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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT (FAMILY) FOR UNION AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

Ecolab Iodine PT3 Family

Product type 3

Case Number in R4BP: BC-VG018734-32

Evaluating Competent Authority: The Netherlands

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Table of Contents

1 CONCLUSION 4

2 ASSESSMENT REPORT 4

2.1 SUMMARY 4
2.1.1 Presentation of the biocidal product (family) 4
A. Identity of the active substance 4
B. Product family composition and formulation 5
C. Intended use(s) 5
D. Hazard and precautionary statements 7
E. Packaging of the biocidal product 7
2.1.2 Summary of the physical, chemical and technical properties 7
2.1.3 Summary of the Human Health Risk Assessment 8
2.1.4 Summary of the Environmental Risk Assessment 25
2.2 GENERAL INFORMATION ABOUT THE PRODUCT APPLICATION 26
2.2.1 Administrative information 26
A. Trade names of the products of the family 26
B. Authorisation holder 26
C. Applicant (if different from authorisation holder) 27
D. Person authorised for communication on behalf of the applicant 27
E. Manufacturer of the products of the family 27
F. Candidate(s) for substitution 29
2.2.2 Product family composition and formulation 30
A. Identity of the active substance 30
B. Qualitative and quantitative information on the composition of the biocidal product family 31
C. Information on technical equivalence 31
D. Information on the substance(s) of concern 31
E. Type of formulation 31
2.2.3 Intended use(s) 31
2.2.4 Hazard and precautionary statements 33
A. Proposed classification and labelling of the biocidal product 33
Packaging of the biocidal product 33
2.2.5 Directions for use 34
A. Instructions for use 34
B. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 35
C. Instructions for safe disposal of the product and its packaging 36
D. Conditions of storage and shelf-life of the product under normal conditions of storage 36
2.2.6 Documentation 36
A. Data submitted in relation to product application 36
B. Access to documentation 36
C. Similar conditions of use 36
2.2.7 Other information 37
2.3 ASSESSMENT OF THE BIOCIDAL PRODUCT FAMILY 38
2.3.1 Physical, chemical and technical properties 38
2.3.2 Physical hazards and respective characteristics 69
2.3.3 Methods for detection and identification 73
2.3.4 Efficacy against target organisms 76
A. Function and field of use 76
B. Organisms to be controlled and products, organisms or objects to be protected 76
C. Effects on target organisms, including unacceptable suffering 76
D. Mode of action, including time delay 76
E. Efficacy data 77
F. Occurrence of resistance and resistance management 90
G. Known limitations 90

H. Evaluation of the label claims 90
I. Relevant information if the product is intended to be authorised for use with other biocidal product(s) 90
2.3.5 Risk assessment for human health 91
A. Assessment of effects on Human Health 91
B. Exposure assessment 101
A. Risk characterisation for human health 126
2.3.6 Risk assessment for animal health 145
2.3.7 Risk assessment for the environment 145
A. Effects assessment on the environment 145
B. Exposure assessment 152
C. Risk characterisation 160
2.3.8 Measures to protect man, animals and the environment 167
A. Recommended methods and precautions 167
B. Identity of relevant combustion products in cases of fire 168
C. Specific treatment in case of an accident 168
D. Possibility of destruction or decontamination following release 169
E. Procedures for waste management of the biocidal product and its packaging 169
F. Procedures for cleaning application equipment where relevant 169
G. Specify any repellents or poison control measures included in the product 169
2.3.9 Assessment of a combination of biocidal products 169
2.3.10 Comparative assessment 170

3 ANNEXES 171

3.1 LIST OF STUDIES FOR THE BIOCIDAL PRODUCT FAMILY 171
3.2 OUTPUT TABLES FROM EXPOSURE ASSESSMENT TOOLS 187
3.3 NEW INFORMATION ON THE ACTIVE SUBSTANCE 202
3.4 RESIDUE BEHAVIOUR 202
3.5 SUMMARIES OF THE EFFICACY STUDIES (B.5.10.1-XX) 202
3.6 CONFIDENTIAL ANNEX 202

1 CONCLUSION

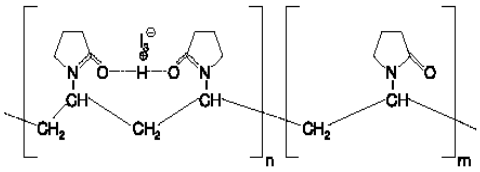
The outcome of the assessment for Ecolab Iodine PT3 Family is specified in the BPC opinion following discussions at the BPC-23 meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website.

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	No ISO common name
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	Min. 995 g/kg (manufactured to the specification of Ph. Eur*)
Structural formula	I-I
Identity details for iodophor 2 (PVP-iodine)	CAS-No: 25655-41-8 EC-No.: not assigned IUPAC Name: Polyvinylpyrrolidone iodine CA Name: 2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. with iodine Common name, synonyms: PVP-iodine Structural formula: m/n=ca 18  Molecular formula: $(C_6H_9NO)x * n\ I2$ Molecular weight: not applicable Ph. Eur* quality used in representative formulations Specification**: 9.0-12.0% available iodine (dried substance), max 2.0% formic acid, max. 8.0% water, max. 6.0% iodide, loss on drying max 8.0%, sulphated ash max 0.1%

* European Pharmacopoeia (Ph. Eur)

B. PRODUCT FAMILY COMPOSITION AND FORMULATION

Qualitative and quantitative information on the composition of the family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine	Iodine	Active substance	7553-56-2	231-442-4	0.11	0.33*
(in the form of PVP iodine, i.e. iodophor type 2; containing 9-12% iodine)	(Polyvinylpyrrolidone iodine)		25655-41-8	not assigned	1	3.0

** the iodine contents are calculated using a nominal purity of 11%. The risk assessment is performed assuming a worst-case concentration of 0.36% available iodine, based on the maximum iodine content in PVP-iodine of 12%, in addition iodide from PVP-iodine, equivalent to max. 0.18%iodine, and max. 0.06% potassium iodate, equivalent to 0.036% iodine, resulting in a max. total iodine concentration of 0.58%.*

The FAO/WHO tolerance for the products within this family is 15% based on an active substance concentration of equal to or less than 0.33% iodine.

The full composition of the product according to Annex III Title 1 is provided in the confidential annex.
The family contains 6 *meta* SPC's. All products within the product family are based on PVP-iodine. Further explanations on the underlying biocidal product family concept are given in the confidential annex.

Information on the substance(s) of concern

As of information available June 2015, there are no substances of concern contained in the products. Analysis and overview according to the criteria laid down in Article 3(f) of Regulation (EU) No. 528/2012 and CA document "CA-Nov14-Doc.5.11 - final" is attached to IUCLID dossier, section 13.

C. INTENDED USE(S)

The family contains 6 *meta* SPC's, which include 7 ready-to-use biocidal products. All *meta* SPC's include intended use #1 for post-milking teat disinfection. *Meta* SPC 3 also includes intended use #2 for pre-milking teat disinfection.

Table 1: Use # 1 –Teat dips or sprays for post-milking disinfection

Product Type(s)	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, yeasts, enveloped viruses
Field of use	Indoor Post-milking disinfection of teats of milk producing animals, e.g. dairy cows, buffaloes, sheep and goats.
Application method(s)	• Manual dipping using a dip cup • Manual spraying using a trigger sprayer • Manual spraying using an electronic sprayer • Automated spraying by robot
Application rate(s) and frequency	3-10 ml (dipping), 10-15 ml (spraying) 1-3 post-milking disinfections per day
Category(ies) of user(s)	Professional
Pack sizes and packaging material	Container, Plastic: HDPE; 0.5-1000L

Table 2: Use # 2 –Teat dips or sprays for pre-milking disinfection

Product Type(s)	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, yeasts
Field of use	Indoor Pre-milking disinfection of teats of milk producing animals, e.g. dairy cows, buffaloes, sheep and goats.
Application method(s)	• Manual dipping using a dip cup • Manual spraying using a trigger sprayer • Manual spraying using an electronic sprayer
Application rate(s) and frequency	3-10 ml (dipping), 10-15 ml (spraying) 1-3 pre-milking disinfections per day
Category(ies) of user(s)	Professional
Pack sizes and packaging material	Container, Plastic: HDPE; 0.5-1000L

D. HAZARD AND PRECAUTIONARY STATEMENTS

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

Classification	
Hazard category	*Meta* SPC 3: Aquatic chronic, category 3 *Meta* SPC 1, 2 and 4-6: No classification (conclusive but not sufficient for classification)
Hazard statement	*Meta* SPC 3: H412, Harmful to aquatic life with long lasting effects. *Meta* SPC 1, 2 and 4-6: none
Labelling	
Signal words	No signal word
Hazard statements	*Meta* SPC 3: H412, Harmful to aquatic life with long lasting effects. *Meta* SPC 1, 2 and 4-6: none
Precautionary statements	*Meta* SPC 3: P273, Avoid release to the environment. *Meta* SPC 1, 2 and 4-6: none
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)**
Container (e.g. jerry can, drum)	0.5 – 1000 L	Plastic: HDPE	screw cap , closure with Turn-lock ring / safety ring / Closure without venting system (HDPE)	professional	Yes

2.1.2 Summary of the physical, chemical and technical properties

The products of this biocidal product family appear to be liquid, brown formulations. Depending on product no odour up to characteristic odour of iodine can be recognised. The

pH is ranging from 2.4 (IoKlar multi) up to 5.5 (Io-Shield D), indicating no concern with regard to classification and labelling. For those products that are outside the range of pH 4-10 acidity has been determined to be between 0.0113% (Ioklar Super Dip D, read-across from IoKlar D) and 0.083% (Veloucid D) of mean equivalent sulphuric acid. The relative density ranges between 0.9670 (Veloucid D) and 1.0303 (Io-Shield D). While long-term storage tests of some products of the family revealed significant decrease in iodine content, subsequent testing of efficacy after storage showed that the required efficacy was still achieved. Shelf-life of the *meta* SPCs is 18 months for *meta* SPC 5 and 24 months for meta SPCs 1-4 and 6.

Testing of physico-chemical hazards did not reveal any physico-chemical hazards arising from the products. Classification is not required in the sense of Regulation (EC) 1272/2008.

2.1.3 Summary of the Human Health Risk Assessment

Endpoint	**Brief description**
Skin corrosion and irritation	Based on intrinsic properties of individual components, the biocidal products pertaining to the BPF are neither corrosive nor irritating to skin.
Eye irritation	Based on intrinsic properties of individual components, the biocidal products pertaining to the BPF are neither damaging nor irritating to eyes.
Respiratory tract irritation	Based on intrinsic properties of individual components, the biocidal products pertaining to the BPF are not irritating to the respiratory tract.
Skin sensitisation	Based on intrinsic properties of individual components, the biocidal products pertaining to the BPF are not sensitising to skin.
Respiratory sensitization (ADS)	Based on intrinsic properties of individual components, the biocidal products pertaining to the BPF are not sensitising to the respiratory tract.
Acute toxicity by oral route	Based on intrinsic properties of individual components, the biocidal products pertaining to the BPF are not acutely toxic via the oral route.
Acute toxicity by inhalation	Based on intrinsic properties of individual components, the biocidal products pertaining to the BPF are not acutely toxic via the inhalation route.
Acute toxicity by dermal route	Based on intrinsic properties of individual components, the biocidal products pertaining to the BPF are not acutely toxic via the dermal route.
Dermal absorption	Read-across is made to one available *in-vitro* human skin dermal absorption study, performed with a PVP-iodine-based product and evaluated in the context of the active substance dossier on iodine (incl. PVP-iodine). In accordance with the most recent EFSA guidance on dermal absorption (EFSA, 2012), a dermal absorption value of 12% was derived which, based on the read-across, was used in the HHRA of the biocidal products pertaining to the BPF.

Other effects	No other toxicological effects (e.g. CMR, STOT RE, STOT SE) to be anticipated from the biocidal products.
Available toxicological data relating to non active substance(s)	No indication that the products pertaining to the BPF contain components that are to be considered as substance(s) of concern.
Available toxicological data relating to a mixture	No indication that the products pertaining to the BPF contain mixtures that a substance(s) of concern is a component of.
Other relevant information • Food and feeding stuffs studies	No applications intended where contact with feeding stuffs may arise. Application of the products pertaining to the BPF may lead to iodine residues in milk. Assessment of potential iodine residues in milk is summarized in the supporting document of the IRG PT3 sub-group and in the respective chapters of the PAR.
Other relevant information • Effects of industrial processing and/or domestic preparation on the magnitude of residues of the biocidal product and other test(s) related to the exposure to humans	However, no indication that during industrial processing and/or domestic preparation toxicologically significant degradation products of iodine arise requiring a separate risk assessment. In conclusion, no risk is identified for iodine teat disinfection products.
Other relevant information • Other tests related to the exposure of humans	Other tests related to exposure of humans not required. Assessment of potential iodine residues in milk is summarized in the supporting document of the IRG PT3 sub-group and in the respective chapters of the PAR.

Reference values

	Study	**NOAEL/ LOAEL**	**Overall assessment factor**	**Value**
$AEL_{short\text{-}term}$	Not derived in the CAR and not relevant for HHRA.			
$AEL_{medium\text{-}term}$	Not derived in the CAR and not relevant for HHRA.			

$AEL_{long\text{-}term}$ = Upper Intake Level (UL)	Human data			Adult: 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/m^3

Risk characterisation

Summary table: scenarios[1] for pre- or post-milking disinfection by dipping or spraying			
Scenario number	**Scenario**	**Primary exposure Description of scenario**	**Exposed group**
1.1	Mixing and loading of RTUs for dip cup or trigger sprayer	Preparation of dip cups: The product (RTU) is filled undiluted into the reservoir of a dip cup. By squeezing the reservoir, the disinfectant is pumped using a dosing pump into the dip cup above the reservoir which is then ready for dipping. By using the dosing pump overdosing can be avoided. Preparation of a trigger sprayer: The product (RTU) is filled undiluted into the reservoir of a sprayer. Re-filling of a dip cup or of a trigger sprayer is done analogously.	professionals
1.2	Mixing and loading for electronic sprayer or robotic milking device	This scenario replaces scenario 1.1 if electronic sprayer or robotic milking device is used. A can containing the RTU product is opened and a sucking lance of the electronic sprayer or robotic milking device is inserted. Empty cans are replaced by new ones.	professionals
2.1	Application of teat disinfectant by manual dipping	Before and/or after milking, the dip cup prepared as described in scenario 1.1 is put over each teat from below making sure that the full length of each teat is immersed into the disinfectant. The exposure during dipping is considered to be covered by the exposure during mixing and loading.	professionals
2.2	Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer	This scenario replaces scenarios 2.1 in case of spray application. Before and/or or after milking, the teats are sprayed with the disinfectant using a trigger sprayer or electronic sprayer making sure that each teat is covered with the disinfectant.	professionals

1 This table is a copy of the table in Chapter 8.3 of the Assessment Report.

2.3	Application of teat disinfectant by robot with automatic sprayer	This scenario replaces scenarios 2.1 and 2.2 in case of spray application by robot. Application by robot takes place only after milking. After robotic milking, the disinfectant is sprayed automatically onto teats from a cluster arm. No exposure due to fully automated system	professionals
3.1	Cleaning of teats by wiping with cloth: removal of freshly applied product	The teats which have been treated with a PVP iodine based disinfectant shortly before are carefully cleaned by wiping with a dry cloth immediately before milking.	professionals
3.2	Cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment	Cleaning of teats by wiping with a dry cloth before milking is only relevant if the cows have received a post-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.	Negligible exposure
3.3	Cleaning of teats by robot: removal of dried residues from post-milking treatment	This scenario replaces scenario 3.2 if teats are cleaned with robot. Before each milking, the teats are cleaned by robot with automatic brushes.	No exposure
4.1	Cleaning of equipment such as dip cups, trigger sprayer and electronic sprayer after use	After disinfection, the reservoir is emptied and the entire dip or spray equipment is cleaned with running water.	professionals

4.2	Rinsing of robotic system	This scenario replaces scenario 4.1 if a robotic system is used. After disinfection, the system is flushed with water: the system is operated for few seconds with water instead of the disinfectant. Exposure is considered negligible.	Negligible exposure

Conclusion of risk characterisation for professional user

Explanatory note:

The exposure assessments according to the CAR are based on the old TNsG 2002 models. Although CAR was agreed upon by all MSs, it turned out during risk assessment of the biocidal products that for some tasks the models that have been chosen are not mapping to the actual use of the biocidal products. In addition, some scenarios have not been considered in the CAR. In the meantime new models have become available that better describe the actual use situations.
Therefore, the exposure assessments are based on model calculations using models and default values from the HEAdhoc Recommendation no. 13 (Jan. 2017).

Local effects

Local effects are only relevant for the application scenario "Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer".

Task/ Scenario	Iodine in air inhaled (mg/m³)	% OEL (1 mg/m³)	Acceptable (yes/no)
Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer [2.2]	6.09E-02	6.1	yes

Combined scenarios: Pre-milking disinfection of 82 animals twice a day. Assessment for the upper limit of the BPF, i.e. max 0.58% total iodine. Intakes which exceed the UL are highlighted in red in the table below.

Scenarios combined	Tier	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 - RTUs Scenarios [1.1; 2.1; 3.1; 4.1]	Tier 1/ none	5.78E-03	58	68	83	114
	Tier 2/ Gloves	5.78E-04	6	16	31	62
Manual spraying using a trigger sprayer - RTUs Scenarios [1.1; 2.2; 3.1; 4.1]	Tier 1/ none	2.09E-02	209	219	234	265
	Tier 2/ Gloves	5.38E-03	54	64	79	110
Manual spraying using an electronic sprayer - RTUs Scenarios [1.2; 2.2; 3.1; 4.1]	Tier 1/ none	1.86E-02	186	196	211	242
	Tier 2/ Gloves	5.15E-03	51	62	77	108

<u>Conclusion (BPF-level): Pre-milking disinfection *of 82 animals twice a day*</u>

<u>Tier 1:</u>

Exposure from biocidal use without considering PPE (Tier 1) results in 58% for manual dipping, 209% and 186% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.

Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 1) results in 68% for manual dipping, 219% and 196% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.

Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 1) results in 83% for manual dipping, 234% and 211% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 114% for manual dipping, 265% and 242% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.

Tier 2:
Exposure from biocidal use considering gloves (Tier 2) results in 6% for manual dipping, 54% and 51% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, considering gloves (Tier 2) results in 16% for manual dipping, 64% and 62% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.
Exposure from biocidal use, including iodine from milk consumption, considering gloves (Tier 2) results in 31% for manual dipping, 79% and 77% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, considering PPE (Tier 2) results in 62% for manual dipping, 110% and 108% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.

Conclusion professional use, pre-milking application- BPF first level
For a total iodine concentration of 0.58% this means that for pre-milking disinfection by manual dipping is safe for the protected (chemical resistant gloves) professional user (i.e. 62% UL).
For a total iodine concentration of 0.58% by manual spraying using a trigger or electronic sprayer for pre-milking disinfection, the UL is exceeded, even when considering PPE (i.e. 110% UL for using a trigger sprayer and 108% UL using an electronic sprayer).
However, as the evaluation of metaSPC3 (see below) shows safe use for the protected (chemical resistant gloves) professional user considering 0.44% total iodine when used for pre-milking application by spraying using a trigger sprayer or an electronic sprayer, the max. total iodine of the BPF needs to be lowered to 0.44% total iodine.

Furthermore, the OEL of 1 mg/m³ for iodine is not reached in the scenario "Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer" for pre-milking disinfection with 6.1% of the OEL.

As only MSPC3 within the BPF contains pre-milking applications, no conclusions need to be drawn for the other MSPCs. The iodine concentration within metaSPC3 (0.44% total iodine) is compared to the BPR (i.e. 0.58% total iodine) and summarized in the table below.

Assessment for the upper limit of the metaSPC3, i.e. max 0.44% total iodine. Intakes which exceed the UL are highlighted in red in the table below.

Scenarios combined	Tier	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 - RTUs Scenarios [1.1; 2.1; 3.1; 4.1]	Tier 1/ none	4.38E-03	44	54	69	100
	Tier 2/ Gloves	5.75E-04	4	15	30	61
Manual spraying using a trigger sprayer - RTUs Scenarios [1.1; 2.2; 3.1; 4.1]	Tier 1/ none	2.07E-02	159	169	184	215
	Tier 2/ Gloves	5.27E-03	41	52	67	98
Manual spraying using an electronic sprayer - RTUs Scenarios [1.2; 2.2; 3.1; 4.1]	Tier 1/ none	1.76E-02	141	152	167	198
	Tier 2/ Gloves	4.96E-03	39	50	65	96

[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 toddler based on UK data (2008).

Conclusion (metaSPC-level): Post-milking disinfection *of 82 animals twice a day*

Tier 1:
Exposure from biocidal use without considering PPE (Tier 1) results in 58% for manual dipping, 207% and 176% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 1) results in 68% for manual dipping, 218% and 187% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.

Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 1) results in 83% for manual dipping, 233% and 202% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 114% for manual dipping, 264% and 233% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.

Tier 2:
Exposure from biocidal use considering gloves (Tier 2) results in 6% for manual dipping, 53% and 50% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, considering gloves (Tier 2) results in 16% for manual dipping, 63% and 60% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.
Exposure from biocidal use, including iodine from milk consumption, considering gloves (Tier 2) results in 31% for manual dipping, 78% and 75% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, considering PPE (Tier 2) results in 62% for manual dipping, 109% and 106% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.

Conclusion professional use, pre-milking application- metaSPC level: metSPC3
Pre-milking disinfection by manual dipping with products included in metaSPC3 (iodine concentration of 0.44% total iodine) for the unprotected professional user the UL is not exceeded (i.e. 100% UL). However, by manual spraying using a trigger or electronic sprayer for pre-milking disinfection, the use of chemical gloves are necessary not to exceed the UL for the professional user (i.e. max. 98% UL). Therefore, for products included in metaSPC3 "Wear chemical resistant gloves for spraying applications" needs to be included in the labelling of the product (included in the use-specific risk mitigation measures of the SPC (use 3.2, paragraph 4.1.2)).

Combined scenarios: Post-milking disinfection of 82 animals twice a day. Assessment for the upper limit of the BPF, i.e. max 0.58% total iodine. Intakes which exceed the UL are highlighted in red in the table below.

Scenarios combined	Tier	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 - RTUs	Tier 1/ none	2.43E-03	24	37	52	83
	Tier 2/					

Scenarios combined	Tier	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; 2.1; 3.2; 4.1]	Gloves	2.43E-04	2	15	30	61
Manual spraying using a trigger sprayer - RTUs Scenarios [1.1; 2.2; 3.2; 4.1]	Tier 1/ none	1.75E-02	175	188	203	233
	Tier 2/ Gloves	5.05E-03	50	63	78	109
Manual spraying using an electronic sprayer - RTUs Scenarios [1.2; 2.2; 3.2; 4.1]	Tier 1/ none	1.52E-02	152	164	179	210
	Tier 2/ Gloves	4.81E-03	48	61	76	106
Automated spraying Scenarios [1.2; 2.3; 3.3; 4.2]	Tier 1/ none	5.94E-04	6	18	33	64
	Tier 2/ Gloves	5.84E-04	6	18	33	64

Conclusion (BPF-level): Post-milking disinfection *of 82 animals twice a day*

Tier 1:

Exposure from biocidal use without considering PPE (Tier 1) results in 24% for manual dipping, 175% and 152% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 6% of the UL for robotic spraying.

Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 1) results in 37% for manual dipping, 188% and 164% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 18% of the UL for robotic spraying.

Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 1) results in 52% for manual dipping, 203% and 179% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 33% of the UL for robotic spraying.

Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 83% for manual dipping, 233% and 210% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 64% of the UL for robotic spraying.

Tier 2:

Exposure from biocidal use considering gloves (Tier 2) results in 2% of the UL for manual dipping, 50% and 48% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and6% of the UL for robotic spraying.

Exposure from biocidal use, including iodine from milk consumption due to teat treatment, considering gloves (Tier 2) results in 15% for manual dipping, 63% and 61% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 18% of the UL for robotic spraying.

Exposure from biocidal use, including iodine from milk consumption, considering gloves (Tier 2) results in 30% for manual dipping, 78% and 76% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 33% of the UL for robotic spraying.

Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, considering gloves (Tier 2) results in 61% for manual dipping, 109% and 106% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 64% of the UL for robotic spraying.

Conclusion professional use, post-milking application- BPF first level

For a total iodine concentration of 0.58% for post-milking disinfection by manual dipping or by automated spraying for the unprotected professional user (i.e. 83% UL for manual dipping and 64% UL for automated spraying) the exposure to iodine is considered safe. However, for a total iodine concentration of 0.58% by manual spraying using a trigger or electronic sprayer for post-milking disinfection, the UL is exceeded, even when considering PPE (i.e. 109% UL for using a trigger sprayer and 106% UL using an electronic sprayer). However, as the evaluation of spraying application by trigger sprayer or an electronic sprayer at metaSPC level shows safe use for the protected (chemical resistant gloves) professional user considering maximally 0.44% total iodine, the max. total iodine of the BPF needs to be lowered to 0.44% total iodine.

Furthermore, the OEL of 1 mg/m³ for iodine is not reached in the scenario "Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer" for post-milking disinfection with 6.1% of the OEL.

Conclusions for the remaining MSPCs can be obtained based on the relative difference in iodine concentration within the MSPCs compared to the limit of the BPF (i.e. 0.58% total iodine) and are summarized in the following table for manual dipping and manual spraying using a trigger sprayer (post-milking). Please note that the calculated factors have been rounded, and thus results slightly differ from the exactly calculated exposure estimates. Intakes which exceed the respective UL are highlighted in red in the table below.

Difference in total iodide concentration compared with MSPC?	Tier	Estimated % UL (0.01 mg/kg bw/day) due to	% UL (0.01 mg/kg bw/day) due to biocidal use + iodine from	% UL (0.01 mg/kg bw/day) due to biocidal use + total	% UL (0.01 mg/kg bw/day) due to biocidal use + total

		biocidal use *	milk due to teat treatment[1]	milk intake[2] *	dietary intake[3]
MSPC1, 0.19% total iodine (post-milking dipping) 3-fold lower total iodine concentration compared with limit of the BPF (0.58% total iodine)	Tier 1/ none	8	20	35	66
	Tier 2/ Gloves	1	13	28	59
MSPC2, 0.27% total iodine (post-milking dipping) 2.1-fold lower total iodine concentration compared with limit of the BPF (0.58% total iodine)	Tier 1/ none	11	24	39	70
	Tier 2/ Gloves	1	14	29	59
MSPC3, 0.44% total iodine (post-milking dipping or spraying) 1.3-fold lower total iodine concentration compared with limit of the BPF (0.58% total iodine)	Tier 1/ none	18-133	31-146	46-161	77-191
	Tier 2/ Gloves	–2-39	14-51	29-66	60-97
MSPC4, 0.22% total iodine (post-milking dipping or spraying) 2.6-fold lower total iodine concentration compared with limit of the BPF (0.58% total iodine)	Tier 1/ none	9-66	22-79	37-94	67-124
	Tier 2/ Gloves	–1-19	13-31	28-46	59-77
MSPC5, 0.22% total iodine (post-milking dipping) 2.6-fold lower total iodine concentration compared with limit of the BPF (0.58% total iodine)	Tier 1/ none	9	22	37	67
	Tier 2/ Gloves	1	13	28	59
MSPC6, 0.27% total iodine (post-milking dipping or spraying) 2.1-fold lower total iodine concentration compared with limit of the BPF (0.58% total iodine)	Tier 1/ none	11-81	24-94	39-109	70-140
	Tier 2/ Gloves	1-23	14-36	29-51	59-82

* The range represent the range between lowest estimated % UL for manual dipping and the highest estimated % UL for manual spraying with a trigger sprayer (pre- or post-milking, whereas pre-milking is worst-case compared to post-milking).
[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 toddler based on UK data (2008).

Conclusion professional use, post-milking application- metaSPC level
Post-milking disinfection by manual dipping and automated spraying considering the BPF (i.e. 0.58% total iodine) was considered safe for the unprotected user, therefore for metaSPC1-5 this application is also considered safe. However, for clarity the specific exposure is included per metaSPC in the table above.
However, by manual spraying using a trigger or electronic sprayer for post-milking disinfection, the use of chemical gloves are necessary not to exceed the UL for the professional user (i.e. max. 97% UL). Therefore, for products included in metaSPC3,4 and 6 "Wear chemical resistant gloves for spraying applications" needs to be included in the labelling of the product (included in the general risk mitigation measures of the SPC (paragraph 5.2)).

Conclusion of risk characterisation for indirect exposure (consumers via residues in food)

During discussions in the human health working group meetings and WebEx meetings for eCAs evaluating iodine based union authorisation applications, the assumptions that could be considered for the exposure to residues via milk were discussed.
The following needs to be considered:

- Exposure in accordance to intended use (WGIII 2017). Therefore, for this application exposure due to either pre- or post-treatment per milking event for the BPF is assessed as products included in the BPF can only be used for pre- or post-application. This is also reflected in the instruction included in the general RMM section of the SPC for metaSPC3 paragraph 5.2 (as this is the only metaSPC that include uses for pre- and post-application): Products can either include post- or pre-application uses.
- Application by robots is considered to be performed three times a day, and manual milking two times per day. For exposure to residues looking at the applied volume of product, on a daily basis there is no difference between automated and manual exposure (10 ml x 3 = 30 ml for automatic robot application, 15 ml x 2 = 30 ml for manual application). This is in line with the conclusion of the Secure Webex meeting (3-10-2017), in which was concluded by eCAs evaluating iodine based union authorisation applications: "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". Therefore, for the exposure calculations information of the O'Brien study is used, which considers 2x manual application.

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 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. As the maximum concentration of the BPF product contains 0.33% available iodine, the values based on the O'Brien study are corrected. (WGIV 2017). Furthermore, as products can be used either for pre- or 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 evaluating 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 evaluating 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 toddlers 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 children/toddlers (200 µg/d) and depicted in the table below. Intakes which exceed the respective UL are highlighted in red in the table below.

Comparison of estimated daily iodine intakes compared to upper limit of pre- or post-milking teat-disinfection– BPF level (based on 0.33% available iodine)

	Adults (0.45 L/day)	**Toddlers (0.46 L/day)**
	Estimated daily intake (µg/day) [% of UL]	**Estimated daily intake (µg/day) [% of UL]**
2x pre-milking application		
Intake from milk due to teat treatment	64 11	65 33
Total milk intake*	154 26	157 79
Total dietary intake**	339 56	253 127
2x post-milking application		
Intake from milk due to teat treatment	75 12	76 38
Total milk intake*	165 27	168 84
Total dietary intake**	350 58	264 132

* 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 toddler based on UK data (2008).

Conclusion: Pre- or post-milking teat-disinfection

For adults, the estimated daily intake of iodine resulting from biocidal product use is maximally 12% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 27% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 58% of the UL.

For toddlers, the estimated daily intake of iodine resulting from biocidal product use is maximally 38% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 84% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 132% of the UL.

As the worst case consumer exposure, taking into account the max. available iodine levels of the BPF, shows exceedance of the UL for toddlers when taken into account intake due to the teat disinfection and dietary intake, we have evaluated the exposure at metaSPC level, for which the same conclusions can be drawn as for BPF-level: the UL for toddlers is exceeded when taken into account teat disinfection and dietary intake.

NL proposal for 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 (i.e. 107-132% of UL or 1.07-1.32 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.

The following options are available for a risk management decision as to whether authorisation can be granted:

1. No authorisation of the product: The estimated total daily intakes exceed the UL for toddlers and are unacceptable.
2. Authorise: The estimated total daily intakes exceed the UL for toddlers; however post authorisation data should be submitted to resolve some of the uncertainties surrounding this risk assessment. These data should include milk residue studies/trials following application of the product.
3. Authorise: Whilst there are exceedances, a socio-economic comparative assessment should be undertaken to show that the benefits outweigh the risks.
4. Authorise: Exceedances of the UL are seen already with dietary intakes arising from iodine background levels. The additional burden arising from teat disinfection is regarded to be of little consequence.

<u>For consideration by MS/ECHA/EFSA:</u> More reliable information on iodine background levels in food items in the EU and a more recent review of all the available data supporting the current UL are required. For the background levels all sources of iodine, and not just those arising from teat treatments, would need to be taken into consideration. Therefore a wider approach to the consumer risk assessments encompassing different regulatory regimes would need to be considered. In addition, applicants for teat disinfection products should be recommended to provide reliable data on residue levels from teat disinfection in milk, e.g. at the time point of active substance renewal.

The NL is of the opinion that it is desirable to derive an EU-harmonised iodine MRL for milk that covers all iodine uses (feed supplementation, teat dips, equipment sanitizers, veterinary medicines). Because milk and dairy products represent major foods for humans and there is a risk of exceeding the tolerable upper intake level for iodine from milk due to the use of iodine as feed supplement either alone or in combination with use in teat dips or sprays, an iodine MRL in milk is considered desirable. The multiple uses of iodine makes the setting of a suitable MRL a challenge, but also support the necessity of deriving an integrative MRL to prevent excess intake by consumers. The level of the MRL needs to be carefully established, since the daily iodine intake in many countries depends (also) on iodine levels in milk. However, as we have an agreed MRL approach (CA-March17-Doc.7.6.c - Final - MRLs-interim approach) and no endorsed MRL guidance for biocides, we propose to consider this at active substance renewal.

Option 2, asking for post authorisation data was discussed in the CA 74 (September 2017) and the majority did not support this proposal. Furthermore, it was acknowledged that biocides are not the main contributor of the exposure level and more discussion was needed. The derivation of an MRL was also discussed, but no conclusions were made on this subject.

For the NL proposal for a risk management decision we refer to the conclusions in chapter 1 of the PAR.

2.1.4 Summary of the Environmental Risk Assessment

Teat disinfectants are released to the environment due to spillage during application, cleaning of the applied equipment, and dripping from cows' teats and udders. As most dairy farms are not connected to the public sewer, residues are predominantly discharged to the manure storage and eventually to soils when manure is applied as a fertiliser. Iodine is not volatile and persistent as it does not degrade biologically of abiotically. Depending on the redox conditions and acidity, iodine will be transformed into iodide or iodate. Both species exist in water, but iodate is the dominant species in soils.

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). Although the iodide concentrations in soils after distribution of sewage sludge on land does result in an exceeding of the PNEC, no unacceptable risks are expected as soils are aerobic and therefore iodine is transformed into iodate for which the PEC is well below the PNEC. However, emission to individual waste water treatment systems may results in malfunctioning of the installation as such systems are vulnerable for high loads of biocides due to their size. Diluted residues and waste water must be discharged to the sewer where legally allowed or to the manure storage.

Release via manure results in unacceptable risks for surface water adjacent agricultural soils (PEC:PNEC ratios up to 5.98) due to runoff and concentrations in groundwater (30-50 µg iodine/L) that are well above the 0.1 µg/L threshold and acceptable human intake limits. However, the calculated concentrations are within the natural background range (0.5-70 µg/L). Because iodine is a natural occurring compounds and many uncertainties exist in the applied methodology as appropriate models for runoff to surface water and leaching to groundwater are not available for inorganic substances like iodine, background concentrations has been accepted as a substitute for the PNEC. From an environmental perspective the application of iodine-based teat disinfectants is therefore acceptable. No risk mitigation measures are necessary.

2.2 GENERAL INFORMATION ABOUT THE PRODUCT APPLICATION

2.2.1 Administrative information

A. TRADE NAMES OF THE PRODUCTS OF THE FAMILY

Trade name	**Country (if relevant)**
Ioklar Super Dip D IoKlar Superdip	All EEA countries (Union authorization)
Io-Shield D IoShield MEPA Barrier D BARIOPROTECT MS Cow Udder BLOCK Iodocop EXTRA	
IoDark Iodocop EXTRA GREEN Mammizan Protect MS Cow Udder BLACK	
Veloucid D VelouCid MEPA Care D Cremadip MS Cow Udder SEPIA	
IoKlar Multi MEPA Iospray Plus D ASTRI-IO DESINTEC MH-Iodine S	
Veloucid Spray D VelouCid Spray MEPA Soft Spray D ASTRI-UC SAC WINTERSPRAY	
MEPA Barrier Spray D IoShield Spray QUARESS-Barrier	

B. AUTHORISATION HOLDER

Name and address of the authorisation holder	Name	Ecolab Deutschland GmbH
	Address	Ecolab-Allee 1, 40789 Monheim, Germany
Telephone:	+49-2173-599-0	
Fax:		
E-mail address:		
Pre-submission phase started on:	25 July 2014 / 3 November 2014	
Pre-submission phase concluded on:	4 December 2014	

Case number in R4BP3:	Communication number: D(2014)5829

C. APPLICANT (IF DIFFERENT FROM AUTHORISATION HOLDER)

Company Name:	Same as authorisation holder.
Address:	
City:	
Postal Code:	
Country:	
Telephone:	
Fax:	
E-mail address:	
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	

D. PERSON AUTHORISED FOR COMMUNICATION ON BEHALF OF THE APPLICANT

Name:	Dr. Ludger Grunwald
Function:	
Address:	Ecolab-Allee 1
City:	Monheim am Rhein
Postal Code:	40789
Country:	Germany
Telephone:	+49-2173-599-1731
Fax:	
E-mail address:	biocides@ecolab.com

E. MANUFACTURER OF THE PRODUCTS OF THE FAMILY

Name of manufacturer	Ecolab Europe GmbH
Address of manufacturer	Richtistrasse 7. Walliselen Switzerland
Location of manufacturing sites	Ecolab Baglan –UK ECOLAB CONTAMINATION CONTROL BRUNEL WAY, BAGLAN ENERGY PARK, NEATH, SA11 2GA South Wales, United Kingdom Ecolab Leeds -UK LOTHERTON WAY, GARFORTH, LEEDS LS25 2JY

	Leeds, West Yorkshire, UK Ecolab Rovigo –Italy Viale del Lavoro 10 , 45100 Rovigo , ITALY Rovigo , ITALY Ecolab Biebesheim –Germany Nalco Deutschland Manufacturing GmbH und Co.KG Justus-von-Liebig-Str. 11 D-64584 Biebesheim, Germany Ecolab NETHERLANDS BV NL01 ECOLAB BRUGWAL 11, 3432NZ, NIEUWEGEIN Ecolab Weavergate, UK ECOLAB WEAVERGATE PLANT WINNINGTON AVENUE NORTHWICH CHESHIRE CW8 3AA Ecolab Mullingar, Ireland Forest Park, Zone C Mullingar Ind. Estate, Mullingar, Co. Westmeath, Ireland Ecolab Maribor, Slovenia Ecolab d.o.o. Vajngerlova 4 2000 Maribor Slovenia Ecolab Rozzano, Italy VIA GRANDI 9/11,20089 ROZZANO (MI),ITALY Ecolab B.V.B.A Havenlaan: 4 3980 Tessenderlo Belgium Ecolab CELRA –Spain Nalco Española Manufacturing, SLU C/Tramuntana s/n Polígono Industrial de Celrà 17460 CELRÀ (Girona) SPAIN Ecolab Chalons, France Ecolab production France SAS BP509, Avenue de Général Patton 51006 Châlons-en-Champagne France Ecolab Mandra, Greece 25km Old National Road Athens Mandra, Attica, Greece

	NALCO FINLAND MANUFACTURING OY Kivikummuntie 1, FIN-07955 Tesjoki

F. CANDIDATE(S) FOR SUBSTITUTION

The active substance contained in the biocidal products of this biocidal product family is not a candidate for substitution.

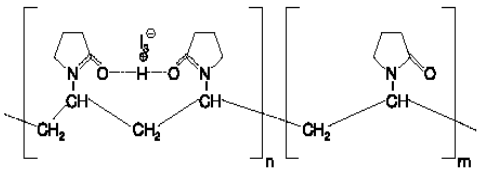
2.2.2 Product family composition and formulation

The full composition of the products is included in the confidential annex.

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

Yes ☒ (Io-Shield D)
No ☐

A. IDENTITY OF THE ACTIVE SUBSTANCE

Main constituent(s)	
ISO name	No ISO common name
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	Min. 995 g/kg (manufactured to the specification of Ph. Eur*)
Structural formula	I-I
Identity details for iodophor 2 (PVP-iodine)	CAS-No: 25655-41-8 EC-No.: not assigned IUPAC Name: Polyvinylpyrrolidone iodine CA Name: 2-Pyrrolidinone, 1-ethenyl-, homopolymer, compd. with iodine Common name, synonyms: PVP-iodine Structural formula: m/n=ca 18  Molecular formula: (C6H9NO)x * n I2 Molecular weight: not applicable Ph. Eur* quality used in representative formulations Specification: 9.0-12.0% available iodine (dried substance), max 2.0% formic acid, max. 8.0% water, max. 6.0% iodide, loss on drying max 8.0%, sulphated ash max 0.1%

* European Pharmacopoeia (Ph. Eur)

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

Please see the confidential annex for further details.

C. INFORMATION ON TECHNICAL EQUIVALENCE

The sources of iodine are the same as evaluated for inclusion in the Union list of approved substances.

For all non-reference sources of iodine used for the products of this family applications for technical equivalence have been submitted. Decisions are available in R4BP.

D. INFORMATION ON THE SUBSTANCE(S) OF CONCERN

As of information available June 2015, there are no substances of concern contained in the products. Analysis and overview according to the criteria laid down in Article 3(f) of Regulation (EU) No. 528/2012 and CA document "CA-Nov14-Doc.5.11 - final" is attached to IUCLID dossier, section 13.

E. TYPE OF FORMULATION

Ready to use water based liquid (FAO/WHO code: AL, any other liquid)

2.2.3 Intended use(s)

Table 1: Use # 1 –Teat dips or sprays for post-milking disinfection (for *meta* SPC 1-6)

Product Type	PT03 – Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, yeasts, enveloped viruses
Field of use	Indoor Post-milking disinfection of teats of milk producing animals (cows, buffaloes, goats, sheep).
Application method(s)	• Manual dipping using a dip cup (post-milking disinfection) • Manual spraying using a trigger sprayer (post-milking disinfection)

	• Manual spraying using an electronic sprayer (post-milking disinfection) • Automated spraying by robot (only post-milking disinfection)
Application rate(s) and frequency	3-10 ml (dipping), 10-15 ml (spraying) (for animals with four teats) 1-3 post-milking disinfections per day
Category(ies) of users	Professional users
Pack sizes and packaging material	Container, Plastic: HDPE; 0.5-1000L
Potential for release into the environment (yes/no)	yes
Potential for contamination of food/feedingstuff (yes/no)	yes

Table 2: Use # 2 –Teat dips or sprays for pre-milking disinfection (for *meta* SPC 3 only)

Product Type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, yeasts
Field of use	Indoor. Pre-milking disinfection of teats of milk producing animals (cows, buffaloes, goats, sheep)
Application method(s)	• Manual dipping using a dip cup (pre-milking disinfection) • Manual spraying using a trigger sprayer (pre-milking disinfection) • Manual spraying using an electronic sprayer (pre-milking disinfection)
Application rate(s) and frequency	3-10 ml (dipping), 10-15 ml (spraying) (for animals with four teats) 1-3 pre-milking disinfections per day
Category(ies) of users	Professional users
Pack sizes and packaging material	0.5 L – 1000 L HDPE container

Potential for release into the environment (yes/no)	yes
Potential for contamination of food/feedingstuff (yes/no)	yes

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 of the individual products of the BPF, and thus the BPF itself	
Hazard category	*Meta* SPC 3: Aquatic chronic, category 3 *Meta* SPC 1, 2 and 4-6: No classification (conclusive but not sufficient for classification)
Hazard statement	*Meta* SPC 3: H412, Harmful to aquatic life with long lasting effects. *Meta* SPC 1, 2 and 4-6: none
Labelling of the individual products of the BPF, and thus the BPF itself	
Signal words	No signal word
Hazard statements	*Meta* SPC 3: H412, Harmful to aquatic life with long lasting effects. *Meta* SPC 1, 2 and 4-6: none
Precautionary statements	*Meta* SPC 3: P273, Avoid release to the environment. *Meta* SPC 1, 2 and 4-6: none
Note	

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)**
Container (e.g. jerry can, drum)	0.5 – 1000 L	Plastic: HDPE	screw cap, closure with Turn-lock ring / safety ring / Closure without	professional	Yes

			venting system (HDPE)		

2.2.5 Directions for use

A. INSTRUCTIONS FOR USE

Use # 1 –Teat dips or sprays for post-milking

Use # 2 –Teat dips or sprays for pre-milking

uses applicable per *meta* SPC					
1	**2**	**3**	**4**	**5**	**6**
Dipping post-milking	Dipping post-milking	Spraying or dipping pre- or post-milking	Spraying or dipping post-milking	Dipping post-milking	Spraying or Dipping post-milking

Always read the label or leaflet before use and follow all the instructions provided
The products must be brought to temperatures above 20°C before use.
The use of a dosing pump for filling the product into the application equipment is recommended.

Manual dipping using a dip cup (pre- or post milking disinfection)
Pre-milking disinfection**– *meta* SPC 3**:
Product to be applied pre-milking by use of a dipping cup.
Clean teats by wiping with cloth before disinfection. Apply product on the whole teats and leave it for 1 minute. Then wipe with a single use paper or a towel.
In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for post-milking disinfection.

Post-milking disinfection**– *meta* SPC 1-6**:
Product, to be applied post-milking by use of a dipping cup.
Apply product on the whole teat and do not wipe it. Keep the cows standing for 5 min. Before the next milking, carefully clean the teats.
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.

Manual spraying using a trigger sprayer or an electronic sprayer (pre- or post-milking disinfection) – *Meta* SPC 3, 4, 6

Pre-milking disinfection**– *meta* SPC 3**:
Product to be applied by spraying pre-milking using manual equipment.
Clean teats by wiping with cloth before disinfection. Apply product on the whole teats and leave it for 1 minute. Then wipe with a single use paper or a towel.

PPE: Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during pre-milking treatment by spraying application.
In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for post-milking disinfection.

Post-milking disinfection**– *meta* SPC 3, 4, 6**:
Product to be applied by spraying post-milking using manual equipment.
Apply product on the whole teat and do not wipe it. Keep the cows standing for 5 min.
Before the next milking, carefully clean the teats.
PPE: Wear chemical resistant gloves during post-milking treatment by spraying .
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.

Automated spraying by robot (only post-milking disinfection)

Post-milking disinfection**– *meta* SPC 3, 4, 6**:
Open the container containing the RTU product and insert a sucking lance of the robotic milking device. The teats are cleaned by robot with automatic brushes. After robotic milking, 10-15 ml of the disinfectant is sprayed automatically onto teats from a cluster arm. Rinsing of the automatic sprayer is done fully automated. Keep the cows standing for 5 min.

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

Use Restrictions:	

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

Potential Health Effects

Eyes: Health injuries are not known or expected under normal use.
Skin: Health injuries are not known or expected under normal use.
Ingestion: Health injuries are not known or expected under normal use.
Inhalation: Health injuries are not known or expected under normal use.

Chronic Exposure: Health injuries are not known or expected under normal use.

First Aid Measures:

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of inhalation of decomposition products in a fire, symptoms may be delayed. Get medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
Ingestion: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

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.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29

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

Store between 5°C and 25°C and away from direct sunlight. Keep out of reach of children. Keep container tightly closed. Store in the original containers.

Shelf life: 18 - 24 months

2.2.6 Documentation

A. DATA SUBMITTED IN RELATION TO PRODUCT APPLICATION

All data submitted in support of the product dossier is referenced in the reference list of this document (attached in Annex).

B. ACCESS TO DOCUMENTATION

The applicant is data owner and listed on the "List of active substances and suppliers" according to BPR, Article 95. The declaration of ownership is attached to section 13 of the active substance dataset in the IUCLID dossier.

C. SIMILAR CONDITIONS OF USE

Outcome of the pre-submission consultation for Union authorisation application under regulation (EU) No 528/2012: "The biocidal product family *Ecolab PT3 Iodine biocidal product family* is deemed to be eligible for Union authorisation."

ECHA communication number: D(2014)5829

2.2.7 Other information

Application codes: Not applicable.

2.3 ASSESSMENT OF THE BIOCIDAL PRODUCT FAMILY

2.3.1 Physical, chemical and technical properties

In the table below the data with regard to the physical and chemical properties of the products is included. To clarify, the products are included in the following *meta* SPCs:

Meta SPC 1: IOKLAR SUPER DIP D
Meta SPC 2: IO-SHIELD D and IODARK
Meta SPC 3: IOKLAR MULTI
Meta SPC 4: VELOUCID SPRAY D
Meta SPC 5: VELOUCID D
Meta SPC 6: MEPA BARRIER SPRAY D

The data package is considered to sufficiently support the proposed family structure. In the confidential annex, a data gap analysis is included with an overview which studies were used to support the BPF structure.

In the table below, the eCA has added remarks where deemed necessary. Where no remarks are made, the information is considered acceptable.

Property	**Guideline and Method**	**Tested Product**	**Results**	**Reference**
Physical state at 20 °C and 101.3 kPa	Visual assessment	Io-shield D Veloucid D Ioklar Multi Veloucid Spray D	Liquid	Woolley, A.J.; White, D.F. (2013), 41003419 Woolley, A.J.; White, D.F. (2013), 41003412 Woolley, A.J. (2014), 41401265 Woolley, A.J.; White, D.F. (2011), 41003417
Colour at 20 °C and 101.3 kPa			Brown	
Odour at 20 °C and 101.3 kPa			Depending on product odourless up to characteristic odour of iodine.	
			eCA comments Depending on the product, colour ranges from dark brown to amber. It is assumed that product with a higher concentrations of PVP-	

Property	Guideline and Method	Tested Product	Results	Reference
			iodine would generate a stronger odour.	
Acidity / alkalinity	CIPAC MT 191	Ioklar Super Dip D	0.06%NaoH (data after storage)	Siebold, D, Schneider, M., 2017
		Io-shield D	Not applicable. According to Regulation (EU) No 528/2012, Annex III, the test is only applicable if the pH is outside the range of 4-10.	
		IoDark	Not applicable. According to Regulation (EU) No 528/2012, Annex III, the test is only applicable if the pH is outside the range of 4-10.	
		Veloucid D	0.083 % (w/w) of mean equivalent sulfuric acid	Woolley, A.J.; White, D. F. (2013), 41003412
		Ioklar Multi	0.0647 % (w/w) of mean equivalent sulfuric acid	Woolley, A.J. (2014), 41401265
		Veloucid Spray D	Not applicable. According to Regulation (EU) No 528/2012, Annex III, the test is only applicable if the pH is outside the range of 4-10.	
		MEPA Barrier Spray D	Not applicable. According to Regulation (EU) No 528/2012, Annex III, the test is only applicable if the pH is outside the range of 4-10.	
		Ioklar D (data used for read-across)	0.0113 % (w/w) of mean equivalent sulfuric acid	Woolley, A.J. (2014), 41101572
			0.0118 % (w/w) of mean equivalent sulfuric acid	Woolley, A.J. (2014), 41102992

Property	Guideline and Method	Tested Product	Results	Reference
pH (neat formulation)	CIPAC MT 75.3	Ioklar Super Dip D	5.1.	Siebold, D, Schneider, M., 2017
		Io-shield D	5.5 (25°C)	Woolley, A.J.; White, D.F. (2013), 41003419
		IoDark	5.3 (25°C)	Siebold, D.; Schneider, M. (2015)
		Veloucid D	4.5 (25°C)	Woolley, A.J.; White, D.F. (2013), 41003412
		Ioklar Multi	2.39 (25°C)	Woolley, A.J. (2014), 41401265
		Veloucid Spray D	4.08 (25°C)	Woolley, A.J.; White, D.F. (2011), 41003417
		MEPA Barrier Spray D	5.25 (25°C)	Siebold, D.; Schneider, M. (2015)
		Ioklar D (data used for read-across)	4.27 (25°C)	Woolley, A.J. (2014), 41101572
			4.32 (25°C)	Woolley, A.J. (2014), 41102992
eCA remark The pH of the various products generally is within the range 4 – 6. However, Ioklar Multi, representative product for meta SPC 3, has a pH of 2.39. No classification thresholds are exceeded. (2< pH <6)				
pH (1% aqueous dispersion)	CIPAC MT 75.3	Ioklar Super Dip D	The difference in the formulation of Ioklar D and Ioklar Super Dip D are not significant, therefore the result can be expected to be similar.	

Property	Guideline and Method	Tested Product	Results	Reference
		Io-shield D	5.8 (25°C)	Woolley, A.J.; White, D.F. (2013), 41003419
		IoDark	Compared to the formulation of [redacted] the additional dye components of IoDark are not considered to significantly impact pH. Therefore it is expected that [redacted] has the same pH as [redacted]	
		Veloucid D	5.3 (25°C)	Woolley, A.J.; White, D.F. (2013), 41003412
		Ioklar Multi	4.06 (25°C)	Woolley, A.J. (2014), 41401265
		Veloucid Spray D	6.15 (25°C)	Woolley, A.J.; White, D.F. (2011), 41003417
		MEPA Barrier Spray D	Composition of MEPA Barrier Spray D is similar to Io-Shield D. Therefore it is expected that MEPA Barrier Spray D has the same pH as Io-Shield D.	
		Ioklar D (data used for read-across)	5.08 (25°C)	Woolley, A.J. (2014), 41101572
			4.84 (25°C)	Woolley, A.J. (2014), 41102992
Relative density / bulk density	EU A.3	Ioklar Super Dip D	1.017g/cm^3 at 20°C.	Siebold, D, Schneider, M., 2017
		Io-shield D	1.0303 (25°C)	Woolley, A.J.; White, D.F. (2013), 41003419

Property	Guideline and Method	Tested Product	Results	Reference
		IoDark	Compared to the formulation of [redacted], the additional dye components of IoDark are not considered to significantly impact relative density. Therefore it is expected that IoDark has the same relative density as [redacted].	
		Veloucid D	0.9670 (25°C)	Woolley, A.J.; White, D.F. (2013), 41003412
		Ioklar Multi	1.0192 (25°C)	Woolley, A.J. (2014), 41401265
		Veloucid Spray D	1.0004 (25°C)	Woolley, A.J.; White, D.F. (2011), 41003417
		MEPA Barrier Spray D	Composition of MEPA Barrier Spray D similar to Io-Shield D. Therefore it is expected that MEPA Barrier Spray D has the same relative density as Io-Shield D.	
		Ioklar D (data used for read-across)	1.0159 (25°C)	Woolley, A.J. (2014), 41101572
			1.0152 (25°C)	Woolley, A.J. (2014), 41102992
Storage stability test – **accelerated storage**	CIPAC MT46.3	Io-shield D	There was no significant change (approximately 2% from the initial value) in the active ingredient content of the test item during storage at 30 ± 2ºC for 18 weeks in a black plastic (opaque) container with a black	Woolley, A.J.; O'Connor, B. (2011), 41003420

Property	Guideline and Method	Tested Product	Results	Reference
			plastic opaque screw on lid. It can be concluded that the product will most likely comply with a shelf life specification of 2 years. Appearance Initial: Dark amber opaque liquid in a black plastic opaque container. Faint antiseptic odour. 18w: Dark amber opaque liquid in a black plastic opaque container. Weak chemical odour. A.s. content: Initial: 0.158% 18w: 0.161% pH (neat / 1% dispersion): Initial: 5.43 / 5.66 18w: 5.31 / 6.08 Relative density: Initial: 1.0304 18w: 1.0220 **eCA remark** The differences after storage are not significant. The plastic containers are not specified within the study. The material is HDPE according to the applicant.	
		IoDark	The active substance concentration stays constant over a period of 8 weeks at 40°C (storage in brown glass ISO-bottles). No significant chemical and physical change occurred in the accelerated stability test thus, it can be concluded	Siebold, D; Schneider, M. (2015)

Property	Guideline and Method	Tested Product	Results	Reference
			that the product will most likely comply with a shelf life specification of 2 years. Appearance Initial: Thick dark brown liquid 8w: Thick dark brown liquid A.s. content: Initial: 0.148% 8w: 0.150% pH (neat): Initial: 5.3 8w: 5.03 **eCA remark** The differences after storage are not significant.	
		Veloucid D	There was a slight increase (approximately 8% from the initial value) in the active ingredient content of the test item during storage at 30 ± 2°C for 18 weeks in a black plastic (opaque) container with a black plastic opaque screw on lid. It can be concluded that the product will most likely comply with a shelf life specification of 2 years. Appearance Initial: Brown opaque liquid in a black plastic opaque container. Weak uncharacteristic odour. 18w: Brown opaque liquid in a black plastic opaque container. Weak uncharacteristic odour. A.s. content: Initial: 0.126%	Woolley, A.J.; White, D.F. (2011), 41003413

Property	Guideline and Method	Tested Product	Results	Reference
			18w: 0.136% pH (neat / 1% dispersion): Initial: 4.53 / 5.38 18w: 4.15 / 4.68 Relative density: Initial: 0.98373 18w: 0.94760 **eCA remark** The active substance content increased by approximately 8%, which is considered to be within the relevant FAO/WHO tolerances. The plastic containers are not specified within the study. The material is HDPE according to the applicant.	
		Ioklar Multi	There was slight decrease (approximately 8%) in the active ingredient content of the test item during storage at 54 ± 2 ºC for 14 days in a black opaque plastic (HDPE) container with a black opaque plastic screw on lid. It can be concluded that the product will most likely comply with a shelf life specification of 2 years. A.s. content: Initial: 0.269% 14d: 0.247% pH (neat / 1% dispersion): Initial: 2.39 / 4.06 14d: 2.26 / 3.94 Relative density: Initial: 1.0192 14d: 1.0165	Woolley, A.J. (2014), 41401265

Property	Guideline and Method	Tested Product	Results	Reference
			eCA remark The differences after storage are not significant. An 8% decrease does not raise concerns with regard to efficacy and toxicology.	
		Veloucid Spray D	There was an approximately 8% increase in the active ingredient content during storage at 30 ± 2°C for 18 weeks in a blue plastic (PE-HD) opaque container with a black plastic screw on lid. It can be concluded that the product will most likely comply with a shelf life specification of 2 years. Initial: Brown opaque liquid in a black plastic opaque container. Odourless. 18w: Brown opaque liquid in a black plastic opaque container. Weak bleach odour. A.s. content: Initial: 0.118% 18w: 0.128% pH (neat / 1% dispersion): Initial: 4.08 / 4.28 18w: 6.15 / 5.43 Relative density: Initial: 1.0004 18w: 1.0165 **eCA remark** The active substance content increased by approximately 8%, which is considered to be within the relevant FAO/WHO tolerances.	Woolley, A.J.; White, D.F. (2011), 41003417

Property	Guideline and Method	Tested Product	Results	Reference
		MEPA Barrier Spray D	The active substance concentration stays constant over a period of 8 weeks at 40°C (stored in brown glass ISO-bottles). No significant chemical and physical change occurred in the accelerated stability test thus, it can be concluded that the product will most likely comply with a shelf life specification of 2 years. Initial: dark brown liquid. 8w: dark brown liquid. A.s. content: Initial: 0.156% 8w: 0.150% pH (neat): Initial: 5.25 8w: 5.13 **eCA remark** The differences after storage are not significant.	Siebold, D; Schneider, M. (2015)
		Ioklar Super Dip D (with higher dye content)	The active substance concentration stays constant over a period of 18 weeks at 30°C (storage in brown glass ISO-bottles). Initial: thick brown liquid 18w: thick brown liquid A.s. content: Initial: 0.1% 18w: 0.08% pH (neat): Initial: 5.06 18w: 3.64 Further it can be concluded that the addition of dye does not	Siebold, D; Schneider, M. (2015)

Property	Guideline and Method	Tested Product	Results	Reference
			have an influence on stability of the product. **eCA remark** The differences after storage are considerable. The decrease in active substance is about 20% and the pH decreased significantly. The product cannot be considered stable. In addition, a comparison to Ioklar Super Dip D (normal dye content) is not possible as there is no study performed using the same storage conditions. The report does not allow the conclusion that an increased dye content does not affect the product's stability.	
		Veloucid D (with higher dye content)	The active substance concentration stays constant over a period of 18 weeks at 30°C (storage in brown glass ISO-bottles). Initial: brown creamy liquid 18w: brown creamy liquid A.s. content: Initial: 0.11% 18w: 0.09% pH (neat): Initial: 4.51 18w: 3.75 Further it can be concluded that the addition of dye does not have an influence on stability of the product.	Siebold, D; Schneider, M. (2015)

Property	Guideline and Method	Tested Product	Results	Reference
			eCA remark The differences after storage are considerable. The decrease in active substance is about 20%. It is however unknown how much the analytical error contributes to this, as the reported active substance content before and after storage only contains 2 and 1 significant digit respectively. The results are in contrast with the study with Veloucid D, with the normal dye content, which showed an increase of iodine of approximately 8%. Considering this study was performed in glass, rather than black plastic as tested for Veloucid D, a comparison of the studies is not entirely possible. The report does not allow the conclusion that an increased dye content does not affect the product's stability.	
		Veloucid Spray D (with higher dye content)	The active substance concentration stays constant over a period of 18 weeks at 30°C (storage in brown glass ISO-bottles). Initial: brown liquid thin as water 8w: brown liquid thin as water A.s. content: Initial: 0.12% 18w: 0.13%	Siebold, D; Schneider, M. (2015)

Property	Guideline and Method	Tested Product	Results	Reference
			pH (neat): Initial: 3.40 18w: 4.02 Further it can be concluded that the addition of dye does not have an influence on stability of the product **eCA remark** The differences after storage are not significant. The active substance content increase of approximately 8% is within the allowed FAO/WHO tolerances. The outcome of the study is similar to that of Veloucid Spray D. Therefore, the conclusion that the increased dye content does not influence the product's stability is considered supported for this specific product.	
Storage stability test – **long term storage at ambient temperature**		Ioklar Super Dip D	Stored in HDPE for 24 months at 24°C **Appearance** Initial: thick brown liquid 6m: no change 12m: no change 18m: no change 24m: no change **Acidity** (CIPAC MT191, as %NaOH) Initial n.d. 6m n.d. 12m n.d. 18m n.d. 24m 0.06 **pH (CIPAC MT75.3)** Initial 5.1 6m 4.1	Siebold, D, Schneider, M., 2017

Property	Guideline and Method	Tested Product	Results	Reference
			12m 3.9 18m 4.0 24m 3.2 **Iodine content (potentiometric titration with thiosulfate, %I_2)** Initial 0.11 6m 0.11 12m 0.10 (-9%) 18m 0.09 (-18%) 24m 0.07 (-36%) **Density (EC A3, 20°C)** Initial 1.017 g/cm^3 6m 1.017 g/cm^3 12m 1.017 g/cm^3 18m 1.016 g/cm^3 24m 1.017 g/cm^3 **Viscosity (OECD 114, 2-100rpm, in mPa.s)** Initial 345 - 8160 6m 306 - 6600 12m 278 - 4800 18m 258 – 1340* 24m 268 – 1410* ** 10 – 100rpm* Efficacy testing after 24 months storage showed that required efficacy was achieved. (EN1656, *Escherichia coli, Staphylococcus aureus* and *Streptococcus uberis,* batch 2453CH8501, test concentration 80%, 5 min, 30C, 1% skimmed milk: log red >5; EN1657, *Candida albicans*, same batch, same conditions, log red >4). Therefore a shelf life of 24 months is concluded. The study did not include information on the actual iodine content of the	Kremlova, E., 2016

Property	Guideline and Method	Tested Product	Results	Reference
			sample, which makes it impossible to confirm that an actually aged sample was tested. However, considering the shelf-life study refers to this report, it is expected that the claim that an aged sample was used is accurate. **eCA remark** <u>Active substance content</u> The product is not chemically stable for 24 months. Efficacy testing was done to address this. The data was reported in study D94/2016, which confirmed the product is still efficacious even though the product cannot be considered physically and chemically stable. <u>Viscosity</u> The viscosity of the product does not remain stable throughout storage, whereas during the accelerated study, viscosity did not dramatically decrease. An explanation was not given. However, the product was proven efficacious after storage in study D94/2016. <u>Acidity</u> The pH of the product was initially >4. Therefore, acidity was not investigated. During storage, the pH appears to decrease. The acidity was determined after 24 months, but reported as %NaOH, which should be as $\%H_2SO_4$. The report	

Property	Guideline and Method	Tested Product	Results	Reference
			contains insufficient detail to retrieve whether the calculation or whether the titration was not performed correctly. Considering the data does not affect the classification and labelling of the product, the data is not considered for the evaluation. <u>Conclusion</u> Although the product is not physically and chemically stable, the provided efficacy data shows the product still performs adequately after 2 years storage.	
		Io-shield D	There was a decrease in the active ingredient content (approximately 17% change for batch 1 and approximately 10% change for batch 2 from the initial values) of the test item during storage at ambient temperature (25 ± 2ºC) for 24 months in black plastic (HDPE) opaque container with a black plastic opaque screw on lid. Appearance: Initial: dark amber opaque viscous liquid with faint antiseptic odour in 10L opaque black plastic container. 3m : no change 6m : no change, except translucent in small volume 12m: no change, except translucent in small volume	Woolley, A.J.; White, D.F. (2013), 41003419

Property	Guideline and Method	Tested Product	Results	Reference
			18m: no change, except translucent in small volume 24m: no change, except translucent in small volume A.s. content: Initial: 0.156%, 0.158% 24m: 0.129%, 0.142% pH (neat / 1% dispersion): Initial: 5.62/5.98, 5.43/5.66 24m: 4.76/5.26, 4.80/5.16 Relative density: Initial: 1.0301, 1.0304 24m: 1.0254, 1.0206 Efficacy testing after storage showed that required efficacy was achieved. (EN1656, *Escherichia coli, Staphylococcus aureus* and *Streptococcus uberis,* batch 3300CH2303, test concentration 1, 50, 80%, 5 min, 30C, 1% skimmed milk: log red >5 at 50 and 80%). Therefore a shelf life of 24 months is concluded. **eCA remark** The provided data is accepted as sufficient evidence that the products is still efficacious after 2 years storage, noting the following deficiencies: • Not the most worst-case situation was tested for efficacy • Although the batch tested was stored for 24 months, no data	Bäumer, U. (2013), 13-04191

Property	Guideline and Method	Tested Product	Results	Reference
			was included in the report on active substance content.	
		IoDark	Compared to the formulation of [redacted], the additional dye components of IoDark are not considered to influence the stability result. Therefore it is expected that IoDark has the same stability [redacted]	
		Veloucid D	There was a decrease in the active ingredient content (approximately 66% change for batch 1 and approximately 54% change for batch 2 from the initial values) of the test item during storage at ambient temperature (25 ± 2°C) for 24 months in black plastic (HDPE) opaque container with a white plastic opaque screw on lid. Appearance: Initial: brown opaque viscous liquid with weak uncharacteristic odour in 10kg opaque black plastic container. 3m: no change 6m: no change 12m: oil visible on top 18m: no change 24m: Amber/dark yellow opaque viscous liquid with a dark brown oil dispersed throughout. No other signs of separation or crystallisation. A.s. content: Initial: 0.129%, 0.126% 24m: 0.0443%, 0.0582% pH (neat / 1% dispersion):	Woolley, A.J.; White, D.F. (2013), 41003412

Property	Guideline and Method	Tested Product	Results	Reference
			Initial: 4.52/5.32, 4.53/5.36 24m: 2.90/4.02, 3.86/4.01 Relative density: Initial: 0.95023 / 0.98373 24m: 1.0030 / 0.99823 Efficacy testing after 18 months storage showed that required efficacy was achieved. (EN1656, *Escherichia coli, Staphylococcus aureus* and *Streptococcus uberis,* batch 3310CHB903, batch 3241CHB501, test concentration 80%, 5 min, 30C, 1% skimmed milk: log red >5). Therefore a shelf life of 18 months is concluded. **eCA remark** A shelf-life of 18 months is accepted based on the data provided, noting the following deficiencies: • Not the most worst-case situation was tested for efficacy • Although the batch tested was stored for 18 months, no data was included in the report on active substance content.	Bäumer, U. (2012), 12-09323/2
		Ioklar Multi	Storage for 2 years at 25°C in 20kg HDPE container. **Iodine content** $\%I_2$ Initial 0.260 6m 0.251 12m 0.246 18m 0.223 24m 0.234 Decline approx. 10% over 24 months.	Woolley, A.J., 2016

Property	Guideline and Method	Tested Product	Results	Reference
			Appearance Brown opaque homogeneous liquid. No change after 6m, 12m, 18m, 24m **Packaging** Black opaque HDPE No change after 6m, 12m, 18m, 24m **Weight change** < 0.05% after after 6m, 12m, 18m, 24m **pH** **$pH_{1\%}$** Initial 2.36 4.16 6m 2.39 4.07 12m 2.45 3.46 18m 2.19 3.99 24m 2.20 3.77 **Acidity (%H_2SO_4)** Initial 0.0631 6m 0.0657 12m 0.0662 18m 0.0649 24m 0.0818 **Density** Initial 1.0186 6m 1.0183 12m 1.0186 18m 1.0184 24m 1.0186 **eCA remark** Changes are not significant after storage. It is noted that at time stamp 18 months, the active substance appears to have decreased by more than 10%. No efficacy data was provided to confirm the product is still efficacious, but there is sufficient data for other products that	

Property	Guideline and Method	Tested Product	Results	Reference
			indicate a decrease of slightly over 10% in iodine content will not negatively affect the products' efficacy.	
		MEPA Barrier Spray D	The composition and content of active substance comparable to Io-Shield D. Therefore, it is expected that MEPA Barrier Spray D has the same stability as Io-Shield D.	
		Ioklar D (data used for read-across)	There was a slight decrease (approximately 16 %) in the active ingredient content of the test item during storage at ambient temperature (25 ± 2 ºC) for 24 months in opaque black plastic (HDPE) square shaped containers with opaque black plastic screw on lids. Appearance: Initial: clear dark brown liquid with faint characteristic odour of iodine in black opaque plastic container. 6m: no change 12m: no data 18m: transparant dark brown liquid with weak characteristic odour of iodine in black opaque plastic container. 24m: transparant dark brown liquid with weak characteristic odour of iodine in black opaque plastic container. A.s. content: Initial: 0.123% 24m: 0.103% pH (neat / 1% dispersion):	Woolley, A.J. (2014), 41101572

Property	Guideline and Method	Tested Product	Results	Reference
			Initial: 4.27 / 5.08 24m: 2.90 / 4.68 Relative density: Initial: 1.0159 24m: 1.0155 **eCA remark** A >10% decrease in active substance content triggers the need for efficacy data. See below for more data on Ioklar D.	
		Ioklar D (data used for read-across)	There was a slight decrease (approximately 15 %) in the active ingredient content of the test item during storage at ambient temperature (25 ± 2 ºC) for 24 months in opaque black plastic (PE-HD) square shaped containers with opaque black plastic screw on lids. Appearance: Initial: clear dark brown liquid with faint characteristic odor of iodine in black opaque plastic container. 6m: transparant dark brown liquid with weak characteristic odor of iodine in black opaque plastic container. 12m: no data 18m: transparent dark brown liquid with weak characteristic odor of iodine in black opaque plastic container. 24m: transparent dark brown liquid with weak characteristic odor of iodine in black opaque plastic container. A.s. content: Initial: 0.127%	Woolley, A.J. (2014), 41102992

Property	Guideline and Method	Tested Product	Results	Reference
			24m: 0.108% pH (neat / 1% dispersion): Initial: 4.32 / 4.84 24m: 2.94 / 4.66 Relative density: Initial: 1.0152 24m: 1.0149 Efficacy testing after 24 months storage showed that required efficacy was achieved. (EN1656, *Escherichia coli, Staphylococcus aureus* and *Streptococcus uberis,* test concentration 80%, 5 min, 30C, 1% skimmed milk: log red >5). Therefore a shelf life of 24 months is concluded. **eCA remark** A shelf-life of 24 months is accepted based on the data provided, noting the following deficiencies: • Not the most worst-case situation was tested for efficacy • Although the batch tested was stored for 24 months, no data was included in the report on active substance content.	Bäumer, U. (2014), 13-18611

eCA remarks on storage stability

An abundant dataset was provided on storage stability, both accelerated and real-time, including data on most representative products in HDPE packaging. Significant differences are observed between stability of products stored at elevated temperatures, depending on their composition and packaging.

The full range of the PVP-iodine / iodine concentrations was not specifically tested. The eCA does not expect the extremes of the active substance content to show significantly different results compared to the tested products due to the relatively narrow meta SPC limits.

Three studies with products with a raised dye content were tested by the applicant. The outcome of those studies suggests that increasing the dye content may negatively

Property	Guideline and Method	Tested Product	Results	Reference
influence stability, but this is not the case for all three products tested. All three tests were performed for 18 weeks at 30°C in glass. As the three studies do not show comparable results, the dataset is insufficient to draw conclusions with regard to the influence of dyes on stability. The eCA would normally not expect the dye content to significantly influence active substance stability, but the studies show that the maximum theoretical dye content per meta SPC may decrease stability. Therefore, the dyes of meta SPC 1 and 2 were grouped according to the proposal by Austria as discussed at the Coordination Group in January 2017, in order to limit the maximum dye content. Those products with an active substance decrease of >10% in the real-time studies were proven still to be sufficiently efficacious by testing aged samples. The shelf-life data provided result in the following shelf-lives per meta SPC: *Meta* SPC1 24 months *Meta* SPC2 24 months *Meta* SPC3 24 months *Meta* SPC4 24 months *Meta* SPC5 18 months *Meta* SPC6 24 months The products are to be stored at temperatures not exceeding 30°C based on the accelerated storage stability data. However, storage conditions were already proposed to be limited to 5 - 25°C. In addition, the products should be stored away from direct sunlight. ***Breakdown products*** Considering in various studies the iodine content declined by more than 10%, it is required to investigate whether, in addition to whether the product is still efficacious, whether any compounds are formed that may influence the risk assessment, e.g. hazardous metabolites. Iodine is an oxidiser and behaves similarly to chlorine and bromine. Generally, iodine oxidises a compound, resulting in the formation of iodide and an oxidised compound. Iodide is taken into account in the risk assessment as this is based on the sum of the total iodine concentration. The oxidised compounds are expected to be hard to identify and unlikely to pose a significant risk. The eCA therefore considers further work to identify breakdown products should not be necessary.				
Storage stability test – **low temperature stability test for liquids**	CIPAC MT39.3	Ioklar Super Dip D	The difference in formulation of Ioklar D and Ioklar Super Dip D are not significant therefore the result can be expected to be similar.	
		Io-shield D	Based on the observations, the test item was considered to be physically stable at 0 ± 2ºC for 7 days.	Woolley, A.J.; O'Connor, B. J. (2011), 41003421

Property	Guideline and Method	Tested Product	Results	Reference
		IoDark	Compared to the formulation of [redacted], the additional dye components of IoDark are not considered to influence the stability result. Therefore it is expected that IoDark has the same stability as [redacted]	
		Veloucid D	Based on the observations, the test item was considered to be physically stable at 0 ± 2°C for at least 7 days.	Woolley, A.J.; O'Connor, B. J. (2011), 41003414
		Ioklar Multi	Based on the observations, the test item was considered to be physically stable to storage at 0 ± 2 ºC for 7 days.	Woolley, A.J. (2014), 41303343
		Veloucid Spray D	Based on the observations, the test item was considered to be physically stable at 0 +/- 2 °C for 7 days.	Woolley, A.J.; O'Connor, B. J. (2011), 41003418
		MEPA Barrier Spray D	Composition and content of active substance comparable to Io-Shield D. Therefore, it is expected that MEPA Barrier Spray D has the same stability as Io-Shield D.	
		Ioklar D (data used for read-across)	Based on the observations, the test item was considered to be physically stable at 0 +/- 2 °C for 7 days.	Woolley, A.J.; White, D. F. (2011), 41101573
eCA remark All products within the family are stable when stored at low temperatures.				
Effects on content of the active substance and technical characteristics of the			Opaque packaging, therefore no impact on content of active	

Property	Guideline and Method	Tested Product	Results	Reference
biocidal product - **light**			substance due to exposure to light expected.	
eCA remark The packaging used is opaque and this would normally be sufficient to not require recommendations for storage. However, iodine is a temperature sensitive, relatively unstable compound. It is therefore recommended to store the products within the family away from direct sunlight.				
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			Temperature: The effect of temperature on the content of the active substance is reported in the accelerated storage reports (Storage at 30°C and for one product at 54°C). Humidity: Humidity conditions during the long-term storage tests has been around 33% in average (see reports attached to IUCLID). Since all products of the biocidal product family are water based formulations, humidity is not expected to influence content of active substance during storage.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			Covered in long-term storage stability reports. In none of the test items a significant change in the appearance of the container material was observed.	
Wettability			Not applicable according to "Guidance on the Biocidal Products Regulation, Volume I, Part A" for Regulation (EU) No 528/2012 (BPR), Version 1.1, November 2014. All products of this biocidal product family are ready to use liquid products. Thus, testing of wettability is not applicable.	

Property	Guideline and Method	Tested Product	Results	Reference
Suspensibility, spontaneity and dispersion stability			Not applicable according to "Guidance on the Biocidal Products Regulation, Volume I, Part A" for Regulation (EU) No 528/2012 (BPR), Version 1.1, November 2014. All products of this biocidal product family are ready to use liquid products. Thus, testing of suspensibility, spontaneity and dispersion stability is not applicable.	
Wet sieve analysis and dry sieve test			Not applicable according to "Guidance on the Biocidal Products Regulation, Volume I, Part A" for Regulation (EU) No 528/2012 (BPR), Version 1.1, November 2014. All products of this biocidal product family are ready to use liquid products. Thus, wet sieve analysis and dry sieve test is not applicable.	
Emulsifiability, re-emulsifiability and emulsion stability			Not applicable according to "Guidance on the Biocidal Products Regulation, Volume I, Part A" for Regulation (EU) No 528/2012 (BPR), Version 1.1, November 2014. All products of this biocidal product family are ready to use liquid products. Thus, testing of emulsifiability, re-emulsifiability and emulsion stability is not applicable.	
Disintegration time			Not applicable according to "Guidance on the Biocidal Products Regulation, Volume I, Part A" for Regulation (EU) No 528/2012 (BPR), Version 1.1, November 2014. All products of this	

Property	Guideline and Method	Tested Product	Results	Reference
			biocidal product family are ready to use liquid products. Thus, testing of disintegration time is not applicable.	
Particle size distribution, content of dust/fines, attrition, friability			Not applicable according to "Guidance on the Biocidal Products Regulation, Volume I, Part A" for Regulation (EU) No 528/2012 (BPR), Version 1.1, November 2014. All products of this biocidal product family are ready to use liquid products. Thus, particle size distribution is not applicable. Although some of the products may be used in spray applications, the products are not sold in or together with spraying equipment.	
Persistent foaming			Not applicable according to "Guidance on the Biocidal Products Regulation, Volume I, Part A" for Regulation (EU) No 528/2012 (BPR), Version 1.1, November 2014. All products of this biocidal product family are ready to use liquid products. Thus, testing of persistent foaming is not applicable.	
Flowability/Pourability/Dustability			Not applicable according to "Guidance on the Biocidal Products Regulation, Volume I, Part A" for Regulation (EU) No 528/2012 (BPR), Version 1.1, November 2014. All products of this biocidal product family are ready to use liquid products. Thus, testing of flowability is not applicable.	
Burning rate — smoke generators			Not applicable according to "Guidance on the	

Property	Guideline and Method	Tested Product	Results	Reference
			Biocidal Products Regulation, Volume I, Part A" for Regulation (EU) No 528/2012 (BPR), Version 1.1, November 2014. All products of this biocidal product family are ready to use liquid products. Thus, testing of burning rate is not applicable.	
Burning completeness — smoke generators			Not applicable according to "Guidance on the Biocidal Products Regulation, Volume I, Part A" for Regulation (EU) No 528/2012 (BPR), Version 1.1, November 2014. All products of this biocidal product family are ready to use liquid products. Thus, testing of burning completeness is not applicable.	
Composition of smoke — smoke generators			Not applicable according to "Guidance on the Biocidal Products Regulation, Volume I, Part A" for Regulation (EU) No 528/2012 (BPR), Version 1.1, November 2014. All products of this biocidal product family are ready to use liquid products. Thus, testing of composition of smoke is not applicable.	
Spraying pattern — aerosols			Not applicable according to "Guidance on the Biocidal Products Regulation, Volume I, Part A" for Regulation (EU) No 528/2012 (BPR), Version 1.1, November 2014. All products of this biocidal product family are ready to use liquid products. Thus, testing of spraying pattern is not applicable. Although some of the products may be	

Property	Guideline and Method	Tested Product	Results	Reference
			used in spray applications, the products are not sold in or together with spraying equipment. Selection of the spray equipment is an individual decision of the biocidal product user.	
Physical compatibility			Not applicable according to "Guidance on the Biocidal Products Regulation, Volume I, Part A" for Regulation (EU) No 528/2012 (BPR), Version 1.1, November 2014. None of the products of this biocidal product family are recommended to be used in combination with other products.	
Chemical compatibility			Not applicable according to "Guidance on the Biocidal Products Regulation, Volume I, Part A" for Regulation (EU) No 528/2012 (BPR), Version 1.1, November 2014. None of the products of this biocidal product family are recommended to be used in combination with other products.	
Degree of dissolution and dilution stability			Not applicable according to "Guidance on the Biocidal Products Regulation, Volume I, Part A" for Regulation (EU) No 528/2012 (BPR), Version 1.1, November 2014. All products of this biocidal product family are ready to use liquid products. Thus, testing of degree of dissolution and dilution stability is not applicable.	
Surface tension				

Property	Guideline and Method	Tested Product	Results	Reference
	Krüss Digital Tensiometer K10ST	Ioklar Super Dip D Batch 4417PU0203	41.55 mN/m at 20°C	Van den Broek, H, 2017
	Krüss Digital Tensiometer K10ST	Veloucid D Batch 3427PU0305	51.55 mN/m at 20°C	Van den Broek, H, 2017a
	Krüss Digital Tensiometer K10ST	IoShield Spray Batch 3037CH5404	33.05 mN/m at 20°C	Van den Broek, H, 2017b
	Krüss Digital Tensiometer K10ST	Astri-IO Batch 3417PU0107	43.15 mN/m at 20°C	Van den Broek, H, 2017c
	Krüss Digital Tensiometer K10ST	Io-Shield D Batch 1426CH6103	36.70 mN/m at 20°C	Van den Broek, H, 2017d
	Krüss Digital Tensiometer K10ST	Astri-UC Batch 3427PU0408	39.7 mN/m at 20°C	Van den Broek, H, 2017e
eCA remark Data were provided, generated using a ring tensiometer. The reported values suggest products are generally surface active, with a surface tension between approximately 30 and 55 mN/m at 20°C.				
Viscosity				
	OECD 114	Ioklar Super Dip D	345 – 8160 mPa.s (10 – 100rpm)	Siebold, D, Schneider, M., 2017
	Rotational viscometer	Ioklar Super Dip D Batch 4417PU0203	1320 mPa.s at 30rpm (spindle 3) and 20°C	Van den Broek, H, 2017
	Rotational viscometer	Veloucid D Batch 3427PU0305	2520 mPa.s at 30rpm (spindle 3) and 20°C	Van den Broek, H, 2017a
	Rotational viscometer	IoShield Spray	8 mPa.s at 30rpm (spindle 3) and 20°C	Van den Broek, H, 2017b

Property	Guideline and Method	Tested Product	Results	Reference
		Batch 3037CH5404		
	Rotational viscometer	Astri-IO Batch 3417PU0107	1.66 mPa.s at 30rpm (spindle 3) and 20°C	Van den Broek, H, 2017c
	Rotational viscometer	Io-Shield D Batch 1426CH6103	1460 mPa.s at 30rpm (spindle 3) and 20°C	Van den Broek, H, 2017d
	Rotational viscometer	Astri-UC Batch 3427PU0408	1.82 mPa.s at 30rpm (spindle 3) and 20°C	Van den Broek, H, 2017[e]

eCA remark
Data was provided using a rational viscometer at one shear rate. There is a clear difference in viscosity of thickened and non-thickened products, thickened products have a viscosity of >1000 mPa.s and non-thickened products having a viscosity of <10 mPa.s at the same conditions (all at 20°C).

The exception is [redacted] which contains a different kind of [redacted] than the other products, which raises the question whether the component indicated as [redacted] isn't more a co-solvent for the [redacted] component (see confidential annex for details on composition).

For thickened products, it is expected shear dependence would be observed. With a relatively low shear stress (30 rpm), the viscosity is higher than at higher shear rates due to the way these thickeners work (shear thinning).

Note on trade names:
Astri-IO is an alternate trade name for IoKlar Multi (meta SPC3). Astri-UC is an alternate trade name for Veloucid Spray D (meta SPC4). IoShield Spray is an alternate trade name of MEPA Barrier Spray D (meta SPC6).

2.3.2 Physical hazards and respective characteristics

Property	Guideline and Method	Tested Product	Results	Reference
Explosives			All products of this biocidal product family are water based, ready to use liquid products. Due to the high water content in the formulations it is	

Property	Guideline and Method	Tested Product	Results	Reference
			not expected that the products may explode. The products do not contain components associated with explosive properties.	
Flammable gases			Not applicable. All products of this biocidal product family are ready to use liquid products.	
Flammable aerosols			All products of this biocidal product family are water based, ready to use liquid products. Due to the high water content in the formulations it is not expected that the products may be flammable. The products do not contain components associated with flammable properties. The products are not expected to form a flammable aerosol due to high water content of formulation if sprayed.	
Oxidising gases			Not applicable. All products of this biocidal product family are water based, ready to use liquid products.	
Gases under pressure			Not applicable. All products of this biocidal product family are water based, ready to use liquid products.	
Flammable liquids	EU A.9 (Flash point)	Ioklar Super Dip D Io-shield D IoDark	Read-across of test result from Io-shield D and Ioklar multi. Composition comparable to Io-Shield D and Ioklar multi. Classification of additional dye components do not indicate alteration of the result. non flammable.	Woolley, A.J.; O'Connor, B.J. (2011), 41003421

Property	Guideline and Method	Tested Product	Results	Reference
		Veloucid D	Read-across of test result from Io-shield D. Composition comparable to Io-Shield D. Classification of additional dye components do not indicate alteration of the result.	
		Ioklar Multi	non flammable.	Woolley, A.J.; O'Connor, B.J. (2011), 41003414
		Veloucid Spray D	non flammable.	Woolley, A.J. (2011), 41303598
		MEPA Barrier Spray D	non flammable.	Woolley, A.J.; O'Connor, B.J. (2011), 41003418
			Read-across of test result from Io-shield D. Composition comparable to Io-Shield D. Classification of additional components [redacted] do not indicate alteration of the result.	
			eCA remark None of the meta SPC specifications include flammable components. Therefore, the products in the family do not have a flashpoint below 60°C.	
Flammable solids			Not applicable. All products of this biocidal product family are water based, ready to use liquid products.	
Self-reactive substances and mixtures			Due to high water content and known experience none of the formulations of the biocidal products family is expected to be self-reactive.	

Property	Guideline and Method	Tested Product	Results	Reference
Pyrophoric liquids			Due to high water content and known experience none of the formulation of the biocidal product family is expected to have pyrophoric properties.	
Pyrophoric solids			Not applicable. All products of this biocidal product family are water based, ready to use liquid products.	
Self-heating substances and mixtures			Due to high water content and known experience none of the formulations of the biocidal product family is expected to be self-heating.	
Substances and mixtures which in contact with water emit flammable gases			Not applicable. All products of this biocidal product family are water based, ready to use liquid products.	
Oxidising liquids	EU A.21	Io-shield D All other products	The oxidising properties were predicted using a procedure designed to be compatible with Method A21 Oxidising Properties (Liquids) of Commission Regulation (EC) No 440/2008 of 30 May 2008 and in accordance with Council Directive 98/8/EC Annex IIB. Based on the polyvinylpyrrolidone iodine, water and the remaining components that are either known to be non-oxidising or are present at insignificant amounts, the oxidising properties have been predicted negative. Based on PVP iodine, water and the remaining components that are either known to be non-oxidising or are present at insignificant amounts, the oxidising properties of all	

Property	Guideline and Method	Tested Product	Results	Reference
			products of the biocidal product family are predicted negative (Refer also to report in '4.13 Oxidising liquids, Io-shield D, Harlan 41003421, Expert statement').	
Oxidising solids			Not applicable. All products of this biocidal product family are water based, ready to use liquid products.	
Organic peroxides			Not applicable, no organic peroxides contained in any of the products of the biocidal product family.	
Corrosive to metals	UN Test C.1	Ioklar Multi	<13.5% weight loss and <120µm intrusion depth respectively after 7 days for both aluminium and steel specimens	Smeykal, H., 2017
eCA remark The worst-case product (highest a.s. content, lowest pH) was tested for corrosiveness to metals. The final report shows that, based on a 7 day test shows the worst-case				
Auto-ignition temperatures of products (liquids and gases)			All products of the biocidal product family consists mainly of water. Thus, auto-ignition of any of the products is not expected.	
Relative self-ignition temperature for solids			Not applicable. All products of this biocidal product family are water based, ready to use liquid products.	
Dust explosion hazard			Not applicable. All products of this biocidal product family are water based, ready to use liquid products.	

Based on the data presented, none of the meta families is classified with regard to physical and chemical hazards.

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		
Ioklar Super Dip D	Due to similar formulation the analytical method for iodine content in Ioklar D is expected to be valid also for Ioklar Super Dip D. Interference of co-formulants is not expected, since co-formulants are covered in the analytical method validations of other biocidal family members or contained in very low concentrations.								
Io-Shield D (analyte : iodine)	Titration with sodium thiosulphate (0.1N)	Standard addition (n=5)	Nominal concentration range: 0.127% w/w to 0.635% w/w (n=5) r^2=1.000 Slope=18.8 Intercept=-5.44*10^{-2}	No interference with non-analytes	96.1 – 98.4	97.5	0.92 Precision: 2.56 (n=5) RSDr: 3.55	Not reported	Woolley, A. J.; White, D.F. (2013), 41003419
IoDark	Influence of co-formulants on the validity of the analytical method is assessed for Io-Shield D as well as Ioklar D. Analytical methods for both products are validated, therefore analytical methods are expected to be valid also for IoDark.								
Veloucid D	Titration with sodium thiosulphate (0.1N)	Standard addition (n=5)	Nominal concentration range: 0.127% w/w to 0.635% w/w (n=5) r^2=1.000 Slope=18.8 Intercept=-5.44*10^{-2}	No interference with non-analytes	94.3 – 99.9	97.9	2.2 Precision: 1.06 (n=5) RSDr: 3.66	Not reported	*Woolley, A.J.; White, D.F. (2013), 41003412*
Ioklar multi	Titration with sodium thiosulphate (0.1N)	Standard addition (n=7)	Nominal concentration range: 0.005 to 0.05 M (n=7, plus blank) r^2=0.999 Slope=473 Intercept=0.152	No interference with non-analytes	96.5 - 104	100	2.1 Precision: 0.63 (n=5) RSDr 3.26	Not reported	*Woolley, A.J. (2014), 41303340*
Veloucid Spray D	Titration with sodium thiosulp	Standard addition (n=5)	Nominal concentration range: 0.127%	No interference with	96.4 - 100	98.8	1.5	Not reported	*Woolley, A.J.; White, D.F.*

	hate (0.1N)		w/w to 0.635% w/w (n=5) r^2=1.000 Slope=18.8 Intercept=-5.44*10^{-2}	non-analytes			Precision: 1.03 (n=5) RSDr: 3.70		*(2011), 410034 17*
MEPA Barrier Spray D	*By comparison of the composition MEPA Barrier Spray D with Io-Shield D it is expected that the analytical method is also valid for MEPA Barrier Spray D.* [redacted]								
Ioklar D	Titration with sodium thiosulphate (0.1N)	Standard addition (n=5)	Nominal concentration range: 0.005 to 0.05 M (n=7, plus blank) R^2=0.998 Slope=481 Intercept=-0.790	No interference with non-analytes	99.4 – 99.9	99.7	0.20 Precision: 2.86 (n=5) RSDr: 3.69	Not reported	*Woolley, A.J.; O'Connor, B. J. (2012), 411015 71*

Titration is a generally accepted, although non-specific, method for determination of the content of substances as iodine. The method and validation provided are considered adequate to ensure the active substance content can be adequately determined.

eCA remark
The method for determination of the iodine content is a commonly used titration method. The validation data is considered sufficient and the method is expected to allow sufficiently accurate iodine determinations for all products within the family.

Accuracy was addressed by standard addition. At least five samples were analysed, at the same theoretical iodine concentration. Therefore, the data can also be used to calculate the repeatability of the method. Separately, the precision of the titration was investigated by successively titrating 5 separately prepared solutions.

The methods all use a comparable procedure: to an aliquot of product, water is added and the pH is adjusted to 5.5 – 6.5 with sodium hydroxide if required. Potassium iodide is added following titration with sodium thiosulphate.

Analytical methods for monitoring:
- Soil: Not relevant, however analytical methods for determination of iodine in soil are presented in CAR, Dec 2013, Doc III A4.
- Air: Some products are applied by spraying. Analytical methods for determination of iodine in air are presented in the AR.
- Water: Not relevant, however analytical methods for determination of iodine in water are presented in CAR, Dec 2013, Doc III A4.
- Animal and human body fluids and tisues: Not relevant, active substance not classified as toxic or very toxic.

Analytical methods for monitoring of active substances and residues in food and feeding stuff: Analytical methods for determination of iodine residues in milk are presented in the AR.

eCA remark
No additional data with regard to methods for monitoring is considered required.

2.3.4 Efficacy against target organisms

A. FUNCTION AND FIELD OF USE

The iodine product family of Ecolab comprises six *meta* SPC's which include seven liquid ready-to-use biocidal products with active substance contents between 1.0% and 3.0% PVP-iodine. The products are intended for the use as non-medical teat disinfectants of milk producing animals, e.g. dairy cows, buffaloes, sheep and goats. This use is included in PT3 (veterinary hygiene). All products can be used after milking and products in *meta* SPC 3 can also be used before milking. The products can be applied by dipping or spraying (manually or automatic (including robotic)). For manual dipping special dip cups are used. The use is restricted for professionals only.

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

The biocidal products reduce the number of vegetative cells of bacteria, viable yeasts cells and number of infectious virus particles of enveloped viruses that occur on the skin of teats of milk producing animals, e.g. dairy cows, sheep and goats, in order to ensure proper teat hygiene. By the appropriate milking hygiene, man is indirectly protected as consumer of milk and milk products.

C. EFFECTS ON TARGET ORGANISMS, INCLUDING UNACCEPTABLE SUFFERING

The biocidal products are disinfectants which have a bactericidal and yeasticidal activity, and, for post-milking use, also activity against enveloped viruses.

D. MODE OF ACTION, INCLUDING TIME DELAY

The mode of action of iodine is non-selective and is based on the following mechanisms, as stated in the CAR for iodine (2013):

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

The rapid penetration of iodine into microorganisms and its mode of action indicate that the time-delay i.e. contact time required for sufficient efficacy depends on the tolerance of the organism to iodine and the concentration of iodine used for treatment. Iodine is more effective at higher temperatures.

E. EFFICACY DATA

The bactericidal and yeasticidal efficacy of the iodine product family of Ecolab was tested according the international standards EN 1656 and EN 1657 under test conditions defined for teat disinfection. EN 1657 was modified by choosing additional test conditions regarding test temperature, interfering substance and contact time as given in EN 1656 for teat disinfectants because no standard exists to test yeasticidal activity of teat disinfectants.
The laboratory studies were performed in a suspension test. Cell suspensions of representative strains of gram-positive and gram-negative bacteria (*Escherichia coli, Staphylococcus aureus* and *Streptococcus uberis*) as well as of yeasts (*Candida albicans*) were diluted in a solution of interfering substance (1% skimmed milk for post-milking application, or 10g/L BSA + 10g/L yeast extract for pre-milking application (high-level soiling)) and mixed with the biocidal product at the intended test concentration. After a contact time of 5 minutes for post-milking application or 1 minute for pre-milking application at 30°C test temperature, the biocidal action was immediately neutralised in a dilution-neutralisation procedure. A sample was then incubated on Petri dishes with nutrient medium and the number of colony forming units was determined. In conclusion, the bactericidal activity of a product is defined according to the guideline EN 1656 as the capability to reduce the viability of the reference strains *Escherichia coli, Staphylococcus aureus* and *Streptococcus uberis* by a factor of minimum 10^5 or 5 lg (99.999%) under the conditions of the test; the yeasticidal activity of a product is defined according to the guideline EN 1657 as the capability to reduce the viability of the reference strain *Candida albicans* by a factor of minimum 10^4 or 4 lg (99.99% reduction).

As no phase 2 step 2 test is available so far, a volunteer test according to EN 1500 was performed to demonstrate efficacy against microbes attached to skin. The test conditions were modified to meet the criteria for teat disinfection. Therefore, the number of test organisms from the fingertips (incl. thumbs) of artificially contaminated hands of 22 subjects was assessed. Representative interfering substance was added to the *E. coli* K12 test strain suspension (post-milking: 10g/L skimmed milk reconstituted ; pre-milking: 10 g/l BSA plus 10 g/l yeast extract). Fingers were dipped into the test strain suspension for five seconds.
The cell counts per hand were determined immediately after dipping according to EN1500. After that volunteers were treated with the test product and with the reference product (RP=1% PVP iodine instead of the reference propan-2-ol), respectively. Therefore, the contaminated part of the hands was dipped into the products with separate beakers for the left and the right hand in each case. After application of the test product or the reference product hands were held fingertips down without rubbing, for the contact time of 5 minutes. After this, the cell counts per hand were determined immediately according to EN 1500. In a subsequent test circle, the remaining products or reference were tested by each volunteer, respectively. This happened in a cross over design or (if several products were tested in parallel) in a latin square design according to EN 1500. The mean reduction achieved with the test product is compared with the mean reduction of a reference

substance and shall not be significantly smaller. Most validation criteria of EN1500 were taken into account. However, the maximum of three values of the reference product below 3 lg (RP<3.00 lg) was considered not feasible, since the mean log reductions of both test and reference products were below 3. This was considered acceptable considering that in the modified test no rubbing of the fingers was involved and a different reference product, relevant for teat disinfection, was used. Therefore, for the evaluation of the modified test the validation criterion was changed to a maximum of three values of RP<2.00 lg.

For efficacy against enveloped viruses a testing procedure according to EN14476 modified to meet agriculture conditions (phase 2 step 1 acc. to EN 14885) has been used. The Vaccinia virus is a widely accepted representative for testing the virucidal activity of disinfectants against enveloped viruses and was therefore chosen for the tests. A suspension of the test virus was added to the test item in presence of 1% skimmed milk as soiling. After a contact time of 5 minutes the virucidal activity was immediately supressed and dilutions thereof were transferred into cell culture units. After incubation the infectivity was determined. Reduction of virus infectivity was calculated from differences of lg virus titres before and after treatment with the test item. The requirements are fulfilled if the test item demonstrates at least a decimal log reduction of 4.

Justification for all products in the family

All products in the *meta* SPC's were tested against bacteria and yeasts for post-milking conditions in suspension tests and simulate-use tests (EN1656, EN1657, EN1500 modified). These tests cover all possible products within the *meta* SPC's, since the composition of the *meta* SPC's do not include a range of concentrations of active substances. The product in *meta* SPC 3 was also tested under pre-milking conditions against bacteria and yeasts (EN1656, EN1657, EN1500 modified).
Tests against enveloped viruses (EN14476:2013/FprA1:2014) were done with 5 products. A justification for read-across was given for the two *meta* SPC's of which the representative products were not tested. Since the concentration active substance in these two products was equal or higher than in the tested products, and the co-formulants are considered not to have a negative influence on the efficacy compared to those in the tested products, it can be expected that the products in *meta* SPC 1 and 3 will also be efficacious against enveloped viruses.
The test results are summarised in the table below.

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**

PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	Ioklar Super Dip D meta 1	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN 1656	Suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentra-tions: 2, 20, 100%*	The test concentrations of 100% (80%)* and 20% decreased the number of the three tested bacterial species by at least 5 lg orders. Therefore the results comply with the requirements for post-milking application.	Matuskova, Z.; Slitrova, J. (2013)
PT3, biocidal product, yeasticidal activity	teat disinfection, post-milking	Ioklar Super Dip D meta 1	*Candida albicans*	EN 1657, modified by choosing additional test conditions as given in EN 1656 for teat disinfectants	Suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentra-tions: 2, 20, 100%*	The test concentrations of 100% (80%)* and 20% decreased the number of the tested yeast species after 5 minutes by at least 4 lg orders. Therefore the results comply with the requirements for post-milking application.	Matuskova, Z.; Slitrova, J. (2013)
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	Io-Shield D meta 2	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN1656	Suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentra-tions: 2, 20, 100%*	The test concentrations of 100% (80%)* and 20% decreased the number of all three tested bacterial species by at least 5 lg orders. Therefore the results comply with the requirements for post-milking application.	Matuskova, Z.; Slitrova, J. (2013)
PT3, biocidal product,	teat disinfecti	Io-Shield D	*Candida albicans*	EN 1657, modified by	Suspension test	The test concentrations of 100% (80%)* and	Matuskova, Z.; Slitrova, J. (2013)

yeasticidal activity	on, post-milking	meta 2		choosing additional test conditions as given in EN 1656 for teat disinfectants	Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentra-tions: 2, 20, 100%*	20% decreased the number of the tested yeast species after 5 minutes by at least 4 lg orders. Therefore the results comply with the requirements for post-milking application.	
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	IoDark meta 2	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN1656	Suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentra-tions: 2, 20, 100%*	The test concentrations of 100% (80%)* and 20% decreased the number of all three tested bacterial species by at least 5 lg orders. Therefore the results comply with the requirements for post-milking application.	Baeumer, U. (2015)
PT3, biocidal product, yeasticidal activity	teat disinfection, post-milking	IoDark meta 2	*Candida albicans*	EN 1657, modified by choosing additional test conditions as given in EN 1656 for teat disinfectants	Suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentra-tions: 2, 20, 100%*	The test concentrations of 100% (80%)* and 20% decreased the number of Candida albicans by at least 4 lg orders after 5 minutes contact time. Therefore the results comply with the requirements for post-milking application.	Baeumer, U. (2015)
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	Veloucid D meta 5	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN1656	Suspension test Interfering substance: 1%	The test concentrations of 100% (80%)* decreased the number of all three tested bacterial species by at least	Baeumer, U. (2012)

					skimmed milk Test temperature : 30°C Contact time: 5 min Test concentra-tions: 100%*	5 lg orders from 1 minute contact time. Therefore the results comply with the requirements for post-milking application.	
PT3, biocidal product, yeasticidal activity	teat disinfecti on, post-milking	Veloucid D meta 5	*Candida albicans*	EN 1657, modified by choosing additional test condition s as given in EN 1656 for teat disinfecta nts	Suspension test Interfering substance: 1% skimmed milk Test temperature : 30°C Contact time: 5 min Test concentra-tions: 2, 20, 100%*	The test concentrations of 100% (80%)* and 20% decreased the number of the tested yeast species after 5 minutes by at least 4 lg orders. Therefore the results comply with the requirements for post-milking application.	Matuskova, Z.; Slitrova, J. (2013)
PT3, biocidal product, bactericidal activity	teat disinfecti on, post-milking	Veloucid Spray D meta 4	*Escherichia coli, Staphylococc us aureus, Streptococc us uberis*	EN 1656	Suspension test Interfering substance: 1% skimmed milk Test temperature : 30°C Contact time: 5 min Test concentra-tions: 2, 20, 100%*	The test concentrations of 100% (80%)* and 20% decreased the number of all three tested bacterial species by at least 5 lg orders. Therefore the results comply with the requirements for post-milking application.	Matuskova, Z.; Slitrova, J. (2013)
PT3, biocidal product, yeasticidal activity	teat disinfecti on, post-milking	Veloucid Spray D meta 4	*Candida albicans*	EN 1657, modified by choosing additional test condition s as given in EN 1656	Suspension test Interfering substance: 1% skimmed milk	The test concentrations of 100% (80%)* and 20% decreased the number of the tested yeast species after 5 minutes by at least 4 lg orders. Therefore the	Matuskova, Z.; Slitrova, J. (2013)

				for teat disinfectants	Test temperature: 30°C Contact time: 5 min Test concentra-tions: 2, 20, 100%*	results comply with the requirements for post-milking application.	
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	MEPA Barrier Spray D meta 6	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN 1656	Suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentra-tions: 2, 20, 100%*	The test concentrations of 20% and 100% (80%)* decreased the number of all three tested bacterial species by at least 5 lg orders after 5 minutes contact time. Therefore the results comply with the requirements for post-milking application.	Baeumer, U. (2014)
PT3, biocidal product, yeasticidal activity	teat disinfection, post-milking	MEPA Barrier Spray D meta 6	*Candida albicans*	EN 1657, modified by choosing additional test conditions as given in EN 1656 for teat disinfectants	Suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentra-tions: 2, 20, 100%*	The test concentrations of 20% and 100% (80%)* decreased the number of *Candida albicans* by at least 4 lg orders after 5 minutes contact time. Therefore the results comply with the requirements for post-milking application.	Baeumer, U. (2014)
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	Ioklar Multi meta 3	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN 1656	Suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C	The test concentrations of 100% (80%)* decreased the number of all three tested bacterial species by at least 5 lg orders. Therefore the results comply with the requirements for post-milking application.	Matuskova, Z.; Slitrova, J. (2013)

					Contact time: 5 min Test concentra-tions: 2, 20, 100%*		
PT3, biocidal product, yeasticidal activity	teat disinfection, post-milking	Ioklar Multi meta 3	*Candida albicans*	EN 1657, modified by choosing additional test conditions as given in EN 1656 for teat disinfectants	Suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentra-tions: 2, 20, 100%*	The test concentrations of 20% and 100% (80%)* decreased the number of *Candida albicans* by at least 4 lg orders after 5 minutes contact time. Therefore the results comply with the requirements for post-milking application.	Matuskova, Z.; Slitrova, J. (2013)
PT3, biocidal product, bactericidal activity	teat disinfection, pre-milking	Ioklar Multi meta 3	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN1656	Suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 30 sec, 1 and 2 min Test concentra-tions: 2, 20, 100%*	The bactericidal efficacy of the test item was tested according to EN 1656 for teat disinfection modified regarding contact time for pre-milking scenario. The intended use concentration of 100% (80%)* decreased the number of all three tested bacterial species within 1 minute by at least 5 lg orders. Since the soiling is not considered correct for pre-milking the results do not fully comply with the requirements for pre-milking application.	Baeumer, U. (2014)
PT3, biocidal product, bactericidal activity	teat disinfection, pre-milking	Ioklar Multi meta 3	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN1656	Suspension test Interfering substance: 3 g/l bovine albumin (low-level soiling), 10 g/l bovine	The bactericidal efficacy of the test item was tested according to EN 1656 for teat disinfection modified regarding contact time and interfering substance for pre-	Matuskova, Z.; Slitrova, J. (2015)

					albumin + 10 g/l yeast extract (high-level soiling) (modified for pre-milking scenario) Test temperature : 30°C Contact time: 1 min Test concentra-tions: 20, 100%*	milking scenario. The intended use concentration of 100% (80%)* decreased the number of all three tested bacterial species within 1 minute by at least 5 lg orders. Therefore the results comply with the requirements for pre-milking application.	
PT3, biocidal product, yeasticidal activity	teat disinfecti on, pre-milking	Ioklar Multi meta 3	*Candida albicans*	EN 1657, modified by choosing additional test condition s as given in EN 1656 for teat disinfecta nts	Suspension test Interfering substance: 1% skimmed milk Test temperature : 30°C Contact time: 30 sec, 1, 2 and 5 min Test concentra-tions: 2, 20, 100%*	The yeasticidal efficacy of the test item was tested according to EN 1657 modified for teat disinfection regarding contact time for pre-milking scenario. The intended use concentration of 100% (80%)* decreased the number of the tested yeast species within 30 seconds by at least 4 lg orders. Since the soiling is not considered correct for pre-milking the results do not fully comply with the requirements for pre-milking application.	Baeumer, U. (2014)
PT3, biocidal product, yeasticidal activity	teat disinfecti on, pre-milking	Ioklar Multi meta 3	*Candida albicans*	EN 1657, modified by choosing additional test condition s as given in EN 1656 for teat disinfecta nts	Suspension test Interfering substance: 1% yeast extract + 1% BSA (high soil load) Test temperature : 30°C Contact time: 30 sec, 1 and 2 min Test concentra-	The yeasticidal efficacy of the test item was tested according to EN 1657 modified for teat disinfection regarding contact time for pre-milking scenario. The intended use concentration of 100% (80%)* decreased the number of the tested yeast species within 30 seconds by at least 4 lg orders. Therefore the results comply with the requirements	Baeumer, U. (2014)

					tions: 2, 20, 100%*	for pre-milking application.	
PT3, biocidal product, activity against enveloped viruses	teat disinfection, post milking	Io-Shield D meta 2	*Vaccinia virus, Elstree strain*	EN 14476 (phase 2, step 1) version EN 14476:2013/FprA1:2014	Suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentrations: 10, 80, 97%	The test product met the requirement with a concentration of 10% in 5 minutes at 30°C under high organic soil simulating dirty conditions (based on the results of the EN 14476:2013/FprA1:2014 test method and proved by "Lycke-method").	Kyas A.; Bäumer U. (2015)
PT3, biocidal product, activity against enveloped viruses	teat disinfection, post milking	Veloucid D meta 5	*Vaccinia virus, Elstree strain*	EN 14476 (phase 2, step 1) version EN 14476:2013/FprA1:2014	Suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentrations: 10, 80, 97%	The test product met the requirement with a concentration of 10% in 5 minutes at 30°C under high organic soil simulating dirty conditions (based on the results of the EN 14476:2013/FprA1:2014 test method and proved by "Lycke-method").	Kyas A.; Bäumer U. (2015)
PT3, biocidal product, activity against enveloped viruses	teat disinfection, post milking	Veloucid Spray D meta 4	*Vaccinia virus, Elstree strain*	EN 14476 (phase 2, step 1) version EN 14476:2013/FprA1:2014	Suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentrations: 10, 80, 97%	The test product met the requirement with a concentration of 10% in 5 minutes at 30°C under high organic soil simulating dirty conditions (based on the results of the EN 14476:2013/FprA1:2014 test method and proved by "Lycke-method").	Kyas A.; Bäumer U. (2015)
PT3, biocidal product, activity against	teat disinfection, post milking	Io-shield Spray meta 6	*Vaccinia virus, Elstree strain*	EN 14476 (phase 2, step 1) version EN	Suspension test Interfering substance:	The test product met the requirement with a concentration of 10% in 5 minutes	Kyas A.; Bäumer U. (2015)

enveloped viruses				14476:2013/FprA1:2014	1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentrations: 10, 80, 97%	at 30°C under high organic soil simulating dirty conditions (based on the results of the EN 14476:2013/FprA1:2014 test method and proved by "Lycke-method").	
PT3, biocidal product, activity against enveloped viruses	teat disinfection, post milking	IoDark meta 2	*Vaccinia virus, Elstree strain*	EN 14476 (phase 2, step 1) version EN 14476:2013/FprA1:2014	Suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentrations: 10, 80, 97%	The test product met the requirement with a concentration of 10% in 5 minutes at 30°C under high organic soil simulating dirty conditions (based on the results of the EN 14476:2013/FprA1:2014 test method and proved by "Lycke-method").	Kyas A.; Bäumer U. (2015)
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	Ioklar Multi meta 3	*Escherichia coli K12*	EN 1500 modified	Volunteer test Interfering substance: 1% skimmed milk Test temperature: ambient Contact time: 5 min Test concentration: 100% Reference substance: 1% PVP iodine	The mean reduction factors for the reference (lg red=2.57) was not found to be significant higher than these of the test product (lg red=2.62). Therefore, loklar Multi fulfilled the requirements of the standard.	Bäumer, U. (2015)
PT3, biocidal product, bactericidal activity	teat disinfection, pre-milking	Ioklar Multi meta 3	*Escherichia coli K12*	EN 1500 modified	Volunteer test Interfering substance: 3 g/l BSA or 10 g/l BSA	The mean reduction factors for the reference (lg red=2.28 clean, lg red=2.46 dirty) was not found to be significant higher than these	Bäumer, U. (2015)

					plus 10 g/l yeast extract Test temperature : ambient Contact time: 1 min, reference product 5 min Test concentra-tion: 100% Reference substance: 1% PVP iodine	of the test product (lg red=2.61 clean, (lg red=2.48 dirty). Therefore, Ioklar Multi, tested under clean and dirty conditions (according to EN 1656), fulfilled the requirements of the standard.	
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	Ioklar Super Dip D meta 1	*Escherichia coli K12*	EN 1500 modified	Volunteer test Interfering substance: 1% skimmed milk Test temperature : ambient Contact time: 5 min Test concentra-tion: 100% Reference substance: 1% PVP iodine	The mean reduction factors for the reference (lg red=2.57) was not found to be significant higher than these of the test product (lg red=2.59). Therefore, Ioklar Super Dip D fulfilled the requirements of the standard.	Bäumer, U. (2015)
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	Io-Shield D meta 2	*Escherichia coli K12*	EN 1500 modified	Volunteer test Interfering substance: 1% skimmed milk Test temperature : ambient Contact time: 5 min Test concentra-tion: 100% Reference substance:	The mean reduction factors for the reference (lg red=2.57) was not found to be significant higher than these of the test product (lg red=2.96). Therefore, Io-Shield D fulfilled the requirements of the standard.	Bäumer, U. (2015)

					1% PVP iodine		
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	Veloucid Spray D meta 4	*Escherichia coli K12*	EN 1500 modified	Volunteer test Interfering substance: 1% skimmed milk Test temperature: ambient Contact time: 5 min Test concentration: 100% Reference substance: 1% PVP iodine	The mean reduction factors for the reference (lg red=2.04) was not found to be significant higher than these of the test product (lg red=2.00). Therefore, Veloucid Spray D fulfilled the requirements of the standard.	Bäumer, U. (2015)
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	Veloucid D meta 5	*Escherichia coli K12*	EN 1500 modified	Volunteer test Interfering substance: 1% skimmed milk Test temperature: ambient Contact time: 5 min Test concentration: 100% Reference substance: 1% PVP iodine	The mean reduction factors for the reference (lg red=2.64) was not found to be significant higher than these of the test product (lg red=2.58). Therefore, Veloucid D fulfilled the requirements of the standard.	Bäumer, U. (2015)
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	MEPA Barrier Spray D meta 6	*Escherichia coli K12*	EN 1500 modified	Volunteer test Interfering substance: 1% skimmed milk Test temperature: ambient Contact time: 5 min	The mean reduction factors for the reference (lg red=2.65) was not found to be significant higher than these of the test product (lg red=2.58). Therefore, MEPA Barrier Spray D fulfilled the requirements of the standard.	Bäumer, U. (2015)

					Test concentra-tion: 100% Reference substance: 1% PVP iodine		
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	IoDark meta 2	*Escherichia coli K12*	EN 1500 modified	Volunteer test Interfering substance: 1% skimmed milk Test temperature : ambient Contact time: 5 min Test concentra-tion: 100% Reference substance: 1% PVP iodine	The mean reduction factors for the reference (lg red=2.57) was not found to be significant higher than those of the test product (lg red=2.60). Therefore, IoDark fulfilled the requirements of the standard.	Bäumer, U. (2015)

*Due to the test procedure of EN 1656 and EN 1657 a product concentration of 100% cannot be tested as a particular dilution always occurs by adding the bacterial suspension and interfering substance. Therefore the maximum test concentration is 80%.

Conclusion on the efficacy of the product

All tested products of the iodine product family of Ecolab demonstrated a bactericidal and yeasticidal efficacy at the intended use concentrations of 1% to 3% PVP-iodine according to EN 1656 and EN 1657 under test conditions defined for teat disinfection. Furthermore, as a phase 2 step 2 test is not available, a modified EN 1500 has been used to demonstrate efficacy against micro-organisms attached to skin. This test was considered relevant since the skin and the form of the fingers can simulate the skin and form of the teats. The justification for the reference product (see IUCLID section 6.7 and R4BPcase number BC-VG018734-32) showed the relevance of this reference product and a read-across to a field trial to compare the results of the simulated-use test to the effect in the field. All products performed better than the reference product, therefore, efficacy was demonstrated.
The virucidal efficacy against Vaccinia virus as a representative for enveloped viruses has been proven according to EN 14476 (phase 2, step 1) version EN 14476:2013/FprA1:2014 modified to meet agricultural conditions. The activity against enveloped viruses is claimed for post milking teat disinfection only.
It can be concluded that all products in this family are efficacious, when used in accordance with the use instructions proposed in the SPC.

All tests were done at 30°C, the temperature of the skin. When the product is at a very low temperature at the start of the treatment (e.g. stored in animal housing at 10°C), the product might cool down the teat skin. This should be prevented because the

product might be less efficacious at low temperature. Therefore, the following sentence will be added to the use instructions of the SPC: The products must be brought to temperatures above 20°C before use.

F. OCCURRENCE OF RESISTANCE AND RESISTANCE MANAGEMENT

As the mode of action is non-selective the occurrence of resistance against iodine is unlikely. Iodine has been used over 170 years as disinfectant for a variety of applications. No reduction in efficacy has been reported to the producers of iodine indicating that no development of resistant microorganisms has occurred so far, as stated in the CAR for iodine (2013).
No resistance management strategies have been developed since no occurrence of resistance has been observed. In addition, it should be noted that Iodine-based products are exclusively applied by professional users, in most cases as part of professional hygiene programs. Therefore, if used according to use instructions, no occurrence of resistance is expected.

G. KNOWN LIMITATIONS

No limitations and no undesirable or unintended side-effects have been observed during these studies.

H. EVALUATION OF THE LABEL CLAIMS

The products in this family are used for the disinfection of teats of milk producing animals, e.g. dairy cows, buffaloes, sheep and goats. The tests demonstrate efficacy for:

- the products in *meta* SPC 3 against bacteria and yeasts when used pre-milking with at least 1 min contact time, and
- the products in *meta* SPC 1 to 6 against bacteria, yeasts and enveloped viruses when used post-milking with at least 5 min contact time.

The products can be applied by:

- manual dipping using a dip cup (pre- or post-milking disinfection)
- manual spraying using a trigger sprayer (pre- or post-milking disinfection)
- manual spraying using an electronic sprayer (pre- or post-milking disinfection)
- automated spraying by robot (only post-milking disinfection)

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

Not applicable. Products are not intended to be used together with other biocidal products.

2.3.5 Risk assessment for human health

A. ASSESSMENT OF EFFECTS ON HUMAN HEALTH

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not corrosive or irritating to skin
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal products pertaining to the BPF.
Classification of the product according to CLP and DSD	No classification required.

Data waiving	
Information requirement	Annex III of BPR, point 8.1 "Skin corrosion or skin irritation"
IUCLID data point	Section 8.1, Skin irritation/corrosion
Justification	Studies on potential skin corrosive or skin irritating properties of the individual products pertaining to the biocidal product family (BPF) are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.1 "Skin corrosion or skin irritation" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." For all products pertaining to the BPF, the exact composition is known. For each of the individual components in the products, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal products themselves is not required. According to the CLP principles, the individual products of the BPF, and thus the BPF itself, do not need to be classified with respect to local effects on the skin. This is supported by test results on the biocidal product Io-Shield, performed as part of the active substance dossier and summarized in IUCLID.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not causing severe damage or eye irritation
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal products pertaining to the BPF.
Classification of the product according to CLP and DSD	No classification required.

Data waiving	
Information requirement	Annex III of BPR, point 8.2 "Eye irritation"
IUCLID data point	Section 8.2, Eye irritation
Justification	Studies on potential eye damaging or eye irritating properties of the individual products pertaining to the biocidal product family (BPF) are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.2 "Eye irritation" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." For all products pertaining to the BPF, the exact composition is known. For each of the individual components in the products, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal products themselves is not required. According to the CLP principles, the individual products of the BPF, and thus the BPF itself, do not need to be classified with respect to local effects on the eyes. This is supported by test results on the biocidal product Io-Shield, performed as part of the active substance dossier and summarized in IUCLID.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Based on intrinsic properties of individual components, the biocidal products pertaining to the BPF are not irritating to the respiratory tract.
Classification of the product according to CLP and DSD	No classification required.

Data waiving	
Information requirement	Up to June 2015, there are no testing requirements for respiratory irritation under the BPR.
IUCLID data point	Section 8.7.1, other endpoints
Justification	Studies on potential respiratory tract irritation properties of the individual products pertaining to the biocidal product family (BPF) are not required. Up to June 2015, there are no testing requirements for respiratory irritation under the BPR (see point "Respiratory irritation" under chapter II, point 8.2 "Eye irritation" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014). Nevertheless, Annex I, chapter 3.8.3.4.5 of Regulation (EC) No 1272/2008 (CLP) allows for extrapolation of the toxicity of a mixture that contains substances classified with respect to specific target organ toxicity after single exposure category 3 (STOT SE, Cat. 3; H335) based on valid data on all components in the mixtures classified with STOT SE, Cat. 3; H335. For all products pertaining to the BPF, the exact composition is known. For each of the individual components in the products, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal products themselves is not required. According to the CLP principles, the individual products of the BPF, and thus the BPF itself, do not need to be classified with respect to respiratory tract irritation.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to skin.
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal products pertaining to the BPF.
Classification of the product according to CLP and DSD	No classification required.

Data waiving	
Information requirement	Annex III of BPR, point 8.3 "Skin sensitisation"
IUCLID data point	Section 8.3, Skin sensitisation
Justification	Studies on potential skin sensitisation properties of the individual products pertaining to the biocidal product family (BPF) are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.3 "Skin sensitisation" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." For all products pertaining to the BPF, the exact composition is known. For each of the individual components in the products, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal products themselves is not required. According to the CLP principles, the individual products of the BPF, and thus the BPF itself, do not need to be classified with respect to skin sensitisation. This is supported by test results on the biocidal product Io-Shield, performed as part of the active substance dossier and summarized in IUCLID.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising to respiratory tract.
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal products pertaining to the BPF.
Classification of the product according to CLP and DSD	No classification required.

Data waiving	
Information requirement	Annex III of BPR, point 8.4 "Respriatory sensitisation" (ADS)
IUCLID data point	Section 8.4, Respiratory sensitisation
Justification	Studies on potential respiratory sensitisation properties of the individual products pertaining to the biocidal product family (BPF) are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.4 "Respiratory sensitisation" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." For all products pertaining to the BPF, the exact composition is known. For each of the individual components in the products, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal products themselves is not required. According to the CLP principles, the individual products of the BPF, and thus the BPF itself, do not need to be classified with respect to respiratory sensitisation.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acutely toxic via the oral route.
Justification for the selected value	Based on intrinsic properties of individual components of the biocidal products pertaining to the BPF.
Classification of the product according to CLP and DSD	No classification required.

Data waiving	
Information requirement	Annex III of BPR, point 8.5.1 "Acute toxicity by oral route"
IUCLID data point	Section 8.5.1, Acute toxicity: oral
Justification	Studies on the potential acute oral toxicity of the individual products pertaining to the biocidal product family (BPF) are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.5 "Acute toxicity" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." For all products pertaining to the BPF, the exact composition is known. For each of the individual components in the products, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal products themselves is not required. According to the CLP principles, the individual products of the BPF, and thus the BPF itself, do not need to be classified with respect to acute oral toxicity.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acutely toxic via the inhalation route.
Justification for the selected value	Based on intrinsic properties of individual components of the biocidal products pertaining to the BPF.

Classification of the product according to CLP and DSD	No classification required.

Data waiving	
Information requirement	Annex III of BPR, point 8.5.2 "Acute toxicity by inhalation"
IUCLID data point	Section 8.5.2, Acute toxicity: inhalation
Justification	Studies on the potential acute inhalation toxicity of the individual products pertaining to the biocidal product family (BPF) are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.5 "Acute toxicity" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." For all products pertaining to the BPF, the exact composition is known. For each of the individual components in the products, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal products themselves is not required. According to the CLP principles, the individual products of the BPF, and thus the BPF itself, do not need to be classified with respect to acute inhalation toxicity.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic via the dermal route.
Justification for the selected value	Based on intrinsic properties of individual components of the biocidal products pertaining to the BPF.
Classification of the product according to CLP and DSD	No classification required.

Data waiving

Information requirement	Annex III of BPR, point 8.5.3 "Acute toxicity by dermal route"
IUCLID data point	Section 8.5.3, Acute toxicity: dermal
Justification	Studies on the potential acute dermal toxicity of the individual products pertaining to the biocidal product family (BPF) are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.5 "Acute toxicity" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." For all products pertaining to the BPF, the exact composition is known. For each of the individual components in the products, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal products themselves is not required. According to the CLP principles, the individual products of the BPF, and thus the BPF itself, do not need to be classified with respect to acute dermal toxicity.

Acute toxicity of product combinations

Data waiving	
Information requirement	Annex III of BPR, point 8.5.4 "Acute toxicity of product combinations"
IUCLID data point	Section 8.5.4, Acute toxicity: product combinations
Justification	Since products of this biocidal product family are not intended to be applied together with other products, an assessment of the potential acute toxicity of product combinations is not required.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Total iodine
Value(s)	12%
Justification for the selected value(s)	Read-across to similar tested mixture.

Data waiving	
Information requirement	Annex III of BPR, point 8.6 "Dermal absorption"
IUCLID data point	Section 8.6, Dermal absorption
Justification	Studies on the dermal absorption of iodine from the individual products pertaining to the biocidal product family (BPF) are not required. According to chapter III, section 8.6 "Information on dermal absorption" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), dermal absorption can be estimated by extrapolation of experimental data obtained with a similar formulation. For the products of the BPF, dermal absorption can be assessed by read-across from an *in-vitro* human skin dermal absorption study evaluated in the context of the active substance dossier on iodine (see CAR on iodine, including PVP-iodine, for PTs 1, 3, 4 and 22, 2013). The study has been performed with a PVP-iodine based RTU product containing 1.35% of PVP-iodine. A mean dermal absorption of 12% has been derived in accordance with the most recent EFSA guidance on dermal absorption (EFSA, 2012) and used for the human health exposure and risk assessments. A justification for the validity and acceptability of a read-across and bridging to available dermal absorption data is provided in an expert statement attached to section 8 of the IUCLID dossier. Based on the conclusions drawn from the read-across, a dermal absorption value of 12% is used in the human health exposure assessments for the use scenarios of the products pertaining to the BPF. Dermal absorption of the BPF was discussed during WGIV 2017. The documents used for the discussion are uploaded in R4BP3 (discussion table included justification as provided by the eCA and overview of BPF and tested formulations as included in the CAR for iodine). The WG agreed on dermal absorption of 12 % for the biocidal product family.

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

There is no indication that the products pertaining to the BPF contain components that are to be considered as substance(s) of concern. An overview of the assessment performed on all co-formulants of the BPF in June 2015 is attached to section 13 of the IUCLID dossier. Consequently, additional toxicological data on non-active substances are not required.

Available toxicological data relating to a mixture that a substance(s) of concern is a component of

There is no indication that the products pertaining to the BPF contain mixtures that a substance(s) of concern is a component of. An overview of the assessment performed on all co-formulants of the BPF in June 2015 is attached to section 13 of the IUCLID dossier. Consequently, additional toxicological data on non-active substances are not required.

Other

Food and feedingstuffs studies

Feeding and metabolism studies in livestock animals are not required as the products pertaining to the biocidal product family (BPF) are not intended for applications where contact with feedingstuffs may arise. Consequently, the transfer of potential residues of the biocidal products to food of animal origin *via* feedingstuffs is not relevant.

Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product

Application of the iodine-based teat-disinfection products pertaining to the biocidal product family (BPF) may lead to iodine residues in milk. The assessment of potential iodine residues in milk is summarized in the statement "*Discussion paper on iodine residues in milk due to iodine-based teat-disinfection: Assessment of consumer safety*" (29 June 2015) of the IRG PT3 sub-group which can be found attached in section 13 of the IUCLID dossier.
Industrial processing and/or domestic preparation of milk such as pasteurisation or fermentation may lead to a reduction of the initial iodine levels in raw milk (see discussion paper for details). However, there is no indication that during processing toxicologically significant degradation products of iodine arise in the pasteurized milk and dairy products which may require a separate risk assessment.
In conclusion, no risk is identified for iodine teat disinfection products.

Other test(s) related to the exposure to humans

Other tests related to the exposure of humans are not required for the products pertaining to the biocidal product family. The exposure of humans in all relevant exposure scenarios has been assessed with accepted exposure models and considering most recent recommendations of HEEG. The results of the human exposure and risk assessments for the intended use scenarios are provided in the respective chapters of the PAR which can be found attached in section 13 of the IUCLID dossier.

The products of the BPF are intended to be applied directly to livestock, i.e. on the animal`s teats. The assessment of potential iodine residues in milk is summarized in the statement "*Discussion paper on iodine residues in milk due to iodine-based teat-disinfection: Assessment of consumer safety*" (29 June 2015) of the IRG PT3 sub-group which can be found attached in section 13 of the IUCLID dossier. Calculations customized to the products

pertaining to the BPF and their relevant use scenarios are assessed in the respective chapters of this document.
In conclusion, no risk is identified for iodine teat disinfection products.

B. EXPOSURE ASSESSMENT

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

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

General considerations:

The disinfection by dipping or spraying takes place indoor before or after each milking, i.e. 1-3 times per day. It is considered that one professional milker milks at maximum 82 animals twice a day. For higher animal numbers or more milkings per day, an additional milker is needed.
The products within the BPF are ready-to-use (RTU) products. The BPF comprises possible RTU products containing PVP-iodine at concentrations in the range of 1-3% (equivalent to 0.12-0.36% available iodine) and potassium iodate at concentrations in the range of 0.025-0.06% (equivalent to 0.015-0.036% iodine) as well as iodide from PVP-iodine in the range of 0.06 – 0.18%, respectively. The total iodine content (available iodine from PVP-iodine, iodine from potassium iodate and iodide from PVP-iodine) is in the range of 0.19-0.58%. Worst-case exposure estimates are calculated for the relevant uses of MSPC3, however, using the highest total iodine concentration of the BPF (i.e. 0.58%).

The RTU products of the BPF contain up to 2.45% PVP-iodine, whereas the upper limit of the BPF was set to 3% PVP-iodine. Thus, as a worst-case, all calculations have been performed with 3% PVP-iodine. However, even if a value of 2.45% PVP-iodine was considered, this would not affect the conclusions that now have been included in the following sections of the PAR for the calculations with 3% PVP-iodine.

Within the CAR the percutaneous absorption of total iodine from two biocide formulations (0.26% and 0.66% w/w iodine) based on *in vitro* penetration studies was evaluated. The results demonstrated that in the concentration range tested, the dermal penetration of total iodine was independent of the concentration of iodine in the biocidal formulations. Therefore, based on these results, a dermal penetration rate for iodine of 12% will be used for the human health exposure assessment and the subsequent risk characterisation of the products within this product family.

The protection factors for personal protective equipment (PPE) used for the exposure assessments are defaults from the HEEG opinion 2010 "Default protection factors for protective clothing and gloves".

As a first step, exposure assessments are performed for those individual scenarios (work tasks). In a second step, the exposure calculated for the individual work tasks are combined (added up) for the following individual treatments:

- Manual dipping using a dip cup (pre- or post-milking disinfection)
- Manual spraying using a trigger sprayer (pre- or post-milking disinfection)
- Manual spraying using an electronic sprayer (pre- or post-milking disinfection)
- Automated spraying by robot (only post-milking disinfection)

Note of the eCA: The exposure assessment is based on the assessment for dairy cows. The teat disinfection of dairy cows is the most important use of the products of the BPF, but not limited to this use. The products can also be used for the disinfection of the teats of buffaloes, sheep and goats.
The exposure assessment for cows also covers the use in buffaloes, sheep and goats:

- Buffaloes: equal to dairy cows, buffaloes have four teats. The application rates per animal and milking are equal to dairy cows. Buffaloes are only milked two times a day. Consequently, the exposure of the milker to iodine teat disinfectants per day is equal or even lower in the case of buffaloes than for cows (assuming a herd with the same number of animals and the same milking techniques).
- Sheep and goats: these animals have only two teats per animal resulting in maximum application rates per animal in the intended use is based on animals with four teats. Therefore, as sheep and goats have two teats per animal maximally 5 ml is need for dipping and 7,5 ml for spraying applications. The animals are only milked 1-2 times per day.

It is therefore concluded that the exposure of a milker of dairy cows covers the exposure of a milker of buffaloes, sheep and goats.

Note of the eCA: Inhalation exposure was a point of discussion at the WGIV, and this issue was closed in ad hoc follow-up (secure WebEx discussion 25-10-2017). The following was concluded: *The ad hoc follow-up members agreed that in these two applications inhalation exposure to vapours could be considered as negligible and therefore inhalation exposure to vapours does not need to be assessed.*
The argumentation provided by the applicants should be included in the PAR.
The argumentation is included in annex 3.2.

List of scenarios

Summary table: scenarios for pre- or post-milking disinfection by dipping or spraying			
Scenario number	**Scenario**	**Primary exposure Description of scenario**	**Exposed group**
1.1	Mixing and loading of RTUs for dip cup or trigger sprayer	Preparation of dip cups: The product (RTU) is filled undiluted into the reservoir of a dip cup. By squeezing the reservoir, the disinfectant is pumped using a dosing pump into the dip cup above the reservoir which is then ready for dipping. By using the dosing pump overdosing can be avoided. Preparation of a trigger sprayer: The product (RTU) is filled undiluted into the reservoir of a sprayer. Re-filling of a dip cup or of a trigger sprayer is done analogously.	professionals
1.2	Mixing and loading for electronic sprayer or robotic milking device	This scenario replaces scenario 1.1 if electronic sprayer or robotic milking device is used. A can containing the RTU product is opened and a sucking lance of the electronic sprayer or robotic milking device is inserted. Empty cans are replaced by new ones.	professionals
2.1	Application of teat disinfectant by manual dipping	Before and/or after milking, the dip cup prepared as described in scenario 1.1 is put over each teat from below making sure that the full length of each teat is immersed into the disinfectant. This scenario is considered to be covered by mixing and loading.	professionals
2.2	Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer	This scenario replaces scenarios 2.1 in case of spray application. Before and/or or after milking, the teats are sprayed with the disinfectant using a trigger sprayer or electronic sprayer making sure that each teat is covered with the disinfectant.	professionals
2.3	Application of teat disinfectant by robot with automatic sprayer	This scenario replaces scenarios 2.1 and 2.2 in case of spray application by robot. Application by robot takes place only after milking. After robotic milking, the disinfectant is sprayed automatically onto teats from a cluster arm. No exposure due to fully automated system	professionals
3.1	Cleaning of teats by wiping with cloth: removal of freshly applied product	The teats which have been treated with a PVP iodine based disinfectant shortly before are carefully cleaned by wiping with a dry cloth immediately before milking.	professionals

3.2	Cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment	Cleaning of teats by wiping with a dry cloth before milking is only relevant if the cows have received a post-milking treatment. The disinfectant is expected to have completely dried up during the time span between treatment and cleaning. Partly the remains may even have either fallen off or rubbed off during this time. Therefore, any exposure to remains of the disinfectant on the teats is considered to be negligible.	Negligible exposure
3.3	Cleaning of teats by robot: removal of dried residues from post-milking treatment	This scenario replaces scenarios 3.2 if teats are cleaned with robot. Before each milking, the teats are cleaned by robot with automatic brushes.	No exposure
4.1	Cleaning of equipment such as dip cups, trigger sprayer and electronic sprayer after use	After disinfection, the reservoir is emptied and the entire dip or spray equipment is cleaned with running water.	professionals
4.2	Rinsing of robotic system	This scenario replaces scenario 4.1 if a robotic system is used. After disinfection, the sprayer is flushed with water: the sprayer is operated for few seconds with water instead of the disinfectant. Exposure is considered negligible.	Negligible exposure

Industrial exposure

Industrial exposure is not relevant.

Professional exposure

Scenario [1.1]: Mixing and loading of RTU for dip cup or trigger sprayer

Description of Scenario [1.1] - Mixing and loading by manual pouring of RTU for dip cup or trigger sprayer
The product (RTU) is filled undiluted into the reservoir of a dip cup or a trigger sprayer. In case of dip cup, by squeezing the reservoir, the disinfectant is pumped with a dosing pump into the dip cup above the reservoir which is then ready for dipping. According to HEAdhoc Recommendation no. 13 (Jan. 2017) – "Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3)" - , Mixing and loading model 4 is recommended for repeated loading of small quantities. For the dermal exposure (hands), the total amount of the required solution that is needed per day is of importance. Manually, cows are miked twice a day, treated either pre- or post-milking, therefore, as worst case the amount needed for one day is: 15 mL product x 2 times a day = 30 mL. For robotic milking, mixing and loading is considered in the next scenario. Considering 82 cows, this results in a total amount of product per day of 30 mL x 82 cows = 2.46 L product/day. For mixing and loading model 4, the indicative hand exposure for handling 5 L is 0.2 ml/treatment is used. Inhalation exposure is not assessed, since aerosol formation is not expected. In addition, as the active substance is complex-bound, evaporation is not considered relevant. The model covers all relevant mixing and loading tasks performed by a worker on an 8-h working day. Thus, re-filling of the equipment with the RTU product is covered within the mixing and loading step and does not need to be assessed separately.

	Parameters	Value
Tier 1	Total iodine (available iodine and iodide from potassium iodate and PVP-iodine) in RTU	0.58%
	Dermal penetration	12%
	Body weight	60 kg
	Indicative value for hand exposure (for handling product volumes of 5 L)	0.2 mL/treatment
	No PPE	0% protection
Tier 2	Gloves	90% protection

Calculations for Scenario [1.1] – Mixing and loading of RTU for dip foam cup or trigger sprayer by manual pouring

In the following, the results of the calculations are provided for scenario 1.1 performed twice a day.

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**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1.1] – M&L model 4	Tier 1/ none	-	2.32E-03	-	2.32E-03
	Tier 2/ Gloves	-	2.32E-04	-	2.32E-04

Comment eCA: For mixing and loading model 4, the indicative hand exposure for handling 5 L is 0.2 ml/treatment. The applicant considers the 5L or 5000 ml the value to be considered for "treatment" in the calculations. The eCA considers for treatment the amount of treatments per day, in other words: 82 cows x 2 milking events/day x 1 pre- or post-application = 164. However, the estimated dermal uptake based on the calculations performed by the applicant are worst case and the resulting conclusions on safe use or the use of PPE are the same using either the 5000 or the 164 value for the calculations. Therefore, the estimated dermal uptake as submitted by the applicant are included above and in the combined assessments.

Further information and considerations on scenario [1.1] – Mixing and loading of RTU for dip cup or trigger sprayer: Local exposure concentration of iodine in air

Local inhalation exposure is not assessed, since aerosol formation is not expected. In addition, as the active substance is complex-bound, evaporation is not considered relevant.

Scenario [1.2]: Mixing and loading of electronic sprayer or robotic milking device

Description of Scenario [1.2] - Mixing and loading of electronic sprayer or robotic milking device		
This scenario replaces scenario 1.1 if electronic sprayer or robotic milking device is used. A can containing the RTU product is opened and a sucking lance of the electronic sprayer, ADF-system or robotic milking device is inserted. The exposure duration of 1 min per day for RTU is used. According to HEAdhoc Recommendation no. 13 (Jan. 2017), the RISKOFDERM toolkit for connecting lines is recommended for automated mixing and loading with an indicative value of 0.92 mg/min for dermal exposure. Inhalation exposure is not assessed, since aerosol formation is not expected. In addition, as the active substance is complex-bound, evaporation is not considered relevant. Connecting transfer lines is performed once a day. Thus, re-filling of the equipment with the RTU product is covered within the mixing and loading step and does not need to be assessed separately.		
	Parameters	Value
Tier 1	Total iodine (available iodine and iodide) in RTU	0.58%
	Dermal penetration	12%
	Body weight	60 kg
	Indicative value for dermal exposure	0.92 mg/min
	Exposure duration	1 min per day
	No PPE	0% protection
Tier 2	Gloves	90% protection

Calculations for Scenario [1.2] – Mixing and loading of electronic sprayer or robotic milking device

In the following, the results of the calculations are provided.

The calculation sheets are provided in Appendix 3.2-II.

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**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1.2] – RISKOFDERM Toolkit, Connecting lines	Tier 1/ none	-	1.07E-05	-	1.07E-05
	Tier 2/ Gloves	-	1.07E-06	-	1.07E-06

Further information and considerations on scenario [1.2] – Mixing and loading of electronic sprayer or robotic milking device: Local exposure concentration of iodine in air

Local inhalation exposure is not assessed, since aerosol formation is not expected. In addition, as the active substance is complex-bound, evaporation is not considered relevant.

Scenario [2.1]: Application of teat disinfectant by manual dipping

Description of Scenario [2.1] - Application of teat disinfectant by manual dipping
Before and/or after milking, the dip cup prepared as described in scenario 1.1 is put over each teat from below making sure that the full length of each teat is immersed into the disinfectant. Dermal exposure during use of the dip cups is not expected based on the design of the dipping cup. This kind of cup has an upper compartment for application of the dip and a lower compartment as a reservoir for the dipping solution. During the application the worker holds the cup at the lower compartment. Thus, direct hand exposure to the RTU or a treated teat is avoided. Based on HEAdhoc Recommendation no. 13 (Jan. 2017), any possible spillage is considered covered by the dermal exposure as calculated by the scenario of mixing and loading.

Scenario [2.2]: Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer

Description of Scenario [2.2] - Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer

This scenario replaces scenarios 2.1 in case of spray application.

Before and/or after milking, the teats are sprayed with the disinfectant using a trigger sprayer or electronic sprayer making sure that each teat is covered with the disinfectant. The 10 sec/animal is used according to the Biocides Human Health Exposure Methodology (vers. 1, Oct. 2015, p. 111). Considering 82 animals to be milked, the total exposure duration results in 13.7 min.

According to the HEAdhoc Recommendation no. 13 (Jan. 2017), the model used is "2. Hand-held trigger spray" from TNsG 2007 for dermal and inhalation exposure estimation.
This model provides the same indicative values as the consumer spraying and dusting model "2. Hand-held trigger spray" from TNsG 2002 used in the CAR.

The trigger spraying model is used for both the trigger spray and electronic spray application. This is based on the assumption that the medium pressure spraying model does not appropriately reflect the small area disinfection by electronic spraying.

Inhalation exposure towards aerosol was assessed. As the active substance is complex-bound, evaporation is not considered relevant.

In the CAR, spraying using an electronic sprayer was not considered.

	Parameters	Value
Tier 1	Total iodine (available iodine and iodide) in RTU	0.58%
	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 m^3/h (0.021 m^3/min)
	Exposure duration	13.7 min, 2 times a day.
	Indicative value for dermal exposure	Hand/forearms: 36.1 mg/min Legs, feet, face: 9.7 mg/min
	Indicative value for inhalation exposure (aerosol)	10.5 mg/m^3
	No PPE	0% protection
Tier 2	Gloves	90% protection

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

In the following, the results of the exposure calculations of scenario 2.2 are provided for 82 animals disinfected before or after each milking, i.e. twice a day.

The calculation sheets are provided in Appendix 3.2-III.

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**	**Estimated total uptake (mg/kg bw/d)**
Scenario [2.2] – Consumer spraying and dusting model 2, 2. Hand-held trigger spray	Tier 1/ none	5.83E-04	1.45E-02	-	1.51E-02
	Tier 2/ Gloves	5.83E-04	4.22E-03	-	4.80E-03

Further information and considerations on scenario [2.2] - Application of teat disinfectant by spraying using a trigger sprayer or electronic 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, 2. Hand-held trigger spray	6.09E-02

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

Description of Scenario [2.3] - Application of teat disinfectant by robot with automatic sprayer
This scenario replaces scenarios 2.1 and 2.2 in case of spray application by robot. Application by robot takes place only after milking. After robotic milking, the disinfectant is sprayed automatically onto teats from a cluster arm. No exposure of professionals occurs due to fully automated system. 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. This scenario was not considered in the CAR.

Scenario [3.1]: Cleaning of teats by wiping with cloth: removal of freshly applied product

Description of Scenario [3.1] - Cleaning of teats by wiping with cloth: removal of freshly applied product
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. To cover this scenario, exposure estimates were made according to HEAdhoc Recommendation no. 13 (Jan. 2017). As a worst-case, based on the Disinfectant Products Fact Sheet (RIVM report 320005003/2006), it is assumed that 0.1% of the amount of the RTU on the surface area (here: the teats and a part of the udder of the cow with 44 cm^2/teat and 176 cm^2/cow) contacts the palm of the hands. 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. Inhalation exposure is not assessed, since aerosol formation is not expected. In addition, as the active substance is complex-bound, evaporation is not considered relevant.

	Parameters	Value
Tier 1	Total iodine (available iodine and iodide) in RTU	0.58%
	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 m^3/h (0.021 m^3/min)
	Surface area of an average teat	44 cm^2
	Surface area per cow (with 4 teats)	176 cm^2
	Percentage of RTU in contact with hands (palms)	0.1%
	No PPE	0% protection
Tier 2	Gloves	90% protection

Calculations for Scenario [3.1] – Cleaning of teats by wiping with cloth for pre-milking disinfection

In the following, the results of the calculations for the scenario 3.1 are provided for 82 animals disinfected before each milking, i.e. twice a day.

The calculation sheets are provided in Appendix 3.2-IV.

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**	**Estimated total uptake (mg/kg bw/d)**
Scenario [3.1] – generic approach acc. to HEAdhoc 13	Tier 1/ none	-	3.35E-03	-	3.35E-03
	Tier 2/ Gloves	-	3.35E-04	-	3.35E-04

Further information and considerations on scenario [3.1] - Cleaning of teats by wiping with cloth for pre-milking disinfection: Local exposure concentration of iodine in air

Local inhalation exposure is not assessed, since aerosol formation is not expected. In addition, as the active substance is complex-bound, evaporation is not considered relevant.

Scenario [3.2]: Cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment

Description of Scenario [3.2] - Cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment
Cleaning of teats by wiping with a dry cloth before milking is only relevant if the cows have received a post-milking treatment. The disinfectant is expected to have completely dried up during the time span between treatment and cleaning. Partly the remains may even have either fallen off or rubbed off during this time. Therefore, any exposure to remains of the disinfectant on the teats is considered to be negligible. Generally, for the cleaning dry disposable paper tissues are used. Since the residues are dry and the tissue is dry as well and disposed after each animal, there is definitely no relevant exposure. Illustrative pictures are attached to section 13 of the IUCLID dossier. 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. This work step was not considered in the CAR.

Scenario [3.3]: Cleaning of teats by robot

Description of Scenario [3.3] - Cleaning of teats by robot
This scenario replaces scenario 3.2 if teats are cleaned with robot. Before each milking, the teats are cleaned by robot with automatic brushes. No exposure of professionals occurs. 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. This scenario was not considered in the CAR.

Scenario [4.1]: Cleaning of equipment such as dip cups, trigger sprayer and electronic sprayer after use

Description of Scenario [4.1] - Cleaning of equipment such as dip cups, trigger sprayer and electronic sprayer after use		
After application, a small amount of diluted product will remain in the application equipment; however this will be highly diluted by the wash-water. Therefore, it is concluded that exposure during cleaning of application equipment is lower in comparison with the exposure during mixing and loading and application operations. Due to the lack of an appropriate exposure model for the scenario "cleaning of equipment", the model RISKOFDERM Toolkit, Connecting lines is used as a surrogate model according to HEAdhoc Recommendation no. 13 (Jan. 2017). Inhalation exposure is not assessed, since aerosol formation is not expected. In addition, as the active substance is complex-bound, evaporation is not considered relevant. The duration for this task is considered to be 5 min. The cleaning step is performed after each milking event, i.e. twice per day.		
	Parameters	Value
Tier 1	Total iodine (available iodine and iodide) in RTU	0.58%
	Dermal penetration	12%
	Body weight	60 kg
	Exposure duration	5 min
	Indicative value for hand exposure	0.92 mg/min
	No PPE	0% protection
Tier 2	Gloves	90% protection

Calculations for Scenario [4.1] - Cleaning of equipment such as dip cups, trigger sprayer after use

In the following, the results of the exposure calculations are provided for 2 times per day.

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**	**Estimated total uptake (mg/kg bw/d)**
Scenario [4.1] – RISKOFDERM Toolkit, Connecting lines	Tier 1/ none	-	1.07E-04	-	1.07E-04
	Tier 2/ Gloves	-	1.07E-05	-	1.07E-05

Further information and considerations on scenario [4.1] - Cleaning of equipment such as dip cups, trigger sprayer after use: Local exposure concentration of iodine in air

Local inhalation exposure is not assessed, since aerosol formation is not expected. In addition, as the active substance is complex-bound, evaporation is not considered relevant.

Calculations for Scenario [4.2] – Rinsing of robotic system

Scenario [4.2]: Rinsing of robotic system

Description of Scenario [4.2] – Rinsing of robotic system
This scenario replaces scenario 4.1 if a robotic system is used. After disinfection, the system is flushed with water: The system is operated for few seconds with water instead of the disinfectant. No exposure of professionals occurs.

Combined scenarios: Pre- or post-milking disinfection of 82 animals by dipping or spraying twice a day

The exposure calculated for the individual work tasks are combined (added up) for the following individual treatments:

- Manual dipping using a dip cup (pre- or post-milking disinfection)
- Manual spraying using a trigger sprayer (pre- or post-milking disinfection)
- Manual spraying using an electronic sprayer (pre- or post-milking disinfection)
- Automated spraying by robot (only post-milking disinfection)

Pre-milking disinfection of 82 animals twice a day

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Manual dipping - RTUs Scenarios [1.1; 2.1; 3.1; 4.1]	Tier 1/ none	-	5.78E-03	5.78E-03
	Tier 2/ Gloves	-	5.78E-04	5.78E-04
Manual spraying using a trigger sprayer - RTUs Scenarios [1.1; 2.2; 3.1; 4.1]	Tier 1/ none	5.83E-04	2.03E-02	2.09E-02
	Tier 2/ Gloves	5.83E-04	4.80E-03	5.38E-03
Manual spraying using an electronic sprayer - RTUs Scenarios [1.2; 2.2; 3.1; 4.1]	Tier 1/ none	5.83E-04	1.80E-02	1.86E-02
	Tier 2/ Gloves	5.83E-04	4.57E-03	5.15E-03

Post-milking disinfection of 82 animals twice a day

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Manual dipping - RTUs Scenarios [1.1; 2.1; 3.2; 4.1]	Tier 1/ none	-	2.43E-03	2.43E-03
	Tier 2/ Gloves	-	2.43E-04	2.43E-04
Manual spraying using a trigger sprayer - RTUs Scenarios [1.1; 2.2; 3.2; 4.1]	Tier 1/ none	5.83E-04	1.69E-02	1.75E-02
	Tier 2/ Gloves	5.83E-04	4.46E-03	5.05E-03
Manual spraying using an electronic sprayer - RTUs Scenarios [1.2; 2.2; 3.2; 4.1]	Tier 1/ none	5.83E-04	1.46E-02	1.52E-02
	Tier 2/ Gloves	5.83E-04	4.23E-03	4.81E-03
Automated spraying by robot - RTUs Scenarios [1.2; 2.3; 3.3; 4.2]	Tier 1/ none	-	1.07E-05	1.07E-05
	Tier 2/ Gloves	-	1.07E-06	1.07E-06

Non-professional exposure

Non-professional exposure is not relevant.

Exposure of the general public

Exposure of the general public is not relevant. The general public does not have access to the milking parlour.

Monitoring data

Concerning human exposure, no monitoring data are available.

Concerning residues in milk, several publications are available:
For the evaluation of dietary exposure, reference to the residue studies summarized and discussed in the CAR and to a new residue study (O`Brien, 2013) is made. For the purpose of product authorization, these studies have been (re-)assessed with a focus on application regimes relevant for IRG Members (including Ecolab) and summarized in the "*Discussion paper on iodine residues in milk due to iodine-based teat-disinfection: Assessment of consumer safety*" (29 June 2015) of the IRG PT3 sub-group. An amended version of this document, in which the worst-case scenario of Ecolab`s BPF (i.e. pre- and post-milking teat-disinfection *via* manual spraying at a maximum concentration of 0.36% available iodine) has been highlighted, is attached to the IUCLID dossier.

Dietary exposure

List of scenarios

Summary table of main representative dietary exposure scenarios			
Scenario number	**Type of use**	**Description of scenario**	**Subject of exposure**
1.	Animal husbandry	pre- or post-milking teat-disinfection	Iodine in milk
		manual application	
		spraying	
		Dairy cows, buffaloes, sheep and goats	

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses			
	Sector of use[1]	**Intended use**	**Reference value(s) [2]**
1.	Veterinary use	Teat-disinfection with veterinary claim (reduction of mastitis)	"no MRL required" for all target tissues according to Commission Regulation (EU) No 37/2010 of 22 Dec. 2009. [Based on an evaluation of the committee for veterinary medicinal products were it was agreed that it would be inappropriate to elaborate MRLs for iodine.
2.	Food additives	Fortification of food (iodised salt)	National regulations in place; 10-75 mg/kg salt (majority of values in the range of 15-30 mg/kg) according to EFSA NDA Panel, 2014, Scientific Opinion on Dietary Reference Values for iodine, EFSA Journal 2014; 12(5);3660 (doi:10.2903/j.efsa.2014.3660)
3.	Feed additives	Supplementation of animal feed	Dairy cows: 5 mg I/kg of complete feedingstuff according to Commission Regulation (EC) No 1459/2005 of 8 Sept. 2005 2 mg I/kg recommended according to EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Scientific opinion on the safety and efficacy of iodine compounds (E2) as feed additives for all animal species […], EFSA Journal 2013; 11(2):3099 (doi:10.2903/j.efsa.2013.3099)

[1] e.g. plant protection products, veterinary use, food or feed additives

[2] e.g. MRLs. Use footnotes for references.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Livestock exposure estimates are required for the risk assessment on animal health as well as for determining the worst-case human exposure estimate (WCCE). However, 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.

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

Production of the biocidal product:
The production is done in a closed system. The raw materials are fed sequentially, using automatic dosing equipment, into a closed stainless steel vessel equipped with a mixer and air extraction to prevent emission into the working environment. For working steps, where exposure of workers cannot be excluded, such as connecting lines or quality control, the workers use adequate PPE. The workers are trained professionals.
From the vessels, the finished product is pumped to the filling station. The filling process is done as an automated process under closed conditions. Exposure of industrial workers is thus minimal.

Environmental exposure: Should spillages occur, they are taken up with inert material (sand, earth, chemical absorbent, etc.) and are collected in dedicated drums properly labeled. They are disposed as chemical waste in accordance with local and national laws and regulations. Consequently, there is no release into the environment and, thus, no environmental exposure assessment is applicable.

Quantitative assessment of workers exposure: Parameters used:		
	Parameters	**Value**
Step 1: Raw material transfer to batch	Model	ART version 1.5
	Emission sources	Near field
	Duration	15 minutes
	Substance product type	Powder
	Process temperature	Room temperature
	Vapour pressure	40.7 Pa
	Liquid mole fraction	Main component
	Activity coefficient	1
	Activity class	Falling liquids
	Situation	Transfer of liquid product with flow of 100 - 1000 l/minute
	Containment level	Open process
	Loading type	Submerged loading, where the liquid dispenser remains below the fluid level reducing the amount of aerosol formation
	Process fully enclosed?	No
	Effective housekeeping practices in place?	Yes
	Work area	Indoors
	Room size	Large workrooms only
	Primary localised controls	Low level containment (90.00 % reduction)
	Ventilation rate	Only good natural ventilation
Step 2: Mixing	Model	ECETOC TRA v3.1
	PROC	8b
	Type of setting	Industrial
	Duration of activity	15 min - 1 hour
	Use of ventilation	Indoors with enhanced general ventilation
	Use of RPE	90%
	Substance in preparation	<1%

Step 3: Filling	Model	ECETOC TRA v3.1
	PROC	3 (worst case, incl. PROC 1 and PROC 2)
	Type of setting	Industrial
	Duration of activity	> 4 hours
	Use of ventilation	Indoors with enhanced general ventilation
	Use of RPE	90%
	Substance in preparation	<1%

Calculations for Scenarios

Summary table: systemic exposure associated with production, formulation, and disposal						
Exposure scenario	**LT inhalative exposure estimate (mg/m³)**	**Risk characterisation ratio – LT inhalative**	**Acceptable**	**LT dermal exposure estimate (mg/kg/day)**	**Risk characterisation ratio – LT dermal**	**Acceptable**
Step 1: Raw material transfer to batch	0.66	6.60E-01	Yes	Not calculated by tool	--	Yes
Step 2: Mixing	9.52E-02	9.52E-02	Yes	3.43E-03	3.43E-01	Yes
Step 3: Filling	3.17E-03	3.17E-03	Yes	6.86E-04	6.86E-02	Yes

Disposal of the biocidal product:
The generation of waste should be avoided or minimized wherever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe way. Significant quantities of waste product residues should not be disposed of via the foul sewer but processed in a suitable effluent treatment plant. Dispose surplus and non-recyclable products via a licensed waste disposal contractor. Disposal of this product, solutions and by-products should at all times comply with the

requirements of environmental protection and waste disposal legislation and any regional authority requirements. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

Aggregated exposure

Aggregated exposure is not assessed, since a respective methodology is not available yet. Nevertheless, in the operator exposure assessment includes the daily iodine intake of 150 µg iodine/person by food.

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] – M/L of RTUs for dip cup or trigger sprayer - M/L model 4	professionals	1 / none	2.32E-03
		2 /Gloves	2.32E-04
[1.2] – M/L of RTU for electronic sprayer or robotic milking device - RISKOFDERM Toolkit, Connecting lines	professionals	1 / none	1.07E-05
		2 / Gloves	1.07E-06
[2.1] – Application by manual dipping	Exposure of professionals is covered by the M/L step.		
[2.2] – Application by spraying using a trigger sprayer or electronic sprayer - Consumer spraying and dusting model 2, 2. Hand-held trigger spray	professionals	1 / none	1.51E-02
		2 / Gloves	4.80E-03
[2.3] – Application by robot with automatic sprayer	Exposure of professionals is not expected.		
[3.1] – Cleaning of teats: removal of freshly applied product - generic approach acc. to HEAdhoc 13	professionals	1 / none	3.35E-03
		2 / Gloves	3.35E-04
[3.2] – Cleaning of teats: removal dried residues	Exposure of professionals is considered to be negligible.		
[3.3] – Cleaning of teats by robot: removal of dried residues	No exposure of professionals occurs.		
[4.1] – Cleaning of equipment after use - RISKOFDERM Toolkit, Connecting lines	professionals	1 / none	1.07E-04
		2 / Gloves	1.07E-05
[4.2] – Rinsing of robotic system	Exposure of professionals is not expected.		

C. RISK CHARACTERISATION FOR HUMAN HEALTH

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
$AEL_{short\text{-}term}$	Not derived in the CAR and not relevant for HHRA.				
$AEL_{medium\text{-}term}$	Not derived in the CAR and not relevant for HHRA.				
$AEL_{long\text{-}term}$ = Upper Intake Level (UL)	Human data				Adult: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/m^3

[1] Please explain background and reason for assessment factor.

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 information, 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.

Explanatory note:

In analogously to the exposure assessment, the risk for the individual work tasks is provided in the following table.

Risk for industrial users

Industrial exposure is not relevant.

Risk for professional users

Systemic effects
Assessment for the upper limit of the BPF, i.e. max 0.58% 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]
M/L of RTUs for dip cup or trigger sprayer [1.1]	1/ none	2.32E-03	23	36	51	81
	2/ Gloves	2.32E-04	2	15	30	61
M/L of RTU for electronic sprayer or robotic milking device [1.2]	1/ none	1.07E-05	0.1	13	28	58
	2/ Gloves	1.07E-06	0.01	12	27	58
Application by manual dipping [2.1]	Exposure of professionals is covered by the M/L step.					

Application by spraying using a trigger sprayer or electronic sprayer [2.2]	1/ none	1.51E-02	151.0	163	178	209
	2/ Gloves	4.80E-03	48.0	60	75	106
Application by robot with automatic sprayer [2.3]	No exposure of professionals occurs.					
Cleaning of teats: removal of freshly applied product [3.1]	1/ none	3.35E-03	34	46	61	92
	2/ Gloves	3.35E-04	3	16	31	62
Cleaning of teats: removal dried residues [3.2]	Exposure of professionals considered to be negligible.					
Cleaning of teats by robot: removal of dried residues [3.3]	No exposure of professionals occurs.					
Cleaning of equipment after use [4.1]	1/ none	1.07E-04	1	14	29	59
	2/ Gloves	1.07E-05	0.1	13	28	58
[4.2] – Rinsing of robotic system	Exposure of professionals is not expected.					

[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 toddler based on UK data (2008).

Calculation sheet is included in annex 3.2.

Local effects

Local effects are only relevant for the application scenario "Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer".

Task/ Scenario	Iodine in air inhaled (mg/m³)	% OEL (1 mg/m³)	Acceptable (yes/no)
Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer [2.2]	6.09E-02	6.1	yes

Combined scenarios

In the following table, the relevant use scenarios per *meta* SPC are summarized:

Time of application	Manual dipping or manual spraying using a trigger sprayer	Manual spraying using an electronic sprayer	Automated spraying by robot
Pre-milking disinfection (82 animals twice a day)	*Meta* SPC3	*Meta* SPC3	
Post-milking disinfection (82 animals twice a day)	all *Meta* SPCs	*Meta* SPC3, *meta* SPC4 and *meta* SPC6	*Meta* SPC3, *meta* SPC4 and *meta* SPC6

Only products within *meta* SPC3 can be applied pre-milking, whereas the products within the other *meta* SPCs are applied by post milking only. An additional evaluation is included of the exposure from manual spraying using an electronic sprayer (pre- or post-milking) or spraying by robot (post-milking only) for evaluation of the need of gloves for these application scenarios.

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

Assessment for the upper limit of the BPF, i.e. max 0.58% total iodine. Intakes which exceed the UL are highlighted in red in the table below.

Scenarios combined	Tier	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 - RTUs Scenarios [1.1; 2.1; 3.1; 4.1]	Tier 1/ none	5.78E-03	58	68	83	114
	Tier 2/ Gloves	5.78E-04	6	16	31	62
Manual spraying using a trigger sprayer - RTUs Scenarios [1.1; 2.2; 3.1; 4.1]	Tier 1/ none	2.09E-02	209	219	234	265
	Tier 2/ Gloves	5.38E-03	54	64	79	110
Manual spraying using an electronic sprayer - RTUs Scenarios [1.2; 2.2; 3.1; 4.1]	Tier 1/ none	1.86E-02	186	196	211	242
	Tier 2/ Gloves	5.15E-03	51	62	77	108

[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 toddler based on UK data (2008).

Calculation sheet is included in annex 3.2 (Ecolab combined prof exposure including residues).

Conclusion (BPF-level): Pre-milking disinfection *of 82 animals twice a day*

Tier 1:

Exposure from biocidal use without considering PPE (Tier 1) results in 58% for manual dipping, 209% and 186% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.

Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 1) results in 68% for manual dipping, 219% and 196% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.

Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 1) results in 83% for manual dipping, 234% and 211% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.

Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 114% for manual dipping, 265% and 242% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.

Tier 2:

Exposure from biocidal use considering gloves (Tier 2) results in 6% for manual dipping, 54% and 51% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.

Exposure from biocidal use, including iodine from milk consumption due to teat treatment, considering gloves (Tier 2) results in 16% for manual dipping, 64% and 62% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.

Exposure from biocidal use, including iodine from milk consumption, considering gloves (Tier 2) results in 31% for manual dipping, 79% and 77% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.

Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, considering PPE (Tier 2) results in 62% for manual dipping, 110% and 108% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.

Conclusion professional use, pre-milking application- BPF first level

For a total iodine concentration of 0.58% this means that for pre-milking disinfection by manual dipping is safe for the protected (chemical resistant gloves) professional user (i.e. 62% UL).

For a total iodine concentration of 0.58% by manual spraying using a trigger or electronic sprayer for pre-milking disinfection, the UL is exceeded, even when considering PPE (i.e. 110% UL for using a trigger sprayer and 108% UL using an electronic sprayer).

However, as the evaluation of metaSPC3 (see below) shows safe use for the protected (chemical resistant gloves) professional user considering 0.44% total iodine when used for pre-milking application by spraying using a trigger sprayer or an electronic sprayer, the max. total iodine of the BPF needs to be lowered to 0.44% total iodine.

Furthermore, the OEL of 1 mg/m³ for iodine is not reached in the scenario "Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer" for pre-milking disinfection with 6.1% of the OEL.

As only MSPC3 within the BPF contains pre-milking applications, no conclusions need to be drawn for the other MSPCs. The iodine concentration within metaSPC3 (0.44% total

iodine) is compared to the BPR (i.e. 0.58% total iodine) and summarized in the table below.

Assessment for the upper limit of the metaSPC3, i.e. max 0.44% total iodine. Intakes which exceed the UL are highlighted in red in the table below.

Scenarios combined	Tier	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 - RTUs Scenarios [1.1; 2.1; 3.1; 4.1]	Tier 1/ none	4.38E-03	44	54	69	100
	Tier 2/ Gloves	5.75E-04	4	15	30	61
Manual spraying using a trigger sprayer - RTUs Scenarios [1.1; 2.2; 3.1; 4.1]	Tier 1/ none	2.07E-02	159	169	184	215
	Tier 2/ Gloves	5.27E-03	41	52	67	98
Manual spraying using an electronic sprayer - RTUs Scenarios [1.2; 2.2; 3.1; 4.1]	Tier 1/ none	1.76E-02	141	152	167	198
	Tier 2/ Gloves	4.96E-03	39	50	65	96

[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) 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 toddler based on UK data (2008).

Calculation sheet is included in annex 3.2 (Ecolab combined prof exposure including residues).

Conclusion (metaSPC-level): Pre-milking disinfection *of 82 animals twice a day*

Tier 1:

Exposure from biocidal use without considering PPE (Tier 1) results in 58% for manual dipping, 207% and 176% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.

Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 1) results in 68% for manual dipping, 218% and 187% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.

Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 1) results in 83% for manual dipping, 233% and 202% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.

Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 114% for manual dipping, 264% and 233% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.

Tier 2:

Exposure from biocidal use considering gloves (Tier 2) results in 6% for manual dipping, 53% and 50% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.

Exposure from biocidal use, including iodine from milk consumption due to teat treatment, considering gloves (Tier 2) results in 16% for manual dipping, 63% and 60% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.

Exposure from biocidal use, including iodine from milk consumption, considering gloves (Tier 2) results in 31% for manual dipping, 78% and 75% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.

Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, considering PPE (Tier 2) results in 62% for manual dipping, 109% and 106% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively.

Conclusion professional use, pre-milking application- metaSPC level: metSPC3

Pre-milking disinfection by manual dipping with products included in metaSPC3 (iodine concentration of 0.44% total iodine) for the unprotected professional user the UL is not exceeded (i.e. 100% UL). However, by manual spraying using a trigger or electronic sprayer for pre-milking disinfection, the use of chemical resistant gloves are necessary not to exceed the UL for the professional user (i.e. max. 98% UL). Therefore, for products included in metaSPC3 "Wear chemical resistant gloves for spraying applications" needs to be included in the labelling of the product (included in the use-specific risk mitigation measures of the SPC (use 3.2, paragraph 4.1.2)).

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

Assessment for the upper limit of the BPF, i.e. max 0.58% total iodine. Intakes which exceed the UL are highlighted in red in the table below.

Scenarios combined	Tier	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 - RTUs Scenarios [1.1; 2.1; 3.2; 4.1]	Tier 1/ none	2.43E-03	24	37	52	83
	Tier 2/ Gloves	2.43E-04	2	15	30	61
Manual spraying using a trigger sprayer - RTUs Scenarios [1.1; 2.2; 3.2; 4.1]	Tier 1/ none	1.75E-02	175	188	203	233
	Tier 2/ Gloves	5.05E-03	50	63	78	109
Manual spraying using an electronic sprayer - RTUs Scenarios [1.2; 2.2; 3.2; 4.1]	Tier 1/ none	1.52E-02	152	164	179	210
	Tier 2/ Gloves	4.81E-03	48	61	76	106
Automated spraying Scenarios [1.2; 2.3; 3.3; 4.2]	Tier 1/ none	5.94E-04	6	18	33	64
	Tier 2/ Gloves	5.84E-04	6	18	33	64

[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 toddler based on UK data (2008).

Calculation sheet is included in annex 3.2 (Ecolab combined prof exposure including residues).

Conclusion (BPF-level): Post-milking disinfection *of 82 animals twice a day*

Tier 1:
Exposure from biocidal use without considering PPE (Tier 1) results in 24% for manual dipping, 175% and 152% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 6% of the UL for robotic spraying.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 1) results in 37% for manual dipping, 188% and 164% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 18% of the UL for robotic spraying.
Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 1) results in 52% for manual dipping, 203% and 179% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 33% of the UL for robotic spraying.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 83% for manual dipping, 233% and 210% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 64% of the UL for robotic spraying.

Tier 2:
Exposure from biocidal use considering gloves (Tier 2) results in 2% of the UL for manual dipping, 50% and 48% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and6% of the UL for robotic spraying.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, considering gloves (Tier 2) results in 15% for manual dipping, 63% and 61% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 18% of the UL for robotic spraying.
Exposure from biocidal use, including iodine from milk consumption, considering gloves (Tier 2) results in 30% for manual dipping, 78% and 76% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 33% of the UL for robotic spraying.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, considering gloves (Tier 2) results in 61% for manual dipping, 109% and 106% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 64% of the UL for robotic spraying.

Conclusion professional use, post-milking application- BPF first level
For a total iodine concentration of 0.58% for post-milking disinfection by manual dipping or by automated spraying for the unprotected professional user (i.e. 83% UL for manual dipping and 64% UL for automated spraying) the exposure to iodine is considered safe. However, for a total iodine concentration of 0.58% by manual spraying using a trigger or electronic sprayer for post-milking disinfection, the UL is exceeded, even when considering PPE (i.e. 109% UL for using a trigger sprayer and 106% UL using an electronic sprayer). However, as the evaluation of spraying application by trigger sprayer or an electronic sprayer at metaSPC level (see below) shows safe use for the protected (chemical resistant gloves) professional user considering maximally 0.44% total iodine, the max. total iodine of the BPF needs to be lowered to 0.44% total iodine.

Furthermore, the OEL of 1 mg/m³ for iodine is not reached in the scenario "Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer" for post-milking disinfection with 6.1% of the OEL.

Conclusions for the remaining MSPCs can be obtained based on the relative difference in iodine concentration within the MSPCs compared to the limit of the BPF (i.e. 0.58% total iodine) and are summarized in the following table for manual dipping and manual spraying using a trigger sprayer (post-milking). Please note that the calculated factors have been rounded, and thus results slightly differ from the exactly calculated exposure estimates. Intakes which exceed the respective UL are highlighted in red in the table below.

Difference in total iodide concentration compared with MSPC?	**Tier**	**Estimated % 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]**
MSPC1, 0.19% total iodine (post-milking dipping) 3-fold lower total iodine concentration compared with limit of the BPF (0.58% total iodine)	Tier 1/ none	8	20	35	66
	Tier 2/ Gloves	1	13	28	59
MSPC2, 0.27% total iodine (post-milking dipping) 2.1-fold lower total iodine concentration compared with limit of the BPF (0.58% total iodine)	Tier 1/ none	11	24	39	70
	Tier 2/ Gloves	1	14	29	59
MSPC3, 0.44% total iodine (post-milking dipping or spraying) 1.3-fold lower total iodine concentration compared with limit of the BPF (0.58% total iodine)	Tier 1/ none	18-133	31-146	46-161	77-191
	Tier 2/ Gloves	–2-39	14-51	29-66	60-97
MSPC4, 0.22% total iodine (post-milking dipping or spraying) 2.6-fold lower total iodine concentration	Tier 1/ none	9-66	22-79	37-94	67-124
	Tier 2/ Gloves	–1-19	13-31	28-46	59-77

compared with limit of the BPF (0.58% total iodine)					
MSPC5, 0.22% total iodine (post-milking dipping) 2.6-fold lower total iodine concentration compared with limit of the BPF (0.58% total iodine)	Tier 1/ none	9	22	37	67
	Tier 2/ Gloves	1	13	28	59
MSPC6, 0.27% total iodine (post-milking dipping or spraying) 2.1-fold lower total iodine concentration compared with limit of the BPF (0.58% total iodine)	Tier 1/ none	11-81	24-94	39-109	70-140
	Tier 2/ Gloves	1-23	14-36	29-51	59-82

* The range represent the range between lowest estimated % UL for manual dipping and the highest estimated % UL for manual spraying with a trigger sprayer (pre- or post-milking, whereas pre-milking is worst-case compared to post-milking).

[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 toddler based on UK data (2008).

Calculation sheet is included in annex 3.2 (Ecolab combined prof exposure including residues).

Conclusion professional use, post-milking application- metaSPC level

Post-milking disinfection by manual dipping and automated spraying considering the BPF (i.e. 0.58% total iodine) was considered safe for the unprotected user, therefore for metaSPC1-5 this application is also considered safe. However, for clarity the specific exposure is included per metaSPC in the table above.

However, by manual spraying using a trigger or electronic sprayer for post-milking disinfection, the use of chemical gloves are necessary not to exceed the UL for the professional user (i.e. max. 97% UL). Therefore, for products included in metaSPC3,4 and 6 "Wear chemical resistant gloves for spraying applications" needs to be included in the labelling of the product (included in the general risk mitigation measures of the SPC (paragraph 5.2)).

Risk for non-professional users

Non-professional exposure is not relevant.

Risk for the general public

Exposure of the general public is not relevant.

Risk for consumers via residues in food

Dietary risk via iodine residues in milk has been assessed for both adults and children/toddlers.

To make the table easier to understand, the columns "systemic NOAEL mg/kg bw/d" and "AEL mg/kg bw/d" have been deleted and the respective values, i.e. the Upper Intake Levels (UL) for adults and children/toddlers, are provided in the footnote.

For details on the approach taken please see the supporting document *"Discussion paper: Iodine residues in milk due to iodine-based teat-disinfection: Assessment of consumer safety"* (29 June 2015) of the IRG PT3 sub-group. An amended version of this document, in which the worst-case scenario of Ecolab`s BPF (i.e. pre- and post-milking teat-disinfection *via* manual spraying at a maximum concentration of 0.36% total iodine has been highlighted, is attached to the IUCLID dossier.
In conclusion, no risk is identified for iodine teat disinfection products (0.36% available iodine) in the Tier-2 assessment considering a market penetration factor of 50% and 27% loss by pasteurization. However, the eCA considers these refinement options not acceptable.

During discussions in the human health working group meetings and WebEx meetings for eCAs evaluating iodine based union authorisation applications, the assumptions that could be considered for the exposure to residues via milk were discussed.
The following needs to be considered:

- Exposure in accordance to intended use (WGIII 2017). Therefore, for this application exposure due to either pre- or post-treatment per milking event for the BPF is assessed as products included in the BPF can only be used for pre- or post-application. This is also reflected in the instruction included in the general RMM section of the SPC for metaSPC3 paragraph 5.2 (as this is the only metaSPC that include uses for pre- and post-application): Products can either include post- or pre-application uses.
- Application by robots is considered to be performed three times a day, and manual milking two times per day. For exposure to residues looking at the applied volume of product, on a daily basis there is no difference between automated and manual exposure (10 ml x 3 = 30 ml for automatic robot application, 15 ml x 2 = 30 ml for manual application). This is in line with the conclusion of the Secure Webex meeting (3-10-2017), in which was concluded by eCAs evaluating iodine based union authorisation applications: "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". Therefore, for the exposure calculations information of the O'Brien study is used, which considers 2x manual application. 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 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. As the maximum concentration of the BPF product contains 0.33% available iodine, the values based on the O'Brien study are corrected. (WGIV 2017). Furthermore, as products can be used either for pre- or 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 evaluating 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 evaluating 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 toddlers 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 children/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 (Ecolab 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- or post-milking teat-disinfection– BPF level (based on 0.33% available iodine)

	Adults (0.45 L/day)	**Toddlers (0.46 L/day)**
	Estimated daily intake (µg/day) [% of UL]	**Estimated daily intake (µg/day) [% of UL]**
2x pre-milking application		
Intake from milk due to teat treatment	64 11	65 33
Total milk intake*	154 26	157 79
Total dietary intake**	339 56	253 127
2x post-milking application		
Intake from milk due to teat treatment	75 12	76 38
Total milk intake*	165 27	168 84
Total dietary intake**	350 58	264 132

* 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 toddler based on UK data (2008).

Conclusion: Pre- or post-milking teat-disinfection

For adults, the estimated daily intake of iodine resulting from biocidal product use is maximally 12% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 27% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 58% of the UL.

For toddlers, the estimated daily intake of iodine resulting from biocidal product use is maximally 38% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 84% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 132% of the UL.

As the worst case consumer exposure, taking into account the max. available iodine levels of the BPF, shows exceedance of the UL for toddlers when taken into account intake due to

the teat disinfection and dietary intake, we have evaluated the exposure at metaSPC level. Intakes which exceed the respective UL are highlighted in red in the table below. Calculations are included in annex 3.2 (Ecolab residues).

Comparison of estimated daily iodine intakes compared to upper limit of pre- or post-milking teat-disinfection– metaSPC level

	Adults (0.45 L/day)	**Toddlers (0.46 L/day)**
	Estimated daily intake (µg/day) [% of UL]	**Estimated daily intake (µg/day) [% of UL]**
2x pre-milking application metaSPC3 (0.27% available iodine)		
Intake from milk due to teat treatment	52 9	53 27
Total milk intake*	142 24	145 73
Total dietary intake**	327 55	241 121
2x post-milking application metaSPC1, 4 and 5 (0.11% available iodine)		
Intake from milk due to teat treatment	25 4	25 13
Total milk intake*	115 19	117 59
Total dietary intake**	300 50	213 107
2x post-milking application metaSPC2 (0.15% available iodine)		
Intake from milk due to teat treatment	34 6	35 17
Total milk intake*	124 21	127 63
Total dietary intake**	309 51	223 111
2x post-milking application metaSPC3 (0.27% available iodine)		
Intake from milk due to teat treatment	61 10	62 31
Total milk intake*	151 25	154 77
Total dietary intake**	336 56	250 125

* 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 toddler based on UK data (2008).

The same conclusion on metaSPC level is drawn as for BPF-level, the UL for toddlers is exceeded when taken into account intake due to the 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 over

estimates 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 teatdisinfection 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. We refer to the general conclusion for further discussion on this topic.

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

Not relevant, since neither additional active substances nor substances of concern are contained in the iodine-based biocidal products within the BPF.

2.3.6 Risk assessment for animal health

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

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

For all components of the product valid data are available through state-of-the art safety data sheets. Synergistic effects between the components are not expected. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal product itself is not necessary.

Further Ecotoxicological studies

No data is available for this endpoint.

Toxicity to aquatic organisms

Short-term toxicity testing on fish

The data on the active substance (as provided in the CAR) give sufficient information and there are no indications of risk due to specific properties of the biocidal product: as already stated under point 9.1, for all components of the products valid data are available allowing classification of the mixture and synergistic effects are not expected. Consequently, it is justified to assess the product on the basis of the active substance only; studies on the aquatic toxicity of the product or of certain components of it are therefore not required.

Short-term toxicity to aquatic invertebrates

The data on the active substance (as provided in the CAR) give sufficient information and there are no indications of risk due to specific properties of the biocidal product: as already stated under point 9.1, for all components of the products valid data are available allowing classification of the mixture and synergistic effects are not expected. Consequently, it is

justified to assess the product on the basis of the active substance only; studies on the aquatic toxicity of the product or of certain components of it are therefore not required.

Growth inhibition study on algae
The data on the active substance (as provided in the CAR) give sufficient information and there are no indications of risk due to specific properties of the biocidal product: as already stated under point 9.1, for all components of the products valid data are available allowing classification of the mixture and synergistic effects are not expected. Consequently, it is justified to assess the product on the basis of the active substance only; studies on the aquatic toxicity of the product or of certain components of it are therefore not required.

Bioconcentration
See section "Bioaccumulation in an appropriate aquatic species" below

Further toxicity studies on aquatic organisms
The data on the active substance (as provided in the CAR) give sufficient information and there are no indications of risk due to specific properties of the biocidal product: as already stated under point 9.1, for all components of the products valid data are available allowing classification of the mixture and synergistic effects are not expected. Consequently, it is justified to assess the product on the basis of the active substance only; studies on the long-term aquatic toxicity of the product or of certain components of it are therefore not required.

Long term toxicity testing on fish
The data on the active substance (as provided in the CAR) give sufficient information and there are no indications of risk due to specific properties of the biocidal product: as already stated under point 9.1, for all components of the products valid data are available allowing classification of the mixture and synergistic effects are not expected. Consequently, it is justified to assess the product on the basis of the active substance only; studies on the long-term aquatic toxicity of the product or of certain components of it are therefore not required.

Long term toxicity testing on invertebrates
The data on the active substance (as provided in the CAR) give sufficient information and there are no indications of risk due to specific properties of the biocidal product: as already stated under point 9.1, for all components of the products valid data are available allowing classification of the mixture and synergistic effects are not expected. Consequently, it is justified to assess the product on the basis of the active substance only; studies on the long-term aquatic toxicity of the product or of certain components of it are therefore not required.

Bioaccumulation in an appropriate aquatic species
The only component which needs to be considered concerning bioconcentration is the active substance since there are no substances of concern in the product. The other components of the product are not expected to affect the respective properties of the active substance. Consequently, no study on bioaccumulation with the product is required.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk
There are no specific non-target organisms which are believed to be at risk. Therefore no respective testing with the product is required.

Studies on sediment dwelling organisms
The data on the active substance (as provided in the CAR) give sufficient information and there are no indications of risk due to specific properties of the biocidal product: as already stated under point 9.1, for all components of the products valid data are available allowing classification of the mixture and synergistic effects are not expected. Consequently, it is justified to assess the product on the basis of the active substance only; studies on the effects on sediment dwelling organisms with the product or of certain components of it are therefore not required.

Effects on aquatic macrophytes
The data on the active substance (as provided in the CAR) give sufficient information and there are no indications of risk due to specific properties of the biocidal product: as already stated under point 9.1, for all components of the products valid data are available allowing classification of the mixture and synergistic effects are not expected. Consequently, it is justified to assess the product on the basis of the active substance only; studies on the effects on aquatic macrophytes with the product or with certain components of it are therefore not required.

Terrestrial toxicity, initial tests

Effects on soil microorganisms
The data on the active substance (as provided in the CAR) give sufficient information and there are no indications of risk due to specific properties of the biocidal product: as already stated under point 9.1, for all components of the products valid data are available allowing classification of the mixture and synergistic effects are not expected. Consequently, it is justified to assess the product on the basis of the active substance only; studies on the effects on soil micro- organisms with the product or with certain components of it are therefore not required.

Effects on earthworms or other soil-dwelling non-target invertebrates
The data on the active substance (as provided in the CAR) give sufficient information and there are no indications of risk due to specific properties of the biocidal product: as already stated under point 9.1, for all components of the products valid data are available allowing classification of the mixture and synergistic effects are not expected. Consequently, it is justified to assess the product on the basis of the active substance only; studies on the effects on earthworm or other soil-dwelling non-target organisms with the product or with certain components of it are therefore not required.

Acute toxicity to plants

The data on the active substance (as provided in the CAR) give sufficient information and there are no indications of risk due to specific properties of the biocidal product: as already stated under point 9.1, for all components of the products valid data are available allowing classification of the mixture and synergistic effects are not expected. Consequently, it is justified to assess the product on the basis of the active substance only; studies on the acute toxicity of the product or of certain components of it are therefore not required.

Terrestrial tests, long term

Reproduction study with earthworms or other soil-dwelling non-target invertebrates

The data on the active substance (as provided in the CAR) give sufficient information and there are no indications of risk due to specific properties of the biocidal product: as already stated under point 9.1, for all components of the products valid data are available allowing classification of the mixture and synergistic effects are not expected. Consequently, it is justified to assess the product on the basis of the active substance only; studies on reproduction of earthworms or of other soil-dwelling non-target invertebrates with the product or with certain components of it are therefore not required.

Effects on birds

Exposure to birds can be excluded. Consequently, no study on birds with the product or with components of it is necessary.
Furthermore, the argumentation as provided for all other 9.2 (further ecotoxicological studies) endpoint applies: The data on the active substance (as provided in the CAR) give sufficient information and there are no indications of risk due to specific properties of the biocidal product.

Effects on arthropods

The products are for indoor use in stables. Consequently, exposure to the environment is secondary (through liquid manure and via STP). In liquid manure, in the STP as well in the concerned environment compartments, Iodine speciates into the ionic forms iodide and/or iodate which have no biocidal activity. Furthermore, iodine is present in the environment at natural background levels which by far exceed any theoretical (additional) iodine levels caused by secondary exposure due to the biocidal use of the products.

Bioconcentration terrestrial

The bioconcentration of iodine is believed not to be influenced by the other components of the products. Therefore, no testing with the products is triggered.

Bioaccumulation terrestrial

The bioconcentration of iodine is believed not to be influenced by the other components of the products. Therefore, no testing with the products is triggered.

Effects on other non-target, non-aquatic organisms

Studies on other non-target, non-aquatic organisms with the components of the product or the product itself are only required if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product.
The data on the active substance as provided in the assessment report is sufficient to perform an environmental risk assessment and there are no indications of risk due to specific properties of the biocidal product.

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

No data is available for this endpoint.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk. Such tests may only be required if tests on other non-target organisms are needed on the basis of intended uses and results from these tests or a preliminary risk assessment indicates risk.
Since, on the basis of intended uses, no specific tests with non-target organism organisms (flora and fauna) are triggered and since there are no indications of risk for such organism, tests with other specific, non-target organisms are not needed.

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

No data is available for this endpoint.
Such tests are not required since the biocidal products are not in the form of bait or granules.

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

No data is available for this endpoint.

Such tests are not required since the biocidal products are not in the form of bait or granules.

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

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

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

The products are intended for use as teat-disinfectants for dairy cows and other milk producing animals. They are used in animal houses (in-door use) and are applied by dipping or spraying to the teats of the animals before and/or after milking. Exposure to the environment is always secondary, via liquid manure and STP. Exposure to air is not relevant due to the low vapour pressure of the active substance. The main route of exposure to the environment is via liquid manure to arable land and grassland. When applying the products to the animal teats by spraying, spray may not reach the animal teats or part of the product applied to the teats may be lost by drip formation. Drip formation may also occur when the products are applied by dipping. In both cases 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 or wet tissue. If disposable tissues are used, the product will end up in the waste bin; if reusable cloths are used (which is not recommended), the removed product will end up in the drain when the cloth are cleaned / washed after the milking.

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

The products are for indoor use (in animal houses) only. Any exposure to the environment is indirect via liquid manure and via STP, leading to a separation of the components before reaching the environment. Therefore, the other components of the products are not likely to influence the fate and behavior (and ecotoxicity) of the active substance. The performance of studies on fate and behaviour in the environment with the product are therefore not triggered.

Leaching behaviour (ADS)

The products are for indoor use (in animal houses) only. Any exposure to the environment is indirect via liquid manure and via STP, leading to a separation of the components before reaching the environment. Therefore, the other components of the products are not likely to influence the fate and behavior (and ecotoxicity) of the active substance. The performance of studies on fate and behaviour in the environment with the product are therefore not triggered.

Testing for distribution and dissipation in soil (ADS)

Since there are no indications that the other components in the products may influence distribution and degradation characteristics, additional studies are not requested. Iodine is contained in the products as PVP iodine. It is to be expected that upon dilution in the liquid

manure, sewage water or sewage sludge, the iodine is liberated resulting in the speciation into iodide (in water) or iodate (predominantly in soil). Consequently, no study on distribution and dissipation is needed with the products.

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

Since there are no indications that the other components in the products may influence distribution and degradation characteristics, additional studies are not requested. Iodine is contained in the products as PVP iodine. It is to be expected that upon dilution in the liquid manure, sewage water or sewage sludge, the iodine is liberated resulting in the speciation into iodide (in water) or iodate (predominantly in soil). Consequently, no study on distribution and dissipation is needed with the products.

Testing for distribution and dissipation in air (ADS)

Since there are no indications that the other components in the products may influence distribution and degradation characteristics, additional studies are not requested. Iodine is contained in the products as PVP iodine. It is to be expected that upon dilution in the liquid manure, sewage water or sewage sludge, the iodine is liberated resulting in the speciation into iodide (in water) or iodate (predominantly in soil). Consequently, no study on distribution and dissipation is needed with the products.

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

The products are not intended for spraying near to surface waters: spraying takes place indoor, i.e. in animal houses and direct exposure of surface waters can be excluded. Therefore, no overspray study is needed to assess risks to aquatic organisms or plant under field conditions.

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

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

B. EXPOSURE ASSESSMENT

The following exposure assessment was performed according to the emission scenario document (ESD) for PT3 (2011). It is the same ESD which was used in the CAR (2013). However, in the CAR only the application method post-dipping twice per day was considered. The iodine concentration was above 3600 ppm and the application rate 7.5 mL/cow/milking resulting in a total application rate per cow of 15 mL/day (= 2 disinfection events per day á 7.5 mL/cow).
The products of the following assessment can either be dipped or sprayed. The application rates are provided in the following table. Since the application rate for spraying is higher compared to the application rate for dipping, the spraying scenario represents the worst case. Risk assessment was only made for cows which is assumed worst-case considering the teats' surface and accompanied consumption per animal. Emission from buffaloes, goats, and sheep is therefore sufficiently covered.

General information

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 EUR 25116 EN - 2011
Approach	Average consumption The products can either be dipped (maximum product volume of 10 ml/cow/milking) or be sprayed (maximum product volume of 15 ml/cow/milking). Since spraying results in a higher application rate per day than dipping, spraying is assessed as worst case. Consequently, the dipping application is covered by the spraying scenario. In case of robotic milking product is only applied by spraying. However, there is no difference concerning environmental release between robotic spraying and manual spraying. Therefore, robotic milking is also covered by the spraying scenario.
Distribution in the environment	Residues are released to the manure/slurry. Soils are indirect exposed when manure/slurry is applied as a soil fertiliser. Subsequently, the active substance may be transported to groundwater due to leaching from the top soil layer or enters the aquatic compartment due to runoff or the drainage system. Emission to the sewage treatment plant and subsequently to surface water is relevant for those farms connected to the municipal sewer.
Groundwater simulation	No. The calculation of the concentration in groundwater was performed according to the approach described in the guidance Vol IV, part B where the concentration in porewater of agricultural soil is used as a first indication for groundwater concentrations. As Focus PEARL is designed for organic substances, emission to groundwater for the nine EU-scenarios was not performed. Note that the limit value for pesticides of 0.1 µg/L specified in the Drinking Water Directive is not applicable for iodine and its iodine species since the definition of pesticides in the Directive is limited to organic substances.
Confidential Annexes	No
Life cycle steps assessed	Production: • Production of active substance iodine: no, always outside the EU Formulation: yes Use: yes Service life: no, not relevant (no service life after application)
Remarks	Emission to air is not considered as it may be expected that iodine and their relevant species (iodide and iodate) are not volatile.

Emission estimation

Formulation of the product:

Environmental exposure: Should spillages occur, they are taken up with inert material (sand, earth, chemical absorbent, etc.) and are collected in dedicated drums properly labeled. They are disposed as chemical waste in accordance with local and national laws

and regulations. Consequently, there is no release into the environment and, thus, no environmental exposure assessment is applicable.

Disposal of the biocidal product:
The generation of waste should be avoided or minimized wherever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe way. Significant quantities of waste product residues should not be disposed of via the foul sewer but processed in a suitable effluent treatment plant. Dispose surplus and non-recyclable products via a licensed waste disposal contractor. Disposal of this product, solutions and by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional authority requirements. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

Disinfection of teats of dairy cows

Teat disinfections are applied by manual dipping, manual spraying or automated spraying. The latter applies when the cows are milked by a robot. The respective application rates for the products are provided in the following table.
As already mentioned in the table "General information" above, spraying can be considered as worst-case covering also dipping. When robotic milking is applied the teats are disinfected by automated equipment. The application volume is lower than for manual spraying. Individual cows maybe milked by a robot and consequently sprayed for teat disinfection up to 5 times per day, in exceptional cases even up to 6 times. However, the average milking frequency per day per herd is always below 3 milking events per day (according to independent research from Dansk Landbrugsradgivning, FarmTestCattle #61 2009). Consequently, automated milking does not need to be considered separately.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Teat disinfection of animals			
Application rate of biocidal product	15	ml/cow/milking	for the application method spraying
Concentration of active substance in the product	3.6	g/L	
Time of application	pre & post[a]	-	-
Number of applications per day	3	d^{-1}	-
Resulting product volume for spraying	90	ml/cow/day	-

[a] The environmental risk assessment refers to the original notification in which authorisation for disinfection before and after milking was requested. Pre milking applications has been removed from the SPC as requested by the applicant during the authorisation process, but PEC and PEC:PNECs values has not been adjusted accordingly as reduction from six to three daily applications has no effect on the final conclusions.

Please note that the following environmental risk assessment is based on an available iodine content of 0.36% as the corresponding meta SPC results in the highest emission to the environment as the products are applied pre- and post milking. However, the

maximum total iodine content in the products of the biocidal product family is 0.58% as products contains additional iodine sources. Therefore, the environmental risk assessment was in addition recalculated taking both the higher concentration of 0.58% and only pre- or post-application (as suggested by Ctgb) into account. The results of this calculation (PEC-values and PEC/PNEC-values) are provided in Annex 3.2.

Calculations for Scenario [*1*]

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$)**	**Remarks**
STP	0.0133 [kg/d]	Daily emission to the sewer system
Soil	0.8586 kg (after 1 manure application) 3.4344 kg (after 4 manure applications)	Amount of active ingredient in manure or slurry after one and four manure application to grassland. Calculations were based on the amount collected over 53 days (0.8586 kg) in accordance to the ESD.
	3.4344 kg	Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to arable land.

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 limits 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 CAR on 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.

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.
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). The corresponding concentrations in soil after one year and ten years taken leaching into account are presented below.

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, no additional calculations using e.g. SWASH were performed as the available models 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 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 or
- Release into slurry/manure

Therefore, both emission pathways are considered in the environmental risk assessment. The scenario via STP is named "Scenario 1a" and the scenario via slurry/manure "Scenario 1b", respectively. The receiving compartments for both exposure pathways 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
Scenario 1 (via STP)	yes	yes	yes	yes	yes	no	yes	yes	no
Scenario 1 (via slurry/ manure)	yes	yes	no	no	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], molweight for iodine (I_2)
Melting point	113.7	°C	Source: ECHA
Boiling point	184.5	°C	Source: ECHA
Vapour pressure (at 25°C)	1 x 10^{-6}	Pa	Source: ECHA Although iodine (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)	100	g/l	Source: ECHA Value for the environmental relevant iodine species iodate and iodide. Solubility of iodine is 0.3 g/L.
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 and K_p
Solids-water partition coefficient in soil (K_p)	5.8	L/kg	Source: ECHA
Solids-water partition coefficient in sediment ($K_{p, sed}$)	200	L/kg	Source: ECHA
Solids-water partition coefficient in suspended matter ($K_{p, susp}$)	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 cannot biodegrade. Depending on whether aerobic or anaerobic conditions prevail, iodine is present in the environment either as iodide or iodate (see CAR for 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
	Scenario 1	
Air	n.r.	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.

Calculated PEC values

Summary table on calculated PEC values for iodine and iodide[1]								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[µg/l]	[µg/l]	[mg/kg_{wwt}]	[µg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
via STP								
	5.32	0.530	2.58E-02	0.0530	2.58E-03	3.31E-02	6.31	--
via slurry/manure – concentrations after four manure applications on grassland and one on arable land. Leaching from the top soil layer between two applications is considered.								
grassland	--	1.65	8.01E-01	--	--	0.0865	16.5	--
arable land	--	0.45	2.20E-02	--	--	0.0238	4.55	--
via slurry/manure – concentrations after ten years. Leaching from the top soil layer between two applications is considered.								
grassland	--	4.96	0.241	--	--	0.265	49.8	--
arable land	--	3.02	0.147	--	--	0.160	30.3	--

[1] Assuming 100% transformation into iodide, i.e. under anaerobic and flooded conditions.

Summary table on calculated PEC values for iodate[1]								
	PEC_{STP}	PEC_{water}	PEC_{sed}	$PEC_{seawater}$	PEC_{seased}	PEC_{soil}	PEC_{GW1}	PEC_{air}
	[µg/l]	[µg/l]	[mg/kg_{wwt}]	[µg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
via STP								
	7.33	0.733	3.57E-02	0.0732	3.57E-03	4.57E-02	8.73	--
via slurry/manure – concentrations after four manure applications on grassland and one on arable land. Leaching from the top soil layer between two applications is considered.								
grassland	--	2.28	0.111	--	--	0.120	22.8	--
arable land	--	0.626	3.04E-02	--	--	0.033	6.28	--
via slurry/manure – concentrations after ten years. Leaching from the top soil layer between two applications is considered.								
grassland	--	6.85	0.333	--	--	0.366	68.8	--
arable land	--	4.18	0.203	--	--	0.220	41.9	--

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

Primary and secondary poisoning

Primary 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.

Secondary poisoning

As iodine is an essential element, internal concentrations are expected to be regulated within small boundaries. Therefore, accumulation and biomagnification in higher tropic levels cannot be expected.

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)

iodine: $PNEC(I_2)_{STP}$ = 2.9 mg iodine/L

Summary table on calculated PEC/PNEC values for iodine	
	$PEC/PNEC_{STP}$
	0.002

The individual PEC/PNEC ratio for the STP scenario for iodine is below 1. For iodide and iodate no PEC/PNEC-values were calculated, since no ecotoxicological reference-values are available. However, the iodide and iodate are less toxic than iodine in the aquatic compartment. The results of the risk characterisation show that there is no unacceptable risk for micro-organisms in the STP from the proposed use of the teat disinfectant products in case of release to the sewer. However, dairy farms are not necessarily connected to the municipal sewer and domestic waste water may be purified on-site by individual (private) 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

iodine: $PNEC(I_2)_{aquatic}$ = 0.59 µg iodine/L
iodate: $PNEC(IO_3^-)_{aquatic}$ = 58.5 µg iodine/L
iodide: $PNEC(I^-)_{aquatic}$ = 0.83 µg iodine/L

iodine: $PNEC(I_2)_{marine}$ = 0.059 µg iodine/L
iodate: $PNEC(IO_3^-)_{marine}$ = 5.85 µg iodine/L
iodide: $PNEC(I^-)_{marine}$ = 0.083 µg iodine/L

The PEC-values and also the PNEC-values for the sediment compartment is calculated with the equilibrium partitioning method based on the $PEC_{aquatic}$ and $PNEC_{aquatic}$, respectively. Consequently, the PEC/PNEC values for the sediment are identical to the PEC/PNEC-values for the aquatic compartment.

Summary table on calculated PEC/PNEC values for iodine				
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**	**PEC/PNEC$_{seawater}$**	**PEC/PNEC$_{seased}$**
via STP				
	0.899	0.899	0.899	0.899
via slurry/manure – PEC:PNEC ratios after four manure applications on grassland and one on arable land. Leaching from the top soil layer between two applications is considered.				
grassland	**2.79**	**2.79**	n.r.	n.r.
arable land	0.768	0.768	n.r.	n.r.
via slurry/manure – PEC:PNEC ratios after ten years. Leaching from the top soil layer between two applications is considered.				
grassland	**8.41**	**8.41**	n.r.	n.r.
arable land	**5.13**	**5.13**	n.r.	n.r.

Summary table on calculated PEC/PNEC values for iodide				
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**	**PEC/PNEC$_{seawater}$**	**PEC/PNEC$_{seased}$**
via STP				
	0.639	0.639	0.639	0.639
via slurry/manure – PEC:PNEC ratios after four manure applications on grassland and one on arable land. Leaching from the top soil layer between two applications is considered.				
grassland	**1.98**	**1.98**	n.r.	n.r.
arable land	0.546	0.546	n.r.	n.r.
via slurry/manure – PEC:PNEC ratios after ten years. Leaching from the top soil layer between two applications is considered.				
grassland	**5.98**	**5.98**	n.r.	n.r.
arable land	**3.64**	**3.64**	n.r.	n.r.

Summary table on calculated PEC/PNEC values for iodate				
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**	**PEC/PNEC$_{seawater}$**	**PEC/PNEC$_{seased}$**
via STP				
	0.013	0.013	0.013	0.013
via slurry/manure – PEC:PNEC ratios after four manure applications on grassland and one on arable land. Leaching from the top soil layer between two applications is considered.				
grassland	0.039	0.039	n.r.	n.r.

Summary table on calculated PEC/PNEC values for iodate				
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**	**PEC/PNEC$_{seawater}$**	**PEC/PNEC$_{seased}$**
arable land	0.011	0.011	n.r.	n.r.
via slurry/manure – PEC:PNEC ratios after ten years. Leaching from the top soil layer between two applications is considered.				
grassland	0.117	0.117	n.r.	n.r.
arable land	0.071	0.071	n.r.	n.r.

The individual PEC/PNEC ratios for iodine, iodide and iodate are below 1 for the aquatic compartment (surface water incl. sediment, marine water incl. sediment), if the exposure pathway via STP is taken into account. No unacceptable risks for the environment can 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 5.98 after ten years of successive manure applications, while iodate results in a PEC:PNEC ratio of 0.117. 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.

Consequently, the results of the risk characterisation show that there is no unacceptable risk for the relevant compartment from the proposed use teat disinfectant products.

Terrestrial compartment

iodine: $PNEC(I_2)_{soil\_EC50}$ = 0.0118 mg iodine/kg_{wwt} (= 0.0134 mg/kg_{dwt})
iodate: $PNEC(IO_3^-)_{soil\_EPM}$ = 0.304 mg iodine/kg
iodide: $PNEC(I^-)_{soil\_EPM}$ = 0.0043 mg iodine/kg

Calculated PEC/PNEC values for iodine		
	$PEC/PNEC_{soil}$	
Scenario 1a (via STP)		
Scenario 1	2.80	
Scenario 1b (via slurry/manure)		
	after one year	**after ten years**
grassland	**7.33**	**22.4**
arable land	**2.02**	**13.5**

Calculated PEC/PNEC values for iodide[1]		
	$PEC/PNEC_{soil}$	
Scenario 1a (via STP)		
Scenario 1	7.69	
Scenario 1b (via slurry/manure)		
	after one year	**after ten years**
grassland	**20.1**	**61.6**
arable land	**5.54**	**37.1**

[1] Assuming 100% transformation into iodide, i.e. under anaerobic and flooded conditions.

Calculated PEC/PNEC values for iodate[1]		
	$PEC/PNEC_{soil}$	
Scenario 1a (via STP)		
Scenario 1	0.150	
Scenario 1b (via slurry/manure)		
	after one year	**after ten years**
grassland	0.393	**1.20**
arable land	0.108	0.725

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

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 remains below the PNEC in case of iodate. However, because iodine and iodine species are not degradable, and losses by leaching and evaporation are negligible, the concentrations and accompanied risks will

increase when soils are fertilised for successive years. Consequently, the PECs for iodate exceed the PNEC as well. 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. As the ecological impact of long-term flooding is more disastrous as 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 iodine species occur naturally in the terrestrial environment for which natural background concentrations varies between 0.5 and 20 mg/kg (global mean value of 5 mg/kg). The expected PECs after ten years (0.265 mg iodine/kg wwt in grassland and 0.160 mg iodine/kg wwt in arable land) are in the lower range and therefore a significant increase of the background concentration cannot be expected. The same conclusion applies if the calculation is based on the total iodine content of 0.58%, i.e. the maximum PEC-soil value for iodine (0.213 mg/kg_{wwt}) is below the lower range of the background. However, one should realise that the anthropogenic immission in soils due to teat disinfection (81.3 g/ha/y) is about three times higher than the natural atmospheric deposition (25.6 g/ha/y[2]), but naturally occurring iodine may be less bioavailable due to strong sorption on organic material or complexation with e.g. metals. Because the PECs for the dominant iodine species are below one and the concentration at the lower end of the natural background concentration, unacceptable risks cannot be expected.

Groundwater

The concentration of iodine and iodide in the soil's pore water is expected to be 49.8 µg /L in grassland and 30.3 µg/L in arable land (iodine and iodide) after repeated manure applications for ten successive years. The predicted iodate concentrations are 68.8 µg/L in grassland and 41.9 µg/L in arable land. Because similar concentrations could be expected in groundwater as well and the concentrations are above 0.1 µg/L, a higher tier exposure assessment is deemed necessary. However, current available models (e.g. PEARL) are not suitable for inorganic substances such as iodine. Also note that the 0.1 µg/L limit is set for organic chemicals and therefore not feasible for iodine. Therefore, the predicted concentrations were compared natural background concentrations. The PECS are expected to be within, the natural background level of iodine in groundwater that ranges between 1 and 70 µg/. Therefore, emission to groundwater is considered acceptable and no risk mitigation measures are necessary.

Primary and secondary poisoning

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

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

Mixture toxicity

Screening step

Screening Step 1: Identification of the concerned environmental compartments

Teat disinfectants (scenario 1): Emission pathways
- via STP
- via slurry/manure

Screening Step 2: Identification of relevant substances

According to the "Transitional Guidance on mixture toxicity assessment for the environment (May 2014)" the following substances need to be considered as relevant for the mixture assessment:
1. active substance
2. substances of concern (SoC)
3. active substances form other PTs
4. other ingredients.

ECOLABs teat disinfectants: The products only contains one active substance and no substances of concern. In addition, no active substances from other PTs and no other ingredients that need consideration are contained.

Screening Step 3: Screen on synergistic interactions

Not applicable, since only one relevant substance contained in products.

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

Conclusion: no assessment of mixture toxicity needed according to the criteria defined in the above table.

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 for the current biocidal product family. 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.

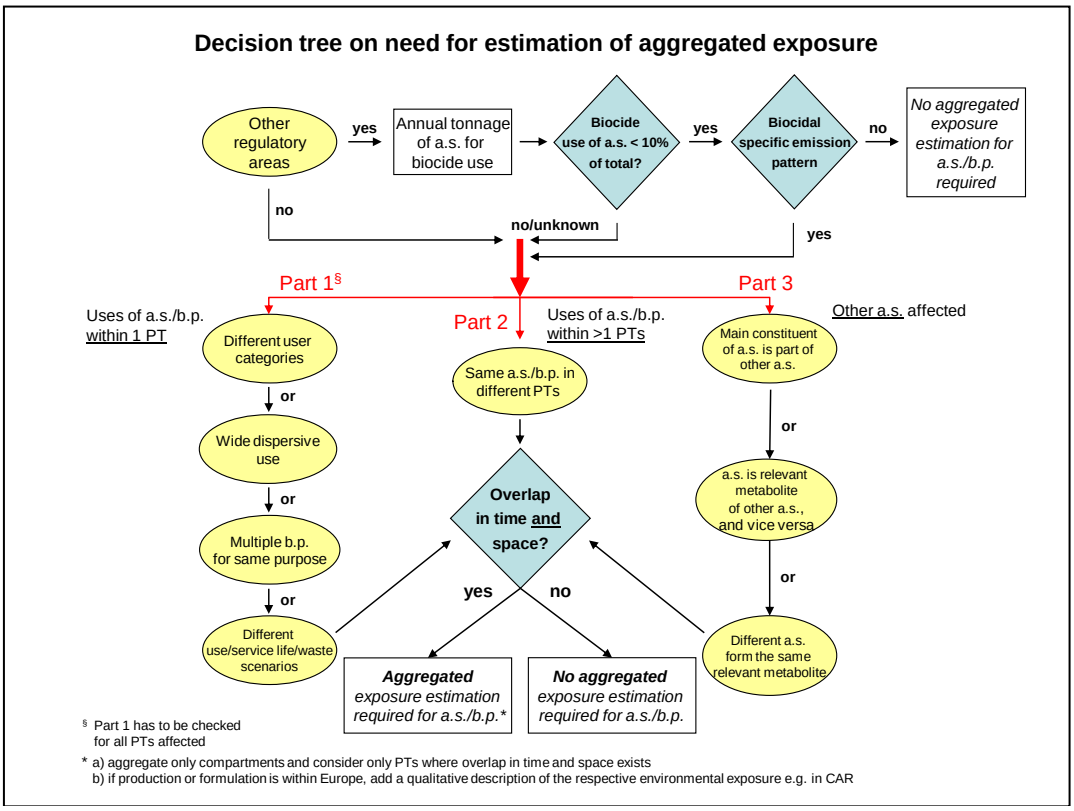


Figure 1: Decision tree on the need for estimation of aggregated exposure

2.3.8 Measures to protect man, animals and the environment

A. RECOMMENDED METHODS AND PRECAUTIONS

Precautions for safe handling and exposure controls:

Engineering measures : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Individual protection measures:
metaSPC3: Wear protective gloves for spraying application.

STORAGE:
Conditions for safe storage:

Keep out of reach of children. Keep container tightly closed. Store in suitable labeled containers.

When both pre- and post-milking disinfection is necessary, an iodine free product must be used for the first or second treatment.

DISPOSAL:
Product : To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage or to the municipal sewer.

Contaminated packaging : Dispose of in accordance with local, state, and federal regulations.
European Waste Catalogue : 200130 - detergents other than those mentioned in 20 01 29

TRANSPORT:
Land transport (ADR/ADN/RID): Not dangerous goods
Air transport (IATA): Not dangerous goods
Sea transport (IMDG/IMO): Not dangerous goods

Firefighting measures:

Suitable extinguishing media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media: None known.

Advice for firefighters:

Special protective equipment for firefighters: Use personal protective equipment.
Further information : Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

B. IDENTITY OF RELEVANT COMBUSTION PRODUCTS IN CASES OF FIRE

Special hazards arising from the substance or mixture:

Hazards from the substance or mixture: Not flammable or combustible.

Hazardous combustion products: Decomposition products may include the following materials:
Carbon oxides
nitrogen oxides (NOx)
Sulphur oxides
Oxides of phosphorus

C. SPECIFIC TREATMENT IN CASE OF AN ACCIDENT

First Aid Measures:

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of inhalation of decomposition products in a fire, symptoms may be delayed. Get medical attention if symptoms occur.
Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Environmental precautions: Do not discharge the product directly to the environment. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer.

D. POSSIBILITY OF DESTRUCTION OR DECONTAMINATION FOLLOWING RELEASE

Methods for cleaning up : Stop leak if safe to do so. Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations. Flush away traces with water. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway.

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

Product : Diluted product can be flushed to sanitary sewer.

Contaminated packaging : Dispose of in accordance with local, state, and federal regulations.
European Waste Catalogue : 200130 - detergents other than those mentioned in 20 01 29

F. PROCEDURES FOR CLEANING APPLICATION EQUIPMENT WHERE RELEVANT

No information available.

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

Not applicable.

2.3.9 Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products.

2.3.10 Comparative assessment

Not applicable.

3 ANNEXES

3.1 LIST OF STUDIES FOR THE BIOCIDAL PRODUCT FAMILY

List of new data submitted in support of the evaluation of the biocidal products

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
						Yes	No
Sections B3 – B5, sorted by author and study no.							
B3.4.1.2	12-09323/1 see 41003412	Bäumer, U.	2014	Test Report 12-09323/1 On the bactericidal efficacy 18 months storage sample...following EN1656; Henkel AG & Co. KGaA, Germany GLP: no Published: no	Ecolab Deutschland GmbH, Germany		N
B3.4.1.2	12-09323/2 see 41003412	Bäumer, U.	2012	Test Report 12-09323/2 On the bactericidal efficacy 18 months storage sample...following EN1656; Henkel AG & Co. KGaA, Germany GLP: no Published: no	Ecolab Deutschland GmbH, Germany		N
B3.4.1.2	12-09323/3	Bäumer, U.	2014	Test Report 12-09323/3 On the yeasticidal efficacy after 18 months storage sample...following EN1657; Henkel AG & Co. KGaA, Germany GLP: no Published: no	Ecolab Deutschland GmbH, Germany		N

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
						Yes	No
B3.4.1.2	13-04191 see 41003419	Bäumer, U.	2013	Test Report 13-04191 On the bactericidal efficacy 24 months storage stability test... following EN 1656; Henkel AG & Co. KGaA, Germany GLP: no Published: no	Ecolab Deutschland GmbH, Germany		N
B3.4.1.2	13-18611/1 see 41102992	Bäumer, U.	2014	Test Report 13-18611/1 On the bactericidal efficacy after 24 months storage at 25°C at Harlan laboratories... following EN 1656; Henkel AG & Co. KGaA, Germany GLP: no Published: no	Ecolab Deutschland GmbH, Germany		N
B3.4.1.2	13-18611/2 see 41102992	Bäumer, U.	2014	Test Report 13-18611/2 On the yeasticidal efficacy after 24 months storage at 25°C at Harlan laboratories... following EN 1657; Henkel AG & Co. KGaA, Germany GLP: no Published: no	Ecolab Deutschland GmbH, Germany		N
B3.4.1.2	150223	Dressen, S.; Mueller, E.	2015	Storage stability report; Ecolab Deutschland GmbH, Germany; GLP: not specified Published: no	Ecolab Deutschland GmbH, Germany		N
B3.4.1.2	14-12079/2 see 150223	Hammes, C.; Schoder, H.	2014	Report of analysis; Henkel AG & Co. KGaA, Germany GLP: no Published:	Ecolab Deutschland GmbH, Germany		N
B3.4.1.2	14-02317/2 see 150223,	Hammes, C.; Schoder, H.	2014	Report of analysis; Henkel AG & Co. KGaA, Germany GLP: no Published:	Ecolab Deutschland GmbH, Germany		N

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
						Yes	No
B3.4.1.2	15-02837/2	Hammes, C.; Schoder, H.	2015	Report of analysis; Henkel AG & Co. KGaA, Germany GLP: no Published: no	Ecolab Deutschland GmbH, Germany		N
B3.4.1.2		Killeen, S.; Meyer, B.	2013	Statement on Stability; Ecolab Deutschland GmbH, Germany GLP: no Published: no	Ecolab Deutschland GmbH, Germany		N
B3.4.1.2	see 41003412	Killeen, S.; Meyer, B.	2012	Evaluation of Months stability based on efficacy data; Ecolab Deutschland GmbH, Germany GLP: no Published: no	Ecolab Deutschland GmbH, Germany		N
B3.4.1.2		Schneider, M; Meyer, B.	2015	Statement on Stability; Ecolab Deutschland GmbH, Germany GLP: no Published: no	Ecolab Deutschland GmbH, Germany		N
B3.8 B3.9	Not indicated [redacted]	van den Broek, H.; Schneider, S.	2017	Test Report Chemical-Physical Properties (Viscosity, Surface Tension) Ecolab Deutschland GmbH, Germany GLP: not specified Published: no	Ecolab Deutschland GmbH, Germany		N
B3.8 B3.9	Not indicated [redacted]	van den Broek, H.; Schneider, S.	2017	Test Report Chemical-Physical Properties (Viscosity, Surface Tension) Ecolab Deutschland GmbH, Germany GLP: not specified Published: no	Ecolab Deutschland GmbH, Germany		N

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted Yes	No
B3.8 B3.9	Not indicated [redacted]	van den Broek, H.; Schneider, S.	2017	Test Report Chemical-Physical Properties (Viscosity, Surface Tension) Ecolab Deutschland GmbH, Germany GLP: not specified Published: no	Ecolab Deutschland GmbH, Germany		N
B3.8 B3.9	Not indicated [redacted]	van den Broek, H.; Schneider, S.	2017	Test Report Chemical-Physical Properties (Viscosity, Surface Tension) Ecolab Deutschland GmbH, Germany GLP: not specified Published: no	Ecolab Deutschland GmbH, Germany		N
B3.8 B3.9	Not indicated [redacted]	van den Broek, H.; Schneider, S.	2017	Test Report Chemical-Physical Properties (Viscosity, Surface Tension) Ecolab Deutschland GmbH, Germany GLP: not specified Published: no	Ecolab Deutschland GmbH, Germany		N
B3.8 B3.9	Not indicated [redacted]	van den Broek, H.; Schneider, S.	2017	Test Report Chemical-Physical Properties (Viscosity, Surface Tension) Ecolab Deutschland GmbH, Germany GLP: not specified Published: no	Ecolab Deutschland GmbH, Germany		N

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
						Yes	No
B3.1 B3.2 B3.4.1.1 B3.4.1.		Siebold, D.; Schneider, M.	2015	ACCELERATED STORAGE STABILITY according to CIPAC MT 46.3; Ecolab Deutschland GmbH, Germany GLP: yes Published: no	Ecolab Deutschland GmbH, Germany		N
B3.1 B3.2 B3.3 B3.4.1.2	41101572	Woolley, A. J.	2014	Determination of Long-Term Storage Stability and Physico-Chemical Characteristics; Harlan Laboratories Ltd, UK GLP: yes Published: no	Ecolab Deutschland GmbH, Germany		N
B3.1 B3.2 B3.3 B3.4.1.2	41102992	Woolley, A. J.	2014	Determination of Long-Term Storage Stability and Physico-Chemical Characteristics; Ecolab Deutschland GmbH, Germany GLP: yes Published: no	Ecolab Deutschland GmbH, Germany		N
B3.4.1.2	41303342	Woolley, A. J.	2016	Ioklar Multi, FC 905008: Determination of Long-Term Stability GLP Unpublished	Ecolab Deutschland GmbH, Germany		N
B.3.4.1.2	Not indicated	Siebold D, Schneider, M.	2017	Storage stability of Ioklar Super DIP D Not GLP Unpublished	Ecolab Deutschland GmbH, Germany		N

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
						Yes	No
B.4	CSL-17-1638.01	Smeykal, H	2017	Ioklar Multi, FC 905008 Determination of physico-chemical properties Corrosive Properties of Liquids (UN Test C.1) GLP Unpublished	Ecolab Deutschland GmbH, Germany		N
B5.1	41303340	Woolley, A. J.	2014	ANALYTICAL METHOD VALIDATION; Harlan Laboratories Ltd., UK GLP: yes Published: no	Ecolab Deutschland GmbH, Germany		N
B3.4.1.3	41303343	Woolley, A.J.	2014	Determination of Low Temperature Stability; Harlan Laboratories Ltd, UK GLP: yes Published: no	Ecolab Deutschland GmbH, Germany		N
B4.6	41303598	Woolley, A. J.	2014	Determination of Flash Point; Harlan Laboratories Ltd., UK GLP: yes Published: no	Ecolab Deutschland GmbH, Germany		N
B3.1 B3.2 B3.3 B3.4.1.1	41401265	Woolley, A. J.	2014	Determination of Accelerated Storage Stability; Harlan Laboratories Ltd, UK GLP: yes Published: no	Ecolab Deutschland GmbH, Germany		N
B3.4.1.3 B4.6	41003414	Wooley, A. J., O'Connor, B. J.	2011	Determination of low temperature stability and flashpoint; Harlan Laboratories Ltd., UK GLP: yes Published: no	Ecolab Deutschland GmbH, Germany		N

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
						Yes	No
B3.4.1.3 B4.6	41003418	Woolley, A. J.; O'Connor, B. J.	2011	Determination of low temperature stability and flash point; Harlan Laboratories Ltd, UK GLP: yes Published: no	Ecolab Deutschland GmbH, Germany		N
B3.4.1.1	41003420	Woolley, A.J.; O'Connor, B.	2011	DETERMINATION OF ACCELERATED STORAGE STABILITY AND PHYSICO-CHEMICAL CHARACTERISTICS; Harlan Laboratories Ltd, UK GLP: yes Published: no	Ecolab Deutschland GmbH, Germany		N
B3.4.1.3 B4.6	41003421	Woolley, A. J.; O'Connor, B. J.		DETERMINATION OF LOW TEMPERATURE STABILITY, FLASH POINT AND OXIDISING PROPERTIES; Harlan Laboratories Ltd, UK GLP: yes Published: no	Ecolab Deutschland GmbH, Germany		N
B5.1	41101571	Woolley, A. J.; O'Connor, B. J.	2012	ANALYTICAL METHOD VALIDATION; Harlan Laboratories Ltd., UK GLP: yes Published: no	Ecolab Deutschland GmbH, Germany		N
B3.1 B3.2 B3.3 B3.4.1.2 B5.1	41003412	Woolley, A. J.; White, D. F.	2013	Determination of long-term storage stability and physico-chemical characteristics; Harlan Laboratories Ltd, UK GLP: yes Published: no	Ecolab Deutschland GmbH, Germany		N

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
						Yes	No
B3.4.1.1	41003413	Woolley, A. J., White, D. F.	2011	Determination of accelerated storage stability and physico-chemical characteristics; Harlan Laboratories Ltd, UK GLP: yes Published: no	Ecolab Deutschland GmbH, Germany		N
B3.1 B3.2 B3.3 B3.4.1.1 B5.1	41003417	Woolley, A. J.; White, D. F.	2011	Determination of accelerated storage stability and physico-chemical characteristics; Harlan Laboratories Ltd., UK GLP: yes Published: no	Ecolab Deutschland GmbH, Germany		N
B3.2 B3.3 B3.4.1.2	41003419	Woolley, A. J.; White, D. F.	2013	DETERMINATION OF LONG-TERM STORAGE STABILITY AND PHYSICO-CHEMICAL CHARACTERISTICS; Harlan Laboratories Ltd, UK GLP: yes Published: no	Ecolab Deutschland GmbH, Germany		N
B3.4.1.3	41101573	Wooley, A. J.; White, D. F.	2011	DETERMINATION OF LOW TEMPERATURE STABILITY; Harlan Laboratories Ltd., UK GLP: yes Published: no	Ecolab Deutschland GmbH, Germany		N

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted Yes	No
Section B6, sorted by author and study no.							
B6.7	12-06284/2	Baeumer, U.	2012	Test Report 12-06284/2 on the bactericidal efficacy following EN 1656; Henkel AG & Co. KGaA, Germany GLP: no Published: no	Ecolab Deutschland GmbH		N
B6.7	14-06888-1	Baeumer, U.	2014	Test Report 14-06888-1 on the yeasticidal efficacy following EN 1657; Henkel AG & Co. KGaA, Germany GLP: no Published: no	Ecolab Deutschland GmbH		N
B6.7	14-06888-3	Baeumer, U.	2014	Test Report 14-06888-3 on the bactericidal efficacy following EN 1656; Henkel AG & Co. KGaA, Germany GLP: no Published: no	Ecolab Deutschland GmbH		N
B6.7	14-16050	Baeumer, U.	2014	Test Report 14-16050 on the yeasticidal efficacy following EN 1657; Henkel AG & Co. KGaA, Germany GLP: no Published: no	Ecolab Deutschland GmbH		N

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted Yes	Confidentiality request submitted No
B6.7	14-16050	Baeumer, U.	2014	Test Report 14-16050 on the bactericidal efficacy following EN 1656; Henkel AG & Co. KGaA, Germany GLP: no Published: no	Ecolab Deutschland GmbH		N
B6.7	14-18725	Baeumer, U.	2014	Test Report 14-18725 on the yeasticidal efficacy following EN 1657; Henkel AG & Co. KGaA, Germany GLP: no Published: no	Ecolab Deutschland GmbH		N
B6.7	15-04340	Baeumer, U.	2015	Test Report 15-04340 on the yeasticidal efficacy following EN 1657; Henkel AG & Co. KGaA, Germany GLP: no Published: no	Ecolab Deutschland GmbH		N
B6.7	15-04340	Baeumer, U.	2015	Test Report 15-04340 on the bactericidal efficacy following EN 1656; Henkel AG & Co. KgaA, Germany GLP: no Published: no	Ecolab Deutschland GmbH		N
B6.7	15-06390-4	Baeumer, U.	2015	Test Report 15-06390-1 on the bactericidal activity according EN 1500; Henkel AG & Co. KGaA, Germany GLP: no Published: no	Ecolab Deutschland GmbH		N

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
						Yes	No
B6.7	15-06390-5	Baeumer, U.	2015	Test Report 15-06390-2 on the bactericidal activity according EN 1500; Henkel AG & Co. KGaA, Germany GLP: no Published: no	Ecolab Deutschland GmbH		N
B6.7	15-06390-6	Baeumer, U.	2015	Test Report 15-06390-3 on the bactericidal activity according EN 1500; Henkel AG & Co. KGaA, Germany GLP: no Published: no	Ecolab Deutschland GmbH		N
B6.7	15-09942-4	Baeumer, U.	2015	Test Report 15-09942-1 on the bactericidal activity according EN 1500, tested under clean conditions according to EN; Henkel AG & Co. KGaA, Germany GLP: no Published: no	Ecolab Deutschland GmbH		N
B6.7	15-09942-5	Baeumer, U.	2015	Test Report 15-09942-2 on the bactericidal activity according EN 1500, tested under dirty conditions according to EN; Henkel AG & Co. KGaA, Germany GLP: no Published: no	Ecolab Deutschland GmbH		N
B6.7	15-09942-6	Baeumer, U.	2015	Test Report 15-09942-3 on the bactericidal activity according EN 1500, tested under dirty conditions according to EN 1656; Henkel AG & Co. KGaA, Germany GLP: no Published: no	Ecolab Deutschland GmbH		N

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted Yes	Confidentiality request submitted No
B6.7	15-09948-5	Baeumer, U.	2015	Test Report 15-09948-1 on the bactericidal activity according EN 1500; Henkel AG & Co. KGaA, Germany GLP: no Published: no	Ecolab Deutschland GmbH		N
B6.7	15-09948-6	Baeumer, U.	2015	Test Report 15-09948-2 on the bactericidal activity according EN 1500; Henkel AG & Co. KGaA, Germany GLP: no Published: no	Ecolab Deutschland GmbH		N
B6.7	15-09948-7	Baeumer, U.	2015	Test Report 15-09948-3 on the bactericidal activity according EN 1500, Henkel AG & Co. KGaA, Germany GLP: no Published: no	Ecolab Deutschland GmbH		N
B6.7	15-09948-8	Baeumer, U.	2015	Test Report 15-09948-4 on the bactericidal activity according EN 1500; Henkel AG & Co. KGaA, Germany GLP: no Published: no	Ecolab Deutschland GmbH		N
B6.7	15-04343-1	Kyas A.; Bäumer U.	2015	Virucidal activity tested against Vacciniavirus, Elstree strain; Henkel AG & Co. KGaA, Germany GLP: no Published: no	ECOLAB Germany GmbH, Germany		N

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted Yes	Confidentiality request submitted No
B6.7	15-04343-2	Kyas A.; Bäumer U.	2015	Virucidal activity of tested against Vacciniavirus, Elstree strain; Henkel AG & Co. KGaA, Germany GLP: no Published: no	ECOLAB Germany GmbH, Germany		N
B6.7	15-06068-1	Kyas A.; Bäumer U.	2015	Virucidal activity tested against Vacciniavirus, Elstree strain, Henkel AG & Co. KGaA, Germany GLP: no Published: no	ECOLAB Germany GmbH, Germany		N
B6.7	15-06068-2	Kyas A.; Bäumer U.	2015	Virucidal activity tested against Vacciniavirus, Elstree strain; Henkel AG & Co. KGaA, Germany GLP: no Published: no	ECOLAB Germany GmbH, Germany		N
B6.7	15-06068-3	Kyas A.; Bäumer U.	2015	Virucidal activity tested against Vacciniavirus, Elstree strain; Henkel AG & Co. KGaA, Germany GLP: no Published: no	ECOLAB Germany GmbH, Germany		N
B6.7	132/2013	Matuskova, Z.; Slitrova, J.	2013	Determination of bactericidal (EN 1656) and yeasticidal (EN1657) activity of the product; Chemila, Chemical and Microbiological Laboratory, Hodonin, Czech Republic GLP: no Published: no	Ecolab Deutschland GmbH		N

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted Yes	No
B6.7	D132/2013	Matuskova, Z.; Slitrova, J.	2013	Determination of bactericidal (EN 1656) and yeasticidal (EN1657) activity of the product, Chemila, Chemical and Microbiological Laboratory, Hodonin, Czech Republic GLP: no Published: no	Ecolab Deutschland GmbH		N
B6.7	D133/2013	Matuskova, Z.; Slitrova, J.	2013	Determination of yeasticidal (EN1657) activity of the product; Chemila, Chemical and Microbiological Laboratory, Hodonin, Czech Republic GLP: no Published: no	Ecolab Deutschland GmbH		N
B6.7	D134/2013	Matuskova, Z.; Slitrova, J.	2013	Determination of bactericidal (EN 1656) and yeasticidal (EN1657) activity of the product; Chemila, Chemical and Microbiological Laboratory, Hodonin, Czech Republic GLP: no Published: no	Ecolab Deutschland GmbH		N
B6.7	D135/2013	Matuskova, Z.; Slitrova, J.	2013	Determination of bactericidal (EN 1656) and yeasticidal (EN1657) activity of the product; Chemila, Chemical and Microbiological Laboratory, Hodonin, Czech Republic GLP: no Published:	Ecolab Deutschland GmbH		N

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted Yes	No
B6.7	D136/2013	Matuskova, Z.; Slitrova, J.	2013	Determination of bactericidal (EN 1656) and yeasticidal (EN1657) activity; Chemila, Chemical and Microbiological Laboratory, Hodonin, Czech Republic GLP: no Published: no	Ecolab Deutschland GmbH		N
B6.7	D47/2015	Matuskova, Z.; Slitrova, J.	2015	Determination of bactericidal (EN 1656:2009/AC) activity, Chemila, Chemical and Microbiological Laboratory, Hodonin, Czech Republic GLP: no Published: no	Ecolab Deutschland GmbH		N

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted Yes	No
Section B8, sorted by author and study no.							
B8.1	06/341-005N	[redacted]	2007	Acute Eye Irritation Study [redacted] GLP: yes Published: no	ECOLAB Deutschland GmbH, Germany		N
B8.1	06/341-006N	[redacted]	2007	Acute Skin Irritation Study [redacted] GLP: yes Published: no	ECOLAB Deutschland GmbH, Germany		N
B8.1	06/341-104T	[redacted]	2007	Skin Sensitisation Test (Guinea Pig Maximisation Test [redacted] GLP: yes Published: no	ECOLAB Deutschland GmbH, Germany		N

Other literature referred to:

Research report from Dansk Landbrugsradgivning, FarmTestCattle #61 2009.

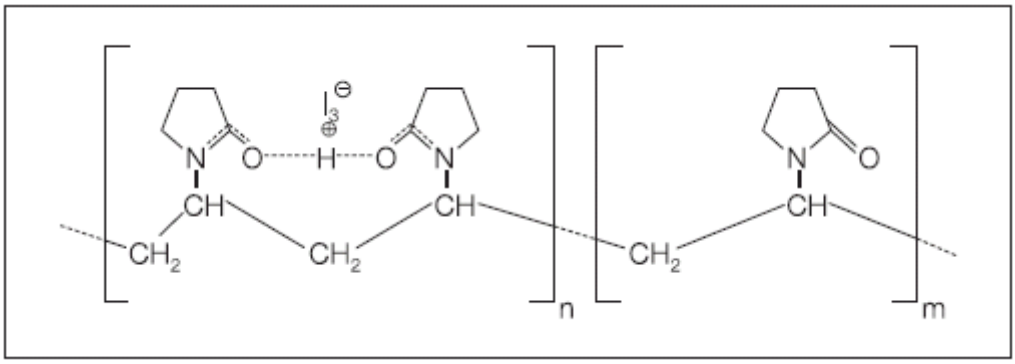
3.2 OUTPUT TABLES FROM EXPOSURE ASSESSMENT TOOLS

Human Health Risk Assessment

INHALATION EXPOSURE

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].

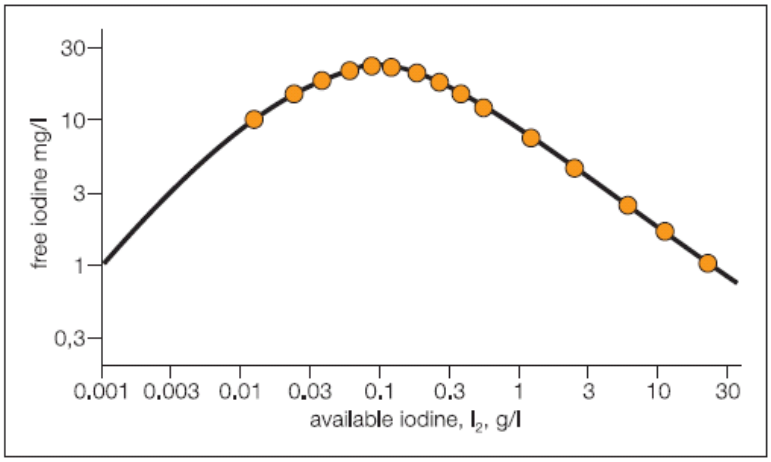


As can be seen from the figure, iodine is complex-bound to the carrier in the form of I_3^-, which is an ionic species resulting from the reaction of molecular iodine (I_2) and iodide (I^-). Of note, it is not bound as molecular iodine I_2, reason why solid PVP-iodine does not smell of iodine and also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



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.

[redacted]

[redacted]

Appendix 3.2-I
Scenario [1.1]: Mixing and loading of RTU for dip cup or trigger sprayer

Mixing and loading of RTU for dip cup or trigger sprayer - 1x/day (pre- or post-milking)

Dermal exposure: Mixing/Loading model 4 (TNsG, 2002); model covers all relevant M/L tasks performed on a 8-h working day
Inhalation exposure: not relevant

		Tier 1	Tier 2 gloves
Product	**Units**		
Density	g/mL	1	1
Active substance	% w/w	0,58	0,58
Body weight	kg	60	60
Dermal penetration rate	%	12	12
Dermal exposure			
Indicative value (hands)	mL/treatment	0,20	0,20
Duration	min		
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	1,160	0,116
Penetration through skin [a.s.]	mg	0,139	0,014
Number of applications/day	counts	1	1
Systemic exposure via dermal route	**mg/kg bw/day**	**2,32E-03**	**2,32E-04**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**23,20**	**2,32**
Exposure by inhalation: not relevant			
Indicative value: not provided in the model	mg/m³		
Duration	min		
Inhalation rate	m³/min	0,021	0,021
Inhaled volume	m³	0	0
Inhaled product	mg	0,000	0,000
Inhalted a.s.	mg	0,00000	0,00000
Inhalted a.s.	mg/m³		
Number of applications	counts	1	1
Systemic exposure via inhalation route	**mg/kg bw/day**	**0,00E+00**	**0,00E+00**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level		**0,000**	**0,000**
Total systemic exposure	**mg/kg bw/day**	**2,32E-03**	**2,32E-04**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**23,20**	**2,32**

Appendix 3.2-II.

Scenario [1.2]: Mixing and loading of electronic sprayer or robotic milking device

Mixing and loading of electronic sprayer or robotic milking device - 1x/day (pre- or post-milking)

Dermal exposure: RISKOFDERM Toolkit, Connecting lines
Inhalation Exposure: not relevant, no exposure calculation required

		Tier 1	Tier 2 gloves
Product	**Units**		
Density	g/ml	1	1
Active substance	% w/w	0,58	0,58
Body weight	kg	60	60
Dermal penetration rate	%	12	12
Dermal exposure			
Indicative value (hands)	mg/min	0,92	0,92
Duration	min	1	1
Potential hand deposit	mg	0,92	0,92
Penetration through gloves	%	100	10
Actual dermal deposit	mg	0,9	0,1
Total dermal exposure			
Total dermal deposit [a.s.]	mg	5,34E-03	5,34E-04
Penetration through skin *[a.s.]*	mg	6,40E-04	6,40E-05
Number of applications	counts	1	1
Systemic exposure via dermal route	**mg/kg bw/day**	**1,07E-05**	**1,07E-06**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**0,11**	**0,01**
Exposure by inhalation: not relevant			
Indicative value: not provided in model	mg/m³		
Duration	min	1	1
Inhalation rate	m³/min	0,021	0,021
Inhaled volume	m³	0,021	0,021
Inhaled product	mg	0,000	0,000
Inhalted a.s.	mg	0,000	0,000
Inhalted a.s.	mg/m³	0,000	0,000
Number of applications	counts	1	1
Systemic exposure via inhalation route	**mg/kg bw/day**	**0,00E+00**	**0,00E+00**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level		**0,000**	**0,000**
Total systemic exposure	**mg/kg bw/day**	**1,07E-05**	**1,07E-06**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**0,11**	**0,01**

Appendix 3.2-III.

Scenario [2.2]: Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer

Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer - 2x/day (pre- or post-milking) Consumer spraying and dusting model 2, 2. Hand-held trigger spray Assumtions acc. to Biocides Human Health Exposure Methodology, 2015: 82 cows, 10 sec/cow			
		Tier 1	**Tier 2 gloves**
Product	**Units**		
Density	g/ml	1	1
Active substance	% w/w	0,58	0,58
Body weight	kg	60	60
Dermal penetration rate	%	12	12
Dermal exposure			
Indicative value (hand/forearms)	mg/min	36,1	36,1
Duration	sec/cow	10	10
Number of cows	counts	82	82
Total duration	min	13,7	13,7
Potential dermal deposit [product]	mg	493	493
Penetration through gloves	%	100	10
Actual dermal deposit [product]	mg	493	49,3
Indicative value (legs, feet, face)	mg/min	9,7	9,7
Duration	sec/cow	10	10
Number of cows	counts	82	82
Total duration	min	13,7	13,7
Potential dermal deposit [product]	mg	132,57	132,57
Clothing penetration	%	100	100
Actual dermal deposit [product]	mg	132,57	132,57
Total dermal exposure			
Total dermal deposit [a.s.]	mg	3,630	1,055
Penetration through skin [a.s.]	mg	0,436	0,127
Number of applications	counts	2	2
Systemic exposure via dermal route	**mg/kg bw/day**	**1,45E-02**	**4,22E-03**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**145,22**	**42,20**
Exposure by inhalation [aerosol]			
Indicative value	mg/m³	10,5	10,5
Duration	sec/cow	10	10
Number of cows	counts	82	82
Total duration	min	13,7	13,7
Inhalation rate	m³/min	0,021	0,021
Inhaled volume	m³	0,287	0,287
Inhaled product	mg	3,014	3,014
Inhalted [a.s.]	mg	0,017	0,017
Inhalted [a.s.]	mg/m³	0,061	0,061
Number of applications	counts	2	2
Systemic exposure via inhalation route	**mg/kg bw/day**	**5,83E-04**	**5,83E-04**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level		**5,83**	**5,83**
Active substance, inhaled per m³	**mg/m³**	**6,09E-02**	**6,09E-02**
OEL	**mg/m³**	**1,0**	**1,0**
% OEL	**%**	**6,09**	**6,09**
Total systemic exposure	**mg/kg bw/day**	**1,51E-02**	**4,80E-03**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**151,04**	**48,03**

Appendix 3.2-IV.

Scenario [3.1]: Cleaning of teats 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 model, worst-case estimate: 0.1% of the amount on the surface area contacts the palm of the hands **Application of the layer thickness (44 cm^2/teat x 4 teats x 0.01 cm = 1.76 g)** **Assumption acc. to Biocides Human Health Exposure Methodology, 2015: 82 cows**			
		Tier 1	**Tier 2**
Product	**Units**		
Density	g/ml	1	1
Active substance	% w/w	0,58	0,58
Body weight	kg	60	60
Dermal penetration rate	%	12	12
Dermal exposure			
Product amount (film thickness approach: 0,44 g/teat)	mg/cow	1760	1760
Number of cows	counts	82	82
Product amount	mg	144320	144320
Product amount with contact to hand (0.1%)	mg	144,32	144,32
Penetration through gloves	%	100	10
Actual dermal deposit	mg	144	14,4
Total dermal exposure			
Total dermal deposit [a.s.]	mg	0,837	0,084
Penetration through skin [a.s.]	mg	0,100	0,010
Number of applications	counts	2	2
Systemic exposure via dermal route	**mg/kg bw/day**	**3,35E-03**	**3,35E-04**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**33,48**	**3,35**
Exposure by inhalation: not relevant			
Indicative value: not provided in model	mg/m^3		
Duration	min		
Inhalation rate	m^3/min	0,021	0,021
Inhaled volume	m^3	0,000	0,000
Inhaled product	mg	0,000	0,000
Inhalted a.s.	mg	0,000	0,000
Inhalted a.s.	mg/m^3		
Number of applications	counts	2	2
Systemic exposure via inhalation route	**mg/kg bw/day**	**0,00E+00**	**0,00E+00**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level		**0,000**	**0,000**
Total systemic exposure	**mg/kg bw/day**	**3,35E-03**	**3,35E-04**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**33,48**	**3,35**

Appendix 3.2-V.

Scenario [4.1]: Cleaning of equipment such as dip cups, trigger sprayer after use.

Cleaning of equipment such as dip cups, trigger sprayer after use - 2x/day (pre- or post-milking)

Dermal exposure: RISKOFDERM toolkit, Connecting lines (surrogate, since no approriate model is available)
Inhalation Exposure: not relevant, no exposure calculation required

		Tier 1	Tier 2
Product	**Units**		
Density	g/ml	1	1
Active substance	% w/w	0,58	0,58
Body weight	kg	60	60
Dermal penetration rate	%	12	12
Dermal exposure			
Indicative value (hands)	mg/min	0,92	0,92
Duration	min	5	5
Potential hand deposit [product]	mg	4,60	4,60
Penetration through gloves	%	100	10
Actual dermal deposit [product]	mg	4,6	0,5
Total dermal exposure			
Total dermal deposit [a.s.]	mg	2,67E-02	2,67E-03
Penetration through skin [a.s.]	mg	3,20E-03	3,20E-04
Number of applications	counts	2	2
Systemic exposure via dermal route	**mg/kg bw/day**	**1,07E-04**	**1,07E-05**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**1,07**	**0,11**
Exposure by inhalation: not relevant			
Indicative value: not provided in model	mg/m³		
Duration	min		
Inhalation rate	m³/min	0,021	0,021
Inhaled volume	m³	0	0
Inhaled product	mg	0,000	0,000
Inhalted a.s.	mg	0,000	0,000
Inhalted a.s.	mg/m³		
Number of applications	counts	1	1
Systemic exposure via inhalation route	**mg/kg bw/day**	**0,00E+00**	**0,00E+00**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level		**0,000**	**0,000**
Total systemic exposure	**mg/kg bw/day**	**1,07E-04**	**1,07E-05**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**1,07**	**0,11**

Combined exposure assessment professional uses including residues

Ecolab combined prof exposure including re

Consumer exposure: Dietary exposure to iodine residues

Ecolab residues.xlsx

Environmental risk assessment using the total iodine content of 0.58%

The following input parameters were used for the emission calculation:

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Teat disinfection of animals			
Application rate of biocidal product	15	ml/cow/milking	for the application method spraying
Concentration of active substance in the product	5.8	g/L	
Time of application	pre OR post	-	-
Number of milking events per day	3	d^{-1}	-
Resulting product volume for spraying	45	ml/cow/day	-

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$)**	**Remarks**
STP	0.011 [kg/d]	Daily emission to the sewer system
Soil	0.692 kg (after 1 manure application) 2.767 kg (after 4 manure applications)	Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to grassland. Since the manure for grassland is applied four times per year, the amount after 1 manure application (0.8586 kg) is multiplied with the factor of 4. The emission of 3.4344 kg was used for the environmental risk assessment on grassland.
	2.767 kg	Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to arable land.

Calculated PEC values

Summary table on calculated PEC values for iodine and iodide[1]								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[µg/l]	[µg/l]	[mg/kg_{wwt}]	[µg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
via STP								
	4.29	0.428	0.021	0.0428	0.0021	0.030	5.53	--
via slurry/manure – concentrations after four manure applications on grassland and one on arable land. Leaching from the top soil layer between two applications is considered.								
grassland	--	1.33	0.065	--	--	0.070	13.3	--
arable land	--	0.37	0.018	--	--	0.019	3.66	--
via slurry/manure – concentrations after ten years. Leaching from the top soil layer between two applications is considered.								
grassland	--	4.01	0.195	--	--	0.210	40.1	--
arable land	--	2.45	0.119	--	--	0.128	24.5	--

[1] Assuming 100% tranforamtion into iodide, i.e. under anaerobic and flooded conditions.

Summary table on calculated PEC values for iodate[1]								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW1}**	**PEC_{air}**
	[µg/l]	[µg/l]	[mg/kg_{wwt}]	[µg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
via STP								
	5.91	0.589	0.029	0.0589	0.0029	0.041	7.63	--
via slurry/manure – concentrations after four manure applications on grassland and one on arable land. Leaching from the top soil layer between two applications is considered.								
grassland	--	1.83	0.089	--	--	0.096	18.4	--
arable land	--	0.505	0.025	--	--	0.026	5.05	--
via slurry/manure – concentrations after ten years. Leaching from the top soil layer between two applications is considered.								
grassland	--	5.52	0.269	--	--	0.289	55.3	--

Summary table on calculated PEC values for iodate[1]								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW1}**	**PEC_{air}**
	[µg/l]	[µg/l]	[mg/kg_{wwt}]	[µg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
arable land	--	3.37	0.164	--	--	0.176	33.7	--

[1] Assuming 100% tranforamtion into iodate, i.e. under aerobic and non-flooded conditions.

C. RISK CHARACTERISATION

Sewage treatment plant (STP)

iodine: $PNEC(I_2)_{STP}$ = 2.9 mg iodine/L

Summary table on calculated PEC/PNEC values for iodine	
	$PEC/PNEC_{STP}$
	1.48E-03

Aquatic compartment

iodine: $PNEC(I_2)_{aquatic}$ = 0.59 µg iodine/L
iodate: $PNEC(IO_3^-)_{aquatic}$ = 58.5 µg iodine/L
iodide: $PNEC(I^-)_{aquatic}$ = 0.83 µg iodine/L

iodine: $PNEC(I_2)_{marine}$ = 0.059 µg iodine/L
iodate: $PNEC(IO_3^-)_{marine}$ = 5.85 µg iodine/L
iodide: $PNEC(I^-)_{marine}$ = 0.083 µg iodine/L

The PEC-values and also the PNEC-values for the sediment copartment is calculated with the equilibrium partitioning method based on the $PEC_{aquatic}$ and $PNEC_{aquatic}$, respectively. Consequently, the PEC/PNEC values for the sediment are identical to the PEC/PNEC-values for the aquatic compartment.

Summary table on calculated PEC/PNEC values for iodine				
	$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**	**$PEC/PNEC_{seawater}$**	**$PEC/PNEC_{seased}$**
via STP				
	0.725	0.725	0.0725	0.0725
via slurry/manure – PEC:PNEC ratios after four manure applications on grassland and one on arable land. Leaching from the top soil layer between two applications is considered.				
grassland	**2.26**	**2.26**	n.r.	n.r.
arable land	0.621	0.621	n.r.	n.r.
via slurry/manure – PEC:PNEC ratios after ten years. Leaching from the top soil layer between two applications is considered.				
grassland	**6.79**	**6.79**	n.r.	n.r.
arable land	**4.15**	**4.15**	n.r.	n.r.

Summary table on calculated PEC/PNEC values for iodide				
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**	**PEC/PNEC$_{seawater}$**	**PEC/PNEC$_{seased}$**
via STP				
	0.515	0.515	0.0515	0.0515
via slurry/manure – PEC:PNEC ratios after four manure applications on grassland and one on arable land. Leaching from the top soil layer between two applications is considered.				
grassland	**1.60**	**1.60**	n.r.	n.r.
arable land	0.441	0.441	n.r.	n.r.
via slurry/manure – PEC:PNEC ratios after ten years. Leaching from the top soil layer between two applications is considered.				
grassland	**4.83**	**4.83**	n.r.	n.r.
arable land	**2.95**	**2.95**	n.r.	n.r.

Summary table on calculated PEC/PNEC values for iodate				
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**	**PEC/PNEC$_{seawater}$**	**PEC/PNEC$_{seased}$**
via STP				
	0.010	0.010	0.001	0.001
via slurry/manure – PEC:PNEC ratios after four manure applications on grassland and one on arable land. Leaching from the top soil layer between two applications is considered.				
grassland	0.031	0.031	n.r.	n.r.
arable land	8.63E-03	8.63E-03	n.r.	n.r.
via slurry/manure – PEC:PNEC ratios after ten years. Leaching from the top soil layer between two applications is considered.				
grassland	0.094	0.094	n.r.	n.r.
arable land	0.058	0.058	n.r.	n.r.

Terrestrial compartment

iodine: $PNEC(I_2)_{soil\_EC50}$ = 0.0118 mg iodine/kg_{wwt} (= 0.0134 mg/kg_{dwt})
iodate: $PNEC(IO_3^-)_{soil\_EPM}$ = 0.304 mg iodine/kg
iodide: $PNEC(I^-)_{soil\_EPM}$ = 0.0043 mg iodine/kg

Calculated PEC/PNEC values for iodine		
	$PEC/PNEC_{soil}$	
Scenario 1a (via STP)		
Scenario 1	**2.51**	
Scenario 1b (via slurry/manure)		
	after one year	**after ten years**
grassland	**5.91**	**17.8**
arable land	**1.63**	**10.9**

Calculated PEC/PNEC values for iodide[1]		
	$PEC/PNEC_{soil}$	
Scenario 1a (via STP)		
Scenario 1	**6.88**	
Scenario 1b (via slurry/manure)		
	after one year	**after ten years**
grassland	**16.2**	**48.8**
arable land	**4.46**	**29.8**

1 Assuming 100% transformation into iodide, i.e. under anaerobic and flooded conditions.

Calculated PEC/PNEC values for iodate[1]		
	$PEC/PNEC_{soil}$	
Scenario 1a (via STP)		
Scenario 1	0.134	
Scenario 1b (via slurry/manure)		
	after one year	**after ten years**
grassland	0.316	0.951
arable land	0.087	0.581

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

3.3 NEW INFORMATION ON THE ACTIVE SUBSTANCE

Not relevant. No new information available.

3.4 RESIDUE BEHAVIOUR

Not applicable.

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

Efficacy studies are summarized in IUCLID section 6.7. and in 2.3.4.

3.6 CONFIDENTIAL ANNEX

Please refer to the separate document for the confidential annex