application:					
initial concentration after one manure application			6,63E-03		
from first manure application		159	6,63E-03	5,58E-03	
from second manure application		106	6,63E-03	5,91E-03	
from third manure application		53	6,63E-03	6,26E-03	
from fourth manure application		0	6,63E-03	6,63E-03	
total concentration in soil directly after fourth manure application	PEC_Nlapp_4_N		2,65E-02	2,44E-02	

Sewage Treatment Plant

Parameter	Symbol	Value	Unit	Origin	Remarks
Local emission to a standard STP or an on-site waste water treatment plant	$Qai\text{-}stp_{i1,i2,i3,i4} = Elocal_{waste\ water}$	3,69E-03	kg/d	O	

ctgb Board for the Authorisation of Plant Protection Products and Biocides

Non-medical teat dips (PT03)

Product	Boumatic Iodine product family
Compound	iodate (IO3-)
Application number	20150623

Grassland

Manure event	Days since manure application	Concentration (mg/kg wwt)			
		degradation		degradation and leaching	
		phosphate	nitrogen	phosphate	nitrogen
PEC after one emanure event		1,39E-02	6,63E-03	1,39E-02	6,63E-03
1	3444	1,39E-02	6,61E-03	3,38E-04	1,61E-04
2	3391	1,39E-02	6,61E-03	3,57E-04	1,71E-04
3	3338	1,39E-02	6,61E-03	3,79E-04	1,81E-04
4	**3285**	1,39E-02	6,61E-03	4,01E-04	1,91E-04
5	3079	1,39E-02	6,61E-03	5,01E-04	2,39E-04
6	3026	1,39E-02	6,61E-03	5,30E-04	2,53E-04
7	2973	1,39E-02	6,61E-03	5,61E-04	2,68E-04
8	**2920**	1,39E-02	6,61E-03	5,94E-04	2,84E-04
9	2714	1,39E-02	6,61E-03	7,42E-04	3,54E-04
10	2661	1,39E-02	6,61E-03	7,86E-04	3,75E-04
11	2608	1,39E-02	6,61E-03	8,32E-04	3,97E-04
12	**2555**	1,39E-02	6,61E-03	8,81E-04	4,21E-04
13	2349	1,39E-02	6,62E-03	1,10E-03	5,25E-04
14	2296	1,39E-02	6,62E-03	1,17E-03	5,56E-04
15	2243	1,39E-02	6,62E-03	1,23E-03	5,89E-04
16	**2190**	1,39E-02	6,62E-03	1,31E-03	6,24E-04
17	1984	1,39E-02	6,62E-03	1,63E-03	7,79E-04
18	1931	1,39E-02	6,62E-03	1,73E-03	8,25E-04
19	1878	1,39E-02	6,62E-03	1,83E-03	8,73E-04
20	**1825**	1,39E-02	6,62E-03	1,94E-03	9,25E-04
21	1619	1,39E-02	6,62E-03	2,42E-03	1,15E-03
22	1566	1,39E-02	6,62E-03	2,56E-03	1,22E-03
23	1513	1,39E-02	6,62E-03	2,71E-03	1,29E-03
24	**1460**	1,39E-02	6,62E-03	2,87E-03	1,37E-03
25	1254	1,39E-02	6,62E-03	3,59E-03	1,71E-03
26	1201	1,39E-02	6,62E-03	3,80E-03	1,81E-03
27	1148	1,39E-02	6,62E-03	4,02E-03	1,92E-03
28	**1095**	1,39E-02	6,62E-03	4,26E-03	2,03E-03
29	889	1,39E-02	6,62E-03	5,32E-03	2,54E-03
30	836	1,39E-02	6,62E-03	5,63E-03	2,69E-03
31	783	1,39E-02	6,62E-03	5,96E-03	2,85E-03
32	**730**	1,39E-02	6,62E-03	6,32E-03	3,01E-03
33	524	1,39E-02	6,62E-03	7,89E-03	3,76E-03
34	471	1,39E-02	6,62E-03	8,35E-03	3,99E-03
35	418	1,39E-02	6,62E-03	8,84E-03	4,22E-03
36	**365**	1,39E-02	6,62E-03	9,36E-03	4,47E-03
37	159	1,39E-02	6,63E-03	1,17E-02	5,58E-03
38	106	1,39E-02	6,63E-03	1,24E-02	5,91E-03
39	53	1,39E-02	6,63E-03	1,31E-02	6,26E-03
40	0	1,39E-02	6,63E-03	1,39E-02	6,63E-03
PEC based on initial concentrations (mg/kg wwt)		5,55E-01	2,65E-01	1,54E-01	7,34E-02
PEC:PNEC		1,82	0,87	0,51	0,24

Arable land

Manure event	Days since manure application	Concentration (mg/kg wwt)			
		degradation		degradation and leaching	
		phosphate	nitrogen	phosphate	nitrogen
PEC after on emanure event		1,07E-02	6,63E-03	1,07E-02	6,63E-03
1	3285	1,07E-02	6,61E-03	4,41E-03	2,73E-03
2	2920	1,07E-02	6,61E-03	4,87E-03	3,01E-03
3	2555	1,07E-02	6,61E-03	5,38E-03	3,32E-03
4	2190	1,07E-02	6,62E-03	5,94E-03	3,67E-03
5	1825	1,07E-02	6,62E-03	6,55E-03	4,05E-03
6	1460	1,07E-02	6,62E-03	7,23E-03	4,47E-03
7	1095	1,07E-02	6,62E-03	7,98E-03	4,93E-03
8	730	1,07E-02	6,62E-03	8,81E-03	5,44E-03
9	365	1,07E-02	6,62E-03	9,72E-03	6,00E-03
10	0	1,07E-02	6,63E-03	1,07E-02	6,63E-03
PEC based on initial concentrations (mg/kg wwt)		1,07E-01	6,62E-02	7,16E-02	4,42E-02
PEC:PNEC		0,35	0,22	0,24	0,15

ctgb Board for the Authorisation of Plant Protection Products and Biocides

Non-medical teat dips (PT03)

Product	Boumatic Iodine product family
Compound	iodate (IO3-)
Application number	20150623

Phosphate imission standards - Concentrations in groundwater and PEARL input values

	concentration in pore water (µg/L)		dose to be entered in PEARL (kg/ha/year)	
	grassland	arable land	grassland	arable land
concentration after four manure application on grassland or one application on arable land				
degradation not considered	1,06E+01	2,05E+00	1,18E-02	3,65E-02
degradation considered	1,06E+01	2,05E+00		
degradation and leaching considered	9,60E+00	2,04E+00		
concentrations after ten years of successive manure applications				
degradation considered	1,06E+02	2,05E+01		
degradation and leaching considered	2,89E+01	1,36E+01		

Phosphate imission standards - Concentrations in surface water and sediment adjacents of grassland

	surface water		sediment		
	PEC (mg/L)	PEC:PNEC	PEC (mg/kg wwt)	PEC:PNEC	
concentration after four manure application on grassland					
degradation not considered	1,06E-03	1,81E-02	5,14E-02	#DEEL/0!	Concentrations are derived from those in pore water by using the default dilition factor (10) and corrected for sorption onto suspended matter.
degradation considered	1,06E-03	1,81E-02	5,14E-02	#DEEL/0!	
degradation and leaching considered	9,57E-04	1,64E-02	4,65E-02	#DEEL/0!	
concentrations after ten years of successive manure applications					
degradation considered	1,06E-02	1,80E-01	5,13E-01	#DEEL/0!	
degradation and leaching considered	2,88E-03	4,93E-02	1,40E-01	#DEEL/0!	

Phosphate imission standards - Concentrations in surface water and sediment adjacents of arable land

	surface water		sediment		
	PEC (mg/L)	PEC:PNEC	PEC (mg/kg wwt)	PEC:PNEC	
concentration after four manure application on arable land					
degradation not considered	2,04E-04	3,49E-03	9,93E-03	#DEEL/0!	Concentrations are derived from those in pore water by using the default dilition factor (10) and corrected for sorption onto suspended matter.
degradation considered	2,04E-04	3,49E-03	9,93E-03	#DEEL/0!	
degradation and leaching considered	2,03E-04	3,48E-03	9,89E-03	#DEEL/0!	
concentrations after ten years of successive manure applications					
degradation considered	2,04E-03	3,49E-02	9,92E-02	#DEEL/0!	
degradation and leaching considered	1,36E-03	2,32E-02	6,60E-02	#DEEL/0!	

Nitrate imission standards - Concentrations in groundwater and PEARL input values

	concentration in pore water (µg/L)		dose to be entered in PEARL (kg/ha)	
	grassland	arable land	grassland	arable land
concentration after four manure application on grassland or one application on arable land				
degradation not considered	5,06E+00	1,27E+00	5,63E-03	2,25E-02
degradation considered	5,06E+00	1,27E+00		
degradation and leaching considered	4,58E+00	1,26E+00		
concentrations after ten years of successive manure applications				
degradation considered	5,06E+01	1,26E+01		
degradation and leaching considered	1,38E+01	8,41E+00		

Nitrate imission standards - Concentrations in surface water and sediment adjacents of grassland

	surface water		sediment		
	PEC (mg/L)	PEC:PNEC	PEC (mg/kg wwt)	PEC:PNEC	
concentration after four manure application on grassland					
degradation not considered	5,05E-04	8,62E-03	2,45E-02	#DEEL/0!	Concentrations are derived from those in pore water by using the default dilition factor (10) and corrected for sorption onto suspended matter.
degradation considered	5,05E-04	8,62E-03	2,45E-02	#DEEL/0!	
degradation and leaching considered	4,57E-04	7,80E-03	2,22E-02	#DEEL/0!	
concentrations after ten years of successive manure applications					
degradation considered	5,04E-03	8,61E-02	2,45E-01	#DEEL/0!	
degradation and leaching considered	1,38E-03	2,35E-02	6,68E-02	#DEEL/0!	

Nitrate imission standards - Concentrations in surface water and sediment adjacents of arable land

	surface water		sediment		
	PEC (mg/L)	PEC:PNEC	PEC (mg/kg wwt)	PEC:PNEC	
concentration after four manure application on arable land					
degradation not considered	1,26E-04	2,16E-03	6,13E-03	#DEEL/0!	Concentrations are derived from those in pore water by using the default dilition factor (10) and corrected for sorption onto suspended matter.
degradation considered	1,26E-04	2,16E-03	6,13E-03	#DEEL/0!	
degradation and leaching considered	1,26E-04	2,15E-03	6,11E-03	#DEEL/0!	
concentrations after ten years of successive manure applications					
degradation considered	1,26E-03	2,15E-02	6,12E-02	#DEEL/0!	
degradation and leaching considered	8,39E-04	1,43E-02	4,08E-02	#DEEL/0!	

ctgb Board for the Authorisation of Plant Protection Products and Biocides

Non-medical teat dips (PT03)

Product	Boumatic Iodine product family
Compound	iodate (IO3-)
Application number	20150623

Predicted environmental concentrations after four manure applications on grassland and one manure application on arable land resulting from disinfection of cow teats. PECs are based on nitrogen imission standards

	Grassland		Arable land	
	PEC (mg/kg wwt)	PEC:PNEC	PEC (mg/kg wwt)	PEC:PNEC
Without degradation in soils	2,65E-02	0,087	6,63E-03	0,022
With degradation in soils	2,65E-02	0,087	6,63E-03	0,022
With degradation in and leaching from soils	2,44E-02	0,08	6,63E-03	0,022

Predicted environmental concentrations after ten years of successive manure applications resulting from disinfection of cow teats. PECs are based on nitrogen imission standards

	Grassland		Arable land	
	PEC (mg/kg wwt)	PEC:PNEC	PEC (mg/kg wwt)	PEC:PNEC
With degradation in soils	2,65E-01	0,871	6,62E-02	0,218
With degradation in and leaching from soils	7,34E-02	0,241	4,42E-02	0,146

Predicted environmental concentrations in water and sediment adjacent of grassland resulting from disinfection of cow teats. PECs are based on nitrogen imission standards

	surface water		sediment	
	PEC (mg/L)	PEC:PNEC	PEC (mg/kg wwt)	PEC:PNEC
concentration after four manure application on grassland				
degradation not considered	5,05E-04	0,009	2,45E-02	#DEEL/0!
degradation considered	5,05E-04	0,009	2,45E-02	#DEEL/0!
degradation and leaching considered	4,57E-04	0,008	2,22E-02	#DEEL/0!
concentrations after ten years of successive manure applications				
degradation considered	5,04E-03	0,086	2,45E-01	#DEEL/0!
degradation and leaching considered	1,38E-03	0,024	6,68E-02	#DEEL/0!

Predicted environmental concentrations in water and sediment adjacent of arable land resulting from disinfection of cow teats. PECs are based on nitrogen imission standards

	surface water		sediment	
	PEC (mg/L)	PEC:PNEC	PEC (mg/kg wwt)	PEC:PNEC
concentration after one manure application on arable land				
degradation not considered	1,26E-04	0,002	6,13E-03	#DEEL/0!
degradation considered	1,26E-04	0,002	6,13E-03	#DEEL/0!
degradation and leaching considered	1,26E-04	0,002	6,11E-03	#DEEL/0!
concentrations after ten years of successive manure applications				
degradation considered	1,26E-03	0,022	6,12E-02	#DEEL/0!
degradation and leaching considered	8,39E-04	0,014	4,08E-02	#DEEL/0!

ctgb Board for the Authorisation of Plant Protection Products and Biocides

Non-medical teat dips (PT03)

Product	Boumatic Iodine product family
Compound	iodate (IO3-)
Application number	20150623

Predicted environmental concentrations after four manure applications on grassland and one manure application on arable land resulting from disinfection of cow teats. PECs are based on phosphate imission standards

	Grassland		Arable land	
	PEC (mg/kg wwt)	PEC:PNEC	PEC (mg/kg wwt)	PEC:PNEC
Without degradation in soils	5,55E-02	0,183	1,07E-02	0,035
With degradation in soils	5,55E-02	0,183	1,07E-02	0,035
With degradation in and leaching from soils	5,11E-02	0,168	1,07E-02	0,035

Predicted environmental concentrations after ten years of successive manure applications resulting from disinfection of cow teats. PECs are based on phosphate imission standards

	Grassland		Arable land	
	PEC (mg/kg wwt)	PEC:PNEC	PEC (mg/kg wwt)	PEC:PNEC
With degradation in soils	5,55E-01	**1,82**	1,07E-01	0,353
With degradation in and leaching from soils	1,54E-01	0,871	7,16E-02	0,218

Predicted environmental concentrations in water and sediment adjacent of grassland resulting from disinfection of cow teats. PECs are based on phosphate imission standards

	surface water		sediment	
	PEC (mg/L)	PEC:PNEC	PEC (mg/kg wwt)	PEC:PNEC
concentration after four manure application on grassland				
degradation not considered	1,06E-03	0,018	5,14E-02	#DEEL/0!
degradation considered	1,06E-03	0,018	5,14E-02	#DEEL/0!
degradation and leaching considered	9,57E-04	0,016	4,65E-02	#DEEL/0!
concentrations after ten years of successive manure applications				
degradation considered	1,06E-02	0,18	5,13E-01	#DEEL/0!
degradation and leaching considered	2,88E-03	0,049	1,40E-01	#DEEL/0!

Predicted environmental concentrations in water and sediment adjacent of arable land resulting from disinfection of cow teats. PECs are based on phosphate imission standards

	surface water		sediment	
	PEC (mg/L)	PEC:PNEC	PEC (mg/kg wwt)	PEC:PNEC
concentration after one manure application on arable land				
degradation not considered	2,04E-04	0,003	9,93E-03	#DEEL/0!
degradation considered	2,04E-04	0,003	9,93E-03	#DEEL/0!
degradation and leaching considered	2,03E-04	0,003	9,89E-03	#DEEL/0!
concentrations after ten years of successive manure applications				
degradation considered	2,04E-03	0,035	9,92E-02	#DEEL/0!
degradation and leaching considered	1,36E-03	0,023	6,60E-02	#DEEL/0!

Appendix 6: STP distribution SimpleTreat 3

ctgb Board for the Authorisation of Plant Protection Products and Biocides

Sewage Treatment Plant

Legend and explanation

Colour	Symbol	Explanation
	S	User (Obligatory)
	S	User (Optional)
	D	Default value
	P	Default value from pickup-list
	O	Intermediate result
	O	Final result

Worksheet	Explanation
Input	Add all the necessary input data here
Defaults	Calculated the daily emission to the sewer
STP	Input for the STP are transformed here where necessary
9-box	Intermediate calculations for the STP
Output_STP	Distribution of the active substance in the STP (concentrations are for emulsifiable MWF only)
Output	Final results and PEC/PNEC ratios

Reference

- Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B: Risk Assessment (Active Substances). European Chemicals Agency, Report no. ECHA-15-G-01-EN, Helsinki, Finland, 2015.
- Struijs J. SimpleTreat 3.0: A model to predict the distribution and elimination of chemicals by sewage treatment plants. National Institute for Human Health and the Environment. RIVM report 719101025, Bilthoven, The Netherlands, 1996.

Notes

Versions

Version	Date	Details
1.0	24-02-2011	De 9box is geverifieerd en geeft dezelfde uitkomsten als EUSUS2.1.1.
1,1	03-03-2011	toegevoegd:
1,2	20-10-2011	Temperatuurcorrectie staat nu standaard op No. Dit is de defaultwaarde in EUSUS. Ook zijn de temperaturen aangepast (12 naar 15°C). Dit is echter alleen van
1,3	17-11-2011	- In het geval van vluchtige stoffen week de emissie naar lucht enkele procenten af tov EUSUS2.1.1. Deze bug is nu opgelost; - Extra sheet toegevoegd. Nu wordt ook de concentratie in het water (dissolved) en de concentratie in het sediment berekend; - Enkele aanpassingen aan de lay-out.
1,4	24-11-2011	Effluent berekeningen kunnen nu ook gemaakt worden op basis van gemeten STP efficienties
1,5	01-06-2012	Monitoring data for OPP and 2-MBT added.
2.0	22-11-2013	Lay-out update
2.1	10-01-2014	Lay-out update
2.2	20-08-2014	Lay-out update and removal of unnecessary cells
2.3	18-05-2015	Converted to XLSX-format (Office 2010)
3.0	18-04-2016	- Emission to soils is now included - Major layout change
3.01	22-04-2016	- Concentrations in air, sludge, and effluent are now calculated from the Fstp_air, Fstp_sludge, and Fstp_water, respectively. Concentrations in air are now in line with EUSES 2.1.2. - Monitoring now includes the distribution over all compartments within the STP. PECstp, PECair, and PECsoil are now calculated from monitoring data (e.g. scientific literature, OECD simulation tests) if available.

ctgb Board for the Authorisation of Plant Protection Products and Biocides

Sewage Treatment Plant

Product	Boumatic Iodine product family
Active substance	Iodine incl metabolites
Application number	20150623

Emission (input from ESD)

Parameter	Symbol	Value	Unit	Origin	Remarks
Emission rate of chemical to the sewer	Elocal	2,67E-03	kg/d	S	ESD's output
Emission rate of chemical to the air	Elocal_air		kg/d	S	ESD's output

Predicted No Effect Concentrations (PNECs)

Parameter	Symbol	Value	Unit	Origin	Remarks
PNEC for sewage treatment plants (STP)	PNECstp	2,9	mg/L	S	
PNEC for surface water (fresh)	PNECwater	0,00059	mg/L	S	
PNEC for sediment (freshwater)	PNECsed		mg/kg wwt	S	
PNEC for soils	PNECsoil		mg/kg wwt	S	

Environmental Fate and Behaviour

Parameter	Symbol	Value	Unit	Origin	Remarks
Molecular weight	MOLW	253,81	g/mol	S	
Melting point of active substance	TEMPmelt	113,7	°C	S	
Vapour pressure at test temperature	VP_exp	1,00E-06	Pa	S	
Test temperature vapour pressure	VP_exp_temp	25	°C	S	
Solubility	SOL_exp	300	mg/L	S	
Test temperature solubility	SOL_exp_temp	25	°C	S	
Experimental Henry's law constant	HENRY_exp		Pa m^3/mol	S	Leave blank if no experimental Henry's constant is available
Temperature at which Henry's law constant is determined	HENRY_exp_temp		°C		Leave blank if no experimental Henry's constant is available
Octanol-water partitioning coefficient (K_{ow})	Kow		-	S	
Chemical class for Koc QSAR	Non hydrophobics			S	
Experimental organic carbon-water partitioning coefficient (K_{oc})	Koc_exp	1,66E+02	L/kg	S	Leave blank if no experimental Koc is available. Use Koc instead of log Koc
Experimentally derived partition coefficient solid-water in suspended matter	Kp_susp_exp	2,20E+02	L/kg	S	Leave blank if no experimentalvalues are available.
Experimentally derived partition coefficient solid-water in soils	Kp_soil_exp	5,80E+00	L/kg	S	Leave blank if no experimentalvalues are available.
Characterization of biodegradability	Not biodegradable			S	
Experimental rate constant for degradation in a STP	Kdeg_STP_exp		/d	S	Leave blank if no experimental degradation rate constant for the STP is available.
Half-life in soil	DT50_soil		d	S	DT50 is 1.0E06 days when empty
Use monitoring data for STP effluent	Monitoring	Yes	-	S	
Compound		Iodine	-	S	Add the compound to the list below if not exist
Fraction of compound present in effluent	Fstp_water_exp	0,800	-	P	
Fraction of compound present in sludge	Fstp_sludge_exp	0,200	-	P	
Fraction of compound present in air	Fstp_air_exp	0,000	-	P	
Fraction of compound degraded	Fstp_deg_exp	0,000	-	P	

Fraction in the STP's compartments based on monitoring data and/or STP simulation tests

Compound	Fraction of active substance in:				
Compound	Effluent	Sludge	Air	Degraded	Source
ADBAC	0,015	0,985	0	0	Clara *et al*. 2007. Water Research 41, 4339-4348
DDAC	0,015	0,985	0	0	Clara *et al*. 2007. Water Research 41, 4339-4348
Diamine	0,015	0,985	0	0	
Iodine	0,8	0,2	0	0	CAR PT01 Iodine First Draft
2-phenylphenol	0,01	0,99	0	0	i.e. Körner *et al*. 2000. Chemosphere 40, 1131-1142
PHMB	0,18	0,82	0	0	final CAR PHMB (2016) - OECD 303A simulation study
IR3535	0,01	0	0	0,99	Final CAR IR3535 (September 2013) - OECD 303A simulation study

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Sewage Treatment Plant

Product	**Boumatic Iodine product family**
Active substance	**Iodine incl metabolites**
Application number	**20150623**

Distribution in the environment

Variable	Symbol	Value	Unit	Origin	Remark
Organic carbon-water partition coefficient	Koc	165,83	L/kg	O	
Effluent dillution factor (fresh water)	dillution	10	-	D	
Concentration of suspended matter in the river	SUSPwater	15	-	D	TGD default (Table 5)
Weight fraction of organic carbon in suspended matter	Foc_susp	0,1	-	D	TGD default (Table 5)
Solid-water partition coefficient in suspended matter	Kp_susp	220	L/kg	D	TGD formula 23
Fraction water in suspended matter	Fwater_susp	0,9	-	D	TGD default (Table 5)
Fraction solids in suspended matter	Fsolid_susp	0,1	-	D	TGD default (Table 5)
Density of the solid phase	RHOsolid	2500	kg/m³	D	TGD default (Table 5)
Suspended matter-water partitioning coefficient	Ksusp_water	55,9	-	O	TGD formula 24
Density of suspended matter	RHOsusp	1150	kg wwt/m³	D	TGD formula 18

Degradation rate constants

Variable	Symbol	Value	Unit	Origin	Remark
Rate constant for degradation in a STP	kdeg	0,00E+00	/d	O	
Rate constant for degradation in soils	kdeg_soil	6,93E-07	/d	O	Rate constant is ln(2)/1.0E06 by default when no data on degradation in soils is available.
Rate constant for removal from soils (degradation and leaching)	ktot_soil	2,70E-04	/d	O	

Correction of vapour pressure, solubility, and Henry's constant for 12°C

Variable	Symbol	Value	Unit	Origin	Remark
Environmental temperature	TEMP_env	285	K	D	TGD default (Table 5)
Enthalpy of vapourisation	H0_VP	50000	J/mol	D	TGD formula 2
Enthalpy of solution	H0_SOL	10000	J/mol	D	TGD formula 3
Gas constant	R_	8,314	Pa m³/mol/K	D	TGD formul 2 and 3
Vapour pressure at the environmental temperature	VP	3,98304E-07	Pa	O	TGD formula 2
Solubility at the environmental temperature	SOL	249,5538357	mol/m³	O	TGD formula 3
Henry's constant at the environmental temperature	HENRY	4,05097E-07	Pa m³mol	O	TGD formula 21

Soil partitioning coefficients

Variable	Symbol	Value	Unit	Origin	Remark
Density of wet soil	RHOsoil	1700	kg wwt/m³	D	
Air-water partition coefficient	Kair_water	1,70964E-10	-	O	TGD formula 22
Volume fraction of water in soils	Fwater_soil	0,2	-	D	TGD default (table 5)
Volume fraction of solids in soils	Fsolid_soil	0,6	-	D	TGD default (table 5)
Volume fraction of air in soils	Fair_soil	0,2	-	D	TGD default (table 5)
Weight fraction of organic carbon in soils	Foc_soil	0,02	-	D	TGD default (table 5)
Partition coefficient solid-water in soils	Kp_soil	5,8	L/kg	O	TGD formula 23
Soil-water partitioning coefficient	Ksoil_water	8,9	-	O	TGD formula 24

Leaching from soils

Variable	Symbol	Value	Unit	Origin	Remark
Fraction of rain water that infiltrates into soil	Finf_soil	0,25	-	D	TGD formula 58
Rate of wet precitipation (700 mm/year)	RAINrate	0,00192	m/d	D	TGD formula 58
first-order rate constant for leaching from soil layer	kleach	0,000269663	/d	O	TGD formula 58
half-life for leaching from soils		2570,420795	d	O	

Distribution of sewage sludge

Variable	Symbol	Value	Unit	Origin	Remark
Sub-cooled liquid varpour pressure	VP_L	4,49E-06	Pa	O	Formula 20, Guidace part B, volume IV.
Fraction associated with aerosol particles	Fass_aer	9,57E-01	-	O	Formula 19, Guidace part B, volume IV.
Standard deposition flux of aerosol-bound compounds at a source strength of 1 kg/d	DEPstd_aer	1,00E-02	mg/m²/d	D	
Deposition flux of gaseous compounds as a function of Henry's Law constant, at a source strength of 1 kg/d	DEPstd_gas	5,00E-04	mg/m²/d	D/O	
Local emission to air from STP during emission episode	Estp_air	0,00E+00	kg/d	O	Formula 35, Guidace part B, volume IV.
Total deposition flux during emission episode	DEPtotal	0,00E+00	mg/m²/d	O	Formula 43, Guidace part B, volume IV. It is assumed that Temission is 365 days. Therefore, DEPtotal=DEPtotal, ann.
Aerial deposition flux per kg of soil	Dair	0,00E+00	mg/kg/d	O	Formula 52, Guidace part B, volume IV.
Depth of soil compartment	DEPTH_soil	0,2	m	D	Table 11, Guidace part B, volume IV.
Averaging time	TIME	30	d	D	Table 11, Guidace part B, volume IV.
Sludge application rate	APPL_sludge	0,5	kg dwt/m²/y	D	Table 11, Guidace part B, volume IV.
Concentration in dry sewage sludge at t=0 d	Csludge_0	9,94E-04	mg/kg dwt	O	Formula 60, Guidace part B, volume IV.
Fraction accumulation in one year	Facc	0,906	-	O	Formula 61, Guidace part B, volume IV.
Concentration in top soils after ten successive sewage applications	Csludge_10	6,64E-03	mg/kg dwt	O	Formula 62, Guidace part B, volume IV.
Concentration in soil after ten years of deposition	Cdep_soil10	0,00E+00	mg/kg dwt	O	Formula 59, Guidace part B, volume IV.
Total concentration in soil after ten years	Csoil10	6,64E-03	mg/kg dwt	O	Formula 63, Guidace part B, volume IV.
Concentration in top soils after ten successive sewage applications - averaged over 30 days	PECsoil	6,64E-03	mg/kg dwt	O	Formula 55, Guidace part B, volume IV.

Organic carbon-water partitioning coefficient pick-up values

Class	Koc
Predominantly hydrophobics	0
Non hydrophobics	0
Phenols, anilines, benzonitriles, nitrobenzenes	0
Acetanilides, carbamates, esters, phenylureas, phosphates, triazines, triazoles, uracils	0
Alcohols, organic acids	0
Acetanilides	0
Alcohols	0
Amides	0
Anilines	0
Carbamates	0
Dinitroanilines	0
Esters	0
Nitrobenzenes	0
Organic acids	0
Phenols, benzonitriles	0
Phenylureas	0
Phosphates	0
Triazines	0
Triazoles	0

Degradation rate constants for the STP pick-up values

Class	kdeg
Readily biodegradable	24
Readily degradable in marine screening test	24
Readily biodegradable, failing 10-d window	7,2
Inherently biodegradable, fulfilling criteria	2,4
Inherently biodegradable, not fulfilling criteria	0
Not biodegradable	0