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

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

(submitted by the evaluating Competent Authority)

Iodine Teat Dip Products

Product type(s) 3

Iodine

Case Number in R4BP: BC-AL019223-55

Evaluating Competent Authority: UKCA

Date: December 2018

Table of Contents

1 CONCLUSION

The evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit authorisation of the biocidal product according to the following:

1.1.1 Usage area

User	Application method	Product type
Professional	Applied directly to animal teats pre and/or post milking via dip spray or foam application methods	PT3- Veterinary hygiene (disinfectant)

1.1.2 Authorised uses

Authorisation is granted for professional, indoor use, for direct application to animal teats, pre and/or post milking, to kill bacteria and yeast. The products may be applied pre and/or post milking depending on the formulation type and application methods, as stated in section 1.1.3

Please note: the applicant had applied for authorisation of this product family, with the products structured into four meta SPCs. Meta SPC 3 (IodoShield Active) is not recommended for authorisation, as it contains Steryl Amine Ethoxylate (2,2'-(Octadecylimino)bisethanol). This was found to be a SoC for the Environment at the requested concentration (see section 2.2.7 – Risk Assessment for the Environment for further details). The APCP Working Group V 2018 recommended non authorisation of Meta SPC 2 ("Intelliblend Concentrate") which was agreed at the BPC-28 meeting.

Details of the original family structure, containing all 4 meta SPCs and the formulation details for them, can be found in the Confidential Annex (section 3.3 of this PAR).

Meta SPCs 1 & 4 as applied for by the applicant, can be recommended for authorisation. Meta SPC 4 will be split into 2 Meta SPCs. These will be authorised as Meta SPC 2 (formerly Meta SPC 4a) and Meta SPC 3 (formerly Meta SPC 4b).

1.1.3 Application rates and frequency

Application rate(s) and frequency	In use Iodine concentration of products in the family is 0.16 – 2.47% (w/w) For concentrated products; dilute product as instructed on product label. In use concentration for concentrated products is 0.29-0.52% Iodine (w/w). Ready-to-use formulations contain 0.16-0.5% (w/w) Iodine. These products should not be diluted before use. Pre-milking: For effective use against bacteria and yeast, product must be left in contact with the skin for at least 60

	seconds. Post-milking: To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes). Pre milking: 2 applications per animal, per day Post milking: 2 applications per animal, per day Quantity of diluted or ready to use product to be applied per application; - 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)

1.1.4 Concentration and sources of active substance in the biocidal product family

The concentration of the active substance Iodine in the biocidal product family is 0.16 – 2.47% w/w. The sources of the formulated active substances are:

SQM Europe N.V.

Nihon Tennen Gas Co., Ltd (Via Mitsui & Co Europe PLC)

Norkem Ltd

Minimum purity of each source is 99.5% w/w.

1.2 Necessary issues accounted for in the product label

Keep out of reach of children

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.

Pre-milking: For effective use against bacteria and yeast, product must be left in contact with the skin for at least 60 seconds.

Post-milking: To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

At the end of the treatment, dispose of 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 farm based waste water treatment plant.

Protect from frost

Do not store at temperatures above 30 ºC

May be corrosive to metals

1.3 Requirement for further information

None

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier[1]	**Country (if relevant)**
Iodine Teat Dip Products	

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	GEA Farm Technologies(UK) Ltd
	Address	Wylye Works Watery Lane Warminster Wiltshire BA12 9HT UK
Pre-submission phase started on	Applicant did not submit a pre-submission application	
Pre-submission phase concluded on	Applicant did not submit a pre-submission application	
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	GEA Farm Technologies(UK) Ltd		
Address of manufacturer	Wylye Works Watery Lane Warminster Wiltshire BA12 9HT UK		
Location of manufacturing sites	Site 1 Wylye Works Watery Lane Warminster Wiltshire BA12 9HT UK	Site 2 Gewerbestraße 5 5325 Plainfeld Austria	Site 3 ul. Olowiana 10 85-461 Bydgoszcz Poland

[1] Please fill in here the identifying product name from R4BP 3.

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

Active substance	Iodine
Name of manufacturer	SQM Europe N.V.
Address of manufacturer	St Pietersvliet 7 bus 8 2000 Antwerp Belgium
Location of manufacturing sites	SQM S.A. Los Militares 4290 Piso 4 Las Condes, Santiago Chile

Active substance	Iodine
Name of manufacturer	Nihon Tennen Gas Co., Ltd (Via Mitsui & Co Europe PLC)
Address of manufacturer	Chiba Plant 2508 Minami-Hinata Shirako-Machi Chosei-Gun 299-4205 Chosei-Gun Japan
Location of manufacturing sites	As above

Active substance	Iodine
Name of manufacturer	Norkem Ltd
Address of manufacturer	Norkem House Bexton Lane Knutsford WA16 9FB United Kingdom
Location of manufacturing sites	Corsayach Oficina Cala Cala S/N Pozo Almonte Chile

2.1.2 Product (family) composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Iodine
IUPAC or EC name	Iodine
EC number	231-442-4
CAS number	7553-56-2
Index number in Annex VI of CLP	053-001-00-3
Minimum purity / content	995 g/kg (manufactured to the specification of Ph. Eur[1])
Structural formula	I_2

CLASSIFICATION FOR THE ACTIVE SUBSTANCE IODINE ACCORDING TO REGULATION (EC) N°1272/2008 FOR HUMAN HEALTH EFEECTS

1. **Harmonised Classification for the Active Substance Iodine according to Regulation (EC) N°1272/2008**

Index Number	EC Number	CAS Number	International Chemical Identification
053-001-00-3	231-442-4	7553-56-2	iodine

CLP Classification (Table 3.1)

Classification	Labelling	Specific	Note

Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	Pictograms, Signal Word Code(s)	Concentration limits, M-Factors	s
Acute Tox. 4	H312	H312		GHS07 GHS09 Wng		
Acute Tox. 4	H332	H332				

2.1.2.2 Candidate(s) for substitution

Iodine is not a Candidate for Substitution as it does not meet the criteria stated in Article 10 of Regulation (EU) 528/2012. A comparative assessment is therefore not required under Article 23 of Regulation (EU) 528/2012.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product Family[2]

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine, pure	Iodine	Active substance	7553-56-2	231-442-4	0.16	2.47

Please note: the above is the authorised iodine concentration range for the family. A concentration range of 0.16 to 5.22 % was applied for. However, following non-authorisation of meta SPC 2 ("*Intelliblend Concentrate*", containing 5.22% iodine), the maximum authorised concentration is 2.47%.

The full formulation composition details are contained within the Confidential Annex of this PAR (section 3.6.1).

2.1.2.4 Information on technical equivalence

The notified sources of iodine are the same as those considered for inclusion in the Union list of approved active substances; in one case technical equivalence has been established (TE decision: EU-0012395-0000). The applicant has confirmed that they are a member of the BPR Iodine Registration Group (IRG), which was the task force responsible for the notified sources of iodine. No further consideration is required.

2.1.2.5 Information on the substance(s) of concern

Please see the Confidential Annex of this PAR (section 3.6.1) for further details.

2.1.2.6 Type of formulation

Any other Liquid (AL) and soluble concentrate (SL)

2 Please delete as appropriate.

2.1.3 Hazard and precautionary statements[3]

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Please note: The applicant applied for authorisation of this product family, with the products structured into 4 Meta SPCs. Meta SPC 3("IodoShield Active") was not authorised, due to the outcome of the Environmental Risk Assessment (see section 2.2.7). Following discussion at Working Group V 2018, it was agreed that a shelf life could not be authorised for meta SPC 2 (*"Intelliblend concentrate")*. As a result, Meta SPC 2 could not be authorised. The classification of Meta SPC 2 and Meta SPC 3 has been included here for completeness.

Former Meta SPC 3 - IodoShield Active (SL) - not authorised	
Hazard category	H290 H318 H373 H411
Hazard statement	Eye Damage Category 1 – Causes serious eye damage STOT RE Category 2 – May cause damage to organs through prolonged or repeated exposure Aquatic Chronic 2 - Toxic to aquatic life with long lasting effects
Labelling	
Signal words	GHS05 – Danger GSH08 – Warning GHS09
Hazard statements	Eye Damage Category 1 – Causes serious eye damage STOT RE Category 2 – May cause damage to organs through prolonged or repeated exposure Aquatic Chronic 2 - Toxic to aquatic life with long lasting effects
Precautionary statements	P260- Do not breathe dust/fumes/gas/mist/vapours/spray. P273- Avoid release to the Environment P280- Wear protective gloves/protective clothing/eye protection/face 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/doctor/… P314- Get medical advice/attention if you feel unwell. P391- Collect spillage P501- Dispose of contents/container to ….
Note	

[3] For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

Former Meta SPC 2 – Intelliblend Concentrate (SL) – not recommended for authorisation	
Hazard category	H318 H373
Hazard statement	Eye Damage Category 1 – Causes serious eye damage STOT RE Category 2 – May cause damage to organs through prolonged or repeated exposure
Labelling	
Signal words	GHS05 – Danger GSH08 - Warning
Hazard statements	Eye Damage Category 1 – Causes serious eye damage STOT RE Category 2 – May cause damage to organs through prolonged or repeated exposure
Precautionary statements	P260- Do not breathe dust/fumes/gas/mist/vapours/spray. P280- Wear protective gloves/protective clothing/eye protection/face 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/doctor/… P314- Get medical advice/attention if you feel unwell.P501- Dispose of contents/container to ….
Note	None required for the environment

Meta SPCs 1 and 4, as applied for by the applicant, can be recommended for authorisation. For authorisation, Meta SPC 4 been split into 2 Meta SPCs. These are authorised as Meta SPC 2 (formerly Meta SPC 4a) and Meta SPC 3 (formerly Meta SPC 4b). The classification of the authorised Meta SPCs is detailed below.

Meta SPC 1- Concentrates (SL)	
Hazard category	H290 H319 H373 H412
Hazard statement	May be corrosive to metals Eye Damage Category 2 – Causes serious eye irritation STOT RE Category 2 – May cause damage to organs through prolonged or repeated exposure Aquatic Chronic 3 - Harmful to aquatic life with long lasting effects
Labelling	
Signal words	GHS07 – Warning GSH08 – Warning

Hazard statements	Eye Damage Category 2– Causes serious eye irritation STOT RE Category 2 – May cause damage to organs through prolonged or repeated exposure Aquatic Chronic 3 - Harmful to aquatic life with long lasting effects
Precautionary statements	P260- Do not breathe dust/fumes/gas/mist/vapours/spray. P264- Wash … thoroughly after handling. P273- Avoid release to the Environment P280- Wear protective gloves/protective clothing/eye protection/face protection. P305+P351+P338- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P314- Get medical advice/attention if you feel unwell. P337+P313-If eye irritation persists: Get medical advice/attention. P501- Dispose of contents/container to ….
Note	

Meta-SPC 2 (formerly Meta SPC 4a) - RTU Products (AL) 'Luxspray 30','Luxspray 50', 'LuxDip50B' and 'LuxDip25'	
Hazard category	H290 H412
Hazard statement	May be corrosive to metals Aquatic Chronic 3 - Harmful to aquatic life with long lasting effects
Labelling	
Signal words	
Hazard statements	Aquatic Chronic 3 - Harmful to aquatic life with long lasting effects
Precautionary statements	P273- Avoid release to the Environment P501- Dispose of contents/container to ….
Note	The environmental classification applies to all products in this group except LuxSpray 15 which does not require environmental classification (see Meat-SPC 4b below)

Meta SPC 3 (formerly Meta SPC 4b) - RTU Products (AL) 'Luxspray 15'	
Hazard category	H290
Hazard statement	May be corrosive to metals
Labelling	
Signal words	None.
Hazard statements	May be corrosive to metals
Precautionary statements	P501- Dispose of contents/container to ….

Note	

2.1.4 Authorised use(s)

2.1.4.1 Use description[4]

Please note: the applicant applied for pre-milking and combined pre and/or post-milking uses for meta SPC 1 (see section 2.2.1 for uses applied for by the applicant). Following discussion at Working Group V 2018, it was agreed that the efficacy data did not support pre-milking uses the applicant decided not to support those uses. Only post-milking uses can be authorised for Meta SPC 1.

Meta SPC 1 - Concentrates - Professional concentrates with 1:3, 1:4 and 1:7 dilution rates

Table 1.1. Use # 1.1 – Concentrates - Professional concentrates with 1:3, 1:4 and 1:7 dilution rates, for application post milking - Dipping

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Veterinary hygiene (disinfectant) for direct application to animal teats, post milking, via dip application method.
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor
Application method(s)	Dipping
Application rate(s) and frequency	Product to be diluted by the relevant rate stated on the label. Either; 1 part product to 3 parts water 1 part product to 4 parts water 1 part product to 7 parts water In use concentration of products between 0.29 and 0.52% (w/w) iodine. 2 post milking applications per animal, per day Quantity of diluted product to be applied per application; - 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)
Category(ies) of users	Professional
Pack sizes and packaging material	Please see section 2.1.7

[4] Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence.

Table 1.2. Use # 1.2 – Concentrates - Professional concentrates with 1:3, 1:4 and 1:7 dilution rates, for application post milking - spraying

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Veterinary hygiene (disinfectant) for direct application to animal teats, post milking, via spray application method.
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor
Application method(s)	Spraying (via manual trigger spray or pneumatic sprayer)
Application rate(s) and frequency	Product to be diluted by the relevant rate stated on the label. Either; 1 part product to 3 parts water 1 part product to 4 parts water 1 part product to 7 parts water In use concentration of products between 0.29 and 0.52% (w/w) iodine. 2 post milking applications per animal, per day Quantity of diluted product to be applied per application; - 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)
Category(ies) of users	Professional
Pack sizes and packaging material	Please see section 2.1.7

Table 1.3. Use # 1.3 – Concentrates - Professional concentrates with 1:3, 1:4 and 1:7 dilution rates, for application post milking - foaming

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Veterinary hygiene (disinfectant) for direct application to animal teats, post milking, via foaming application method.
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor
Application method(s)	Foaming

Application rate(s) and frequency	Product to be diluted by the relevant rate stated on the label. Either; 1 part product to 3 parts water 1 part product to 4 parts water 1 part product to 7 parts water In use concentration of products between 0.29 and 0.52% (w/w) iodine. 2 post milking applications per animal, per day Quantity of diluted product to be applied per application; - 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)
Category(ies) of users	Professional
Pack sizes and packaging material	Please see section 2.1.7

Former Meta SPC 2 – Intelliblend Concentrate - Professional concentrate for 1:9 dilution - – NOT AUTHORISED

Former Meta SPC 3 –Iodoshield active – NOT AUTHORISED

Meta-SPC 2 (formerly Meta SPC 4a)- RTU Products - Professional RTU Liquid

Table 2.1. Use # 2.1 – RTU Products - Professional RTU Liquid, for application pre milking – Dipping

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Veterinary hygiene (disinfectant) for direct application to animal teats, pre milking, via dip application method
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor
Application method(s)	Dipping
Application rate(s) and frequency	Ready to use formulation In use concentration 0.16-0.30% (w/w) iodine. 2 pre milking applications per animal, per day Quantity of RTU product to be applied per application; - 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)
Category(ies) of users	Professional

Pack sizes and packaging material	Please see section 2.1.7

Table 2.2. Use # 2.2 – RTU Products - Professional RTU Liquid, for application pre milking - spraying

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Veterinary hygiene (disinfectant) for direct application to animal teats, pre milking, via spray application method
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor
Application method(s)	Spraying (via manual trigger spray or pneumatic sprayer)
Application rate(s) and frequency	Ready to use formulation In use concentration 0.16-0.30% (w/w) iodine. 2 pre milking applications per animal, per day Quantity of RTU product to be applied per application; - 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)
Category(ies) of users	Professional
Pack sizes and packaging material	Please see section 2.1.7

Table 2.3. Use # 2.3 – RTU Products - Professional RTU Liquid, for application pre milking – foaming

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Veterinary hygiene (disinfectant) for direct application to animal teats, pre milking, via foaming application method
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor
Application method(s)	Foaming
Application rate(s) and frequency	Ready to use formulation In use concentration 0.16-0.30% (w/w) iodine. 2 pre milking applications per animal, per day Quantity of RTU product to be applied per application;

	- 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)
Category(ies) of users	Professional
Pack sizes and packaging material	Please see section 2.1.7

Table 2.4. Use # 2.4 – RTU Products - Professional RTU Liquid, for application post milking – Dipping

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Veterinary hygiene (disinfectant) for direct application to animal teats, post milking, via dip application method
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor
Application method(s)	Dipping
Application rate(s) and frequency	Ready to use formulation In use concentration 0.16-0.50% (w/w) iodine. 2 post milking applications per animal, per day Quantity of RTU product to be applied per application; - 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)
Category(ies) of users	Professional
Pack sizes and packaging material	Please see section 2.1.7

Table 2.5. Use # 2.5 – RTU Products - Professional RTU Liquid, for application post milking – spraying

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Veterinary hygiene (disinfectant) for direct application to animal teats, post milking, via spray application method
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor
Application method(s)	Spraying (via manual trigger spray or pneumatic sprayer)
Application rate(s) and frequency	Ready to use formulation

	In use concentration 0.16-0.50% (w/w) iodine. 2 post milking applications per animal, per day Quantity of RTU product to be applied per application; - 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)
Category(ies) of users	Professional
Pack sizes and packaging material	Please see section 2.1.7

Table 2.6. Use # 2.6 – RTU Products - Professional RTU Liquid, for application post milking – foaming

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Veterinary hygiene (disinfectant) for direct application to animal teats, post milking, via foaming application methods
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor
Application method(s)	Foaming
Application rate(s) and frequency	Ready to use formulation In use concentration 0.16-0.50% (w/w) iodine. 2 post milking applications per animal, per day Quantity of RTU product to be applied per application; - 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)
Category(ies) of users	Professional
Pack sizes and packaging material	Please see section 2.1.7

Table 2.7. Use # 2.7 – RTU Products - Professional RTU Liquid, for application pre and post milking-Dipping

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Veterinary hygiene (disinfectant) for direct application to animal teats pre and post milking via dip application method
Target organism	Bacteria

(including development stage)	Yeast
Field of use	Indoor
Application method(s)	Dipping
Application rate(s) and frequency	Ready to use formulation In use concentration 0.16-0.30% (w/w) iodine. 2 pre milking applications per animal, per day 2 post milking applications per animal, per day Quantity of RTU product to be applied per application; - 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)
Category(ies) of users	Professional
Pack sizes and packaging material	Please see section 2.1.7

Table 2.8. Use # 2.8 – RTU Products - Professional RTU Liquid, for application pre and post milking- spraying

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Veterinary hygiene (disinfectant) for direct application to animal teats pre and post milking via spray application methods
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor
Application method(s)	Spraying (via manual trigger spray or pneumatic sprayer)
Application rate(s) and frequency	Ready to use formulation In use concentration 0.16-0.30% (w/w) iodine. 2 pre milking applications per animal, per day 2 post milking applications per animal, per day Quantity of RTU product to be applied per application; - 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)
Category(ies) of users	Professional
Pack sizes and packaging material	Please see section 2.1.7

Table 2.9. Use # 2.9 – RTU Products - Professional RTU Liquid, for application pre and post milking - foaming

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Veterinary hygiene (disinfectant) for direct application to animal teats pre and post milking via foaming application method
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor
Application method(s)	Foaming
Application rate(s) and frequency	Ready to use formulation In use concentration 0.16-0.30% (w/w) iodine. 2 pre milking applications per animal, per day 2 post milking applications per animal, per day Quantity of RTU product to be applied per application; - 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)
Category(ies) of users	Professional
Pack sizes and packaging material	Please see section 2.1.7

Meta-SPC 3 (formerly Meta SPC 4b)- RTU Products - Professional RTU Liquid

Table 3.1. Use # 3.1 – RTU Products - Professional RTU Liquid, for application pre milking – Dipping

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Veterinary hygiene (disinfectant) for direct application to animal teats, pre milking, via dip application method
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor
Application method(s)	Dipping
Application rate(s) and frequency	Ready to use formulation In use concentration 0.16% (w/w) iodine. 2 pre milking applications per animal, per day Quantity of RTU product to be applied per application;

	- 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)
Category(ies) of users	Professional
Pack sizes and packaging material	Please see section 2.1.7

Table 3.2. Use # 3.2 – RTU Products - Professional RTU Liquid, for application pre milking - spraying

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Veterinary hygiene (disinfectant) for direct application to animal teats, pre milking, via spray application method
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor
Application method(s)	Spraying (via manual trigger spray or pneumatic sprayer)
Application rate(s) and frequency	Ready to use formulation In use concentration 0.16% (w/w) iodine. 2 pre milking applications per animal, per day Quantity of RTU product to be applied per application; - 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)
Category(ies) of users	Professional
Pack sizes and packaging material	Please see section 2.1.7

Table 3.3. Use # 3.3 – RTU Products - Professional RTU Liquid, for application pre milking – foaming

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Veterinary hygiene (disinfectant) for direct application to animal teats, pre milking, via foaming application method
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor
Application method(s)	Foaming
Application rate(s) and frequency	Ready to use formulation

	In use concentration 0.16% (w/w) iodine. 2 pre milking applications per animal, per day Quantity of RTU product to be applied per application; - 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)
Category(ies) of users	Professional
Pack sizes and packaging material	Please see section 2.1.7

Table 3.4. Use # 3.4 – RTU Products - Professional RTU Liquid, for application post milking – Dipping

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Veterinary hygiene (disinfectant) for direct application to animal teats, post milking, via dip application method
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor
Application method(s)	Dipping
Application rate(s) and frequency	Ready to use formulation In use concentration 0.16% (w/w) iodine. 2 post milking applications per animal, per day Quantity of RTU product to be applied per application; - 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)
Category(ies) of users	Professional
Pack sizes and packaging material	Please see section 2.1.7

Table 3.5. Use # 3.5 – RTU Products - Professional RTU Liquid, for application post milking – spraying

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Veterinary hygiene (disinfectant) for direct application to animal teats, post milking, via spray application method
Target organism (including development stage)	Bacteria Yeast

Field of use	Indoor
Application method(s)	Spraying (via manual trigger spray or pneumatic sprayer)
Application rate(s) and frequency	Ready to use formulation In use concentration 0.16% (w/w) iodine. 2 post milking applications per animal, per day Quantity of RTU product to be applied per application; - 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)
Category(ies) of users	Professional
Pack sizes and packaging material	Please see section 2.1.7

Table 3.6. Use # 3.6 – RTU Products - Professional RTU Liquid, for application post milking – foaming

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Veterinary hygiene (disinfectant) for direct application to animal teats, post milking, via foaming application methods
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor
Application method(s)	Foaming
Application rate(s) and frequency	Ready to use formulation In use concentration 0.16% (w/w) iodine. 2 post milking applications per animal, per day Quantity of RTU product to be applied per application; - 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)
Category(ies) of users	Professional
Pack sizes and packaging material	Please see section 2.1.7

Table 3.7. Use # 3.7 – RTU Products - Professional RTU Liquid, for application pre and post milking-Dipping

Product Type	PT3- Veterinary hygiene (disinfectant)

Where relevant, an exact description of the authorised use	Veterinary hygiene (disinfectant) for direct application to animal teats pre and post milking via dip application method
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor
Application method(s)	Dipping
Application rate(s) and frequency	Ready to use formulation In use concentration 0.16% (w/w) iodine. 2 pre milking applications per animal, per day 2 post milking applications per animal, per day Quantity of RTU product to be applied per application; - 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)
Category(ies) of users	Professional
Pack sizes and packaging material	Please see section 2.1.7

Table 3.8. Use # 3.8 – RTU Products - Professional RTU Liquid, for application pre and post milking- spraying

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Veterinary hygiene (disinfectant) for direct application to animal teats pre and post milking via spray application methods
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor
Application method(s)	Spraying (via manual trigger spray or pneumatic sprayer)
Application rate(s) and frequency	Ready to use formulation In use concentration 0.16% (w/w) iodine. 2 pre milking applications per animal, per day 2 post milking applications per animal, per day Quantity of RTU product to be applied per application; - 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)
Category(ies) of users	Professional

Pack sizes and packaging material	Please see section 2.1.7

Table 3.9. Use # 3.9 – RTU Products - Professional RTU Liquid, for application pre and post milking - foaming

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Veterinary hygiene (disinfectant) for direct application to animal teats pre and post milking via foaming application method
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor
Application method(s)	Foaming
Application rate(s) and frequency	Ready to use formulation In use concentration 0.16% (w/w) iodine. 2 pre milking applications per animal, per day 2 post milking applications per animal, per day Quantity of RTU product to be applied per application; - 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)
Category(ies) of users	Professional
Pack sizes and packaging material	Please see section 2.1.7

2.1.4.1 Use-specific risk instructions for use

Meta SPC 1 - Concentrates - Professional concentrates with 1:3, 1:4 and 1:7 dilution rates

Use # 1.1 – Concentrates - Professional concentrates with 1:3, 1:4 and 1:7 dilution rates, for post milking - Dipping

Dilute product before application according to the ratio specified on the product label
For manual dilution of the concentrate; Add the ratio of concentrate and water, specified on the product label, to a suitably sized container to achieve the required dilution rate. Mix to a uniform solution
Application via dip Cup: Using a traditional dip cup with non-return valves, dispense diluted product into the reservoir. Screw down the applicator portion. Squeeze the reservoir to fill the applicator. Cover the bottom two thirds of each teat with material.
Dip at least 2/3 of the teat length with diluted product immediately after milking

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

Dispose of unused material after each milking

The same solution can be applied to multiple animals during the same milking session.

Use # 1.2 – Concentrates - Professional concentrates with 1:3, 1:4 and 1:7 dilution rates, for post milking - spraying

Dilute product before application according to the ratio specified on the product label

For manual dilution of the concentrate; Add the ratio of concentrate and water, specified on the product label, to a suitably sized container to achieve the required dilution rate. Mix to a uniform solution

Application via pneumatic sprayer: Uptake lance of spray system is placed in the container of the diluted product. The diluted product is then pumped to a spray lance located in the milking parlour. The spray lance is then used to cover the bottom two thirds of teats in the diluted product

Application via manual trigger spray: Fill trigger spray bottle with diluted product. Use trigger spray to cover the bottom two thirds of each teat with diluted product

Spray at least 2/3 of the teat length with diluted product immediately after milking

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

Use # 1.3 – Concentrates - Professional concentrates with 1:3, 1:4 and 1:7 dilution rates, for post milking - foaming

Dilute product before application according to the ratio specified on the product label

For manual dilution of the concentrate; Add the ratio of concentrate and water, specified on the product label, to a suitably sized container to achieve the required dilution rate. Mix to a uniform solution

Application via foaming Dip cup: As for dip cup, however, when squeezed, the liquid is forced through a fine mesh, mixing with air and forming foam. This is then applied to the bottom two thirds of the cow's udder

Dip at least 2/3 of the teat length with diluted product immediately after milking

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

The same solution can be applied to multiple animals during the same milking session. Cups should be refilled with fresh solution before starting new milking session

Former Meta SPC 2 – Intelliblend Concentrate - Professional concentrate for 1:9 dilution – NOT AUTHORISED

Former Meta SPC 3 –Iodoshield active – NOT AUTHORISED

Meta SPC 2 & 3 – RTU Products - Professional RTU Liquid

Use # 2.1 & 3.1 – RTU Products - Professional RTU Liquid, for application pre milking - Dipping

Application via dip Cup: Using a traditional dip cup with non-return valves, dispense RTU product into the reservoir. Screw down the applicator portion. Squeeze the reservoir to fill the applicator. Cover the bottom two thirds of each teat with material. Dispose of unused material after each milking

The same solution can be applied to multiple animals during the same milking session. Cups should be refilled with fresh solution before starting new milking session

Use # 2.2 & 3.2 – RTU Products - Professional RTU Liquid, for application pre milking - spraying

Application via pneumatic sprayer: Uptake lance of spray system is placed in the container of the RTU product. The RTU product is then pumped to a spray lance located in the milking parlour. The spray lance is then used to cover the bottom two thirds of teats in the RTU product

Application via manual trigger spray: Fill trigger spray bottle with RTU product. Use trigger spray to cover the bottom two thirds of each teat with RTU product

Use # 2.3 & 3.3 – RTU Products - Professional RTU Liquid, for application pre milking - foaming

Application via foaming Dip cup: As for dip cup, however, when squeezed, the liquid is forced through a fine mesh, mixing with air and forming foam. This is then applied to the bottom two thirds of the cow's udder

The same solution can be applied to multiple animals during the same milking session. Cups should be refilled with fresh solution before starting new milking session

Use # 2.4 & 3.4 – RTU Products - Professional RTU Liquid, for application post milking - Dipping

Application via dip Cup: Using a traditional dip cup with non-return valves, dispense RTU product into the reservoir. Screw down the applicator portion. Squeeze the reservoir to fill the applicator. Cover the bottom two thirds of each teat with material. Dispose of unused material after each milking

Dip at least 2/3 of the teat length with RTU product immediately after milking

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

The same solution can be applied to multiple animals during the same milking session. Cups should be refilled with fresh solution before starting new milking session

Use # 2.5 & 3.5 – RTU Products - Professional RTU Liquid, for application post milking - spraying

Application via pneumatic sprayer: Uptake lance of spray system is placed in the

container of the RTU product. The RTU product is then pumped to a spray lance located in the milking parlour. The spray lance is then used to cover the bottom two thirds of teats in the RTU product

Application via manual trigger spray: Fill trigger spray bottle with RTU product. Use trigger spray to cover the bottom two thirds of each teat with RTU product

Dip at least 2/3 of the teat length with RTU product immediately after milking

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

Use # 2.6 & 3.6 – RTU Products - Professional RTU Liquid, for application post milking - foaming

Application via foaming Dip cup: As for dip cup, however, when squeezed, the liquid is forced through a fine mesh, mixing with air and forming foam. This is then applied to the bottom two thirds of the cow's udder

Dip at least 2/3 of the teat length with RTU product immediately after milking

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

The same solution can be applied to multiple animals during the same milking session. Cups should be refilled with fresh solution before starting new milking session

Use # 2.7 & 3.7 – RTU Products - Professional RTU Liquid, for application pre and post milking-Dipping

Application via dip Cup: Using a traditional dip cup with non-return valves, dispense RTU product into the reservoir. Screw down the applicator portion. Squeeze the reservoir to fill the applicator. Cover the bottom two thirds of each teat with material. Dispose of unused material after each milking

Post-milking:

Dip at least 2/3 of the teat length with RTU product immediately after milking

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

The same solution can be applied to multiple animals during the same milking session. Cups should be refilled with fresh solution before starting new milking session

Use # 2.8 & 3.8 – RTU Products - Professional RTU Liquid, for application pre and post milking- spraying

Application via pneumatic sprayer: Uptake lance of spray system is placed in the container of the RTU product. The RTU product is then pumped to a spray lance located in the milking parlour. The spray lance is then used to cover the bottom two thirds of teats in the RTU product

Application via manual trigger spray: Fill trigger spray bottle with RTU product. Use trigger spray to cover the bottom two thirds of each teat with RTU product

Post-milking:

Dip at least 2/3 of the teat length with RTU product immediately after milking

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

Use # 2.9 & 3.9 – RTU Products - Professional RTU Liquid, for application pre and post milking - foaming

Application via foaming Dip cup: As for dip cup, however, when squeezed, the liquid is forced through a fine mesh, mixing with air and forming foam. This is then applied to the bottom two thirds of the cow's udder Post-milking: Dip at least 2/3 of the teat length with RTU product immediately after milking To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes). The same solution can be applied to multiple animals during the same milking session. Cups should be refilled with fresh solution before starting new milking session

2.1.4.2 Use-specific risk mitigation measures

Meta SPC 1:

Use # 1.1 – Concentrates - Professional concentrates with 1:3, 1:4 and 1:7 dilution rates, for post milking - Dipping

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

Use # 1.2 – Concentrates - Professional concentrates with 1:3, 1:4 and 1:7 dilution rates, for post milking - spraying

Wear protective chemical resistant gloves and eye protection when handling the concentrate Wear protective chemical resistant gloves and boots when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information). A protective coverall (at least type 6, EN 13034) shall be worn

Use # 1.3 – Concentrates - Professional concentrates with 1:3, 1:4 and 1:7 dilution rates, for post milking - foaming

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

Former Meta SPC 2:Intelliblend Concentrate - Professional concentrate for 1:9 dilution – NOT AUTHORISED

Former Meta SPC 3 –Iodoshield active – NOT AUTHORISED

Meta SPC 2 & 3:

Use # 2.1 & 3.1 – RTU Products - Professional RTU Liquid, for application pre milking - Dipping

Use # 2.2 & 3.2 – RTU Products - Professional RTU Liquid, for application pre milking - spraying

Wear protective chemical resistant gloves when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information)

Use # 2.3 & 3.3 – RTU Products - Professional RTU Liquid, for application pre milking - foaming

Use # 2.4 & 3.4 – RTU Products - Professional RTU Liquid, for application post milking - Dipping

Use # 2.5 & 3.5 – RTU Products - Professional RTU Liquid, for application post milking - spraying

Wear protective chemical resistant gloves and boots when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information). A protective coverall (at least type 6, EN 13034) shall be worn

Use # 2.6 & 3.6 – RTU Products - Professional RTU Liquid, for application post milking - foaming

Use # 2.7 & 3.7 – RTU Products - Professional RTU Liquid, for application pre and post milking - Dipping

Wear protective chemical resistant gloves when applying the product by dipping (glove material to be specified by the authorisation holder within the product information). This product can be used for pre- and post-milking disinfection in combination.

However, it should not be used in combination with a different iodine-based product.

Use # 2.8 & 3.8 – RTU Products - Professional RTU Liquid, for application pre and post milking - spraying

Wear protective chemical resistant gloves and boots when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information). A protective coverall (at least type 6, EN 13034) shall be worn This product can be used for pre- and post-milking disinfection in combination. However, it should not be used in combination with a different iodine-based product.

Use # 2.9 & 3.9 – RTU Products - Professional RTU Liquid, for application pre and post milking- foaming

Wear protective chemical resistant gloves when applying the product by foaming (glove material to be specified by the authorisation holder within the product information). This product can be used for pre- and post-milking disinfection in combination. However, it should not be used in combination with a different iodine-based product.

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

Meta SPC 1 (use # 1.1 – 1.3) – Concentrates - Professional concentrates with 1:3, 1:4 and 1:7 dilution rates

See 2.1.5.3

Former Meta SPC 2 – Intelliblend Concentrate - Professional concentrate for 1:9 dilution – NOT AUTHORISED

Former Meta SPC 3 –Iodoshield active – NOT AUTHORISED

Meta SPC 2 & 3 (use # 2.1 & 3.1 – 2.9 & 3.9) – RTU Products - Professional RTU Liquid

See 2.1.5.3

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

Meta SPC 1 (use # 1.1 – 1.3) – Concentrates - Professional concentrates with 1:3, 1:4 and 1:7 dilution rates

See 2.1.5.4

Former Meta SPC 2 – Intelliblend Concentrate - Professional concentrate for 1:9 dilution – NOT AUTHORISED

Former Meta SPC 3 –Iodoshield active – NOT AUTHORISED

Meta SPC 2 & 3 (use # 2.1 & 3.1 – 2.9 & 3.9) – RTU Products - Professional RTU Liquid

See 2.1.5.4

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

Meta SPC 1 (use # 1.1 – 1.3) – Concentrates - Professional concentrates with 1:3, 1:4 and 1:7 dilution rates

A shelf life of 12 months is supported

Former Meta SPC 2 – Intelliblend Concentrate - Professional concentrate for 1:9 dilution – NOT AUTHORISED

Former Meta SPC 3 –Iodoshield active – NOT AUTHORISED

Meta SPC 2 & 3 (use # 2.1 & 3.1 – 2.9 & 3.9) – RTU Products - Professional RTU Liquid

A shelf life of 12 months is supported

2.1.5 General directions for use

2.1.5.1 Instructions for use[5]

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. For post milking application; spray or dip at least 2/3 of the teat length with diluted product immediately after milking Product can be used during the entire lactation period Before attaching the milking cluster, all teat-dip residues should be removed with either a single use towel or re-usable cloth. One cloth should be used per cow For effective use against bacteria and yeast, product must be left in contact with the skin for at least 60 seconds

[5] Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

2.1.5.2 Risk mitigation measures

Keep out of reach of children.

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

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

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

Remove and wash contaminated clothing before re-use.

After inhalation: Move to fresh air in case of accidental inhalation of fumes from overheating or combustion.

If you feel unwell, seek medical advice.

After contact with skin: Wash with water and soap as a precaution. Consult a doctor if skin irritation persists.

After contact with eyes: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Seek medical treatment by eye specialist.

After ingestion: Rinse out mouth and give plenty of water to drink. Never give anything by mouth to an unconscious person. Consult a physician.

Large spills should be contained using a chemical spill kit, soaked up using absorbent material such as kieselgur and disposed of as Hazardous waste.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Dispose of in accordance with local regulations.

At the end of the treatment, dispose of 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 farm based waste water treatment plant

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

Protect from frost

Do not store at temperatures above 30 ºC

2.1.6 Other information

None

2.1.7 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)**
HDPE drum	10 – 200 L (10, 20, 25 or 200 L)	HDPE	Tamper evident lid	Professional	Yes. HDPE packaging tested in ambient temperature shelf life studies for a selection of products within the BPF. No adverse interactions were observed. This is considered acceptable to support the HDPE packaging for the entire BPF.
HDPE IBC drum	1000 L	HDPE in a galvanised steel frame	Tamper evident lid	Professional	

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Please see Annex 3.1 of this PAR for a reference list of studies submitted to support this application.

2.1.8.2 Access to Documentation

The applicant has submitted a declaration of ownership from SCC GmbH. This states that GEA Farm Technologies (UK) Ltd; "have propriety and ownership rights to the complete Iodine active substance dossiers submitted by the IRG for product types 3, 4 and 22 and own or have received access rights to the data included in the dossiers"

2.1.8.3 Similar conditions of use

A pre-submission application was not submitted for Iodine Teat Dip Products. The applicant submitted a rationale to confirm that the products in the family would have similar conditions of use across the Union. The document can be found in section 13 of the IUCLID dossier ("*Rational Regarding Union Authorisation (Use Conditions Across the Union) of Iodine Teat Dips*", dated 24 August 2015).

2.2 Assessment of the biocidal product (family)

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

Table 4. Intended use # 1 – Professional concentrates with 1:3, 1:4 and 1:7 dilution rates, for pre and/or post milking[6] (Meta SPC 1 of applicant's draft SPC)

Product Type(s)	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Product to be diluted in line with use instructions. Product is then applied to the bottom two thirds of a cow's udder using either a specially made teat dip cup or a spray system.
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor
Application method(s)	Dip Cup Foaming dip cup Pneumatic sprayer Manual Sprayer (trigger spray)
Application rate(s) and frequency	Frequency: 2 pre and/or post milking applications per day Quantity of product to be used per application; - 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)
Category(ies) of user(s)	Professional
Pack sizes and packaging material	10 – 200 litre HDPE drum with tamper evident lid 1000 litre HDPE IBC drum in galvanised steel frame

Table 5. Intended use # 2 – Professional concentrate for 1:9 dilution, for application pre and/or post milking (Meta SPC 2 of applicant's draft SPC)

Product Type(s)	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Product to be diluted in line with use instructions. Product is then applied to the bottom two thirds of a cow's udder using either a specially made teat dip cup or a spray

6 Copy this section as many times as necessary (one table per use).

	system.
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor
Application method(s)	Dip cup Foaming dip cup Pneumatic sprayer Manual Sprayer (trigger spray)
Application rate(s) and frequency	Frequency: 2 pre and/or post milking applications per day Quantity of product to be used per application; - 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)
Category(ies) of user(s)	Professional
Pack sizes and packaging material	10 – 200 litre HDPE drum with tamper evident lid 1000 litre HDPE IBC drum in galvanised steel frame

Table 6. Intended use # 3 – Professional concentrate for 1:3 dilution, for application post milking (Meta SPC 3 of applicant's draft SPC)

Product Type(s)	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Product to be diluted in line with use instructions. Product is then applied to the bottom two thirds of a cow's udder using either a specially made teat dip cup or a spray system.
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor
Application method(s)	Dip cup Pneumatic sprayer Manual Sprayer (trigger spray)
Application rate(s) and frequency	Frequency: 2 pre and/or post milking applications per day Quantity of product to be used per application; - 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)
Category(ies) of user(s)	Professional
Pack sizes and packaging material	10 – 200 litre HDPE drum with tamper evident lid 1000 litre HDPE IBC drum in galvanised steel frame

Meta SPC 3 was not authorised by the UK CA.

Table 7. Intended use # 4 – Professional RTU Liquid, for application pre and/or post milking (Meta SPC 4 of applicant's draft SPC)

Product Type(s)	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Product is applied to the bottom two thirds of a cow's udder using either a specially made teat dip cup or a spray system.
Target organism (including development stage)	Bacteria Yeast
Field of use	Indoor
Application method(s)	Dip cup Foaming dip cup Pneumatic sprayer Manual Sprayer (trigger spray)
Application rate(s) and frequency	Frequency: 2 pre and/or post milking applications per day Quantity of product to be used per application; - 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)
Category(ies) of user(s)	Professional
Pack sizes and packaging material	10 – 200 litre HDPE drum with tamper evident lid 1000 litre HDPE IBC drum in galvanised steel frame

2.2.2 Physical, chemical and technical properties

The GEA Iodine Teat Dip Product family is separated into four meta-SPCs. Meta-SPCs 1, 2 and 3 contain concentrate products and meta-SPC 4 RTU products. The full BPF details can be found in the Confidential Annex, with the following summary being relevant to the physical, chemical and technical properties table:

Meta SPC1: Concentrates (SL formulations)
Lead products:
Ioklene Concentrate
Maxadine C
Dunglinson Super IO 421 Concentrate
Priodine

~~Meta-SPC 2: Concentrate (SL formulation)~~
~~Lead products:~~
~~Intelliblend concentrate~~

NB: Meta-SPC 2 (Intelliblend concentrate) is no longer being supported in this application. For completeness, the evaluation of the physical, chemical and technical properties for meta-SPC 2 has been retained in this document.

~~Meta-SPC 3: Concentrate (SL formulation)~~
~~Lead products:~~
~~Iodoshield Active~~
NB: Meta-SPC 3 (Indoshield Active product) is no longer being supported in this application. For completeness, the evaluation of the physical, chemical and technical properties for meta-SPC 3 has been retained in this document.

Meta-SPC 4 : RTU (AL-RTU formulations)
Lead products:
LuxSpray 15 (meta SPC 4b)
LuxSpray 30 (meta SPC 4a)
LuxSpray 50 (meta SPC 4a)
LuxDip 50B (meta SPC 4a)
LuxDip 25 (meta SPC 4a)

None of these products were the representative formulation considered for BPR inclusion. The physical, chemical and storage stability data submitted to support the formulations are summarised in the following table.

Property	Guideline and Method	Tested product	Results	Reference	UK CA Comments
Physical state at 20 °C and 101.3 kPa	Visual assessment	All products of the BPF	Brown liquid, iodine odour	IUCLID 3.1 and storage studies	Acceptable
Colour at 20 °C and 101.3 kPa	Visual assessment	All products of the BPF	Brown	IUCLID 3.1	Acceptable
Odour at 20 °C and 101.3 kPa	Not specified	All products of the BPF	Typical iodine odour	IUCLID 3.1	Acceptable
pH	pH meter method, based on method in British Pharmacopeia (1993), Appendix V L p.A120., considered equivalent to CIPAC MT 75.3.	Ioklene conc.	2 (20% solution)	Hampson, I. and Hackett, J. (2014) GEA008	Acceptable. Although the recommended CIPAC method MT 75.3 was not used, the pH was conducted using a calibrated pH meter and therefore this is considered to be comparable and acceptable. The exact temperatures of each determination were not reported, but the SOP stated calibration was conducted between 15 - 30ºC and it can be assumed the tests were conducted within this range. The pH values reported are those of the in-use concentrations; for the RTU products this is the neat formulation, but for the concentrates the specified concentrations were tested. Although in accordance with the BPR pH should be conducted on
		Maxadine C	2.35 (25% solution)	Barker, L. and Hill, J. (2015) GEA033	
		DS IO 421	1.65 (20% solution)	Barker, L. and Hill, J. (2015) GEA032	
		Priodine	1.90 (12.5% solution)	Hampson, I. and Hackett, J. (2014) GEA009	
		Intelliblend concentrate	2.23 (10% soln)	Barker, L. and Hill, J. (2015) GEA034	
		IodoShield Active	2.5 (neat)	UK Stability study.pdf (2013) attached in IUCLID 3.4.1. No author stated.	
		LuxSpray 15	2.6	Hampson, I. and	

Property	Guideline and Method	Tested product	Results		Reference	UK CA Comments
					Hackett, J. (2014) GEA010	the neat aqueous formulation, this is not of concern in this case, as acidity has been provided on all products.
		LuxSpray30	2.1		Hampson, I. and Hackett, J. (2014) GEA007	
		LuxSpray 50	2.3		Hampson, I. and Hackett, J. (2014) GEA012	
		Luxdip 50B	4.7		Hampson, I. and Hackett, J. (2014) GEA011	
		Luxdip 25	4.2		Hampson, I. and Hackett, J. (2014) GEA013	
Acidity / alkalinity	OECD 122, tests conducted at 20ºC.		Acidity as % m/m H_2SO_4			Acceptable. Toxicology will consider classification. Data on priodine, iodoshield active and luxspray 15 were not provided before storage. However, the pH of the products remained stable over the products shelf life (12 months) and the post storage acidity data was conducted after much longer storage period. Additionally, the general trend that acidities increase after storage means that the post storage results for priodine, iodoshield active and luxspray 15 (4 yrs, 15 months and 4 yrs respectively) are considered to
			Initial	Post-storage (time period from manufacture to test date)		
		Ioklene conc.	0.147	0.231 (1 yr)	Barker, L. 2015 (GEA035) And Hampson, I. (2016) [post-storage results]	
		Maxadine C	0.247	0.307 (1.5 yrs)		
		DS IO 421	0.212	0.359 (1.5 yrs)		
		Priodine	Not provided	0.433 (4 yrs)		
		Intelliblend concentrate	0.57	0.817 (3.5 yrs)		
		IodoShield Active	Not provided	0.191 (15 months)		
		LuxSpray 15	Not provided	0.038 (4 yrs)		
		LuxSpray30	0.022	0.062 (4 yrs)		
		LuxSpray 50	0.02	0.092 (4 yrs)		
		Luxdip 50B	0.10	0.092 (4 yrs)		

Property	Guideline and Method	Tested product	Results		Reference	UK CA Comments
		Luxdip 25	0.09	0.085 (4 yrs)		represent a worst case, therefore no further information is considered necessary. Post storage results were conducted on samples ranging from 15 months to 4 years after their date of manufacture. Samples were stored in commercial packs in conditions similar to those in the ambient storage study.
Relative density / bulk density (g/cm^3 at 20 °C)	Method from British Pharmacopeia 1993, Vol.II Appendix V H,p.A115., Hydrometer.	Ioklene conc.	1.09		Hampson, I. and Hackett, J. (2014) GEA008	Acceptable. Determinations were conducted at 20ºC and the method used is considered comparable to OECD 109.
		Maxadine C	1.05		Barker, L. and Hill, J. (2015) GEA033	
		DS IO 421	1.085		Barker, L. and Hill, J. (2015) GEA032	
		Priodine	1.042		Hampson, I. and Hackett, J. (2014) GEA009	
		Intelliblend concentrate	1.085		Barker, L. and Hill, J. (2015) GEA034	
		IodoShield Active	1.17		Communication with applicant. Mean of 4 values from recent batches of formulation.	

Property	Guideline and Method	Tested product	Results	Reference	UK CA Comments
		LuxSpray 15	1.013	Hampson, I. and Hackett, J. (2014) GEA010	
		LuxSpray30	1.026	Hampson, I. and Hackett, J. (2014) GEA007	
		LuxSpray 50	1.072	Hampson, I. and Hackett, J. (2014) GEA012	
		Luxdip 50B	1.027	Hampson, I. and Hackett, J. (2014) GEA011	
		Luxdip 25	1.022	Hampson, I. and Hackett, J. (2014) GEA013	
Storage stability test – **accelerated storage**	-		No accelerated storage results were provided for Ioklene concentrate, Priodine, LuxSpray 15, LuxSpray 30, LuxSpray 50, Luxdip 50B and Luxdip 25. Accelerated storage was provided for the following products: Maxadine C, DS IO 421, Iodoshield and Intelliblend concentrate. These results are presented below. Active content is presented as %w/w.	-	In accordance with the ECHA guidance on BPR, Nov. 2014, Section 3.4.1.1, accelerated storage may not be required if full ambient temperature storage is presented and it can be demonstrated the products won't be stored above 30 ºC. Acceptable ambient temperature storage has been provided for all the relevant products of the BPF. The example product labels provided include the phrases: 'protect from direct sunlight' and 'store in a cool dark place, preferably 5 – 20 ºC' or words to similar effect, therefore accelerated storage is not

Property	Guideline and Method	Tested product	Results	Reference	UK CA Comments
					required. It should be noted that as long as a label phrase is present indicating the biocidal product should not be stored at temperatures above 30 ºC, this is considered acceptable.
	Titration with sodium thiosulfate pH meter Visual	Maxadine C	<u>Active content</u> Before: 2.07 After(14 days 54ºC): 1.19 <u>pH</u> Before: 2.35 After(14 days 54ºC): 1.70 <u>Appearance</u> Before: brown liquid, typical iodine After(14 days 54ºC): no change	Barker, L. and Hill, J. (2015) GEA033	Acceptable. Active content decreased by 43% following accelerated storage. The applicant notes this is likely to be temperature related and ambient storage stability data on very similar products (Ioklene conc and Priodine) indicate acceptable storage after 12 months
	Titration with sodium thiosulfate pH meter Visual	DS IO 421 concentrate	<u>Active content</u> Before: 2.617 After(14 days 54ºC): 2.38 <u>pH</u> Before: 1.65 After(14 days 54ºC): 1.93 <u>Appearance</u> Before: brown liquid, typical iodine After(14 days 54ºC): no change	Barker, L. and Hill, J. (2015) GEA032	Acceptable.

Property	Guideline and Method	Tested product	Results	Reference	UK CA Comments
	Titration with sodium thiosulfate pH meter Visual	Intelliblend	Active content Before: 5.05 After(14 days 54ºC): 2.95 pH (neat) Before: 2.23 After(14 days 54ºC): 2.0 Appearance Before: brown liquid, typical iodine After(14 days 54ºC): no change	Barker, L. and Hill, J. (2015) GEA034	Acceptable. Active content decreased by 41.6% following accelerated storage. The applicant notes this is likely to be temperature related and ambient storage stability data on Priodine (≈50% dilution of Intellibend) indicates acceptable storage after 12 months. In addition the applicant has only requested a 6 month shelf life
Storage stability test – **low temperature stability test for liquids**	-		No low temperature storage results were provided for the products, apart from Iodoshield, the results of which are displayed below.	-	The product labels contain the phrase 'protect from frost' or words to a similar effect, therefore low temperature data is not strictly required.
	Not specified	IodoShield	Active content Before: 2.37 After(14 days -18ºC): 2.37 pH (neat) Before: 2.5 After(14 days -18ºC): 2.5 Appearance Before: brown liquid, typical iodine After(14 days -18ºC): no change	UK Stability study.pdf (2013) attached in IUCLID 3.4.1. No author stated.	Insufficient information was included in the study report to determine if the pH method was acceptable (e.g. CIPAC MT 75.3) and no reference to the method used for active content determination was included. This is not of concern, as this data is not strictly required as the labels will contain the statement 'protect from frost' or words to a similar effect.
			For post-storage acidity data see the acidity results reported above. Active content is presented as %w/w.		**All products:** It can be considered that acceptable acidity data has been provided to

Property	Guideline and Method	Tested product	Results	Reference	UK CA Comments
Storage stability test – **long term storage**	Active content method = titration with sodium thiosulfate pH = pH meter, comparable to CIPAC MT 75.3 appearance = visual dilution stability = MT 41	Ioklene conc.	<u>Active content</u> Before: 1.38 After(6months): 1.34 After(12months): 1.33 After(24months): 1.34 <u>pH</u> Before: 2 After(6months): 1.088 After(12months): 1.089 After(24months): 1.26 <u>Appearance</u> Before: brown liquid, typical iodine After(6/12/24month): no change <u>Dilution stability</u> After 11 months storage: No visible precipitates or layering (20% dilution)	Hampson, I. and Hackett, J. (2014) GEA008 & Amended Hampson, I. (2016), attached in IUCLID 3.5 (dilution stability)	accommodate the claimed shelf lives of all the individual products in the BPF. The study reports include active content data as an initial determination within the study, but also an initial QC value. Degradation with respect to both these initial values are considered when discussing the supported shelf lives for the meta-SPCs. Refer to discussion below this table on shelf lives. The initial active content determined in the storage study is outside of the tolerance limits set by the applicant (section 2.1.2.3) but it is still within the FAO agreed tolerance limits (±15%) therefore this is considered acceptable. The active content and appearance are considered stable over 24 months. The acidity after 1 year storage has been determined. A shelf life of 12 months is claimed and this is supported. Acceptable dilution stability on a stored sample has been provided in amended Hampson, I (2016). The sample was stored for 11 months under conditions

Property	Guideline and Method	Tested product	Results	Reference	UK CA Comments
					comparable to ambient storage. This is considered sufficient to support the claimed shelf life of 12 months (see below table). No initial results are provided, but considering that the stored samples are acceptable this is not thought to be of concern.
		Maxadine C	No ambient storage data provided, apart from: <u>Dilution stability</u> No visible precipitates or layering (25% dilution)	- Amended Hampson, I. (2016), attached in IUCLID 3.5 (dilution stability)	A 12 month shelf life is claimed and is supported by accelerated storage data on Maxadine C and extrapolation of long term storage on related products Ioklene conc and Priodine in meta-SPC 1. Acceptable dilution stability on a stored sample has been provided in amended Hampson, I (2016). The sample was stored for at least 1 year under conditions comparable to ambient storage. This is considered sufficient to support the claimed shelf life of 12 months (see below table). No initial results are provided, but considering that the stored samples are acceptable this is not thought to be of concern.
		DS IO 421	No ambient storage data provided, apart from: <u>Dilution stability</u> No visible precipitates or layering	Amended Hampson, I. (2016), attached in IUCLID 3.5 (dilution stability)	A 12 month shelf life is supported by accelerated storage data on DS IO 421 and extrapolation of long term storage on related products Ioklene conc and Priodine in

Property	Guideline and Method	Tested product	Results	Reference	UK CA Comments
			(20% dilution)		meta-SPC 1. Acceptable dilution stability on a stored sample has been provided in amended Hampson, I (2016). The sample was stored for at least 1 year under conditions comparable to ambient storage. This is considered sufficient to support the claimed shelf life of 12 months (see below table). No initial results are provided, but considering that the stored samples are acceptable this is not thought to be of concern.
		Priodine	<u>Active content</u> Before: 2.38 (Initial QC = 2.42) After(6months): 2.29 After(12months): 2.25 After(24months): 2.25 <u>pH</u> Before: 1.9 After(6months): 1.5 After(12months): 1.6 After(24months): 1.97 <u>Appearance</u> Before: brown liquid, typical iodine After(6/12/24month): no change <u>Dilution stability</u> After 3 years storage: Several very	Hampson, I. and Hackett, J. (2014) GEA009	The active content degrades by 5.5 - 7% following 1 and 2 years storage. This is within the maximum allowed 10 % as stated in the ECHA guidance, Nov. 2014 and the applicant has confirmed that a shelf life of 12 months is claimed and this is supported. The active content, pH and appearance are considered stable over a 12 month period. Acceptable dilution stability on a stored sample has been provided in amended Hampson, I (2016). The sample was stored for 3 years under conditions comparable to ambient storage. This is

Property	Guideline and Method	Tested product	Results	Reference	UK CA Comments
			small solid particles. Not sufficient to constitute a layer. (12.5% dilution)		considered sufficient to support the claimed shelf life of 12 months (see below table). No initial results are provided, but considering that the stored samples are acceptable this is not thought to be of concern.
		Intelliblend concentrate	No ambient storage data provided, apart from: <u>Dilution stability</u> No visible precipitates or layering (10% dilution)	Amended Hampson, I. (2016), attached in IUCLID 3.5 (dilution stability)	6 month shelf life is claimed. This is considered acceptable based on the accelerated storage and ambient storage stability data on Priodine (≈50% dilution of Intellibend) indicating acceptable storage after 12 months. Acceptable dilution stability on a stored sample has been provided in amended Hampson, I (2016). The sample was stored for at least 3 years under conditions comparable to ambient storage. This is considered sufficient to support the claimed shelf life of 6 months (see below table). No initial results are provided, but considering that the stored samples are acceptable this is not thought to be of concern.
		IodoShield Active	<u>Active content (%w/w, results on 3 batches were reported)</u> Before: 2.37; 2.36; 2.36 After(6months): 2.31; 2.32; 2.29	UK Stability study.pdf (2013) attached in IUCLID 3.4.1. No author	The active content degrades by 3 – 6.3% following 2 years storage. The maximum active content degradation after 12 months is

Property	Guideline and Method	Tested product	Results	Reference	UK CA Comments
			After(12months): 2.27; 2.28; 2.26 After(24months): 2.22; 2.29; 2.22 <u>pH (neat, results on 3 batches were reported)</u> Before: 2.5; 2.5; 2.5 After(6months): 2.4; 2.4; 2.4 After(12months): 2.3; 2.2; 2.2 After(24months): 2.2; 2.1; 2.1 <u>Appearance</u> Before: brown liquid, typical iodine After(6/12/24month): no change <u>Dilution stability</u> Several very small solid particles. Not sufficient to constitute a layer. (25% dilution)	stated.	4.4%, both of which are within the allowed 10% as stated in the ECHA guidance. The applicant has confirmed that a shelf life of 12 months is claimed and this is supported. The pH and appearance are considered stable over a 12 month period. Acceptable dilution stability on a stored sample has been provided in amended Hampson, I (2016). The sample was stored for 1 year under conditions comparable to ambient storage. This is considered sufficient to support the claimed shelf life of 12 months (see below table). No initial results are provided, but considering that the stored samples are acceptable this is not thought to be of concern.
		LuxSpray 15	<u>Active content</u> Before: 0.180 (Initial QC = 0.180) After(6months): 0.160 After(12months): 0.152 After(24months): 0.166 <u>pH</u> Before: 2.6 After(6months): 2.4 After(12months): 2.6	Hampson, I. and Hackett, J. (2014) GEA010	The active content degrades by 7.8% following 2 years storage, but a shelf life of 12 months is claimed for the products. The active content degradation after 12 months is actually greater at 16%, but as the 24 month data is considered acceptable it is likely that this is considered to be an error in the method performance

Property	Guideline and Method	Tested product	Results	Reference	UK CA Comments
			After(24months): 2.42 <u>Appearance</u> Before: brown liquid, typical iodine After(6/12/24month): no change		and there are no concerns over a 12 month shelf life. The pH and appearance are considered stable over this period. Dilution stability is not required for RTU formulations.
		LuxSpray30	<u>Active content</u> Before: 0.275 (Initial QC = 0.320) After(6months): 0.269 After(12months): 0.268 After(24months): 0.264 <u>pH</u> Before: 2.1 After(6months): 2.1 After(12months): 2.2 After(24months): 2.3 <u>Appearance</u> Before: brown liquid, typical iodine After(6/12/24month): no change	Hampson, I. and Hackett, J. (2014) GEA007	The active content degrades by 4 – 17.5% (17.5% compared to initial QC active content) following 2 years storage, but a shelf life of 12 months is claimed for the products. The active content degradation after 12 months is 2.5 – 16.3%. The applicant claims that even with this high percentage reduction there would still be enough iodine for the product to be effective. This has been be confirmed by efficacy (see section 2.2.5.5). The pH and appearance are considered stable over the shelf life period. Dilution stability is not required for RTU formulations.
		LuxSpray 50	<u>Active content</u> Before: 0.476 (Initial QC = 0.510) After(6months): 0.464 After(12months): 0.454 After(24months): 0.446 <u>pH</u>	Hampson, I. and Hackett, J. (2014) GEA012	The active content degrades by at least 6.3% following 2 years storage, but a shelf life of 12 months is claimed for the products. The active content degradation after 12 months is 4.6 - 11 %. According to efficacy

Property	Guideline and Method	Tested product	Results	Reference	UK CA Comments
			Before: 2.3 After(6months): 1.9 After(12months): 2.3 After(24months): 2.2 <u>Appearance</u> Before: brown liquid, typical iodine After(6/12/24month): no change		this degradation is considered acceptable (see section 2.2.5.5), therefore a 12 month shelf life is supported. The pH and appearance are considered stable over this time period. Dilution stability is not required for RTU formulations.
		Luxdip 50B	<u>Active content</u> Before: 0.610 (Initial QC = 0.630) After(6months): 0.582 After(12months): 0.584 After(24months): 0.541 <u>pH</u> Before: 4.6 After(6months): 4.7 After(12months): 4.4 After(24months): 4.6 <u>Appearance</u> Before: brown liquid, typical iodine After(6/12/24month): no change	Hampson, I. and Hackett, J. (2014) GEA011	The active content degrades by at least 11% following 2 years storage, but a shelf life of 12 months is claimed for the products. The active content degradation after 12 months is within the maximum allowed 10 % as stated in the ECHA guidance, Nov. 2014. The pH and appearance are considered stable over a 24 month period. The initial content is 22% higher than the target content of 0.5% (Tolerance limits only allow ±15%) for the product, however the storage stability data can still be used to support the product as this is only a minor change (0.11%) in the formulation. Note: Applicant was queried on this and has replied that QC procedures have been put in place to ensure

Property	Guideline and Method	Tested product	Results	Reference	UK CA Comments
					this does not happen again. Dilution stability is not required for RTU formulations.
		Luxdip 25	<u>Active content</u> Before: 0.318 (Initial QC = 0.330) After(6months): 0.298 After(12months): 0.298 After(24months): 0.286 <u>pH</u> Before: 4.2 After(6months): 4.3 After(12months): 4.1 After(24months): 4.2 <u>Appearance</u> Before: brown liquid, typical iodine After(6/12/24month): no change	Hampson, I. and Hackett, J. (2014) GEA013	The active content degrades by at least 10% following 2 years storage, but a shelf life of 12 months is claimed for the products. The active content degradation after 12 months is 6.3 – 9.7%, which is within the maximum allowed 10 % as stated in the ECHA guidance, Nov. 2014. The pH and appearance are considered stable over a 24 month period. Dilution stability is not required for RTU formulations. The initial content is 27% higher than the target content of 0.25% (Tolerance limits only allow ±15%) for the product, however the storage stability data can still be used to support the product as this is only a minor change (0.06%) in the formulation. Note: Applicant was queried on this and has replied that QC procedures have been put in place to ensure this does not happen again.

Property	Guideline and Method	Tested product	Results	Reference	UK CA Comments
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Case	All products	The product labels state to store the product away from direct sunlight.	-	Acceptable
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Case	All products	See accelerated and ambient storage results	-	Acceptable. See the results of the accelerated and ambient storage studies on various products. The humidity was not recorded in any of the studies, but label phrases prevent the products being stored at extreme temperatures.
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Visual	All products	For the ambient storage stability all products tested were stored in 5 L HDPE drums. In all cases the container was not misshapen and had not deteriorated significantly in any way, though some brown staining was observed.	See individual storage stability reports	Acceptable. It should be noted that the containers were stored for 2 years and were considered acceptable over this time period. This accommodates the claimed shelf lives of all the meta-SPCs in the BPF. The data available is considered sufficient to support the HDPE packaging for the whole BPF.
Persistent foaming	CIPAC MT 47.2	All concentrate products:	mLs foam after 1 min (concentration tested)	Hampson, I. (2016), attached in IUCLID 3.5	The dilutions tested correspond to the proposed uses requested. The level of foam exceeds the regulatory maximum of 60 mLs after 1 minute. The applicant
		Ioklene	100 (20% solution)		
		Maxadine C	100 (25% solution)		
		DS IO 421	100 (20% solution)		

Property	Guideline and Method	Tested product	Results	Reference	UK CA Comments
		Priodine	90 (12.5% solution)		notes that the products are typically made up in a dip cup or in an empty plastic drum before being capped and having a dosing line inserted, therefore foaming is not an issue. It has also been confirmed that no complaints of excessive foam have been received for any GEA iodine concentrate. This is considered acceptable.
		Intelliblend	100 (10% solution)		
		IodoShield Active	120 (25% solution)		
	-	All RTU products	No data	-	Acceptable. Persistent foam not required for RTU products as dilution with water is not required.
Physical compatibility	Case	All products	Iodine products are known to be incompatible with products based on chlorhexidine gluconate and sodium hypochlorite. These products should not be mixed together.	-	Acceptable. The products are not designed to be used in conjunction with any other products and no claims of compatibility are made on the label. No further consideration is required.
Chemical compatibility	Case	All products	Iodine products are known to be incompatible with products based on chlorhexidine gluconate and sodium hypochlorite. These products should not be mixed together.	-	Acceptable. The products are not designed to be used in conjunction with any other products and no claims of compatibility are made on the label. No further consideration is required.
Degree of dissolution and dilution stability	CIPAC MT 41	Ioklene	No visible precipitates or layering (20% dilution)	Amended Hampson, I. (2016), attached in IUCLID 3.5	Acceptable. The dilutions tested correspond to the proposed uses requested. Note that these results are conducted on stored samples.
		Maxadine C	No visible precipitates or layering (25% dilution)		

Property	Guideline and Method	Tested product	Results		Reference	UK CA Comments
		DS IO 421	No visible precipitates or layering (20% dilution)			Initial determinations are not thought to be required, as stored samples represent a worst case and no concerns are raised.
		Priodine	Several very small solid particles. Not sufficient to constitute a layer. 12.5% dilution)			
		Intelliblend	No visible precipitates or layering (10% dilution)			
		IodoShield Active	Several very small solid particles. Not sufficient to constitute a layer. (25% dilution)			
	Case	All RTU products	No data		-	Acceptable. Data not required for products that are not diluted in water.
Surface tension	OECD 115 and EC A5		Surface tension of a 1g/L solution, mN/m	temp., ºC	Drake, 2017 (ENV11345/161102-21)	Acceptable.
		Ioklene conc.	43	20.4		
		Maxadine C	44.1	20.4		
		DS IO 421	45.6	20.0		
		Priodine	43.8	20.3		
		Intelliblend	43.8	20.4		
		IodoShield Active	40.7	20.5		
		Luxspray 15	46.9	19.6		
		Luxspray 30	48.8	19.5		
		Luxspray 50	44.2	19.5		
		Luxdip 50B	58.9	20.1		
Viscosity	OECD 114, cannon-fenske and U-tube reverse flow viscometers		Kinematic viscosity		Drake, 2017 (ENV11345/161102-161121)	Acceptable. There are no hydrocarbons in the formulations, therefore no classification as an aspiration hazard is necessary.
			20 ºC, mm^2/s	40 ºC, mm^2/s		
		Ioklene conc.	13.09	6.14		
		Maxadine C	10.64	7.37		
		DS IO 421	42.75	23.50		

Property	Guideline and Method	Tested product	Results		Reference	UK CA Comments
		Priodine	11.46	16.33		
		Intelliblend	110.00	43.10		
		IodoShield Active	167.75	6.80		
		Luxspray 15	1.46	0.88		
		Luxspray 30	1.69	1.04		
		Luxspray 50	2.03	1.49		
		Luxdip 50B	595.50	366.90		
		Luxdip 25	667.70	255.80		

With regards to storage stability, the following shelf life can be recommended for the meta SPCs, based on the storage stability data submitted:

Meta-SPC 1 (Concentrates): 12 months

Meta-SPC 2 (Intelliblend): 6 months (based on accelerated storage data only, may be re-assessed following provision of ambient temperature storage)

Meta-SPC 3 (Iodoshield Active): 12 months

Meta-SPC 4 (RTU LuxSpray / LuxDip): 12 months

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA comments
Explosives	Case	All products	All products of this biocidal product family are water based products. Due to the water content in the formulations it is not expected that the products may explode. The products do not contain components	IUCLID dossier, 4.1.	Acceptable

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA comments
			associated with explosive properties.		
Flammable liquids	Case	All products	All products of this biocidal product family are aqueous solutions of non-flammable components. The most concentrated product still contains a significant proportion of water. According to the Recommendation of the Transport of Dangerous Goods Manual of Tests and Criteria (2009, page 447), "*the procedure only applies to possible flammable mixtures containing known flammable liquids in defined concentrations although they may contain non-volatile components e.g. polymers, additives etc*." The composition of the mixtures is accurately known and does not contain any flammable liquids.	IUCLID dossier, 4.2.	Acceptable
Self-reactive substances and mixtures	Case	All products	None of the formulations of the biocidal products family is expected to be self-reactive.	IUCLID dossier	Acceptable
Pyrophoric liquids	Case	All products	Due to water content and known experience none of the formulation of the biocidal product family is expected to have pyrophoric properties.	IUCLID dossier	Acceptable
Self-heating substances and mixtures	Case	All products	None of the formulations of the biocidal product family is expected to be self-heating.	IUCLID dossier	Acceptable
Substances and mixtures which in	Case	All products	Not applicable. All products of this biocidal product family are water-	IUCLID dossier	Acceptable

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA comments
contact with water emit flammable gases			based, liquid products.		
Oxidising liquids	Case	All products	Based on iodine, water and the remaining components that are known to be non-oxidising the oxidising properties of all products of the biocidal product family are predicted negative.	IUCLID dossier, 4.4.	Acceptable
Organic peroxides	Case	All products	Not applicable, no organic peroxides contained in any of the products of the biocidal product family.	IUCLID dossier	Acceptable
Corrosive to metals	Recommendations on the Transport of Dangerous Goods Manual of Tests Criteria, 6th Edition United Nations 2015 ST/SG/AC10/ 11/Rev 6 Section 37.4	Clinidip Superconcentrate (DS IO 421) Intelliblend concentrate	The sample gave a positive result for steel (fully immersed sample gave a corrosion rate of >6.25mm/year). The sample gave a negative result for aluminium (all samples indicated a corrosion rate of <6.25mm/year). Full results are provided in the image below this results table. For both metals localised corrosion did not exceed the minimum intrusion depths for a positive result. The fully immersed steel coupon showed evidence of increased pitting at the bottom and sides, but no holes deep enough to produce a positive result when examined. The sample gave a positive result for	Study summary ENV11775/ECO180102 Study summary ENV11774/ECO180101	Acceptable, the product Clinidip Superconcentrate is classified as being corrosive to metals. Acceptable, the product

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference	UK CA comments
			steel (half and fully immersed coupons gave a corrosion rate of >6.25mm/year). The sample gave a positive result for aluminium (fully immersed coupon gave a corrosion rate of >6.25mm/year). Full results are provided in the image below this results table. For both metals, localised corrosion did not exceed the minimum intrusion depths for a positive result. The half and fully immersed steel coupons show evidence of pitting on the surface, but none of the holes were deep enough to produce a positive result when examined visually or with microscopy.		Intelliblend Concentrate is classified as being corrosive to metals. The two products tested contain the highest iodine content (Intelliblend concentrate at 5.22 % iodine), and have the lowest pH values. These are therefore considered the worst case products with respect to corrosivity to metals in the product family. As not every product in the family have been tested, as a conservative approach, every product should be classified as being corrosive to metals and therefore contain the hazard statement H290 'May be corrosive to metals'.
Auto-ignition temperatures of products (liquids and gases)	Case	All products	All products of the biocidal product family are water based formulations. Thus, auto-ignition of any of the products is not expected.	IUCLID dossier	Acceptable

Clinidip Superconcentrate (DS IO 421) corrosivity to metals full results:

Treatment	Steel (21 days exposure)					Aluminium (28 days exposure)				
	Initial Mass (g)	Final Mass (g)	Mass Loss (g)	Mass Loss (%)	Corrosion	Initial Mass (g)	Final Mass (g)	Mass Loss (g)	Mass Loss (%)	Corrosion
Vapour phase	10.711	9.1705	1.5405	14.38%	Negative	3.6845	3.4591	0.2254	6.13%	Negative
Half Immersed	10.6495	9.1865	1.463	13.74%	Negative	3.6776	3.3246	0.353	10.62%	Negative
Fully Immersed	10.7250	4.645	6.08	56.69%	Positive	3.6758	2.5733	1.1025	30%	Negative
Blank Reference	10.6607	10.6532	0.0075	0.07%	Negative	-	-	-	-	-

Intelliblend concentrate corrosivity to metals full results:

Treatment	Steel (21 days exposure)					Aluminium (28 days exposure)				
	Initial Mass (g)	Final Mass (g)	Mass Loss (g)	Mass Loss (%)	Corrosion	Initial Mass (g)	Final Mass (g)	Mass Loss (g)	Mass Loss (%)	Corrosion
Vapour phase	10.6699	9.7234	0.9465	8.87%	Negative	3.6585	3.5729	0.0856	2.34%	Negative
Half Immersed	10.5953	5.8252	4.7701	45.02%	Positive	3.6627	3.3774	0.2853	7.79%	Negative
Fully Immersed	10.6925	1.3087	9.3838	87.78%	Positive	3.6757	0.9621	2.7136	73.83%	Positive
Blank Reference	10.6607	10.6532	0.0075	0.07%	Negative	-	-	-	-	-

Conclusion on the physical hazards and respective characteristics of the product
The meta SPCs are classified as being corrosive to metals; 'H290, may be corrosive to metals'.

2.2.4 Methods for detection and identification

Analytical methods for the active and impurities in the technical material

The source of the active substance is the same as those considered for EU inclusion, therefore methods of analysis for the active substance and impurities have already been considered. No further consideration is required.

Analytical methods for the active substance in the biocidal product

Report: Study to determine the accuracy, linearity and repeatability of SAM003A. Determination of iodine in finished products. Hampson and Hackett, 2012, GEA0019.

The method used to determine the iodine content of the BPF products is a potentiometric titration. The method is based on the assay methods given in the British Pharmacopoeia 2013, Volume I&II British Pharmacopoeia 2013, Volume I & II (Assay for Iodine), Volume III Formulated Preparations (Aqueous Iodine Oral Solution, Alcoholic Iodine Solution, Povidone Iodine eye drops and mouthwash and Assay of Povidone Iodine Solution). The method uses a pH meter with millivolt readout and appropriate electrodes.

The titration is carried out with sodium thiosulphate to determine the amount of iodine. It is not possible to use an iodine indicator in this instance as they have been found not to work.

Samples were prepared as follows:

Accurately weigh the according to following guide the iodophor formulations into wide mouth conical flask;

Nominal Concentration/ %	Approximate weight/ g	Example product
20	1-1.4	Biodyne
14	1.4-1.6	Iocol
5	4.0-5.0	Luxconc 9:1
2.5	8.0-9.0	Clinidip Superconcentrate
2.0	9.5-11	Clinidip L Concentrate
1.5	12.0-15.0	Ioklene Conc
0.5	30-50	LuxSpray 50
0.3	70-80	LuxSpray 30
0.15	95-115	LuxSpray 15

For solutions of nominal concentration below 0.15% use a lower strength thiosulphate solution such as 0.01 M. Adjust weight and calculations accordingly. Then add 150 ml of deionised water and 15 ml of 0.1 M hydrochloric acid to the conical flask. Dissolve completely by swirling the flask for 10-15 seconds. Place the electrode into the conical flask. If required change reading on the pH meter from pH value to millivolt (mV). Initial reading should be in the range 400-750 mV.

Titrate with the 0.1 N sodium thiosulphate solution from the burette. Add the sodium thiosulphate solution to the conical flask whilst swirling the contents. Continue until the

reading reaches 250 mV and a pale yellow colour is seen in the flask. Pause and then, drop wise, continue until meter reading has fallen to 240 mV or below and the colour clears. Stop and wait. If reading increases and yellow colour returns then repeat drop wise addition until reading again falls to 240 mV or below and solution becomes colourless.

The amount of iodine present should be equivalent to between 10-18 ml of sodium thiosulphate solution for all formulations. The colour of the solution should become totally colourless at or about the end point but leave the solution to stand for a few minutes to ensure that no colour returns or the mV reading increases.

Take the end point as being the titre volume of sodium thiosulphate determined above. Each ml of 0.1 M sodium thiosulphate solution is equivalent to 12.69 mg of iodine. Hence the iodine content is given by the following:

I = V x 12.69 mg

The concentration of iodine in the sample is given by the following calculation:

% Iodine w/w = (V × 12.69) / (W × 10)

W = weight of sample in grams and V is the volume of sodium thiosulphate solution used.

The following validation data were presented on a range of nominal iodine solutions. The composition of these nominal solutions is as follows:

20% iodine solution formula	
Water	70.580%
Caustic soda solution (32%)	9.420%
Iodine crystalline	20.000%

A 20 % w/w sample was synthesised and then diluted to give 6 samples with nominal concentrations of 0.1 – 20 % w/w. Recoveries were calculated by comparing the calculated concentration with the experimentally derived concentration of the various nominal samples.

The solution used for validation is not comparable to the individual products in the BPF. In general, method validation should be conducted on the products to be authorised. However, considering that the products are water-based formulations and the technique of titration with iodine is a well-known technique for determining iodine in aqueous solutions, in this instance, the fact that the method validation has been conducted on nominal solutions is not of great concern and the method is considered fit for purpose.

LOQ	**Recovery fortification level**	**Recoveries % range (mean)**	**Repeatability % RSD (n)**	**Linearity**	**Specificity**

0.1 % w/w	20 %w/w	97.3 – 98.9 (97.9, n=5)	0.44(5) Horwitz %RSD = 1.71	Titrations are well-known to be linear techniques and therefore linearity data are not strictly required. A graph was plotted of experimental vs calculated concentrations	Titration with sodium thiosulfate is a well-documented analytical method specific for iodine.
	2 %w/w	99.6 – 108.3 (104, n=5) (n=5)	3.57 (5) Horwitz %RSD = 2.41		
	1 %w/w	100.1 – 100.5 (100.4, n=5)	0.2 (5) Horwitz %RSD = 2.68		
	0.5 %w/w	98.2 – 99.4 (99, n=5)	0.5 (5) Horwitz %RSD = 2.97		
	0.25 %w/w	98 – 99.6 (98.6, n = 5)	0.7 (5) Horwitz %RSD = 3.30		
	0.1 %w/w	96 – 97 (96.4, n=5)	0.6 (5) Horwitz %RSD = 3.79		

The method is considered fit for purpose, although not validated in accordance with the ECHA guidance and BPR.

The CAR lists the following relevant impurities for iodine:

Limits according to the European Pharmacopoeia

1) Bromides and chlorides ≤ 0.25 g/kg

2) Non-volatile substances ≤ 1 g/kg

No method of analysis for the relevant impurities for iodine have been provided or referred to by the applicant; however, the CAR also states:

The impurities specified are not considered relevant and as they are either below 1 g/kg (bromide and chlorides) or non-specific (non-volatiles) they should normally not be specified in the reference specification for biocidal purpose.

Therefore, no further consideration of the relevant impurities associated with iodine is required.

Analytical methods for the monitoring of residues (soil, water, air, body fluids and tissues and food)

Methods of analysis for the determination of iodine residues in air and water have previously been evaluated and accepted at EU level. Methods for detection in soil were not required as the as the PECs calculated for soil and water were low compared to the natural background concentrations in these compartments and as iodine is not classified as toxic or highly toxic. For body fluids and tissues methods are not required as the active substance is not considered toxic.
The following endpoints for methods of analysis for the determination of residues in food/feed of animal origin were presented in the CAR:

Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Determination of iodide in milk and milk powder: HPLC with electrochemical detection (ISO 14378), Applicability range in whole milk: 0.03 µg/g to 1 µg/g Applicability range in dried skim milk: 0.3 µg/g to 10.0 µg/g Method acceptable as such. Nevertheless, the final conclusion on the need for such a method and the LOQ to be required has to be referred to the product authorisation stage when the final guidance for dietary risk assessment is available.

CHEMISTRY

DECISION
Under Regulation (EU) No 528/2012 a **union authorisation of the BPF may be recommended.**

DATA REQUIRMENTS FOR POST AUTHORISATION
None

CLASSIFICATION
All meta SPCs are classified as being corrosive to metals; 'H290, may be corrosive to metals'.

LABEL AMENDMENTS
All labels should include the following (or words to a similar effect):
'Protect from frost'
'Do not store at temperatures above 30 ºC'
'H290: may be corrosive to metals'

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The applicant provided in use concentrations for the products in the Iodine Teat Dip Product Family of 0.15-0.50% free iodine. The UK CA have calculated the in use concentrations as being 0.16 – 0.52% (see section 2.2.5.12, *Risk for consumers via residues in food*, Table 1) The products are for use in product type 3 for teat disinfection and are for professional use only.

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

The products are for the control bacteria and yeast. They are for use on lactating animals' teats as part of the milking process.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The products are applied to the teats by dipping, foaming or spraying. The teat is dipped, foamed or sprayed up to a minimum of two thirds of its length with the diluted or neat product (containing 0.16-0.52% free iodine), a minimum contact time of 60 seconds for pre-milking applications is stipulated then the teats can be wiped and dried.

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

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

The product is intended to destroy bacteria and yeasts present on the teats of lactating animals (see section 2.2.5.4, below for details).

No unacceptable suffering is foreseen as a result of the use of this product.

2.2.5.4 Mode of action, including time delay

The applicant has provided the following statement:

'As described for the biocidal active substance, the effects of iodine are rapid and non-selective. The germicidal properties result from the oxidation of various molecules of the organisms leading to damage to the cell wall or viral capsid, metabolic inhibition or interference with the respiratory chain.'

The UK CA accepts the applicants' statement of the mode of action of the product family.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)					
Function and field of use envisaged	**Test substance**	**Test organism(s)**	**Test method/ Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Disinfection of lactating animals' teats. Phase 2 Step 1 Bacteria	Priodine (Meta SPC1)	Bacteria (*S. aureus, S. uberis, E.coli)*	The EN1656 standard protocol was followed. The test was conducted at 30°C ± 1°C with 10 g/L Bovine Serum Albumin and 10g/L yeast extract. The product was tested at a concentration of 7:1	When a contact time of 2 or 3 minutes was used, for all the test organisms, a greater than 5 log reduction (the pass criterion for the standard) was observed. When a contact time of 90 seconds was used	Watson, D. C. 2017 (17A.030VT2.GFT, 17A.030VT3.GFT and 17A.030VT4.GFT)

			with a contact time of 90 seconds, 2 and 3 minutes.	for *E.coli* and *S. aureus* a greater than 5 log reduction was observed, however a 4.5 log reduction was observed for *S. uberis*.	
	Priodine (Meta SPC1)	Bacteria (*S. aureus, S. uberis, E.coli)*	The EN1656 standard protocol was followed. The test was conducted at 30°C ± 1°C with 10 g/L skimmed milk. The product was tested at a concentration of 7:1 with a contact time of 5 minutes.	For all the test organisms, a greater than 5 log reduction (the pass criterion for the standard) was observed.	Watson, D. C. 2016 (16L.055VT2.GFT)
	LuxSpray 15 (Meta SPC4) (Batch 1590812WB8 – Manufactured Sept 2015, tested Sept 2016)	Bacteria (*S. aureus, S. uberis, E.coli)*	The EN1656 standard protocol was followed. The test was conducted at 30°C ± 1°C with 10 g/L Bovine Serum Albumin and 10g/L yeast extract. The product was tested neat with a contact time of 60 seconds.	For all the test organisms, a greater than 5 log reduction (the pass criterion for the standard) was observed.	Watson, D. C. 2016 (16J.010VT3.GFT)
	LuxSpray 15 (Meta SPC4)	Bacteria (*S. aureus, S. uberis, E.coli)*	The EN1656 standard protocol was followed. The test was conducted at 30°C ± 1°C with 10g/L skimmed milk. The product was tested neat with a contact time of 5 minutes.	For all the test organisms, a greater than 5 log reduction (the pass criterion for the standard) was observed.	Watson, D. C. 2015 (15G.145VT.GFT)
	LuxSpray 15 (Meta SPC4) (Batch 1262603WB6 – Manufactured 2012, tested May 2016)	Bacteria (*S. aureus, S. uberis, E.coli)*	The EN1656 standard protocol was followed. The test was conducted at 30°C ± 1°C with 10g/L skimmed milk. The product was tested neat with a contact time of 5 minutes.	For all the test organisms, a greater than 5 log reduction (the pass criterion for the standard) was observed.	Watson, D. C. 2016 (16D.033VT.GFT)
	LuxSpray 50 (Meta SPC4)	Bacteria (*S. aureus, S.*	The EN1656 standard protocol	For all the test organisms, a	Watson, D. C. 2012 (12J.039VB-T.GFT)

		uberis, E.coli)	was followed. The test was conducted at 30°C ± 0.5°C with 10g/L skimmed milk. The product was tested neat* with a contact time of 5 minutes.	greater than 5 log reduction (the pass criterion for the standard) was observed.	
	LuxSpray 50 (Meta SPC4) (Batch 1271110WB0 – Manufactured 2012, tested May 2016)	Bacteria (*S. aureus, S. uberis, E.coli)*	The EN1656 standard protocol was followed. The test was conducted at 30°C ± 1°C with 10g/L skimmed milk. The product was tested neat with a contact time of 5 minutes.	For all the test organisms, a greater than 5 log reduction (the pass criterion for the standard) was observed.	Watson, D. C. 2016 (16D.035VT.GFT)
	LuxDip 25 (Meta SPC4)	Bacteria (*S. aureus, S. uberis, E.coli)*	The EN1656 standard protocol was followed. The test was conducted at 30°C ± 0.5°C with 10g/L skimmed milk. The product was tested neat with a contact time of 5 minutes.	For all the test organisms, a greater than 5 log reduction (the pass criterion for the standard) was observed.	Watson, D. C. 2014 (14L.050VT2.GFT)
	LuxDip 25 (Meta SPC4) (Batch 1261401WB5 – Manufactured 2012, tested May 2016)	Bacteria (*S. aureus, S. uberis, E.coli)*	The EN1656 standard protocol was followed. The test was conducted at 30°C ± 1°C with 10g/L skimmed milk. The product was tested neat with a contact time of 5 minutes.	For all the test organisms, a greater than 5 log reduction (the pass criterion for the standard) was observed.	Watson, D. C. 2016 (16D.036VT.GFT)
	LuxDip 50B (Meta SPC4)	Bacteria (*S. aureus, S. uberis, E.coli)*	The EN1656 standard protocol was followed. The test was conducted at 30°C ± 1°C with 10g/L skimmed milk. The product was tested neat with a contact time of 5 minutes.	For all the test organisms, a greater than 5 log reduction (the pass criterion for the standard) was observed.	Watson, D. C. 2015 (15F.172VT.GFT)
	LuxDip 50B (Meta SPC4)	Bacteria (*S. aureus, S.*	The EN1656 standard protocol	For all the test organisms, a	Watson, D. C. 2016 (16D.037VT.GFT)

	(Batch 1262909WB8 – Manufactured 2012, tested May 2016)	*uberis, E.coli)*	was followed. The test was conducted at 30°C ± 1°C with 10g/L skimmed milk. The product was tested neat with a contact time of 5 minutes.	greater than 5 log reduction (the pass criterion for the standard) was observed.	
	LuxSpray 30 (Meta SPC4)	Bacteria (*S. aureus, S. uberis, E.coli)*	The EN1656 standard protocol was followed. The test was conducted at 30°C ± 0.5°C with 10g/L skimmed milk. The product was tested neat with a contact time of 5 minutes.	For all the test organisms, a greater than 5 log reduction (the pass criterion for the standard) was observed.	Watson, D. C. 2012 (12B.027VEcSaSu.GFT)
	LuxSpray 30 (Meta SPC4) (Batch 1271620WB0 – Manufactured 2012, tested May 2016)	Bacteria (*S. aureus, S. uberis, E.coli)*	The EN1656 standard protocol was followed. The test was conducted at 30°C ± 1°C with 10g/L skimmed milk. The product was tested neat with a contact time of 5 minutes.	For all the test organisms, a greater than 5 log reduction (the pass criterion for the standard) was observed.	Watson, D. C. 2016 (16D.034VT.GFT)
Disinfection of lactating animals' teats. Phase 2 Step 1 Yeast	Priodine (Meta SPC1)	Yeast (C. albicans)	The EN1657 standard protocol was followed. The test was conducted at 30°C ± 1°C with 10 g/L Bovine Serum Albumin and 10g/L yeast extract. The product was tested at a concentration of 7:1 with a contact time of 60 seconds.	A greater than 4 log reduction (the pass criterion for the standard) was observed.	Watson, D. C. 2016 (16L.055VY.GFT)
	Priodine (Meta SPC1)	Yeast (C. albicans)	The EN1657 standard protocol was followed. The test was conducted at 30°C ± 1°C with 10 g/L skimmed milk. The product was tested at a concentration of 7:1 with a contact time	A greater than 4 log reduction (the pass criterion for the standard) was observed.	Watson, D. C. 2016 (16L.055VY2.GFT)

			of 5 minutes.		
	LuxSpray 15 (Meta SPC4)	Yeast *(C. albicans)*	The EN1657 standard protocol was followed. The test was conducted at 30°C ± 1°C with 10 g/L Bovine Serum Albumin and 10g/L yeast extract. The product was tested neat with a contact time of 60 seconds.	A greater than 4 log reduction (the pass criterion for the standard) was observed.	Watson, D. C. 2016 (16L.054VY.GFT)
	LuxSpray 15 (Meta SPC4)	Yeast *(C. albicans)*	The EN1657 standard protocol was followed. The test was conducted at 30°C ± 1°C with 10 g/L skimmed milk. The product was tested neat with a contact time of 5 minutes.	A greater than 4 log reduction (the pass criterion for the standard) was observed.	Watson, D. C. 2015 (15G.145VCa.GFT)
	LuxSpray 50 (Meta SPC4)	Yeast *(C. albicans)*	The EN1657 standard protocol was followed. The test was conducted at 30°C ± 0.5°C with 10g/L skimmed milk. The product was tested neat with a contact time of 5 minutes.	A greater than 4 log reduction (the pass criterion for the standard) was observed.	Watson, D. C. 2012 (12J.039VCa-T.GFT)
	LuxDip 25 (Meta SPC4)	Yeast *(C. albicans)*	The EN1657 standard protocol was followed. The test was conducted at 10°C ± 0.5°C with 10 g/L Bovine Serum Albumin and 10g/L yeast extract. The product was tested neat with a contact time of 30 minutes.	A greater than 4 log reduction (the pass criterion for the standard) was observed.	Watson, D. C. 2012 (12B.044VCa-H.GFT)
	LuxDip 50B (Meta SPC4)	Yeast *(C. albicans)*	The EN1657 standard protocol was followed. The test was conducted at 10°C ± 0.5°C with 10 g/L Bovine Serum Albumin and 10g/L yeast extract.	A greater than 4 log reduction (the pass criterion for the standard) was observed.	Watson, D. C. 2012 (12B.045VCa-H.GFT)

			The product was tested neat with a contact time of 30 minutes.		
Disinfection of lactating animals' teats. Phase 2 Step 2 Bacteria	LuxSpray 15 (Meta SPC4)	Bacteria (S. aureus)	Testing based on EN14349 and EN16437 (following the protocol submitted to the efficacy working group by the iodine registration group). Vitro-skin and the drop/dip method was used. The product was tested neat. The test was conducted at 30°C ± 0.5°C with 10g/L skimmed milk solution and a contact time of 60 seconds.	When tested neat greater than 4 log reduction (the pass criterion agreed) was observed.	Gradle, C. 2016 (e)
	LuxSpray 50 (Meta SPC4)	*Bacteria (S. aureus)*	Testing based on EN14349 and EN16437. Vitro-skin and the drop/drop method was used. The product was tested neat. The test was conducted at 30°C ± 0.5°C with 10g/L skimmed milk solution and a contact time of 5 minutes.	When tested neat greater than 4 log reduction (the pass criterion agreed) was observed.	Gradle, C. 2016 (b)
	LuxDip 25 (Meta SPC4)	*Bacteria (S. aureus)*	Testing based on EN14349 and EN16437. Vitro-skin and the drop/dip method was used. The product was tested neat. The test was conducted at 30°C ± 0.5°C with 10g/L skimmed milk solution and a contact time of 5 minutes.	When tested neat greater than 4 log reduction (the pass criterion agreed) was observed.	Gradle, C. 2016 (c)
	LuxDip 50B (Meta SPC4)	*Bacteria (S. aureus)*	Testing based on EN14349 and EN16437.	When tested neat greater than 4 log reduction (the pass	Gradle, C. 2016 (d)

			Vitro-skin and the drop/dip method was used. The product was tested neat. The test was conducted at 30°C ± 0.5°C with 10g/L skimmed milk solution and a contact time of 5 minutes.	criterion agreed) was observed.	
	IodoShield Active (Meta SPC3)	Bacteria (*S. aureus*)	Testing based on EN14349 and EN16437. Vitro-skin and the drop/drop method was used. The product was tested at a dilution of 9:1. The test was conducted at 30°C ± 0.5°C with 10g/L skimmed milk solution and a contact time of 5 minutes.	A greater than 4 log reduction (the pass criterion agreed) was observed.	Gradle, C. 2016 (a)

**Note: Due to the methodology – i.e. the addition of soiling agents and test inoculum the maximum concentration that can be tested is an 80% solution of the test product*

Conclusion on the efficacy of the product

The label claims for the product family are 'for use as a teat dip'/'for teat disinfection'.

On some of the product labels provided the following statements were also noted:

'broad spectrum biocide'
'forms a viscous protective coating for long-lasting disinfection and resistance against bacteria between milking's'

The UK CA considers that the applicant should always ensure it is clearly stated which target organisms efficacy has been demonstrated against on the product label. Therefore although claims like 'broad spectrum biocide' and 'for teat disinfection' may be acceptable they should be accompanied by a clear indication of the target organisms against which the product has been demonstrated to be effective e.g. for teat disinfection (kills bacteria and yeast) (or equivalent wording).

No data have been provided to support any residual efficacy of the products therefore any claims implying residual efficacy should be removed from product labels. Therefore the claim 'forms a viscous protective coating for long-lasting disinfection and resistance against bacteria between milking's' is not acceptable.

The UK CA notes that the example product label provided for the product Iodoshield Active includes the label claim 'to assist in decreasing the bacterial invasion of the teat'. The UK CA considers that this claim is not biocidal (following consultation with other Member States and the Veterinary Medicines Directorate in the UK) and is therefore not acceptable.

It is also noted that some of the products in the family made claims relating to use for disinfection of surfaces, protective equipment etc., and no data were provided to support these claims. The applicant has agreed to remove all such claims from the product family.

It is typically not considered practical to have a pre-milking contact time in excess of 60 seconds or a post-milking contact time in excess of 5 minutes for teat disinfectants. The applicant has stated (and it is reflected in the instructions for the product family) that the minimum pre- milking contact time for the product is 15 seconds. The applicant has not specified a minimum contact time for post milking applications. The UK CA considers that either the minimum contact time should be specified or it should be made clear that when used for post milking applications the product should not be wiped off after application to ensure the required contact time is achieved.

The in-use free iodine concentrations of the products in the family range between 0.16-0.52%. The product LuxSpray 15 is a ready to use formulation which contains 0.16% iodine it is therefore one of the products in the family with the lowest active substance concentration. It contains relatively few different co-formulates compared to many other products in the product family. It is for use in pre-milking (and post milking applications) and is therefore one of the products in the family used with the shortest contact time. The product LuxSpray 15 passed the relevant phase 2 step 1 and phase 2 step 2 tests with bacteria and yeast.

In order to demonstrate that the variation in non-active components present in the product family does not impact upon the efficacy of the products within the family the applicant has also provided efficacy tests for products from each of the meta-SPCs. The applicant submitted phase 2 step 1 tests in support of the product family's bactericidal (EN1656) and yeasticidal (EN1657) activity using the products Priodine, LuxSpray 15, LuxSpray 50, LuxDip 25 and LuxDip 50B. The product Prodine is from meta-SPC 1 and the 'Lux' products are from meta-SPC 2. An additional test using bacteria was provided for LuxSpray 30. All the tests were conducted at the recommended in use concentration for the products and demonstrate the efficacy of the products according to the pass criteria for the relevant standard protocol except for the phase 2 step 1 test conducted using Prodine with a contact time of 90 seconds which did not meet the pass criteria for the test for one of the organisms tested (a log 4.5 reduction was observed, not the required log 5 reduction).

The concentrations of the co-formulants in the products tested vary. The products tested are generally representative of the ranges of concentrations of each co-formulant stated in the overall product family.

The tests submitted show that the results for these products are comparable and the UK

CA therefore considers that the products within SPC specification limits can be expected to have a similar biocidal efficacy.

The applicant has also conducted phase 2 step 2 testing following the protocol submitted to the efficacy working group by the iodine registration group using:

- the product IodoShield active from meta-SPC 3 with a contact time of 5 minutes
- the product LuxSpray 15 from meta-SPC 2 with a contact time of 1 minute
- the products LuxSpray 50, LuxDip 25 and LuxDip 50B from meta-SPC 2 with a contact time of 5 minutes

Using either the drop/drop or drop/dip protocol as appropriate for the products. In the tests the agreed 4 log reduction was observed in all cases when the products were tested at the recommended in use concentration. LuxSpray15 represents the lowest active substance concentration for the family as discussed above and passed the test with a 60 second contact time supporting the use of the family for pre-milking applications. The results for the other products tested in the phase 2 step 2 tests did not indicate issues with the performance of other formulations in the family. The UK CA considers that the phase 2 step 2 tests provided demonstrate the efficacy of the product family.

Whilst the UK CA recognises that in one of the phases 2 step 1 tests conducted for one of the products in the family for one organism tested the required pass criterion was not reached we consider that given that the efficacy of the product family has been demonstrated using LuxSpray 15 and the efficacy of the products in both meta-SPCs have been demonstrated in the phase 2 step 2 tests the data package when viewed as a whole is sufficient to support the efficacy of the product family.

The product family contains coformulants that have been identified as active substances (citric acid, phosphoric acid, sodium hydroxide and potassium iodide), some of which have been notified as disinfectants. However, none of these coformulants have been declared as active substances in the product family.
The applicant has stated that citric acid, phosphoric acid and sodium hydroxide are included in the family as pH modifiers. They are added in small amounts (max. 0.35% individually) to the products. They are not present in all the products in the family. The applicant has provided the following statement to justify why these components can be considered to be non-active in this product family:

> 'Citric Acid- Citric acid is used in the products LuxDip 50B and LuxDip 25 to adjust their pH. It is present at a maximum of 0.2% w/w. Whilst this is a comparable concentration to that of iodine, citric acid is a much less potent biocide. A document entitled Inventory of Biocides used in Denmark suggests that the minimum concentration used in biocidal products where it acts as an active is 0.5% w/w with over 2% being a more common concentration. In addition, our products LuxSpray 50, 30 and 15 are all effective under EN 1656:2009 conditions and none contain citric acid.
>
> Potential alternate pH adjusters would include Lactic or Phosphoric acids, both of which could cause the same objection.
> Other than that we would be reduced to using strong acids which would result in health and safety concerns and dependent on the acid, formulation problems.
>
> Phosphoric Acid- Present in 1 concentrated product at 0.063%. At such a low concentration, this substance is unlikely to act as a

biocide. Especially considering said product is diluted before use.'

'The sodium Hydroxide is present in the products LuxDip 25 and 50B due to the fact that the iodine is initially dissolved in a Sodium Hydroxide solution in order to create the iodine premix that we use for these products. The premix is then added to the batch mix and pH adjusted down, with citric acid, to an acidic pH. As such, whilst it is added to the formulation, there is unlikely to be any Hydroxide anion present in the final mix.

The Potassium Iodide present in Iodoshield is there to improve product stability.'

The UK CA accepts the applicants' arguments that the acids are included in the products in concentrations that are unlikely to significantly contribute to their efficacy. The UK CA also notes that potassium iodide is only present in one of the concentrate products which is diluted 9:1 before use and is present at significantly lower concentrations that the active substance iodine. The UK CA considers that the applicant has provided sufficient information to justify that these components should not significantly contribute to the efficacy of the product and/or were not included with that intention.

None of the components in question are included in LuxSpray 15. As discussed above this product has the lowest in use free iodine concentration and has been demonstrated to be efficacious when used with a contact time of 60 seconds. This demonstrates that the components in question are not required to achieve the required level of efficacy for the product family.

The UK CA considers that it is reasonable not to consider citric acid, phosphoric acid, sodium hydroxide and potassium iodide to be active substances in this biocidal product family.

The UK CA considers the data submitted to be acceptable in support of the product family's bactericidal and yeasticidal efficacy for pre and post milking applications, with a minimum contact time of 1 minute.

As a result of the evaluation of the physical, chemical and technical properties of the products in the product family it has been identified that after 12 months of storage for the products LuxSpray 50 and LuxSpray 30 there is a loss of the active substance in excess of 10%. Efficacy data have been provided for samples of LuxSpray 50 and 30 manufactured in (July) 2012 and tested in (May) 2016. These data (EN1656, bacteria, 5 minute contact time) demonstrate that the products are still efficacious. A sample of LuxSpray 15 manufactured (June) 2012 was also tested (EN1656, bacteria, 1 and 5 minute contact time) in (May) 2016 and demonstrated the efficacy of the product after ageing. The active content post ageing (for 12 and 24 months) determined in the chemistry studies for LuxSpray 50 and LuxSpray 30 is greater than the concentration of active substance in LuxSpray 15 before and after ageing. The UK CA therefore considers that the products LuxSpray 50 and LuxSpray 30 can reasonably be expected to be efficacious at the end of the requested 12 month shelf life despite the loss of the active substance in excess of 10%.

In the phase 2 step 2 tests, only S. aureus has been tested because it was the most resistant bacteria in the phase 2 step 1 tests.

2.2.5.6 Occurrence of resistance and resistance management

The applicant has not provided a specific statement in relation to resistance. In the review of iodine as an active substance, in relation to teat dips it is stated that 'no evidence was found of bacteria developing resistance to iodine or iodine based disinfectants. Further, development of resistance is not expected due to its unspecific mode of action.'

The UK CA accepts that there is no significant risk of the development of resistance for this active substance and product family, however, if the applicant becomes aware of any reports of resistance to the active substance iodine and/or the product family these should be reported to appropriate bodies (such as the efficacy working group and/or concerned member states) so that it can be determined if further action is required.

2.2.5.7 Known limitations

Always read the label or leaflet before use and follow all the instructions provided.

The product must be brought to a temperature of above 20°c before use. Leave the product until next milking.

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

2.2.5.8 Evaluation of the label claims

The UKCA considers that the following label claims have been supported:

- For teat disinfection* (*kills bacteria and yeast) pre-milking
- For teat disinfection* (*kills bacteria and yeast) post-milking
- Minimum contact time 60 seconds (for both pre and post milking applications)

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

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

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

Not relevant for this product.

Risk assessment for human health

2.2.6 Assessment of effects on Human Health

Skin corrosion and irritation

The following Meta SPCs will be described as Meta SPC 1, 2, 3 or 4 throughout the assessment of effects on Human Health. They correspond to the following formulations:

Meta SPC 1 – Concentrates (SL)
Meta SPC 2 – Intelliblend Concentrate (SL)
Meta SPC 3 – IodoShield Active (SL)
Meta SPC 4- RTU (AL)

The classification of the 4 Meta SPCs within this BPF has been determined using the conventional Method described in the Guidance on the Application of the CLP Criteria Version 4.1 (June 2015). The applicant has submitted calculation documents in the Section 13 of the IUCLID dossier (Raw material SDS and product classification sheets from NCEC For submission May 2016.zip) which were used for some of the endpoints. Please find the calculation details (Calculation Method according to Regulation (EC) N°1272/2008) in the Confidential Annex of the PAR.

Conclusion used in Risk Assessment – Skin corrosion and irritation Meta SPC 1	
Value/conclusion	The formulations included in the Meta SPC "concentrates" are not irritating to the skin
Justification for the value/conclusion	The classification has been determined using the calculation method.
Classification of the product according to CLP	No classification for skin irritation required.

Conclusion used in Risk Assessment – Skin corrosion and irritation Meta SPC 2	
Value/conclusion	The formulations included in the Meta SPC "concentrates with H318 classification" are not irritating to the skin
Justification for the value/conclusion	The classification has been determined using the calculation method.
Classification of the product according to CLP	No classification for skin irritation required.

Conclusion used in Risk Assessment – Skin corrosion and irritation Meta SPC 3	
Value/conclusion	The formulations included in the Meta SPC "concentrates with H318 classification" are not irritating to the skin
Justification for the value/conclusion	The classification has been determined using the calculation method.
Classification of the	No classification for skin irritation required.

product according to CLP	

Conclusion used in Risk Assessment – Skin corrosion and irritation Meta SPC 4	
Value/conclusion	The formulations included in the Meta SPC "RTU Products" are not irritating to the skin
Justification for the value/conclusion	The classification has been determined using the calculation method.
Classification of the product according to CLP	No classification for skin irritation required.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation Meta SPC 1	
Value/conclusion	The formulations included in the Meta SPC "concentrates" are irritating to the eyes (Category 2)
Justification for the value/conclusion	The classification has been determined using the calculation method.
Classification of the product according to CLP	Classification for H319 – Eye damage Category 2 – is required.

Conclusion used in Risk Assessment – Eye irritation Meta SPC 2	
Value/conclusion	The formulations included in the Meta SPC "concentrates with H318 classification" are corrosive to the eyes
Justification for the value/conclusion	The classification has been determined using the calculation method.
Classification of the product according to CLP	Classification for H318 – Eye damage Category 1 – is required.

Conclusion used in Risk Assessment – Eye irritation Meta SPC 3	
Value/conclusion	The formulations included in the Meta SPC "concentrates with H318 classification" are corrosive to the eyes
Justification for the value/conclusion	The classification has been determined using the calculation method.
Classification of the product according to CLP	Classification for H318 – Eye damage Category 1 – is required.

Conclusion used in Risk Assessment – Eye irritation Meta SPC 4	
Value/conclusion	The formulations included in the Meta SPC "RTU Products" are not irritating to the eyes
Justification for the value/conclusion	The classification has been determined using the calculation method.

Classification of the product according to CLP	No Classification for eye irritancy required.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation **Meta SPC 1** **Meta SPC 2** **Meta SPC 3** **Meta SPC 4**	
Value/conclusion	All formulation within the BPF are not irritant to the respiratory tract.
Justification for the conclusion	The classification has been determined using the calculation method.
Classification of the product according to CLP	No classification for Respiratory tract irritation is required.

Specific target organ toxicity – Repeated exposure (STOT RE)

Conclusion used in the Risk Assessment – Specific target organ toxicity (STOT RE) **Meta SPC 1**	
Value/conclusion	Meta SPC 1 is toxic to the thyroid following repeated exposure.
Justification for the conclusion	The classification has been determined using the calculation method.
Classification of the product according to CLP	Classification for STOT RE Category 2 is required.

Conclusion used in the Risk Assessment – Specific target organ toxicity (STOT RE) **Meta SPC 2**	
Value/conclusion	Meta SPC 2 is toxic to the thyroid following repeated exposure.
Justification for the conclusion	The classification has been determined using the calculation method.
Classification of the product according to CLP	Classification for STOT RE Category 2 is required.

Conclusion used in the Risk Assessment – Specific target organ toxicity (STOT RE) **Meta SPC 3**	
Value/conclusion	Meta SPC 3 is toxic to the thyroid following repeated exposure.

Justification for the conclusion	The classification has been determined using the calculation method.
Classification of the product according to CLP	Classification for STOT RE Category 2 is required.

Conclusion used in the Risk Assessment – Specific target organ toxicity (STOT RE) **Meta SPC 4**	
Value/conclusion	Meta SPC 4 is not toxic to the thyroid following repeated exposure.
Justification for the conclusion	The classification has been determined using the calculation method.
Classification of the product according to CLP	Classification for STOT RE is not required.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation **Meta SPC 1**	
Value/conclusion	Not sensitising to skin.
Justification for the value/conclusion	None of the co-formulants are classified for skin sensitisation or suspected to be skin sensitisers.
Classification of the product according to CLP and DSD	GEA Iodine Teat Dip BPF should not be classified for Skin Sensitisation according to Regulation (EC) N°1272/2008.

Conclusion used in Risk Assessment – Skin sensitisation **Meta SPC 2**	
Value/conclusion	Not sensitising to skin.
Justification for the value/conclusion	None of the co-formulants are classified for skin sensitisation or suspected to be skin sensitisers.
Classification of the product according to CLP and DSD	GEA Iodine Teat Dip BPF should not be classified for Skin Sensitisation according to Regulation (EC) N°1272/2008.

Conclusion used in Risk Assessment – Skin sensitisation **Meta SPC 3**	
Value/conclusion	Not sensitising to skin.
Justification for the value/conclusion	None of the co-formulants are classified for skin sensitisation or suspected to be skin sensitisers.
Classification of the product according to CLP and DSD	GEA Iodine Teat Dip BPF should not be classified for Skin Sensitisation according to Regulation (EC) N°1272/2008.

Conclusion used in Risk Assessment – Skin sensitisation **Meta SPC 4**

Value/conclusion	Not sensitising to skin.
Justification for the value/conclusion	None of the co-formulants are classified for skin sensitisation or suspected to be skin sensitisers.
Classification of the product according to CLP and DSD	GEA Iodine Teat Dip BPF should not be classified for Skin Sensitisation according to Regulation (EC) N°1272/2008.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation **Meta SPC 1** **Meta SPC 2** **Meta SPC 3** **Meta SPC 4**	
Value/conclusion	Not sensitising to the respiratory system.
Justification for the value/conclusion	None of the co-formulants are classified for Respiratory sensitisation or suspected to be respiratory sensitisers.
Classification of the product according to CLP	GEA Iodine Teat Dip BPF should not be classified for Respiratory Sensitisation according to Regulation (EC) N°1272/2008.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity Meta SPC 1	
Value	Not acutely toxic via the oral route.
Justification for the selected value	The classification has been determined using the calculation method.
Classification of the product according to CLP	No classification for Acute Oral toxicity is required.

Value used in the Risk Assessment – Acute oral toxicity Meta SPC 2	
Value	Not acutely toxic via the oral route.
Justification for the selected value	The classification has been determined using the calculation method.
Classification of the product according to CLP	No classification for Acute Oral toxicity is required.

Value used in the Risk Assessment – Acute oral toxicity Meta SPC 3	
Value	Not acutely toxic via the oral route.
Justification for the selected value	The classification has been determined using the calculation method.
Classification of the product according to CLP	No classification for Acute Oral toxicity is required.

Value used in the Risk Assessment – Acute oral toxicity Meta SPC 4	
Value	Not acutely toxic via the oral route.
Justification for the selected value	The classification has been determined using the calculation method.
Classification of the product according to CLP	No classification for Acute Oral toxicity is required.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity Meta SPC 1	
Value	Not acutely toxic via inhalation.
Justification for the selected value	The classification has been determined using the calculation method.
Classification of the product according to CLP	No classification for Acute Inhalation toxicity is required.

Value used in the Risk Assessment – Acute inhalation toxicity Meta SPC 2	
Value	Not acutely toxic via inhalation.
Justification for the selected value	The classification has been determined using the calculation method.
Classification of the product according to CLP	No classification for Acute Inhalation toxicity is required.

Value used in the Risk Assessment – Acute inhalation toxicity Meta SPC 3	
Value	Not acutely toxic via inhalation.
Justification for the selected value	The classification has been determined using the calculation method.
Classification of the product according to CLP	No classification for Acute Inhalation toxicity is required.

Value used in the Risk Assessment – Acute inhalation toxicity Meta SPC 4	
Value	Not acutely toxic via inhalation.
Justification for the selected value	The classification has been determined using the calculation method.
Classification of the product according to CLP	No classification for Acute Inhalation toxicity is required.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity Meta SPC 1	
Value	Not acutely toxic via the dermal route.
Justification for the selected value	The classification has been determined using the calculation method.
Classification of the product according to CLP	No classification for Acute Dermal toxicity is required.

Value used in the Risk Assessment – Acute dermal toxicity Meta SPC 2	
Value	Not acutely toxic via the dermal route.
Justification for the selected value	The classification has been determined using the calculation method.
Classification of the product according to CLP	No classification for Acute Dermal toxicity is required.

Value used in the Risk Assessment – Acute dermal toxicity Meta SPC 3	
Value	Not acutely toxic via the dermal route.
Justification for the selected value	The classification has been determined using the calculation method.
Classification of the product according to CLP	No classification for Acute Dermal toxicity is required.

Value used in the Risk Assessment – Acute dermal toxicity Meta SPC 4	
Value	Not acutely toxic via the dermal route.
Justification for the selected value	The classification has been determined using the calculation method.
Classification of the product according to CLP	No classification for Acute Dermal toxicity is required.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Iodine PT-3
Value(s)*	**Meta SPC 1: 12 % for concentrates and diluted formulations** **Meta SPC 2: 12% for concentrates and diluted formulations** **Meta SPC 3: 12% for concentrates and diluted formulations** **Meta SPC 4: 12%**
Justification for the selected value(s)	***<u>On Meta SPC 1 products</u>*** The applicant proposes a dermal absorption value of 12% for this Meta-SPC based on the value agreed in CAR (Iodine PT-3 2013, SE). **UK CA consideration and conclusion:** Read across has been performed between Masodine 1:3, Io-shield and Iodine Teat Dip Products Product type 3 meta-SPC 1 and details can be found in Section 3.7 Member State only Confidential Annex. Although it does not strictly adhere to the EFSA guidance on dermal absorption (2012), expert judgement has been employed based on the following reasons. Meta SPC 1 is classified for eye irritancy Category 2 and STOT RE Category 2. It contains a higher concentration of iodine and surfactants than in MASODINE 1:3 and Iodoshield. According to the assessment report for Iodine, the dermal absorption values for Io-shield (12%) and Masodine 1:3 (11.3%) were similar at the tested concentrations of 0.26% and 0.66% total iodine respectively. This suggested that the dermal penetration of total iodine was independent of the concentration of iodine in the biocidal formulations. Furthermore, increases in active substance are predominantly predicted to decrease dermal absorption, therefore, the higher percentage of total iodine in Iodine Teat Dip Products Product type 3 (Iodine) Meta-SPC 1 will not have a detrimental effect on dermal absorption and the values derived from lower concentrations are considered to be conservative. All the formulations are predominantly water based with varying proportions of emollients and surfactants but they share similar physico-chemical properties. Masodine 1:3 is the representative product which has the highest content of emollient and surfactant and is considered the worst case yet its composition did not impact on dermal absorption compared to Io-Shield with higher water content. As the type of solvent or surfactant and the concentration of these components did not impact on the absorption of iodine in the assessment report, the values attained from Io-Shield and Masodine 1:3 are applicable to Iodine Teat Dip Products Product type 3 Meta-SPC 1. Moreover, most of the surfactants used in Meta-SPC 1 are part of the

	'pre-mix' that when mixed with technical grade iodine forms the following iodophor (see Confidential Section 3.6 for details). There can be therefore considered of less biologically relevance as they are essential for the formulation process. Finally, Iodine Teat Dip Products Product type 3 Meta-SPC 1 is not skin irritant or skin sensitiser and therefore this does not impact on dermal absorption. **Conclusion UK CA** Overall, it is considered appropriate to apply a dermal absorption value of 12% in the exposure risk assessment. This value is also applicable to diluted meta-SPC 1 formulations. ***On Meta SPC 2*** The applicant proposes a dermal absorption value of 12% for this Meta-SPC based on the value agreed in CAR (Iodine PT-3 2013, SE). **UK CA consideration and conclusion:** Read across has been performed between Masodine 1:3, Io-shield and Iodine Teat Dip Products Product type 3 meta-SPC 2 and details can be found in Section 3.7 Member State only Confidential Annex. Although it does not strictly adhere to the EFSA guidance on dermal absorption (2012), expert judgement has been employed based on the following reasons. This Meta SPC is classified for eye damage Category 1 and STOT RE Category 2. It contains higher concentrations of iodine and surfactants than in MASODINE 1:3 and Iodoshield. According to the assessment report for Iodine, the dermal absorption values for Io-shield (12%) and Masodine 1:3 (11.3%) were similar at the tested concentrations of 0.26% and 0.66% total iodine respectively. This suggested that the dermal penetration of total iodine was independent of the concentration of iodine in the biocidal formulations. Furthermore, increases in active substance are predominantly predicted to decrease dermal absorption, therefore, the higher percentage of total iodine in Iodine Teat Dip Products Product type 3 (Iodine) Meta-SPC 2 will not have a detrimental effect on dermal absorption and the values derived from lower concentrations are considered to be conservative. The formulation is water based with higher proportion of surfactants but they share similar physico-chemical properties. Masodine 1:3 is the representative product which has the highest content of emollient and surfactant and is considered the worst case yet its composition did not impact on dermal absorption compared to Io-Shield with higher water content. As the type of solvent or surfactant and the concentration of these components did not impact on the absorption of iodine in the assessment report, the values attained from Io-Shield and Masodine 1:3 are applicable to Iodine Teat Dip Products Product type 3 Meta-SPC 2. Moreover, most of the surfactants used in Meta-SPC 2 are part of the

	'pre-mix' that when mixed with technical grade iodine forms the following iodophor (see Confidential Section 3.6 for details). There can be therefore considered of less biologically relevance as they are essential for the formulation process. Finally, Iodine Teat Dip Products Product type 3 Meta-SPC 2 is not skin irritant or skin sensitiser and therefore this does not impact on dermal absorption. **Conclusion UK CA** Overall, it is considered appropriate to apply a dermal absorption value of 12% in the exposure risk assessment. This value is also applicable to diluted meta-SPC 2 formulation. ***<u>On Meta SPC 3</u>*** The applicant proposes a dermal absorption value of 12% for this Meta-SPC based on the value agreed in CAR (Iodine PT-3 2013, SE). **UK CA consideration and conclusion:** Read across has been performed between Masodine 1:3, Io-shield and Iodine Teat Dip Products Product type 3 meta-SPC 3 and details can be found in Section 3.7 Member State only Confidential Annex. Although it does not strictly adhere to the EFSA guidance on dermal absorption (2012), expert judgement has been employed based on the following reasons. This Meta SPC is classified for eye damage Category 1 and STOT RE Category 2. It contains higher concentration of iodine and surfactants than in MASODINE 1:3 and Iodoshield. According to the assessment report for Iodine, the dermal absorption values for Io-shield (12%) and Masodine 1:3 (11.3%) were similar at the tested concentrations of 0.26% and 0.66% total iodine respectively. This suggested that the dermal penetration of total iodine was independent of the concentration of iodine in the biocidal formulations. Furthermore, increases in active substance are predominantly predicted to decrease dermal absorption, therefore, the higher percentage of total iodine in Iodine Teat Dip Products Product type 3 (Iodine) Meta-SPC 3 will not have a detrimental effect on dermal absorption and the values derived from lower concentrations are considered to be conservative. The formulation is water based with higher proportion of surfactants but they share similar physico-chemical properties. Masodine 1:3 is the representative product which has the highest content of emollient and surfactant and is considered the worst case yet its composition did not impact on dermal absorption compared to Io-Shield with higher water content. As the type of solvent or surfactant and the concentration of these components did not impact on the absorption of iodine in the assessment report, the values attained from Io-Shield and Masodine 1:3 are applicable to Iodine Teat Dip Products Product type 3 Meta-SPC 3.

	Moreover, some of the surfactants used in Meta-SPC 3 are part of the 'pre-mix' that when mixed with technical grade iodine forms the following iodophor (see Confidential Annex - Section 3.3 for details). There can be therefore considered of less biologically relevance as they are essential for the formulation process. Finally, Iodine Teat Dip Products Product type 3 Meta-SPC 3 is not skin irritant or skin sensitiser and therefore this does not impact on dermal absorption. **Conclusion UK CA** Overall, it is considered appropriate to apply a dermal absorption value of 12% in the exposure risk assessment. This value is also applicable to diluted meta-SPC 2 formulation. ***On Meta SPC 4 (RTU products)*** The applicant has submitted the justification below: • MASODINE 1:3 (alternative code: BIOCIDE 1006): The iodophor type 1 (i.e. alcohol ethoxylate-complexed iodine) based concentrate MASODINE 1:3 has been tested as a 25% dilution of the concentrate (0.66% (w/w) total iodine). The study followed the OECD Guidelines N° 428. • The concentration of the active substance iodine in the tested product MASODINE 1:3 (0.66%) is similar to the maximum concentration present in the RTU products within GEA Farm Technoloies Iodine Teat dip BPF. • The concentration of the surfactants is higher in the tested product MASODINE 1:3 when compared with the maximum concentration found in the RTU products within GEA Farm Technologies Iodine Teat dip BPF. Therefore, the potential effects of the surfactants on the dermal absorption of iodine are covered by the tested product MASODINE 1:3. • The maximum concentration of surfactants present in the RTU products within GEA Farm Technologies Iodine Teat dip BPF is similar to the concentration of surfactants in the tested product MASODINE 1:3. • None of the co-formulants present in the RTU products within GEA Farm Technologies Iodine Teat dip BPF are classified for skin irritancy or skin sensitisation. • Based on these considerations, the tested formulation MASODINE 1:3 and the RTU products within GEA Farm Technologies Iodine Teat dip BPF can be considered similar. The applicant proposes a dermal absorption value of 12% for this Meta-SPC based on the value agreed in CAR (Iodine PT-3 2013, SE).

	UK CA consideration and conclusion: Read across has been performed between Masodine 1:3, Io-shield and Iodine Teat Dip Products Product type 3 meta-SPC 4 and details can be found in Section 3.7 Member State only Confidential Annex. Although it does not strictly adhere to the EFSA guidance on dermal absorption (2012), expert judgement has been employed based on the following reasons. This Meta SPC is not classified for human health effects. According to the assessment report for Iodine, the dermal absorption values for Io-shield (12%) and Masodine 1:3 (11.3%) were similar at the tested concentrations of 0.26% and 0.66% total iodine respectively. The Iodine Teat Dip Products Product type 3 (Iodine) Meta-SPC 4 contains similar concentration of iodine. The formulations are predominantly water based with lower proportion of surfactants and they share similar physico-chemical properties. Therefore the values attained from Io-Shield and Masodine 1:3 are applicable to Iodine Teat Dip Products Product type 3 Meta-SPC 4. Finally, Iodine Teat Dip Products Product type 3 Meta-SPC 4 is not skin irritant or skin sensitiser and therefore this does not impact on dermal absorption. **Conclusion UK CA** Overall, it is considered appropriate to apply a dermal absorption value of 12% in the exposure risk assessment.

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

Two Substances of Concern were identified for Meta SPCs 2 and 3. These trigger the classification of Meta SPCs 2 and 3 for Eye Damage Category 1 (H318). For details of the SoCs identified please see the Confidential Annex of this PAR (section 3.3.4).

According to the guidance on the Identification and evaluation of substances of concern (SoCs) in relation to human health (toxicological) endpoints, CA-Nov14-Doc.5.11, the SoCs contained in the products of the Meta SPC 2 and 3 should be allocated in Band B. Associated evaluation and risk management requirements according to the SoC banding approach for 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". This has been accounted for and addressed in the respective parts of this PAR.

One Substance of Concern was identified for Meta SPC 1. This triggers classification of the Meta SPC for Eye Damage Category 2 (H319). For details of the SoC identified for Meta SPC 1 please see the Confidential Annex of this PAR (section 3.3.4).

The SoC identified for Meta SPC 1 is considered a Band A SoC. Associated evaluation and risk management requirements according to the SoC banding approach for Band A are limited to the "Application of S-phrases/P-statements normally associated with

concerned R-phrases/H statements". This has been accounted for and addressed in the respective parts of this PAR.

No SoCs were identified in the Meta SPC 4.

2.2.6.1 Exposure assessment

The Iodine Teat Dip product family is used for the disinfection of cow teats and other milkable animals. Cows are considered worst-case with reference to teat disinfection, as herds are larger than herds of buffaloes, sheep and goats. In addition cows have a higher number of teats compared to other dairy species like sheep and goats (TAB version 1.3, 2017, p.27). Products which have an in-use dilution of <0.32 % w/w iodine can be applied both pre- and/or post- milking whereas products which have an in-use dilution of >0.32% w/w can be used post-milking only.

Products are supplied as soluble (liquid) concentrates or ready-to-use products and application is through spraying, dipping or foaming. Soluble (liquid) concentrates must be diluted with water prior application. When applied pre- milking, the product is wiped off the teats after the required contact time, before attaching the teats to the milking unit.

Farmers are likely to apply the product themselves and are considered to be professional users for this type of product, i.e. they are used to handling these product types regularly, they have access to relevant safety information and they can be expected to wear personal protective equipment (PPE) when handling the products.

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

In line with the TNsG on Human Exposure to Biocidal Products, the UK CA has carried out an exposure assessment for human health based on a tiered approach.

INTENDED USES

Overview of the Meta SPCs/products within the Iodine Teat Dip biocidal product family

Meta SPC	**Product name**	**Concentrate / RTU**	**Concentrate (% w/w total iodine)**	**Pre-milking dilution (% w/w**	**Post-milking dilution**

				total iodine)	**(% w/w total iodine)**
1	Ioklene concentrate	Concentrate	1.58	0.32	0.32
	Maxadine C	Concentrate	2.06	-	0.52
	Dunglinson super IO 421 concentrate	Concentrate	2.47	-	0.49
	Priodine	Concentrate	2.32	0.29	0.29
2	Intelliblend concentrate *	Concentrate	5.22	-	0.52
3	IodoShield Active	Concentrate	2.39	-	0.48
4	LuxSpray 15	RTU	-	0.16	0.16
	LuxSpray 30	RTU	-	0.3	0.3
	LuxSpray 50	RTU	-	-	0.5
	LuxDip 50B	RTU	-	-	0.5
	LuxDip 25	RTU	-	0.25	0.25

***** *Intelliblend concentrate is for use in the Intelliblend automated mixing system. The concentrate is supplied in a drum and transferred to the automated mixing system via a lance. The changing of the concentrate drum and connecting of lines is carried out by employees of the product supplier. The farmer will therefore only have contact with the diluted product when decanting from the holding tank.*

Overview of applications and application rates for the Iodine Teat Dip biocidal product family

Application	Maximum application rate of the in-use dilution	Maximum concentration of the in-use dilution
Dip application (liquid or foam)	10 mL/cow/treatment	0.52 % w/w iodine (for products applied post-milking only) 0.32 % w/w iodine (for products applied both pre- and/or post- milking)
Spray application	10 mL/cow/treatment	0.52 % w/w iodine (for products applied post-milking only) 0.32 % w/w iodine (for products applied both pre-

and/or post- milking)

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1a.	Mixing/loading of concentrated product	Primary exposure –mixing/loading of the concentrate (meta SPC 1 & 3)	Professionals
1b.	Decanting of ready-to-use product	Primary exposure –decanting of the ready-to-use product (meta SPC 2 & 4)	Professionals
1c.	Connecting lines	Primary exposure – inserting lance into the concentrate drum to transfer the concentrated product into the Intelliblend automated mixing system (meta SPC 2)	Professionals
2.	Application through spraying	Primary exposure – cow teat disinfection through spraying using a manual trigger sprayer or pneumatic sprayer (meta SPCs 1, 2, 3 & 4)	Professionals
3.	Application through the use of dipping cups	Primary exposure – cow teat disinfection through the use of dipping cups (meta SPCs 1, 2, 3 & 4)	Professionals
4.	Drying of teats	Primary exposure – removal of freshly applied product before attachment of milk clusters (meta SPCs 1, 2, 3 & 4)	Professionals
5.	Cleaning of equipment	Primary exposure – cleaning of equipment after use (meta SPCs 1, 2, 3 & 4)	Professionals

Industrial exposure

The Iodine Teat Dip product family is not intended for use by industrial users.

Professional exposure

Primary exposure to biocidal products occurs to the individual who directly uses/applies the products. The professional use of the Iodine Teat Dip biocidal product family may result in primary exposure, via skin contact or via inhalation. The products will be applied by professionals and as such contamination by ingestion is not expected to occur. The oral route is not considered further.

Whilst elemental iodine has a high vapour pressure of 40.7 Pa at 20ºC, the iodine CAR informs us that evaporation of iodine from water based products is assumed to be very low. The applicant has confirmed that the products are iodophors and most of the iodine present is held in a complex. The key indicator is that when natural- coloured HDPE is in the presence of iodine, it discolours rapidly and this does not happen, even for the concentrated products. As iodine is complex bound, evaporation is not expected and inhalation to volatilised residues is therefore considered negligible.

Scenario 1a – Mixing/loading of the concentrated products (meta-SPCs 1 & 3)

Mixing and loading the biocidal product into spray equipment or dipping cups will result in exposure to iodine via the dermal and inhalation routes. HEAdhoc recommendation no. 13 (agreed at WGI, 2017) suggests that exposure during repeated mixing and loading of smaller quantities of product should be assessed using Mixing and loading model 4. The guidance informs us that the re-filling of equipment with the diluted product will be covered within this mixing and loading step and does not need to be assessed separately. This is because the model covers all relevant mixing and loading tasks performed by a worker on an 8 hour working day.

Description of Scenario 1a		
Professional users mixing/loading a concentrated product (Meta SPCs 1 & 3) *Potential exposure is via the dermal route.*		
	Parameters	Value
Tier 1	Maximum concentration of iodine in the concentrate	2.47% w/w
	Adult bodyweight	60 kg
	Dermal penetration of iodine	12%
	Indicative potential hand exposure value for pouring from a 1 litre container (75th percentile)	0.01 ml
Tier 2	PPE: protective gloves	90% protection (10% penetration)

Tier 1 assessment

It is assumed that no personal protective equipment is worn.

Mixing and loading model 4 provides indicative hand exposure values of 0.01 ml/treatment for 1 L containers, 0.2 ml/treatment for 5 L containers and 0.5 ml/treatment for 10 & 20 L containers. The guidance recommends that the indicative value should be used in line with the total amount of required solution/day.

Taking into account 2 milking events / farmer / day and considering that products can be applied pre- and post- milking at an application rate of 10 ml solution / cow / treatment, the total amount of solution applied per day can be calculated as 10 ml x 4 x 82 = 3.28 L. For products that can be applied post- milking only, the total amount of in-use solution applied per day can be calculated as 10 ml x 2 x 82 = 1.64 litres. For concentrated products, the lowest ratio for dilution is 1:3 therefore, regardless of whether the product is applied post- milking only or pre-and post- milking, the indicative exposure value of 0.01 ml is most appropriate as the amount of concentrated product use will be < 1 L.

The highest concentration of iodine in Meta SPC 1 & 3 is 2.47% w/w. Based on a default adult bodyweight of 60 kg and using a dermal absorption value of 12%, systemic exposure during mixing/loading of concentrated products can be calculated as follows:

- 0.01 ml x 2.47% w/w iodine x 12% / 60 kg = 4.94 x 10^{-4} mg/kg bw/day*

*assuming a product density of 1g/ml

Tier 2 assessment

The 'Tier 1' exposure assessment is refined by including in the calculations:

- The protection afforded by gloves. HEEG opinion 9 informs us that protective gloves provide 90% protection for challenges by a liquid.

Calculations for Scenario 1a

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg a.s./day)	**Estimated dermal uptake** (mg a.s. /day)	**Estimated oral uptake** (mg a.s./day)	**Estimated total uptake** (mg a.s./kg bw/day)
Scenario 1a	1 (no PPE)	negligible	0.0296	n.a.	4.94×10^{-4}
Scenario 1a	2 (gloves)	negligible	0.0030	n.a.	4.94×10^{-5}

Scenario 1b – Decanting of the ready-to-use products (meta-SPC 2 & 4)

Meta SPC 4 contains ready-to-use products which can be decanted directly into application equipment. Meta SPC 2 is supplied as a concentrate in a drum for use in the Intelliblend automated mixing system. Exposure for transfer of the concentrate into the automated mixing system is considered under scenario 1c below. The draft label informs us that the output pipe should be placed into a suitably sized jerry can or drum therefore it is necessary to consider a farmer decanting smaller quantities of the diluted product into application equipment.

HEAdhoc recommendation no.13 (agreed at the Human Heath WGI, 2017) informs us that Mixing and loading model 4 should be used to estimate dermal exposure for a professional user repeatedly decanting smaller quantities of ready-to-use product.

Description of Scenario 1b		
Professional users decanting product (meta SPC 2 & 4). *Potential exposure is via the dermal route*		
	Parameters	Value
Tier 1	Maximum concentration of iodine (meta SPC 2 & 4)	0.52% w/w
	Adult bodyweight	60 kg
	Dermal penetration of iodine	12%
	Indicative potential hand exposure value for pouring from a 5 L container (75th percentile)	0.2 ml

Tier 2	PPE: protective gloves	90% protection (10% penetration)

Tier 1 assessment

It is assumed that no personal protective equipment is worn.

A total of 3.28 L of solution is required per day when the product is applied pre- and post-milking and a total of 1.64 L of solution is required when the product is applied post-milking only (please refer to scenario 1a for details of this calculation). As such, the indicative value of 0.2 ml (applicable to pouring from a 5 L container) from Mixing and loading model 4 is most appropriate for estimating exposure during decanting. For post-milking only, the highest iodine concentration across Meta SPC 2 & 4 is 0.52% w/w (applicable to the in-use dilution of Intelliblend Concentrate which is mixed automatically in the Intelliblend mixing system to produce a ready-to-use product). For pre and/or post milking, the highest in-use concentration is 0.3% w/w (applicable to Meta SPC 4 only). Based on a default adult bodyweight of 60 kg and using a dermal absorption value of 12%, systemic exposure to iodine during decanting can be calculated as follows:

For post-milking only (Meta SPC 2 & 4):

- 0.2 ml x 0.52% w/w iodine x 12% / 60 kg = 2.08 x 10^{-3} mg/kg bw/day*

For pre- and/or post- milking (Meta SPC 4)

- 0.2 ml x 0.3% w/w iodine x 12% / 60 kg = 1.2 x 10^{-3} mg/kg bw/day*

*based on a product density of 1g/ml

Tier 2 assessment

The 'Tier 1' exposure assessment is refined by including in the calculations:

- The protection afforded by gloves. HEEG opinion 9 (2010) informs us that protective gloves provide 90% protection from liquids.

Calculations for Scenario 1b

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg a.s./day)	**Estimated dermal uptake** (mg a.s. /day)	**Estimated oral uptake** (mg a.s./day)	**Estimated total uptake** (mg a.s./kg bw/day)
Scenario 1b (post-milking only)	1 (no PPE)	Negligible	0.1248	n.a.	0.0021
Scenario	2 (gloves)	Negligible	0.0125	n.a.	0.0002
	1 (no PPE)	Negligible	0.0720	n.a.	0.0012

1b (pre and/or post milking)	2 (gloves)	Negligible	0.0072	n.a.	0.0001

Scenario 1c – Connecting lines *(meta-SPC 2)*

Meta SPC 2 (Intelliblend Concentrate) is used in an automated mixing system. The applicant informs us that the concentrate drums are changed by main dealer employees. Exposure to the concentrated product is possible when inserting a lance into the drum to transfer the concentrated product into the Intelliblend automated mixing system.

HEAdhoc recommendation no.13 (agreed at the Human Heath WGI, 2017) informs us that the indicative value from the RISKOFDERM toolkit for connecting lines can be used for this task along with a one minute duration. Inhalation exposure is not considered relevant.

Description of Scenario 1c		
Professional users (main dealer employees) connecting lines (meta SPC 2). *Potential exposure is via the dermal route.*		
	Parameters	Value
Tier 1	Maximum concentration of iodine	5.22% w/w
	Adult bodyweight	60 kg
	Dermal penetration of iodine	12%
	Indicative potential hand exposure value for connecting lines	0.92 mg/min
	Exposure duration	1 minute
Tier 2	PPE: protective gloves	90% protection (10% penetration)

Tier 1 assessment

It is assumed that no personal protective equipment is worn.

The iodine concentration in the concentrated product is 5.22% w/w iodine. Based on a default adult bodyweight of 60 kg and using a dermal absorption value of 12%, systemic exposure to iodine during decanting can be calculated as follows:

- 0.92 mg x 5.2% w/w iodine x 12% / 60 kg = 9.568 x 10^{-5} mg/kg bw/day

Tier 2 assessment

The 'Tier 1' exposure assessment is refined by including in the calculations:

- The protection afforded by gloves. HEEG opinion 9 (2010) informs us that protective gloves provide 90% protection from liquids.

Calculations for Scenario 1c

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg a.s./day)	**Estimated dermal uptake** (mg a.s. /day)	**Estimated oral uptake** (mg a.s./day)	**Estimated total uptake** (mg a.s./kg bw/day)
Scenario 1c	1 (no PPE)	Negligible	0.0057	n.a.	9.568×10^{-5}
Scenario 1c	2 (gloves)	Negligible	0.0006	n.a.	9.568×10^{-6}

Scenario 2 – Cow teat disinfection through manual trigger spraying or pneumatic spraying (Meta SPCs 1, 2, 3 & 4)

The applicant informs us that the Iodine Teat Dip product family may be applied to cow teats through manual trigger spraying or pneumatic spraying. HEAdhoc recommendation no. 13 (2017) informs us that dermal exposure during the application of the products through manual trigger spraying or electronic spraying should be assessed using Consumer product spraying and dusting model 2. The UK CA considers this model is also suitable to estimate exposure using a pneumatic sprayer.

The HEAdhoc recommendation suggests an exposure duration of 55 minutes when application occurs both pre- and post- milking based on a spray duration of 10 seconds/cow/treatment and taking into account 2 milking events / farmer / day. Based on a pro-rata extrapolation, the exposure time for a user applying products post-milking or pre-milking only is 27.5 minutes. For products that can be applied pre- and/or post-milking, the highest in-use concentration is 0.32% w/w iodine. For products that can be applied post-milking only, the highest in-use concentration is 0.52% w/w iodine.

Description of Scenario 2		
An adult disinfects cow teats using a manual sprayer. *Potential exposure is via the dermal and inhalation route.*		
Tier	Parameters	Value
	In-use concentration of iodine (pre and/or post milking products)	0.32 % w/w
	In-use concentration of iodine (post-milking only)	0.52% w/w
	Adult bodyweight	60 kg
	Adult inhalation rate	1.25 m^3/hour
	Dermal penetration of iodine	12 %
	Exposure duration (pre- and post- milking)	55 minutes
	Exposure duration (pre- or post- milking only)	27.5 minutes

	Hand and forearm indicative exposure value (75th percentile)(no PPE)	36.1 mg/minute
	Legs, feet and face indicative exposure value (75th percentile)(no PPE)	9.7 mg/minute
	Inhalation indicative exposure value	10.5 mg/m^3
2	PPE: gloves	90% protection
3	PPE: coated coveralls and boots	90% protection

Tier 1 assessment

It is assumed that no protective equipment is worn.

Tier 2 assessment

The 'Tier 1' exposure assessment is refined by including in the calculations:

- The protection afforded by gloves. HEEG opinion 9 informs us that suitable protective gloves will provide 90% protection from liquid challenges.

Tier 3 assessment

The 'Tier 2' exposure assessment is refined by including in the calculations:

- The protection afforded by coated coveralls/boots. HEEG opinion 9 (2010) informs us that suitable protective coveralls will provide 90% protection.

Calculations for Scenario 2

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg a.s./day)	**Estimated dermal uptake** (mg a.s./day)	**Estimated oral uptake** (mg a.s./day)	**Estimated total uptake** (mg a.s./kg bw/day)
2 (pre- and post-milking)	1 (no PPE)	0.0385	0.9673	n.a.	0.0168
	2 (gloves)	0.0385	0.2811	n.a.	0.0053
	3 (gloves, coveralls & boots)	0.0385	0.0967		0.0023
2 (post-milking only)	1 (no PPE)	0.0313	0.7859	n.a.	0.0136
	2 (gloves)	0.0313	0.2284	n.a.	0.0043
	3 (gloves, coveralls & boots)	0.0313	0.0786	n.a.	0.0018
2 (pre-milking	1 (no PPE)	0.0193	0.4836	n.a.	0.0084
	2 (gloves)	0.0193	0.1406	n.a.	0.0027

only)	3 (gloves, coveralls & boots)	0.0193	0.0484	n.a.	0.0011
Detailed calculations can be found in Annex 3.2, Tables 1.1 – 1.9					

Local effects

Iodine has an OEL of 1 mg/m^3. For the highest in-use dilution of 0.52% w/w, the air concentration is calculated to be 0.0546 mg/m^3 of iodine using the indicative inhalation value of 10.5 mg/m^3 for consumer product spraying and dusting model 2.

Scenario 3 – Cow teat disinfection through dipping cups (liquid or foam) (Meta SPCs 1, 2, 3 & 4)

HEAdhoc recommendation no. 13 (2017) informs us that exposure during the use of dipping cups is covered by the exposure estimate for a user mixing and loading the product (please refer to scenario 1a / 1b above). Furthermore, it is assumed that dipping cups are designed specifically for this task. This cup has an upper compartment for application of the dip and a lower 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 biocide product or a treated teat is avoided. As such, no further consideration of cow teat disinfection through dipping is required. It was agreed at HEAdhoc-1-2016 meeting that application of a biocidal product in the form of foam by dipping cups is covered by the application of liquid by dipping cups.

Scenario 4 – Removal of freshly applied product pre-milking (Meta SPC 1 & 4)

The draft labels for the Iodine Teat Dip product family inform the user to dry teats with a disposable paper towel before fitting the milking cluster. As such, estimated exposure during the removal of freshly applied product pre-milking is required. The highest in-use concentration of iodine applied pre-milking is 0.32 % w/w iodine.

As iodine is complex-bound in the formulation, no evaporation is expected and therefore an inhalation exposure estimate is not required.

Description of Scenario 4		
A professional user wiping cow teats with a dry paper towel after application of the product (prior to fitting the milking cluster) *Potential exposure is via the dermal route.*		
	Parameters	Value
Tier 1	In-use concentration of total iodine (pre-milking)	0.32 % w/w
	Adult bodyweight	60 kg
	Surface area of cow teat	44 cm^2
	Thickness of liquid layer on teat	0.01 cm
	Dermal penetration	12 %
Tier 2	Protection afforded by gloves	90 % protection (10 % penetration)

Tier 1 assessment

It is assumed that no protective equipment is worn.

HEAdhoc recommendation no. 13 (2017) informs us that hand exposure can be calculated as 0.1% of the amount of biocidal product on the surface area. The recommendation suggests that the surface area corresponds to the total surface area of the teats of a herd of dairy cow and provides a surface area of 44 cm^2/teat. To calculate the amount of the biocidal product on the surface area, the layer thickness approach is considered appropriate; HEEG opinion 16 informs us that the estimated thickness of the liquid layer on the skin is 0.01 cm. The total amount of biocidal product on a herd of cows can therefore be calculated as 44 cm^2/teat x 4 teats x 0.01 cm x 82 cows = 144.32 cm^3 = 144.32 g of in-use solution (assuming a density of 1g/cm^3).

Assuming that there are two pre-milking applications/day, hands are exposed to 0.1% of the amount of product on cow teats for each application and the highest in-use dilution for pre-milking is 0.32% w/w, the external dose on hands during removal of freshly applied product pre-milking can be calculated as 144.32 g x 2 x 0.1% x 0.32% = 0.9236 mg iodine/day

The systemic does is then calculated taking into account a dermal absorption value of 12% and an adult bodyweight of 60 kg (i.e. 0.9236 x 12% / 60 kg = 0.0018 mg/kg bw/day).

Tier 2 assessment

The 'Tier 1' exposure assessment is refined by including in the calculations:

- The protection afforded by gloves. HEEG opinion 9 informs us that suitable protective gloves will provide 90 % protection.

Calculations for Scenario 4

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg a.s./day)	**Estimated dermal uptake** (mg a.s./day)	**Estimated oral uptake** (mg a.s./day)	**Estimated total uptake** (mg a.s./kg bw/day)
4	1 (no PPE)	negligible	0.1108	n.a.	0.0018
4	2 (gloves)	negligible	0.0111	n.a.	0.0002

Scenario 5 – Cleaning of equipment (Meta SPC 1-4)

HEAdhoc Recommendation no. 13 (2017) proposes that the indicative value of the RISKOFDERM 'loading liquid, automated or semi-automated' for the cleaning phase of different equipment (dipping cup, spraying nozzle etc.) of 0.92 mg/min is most appropriate to assess the cleaning of equipment. The guidance also suggests an exposure duration of 5 minutes. Any product left in the equipment is likely to be highly diluted during cleaning however, using a pre-cautionary approach, it is assumed the

cleaning water contains 0.52% w/w iodine (i.e. it is assumed there is no further dilution of the in-use product with cleaning water). As cleaning activities have a negligible contribution to overall exposure, the UK CA has assessed the highest in-use concentration across the biocide product family only.

Description of Scenario 5		
A professional user cleaning treatment equipment after application of the Iodine Teat Dip biocidal product family. *Potential exposure is via the dermal route.*		
	Parameters	Value
Tier 1	Maximum in-use concentration of total iodine	0.52 % w/w
	Adult bodyweight	60 kg
	Indicative exposure value (hands only)	0.92 mg/min
	Task duration	5 minutes
	Dermal penetration	12 %
Tier 2	Protection afforded by gloves	90 % protection (10 % penetration)

Tier 1 assessment

It is assumed that no protective equipment is worn.

Based on the assumption that a user cleaning equipment is exposed 4.6 mg product/day (i.e. 0.92 mg x 5 minutes) and assuming that the product contains 0.52% w/w iodine, systemic exposure can be calculated as follows (based on a default adult bodyweight of 60 kg and a dermal absorption value of 12%):

4.6 mg x 0.52% x 12% / 60 kg = 0.00005 mg iodine/day

Tier 2 assessment

The 'Tier 1' exposure assessment is refined by including in the calculations:

- The protection afforded by gloves. HEEG opinion 9 (2010) informs us that suitable protective gloves will provide 90 % protection.

Calculations for Scenario 5

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg a.s./day)	**Estimated dermal uptake** (mg a.s./day)	**Estimated oral uptake** (mg a.s./day)	**Estimated total uptake** (mg a.s./kg bw/day)
5	1 (no PPE)	negligible	0.0029	n.a.	0.00005

5	2 (gloves)	negligible	0.00029	n.a.	0.000005

Combined scenarios

It is possible that a professional user (farmer) may carry out a number of scenarios across one day. A professional user may mix/load or decant the product, apply the product to cow teats through spraying or dipping, remove the freshly applied product (pre-milking only) and clean equipment. Combined exposure from these scenarios is considered in the table below for pre- and post- milking and post- milking only.

Summary table: combined systemic exposure from professional uses for pre- and post-milking (in-use concentration of 0.32 % w/w iodine)					
Scenarios combined		**Estimated inhalation uptake** (mg a.s./day)	**Estimated dermal uptake** (mg a.s./day)	**Estimated oral uptake** (mg a.s./day)	**Estimated total uptake** (mg a.s./kg bw/day)
Meta-SPC 1 1a, 2, 4 & 5; mixing/loading the concentrate, spray application, removal of the product pre-milking and post-application cleaning of equipment	Tier 1 (no PPE)	0.0385	1.1106	n.a.	0.0192
	Tier 2 (gloves)	0.0385	0.2955	n.a.	0.0056
	Tier 3 (gloves, coveralls & boots for spraying, gloves for other activities)	0.0385	0.1111	n.a.	0.0025
Meta SPC 1 1a, 3, 4 & 5; mixing/loading the concentrate, dip application, removal of product pre-milking and post-application cleaning of equipment	Tier 1 (no PPE)	negligible	0.1433	n.a.	0.0024
	Tier 2 (gloves)	negligible	0.0144	n.a.	0.0002
Meta SPC 4 1b, 2, 4 & 5; decanting (RTU), spray application, removal of the product pre-	Tier 1 (no PPE)	0.0385	1.1530	n.a.	0.0199
	Tier 2 (gloves)	0.0385	0.2997	n.a.	0.0056

milking and post-application cleaning of equipment	Tier 3 (gloves, coveralls & boots for spraying, gloves for other activities)	0.0385	0.1153	n.a.	0.0026
Meta SPC 4 1b, 3, 4 & 5; decanting (RTU), dip application, removal of the product pre-milking and post-application cleaning of equipment	Tier 1 (no PPE)	negligible	0.1857	n.a.	0.0031
	Tier 2 (gloves)	negligible	0.0186	n.a.	0.0003

Summary table: combined systemic exposure from professional uses for post-milking only (in-use concentration of 0.52% w/w iodine)					
Scenarios combined		**Estimated inhalation uptake** (mg a.s./day)	**Estimated dermal uptake** (mg a.s./day)	**Estimated oral uptake** (mg a.s./day)	**Estimated total uptake** (mg a.s./kg bw/day)
Meta-SPC 1 & 3 1a, 2 & 5; mixing/loading the concentrate, spray application and post-application cleaning of equipment	Tier 1 (no PPE)	0.0313	0.8184	n.a.	0.0142
	Tier 2 (gloves)	0.0313	0.2317	n.a.	0.0044
	Tier 3 (gloves, coveralls & boots for spraying, gloves for other activities)	0.0313	0.0819	n.a.	0.0019
Meta SPC 1 & 3 1a, 3 & 5;	Tier 1 (no PPE)	negligible	0.0325	n.a.	0.0005

mixing/loading the concentrate, dip application and post-application cleaning of equipment	Tier 2 (gloves)	negligible	0.0033	n.a.	0.0001
Meta SPC 2 & 4 1b, 2 & 5; decanting (RTU), spray application and post-application cleaning of equipment	Tier 1 (no PPE)	0.0313	0.9136	n.a.	0.0157
	Tier 2 (gloves)	0.0313	0.2412	n.a.	0.0045
	Tier 3 (gloves, coveralls & boots for spraying, gloves for other activities)	0.0313	0.0914	n.a.	0.0020
Meta SPC 2 & 4 1b, 3 & 5; decanting (RTU), dip application and post-application cleaning of equipment	Tier 1 (no PPE)	negligible	0.1277	n.a.	0.0021
	Tier 2 (gloves)	negligible	0.0128	n.a.	0.0002

Summary table: combined systemic exposure from professional uses for pre-milking only (in-use concentration of 0.32% w/w iodine)					
Scenarios combined		**Estimated inhalation uptake** (mg a.s./day)	**Estimated dermal uptake** (mg a.s./day)	**Estimated oral uptake** (mg a.s./day)	**Estimated total uptake** (mg a.s./kg bw/day)
Meta-SPC 1 1a, 2, 4 & 5; mixing/loading the concentrate, spray application, removal of freshly applied product	Tier 1 (no PPE)	0.0193	0.6269	n.a.	0.0108
	Tier 2 (gloves)	0.0193	0.1550	n.a.	0.0029

pre-milking and post-application cleaning of equipment	Tier 3 (gloves, coveralls & boots for spraying, gloves for other activities)	0.0193	0.0628	n.a.	0.0014
Meta SPC 1 1a, 3, 4 & 5; mixing/loading the concentrate, dip application and post-application cleaning of equipment	Tier 1 (no PPE)	negligible	0.1433	n.a.	0.0024
	Tier 2 (gloves)	negligible	0.0144	n.a.	0.0002
Meta SPC 4 1b, 2, 4 & 5; decanting (RTU), spray application, removal of freshly applied product pre-milking and post-application cleaning of equipment	Tier 1 (no PPE)	0.0193	0.6693	n.a.	0.0115
	Tier 2 (gloves)	0.0193	0.1592	n.a.	0.0030
	Tier 3 (gloves, coveralls & boots for spraying, gloves for other activities)	0.0193	0.0670	n.a.	0.0014
Meta SPC 4 1b, 3, 4 & 5; decanting (RTU), dip application, removal of freshly applied product pre-milking and post-application cleaning of equipment	Tier 1 (no PPE)	negligible	0.1857	n.a.	0.0031
	Tier 2 (gloves)	negligible	0.0186	n.a.	0.0003

Non-professional exposure

The products are not intended for non-professional use.

Exposure of the general public

The general public do not have access to milking parlours and as such exposure to the general public is not considered relevant.

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

The modelling of exposures and subsequent risk characterisation during production and formulation of Iodine Teat Dip biocidal product family is addressed under EU legislation (e.g. Directive 98/24/EC) and is not repeated under 528/2012 (agreed at Biocides Technical Meeting TMI06). The UK has not considered exposure from production of the biocidal product further.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier (PPE)**	**Estimated total uptake** (mg a.s./kg bw/day)
Scenario 1a: mixing/loading	Professionals	1 (no PPE)	0.0005
		2 (gloves)	0.00005
Scenario 1b: decanting (post-milking only)	Professionals	1 (no PPE)	0.0021
		2 (gloves)	0.0002
Scenario 1b: decanting (pre- and/or post-milking only)	Professionals	1 (no PPE)	0.0012
		2 (gloves)	0.0001
Scenario 1c: connecting lines	Professionals	1 (no PPE)	0.0001
		2 (gloves)	0.00001
Scenario 2: manual spraying (pre- and post-milking)	Professionals	1 (no PPE)	0.0168
		2 (gloves)	0.0053
		3 (gloves & coveralls)	0.0023
Scenario 2: manual spraying (post- milking only)	Professionals	1 (no PPE)	0.0136
		2 (gloves)	0.0043
		3 (gloves & coveralls)	0.0018
Scenario 2: manual spraying (pre-milking only)	Professionals	1 (no PPE)	0.0084
		2 (gloves)	0.0027
		3 (gloves & coveralls)	0.0011

Scenario 3: application via dipping cups	Professionals	Covered by scenarios 1a / 1b	
Scenario 4: drying of teats pre-milking	Professionals	1 (no PPE)	0.0018
		2 (gloves)	0.0002
Scenario 5: cleaning of equipment	Professionals	1 (no PPE)	4.38×10^{-5}
		2 (gloves)	4.38×10^{-6}

Risk for consumers via residues in food

Introduction

In place of trials data to determine residues of iodine in milk following use of the products within GEA iodine teat dip product family, the applicant (GEA Farm Technologies (UK) Ltd.) is relying on the data reported in the CAR. These data are supported by a discussion paper "*Iodine residues in milk due to iodine-based teat-disinfection: Assessment of consumer safety*" (SCC, 29 June 2015), sponsored by the Iodine Registration Group (IRG) of which the applicant is a member. However it should be noted that the approach described in this discussion paper has not entirely been followed, instead decisions made in the human health working groups meeting and WebEx meetings have been implemented.

The IRG discussion paper performs a re-assessment of two of the residues studies in milk referenced in the Iodine PT3 CAR (one study with pre-milking applications and one study with post-milking applications), as well as consideration of a more recent publication "*Iodine concentrations in milk*" [REF 1]. These data are used to present an approach based on linear extrapolation of iodine residues in milk from the CAR data across different in-use concentrations of iodine and numbers of product applications per day.

The products in the GEA iodine teat dip product family have slightly different in-use concentrations and use patterns. This information has been summarised in Table 1. The maximum in-use concentrations are highlighted with red text. Even though it is noted that both iodine and the iodine in potassium iodide are equally relevant for dietary exposure (total iodine), as the O'Brien study was based on 0.5 % available iodine the maximum available iodine content has been considered in the dietary risk assessment. This is only applicable to the product 'IodoShield Active'.

Table 1 – In-use concentrations and use patterns for GEA iodine teat dip product family (the worst case uses are highlighted with red text)

Product name	Iodine content	Dilution rate (taken from the label)	In-use concentration	Milkings per day (taken from SPC)	Use pattern
Ioklene	1.58	1:4	0.32	2	Pre- and post-

Maxadine C	2.06	1:3	0.52	2	Post-
Dunglinsom Super IO 421 concentrate	2.47	1:4	0.49	2	Post-
Priodine	2.32	1:7	0.29	2	Pre-
LuxSpray 15	0.16	RTU	0.16	2	Pre- and post-
LuxSpray 30	0.3	RTU	0.30	2	Pre- and post-
LuxSpray 50	0.5	RTU	0.50	2	Post-
LuxDip 50B	0.5	RTU	0.50	2	Post-
LuxDip 25	0.25	RTU	0.25	2	Post-
Intelliblend concentrate	5.22	1:9	0.52	2	Post-
IodoShield Active	2.15 + 0.32 (KI) = 2.39 total	1:9 or 1:4	0.43	2	Post-

Based on the above table, the maximum in use concentration for a product applied pre- and post-milking is 0.32 %. For a product used only once per milking, the maximum in use concentration is 0.52 % applied post-milking. These worst case products also support the worst case values at the product family level.

The applicant stated that the product is applied at two milkings per day (either post-milking or pre- and post-milking). The UK CA considers that there may be some farms where cows may be milked three times a day using robotic milking systems (and as such the products may be applied up to 6 times a day). Milking by robots is considered to be performed on average three times per day, and manual milking two times per day. At the Secure WebEx meeting (3-10-2017) it was concluded that '*the expected iodine residues in milk from two milking events per day for manual milking and from three events per day for automatic milking are considered comparable*'. Looking at the applied volume of product, on a daily basis there is little difference between automatic and manual milking. Therefore for the exposure calculations, data from 2x manual application in the O'Brien 2013 study is considered appropriate to support the robotic milking uses in the GEA iodine teat dip product family.

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

A comparison of the use patterns and resulting worst case iodine residues in milk considered within the CAR (studies considered sufficiently detailed and relevant by the IRG and UK CA) and O'Brien 2013 is presented in the tables below. The three studies summarised below (5 trials in total) are considered relevant to the proposed use patterns of iodine.

Table 2 - Residues of iodine in milk reported in iodine PT3 CAR studies and O'Brien 2013 [REF 1]

CAR Study	Iodine (%)	Applications	Mean treated residue (µg/L) [range]	Mean control residue (µg/L) [range]	Difference (additional iodine residues in milk)

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

† These values were reported in µg/kg however have been converted to µg/L based on the density of whole milk being 1030 g/L [REF 5].

Within the IRG discussion paper, the trials *Iwarsson (A)* and *Iwarsson (C)* in the table above have been used to support an approximately linear extrapolation of the iodine content in milk is possible based on the concentration of iodine in a teat disinfectant solution, as well as for increasing numbers of applications of teat disinfectant.

A more recent study (O'Brien, 2013) [REF 1] has been published where the effect of milk iodine concentrations of a teat-spray containing 0.5 % iodine and applied post- or pre- and post-milking were investigated. Another objective of this study was to quantify combined effects of teat disinfection and dietary supplementation of iodine. Feed fortification levels tested were 30 mg and 70 mg per cow per day. In this evaluation, only the results of the teat disinfection without considering the influence of iodine supplementation by feed are presented. The results of the study have been presented in Table 2, and have been extrapolated to match the 'GEA iodine teat dip product family' in-use conditions in Table 3. These residue levels reported for a manual spraying scenario are considered to represent the worst-case in terms of current application types (i.e. dipping, spraying or foaming) and level of automation (manual, semi-automatic or automatic/robotic milking).

For the control group in "*Iodine concentrations in milk*" [REF 1], in which cows were treated with non-iodine teat disinfectant and 0 mg iodine/day feed supplementation, a 'baseline' of 217 µg/kg iodine in milk was established. This is equivalent to 224 µg/L based on the density of whole milk (1030 g/L), [REF 5]. This value can be considered to be in broad agreement with the mean value of 311 µg/L iodine in milk (range = 80 to 930 µg/L) reported in the 2000 UK MAFF Survey [REF 8], assuming that the additional iodine content may be accounted for by the use of iodine-based teat disinfectants and feed supplementation. It is noted that values reported by the EFSA in monitoring studies conducted within the EU indicate mean levels of iodine in milk of 100 - 200 µg/L [REFs 2 and 3]. The most appropriate background level to use in the risk assessment was discussed and agreed in the Secure WebEx meeting (3-10-2017), where it was concluded that: '*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.'

Based on the assumed linear relationship between both iodine concentration and iodine residues in milk, and the agreed background levels in milk of 200 µg/L, the estimated residues of iodine in milk have been derived and presented in Table 3. The average milk yield in O'Brien, 2013 was reported as 21.6 kg/cow/day, which is in line with the value of 20 L/day as stated in the draft proposal for teat treatment scenarios. Therefore no further considerations to milk yields are considered within this evaluation.

Table 3 - Estimated residues of iodine in milk based on extrapolation of O'Brien 2013 data

Product	Iodine (%)	Applications	Estimated mean residues of iodine in milk (µg/L)	
			Proposed teat treatment	Total (+ 200)
O'Brien 2013	0.500	2x pre-milking†	215	415
O'Brien 2013	0.500	2x post-milking	251	451
O'Brien 2013	0.500	2x pre- and 2x post-milking	466	666
GEA iodine teat dip products	0.52	2x post-milking	261	461
GEA iodine teat dip products	0.32	2x pre- and 2x post-milking	298	498

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

Example calculation for 2x post-milking:
Additional iodine residues in milk from O'Brien, 2013, 2 milkings, 0.5 % iodine = 251 µg/L
For 2 milkings at 0.5 % iodine total = 251 µg/L + 200 µg/L = 451 µg/L
For 2 milkings at 0.52 % iodine proposed teat treatment = 251 µg/L x (0.52/0.5) = 261 µg/L
For 2 milkings at 0.52 % iodine total = 261 µg/L + 200 µg/L = 461 µg/L

Intake values (milk consumption) for dietary risk assessment

There are several sources of milk consumption data available to undertake the consumer intake assessments. Each of these is considered in turn below.

The applicant based their dietary risk assessments on an intake value of **0.5 L milk/day** for both adults and toddlers. Although this is the value used in the equivalent dietary risk assessment performed in the CAR, no details are provided on the origin of this intake value and it is specified that refinement of the dietary risk assessment may be required at product authorisation.

Using the 'EU food basket' approach, **1.5 L milk/day** is the intake value stated in the ECHA "Draft general procedures for assessment", based on the EMA "Vol 8 of the Rules Governing Medicinal Products in the EU". However it is unclear which consumers the consumption data relates to (i.e. children or adults). In addition, it is unclear if the consumption data relates to a mean consumption, a large portion size or another

percentile. Hence the use of this value could lead to an overestimate of intakes for certain population consumer groups.

The EFSA Comprehensive European Food Consumption Database states an intake value of **1.05 L milk/day** for toddlers, the value referenced in the EFSA *"Scientific Opinion on the safety and efficacy of iodine compounds (E2) as feed additives for all animal species"* [REF 3]. The EFSA PRIMo v2 model contains relevant information for commodities and their consumption levels within EU populations. For children, the large portion consumption (at the 97.5th percentile of consumers only) is 1080.70 g/child (UK children). When factoring in the average density of milk (1080.70 g/child divided by 1030 g/L) the large portion consumption for children is 1.049 L, which agrees with the consumption rate of **1.05 L milk/day** [REF 3]. However, as these values represent a large portion intake for an acute risk assessment then these values have not been considered further.

The EFSA PRIMo v2 consumption model contains consumption data provided by several member states covering both acute and chronic risk assessments. This model is routinely used to make regulatory decisions for plant protection products under Regulation (EC) No. 1107/2009 and Regulation (EC) No. 396/2005. These decisions include the consumer risk assessments for the approval/renewal of active substances and for setting MRLs. Table 4 presents the mean chronic intake values for milk from this model.

Table 4 – Mean chronic intakes for milk from the EFSA PRIMo v2 model

Consumer group	Highest mean intake (g/kg bw/day)	Body weight (kg)†	g/person	L per day‡
Adult	6.5621 (NL – general)	70	459	0.45
Toddler	39.6226 (FR toddler)	12	475	0.46

† Taken from [REF 7]
‡ Density of whole milk 1030 g/L [REF 5]

As a chronic risk assessment (see section 'Comparison of estimated iodine intakes with reference values') is being undertaken only the intake values from the EFSA PRIMo v2 consumption model (**0.45 L adult and 0.46 L toddler**) have been used to estimate the dietary exposure of adults and toddlers to iodine. These values have been agreed at HH WG IV 2017. The estimated dietary exposure results are presented in Table 6.

Toxicological reference values for iodine

In lieu of toxicological endpoints (ADI and ARfD) for risk assessment, the following tolerable upper intake levels (UL) , defined as '*the maximum level of total chronic daily intake of a nutrient (from all sources) judged to be unlikely to pose a risk of adverse health effects to humans*', were reported by the European Scientific Committee on Food (SCF) [REF 4]:

Table 5 - Upper Intake Levels (UL) for iodine established by the EU SCF

Population sub-group	UL (µg/day)
Children, 1-3 years	200

Children, 4-6 years	250
School pupils, 7-10 years	300
School pupils, 11-14 years	450
Adolescents, 14-18 years	500
Adults (≥ 19 years)	600
Pregnant and lactating women	600

The above UL values were used as reference values for the human health risk assessments performed in the iodine PT3 CAR. It is noted that the value of 600 µg/day for adults was derived from a study in human volunteers by applying a safety factor of 3 to the LOAEL of 1700-1800 µg iodine/day, at which marginal changes in thyroid stimulating hormone (TSH) levels were observed. On this basis, minor exceedances of the UL (up to 110-115% of the UL) are considered to be acceptable. As iodine was administered daily for 14 days in this study, the UL reflects a repeated exposure effect rather than an acute effect arising from a single exposure and thus the risk assessment should include parameters that are appropriate to estimating a chronic intake.

The UL was scaled for other age groups by adjusting for lower bodyweights.

The consumer intake assessments for iodine have been undertaken using EU mean chronic consumption data for consumers and non-consumers. Using acute intake consumption data to assess intakes against the UL would not be appropriate given the basis of the UL. This approach was also agreed at the HH WG-III-2017 (May 2017) meeting.

Additional considerations

The IRG discussion paper proposes that there is an approximate 50 % market penetration of iodine-based teat disinfectants within the EU, and that therefore the above iodine concentrations in milk and subsequent intakes can be reduced by 50 % to take account of "bulk mixing" with milk that has not been exposed to iodine-based teat disinfectants. It was agreed at the HH WG-II-2017 (March 2017) that the refinement of iodine levels in milk was not possible based on the EU market share. This is due to the uncertainty in the exact market penetration iodine teat disinfection products have. To confirm whether the 50 % market share value is correct more up to date data would be required. Furthermore this refinement would not be relevant to protecting consumers at a local level.

The IRG discussion paper also proposes a reduction in iodine content of 27 % as a result of pasteurisation of milk, based on the *EFSA Scientific Opinion on the safety and efficacy of iodine compounds (E2) as feed additives for all animal species: calcium iodate anhydrous and potassium iodide* [REF 3]. However, the sources referred to in both the EFSA Scientific Opinion and IRG discussion paper do not clearly support a reduction of iodine concentration in milk resulting from pasteurisation. It was also noted that the studies have been conducted with iodine feed supplements, where the iodine is secreted into the milk, rather than iodine residues in milk arising from iodine teat disinfectant products. Within the HH WG-II-2017 (March 2017) meeting, it was considered plausible that iodine can be lost during pasteurisation, however the literature review highlighted inconsistencies in the levels of reduction and it was inconclusive in deciding whether pasteurisation reduces the iodine concentration in milk. It was agreed at the HH WG-II-2017 (March 2017) that the impact of pasteurisation on iodine levels in milk could not be

concluded based on the current information and therefore the refinement not applied at this time.

Exposure assessments

It is recognised that although iodine is essential for life, higher doses are toxic. For this reason the mean exposure to iodine from the rest of the diet has also been presented. The total iodine level in the diet and the iodine level in milk vary greatly between different regions in Europe. According to the European Scientific Committee on Food, the most important sources of iodine in industrialised countries are dairy products. More recently, calculations by EFSA confirm that for both adults and toddlers, milk is by far the main source of iodine, followed by eggs [REF 3].

The mean exposure to other sources of iodine is taken from the UK paper on 'UK retail survey of iodine in UK product dairy foods' [REF 6]. Within this study 350 samples of dairy and seaweed products were purchased from eight areas of the UK. Analysis was completed at the Imperial College Reactor Centre which is accredited by the UKAS for analysis of iodine in food. The levels of iodine found were generally in a similar range to those reported from previous surveys [REF 8]. Furthermore, the reported values are in agreement with an EFSA scientific opinion on the use of iodine in feeding stuffs. Therefore the values in this report can reliably be used in the consumer exposure assessment of iodine teat treatments. However it should be noted that as this is a UK study report the body weights used in the calculations are 76 kg for adults and 14.5 kg for an infant. These are different to the values of 70 kg and 12 kg used in the consumption calculations.

The mean exposures from other sources of iodine from this reference have been calculated, by removing mean exposure from milk from the mean exposure from the rest of the diet, to be 185 µg/day for adults and 96 µg/day for infants. These values were discussed and agreed in the Secure WebEx meeting (3-10-2017). Iodine residues in milk can also arise as a result of livestock consumption of naturally occurring levels in grass or as a result of feed supplements. For this reason the background levels in milk of 200 µg/L will be taken into account during the risk assessment. As described previously, this value has been agreed at WG discussions.

For comparison, the mean concentration of iodine in cows milk from the 'UK retail survey of iodine in UK product dairy foods' was 0.3 mg/kg which is equivalent to 309 µg/L. The lowest and highest recorded concentrations were 72.1 and 1030 µg/L respectively. The values are also in agreement with the FEEDAP scientific opinion, [REF 9] where the values observed in bulk milk throughout Europe are reported as 60 – 250 µg/L. It was also noted that the UK survey results showed a trend to suggest iodine levels are consistently lower in summer than winter, the following reasons were stated: *'The seasonal variation reported in previous studies was considered to result from the greater use of compound feedingstuffs during winter months. Iodine may be naturally present in the ingredients used in animal feedstuffs or may be added via feed supplements.'*

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

- Iodine intakes resulting from only the proposed teat treatment.
- Iodine intakes from milk (sum of; the proposed teat treatment + background levels in milk (200 µg/L)).

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

The estimated dietary intakes of iodine have been compared to the relevant UL for adults (600 µg/day) and infants (200 µg/day) in Table 6. Intakes which exceed the respective UL are highlighted in red text.

Table 6 - Comparison of estimated daily iodine intakes of adults and infants to the relevant UL

	Adults (0.45 L)	**Infants (0.46 L)**
	Estimated daily intake (µg/day) [% of UL]	**Estimated daily intake (µg/day) [% of UL]**
2x post-milking applications (0.52 % iodine)		
Intakes from proposed teat treatment	117 [19.6 % UL]	120 [60.0 % UL]
Total milk intake†	207 [34.6 % UL]	212 [106.0 % UL]
Total dietary intake‡	392 [65.4 % UL]	308 [154.0 % UL]
2x pre- and 2x post-milking (0.32 % iodine)		
Intakes from proposed teat treatment	134 [22.4 % UL]	137 [68.5 % UL]
Total milk intake†	224 [37.4 % UL]	229 [114.5 % UL]
Total dietary intake‡	409 [68.2 % UL]	325 [162.5 % UL]

† Total milk intake is the sum of the estimated additional intake resulting from the transfer into milk following teat disinfection and the background milk value of 200 µg/L.
‡ Total dietary intake is the sum of; the estimated additional intake, the baseline milk value and the mean intake associated with other dietary sources.

Example calculation for 2x post-milking applications for adults:
Data taken from Table 3: From teat treatment: 261 µg/L, background milk: 200 µg/L, total milk = 461 µg/L.
Iodine from other sources = 185 µg/day.

Iodine intake from teat treatment = 261 µg/L x 0.45 L = 117 µg/day
Percentage UL = (117/600) x 100 = 19.6 %

Total iodine from milk intake = 461 µg/L x 0.45 L = 207 µg/day
Percentage UL = (207/600) x 100 = 34.6 %

Total dietary intake = 207 µg/day + 185 µg/day = 392 µg/day
Percentage UL = (392/600) x 100 = 65.4 %

References

1 *Iodine concentrations in milk* (O'Brien *et. al.*, *Irish Journal of Agricultural and Food Research*; 52: 209-216, 2013)

2 *Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the request from the Commission on the use of iodine in feedingstuffs* (The EFSA Journal (2005) 168, 1-42)

3 *Scientific Opinion on the safety and efficacy of iodine compounds (E2) as feed additives for all animal species* (EFSA Journal 2013; 11(2): 3099)

4 *Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of iodine* (SCF/CS/NUT/UPPLEV/26 Final - 7 October 2002)

5 *Ullmann's Food and Feed, 3 Volume set*. (Elvers, B. (2017). 1st ed. Weinheim, Germany: Wiley-VCH, page 344)

6 *Retail survey of iodine in UK produced dairy foods* (FSIS 02/08, 16 June 2008)

7 *Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data* (EFSA Scientific Committee, EFSA Journal, 2012;10(3):2579)

8 *MAFF iodine in milk* (MAFF, 2000, Food Survey Information Sheet No.198/00)

9 *Scientific Opinion on the safety and efficacy of iodine compounds (E2) as feed additives for all species: calcium iodate anhydrous and potassium iodide, based on a dossier submitted by HELM AG* (EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), EFSA Journal, 2013;11(2):3101)

2.2.6.2 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 (0.2 mg/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.				

Risk for industrial users

The products are not intended for industrial use.

Risk for professional users

Systemic effects

Task/ Scenario	Tier (PPE)	AEL mg/kg bw/d	Estimated uptake mg a.s./kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 1a- mixing/loading of the concentrate (Meta-SPC 1 & 3)	1 (no PPE)	0.01	0.0005	5%	yes
	2 (gloves)	0.01	0.00005	<1%	yes
Scenario 1b – decanting of RTU product post-milking only (Meta-SPC 2 & 4)	1 (no PPE)	0.01	0.0021	21%	yes
	2 (gloves)	0.01	0.0002	2%	yes
Scenario 1b – decanting of RTU product pre and/or post- milking (Meta-SPC 4)	1 (no PPE)	0.01	0.0012	12%	Yes
	2 (gloves)	0.01	0.0001	1%	Yes
Scenario 1c – connecting lines (Meta SPC 2)	1 (no gloves)	0.01	0.0001	1%	yes
	2 (gloves)	0.01	0.00001	< 1%	yes
Scenario 2 – application through	1 (no PPE)	0.01	0.0168	168%	no

spraying pre- and post- milking (Meta-SPC 1 & 4)	2 (gloves)	0.01	0.0053	53%	yes
	3 (gloves, coveralls & boots)	0.01	0.0023	23%	yes
Scenario 2 – application through spraying post-milking only (Meta SPC 1, 2, 3 & 4)	1 (no PPE)	0.01	0.0136	136%	no
	2 (gloves)	0.01	0.0043	43%	yes
	3 (gloves, coveralls & boots)	0.01	0.0018	18%	yes
Scenario 2 – application through spraying pre-milking only (Meta SPC 1 & 4)	1 (no PPE)	0.01	0.0084	84%	yes
	2 (gloves)	0.01	0.0027	27%	yes
	3 (gloves, coveralls & boots)	0.01	0.0011	11%	yes
Scenario 3 – application through the use of dipping cups (Meta-SPC 1, 2, 3 & 4)	Covered by scenarios 1a / 1b				
Scenario 4 – removal of freshly applied product (pre-milking) (Meta-SPC 1 & 4)	1 (no PPE)	0.01	0.0018	18%	yes
	2 (gloves)	0.01	0.0002	2%	yes
Scenario 5 – cleaning of equipment (Meta-SPC 1, 2, 3 & 4)	1 (no PPE)	0.01	4.83×10^{-5}	<1%	yes
	2 (gloves)		4.83×10^{-6}	<1%	yes

Combined scenarios from primary exposure (2 milking events per day, pre- and post- milking, in-use concentration of 0.32% w/w iodine)

Scenarios combined	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Meta SPC 1 1a, 2, 4 & 5 (mixing/loading, application through spraying pre- and post-milking, removal of freshly applied product pre-milking and cleaning of equipment)	1 (no PPE)	0.01	0.0192	192%	no
	2 (gloves)		0.0056	56%	yes
	3 (gloves, coveralls & boots for spraying, gloves for other activities)		0.0025	25%	yes

Meta SPC 1 1a, 3, 4 & 5 (mixing/loading, application through dipping pre- and post-milking, removal of freshly applied product pre-milking and cleaning of equipment)	1 (no PPE)	0.01	0.0024	24%	yes
	2 (gloves)		0.0002	2%	yes
Meta SPC 4 1b, 2, 4 & 5 (decanting, application through spraying pre- and post- milking, removal of freshly applied product pre-milking and cleaning of equipment)	1 (no PPE)	0.01	0.0199	199%	no
	2 (gloves)		0.0056	56%	yes
	3 (gloves, coveralls & boots for spraying, gloves for other activities)		0.0026	26%	yes
Meta SPC 4 1b, 3, 4 & 5 (decanting, application through dipping pre- and post- milking, removal of freshly applied product pre-milking and cleaning of equipment)	1 (no PPE)	0.01	0.0031	31%	yes
	2 (gloves)		0.0003	3%	yes

Combined scenarios from primary exposure + total dietary intake (2 milking events per day, pre- and post- milking, in -use concentration of 0.32% w/w iodine)

Total dietary intake for an adult is estimated to be 409 µg/day (equivalent to 0.0068 mg/kg bw/day) when the product is applied pre- and post- milking. This value has been added to the estimated professional exposure estimates. For details of the dietary exposure assessment, please refer to "Risk for consumers via residues in food" below.

Scenarios combined	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Meta SPC 1 1a, 2, 4, 5 (mixing/loading, application through spraying pre- and post-milking, removal of freshly applied product pre-milking and cleaning of	1 (no PPE)	0.01	0.0260	260%	no
	2 (gloves)		0.0124	124%	no
	3 (gloves, coveralls &		0.0093	93%	yes

equipment) + total dietary intake (2 x pre and 2 x post milking)	boots for spraying, gloves for other activities)				
Meta-SPC 1 1a, 3, 4 & 5 (mixing/loading, application through dipping pre- and post-milking, removal of freshly applied product pre-milking and cleaning of equipment) + total dietary intake (2 x pre and 2 x post milking)	1 (no PPE)	0.01	0.0092	92%	yes
	2 (gloves)		0.0071	71%	yes
Meta-SPC 4 1b, 2, 4 & 5 (decanting, application through spraying pre- and post- milking, removal of freshly applied product pre-milking and cleaning of equipment) + total dietary intake (2 x pre and 2 x post milking)	1 (no PPE)	0.01	0.0267	267%	no
	2 (gloves)		0.0125	125%	no
	3 (gloves , coveralls & boots for spraying, gloves for other activities)		0.0094	94%	yes
Meta-SPC 4 1b, 3, 4 & 5 (decanting, application through dipping pre- and post- milking, removal of freshly applied product pre-milking and cleaning of equipment) + total dietary intake (2 x pre and 2 x post milking)	1 (no PPE)	0.01	0.0099	99%	yes
	2 (gloves)		0.0071	71%	yes

Combined scenarios from primary exposure (2 milking events per day, post-milking only, in-use concentration of 0.52% w/w iodine)

Scenarios combined	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Meta SPC 1 & 3	1 (no PPE)	0.01	0.0142	142%	no

1a, 2, & 5 (mixing/loading, application through spraying post-milking, and cleaning of equipment)	2 (gloves)		0.0044	44%	yes
	3 (gloves, coveralls & boots for spraying, gloves for other activities)		0.0019	19%	yes
Meta SPC 1 & 3 1a, 3 & 5 (mixing/loading, application through dipping post-milking and cleaning of equipment)	1 (no PPE)	0.01	0.0005	5%	yes
	2 (gloves)		0.0001	1%	yes
Meta SPC 2 & 4 1b, 2 & 5 (decanting, application through spraying post- milking and cleaning of equipment)	1 (no PPE)	0.01	0.0157	157%	no
	2 (gloves)		0.0045	45%	yes
	3 (gloves , coveralls & boots for spraying, gloves for other activities)		0.0020	20%	yes
Meta SPC 2 & 4 1b, 3 & 5 (decanting, application through dipping post- milking and cleaning of equipment)	1 (no PPE)	0.01	0.0021	21%	yes
	2 (gloves)		0.0002	2%	yes

Combined scenarios from primary exposure + total dietary intake (2 milking events per day, post- milking only, in-use concentration of 0.52% w/w iodine)
Total dietary intake for an adult is estimated to be 392 µg/day (equivalent to 0.0065 mg/kg bw/day) when the product is applied pre- and post- milking. This value has been added to the estimated professional exposure estimates. For details of the dietary exposure assessment, please refer to "Risk for consumers via residues in food" below.

Scenarios combined	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Meta SPC 1 & 3 1a, 2 & 5 (mixing/loading,	1 (no PPE)	0.01	0.0207	207%	no

application through spraying post-milking and cleaning of equipment) + total dietary intake (2 x post milking)	2 (gloves)		0.0109	109%	no
	3 (gloves, coveralls & boots for spraying, gloves for other activities)		0.0084	84%	yes
Meta-SPC 1 & 3 1a, 3 & 5 (mixing/loading, application through dipping post-milking and cleaning of equipment) + total dietary intake (2 x post milking)	1 (no PPE)	0.01	0.0071	71%	yes
	2 (gloves)		0.0066	66%	yes
Meta-SPC 2 & 4 1b, 2 & 5 (decanting, application through spraying post- milking and cleaning of equipment) + total dietary intake (2 x post milking)	1 (no PPE)	0.01	0.0223	223%	no
	2 (gloves)		0.0111	111%	no
	3 (gloves, coveralls & boots for spraying, gloves for other activities)		0.0086	86%	yes
Meta-SPC 2 & 4 1b, 3 & 5 (decanting, application through dipping post- milking and cleaning of equipment) + total dietary intake (2 x post milking)	1 (no PPE)	0.01	0.0087	87%	yes
	2 (gloves)		0.0067	67%	yes

Combined scenarios from primary exposure (2 milking events per day, pre-milking only, in-use concentration of 0.32% w/w iodine)

Scenarios combined	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Meta SPC 1	1 (no PPE)	0.01	0.0108	108%	no

1a, 2, 4 & 5 (mixing/loading, application through spraying post-milking, removal of freshly applied product pre-milking and cleaning of equipment)	2 (gloves)		0.0029	29%	yes
	3 (gloves, coveralls & boots for spraying, gloves for other activities)		0.0014	14%	yes
Meta SPC 1 1a, 3, 4 & 5 (mixing/loading, application through dipping, removal of freshly applied product pre-milking and post-milking and cleaning of equipment)	1 (no PPE)	0.01	0.0024	24%	yes
	2 (gloves)		0.0002	2%	yes
Meta SPC 4 1b, 2, 4 & 5 (decanting, application through spraying post-milking, removal of freshly applied product pre-milking and cleaning of equipment)	1 (no PPE)	0.01	0.0115	115%	no
	2 (gloves)		0.0030	30%	yes
	3 (gloves, coveralls & boots for spraying, gloves for other activities)		0.0014	14%	yes
Meta SPC 4 1b, 3, 4 & 5 (decanting, application through dipping post-milking, removal of freshly applied product pre-milking and cleaning of equipment)	1 (no PPE)	0.01	0.0031	31%	yes
	2 (gloves)		0.0003	3%	yes

Combined scenarios from primary exposure + total dietary intake (2 milking events per day, pre- milking only, in-use concentration of 0.32% w/w iodine)
Total dietary intake for an adult is estimated to be 409 µg/day (equivalent to 0.0068 mg/kg bw/day) when the product is applied pre- and post- milking. This is used as a worst case value for dietary intake value for pre-milking only. This value has been added to the estimated professional exposure estimates. For details of the dietary exposure assessment, please refer to "Risk for consumers via residues in food" below.

Scenarios combined	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)

Meta SPC 1 1a, 2, 4 & 5 (mixing/loading, application through spraying post-milking, removal of freshly applied product pre-milking and cleaning of equipment) + total dietary intake (2 x pre and 2 x post milking)	1 (no PPE)	0.01	0.0176	176%	no
	2 (gloves)		0.0097	97%	yes
	3 (gloves, coveralls & boots for spraying, gloves for other activities)		0.0082	82%	yes
Meta-SPC 1 1a, 3, 4 & 5 (mixing/loading, application through dipping post-milking, removal of freshly applied product pre-milking and cleaning of equipment) + total dietary intake (2 x pre and 2 x post milking)	1 (no PPE)	0.01	0.0092	92%	yes
	2 (gloves)		0.0071	71%	yes
Meta-SPC 4 1b, 2, 4 & 5 (decanting, application through spraying post-milking, removal of freshly applied product pre-milking and cleaning of equipment) + total dietary intake (2 x pre and 2 x post milking)	1 (no PPE)	0.01	0.0183	183%	no
	2 (gloves)		0.0098	98%	yes
	3 (gloves, coveralls & boots for spraying, gloves for other activities)		0.0083	83%	yes
Meta-SPC 4 1b, 3, 4 & 5 (decanting, application through dipping post-milking, removal of freshly applied product pre-milking and cleaning of equipment) + total dietary intake (2 x pre and 2 x post milking)	1 (no PPE)	0.01	0.0099	99%	yes
	2 (gloves)		0.0071	71%	yes

Local effects

The classification of each meta-SPC is as follows:

Meta SPC 1: H319 (eye irritation Cat 2)
H373 (STOT-RE Cat 3 – thyroid repeated exposure)

Meta SPC 2: H318 (eye irritation Cat 1)
H373 (STOT-RE Cat 3 – thyroid repeated exposure)

Meta SPC 3: H318 (eye irritation Cat 1)
H373 (STOT-RE Cat 3 – thyroid repeated exposure)

Meta SPC 4: No classification

As Meta SPCs 1, 2 and 3 are classified as H319 (causes serious eye irritation) or H318 (causes serious eye damage), gloves and eye/face protection must be worn when handling the concentrate. Meta-SPC 4 is not classified with respect to human health.

Iodine has an OEL (occupational exposure limit) of 1 mg/m^3. The maximum air concentration is calculated to be 0.0546 mg/m^3 of iodine for scenario 2 (manual spraying) hence the OEL is not expected to be exceeded from the use of the products.

Conclusion

It is necessary to consider combined exposure to iodine from primary exposure during application of the products and total dietary intake (agreed at the human health WG IV, 2017). When taking this into account, the following conclusions can be made:

<u>For meta-SPC 1 applied pre– and/or post- milking or post-milking only</u>

- Pre- and post- milking: Acceptable combined exposure equivalent to 92% of the AEL is calculated for application via dipping without the use of PPE. Combined exposure equivalent to 93% of the AEL is calculated for application via spraying with the use of gloves, coated coveralls and chemical resistant boots.

- Post-milking: Acceptable combined exposure equivalent to 71% of the AEL for application via manual dipping is calculated without the use of PPE. Combined exposure equivalent to 84% of the AEL is calculated for application via spraying with the use of gloves, coated coveralls and chemical resistant boots.

- Pre-milking: Acceptable combined exposure equivalent to 92% of the AEL for application via manual dipping is calculated without the use of PPE. Combined exposure equivalent to 97% of the AEL is calculated for application via spraying with the use of gloves.

<u>For meta-SPC 2 applied post-milking only</u>

- Post-milking: Acceptable combined exposure equivalent to 87% of the AEL for application via manual dipping without the use of PPE. Combined exposure equivalent to 86% of the AEL is calculated for application via spraying with the use of gloves, coated coveralls and chemical resistant boots.

<u>For Meta-SPC 3 applied post-milking only</u>

- Post-milking: Acceptable combined exposure equivalent to 71% of the AEL for application via manual dipping is calculated without the use of PPE. Combined exposure equivalent to 84% of the AEL is calculated for application via spraying with the use of gloves, coated coveralls and chemical resistant boots.

For meta-SPC 4 applied pre –and/or post- milking or post-milking only

- Pre- and post- milking: Acceptable combined exposure equivalent to 71% of the AEL is calculated for application via dipping with the use of gloves. Combined exposure equivalent to 94% of the AEL is calculated for application via spraying with the use of gloves, coated coveralls and chemical resistant boots.
- Post-milking: Acceptable combined exposure equivalent to 87% of the AEL for application via manual dipping without the use of PPE. Combined exposure equivalent to 86% of the AEL is calculated for application via spraying with the use of gloves, coated coveralls and chemical resistant boots.
- Pre-milking: Acceptable combined exposure equivalent to 99% of the AEL for application via manual dipping without the use of PPE. Combined exposure equivalent to 98% of the AEL is calculated for application via spraying with the use of gloves.

Based on the exposure assessment and considering the hazard classification of each meta-SPC, the following PPE phrases are required:

Meta SPC 1 - concentrates	
Pre- milking only	
Use 1 .1 (pre-milking, dipping)	Wear protective chemical resistant gloves and eye protection when handling the concentrate (glove material to be specified by the authorisation holder within the product information).
Use 1.2 (pre-milking, spraying)	Wear protective chemical resistant gloves and eye protection when handling the concentrate Wear protective chemical resistant gloves when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information)
Use 1.3 (pre-milking, foaming)	Wear protective chemical resistant gloves and eye protection when handling the concentrate (glove material to be specified by the authorisation holder within the product information).
Post- milking only	
Use 1.4 (post-milking, dipping)	Wear protective chemical resistant gloves and eye protection when handling the concentrate (glove material to be specified by the authorisation holder within the product information).
Use 1.5 (post-milking, spraying)	Wear protective chemical resistant gloves and eye protection when handling the concentrate Wear protective chemical resistant gloves and boots when applying the product by manual spraying (glove

	material to be specified by the authorisation holder within the product information). A protective coverall (at least type 6, EN 13034) shall be worn
Use 1.6 (post-milking, foaming)	Wear protective chemical resistant gloves and eye protection when handling the concentrate (glove material to be specified by the authorisation holder within the product information).
Pre- and post- milking	
Use 1.7 (pre- and post-milking, dipping)	Wear protective chemical resistant gloves and eye protection when handling the concentrate (glove material to be specified by the authorisation holder within the product information).
Use 1.8 (pre- and post-milking, spraying)	Wear protective chemical resistant gloves and eye protection when handling the concentrate Wear protective chemical resistant gloves and boots when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information). A protective coverall (at least type 6, EN 13034) shall be worn
Use 1.9 (pre- and post- milking, foaming)	Wear protective chemical resistant gloves and eye protection when handling the concentrate (glove material to be specified by the authorisation holder within the product information).
Meta SPC 2 – Intelliblend concentrate	
Post-milking use only	
Use 2.0 (post- milking, dipping)	Wear protective chemical resistant gloves and eye protection when handling the concentrate (glove material to be specified by the authorisation holder within the product information).
Use 2.2 (post- milking, spraying)	Wear protective chemical resistant gloves and eye protection when handling the concentrate Wear protective chemical resistant gloves and boots when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information).

	A protective coverall (at least type 6, EN 13034) shall be worn
Use 2.3 (post- milking, foaming)	Wear protective chemical resistant gloves and eye protection when handling the concentrate (glove material to be specified by the authorisation holder within the product information).
Meta SPC 3 – concentrates	
Post-milking use only	
Use 3.1 (post- milking, dipping)	Wear protective chemical resistant gloves and eye protection when handling the concentrate (glove material to be specified by the authorisation holder within the product information).
Use 3.2 (post- milking, spraying)	Wear protective chemical resistant gloves and eye protection when handling the concentrate Wear protective chemical resistant gloves and boots when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information). A protective coverall (at least type 6, EN 13034) shall be worn
Use 3.3 (post- milking, foaming)	Wear protective chemical resistant gloves and eye protection when handling the concentrate (glove material to be specified by the authorisation holder within the product information).
Meta SPC 4 – RTU liquids	
Pre-milking use only	
Use 4.1 (pre-milking, dipping)	-
Use 4.2 (pre-milking, spraying)	Wear protective chemical resistant gloves when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information)
Use 4.3 (pre-milking, foaming)	-
Post-milking use only	
Use 4.4 (post-milking, dipping)	-
Use 4.5 (post-milking, spraying)	Wear protective chemical resistant gloves and boots when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information).

	A protective coverall (at least type 6, EN 13034) shall be worn
Use 4.6 (post-milking, foaming)	-
Pre- and post- milking	
Use 4.7 (pre- and post-milking, dipping)	Wear protective chemical resistant gloves when applying the product by dipping (glove material to be specified by the authorisation holder within the product information).
Use 4.8 (pre- and post-milking, spraying)	Wear protective chemical resistant gloves and boots when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information). A protective coverall (at least type 6, EN 13034) shall be worn
Use 4.9 (pre- and post- milking, foaming)	Wear protective chemical resistant gloves when applying the product by foaming (glove material to be specified by the authorisation holder within the product information).

Risk for non-professional users

The products are not intended for non-professional use.

Risk for the general public

As milking parlours are not accessible to the general public, there is no risk to the general public.

Risk for consumers via residues in food

Comparison of estimated daily iodine intakes of adults and infants to the relevant UL

	Adults (0.45 L)	**Infants (0.46 L)**
	Estimated daily intake (µg/day) [% of UL]	**Estimated daily intake (µg/day) [% of UL]**
2x post-milking applications (0.52 % iodine)		
Intakes from proposed teat treatment	117 [19.6 % UL]	120 [60.0 % UL]
Total milk intake†	207 [34.6 % UL]	212 [106.0 % UL]
Total dietary intake‡	392 [65.4 % UL]	308 [154.0 % UL]
2x pre- and 2x post-milking (0.32 % iodine)		

Intakes from proposed teat treatment	134 [22.4 % UL]	137 [68.5 % UL]
Total milk intake†	224 [37.4 % UL]	229 [114.5 % UL]
Total dietary intake‡	409 [68.2 % UL]	325 [162.5 % UL]

† Total milk intake is the sum of the estimated additional intake resulting from the transfer into milk following teat disinfection and the background milk value of 200 µg/L.
‡ Total dietary intake is the sum of; the estimated additional intake, the baseline milk value and the mean intake associated with other dietary sources.

Conclusions

For the worst case (i.e. 2x pre- and 2x post-milking treatments, 0.32 % iodine) estimated dietary intakes of iodine the following conclusions can be made:

For adults, the estimated daily intake of iodine resulting from the worst case proposed biocidal product use is 22.4 % of the UL. When this additional iodine is added to the baseline milk value the daily intake of iodine from milk consumption is 37.4 % of the UL. Finally, a total dietary intake of iodine resulting from other dietary sources, the baseline milk value and the estimated iodine resulting from the worst case proposed biocidal product use is 68.2 % of the UL.

For infants, the estimated daily intake of iodine resulting from the worst case proposed biocidal product use is 68.5 % of the UL. When this additional iodine is added to the baseline milk value the daily intake of iodine from milk consumption is 114.5 % of the UL. Finally, a total dietary intake of iodine resulting from other dietary sources, the baseline milk value and the estimated iodine resulting from the worst case proposed biocidal product use is 162.5 % of the UL.

The exceedance of the UL as a result of iodine intake is not a new issue. The 'UK retail survey of iodine in UK product dairy foods' [REF 6] 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, [REF 9]. 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.

Contribution from other sources

The dietary intake assessments have not considered the contribution from residues of iodine in drinking water, salt or supplements.

With regards to ground water the CAR indicates background levels of 1-70 µg/L for iodine. However, it is recognised that iodine levels (and hence consumption) will vary significantly from region to region across the EU and there is no agreement on what background level should be used to undertake realistic exposure assessments.

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.

As with drinking water, the levels of iodine in salt and that used in the fortification of other food items or supplements will vary significantly from region to region across the EU due to different requirements in each individual country. Therefore no agreed background values have been proposed or accounted for in this risk assessment. Again, this issue should be part of the consideration by MS/ECHA/EFSA in obtaining more reliable information on the sources of iodine in the diet.

Iodine can be consumed from many different sources, however in many countries, 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 animal 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 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.

UK Decision

Based on the estimated total intakes for adults, the risk for consumers via residues in food is acceptable for the worst case milking application. In contrast, the estimated total daily intake for toddlers exceeds the UL for both assessed scenarios (154.0 – 162.5 % of UL). 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), rather than the teat treatment alone. 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 leads 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.

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 outcome of the risk management decision will be specified in the BPC opinion following discussions at the BPC-28 meeting of the Biocidal Products Committee (BPC).

References

1 *Iodine concentrations in milk* (O'Brien *et. al*., *Irish Journal of Agricultural and Food Research*; 52: 209-216, 2013)

2 *Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the request from the Commission on the use of iodine in feedingstuffs* (The EFSA Journal (2005) 168, 1-42)

3 *Scientific Opinion on the safety and efficacy of iodine compounds (E2) as feed additives for all animal species* (EFSA Journal 2013; 11(2): 3099)

4 *Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of iodine* (SCF/CS/NUT/UPPLEV/26 Final - 7 October 2002)

5 *Ullmann's Food and Feed, 3 Volume set*. (Elvers, B. (2017). 1st ed. Weinheim, Germany: Wiley-VCH, page 344)

6 *Retail survey of iodine in UK produced dairy foods* (FSIS 02/08, 16 June 2008)

7 *Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data* (EFSA Scientific Committee, EFSA Journal, 2012;10(3):2579)

8 *MAFF iodine in milk* (MAFF, 2000, Food Survey Information Sheet No.198/00)

9 *Scientific Opinion on the safety and efficacy of iodine compounds (E2) as feed additives for all species: calcium iodate anhydrous and potassium iodide, based on a dossier submitted by HELM AG* (EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), EFSA Journal, 2013;11(2):3101)

2.2.7 Risk assessment for animal health

The Committee for Veterinary Medicinal Products (CVMP) has reviewed iodine for the use in veterinary medicine as antiseptic, sanitiser, teat dip for prevention and control of the mastitis, topical preparation for preventing wounds infections. CVMP reported that "only small increases in serum iodine concentration were found after teat dipping indicating that the procedure had a negligible effect on tissue iodine concentrations". As teat dipping does not increase significantly the iodine concentration in animal tissues, it could be concluded that the use of iodine in teat disinfection does not raise systemic concerns for animal health.

To the best of our knowledge, undesirable local effects on the skin of lactating animals, such as chapping, lesions, drying, or caustic reactions, have not been reported in the public literature following teat disinfection with iodine-based products. This may be explained by the fact that, in general, teat dip products contain skin conditioning emollients that maintain the skin in good conditions. In addition, publicly available information on veterinary medicinal products containing iodine for prevention and control of mastitis shows that such products are well-tolerated by the lactating animals and even improve teat condition.

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

The product contains only one active substance (iodine) and, for the purposes of the environmental risk assessment, one Substances of Concern (SoC) (Steryl Amine Ethoxylate (2,2'-(Octadecylimino)bisethanol)). Note that other SOC's have been identified as being relevant for the Human Health assessment; these are discussed within the Human Health section and are not relevant to the Environmental risk assessment.

Toxicity data for iodine can be obtained from the CAR. The PNECs are summarised below:

STP:
Iodine: $PNEC(I_2)_{STP}$ = 2.9 mg iodine/L
Iodide and iodate: no PNEC derived in the CAR (2013) on iodine.

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

According to the CAR: The natural background levels of iodine in freshwater sediments is typically 6 mg/kg. Thus, in analogy with the $PNEC_{aquatic}$ the derived $PNEC_{sediment}$ values are very conservative and may be regarded as unrealistic. Given that both PEC's and PNEC's

are calculated using the partitioning equilibrium method, the derived PNEC will not be used in the risk assessment.

Therefore, they are presented for information but will not be used for the risk assessment.

Iodine: $PNEC(I_2)_{sediment}$ = 0.029 mg iodine/kg
Iodate: $PNEC(IO_3^-)_{sediment}$ = 2.84 mg iodine/kg
Iodide: $PNEC(I^-)_{sediment}$ = 0.043 mg iodine/kg

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

PBT
The UK CA considers that a comprehensive PBT assessment is not relevant in the case of iodine. The term persistence is not appropriate, since iodine is an element and not degradable. Estimation of bioaccumulation potential for iodine is not considered relevant. In the concerned environmental compartments iodine speciates into the ionic forms iodide and iodate. In line with what has been discussed for inorganic metals (e.g. Ni and Zn), bioaccumulation is not relevant because these substances (and iodine) are regulated in animals of several taxonomic groups. The acute toxicity to mammals is low, but iodine is very toxic to aquatic organisms. However, the screening T criterion (L(E)C50 to aquatic organisms less than 0.1 mg/L) is not fulfilled, and there is no chronic data available, which is needed to assess the T criterion.

PNECs for Steryl Amine Ethoxylate (2,2'-(Octadecylimino)bisethanol) CAS 10213-78-2 have been taken from the REACH dossier (https://echa.europa.eu/registration-dossier/-/registered-dossier/17336/6/1)

PNEC aqua (freshwater) = 0.684 µg/L
PNEC aqua (freshwater intermittent release) = 0.87 µg/L
PNEC aqua (marine water) = 0.068 µg/L
PNEC STP = 3.5 mg/L
PNEC sediment (freshwater) = 1.692 mg/kg sediment dw
PNEC sediment (marine water) = 0.169 mg/kg sediment dw
PNEC soil = 5 mg/kg soil dw
PNEC oral = 7.77 mg/kg food
With a log Kow of 3.6 the BCFBAF model predicts a BCF of 110 L/kg wwt without metabolism and 14.7 L/kg wwt with metabolism.

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

No additional data are required.

Further Ecotoxicological studies

Data waiving	
Information requirement	Further Ecotoxicological studies
Justification	No additional data are required.

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

Data waiving	
Information requirement	Effects on other non-target organisms.
Justification	No additional data are required.

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

Data waiving	
Information requirement	Supervised trials.
Justification	No additional data are required.

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

Data waiving	
Information requirement	Acceptance by ingestion.
Justification	No additional data are required.

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

No additional data are required.

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

The products are intended for use as teat-disinfectants for dairy cows. They are used in animal houses (indoor use) and are applied by dipping, foaming or spraying to the teats of the animals before and/or after milking. Exposure to the environment is always secondary, via liquid manure and STP. Exposure to air is not relevant due to the low vapour pressure of the active substance. The main route of exposure to the environment is via liquid manure to arable land and grassland. When applying the products to the animal teats by spraying, spray may not reach the animal teats or part of the product applied to the teats may be lost by drip formation. Drip formation may also occur when the products are applied by dipping. Droplets from teat dip/spray solution may drip on the milking parlour floor after application. As a worst case scenario, it is assumed that 50% of product applied on the teats drips onto the floor

(according to the Emission Scenario Documents (ESD) for PT3). Potential spilled solution can either reach the manure or the waste water, depending on whether the cows are milked in the stable (emission to manure) or in a milking parlour (emission to wastewater). 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; if reusable cloths are used (which is not recommended), the removed product will end up in the drain when the cloths are cleaned/washed after the milking.

Further studies on fate and behaviour in the environment (ADS)
Not needed since available data set is sufficient for the risk assessment.

Leaching behaviour (ADS)
Not applicable for the uses assessed.

Testing for distribution and dissipation in soil (ADS)
No new data are available. Data reported in the CAR is sufficient for the risk assessment.

Testing for distribution and dissipation in water and sediment (ADS)
No new data are available. Data reported in the CAR is sufficient for the risk assessment

Testing for distribution and dissipation in air (ADS)
No new data are available. Data reported in the CAR is sufficient for the 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)

Acute aquatic toxicity

Data waiving	
Information requirement	Acute aquatic toxicity
Justification	No additional data are required.

Chronic aquatic toxicity

Data waiving	
Information requirement	Chronic aquatic toxicity
Justification	No additional data are required.

Measured aquatic bioconcentration

No additional data are required.

Estimated aquatic bioconcentration

No additional data are required.

Data waiving	
Information requirement	Aquatic bioconcentration
Justification	No additional data are required.

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

No additional data are required. No such spraying treatment is intended.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 3
Assessed scenarios	Scenario 1: Disinfection of teats of dairy cows
ESD(s) used	Emission Scenario Document for Product Type 3 Veterinary hygiene biocidal products EUR 25116 EN – 2011 TGD 2003
Approach	Scenario 1: Average consumption The products can either be applied by • Dipping/foaming: pre, post or pre & post (product volume of up to 10 mL/cow/treatment) or • Spraying: pre, post or pre & post (product volume of up to 15 mL/cow/treatment). Since spraying results in the highest application rate per day, it is the worst case. Consequently, the dipping applications are covered by the assessment of the spraying treatments.
Distribution in the environment	In agreement with the CAR (2013) on iodine.
Groundwater simulation	The calculation of the concentration in groundwater was conducted according to the approach described in the Guidance on the BPR Vol IV Part B where the concentration in pore water of agricultural soil is used as a first indication for groundwater concentrations. 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. Iodine and iodine species are not xenobiotic substances but essential nutrients, present at high natural background levels. In the CAR for iodine PECgw values for PT3 were calculated based on the PECsoil for application to grassland and arable land. Uses were considered acceptable if the calculated iodine concentrations in groundwater were above the mean natural background concentration of 1 µg/L but they were still below the maximum natural background concentration of iodine of 70 µg/L. For the Substance of Concern, Steryl Amine Ethoxylate (2,2'-(Octadecylimino)bisethanol), uses were considered acceptable with respect to groundwater if predicted concentrations were below 0.1 µg/L.
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: no service life after application
Remarks	Scenario 1- In the following sections the use of the product Ioklene concentrate pre-milking and Intelliblend concentrate post-milking by spray application two times per day is investigated. This is considered to be the worst case representative use for the BP family in terms of total amount of iodine applied and covers the environmental risk from iodine for all products in the family. With respect to the Substance of Concern (Steryl Amine Ethoxylate (2,2'-(Octadecylimino)bisethanol)), the worst case use is the application of Iodoshield Active post-milking twice per day; the SoC is present only in Iodoshield Active, which is the only product contained within meta-SPC 3.

Emission estimation

Formulation of the product

The whole formulation process is conducted indoor under industrial quality and safety conditions 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. From the vessels, the finished product is pumped to filling station. The filling process is done as an automated process under closed conditions.

Any spillage during production is absorbed with inert material (sand, earth, chemical absorbent, etc.) and collected in dedicated drums properly labelled, and disposed of as

chemical waste via an approved waste management organisation in accordance with local and national laws and regulations. Consequently, there is no release into the environment and, thus, no environmental exposure and risk assessment is applicable.

Scenario 1: Disinfection of teats of dairy cows

Teat disinfectants are applied by dipping/foaming or spraying. As already mentioned in the table "General information" above, spraying can be considered as worst-case covering also dipping/foaming.

The applicant has based their risk assessment on a maximum of two milkings per day. It is noted that the ESD (2011) for PT3 indicates that an average assessment of two milkings per day is acceptable for manual application.

The calculated emissions in this section represent the identified worst case use within the product family, based upon both product concentration (taking account of dilution where relevant), the individual uses (pre-, post-, pre- plus post-milking treatments) and application method (spraying vs. dipping/foaming) (see section 2.1.3 for full details). The identified worst case use is the use of the product Ioklene concentrate applied pre-milking and Intelliblend concentrate applied post-milking two times per day by spraying (15 mL/cow/application). Ioklene concentrate and Intelliblend concentrate are diluted prior to use to give the following in-use concentrations (0.32% and 0.52% iodine (w/w%) respectively). Therefore the emission estimate has been based upon four treatments of 15 mL/cow, with an overall concentration of 0.42 % w/w total iodine, accounting for the level of iodine in the 15 ml pre milking treatment solution and the 15 ml post milking treatment solution (see table below for scenario 1). This results in a total application of 60 mL product/cow/day. In line with the ESD (2011) a herd size of 100 cows is used for the environmental risk assessment and 300 days of lactation period per annum.

According to the CAR (2013) on iodine the assessment is performed for iodine, iodide and iodate. Iodate may be considered to be the dominant chemical form of iodine in the soil solution under non-flooded soil conditions. For the overall summary of PECs, values for iodine, iodide and iodate have been reported, similar to the CAR on iodine. The rationale for doing so is that it is assumed that iodine is transformed to iodide in the alkaline anaerobic conditions in the manure. After spreading and mixing into the top layer of agricultural soil it will predominantly be transformed into iodate. For the calculation of PEC values following the application of manure onto grassland or arable land it is therefore assumed that 100% iodine is transferred either to 2 iodide or iodate ions. The molecular weight of 2 iodide ions corresponds to the molecular weight of iodine, consequently the PECs for iodide are the same as for iodine. The molecular weight of 2 iodate ions is a factor of 1.382 greater than the molecular weight of iodine, therefore the PECs for iodate were calculated by multiplying the PECs of iodine by this factor.

With regards to emissions through the STP, it is clearly described in the CAR that only 14% of the original iodine content is transformed into iodide. Therefore, the same assumption was taken by the UK CA in the assessment of the application of sewage sludge to agricultural land.

Input parameters for calculating the local emission of <u>iodine</u> for the worst case: Luxspray 30 applied pre-milking and Luxspray 50 applied post-milking, three times per day)

Input		Value	Unit	Remarks
Scenario 1: Teat disinfection of animals				
Application rate of biocidal product		15	ml/cow/application	Spray application. Total of 30 mL per milking event assuming pre and post-milking application.
Total iodine in-use solution: **pre-milking**		0.32	% w/w	Ioklene concentrate diluted 1:4.
Total iodine in-use solution: **post-milking**		0.52	% w/w	Intelliblend concentrate diluted 1:9
Time of application		pre & post milking	-	Ioklene concentrate pre and Intelliblend concentrate post milking
Number of milking events per day		2	d^{-1}	
Resulting product volume for spraying		60	mL/cow/day	Daily amount for two pre and two post applications per day, based upon 15 mL per application (spray application). 15 mL Luxspray 30 + 15 mL Luxspray 50.
Resulting overall concentration of spray solution		0.42	% w/w	i.e. 30ml (0.32 % w/w) + 30ml (0.52 % w/w)

As Steryl Amine Ethoxylate (2,2'-(Octadecylimino)bisethanol, has been highlighted as a Substance of Concern, it is also necessary to derive PEC values for relevant environmental compartments. The SoC is present in only one product in the product family, Iodoshield Active. Iodoshield Active is the only product contained within meta SPC 3 and, as such, direct evaluations of Iodoshield Active can be considered to be wholly representative of meta SPC 3. Iodoshield Active is a concentrate for use post milking only (at a dilution ratio of 20% product) containing the SoC at a concentration of 3.35% (w/w). For the purposes of emissions calculations it is therefore assumed that 30 mL of diluted Iodoshield Active is applied per cow per day; two milking events per day at an application rate of 15 mL per cow per milking event. Derivation of the total application of SoC for use in Scenario 1 calculations is shown in the below table.

Input parameters for calculating the local emission of SoC for the worst case: Iodoshield Active applied post-milking, twice a day)			
Input	**Value**	**Unit**	**Remarks**
Scenario 1: Teat disinfection of animals			
Application rate of biocidal product as used	15	ml/cow/application	Spray application.
Total Steryl Amine Ethoxylate (2,2'-(Octadecylimino)bisethanol in concentrate	3.35	% w/w	Concentrate density = 1.170 g/mL)
Dilution ratio of Iodoshield Active	4:1	water:product	
Total Iodoshield Active applied per application	3	mL/cow/application	15 mL assuming a 4:1 dilution ratio
Time of application	post milking	-	
Number of milking events per day	2	d^{-1}	
Resulting product volume for dipping	6	mL/cow/day	Two applications of Iodoshield Active. 3.75 mL per application (total of 7.5 mL)
Mass of Iodoshield Active applied	7.02	g/cow/day	Corrected for product density
Resulting Steryl Amine Ethoxylate (2,2'-(Octadecylimino)bisethanol application	**0.235**	**g/cow/day**	3.35% SoC content

The scenarios in the ESD for PT3 result in an emission estimation, i.e. the calculation of "$Elocal_{compartment}$" to the STP and also in the calculation of PEC values in soil from the emission from slurry/manure.

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 phosphate. Depending on the amount of nitrogen or phosphate 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_2O_5/ha for grassland and 85 kg P_2O_5/ha for arable land) is calculated using the equations as proposed in the ESD for PT3. The PECs calculated for application to grassland and arable land are presented for both nitrogen and phosphate in the table below. It is stated in the CAR (2013) for iodine that the focus for the iodine species should be on the nitrogen standard.

Calculations for Scenario 1

The calculations sheet for the emission estimation are attached in Annex 3.2.

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission (Elocal $_{wastewater)}$**	**Remarks**
STP	Iodine: 0.0104 kg/d SoC: 0.0121 kg/d	Iodine: for pre- plus post-milking disinfection two times per day SoC: for post milking disinfection twice per day
	Local emission (PIEC)	
SOIL - Immission standard for phosphate -grassland	Iodine/iodide: 0.039 mg/kg$_{wwt}$ Iodate: 0.081 mg/kg$_{wwt}$ SoC: 0.036 mg/kg$_{wwt}$	Iodine: for pre- plus post-milking disinfection two times per day SoC: for post milking disinfection twice per day
SOIL - Immission standard for phosphate- arable land	Iodine/iodide: 0.03 mg/kg$_{wwt}$ Iodate: 0.063 mg/kg$_{wwt}$ SoC: 0.028 mg/kg$_{wwt}$	Iodine: for pre- plus post-milking disinfection two times per day SoC: for post milking disinfection twice per day
SOIL - Immission standard for nitrogen-grassland	Iodine/iodide: 0.019 mg/kg$_{wwt}$ Iodate: 0.039 mg/kg$_{wwt}$ SoC: 0.017 mg/kg$_{wwt}$	Iodine: for pre- plus post-milking disinfection two times per day SoC: for post milking disinfection twice per day
SOIL - Immission standard for nitrogen-arable land	Iodine/iodide: 0.019 mg/kg$_{wwt}$ Iodate: 0.039 mg/kg$_{wwt}$ SoC: 0.017 mg/kg$_{wwt}$	Iodine: for pre- plus post-milking disinfection two times per day SoC: for post milking disinfection twice per day

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:

- Scenario 1a: release via STP
- Scenario 1b: via slurry/manure

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

In the case of release via the STP the distribution in the environment and resulting PEC values were calculated following the guidance provided in the ECHA Guidance on BPR Volume IV part B (2015) and the available endpoints for the active substance e.g. physical chemical properties, solid-water partition coefficients etc as detailed in the CAR on iodine.

Iodine input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	253.81	g/mol	CAR (2013) on iodine
Melting point	113.7	°C	CAR (2013) on iodine
Boiling point	184.5	°C	CAR (2013) on iodine
Vapour pressure (at 25°C)	1×10^{-6}	Pa	CAR (2013) on iodine
Water solubility (at 25°C)	100	g/l	CAR (2013) on iodine
Organic carbon/water partition coefficient (Koc)	165.83	l/kg	CAR (2013) on iodine
Solids-water partition coefficient in soil	5.8	l/kg	CAR (2013) on iodine
Solids-water partition coefficient in sediment	200	l/kg	CAR (2013) on iodine
Solids-water partition coefficient in suspended matter	220	l/kg	CAR (2013) on iodine
Biodegradability*	Not biode-gradable		Inorganic substance

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

SoC input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	357.61	g/mol	From REACH dossier
Melting point		°C	From REACH dossier
Boiling point		°C	From REACH dossier
Vapour pressure (at 25°C)	6.1E-7	Pa	From REACH dossier
Water solubility (at 20°C)	0.6	g/l	From REACH dossier
Log Octanol/water partition coefficient	3.8	Log 10	From REACH dossier
Organic carbon/water partition coefficient (Koc)	90.52	l/kg	From REACH dossier
Solids-water partition coefficient in soil ($K_{p,soil}$)	1.81	l/kg	Calculated by UK CA following ECHA

			guidance on the BPR
Solids-water partition coefficient in sediment ($K_{p,sed}$)	4.53	l/kg	Calculated by UK CA following ECHA guidance on the BPR
Solids-water partition coefficient in suspended matter ($K_{p,susp}$)	9.05	l/kg	Calculated by UK CA following ECHA guidance on the BPR
Biodegradability	Readily Biodegradable – 10 day window not fulfilled		From REACH dossier

Calculated fate and distribution in the STP- values for iodine taken from the Iodine CAR (2013), values for SoC calculated by UK CA using SimpleTreat.	
Compartment	Percentage [%]
	Scenario 1 and 2
Air	Iodine: n.r. SoC: 0
Water	Iodine: 80 SoC: 12
Sludge	Iodine: 20 SoC: 1
Degraded in STP	Iodine: 0 SoC: 87

n.r. (not relevant)

Calculated PEC values

In the following tables the calculated PEC values for iodine and its transformation products iodide and iodate are provided for the identified worst case, the use of Ioklene concentrate pre-milking and Intelliblend concentrate post-milking treatment by spraying. In addition the calculated PEC values for the SoC are provided for the proposed use of Iodoshield Active concentrate.

The agreed endpoints in relation to F_{STP} and the estimated emission to STP were introduced into the equations detailed in the ECHA Guidance on BPR Volume IV Part B (2015). Equation 38 was used to determine the PEC_{STP} and additionally equation 48 to determine the $PEC_{localwater}$ and equation 50 to determine the $PEC_{localsed}$. The resulting PECs are detailed below.

The emission to soil from the application of sewage sludge has been determined using equations 54 and 62 from the ECHA guidance on BPR Vol IV part B for each of the different soil types to give PEC $local_{agrsoil}$ and PEC $local_{grasssoil}$ values.

Specifically for iodine the input values from the iodine CAR were used (Doc IIB, Appendix II, page 123). Leaching was taken into account (using equation 58) in the calculation of the first order rate constant for removal from top soil, and PECsoil values are based on $C_{sludgesoil10}$ values (the initial concentration after application of sludge in the 10th year).

Please note that for the exposure route via STP it is assumed that the total iodine concentration in soil is transformed into iodate (100%), but only 14% in iodide (see CAR for iodine (2013)). In contrast, for the direct release into the environment (e.g. when applied via slurry/manure), it is assumed that iodine is transformed into iodate (100%) or iodide (100%) in agricultural soil.

The emission to soil from the application of slurry/manure has been determined based upon the nitrogen immission standard for grassland, four applications per year and 10 consecutive years loading with leaching and degradation in soil. This has been calculated in accordance with the Technical Agreements for Biocides (TAB) version 1.3 (August

2017), ENV125 (AHEE Recommendation for PT 18 (WG-V-2015)), with the additional amendment that the Tgr-int$_{no_manure}$ value for application to grassland has been amended to 365 days as agreed at WG-I-2018.

The emission to groundwater was considered following application of both slurry manure and sewage sludge following 10 consecutive years loading with leaching in soil.

The emission to groundwater following the application of slurry manure to the field was calculated at 39.3 µg/L iodine/iodide and 54.3 µg/L iodate. These values are greater than the range considered within the CAR for iodine/iodide (2.11 – 4.43 µg/L) and iodate (2.92 – 6.12 µg/L).

The emission to groundwater following application of sewage sludge to the field PEC local$_{agrsoil}$ value was applied to the equation 68 from the ECHA guidance on BPR Vol IV part B. For the emissions through STP, the transformation as described above is assumed for iodine, iodide and iodate.

The calculated PEC values due to the use of Ioklene concentrate pre-milking and Intelliblend concentrate post-milking by spray application for iodine and the use of Iodoshield Active post milking for the SoC (Scenario 1) are detailed below:

Summary table on calculated PEC values					
Scenario 1 (via STP and slurry/manure)					
PEC_{STP}	**PEC_{water}** *	**PEC_{sed}**	**PEC_{soil}** (manure/slurry application nitrogen standard grassland)	**PEC_{soil}** (sludge application, worst case agr soil)	**PEC_{GW}**
[µg/l]	[µg/l]	[µg/kg$_{wwt}$]	[mg/kg$_{wwt}$]	[mg/kg$_{wwt}$]	[µg/l]
Iodine: 4.16 SoC: 0.61	Iodine/ iodide: 0.416* Iodate: 0.575 SoC: 0.061	Iodine/ iodide: 20.0 Iodate: 27.64 SoC: 0.17	Iodine/iodide: 0.206 Iodate: 0.28 SoC: 0.017	Iodine: 0.0286 Iodide: 0.004 Iodate: 0.039 SoC: 1.6E-04	From manure/slurry Iodine/iodide: 39.3 Iodate: 54.3 SoC: 0.01 From sewage sludge Iodine: 5.36 Iodide: 0.75 Iodate: 7.41 SoC: 0.01

* Following consideration of PEC_{GW} value following manure/slurry application, PECs in surface water were calculated using the approach provided in the ESD for PT18 (OECD no. 14) on page 58 and a standard run-off dilution factor of 10 was applied to the PEC_{GW} value. In addition these values were also corrected for sorption onto suspended matter to give values of 3.92 µg/L iodine/iodide, 5.4 µg/L iodate and 1.73 µg/L Steryl Amine Ethoxylate (2,2'-(Octadecylimino)bisethanol. As these run-off values are higher than the PEC_{water} via the STP route, these values were taken through the risk characterisation.

Primary and secondary poisoning

Because the product is mainly applied indoors and not released to the environment directly, direct uptake by non-target organisms cannot be expected. Moreover, because

iodine is an essential nutrient and its hydrophobicity does not exceed the trigger value for bioaccumulation, excessive passive uptake cannot be expected. Therefore, the PEC will not exceed the oral PNEC. No risks from primary and secondary poisoning are expected.

2.2.8.3 Risk characterisation

In the risk assessment for iodine, when the PEC/PNEC values are calculated to be above 1, comparison with the natural background levels in the concerned compartment is made. According to the CAR (2013) on iodine the PEC/PNEC values above 1 are acceptable, if the PEC-values are within the background concentrations.

According to the CAR (2013) on iodine the natural background concentrations in various compartments are:

Background concentration of iodine in the environment	
Compartment	**natural background concentration**
Air	-
STP	-
Surface water	0.5 – 20 µg iodine/L
Fresh water sediment	typically 6 mg iodine/kg
Sea water	45 - 60 µg iodine/L
Maine sediment	3 - 400 mg iodine/kg
Soil	0.5 – 20 mg/kg_{dwt} with extremes up to 90 mg/kg_{dwt} (corresponding to 0.4 - 18 mg iodine/kg_{wwt} with extremes up to 86 mg/kg_{wwt})
Groundwater	< 1-70 µg iodine/L (with extremes up to 400 µg/L)

With regards to the SoC, PEC/PNEC ratios must be below 1 for soil, surface water and sediment compartments and predicted concentrations in groundwater must be below 0.1 µg/L for an acceptable risk in all compartments.

Atmosphere

Conclusion (iodine): In view of the high background values of iodine in air, emission to air resulting from application of iodine as disinfectant is not considered to be relevant. Furthermore, iodine is assumed to speciate into non-volatile iodide and iodate in the different compartments it is released to. Consequently, air is not an environmental compartment of concern and the potential effect on the ozone layer could be considered as negligible (CAR (2013) on iodine).

Conclusion (SoC):

Based upon the vapour pressure of 6.1 x 10^{-7} Pa the SoC, it is not envisaged that there will be significant emission to air and no further consideration is required.

Sewage treatment plant (STP)

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

SoC: $PNEC_{STP}$ = 3.5 mg/L

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Scenario 1	Iodine: 4.16E-03 ÷ 2.9 = 1.43E-03
	SoC: 6.1E-04 ÷ 3.5 = 1.74E-04

Conclusion (Iodine): The individual PEC/PNEC ratio for the STP scenario for iodine is below the trigger value of 1. Since no ecotoxicological reference values are available, no PEC/PNEC-values were calculated for iodide and iodate. However, iodide and iodate are less toxic than iodine in the aquatic compartment (see PNEC-values below).

Therefore, it is concluded that there is no unacceptable risk for the STP from the proposed use of the worst case products Ioklene concentrate and Intelliblend concentrate (pre and post-milking respectively).

Conclusion (SoC): The individual PEC/PNEC ratio for the STP scenario for SoC is below the trigger value of 1.

Therefore, it is concluded that there is no unacceptable risk for the STP from the proposed use of Iodoshield Active (post-milking only).

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
SoC: $PNEC_{aquatic}$ = 0.68 µg/L

The PEC and PNEC values for the sediment compartment for Scenario 1 – via STP are calculated with the equilibrium partitioning method based on the $PEC_{aquatic}$ and $PNEC_{aquatic}$ in line with the TGD (2003). Consequently, the PEC/PNEC values for the sediment are identical to the PEC/PNEC values for fresh water or seawater.

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{water}$
Scenario 1 (via slurry/manure)	Iodine: 3.92 ÷ 0.59 = **6.64** Iodide: 3.92 ÷ 0.83 = **4.72** Iodate: 5.4 ÷ 58.5 = 0.092
	SoC: 1.73 ÷ 0.68 = **2.54**
Scenario 1 (via STP)	Iodine: 0.416 ÷ 0.59 = 0.705 Iodide: 0.416 ÷ 0.83 = 0.5 Iodate: 0.58÷ 58.5 = 0.01

	SoC: 0.061 ÷ 0.68 = 0.09

Conclusion (iodine):

Scenario 1: For surface water the PEC/PNEC ratio is greater than 1 for exposure via land application of slurry manure (4.75 respectively). As iodine is a naturally occurring substance PEC/PNEC values above 1 are acceptable, if the PEC-values are within the background concentrations (for more details see CAR on iodine (2013)). The maximum surface water concentration is 3.92 µg iodine/L. This value is within the natural background concentration in freshwater (river and lake) of 0.5-20 µg/L. Therefore, it is concluded that there is no unacceptable risk for the aquatic compartment from the proposed use of the worst case products (spray application of Ioklene concentrate pre-milking and Intelliblend concentrate post-milking).

The risk to marine water from the STP route can be considered to be covered by the assessment for freshwater. Because although the PNEC value for marine waters is 10 x less than for fresh water (in CAR for iodine 2013), the dilution is considered to be 10 x more therefore the PEC:PNEC ratio remains the same.

Conclusion (SoC):
Scenario 1: For surface water the PEC/PNEC ratio is greater than 1 for exposure via land application of slurry manure (3.19 respectively). The PEC value is based upon the use of Iodoshield Active Concentrate being used post milking twice a day. To restrict the use of the product to once a day would still result in a PEC/PNEC >1 for this compound. It is therefore concluded that the use of Iodoshield Active Concentrate cannot be supported due to an unacceptable risk from Steryl Amine Ethoxylate (2,2'-(Octadecylimino)bisethanol levels in surface water. Iodoshield Active is the only product within the family that contains Steryl Amine Ethoxylate (2,2'-(Octadecylimino)bisethanol, this is also the only product within met SPC 3; as such authorisation of meta SPC 3 cannot currently be supported and it should be removed from the product family prior to Union Authorisation.

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
SoC: $PNEC_{soil}$ = 4.42 mg/kg_{wwt} (5 mg/kg_{dwt})

In the following tables the calculated PEC/PNEC values for iodine and its transformation products iodide and iodate are provided considering pre- and post- milking treatments.

Calculated PEC/PNEC values: iodine	
	$PEC/PNEC_{soil}$
Scenario 1a (via STP)	0.0286 ÷ 0.0118 = **2.42**

Scenario 1b (via slurry/manure)	
Nitrogen standard, grassland (worst case)	0.206 ÷ 0.0118 = **17.45**
Calculated PEC/PNEC values: <u>iodide</u>	
	PEC/PNEC$_{soil}$
Scenario 1a (via STP)	0.004 ÷ 0.0043 = 0.93
Scenario 1b (via slurry/manure)	
Nitrogen standard, grassland	0.206 ÷ 0.0043 = **47.9**
Nitrogen standard, arable land	0.206 ÷ 0.0043 = **4**
Calculated PEC/PNEC values: <u>iodate</u>	
	PEC/PNEC$_{soil}$
Scenario 1a (via STP)	0.039 ÷ 0.304 = 0.13
Scenario 1b (via slurry/manure)	
Nitrogen standard, grassland	0.28 ÷ 0.304 = 0.92
Calculated PEC/PNEC values: <u>SoC</u>	
	PEC/PNEC$_{soil}$
Scenario 1a (via STP)	9.74E-5 ÷ 4.42 = 2.20E-5
Scenario 1b (via slurry/manure)	
Nitrogen standard, grassland	0.017 ÷ 4.42 = 3.85E-3
Nitrogen standard, arable land	0.017 ÷ 4.42 = 3.85E-3

<u>Conclusion (iodine)</u>:

<u>Scenario 1</u>:
The individual PEC/PNEC ratios for iodine and iodide exceed for the terrestrial compartment for both emission pathways (indirect via STP and direct via slurry/manure).

Only the PEC/PNEC values for the species iodate, which is the predominant species in soil under aerobic conditions, are below 1.

As iodine is a naturally occurring substance PEC/PNEC values above 1 are acceptable, if the PEC-values are within the background concentrations (for more details see CAR on iodine (2013)). Iodine is not a xenobiotic substance and is present in the soil at natural background levels of 0.4-18 mg/kg$_{wwt}$ soil (CAR, 2013, Doc IIC, PT3, p.23).

The PEC values for iodine/iodide and iodate in the calculation described above (section *B. Exposure Assessment*) are all significantly below the maximum limit of the background concentrations.

Therefore, it is concluded that there is no unacceptable risk for soil from the proposed use of the worst case products (spray application of Ioklene concentrate pre-milking and Intelliblend concentrate post-milking).

Conclusion (SoC):

The individual PEC/PNEC ratios for soil are below the trigger value of 1. Therefore, it is concluded that there is no unacceptable risk to soil from the proposed use of Iodoshield Active (post-milking only).

Groundwater

Conclusion (iodine):

Scenario 1:

The calculated PEC_{gw} values for both emission pathways are above the limit values of 0.1 µg/L provided for pesticides in the Drinking Water Directive 98/83/EC.

However, it is stated in the CAR (2013) on iodine that the trigger value of 0.1 µg/L is limited to organic substances and their relevant metabolites and degradation products. Since iodine and its species are inorganic substances, which are not xenobiotic but essential nutrients, it is concluded in the CAR (2013) on iodine that the concentration of 0.1 µg/L for pesticides is not applicable.

The maximum estimated values in the calculations above are 39.3 µg/L for iodine/iodide and 54.3 µg/L for iodate for the land application of slurry manure (Scenario 1). Values for iodine are above the mean natural background concentration of 1 µg/L, but they are still below the maximum natural background concentration of 70 µg/L (up to 400 µg/L in exceptional cases) as provided in the CAR (2013) on iodine.

In addition, the PEC values in groundwater were calculated in line with the TGD (2003) approach using the pore water concentration in soil as indication for the groundwater level. In this approach no removal, dilution or transformation processes like e.g. lateral transport or plant uptake are taken into account. Therefore, the calculated concentration is an overestimation of the real concentrations in groundwater. The risk is therefore considered acceptable.

Conclusion (SoC):

Scenario 1:

The calculated PEC_{gw} values for both emission pathways are below the limit values of 0.1 µg/L provided for pesticides in the Drinking Water Directive 98/83/EC. Therefore, the risk to groundwater through the use of Iodoshield Active post-milking is considered to be acceptable

Primary and secondary poisoning

Because the product is mainly applied indoors and not released to the environment directly, direct uptake by non-target organisms 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

With the exception of Iodoshield Active Concentrate consideration of mixture toxicity is not required because the other products within the family contain only one active substance and no other substances of concern. Consideration of mixture toxicity is required to be considered for the product Iodoshield Active Concentrate as this product contains the active substance iodine and the SoC substance Steryl Amine Ethoxylate (2,2'-(Octadecylimino)bisethanol). However as iodine and its species are inorganic substances, which are not xenobiotic but essential nutrients that occur within the environment at a range of levels it is not appropriate to consider the combined toxicity of this active substance with the SoC. Furthermore, the environmental risk assessment for the product Iodoshield Active Concentrate indicates an unacceptable risk to surface water and hence the authorisation of this product is not supported.

Aggregated exposure (combined for relevant emmission sources)

At the time of preparation of this CAR, no EU agreed guidance was available on how to perform a full aggregated exposure assessment. Therefore no assessment has been made at this stage. This area may need to be reassessed in the future once agreed guidance has been made available. This may need to take place at active substance renewal stage, or at product authorisation stage, depending on when such guidance becomes available.

Overall conclusion on the risk assessment for the environment of the product
Iodine With regards to the active substance iodine, the above environmental exposure assessment confirms that there is no unacceptable risk in any relevant environmental compartment through the proposed uses of these iodine containing teat dips (Scenario 1). Whilst some PEC/PNEC ratios are in excess of 1, the UK CA considers maximum PEC values to be below natural background levels of iodine in all instances. The iodine exposure calculations are based upon a worst case scenario of two milkings per day using a spray application of Ioklene concentrate pre and Intelliblend concentrate post milking- this exposure assessment covers the risk for iodine from all products within the product family (all meta SPC's) up to two milkings per day. SoC (Steryl Amine Ethoxylate (2,2'-(Octadecylimino)bisethanol))With regards to the SoC, Steryl Amine Ethoxylate (2,2'-(Octadecylimino)bisethanol), (a co-formulant in the product Iodoshield Active Concentrate) the above environmental exposure assessment indicates an unacceptable risk to surface waters from the use of Iodoshield Active Concentrate as proposed i.e. post milking only, twice a day via spray application and a dilution rate of 1:4; based upon the level of failure, it is

clear that the PEC:$PNEC_{surface\ water}$ will also be exceeded for one milking per day. Based upon the risk assessment above authorisation of the products containing the SoC cannot be supported. Iodoshield Active is the only product in the product family that contains Steryl Amine Ethoxylate (2,2'-(Octadecylimino)bisethanol), it is also the only product within meta SPC 3. Therefore, authorisation of products within meta SPC 3 cannot be supported and the the meta SPC must be removed from the product family prior to Union Authorisation being given.

Overall

With the exception of Iodoshield Active (meta SPC 3), all products in all other meta SPC's within the product family show an acceptable risk to the environment up to two milkings per day,.

2.2.9 Measures to protect man, animals and the environment

Based upon the proposed use rates, meta SPC 3 should be removed from the product family prior to Union Authorisation being granted- the Steryl Amine Ethoxylate (2,2'-(Octadecylimino)bisethanol) content of products in this meta SPC demonstrate an unacceptable risk to surface water.

3 Annexes[7]

3.1 List of studies for the biocidal product (family)

[7] When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

3.2 Output tables from exposure assessment tools

HUMAN HEALTH OUTPUT TABLES

Figure 1.1 Scenario 3, Tier 1 assessment: primary exposure to iodine for a professional user applying the product pre- and post- milking through spray equipment for 55 minutes per day. No PPE.

General Exposure Calculator			
In-Use	active substance [a.s.]	0.32	% w/w
Product	density of in-use product	1.00	g ml^{-1}
Hand exposure			
indicative value		36.10	mg min^{-1}
task duration		55	min
glove penetration		100.00	%
Actual deposit on hands[in-use product]		1985.5000	mg
Rest of body exposure			
indicative value		9.70	mg min^{-1}
task duration		55	min
potential dermal deposit on body		533.50	mg
clothing penetration		100.00	%
Actual deposit on body [in-use product]		533.5000	mg
Foot exposure			
indicative value		0.00	mg min^{-1}
task duration		55	min
shoe penetration		100.00	%
Actual deposit on feet [in-use product]		0.0000	mg
Total actual dermal exposure:			
in-use product		**2519.0000**	mg
active substance		**8.0608**	mg
Skin penetration		12.00	%
Total dermal systemic exp. [a.s.]		**0.9673**	mg
Inhalation rate (default)		1.25	m^3 h^{-1}
Exposure by inhalation			
indicative value		10.50	mg m^{-3}
task duration		55	min
volume of air inhaled during task		1.1458	m^3
in-use product inhaled		**12.0313**	mg
active substance inhaled		**0.0385**	mg
No. of task cycles/day (default)		1	
Task cycle multiplier (default)		1	factor
Dose - no RPE			
total systemic exp. - skin & inhalation		1.0058	mg d^{-1}
body weight (default)		60.00	kg
Total systemic dose [a.s.] - no RPE		**0.0168**	mg $kg^{-1}d^{-1}$

Figure 1.2. Scenario 3, Tier 2 assessment: primary exposure to total iodine for a professional user applying the product pre- and post- milking through spray equipment for 55 minutes per day. PPE: gloves.

General Exposure Calculator			
In-Use	active substance [a.s.]	0.32	% w/w
Product	density of in-use product	1.00	g ml^{-1}
Hand exposure			
indicative value		36.10	mg min^{-1}
task duration		55	min
glove penetration		10.00	%
Actual deposit on hands[in-use product]		198.5500	mg
Rest of body exposure			
indicative value		9.70	mg min^{-1}
task duration		55	min
potential dermal deposit on body		533.50	mg
clothing penetration		100.00	%
Actual deposit on body [in-use product]		533.5000	mg
Foot exposure			
indicative value		0.00	mg min^{-1}
task duration		55	min
shoe penetration		100.00	%
Actual deposit on feet [in-use product]		0.0000	mg
Total actual dermal exposure:			
in-use product		**732.0500**	mg
active substance		**2.3426**	mg
Skin penetration		12.00	%
Total dermal systemic exp. [a.s.]		**0.2811**	mg
Inhalation rate (default)		1.25	m^3 h^{-1}
Exposure by inhalation			
indicative value		10.50	mg m^{-3}
task duration		55	min
volume of air inhaled during task		1.1458	m^3
in-use product inhaled		**12.0313**	mg
active substance inhaled		**0.0385**	mg
No. of task cycles/day (default)		1	
Task cycle multiplier (default)		1	factor
Dose - no RPE			
total systemic exp. - skin & inhalation		0.3196	mg d^{-1}
body weight (default)		60.00	kg
Total systemic dose [a.s.] - no RPE		**0.0053**	mg $kg^{-1}d^{-1}$

Figure 1.3. Scenario 3, Tier 3 assessment: primary exposure to total iodine for a professional user applying the product pre- and post- milking through spray equipment for 55 minutes per day. PPE: gloves, coated coveralls and boots

General Exposure Calculator			
In-Use	active substance [a.s.]	0.32	% w/w
Product	density of in-use product	1.00	g ml^{-1}
Hand exposure			
indicative value		36.10	mg min^{-1}
task duration		55	min
glove penetration		10.00	%
Actual deposit on hands[in-use product]		198.5500	mg
Rest of body exposure			
indicative value		9.70	mg min^{-1}
task duration		55	min
potential dermal deposit on body		533.50	mg
clothing penetration		10.00	%
Actual deposit on body [in-use product]		53.3500	mg
Foot exposure			
indicative value		0.00	mg min^{-1}
task duration		55	min
shoe penetration		100.00	%
Actual deposit on feet [in-use product]		0.0000	mg
Total actual dermal exposure:			
in-use product		**251.9000**	mg
active substance		**0.8061**	mg
Skin penetration		12.00	%
Total dermal systemic exp. [a.s.]		**0.0967**	mg
Inhalation rate (default)		1.25	m^3 h^{-1}
Exposure by inhalation			
indicative value		10.50	mg m^{-3}
task duration		55	min
volume of air inhaled during task		1.1458	m^3
in-use product inhaled		**12.0313**	mg
active substance inhaled		**0.0385**	mg
No. of task cycles/day (default)		1	
Task cycle multiplier (default)		1	factor
Dose - no RPE			
total systemic exp. - skin & inhalation		0.1352	mg d^{-1}
body weight (default)		60.00	kg
Total systemic dose [a.s.] - no RPE		**0.0023**	mg $kg^{-1}d^{-1}$

Figure 1.4 Scenario 3, Tier 1 assessment: primary exposure to iodine for a professional user applying the product post-milking through spray equipment for 27.5 minutes per day. No PPE.

General Exposure Calculator			
In-Use	active substance [a.s.]	0.52	% w/w
Product	density of in-use product	1.00	g ml^{-1}
Hand exposure			
indicative value		36.10	mg min^{-1}
task duration		27.5	min
glove penetration		100.00	%
Actual deposit on hands[in-use product]		992.7500	mg
Rest of body exposure			
indicative value		9.70	mg min^{-1}
task duration		27.5	min
potential dermal deposit on body		266.75	mg
clothing penetration		100.00	%
Actual deposit on body [in-use product]		266.7500	mg
Foot exposure			
indicative value		0.00	mg min^{-1}
task duration		27.5	min
shoe penetration		100.00	%
Actual deposit on feet [in-use product]		0.0000	mg
Total actual dermal exposure:			
in-use product		**1259.5000**	mg
active substance		**6.5494**	mg
Skin penetration		12.00	%
Total dermal systemic exp. [a.s.]		**0.7859**	mg
Inhalation rate (default)		1.25	m^3 h^{-1}
Exposure by inhalation			
indicative value		10.50	mg m^{-3}
task duration		27.5	min
volume of air inhaled during task		0.5729	m^3
in-use product inhaled		**6.0156**	mg
active substance inhaled		**0.0313**	mg
No. of task cycles/day (default)		1	
Task cycle multiplier (default)		1	factor
Dose - no RPE			
total systemic exp. - skin & inhalation		0.8172	mg d^{-1}
body weight (default)		60.00	kg
Total systemic dose [a.s.] - no RPE		**0.0136**	mg $kg^{-1}d^{-1}$

Figure 1.5. Scenario 3, Tier 2 assessment: primary exposure to total iodine for a professional user applying the product post-milking through spray equipment for 27.5 minutes per day. PPE: gloves.

General Exposure Calculator			
In-Use	active substance [a.s.]	0.52	% w/w
Product	density of in-use product	1.00	g ml^{-1}
Hand exposure			
indicative value		36.10	mg min^{-1}
task duration		27.5	min
glove penetration		10.00	%
Actual deposit on hands[in-use product]		99.2750	mg
Rest of body exposure			
indicative value		9.70	mg min^{-1}
task duration		27.5	min
potential dermal deposit on body		266.75	mg
clothing penetration		100.00	%
Actual deposit on body [in-use product]		266.7500	mg
Foot exposure			
indicative value		0.00	mg min^{-1}
task duration		27.5	min
shoe penetration		100.00	%
Actual deposit on feet [in-use product]		0.0000	mg
Total actual dermal exposure:			
in-use product		**366.0250**	mg
active substance		**1.9033**	mg
Skin penetration		12.00	%
Total dermal systemic exp. [a.s.]		**0.2284**	mg
Inhalation rate (default)		1.25	m^3 h^{-1}
Exposure by inhalation			
indicative value		10.50	mg m^{-3}
task duration		27.5	min
volume of air inhaled during task		0.5729	m^3
in-use product inhaled		**6.0156**	mg
active substance inhaled		**0.0313**	mg
No. of task cycles/day (default)		1	
Task cycle multiplier (default)		1	factor
Dose - no RPE			
total systemic exp. - skin & inhalation		0.2597	mg d^{-1}
body weight (default)		60.00	kg
Total systemic dose [a.s.] - no RPE		**0.0043**	mg $kg^{-1}d^{-1}$

Figure 1.6. Scenario 3, Tier 3 assessment: primary exposure to total iodine for a professional user applying the product post-milking through spray equipment for 27.5 minutes per day. PPE: gloves, coated coveralls and boots

General Exposure Calculator			
In-Use	active substance [a.s.]	0.52	% w/w
Product	density of in-use product	1.00	g ml^{-1}
Hand exposure			
indicative value		36.10	mg min^{-1}
task duration		27.5	min
glove penetration		10.00	%
Actual deposit on hands[in-use product]		99.2750	mg
Rest of body exposure			
indicative value		9.70	mg min^{-1}
task duration		27.5	min
potential dermal deposit on body		266.75	mg
clothing penetration		10.00	%
Actual deposit on body [in-use product]		26.6750	mg
Foot exposure			
indicative value		0.00	mg min^{-1}
task duration		27.5	min
shoe penetration		100.00	%
Actual deposit on feet [in-use product]		0.0000	mg
Total actual dermal exposure:			
in-use product		**125.9500**	mg
active substance		**0.6549**	mg
Skin penetration		12.00	%
Total dermal systemic exp. [a.s.]		**0.0786**	mg
Inhalation rate (default)		1.25	m^3 h^{-1}
Exposure by inhalation			
indicative value		10.50	mg m^{-3}
task duration		27.5	min
volume of air inhaled during task		0.5729	m^3
in-use product inhaled		**6.0156**	mg
active substance inhaled		**0.0313**	mg
No. of task cycles/day (default)		1	
Task cycle multiplier (default)		1	factor
Dose - no RPE			
total systemic exp. - skin & inhalation		0.1099	mg d^{-1}
body weight (default)		60.00	kg
Total systemic dose [a.s.] - no RPE		**0.0018**	mg $kg^{-1}d^{-1}$

Figure 1.7 Scenario 3, Tier 1 assessment: primary exposure to iodine for a professional user applying the product pre-milking through spray equipment for 27.5 minutes per day. No PPE.

General Exposure Calculator			
In-Use	active substance [a.s.]	0.32	% w/w
Product	density of in-use product	1.00	g ml^{-1}
Hand exposure			
indicative value		36.10	mg min^{-1}
task duration		27.5	min
glove penetration		100.00	%
Actual deposit on hands[in-use product]		992.7500	mg
Rest of body exposure			
indicative value		9.70	mg min^{-1}
task duration		27.5	min
potential dermal deposit on body		266.75	mg
clothing penetration		100.00	%
Actual deposit on body [in-use product]		266.7500	mg
Foot exposure			
indicative value		0.00	mg min^{-1}
task duration		27.5	min
shoe penetration		100.00	%
Actual deposit on feet [in-use product]		0.0000	mg
Total actual dermal exposure:			
in-use product		**1259.5000**	mg
active substance		**4.0304**	mg
Skin penetration		12.00	%
Total dermal systemic exp. [a.s.]		**0.4836**	mg
Inhalation rate (default)		1.25	m^3 h^{-1}
Exposure by inhalation			
indicative value		10.50	mg m^{-3}
task duration		27.5	min
volume of air inhaled during task		0.5729	m^3
in-use product inhaled		**6.0156**	mg
active substance inhaled		**0.0193**	mg
No. of task cycles/day (default)		1	
Task cycle multiplier (default)		1	factor
Dose - no RPE			
total systemic exp. - skin & inhalation		0.5029	mg d^{-1}
body weight (default)		60.00	kg
Total systemic dose [a.s.] - no RPE		**0.0084**	mg $kg^{-1}d^{-1}$

Figure 1.8 Scenario 3, Tier 2 assessment: primary exposure to iodine for a professional user applying the product pre-milking through spray equipment for 27.5 minutes per day. PPE: gloves.

General Exposure Calculator			
In-Use	active substance [a.s.]	0.32	% w/w
Product	density of in-use product	1.00	g ml^{-1}
Hand exposure			
indicative value		36.10	mg min^{-1}
task duration		27.5	min
glove penetration		10.00	%
Actual deposit on hands[in-use product]		99.2750	mg
Rest of body exposure			
indicative value		9.70	mg min^{-1}
task duration		27.5	min
potential dermal deposit on body		266.75	mg
clothing penetration		100.00	%
Actual deposit on body [in-use product]		266.7500	mg
Foot exposure			
indicative value		0.00	mg min^{-1}
task duration		27.5	min
shoe penetration		100.00	%
Actual deposit on feet [in-use product]		0.0000	mg
Total actual dermal exposure:			
in-use product		**366.0250**	mg
active substance		**1.1713**	mg
Skin penetration		12.00	%
Total dermal systemic exp. [a.s.]		**0.1406**	mg
Inhalation rate (default)		1.25	m^3 h^{-1}
Exposure by inhalation			
indicative value		10.50	mg m^{-3}
task duration		27.5	min
volume of air inhaled during task		0.5729	m^3
in-use product inhaled		**6.0156**	mg
active substance inhaled		**0.0193**	mg
No. of task cycles/day (default)		1	
Task cycle multiplier (default)		1	factor
Dose - no RPE			
total systemic exp. - skin & inhalation		0.1598	mg d^{-1}
body weight (default)		60.00	kg
Total systemic dose [a.s.] - no RPE		**0.0027**	mg $kg^{-1}d^{-1}$

Figure 1.9 Scenario 3, Tier 3 assessment: primary exposure to iodine for a professional user applying the product pre-milking through spray equipment for 27.5 minutes per day. PPE: gloves, coated coveralls and boots.

General Exposure Calculator			
In-Use	active substance [a.s.]	0.32	% w/w
Product	density of in-use product	1.00	g ml^{-1}
Hand exposure			
indicative value		36.10	mg min^{-1}
task duration		27.5	min
glove penetration		10.00	%
Actual deposit on hands[in-use product]		99.2750	mg
Rest of body exposure			
indicative value		9.70	mg min^{-1}
task duration		27.5	min
potential dermal deposit on body		266.75	mg
clothing penetration		10.00	%
Actual deposit on body [in-use product]		26.6750	mg
Foot exposure			
indicative value		0.00	mg min^{-1}
task duration		27.5	min
shoe penetration		100.00	%
Actual deposit on feet [in-use product]		0.0000	mg
Total actual dermal exposure:			
in-use product		**125.9500**	mg
active substance		**0.4030**	mg
Skin penetration		12.00	%
Total dermal systemic exp. [a.s.]		**0.0484**	mg
Inhalation rate (default)		1.25	m^3 h^{-1}
Exposure by inhalation			
indicative value		10.50	mg m^{-3}
task duration		27.5	min
volume of air inhaled during task		0.5729	m^3
in-use product inhaled		**6.0156**	mg
active substance inhaled		**0.0193**	mg
No. of task cycles/day (default)		1	
Task cycle multiplier (default)		1	factor
Dose - no RPE			
total systemic exp. - skin & inhalation		0.0676	mg d^{-1}
body weight (default)		60.00	kg
Total systemic dose [a.s.] - no RPE		**0.0011**	mg $kg^{-1}d^{-1}$

ENVIRONMENTAL OUTPUT TABLES

Iodine:

Input parameters				
Parameters	***Nomenclature***	**Value**	**Unit**	**Origin**
Input				
Type of housing/manure storage	*cat-subcat (i1)*	Dairy cows	[-]	**D** (Appendix 1: Table 7)
Type of biocide	*bioctype (i2)*	Disinfectant	[-]	**D** (Appendix 1: Table 7)
Type of application	*appway (i3)*	Dipping	[-]	**D** (Appendix 1: Table 7)
Relevant emission stream	*stream (i4)*	slurry/stp	[-]	**P** (Appendix 1: Table 7)
Content of active ingredient in formulation (product)	*Fbioc*	**4.22**	g l^{-1}	**S**
Amount of (undiluted) product prescribed to be used for one treatment (dipping of the four teats) of one animal	$Vprod_{i1,i2,i3}$	**0.03**	l	**S**
Dilution factor (for preparation of the working solution from the formulation (product))	$F_{dil}^{(A)}$	**1**	[-]	**S**
Fraction of active ingredient released	$F_{STP\_il,i2,i3,i4}$	0.5	[-]	**D**
	$F_{slurry/manure\_i1,i2,i3,i4}^{(E)}$	0.5	[-]	**D**
	F_{air}	0	[-]	**D**
	F_{teat}	0.5	[-]	**D**
Number of teat dipping events for one animal and one day (dipping of the four teats of one animal = one disinfectant application)	*Napp-teat*	3	[-]	**D**
Number of days of lactation period (corresponds to number of emission days)	*Nday-lact (= Temission)*	300	d	**D**
Number of disinfectant applications in one year (equals number of disinfectant applications in one lactation period)	*Napp-bioc*	900		**D**
Interval between two disinfectant applications (dipping events)	*Tbioc-int*	0.33333333	[-]	**D**
Number of manure applications for grassland	*Nlapp-grass*	4	[-]	**D**
Number of manure applications for arable land	*Nlapp-arab*	1	[-]	**D**
Manure application time interval for grassland	*Tgr-int*	53	d	**D/S** (Appendix 1: Table 12)
Manure application time interval for arable land	*Tar-int*	212	d	**D/S** (Appendix 1: Table 12)
Number of animals in housing for every relevant category/subcategory *i1*	$Nanimal_{i1}$	100	[-]	**D/S** (Appendix 1: Table 8)
Amount of phosphate per animal for every relevant category/subcategory *i1*	$Qphosph_{i1}$	0.10466	kg anim.$^{-1}$ d^{-1}	**D/S** (Appendix 1: Table 11)
Amount of nitrogen per animal for every relevant category/subcategory *i1*	$Qnitrog_{i1}$	0.33890	kg anim.$^{-1}$ d^{-1}	**D/S** (Appendix 1: Table 11)
If phosphate immission standards are applied				
Phosphate immission standard for one year on grassland	$Q_{P2O5,grassland}$	110	kg ha^{-1} yr^{-1}	**D** (Appendix 1: Table 13)
Phosphate immission standard for one year on arable land	$Q_{P2O5,arable}$	85	kg ha^{-1} yr^{-1}	**D** (Appendix 1: Table 13)
If nitrogen immission standards are applied				

Nitrogen immission standard for one year on grassland	$Q_{N,grassland}$	170	kg ha^{-1} yr^{-1}	**D** (Appendix 1: Table 13)
Nitrogen immission standard for one year on arable land	$Q_{N,arable}$	170	kg ha^{-1} yr^{-1}	**D** (Appendix 1: Table 13)
Mixing depth with soil, grassland	$DEPTH_{grassland}^{(C)}$	0.05	m	**D**
Mixing depth with soil, arable land	$DEPTH_{arable\_land}^{(C)}$	0.20	m	**D**
Density of wet bulk soil	$RHO_{soilwet}^{(C,D)}$	1700	kg m^{-3}	**D**

Output parameters				
Parameters	***Nomenclature***	**Value**	**Unit**	**Origin**
Output				
Soil exposure For stream i4=1 and 3				
Concentration of the biocide (active ingredient) in soil (mg kg^{-1}) in the case of an immission standard for **phosphate** and land application on **grassland**	$PIECgrs\text{-}P2O5_{i1,i2,i3,i4}$	**5.87E-02**	mg kg^{-1} w/w	**O**
Concentration of the biocide (active ingredient) in soil (mg kg^{-1}) in the case of an immission standard for **phosphate** and land application on **arable land**	$PIECars\text{-}P2O5_{i1,i2,i3,i4}$	**4.54E-02**	mg kg^{-1} w/w	**O**
Concentration of the biocide (active ingredient) in soil (mg kg^{-1}) in the case of an immission standard for **nitrogen** and land application on **grassland**	$PIECgrs\text{-}N_{i1,i2,i3,i4}$	**2.80E-02**	mg kg^{-1} w/w	**O**
Concentration of the biocide (active ingredient) in soil (mg kg^{-1}) in the case of an immission standard for **nitrogen** and land application on **arable land**	$PIECars\text{-}N_{i1,i2,i3,i4}$	**2.80E-02**	mg kg^{-1} w/w	**O**
STP				
Local emission to a standard STP or an on-site water water treatment plant	$Qai\text{-}stp_{i1,i2,i3,i4} = Elocal_{waste\ water}$	**1.56E-02**	kg d^{-1}	**O**

Intermediate calculations				
Number of biocide applications during storage period for application on grassland	$Napp\text{-}manure_{gr}$	**159**	[-]	**O**
Number of biocide applications during storage period for application on arable land	$Napp\text{-}manure_{ar}$	**636**	[-]	**O**
Amount of active ingredient to be used for one application (one treatment of one animal)	$Qai\text{-}prescr_{i1,i2,i3}$	**1.27E-04**	kg	**O**
Amount of active ingredient in relevant stream *i4* after one application	*Qai_STP*	**6.33E-03**	kg	**O**
	Qai_slurry/manure	**6.33E-03**	kg	**O**
Amount of active ingredient in relevant stream i4 after one application	$Qai_{i1,i2,i3}$	**6.33E-03**		
Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to grassland	$Qai\text{-}grass_{i1,i2,i3,i4}$	**1.0065**	kg	**O**

Amount of active ingredient in manure or slurry after the relevant number of applications for the manure application to arable land	$Qai\text{-}arab_{i1,i2,i3,i4}$	**4.0259**	kg	**O**
Amount of **phosphate** produced during the relevant period for every relevant (sub)category of animal/housing *i1* and application to **grassland**	$Qphosp\text{-}grass_{i1,i4}$	**554.7**	kg	**O**
Amount of **phosphate** produced during the relevant period for every relevant (sub)category of animal/housing *i1* and application to **arable land**	$Qphosp\text{-}arab_{i1,i4}$	**2218.8**	kg	**O**
Amount of **nitrogen** produced during the relevant period for every relevant (sub)category of animal/housing *i1* and application to **grassland**	$Qnitrog\text{-}grass_{i1,i4}$	**1796.2**	kg	**O**
Amount of **nitrogen** produced during the relevant period for every relevant (sub)category of animal/housing *i1* and application to **arable land**	$Qnitrog\text{-}arab_{i1,i4}$	**7184.7**	kg	**O**

Steryl Amine Ethoxylate (2,2'-(Octadecylimino)bisethanol):

Input parameters				
Parameters	***Nomenclature***	**Value**	**Unit**	**Origin**
Input				
Type of housing/manure storage	*cat-subcat (i1)*	Dairy cows	[-]	**D** (Appendix 1: Table 7)
Type of biocide	*bioctype (i2)*	Disinfectant	[-]	**D** (Appendix 1: Table 7)
Type of application	*appway (i3)*	Dipping	[-]	**D** (Appendix 1: Table 7)
Relevant emission stream	*stream (i4)*	slurry/stp	[-]	**P** (Appendix 1: Table 7)
Content of active ingredient in formulation (product)	*Fbioc*	**7.83**	g l^{-1}	**S**
Amount of (undiluted) product prescribed to be used for one treatment (dipping of the four teats) of one animal	$Vprod_{i1,i2,i3}$	**0.015**	l	**S**
Dilution factor (for preparation of the working solution from the formulation (product))	$F_{dil}^{(A)}$	**1**	[-]	**S**
Fraction of active ingredient released	$F_{STP\_il,i2,i3,i4}$	0.5	[-]	**D**
	$F_{slurry/manure\_i1,i2,i3,i4}^{(E)}$	0.5	[-]	**D**
	F_{air}	0	[-]	**D**
	F_{teat}	0.5	[-]	**D**
Number of teat dipping events for one animal and one day (dipping of the four teats of one animal = one disinfectant application)	*Napp-teat*	2	[-]	**D**
Number of days of lactation period (corresponds to number of emission days)	*Nday-lact (= Temission)*	300	d	**D**
Number of disinfectant applications in one year (equals number of disinfectant applications in one lactation period)	*Napp-bioc*	600		**D**
Interval between two disinfectant applications (dipping events)	*Tbioc-int*	0.5	[-]	**D**
Number of manure applications for grassland	*Nlapp-grass*	4	[-]	**D**
Number of manure applications for arable land	*Nlapp-arab*	1	[-]	**D**
Manure application time interval for grassland	*Tgr-int*	53	d	**D/S** (Appendix 1: Table 12)
Manure application time interval for arable land	*Tar-int*	212	d	**D/S** (Appendix 1: Table 12)
Number of animals in housing for every relevant category/subcategory *i1*	$Nanimal_{i1}$	100	[-]	**D/S** (Appendix 1: Table 8)
Amount of phosphate per animal for every relevant category/subcategory *i1*	$Qphosph_{i1}$	0.10466	kg anim.$^{-1}$ d^{-1}	**D/S** (Appendix 1: Table 11)

Amount of nitrogen per animal for every relevant category/subcategory *i1*	$Qnitrog_{i1}$	0.33890	kg anim.$^{-1}$ d^{-1}	**D/S** (Appendix 1: Table 11)
If phosphate immission standards are applied				
Phosphate immission standard for one year on grassland	$Q_{P2O5,grassland}$	110	kg ha^{-1} yr^{-1}	**D** (Appendix 1: Table 13)
Phosphate immission standard for one year on arable land	$Q_{P2O5,arable}$	85	kg ha^{-1} yr^{-1}	**D** (Appendix 1: Table 13)
If nitrogen immission standards are applied				
Nitrogen immission standard for one year on grassland	$Q_{N,grassland}$	170	kg ha^{-1} yr^{-1}	**D** (Appendix 1: Table 13)
Nitrogen immission standard for one year on arable land	$Q_{N,arable}$	170	kg ha^{-1} yr^{-1}	**D** (Appendix 1: Table 13)
Mixing depth with soil, grassland	$DEPTH_{grassland}^{(C)}$	0.05	m	**D**
Mixing depth with soil, arable land	$DEPTH_{arable\_land}^{(C)}$	0.20	m	**D**
Density of wet bulk soil	$RHO_{soilwet}^{(C,D)}$	1700	kg m^{-3}	**D**

Output parameters				
Parameters	***Nomenclature***	**Value**	**Unit**	**Origin**
Output				
Soil exposure For stream i4=1 and 3				
Concentration of the biocide (active ingredient) in soil (mg kg^{-1}) in the case of an immission standard for **phosphate** and land application on **grassland**	$PIECgrs\text{-}P2O5_{i1,i2,i3,i4}$	**3.63E-02**	mg kg^{-1} w/w	**O**
Concentration of the biocide (active ingredient) in soil (mg kg^{-1}) in the case of an immission standard for **phosphate** and land application on **arable land**	$PIECars\text{-}P2O5_{i1,i2,i3,i4}$	**2.81E-02**	mg kg^{-1} w/w	**O**
Concentration of the biocide (active ingredient) in soil (mg kg^{-1}) in the case of an immission standard for **nitrogen** and land application on **grassland**	$PIECgrs\text{-}N_{i1,i2,i3,i4}$	**1.73E-02**	mg kg^{-1} w/w	**O**
Concentration of the biocide (active ingredient) in soil (mg kg^{-1}) in the case of an immission standard for **nitrogen** and land application on **arable land**	$PIECars\text{-}N_{i1,i2,i3,i4}$	**1.73E-02**	mg kg^{-1} w/w	**O**
STP				
Local emission to a standard STP or an on-site water water treatment plant	$Qai\text{-}stp_{i1,i2,i3,i4} = Elocal_{waste\ water}$	**9.65E-02**	kg d^{-1}	**O**

Intermediate calculations				
Number of biocide applications during storage period for application on grassland	$Napp\text{-}manure_{gr}$	**106**	[-]	**O**
Number of biocide applications during storage period for application on arable land	$Napp\text{-}manure_{ar}$	**424**	[-]	**O**
Amount of active ingredient to be used for one application (one treatment of one animal)	$Qai\text{-}prescr_{i1,i2,i3}$	**1.47E-04**	kg	**O**
Amount of active ingredient in relevant stream *i4* after one application	Qai_STP	**5.87E-03**	kg	**O**
	$Qai\_slurry/manure$	**5.87E-03**	kg	**O**

Amount of active ingredient in relevant stream i4 after one application	$Qai_{i1,i2,i3}$	**5.87E-03**		
Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to grassland	$Qai\text{-}grass_{i1,i2,i3,i4}$	**0.6225**	kg	**O**
Amount of active ingredient in manure or slurry after the relevant number of applications for the manure application to arable land	$Qai\text{-}arab_{i1,i2,i3,i4}$	**2.4899**	kg	**O**
Amount of **phosphate** produced during the relevant period for every relevant (sub)category of animal/housing *i1* and application to **grassland**	$Qphosp\text{-}grass_{i1,i4}$	**554.7**	kg	**O**
Amount of **phosphate** produced during the relevant period for every relevant (sub)category of animal/housing *i1* and application to **arable land**	$Qphosp\text{-}arab_{i1,i4}$	**2218.8**	kg	**O**
Amount of **nitrogen** produced during the relevant period for every relevant (sub)category of animal/housing *i1* and application to **grassland**	$Qnitrog\text{-}grass_{i1,i4}$	**1796.2**	kg	**O**
Amount of **nitrogen** produced during the relevant period for every relevant (sub)category of animal/housing *i1* and application to **arable land**	$Qnitrog\text{-}arab_{i1,i4}$	**7184.7**	kg	**O**

3.3 Confidential annex

See R4BP3 asset

3.4 Member State Confidential Annex

See R4BP3 asset