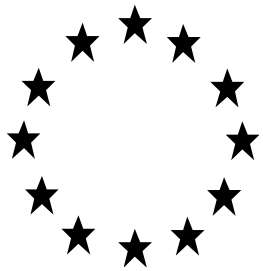
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT FOR UNION AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



HYPRED's iodine based products

Product type 3

Active substance: **Iodine**

Case Number in R4BP: **BC-LC018584-49**

Evaluating Competent Authority: **The Netherlands**

Date: 03/01/2018

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1 CONCLUSION

The outcome of the assessment for the biocidal product family 'HYPRED's iodine based products' 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

IDENTITY OF THE ACTIVE SUBSTANCE

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

FAMILY COMPOSITION AND FORMULATION
Qualitative and quantitative information on the composition of the family

The FAO tolerance limit of the active substance content at the point of manufacture is ±15% for products containing up to 25 g/kg active substance and ±10% for products containing above 25 up to 100g/kg active substance.

Family: *HYPRED's iodine based products*

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
Iodine	Iodine	Active substance	7553-56-2	231-442-4	0.25	2.50
Alcohols C12-14 ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), α-C12-14-(even numbered)-alkyl-ω-hydroxy-	Non-active substance	68439-50-9	-	2.697 (pure 2.428)	24.199 (pure 21.779)

meta SPC 1: Dipping products – Ready to use

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
Iodine	Iodine	Active substance	7553-56-2	231-442-4	0.25	0.49
Alcohols C12-14	Poly(oxy-1,2-	Non-active	68439-50-9	-	2.697	4.993

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
ethoxylated (11 mol EO average molar ratio)	ethanediyl), α-C12-14-(even numbered)-alkyl-ω-hydroxy-	substance			(pure 2.428)	(pure 4.494)

meta SPC 2: Dipping, spraying, foaming products – Ready to use

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine	Iodine	Active substance	7553-56-2	231-442-4	0.25	0.49
Alcohols C12-14 ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), α-C12-14-(even numbered)-alkyl-ω-hydroxy-	Non-active substance	68439-50-9	-	2.697 (pure 2.428)	4.690 (pure 4.221)

meta SPC 3: Dipping, spraying, foaming - Concentrated products

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine	Iodine	Active substance	7553-56-2	231-442-4	2.50	2.50
Alcohols C12-14 ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), α-C12-14-(even numbered)-alkyl-ω-hydroxy-	Non-active substance	68439-50-9	-	24.199 (pure 21.779)	24.199 (pure 21.779)

meta SPC 4: Dipping products reaching virucidal activity – Ready to use

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine	Iodine	Active substance	7553-56-2	231-442-4	0.50	0.50
Alcohols C12-14 ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), α-C12-14-(even numbered)-alkyl-ω-hydroxy-	Non-active substance	68439-50-9	-	4.993 (pure 4.494)	4.993 (pure 4.494)

meta SPC 5: Dipping, spraying, foaming products 5500 ppm – Ready to use

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine	Iodine	Active substance	7553-56-2	231-442-4	0.55	0.55
Alcohols C12-14	Poly(oxy-1,2-	Non-active	68439-50-	-	4.690	4.690

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
ethoxylated (11 mol EO average molar ratio)	ethanediyl), α-C12-14-(even numbered)-alkyl-ω-hydroxy-	substance	9		(pure 4.221)	(pure 4.221)

The full composition of HYPRED's iodine based products and identity of its ingredients are confidential. This information is provided separately in the confidential annex 3.6.

Information on the substance(s) of concern

Further information on the substance(s) of concern is provided in paragraph 2.3.5 and more specific information is included in the confidential annex 3.6.

INTENDED USE(S)

meta SPC 1: *Dipping products – Ready to use*

Table 1: Use # 1.1 – Manual or Automated Dipping After Milking

Product Type	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	- Bacteria - Yeasts - Algae
Field of use	Indoor Disinfection of teats of milk producing animals by dipping after milking
Application method(s)	Manual or automated disinfection of teats by dipping after milking. Dipping cup or Automated dipping machine
Application rate(s) and frequency	Application rate: - cows and buffaloes (3 to 10ml: 5 ml recommended) - sheep (1.5 to 5 ml: 1.5 ml recommended) - goats (2.5 to 6 ml: 2.5 ml recommended) Frequency: 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5 ,10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000 L
Potential for release into the environment (yes/no)	Release via STP, Manure/slurry
Potential for contamination of	Systematic cleaning and drying to avoid any contamination of milk

food/feedingstuff (yes/no)	

meta SPC 2 : *Dipping, spraying, foaming products – Ready to use*

Table 2 : Use # 2.1 – Manual or Automated Dipping, Foaming or Spraying Before Milking

Product Type	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	- Bacteria - Yeasts
Field of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying before milking
Application method(s)	Manual or automated disinfection of teats by dipping, foaming or spraying before milking. Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	Application rate: - cows and buffaloes (3 to 10ml: 5 to 8 ml recommended) - sheep (1.5 to 5 ml: 1.5 to 3 ml recommended) - goats (2.5 to 6 ml: 2.5 to 4 ml recommended) Frequency: 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000 L
Potential for release into the environment (yes/no)	Release via STP, Manure/slurry
Potential for contamination of food/feedingstuff (yes/no)	Systematic cleaning and drying to avoid any contamination of milk

Table 3 : Use # 2.2 – Manual or Automated Dipping, Foaming or Spraying after milking

Product Type	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	- Bacteria - Yeasts - Algae
Field of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying after milking
Application method(s)	Manual or automated disinfection of teats by dipping, foaming or spraying after milking. Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	Application rate: - cows and buffaloes (3 to 10ml: 5 to 8 ml recommended) - sheep (1.5 to 5 ml: 1.5 to 3 ml recommended) - goats (2.5 to 6 ml: 2.5 to 4 ml recommended) Frequency: 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000 L
Potential for release into the environment (yes/no)	Release via STP, Manure/slurry
Potential for contamination of food/feedingstuff (yes/no)	Systematic cleaning and drying to avoid any contamination of milk

meta SPC 3*: Dipping, spraying, foaming concentrated products*

Table 4 : Use # 3.1 – Manual or Automated Dipping, Foaming or Spraying Before Milking

Product Type	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	- Bacteria - Yeasts
Field of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying before milking.
Application method(s)	Manual or automated Disinfection of teats by dipping, foaming or spraying before milking. Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	A dilution at 10% (v/v) should be prepared. Application rate for the diluted product: - cows and buffaloes (3 to 10ml: 5 to 8 ml recommended) - sheep (1.5 to 5 ml: 1.5 to 3 ml recommended) - goats (2.5 to 6 ml: 2.5 to 4 ml recommended) Frequency: 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5,10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000 L
Potential for release into the environment (yes/no)	Release via STP, Manure/slurry
Potential for contamination of food/feedingstuff (yes/no)	Systematic cleaning and drying to avoid any contamination of milk

Table 5: Use # 3.2 – Manual or Automated Dipping, Foaming or Spraying After Milking

Product Type	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	- Bacteria - Yeasts - Algae - Viruses
Field of use	Indoor Disinfection of teats of milk producing animals by dipping after milking
Application method(s)	Manual disinfection of teats by dipping, foaming or spraying after milking. Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	For disinfection of bacteria, yeasts and algae a dilution at 10% (v/v) should be prepared. For disinfection of viruses a dilution at 20% (v/v) should be prepared Application rate: - cows and buffaloes (3 to 10ml: 5 to 8 ml recommended) - sheep (1.5 to 5 ml: 1.5 to 3 ml recommended) - goats (2.5 to 6 ml: 2.5 to 4 ml recommended) Frequency: 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000 L
Potential for release into the environment (yes/no)	Release via STP, Manure/slurry
Potential for contamination of food/feedingstuff (yes/no)	Systematic cleaning and drying to avoid any contamination of milk

meta SPC 4: *Dipping products reaching virucidal activity – Ready to use*

Table 6: Use # 4.1 – Manual or Automated Dipping After Milking

Product Type	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	- Bacteria - Yeasts - Algae - Viruses
Field of use	Indoor Disinfection of teats of milk producing animals by dipping after milking
Application method(s)	Manual or automated disinfection of teats by dipping after milking. Dipping cup or Automated dipping machine
Application rate(s) and frequency	Application rate: - cows and buffaloes (3 to 10ml: 5 ml recommended) - sheep (1.5 to 5 ml: 1.5 ml recommended) - goats (2.5 to 6 ml: 2.5 ml recommended) Frequency: 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5 ,10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000 L
Potential for release into the environment (yes/no)	Release via STP, Manure/slurry
Potential for contamination of food/feedingstuff (yes/no)	Systematic cleaning and drying to avoid any contamination of milk

meta SPC 5: *Dipping, spraying, foaming products 5500 ppm– Ready to use*

Table 7: Use # 5.1 – Manual or Automated Dipping, Foaming or Spraying Before Milking

Product Type	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	- Bacteria - Yeasts
Field of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying before milking
Application method(s)	Manual or automated disinfection of teats by dipping, foaming or spraying before milking. Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	Application rate: - cows and buffaloes (3 to 10ml: 5 to 8 ml recommended) - sheep (1.5 to 5 ml: 1.5 to 3 ml recommended) - goats (2.5 to 6 ml: 2.5 to 4 ml recommended) Frequency: 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000 L
Potential for release into the environment (yes/no)	Release via STP, Manure/slurry
Potential for contamination of food/feedingstuff (yes/no)	Systematic cleaning and drying to avoid any contamination of milk

Table 8: Use # 5.2 – Manual or Automated Dipping, Foaming or Spraying after milking

Product Type	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	- Bacteria - Yeasts - Algae - Viruses
Field of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying after milking
Application method(s)	Manual or automated disinfection of teats by dipping, foaming or spraying after milking. Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	Application rate: - cows and buffaloes (3 to 10ml: 5 to 8 ml recommended) - sheep (1.5 to 5 ml: 1.5 to 3 ml recommended) - goats (2.5 to 6 ml: 2.5 to 4 ml recommended) Frequency: 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000 L
Potential for release into the environment (yes/no)	Release via STP, Manure/slurry
Potential for contamination of food/feedingstuff (yes/no)	Systematic cleaning and drying to avoid any contamination of milk

HAZARD AND PRECAUTIONARY STATEMENTS

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

meta SPC 1: Dipping products – Ready to use

Classification	
Hazard category	Eye Irrit 2 Aquatic Chronic 3
Hazard statement	H319: Causes serious eye irritation. H412: Harmful to aquatic life with long lasting effects.
	
Labelling	
Signal words	Warning
Hazard statements	H319: Causes serious eye irritation. H412: Harmful to aquatic life with long lasting effects.
Precautionary statements	P102: Keep out of reach of children. P264: Wash hands thoroughly after handling. P280: Wear protective gloves/protective clothing/eye protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313: If eye irritation persists: Get medical advice/attention.
Note	

meta SPC 2: Dipping, spraying, foaming products – Ready to use

Classification	
Hazard category	Eye Irrit 2 Aquatic Chronic 3
Hazard statement	H319: Causes serious eye irritation. H412: Harmful to aquatic life with long lasting effects.
	
Labelling	
Signal words	Warning
Hazard statements	H319: Causes serious eye irritation. H412: Harmful to aquatic life with long lasting effects.
Precautionary statements	P102: Keep out of reach of children. P264: Wash hands thoroughly after handling. P280: Wear protective gloves/protective clothing/eye protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313: If eye irritation persists: Get medical advice/attention.
Note	

meta SPC 3 : Dipping, spraying, foaming - Concentrated products

Classification	
Hazard category	Corrosive to metals 1 Eye Dam. 1 STOT RE 2 Aquatic Chronic 2
Hazard statement	H290: May be corrosive to metals H318: Causes serious eye damage. H373: May cause damage to organs through prolonged or repeated exposure. H411 : Toxic to aquatic life with long lasting effects
	
Labelling	
Signal words	Danger
Hazard statements	H290: May be corrosive to metals H318: Causes serious eye damage. H373: May cause damage to organs through prolonged or repeated exposure. H411 : Toxic to aquatic life with long lasting effects
Precautionary statements	P102: Keep out of reach of children. P260: Do not breathe mist/vapours/spray. P264: Wash hands thoroughly after handling. P280: Wear protective gloves/protective clothing/eye protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER or doctor/physician. P314: Get medical advice/attention if you feel unwell. P501: Dispose of contents/container in accordance with local/regional/national/international regulations.
Note	

meta SPC 4 : Dipping products reaching virucidal activity – Ready to use

Classification	
Hazard category	Eye Irrit 2 Aquatic Chronic 3
Hazard statement	H319: Causes serious eye irritation. H412: Harmful to aquatic life with long lasting effects.
	
Labelling	
Signal words	Warning
Hazard statements	H319: Causes serious eye irritation. H412: Harmful to aquatic life with long lasting effects.
Precautionary statements	P102: Keep out of reach of children. P264: Wash hands thoroughly after handling. P280: Wear protective gloves/protective clothing/eye protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313: If eye irritation persists: Get medical advice/attention.
Note	

meta SPC 5 : Dipping, spraying, foaming products 5500 ppm – Ready to use

Classification	
Hazard category	Eye Irrit 2 Aquatic Chronic 3
Hazard statement	H319: Causes serious eye irritation. H412: Harmful to aquatic life with long lasting effects.
	
Labelling	
Signal words	Warning
Hazard statements	H319: Causes serious eye irritation. H412: Harmful to aquatic life with long lasting effects.
Precautionary statements	P102: Keep out of reach of children. P264: Wash hands thoroughly after handling. P280: Wear protective gloves/protective clothing/eye protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313: If eye irritation persists: Get medical advice/attention.
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)
Jerrycan	5 liters	HDPE	HDPE	Professional users	Yes
Jerrycan	10 liters	HDPE	HDPE	Professional users	Yes
Jerrycan	22 liters	HDPE	HDPE	Professional users	Yes
Drum	60 liters	HDPE	HDPE	Professional users	Yes
Drum	120 liters	HDPE	HDPE	Professional users	Yes
Drum	220 liters	HDPE	HDPE	Professional users	Yes
IBC	1000 liters	HDPE	HDPE	Professional users	Yes

2.1.2 Summary of the physical, chemical and technical properties

Property	Summary
Physical state, colour and odour at 20 °C and 101.3 kPa	Products included in HYPRED's iodine based product family are Brown liquid with characteristic or iodine odour
pH	Pure pH of each product in the family are the following : Liq-io 5500: 5 at 20.4°C Liq-io 2500: 5.04 at 21°C Dip-io 5000: 4.18 at 19.7 °C Dip-io 2500: 4.67 at 20.8 °C Liq-io concentrate: 4.06 at 20.2 °C
Relative density	Relative density of each individual product included in the family are the following : Liq-io 5500: 1.025 ± 0.001 at 20.5 °C Liq-io 2500: 1.020 ± 0.001 at 20.1 °C Dip-io 5000: 1.023 ± 0.001 at 20.8 °C Dip-io 2500: 1.006 ± 0.001 at 20.7 °C Liq-io concentrate: 1.108 ± 0.001 at 20.2 °C
Storage stability	Products included in HYPRED's iodine based product family are stable according to accelerated storage test (at 30°C +/-2°C for 18 weeks), long term storage test at ambient temperature and low temperature stability test
Persistent foaming	The level of foam generated of concentrate product in HYPRED's iodine based product family at in use concentration is too high to use CIPAC MT 47.2. As the product is intended to produce foam, the persistent foaming test was waived.

Dilution stability	Concentrate product in HYPRED's iodine based product family at the maximum in use concentration is stable.
Surface tension	The surface tension of the tested product lies between 32.0 and 38.4 mN/m at 20.0 °C HYPRED's iodine based products were considered as surface active.
Viscosity	Dynamic viscosity Liq-io 5500: 1.73 mPa.s ± 0.02 mPa.s at 20.0 °C ± 0.2 °C 1.12 mPa.s ± 0.02 mPa.s at 40.0 °C ± 0.2 °C. Liq-io 2500: 1.51 mPa.s ± 0.02 mPa.s at 20.0 °C ± 0.2 °C 1.16 mPa.s ± 0.02 mPa.s at 40.0 °C ± 0.2 °C Liq-io concentrate: 113 mPa.s at 20.0 °C ± 0.2 °C 50.9 mPa.s at 40.0 °C ± 0.2 °C. Dip-io 5000 and Dip-io 2500: The dynamic viscosity (η) of Dip-io 5000 and Dip-io 2500, measured at 20.0 ± 0.2 °C and 40.0 ± 0.2 °C, varies with the shear rate.

2.1.3 Summary of the Human Health Risk Assessment

Endpoint	**Brief description**
Skin corrosion and irritation	Products included in HYPRED's iodine based products family are not classified skin corrosive or skin irritant
Eye irritation	Ready to use products in HYPRED's iodine based products family are Eye Irritant Category 2 - H319: Causes serious eye irritation. Concentrate product in HYPRED's iodine based products family is Eye Damage Category 1 - H318: Causes serious eye damage
Skin sensitisation	Not relevant - HYPRED's iodine based product family doesn't contain a component classified as skin sensitizer.
Respiratory sensitization (ADS)	Not relevant - HYPRED's iodine based product family doesn't contain a component classified as respiratory sensitizer.
Acute toxicity by oral route	According to the Regulation 1272/2008/CE, the Acute Toxicity Estimate (ATE) oral calculated for products included in HYPRED's iodine based product family is greater than 2000 mg/kg.
Acute toxicity by dermal route	According to the Regulation 1272/2008/CE, the Acute Toxicity Estimate (ATE) dermal calculated for products included in HYPRED's iodine based product family is greater than 2000 mg/kg.
Acute toxicity by inhalation	According to the Regulation 1272/2008/CE, the Acute Toxicity Estimate (ATE) inhalation calculated for products included in HYPRED's iodine based product family is greater than 5 mg/l.
Dermal absorption	Read-across is made to two *in-vitro* human skin dermal absorption studies: one performed with an iodophor type 1-based product and one with a PVP-iodine-based product and evaluated in the context of the active substance dossier on iodine (incl. PVP-iodine). In both studies, a dermal absorption value of ca. 12% has been derived which, based on the read-across, has been used in

	the HHRA for the biocidal products pertaining to the HYPRED's BPF "HYPRED's iodine based products".
Available toxicological data relating to non active substance(s)	Not relevant. According to the note for discussion on substances of concern (SoC), CA-Nov14-Doc.5.11, products of HYPRED's BPF containing the SoC (see confidential Annex 3.6) at different concentrations end up in Band A or B. Associated evaluation and risk management requirements according to the SoC banding approach which, in the case of the more "severe" Band B, are limited to a *"Qualitative exposure and risk assessment to determine whether S-phrases/P-statements normally associated with concerned R-phrases/H statements are sufficient or whether other risk mitigation measures should be applied"* have been accounted for and addressed in the respective parts of this PAR.
Available toxicological data relating to a mixture	No toxicological data relating to a mixture that a substance(s) of concern is a component is provided.
Other relevant information • Food and feeding stuffs studies	No applications are intended where contact with feeding stuffs may arise. Application of the products pertaining to HYPRED's 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 included in IUCLID. An evaluation on residues is made 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	There is no indication that during industrial processing and/or domestic preparation toxicologically significant degradation products of iodine arise requiring a separate risk assessment.
Other relevant information • Other tests related to the exposure of humans	Other tests related to exposure of humans are not required. Assessment of potential iodine residues in milk is summarized in the supporting document of the IRG PT3 sub-group included in IUCLID. An evaluation on residues is made in the respective chapters of the PAR.

Reference values

Reference	Study	NOAEL (LOAEL)	AF	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				600 µg/day (0.01 mg/kg bw/d)
ARfD	According to CAR, not applicable. Substance is not acute toxic or harmful.				
ADI	Not derived in the CAR and not relevant for HHRA. Instead of an ADI, a Recommended daily intake of 150-200 µg/day is given in the CAR.				
AEC = OEL (Occupational exposure limit)	Human data				0.1 ppm / 1 mg/m3

Risk characterisation

Summary table: scenarios for pre- or post-milking disinfection by dipping, foaming or spraying			
Scenario number	**Scenario**	**Primary exposure Description of scenario**	**Exposed group**
1.1	Mixing and loading of concentrates for dip / foam cup or trigger sprayer or electronic sprayer, automated dipping/foaming-system or robotic milking device	The concentrated product is diluted 1:5 or 1:10 by decanting or by pumping. Preparation of dip / foam cups: The diluted product is filled into the reservoir of a dip / foam cup. By squeezing the reservoir, the disinfectant is pumped into the dip / foam cup above the reservoir which is then ready for dipping / foaming. Preparation of a trigger sprayer: The diluted product is filled into the reservoir of a sprayer. For loading of electronic sprayer, automated dipping/foaming-system or robotic milking device (for automated spraying) : A sucking lance of the electronic sprayer, automated dipping/foaming-system or robotic milking device is inserted in a can containing the diluted product.	professionals
1.2	Mixing and loading of RTUs for dip / foam cup or trigger sprayer	This scenario replaces scenario 1.1 if RTUs are used. Preparation of dip / foam cups: The product (RTU) is filled undiluted into the reservoir of a dip /foam cup. By squeezing the reservoir, the disinfectant is pumped into the dip / foam cup above the reservoir which is then ready for dipping. Preparation of a trigger sprayer: The product (RTU) is filled undiluted into the reservoir of a sprayer. Re-filling of a dip / foam cup or of a trigger sprayer is done analogously.	professionals
1.3	Mixing and loading for electronic sprayer, automated dipping/foaming-system or robotic milking device	This scenario is performed if electronic sprayer, automated dipping/foaming system or robotic milking device (for automated spraying) and RTU are used, and thus replaces scenario 1.2. A can containing the RTU product is opened and a sucking lance of the electronic sprayer, automated dipping/foaming system or robotic milking device is inserted. Empty cans are replaced by new ones.	professionals
2.1	Application of teat disinfectant by manual dipping / foam	Before or after milking, the dip / foam cup prepared as described in scenario 1.1 or 1.2 is put over each teat from below making sure that the full length of each teat is immersed into the disinfectant.	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 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 automated dipping/foaming-system or robot with automatic sprayer	This scenario replaces scenarios 2.1 and 2.2 in case of automated dipping/foaming/spraying-system or spraying by robot. Before or after milking, the disinfectant is sprayed automatically by robot onto teats from a cluster arm. In case of automated dipping/foaming system, the vacuum is shut off and the teat dip/foam is injected into a manifold on the claw piece. The teats are coated with dip/foam.	No exposure
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.	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/foam cups, trigger sprayer after use	After disinfection, the reservoir is emptied and the entire dip / foam or spray equipment is cleaned with water.	professionals
4.2	Rinsing of automated dipping/foaming-system	Every liner of the automated dipping/foaming-system is thoroughly rinsed with water and blown out with compressed air. Afterwards, the milking system is ready for the next milking event. The whole process is automated and, therefore, there is no human exposure.	No exposure
4.3	Rinsing of electronic sprayer	This scenario replaces scenarios 4.1 and 4.2 if an electronic sprayer 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

Conclusion of risk characterisation for industrial user

Not relevant

Conclusion of risk characterisation for professional user

Local effects
Products included in metaSPC1, 2, 4 and 5 are classified with H319: Causes serious eye irritation. Additionally, products included in metaSPC3 are classified with H318: Causes serious eye damage. Consequently, due to the eye damaging or eye irritating properties, goggles are to be used during handling of the products.

Local effects via inhalation will only take place during the spray application (task 2.2). The local exposure concentrations are provided in the following table for the worst-case concentrations of total iodine used during the individual tasks.

Task/ Scenario	Iodine in air inhaled (mg/m³)	% OEL (1 mg/m³)	Acceptable (yes/no)
[2.2] – Application of teat disinfectant by manual spraying – **0.7489% total iodine**	7.86E-02	7.9	yes
[2.2] – Application of teat disinfectant by manual spraying – **0.689% total iodine**	7.23E-02	7.2	yes
[2.2] – Application of teat disinfectant by manual spraying – **0.344% total iodine**	3.61E-02	3.6	yes

Systemic effects for the combined scenarios (all tasks) when performing pre-milking disinfection of 82 animals twice a day

- Concentrate: 3.44% total iodine; in-use concentration: 0.344% total iodine (metaSPC3)
- RTU: 0.7489% total iodine(metaSPC 2/5)
- 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/ Foaming - concentrate (meta SPC3) Scenarios [1.1; 2.1; 3.1; 4.1]	1/ none	2.78E-03	28	36	51	82
	2/ Gloves	2.78E-04	3	11	26	57

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/ Foaming - RTU (meta SPC2/5) Scenarios [1.2; 2.1; 3.1; 4.1]	1/ none	7.39E-03	74	92	107	138
	2/ Gloves	7.39E-04	7	25	40	71
Manual spraying using a trigger sprayer – concentrate (meta SPC3) Scenarios [1.1; 2.2; 3.1; 4.1]	1/ none	1.17E-02	117	125	140	171
	2/ Gloves and coverall	1.48E-03	15	23	38	69
Manual spraying using a trigger sprayer - RTU (meta SPC2/5) Scenarios [1.2; 2.2; 3.1; 4.1]	1/ none	2.69E-02	269	287	305	333
	2/ Gloves and coverall	3.37E-03	34	52	67	98
Manual spraying using an electronic sprayer - concentrate (meta SPC3) Scenarios [1.1; 2.2; 3.1; 4.3]	1/ none	1.17E-02	117	125	140	171
	2/ Gloves and coverall	1.48E-03	15	23	38	69

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 spraying using an electronic sprayer - RTU (meta SPC2/5) Scenarios [1.3; 2.2; 3.1; 4.3]	1/ none	2.38E-02	238	256	271	302
	2/ Gloves and coverall	3.06E-03	31	49	64	95
Automated spraying or automated dipping/foaming - concentrate (meta SPC3) Scenarios [1.1; 2.3; 4.2]	1/ none	7.62E-04	8	16	31	62
	2/ Gloves	7.62E-05	1	9	24	55
Automated spraying or automated dipping/foaming – RTU (meta SPC2/5) Scenarios [1.3; 2.3; 4.2]	1/ none	1.38E-05	0	18	33	64
	2/ Gloves	1.38E-06	0	18	33	64

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

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

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

Calculation sheet is included in annex 3.2.

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

Tier 1:
When using the concentrated product (3.44% total iodine; in-use conc.: 0.344%), **Exposure from biocidal use** without considering PPE (Tier 1) results in 28% of the UL for manual dipping/foaming, 117% of the UL for manual spraying using a trigger sprayer or an electronic sprayer, respectively, and 8% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 1) results in 36% for manual dipping/foaming, 125% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 16% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 1) results in 51% for manual dipping/foaming, 140% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 31% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 82% for manual dipping/foaming, 171% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 62% of the UL for automated spraying or automated dipping/foaming.

When using the RTU product (0.7489% total iodine - metaSPC2/5), **exposure from biocidal use** without considering PPE (Tier 1) results in 74% of the UL for manual dipping/foaming, 269% or 238% of the UL for manual spraying using a trigger sprayer or an electronic sprayer, respectively, and 0% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 1) results in 92% for manual dipping/foaming, 287% and 256% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 18% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 1) results in 107% for manual dipping, 302% and 271% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 33% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 138% for manual dipping/foaming, 333% and 302% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 64% of the UL for automated spraying or automated dipping/foaming.

Tier 2:
When using the concentrated product (3.44% total iodine; in-use conc.: 0.344%), **Exposure from biocidal use** considering PPE (Tier 2) results in 3% of the UL for manual dipping/foaming, 15% of the UL for manual spraying using a trigger sprayer or an electronic sprayer, respectively, and 1% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, considering PPE (Tier 2) results in 11% for manual dipping/foaming, 23% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 9% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption, considering PPE (Tier 2) results in 26% for manual dipping/foaming, 38% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 24% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, considering PPE (Tier 2) results in 57% for manual dipping/foaming, 69%

of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 55% of the UL for automated spraying or automated dipping/foaming.

When using the RTU product (0.7489% total iodine - metaSPC2/5), **exposure from biocidal use** without considering PPE (Tier 2) results in 7% of the UL for manual dipping/foaming, 34% and 31% of the UL for manual spraying using a trigger sprayer or an electronic sprayer, respectively, and 0% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 2) results in 25% for manual dipping, 52% and 49% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 18% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 2) results in 40% for manual dipping/foaming, 67% and 64% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 33% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 2) results in 71% for manual dipping/foaming, 98% and 95% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 64% of the UL for automated spraying or automated dipping/foaming.

Conclusions pre-milking application:

When using the concentrate:
For manual and automated dip/foam applications and for automated spraying, no PPE is needed for safe use.
For manual spraying application using a trigger sprayer or electronic sprayer, chemical resistant gloves (90% protection) and coverall (90% protection) are needed for safe use.

When using RTUs:
For automated dip/foam applications and for automated spraying, no PPE is needed for safe use.
For manual dip/foam applications, chemical resistant gloves (90% protection) are needed for safe use.
For manual spraying application using a trigger sprayer or electronic sprayer chemical resistant gloves (90% protection) and coverall (90% protection) are needed for safe use.

Furthermore, the OEL of 1 mg/m³ for iodine is not reached in any "pre-milking disinfection"-scenario. The maximum value was 7.9% of the OEL calculated for application of teat disinfection by spraying using a trigger sprayer or electronic sprayer.

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

- Concentrate: 3.44% total iodine; in-use concentration: 0.689% total iodine (metaSPC3)
- RTU: 0.9058% total iodine (metaSPC1/4); 0.7489 % total iodine (metaSPC2/5)
- 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/ foaming - concentrate (meta SPC3) Scenarios [1.1; 2.1; 3.2; 4.1]	1/ none	8.26E-04	8	27	42	73
	2/ Gloves	8.26E-05	1	20	35	66
Manual dipping/ foaming - RTU (meta SPC2/5) Scenarios [1.2; 2.1; 3.2; 4.1]	1/ none	3.06E-03	31	52	67	98
	2/ Gloves	3.06E-04	3	24	39	70
Manual dipping/ foaming - RTU (meta SPC1/4) Scenarios [1.2; 2.1; 3.2; 4.1]	1/ none	3.71E-03	37	56	71	102
	2/ Gloves	3.71E-04	4	23	38	69
Manual spraying using a trigger sprayer - concentrate (meta SPC3)	1/ none	1.88E-02	188	207	222	253
	2/ Gloves and coverall	2.50E-03	25	44	59	90

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; 2.2; 3.2; 4.1]						
Manual spraying using a trigger sprayer RTU (meta SPC2/5) Scenarios [1.2; 2.2; 3.2; 4.1]	1/ none	2.26E-02	226	247	262	293
	2/ Gloves and coverall	2.93E-03	29	50	65	96
Manual spraying using an electronic sprayer - concentrate (meta SPC3) Scenarios [1.1; 2.2; 3.2; 4.3]	1/ none	1.87E-02	187	206	221	252
	2/ Gloves and coverall	2.49E-03	25	44	59	90
Manual spraying using an electronic sprayer - RTU (meta SPC2/5) Scenarios [1.3; 2.2; 3.2; 4.3]	1/ none	1.96E-02	196	216	231	262
	2/ Gloves and coverall	2.63E-03	26	47	62	93
Automated spraying by robot or automated dipping/foaming - concentrate (meta SPC3)	1/ none	7.62E-04	8	27	42	73
	2/ Gloves	7.62E-05	1	20	35	66

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; 2.3; 3.3; 4.2]						
Automated spraying by robot or automated dipping/foaming - RTU (meta SPC2/5) Scenarios [1.3; 2.3; 3.3; 4.2]	1/ none	1.38E-05	0	21	36	67
	2/ Gloves	1.38E-06	0	21	36	67

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

Calculation sheet is included in annex 3.2.

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

Tier 1:
When using the concentrated product (3.44% total iodine; in-use conc.: 0.689%), **Exposure from biocidal use** without considering PPE (Tier 1) results in 8% of the UL for manual dipping/foaming, 188% or 187% of the UL for manual spraying using a trigger sprayer or an electronic sprayer, respectively, and 8% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 1) results in 27% for manual dipping, 207% and 206% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 27% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 1) results in 42% for manual dipping, 222% and 221% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 42% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 73% for manual dipping, 253%

and 252% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 73% of the UL for automated spraying or automated dipping/foaming.

When using the RTU product (0.9058% total iodine – metaSPC1/4), **exposure from biocidal use** without considering PPE (Tier 1) results in 37% of the UL for manual dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 1) results in 56% for manual dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 1) results in 71% for manual dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 102% for manual dipping/foaming.

When using the RTU product (0.7489% total iodine - metaSPC2/5), **exposure from biocidal use** without considering PPE (Tier 1) results in 31% of the UL for manual dipping/foaming, 226% or 196% of the UL for manual spraying using a trigger sprayer or an electronic sprayer, respectively, and 0% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 1) results in 52% for manual dipping, 247% and 216% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 21% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 1) results in 67% for manual dipping, 262% and 231% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 36% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 98% for manual dipping, 293% and 262% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 67% of the UL for automated spraying or automated dipping/foaming.

Tier 2:
When using the concentrated product (3.44% total iodine; in-use conc.: 0.344%), **Exposure from biocidal use** considering PPE (Tier 2) results in 1% of the UL for manual dipping/foaming, 25% of the UL for manual spraying using a trigger sprayer or an electronic sprayer, respectively, and 1% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, considering PPE (Tier 2) results in 20% for manual dipping/foaming, 44% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 20% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption, considering PPE (Tier 2) results in 35% for manual dipping/foaming, 59% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 35% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, considering PPE (Tier 2) results in 66% for manual dipping, 90% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 66% of the UL for automated spraying or automated dipping/foaming.

When using the RTU product (0.9058% total iodine – metaSPC1/4), **exposure from biocidal use** considering PPE (Tier 2) results in 4% of the UL for manual dipping/foaming.

Exposure from biocidal use, including iodine from milk consumption due to teat treatment, considering PPE (Tier 2) results in 23% for manual dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption, considering PPE (Tier 2) results in 38% for manual dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, considering PPE (Tier 2) results in 69% for manual dipping/foaming.

When using the RTU product (0.7489% total iodine - metaSPC2/5), **exposure from biocidal use** without considering PPE (Tier 2) results in 3% of the UL for manual dipping/foaming, 29% or 26% of the UL for manual spraying using a trigger sprayer or an electronic sprayer, respectively, and 0% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 2) results in 24% for manual dipping, 50% and 47% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 21% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 2) results in 39% for manual dipping, 65% and 62% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 36% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 2) results in 70% for manual dipping, 96% and 93% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 67% of the UL for automated spraying or automated dipping/foaming

Conclusions post-milking application:

When using the concentrate:
For manual and automated dip/foam applications and for automated spraying, no PPE is needed for safe use.
For manual spraying application using a trigger sprayer or electronic sprayer, chemical resistant gloves (90% protection) and coverall (90% protection) are needed for safe use.

When using RTUs:
For manual and automated dip/foam applications and for automated spraying, no PPE is needed for safe use.
For manual spraying application using a trigger sprayer or electronic sprayer, chemical resistant gloves (90% protection) and coverall (90% protection) are needed for safe use.

Furthermore, the OEL of 1 mg/m³ for iodine is not reached in any "post-milking disinfection"-scenario. The maximum value was 7.9% of the OEL calculated for application of teat disinfectant by spraying.

Risk for consumers via residues in food

In the table below, the same relevant principles as described in the section dealing with effects on humans have been used. Dietary risk via iodine residues in milk has been assessed for both adults and children.

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) (Doc 13-010 presented in section 13 of IUCLID dossier) of the IRG PT3 sub-group. Tier 1 calculations as included in IUCLID of the IRG PT3 sub-group represent the theoretical total iodine residues in milk due to pre- or post-milking teat disinfection by spraying (worst case with 0.55% available iodine and 0.9058% total iodine) extrapolated from data of O'Brien (2013). However, it should be noted that in this study for the Tier2 assessment it is assumed that the iodine content is reduced by 50% as the milk from various milking farms are mixed assuming that 50% of these farms do not use iodine based teat disinfection. Tier 2 includes a reduction in iodine concentration of 27% due to pasteurization, as was also taken in the EFSA (2013) opinion on the safety and efficacy of iodine compound (E2) as feed additives. Furthermore, 0.5 L consumption of milk was considered for both adults and children/toddlers, and is in line with the CAR for iodine.

During discussions in the human health working group meetings and WebEx meetings for eCA evaluating iodine based union authorisations 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. Therefore, for this application exposure due to either pre- or post-treatment per milking event for *meta* SPC3 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 metaSPC2, 3, and 5 paragraph 5.2 (these metaSPCs include uses for pre- and post-application): Products can either include post- or pre-application uses. metaSPC 5 is considered worst case as it contains the highest concentration available iodine.
- For exposure to residues the following was concluded by eCAs from iodine based union authorisation applications (Secure Webex meeting (3-10-2017)): "The expected iodine residues in milk from two milking events per day for manual milking and from three events per day for automatic milking are considered comparable". 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 infant/toddlers (EFSA PRIMo version 2, based on highest mean for French population).
- For the calculations information from the O'Brien study was used. The O'Brien study assessed the effect of a teat disinfection product is used, based on 0.5% available iodine on the total iodine content in milk. As the maximum concentration of the BPF products contain 0.55% available iodine (metaSPC5), 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 from iodine based union authorisation applications: "General support was given to the derivation of an EU harmonised value. The value of 200 µg/L iodine in milk was considered appropriate as an EU harmonised value, based on the monitoring data from EFSA 2013 (EFSA Journal 2013;11(2):3101) and the O'Brien study."
- Iodine dietary intake from other sources than milk was also discussed in the Secure Webex meeting (3-10-2017), in which was concluded by eCAs from iodine based union authorisation applications: "The values from the UK survey were considered adequate to represent the EU iodine dietary intake from sources other than milk. Rounding of the values to 185 µg/day for adults and 96 µg/day for toddler was agreed." It should be noted that these values excluded iodine intake from milk. Furthermore, within this UK study (UK retail survey of iodine in UK produced dairy foods, FSIS 02/08, 16 June 2008) 350 samples of dairy and seaweed products were purchased from eight areas of the UK. Levels of iodine found were generally in similar ranges to those reported from previous surveys (MAFF iodine in milk), Furthermore the reported values are in agreement with an EFSA scientific opinion on the use of iodine in feeding stuffs. It is noted that in the UK study report for the calculations for body weights 76 for adults and 14.5 kg for infants are considered, whereas 70 kg and 12 kg are used in the consumption calculations. Moreover, during the discussion at the Secure WebEx meeting it was noted that comparable values could be obtained from French and German monitoring studies.

The estimated dietary intakes of iodine have been compared to the relevant UL for adults (600 µg/d) and infants/toddlers (200 µg/d) and depicted in the table below. Intakes which exceed the respective UL are highlighted in red in the table below. Calculations are included in annex 3.2 (Hypred 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 - worst case: metaSPC5 (0.55% available iodine)

	Adults (0.45 L/day)	**Toddler (0.46 L/day)**
	Estimated daily intake (µg/day) [% ofUL]	**Estimated daily intake (µg/day) [% ofUL]**

2x pre-milking application by manual dipping/spraying		
Intake from milk due to teat treatment	107 18	109 54
Total milk intake*	197 33	201 100
Total dietary intake**	382 64	297 148
2x post-milking application by manual dipping/spraying		
Intake from milk due to teat treatment	124 21	127 64
Total milk intake*	214 36	219 110
Total dietary intake**	399 67	315 158

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

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

Conclusion: Pre- or post-milking teat-disinfection

For adults, the estimated daily intake of iodine resulting from biocidal product use is 18% or 21% of the UL for either pre- or post-application. When background values for iodine in milk is added, the iodine intake from milk consumption is 33% or 36% of the UL for either pre- or post-application. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to 64% or 67% of the UL for either pre- or post-application.

For toddler, the estimated daily intake of iodine resulting from biocidal product use is 54% or 64% of the UL for either pre- or post-application. When background values for iodine in milk is added, the iodine intake from milk consumption is 100 or 110% of the UL for either pre- or post-application. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to 148% or 158% of the UL for either pre- or post-application.

Above we show the results of the worst-case of the BPF, metaSPC5, which shows exceedance of the UL for children (including total milk intake and total dietary intake). Below we have included an table, showing the results for the other metaSPCs, taken into account the intended use for pre- or post-application. Intakes which exceed the respective UL are highlighted in red in the table below. Calculations are included in annex 3.2 (Hypred 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)	**Toddler (0.46 L/day)**
	Estimated daily intake (µg/day) [% of UL]	**Estimated daily intake (µg/day) [% of UL]**
2x post-milking application metaSPC1/2 (0.49% available iodine)		
Intake from milk due to teat treatment	111 18	113 57
Total milk intake*	201	205

	33	103
Total dietary intake**	386 64	301 151
2x pre-milking application metaSPC2 (0.49% available iodine)		
Intake from milk due to teat treatment	95 16	97 49
Total milk intake*	185 31	189 95
Total dietary intake**	370 62	285 143
2x pre-milking application metaSPC3 (0.25% available iodine)		
Intake from milk due to teat treatment	48 8	50 25
Total milk intake*	138 23	142 71
Total dietary intake**	323 54	238 119
2x post-milking application metaSPC3 (0.25% available iodine)		
Intake from milk due to teat treatment	57 9	58 29
Total milk intake*	147 24	150 75
Total dietary intake**	332 55	246 123
2x post-milking application metaSPC3/4 (0.5% available iodine)		
Intake from milk due to teat treatment	113 19	116 58
Total milk intake*	203 34	208 104
Total dietary intake**	388 65	304 152

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

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

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

NL decision

Based on the estimated total intakes for adults, the human health risk is acceptable in all milking applications. In contrast, the estimated total daily intake for toddlers exceeds the UL in all scenarios (i.e. 119-158% of UL or 1.19-1.58 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.

For consideration by MS/ECHA/EFSA: 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 general conclusions in chapter 1 of this 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 abiologically. 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 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 8.05) due to runoff and concentrations in groundwater (42-69 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

TRADE NAMES OF THE PRODUCTS OF THE FAMILY

Trade name in *meta SPC 1 :* ***Dipping products – Ready to use***	**Country (if relevant)**
Dip-io 2500 JOD DIP IODERM PSP DERMINO FR Iododip IODEX EXTRA Iodystrong DERMIODE INO IODE EPAIS INO STAR + IODACTIV 2500 IODIUM BX2500 Usual Iod Post ASiRAL Dip Coat IODOCAN EXTRA UDDER PLUS PRIMADIODE CERTIODE EPAIS IODIPACK GEL HELIO IODE EPAIS VAGEL GELAPIS ACTIV IOSAPIS GEL ZENCARE FLASH REPROGEL DERMADINE + KRONI Jod Dipp 2500 WÜBBELMANN JOD DIP Iodine Cleaner&Sanitizer MUNGIFILM ZEP FS FILMIODINE NIPPLE NP Dip-io YB MAX INO Io Dip MAX JOD DIP YB MAX IodoDip YB MAX Iodium Dip YB MAX JodyDip YB MAX Delta IoDip YB MAX	

Trade name in *meta SPC 2 :* ***Dipping, spraying, foaming products – Ready to use***	**Country (if relevant)**
Liq-io 2500 JOD SPRAY IODINE 3000 RTU IODEX 2500 Usual Iod Liquid Iodoliquid Iodospray DESINTEAT IODYSPRAY RBT 2500 IODY'FLASH INO IODE SPRAY IODYPRO 2500 IODYPRO BL2500 Robot Liq-io 25 ADF iDip+ ASiRAL Dip Spray J IODIPACK HELIO IODE LIQUIDE POLY-IODE CERTIODE LIQUIDE IOSAPIS FLUID GELAPIS ROBOT ZENCARE SPRAY HELIO IODE SPRAY + IODIP + KRONI Jod Spray 2500 WÜBBELMANN JOD LIQUID Liq-io YB MAX INO Io Liquid Max Iodoliquid YB MAX Iodospray YB MAX Desinteat YB MAX Iodium Spray YB MAX JodySpray YB MAX Delta IoSpray YB MAX	

Trade name in *meta SPC 3 :* ***Dipping, spraying, foaming - Concentrated products***	**Country (if relevant)**
Liq-io concentrate INO Jod Konzentrat Usual Iod Concent Iodoconcentrat D 10 IODINE D 5 IODINE Liq-io C INO IODE C D 4 IODINE ADF iDip+ concentrate Mammizan Concentré	

Trade name in *meta SPC 4 :* ***Dipping products reaching virucidal activity – Ready to use***	**Country (if relevant)**
Dip-io 5000 IODIUM TX INO JOD 50 DIP Usual Iod Post + IODIUM PRO DIP IODERM PSP + IODEX EXTRA + Iododip + IODYSTRONG PLUS INO TREMP INO STAR IODACTIV 5000 DERMINO IODERM 5000 IODIUM BX5000 HOEVE-PLUS DIP TREMPASEPT IODE DERMADINE MAMMO-DERM KRONI Jod Dipp 5000	

Trade name in *meta SPC 5 :* ***Dipping, spraying, foaming products 5500 ppm – Ready to use***	**Country (if relevant)**
Liq-io 5500 IODYPRO INO JOD 50 Liquid Usual Iod Liquid + IODIUM PRO SPRAY IODEX Iodoliquid + Iodospray Plus DESINTEAT PLUS ROBOSPRAY IODE INOTRAYON IODYPRO 5500 Robot Liq-io 55 IODYPRO BL5500 ADF iDip+ 5500 HOEVE-JODIUM SPRAY GRUPAIODE IODOCAN JOFO JODI PLUS K-AGRO PRODIP ID IODIP HELIO IODE SPRAY MAMMO-JOD KRONI Jod Spray 5500 MUNGI-IOD LELY QUARESS-Iodine	

AUTHORISATION HOLDER

Name and address of the authorisation holder	Name	HYPRED SAS
	Address	55, Boulevard Jules Verger BP 10180 35803 DINARD Cedex France
Telephone:	+33 2 99 16 50 00	
Fax:	+33 2 99 16 50 20	
E-mail address:	regulatory@hypred.com	
Pre-submission phase started on:	13 October 2014	
Pre-submission phase concluded on:	18 December 2014	
Case number in R4BP3:	Pre-submission case number: BC-MA015716-54	

APPLICANT (IF DIFFERENT FROM AUTHORISATION HOLDER)

Company Name:	Not relevant
Address:	
City:	
Postal Code:	
Country:	
Telephone:	
Fax:	
E-mail address:	
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	

PERSON AUTHORISED FOR COMMUNICATION ON BEHALF OF THE APPLICANT

Name:	Isabelle Demoment
Function:	Regulatory Manager
Address:	55, Boulevard Jules Verger
City:	DINARD
Postal Code:	BP 10180
Country:	France
Telephone:	+33299165035
Fax:	
E-mail address:	biocide@hypred.com

MANUFACTURER(S) OF THE PRODUCTS OF THE FAMILY

Name of manufacturer	HYPRED SAS
Address of manufacturer	55, Boulevard Jules Verger BP 10180 35803 DINARD Cedex

	France
Location of manufacturing sites	HYPRED SAS 55, Boulevard Jules Verger – BP10180 - 35803 Dinard Cedex - France HYPRED GmbH Marie-Curie-Straße 23 – 53332 Bornheim – Sechtem Germany HYPRED IBERICA S.L Pol. Ind. Arazuri-Orcoyen C/C nº 32– 31160 Orcoyen – NAVARRA - Spain HYPRED Italia s.r.l. Strada Montodine-Gombito Loc. Cà Nova – 26010 Ripalta Arpina CR Italy HYPRED POLSKA SP. Z O.O. NIEPRUSZEWO, KASZTANOWA 4, 64-320 BUK Poland

CANDIDATE(S) FOR SUBSTITUTION

HYPRED's iodine based products doesn't contain an active substance candidate for substitution.

2.2.2 Family composition and formulation

NB: The full composition of the products according to Annex III Title 1 are provided in the confidential annex.

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

Yes ☐
No ☒

IDENTITY OF THE ACTIVE SUBSTANCE

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

QUALITATIVE AND QUANTITATIVE INFORMATION ON THE COMPOSITION OF THE BIOCIDAL FAMILY

The product family consists of 7 members, 5 ready-to-use products and 1 concentrate. All products are iodine-based liquid solutions. The iodine concentration in the ready-to-use solutions is: 0.25 – 0.55 %.
The products are divided in 5 *meta* SPCs. The first one consists of 2 ready to use products. The second *meta* SPC also consists of 2 ready to use products. The third *meta* SPC consists of 1 concentrate. The fourth *meta* SPC consists of 1 ready to use product. The fifth *meta* SPC consists of 1 ready to use product.

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
IODINE	IODINE	Active substance	7553-56-2	231-442-4	0.25	2.50
Alcohols C12-14 ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), α-C12-14-(even numbered)-alkyl-ω-hydroxy-	Substance of concern	68439-50-9	-	2.697 (pure 2.428)	24.199 (pure 21.779)

See the confidential annex for further details.

INFORMATION ON TECHNICAL EQUIVALENCE

The source of substance is the same as was evaluated for inclusion in the Union list of approved active substances.

INFORMATION ON THE SUBSTANCE(S) OF CONCERN

The family contains 2.697-24.199% w/w alcohols C12-14 ethoxylated (90%), which is a substance of concern. For further details refer to the confidential annex.

TYPE OF FORMULATION

AL (ready to use) and SL (concentrate)

2.2.3 Intended uses

Use 1.1 in ***meta* SPC 1 : *Dipping products – Ready to use***

Table 1: Use # 1.1 – Manual or Automated Dipping after milking

Product Type	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	- Bacteria - Yeasts - Algae
Field of use	Indoor Disinfection of teats of milk producing animals by dipping after milking
Application method(s)	Manual or automated disinfection of teats by dipping after milking. Dipping cup or Automated dipping machine
Application rate(s) and frequency	Application rate : - cows and buffaloes (3 to 10ml : 5 ml recommended) - sheep (1.5 to 5 ml : 1.5 ml recommended) - goats (2.5 to 6 ml : 2.5 ml recommended) Frequency :2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5 ,10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000 L
Potential for release into the environment (yes/no)	Release via STP, Manure/slurry
Potential for contamination of food/feedingstuff (yes/no)	Systematic cleaning and drying to avoid any contamination of milk

Use 2.1 and Use 2.2 in *meta* SPC 2 : *Dipping, spraying, foaming products – Ready to use*

Table 2 : Use # 2.1 – Manual Dipping, Spraying or Foaming Before Milking

Product Type	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	- Bacteria - Yeasts
Field of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying before milking
Application method(s)	Manual or automated disinfection of teats by dipping, foaming or spraying before milking. Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	Application rate : - cows and buffaloes (3 to 10ml : 5 to 8 ml recommended) - sheep (1.5 to 5 ml : 1.5 to 3 ml recommended) - goats (2. to 6 ml : 2.5 to 4 ml recommended) Frequency :2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5 ,10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000 L
Potential for release into the environment (yes/no)	Release via STP, Manure/slurry
Potential for contamination of food/feedingstuff (yes/no)	Systematic cleaning and drying to avoid any contamination of milk

Table 3 : Use # 2.2 – Manual or Automated Dipping, Foaming or Spraying After Milking

Product Type	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	- Bacteria - Yeasts - Algae
Field of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying after milking
Application method(s)	Manual or automated disinfection of teats by dipping, foaming or spraying after milking. Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	Application rate : - cows and buffaloes (3 to 10ml : 5 to 8 ml recommended) - sheep (1.5 to 5 ml : 1.5 to 3 ml recommended) - goats (2.5 to 6 ml : 2.5 to 4 ml recommended) Frequency :2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5 ,10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000 L
Potential for release into the environment (yes/no)	Release via STP, Manure/slurry
Potential for contamination of food/feedingstuff (yes/no)	Systematic cleaning and drying to avoid any contamination of milk

Use 3.1 and 3.2 in *meta* SPC 3 : Dipping, spraying, foaming -Concentrated products

Table 4 : Use # 3.1 – Manual or Automated Dipping, Foaming or Spraying Before Milking

Product Type	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	- Bacteria - Yeasts
Field of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying before milking.
Application method(s)	Manual or automated Disinfection of teats by dipping, foaming or spraying before milking. Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	A dilution at 10% (v/v) should be prepared. Application rate for the diluted product : - cows and buffaloes (3 to 10ml : 5 to 8 ml recommended) - sheep (1.5 to 5 ml : 1.5 to 3 ml recommended) - goats (2.5 to 6 ml : 2.5 to 4 ml recommended) Frequency :2 to 6 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5,10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000 L
Potential for release into the environment (yes/no)	Release via STP, Manure/slurry
Potential for contamination of food/feedingstuff (yes/no)	Systematic cleaning and drying to avoid any contamination of milk

Table 5 : Use # 3.2 – Manual or Automated Dipping, Foaming or Spraying After Milking

Product Type	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	- Bacteria - Yeasts - Algae - Viruses
Field of use	Indoor Disinfection of teats of milk producing animals by dipping after milking
Application method(s)	Manual disinfection of teats by dipping, foaming or spraying after milking. Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	For disinfection of bacteria, yeasts and algae a dilution at 10% (v/v) should be prepared. For disinfection of viruses a dilution at 20% (v/v) should be prepared Application rate : - cows and buffaloes (3 to 10ml : 5 to 8 ml recommended) - sheep (1.5 to 5 ml : 1.5 to 3 ml recommended) - goats (2.5 to 6 ml : 2.5 to 4 ml recommended) Frequency :2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000 L
Potential for release into the environment (yes/no)	Release via STP, Manure/slurry
Potential for contamination of food/feedingstuff (yes/no)	Systematic cleaning and drying to avoid any contamination of milk

Use 4.1 in *meta* SPC 4 : *Dipping products reaching virucidal activity – Ready to use*

Table 6: Use # 4.1 – Manual or Automated Dipping After Milking

Product Type	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	- Bacteria - Yeasts - Algae - Viruses
Field of use	Indoor Disinfection of teats of milk producing animals by dipping after milking
Application method(s)	Manual or automated disinfection of teats by dipping after milking. Dipping cup or Automated dipping machine
Application rate(s) and frequency	Application rate : - cows and buffaloes (3 to 10ml : 5 ml recommended) - sheep (1.5 to 5 ml : 1.5 ml recommended) - goats (2.5 to 6 ml : 2.5 ml recommended) Frequency: 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5 ,10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000 L
Potential for release into the environment (yes/no)	Release via STP, Manure/slurry
Potential for contamination of food/feedingstuff (yes/no)	Systematic cleaning and drying to avoid any contamination of milk

Use 5.1 and Use 5.2 in *meta* SPC 5 : *Dipping, spraying, foaming products 5500 ppm– Ready to use*

Table 7 : Use # 5.1 – Manual or Automated Dipping, Spraying or Foaming Spraying Before Milking

Product Type	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	- Bacteria - Yeasts
Field of use	Indoor Disinfection of teats of milk producing animals by dippingfoaming or spraying before milking
Application method(s)	Manual or automated disinfection of teats by dipping or foaming or spraying before milking. Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	Application rate : - cows and buffaloes (3 to 10ml : 5 to 8 ml recommended) - sheep (1.5 to 5 ml : 1.5 to 3 ml recommended) - goats (2.5 to 6 ml : 2.5 to 4 ml recommended) Frequency :2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000 L
Potential for release into the environment (yes/no)	Release via STP, Manure/slurry
Potential for contamination of food/feedingstuff (yes/no)	Systematic cleaning and drying to avoid any contamination of milk

Table 8 : Use # 5.2 – Manual or Automated Dipping, Foaming or Spraying after milking

Product Type	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	- Bacteria - Yeasts - Algae - Viruses
Field of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying after milking
Application method(s)	Manual or automated disinfection of teats by dipping, foaming or spraying after milking. Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	Application rate : - cows and buffaloes (3 to 10ml : 5 to 8 ml recommended) - sheep (1.5 to 5 ml : 1.5 to 3 ml recommended) - goats (2.5 to 6 ml : 2.5 to 4 ml recommended) Frequency :2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000 L
Potential for release into the environment (yes/no)	Release via STP, Manure/slurry
Potential for contamination of food/feedingstuff (yes/no)	Systematic cleaning and drying to avoid any contamination of milk

2.2.4 Hazard and precautionary statements

PROPOSED CLASSIFICATION AND LABELLING OF THE BIOCIDAL PRODUCT
Classification and Labelling according to Regulation (EC) No 1272/2008:

meta SPC 1: ***Dipping products – Ready to use***

Classification	
Hazard category	Eye Irrit 2 Aquatic Chronic 3
Hazard statement	H319: Causes serious eye irritation. H412: Harmful to aquatic life with long lasting effects.
	
Labelling	
Signal words	Warning
Hazard statements	H319: Causes serious eye irritation. H412: Harmful to aquatic life with long lasting effects.
Precautionary statements	P102: Keep out of reach of children. P264: Wash hands thoroughly after handling. P280: Wear protective gloves/protective clothing/eye protection. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313: If eye irritation persists: Get medical advice/attention.
Note	

meta SPC 2: ***Dipping, spraying, foaming products – Ready to use***

Classification	
Hazard category	Eye Irrit 2 Aquatic Chronic 3
Hazard statement	H319: Causes serious eye irritation. H412: Harmful to aquatic life with long lasting effects.
	
Labelling	
Signal words	Warning
Hazard statements	H319: Causes serious eye irritation. H412: Harmful to aquatic life with long lasting effects.
Precautionary statements	P102: Keep out of reach of children. P264: Wash hands thoroughly after handling. P280: Wear protective gloves/protective clothing/eye protection. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313: If eye irritation persists: Get medical advice/attention.
Note	

meta SPC 3: ***Dipping, spraying, foaming - Concentrated products***

Classification	
Hazard category	Corrosive to metals 1 Eye Dam. 1 STOT RE 2 Aquatic Chronic 2
Hazard statement	H290: May be corrosive to metals H318: Causes serious eye damage. H373: May cause damage to thyroid through prolonged or repeated exposure, oral route. H411 : Toxic to aquatic life with long lasting effects
	
Labelling	
Signal words	Danger
Hazard statements	H290: May be corrosive to metals H318: Causes serious eye damage. H373: May cause damage to thyroid through prolonged or repeated exposure, oral exposure. H411 : Toxic to aquatic life with long lasting effects
Precautionary statements	P102: Keep out of reach of children. P260: Do not breathe mist/vapours/spray. P264: Wash hands thoroughly after handling. P280: Wear protective gloves/protective clothing/eye protection. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER or doctor/physician. P314: Get medical advice/attention if you feel unwell. P501: Dispose of contents/container in accordance with local/regional/national/internationalregulations.
Note	

meta SPC 4 : ***Dipping products reaching virucidal activity– Ready to use***

Classification	
Hazard category	Eye Irrit 2 Aquatic Chronic 3
Hazard statement	H319: Causes serious eye irritation. H412: Harmful to aquatic life with long lasting effects.
	
Labelling	
Signal words	Warning
Hazard statements	H319: Causes serious eye irritation. H412: Harmful to aquatic life with long lasting effects.
Precautionary statements	P102: Keep out of reach of children. P264: Wash hands thoroughly after handling. P280: Wear protective gloves/protective clothing/eye protection. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313: If eye irritation persists: Get medical advice/attention.
Note	

meta SPC 5 : ***Dipping, spraying, foaming products 5500 ppm– Ready to use***

Classification	
Hazard category	Eye Irrit 2 Aquatic Chronic 3
Hazard statement	H319: Causes serious eye irritation. H412: Harmful to aquatic life with long lasting effects.
	
Labelling	
Signal words	Warning
Hazard statements	H319: Causes serious eye irritation. H412: Harmful to aquatic life with long lasting effects.
Precautionary statements	P102: Keep out of reach of children. P264: Wash hands thoroughly after handling. P280: Wear protective gloves/protective clothing/eye protection. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313: If eye irritation persists: Get medical advice/attention.
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)**
Jerrycan	5 liters	HDPE	HDPE	Professional users	Yes
Jerrycan	10 liters	HDPE	HDPE	Professional users	Yes
Jerrycan	22 liters	HDPE	HDPE	Professional users	Yes
Drum	60 liters	HDPE	HDPE	Professional users	Yes
Drum	120 liters	HDPE	HDPE	Professional users	Yes
Drum	220 liters	HDPE	HDPE	Professional users	Yes
IBC	1000 liters	HDPE	HDPE	Professional users	Yes

2.2.5 Directions for use

I - META SPC 1 : DIPPING PRODUCTS – READY TO USE

A. INSTRUCTIONS FOR USE

Use # 1.1 - Manual or automated dipping after milking

Always read the label or leaflet before use and follow all the instructions provided.
The product must be brought to a temperature above 20°C before use.

The use of a dosing pump for filling the product into the application equipment is recommended. Fill the dipping cup manually or automatically with the ready to use product.
Apply by dipping manually or automatically on animal's teats on the full length of the teat after milking.
Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).
At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.
Where necessary, repeat the application after each milking.
Clean the application equipment regularly with warm water.

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

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID INSTRUCTIONS
- In the event of inhalation : Bring to fresh air.
- In the event of contact with the skin : Wash with water.
- In the event of contact with the eyes :
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
- In the event of ingestion : Rinse mouth. Do NOT induce vomiting. Get medical advice.
Refer to the safety data sheet available for professional user : it contains an emergency phone number.

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.
The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste.

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

Shelf life: 2 years in HDPE. Do not store at a temperature higher than 30°C

II - META SPC 2 : DIPPING, SPRAYING, FOAMING PRODUCTS – READY TO USE

A. INSTRUCTIONS FOR USE

Use # 2.1 - Manual or automated dipping, foaming or spraying before milking

Always read the label or leaflet before use and follow all the instructions provided.
The product must be brought to a temperature above 20°C before use.

The use of a dosing pump for filling the product into the application equipment is recommended. Fill the dipping / foaming cup / sprayer manually or automatically with the ready to use product.
Eliminate all visible dirt before applying the product.
Manual or automatic dipping / foaming / spraying on animal's teats on the full length of the teat before milking.
Let the product act at least one minute.
Use the teat cleaning and wiping method systematically before attaching the milking cluster.

Where necessary repeat the application at each milking.
Clean the application equipment regularly with warm water.

Use # 2.2 – Manual or Automated dipping, foaming or spraying after milking

Always read the label or leaflet before use and follow all the instructions provided.
The product must be brought to a temperature above 20°C before use.

The use of a dosing pump for filling the product into the application equipment is recommended. Fill the dipping / foaming cup / sprayer manually or automatically with the ready to use product.
Manual or automatic dipping / foaming / spraying on animal's teats on the full length of the teat after milking.
Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).
At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.

Where necessary, repeat the application at each milking
Clean regularly the application equipment with warm water.

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

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID INSTRUCTIONS
- In the event of inhalation : Bring to fresh air.
- In the event of contact with the skin : Wash with water.
- In the event of contact with the eyes :
  IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.
- In the event of ingestion : Rinse mouth. Do NOT induce vomiting. Get medical advice.
Refer to the safety data sheet available for professional user : it contains an emergency phone number.

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.
The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste.

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

Shelf life: 2 years in HDPE
Do not store at a temperature higher than 30°C

III - META SPC 3 : DIPPING, SPRAYING, FOAMING - CONCENTRATED PRODUCTS

A. INSTRUCTIONS FOR USE

Use # 3.1 - Manual or automated dipping, foaming or spraying before milking

Always read the label or leaflet before use and follow all the instructions provided.
The product must be brought to a temperature above 20°C before use.

Prepare a dilution at 10% (v/v: 10 ml product, add water up to 100ml) for bactericidal and yeasticidal activity.
The use of a dosing pump for filling the product into the application equipment is recommended. Fill the dipping / foaming cup / sprayer manually or automatically with the prepared dilution.
Eliminate all visible dirt before applying the product.
Manual or automatic dipping / foaming / spraying on animal's teats on the full length of the teat before milking.
Let the product act at least one minute.
Use the teat cleaning and wiping method systematically before attaching the milking cluster.

Where necessary, repeat the application at each milking
Clean the application equipment regularly with warm water.

Use # 3.2 – Manual or Automated dipping, foaming or spraying after milking

Always read the label or leaflet before use and follow all the instructions provided.
The product must be brought to a temperature above 20°C before use.

Prepare a dilution at 10% (v/v: 10 ml product, add water up to 100ml) for bactericidal, yeasticidal and algaecidal activity or 20% (v/v: 20 ml product, add water up to 100ml) in case virucidal activity is also needed.
The use of a dosing pump for filling the product into the application equipment is recommended. Fill the dipping / foaming cup / sprayer manually or automatically with the prepared dilution.
Manual or automatic dipping / foaming / spraying on animal's teats on the on the full length of the teat after milking.
Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).
At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.

Where necessary, repeat the application at each milking
Clean the application equipment regularly with warm water.

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

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.
FIRST AID INSTRUCTIONS :

- In the event of inhalation : Bring to fresh air.
- In the event of contact with the skin : Wash with water.
- In the event of contact with the eyes :
  Rinse at once with a soft stream of water for at least 15 minutes, eyes wide open.
  Remove contact lenses if present and easy to do. Continue rinsing.
  Immediately call a POISON CENTER or doctor/physician.
- In the event of ingestion : Rinse mouth. Do NOT induce vomiting. Get medical advice.

Refer to the safety data sheet available for professional user : it contains an emergency phone number

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.
The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste.

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

Shelf life: 2 years in HDPE
Do not store at a temperature higher than 30°C

IV - META SPC 4 : DIPPING PRODUCTS REACHING VIRUCIDAL ACTIVITY– READY TO USE

A. INSTRUCTIONS FOR USE

Use # 4.1 - Manual or automated dipping after milking

Always read the label or leaflet before use and follow all the instructions provided.
The product must be brought to a temperature above 20°C before use.

The use of a dosing pump for filling the product into the application equipment is recommended. Fill the dipping cup manually or automatically with the ready to use product.
Apply by dipping manually or automatically on animal's teats on the full length of the teat after milking.
Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).
At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.
Where necessary, repeat the application after each milking.
Clean the application equipment regularly with warm water.

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

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID INSTRUCTIONS
- In the event of inhalation : Bring to fresh air.
- In the event of contact with the skin : Wash with water.
- In the event of contact with the eyes :
  IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  If eye irritation persists: Get medical advice/attention.
- In the event of ingestion : Rinse mouth. Do NOT induce vomiting. Get medical advice.
  Refer to the safety data sheet available for professional user : it contains an emergency phone number.

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.
The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste.

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

Shelf life: 2 years in HDPE. Do not store at a temperature higher than 30°C

V - META SPC 5 : DIPPING, SPRAYING, FOAMING PRODUCTS 5500 PPM – READY TO USE

A. INSTRUCTIONS FOR USE

Use # 5.1 - Manual or automated dipping, foaming or spraying before milking

Always read the label or leaflet before use and follow all the instructions provided.
The product must be brought to a temperature above 20°C before use.

The use of a dosing pump for filling the product into the application equipment is recommended. Fill the dipping / foaming cup / sprayer manually or automatically with the ready to use product.
Eliminate all visible dirt before applying the product.
Manual or automatic dipping / foaming / spraying on animal's teats on the full length of the teat before milking.
Let the product act at least one minute.
Use the teat cleaning and wiping method systematically before attaching the milking cluster.

Where necessary repeat the application at each milking.
Clean the application equipment regularly with warm water.

Use # 5.2 – Manual or Automated dipping, foaming or spraying after milking

Always read the label or leaflet before use and follow all the instructions provided.
The product must be brought to a temperature above 20°C before use.

The use of a dosing pump for filling the product into the application equipment is recommended. Fill the dipping / foaming cup / sprayer manually or automatically with the ready to use product.
Manual or automatic dipping / foaming / spraying on animal's teats on the full length of the teat after milking.
Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).
At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.

Where necessary, repeat the application at each milking
Clean regularly the application equipment with warm water.

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

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID INSTRUCTIONS
- In the event of inhalation : Bring to fresh air.
- In the event of contact with the skin : Wash with water.
- In the event of contact with the eyes :
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
- In the event of ingestion : Rinse mouth. Do NOT induce vomiting. Get medical advice.
Refer to the safety data sheet available for professional user : it contains an emergency phone number.

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 municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.
The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste.

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

Shelf life: 2 years in HDPE
Do not store at a temperature higher than 30°C

2.2.6 Documentation

A. DATA SUBMITTED IN RELATION TO FAMILY PRODUCT APPLICATION

Data submitted in relation to family product application are presented in the reference list presented in annex 3.1 (which is a confidential annex).

B. ACCESS TO DOCUMENTATION

HYPRED SAS is a member of the Iodine Registration Group (IRG) which submitted a complete dossier for the approval of the biocidal active substance iodine under the Biocidal Products Regulation 528/2012 for use in product type 3, 4 and 22.

Therefore, HYPRED SAS have proprietary and ownership rights to the iodine complete substance dossier submitted by the IRG for product type 3 and own or have received access rights to the data included in HYPRED's iodine based products family dossier.

The declaration on ownership of data and access rights is presented in Section 13 in IUCLID (Doc 13-002).

C. SIMILAR CONDITIONS OF USE

Outcome of the pre-submission consultation (n° D(2014) 5830) is presented in Section 13 in IUCLID (Doc 13-001). According to this document the biocidal product family HYPRED's iodine based products is deemed to be eligible for Union authorisation.

2.2.7 Other information

No other information

2.3 ASSESSMENT OF THE BIOCIDAL FAMILY

2.3.1 Physical, chemical and technical properties

Trade name tested	***meta* SPC**
Dip-io 2500 Dip-io YB MAX	1
Liq-io 2500 Liq-io YB MAX	2
Liq-io concentrate	3
Dip-io 5000	4
Liq-io 5500	5

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**
Physical state at 20 °C and 101.3 kPa	Visual observation (internal method: AL1)	100% Liq-io 5500 Liq-io 2500 Dip-io 5000 Dip-io 2500 Liq-io concentrate	All products included in the family are liquid	Section 3.1 in IUCLID Gougeon. S (2014) Doc 3.1-001 Doc 3.1-002 Doc 3.1-003 Doc 3.1-004 Doc 3.1-005
Colour at 20 °C and 101.3 kPa	Visual observation (internal method: AL1)	100% Liq-io 5500 Liq-io 2500 Dip-io 5000 Dip-io 2500 Liq-io concentrate	All products included in the family are brown	Section 3.1 in IUCLID Gougeon. S (2014) Doc 3.1-001 Doc 3.1-002 Doc 3.1-003 Doc 3.1-004 Doc 3.1-005
Odour at 20 °C and 101.3 kPa	Olfactory inspection (internal method: AL1)	100% Liq-io 5500 Liq-io 2500 Dip-io 5000 Dip-io 2500 Liq-io concentrate	Liq-io 5500: Characteristic Liq-io 2500: Iodine Dip-io 5000: Iodine Dip-io 2500:Slight odour of iodine Liq-io concentrate: Characteristic	Section 3.1 in IUCLID Gougeon. S (2014) Doc 3.1-001 Doc 3.1-002 Doc 3.1-003 Doc 3.1-004 Doc 3.1-005
Acidity / alkalinity	OECD 122	100% Liq-io 5500 Liq-io 2500 Dip-io 5000 Dip-io 2500	pH data: Liq-io 5500: 5 at 20.4°C Liq-io 2500: 5.04 at 21°C Dip-io 5000:	Section 3.2 in IUCLID Demangel. B (2014) Doc 3.2-001

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		Liq-io concentrate	4.18 at 19.7 °C Dip-io 2500: 4.67 at 20.8 °C Liq-io concentrate: 4.06 at 20.2 °C Acidity Liq-io concentrate: 0.32% as H_2SO_4 at 20+/-0.2°C Acidity Dip-io 5000: 0.24% as H_2SO_4 at 20+/- 0.2°C	Doc 3.2-002 Doc 3.2-003 Doc 3.2-004 Doc 3.2-005 Gougeon (2016) Doc 3.2-006 Doc 3.2-007
Relative density / bulk density	OECD 109	100% Liq-io 5500 Liq-io 2500 Dip-io 5000 Dip-io 2500 Liq-io concentrate	Relative density: Liq-io 5500: 1.025 ± 0.001 at 20.5°C Liq-io 2500: 1.020 ± 0.001 at 20.1°C Dip-io 5000: 1.023 ± 0.001 at 20.8°C. Dip-io 2500: 1.006 ± 0.001 at 20.7°C Liq-io concentrate: 1.108 ± 0.001 at 20.2°C	Section 3.3 in IUCLID Demangel. B (2014) Doc 3.3-001 Doc 3.3-002 Doc 3.3-003 Doc 3.3-004 Doc 3.3-005
Storage stability test – **accelerated storage**	CIPAC MT 46.3 18 weeks at 30°C in HDPE	100% Liq-io 5500 Liq-io 2500 Dip-io 5000 Dip-io 2500 Liq-io concentrate	**Liq-io 5500:** **Before storage:** *Iodine content:* 0.54% w/w *Iodide content:* 0.22% w/w *Iodate content:* ≤0.0011% w/w *Total iodine element content:* 0.75% w/w *Appearance:* opaque homogeneous brown liquid *Odour:* characteristic *pH neat:* 5.01 *Relative density:* 1.024 *Viscosity 20°C (60rpm):* 1.6 mPa.s *Viscosity 40°C (60rpm):* 1.4 mPa.s **After storage:** *Packaging:* no deviation *Weight loss:* No deviation	Section 3.4 in IUCLID Gougeon. S (2014) Doc 3.4.1-001.1 Doc 3.4.1-001.2 Doc 3.4.1-001.3 Doc 3.4.1-001.4 Doc 3.4.1-001.5

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Iodine content: 0.51% w/w *Iodide content:* 0.23% w/w *Iodate content:* ≤0.0011% w/w *Total iodine element content:* 0.74% w/w *Appearance:* opaque homogeneous brown liquid *Odour:* characteristic *pH neat:* 4.89 *Relative density:* 1.024 *Viscosity 20°C (60rpm):* 1.5 mPa.s *Viscosity 40°C (60rpm):* 1.3 mPa.s Active substance decrease during storage: 5.56%w/w **Liq-io 2500:** **Before storage:** *Iodine content:* 0.24% w/w *Iodide content:* 0.095% w/w *Iodate content:* ≤0.0004% w/w *Total iodine element content:* 0.34% w/w *Appearance:* opaque homeneous brown liquid *Odour:* iodine *pH neat:* 4.95 *Relative density:* 1.020 *Viscosity 20°C (60rpm):* 1.3 mPa.s *Viscosity 40°C (60rpm):* 1.6 mPa.s **After storage:** *Packaging:* no deviation *Weight loss:* No deviation *Iodine content:*	

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>0.22% w/w
Iodide content:
0.12% w/w
Iodate content:
≤0.0007% w/w
Total iodine element content:
0.34% w/w
Appearance: opaque homogeneous brown liquid
Odour: iodine
pH neat: 4.90
Relative density: 1.020
Viscosity 20°C (60rpm):
1.4 mPa.s
Viscosity 40°C (60rpm):
1.7 mPa.s
<u>Active substance decrease during storage: 8.33%w/w</u>

Dip-io 5000:
Before storage:
Iodine content:
0.49% w/w
Iodide content:
0.42% w/w
Iodate content:
≤0.0012% w/w
Total iodine element content:
0.91% w/w
Appearance:
Thick homogeneous brown liquid
Odour: iodine
pH neat: 4.20
Relative density: 1.026
Viscosity in mPa.s
<table><tr><td></td><td>20°C</td><td>40°C</td></tr><tr><td>rpm</td><td></td><td></td></tr><tr><td>6</td><td>4741</td><td>4661</td></tr><tr><td>3</td><td>8618</td><td>8505</td></tr><tr><td>1.5</td><td>16456</td><td>15727</td></tr><tr><td>0.6</td><td>33493</td><td>31068</td></tr></table>After storage:
Packaging:
no deviation
Weight loss:
-0.1% w/w</td><td></td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>Iodine content:
0.47% w/w
Iodide content:
0.43% w/w
Iodate content:
≤0.0009% w/w
Total iodine element content:
0.90% w/w
Appearance:
Thick homogeneous brown liquid
Odour: iodine
pH neat: 4.14
Relative density: 1.024
Viscosity in mPa.s
<table>
<tr><td></td><td>20°C</td><td>40°C</td></tr>
<tr><td>rpm</td><td></td><td></td></tr>
<tr><td>6</td><td>4212</td><td>3821</td></tr>
<tr><td>3</td><td>7768</td><td>6789</td></tr>
<tr><td>1.5</td><td>14147</td><td>12117</td></tr>
<tr><td>0.6</td><td>29569</td><td>23820</td></tr>
</table>
<u>Active substance decrease during storage: 4.08%w/w</u>

Dip-io 2500:
Before storage:
Iodine content:
0.25% w/w
Iodide content:
0.17% w/w
Iodate content:
≤0.0005% w/w
Total iodine element content:
0.41% w/w
Appearance:
Thick homogeneous brown liquid
Odour: Slight iodine
pH neat: 4.76
Relative density: 1.009
Viscosity in mPa.s
<table>
<tr><td></td><td>20°C</td><td>40°C</td></tr>
<tr><td>rpm</td><td></td><td></td></tr>
<tr><td>12</td><td>2385</td><td>2256</td></tr>
<tr><td>6</td><td>4291</td><td>3939</td></tr>
<tr><td>3</td><td>7828</td><td>7653</td></tr>
<tr><td>1.5</td><td>14167</td><td>12517</td></tr>
</table>
</td><td></td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			0.6 | 29419 | 24670 **After storage:** *Packaging:* no deviation *Weight loss:* No deviation *Iodine content:* 0.23% w/w *Iodide content:* 0.19% w/w *Iodate content:* ≤0.0004% w/w *Total iodine element content:* 0.42% w/w *Appearance:* Thick homogeneous brown liquid *Odour:* Slight iodine *pH neat:* 4.68 *Relative density:* 1.011 *Viscosity in mPa.s* rpm | 20°C | 40°C 12 | 2236 | 2113 6 | 4064 | 3657 3 | 7393 | 6728 1.5 | 13657 | 11638 0.6 | 28144 | 22745 Active substance decrease during storage: 8.00%w/w **Liq-io concentrate:** **Before storage:** *Iodine content:* 2.45% w/w *Iodide content:* 0.95% w/w *Iodate content:* ≤0.005% w/w *Total iodine element content:* 3.40% w/w *Appearance:* opaque homogeneous brown liquid *Odour:* characteristic *pH neat:* 3.98 *Acidity(neat and 20%):* no data	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			pH 10%: 4.18 *pH 20%:* 3.95 *Relaive density:* 1.108 *Viscosity 20°C (6rpm):* 89 mPa.s *Viscosity 40°C (6rpm):* 72 mPa.s *Dilution stability 20%:*No separated material **After storage:** *Packaging:* no deviation *Weight loss:* No deviation *Iodine content:* 2.39% w/w *Iodide content:* 1.05% w/w *Iodate content:* ≤0.004% w/w *Total iodine element content:* 3.44% w/w *Appearance:* opaque homogeneous brown liquid *Odour:* characteristic *pH neat:* 3.94 *Acidity (neat and 20%):* 0.07 *pH 10%:* 4.11 *pH 20%:* 3.84 *Relative density:* 1.107 *Viscosity 20°C (6rpm):* 79 mPa.s *Viscosity 40°C (6rpm):* 66 mPa.s *Dilution stability 20%:*No separated material <u>Active substance decrease during storage: 2.45%w/w</u> After 18 weeks of storage stability procedure at 30 +/- 2 °C in HDPE, the content of the active substance iodine, the packaging materials and all of the physicochemical	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			properties except viscosity are considered as stable for Liq-io 5500, Liq-io 2500, Dip-io 2500, Dip-io 5000 and Liq-io concentrate. The viscosity decreases during storage for Liq-io concentrate, Dip-io 2500 and Dip-io 5000. This decrease will, however, not change the application properties and is therefore acceptable. The level of foam generated at in use concentration is too high to use CIPAC MT 47.2. As the product is intended to produce foam, the persistent foaming test was waived. No degradation products of toxicological significance are formed.	
Storage stability test – **long term storage at ambient temperature**	Long term storage test at 20°C +/- 2°C for 2 years in HDPE According to Guidance on the Biocidal Product Regulation - Vol I Part A Information requirements	100% Liq-io 5500 Liq-io 2500 Dip-io 5000 Dip-io 2500 Liq-io concentrate	**Liq-io 5500** **Before storage** *Iodine content:* 0.54% w/w *Iodide content:* 0.22% w/w *Iodate content:* ≤0.0011% w/w *Total iodine element content:* 0.75% w/w *Appearance:* opaque homogeneous brown liquid *Odour:* characteristic *pH neat:* 5.01 *Relative density:* 1.024 *Viscosity 20°C (60rpm):* 1.6 mPa.s *Viscosity 40°C (60rpm):* 1.4 mPa.s **After storage**	Section 3.4 in IUCLID Gougeon. S (2014-2016) Doc 3.4.1-003.1 Doc 3.4.1-003.2 Doc 3.4.1-003.3 Doc 3.4.1-003.4 Doc 3.4.1-003.5

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Packaging: no deviation *Weight loss:* No deviation *Iodine content:* 0.51% w/w *Iodide content:* 0.2477% w/w *Iodate content:* ≤0.0012% w/w *Total iodine element content:* 0.7595% w/w *Appearance:* opaque homogeneous brown liquid *Odour:* characteristic *pH neat:* 4.88 *Relative density:* 1.024 *Viscosity 20°C (60rpm):* 1.6 mPa.s *Viscosity 40°C (60rpm):* 1.0 mPa.s Active substance decrease during storage: 5.56%w/w **Liq-io 2500** **Before storage** *Iodine content:* 0.24% w/w *Iodide content:* 0.095% w/w *Iodate content:* ≤0.0004% w/w *Total iodine element content:* 0.34% w/w *Appearance:* opaque homogeneous brown liquid *Odour:* iodine *pH neat:* 4.95 *Relative density:* 1.020 *Viscosity 20°C (60rpm):* 1.3 mPa.s *Viscosity 40°C (60rpm):* 1.6 mPa.s **After storage** *Packaging:* no deviation *Weight loss:* No deviation	

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>Iodine content:
0.22% w/w
Iodide content:
0.11% w/w
Iodate content:
≤0.0005% w/w
Total iodine element content: 0.34% w/w
Appearance: opaque homogeneous brown liquid
Odour: iodine
pH neat: 4.89
Relative density: 1.020
Viscosity 20°C (60rpm):
1.4 mPa.s
Viscosity 40°C (60rpm):
1.0 mPa.s
<u>Active substance decrease during storage: 8.33%w/w</u>

Dip-io 5000
Before storage
Iodine content:
0.49% w/w
Iodide content:
0.42% w/w
Iodate content:
≤0.0012% w/w
Total iodine element content: 0.91% w/w
Appearance: Thick homogeneous brown liquid
Odour: iodine
pH neat: 4.20
Relative density: 1.026
Viscosity in mPa.s
<table>
<tr><td></td><td>20°C</td><td>40°C</td></tr>
<tr><td>rpm</td><td></td><td></td></tr>
<tr><td>6</td><td>4741</td><td>4661</td></tr>
<tr><td>3</td><td>8618</td><td>8508</td></tr>
<tr><td>1.5</td><td>16456</td><td>15727</td></tr>
<tr><td>0.6</td><td>33493</td><td>31068</td></tr>
</table>
After storage
Packaging:
no deviation
Weight loss:0%
Iodine content:
0.47% w/w</td><td></td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>Iodide content:
0.44% w/w
Iodate content:
≤0.0009% w/w
Total iodine element content: 0.90% w/w
Appearance: Thick homogeneous brown liquid
Odour: iodine
pH neat: 4.09
Relative density: 1.030
Viscosity in mPa.s
<table>
<tr><td></td><td>20°C</td><td>40°C</td></tr>
<tr><td>rpm</td><td></td><td></td></tr>
<tr><td>6</td><td>4277</td><td>4297</td></tr>
<tr><td>3</td><td>7708</td><td>7608</td></tr>
<tr><td>1.5</td><td>13387</td><td>13047</td></tr>
<tr><td>0.6</td><td>28794</td><td>25919</td></tr>
</table>
<u>Active substance decrease during storage: 4.08%w/w</u>

Dip-io 2500
Before storage
Iodine content:
0.25% w/w
Iodide content:
0.17% w/w
Iodate content:
≤0.0005% w/w
Total iodine element content: 0.41% w/w
Appearance: Thick homogeneous brown liquid
Odour: Slight iodine
pH neat: 4.76
Relative density: 1.009
Viscosity in mPa.s
<table>
<tr><td></td><td>20°C</td><td>40°C</td></tr>
<tr><td>rpm</td><td></td><td></td></tr>
<tr><td>12</td><td>2385</td><td>2256</td></tr>
<tr><td>6</td><td>4291</td><td>3939</td></tr>
<tr><td>3</td><td>7828</td><td>7653</td></tr>
<tr><td>1.5</td><td>14167</td><td>12517</td></tr>
<tr><td>0.6</td><td>29419</td><td>24670</td></tr>
</table>
After storage
Packaging:
no deviation</td><td></td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>Weight loss:-0.1%
Iodine content:
0.23% w/w
Iodide content:
0.18% w/w
Iodate content:
≤0.0006% w/w
Total iodine element content:
0.41% w/w
Appearance:
Thick homogeneous brown liquid
Odour: Slight iodine
pH neat: 4.66
Relative density: 1.015
Viscosity in mPa.s
<table>
<tr><td></td><td>20°C</td><td>40°C</td></tr>
<tr><td>rpm</td><td></td><td></td></tr>
<tr><td>12</td><td>2260</td><td>2247</td></tr>
<tr><td>6</td><td>4087</td><td>3857</td></tr>
<tr><td>3</td><td>7693</td><td>7523</td></tr>
<tr><td>1.5</td><td>14097</td><td>11748</td></tr>
<tr><td>0.6</td><td>30069</td><td>23995</td></tr>
</table>
<u>Active substance decrease during storage: 8.00%w/w</u>

Liq-io concentrate Before storage
Iodine content:
2.45% w/w
Iodide content:
0.95% w/w
Iodate content:
≤0.005% w/w
Total iodine element content: 3.40% w/w
Appearance: opaque homogeneous brown liquid
Odour: characteristic
pH neat: 3.98
Acidity(neat and 20%): no data
pH 10%: 4.18
pH 20%: 3.95
Relative density: 1.108
Viscosity 20°C (6rpm): 89 mPa.s</td><td></td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Viscosity 40°C (6rpm): 72 mPa.s 54ml after 1 minute *Dilution stability 20%:*No separated material **After storage** *Packaging:* no deviation *Weight loss:* No deviation *Iodine content:* 2.40% w/w *Iodide content:* 1.05% w/w *Iodate content:* ≤0.004% w/w *Total iodine element content:* 3.45% w/w *Appearance:* opaque homogeneous brown liquid *Odour:* characteristic *pH neat:* 3.85 *pH 10%:* 4.13 *pH 20%:* 3.83 *Acidity neat:* 0.34 *Acidity 20%:* 0.07 *Relative density:* 1.109 *Viscosity 20°C (6rpm):* 94 mPa.s *Viscosity 40°C (6rpm):* 76 mPa.s *Dilution stability 20%:*No separated material For all products, the content of the active substance iodine, the packaging materials and all of the physicochemical properties except viscosity are considered as stable. <u>Active substance decrease during storage: 2.04%w/w</u> The viscosity decreases during storage for Liq-io concentrate, Dip-io 2500 and Dip-io 5000. This	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			decrease will, however, not change the application properties and is therefore acceptable. The level of foam generated at in use concentration is too high to use CIPAC MT 47.2. As the product is intended to produce foam, the persistent foaming test was waived. No degradation products of toxicological significance are formed.	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3 7 days at 0°C in HDPE	100% Liq-io 5500 Liq-io 2500 Dip-io 5000 Dip-io 2500 Liq-io concentrate	Appearance of Liq-io 5500, Liq-io 2500, Dip-io 5000, Dip-io 2500, Liq-io concentrate is stable according to the specifications after 7 days storage procedure at 0°C. Liq-io 5500, Liq-io 2500, Dip-io 5000, Dip-io 2500, Liq-io concentrate are stable after 3 freeze/thaw cycles.	Section 3.4 in IUCLID Gougeon. S (2014) Doc 3.4.1-002.1 Doc 3.4.1-002.2 Doc 3.4.1-002.3 Doc 3.4.1-002.4 Doc 3.4.1-002.5
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	Data waived : The effect of light is not relevant because products are stored in opaque packaging, so the products are not in contact with light.	-
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	Data waived : The effect of temperature and humidity is included in the storage stability studies.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			Storage stability tests are conducted in 5L HDPE jerrycans. No change of the packaging (weight, appearance) was observed.	
Wettability	-	-	Data waived : Not applicable because HYPRED's iodine based products are liquid products	-
Suspensibility, spontaneity and dispersion stability	-	-	Data waived : Not applicable because HYPRED's iodine based products are liquid products	-
Wet sieve analysis and dry sieve test	-	-	Data waived : Not applicable because HYPRED's iodine based products are liquid products	-
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Data waived : Not applicable because HYPRED's iodine based products are liquid products	-
Disintegration time	-	-	Data waived : Not applicable because HYPRED's iodine based products are liquid products	-
Particle size distribution, content of dust/fines, attrition, friability	-	-	Data waived : HYPRED's iodine based products are liquid products. Although some of the products may be used in spray applications, the products are not sold in or together with spraying equipment which makes it not possible to test the equipment that is actually used. Moreover, the risk assessment is based on the assumption that there will be only large droplets present upon	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			use and information on particle size is not needed to complete the risk assessment.	
Persistent foaming	-	-	Liq-io concentrate at 10 and 20% v/v : The level of foam generated at in use concentration is too high to use CIPAC MT 47.2. As the product is intended to produce foam, the persistent foaming test was waived. Not relevant for ready to use liquid included in HYPRED's iodine based products family (Liq-io 5500, Liq-io 2500, Dip-io 2500, Dip-io 5000)	-
Flowability/Pourability/Dustability	-	-	Data waived : Not applicable because HYPRED's iodine based products are liquid products	-
Burning rate — smoke generators	-	-	Data waived : Not applicable data.	-
Burning completeness — smoke generators	-	-	Data waived : Not applicable data.	-
Composition of smoke — smoke generators	-	-	Data waived : Not applicable data.	-
Spraying pattern — aerosols	-	-	Data waived : Not applicable because HYPRED's iodine based products are not stored in aerosols.	-
Physical compatibility	-	-	Data waived : Not relevant because HYPRED's iodine based products are not co-applied with other substances, mixtures or products	-
Chemical compatibility	-	-	Data waived : Not relevant because HYPRED's iodine based products are not co-	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			applied with other substances, mixtures or products	
Degree of dissolution and dilution stability	CIPAC MT41	Liq-io concentrate at 20% v/v	Liq-io concentrate diluted at 20 % (v/v) in standard water C is stable over 18h at 20 ± 2 °C. Liq-io concentrate is the only product in *meta* SPC 3 and the only product in the family which is not ready to use. 20% v/v is the highest in use concentration. Therefore the provided data are representative for the family. Not relevant for ready to use liquid included in HYPRED's iodine based products family. (Liq-io 5500, Liq-io 2500, Dip-io 2500, Dip-io 5000)	Section 3.5 in IUCLID Gougeon. S (2014) Doc 3.5-003
Surface tension	OECD 115	100% for ready to use formula (Liq-io 5500, Liq-io 2500, Dip-io 5000, Dip-io 2500) 10% v/v, 20 % v/v and 100% for concentrate formula (Liq-io concentrate)	Liq-io 5500 (pure) : 32.9 mN/m ± 0.2 mN/m at 20.0 °C Liq-io 2500 (pure) : 33.3 mN/m ± 0.3 mN/m at 20.3 °C Dip-io 5000 (pure) : 38 mN/m ± 0.2 mN/m at 20.0 °C Dip-io 2500 (pure) : 38.4 mN/m ± 0.2 mN/m at 20.2 °C Liq-io concentrate (pure) : 32.0 mN/m ± 0.2 mN/m at 20.1 °C. Liq-io concentrate (20% v/v) : 34.7 mN/m ± 0.1 mN/m at 20.1 °C. Liq-io concentrate (10% v/v) : 35 mN/m ± 0.2 mN/m at 20 °C.	Section 3.8 in IUCLID Demangel. B (2014) Doc 3.8-001 Doc 3.8-002 Doc 3.8-003 Doc 3.8-004 Doc 3.8-005

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			HYPRED's iodine based products were considered as surface-active.	
Viscosity	OECD114	100% Liq-io 5500 Liq-io 2500 Dip-io 5000 Dip-io 2500 Liq-io concentrate	Dynamic viscosity <u>Liq-io 5500 :</u> 1.73 mPa.s ± 0.02 mPa.s at 20.0 °C ± 0.2 °C 1.12 mPa.s ± 0.02 mPa.s at 40.0 °C ± 0.2 °C. <u>Liq-io 2500 :</u> 1.51 mPa.s ± 0.02 mPa.s at 20.0 °C ± 0.2 °C 1.16 mPa.s ± 0.02 mPa.s at 40.0 °C ± 0.2 °C <u>Liq-io concentrate :</u> 113 mPa.s at 20.0 °C ± 0.2 °C 50.9 mPa.s at 40.0 °C ± 0.2 °C. Taking into account the results obtained at 20.0 °C and 40.0 °C, Liq-io 5500, Liq-io 2500 and Liq-io concentrate were considered to have newtonian properties in the experimental conditions used. <u>Dip-io 5000 and Dip- io 2500 :</u> The dynamic viscosity (η) of Dip-io 5000 and Dip-io 2500, measured at 20.0 ± 0.2 °C and 40.0 ± 0.2 °C, varies with the shear rate. Taking into account the results obtained at 20.0 and 40.0 °C, Dip-io 5000 and Dip-io 2500 are considered to have non Newtonian properties.	Section 3.9 in IUCLID Demangel. B (2015) Doc 3.9-001 Doc 3.9-002 Doc 3.9-005 Gougeon. S (2014) Doc 3.9-003 Doc 3.9-004

Based on the long term stability data a shelf life of 2 years in HDPE is supported for all products in the family. Accelerated storage stabilities were performed during 18 weeks at 30°C. Therefore The sentence 'Do not store at a temperature higher than 30°C' will be included in the storage conditions.

Representativeness of data for the family
The provided data are considered to cover the complete family including non-existing theoretical products.

2.3.2 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	-	-	Data waived : Not applicable because HYPRED's iodine based products don't contain substances classified as explosive.	-
Flammable gases	-	-	Data waived : Not applicable because HYPRED's iodine based products are not gases.	-
Flammable aerosols	-	-	Data waived : Not applicable because HYPRED's iodine based products are not aerosols.	-
Oxidising gases	-	-	Data waived : Not applicable because HYPRED's iodine based products are not gases	-
Gases under pressure	-	-	Data waived : Not applicable because HYPRED's iodine based products are not gases	-
Flammable liquids	-	-	Data waived : Not applicable because HYPRED's iodine based products don't contain substances	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			classified as flammable.	
Flammable solids	-	-	Data waived : Not applicable because HYPRED's iodine based products are not solids	-
Self-reactive substances and mixtures	-	-	Data waived : Not applicable because HYPRED's iodine based products are not self-reactive mixtures	-
Pyrophoric liquids	-	-	Data waived : Not applicable because HYPRED's iodine based products are not pyrophoric liquid.	-
Pyrophoric solids	-	-	Data waived : Not applicable because HYPRED's iodine based products are not solids	-
Self-heating substances and mixtures	-	-	Data waived : Not applicable because HYPRED's iodine based products are not self-heating mixtures	-
Substances and mixtures which in contact with water emit flammable gases	-	-	Data waived : Not applicable because HYPRED's iodine based products are not mixtures which in contact with water emit flammable gases.	-
Oxidising liquids	-	-	Data waived : Not applicable because HYPRED's iodine based products don't contain substances classified as oxidizing.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Oxidising solids	-	-	Data waived : Not applicable because HYPRED's iodine based products are not solids	-
Organic peroxides	-	-	Data waived : Not applicable because HYPRED's iodine based products are not organic peroxides.	-
Corrosive to metals	UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Test C.1.	100% Dip-io 5000 Liq-io concentrate	Dip-io 5000: Tested during 28 days. Test material: steel (type S275JR) and aluminium (type 7075-T6 non-clad) The percentage mass losses on steel and aluminium were found to be < 51.5 % over 28 days and the maximum pit depth on the aluminium / steel coupons was < 480 µm. The sample is therefore exempt from classification as a corrosive substance of UN Class 8, Packing group III (according to the UN Transport of Dangerous Goods Recommendations). DIP IO 5000 is considered as a worst case regarding all other products which are ready to use with pH > 4.5.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Liq-io concentrate: Tested during 7 and 28 days. Test material: steel (type S275JR) and aluminium (type 7075-T6 non-clad) Results 7 days: The percentage mass losses on steel and aluminium were found to be < 13.5 % over 7 days, however, the maximum pit depth on the aluminium and steel coupons was > 120 µm. The sample is therefore a candidate for classification as a corrosive substance of UN Class 8, Packing group III (according to the UN Transport of Dangerous Goods Recommendations) . Results 28 days: The percentage mass losses on steel and aluminium were found to be < 51.5 % over 28 days, however, the maximum pit depth on the aluminium and steel coupons was > 480 µm. The sample is therefore a candidate for classification as a corrosive substance of UN Class 8, Packing group III	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			(according to the UN Transport of Dangerous Goods Recommendations)	
Auto-ignition temperatures of products (liquids and gases)	-	-	Data waived : Not applicable because HYPRED's iodine based products are not ignited with a hot surface.	-
Relative self-ignition temperature for solids	-	-	Data waived : Not applicable because HYPRED's iodine based products are not solids	-
Dust explosion hazard	-	-	Data waived : Not applicable because HYPRED's iodine based products are liquid.	-

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 (n)		
Active substance Iodine	Potentiometric method at pH=5 HYPRED's method AL213 (for Liq-io concentrate) HYPRED's method AL214 (for Liq-io 5500, Liq-io 2500, Dip-io 5000, Dip-io 2500)	pH5 buffer: solution: 4g/L sodium iodate (20mmol/L) (n=10)	Not applicable The consumed volume in titration is directly related to the amount of analyte in the test solution. A calibration where a technical signal is related to a concentration is not applicable for titration methods.	The titration of Iodine with sodium thiosulphate is specific for Iodine at pH 5 Experiment was performed in the presence of 1.8g/200 mL alcohol ethoxylate to investigate interference.	99.0 – 99.7	99.4	0.15 (10)	Not relevant: The purpose of method is the determination of Iodine in biocidal products and not the determination of residues of Iodine in specific media. AL213 method covers iodine products containing >= 1% iodine AL214 method covers iodine products containing 0.2 to 1% w/w iodine	Ladril.S Doc 5-001 Doc 5-002 Doc 5-003
Iodate	Potentiometric method at acid pH HYPRED's method AL213 (for Liq-io concentrate) HYPRED's method AL214 (for Liq-io 5500, Liq-io 2500, Dip-io 5000, Dip-io 2500)	Strong acid medium (I_2+IO_3^-): 4g/L sodium iodate (20mmol/L) solution (n=10)	Not applicable The consumed volume in titration is directly related to the amount of analyte in the test solution. A calibration where a technical signal is related to a concentration is not applicable for titration methods.	Yes Iodates are taken into account in a strong acid medium Experiment was performed in the presence of 1.8g/200 mL alcohol ethoxylate to investigate interference.	99.7 – 100.4	100.1	0.25 (10)	Not relevant Concentration of iodates is linked to the concentration in iodine at pH=5 The purpose of method is the determination of Iodine + iodates in biocidal products and not the determination of residues in specific media.	Ladril.S Doc 5-001 Doc 5-002 Doc 5-003

Co-formulant: iodide	HPLC method HYPRED's method AL215	8.32 - 99.84 mg/L (n=5)	Yes : The method is linear $r^2 > 0.999$ Tested concentration range: 5.17- 103.40 mg/L (n=5)	Yes : The method is specific to iodides	97 - 102.1	100.3	1.8 (5)	LOQ = first standard level: 5 mg/l	Ladril.S Doc 5-004 Doc 5-005

Principle of the method AL213 and AL214
Quantification of iodine I_2 and iodate IO_3^- content in HYPRED's iodine based products by potentiometric titration under two pH conditions: Buffered medium pH = 5 for I_2 only and strong acid medium for I_2 + IO_3^-, so IO_3^- content is obtained by subtraction. AL 213 method applies to products containing more than 1% I_2 (Liq-io concentrate). AL 214 method applies to products containing less than 1% I_2 (Liq-io 5500, Liq-io 2500, Dip-io 5000, Dip-io 2500)

Principle of the method AL215
The iodine products contain, among other things, iodine and iodide. The quantification of iodide by HPLC is disturbed by the presence of iodine. By reducing the iodine I_2 into I^- the total iodides in the sample can be dosed by adding sodium thiosulphate. The dosed iodides therefore correspond to the total iodides. To determine the I^- content initially present, the I_2 content (potentiometric dosing - see method AL 213 or AL 214) has to be known and obtained by difference.

Sample preparation
Method AL 213
Quantification in buffered medium pH = 5 (I_2 only)
Dependant on the expected amount of I_2 1 or 3g sample is used. 250 mL acetate buffer (pH 5) is added and the mixture is stirred.
Quantification in strong acid medium (I_2 + IO_3^-)
Dependant on the expected amount of I_2 1 or 3g sample is used. 200 mL demineralised water is added. Subsequently 10 mL H_2SO_4 5N is added and the mixture is stirred.
Method AL 214
Quantification in buffered medium pH = 5 (I_2 only)
Dependant on the expected amount of I_2 20 or 10g sample is used. 250 mL acetate buffer (pH 5) is added and the mixture is stirred.
Quantification in strong acid medium (I_2 + IO_3^-)
Dependant on the expected amount of I_2 20 or 10g sample is used. 200 mL demineralised water is added. Subsequently 10 mL H_2SO_4 5N is added and the mixture is stirred.
Method AL 215
Quantification of I^-
Dependant on the expected amount of I^- 0.2, 1, 4 or 8g sample is used. The vial is filled up to 100ml with ultra pure water. The mixture is well mixed. 0.2 mL of $Na_2S_2O_3$ 0.1 N is added to 1ml of the previous solution and filled up to 10ml with ultra pure water.

Iodine precision
The precision for iodine was determined by using 10 samples of two formulations and calculating the corresponding RSD (0.10% for high iodine, 0.2% for low iodine), compared to the RSDr (0.94% for high iodine, 1.65% for low iodine). In addition, the low iodine formulation was additionally tested under strong acid conditions, resulting in an %RSD of 0.1 (n=10, RSDr = 1.65%).

Iodate precision
See iodine (iodate is calculated by subtraction)

Iodide precision
The precision for iodide was determined by injecting 10 samples of two concentrations of two products and calculating the corresponding RSD compared to the RSDr.

	Concentration product in solution	% RSD	% RSD_r
Liq-io concentrate	1.0843g/100 mL	0.3	2.23
	2.0022g/100 mL	0.3	2.23
Dip-io 2500	4.1415g/50 mL	2.2	3.05
	8.0273g/50 mL	0.4	3.05

Conclusion
The provided analytical methods are sufficiently validated and fit for purpose.

Analytical methods for monitoring (see methods described in detail in the CAR, Dec. 2013, Doc III A4.2):

- Soil: Not required, however analytical methods for determination of iodine in soil are presented in CAR.
- Air:
  - Dipping/foaming use scenarios: Not relevant, however analytical methods for determination of iodine in air are presented in CAR.
  - Spraying use scenarios: May be relevant for workers exposure in spray application. Analytical methods for determination of iodine in air are presented in CAR.
- Water: Analytical methods for determination of iodine in water are presented in CAR.
- Animal and human body fluids and tissues: Not required, active substance not classified as toxic or very toxic.

Analytical methods for monitoring of active substances and residues in food and feeding stuff (see methods described in detail in the CAR, Dec. 2013, Doc III A4.3):
Analytical methods for determination of iodine residues in milk are presented in CAR.

Representativeness of data for the family
The provided data are considered to cover the entire family.

2.3.4 Efficacy against target organisms

A. FUNCTION AND FIELD OF USE

Function :

The products in this family are teat disinfectants to be used either before or after milking on milk producing animals. All pre-milking products in the family have bactericidal and yeasticidal effect. All post-milking products in the family have bactericidal, yeasticidal, and algaecidal effect. Post-milking products with 0.5% iodine and more (*meta* SPC 3, 4, 5) also have virucidal effect.

Field of use :

PT3: Teat disinfection of milk producing animals
Indoor use.
The family contains ready to use products and concentrated products.

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

B. Organisms to be controlled:

Bacteria, Yeasts, Algae, Viruses.
An algicidal claim was made for the use against the algae *Prototheca.* These are colourless algae that can cause mastitis in dairy cattle.
All pre-milking products in the family have bactericidal and yeasticidal effect (*meta* SPC 2, 3, 5).
All post-milking products in the family have bactericidal, yeasticidal, and algaecidal effect (*meta* SPC 1, 2, 3, 4, 5).
Post-milking products with 0.5% iodine and more (*meta* SPC 3, 4, 5) also have virucidal effect.

C. EFFECTS ON TARGET ORGANISMS, INCLUDING UNACCEPTABLE SUFFERING

The efficacy of iodine as a biocide has been demonstrated over 170 years of use. Iodine has a killing effect on the target organisms.

D. MODE OF ACTION, INCLUDING TIME DELAY

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

Time delay: There is no time delay. The products used before milking are efficacious in 1 minute and the products used after milking are efficacious in 5 minutes.

E. EFFICACY DATA

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Bactericide	PT 3 Ready to use	Liq-io 5500	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN1656	1 min contact time, 30°C In presence of skimmed milk 1% Concentration tested : 1, 5, 20, 50, 80 % v/v	Liq-io 5500 is bactericidal at 5% w/w	AF.Gabillet Doc 6.7-001.1
Yeasticide	PT 3 Ready to use	Liq-io 5500	*Candida albicans*	EN1657	1 min contact time, 30°C In presence of skimmed milk 1% Concentration tested : 1, 5, 20, 50, 80 % v/v	Liq-io 5500 is yeasticidal at 5% w/w	M.Teulier Doc 6.7-001.2
Virucide	PT 3 Ready to use	Liq-io 5500	ECBO	EN14675 (2013*)	5 min contact time, 30°C In presence of skimmed milk 1% Concentration tested : 1, 5, 10, 20 % v/v	Liq-io 5500 is virucidal at 5% w/w	JP.Chiron Doc 6.7-001.3
Virucide	PT 3 Ready to use	Liq-io 5500	Vaccinia virus (orthopox virus)	EN14675 (2013*)	5 min contact time, 30°C In presence of skimmed milk 1% Concentration tested : 10, 20, 30, 40 % v/v	Liq-io 5500 is virucidal at 30% v/v	JP.Chiron Doc 6.7-001.3
Bactericide	PT 3 Ready to use	Liq-io 5500	*Listeria monocytogenes Streptococcus agalactiae*	EN1656	1 min contact time, 30°C In presence of skimmed milk 1% Concentration tested : 1, 2, 3, 50, 80 % v/v	Liq-io 5500 is bactericidal against *Listeria monocytogenes and Streptococcus agalactiae* at 3% v/v	AF.Gabillet Doc 6.7-001.4
Algaecide	PT 3 Ready to use	Liq-io 5500	*Prototheca wickerhamii***	EN1657	1 min contact time, 30°C In presence of skimmed milk 1% Concentration tested : 1, 2, 3, 50, 80 % v/v	Liq-io 5500 is algaecidal against *Prototheca wickerhamii* at 50% v/v	AF.Gabillet Doc 6.7-001.5

Bactericide	PT 3 Ready to use	Liq-io 2500	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN1656	1 min contact time, 30°C In presence of skimmed milk 1% Concentration tested : 5, 35, 50, 65, 80 % v/v	Liq-io 2500 is bactericidal at 35% v/v	M.Teulier Doc 6.7-002.1
Bactericide	PT 3 Ready to use	Liq-io 2500	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN1656	1 min contact time, 30°C In presence of 3g/L Bovine albumin Concentration tested : 0.1, 80 % v/v	Liq-io 2500 is bactericidal at 80% v/v	AF.Gabillet Doc 6.7-002.5
Yeasticide	PT 3 Ready to use	Liq-io 2500	*Candida albicans*	EN1657	1 min contact time, 30°C In presence of skimmed milk 1% Concentration tested : 5, 35, 50, 65, 80 % v/v	Liq-io 2500 is yeasticidal at 5% v/v	AF.Gabillet Doc 6.7-002.2
Yeasticide	PT 3 Ready to use	Liq-io 2500	*Candida albicans*	EN1657	1 min contact time, 30°C In presence of 3g/L Bovine albumin Concentration tested : 0.1, 80 % v/v	Liq-io 2500 is yeasticidal at 80% v/v	AF.Gabillet Doc 6.7-002.6
Bactericide	PT 3 Ready to use	Liq-io 2500	*Listeria monocytogenes Streptococcus agalactiae*	EN1656	1 min contact time, 30°C In presence of skimmed milk 1% Concentration tested : 1, 2, 5, 10, 80 % v/v	Liq-io 2500 is bactericidal against *Listeria monocytogenes and Streptococcus agalactiae* at 10% v/v	M.Teulier Doc 6.7-002.3
Algaecide	PT 3 Ready to use	Liq-io 2500	*Prototheca wickerhamii***	EN1657	1 min contact time, 30°C In presence of skimmed milk 1% Concentration tested : 5, 8, 10, 20, 80 % v/v	Liq-io 2500 is algaecidal against *Prototheca wickerhamii* at 8% v/v	AF.Gabillet Doc 6.7-002.4
Bactericide	PT 3 Ready to use	Dip-io 5000	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN1656	5 min contact time, 30°C In presence of skimmed milk 1% Concentration tested : 1, 5, 20, 50, 80 % v/v	Dip-io 5000 is bactericidal at 5% v/v	M.Teulier Doc 6.7-003.1
Yeasticide	PT 3	Dip-io 5000	*Candida albicans*	EN1657	5 min contact time 30°C	Dip-io 5000 is yeasticidal at 5% v/v	M.Teulier Doc 6.7-003.2

	Ready to use				In presence of skimmed milk 1% Concentration tested : 1, 5, 20, 50, 80 % v/v		
Virucide	PT 3 Ready to use	Dip-io 5000	ECBO	EN14675	5 min contact time 30°C In presence of skimmed milk 1% Concentration tested : 1, 2.5, 5, 30, 70, 97 % v/v	Dip-io 5000 is virucidal at 5% v/v	JP.Chiron Doc 6.7-003.3
Virucide	PT 3 Ready to use	Dip-io 5000	Vaccinia virus (orthopox virus)	EN14675	5 min contact time 30°C In presence of skimmed milk 1% Concentration tested : 30, 50, 80, 97 % v/v	Dip-io 5000 is virucidal at 97% v/v	JP.Chiron Doc 6.7-003.3
Bactericide	PT 3 Ready to use	Dip-io 2500	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN1656	5 min contact time, 30°C In presence of skimmed milk 1% Concentration tested : 5, 35, 50, 65, 80 % v/v	Dip-io 2500 is bactericidal at 5% v/v	M.Teulier Doc 6.7-004.1
Yeasticide	PT 3 Ready to use	Dip-io 2500	*Candida albicans*	EN1657	5 min contact time, 30°C In presence of skimmed milk 1% Concentration tested : 5, 35, 50, 65, 80 % v/v	Dip-io 2500 is yeasticidal at 5% v/v	A.F Gabillet Doc 6.7-004.2
Bactericide	PT 3 Ready to use	Dip-io 2500	*Listeria monocytogenes Streptococcus agalactiae*	EN1656	5 min contact time, 30°C In presence of skimmed milk 1% Concentration tested : 1, 2, 5, 10, 80 % v/v	Dip-io 2500 is bactericidal against *Listeria monocytogenes and Streptococcus agalactiae* at 5% v/v	A.F Gabillet Doc 6.7-004.3
Algaecide	PT 3 Ready to use	Dip-io 2500	*Prototheca wickerhamii***	EN1657	5 min contact time, 30°C In presence of skimmed milk 1% Concentration tested : 3, 5, 8, 15, 80 % v/v	Dip-io 2500 is algaecidal against *Prototheca wickerhamii* at 8% v/v	AF.Gabillet Doc 6.7-004.4

Bactericide	PT 3 Concentrated liquid to be diluted at 10% or 20 % for bactericidal activity	Liq-io concen-trate	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN1656	1 min contact time, 30°C In presence of skimmed milk 1% Concentration tested : 0.2, 1, 5, 10, 20 % v/v	Liq-io concentrate is bactericidal at the concentration of 1% v/v	AF.Gabillet Doc 6.7-005.1
Bactericide	PT 3 Concentrated liquid to be diluted at 10% or 20 % for bactericidal activity	Liq-io concen-trate	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN1656	1 min contact time, 30°C In presence of 3g/L Bovine albumin Concentration tested : 0.1, 10 % v/v	Liq-io concentrate is bactericidal at the concentration of 10% v/v	AF.Gabillet Doc 6.7-005.4
Yeasticide	PT 3 Concentrated liquid to be diluted at 10% or 20 % for yeasticidal activity	Liq-io concen-trate	*Candida albicans*	EN1657	1 min contact time, 30°C In presence of skimmed milk 1% Concentration tested : 0.2, 1, 5, 10, 20 % v/v	Liq-io concentrate is yeasticidal at the concentration of 1% v/v	M.Teulier Doc 6.7-005.2
Yeasticide	PT 3 Concentrated liquid to be diluted at 10% or 20 % for yeasticidal activity	Liq-io concen-trate	*Candida albicans*	EN1657	1 min contact time, 30°C In presence of 3g/L Bovine albumin Concentration tested : 0.1, 10 % v/v	Liq-io concentrate is yeasticidal at the concentration of 10% v/v	M.Teulier Doc 6.7-005.5
Virucide	PT 3 Concentrated liquid to be diluted at 20 % for virucidal activity	Liq-io concen-trate	ECBO	EN14675	5 min contact time, 30°C In presence of skimmed milk 1% Concentration tested : 0.2, 0.5, 1, 2 % v/v	Liq-io concentrate is virucidal at the concentration of 1% v/v	JP.Chiron Doc 6.7-005.3
Virucide	PT 3 Concentrated liquid to be diluted at 20 % for virucidal activity	Liq-io concen-trate	Vaccinia virus (orthopox virus)	EN14675	5 min contact time, 30°C In presence of skimmed milk 1% Concentration tested : 2, 5, 10, 20 % v/v	Liq-io concentrate is virucidal at the concentration of 20% v/v	JP.Chiron Doc 6.7-005.3
Bactericide	PT 3 Ready to use	Liq-io 2500	*Staphylococcus aureus*	LMH modified EN16437 (Drop/Dip)	5 minutes contact time, 30°C In presence of skimmed milk 1%	Liq-io 2500 presents a logarithmic reduction of 4.64	AF.Gabillet Doc 6.7-007.1

					Concentration tested : 100 % v/v		
Bactericide	PT 3 Ready to use	Liq-io 2500	*Staphylococcus aureus*	LMH modified EN16437 (Drop/Dip)	30 seconds contact time, 30°C In presence of skimmed milk 1% Concentration tested : 100 % v/v	Liq-io 2500 presents a logarithmic reduction of 3.24 ***	AF.Gabillet Doc 6.7-007.2
Bactericide	PT 3 Ready to use	Liq-io 2500	*Staphylococcus aureus, Escherichia coli, Streptococcus uberis*	LMH modified EN16437 (Drop/Dip)	1 minute contact time, 30°C in presence of 3 g/l albumin bovine Concentration tested : 100 % v/v	Liq-io 2500 presents a logarithmic reduction of 4.75	AF.Gabillet Doc 6.7-007.4
Yeasticide	PT 3 Ready to use	Liq-io 2500	*Candida albicans*	LMH modified EN16437 (Drop/Dip)	1 minute contact time, 30°C In presence of 3 g/l albumin bovine Concentration tested : 100 % v/v	Liq-io 2500 presents a logarithmic reduction of 4.04	AF.Gabillet Doc 6.7-007.5

***:** The test with Liq-io 5500 was performed in September 2014 with the validation protocol according to the 2013 version of EN14675. This test was accepted since only in November 2014 the draft EN 14675 included a new step of validation. DIP IO 5000 tested in December 2014 with this new validation step.

****:** There are no standard test organisms for mastitis causing algae. Only algae from the genus Prototeca (an unicellular alga that does not have any chloroplast, with a macroscopic morphology close to the yeasts) are known to cause mastitis, e.g. *P. zopfii* and *P. wickerhamii*. Therefore, the tests with this organism were considered relevant and the tests were accepted.

*****:** This test doesn't show sufficient log reduction at 30 seconds contact time, however, this contact time/soiling combination is not relevant for the intended use (post-milking disinfection).

Conclusion on the efficacy of the product

General conclusions on the biocidal product family.

This biocidal product family of teat disinfectants consists of 5 *meta* SPC's. The active substance of this family is Iodine. For the different *meta* SPC's efficacy test data have been submitted. Depending on the intended use, pre or after milking disinfection of teats, efficacy tests under different conditions (3g/L Bovine albumin or skimmed milk 1% resp.) have been submitted.
The tests demonstrated the following:

- All pre-milking products in the family have bactericidal and yeasticidal effect at minimal contact time of 1 minute (*meta* SPC 2, 3, 5).
- All post-milking products in the family have bactericidal, yeasticidal, and algaecidal effect at minimal contact time of 5 minute (*meta* SPC 1, 2, 3, 4, 5). Efficacy at a contact time of 1 minute with milk soiling was not fully demonstrated since a phase2, step2 test at 30 seconds did not pass the 4 log reduction criterion (lg red=3.24). Only the test with 5 min contact time did, 1 min was not tested.

- Post-milking products with 0.5% iodine and more (*meta* SPC 3, 4, 5) also have virucidal effect at minimal contact time of 5 minutes.

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.

Conclusion at *meta* SPC level

Some tests (simulated-use tests, virus tests) have only been done with one or two products. For bactericidal, algaecidal, yeasticidal efficacy testing Liq-io 2500 can be seen as the worst case test product for this family, since it contains the lowest concentration of iodine and of the co-formulants that might have a slight positive effect on the efficacy. Therefore, test results with Liq-io 2500 against *Prototheca wickerhamii* can be waived for all other *meta* SPC's.
According to discussions in the WG efficacy the modified EN16437 can be performed with *S. aureus* only, as worst-case test organism. Therefore, data with other bacteria have been waived for these tests.
Tests are available in all conditions mandatory for supported uses.
For virucidal activity, products claiming this activity have been individually tested and support *meta* SPC 3, 4 and 5.

***meta* SPC 1 (Dipping products – Ready to use)**
Ready-to-use disinfectant intended to disinfect the teats **after milking** (bactericidal; yeasticidal; algaecidal).
- *meta* SPC 1 products are bactericidal in presence of skimmed milk 1% for 5 minutes contact time at 30°C towards the strains *Escherichia coli, Staphylococcus aureus, Streptococcus uberis, Listeria monocytogenes, Streptococcus agalactiae*
- *meta* SPC 1 products are yeasticidal in presence of skimmed milk 1% for 5 minutes contact time at 30°C towards *Candida albicans*,
- *meta* SPC 1 products are algaecidal in presence of skimmed milk 1% for 5 minutes contact time at 30°C towards *Prototheca wickerhamii*

***meta* SPC 2 (Dipping, spraying, foaming products – Ready to use)**
Ready-to-use disinfectant intended to disinfect the teats:
before milking (bactericidal, yeasticidal) or
after milking (bactericidal, yeasticidal, algaecidal).
2.1 For before milking:

- *meta* SPC 2 products are bactericidal in presence of albumin bovine 3g/l for 1 minute contact time at 30°C towards the strains *Escherichia coli, Staphylococcus aureus, Streptococcus uberis*
- *meta* SPC 2 products are yeasticidal in presence of albumin bovine 3 g/l for 1 minute contact time at 30°C towards *Candida albicans*

2.2 For after milking:
- *meta* SPC 2 products are bactericidal in presence of skimmed milk 1% for 1 minute contact time at 30°C towards the strains *Escherichia coli, Staphylococcus aureus, Streptococcus uberis, Listeria monocytogenes, Streptococcus agalactiae*
- *meta* SPC 2 products are yeasticidal in presence of skimmed milk 1% for 1 minute contact time at 30°C towards *Candida albicans*,
- *meta* SPC 2 products are algaecidal in presence of skimmed milk 1% for 1 minute contact time at 30°C towards *Prototheca wickerhamii*

***meta* SPC 3 (Dipping, spraying, foaming - Concentrated products)**
Concentrated disinfectant
Intended to disinfect the teats before or after milking:
before milking (bactericidal, yeasticidal), to be diluted at 10% v/v or
after milking (bactericidal; yeasticidal; algaecidal), to be diluted at 10% v/v
after milking (virucidal activity), to be diluted at 20% v/v.

3.1 For before milking:
- *meta* SPC 3 products are bactericidal in presence of albumin bovine 3g/l for 1 minute contact time at 30°C towards the strains *Escherichia coli, Staphylococcus aureus, Streptococcus uberis* at the concentration of 10% v/v and 20% v/v
- *meta* SPC 3 products are yeasticidal in presence of albumin bovine 3 g/l for 1 minute contact time at 30°C towards *Candida albicans* at the concentration of 10 % v/v and 20 % v/v

3.2 For after milking:
- *meta* SPC 3 is bactericidal in presence of skimmed milk 1% for 1 minute contact time at 30°C towards the strains *Escherichia coli, Staphylococcus aureus, Streptococcus uberis, Listeria monocytogenes, Streptococcus agalactiae* at the concentration of 10% v/v and 20% v/v
- *meta* SPC 3 is yeasticidal in presence of skimmed milk 1% for 1 minute contact time at 30°C towards *Candida albicans* at the concentration of 10 % v/v and 20 % v/v
meta SPC 3 is algaecidal in presence of skimmed milk 1% for 1 minute contact time at 30°C towards *Prototheca wickerhamii* at the concentration of 10 % v/v and 20 % v/v
- *meta* SPC 3 is virucidal in presence of skimmed milk 1% for 5 minutes contact time at 30°C towards ECBO virus and Orthopox virus at the concentration of 20%.

***meta* SPC 4 (Dipping products with virucidal activity– Ready to use)**
Ready-to-use disinfectant bactericidal; yeasticidal; algaecidal and virucidal intended to disinfect the teats after milking.
- *meta* SPC 4 products are bactericidal in presence of skimmed milk 1% for 5 minutes contact time at 30°C towards the strains *Escherichia coli, Staphylococcus aureus, Streptococcus uberis, Listeria monocytogenes, Streptococcus agalactiae*
- *meta* SPC 4 products are yeasticidal in presence of skimmed milk 1% for 5 minutes contact time at 30°C towards *Candida albicans*,
- *meta* SPC 4 products are algaecidal in presence of skimmed milk 1% for 5 minutes contact time at 30°C towards *Prototheca wickerhamii*
- *meta* SPC 4 products are virucidal in presence of skimmed milk 1% for 5 minutes contact time at 30°C towards ECBO virus and Orthopox virus

***meta* SPC 5 (Dipping, spraying, foaming products 5500 ppm – Ready to use) Ready-to-use disinfectant** intended to disinfect the teats before milking or after milking:
before milking (bactericidal, yeasticidal), or
after milking (bactericidal, yeasticidal, algaecidal, virucidal activity).

5.1 For pre-milking:
- *meta* SPC 5 products are bactericidal in presence of albumin bovine 3g/l for 1 minute contact time at 30°C towards the strains *Escherichia coli, Staphylococcus aureus, Streptococcus uberis*
- *meta* SPC 5 products are yeasticidal in presence of albumin bovine 3 g/l for 1 minute contact time at 30°C towards *Candida albicans*

5.2 For after milking:
- *meta* SPC 5 products are bactericidal in presence of skimmed milk 1% for 1 minute contact time at 30°C towards the strains *Escherichia coli, Staphylococcus aureus, Streptococcus uberis, Listeria monocytogenes, Streptococcus agalactiae*
- *meta* SPC 5 products are yeasticidal in presence of skimmed milk 1% for 1 minute contact time at 30°C towards *Candida albicans*,
- *meta* SPC 5 products are algaecidal in presence of skimmed milk 1% for 1 minute contact time at 30°C towards *Prototheca wickerhamii*
- *meta* SPC 5 products are virucidal in presence of skimmed milk 1% for 5 minutes contact time at 30°C towards ECBO virus and Orthopox virus

F. OCCURRENCE OF RESISTANCE AND RESISTANCE MANAGEMENT

Taking into account the mode of action of iodine which is non-selective, development of resistance against HYPRED's iodine based products is unlikely.
Iodine / iodophors have been used for over 170 years as disinfectants for a variety of applications. Such applications include disinfection of teats and udder for milkable animals. No reduction in efficacy was reported for such applications indicating that no development of resistant microorganisms or viruses has occurred.

G. KNOWN LIMITATIONS

Not relevant.
No limitation of efficacy has been observed following use of iodine based products for the disinfection of teats or udder for milkable animals.

H. EVALUATION OF THE LABEL CLAIMS

Label claim of each product including in HYPRED's iodine based products family are presented below. For each *Meta* SPC the target organisms, contact time and mode of application are described.

***Meta* SPC 1 :**

Meta SPC 1 is a ready-to-use disinfectant intended to disinfect the teats of milk producing animals after milking.
The product is efficacious against bacteria, yeasts, and algae.
Quick action: Bactericidal, yeasticidal and algaecidal in 5 minutes.

Instruction for use :
Always read the label or leaflet before use and follow all the instructions provided.
The product must be brought to a temperature above 20°C before use.
The use of a dosing pump for filling the product into the application equipment is recommended.
Fill the dipping cup manually or automatically with the ready to use product.
Apply by dipping manually or automatically on animal's teats on the full length of the teat after milking.
- cows and buffaloes (3 to 10ml: 5 ml recommended)
- sheep (1.5 to 5 ml: 1.5 ml recommended)
- goats (2.5 to 6 ml: 2.5 ml recommended)

Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).

At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.
Where necessary, repeat the application after each milking.
Clean the application equipment regularly with warm water.

***Meta* SPC 2:**

Meta SPC 2 is a ready-to-use disinfectant intended to disinfect the teats of milk producing animals, either before milking or after milking.
The product is efficacious against bacteria, yeasts, when used before milking.
The product is efficacious against bacteria, yeasts, and algae when used after milking.
Quick action: Efficacious in 1 minute before milking and 5 minutes after milking.

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

Before milking:
Fill the dipping/foaming cup/sprayer manually or automatically with the ready to use product.
Eliminate all visible dirt before applying the product.
Manual or automatic dipping/spraying/foaming on animal's teats on the full length of the teat. (consult table for recommended application rate)
Let the product act at least one minute.
Use the teat cleaning and wiping method systematically before attaching the milking cluster.

After milking:
Fill the dipping / foaming cup/ sprayer manually or automatically with the ready to use product.
Manual or automatic dipping / foaming / spraying on animal's teats on the full length of the teat (consult table for recommended application rate).
Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).
At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.

Note: When both pre- and post-milking disinfection is performed only one of the disinfection can be done with this product, the other should be done with a product based on another active substance (not iodine).

In any cases
Where necessary repeat the application at each milking.
Clean regularly the application equipment with warm water.

	Application rate
cows and buffaloes	3 to 10ml: 5 to 8 ml recommended
sheep	1.5 to 5 ml: 1.5 to 3 ml recommended
goats	2.5 to 6 ml: 2.5 to 4 ml recommended

***Meta* SPC 3:**

Meta SPC 3 is a concentrated disinfectant intended to disinfect the teats of milk producing animals, either before milking or after milking.
When used before milking the product diluted at 10% (v/v: 10 ml product, add water up to 100ml) is efficacious against bacteria and yeasts.
When used after milking the product diluted at 10% (v/v: 10 ml product, add water up to 100ml) is efficacious against bacteria, yeasts, algae and the product diluted at 20%)v/v: 10 ml product, add water up to 100ml) is efficacious against viruses.
Quick action: Efficacious in 1 minute before milking and 5 minutes after milking.

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

Before milking (bactericidal and yeasticidal)
Prepare a dilution at 10% (v/v: 10 ml product, add water up to 100ml) for bactericidal and yeasticidal activity.
Fill the dipping/ foaming cup/ sprayer manually or automatically with the prepared dilution.
Eliminate all visible dirt before applying the product.
Manual or automatic dipping/ spraying/foaming on animal's teats on the full length of the teat (consult table for recommended application rate).
Let the product act at least one minute.
Use the teat cleaning and wiping method systematically before attaching the milking cluster.

After milking (bactericidal, yeasticidal, algaecidal and virucidal):
Prepare a dilution at 10% (v/v: 10 ml product, add water up to 100ml) for bactericidal, yeasticidal and algaecidal activity or 20% (v/v: 10 ml product, add water up to 100ml) in case virucidal activity is also needed.
Fill the dipping/ foaming cup/ sprayer manually or automatically with the prepared dilution.
Manual or automatic dipping/foaming/ spraying on animal's teats (consult table for recommended application rate).
Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).
At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.

Note: When both pre- and post-milking disinfection is performed only one of the disinfection can be done with this product, the other should be done with a product based on another active substance (not iodine).

In any cases
Where necessary, repeat the application at each milking
Clean regularly the application equipment with warm water.

	Application rate
cows and buffaloes	3 to 10ml : 5 to 8 ml recommended
sheep	1.5 to 5 ml : 1.5 to 3 ml recommended
goats	2.5 to 6 ml : 2.5 to 4 ml recommended

***Meta* SPC 4:**

Meta SPC 4 is a ready-to-use disinfectant intended to disinfect the teats of milk producing animals after milking.
The product is efficacious against bacteria, yeasts, algae and viruses.
Quick action: Bactericidal, yeasticidal, algaecidal and virucidal in 5 minutes.

Instruction for use:
Always read the label or leaflet before use and follow all the instructions provided.
The product must be brought to a temperature above 20°C before use.
Fill the dipping cup manually or automatically with the ready to use product.
The use of a dosing pump for filling the product into the application equipment is recommended.
Apply by dipping manually or automatically on animal's teats on the full length of the teat after milking.
- cows and buffaloes (3 to 10ml: 5 ml recommended)
- sheep (1.5 to 5 ml: 1.5 ml recommended)
- goats (2.5 to 6 ml: 2.5 ml recommended)

Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).
At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.
Where necessary, repeat the application after each milking.
Clean the application equipment regularly with warm water.

***Meta* SPC 5:**

Meta SPC 5 is a ready-to-use disinfectant intended to disinfect the teats of milk producing animals, either before milking or after milking.
When used before milking the product is efficacious against bacteria and yeasts, .
When used after milking the product is efficacious against bacteria, yeasts, algae, and viruses.
Quick action: Efficacious in 1 minute before milking and 5 minutes after milking.

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

Before milking for bactericidal and yeasticidal activity :
Fill the dipping/foaming cup/sprayer manually or automatically with the ready to use product.
Eliminate all visible dirt before applying the product.
Manual or automatic dipping/spraying/foaming on animal's teats. (consult table for recommended application rate)
Let the product act at least one minute.
Use the teat cleaning and wiping method systematically before attaching the milking cluster.

After milking for bactericidal, yeasticidal, algaecidal and virucidal activity :
Fill the dipping/foaming cup/sprayer manually or automatically with the ready to use product.
Manual or automatic dipping/foaming/spraying on animal's teats on the full length of the teat (consult table for recommended application rate).
Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).
At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.

Note: When both pre- and post-milking disinfection is performed only one of the disinfections can be done with this product, the other should be done with a product based on another active substance (not iodine).

In any cases:
Where necessary repeat the application at each milking.
Clean regularly the application equipment with warm water.

	Application rate
cows and buffaloes	3 to 10ml : 5 to 8 ml recommended
sheep	1.5 to 5 ml : 1.5 to 3 ml recommended
goats	2.5 to 6 ml : 2.5 to 4 ml recommended

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

Not relevant.
HYPRED's iodine based products are not intended to be use with other biocidal products.

2.3.5 Risk assessment for human health

Overview BPF	
metaSPC1	RTU (0.9058 % total iodine) Used for post-application Applied by: • Manual dipping/foaming using a dip/foam cup • Manual spraying using a trigger sprayer • Manual spraying using an electronic sprayer • Automated spraying or dipping/foaming by robot Representative product - Dip-io YB MAX, Dip-io 2500
metaSPC2	RTU (0.7489 % total iodine) Used for either pre- or post-application Applied by: • Manual dipping/foaming using a dip/foam cup • Manual spraying using a trigger sprayer • Manual spraying using an electronic sprayer • Automated spraying or dipping/foaming by robot Representative product - Liq-io YB MAX, Liq-io 2500
metaSPC3	Concentrate (3.44% total iodine, in-use concentration: 0.344% total iodine (pre-milking) or 0.689% (post-milking)) Used for either pre- or post-application Applied by: • Manual dipping/foaming using a dip/foam cup • Manual spraying using a trigger sprayer • Manual spraying using an electronic sprayer • Automated spraying or dipping/foaming by robot Representative product - Liq-io concentrate
metaSPC4	RTU (0.9058 % total iodine) Used for post-application Applied by: • Manual dipping/foaming using a dip/foam cup • Manual spraying using a trigger sprayer • Manual spraying using an electronic sprayer • Automated spraying or dipping/foaming by robot

	Representative product - Dip-io 5000
metaSPC5	RTU (0.7489 % total iodine) Used for either pre- or post-application Applied by: • Manual dipping/foaming using a dip/foam cup • Manual spraying using a trigger sprayer • Manual spraying using an electronic sprayer • Automated spraying or dipping/foaming by robot Representative product - Liq-io 5500

ASSESSMENT OF EFFECTS ON HUMAN HEALTH

Skin corrosion and irritation

No study on skin corrosion and irritation is provided for HYPRED's iodine based products.

There are valid data available on each of the components sufficient to classify HYPRED's iodine based products according to the rules laid down in Regulation (EC) 1272/2008 (CLP) and synergistic effects between any of the components are not expected.

According to the Table 3.2.3 Annex I, Part 3 of the Regulation 1272/2008/EC:

- Liq-io 5500 is not classified as skin irritant as it contains less than 10 % of substances classified Skin Irrit cat 2.
  So, Liq-io 5500 is not irritant to skin
- Liq-io YB MAX is not classified as skin irritant as it contains less than 10 % of substances classified Skin Irrit cat 2.
  So, Liq-io YB MAX is not irritant to skin
- Liq-io 2500 is not classified as skin irritant as it contains less than 10 % of substances classified Skin Irrit cat 2.
  So, Liq-io 2500 is not irritant to skin
- Dip-io 5000 is not classified as skin irritant as it contains less than 10 % of substances classified Skin Irrit cat 2.
  So, Dip-io 5000 is not irritant to skin
- Dip-io YB MAX is not classified as skin irritant as it contains less than 10 % of substances classified Skin Irrit cat 2.
- So, Dip-io 5000 is not irritant to skinDip-io 2500 is not classified as skin irritant as it contains less than 10 % of substances classified Skin Irrit cat 2.
  So, Dip-io 2500 is not irritant to skin
- Liq-io concentrate is not classified as skin irritant as it contains less than 10 % of substances classified Skin Irrit cat 2.
  So, Liq-io concentrate is not irritant to skin

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritant to skin
Justification for the value/conclusion	HYPRED's iodine based products contain less than 10 % of substances classified Skin Irrit cat 2. Nor does the pH trigger classification for skin corrosion or irritation.
Classification of the product according to CLP	Not classified for skin corrosion and irritation according to CLP regulation

Eye irritation

No studies on eye irritation are provided for products included in the biocidal product family. However, an acute Eye irritation/corrosion test according to OECD 405 conducted on IODACTIV is provided.

As the concentration of H318 and H319 classified substances in *meta* SPC1, *meta* SPC2, *meta* SPC 4 and *meta* SPC 5 are slightly below the concentration of H318 and H319 classified components in IODACTIV, the outcome of the study could be used for the classification of *meta* SPC1, *meta* SPC2, *meta* SPC 4 and *meta* SPC 5.

Full composition of IODACTIV in comparison with *meta* SPC1/4 and *meta* SPC5 is described in "Doc 8.2-001.2 Eye Irritation liq-io 5500" and "Doc 8.2-003.2 Eye Irritation Dip-io 5000" (section 8.1.2 in IUCLID).

As Liq-io concentrate (*meta* SPC3) is not comparable to IODACTIV, the classification for eye irritation/eye damage will be in accordance with the calculation rules of CLP (Table 3.3.3 Annex I, Part 3 of the Regulation 1272/2008/EC):

- Liq-io concentrate (*meta* SPC3) is classified as Eye damage 1 as it contains >= 3% of a substance classified Eye Damage cat 1.
  So Liq-io concentrate is classified as Eye Damage Category 1 - H318: Causes serious eye damage

***Meta* SPC1, *meta* SPC2, *meta* SPC4 and *meta* SPC5**

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance ,Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility*	**Remarks** *(e.g. major deviations)*	**Reference**
Acute Eye Irritation/Corrosion test in the rabbit OECD 405 Reliability: 1	Rabbit New Zealand Albino 3 Males	IODACTIV (0.5% iodine) Dose: 0.1 ml	IODACTIV should be classified as Eye Irritant Category 2 according to the Regulation 1272/2008/EC Average scores Chemosis: 1.3; 1.0; 0.7 Redness: 2.0; 2.3, 2.0 Iris: 0.7; 1.3; 0.7 Cornea: 1.7; 1.7; 1.3	-	Section 8.2 in IUCLID Masson. D (2001) Doc 8.2-001.1

So according to the extrapolation principle, meta SPC1, *meta* SPC2, *meta* SPC4 and *meta* SPC5 are classified as Eye Irritant Category 2 H319: Causes serious eye irritation based on the eye irritation study with IODACTIV.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Ready to use products of *meta* SPC1 (Dip-io 2500, Dip-io YB MAX), *meta* SPC2 (Liq-io 2500, Liq-io YB MAX), *meta* SPC4 (Dip-io 5000) as well as of *meta* SPC5 (Liq-io 5500) in the HYPRED's iodine based products family are Eye irritants. The concentrate product included in *meta* SPC3 (Liq-io concentrate) in the HYPRED's iodine based products family is classified for Eye damage.
Justification for the value/conclusion	Based on the extrapolation principle presented in Annex I, Point 1.1.3 of the Regulation 1272/2008/EC, Acute Eye irritation/corrosion test according to OECD 405 conducted on IODACTIV can be used for Liq-io YB MAX, Liq-io 5500, Dip-io YB MAX and Dip-io 5000. Comparison of representative formulations to IODACTIV is included in the confidential part of the PAR (paragraph 6.4)
Classification of the product according to CLP	**Classification according to CLP:** Ready to use products Liq-io 5500, Liq-io YB MAX, Liq-io 2500, Dip-io 5000, Dip-io YB MAX, Dip-io 2500 are classified : Eye Irritant Category 2 H319: Causes serious eye irritation Concentrate product Liq-io concentrate is classified: Eye Damage Category 1 - H318: Causes serious eye damage

Respiratory tract irritation

Data waiving	
Information requirement	Not relevant
Justification	HYPRED's iodine based products don't contain a component classified as respiratory irritant.

Skin sensitization

Data waiving	
Information requirement	Not relevant
Justification	HYPRED's iodine based products don't contain a component classified as skin sensitizer. According to the Table 3.4.3 Annex I, Part 3 of the Regulation 1272/2008/EC, products are not classified as skin sensitizer.

Respiratory sensitization (ADS)

Data waiving	
Information requirement	Not relevant
Justification	HYPRED's iodine based products don't contain a component classified as respiratory sensitizer.

Acute toxicity

Acute toxicity by oral route

No study on acute toxicity by oral route is provided for HYPRED's iodine based products.

There are valid data available on each of the components sufficient to classify HYPRED's iodine based products according to the rules laid down in Regulation (EC) 1272/2008 (CLP) and synergistic effects between any of the components are not expected.

According to the Regulation 1272/2008/EC, the Acute Toxicity Estimate (ATE) of the mixture is determined by calculation from the ATE values for all relevant ingredients according to the following formula for Oral Toxicity:

$$\frac{100}{ATE_{mix}} = \sum_{n} \frac{C_i}{ATE_i}$$

where:
Ci = concentration of ingredient i (% w/w or % v/v)
i = the individual ingredient from 1 to n
n = the number of ingredients
ATEi = Acute Toxicity Estimate of ingredient i.

According to this calculation, the ATE oral of Liq-io 5500, Liq-io YB MAX, Liq-io 2500, Dip-io 5000,Dip-io YB MAX, Dip-io 2500 and Liq-io concentrate is greater than 2000 mg/kg. (reference: section 8.5.1 of IUCLID dossier)

So HYPRED's iodine based products are not classified as fatal, toxic or harmful if swallowed.

Value used in the Risk Assessment – Acute oral toxicity	
Value	ATE oral of Liq-io 5500, Liq-io YB MAX, Liq-io 2500, Dip-io 5000, Dip-io YB MAX, Dip-io 2500 and Liq-io concentrate is greater than 2000 mg/kg.
Justification for the selected value	Calculation from the ATE values for all relevant ingredients according to the regulation 1272/2008/EC. Calculations are included in the confidential part of the PAR (paragraph 3.6.5)
Classification of the product according to CLP	Not classified in accordance to CLP regulation

Acute toxicity by inhalation

No study on acute toxicity by inhalation is provided for HYPRED's iodine based products.

There are valid data available on each of the components sufficient to classify HYPRED's iodine based products according to the rules laid down in Regulation (EC) 1272/2008 (CLP) and synergistic effects between any of the components are not expected.

According to the Regulation 1272/2008/EC, the Acute Toxicity Estimate (ATE) of the mixture is determined by calculation from the ATE values for all relevant ingredients according to the following formula for Inhalation Toxicity:

$$\frac{100}{ATE_{mix}} = \sum_{n} \frac{C_i}{ATE_i}$$

where:
Ci = concentration of ingredient i (% w/w or % v/v)
i = the individual ingredient from 1 to n
n = the number of ingredients
ATEi = Acute Toxicity Estimate of ingredient i.

According to this calculation, the ATE inhalationl of Liq-io 5500, Liq-io YB MAX, Liq-io 2500, Dip-io 5000, Dip-io YB MAX, Dip-io 2500 and Liq-io concentrate is greater than 5 mg/l. (reference: section 8.5.2 of IUCLID dossier)

So HYPRED's iodine based products are not classified as fatal, toxic or harmful by inhalation.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	ATE inhalation of Liq-io 5500, Liq-io YB MAX, Liq-io 2500, Dip-io 5000, Dip-io YB MAX, Dip-io 2500 and Liq-io concentrate is greater than 5 mg/l.
Justification for the selected value	Calculation from the ATE values for all relevant ingredients according to the regulation 1272/2008/EC. Calculations are included in the confidential part of the PAR (paragraph 3.6.5)
Classification of the product according to CLP	Not classified in accordance to CLP regulation

Acute toxicity by dermal route

No study on acute toxicity by dermal route is provided for HYPRED's iodine based products.

There are valid data available on each of the components sufficient to classify HYPRED's iodine based products according to the rules laid down in Regulation (EC) 1272/2008 (CLP) and synergistic effects between any of the components are not expected.

According to the Regulation 1272/2008/EC, the Acute Toxicity Estimate (ATE) of the mixture is determined by calculation from the ATE values for all relevant ingredients according to the following formula for Dermal Toxicity:

$$\frac{100}{ATE_{mix}} = \sum_{n} \frac{C_i}{ATE_i}$$

where:

Ci = concentration of ingredient i (% w/w or % v/v)
i = the individual ingredient from 1 to n
n = the number of ingredients
ATEi = Acute Toxicity Estimate of ingredient i.

According to this calculation, the ATE dermal of Liq-io 5500, Liq-io YB MAX, Liq-io 2500, Dip-io 5000, Dip-io YB MAX, Dip-io 2500 and Liq-io concentrate is greater than 2000 mg/kg. (reference: section 8.5.3 of IUCLID dossier)

So HYPRED's iodine based products are not classified as fatal, toxic or harmful by contact with skin.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	ATE dermal of Liq-io 5500, Liq-io YB MAX, Liq-io 2500, Dip-io 5000, Dip-io YB MAX, Dip-io 2500 and Liq-io concentrate is greater than 2000 mg/kg.
Justification for the selected value	Calculation from the ATE values for all relevant ingredients according to the regulation 1272/2008/EC. Calculations are included in the confidential part of the PAR (paragraph 3.6.5)
Classification of the product according to CLP	Not classified in accordance to CLP regulation

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Total iodine
Value(s)*	12% (evidence that dermal absorption is independent of concentration; concentration range covered by test data: 0.26 – 0.66% total iodine)
Justification for the selected value(s)	Studies on the dermal absorption of iodine from the individual products pertaining to the BPF are not required.

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 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 to two *in-vitro* human skin dermal absorption studies 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). These studies have been performed with an iodophor type 1-based biocidal product at an *in-use* concentration of 0.66% total iodine and a PVP-iodine based RTU product containing 0.26% total iodine. In accordance with the most recent EFSA guidance on dermal absorption (EFSA, 2012), a mean dermal absorption of 12% total iodine has been derived for both these tested products 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 the IUCLID dossier (Doc 8.6-001 in section 8.6). As explained in the statement on dermal penetration (Doc 8.6-001, read across from the *in vitro* human skin dermal penetration study performed with products containing total iodine at concentrations in the range of 0.26-0.66% is possible to the concentrate, their in-use dilutions and the RTU products. The dermal penetration value of 12% determined for the mentioned concentration range can be read across to all products within the BPF. For the concentrates, which have considerably higher iodine contents than the tested products, the 12 % dermal penetration value is a worst case, since dermal penetration is normally inversely related to concentration. 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)

According to the note for discussion on substances of concern (SoC), CA-Nov14-Doc.5.11, products of HYPRED's BPF containing the SoC at different concentrations end up in the following bands:

- Band A: Dip-Io 2500, Dip-io YB MAX, Dip-Io 5000, Liq-Io 2500, Liq-io YB MAX, Liq-Io 5500 or products included in metaSPC1, 2, 4 and 5
- Band B: Liq-Io Concentrate or products included in metaSPC3

Associated evaluation and risk management requirements for these bands according to the note for discussion are:

- Band A: Application of P-statements normally associated with concerned H-statements
- Band B: Qualitative exposure and risk assessment to determine whether P-statements normally associated with concerned H statements are sufficient or whether other risk mitigation measures should be applied.

The requirements of this banding approach have been accounted for and addressed in the respective parts of this PAR.

More specific information and evaluation on the substances of concern is provided in the confidential annex 3.6.

Available toxicological data relating to a mixture

Based on the classification rules, metaSPC3 contains a co-formulant which is classified with H372. Taking into account the concentration of this co-formulant in the formulation, products included in metaSPC3 need to be classified with H373: May cause damage to organs thyroid through prolonged or repeated exposure, oral route.

Other

Food and feedingstuffs studies

Feeding and metabolism studies in livestock animals are not required as the products pertaining to HYPRED's 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 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 to the IUCLID dossier (Doc 13-010 in section 13). In addition, a risk assessment for consumers via residues in food is provided in section 2.3.5C.

Industrial processing and/or domestic preparation of milk such as pasteurization 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.

Other test(s) related to the exposure to humans

Not applicable

EXPOSURE ASSESSMENT

Introductory note on the transferability of the following exposure assessment to buffaloes, sheep and goats

The following exposure assessment is performed for the use in 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 applicants holds the opinion that the following 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 of 5 mL (sheep) and 6 mL (goats) for dipping and spraying and 2.5 mL (sheep) to 3 mL (goats) for foaming. 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.

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

n.a.: not applicable

Explanatory note:

Please note that the following abbreviations are used for the different *meta*-levels:

- *Meta* SPC1: corresponds to "Dipping products - ready to use"
- *Meta* SPC2: corresponds to "Dipping, foaming, spraying products - ready to use"
- *Meta* SPC3: corresponds to "Dipping, foaming, spraying Concentrated products"
- *Meta* SPC4: corresponds to " Dipping products reaching virucidal activity – Ready to use"
- *Meta* SPC5: corresponds to "Dipping, foaming, spraying products 5500 ppm – Ready to use"

As a first step, exposure assessments are performed for all individual scenarios (work tasks) which are relevant for teat disinfection (see table "list of scenarios" below) considering the highest total iodine concentrations (for more details, please refer to "general considerations" provided on the next page).

In a second step, the exposure calculated for the individual work tasks are combined (added up) for the following individual treatments:

- Pre-milking disinfection
    - Manual dipping/foaming using a dip/foam cup (This applies to *meta* SPC 2, *meta* SPC 3 and *meta* SPC 5.)
    - Manual spraying using a trigger sprayer (This applies to *meta* SPC 2, *meta* SPC 3 and *meta* SPC 5.)
    - Manual spraying using an electronic sprayer (This applies to *meta* SPC 2, *meta* SPC 3 and *meta* SPC5.)
    - Automated spraying by robot or automatic dipping/foaming (This applies to *meta* SPC 2, *meta* SPC 3 and *meta* SPC5.)
- Post-milking disinfection
    - Manual dipping/foaming using a dip/foam cup (This applies to *meta* SPC 1, *meta* SPC 2, *meta* SPC 3, *meta* SPC 4 and *meta* SPC 5.)
    - Manual spraying using a trigger sprayer (This applies to *meta* SPC 2, *meta* SPC 3 and *meta* SPC 5.)
    - Manual spraying using an electronic sprayer (This applies to *meta* SPC 2, *meta* SPC 3 and *meta* SPC 5.)
    - Automated spraying by robot or automatic dipping/foaming (This applies to *meta* SPC 2, *meta* SPC 3 and *meta* SPC 5.)

General considerations:

The disinfection by dipping, foaming or spraying takes place indoor before or after each milking, i.e. 1-6 times per day. In line with the CAR, it is considered that one professional milker milks at maximum 65 animals twice a day. For higher animal numbers or more milkings per day, an additional milker is needed. However, the number of cows to be treated have been discussed in the EU. Therefore the assessment is adapted to be 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) and 82 cows are included in the exposure calculations.
The products within the BPF are concentrated or ready-to-use (RTU) products. The concentrate for pre or post-milking disinfection by dipping, spraying, foaming (*meta* SPC3) contains available iodine and iodide at concentrations of 2.50% and 0.935%, respectively (equivalent to 3.44% total iodine). The concentrate is to be diluted 1:5 (20% dilution) for post-milking disinfection or 1:10 (10% dilution) for pre or post-milking disinfection resulting in in-use concentrations in the range of 0.344-0.689% total iodine.
The RTU products for post-milking disinfection only by dipping (*meta* SPC1 and *meta* SPC4) contain available iodine and iodide at concentrations in the range of 0.25-0.5% and 0.167-0.406% (equivalent to 0.4207-0.9058% total iodine). The RTU products for pre- or post-milking disinfection by dipping, spraying, foaming contain (*meta* SPC2 and *meta* SPC5) available iodine and iodide at concentrations in the range of 0.25-0.55% and 0.091-0.199%, respectively (equivalent to 0.344-0.7489% total iodine).

As explained in the statement on dermal penetration (Doc 8.6-001), read across from the *in vitro* human skin dermal penetration study performed with products containing total iodine at concentrations in the range of 0.26-0.66% is possible to the concentrate, their in-use dilutions and the RTU products. The dermal penetration value of 12% determined for the mentioned concentration range can be read across to all products within the BPF. For the concentrates, which have considerably higher iodine contents than the tested products, the 12 % dermal penetration value is a worst case, since dermal penetration is normally inversely related to concentration.
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", including a protection factor of 90% for gloves.

These general considerations apply to all scenarios (work tasks) provided in the following "List of scenarios". Consequently, these considerations are not repeated in the descriptions of the individual scenarios.

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, foaming or spraying			
Scenario number	**Scenario**	**Primary exposure Description of scenario**	**Exposed group**
1.1	Mixing and loading of concentrates for dip / foam cup or trigger sprayer or electronic sprayer, automated dipping/foaming-system or robotic milking device	The concentrated product is diluted 1:5 or 1:10 by decanting or by pumping. Preparation of dip / foam cups: The diluted product is filled into the reservoir of a dip / foam cup. By squeezing the reservoir, the disinfectant is pumped into the dip / foam cup above the reservoir which is then ready for dipping / foaming. Preparation of a trigger sprayer: The diluted product is filled into the reservoir of a sprayer. For loading of electronic sprayer, automated dipping/foaming-system or robotic milking device (for automated spraying) : A sucking lance of the electronic sprayer, automated dipping/foaming-system or robotic milking device is inserted in a can containing the diluted product.	professionals
1.2	Mixing and loading of RTUs for dip / foam cup or trigger sprayer	This scenario replaces scenario 1.1 if RTUs are used. Preparation of dip / foam cups: The product (RTU) is filled undiluted into the reservoir of a dip /foam cup. By squeezing the reservoir, the disinfectant is pumped into the dip / foam cup above the reservoir which is then ready for dipping. Preparation of a trigger sprayer: The product (RTU) is filled undiluted into the reservoir of a sprayer. Re-filling of a dip / foam cup or of a trigger sprayer is done analogously.	professionals
1.3	Mixing and loading for electronic sprayer, automated dipping/foaming-system or robotic milking device	This scenario is performed if electronic sprayer, automated dipping/foaming system or robotic milking device (for automated spraying) and RTU are used, and thus replaces scenario 1.2. A can containing the RTU product is opened and a sucking lance of the electronic sprayer, automated dipping/foaming system or robotic milking device is inserted. Empty cans are replaced by new ones.	professionals
2.1	Application of teat disinfectant by manual dipping / foam	Before or after milking, the dip / foam cup prepared as described in scenario 1.1 or 1.2 is put over each teat from below making sure that the full length of each teat is immersed into the disinfectant.	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 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 automated dipping/foaming-system or robot with automatic sprayer	This scenario replaces scenarios 2.1 and 2.2 in case of automated dipping/foaming/spraying-system or spraying by robot. Before or after milking, the disinfectant is sprayed automatically by robot onto teats from a cluster arm. In case of automated dipping/foaming system, the vacuum is shut off and the teat dip/foam is injected into a manifold on the clawpiece. The teats are coated with dip/foam.	No exposure
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.	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/foam cups, trigger sprayer after use	After disinfection, the reservoir is emptied and the entire dip / foam or spray equipment is cleaned with water.	professionals
4.2	Rinsing of automated dipping/foaming-system	Every liner of the automated dipping/foaming-system is thoroughly rinsed with water and blown out with compressed air. Afterwards, the milking system is ready for the next milking event. The whole process is automated and, therefore, there is no human exposure.	No exposure
4.3	Rinsing of electronic sprayer	This scenario replaces scenarios 4.1 and 4.2 if an electronic sprayer 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 concentrates for dip / foam cup, trigger sprayer or electronic sprayer, automated dipping/foaming-system or robotic milking device

Description of Scenario [1.1] - Mixing and loading of concentrate by manual pouring for dip / foam cup, trigger sprayer or electronic sprayer, automated dipping/foaming-system or robotic milking device		
The concentrated product is diluted (1:5, i.e. one part product on 4 parts clean water or 1:10, i.e. one part product on 9 parts clean water) by decanting. The diluted product is filled into the reservoir of a dip / foam cup or a trigger sprayer. In case of dip / foam cup, by squeezing the reservoir, the disinfectant is pumped into the dip / foam cup above the reservoir which is then ready for dipping / foaming. In case of loading of electronic sprayer, automated dipping/foaming-system or robotic milking device (for automated spraying) the sucking lance of the electronic sprayer, automated dipping/foaming-system or robotic milking device is inserted in a can containing the diluted product. In line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017), for mixing and loading of concentrated product for dermal exposure, mixing and loading model 4 is used. For the dermal exposure, the total amount of the required solution that is needed per day is of importance. Manually, cows are miked twice a day, however, for robotic milking, cows can be milked three times a day. Only, *meta* SPC3 contains concentrated products, and can be used either pre- or post-milking and the max amount used for cows and buffaloes is 10 ml. Therefore, as worst case the amount needed for one day is: 10ml diluted product x 3 times a day = 30 ml. As the product is used at max 20% (v/v) dilutions, max (30 ml x20% =) 6 ml concentrated product per cow/day is used. Considering 82 cows, this results in a total amount of product per day of 6 ml x 82 cows = 492 ml = 0.5 liter product/day. For mixing and loading model 4, the indicative hand exposure for handling 1 L is 0.01 ml/treatment. In case of loading of electronic sprayer, automated dipping/foaming-system or robotic milking device (for automated spraying) the sucking lance of the electronic sprayer, automated dipping/foaming-system or robotic milking device is inserted in a can containing the RTU product. Therefore, the exposure for the manual scenario is considered worst-case, and therefore used in the exposure calculation. As iodine in the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed. Exposure from (re)-filling of dipping cups or sprayer with the diluted concentrate is assumed to be covered by the overall M/L step of the concentrate.		
	Parameters	Value

Tier 1	Total iodine (available iodine and iodide) (*meta* SPC3)	3.44%
	Dermal penetration	12%
	Body weight	60 kg
	indicative dermal exposure value (mixing and loading model 4)	0.01 ml/event
	events per day	1
	No PPE	0% protection
Tier 2	Gloves	90% protection

Calculations for Scenario [1.1] – Mixing and loading of concentrate by manual pouring for dip / foam cup, trigger sprayer or electronic sprayer, automated dipping/foaming system or robotic milking device

In the following, the results of the calculations are provided for scenario 1.1 mixing and loading of concentrate (*meta* SPC 3)_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	-	7.62E-04*	-	7.62E-04
	Tier 2/ Inside gloves	-	7.62E-05	-	7.62E-05

*****(0.01 ml/treatment x 3.44% iodine equivalents in product x 1.108 g/mL (relative density Liq-io concentrate) x 1000 mg/g x 12% dermal absorption)/60 kg = 7.62E-04 mg/kg bw/d.

II. Scenario [1.2]: Mixing and loading of RTU for dip / foam cup or trigger sprayer

Description of Scenario [1.2] - Mixing and loading of RTU for dip / foam cup or trigger sprayer

This scenario replaces scenario 1.1 if RTUs are used.

The product (RTU) is filled undiluted into the reservoir of a dip / foam cup or a trigger sprayer. In case of dip / foam cup, by squeezing the reservoir, the disinfectant is pumped into the dip / foam cup above the reservoir which is then ready for dipping.
CAR.

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

For the dermal exposure, the total amount of the required solution that is needed per day is of importance. Manually, cows are miked twice a day, treated either pre- or post-milking, therefore, as worst case the amount needed for one day is: 10 ml product x 2 times a day = 20 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 20 ml x 82 cows = 1.6 L product/day.
For mixing and loading model 4, the indicative hand exposure for handling 5 L is 0.2 ml/treatment is used.

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

This M/L step is considered to also cover exposure from refilling of dipping/foaming cups or sprayer.

	Parameters	Value
Tier 1	Total iodine (available iodine and iodide) in RTU considered for assessing pre-milking or post milking treatments (*meta* SPC2/*meta* SPC5)	0.7489%
	Total iodine (available iodine and iodide) in RTU considered for assessing post-milking treatments (*meta* SPC1/*meta* SPC 4)	0.9058%
	Dermal penetration	12%
	Body weight	60 kg
	indicative dermal exposure value (mixing and loading model 4)	0.2 ml/event
	events per day	1
	No PPE	0% protection
Tier 2	Gloves	90% protection

Calculations for Scenario [1.2] – Mixing and loading of RTU for dip / foam cup or trigger sprayer

In the following, the results of the calculations are provided for scenario 1.2 performed twice a day when using a **RTU product containing 0.7489% total iodine (***meta* **SPC2/** *meta* **SPC5)**.

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] – M/L model 4–	Tier 1/ none	-	3.00E-03*	-	3.00E-03
	Tier 2/ gloves	-	3.00E-04	-	3.00E-04

*****(0.2 ml/treatment x 0.7489% iodine equivalents in product x 1.0 g/mL (relative density RTU) x 1000 mg/g x 12% dermal absorption)/60 kg = 3.00E-03 mg/kg bw/d.

In the following, the results of the calculations are provided for scenario 1.2 performed twice a day when using a **RTU product containing 0.9058% total iodine** *meta* **SPC1/** *meta* **SPC4)**.

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] – M/L model 4	Tier 1/ none	-	3.62E-03*	-	3.62E-03
	Tier 2/ Gloves	-	3.62E-04	-	3.62E-04

*(0.2 ml/treatment x 0.9058% iodine equivalents. in product x 1.0 g/mL (relative density RTU) x 1000 mg/mL x 12% dermal absorption)/60 kg = 3.62E-03 mg/kg bw/d.

Scenario [1.3]: Mixing and loading of electronic sprayer, automated dipping/foaming-system or robotic milking device

Description of Scenario [1.3] - Mixing and loading of electronic sprayer, automated dipping/foaming-system or robotic milking device		
This scenario is performed if electronic sprayer, automated dipping/foaming system or robotic milking device (for automated spraying) and RTUs are used, and thus replaces scenario 1.2. A can containing the RTU product is opened and a sucking lance of the electronic sprayer, automated dipping/foaming-system or robotic milking device (for automated spraying) is inserted. In line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017), for mixing and loading of robot or electronic sprayer, RISKOFDERM toolkit for connecting lines is used. The indicative value of the RISKOFDERM toolkit for connecting lines is 0.92 mg/min. The duration is 1 minute. In line with HEAdhoc recommendation no. 13, Inhalation exposure is not considered relevant, therefore no exposure calculations are included. This scenario was not considered in the CAR.		
	Parameters	Value
Tier 1	Total iodine (available iodine and iodide) in RTU considered for assessing pre-milking or post milking treatments (*meta* SPC2/5)	0.7489%
	Total iodine (available iodine and iodide) in RTU considered for assessing post-milking treatments (*meta* SPC1/4)	0.9058%
	Dermal penetration	12%
	Body weight	60 kg
	indicative value of RISKOFDERM toolkit for connecting lines	0.92 mg/min
	Exposure duration	1 min per day
	No PPE	0% protection
Tier 2	Gloves	90% protection

Calculations for Scenario [1.3] – Mixing and loading of electronic sprayer, automated dipping/foaming-system or robotic milking device (for automated spraying)

In the following, the results of the calculations are provided for scenario 1.3 performed twice a day when using a **RTU product containing 0.7489% total iodine (*meta* SPC-2/5)**.

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 [1.3] – RISKOFDERM Connecting lines	Tier 1/ none	-	1.38E-05*	-	1.38E-05
	Tier 2/ Gloves	-	1.38E-06	-	1.38E-06

*****(0.92 mg/min x 1 min x 0.7489% iodine equivalents in product x 12% dermal absorption)/60 kg = 1.38E-05 mg/kg bw/d.

In the following, the results of the calculations are provided for scenario 1.3 performed twice a day when using a **RTU product containing 0.9058% total iodine (*meta* SPC-1/4)**.

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 [1.3] – RISKOFDERM Connecting lines	Tier 1/ none	-	1.67E-05*	-	1.67E-05
	Tier 2/ Gloves	-	1.67E-06	-	1.67E-06

*****(0.92 mg/min x 1 min x 0.9058% iodine equivalents in product x 12% dermal absorption)/60 kg = 1.67E-05 mg/kg bw/d.

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

Description of Scenario [2.1] - Application of teat disinfectant by manual dipping / foaming
Before or after milking, the dip / foam cup prepared as described in scenario 1.1 or 1.2 is put over each teat from below making sure that the full length of each teat is immersed into the disinfectant. Dipping model 4, which was used in the CAR for calculating exposure from dipping, is not considered relevant for estimating this exposure scenario in HEAdhoc recommendation 6, as this model is derived from "semiautomatic dipping in open vats (fishing nets)". This task cannot really be compared to manual disinfection of cow teats with a dipping cup (HEAdhoc recommendation 6, note 17) In line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017), for application by dipping indicate the exposure during the use of dipping cups is covered by the dermal exposure as calculated by the scenario of mixing and loading. Furthermore, it is assumed that dipping cups are designed specifically for this task. This cup has an upper compartment as reservoir for the dipping solution. During the application the worker holds the cup at the lower compartment, so direct hand exposure to the biocidal product or treated teat is avoided. Furthermore, During the HEAdhoc-1-2016 meeting, it was considered that the application of a biocidal product in the form of a foam by dipping cups is deemed covered by the application of a liquid by the same method. Additionally, as iodine is the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed.

Scenario [2.2]: Application 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 manual spray application. Before 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. In line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017), for application by spraying (both manual trigger spraying and electronic spraying (not with robot)) Hand-held trigger spray model (consumer product spraying and dusting model 2, Biocides Human Health Exposure Methodology) is used. The following assumptions are considered in the calculations: - The farmer milks 82 cows twice a day - The spraying time per cow/event is 10 seconds - Results in (10 seconds *82 cows)/60 = 13.7 min exposure time In the CAR, spraying using an electronic sprayer was not considered.		
	Parameters	Value
Tier 1	Total iodine (available iodine and iodide) in RTU (*meta* SPC2)	0.7489%
	Total iodine (available iodine and iodide) in diluted concentrate (20% dilution), max conc post-milking application (*meta* SPC3)	0.689%
	Total iodine (available iodine and iodide) in diluted concentrate (10% dilution), max conc pre-milking application (*meta* SPC3)	0.344%
	Dermal penetration	12%
	Body weight	60 kg
	Inhalation rate (short- and long-term; acc. to HEEG opinion "Default human factor values for use in exposure assessments for biocidal products", 2013)	1.25 m³/h (0.021 m³/min)
	Exposure duration	13.7 min, 2 times a day.
	Indicative value for dermal exposure	Hand/forearms: 36.1 mg/min Legs, feet, face: 9.7 mg/min
	No PPE	0% protection
Tier 2	Gloves and coverall	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 when using a **RTU product containing 0.7489% total iodine (***meta* **SPC2/5)**.

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. Hand-held trigger spray	Tier 1/ none	7.46E-04	1.88E-02	-	1.95E-02
	Tier 2/ Inside gloves (acc. to model)	7.46E -04	1.88E-03	-	2.63E-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 (for 0.7489% total iodine)

Summary table: estimated exposure from professional uses	
Exposure scenario	**Iodine in air inhaled (mg/m³)**
Scenario [2.2] – Consumer spraying and dusting model 2, Hand-held trigger spray	7.86E-02

The calculation sheets are provided in Appendix 3.2-I.

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 when using **diluted concentrate (20% dilution) containing 0.689% total iodine (***meta* **SPC3)**.

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. Hand-held trigger spray	Tier 1/ none	6.87E-04	1.73E-02	-	1.80E-02
	Tier 2/ Inside gloves (acc. to model)	6.87E-04	1.73E-03	-	2.42E-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 (for 0.689% total iodine)

Summary table: estimated exposure from professional uses	
Exposure scenario	**Iodine in air inhaled (mg/m³)**
Scenario [2.2] – Consumer spraying Model 2. Hand-held trigger spray	7.23E-02

The calculation sheets are provided in Appendix II

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 when using **diluted concentrate (10% dilution) containing 0.344% total iodine** (*meta* SPC3, max conc pre-milking application for concentrates).

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. Hand-held trigger spray	Tier 1/ none	3.43E-04	8.61E-03	-	8.95E-03
	Tier 2/ Inside gloves (acc. to model)	3.43E-04	8.61E-04	-	1.20E-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 (for 0.344% total iodine)

Summary table: estimated exposure from professional uses	
Exposure scenario	**Iodine in air inhaled (mg/m³)**
Scenario [2.2] – Consumer Spraying and dusting Model 2. Hand-held trigger spray	3.61E-02

The calculation sheets are provided in Appendix 3.2 III.

Scenario [2.3]: Application of teat disinfectant by automated dipping/foaming-system or robot with automatic sprayer

Description of Scenario [2.3] - Application of teat disinfectant by automated dipping/foaming-system or robot with automatic sprayer
This scenario replaces scenarios 2.1. and 2.2 in case of spray application by robot or in case of automated dipping/foaming. Before or after robotic milking, the disinfectant is sprayed automatically by robot onto teats from a cluster arm. No exposure of professionals occurs. In case of automated dipping/foaming, before or after milking, the vacuum is shut off and the teat dip is injected into a manifold on the clawpiece. The teats are coated with dip when the teat cup is withdrawn. 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 [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.

As alternative approach, the applicant proposed to assess the dermal exposure assuming a worst-case exposure estimate of 0.1% of the amount on the surface area (here the teats and a part of the udder) based on the Disinfectant Products Fact Sheet (RIVM report 320005003/2006), which is in line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017) for this exposure scenario. To calculate the amount of the biocidal product 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 82 cows (=1.76 ml/cow).
Additionally, as iodine is the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed.

	Parameters	Value
Tier 1	Total iodine (available iodine and iodide) in RTU	0.7489%
	Total iodine (available iodine and iodide) in diluted concentrate (10% dilution), max conc pre-milking application (*meta* SPC3)	0.344%
	Dermal penetration	12%
	Body weight	60 kg
	Use frequency	2/day
	Surface area (teats of the cow)	44 cm^2/teat, 176 cm^2/cow
	Layer thickness on surface area	0.01 cm
	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 when using a **RTU product containing 0.7489% total iodine (*meta* SPC 5)**.

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] – HEAdhoc recom 13, item 8	Tier 1/ none	-	4.32E-03 *	-	4.32E-03
	Tier 2/ Gloves	-	4.32E-04	-	4.32E-04

*44 cm^2/teat x 4 teats x 0.01 cm x 82 cows x 0.1% x 1.0 g/ml (relative density RTU) x 1000 mg/g x 0.7489% a.s. x 12% dermal absorption / 60 kg bw x 2 times per day

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 when using **diluted concentrate (10% dilution) containing 0.344% total iodine (***meta* **SPC3, max conc pre-milking application).**

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] – HEAdhoc recom 6	Tier 1/ none	-	1.99E-03*	-	1.99E-03
	Tier 2/ Gloves	-	1.99E-04	-	1.99E-04

* 44 cm^2/teat x 4 teats x 0.01 cm x 82 cows x 0.1% x 1.0 g/ml (relative density RTU) x 1000 mg/g x 0.344% a.s. x 12% dermal absorption / 60 kg bw x 2 times per day

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 and either fallen off or rubbed off during the time span between treatment and cleaning. Therefore, any exposure to remains of the disinfectant on the teats is considered to be negligible. Generally dry disposable paper tissues are used. Since the residues (if any) are dry and the tissue is dry as well and disposed after each animal, there is definitely no relevant exposure. This conclusion is in line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017) for this exposure scenario. This work step was not considered in the CAR.

Scenario [3.3]: Cleaning of teats by robot: removal of dried residues from post milking treatment

Description of Scenario [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 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/foam cups, trigger sprayer after use

Description of Scenario [4.1] - Cleaning of equipment such as dip/foam cups, trigger sprayer after use

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

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

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

	Parameters	Value
Tier 1	Total iodine (available iodine and iodide) in RTU considered for assessing pre-milking or post milking treatments (*meta* SPC2/5)	0.7489%
	Total iodine (available iodine and iodide) in RTU considered for assessing post-milking treatments (*meta* SPC1/4)	0.9058%
	Total iodine (available iodine and iodide) in diluted concentrate (20% dilution), max conc post-milking application (meta SPC3)	0.689%
	Total iodine (available iodine and iodide) in diluted concentrate (10% dilution), max conc pre-milking application (meta SPC3)	0.344%
	Dermal penetration	12%
	Body weight	60 kg
	indicative value of RISKOFDERM 'Loading liquid, automated or semi-automated'	0.92 mg/min
	Exposure duration	5 min per day
	No PPE	0% protection
Tier 2	Gloves	90% protection

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

In the following, the results of the calculations are provided for scenario 4.1 performed twice a day when using a **RTU product containing 0.7489% total iodine (*meta* SPC-2/5)**.

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] – 'Loading liquid, automated or semi-automated'	Tier 1/ none	-	6.89E-05*	-	6.89E -05
	Tier 2/ Gloves	-	6.89E -06	-	6.89E -06

*****(0.92 mg/min x 5 min x 0.7489% iodine equivalents in product x 12% dermal absorption)/60 kg = 6.89E -05

In the following, the results of the calculations are provided for scenario 4.1 performed twice a day when using a **RTU product containing 0.9058% total iodine(*meta* SPC-1/4)**.

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] – 'Loading liquid, automated or semi-automated'	Tier 1/ none	-	8.33E -05*	-	8.33E -05
	Tier 2/ Gloves	-	8.33E -06	-	8.33E -06

*****(0.92 mg/min x 5 min x 0.9058% iodine equivalents in product x 12% dermal absorption)/60 kg = 8.33E-05

In the following, the results of the calculations are provided for scenario 4.1 performed twice a day when using a **concentrated product containing 0.689% total iodine(post milking, meta-SPC3)**.

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] – 'Loading liquid, automated or semi-automated'	Tier 1/ none	-	6.34E -05*	-	6.34E -05
	Tier 2/ Gloves	-	6.34E -06	-	6.34E -06

*****(0.92 mg/min x 5 min x 0.689% iodine equivalents in product x 12% dermal absorption)/60 kg = 6.34E-05

In the following, the results of the calculations are provided for scenario 4.1 performed twice a day when using a **concentrated product containing 0.344% total iodine(pre-milking, meta-SPC3)**..

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] – 'Loading liquid, automated or semi-automated'	Tier 1/ none	-	3.16E -05*	-	3.16E -05
	Tier 2/ Gloves	-	3.16E -06	-	3.16E -06

*****(0.92 mg/min x 5 min x 0.344% iodine equivalents in product x 12% dermal absorption)/60 kg = 3.16E

Scenario [4.2] - Rinsing of automated dipping/foaming-system

Description of Scenario [4.2] – Rinsing of automated dipping/foaming-system
This scenario replaces scenario 4.1 if automated dipping/foaming-system is used. Every liner of the automated dipping/foaming-system is thoroughly rinsed with water and blown out with compressed air. Afterwards, the milking system is ready for the next milking event. The whole process is automated and, therefore, there is no human exposure. This scenario was not considered in the CAR.

Scenario [4.3] - Rinsing of electronic sprayer

Description of Scenario [4.3] - Rinsing of electronic sprayer
This scenario replaces scenario 4.1 and 4.2 if electronic sprayer 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. This scenario was not considered in the CAR.

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

Explanatory note:

The exposure calculated for the individual work tasks are combined (added up) for the following individual treatments considering the respective worst-case concentrations of total iodine:

- Pre-milking disinfection using concentrate (3.44% total iodine; in-use concentration: 0.344% total iodine) or RTU (0.7489% total iodine)
    - Manual dipping/foaming using a dip/foam cup (This applies to *meta* SPC 2, *meta* SPC 3 and *meta* SPC 5.)
    - Manual spraying using a trigger sprayer (This applies to *meta* SPC 2, *meta* SPC 3 and *meta* SPC 5.)
    - Manual spraying using an electronic sprayer or automatic dipping/foaming (This applies to *meta* SPC 2, *meta* SPC 3 and *meta* SPC 5.)
    - Automated spraying by robot (This applies to *meta* SPC 2, *meta* SPC 3 and *meta* SPC 5.)
- Post-milking disinfection using concentrate (3.44% total iodine; in-use concentration: 0.689% total iodine) or RTU (0.9058% total iodine) or RTU (07489 % total iodine)
    - Manual dipping/foaming using a dip/foam cup (This applies to *meta* SPC 1, *meta* SPC 2, *meta* SPC 3, *meta* SPC 4 and *meta* SPC 5.)
    - Manual spraying using a trigger sprayer (This applies to *meta* SPC 2, *meta* SPC 3 and *meta* SPC 5.)
    - Manual spraying using an electronic sprayer (This applies to *meta* SPC 2, *meta* SPC 3 and *meta* SPC 5.)
    - Automated spraying by robot or automatic dipping/foaming (This applies to *meta* SPC 2, *meta* SPC 3 and *meta* SPC 5.)

Pre- milking disinfection of 82 animals twice a day

In the following table, the different pre-milking treatments are assessed. The combined exposure resulting from the work tasks relevant for the different treatments are provided for the following products:

- Concentrate: 3.44% total iodine; in-use concentration: 0.344% total iodine (*meta* SPC3)
- RTU: 0.7489% total iodine (*meta* SPC2/5)

The scenarios considered are mixing and loading of concentrate [1.1] or RTUs [1.2 or 1.3], application [2.1, 2.2, or 2.3], cleaning of teats before milking (removal of freshly applied product) [3.1] and cleaning of equipment [4.1, 4.2 or 4.3].

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 / foaming -concentrate Scenarios [1.1; 2.1; 3.1; 4.1] – *meta* SPC3	Tier 1/ none	-	2.78E-03	2.78E-03
	Tier 2/ Gloves	-	2.78E-04	2.78E-04
Manual dipping / foaming - RTU Scenarios [1.2; 2.1; 3.1; 4.1] – *meta* SPC2/5	Tier 1/ none	-	7.39E-03	7.39E-03
	Tier 2/ Gloves	-	7.39E-04	7.39E-04
Manual spraying using a trigger sprayer - concentrate Scenarios [1.1; 2.2; 3.1; 4.1] – *meta* SPC 3	Tier 1/ none	3.46E-04	1.14E-02	1.17E-02
	Tier 2/ Gloves, coverall	3.46E-04	1.14E-03	1.48E-03
Manual spraying using a trigger sprayer - RTU Scenarios [1.2; 2.2; 3.1; 4.1] *meta* SPC 2/5	Tier 1/ none	7.52E-04	2.61E-02	2.69E-02
	Tier 2/ Gloves, coverall	7.52E-04	2.61E-03	3.37E-03

Manual spraying using an electronic sprayer – concentrate – *meta* SPC3 Scenarios [1.1; 2.2; 3.1; 4.3] – *meta* SPC3	Tier 1/ none	3.46E-04	1.14E-02	1.17E-02
	Tier 2/ Gloves, coverall	3.46E-04	1.14E-03	1.48E-03
Manual spraying using an electronic sprayer - RTU Scenarios [1.3; 2.2; 3.1; 4.3] – *meta* SPC2/5	Tier 1/ none	7.52E-04	2.31E-02	2.38E-02
	Tier 2/ Gloves, coverall	7.52E-04	2.31E-03	3.06E-03
Automated spraying or automated dipping/foaming - concentrate Scenarios [1.1; 2.3; 3.3, 4.2] *meta* SPC3	Tier 1/ none	-	7.62E-04	7.62E-04
	Tier 2/ Gloves	-	7.62E-05	7.62E-05
Automated spraying – RTU or automated dipping/foaming Scenarios [1.3; 2.3; 3.3, 4.2] – *meta* SPC2/5	Tier 1/ none	-	1.38E-05	1.38E-05
	Tier 2/ Gloves	-	1.38E-06	1.38E-05

Post- milking disinfection of 82 animals twice a day

In the following table, the different post-milking treatments are assessed. The combined exposure resulting from the work tasks relevant for the different treatments are provided for the following products:

- Concentrate: 3.44% total iodine; in-use concentration: 0.689% total iodine (*meta* SPC3)
- RTU: 0.9058% total iodine (*meta* SPC1/4)
  0.7489 % total iodine (*meta* SPC2/5)

The scenarios considered are [1.1] or RTUs [1.2. or 1.3], cleaning of teats before milking: removal of dried product) [3.2 or 3.3], application [2.1, 2.2, or 2.3] and cleaning of equipment [4.1, 4.2 or 4.3].

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 / foaming -concentrate Scenarios [1.1; 2.1; 3.2; 4.1] – *meta* SPC3	Tier 1/ none	-	8.26E-04	8.26E-04
	Tier 2/ Gloves	-	8.26E-05	8.26E-05
Manual dipping / foaming - RTU Scenarios [1.2; 2.1; 3.2; 4.1] – *meta* SPC2/5	Tier 1/ none	-	3.06E-03	3.06E-03
	Tier 2/ Gloves	-	3.06E-04	3.06E-04
Manual dipping / foaming - RTU Scenarios [1.2; 2.1; 3.2; 4.1] – *meta* SPC1/4	Tier 1/ none	-	3.71E-03	3.71E-03
	Tier 2/ Gloves	-	3.71E-04	3.71E-04
Manual spraying using a trigger sprayer - concentrate Scenarios [1.1; 2.2; 3.2; 4.1] - *meta* SPC3	Tier 1/ none	6.92E-04	1.81E-02	1.88E-02
	Tier 2/ Gloves, coverall	6.92E-04	1.81E-03	2.50E-03
Manual spraying using a trigger sprayer - RTU Scenarios [1.2; 2.2; 3.2; 4.1] – *meta* SPC2/5	Tier 1/ none	7.52E-04	2.18E-02	2.26E-02
	Tier 2/ Gloves, coverall	7.52E-04	2.18E-03	2.93E-03
Manual spraying using an electronic sprayer - concentrate Scenarios [1.1; 2.2; 3.2; 4.3] – *meta* SPC3	Tier 1/ none	6.92E-04	1.80E-02	1.87E-02
	Tier 2/ Gloves, coverall	6.92E-04	1.80E-03	2.49E-03
Manual spraying using an electronic sprayer - RTU	Tier 1/ none	7.52E-04	1.88E-02	1.96E-02
	Tier 2/	7.52E-04	1.88E-03	2.63E-03

Scenarios [1.3; 2.2; 3.2; 4.3] – *meta* SPC2/5	Gloves, coverall			
Automated spraying by robot or automated dipping/foaming - concentrate Scenarios [1.1; 2.3; 3.3; 4.2] – *meta* SPC3	Tier 1/ none	-	7.62E-04	7.62E-04
	Tier 2/ Gloves	-	7.62E-05	7.62E-05
Automated spraying by robot or automated dipping/foaming - RTU Scenarios [1.3;2.3; 3.3; 4.2] – *meta* SPC2/5	Tier 1/ none	-	1.38E-05	1.38E-05
	Tier 2/ Gloves	-	1.38E-06	1.38E-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 from use of the product, 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 Hypred) and summarized in the "*Discussion paper on iodine residues in milk due to iodine-based teat-disinfection: Assessment of consumer safety*" of 29 June 2015 (Doc 13-010 presented in section 13 of 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	

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) ((Doc 13-010 presented in section 13 of IUCLID dossier) of the IRG PT3 sub-group.

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
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

Scenario [1]: Pre- or post-milking teat-disinfection by manual spraying

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. Meat was therefore not considered to be the major source of dietary iodine for the consumer.

As iodine is excreted in milk, and iodine-based teat disinfection does result in increased iodine levels in milk, a worst-case dietary exposure assessment from possible residues in milk is performed. The evaluation of exposure to iodine from milk, is based on a study from O'-Brien (2013) on iodine measurements in milk (see "Monitoring Data" below). However, it should be noted that in the document of the PT3 sub-group for the Tier2 assessment it is assumed that the iodine content is reduced by 50% as the milk from various milking farms are mixed assuming that 50% of these farms do not use iodine based teat disinfection. The eCA considers this not acceptable. The included values below are without the 50% reduction assumption for mixing milk of various origins, however includes the reduction by pasteurization.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

Not required since iodine-based products of the BPF are not used in a manner which may cause direct contact with food. Calculations for estimating dietary exposure via residues in milk and livestock exposure have been provided above.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

Not required since iodine-based products of the BPF are not used in a manner which may cause direct contact with food. Calculations for estimating dietary exposure via residues in milk and livestock exposure have been provided above.

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 filling station. The filling process is done as an automated process under closed conditions. Exposure of industrial workers is thus minimal.

Disposal of the biocidal product:

Disposal of products and drums has to be done in accordance with local and national regulations. Empty product containers are rinsed off at least twice with water and consigned to normal waste. The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste. Respective exposures are covered by those for post-application.

Aggregated exposure

For aggregated exposure assessment, see chaper "RISK CHARACTERISATION FOR HUMAN HEALTH, combined scenarios pre-milking and post-milking disinfection".

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake [mg/kg bw/day]**
[1.1] – M/L of concentrate for dip/foam cup or trigger sprayer – **3.44% total iodine** (metaSPC3)	professionals	1/none	7.62E-04
		2/Gloves	7.62E-05
[1.2] – M/L of RTU for dip/foam cup or trigger sprayer - **0.7489% total iodine** (metaSPC2/5)	professionals	1/none	3.00E-03
		2/Gloves	3.00E-04
[1.2] – M/L of RTU for dip cup - **0.9058% total iodine** (metaSPC1/4)	professionals	1/none	3.62E-03
		2/Gloves	3.62E-04
[1.3] – M/L of RTU for electronic sprayer, automated dipping/foaming-system or robotic milking device - **0.7489% total iodine** (metaSPC2/5)	professionals	1/none	1.38E-05
		2/Gloves	1.38E-06
[1.3] – M/L of RTU for electronic sprayer, automated dipping/foaming-system or robotic milking device - **0.9058% total iodine** (metaSPC1/4)	professionals	1/none	1.67E-05
		2/Gloves	1.67E-06
[2.1] – Application of teat disinfectant by manual dipping/foaming	Exposure of professionals during application by manual dipping/foaming is considered to be covered by the M/L scenario.		
[2.2] – Application of teat disinfectant by manual spraying - **0.7489% total iodine** (metaSPC2/5)	professionals	1/none	1.95E-02
		2/Gloves and coverall	2.63E-03
[2.2] – Application of teat disinfectant by manual spraying - **0.689% total iodine** (metaSPC3-20% v/v)	professionals	1/none	1.80E-02
		2/Gloves and coverall	2.42E-02
	professionals	1/none	8.95E-03

[2.2] – Application of teat disinfectant by manual spraying - **0.344% total iodine** (metaSPC3 – 10% v/v)		2/Gloves and coverall	1.20E-03
[2.3] – Application of teat disinfectant by automated dipping/foaming or automatic sprayer	No exposure of professionals occurs during automated dipping/foaming or automated spraying.		
[3.1] - – Cleaning of teats with cloth: removal of freshly applied product - **0.7489% total iodine** (metaSPC2/5)	professionals	1/none	4.32E-03
		2/ Gloves	4.32E-04
[3.1] – Cleaning of teats with cloth: removal of freshly applied product - **0.344% total iodine** (metaSPC3 – 10% v/v)	professionals	1/none	1.99E-03
		2/ Gloves	1.99E-04
[3.2] - Cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment	Exposure of professionals considered to be negligible during cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment.		
[3.3] - Cleaning of teats by robot: removal of dried residues from post-milking treatment	No exposure of professionals occurs during cleaning of teats by robot.		
[4.1] - Cleaning of equipment such as dip/foam cups, trigger sprayer after use- **0.7489% total iodine** (metaSPC2/5)	professionals	1/none	6.89E-05
		2/ Gloves	6.89E-06
[4.1] - Cleaning of equipment such as dip/foam cups, trigger sprayer after use- **0.9058% total iodine** (metaSPC1/4)	professionals	1/none	8.33E-05
		2/ Gloves	8.33E-06
[4.1] - Cleaning of equipment such as dip/foam cups, trigger sprayer after use-**0.689% total iodine** (metaSPC3 – 20% v/v)	professionals	1/none	6.34E-05
		2/ Gloves	6.34E-06
	professionals	1/none	3.16E-05

[4.1] - Cleaning of equipment such as dip/foam cups, trigger sprayer after use- **0.344% total iodine** (metaSPC3 – 10% v/v)		2/ Gloves	3.16E-06
[4.2] – Rinsing of automated dipping/foaming-system	No exposure of professionals occurs during rinsing of automated dipping/foaming-system.		
[4.3] – Rinsing of electronic sprayer	Exposure of professionals considered to be negligible during rinsing of electronic sprayer.		

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/m3

Residue definitions

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

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

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

- According to the working document CA-Dec13-Doc.5.1.e on the *Establishment of maximum residue levels for residues of active substances contained in biocidal products* duplication of work for biocidal active substances for which MRLs already exist due to uses in other areas should as far as possible be avoided. It is further stated in the working document that MRLs for pharmacologically active substances in animals set in Regulation No 37/2010 should in most cases be applicable, as long as the concerned species are covered. According to the first bullet point, MRLs have not been established for any food producing species.

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

Risk for industrial users

Industrial exposure is not relevant.

Risk for professional users

Explanatory note:

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

Risk for professional users

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

Systemic effects

As a worst-case, the estimated daily iodine intakes for metaSPC5, post-milking (0.55% available iodine) have been added to the individual tasks/scenarios.

Task/ Scenario	Tier/ PPE	Estimated uptake mg/kg bw/d	% UL (0.01 mg/kg bw/day) due to biocidal use	% UL (0.01 mg/kg bw/day) due to biocidal use + iodine from milk due to teat treatment[1]	% UL (0.01 mg/kg bw/day) due to biocidal use + total milk intake[2]	% UL (0.01 mg/kg bw/day) due to biocidal use + total dietary intake[3]
[1.1] – M/L of concentrate for dip/foam cup or trigger sprayer – **3.44% total iodine** (metaSPC3)	1/ none	7.62E-04	8	29	44	75
	2/ Gloves	7.62E-05	1	22	37	68
[1.2] – M/L of RTU for dip/foam cup or trigger sprayer - **0.7489% total iodine**	1/ none	3.00E-03	30	51	66	97
	2/ Gloves	3.00E-04	3	24	39	70

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]
(metaSPC2/5)						
[1.2] – M/L of RTU for dip/foam cup or trigger sprayer - **0.9058% total iodine** (metaSPC1/4)	1/ none	3.62E-03	36	57	72	103
	2/ Gloves	3.62E-04	4	25	40	71
[1.3] – M/L of RTU for electronic sprayer, automated dipping/foaming-system or robotic milking device - **0.7489% total iodine** (metaSPC2/5)	1/ none	1.38E-05	0	21	36	67
	2/ Gloves	1.38E-06	0	21	36	67
[1.3] – M/L of RTU for electronic sprayer, automated dipping/foaming-system or robotic milking device - **0.9058% total iodine** (metaSPC1/4)	1/ none	1.67E-05	0	21	36	67
	2/ Gloves	1.67E-06	0	21	36	67
[2.1] – Application of teat disinfectant by manual dipping/foaming	No exposure of professionals occurs.					

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]
[2.2] – Application of teat disinfectant by manual spraying - **0.7489% total iodine** (metaSPC2/5)	1/ none	1.95E-02	195	216	231	262
	2/ Gloves and coverall	2.63E-03	26	47	62	93
[2.2] – Application of teat disinfectant by manual spraying - **0.689% total iodine** (metaSPC3 – 120% v/v)	1/ none	1.80E-02	180	200	215	246
	2/ Gloves and coverall	2.42E-03	24	45	60	91
[2.2] – Application of teat disinfectant by manual spraying - **0.344% total iodine** (metaSPC3 – 10% v/v)	1/ none	8.95E-03	90	111	126	157
	2/ Gloves and coverall	1.20E-03	12	33	48	79
[2.3] – Application of teat disinfectant by automated dipping/foaming or automatic sprayer	No exposure of professionals occurs.					
[2.3] – Application of teat disinfectant by automated	No exposure of professionals occurs.					

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]
dipping/foaming or automatic sprayer						
[3.1] – Cleaning of teats with cloth: removal of freshly applied product - **0.7489% total iodine** (metaSPC2/5)	1/ none	4.32E-03	43	64	79	110
	2/Gloves	4.32E-04	4	25	40	71
[3.1] – Cleaning of teats with cloth: removal of freshly applied product - **0.344% total iodine** (metaSPC3 – 10% v/v)	1/ none	1.99E-03	20	41	56	87
	2/Gloves	1.99E-04	2	23	38	69
[3.2] - Cleaning of teats by wiping with cloth (removal of dried residues from post-milking treatment	Exposure of professionals considered to be negligible.					
[3.3] – Cleaning of teats by robot removal of dried residues from post-milking treatment	No exposure of professionals occurs.					

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]
[4.1] - Cleaning of equipment such as dip/foam cups, trigger sprayer after use- **0.7489% total iodine** (metaSPC2/5)	1/ none	6.89E-05	1	22	37	68
	2/Gloves	6.89E-06	0	21	36	67
[4.1] - Cleaning of equipment such as dip/foam cups, trigger sprayer after use- **0.9058% total iodine** (metaSPC1/4)	1/ none	8.33E-05	1	22	37	68
	2/Gloves	8.33E-06	0	21	36	67
[4.1] - Cleaning of equipment such as dip/foam cups, trigger sprayer after use- **0.689% total iodine**(metaSPC3 – 20% v/v)	1/ none	6.34E-05	1	22	37	68
	2/Gloves	6.34E-06	0	21	36	67
[4.1] - Cleaning of equipment such as dip/foam cups, trigger sprayer after use- **0.344% total iodine** (metaSPC3 – 10% v/v)	1/ none	3.16E-05	0	21	36	67
	2/Gloves	3.16E-06	0	21	36	67

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]
[4.2] – Rinsing of automated dipping/foaming-system	No exposure of professionals occurs.					
[4.3] – Rinsing of electronic sprayer	Negligible exposure of professionals occurs.					

[1] as worst case, values derived from post-application use are included. However, the outcome would be comparable when values derived from pre-application use would be included.
[2] Total milk intake is the sum of the estimated additional intake resulting from the transfer into milk following teat disinfection (based on O'Brien) and the background milk value of 200 µg/L (EFSA 2013)
[3] Total dietary intake is the sum of the estimated additional intake resulting from the transfer into milk following teat disinfection (based on O'Brien), the background milk value of 200 µg/L (EFSA 2013) and 185 µg/d for adult or 96 µg/d for infant based on UK data (2008).

Calculation sheet is included in annex 3.2.

Local effects

Products included in metaSPC1, 2, 4 and 5 are classified with H319: Causes serious eye irritation. Additionally, products included in metaSPC3 are classified with H318: Causes serious eye damage. Consequently, due to the eye damaging or eye irritating properties, goggles are to be used during handling of the products.

Local effects via inhalation will only take place during the spray application (task 2.2). The local exposure concentration is provided in the following table for the worst-case concentrations of the individual tasks.

Task/ Scenario	Iodine in air inhaled (mg/m³)	% OEL (1 mg/m³)	Acceptable (yes/no)
[2.2] – Application of teat disinfectant by manual spraying – **0.7489% total iodine**	7.86E-02	7.9	yes
[2.2] – Application of teat disinfectant by manual spraying – **0.689% total iodine**	7.23E-02	7.2	yes
[2.2] – Application of teat disinfectant by manual spraying – **0.344% total iodine**	3.61E-02	3.6	yes

Combined scenarios

Explanatory note:

Analogously to the exposure assessment, the combined risk for the following treatments is calculated considering the respective worst-case concentrations of total iodine:

- Pre-milking disinfection using concentrate (3.44% total iodine; in-use concentration: 0.344% total iodine) or RTU (0.7489% total iodine)
    - Manual dipping/foaming using a dip/foam cup (This applies to *meta* SPC 2, *meta* SPC 3 and *meta* SPC 5.)
    - Manual spraying using a trigger sprayer (This applies to *meta* SPC 2, *meta* SPC 3 and *meta* SPC5.)
    - Manual spraying using an electronic sprayer (This applies to *meta* SPC 2, *meta* SPC 3 and *meta* SPC5.)
    - Automated spraying by robot or automated dipping/foaming (This applies to *meta* SPC 2, *meta* SPC 3 and *meta* SPC5.)
- Post-milking disinfection using concentrate (3.44% total iodine; in-use concentration: 0.689% total iodine),r RTU (0.9058% total iodine) or RTU (0.7489% total iodine)
    - Manual dipping/foaming using a dip/foam cup (This applies to *meta* SPC 1, *meta* SPC 2, *meta* SPC 3, *meta* SPC4 or *meta* SPC5.)
    - Manual spraying using a trigger sprayer (This applies to *meta* SPC 2, *meta* SPC 3 and *meta* SPC5.)
    - Manual spraying using an electronic sprayer (This applies to *meta* SPC 2, *meta* SPC 3 and *meta* SPC5.)
    - Automated spraying by robot or automated dipping/foaming (This applies to *meta* SPC 2, *meta* SPC 3 and *meta* SPC5.)

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

- Concentrate: 3.44% total iodine; in-use concentration: 0.344% total iodine (metaSPC3)
- RTU: 0.7489% total iodine (metaSPC 2/5)
- Intakes which exceed the UL are highlighted in red in the table below.

For the calculation of the "iodine from milk due to teat treatment", the metaSPC related residue values (as indicated in section "Risk for consumers via residues in food") have been added to the worker exposure estimates as it is reasonable to assume that a farmer drinks its own milk.

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/ Foaming - concentrate (meta SPC3) Scenarios [1.1; 2.1; 3.1; 4.1]	1/ none	2.78E-03	28	36	51	82
	2/ Gloves	2.78E-04	3	11	26	57
Manual dipping/ Foaming - RTU (meta SPC2/5) Scenarios [1.2; 2.1; 3.1; 4.1]	1/ none	7.39E-03	74	92	107	138
	2/ Gloves	7.39E-04	7	25	40	71
Manual spraying using a trigger sprayer – concentrate (meta SPC3) Scenarios [1.1; 2.2; 3.1; 4.1]	1/ none	1.17E-02	117	125	140	171
	2/ Gloves and coverall	1.48E-03	15	23	38	69

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 spraying using a trigger sprayer - RTU (meta SPC2/5) Scenarios [1.2; 2.2; 3.1; 4.1]	1/ none	2.69E-02	269	287	305	333
	2/ Gloves and coverall	3.37E-03	34	52	67	98
Manual spraying using an electronic sprayer - concentrate (meta SPC3) Scenarios [1.1; 2.2; 3.1; 4.3]	1/ none	1.17E-02	117	125	140	171
	2/ Gloves and coverall	1.48E-03	15	23	38	69
Manual spraying using an electronic sprayer - RTU (meta SPC2/5) Scenarios [1.3; 2.2; 3.1; 4.3]	1/ none	2.38E-02	238	256	271	302
	2/ Gloves and coverall	3.06E-03	31	49	64	95
Automated spraying or automated dipping/foaming - concentrate (meta SPC3) Scenarios [1.1; 2.3; 4.2]	1/ none	7.62E-04	8	16	31	62
	2/ Gloves	7.62E-05	1	9	24	55
	1/	1.38E-05	0	18	33	64

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]
Automated spraying or automated dipping/foaming – RTU (meta SPC2/5) Scenarios [1.3; 2.3; 4.2]	none					
	2/ Gloves	1.38E-06	0	18	33	64

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

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

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

Calculation sheet is included in annex 3.2.

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

Tier 1:
When using the concentrated product (3.44% total iodine; in-use conc.: 0.344%), **Exposure from biocidal use** without considering PPE (Tier 1) results in 28% of the UL for manual dipping/foaming, 117% of the UL for manual spraying using a trigger sprayer or an electronic sprayer, respectively, and 8% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 1) results in 36% for manual dipping/foaming, 125% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 16% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 1) results in 51% for manual dipping/foaming, 140% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 31% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 82% for manual dipping/foaming, 171% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 62% of the UL for automated spraying or automated dipping/foaming.

When using the RTU product (0.7489% total iodine - metaSPC2/5), **exposure from biocidal use** without considering PPE (Tier 1) results in 74% of the UL for manual dipping/foaming, 269% or

238% of the UL for manual spraying using a trigger sprayer or an electronic sprayer, respectively, and 0% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 1) results in 92% for manual dipping/foaming, 287% and 256% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 18% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 1) results in 107% for manual dipping, 302% and 271% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 33% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 138% for manual dipping/foaming, 333% and 302% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 64% of the UL for automated spraying or automated dipping/foaming.

Tier 2:
When using the concentrated product (3.44% total iodine; in-use conc.: 0.344%), **Exposure from biocidal use** considering PPE (Tier 2) results in 3% of the UL for manual dipping/foaming, 15% of the UL for manual spraying using a trigger sprayer or an electronic sprayer, respectively, and 1% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, considering PPE (Tier 2) results in 11% for manual dipping/foaming, 23% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 9% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption, considering PPE (Tier 2) results in 26% for manual dipping/foaming, 38% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 24% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, considering PPE (Tier 2) results in 57% for manual dipping/foaming, 69% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 55% of the UL for automated spraying or automated dipping/foaming.

When using the RTU product (0.7489% total iodine - metaSPC2/5), **exposure from biocidal use** without considering PPE (Tier 2) results in 7% of the UL for manual dipping/foaming, 34% and 31% of the UL for manual spraying using a trigger sprayer or an electronic sprayer, respectively, and 0% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 2) results in 25% for manual dipping, 52% and 49% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 18% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 2) results in 40% for manual dipping/foaming, 67% and 64% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 33% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 2) results in 71% for manual dipping/foaming, 98% and 95% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 64% of the UL for automated spraying or automated dipping/foaming.

Conclusions pre-milking application:

When using the concentrate:
For manual and automated dip/foam applications and for automated spraying, no PPE is needed for safe use.
For manual spraying application using a trigger sprayer or electronic sprayer, chemical resistant gloves (90% protection) and coverall (90% protection) are needed for safe use.

When using RTUs:
For automated dip/foam applications and for automated spraying, no PPE is needed for safe use.
For manual dip/foam applications, chemical resistant gloves (90% protection) are needed for safe use.
For manual spraying application using a trigger sprayer or electronic sprayer chemical resistant gloves (90% protection) and coverall (90% protection) are needed for safe use.

Furthermore, the OEL of 1 mg/m³ for iodine is not reached in any "pre-milking disinfection"-scenario. The maximum value was 7.9% of the OEL calculated for application of teat disinfection by spraying using a trigger sprayer or electronic sprayer.

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

- Concentrate: 3.44% total iodine; in-use concentration: 0.689% total iodine (metaSPC3)
- RTU: 0.9058% total iodine (metaSPC1/4); 0.7489 % total iodine (metaSPC2/5)
- Intakes which exceed the UL are highlighted in red in the table below.

For the calculation of the "iodine from milk due to teat treatment", the metaSPC related residue values (as indicated in section "Risk for consumers via residues in food") have been added to the worker exposure estimates as it is reasonable to assume that a farmer drinks its own milk.

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/ foaming - concentrate (meta SPC3) Scenarios [1.1; 2.1; 3.2; 4.1]	1/ none	8.26E-04	8	27	42	73
	2/ Gloves	8.26E-05	1	20	35	66
Manual dipping/ foaming - RTU (meta SPC2/5) Scenarios [1.2; 2.1; 3.2; 4.1]	1/ none	3.06E-03	31	52	67	98
	2/ Gloves	3.06E-04	3	24	39	70
Manual dipping/ foaming - RTU (meta SPC1/4) Scenarios [1.2; 2.1; 3.2; 4.1]	1/ none	3.71E-03	37	56	71	102
	2/ Gloves	3.71E-04	4	23	38	69

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 spraying using a trigger sprayer - concentrate (meta SPC3) Scenarios [1.1; 2.2; 3.2; 4.1]	1/ none	1.88E-02	188	207	222	253
	2/ Gloves and coverall	2.50E-03	25	44	59	90
Manual spraying using a trigger sprayer RTU (meta SPC2/5) Scenarios [1.2; 2.2; 3.2; 4.1]	1/ none	2.26E-02	226	247	262	293
	2/ Gloves and coverall	2.93E-03	29	50	65	96
Manual spraying using an electronic sprayer - concentrate (meta SPC3) Scenarios [1.1; 2.2; 3.2; 4.3]	1/ none	1.87E-02	187	206	221	252
	2/ Gloves and coverall	2.49E-03	25	44	59	90
Manual spraying using an electronic sprayer - RTU (meta SPC2/5) Scenarios [1.3; 2.2; 3.2; 4.3]	1/ none	1.96E-02	196	216	231	262
	2/ Gloves and coverall	2.63E-03	26	47	62	93

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]
Automated spraying by robot or automated dipping/foaming - concentrate (meta SPC3) Scenarios [1.1; 2.3; 3.3; 4.2]	1/ none	7.62E-04	8	27	42	73
	2/ Gloves	7.62E-05	1	20	35	66
Automated spraying by robot or automated dipping/foaming - RTU (meta SPC2/5) Scenarios [1.3; 2.3; 3.3; 4.2]	1/ none	1.38E-05	0	21	36	67
	2/ Gloves	1.38E-06	0	21	36	67

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

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

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

Calculation sheet is included in annex 3.2.

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

Tier 1:
When using the concentrated product (3.44% total iodine; in-use conc.: 0.689%), **Exposure from biocidal use** without considering PPE (Tier 1) results in 8% of the UL for manual dipping/foaming, 188% or 187% of the UL for manual spraying using a trigger sprayer or an electronic sprayer, respectively, and 8% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 1) results in 27% for manual dipping, 207 and 206% of

the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 27% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 1) results in 42% for manual dipping, 222% and 221% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 42% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 73% for manual dipping, 253% and 252% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 73% of the UL for automated spraying or automated dipping/foaming.

When using the RTU product (0.9058% total iodine – metaSPC1/4), **exposure from biocidal use** without considering PPE (Tier 1) results in 37% of the UL for manual dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 1) results in 56% for manual dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 1) results in 71% for manual dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 102% for manual dipping/foaming.

When using the RTU product (0.7489% total iodine - metaSPC2/5), **exposure from biocidal use** without considering PPE (Tier 1) results in 31% of the UL for manual dipping/foaming, 226% or 196% of the UL for manual spraying using a trigger sprayer or an electronic sprayer, respectively, and 0% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 1) results in 52% for manual dipping, 247% and 216% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 21% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 1) results in 67% for manual dipping, 262% and 231% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 36% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 98% for manual dipping, 293% and 262% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 67% of the UL for automated spraying or automated dipping/foaming.

Tier 2:
When using the concentrated product (3.44% total iodine; in-use conc.: 0.344%), **Exposure from biocidal use** considering PPE (Tier 2) results in 1% of the UL for manual dipping/foaming, 25% of the UL for manual spraying using a trigger sprayer or an electronic sprayer, respectively, and 1% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, considering PPE (Tier 2) results in 20% for manual dipping/foaming, 44% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 20% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption, considering PPE (Tier 2) results in 35% for manual dipping/foaming, 59% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 35% of the UL for automated spraying or automated dipping/foaming.

Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, considering PPE (Tier 2) results in 66% for manual dipping, 90% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 66% of the UL for automated spraying or automated dipping/foaming.

When using the RTU product (0.9058% total iodine – metaSPC1/4), **exposure from biocidal use** considering PPE (Tier 2) results in 4% of the UL for manual dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, considering PPE (Tier 2) results in 23% for manual dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption, considering PPE (Tier 2) results in 38% for manual dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, considering PPE (Tier 2) results in 69% for manual dipping/foaming.

When using the RTU product (0.7489% total iodine - metaSPC2/5), **exposure from biocidal use** without considering PPE (Tier 2) results in 3% of the UL for manual dipping/foaming, 29% or 26% of the UL for manual spraying using a trigger sprayer or an electronic sprayer, respectively, and 0% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 2) results in 24% for manual dipping, 50% and 47% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 21% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 2) results in 39% for manual dipping, 65% and 62% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 36% of the UL for automated spraying or automated dipping/foaming.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 2) results in 70% for manual dipping, 96% and 93% of the UL for manual spraying using a trigger sprayer or electronic sprayer, respectively, and 67% of the UL for automated spraying or automated dipping/foaming

Conclusions post-milking application:

When using the concentrate:
For manual and automated dip/foam applications and for automated spraying, no PPE is needed for safe use.
For manual spraying application using a trigger sprayer or electronic sprayer, chemical resistant gloves (90% protection) and coverall (90% protection) are needed for safe use.

When using RTUs:
For manual and automated dip/foam applications and for automated spraying, no PPE is needed for safe use.
For manual spraying application using a trigger sprayer or electronic sprayer, chemical resistant gloves (90% protection) and coverall (90% protection) are needed for safe use.

Furthermore, the OEL of 1 mg/m³ for iodine is not reached in any "post-milking disinfection"-scenario. The maximum value was 7.9% of the OEL calculated for application of teat disinfectant by spraying.

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.

To make the following 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, 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) (Doc 13-010 presented in section 13 of IUCLID dossier) of the IRG PT3 sub-group. Tier 1 calculations as included in IUCLID of the IRG PT3 sub-group represent the theoretical total iodine residues in milk due to pre- or post-milking teat disinfection by spraying (worst case with 0.55% available iodine and 0.9058% total iodine) extrapolated from data of O'Brien (2013). However, it should be noted that in this document for the Tier2 assessment it is assumed that the iodine content is reduced by 50% as the milk from various milking farms are mixed assuming that 50% of these farms do not use iodine based teat disinfection. Tier 2 includes a reduction in iodine concentration of 27% due to pasteurization, as was also taken in the EFSA (2013) opinion on the safety and efficacy of iodine compound (E2) as feed additives. Furthermore, 0.5 L consumption of milk was considered for both adults and children/toddlers, and is in line with the CAR for iodine.

During discussions in the human health working group meetings and WebEx meetings for eCA evaluating iodine based union authorisations 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. Therefore, for this application exposure due to either pre- or post-treatment per milking event for *meta* SPC3 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 metaSPC2,3, and 5 paragraph 5.2 (these metaSPCs include uses for pre- and post-application): Products can either include post- or pre-application uses. metaSPC 5 is considered worst case as it contains the highest concentration available iodine.
- For exposure to residues the following was concluded by eCAs from iodine based union authorisation applications (Secure Webex meeting (3-10-2017)): "The expected iodine residues in milk from two milking events per day for manual milking and from three events per day for automatic milking are considered comparable". 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 infant/toddlers (EFSA PRIMo version 2, based on highest mean for French population).
- For the calculations information from the O'Brien study was used. The O'Brien study assessed the effect of a teat disinfection product is used, based on 0.5% available iodine on the total

iodine content in milk. As the maximum concentration of the BPF products contain 0.55% available iodine (metaSPC5), 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 from iodine based union authorisation applications: "General support was given to the derivation of an EU harmonised value. The value of 200 µg/L iodine in milk was considered appropriate as an EU harmonised value, based on the monitoring data from EFSA 2013 (EFSA Journal 2013;11(2):3101) and the O'Brien study."
- Iodine dietary intake from other sources than milk was also discussed in the Secure Webex meeting (3-10-2017), in which was concluded by eCAs from iodine based union authorisation applications: "The values from the UK survey were considered adequate to represent the EU iodine dietary intake from sources other than milk. Rounding of the values to 185 µg/day for adults and 96 µg/day for toddler was agreed." It should be noted that these values excluded iodine intake from milk. Furthermore, within this UK study (UK retail survey of iodine in UK produced dairy foods, FSIS 02/08, 16 June 2008) 350 samples of dairy and seaweed products were purchased from eight areas of the UK. Levels of iodine found were generally in similar ranges to those reported from previous surveys (MAFF iodine in milk), Furthermore the reported values are in agreement with an EFSA scientific opinion on the use of iodine in feeding stuffs. It is noted that in the UK study report for the calculations for body weights 76 for adults and 14.5 kg for infants are considered, whereas 70 kg and 12 kg are used in the consumption calculations. Moreover, during the discussion at the Secure WebEx meeting it was noted that comparable values could be obtained from French and German monitoring studies.

The estimated dietary intakes of iodine have been compared to the relevant UL for adults (600 µg/d) and infants/toddlers (200 µg/d) and depicted in the table below. Intakes which exceed the respective UL are highlighted in red in the table below. Calculations are included in annex 3.2 (Hypred 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 - worst case: metaSPC5 (0.55% available iodine)

	Adults (0.45 L/day)	**Toddler (0.46 L/day)**
	Estimated daily intake (µg/day) [% ofUL]	**Estimated daily intake (µg/day) [% ofUL]**
2x pre-milking application by manual dipping/spraying		
Intake from milk due to teat treatment	107 18	109 54
Total milk intake*	197 33	201 100
Total dietary intake**	382 64	297 148
2x post-milking application by manual dipping/spraying		
Intake from milk due to teat treatment	124 21	127 64
Total milk intake*	214 36	219 110
Total dietary intake**	399 67	315 158

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

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

Conclusion: Pre- or post-milking teat-disinfection

For adults, the estimated daily intake of iodine resulting from biocidal product use is 18% or 21% of the UL for either pre- or post-application. When background values for iodine in milk is added, the iodine intake from milk consumption is 33% or 36% of the UL for either pre- or post-application. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to 64% or 67% of the UL for either pre- or post-application.

For toddler, the estimated daily intake of iodine resulting from biocidal product use is 54% or 64% of the UL for either pre- or post-application. When background values for iodine in milk is added, the iodine intake from milk consumption is 100 or 110% of the UL for either pre- or post-application. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to 148% or 158% of the UL for either pre- or post-application.

Above we show the results of the worst-case of the BPF, metaSPC5, which shows exceedance of the UL for children (including total milk intake and total dietary intake). Below we have included an table, showing the results for the other metaSPCs, taken into account the intended use for pre- or post-application. Intakes which exceed the respective UL are highlighted in red in the table below. Calculations are included in annex 3.2 (Hypred 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)	**Toddler (0.46 L/day)**

	Estimated daily intake (µg/day) [% of UL]	Estimated daily intake (µg/day) [% of UL]
2x post-milking application metaSPC1/2 (0.49% available iodine)		
Intake from milk due to teat treatment	111 18	113 57
Total milk intake*	201 33	205 103
Total dietary intake**	386 64	301 151
2x pre-milking application metaSPC2 (0.49% available iodine)		
Intake from milk due to teat treatment	95 16	97 49
Total milk intake*	185 31	189 95
Total dietary intake**	370 62	285 143
2x pre-milking application metaSPC3 (0.25% available iodine)		
Intake from milk due to teat treatment	48 8	50 25
Total milk intake*	138 23	142 71
Total dietary intake**	323 54	238 119
2x post-milking application metaSPC3 (0.25% available iodine)		
Intake from milk due to teat treatment	57 9	58 29
Total milk intake*	147 24	150 75
Total dietary intake**	332 55	246 123
2x post-milking application metaSPC3/4 (0.5% available iodine)		
Intake from milk due to teat treatment	113 19	116 58
Total milk intake*	203 34	208 104
Total dietary intake**	388 65	304 152

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

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

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

Exposure to iodine via drinking water was not taken into account in the risk assessment. The use of the iodine teat treatments could potentially contribute to the levels found in groundwater. As part of the environmental risk assessment PEC have been estimated. However, the main issue with these estimated PEC is that they are significant 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 teat disinfection which was much higher (e.g. 461 µg/kg for 2-times post milking applications, equal to 475 µg/L assuming a milk density of 1.03), one could consider the O`Brien study worst case.

Several studies have been conducted to experimentally determine the contribution to iodine levels in milk from use of iodine containing teat dips [Conrad & Hemken, 1978; Hemken, 1980; Sheldrake et al. 1980; Hemken et al, 1981; Galton et al., 1984; Berg & Padgitt, 1985; Van Ryssen et al, 1985; Galton et al., 1986; Aumont, 1987; Bruhn et al, 1987; Swanson et al., 1990; Rasmussen et al., 1991; Ingawa et al., 1992; Serieys & Poutrel, 1996]. Interpretation of these experiments is hampered by the fact that total iodine levels in milk fluctuate considerably between and within cows because of differences and changes of iodine levels in feed during the course of the study. Furthermore, iodine levels in milk fluctuate because total iodine levels in milk derived from teat dips decrease with milk yield and because some analytical methods are not able to detect iodine from iodophors.

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

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

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

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

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

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

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

According to the note for discussion on substances of concern (SoC); CA-Nov14-Doc.5.11, the concentrated product of HYPRED´s BPF containing the SoC end up in Band B due to eye damaging properties, while the RTU products end up in Band A due to eye irritating properties. Consequently, due to the eye damaging or eye irritating properties, goggles are to be used during handling of the products.

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

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

Aquatic acute toxicity
The only component in HYPRED's iodine based products which is classified as
- Hazardous to the aquatic environment – Category 1
- Hazard statement H 400 : Very toxic to aquatic life

is the active substance iodine with a M factor of 1 according to the table 4.1.3, Part 4 : Environmental Hazards, Appendix I of the Regulation 1272/2008/CE.

When using the table 4.1.1, Environmental Hazards, Appendix I of the Regulation 1272/2008/CE, we can conclude that HYPRED's iodine based products can't be considered as having acute aquatic toxicity because the concentration of iodine is comprised between 0.25 and 2.5 % w/w.

Chronic aquatic toxicity
Two components in HYPRED's iodine based products are classified for aquatic chronic toxicity, namely the active substance iodine and C12-C14 ethoxylated alcohols.

In absence of chronic endpoints, iodine is according to Regulation 286/2011 classified as 'H 410 - Very toxic to aquatic life with long-lasting effects' based on an LC_{50} of 0.59 mg/L. The corresponding M-factor is one. The iodine concentrations within the product family ranging from 0.25 to 2.5 %. Therefore, products in *meta* SPC1, *meta* SPC2, *meta* SPC4 and *meta* SPC5 with iodine concentration ranging from 0.25 to 0.55% must be according to Regulation 286/2011 classified as 'H412 - Harmful to aquatic life with long-lasting effects'.
Product in *meta* SPC3 with iodine concentration of 2.5% must be be according to Regulation 286/2011 classified as 'H411 - Toxic to aquatic life with long lasting effects'.

Beside of the active substance, only C12-C14 ethoxylated alcohols is classified for the environment (H412 - Harmful to aquatic life with long-lasting effects (Aquatic Chronic Category 3')). According to the Table 4.1.2 of the Regulation 286/2011/EC which modifies the Regulation 1272/2008/EC, C12-C14 ethoxylated alcohols in none of the HYPRED's iodine based products within the product family leads to a chronic classification as the concentration is always below 25%. Therefore, none of the products contains a substance of concern other than the active substance.

Further Ecotoxicological studies

No new data is available for HYPRED's iodine based products.

Data waiving	
Information requirement	Not relevant
Justification	There are valid data available on each of the components and synergistic effects between any of the components are not expected.

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

No new data is available for HYPRED's iodine based products.

Data waiving	
Information requirement	Not relevant
Justification	No additional test on other target organisms is needed on the basis of intended uses, data available on the active substance or risk assessment.

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

No new data is available for HYPRED's iodine based products.

Data waiving	
Information requirement	Not relevant
Justification	HYPRED's iodine based 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 new data is available for HYPRED's iodine based products.

Data waiving	
Information requirement	Not relevant
Justification	HYPRED's iodine based 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)

No new data is available for HYPRED's iodine based products.

Data waiving	
Information requirement	Not relevant
Justification	No additional test on secondary ecological effect is needed on the basis of intended uses, data available on the active substance or risk assessment.

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 milkable animals. They are predominantly used in animal houses (indoor use). Products may also be applied in milking robots to which animals has voluntary access. The products are applied by dipping, foaming or spraying to the teats of the animals before or after milking. Exposure to the environment is predominantly secondary, i.e., via liquid manure to soils or to surface water via the municipal sewer. Exposure to air during application is not relevant due to the low vapour pressure of the active substance.

When applying the products to the animal teats by spraying, spray may not reach the animal teats or part of the product applied to the teats may be lost by drip formation. Drip formation may also occur when the products are applied by dipping or foaming. In both cases losses are possible into the liquid manure (release pathway via manure spreading on grassland or arable land) or the sewer system (release pathway via STP). If applied post-milking, the products will only partly remain on the animal teats between two milking events. The part which simply falls off or is lost due to contact with the surfaces (e.g. when the cows lie down for rest) will finally end up in the liquid manure. The part remaining on the teats will be removed before the next milking by wiping with a dry cloth or a single paper towel. If disposable tissues are used, the product will end up in the waste bin.

Residues are also released to the environment during cleaning of the applied equipment such as milking cups and reusable milking cloths. Considering that most farms are not connected to the municipal sewer, waste water is often released to the manure depot instead. If present, residues may be released to individual sewage treatment plants as well when equipment is for instance rinsed above sinks. In all other cases release to the municipal sewer and subsequently to a sewage treatment plant (STP) is likely.

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

No new data is available for HYPRED's iodine based products.

Data waiving	
Information requirement	Not relevant
Justification	No additional test on secondary ecological effect is needed on the basis of intended uses, data available on the active substance or risk assessment.

Leaching behaviour (ADS)

The performance of a study on leaching (e.g. from treated surfaces) is neither applicable nor relevant for the use as teat disinfectant.
General statement on further studies: 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 behaviour (and ecotoxicity) of the active substance. The performance of studies on fate and behaviour in the environment with the product is therefore not triggered.

Testing for distribution and dissipation in soil (ADS)

No new data is available for HYPRED's iodine based products.

Data waiving	
Information requirement	Not relevant
Justification	No additional test on secondary ecological effect is needed on the basis of intended uses, data available on the active substance or risk assessment.

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

No new data is available for HYPRED's iodine based products.

Data waiving	
Information requirement	Not relevant
Justification	No additional test on secondary ecological effect is needed on the basis of intended uses, data available on the active substance or risk assessment.

Testing for distribution and dissipation in air (ADS)

No new data is available for HYPRED's iodine based products.

Data waiving	
Information requirement	Not relevant
Justification	No additional test on secondary ecological effect is needed on the basis of intended uses, data available on the active substance or risk assessment.

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

No new data is available for HYPRED's iodine based products.

Data waiving	
Information requirement	Not relevant
Justification	HYPRED's iodine based products are not intended to be sprayed near to surface waters.

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

Not relevant.

EXPOSURE ASSESSMENT

Introductionary note on the transferability of the following exposure assessment to buffaloes, sheep and goats

The following exposure assessment is performed for the scenario "Disinfection of teats of 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 applicant holds the opinion that the following exposure assessment for cows also covers the use in buffaloes, sheep and goats:

- Buffaloes: equal to dairy cows, buffaloes have four teats. The application rate per animal and milking is equal to dairy cows. Since buffaloes are only milked two times a day, the

iodine emission to the environment due to the use of teat disinfectants is lower than for a herd of dairy cows (assuming the same number of animals per herd).

- Sheep and goats: these animals have only two teats per animal resulting in application rates per animal of up to 5 mL (sheep) and up to 6 mL (goats) for dipping and spraying and 2.5 mL (sheep) to 3 mL (goats) for foaming. The animals are only milked 1-2 times per day.

It is therefore concluded that the exposure assessment for dairy cows covers buffaloes, sheep and goats, which was confirmed at WG-V-2017.

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, JRC Scientific and Technical Reports, Report nr. EUR 25116 EN, Publications Office of the European Union, Luxembourg, 2011
Approach	Average consumption The products can either be applied by • manual or automatic dipping (Use 1.1, 4.1): post milking (product volume of 3-10 ml/cow/treatment) • Manual or automatic dipping, foaming or spraying (Use 2.1, 3.1, 5.1) Pre milking (product volume of 3-10 ml/cow/treatment) • Manual or automatic dipping, foaming or spraying (Use 2.2, 3.2, 5.2) Post milking (product volume of 3-10 ml/cow/treatment)
Distribution in the environment	In agreement with the CAR (2013) on iodine (see also table below).
Groundwater simulation	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 pore water 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 of active substance iodine: not assessed; the production takes place outside the EU. Formulation: assessed (statement) Use: assessed Service life: not assessed, 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:

The formulation is done in a system with automated dosing of most ingredients. The components are stepwise added into a closed vessel equipped with an automated stirrer. The filling of the containers (e.g. bottles and drums) is done in an automated filling and packaging installation. The production site is further equipped with exhaust air ventilation. Where relevant, workers wear PPE. Manual work is reduced to a minimum. Thus exposure of workers is negligible.

Any spills are taken up, collected and treated as chemical waste. Consequently, there is no release into the environment.

Disinfection of teats of dairy cows

Teat disinfections are applied by manual or automatic-dipping, by manual or automatic foaming, or by manual or automatic spraying (3-10 mL/event). The latter applies when the cows are milked by a robot. The respective application rates for the products are provided in the following table.
The maximum number of milking events per day is three. When robotic milking is applied, individual cows maybe milked 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 milkings per day (experience from a test house specialised in veterinary farm research member). Consequently, the maximum number of milking events is 3 per day also for robotic milking.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Teat disinfection of animals			
Application rate of biocidal product	10[a]	ml/cow/treatment	for the application method spraying (worst-case)
Concentration of active substance in the product	7.489	g/L	Calculated from the max. in-use-concentration of 0.550% iodine and the max. concentration of 0.235% sodium iodide in the applied products[b]. To assess the risks related to iodate (IO_3^-), the concentration is multiplied by 1.382 representing the differences in molar weight.
Time of application	pre & post[c]	-	worst-case approach based on the first draft SPC of the applicant
Number of milking events per day	3	d^{-1}	value for automatic milking in milking robots (worst-case)
Resulting product volume for spraying	60	ml/cow/day	corresponding worst-case consumption

[a] According to the applicant's recommendations. See SPC for more details;

[b] Please refer to the explanations provided in: 2.3.5 Risk assessment for human health, B. Exposure assessment/General considerations

[c] 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.

Although the iodine concentration in *meta* SPC-4 is higher (9.06 g/L), *meta* SPC-2 results in the highest emission to the environment as products were initially intended for both pre- and post-milking, i.e. six applications per day. Therefore, PECs were only calculated for *meta* SPC-2.

Calculations for Scenario [1]

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$)**	**Remarks**
STP	0.0185 kg iodine/d	Daily emission to the sewer system
Soil grassland	1.19 kg	Amount of active ingredient in manure or slurry at the end of the storage period (53 days, one manure application). Note that grasslands are fertilised four times annually
Soil arable land	4.76 kg	Amount of active ingredient in manure or slurry at the end of the storage period (212 days)

***** In the ESD it is assumed that 4 applications of manure per year are made to grassland. The formula of the ESD calculates the $Elocal_{soil}$ for the first application only. The resulting value is multiplied with 4 to obtain the total yearly emission to soil, which is the basis for the ERA.

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 is 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 iodine or iodate. Limited information on the behaviour of iodate and iodine 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

Both emission pathways are considered: the scenario via STP is named "Scenario 1a" and the scenario via slurry/manure is named "Scenario 1b". The receiving compartments for these scenarios are different (see the following table).

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1a (via STP)	yes	yes	yes	yes	yes	no	yes	yes	no
Scenario 1b (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 25C)	1×10^{-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	mg/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 (log K_{ow})	-	-	inorganic substance
Organic carbon/water partition coefficient (K_{oc})	165.83	l/kg	not applied in the risk assessment. Overruled by K_d.
Solids-water partition coefficient in soil (k_d)	5.8	l/kg	Source: ECHA
Solids-water partition coefficient in sediment (Kp_{sed})	200	l/kg	Source: ECHA

Solids-water partition coefficient in suspended matter (Kd_{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								
	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								
	7.40	0.738	0.036	0.074	3.58E-03	0.046	8.53	--
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	--	2.22	0.108	--	--	0.120	22.9	--
arable land	--	0.610	0.030	--	--	0.033	6.30	--
via slurry/manure – concentrations after ten years. Leaching from the top soil layer between two applications is considered.								
grassland	--	6.68	0.325	--	--	0.361	69.0	--
arable land	--	4.07	0.198	--	--	0.220	42.1	--

Summary table on calculated PEC values for iodate								
	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								
	--	1.02	0.050	0.102	2.59E-03	0.064	11.8	--
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	--	3.07	0.149	--	--	0.166	31.7	--
arable land	--	0.843	0.041	--	--	0.046	8.71	--
via slurry/manure – concentrations after ten years. Leaching from the top soil layer between two applications is considered.								
grassland	--	9.23	0.449	--	--	0.499	95.4	--
arable land	--	5.63	0.274	--	--	0.305	58.2	--

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

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

RISK CHARACTERISATION

Atmosphere

Conclusion:

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	
	$PEC/PNEC_{STP}$
Scenario 1	0.003

Conclusion: 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 (see the PNEC-values for the aquatic compartment below).

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 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				
	1.25	n.r.	**1.25**	n.r.
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	**3.79**	n.r.	n.r.	n.r.
arable land	**1.03**	n.r.	n.r.	n.r.

Summary table on calculated PEC/PNEC values for iodine				
	$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**	**$PEC/PNEC_{seawater}$**	**$PEC/PNEC_{seased}$**
via slurry/manure – PEC:PNEC ratios after ten years. Leaching from the top soil layer between two applications is considered.				
grassland	**11.3**	n.r.	n.r.	n.r.
arable land	**6.91**	n.r.	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				
	0.892	n.r.	0.892	n.r.
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	**2.67**	n.r.	n.r.	n.r.
arable land	0.735	n.r.	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	**8.05**	n.r.	n.r.	n.r.
arable land	**4.91**	n.r.	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				
	0.017	n.r.	0.017	n.r.
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	0.052	n.r.	n.r.	n.r.
arable land	0.014	n.r.	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	0.158	n.r.	n.r.	n.r.
arable land	0.096	n.r.	n.r.	n.r.

Conclusion:

The individual PEC/PNEC ratios for iodine, iodide and iodate are above 1 for the aquatic compartment (surface water incl. sediment, marine water incl. sediment). In case of release to the sewer, only a small exceedance of the PNEC for iodide is expected. However, considering that iodine is transformed into iodide or iodate for which the accompanied risks are acceptable, no risks are expected in case of emission to the sewer.

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 8.05 after ten years of successive manure applications, while iodate results in a PEC:PNEC ratio of 0.158. Unacceptable risks may be expected in surface water low in oxygen. Iodine is however a natural occurring compound for which aquatic background levels are reported between 0.5 and 20 µg/L. Moreover, many uncertainties exist as currently available higher tier modelling (FOCUS PEARL, SWASH) are not suitable for inorganic substances such as iodine. It was therefore agreed that the natural background concentration replaces the PNEC as environmental standard. The accompanied risks are therefore considered acceptable.

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		
Scenario 1a (via STP)		
	$PEC/PNEC_{soil}$	
Scenario 1	**3.90**	
Scenario 1b (via slurry/manure)		
	after one year	**after ten years**
Nitrogen standard, grassland	**10.2**	**30.6**
Nitrogen standard, arable land	**2.80**	**18.7**

Calculated PEC/PNEC values for iodide	
Scenario 1a (via STP)	
	$PEC/PNEC_{soil}$
Scenario 1	**10.7**

Calculated PEC/PNEC values for iodide		
Scenario 1b (via slurry/manure)		
	after one year	**after ten years**
Nitrogen standard, grassland	**27.9**	**84.0**
Nitrogen standard, arable land	**7.68**	**51.3**

Calculated PEC/PNEC values for iodate		
Scenario 1a (via STP)		
	$PEC/PNEC_{soil}$	
Scenario 1	0.209	
Scenario 1b (via slurry/manure)		
	after one year	**after ten years**
Nitrogen standard, grassland	0.545	**1.64**
Nitrogen standard, arable land	0.150	**1.00**

Conclusion:

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 occurs 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 (0.361 mg iodine/kg wwt in grassland and 0.220 mg iodine/kg wwt in arable land) are in the lower range and therefore a significant increase of the background concentration cannot be expected, although it should be realised that anthropogenic imission to soils due to teat disinfection (156 g/ha/y) is about six times higher than the natural atmospheric deposition (25,6 g/ha/y[1]). However, naturally occurring iodine may be less bioavailable due to

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

strong sorption on organic material or complexation with e.g. metals. Unacceptable risks in soils are conclusively not expected.

Groundwater

The concentration of iodine and iodide in the soil's pore water is expected to be 69 µg /L in grassland and 42.1 µg/L in arable land (iodine and iodide) after repeated manure applications for ten successive years. The predicted iodate concentrations are 95.4 µg/L in grassland and 58.2 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 to 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/L. 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.

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 assessement:
1. active substance
2. substances of concern (SoC)
3. active substances from other PTs
4. other ingredients.

Hypreds teat disinfectants: Only one active substance and one substances of concern (see confidential Annex 3.6) are contained in the product. In addition, no active substances from other PTs and no other ingredients that need consideration are contained.
The substance of concern is only classified for its eye irritating properties but not for environmental effects and thus not relevant for consideration in the environmental risk assessment (number of relevant substances = 1, i.e. only active substance) as explained previously.

Screening Step 3: Screen on synergistic interactions

Synergistic effects are not expected, since there is no direct release into any environmental compartment.

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 emission 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.

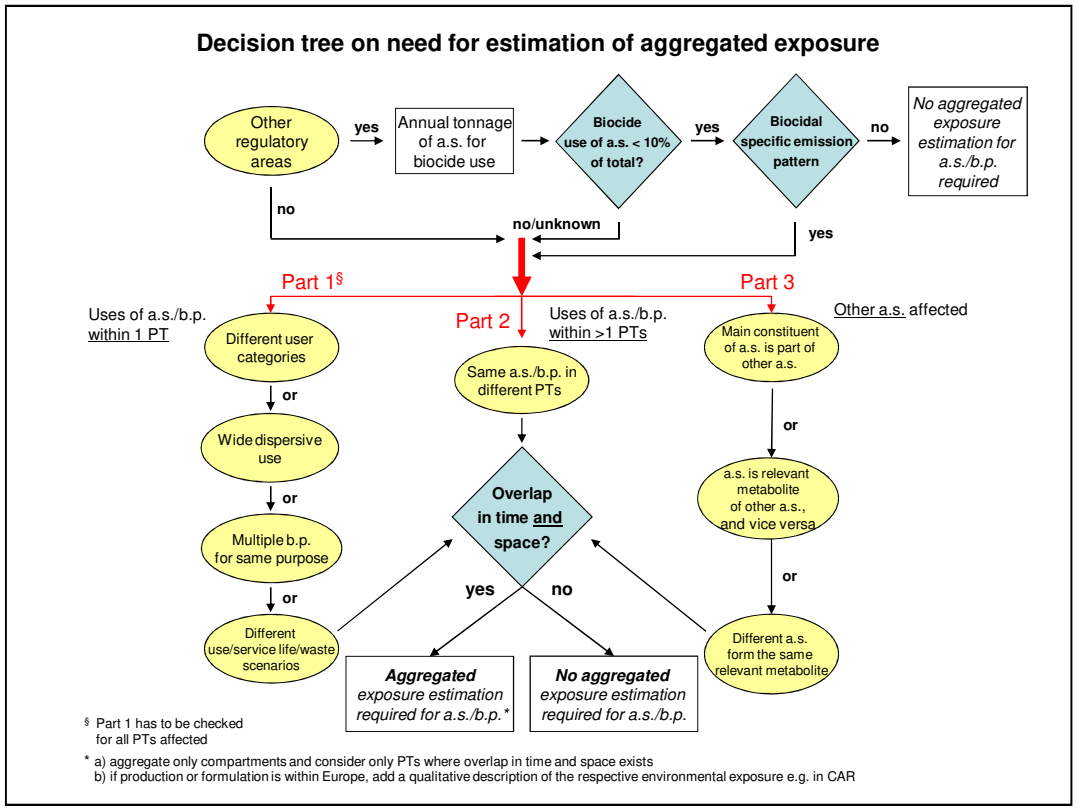


Figure 1: Decision tree on the need for estimation of aggregated exposure

2.3.8 Measures to protect man, animals and the environment

RECOMMENDED METHODS AND PRECAUTIONS

Methods and precautions concerning handling and use

Personal protective equipment :

Eye/face protection :
Wear safety goggles compliant with standard EN 166.

Hand protection :
Wear protective gloves with chemical resistance.

Skin protection :
Wear boots and a protective cloth with chemical resistance.

Respiratory protection :
No special protection measure is required.

Health measures :
After using, wash systematically all personal protective equipment.

Methods and precautions concerning storage
Shelf life: 2 years
Store at room temperature.

Methods and precautions concerning transport
Products included in *meta* SPC 1, *meta* SPC 2, *meta* SPC 4 and *meta* SPC 5 are not classified for transport.

Products included in *meta* SPC 3 are classified for transport towards environment.

Methods and precautions concerning fire
HYPRED's iodine based products are non-flammable.
Hazardous decomposition products : None to our knowledge in standard conditions of use.
Extinguishing media :
- Suitable extinguishing media : Water, powder extinguisher, foam, carbon dioxide; Agents compatible with other products involved into fire.
- Unsuitable extinguishing media : None from our knowledge.

Advice for firefighters :
Wear independent respiratory equipment and protective suit.
Collect contaminated firefighting water separately, must not be discharged into the drains.
Keep containers cool by spraying with water if exposed to fire

Measures to protect environment
Do not discharge the product directly to the environment.
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 burning into biogas installation) or to the municipal sewer if legally allowed.

IDENTITY OF RELEVANT COMBUSTION PRODUCTS IN CASES OF FIRE

None to our knowledge.

SPECIFIC TREATMENT IN CASE OF AN ACCIDENT

First aid measures

For products included in *meta* SPC1, *meta* SPC 2, *meta* SPC 4 and *meta* SPC 5:
Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.
FIRST AID INSTRUCTIONS
- In the event of inhalation : Bring to fresh air.
- In the event of contact with the skin : Wash with water.
- In the event of contact with the eyes :
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
- In the event of ingestion : Rinse mouth. Do NOT induce vomiting. Get medical advice.
Refer to the safety data sheet available for professional user : it contains an emergency phone number.

For product included in *meta* SPC3 :
Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID INSTRUCTIONS :
- In the event of inhalation : Bring to fresh air.
- In the event of contact with the skin : Wash with water.
- In the event of contact with the eyes :
Rinse at once with a soft stream of water for at least 15 minutes, eyes wide open.
Remove contact lenses if present and easy to do. Continue rinsing.
Immediately call a POISON CENTER or doctor/physician.
- In the event of ingestion : Rinse mouth. Do NOT induce vomiting. Get medical advice.
Refer to the safety data sheet available for professional user : it contains an emergency phone number

Emergency measures to protect the environment in case of accidental release

Evacuate non-essential staff and those not equipped with individual protection equipement.

Evacuate the personnel to a safe location.
Keep people upwind and away from the location of the flow/leak.
Use personal protection equipment.

Small spillage : Wash with plenty of water.

Large spillage : Mark out, dyke up with an inert absorbant and pump in an emergency tank. Keep in suitable, properly labelled and closed containers for disposal. Never return spills in original containers for re-use.

POSSIBILITY OF DESTRUCTION OR DECONTAMINATION FOLLOWING RELEASE

Soil : Collect contaminated soil in a suitable container and dispose of as hazardous waste.

PROCEDURES FOR WASTE MANAGEMENT OF THE BIOCIDAL PRODUCT AND ITS PACKAGING

Eliminate the product and its packaging in accordance with applicable local and national regulations.

Empty product containers are rinsed off at least twice with water and consigned to normal waste
The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste.

PROCEDURES FOR CLEANING APPLICATION EQUIPMENT WHERE RELEVANT

After manual application, reservoir of dipping/foaming cup or sprayer are emptied and the entire dip/foam or spray equipment is cleaned with water.
After automated application by dipping or foaming : Every liner of the automated dipping-system is thoroughly rinsed with water and blown out with compressed air
After automated application by spraying : the sprayer is flushed with water: the sprayer is operated for few seconds with water.

SPECIFY ANY REPELLENTS OR POISON CONTROL MEASURES INCLUDED IN THE PRODUCT

No repellent or poison control measures have been included in the preparation and are present to prevent action against non-target organisms.
No contact with non-target organisms is likely.

2.3.9 Assessment of a combination of biocidal products

Not relevant: HYPRED's iodine biocidal products are not intended to be authorised for the use with other biocidal products.

2.3.10 Comparative assessment

Not relevant: HYPRED's iodine biocidal products are not containing an active substance meeting the exclusion criteria.

3 ANNEXES

3.1 LIST OF STUDIES/DOCUMENTS FOR THE BIOCIDAL FAMILY

BPR datapoint	Study N°	Author	Year	Title	Owner of data	Data protection claimed y/n	Confidentiality request submitted y/n
2.3	No report n° Doc 2.3-001.2	Cosayach	2015	CoA Cosayach	Cosayach	n	n
2.3	Report n°: Mo5233 Doc 2.3-001.3	Dr Sven Manka - Biogenius	2015	UV/Vis-spectroscopic properties of PRILLED Iodine	Cosayach	y	n
2.3	No report n° Doc 2.3-001.5	Acf Minera	2015	CoA Prilled Iodine	Acf Minera	n	n
2.3	Report n°: Mo5236 Doc 2.3-001.6	Dr Sven Manka - BioGenius	2015	UV/Vis-spectroscopic properties of PRILLED Iodine	Acf minera	y	n
2.3	Report n° : 103670 Doc 2.3-001.8	SQM Europe NV	2015	CoA Prilled Iodine	SQM Europe NV	n	n
2.3	Report n° : 204615 Doc 2.3-001.9	SQM Europe NV	2015	CoA Prilled Iodine	SQM Europe NV	n	n
2.3	No report n° Doc 2.3-001.10	Dr Anibal Valenzuela Sobarzo	2015	Iodine – UV Spectrum in Chloroform (batch number : 2821176427 -2821176506	SQM	y	n
2.3	No report n° Doc 2.3-001.11	Dr Anibal Valenzuela Sobarzo	2015	Iodine – UV Spectrum in Chloroform (batch number : 2821176907-2821176986)	SQM	y	n

2.3	No report n° Doc 2.3-001.12	Dr Anibal Valenzuela Sobarzo	2015	Iodine – UV Spectrum in Chloroform (batch number : 2821177387-2821177446)	SQM	y	n
2.3	No report n° Doc 2.3-001.13	Dr Anibal Valenzuela Sobarzo	2015	Iodine – UV Spectrum in Chloroform (batch number : 1821318000-1821318076)	SQM	y	n
2.3	No report n° Doc 2.3-001.14	Dr Anibal Valenzuela Sobarzo	2015	Iodine – UV Spectrum in Chloroform (batch number : 1821317176-1821317255)	SQM	y	n
2.3	No report n° Doc 2.3-001.15	Dr Anibal Valenzuela Sobarzo	2015	Iodine – UV Spectrum in Chloroform (batch number : 1821318208-1821318284)	SQM	y	n
3.1/01	No report n° Doc 3.1-001	S.Gougeon - HYPRED	2014	CoA Liq-io 5500	HYPRED	n	n
3.1/02	No report n° Doc 3.1-002	S.Gougeon - HYPRED	2014	CoA Liq-io 2500	HYPRED	n	n
3.1/03	No report n° Doc 3.1-003	S.Gougeon - HYPRED	2014	CoA Dip-io 5000	HYPRED	n	n
3.1/04	No report n° Doc 3.1-004	S.Gougeon - HYPRED	2014	CoA Dip-io 2500	HYPRED	n	n
3.1/05	No report n° Doc 3.1-005	S.Gougeon - HYPRED	2014	CoA Liq-io concentrate	HYPRED	n	n
3.2/01	Report n° :14-908007-044 Doc 3.2-001	B.Demangel - DEFITRACES	2014	Determination of pH values on Liq-io 5500	HYPRED	y	n
3.2/02	Report n° :14-908007-038 Doc 3.2-002	B.Demangel - DEFITRACES	2014	Determination of pH values on Liq-io 2500	HYPRED	y	n
3.2/03	Report n° :14-908007-034	B.Demangel - DEFITRACES	2014	Determination of pH values on Dip-io 5000	HYPRED	y	n

	Doc 3.2-003						
3.2/04	Report n° :14-908007-036 Doc 3.2-004	B.Demangel - DEFITRACES	2014	Determination of pH values on Dip-io 2500	HYPRED	y	n
3.2/05	Report n° :14-908007-040 Doc 3.2-005	B.Demangel - DEFITRACES	2014	Determination of pH values on Liq-io concentrate	HYPRED	y	n
3.2/06	No report n° Doc 3.2-006	S.Gougeon - HYPRED	2016	Acidity of Liq-io concentrate	HYPRED	y	n
3.2/07	No report n° Doc 3.2-007	S.Gougeon - HYPRED	2016	Acidity of Dip-io 5000	HYPRED	y	n
3.3/01	Report n° :14-908007-044 Doc 3.3-001	B.Demangel - DEFITRACES	2014	Relative density on Liq-io 5500	HYPRED	y	n
3.3/02	Report n° :14-908007-038 Doc 3.3-002	B.Demangel - DEFITRACES	2014	Relative density on Liq-io 2500	HYPRED	y	n
3.3/03	Report n° :14-908007-034 Doc 3.3-003	B.Demangel - DEFITRACES	2014	Relative density on Dip-io 5000	HYPRED	y	n
3.3/04	Report n° :14-908007-036 Doc 3.3-004	B.Demangel - DEFITRACES	2014	Relative density on Dip-io 2500	HYPRED	y	n
3.3/05	Report n° :14-908007-040 Doc 3.3-005	B.Demangel - DEFITRACES	2014	Relative density on Liq-io concentrate	HYPRED	y	n
3.4.1/ 01	No report n° Doc 3.4.1-001.1	S.Gougeon - HYPRED	2014	Liq-io 5500 Accelerated storage test 30 +/- 2°C for 18 weeks	HYPRED	y	n
3.4.1/ 02	No report n°	S.Gougeon - HYPRED	2014	Liq-io 2500 Accelerated storage	HYPRED	y	n

	Doc 3.4.1-001.2			test 30 +/- 2°C for 18 weeks			
3.4.1/03	No report n° Doc 3.4.1-001.3	S.Gougeon - HYPRED	2014	Dip-io 5000 Accelerated storage test 30 +/- 2°C for 18 weeks	HYPRED	y	n
3.4.1/04	No report n° Doc 3.4.1-001.4	S.Gougeon - HYPRED	2014	Dip-io 2500 Accelerated storage test 30 +/- 2°C for 18 weeks, report n° : n, test lab : HYPRED, GLP : n, published : n	HYPRED	y	n
3.4.1/05	No report n° Doc 3.4.1-001.5	S.Gougeon - HYPRED	2014	Liq-io concentrate Accelerated storage test 30 +/- 2°C for 18 weeks	HYPRED	y	n
3.4.1/06	No report n° Doc 3.4.1-002.1	S.Gougeon - HYPRED	2014	Liq-io 5500 Low temperature stability study	HYPRED	y	n
3.4.1/07	No report n° Doc 3.4.1-002.2	S.Gougeon - HYPRED	2014	Liq-io 2500 Low temperature stability study	HYPRED	y	n
3.4.1/08	No report n° Doc 3.4.1-002.3	S.Gougeon - HYPRED	2014	Dip-io 5000 Low temperature stability study	HYPRED	y	n
3.4.1/09	No report n° Doc 3.4.1-002.4	S.Gougeon - HYPRED	2014	Dip-io 2500 Low temperature stability study	HYPRED	y	n
3.4.1/10	No report n° Doc 3.4.1-002.5	S.Gougeon - HYPRED	2014	Liq-io concentrate Low temperature stability study	HYPRED	y	n
3.4.1/11	No report n° Doc 3.4.1-003.1	S.Gougeon - HYPRED	2014	Liq-io 5500 Long term storage test at 20 +/- 2°C for 2 years	HYPRED	y	n

3.4.1/ 12	No report n° Doc 3.4.1-003.2	S.Gougeon - HYPRED	2014	Liq-io 2500 Long term storage test at 20 +/- 2°C for 2 years	HYPRED	y	n
3.4.1/ 13	No report n° Doc 3.4.1-003.3	S.Gougeon - HYPRED	2014	Dip-io 5000 Long term storage test at 20 +/- 2°C for 2 years	HYPRED	y	n
3.4.1/ 14	No report n° Doc 3.4.1-003.4	S.Gougeon - HYPRED	2014	Dip-io 2500 Long term storage test at 20 +/- 2°C for 2 years	HYPRED	y	n
3.4.1/ 15	No report n° Doc 3.4.1-003.5	S.Gougeon - HYPRED	2014	Liq-io concentrate Long term storage test at 20 +/- 2°C for 2 years	HYPRED	y	n
3.5/03	No report n° Doc 3.5-003	S.Gougeon - HYPRED	2014	Dilution stability of Liq-io concentrate diluted at 20 %	HYPRED	y	n
3.8/01	Report n° :14-908007-042 Doc 3.8-001	B.Demangel - DEFITRACES	2014	Surface tension test on Liq-io 5500	HYPRED	y	n
3.8/02	Report n° :14-908007-013 Doc 3.8-002	B.Demangel - DEFITRACES	2014	Surface tension test on IODE 2500 SPRAY	HYPRED	y	n
3.8/03	Report n° :14-908007-015 Doc 3.8-003	B.Demangel - DEFITRACES	2015	Surface tension test on Dip-io 5000	HYPRED	y	n
3.8/04	Report n° :14-908007-012 Doc 3.8-004	B.Demangel - DEFITRACES	2015	Surface tension test on Dip-io 2500	HYPRED	y	n
3.8/05	Report n° :14-908007-016 Doc 3.8-005	B.Demangel - DEFITRACES	2014	Surface tension test on Liq-io concentrate	HYPRED	y	n
3.9/01	Report n° :14-908007-005	B.Demangel - DEFITRACES	2015	Viscosity on Liq-io 5500	HYPRED	y	n

	Doc 3.9-001						
3.9/02	Report n° :14-908007-004 Doc 3.9-002	B.Demangel - DEFITRACES	2015	Viscosity on Liq-io 2500	HYPRED	y	n
3.9/03	No report n° Doc 3.9-003	S.Gougeon - HYPRED	2014	Viscosity on Dip-io 5000	HYPRED	y	n
3.9/04	No report n° Doc 3.9-004	S.Gougeon - HYPRED	2014	Viscosity on Dip-io 2500	HYPRED	y	n
3.9/05	Report n° :14-908007-006 Doc 3.9-005	B.Demangel - DEFITRACES	2015	Viscosity on Liq-io concentrate	HYPRED	y	n
4.16	No report n° GLP3016002499BR1V1/2017	Mr Shajad Younis	2017	Corrosion to Metals Testing on a Sample of Dip-io 5000	HYPRED	y	n
4.16	No report n° GLP3016002499AR1V2/2017	Mr Shajad Younis	2017	Corrosion to Metals Testing on a Sample of Liq-io Concentrate	HYPRED	y	n
5/01	No report n° Doc 5-001	S.Ladril Maisonneuve - HYPRED	2015	AL 214v03 Determination of the Iodine and iodates content in iodine products	HYPRED	y	n
5/02	No report n° Doc 5-002	S.Ladril Maisonneuve - HYPRED	2015	AL 213v03 Determination of the Iodine and iodates content in concentrated iodine products	HYPRED	y	n
5/03	No report n° Doc 5-003	S.Ladril Maisonneuve - HYPRED	2014	Validation report for methods AL 213 and AL 214	HYPRED	y	n

				Doc 5-003			
5/04	No report n° Doc 5-004	S.Ladril Maisonneuve - HYPRED	2015	AL 215 v 03 dosage of iodide by HPLC	HYPRED	y	n
5/05	No report n° Doc 5-005	S.Ladril Maisonneuve - HYPRED	2014	Validation report for method AL215	HYPRED	y	n
6.7/01	Report n° : 3422-1 Doc 6.7-001.1	AF. Gabillet - LMH	2014	Bactericidal efficacy test according to the methodology of the norm EN1656 (March 2010) Liq-io 5500	HYPRED	y	n
6.7/02	Report n° : 3423-1 Doc 6.7-001.2	M.Teulier - LMH	2014	Yeasticidal efficiency test according to the methodology of the norm EN1657 (April 2006) Liq-io 5500	HYPRED	y	n
6.7/03	Report n° : MIC 14/09-161.EV LMH Doc 6.7-001.3	JP. Chiron - ADREMI	2014	Liq-io 5500 Quantitative suspension test for evaluation of virucidal activity in the presence of 1% skimmed milk / 5 minutes / 30°C	HYPRED	y	n
6.7/04	Report n° : 3567-1 Doc 6.7-001.4	AF. Gabillet - LMH	2015	Bactericidal efficacy test according to the methodology of the norm EN1656 (March 2010) Liq-io 5500	HYPRED	y	n
6.7/05	Report n° : 3568-1 Doc 6.7-001.5	AF. Gabillet - LMH	2015	Antimicrobial activity against Prototheca wickerhamii DSM 10639 according to the methodology of the standard EN1657 (April 2006) Liq-io 5500	HYPRED	y	n
6.7/06	Report n° : 3403-1 Doc 6.7-002.1	M.Teulier - LMH	2014	Bactericidal efficacy test according to the methodology of the	HYPRED	y	n

				norm EN1656 (March 2010) Liq-io 2500			
6.7/07	Report n° : 3328-1 Doc 6.7-002.2	AF. Gabillet - LMH	2014	Yeasticidal efficiency test according to the methodology of the norm EN1657 (April 2006) Liq-io 2500	HYPRED	y	n
6.7/08	Report n° : 3650-1 Doc 6.7-002.3	M.Teulier - LMH	2015	Bactericidal efficacy test according to the methodology of the norm EN1656 (March 2010) Liq-io 2500, , test lab : LMH, GLP : n, published : n	HYPRED	y	n
6.7/09	Report n° : 3617-1 Doc 6.7-002.4	AF. Gabillet - LMH	2015	Antimicrobial activity against Prototheca wickerhamii DSM 10639 according to the methodology of the standard EN1657 (April 2006) Liq-io 2500	HYPRED	y	n
6.7/10	Report n° : 3759-1 Doc 6.7-002.5	AF. Gabillet - LMH	2015	Bactericidal efficacy test according to the methodology of the norm EN1656 (March 2010) Liq-io 2500	HYPRED	y	n
6.7/11	Report n° : 3758-1 Doc 6.7-002.6	AF. Gabillet - LMH	2014	Yeasticidal efficiency test according to the methodology of the norm EN1657 (April 2006) Liq-io 2500	HYPRED	y	n
6.7/12	Report n° : 3404-1 Doc 6.7-003.1	M.Teulier - LMH	2014	Bactericidal efficacy test according to the methodology of the norm EN1656 (March 2010) Dip-io 5000, , test lab : LMH, GLP : n, published : n	HYPRED	y	n
6.7/13	Report n° : 3405-1	M.Teulier - LMH	2014	Yeasticidal efficiency test according to the methodology of the	HYPRED	y	n

	Doc 6.7-003.2			norm EN1657 (April 2006) Dip-io 5000			
6.7/14	Report n° : MIC 14/12-021.EV LMH Doc 6.7-003.3	JP. Chiron - ADREMI	2014	Dip-io 5000 Quantitative suspension test for evaluation of virucidal activity in the presence of 1% skimmed milk / 5 minutes / 30°C,	HYPRED	y	n
6.7/15	report n° : 3402-1 Doc 6.7-004.1	M.Teulier - LMH	2014	Bactericidal efficacy test according to the methodology of the norm EN1656 (March 2010) Dip-io 2500	HYPRED	y	n
6.7/16	Report n° : 3326-1 Doc 6.7-004.2	AF. Gabillet - LMH	2014	Yeasticidal efficiency test according to the methodology of the norm EN1657 (April 2006) Dip-io 2500	HYPRED	y	n
6.7/17	Report n° : 3651-1 Doc 6.7-004.3	AF. Gabillet - LMH	2015	Bactericidal efficacy test according to the methodology of the norm EN1656 (March 2010) Dip-io 2500	HYPRED	y	n
6.7/18	Report n° : 3618-1 Doc 6.7-004.4	AF. Gabillet - LMH	2015	Antimicrobial activity against Prototheca wickerhamii DSM 10639 according to the methodology of the standard EN1657 (April 2006) Dip-io 2500	HYPRED	y	n
6.7/19	Report n° : 3408-1 Doc 6.7-005.1	AF. Gabillet - LMH	2014	Bactericidal efficacy test according to the methodology of the norm EN1656 (March 2010) Liq-io concentrate	HYPRED	y	n
6.7/20	Report n° : 3409-1	M.Teulier - LMH	2014	Yeasticidal efficiency test according to the methodology of the	HYPRED	y	n

	Doc 6.7-005.2			norm EN1657 (April 2006) Liq-io concentrate			
6.7/21	Report n° : MIC 14/12-161.EV LMH Doc 6.7-005.3	JP. Chiron - ADREMI	2015	Liq-io concentrate Quantitative suspension test for evaluation of virucidal activity in the presence of 1% skimmed milk / 5 minutes / 30°C	HYPRED	y	n
6.7/22	Report n° : 3757-1 Doc 6.7-005.4	M.Teulier - LMH	2015	Bactericidal efficacy test according to the methodology of the norm EN1656 (March 2010) Liq-io concentrate	HYPRED	y	n
6.7/23	Report n° : 3760-1 Doc 6.7-005.5	M.Teulier - LMH	2015	Yeasticidal efficiency test according to the methodology of the norm EN1657 (April 2006) Liq-io concentrate	HYPRED	y	n
6.7/24	Report n° : 3396-1 Doc 6.7-006	AF. Gabillet - LMH	2015	Bactericidal efficacy test according to the methodology of the norm EN1040 (April 2006) Citric acid 0.6% at pH 3.3	HYPRED	y	n
6.7/25	Report n° : 3528-2 Doc 6.7-007.1	AF. Gabillet - LMH	2015	Efficacy test for bactericidal activity on a porous surface (VITRO SKIN synthetic skin) in accordance with a protocol adapted from the EN16437 standard (March 2014) Liq-io 2500	HYPRED	y	n
6.7/26	Report n° : 3529-2	AF. Gabillet - LMH	2015	Efficacy test for bactericidal activity on a porous surface	HYPRED	y	n

	Doc 6.7-007.2			(VITRO SKIN synthetic skin) in accordance with a protocol adapted from the EN16437 standard (March 2014) Liq-io 2500			
6.7/27	Doc 6.7-007.3	LMH	2015	LMH modified EN 16437 (Drop/Dip)	HYPRED	y	n
6.7/28	Report n° 3772-1 Doc 6.7-007.4	LMH	2016	Efficacy test for bactericidal activity on a synthetic skin according to a protocol adapted from the EN16437 (march 2014) standard in drop/dip LIQ-IO 2500	HYPRED	y	n
6.7/29	Report n° 3774-1 Doc 6.7-007.5	LMH	2016	Efficacy test for yeasticidal activity on a synthetic skin according to a protocol adapted from the EN16437 (march 2014) standard in drop/dip LIQ-IO 2500	HYPRED	y	n
8.2/01	Report n° : Th 425/01-2374 Doc 8.2-001.1	D.Masson – EVIC FRANCE	2010	Acute Eye irritation/corrosion test in the rabbit IODACTIV	HYPRED	y	n
8.2/02	No Report n° Doc 8.2-001.2	HYPRED	2015	Eye irritation Liq-io 5500	HYPRED	y	n
8.2/03	No Report n° Doc 8.2-003.2	HYPRED	2015	Eye irritation Dip-io 5000	HYPRED	y	n
8.6/01	Report n°: BC884-00005 Doc 8.6-001	Dr Silvia Wagner - SCC	2015	Dermal absorption of iodine from products pertaining to Hypred's BPF	IRG	y	n
-	Doc 13-001	Hugues Kenigswald - ECHA	2014	Outcome pre-submission consultation : UP-APP	HYPRED	y	n

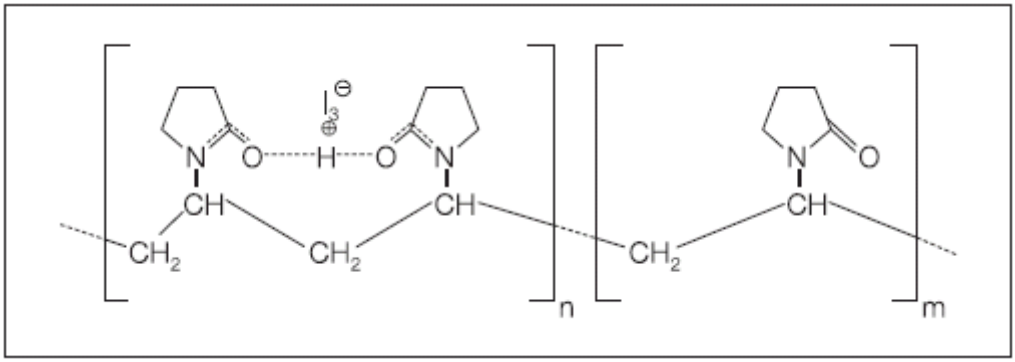
				outcome_Hypred_2014-12-18			
-	Doc 13-002	Dr Silvia Wagner - SCC	2015	Declaration of ownership of data and access rights IODINE	IRG	y	n
-	Doc 13-010	Dr Silvia Wagner - SCC	2015	Discussion paper on iodine residues in milk – Assessment of consumer safety	IRG	y	n
-	Doc 13-011	Dr Silvia Wagner/Dr Hans Josef Leusch - SCC	2015	Considerations on animal health : Exposure and risk assessment for dairy cows treated with iodine based teat disinfectants	IRG	y	n
IUCLID section 13	Doc 13-012	Dr Silvia Wagner/Dr Hans Josef Leusch - SCC	2015	Considerations on animal health : Exposure and risk assessment for buffaloes, sheep and goats treated with iodine based teat disinfectants	IRG	y	n
IUCLID section 13	Doc 13-013	Anonymous - SCC	2015	Calculations sheet DRA iodine residues in milk_Hypred	HYPRED	y	n

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.

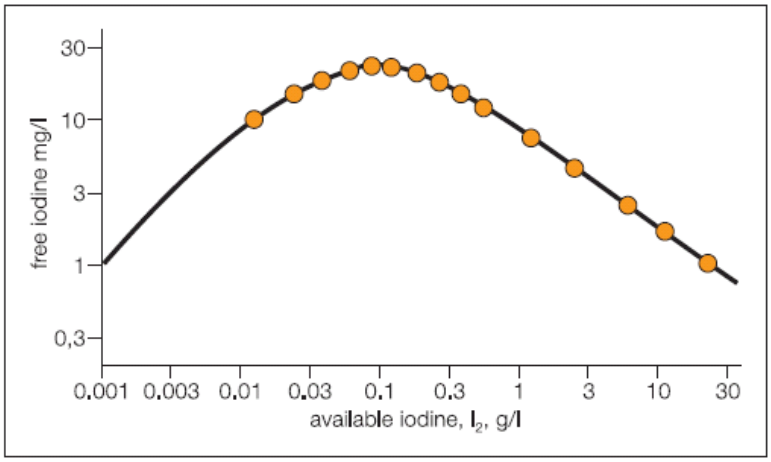
In the following, PVP-iodine (iodophor type 2) is taken as an example iodophor. However, the considerations are expected to also apply to other types of iodophors such as iodophor type 1 (iodine complexed with surfactants).
The predicted structure of solid PVP-iodine as provided in the iodine dossier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

References
Ref [1]

Technical Information

August 2010
Supersedes issue dated June 2008

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PVP-Iodine grades

Povidone, iodinated Ph. Eur., Povidone-Iodine USP

® = Registered trademark of BASF group

Disinfectants

TDS_BASF_PVP-Iodine-grades.pdf

Ref [2]

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

20.3.2.1 Iodophors

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

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

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

Appendix 3.2-I

Scenario [2.2]: Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer when using a RTU product containing 0.7489% total iodine (*meta* SPC2/5)

Consumer spraying and dusting model 2 Hand-held trigger spray		**Tier 1**	**Tier 2**
Product			
active substance	% w/w	0,7489	0,7489
body weight	kg	60	60
dermal absorption	%	12	12
Dermal exposure			
Potential hand/forearm exposure			
indicative value	mg/min	36,1	36,1
duration	min	13,7	13,7
potential hand deposit	mg	493,37	493,37
penetration through gloves	%	100	10
actual hand deposit	mg	493,37	49,34
Potential legs, feet and face exposure			
indicative value	mg/min	9,7	9,7
duration	min	13,7	13,7
potential legs, feet and face deposit	mg	132,5667	132,5667
penetration through clothing	%	100	10
actual legs, feet and face deposit	mg	132,57	13,26
Total dermal dermal exposure			
total dermal deposit (a.s.)	mg	4,69	0,47
penetration through skin (a.s.)	mg	0,56	0,06
number of applications	counts	2,00	2,00
systemic exposure via dermal route	**mg/kg bw/d**	**1,88E-02**	**1,88E-03**
% Upper intake level	**%**	**187,50**	**18,75**
Inhalation exposure			
indicative value	mg/m3	10,5	10,5
duration	min	13,7	13,7
inhalation rate	m3/min	0,02	0,02
inhaled volume	m3	0,28	0,28
inhaled product	mg	2,99	2,99
inhaled a.s.	mg	0,02	0,02
inhaled a.s.	m/m3	0,08	0,08
number of applications	counts	2,00	2,00
systemic exposure via inhalation route	**mg/kg bw/d**	**7,46E-04**	**7,46E-04**
% Upper intake level	**%**	**7,46**	**7,46**
active substance	**mg/m3**	**7,86E-02**	**7,86E-02**
OEL	**mg/m3**	**1**	**1**
% OEL	**%**	**7,86**	**7,86**
Total systemic exposure	**mg/kg bw/d**	**1,95E-02**	**2,62E-03**
% Upper intake level	**%**	**194,97**	**26,21**

Appendix 3.2-II

Scenario [2.2]: Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer when using diluted concentrate (20% dilution) containing 0.689% total iodine (*meta* SPC3)

Consumer spraying and dusting model 2 Hand-held trigger spray		Tier 1	Tier 2
Product			
active substance	% w/w	0,689	0,689
body weight	kg	60	60
dermal absorption	%	12	12
Dermal exposure			
Potential hand/forearm exposure			
indicative value	mg/min	36,1	36,1
duration	min	13,7	13,7
potential hand deposit	mg	493,37	493,37
penetration through gloves	%	100	10
actual hand deposit	mg	493,37	49,34
Potential legs, feet and face exposure			
indicative value	mg/min	9,7	9,7
duration	min	13,7	13,7
potential legs, feet and face deposit	mg	132,5667	132,5667
penetration through clothing	%	100	10
actual legs, feet and face deposit	mg	132,57	13,26
Total dermal dermal exposure			
total dermal deposit (a.s.)	mg	4,31	0,43
penetration through skin (a.s.)	mg	0,52	0,05
number of applications	counts	2,00	2,00
systemic exposure via dermal route	**mg/kg bw/d**	**1,73E-02**	**1,73E-03**
% Upper intake level	**%**	**172,51**	**17,25**
Inhalation exposure			
indicative value	mg/m3	10,5	10,5
duration	min	13,7	13,7
inhalation rate	m3/min	0,02	0,02
inhaled volume	m3	0,28	0,28
inhaled product	mg	2,99	2,99
inhaled a.s.	mg	0,02	0,02
inhaled a.s.	m/m3	0,07	0,07
number of applications	counts	2,00	2,00
systemic exposure via inhalation route	**mg/kg bw/d**	**6,87E-04**	**6,87E-04**
% Upper intake level	**%**	**6,87**	**6,87**
active substance	**mg/m3**	**7,23E-02**	**7,23E-02**
OEL	**mg/m3**	**1**	**1**
% OEL	**%**	**7,23**	**7,23**
Total systemic exposure	**mg/kg bw/d**	**1,79E-02**	**2,41E-03**
% Upper intake level	**%**	**179,37**	**24,12**

Appendix 3.2-III

Scenario [2.2]: Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer when using diluted concentrate (10% dilution) containing 0.344% total iodine (*meta* SPC3, max conc pre-milking application for concentrates)

Consumer spraying and dusting model 2 Hand-held trigger spray		**Tier 1**	**Tier 2**
Product			
active substance	% w/w	0,344	0,344
body weight	kg	60	60
dermal absorption	%	12	12
Dermal exposure			
Potential hand/forearm exposure			
indicative value	mg/min	36,1	36,1
duration	min	13,7	13,7
potential hand deposit	mg	493,37	493,37
penetration through gloves	%	100	10
actual hand deposit	mg	493,37	49,34
Potential legs, feet and face exposure			
indicative value	mg/min	9,7	9,7
duration	min	13,7	13,7
potential legs, feet and face deposit	mg	132,5667	132,5667
penetration through clothing	%	100	10
actual legs, feet and face deposit	mg	132,57	13,26
Total dermal dermal exposure			
total dermal deposit (a.s.)	mg	2,15	0,22
penetration through skin (a.s.)	mg	0,26	0,03
number of applications	counts	2,00	2,00
systemic exposure via dermal route	**mg/kg bw/d**	**8,61E-03**	**8,61E-04**
% Upper intake level	**%**	**86,13**	**8,61**
Inhalation exposure			
indicative value	mg/m3	10,5	10,5
duration	min	13,7	13,7
inhalation rate	m3/min	0,02	0,02
inhaled volume	m3	0,28	0,28
inhaled product	mg	2,99	2,99
inhaled a.s.	mg	0,01	0,01
inhaled a.s.	m/m3	0,04	0,04
number of applications	counts	2,00	2,00
systemic exposure via inhalation route	**mg/kg bw/d**	**3,43E-04**	**3,43E-04**
% Upper intake level	**%**	**3,43**	**3,43**
active substance	**mg/m3**	**3,61E-02**	**3,61E-02**
OEL	**mg/m3**	**1**	**1**
% OEL	**%**	**3,61**	**3,61**
Total systemic exposure	**mg/kg bw/d**	**8,96E-03**	**1,20E-03**
% Upper intake level	**%**	**89,56**	**12,04**

Combined exposure assessment professional uses including residues

2017-11-05_HHRA_a
cc. to HEAdhoc13_Hy

Consumer exposure: Dietary exposure to iodine residues

2017-11-05_DRA
iodine residues in milk

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)

Summary of the efficacy studies are presented in part 2.3.4 and in IUCLID part 6.7.

3.6 CONFIDENTIAL ANNEX

Please refer to the separate document for the confidential annex.